

08-078

ORIGINAL

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ILLINOIS HEALTH FACILITIES PLANNING BOARD
APPLICATION FOR PERMIT

OCT 07 2008

HEALTH FACILITIES
PLANNING BOARD

SECTION I. IDENTIFICATION, GENERAL INFORMATION, AND CERTIFICATION

This section must be completed for all projects.

A. Facility/Project Identification

Facility Name South Loop Endoscopy & Wellness Center, LLC
Street Address 2336-40 S. Wabash City Chicago
County Cook Zip 60616 Health Service Planning Area 6

B. Applicant Identification (provide for each co-applicant [refer to Part 1130.220] and insert after this page)

Exact Legal Name South Loop Endoscopy & Wellness Center, LLC
Address 2336-40 S. Wabash, Chicago, IL 60616
Name of Registered Agent Ken Sain
Name of Chief Executive Officer David Chua, M.D.
CEO Address 2900 Oak Brook Hills Road Oak Brook, IL 60523 Telephone No. (630) 889-9889

Type of Ownership:

Non-profit Corporation For-profit Corporation Limited Liability Company
 Partnership Governmental Sole Proprietorship Other (specify) _____

Corporations and limited liability companies must provide an Illinois certificate of good standing; partnerships must provide the name of the state in which organized and the name and address of each partner specifying whether each is a general or limited partner.

APPEND DOCUMENTATION AS ATTACHMENT IDEN-1 AFTER THE LAST PAGE OF THIS SECTION.

C. Primary Contact Person (person who is to receive correspondence or inquiries during the review period)

Name Ira Rogal Title Consultant
Company Name Shea, Paige & Rogal, Inc.
Address 547 S. LaGrange Road, LaGrange, IL 60525
Telephone No. (708) 482-4820 E-mail Address IAR4@aol.com Fax No. (708) 482-1091

D. Additional Contact Person (person such as consultant, attorney, financial representative, registered agent, etc. who also is authorized to discuss application and act on behalf of applicant)

Name Billie J. Paige Title Consultant
Company Name Shea, Paige & Rogal, Inc.
Address 547 S. LaGrange Road, LaGrange, IL 60525
Telephone No. (708) 482-4820 E-mail Address stargazer23@msn.com Fax No. (708) 482-1091

E. Post Permit Contact Person (person to whom all correspondence and inquiries pertaining to the project subsequent to permit issuance are to be directed)

Name David Chua, M.D. Title Manager
Company Name _____
Address 1 S. 280 Summit, Oak Brook Terrace, IL 60181
Telephone No. (630) 889-9889 E-mail Address wendy2900@gmail.com Fax No. (630)

F. Site Ownership (complete this information for each applicable site and insert after this page)

Exact Legal Name of Person Who Owns Site Summit Real Estate, LLC
Address of Site Owner 1 S. 280 Summit, Oak Brook Terrace, IL 60181
Street Address or Legal Description of Site 2334 S. Wabash, Chicago, IL 60616

G. Operating Entity/Licensee (complete this information for each applicable facility and insert after this page)

Exact Legal Name South Loop Endoscopy & Wellness Center, LLC
Address 2334 S. Wabash, Chicago, IL 60616

Type of Ownership:

Non-profit Corporation For-profit Corporation Limited Liability Company
 Partnership Governmental Sole Proprietorship Other (specify) _____

Corporations and limited liability companies must provide an Illinois certificate of good standing; partnerships must provide the name of the state in which organized and the name and address of each partner specifying whether each is a general or limited partner.

APPEND DOCUMENTATION AS ATTACHMENT IDEN-2 AFTER THE LAST PAGE OF THIS SECTION.

H. Organizational Relationships

Provide (for each co-applicant) an organization chart containing the name and relationship of any person who is related (related person is defined in Part 1130.140). If the related person is participating in the development or funding of the project, describe the interest and the amount and type of any financial contribution.

APPEND DOCUMENTATION AS ATTACHMENT IDEN-3 AFTER THE LAST PAGE OF THIS SECTION.

I. Status of Previous Certificate of Need Projects

Provide the project number for any of the applicant's projects that have received permits but are not yet complete (completion is defined in Part 1130.140) and provide the current status of the project. If all projects are complete, indicate NONE:

J. Flood Plain Requirements (refer to instructions for completion of this application)

Provide documentation regarding compliance with the Flood Plain requirements of Executive Order #4, 1979.

APPEND DOCUMENTATION AS ATTACHMENT IDEN-4 AFTER THE LAST PAGE OF THIS SECTION.

K. Historic Resources Preservation Act Requirements (refer to instructions for completion of this application)

Provide documentation regarding compliance with the requirements of the Historic Resources Preservation Act.

APPEND DOCUMENTATION AS ATTACHMENT IDEN-5 AFTER THE LAST PAGE OF THIS SECTION.

L. Project Classification (check those applicable, refer to Part 1110.40 and Part 1120.20.b)

- | | |
|---|--|
| 1. Part 1110 Classification | 2. Part 1120 Applicability or Classification: (check one only) |
| <input checked="" type="checkbox"/> Substantive | <input type="checkbox"/> Part 1120 Not Applicable <input type="checkbox"/> Category A Project |
| <input type="checkbox"/> Non-substantive | <input type="checkbox"/> DHS or DVA Project <input checked="" type="checkbox"/> Category B Project |

M. Narrative Description

Provide in the space below a brief narrative description of the project. Explain what is to be done, **NOT** why it is being done. Include the rationale as to the project's classification as substantive or non-substantive. If the project site does NOT have a street address, include a legal description of the site.

Applicant proposes a single specialty ASTC to be located at 2336-40 S. Wabash in Chicago. It will contain two procedure rooms limited to gastroenterology procedures.

Applicant will be owned by Dr. David Chua who provided all of the referrals.

This project is substantive because it proposes establishing a new health care facility.

N. Project Costs and Sources of Funds

Complete the following table listing all costs (refer to Part 1120.110) associated with the project. When a project or any component of a project is to be accomplished by lease, donation, gift, or other means, the fair market or dollar value (refer to Part 1130.140) of the component must be included in the estimated project cost. If the project contains components that are not related to the provision of health care, complete an additional table for the portions that are solely for health care and insert that table following this page (e.g. separate a nursing home's costs from the components of a retirement community; separate patient care area costs from a hospital project that includes a parking garage). Note, the use and sources of funds must equal.

PROJECT USES AND SOURCES OF FUNDS	
USE OF FUNDS	AMOUNT
Preplanning Costs	\$10,000
Site Survey and Soil Investigation	0
Site Preparation	0
Off Site Work	0
New Construction Contracts	
Modernization Contracts	480,000
Contingencies	48,000
Architectural/Engineering Fees	38,400
Consulting and Other Fees	60,000
Movable or Other Equipment (not in construction contracts)	575,000
Bond Issuance Expense (project related)	0
Net Interest Expense During Construction (project related)	
Fair Market Value of Leased Space or Equipment	329,398
Other Costs To Be Capitalized	
Acquisition of Building or Other Property (excluding land)	
TOTAL USES OF FUNDS	\$1,540,798
SOURCE OF FUNDS	AMOUNT
Cash and Securities	
Pledges	
Gifts and Bequests	
Bond Issues (project related)	
Mortgages	\$1,211,400
Leases (fair market value)	329,398
Governmental Appropriations	
Grants	
Other Funds and Sources	
TOTAL SOURCES OF FUNDS	\$1,540,798

O. Related Project Costs

1. Provide the following information, as applicable, with respect to any land related to the project that will be or has been acquired during the last two calendar years:

No land acquisition is related to project;

Purchase Price \$ _____; Fair Market Value \$ _____

2. Does the project involve establishment of a new facility or a new category of service?

Yes No

If yes, provide the dollar amount of all non-capitalized operating start-up costs (including operating deficits) through the first full fiscal year when the project achieves or exceeds the target utilization specified in Part 1100.

Estimated start-up costs and operating deficit cost is \$ 206,400.00.

P. Project Status and Completion Schedules

1. Indicate the stage of the project's architectural drawings:

None or not applicable Schematics Preliminary Working Final

2. Provide the following dates (indicate N/A for any item that is not applicable):

25% of project costs expended 06/09 50% of project costs expended 09/09
75% of project costs expended 12/09 95% of project costs expended 02/10
100% of project costs expended 04/10 Midpoint of construction date 09/09
Anticipated project completion date (refer to Part 1130.140) 12/09

3. Indicate the following with respect to project expenditures or to obligation (refer to Part 1130.140):

- Purchase orders, leases, or contracts pertaining to the project have been executed;
- Project obligation is contingent upon permit issuance. Provide a copy of the contingent "certification of obligation" document, highlighting any language related to CON contingencies.
- Project obligation will occur after permit issuance.

APPEND DOCUMENTATION AS ATTACHMENT INFO-6 AFTER THE LAST PAGE OF THIS SECTION.

Q. Cost/Space Requirements

Provide in the format of the following example the gross square footage (GSF) and the attributable portion of total project cost for each department/area. Identify each piece of major medical equipment. The sum of the department costs **MUST** equal the total estimated project costs. Indicate if any space is being reallocated for a different purpose. Include outside wall measurement plus the department or area's portion of the surrounding circulation space. Indicate the proposed use of any vacated space.

Dept. / Area	Cost	Gross Square Feet		Amount of Proposed Total Gross Square Feet That Is:			
		Existing	Proposed	New Const.	Modernized	As Is	Vacated Space
Dietary	1,150,000	3,000	6,000	3,000	1,000	2,000	
Radiation Therapy	3,250,000	4,000	5,500	5,500			
Medical Records	300,000	2,500	6,500		4,000	2,500	
TOTALS	4,700,000	9,500	18,000	8,500	5,000	4,500	

APPEND DOCUMENTATION AS ATTACHMENT INFO-7 AFTER THE LAST PAGE OF THIS SECTION.

R. Facility Bed Capacity and Utilization

N/A

1. Complete the following chart as applicable. Complete a separate chart for each facility that is part of the project and insert following this page. Provide the existing bed capacity and utilization data for the latest 12 month period for which data is available. Any bed capacity discrepancy from the Inventory will result with the application being deemed incomplete.

FACILITY NAME _____ CITY _____

REPORTING PERIOD DATES: From _____ to _____

Category of Service	Authorized Beds	Admissions	Patient Days	Bed Changes	Proposed Beds
Medical/Surgical					
Pediatrics					
Obstetrics					
Intensive Care					
Neonatal ICU					
Acute Mental Illness					
Rehabilitation					
Nursing Care					
Sheltered Care					
Other (identify)					
Other (identify)					
Other (identify)					
TOTALS					

2. Is the facility certified for participation in the Medicare "swing bed" (i.e. acute care beds certified for extended care) program? Yes No
3. For the following categories of service, indicate the number of existing beds that are Medicare certified and the number of existing beds that are Medicaid certified (if none, so indicate):

Service	# Medicare Beds	# Medicaid Beds
Nursing Care	_____	_____
ICF/DD Adult	_____	_____
Children DD	_____	_____

S. Certification

The application must be signed by the authorized representative(s) of the applicant entity. The authorized representative(s) are in the case of a corporation, any two of its officers or members of its board of directors; in the case of a limited liability company, any two of its managers or members (or the sole manager or member when two or more managers or members do not exist); in the case of a partnership, two of its general partners (or the sole general partner when two or more general partners do not exist); in the case of estates and trusts, two of its beneficiaries (or the sole beneficiary when two or more beneficiaries do not exist); and in the case of a sole proprietor, the individual that is the proprietor. The signature(s) must be notarized. If the application has co-applicants, a separate certification page must be completed for each co-applicant and inserted following this page. One copy of the application must have the ORIGINAL signatures for all persons that sign for the applicant and for each of the co-applicants.

This Application for Permit is filed on behalf of *South Loop Endoscopy & Wellness Center, LLC* in accordance with the requirements and procedures of the Illinois Health Facilities Planning Act. The undersigned certifies that he or she has the authority to execute and file this application for permit on behalf of the applicant entity. The undersigned further certifies that the data and information provided herein, and appended hereto, are complete and correct to the best of his or her knowledge and belief. The undersigned also certifies that the permit application fee required for this application is sent herewith or will be paid upon request.

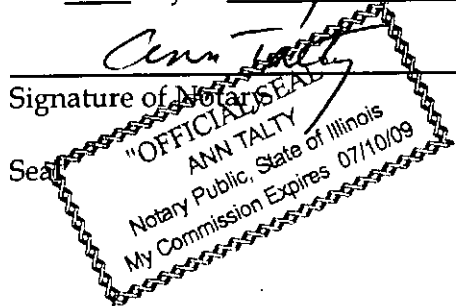
[Handwritten Signature]
Signature

Printed Name David Chua, M.D.

Printed Title Manager

Notarization:
Subscribed and sworn to before me
this 21 day of July 2008

[Handwritten Signature]
Signature of Notary



Signature

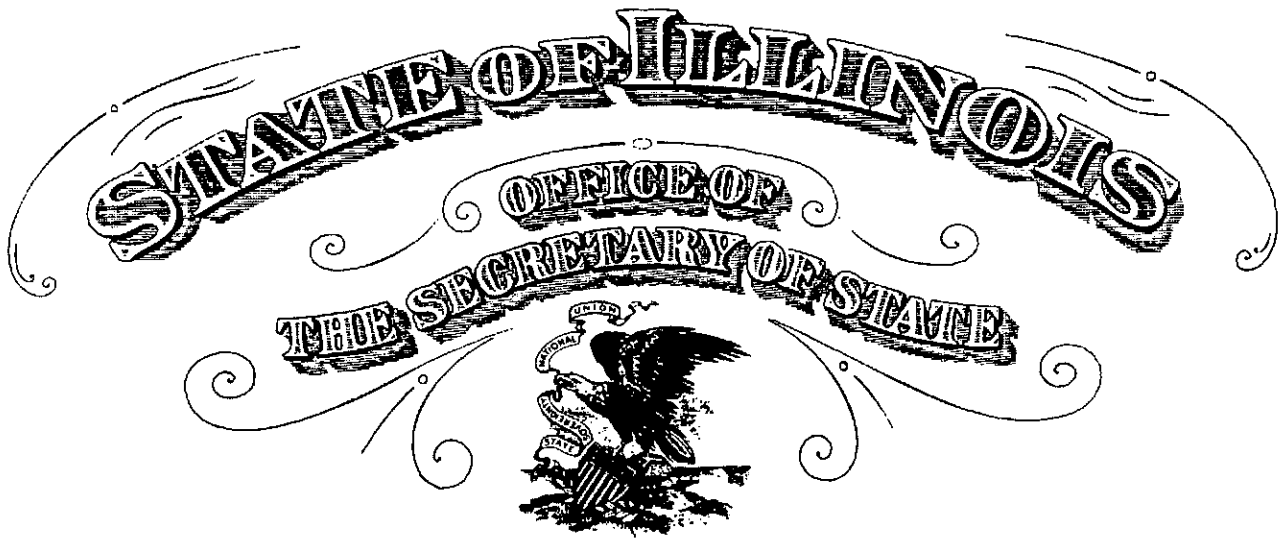
Printed Name _____

Printed Title _____

Notarization:
Subscribed and sworn to before me
this ____ day of _____

Signature of Notary

Seal



To all to whom these Presents Shall Come, Greeting:

I, Jesse White, Secretary of State of the State of Illinois, do hereby certify that

SOUTH LOOP ENDOSCOPY & WELLNESS CENTER, LLC, HAVING ORGANIZED IN THE STATE OF ILLINOIS ON MAY 16, 2008, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE LIMITED LIABILITY COMPANY ACT OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LIMITED LIABILITY COMPANY IN THE STATE OF ILLINOIS.



Authentication #: 0827501866

Authenticate at: <http://www.cyberdriveillinois.com>

In Testimony Whereof, I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this 1ST day of OCTOBER A.D. 2008 .

Jesse White

SECRETARY OF STATE



Illinois State Water Survey

Main Office • 2204 Griffith Drive • Champaign, IL 61820-7495 • Tel (217) 333-2210 • Fax (217) 333-6540
Peoria Office • P.O. Box 697 • Peoria, IL 61652-0697 • Tel (309) 671-3196 • Fax (309) 671-3106



Special Flood Hazard Area Determination pursuant to Governor's Executive Order 5 (2006) (supersedes Governor's Executive Order 4 (1979))

Requester: Ira Rogal
Address: Shea, Paige & Rogal, Inc., 547 S. LaGrange Rd.
City, state, zip: LaGrange, IL 60525 Telephone: (708) 482-4820

Site description of determination:

Site address: 2334-2336 S. Wabash Ave.
City, state, zip: Chicago, IL
County: Cook Sec¼: NW¼ of NW¼ Section: 27 T. 39 N. R. 14 E. PM: 3rd
Subject area: Parcel ID 17-27-108-018-0000, which is within the area bounded by S. Wabash Ave. on the east, the CTA ROW on the west, E. 23rd St. on the north, and E. 24th St. on the south.

The property described above IS NOT located in a Special Flood Hazard Area or a shaded Zone X floodzone.

Floodway mapped: N/A Floodway on property: No
Source used: FEMA Flood Insurance Rate Map (FIRM). An annotated copy is attached.
Community name: City of Chicago, IL Community number: 170074
Panel/map number: 17031C0507 F Effective Date: November 6, 2000
Flood zone: X [unshaded] Base flood elevation: N/A ft NGVD 1929

- N/A a. The community does not currently participate in the National Flood Insurance Program (NFIP). NFIP flood insurance is not available; certain State and Federal assistance may not be available.
- N/A b. Panel not printed: no Special Flood Hazard Area on the panel (panel designated all Zone C or unshaded X).
- N/A c. No map panels printed: no Special Flood Hazard Areas within the community (NSFHA).

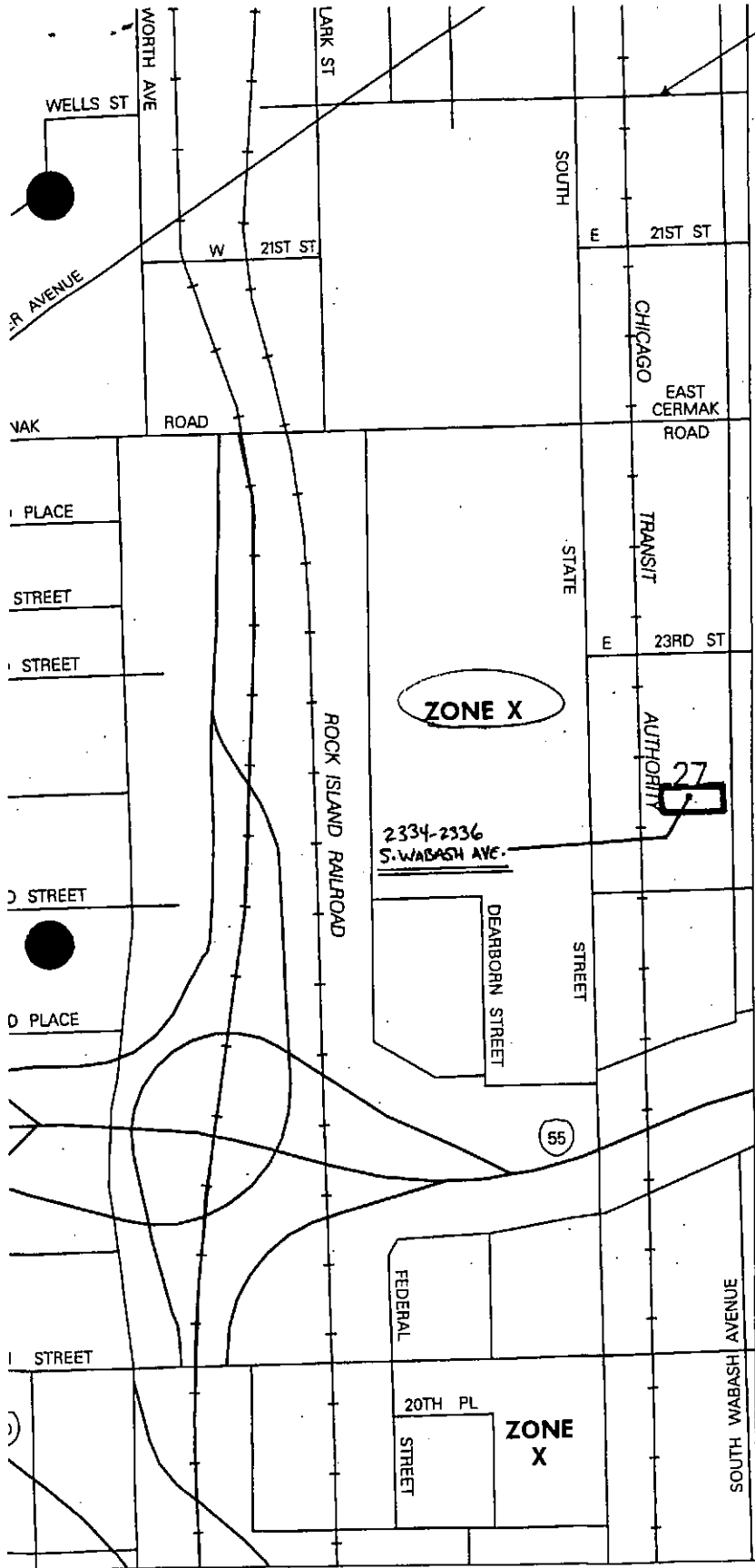
The primary structure on the property:

- N/A d. Is located in a Special Flood Hazard Area. Any activity on the property must meet State, Federal, and local floodplain development regulations. Federal law requires that a flood insurance policy be obtained as a condition of a federally-backed mortgage or loan that is secured by the building.
- N/A e. Is located in shaded Zone X or B (500-yr floodplain). Conditions may apply for local permits or Federal funding.
- X f. Is not located in a Special Flood Hazard Area or 500-year floodplain area shown on the effective FEMA map.
- N/A g. A determination of the building's exact location cannot be made on the current FEMA flood hazard map.
- N/A h. Exact structure location is not available or was not provided for this determination.

Note: This determination is based on the current Federal Emergency Management Agency (FEMA) flood hazard map for the community. This letter does not imply that the referenced property will or will not be free from flooding or damage. A property or structure not in a Special Flood Hazard Area may be damaged by a flood greater than that predicted on the FEMA map or by local drainage problems not mapped. This letter does not create liability on the part of the Illinois State Water Survey, or employee thereof for any damage that results from reliance on this determination. This letter does not exempt the project from local stormwater management regulations.

Questions concerning this determination may be directed to Bill Saylor (217/333-0447) at the Illinois State Water Survey. Questions concerning requirements of Governor's Executive Order 5 (2006), or State floodplain regulations, may be directed to John Lentz (847/608-3100 x2022) at the IDNR Office of Water Resources.

William Saylor Title: ISWS Surface Water & Floodplain Information Date: 5/29/2008
William Saylor, CFM IL-02-00107, Illinois State Water Survey



APPROXIMATE SCALE



— LEGEND ON REVERSE —

NATIONAL FLOOD INSURANCE PROGRAM

**FIRM
FLOOD INSURANCE RATE MAP
COOK COUNTY,
ILLINOIS
AND INCORPORATED AREAS**

PANEL 507 OF 832

(SEE MAP INDEX FOR PANELS NOT PRINTED)

CONTAINS:

COMMUNITY	NUMBER	PANEL	SUFFIX
CHICAGO, CITY OF	170074	0507	F

Notice to User: The MAP NUMBER shown below should be used when placing map orders; the COMMUNITY NUMBER shown above should be used on Insurance applications for the subject community.

**MAP NUMBER
17031C0507 F**

**EFFECTIVE DATE:
NOVEMBER 6, 2000**



Federal Emergency Management Agency

87° 37'

- WS/LSWS 5/29/2008



**Illinois Historic
Preservation Agency**

FAX (217) 782-8161

1 Old State Capitol Plaza • Springfield, Illinois 62701-1512 • www.illinois-history.gov

Cook County
Chicago

CON - Establish an Ambulatory Surgical Treatment Center
2334-36 S. Wabash Ave.
IHPA Log #005052708

July 11, 2008

Ira Rogal
Shea, Paige & Rogal, Inc.
547 S. LaGrange Road
LaGrange, IL 60525

Dear Mr. Rogal:

This letter is to inform you that we have reviewed the information provided concerning the referenced project.

Our review of the records indicates that no historic, architectural or archaeological sites exist within the project area.

Please retain this letter in your files as evidence of compliance with Section 4 of the Illinois State Agency Historic Resources Preservation Act (20 ILCS 3420/1 et. seq.). This clearance remains in effect for two years from date of issuance. It does not pertain to any discovery during construction, nor is it a clearance for purposes of the Illinois Human Skeletal Remains Protection Act (20 ILCS 3440).

If you have any further questions, please contact Patrick Gleason, Cultural Resources Manager, 1 Old State Capitol Plaza, Springfield, IL 62701, 217/785-3977.

Sincerely,

Anne E. Haaker
Anne E. Haaker
Deputy State Historic
Preservation Officer

ATTACHMENT IDEN-5

13

COST/SPACE REQUIREMENTS

<u>Department</u>	<u>Cost (\$)</u>	<u>Present</u>	<u>Upon Project Completion</u>	<u>(Total Gross Square Feet)</u>	
				<u>New</u>	<u>Remodeled</u>
ASTC	\$1,540,798	0	3,000		3,000

ATTACHMENT INFO-7

SECTION III. GENERAL REVIEW CRITERIA

This section is applicable to all projects EXCEPT those projects that are solely for discontinuation with no project costs and those projects that are non-substantive and subject only to a Part 1120 review. Refer to Part 1110.40 for the requirement for non-substantive projects.

A. Criterion 1110.230.a, Location

Check if the project will result in any of the following: establishment of a health care facility;
 establishment of a category of service; acquisition of major medical equipment (for treating inpatients) that is not or will not be located in a health care facility and is not being acquired by or on behalf of a health care facility. If NO boxes are checked, this criterion is not applicable. If any box is checked, read the criterion and submit the following:

1. A map (8 1/2" x 11") of the area showing:
 - a. the location of the applicant's facility or project;
 - b. the name and location of all the other facilities providing the same service within the planning area and surrounding planning areas within 30 minutes travel time of the proposed facility;
 - c. the distance (in miles) and the travel time (under normal driving conditions) from the applicant's facility to each of the facilities identified in b. above;
 - d. an outline of the proposed target population area.
2. For existing facilities, provide patient origin data for all admissions for the last 12 months presented by zip code. Note this information must be based upon the patient's legal residence other than a health care facility for the last 6 months immediately prior to admission. For all other projects for which referrals are required patient origin data for the referrals must be provided.
3. The ratio of beds to population (population will be based upon the latest census data by zip code) within 30 minutes travel time of the proposed project.
4. The status of the project in the zoning process. Provide letter(s) from the appropriate local officials.
5. Evidence of legal site ownership, possession, or option to purchase or lease.

APPEND DOCUMENTATION AS ATTACHMENT GRC-1 AFTER THE LAST PAGE OF THIS SECTION.

B. Criterion 1110.230.b, Background of Applicant

Read the criterion and submit the following information:

1. A listing of all health care facilities owned or operated by the applicant, including licensing, certification and accreditation identification numbers, if applicable.
2. Proof of current licensing and, if applicable, certification and accreditation of all health care facilities owned or operated by the applicant.
3. A certification from the applicant listing any adverse action taken against any facility owned or operated by the applicant during the three (3) years prior to the filing of the application.

C. Criterion 1110.230(c), Alternatives to the Proposed Project

Read the criterion and provide the following information:

1. Provide a comparison of all of the alternatives considered including the alternative of doing nothing. The comparison must address cost benefit analyses, patient access, quality, and short and long-term financial benefits.
2. Discuss why the alternative of using other area facilities or resources to meet the needs identified in your project is not feasible.
3. Discuss why the alternative of utilizing underutilized bed or other space in the facility is not feasible.

4. If the alternative selected is based solely or in part on improved quality of care, provide empirical evidence (including quantified outcome data) that verifies improved quality of care.

APPEND DOCUMENTATION AS ATTACHMENT GRC-3 AFTER THE LAST PAGE OF THIS SECTION.

D. Criterion 1110.230(d), Need for the Project

Is the need for the project based upon need assessment per Part 1100 or a variance?

Yes No

If no is indicated, read the criterion and submit the following as applicable:

1. Copies of area market studies including explanations regarding how and when these studies were performed.
2. Calculation of the need for the beds or services including the models used to estimate the need (all assumptions used in the model and the mathematical calculations must be included).
3. Identification of the individuals likely to use the proposed beds or service by:

Provide letters from physicians or hospitals which document how many patients were referred for this service in the past 12 months, where the patients were referred and how many patients will be referred annually to the proposed project.

4. If the project is for the acquisition of major medical equipment that does NOT result in the establishment of a category of service, provide documentation that the equipment will achieve or exceed the applicable target utilization levels specified in Appendix B of Part 1110 within 12 months after acquisition.

APPEND DOCUMENTATION AS ATTACHMENT GRC-4 AFTER THE LAST PAGE OF THIS SECTION.

E. Criterion 1110.230(e), Size of Project

Read the criterion and provide the following:

1. For any department involved in this project that has a square footage which exceeds the State Norm found in Appendix B of Part 1110 or if no State Norm is shown in Appendix B, provide:
 - a. a rationale explaining how the proposed square footage was determined;
 - b. copies of any standards used to determine appropriate square footage;
 - c. architectural drawings showing any design impediments in the existing facility; and
 - d. if the project is for the conversion of beds from one category of service to another an explanation as to why the excess space within the facility cannot be more appropriately used for other purposes.

APPEND DOCUMENTATION AS ATTACHMENT GRC-5 AFTER THE LAST PAGE OF THIS SECTION.

SECTION III. GENERAL REVIEW CRITERIA

A. Criterion 1110.230.a., Location

1. MAPS

- a. A map of the area showing the location of the project site is included as Attachment GRC-1-1.
- b. The names and locations of all other hospitals providing surgery and all ASTCs within 30 minutes travel time of the proposed facility is included as Attachment GRC-1-2. A map showing the location of those facilities is included as Attachment GRC-1-3.
- c. The distance (in miles) and the travel time (under reasonable driving conditions) from the applicant's facility to each of the facilities identified in (b) is also listed on Attachment GRC-1-2.
- d. An outline of the proposed target population area is included in Attachment GRC-1-1.

2. Referral letters are included in Section ASTC-2.

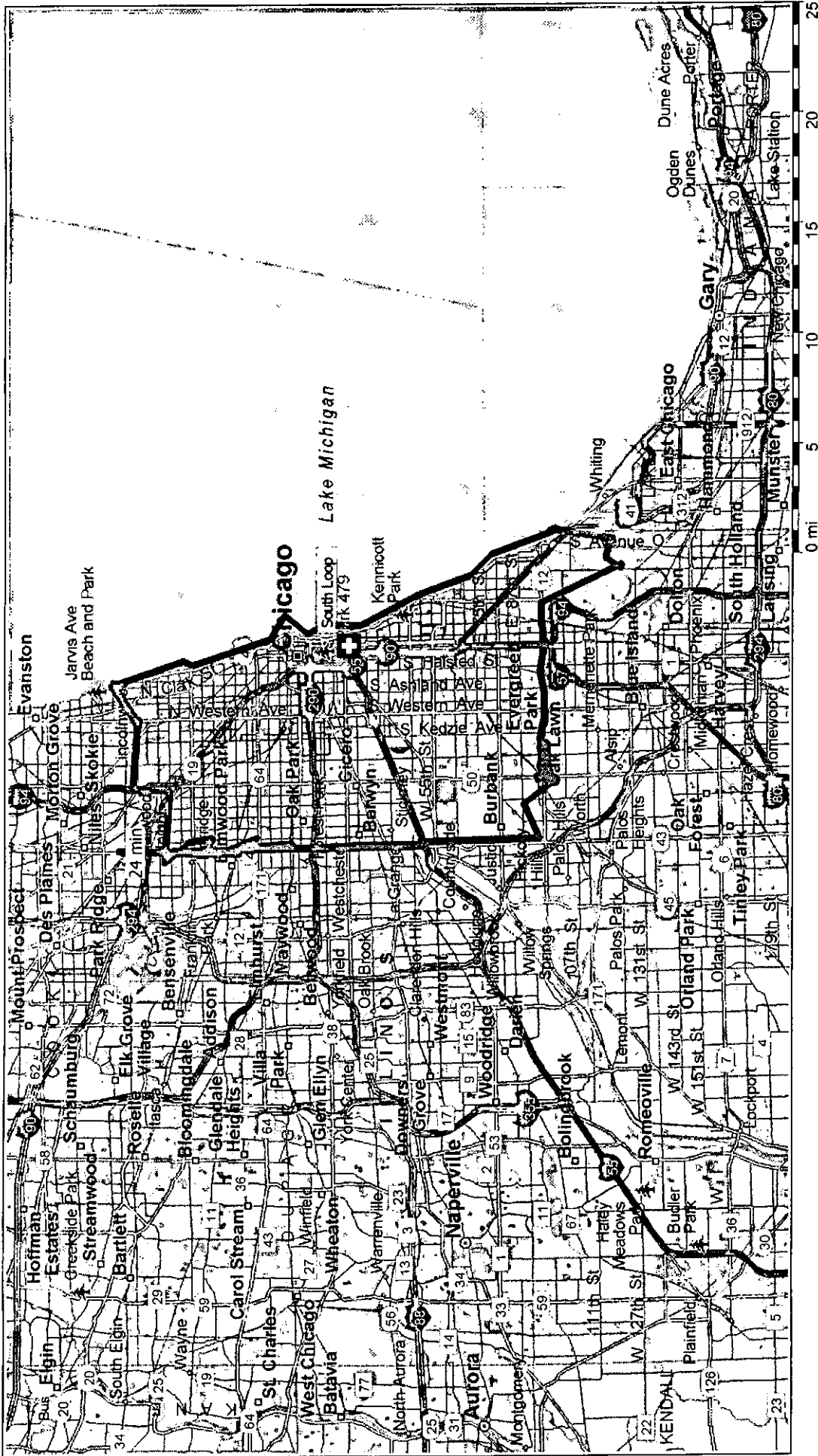
3. N/A: THE RATIO OF BEDS TO POPULATION

4. A letter regarding zoning is included as Attachment GRC-1-4

5. A lease is included as Attachment GRC-1-5

ATTACHMENT GRC-1

2336 s wabash



ATTACHMENT GRC-1-1

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FACILITIES WITHIN A 30-MINUTE DRIVE TIME

		<u>*TRAVEL TIME</u> (in minutes)	<u>MILES</u>
1.	25 East Same Day Surgery	10	2.39
2.	Advanced Ambulatory Surgical Center	27	15.75
3.	Albany Medical Surgery Center	10	4.55
4.	American Women's Medical Group	18	8.76
5.	CMP Surgicenter	23	9.73
6.	Foot & Ankle Clinics of America, LLC	10	4.96
7.	Fullerton Surgery Center, Inc.	30	11.52
8.	Hispanic-American Endoscopy Center, LLC	24	9.89
9.	River North Same Day Surgery Center	14	3.31
10.	Rush Medical Center	10	5.43
11.	Rush Surgicenter – Professional Building	10	5.53
12.	Six Corners Same Day Surgery	24	12.66
13.	Southwestern Medical Center, LLC	23	13.01
14.	Surgicore	26	13.98
15.	The Surgery Center at 900 N. Michigan	15	3.47
16.	Water Tower Surgicenter	14	3.35
17.	Advocate Illinois Masonic Medical Center	24	7.47
18.	Kindred Hospital Chicago North	25	11.43
19.	Lincoln Park Hospital	20	6.39
20.	Louis A. Weiss Memorial Hospital	25	9.10

***Map Quest x 1.25**

		<u>TRAVEL TIME</u> (in minutes)	<u>MILES</u>
21.	Northwestern Memorial Hospital	14	3.46
22.	Thorek Hospital & Medical Center	24	8.51
23.	Children's Memorial Hospital	21	6.59
24.	Loretto Hospital	19	10.32
25.	Mount Sinai Hospital Medical Center	17	4.42
26.	Norwegian American Hospital	22	8.80
27.	Saint Mary of Nazareth Hospital	19	7.37
28.	Saint Anthony Hospital	10	2.34
29.	Saint Elizabeth Hospital	20	8.10
30.	University of Illinois Medical Center at Chicago	14	5.81
31.	Jackson Park Hospital	23	13.25
32.	Mercy Hospital & Medical Center	3	.53
33.	Michael Reese Hospital & Medical Center	4	1.08
34.	Roseland Community Hospital	25	12.06
35.	Saint Bernard Hospital	11	5.75
36.	Concord Medical Center	1	.2
37.	Illinois Eye Institute Ambulatory Surgery Center	4	1.11
38.	Kindred Hospital Chicago Central	25	12.27
39.	Neurologic & Orthopedic Institute of Chicago	28	10.76
40.	John Stroger Hospital of Cook County	14	5.99
41.	Sacred Heart Hospital	20	8.29
42.	Provident Hospital of Cook County	14	4.96
43.	Holy Cross Hospital	25	9.22

		<u>TRAVEL TIME</u> (in minutes)	<u>MILES</u>
44.	South Shore Hospital	23	8.85
45.	Trinity Hospital	23	11.62
46.	University of Chicago Medical Center	18	7.02

LAW OFFICES
CARROLL & SAIN
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September 29, 2008

Mr. Jeffrey Mark
Illinois Health Facilities Planning Board
525 W. Jefferson Street
Springfield, IL 62761

Dear Mr. Mark:

We represent the owner of 2336-2340 S. Wabash, Chicago, Illinois.

The owner is in the process of obtaining zoning to allow the use of the property as an ambulatory surgical treatment center.

Very truly yours,

CARROLL & SAIN

Kenneth W. Sain

ATTACHMENT GRC-1-4

COMMERCIAL LEASE

THIS LEASE ("Lease") is entered into and made as of the 4 day of September, 2008 to be effective as of the date that the Illinois Health Planning Board ("IHFPB") approves and grants a Certificate of Need for an Ambulatory Endoscopy Center to the tenant, by and between, **Sunset Real Estate, LLC** ("Landlord") and **South Loop Endoscopy Center, LLC** located at 2336 and 2340 South Wabash Street in the City of Chicago ("Tenant").

WITNESSETH:

Landlord in consideration of the rents and covenants hereinafter set forth, does hereby demise, let and lease to Tenant, and Tenant does hereby hire, take and lease from Landlord, on the terms and conditions hereinafter set forth, the following described space (the "Premises"), to have and to hold the same, with all appurtenances, unto the Tenant for the term hereinafter specified.

1. **Description of the Premises.** The Premises are located in the City of Chicago, State of Illinois, in the building commonly known as 2336 and 2340 South Wabash Street (the "Building"), consisting of approximately (3,000) rentable square feet in the area designated in the first floor area, as depicted on Exhibit A attached hereto and made a part hereof.

2. **Lease Term.** The term of this Lease shall be for a period of five (5) years, commencing on the effective date of this agreement (the "Commencement Date"), and ending 60 months thereafter (the "Expiration Date"), unless the tenant is in default under the terms of this agreement and such default has not been cured after written and timely notice of such default is given to the tenant by the landlord. Provided that the Tenant is not in default under the Lease and upon written notice served upon the Landlord not less than nine (9) months prior to the Expiration Date Tenant shall have the exclusive option right to continue to renew the term of this Lease for a period of five (5) years (the "option terms"), commencing on the day following the Expiration Date.

3. **Rent.**

(a) **Base Rent.** Tenant shall pay to the Landlord as annual base rent for the Premises the sum of Dollars (\$ 82,500.00) payable in equal monthly installments of Six Thousand and Eight Hundred and Seventy-Five Dollars (\$6,875.00) each, in advance, on or before the first day of the commencement of the lease and each and every month thereafter for the sixty (60) months of this Lease; provided, however, that if the Commencement Date shall be a day other than the first day of a calendar month, the base rent installment for such first or last fractional month shall be prorated accordingly.

(b) **Annual Rental Adjustment.** Commencing on the third anniversary date of the Commencement Date of this Lease, and for each successive anniversary thereafter of the Commencement Date throughout the term of this Lease (each such date shall be referred to in this section as an "Adjustment Date"), including any option terms, the base rent shall increase by the greater of: (i) three percent (3%) over the prior term's Base Rent; or (ii) an amount equal to the increase in the Consumer Price Index as of the applicable Adjustment Date as compared to that index as of the Commencement Date (in the event of the first Adjustment Date) or the prior Adjustment Date, as the case may be. For the purposes of this paragraph, Consumer Price Index shall be for all Urban Consumers (CPI-U),

all items, U.S. City Average (1982-84 =100) published by the United States Department of Labor, Bureau of Labor Statistics. If the CPI-U is discontinued, comparable statistics published by a responsible financial periodical or recognized authority selected by Landlord shall be used for making the computation set forth above.

(c) **Real Estate and Other Taxes.** Tenant shall pay its pro rata share of the real estate taxes during this Lease term. For the purposes of this paragraph, the term "real estate taxes" includes all real estate taxes, assessments, water and sewer rents and all other kinds of governmental impositions and charges, whether ordinary, extraordinary, general or special, foreseen or unforeseen, and every installment thereof (including any interest on installment payments) which during the term hereof, are levied, assessed, or imposed upon the Building and Premises, become due and payable, or arise in connection with, the use, occupancy, or possession of the Premises. For purposes of this paragraph, Tenant's *pro rata* share is sixteen.seven percent (16.7%).

(d) **Operating Expenses.** Throughout the term of this Lease and any option terms, Tenant shall pay as additional rent its pro rata share of all common area maintenance and operating expenses incurred at the Premises. Such operating expenses include, but shall not be limited to, the following: cost of Landlord's insurance (as required pursuant to paragraph 11(d) of this Lease), supplies, window cleaning, heating and air conditioning, repairs and maintenance of the Premises, reasonable expenses incurred in seeking to obtain reductions in real estate taxes, reasonable management fees, service contracts, landscaping, parking lot maintenance and snow removal and sign maintenance. Said operating expenses shall be reasonably estimated by Landlord and shall be payable in equal monthly installments during each calendar year of the Lease in one-twelfth (1/12) of the estimated amount. Such amounts shall be adjusted each calendar year based on the actual expenses incurred by Landlord. For purposes of this paragraph, Tenant's pro rata share is sixteen.seven percent (16.7%).

(e) **Service Charge.** If any installment of base rent or additional rent provided for herein, or any part thereof, is not paid within ten business (10) days after its due date, it shall bear interest from the date due until the date paid at the annual rate of twelve percent (12%).

4. **Security Deposit.** Upon the execution hereof, Tenant shall deposit with landlord the sum of Twenty Five Hundred Dollars (\$2,500.00) to be held as security for the fulfillment of Tenant's obligations hereunder. In the event of any default by Tenant, in addition to and without prejudice to any other rights and remedies available to Landlord, Landlord may apply or retain all or any part of such security to cure the default or to reimburse Landlord for any sum which Landlord may spend by reason of the default. In the case of every such application or retention, Tenant shall, on demand, pay to Landlord the sum applied or retained which shall be added to the security deposit so that the same shall be restored to its original amount. If, at the end of the lease term, Tenant is not in default under this Lease, the security deposit, or any balance thereof, shall be returned to Tenant, without interest. It is expressly understood and agreed that the security deposit is not an advance payment of or on account of the rent herein reserved or any part or installment thereof or a measure of Landlord's damages.

5. **Condition of Premises.** Tenant's taking possession of the Premises shall be conclusive evidence as against Tenant that the Premises were in good order and satisfactory condition when Tenant took possession. No agreement of Landlord to alter, remodel, decorate, clean or improve the Premises, and no representation respecting the

condition of the Premises has been made by Landlord to Tenant (or relied upon by Tenant), other than as may be contained in this Lease.

6. Use of the Premises.

(a) **Specific Use.** The Premises shall be occupied and used exclusively for a Endoscopy and Wellness office, patient exam areas and surgical rooms and shall not be used for any other purpose.

(b) **Covenants Regarding Use.** In connection with its use of the Premises, Tenant agrees to do the following:

(i) Tenant shall be responsible for the acquisition, installation, maintenance and use all medical equipment and devices installed pursuant to proper governmental authorizations and approvals and carry appropriate insurance covering its operations.

(ii) Tenant shall use the Premises and conduct its business thereon in a safe, careful, reputable and lawful manner; shall keep and maintain the Premises in as good a condition as they were when Tenant first took possession thereof, subject to ordinary wear and tear.

(iii) Tenant shall not commit in, on or about the Premises or the Building, any act of waste, including any act which might deface, damage or destroy the Building or any part thereof; use on the Premises any hazardous substance, equipment or other thing which might cause injury to person or property or increase the danger of fire or other casualty in, on or about the Premises; emit any objectionable or offensive noise or odors from the premises; or do anything which would disturb or tend to disturb other tenants occupying leased space in the Building.

(iv) Tenant shall not use the Premises for any purpose or in any manner which would invalidate any policy of insurance now or hereafter carried on the Building. Should Tenant fail to comply with this covenant, Landlord may, at its option, require Tenant to stop engaging in such activity.

(c) **Compliance with Laws.** Tenant shall comply with all laws, statutes, ordinances, rules, regulations and orders of any federal, state, municipal or other government or agency thereof having jurisdiction over and relating to the use, condition and occupancy of the Premises.

(d) **Compliance with Building Rules and Regulations.** Tenant shall at all times comply with the rules and regulations as stipulated in writing to it by the Landlord. Landlord shall have the right to make such additional rules and regulations governing the use and occupancy of the Premises as Landlord sees fit for the operation of the Building.

1. Utilities and Other Building Services.

(a) **Tenant's Expense.** If separately metered, Tenant shall pay, directly to the appropriate supplier, for all electricity, gas, water and other utilities, interior janitorial services rendered for the Premises and for sanitary sewer service fees for water, electric and gas, if any. In the event Tenant fails to timely make payment for any of the foregoing, Landlord reserves the right to submit such payment, which shall then become additional rent due and owing from Tenant.

(b) **Services to be Provided.** Landlord shall not be responsible for furnishing any services other than those set forth in section 3 (d) herein.

(c) **Interruption of Services.** Tenant understands, acknowledges and agrees that any one or more of the utilities or other building services identified above may be interrupted by reason of accident, emergency or other causes beyond Landlord's control, or may be discontinued or diminished temporarily by Landlord or other persons until certain repairs, alterations or improvements can be made; that Landlord does not represent or warrant the uninterrupted availability of such utilities or building services; and that any such temporary interruption shall not be deemed an eviction or disturbance of Tenant's right to possession, occupancy and use of the Premises or any part thereof, or render Landlord liable to Tenant in damages by abatement of rent or otherwise, or relieve Tenant from the obligation to perform its covenants under this Lease. Landlord shall use best efforts and take reasonable action to cure any interruptions in utilities or other building services.

2. **Parking.** The parties acknowledge that the tenant, its employees, agents, customers and invitees shall have the use of the parking lot on a first-come first-served basis.

3. **Signs.** Tenant shall not be permitted to inscribe, paint, affix or display any signs, advertisements or notices on or in the Building or in the Premises and visible from outside same without in each case the written consent of Landlord. All signage must conform to Building standards of uniformity.

4. **Repair, Maintenance, Alterations, Improvements and Fixtures.**

(a) **Repair and Maintenance of the Premises.** Tenant shall, at its own expense, keep and maintain in good order, condition and repair or replace if necessary, the electrical, plumbing, heating, ventilation and air conditioning serving the Premises, and shall make all necessary repairs to the Premises and any systems exclusively serving the Premises.

(b) **Alterations or Improvements.** Tenant shall not make, nor permit to be made, alterations or improvements to the Premises unless Tenant obtains the prior written consent of Landlord thereto. In the event such consent is granted and before commencing any such alterations or improvements, Tenant shall submit the plans and specifications therefore to Landlord or its agent, for Landlord's written approval, which Landlord shall not unreasonably withhold. All work to be done by Tenant shall be performed in strict accordance with the approved plans and specifications, laws, statutes, ordinances and regulations. In addition, before commencing any such work, Tenant shall obtain all necessary consent, authorizations and licenses from federal, state and/or municipal authorities having jurisdiction over the work to be done. Any such work shall be done in a good and workmanlike manner in accordance with the plans and specifications previously approved. All persons who do any such work, whether Tenant, its contractors, or other persons, must be fully covered by Worker's Compensation Insurance, and the certificate therefore must be furnished to Landlord before any such work is commenced. Tenant shall indemnify and hold Landlord harmless from all claims for personal injury, death, or property damage occurring during the progress, or as a result of any work done in or about the premises. In addition, Tenant shall also indemnify and hold Landlord harmless against all bills for labor performed and equipment, fixtures and material furnished to the above Tenant in connection with the work, and against all liens, bills, or claims therefore or against the Premises, and from and against all loss, damages, costs, expenses, suits, claims and demands whatsoever.

5. **Fire or Other Casualty; Casualty Insurance.**

(a) **Substantial Destruction of the Building.** If the Building should be substantially destroyed (which, as used herein, means destruction or damage to at least 75% of the Building) by fire or other casualty, Landlord may, at its option, terminate this Lease by giving written notice thereof to the Tenant within sixty (60) days of such casualty. In such event, the rent shall be apportioned to and shall cease as of the date of such casualty. If Landlord does not exercise its option to terminate this Lease as aforesaid, then Landlord shall reconstruct and restore the Premises as provided below in subparagraph 11(b).

(b) **Substantial Destruction of the Premises.** If the Premises should be substantially destroyed, or rendered wholly untenable for the purpose for which they were leased, by fire or other casualty and the Building is not substantially destroyed as provided above, then:

(i) Landlord may reconstruct and restore the Premises, at Landlord's expense, and subject to the availability of insurance proceeds, to substantially the same condition as they were prior to the casualty, excluding any improvements, alterations, additions and/or fixtures performed by or the property of Tenant. This option shall be exercised by Landlord giving written notice to Tenant within sixty (60) days after the date of the casualty, and upon the exercise thereof rent shall be abated from the date of the casualty until substantial completion of the reconstruction of the Premises whereupon this Lease shall continue in full force and effect for the balance of the term upon the same terms, conditions and covenants as are contained herein. Landlord shall use reasonable diligence in completing such reconstruction repairs. If Landlord fails to exercise its option to reconstruct and restore, this Lease shall be terminated as of the date of the casualty, to which date rent shall be apportioned and shall thereafter cease.

(ii) If the casualty occurs during the last twelve (12) months of the term of this Lease, Landlord shall have the right and option to terminate this Lease as of the date of the casualty, which option shall be exercised by written notice to be given to Tenant within sixty (60) days after the date of such casualty. If this option is exercised, rent shall be apportioned to and shall cease as of the date of the casualty.

(c) **Partial Destruction of the Premises.** If the Premises should be rendered partially untenable for the purpose for which they were leased (which, as used herein, means such destruction or damage as would prevent Tenant from carrying on its business on the Premises to an extent exceeding 40% of its normal business activity) by fire or other casualty, then such damaged part of the Premises shall be reconstructed and restored, at Tenant's expense, to substantially the same condition as it was prior to the casualty; rent shall be equitably abated from the date of the casualty until substantial completion of the reconstruction repairs and in determining an equitable abatement of base rent, consideration shall be given to the proportion which the area damaged is to the entire area of the Premises and to the importance to Tenant of the area destroyed or damaged in conducting its business; and this Lease shall continue in full force and effect for the balance of the term. Tenant shall use reasonable diligence in completing such reconstruction repairs, but in the event Tenant fails to complete the same within sixty (60) days from the date of the casualty, Landlord may, at its option, terminate this Lease upon giving Tenant written notice to that effect, whereupon both parties shall be released from all further obligations and liability hereunder.

(d) **Casualty Insurance.**

(i) Landlord shall be responsible for insuring and shall at all times during the term of this Lease carry, at its own expense, a policy of all risk insurance which insures the Building, including the Premises, against loss or damage by fire or other casualty (namely, the perils against which insurance is afforded by the standard fire insurance policy and extended coverage endorsement); provided, however, that Landlord shall not be responsible for, and shall not be obligated to insure against, any loss or damage to personal property (including, but not limited to, any furniture, machinery, medical equipment, goods or supplies) of Tenant or which Tenant may have on the Premises or any trade fixtures installed by or paid for by Tenant on the Premises or any additional improvements which Tenant may construct on the Premises.

(ii) Tenant shall carry insurance during the entire term hereof insuring Tenant, and insuring Landlord, Landlord's beneficiaries; and their respective agents, partners and employees, as their interests may appear, with terms, coverages, limits and with companies satisfactory to Landlord, and with such increases in limits as Landlord may from time to time request, but initially Tenant shall maintain the following coverages in the following amounts:

(aa) Public liability insurance with broad form comprehensive general liability endorsement, including contractual liability insurance covering Tenant's indemnity obligations hereunder, in an amount not less than \$3,000,000 combined single limit per occurrence.

(bb) "All risk" physical damage insurance including fire, sprinkler leakage, vandalism and extended coverage for the full replacement

cost of all additions, improvements and alterations to the Premises and of all furniture, trade fixtures, equipment, merchandise and all other items of Tenant's property on the Premises.

(cc) Business interruption or extra expense insurance with limits not less than those carried by a prudent tenant.

(dd) Worker's Compensation Insurance.

(a) **Waiver of Subrogation.** Tenant hereby releases Landlord and each of Landlord's employees, agents, customers and invitees from any and all liability for any loss, damage or injury to person or property occurring in, on or about or to the Premises, improvements to the Building or personal property within the Building, by reason of fire or other casualty which are covered by valid applicable standard fire and extended coverage insurance policies and to the extent such losses are recoverable. Because the provisions of this Paragraph will preclude the assignment of any claim mentioned herein by way of subrogation or otherwise to an insurance company or any other person, Tenant to this Lease shall give to each insurance company which has issued to it one or more policies of fire and extended coverage insurance notice of the terms of the mutual releases contained in this Paragraph, and have such insurance policies properly endorsed, if necessary, to prevent the invalidation of insurance coverages by reason of the mutual releases contained in this Paragraph.

(b) **Increase of Insurance Risk.** Tenant shall comply with all applicable laws and ordinances, all orders and decrees of court and all requirements of other governmental authority, and shall not directly or indirectly make any use of the Premises which may thereby be prohibited or be dangerous to person or property or which may jeopardize any insurance coverage, or may increase the cost of insurance or require additional insurance coverage. If, by reason of the failure of Tenant to comply with the provisions of this Subparagraph 1(f), any cost of insurance is increased, then, in addition to any other rights and remedies available to Landlord, Tenant shall make immediate payment of or reimburse Landlord for the increased insurance cost, in the same manner as the installment of Rent with which they are billed, or if billed separately, within ten (10) days after such billing.

2. **Liability and Indemnification.** Tenant shall be responsible for, shall insure against, and shall indemnify Landlord, Landlord's beneficiaries and agents and hold them harmless from, any and all liability for any loss, damage or injury to person or property occurring in or on the Premises and Tenant hereby releases Landlord, Landlord's beneficiaries and agents from any and all liability for the same and waives any claims against Landlord, Landlord's beneficiaries and its agents. Tenant's obligation to indemnify hereunder shall include the duty to defend against any claims asserted by reason of such loss, damage or injury and to pay any judgments, settlements, costs, fees and expenses, including attorneys' fees, incurred in connection therewith.

3. **Eminent Domain.** If the whole or any part of the Premises shall be taken for public or quasi-public use by a governmental authority under the power of eminent domain or shall be conveyed to a governmental authority in lieu of such taking, and if such taking or conveyance shall cause the remaining part of the Premises to be untenable and inadequate for use by Tenant for the purpose for which they were leased, then Tenant may, at its option, terminate this Lease. If a part of the Premises shall be taken or conveyed but the remaining part is tenantable and adequate for Tenant's use, then this Lease shall be terminated as to the part taken or conveyed as of the date Tenant surrenders possession. Landlord shall make such repairs, alterations and improvements as may be necessary to render the part not taken or conveyed tenantable and the rent shall be reduced in proportion to the part of the Premises so taken or conveyed. Tenant shall not be entitled to any part of any award that may be made for such taking nor to any damages.

4. **Liens.** If, because of any act or omission of Tenant or anyone claiming by, through, or under Tenant, any mechanic's lien or other lien shall be filed against the Premises or the Building or against such property of Landlord (whether or not such lien is valid or enforceable as such), Tenant shall, at its own expense, cause the same to be discharged of record within a reasonable period of time or promptly contest same and post bond in an amount not less than two (2) times the amount of the claim, not to exceed thirty (30) days, after the date of filing thereof, and shall also defend and indemnify Landlord and hold it harmless from any and all claims, losses, damages, judgments, settlements, costs and expenses, including attorneys' fees, resulting therefrom or by reason thereof.

5. **Rental, Personal Property and Other Taxes.**

(a) Tenant shall pay before delinquency any and all taxes, assessments, fees or charges (hereinafter referred to as "taxes"), including any sales, gross income, rental, business occupation or other taxes, levied or imposed upon Tenant's business operation in the Premises and any personal property or similar taxes levied or imposed upon Tenant's trade fixtures, leasehold improvements or personal property located within the Premises. In the event any such taxes are charged to the account of, or are levied or imposed upon the property of, Landlord, Tenant shall reimburse Landlord for the same as additional rent. Notwithstanding the foregoing, Tenant shall have the right to contest in good faith any such tax and to defer payment, if required, until after Tenant's liability therefor is finally determined.

(b) If any trade fixtures, alterations or improvements or business machines and whether they are installed or paid for by Landlord or Tenant and whether or not they are affixed to and become a part of the realty and the property of Landlord, are assessed for real property tax purposes at a valuation higher than that at which other such property in other leased space in the Building is assessed, then Tenant shall reimburse Landlord as additional rent for the amount of real property taxes shown on the appropriate county official's records as having been levied upon the Building or other property of Landlord by reason of such excess assessed valuation.

6. **Assignment and Subletting.** Tenant shall not, without the prior written consent of Landlord, sublease or assign the leased Premises, such consent by the Landlord shall not be unreasonably withheld. In the event of any such permitted assignment or subletting, Tenant shall nevertheless at all times remain fully responsible and liable for the payment of rent and the performance and observance of all of the tenant's other obligations under the terms, conditions and covenants of this Lease. Any transfer of this Lease by sale, merger, consolidation or liquidation of Tenant's business shall constitute an assignment under this Lease. The transfer of a majority of the shares of stock/membership interests in Tenant shall also constitute an assignment for purposes of this Lease.

7. **Subordination of Lease to Mortgages.** This Lease is subject and subordinate to any mortgage, deed of trust or similar encumbrance presently existing or hereafter voluntarily placed on the Building or Premises, including any renewals, extensions or modifications thereof; and the recording of any such mortgage, deed of trust or similar encumbrance shall make it prior and superior to this Lease regardless of the date of execution or recording of either documents. Tenant shall, within ten (10) days' of Landlord's request, execute and deliver to Landlord, without cost, any instrument which may be deemed necessary or desirable by Landlord to confirm the subordination of this Lease. Failure by Tenant to so execute and deliver any such document shall be deemed a default under this Lease. Landlord shall deliver to Tenant, by such Mortgagee, grantee, settlor or other party executing such encumbrances, an agreement in form and substance satisfactory to Tenant, agreeing that in the event of a foreclosure or other such terminating event, Tenant may remain in possession of the Premises pursuant to the terms of this Lease so long as Tenant continues to perform its obligations hereunder and further agreeing that the purchaser at a foreclosure sale, will assume all the obligations of Landlord.

8. **Defaults and Remedies.**

(a) **Default by Tenant and Remedies of Landlord.** If at any time or times Tenant defaults in the payment of rent or of any part thereof and such default shall continue for a period of seven (7) business days or Tenant fails to pay any other monies that may fall due or become payable, or defaults in the due and full observance or performance of any other covenant, provision or condition herein required to be kept, performed or observed by Tenant (including but not limited to Tenant's obligations pursuant to Paragraph 6 of this Lease), and if any such default continues for a period of twenty (20) days after written notice to Tenant thereof, Landlord may at any time during the continuation of such default, by written notice to Tenant, declare the term of this Lease canceled.

(b) **Remedies.** Upon the occurrence of any default by Tenant under this Lease, Landlord may, at its option, with or without notice or demand of any kind to Tenant or any other person, have any one or more of the following described remedies in addition to all other rights and remedies provided at law, in equity or elsewhere herein:

(i) Landlord may terminate this Lease and the term created hereby, in which event Landlord may forthwith repossess the Premises and be entitled to recover forthwith (in addition to any other sums or damages for which Tenant may be liable to Landlord) as damages a sum of money equal to the excess of the value of the Rent provided to be paid by Tenant for the balance of the term over the fair market rental value of the Premises, after deduction of all anticipated expenses of reletting, for said period. Should the fair market rental value of the Premises, after deduction of all anticipated expenses of reletting, for the balance of the term exceed the value of the Rent provided to be paid by Tenant for the balance of the term, Landlord shall have no obligation to pay to Tenant the excess or any part thereof or to credit such excess or any part thereof against any other sums or damages for which Tenant may be liable to Landlord.

(ii) Landlord may terminate Tenant's right of possession and may repossess the Premises by forcible entry and detainer suit, by taking peaceful possession or otherwise, without terminating this Lease, in which event Landlord may, but shall be under no obligation to, relet the same for the account of Tenant, for such rent and upon such terms as shall be satisfactory to Landlord. For the purpose of such reletting, Landlord is authorized to decorate, repair, remodel or alter the Premises. If Landlord shall fail to relet the Premises, Tenant shall pay to Landlord as damages a sum equal to the amount of the Rent reserved in this Lease for the balance of the term. If the Premises are relet and a sufficient sum shall not be realized from such reletting after paying all of the costs and expenses of all reasonable decoration, repairs, remodeling, alterations and additions and the expenses of such reletting and of the collection of the rent accruing therefrom to satisfy the Rent provided for in this Lease, Tenant shall satisfy and pay the same upon demand therefor from time to time. Tenant shall not be entitled to any rents receive by Landlord in excess of the Rent provided for in this Lease. Tenant agrees that Landlord may file suit to recover any sums falling due under the terms of this Paragraph 18 from time to time and that no suit or recovery of any portion due Landlord hereunder shall be any defense to any subsequent action brought for any amount not theretofore reduced to judgment in favor of Landlord.

(iii) In consideration of the mutual benefits arising under this Lease, Tenant hereby grants to Landlord a lien on all property of Tenant now or hereafter placed in or upon the Premises, and such property shall be and remain subject to such lien of Landlord for payment of all rent and other sums agreed to be paid by Tenant herein, excluding rented equipment leased by Tenant. Said lien shall be in addition to and cumulative of the Landlord's liens provided by law.

(c) **Non-Waiver of Defaults.** The failure or delay by Landlord hereto to enforce or exercise at any time any of the rights or remedies or other provisions of this Lease shall not be construed to be a waiver thereof, nor affect the validity of any part of this Lease or the right of Landlord thereafter to enforce each and every such right or remedy or other provisions. No waiver of any default and breach of this Lease shall be held to be a waiver of any other default or breach.

(d) **Attorney's Fees.** In the event Tenant defaults in the performance or observance of any of the terms, conditions, covenants or obligations contained in this Lease and Landlord places the enforcement of all or any part of this Lease in the hands of an attorney, Tenant agrees to reimburse Landlord for the attorneys' fees incurred thereby, whether or not suit is actually filed.

9. **Access to the Premises.** Landlord, its employees and agents and any mortgagee of the Premises shall have the right to enter any part of the Premises during regular business hours for the purposes of examining or inspecting the same, showing the same to prospective purchasers, mortgagees or tenants and for making such repairs, alterations or improvements to the Premises as Landlord may deem necessary or desirable. Tenant may reasonably deny the Landlord or its agents from entering any surgery procedure room when a surgical procedure is underway. If representatives of Tenant shall not be present to open and permit such entry into the Premises at any time when such entry is necessary or permitted hereunder, Landlord and its employees and agents may enter the Premises by means of a master key or otherwise. Landlord shall incur no liability to Tenant for such entry. No such entry shall constitute an eviction of Tenant or a termination of this Lease, nor entitle Tenant to any abatement of rent therefor.

10. **Surrender of Premises.** Upon the expiration or earlier termination of this Lease, Tenant shall surrender the Premises to Landlord, together with all alterations, improvements and other property as provided elsewhere herein, in broom-clean condition and in good order, condition and repair, except for ordinary wear and tear and damage which Tenant is not obligated to repair, failing which, Landlord may restore the Premises to such condition at Tenant's expense. Upon such expiration or termination Tenant's trade fixtures, furniture and equipment shall remain Tenant's property, and Tenant shall have the right to promptly remove the same. Tenant shall promptly repair any damage caused by any such removal, and shall restore the Premises to the condition existing prior to the installation of the items so removed.

11. **Holding Over.** In the event Tenant remains in possession of the Premises after the expiration or earlier termination of this Lease, such holding over shall not be deemed to renew this Lease. Tenant shall pay Landlord two hundred percent (200%) of the base rental and other charges during such period, and any damages sustained by Landlord on account of such holding over.

12. **Quiet Enjoyment.** If and so long as Tenant pays the prescribed rent and performs or observes all of the terms, conditions, covenants and obligations of this Lease required to be performed or observed by it hereunder, Tenant shall at all times during the term hereof have the peaceable and quiet enjoyment, possession, occupancy and use of the Premises without any interference from Landlord or any person or

persons claiming the Premises by, through or under Landlord, subject to any mortgages, underlying leases or other matters of record to which this Lease is or may become subject. Landlord represents and warrants that it has full right and power to execute and perform this Lease and to grant the estate demised herein.

13. **Notice and Place of Payment.**

(a) All rent and other payments required to be made by Tenant to Landlord shall be delivered or mailed to Landlord at the address set forth below or any other address Landlord may specify from time to time by written notice given to Tenant.

(b) Any notice, demand or request required or permitted to be given under this Lease or by law shall be deemed to have been given if reduced to writing and delivered in person or mailed by registered or certified mail, postage prepaid, to the party who is to receive such notice, demand or request at the address set forth below. When so mailed, such notice, demand or request shall be deemed to have been given as of the date it was so delivered or mailed.

Landlord: **Sunset Real Estate, LLC**

Telephone:
Facsimile:

with copy to: Carroll & Sain
7250 North Cicero Avenue, Ste. 200
Lincolnwood, Illinois 60712
Telephone: (847) 568-7000
Facsimile: (847) 568-7008

Tenant: **South Loop Endoscopy Center, LLC**

Telephone:
Facsimile:

with copy to: _____

Telephone:
Facsimile:

1. **Miscellaneous General Provisions.**

(a) Any amounts of money to be paid by Tenant to Landlord pursuant to the provisions of this Lease, whether or not such payments are denominated "rent" or "additional rent" and whether or not they are to be periodic or recurring, shall be deemed as "rent" or "additional rent" for

purposes of this Lease; and any failure to pay any of the same shall entitle Landlord to exercise all of the rights and remedies afforded hereby or by law for the collection and enforcement of Tenant's obligation to pay rent. Tenant's obligation to pay any such rent or additional rent pursuant to the provisions of this Lease shall survive the expiration or other termination of this Lease and the surrender of possession of the Premises after any holdover period.

(b) Tenant shall, within ten (10) days following receipt of a written request from Landlord, execute, acknowledge and deliver to Landlord or to any lender, purchaser or prospective lender or purchaser designated by Landlord a written statement certifying (i) that this Lease is in full force and effect and unmodified (or, if modified, stating the nature of such modification), (ii) the date to which rent has been paid, and (iii) that there are not, to Tenant's knowledge, any uncured defaults (or specifying such defaults if any are claimed). Any such statement may be relied upon by any prospective purchaser or mortgagee of all or any part of the Premises. Tenant's failure to deliver such statement within such period shall be conclusive upon Tenant that this Lease is in full force and effect and unmodified, and that there are no uncured defaults in Landlord's performance hereunder.

(c) If requested by Landlord, a Memorandum of Lease, containing the information required by Illinois law concerning this Lease shall be prepared, executed by both parties and filed for record in the office of the Recorder in the County in which the Premises is located.

(d) Each party hereto shall indemnify and hold harmless the other party for any and all liability incurred in connection with the negotiation or execution of this Lease for any real estate broker's commission or finder's fee which has been earned by a real estate broker or other person on such party's behalf.

(e) This Lease and all matters pertinent thereto shall be construed and enforced in accordance with the laws of the State of Illinois.

(f) This Lease, including all Exhibits, Riders and Addenda, constitutes the entire agreement between the parties hereto and may not be modified except by an instrument in writing executed by the parties hereto.

(g) This Lease and the respective rights and obligations of the parties hereto shall inure to the benefit of and be binding upon the successors and assigns of the parties hereto as well as the parties themselves; provided, however, that Landlord, its successors and assigns shall be obligated to perform Landlord's covenants under this Lease only during and in respect of their successive periods as Landlord during the term of this Lease.

(h) If any provision of this Lease shall be held to be invalid, void or unenforceable, the remaining provisions hereof shall not be affected or impaired, and such remaining provisions shall remain in full force and effect.

(i) Landlord shall not, by virtue of the execution of this Lease or the leasing of the Premises to Tenant, become or be deemed a partner of Tenant in the conduct of Tenant's business on the Premises or otherwise.

(j) As used in this Lease, the word "person" shall mean and include, where appropriate, an individual, corporation, partnership or other entity; the plural shall be substituted for the singular, and the singular for the plural, where appropriate; and words of any gender shall include any other gender. The topical headings of the several paragraphs of this Lease are inserted only as a matter of convenience and reference, and do not affect, define, limit or describe the scope or intent of this Lease.

(k) Tenant shall look solely to Landlord's estate and interest in the Premises or the proceeds thereof for the satisfaction of any right of Tenant for collection of a judgment or other judicial process against Landlord, and no other property of Landlord shall be subject to levy, lien, execution or attachment for satisfaction of Tenant's rights or remedies hereunder.

(l) Landlord and Tenant represent and warrant to each other that it has not engaged any broker or finder in connection with this Lease or the transactions contemplated hereby.

(m) Tenant shall not store, use or dispose of any hazardous, toxic or radioactive materials, including asbestos, PCB's, and radioactive substances, or any flammable oils or fluids, or any explosives or other articles deemed by Landlord to be hazardous to persons or property or any other item which shall increase the rate of insurance on the Building or the Premises (collectively, "Hazardous Materials"), other than such quantities and types of Hazardous Materials and other substances which are normally used as part of the permitted uses hereunder and are not likely in Landlord's opinion to cause injury to any person or damage to the Building or the Premises. Tenant at its sole cost and expense shall comply with all laws, rules and regulations relating to the storage, use and disposal of such Hazardous Materials, including any reasonable regulations imposed by Landlord. Tenant shall be solely responsible for and shall defend, indemnify and hold Landlord and Landlord's agents harmless from and against all claims, costs and liabilities, including attorneys' fees and costs, arising out of or in connection with such Hazardous Materials including without limitation the storage, disposal, removal and clean-up of the Hazardous Materials and the work and materials necessary to return the Premises and Building to their condition existing prior to Tenant's placement of the Hazardous Materials on the Premises. In no event shall Tenant permit a release of any Hazardous Material to the environment from the Premises. Tenant's obligations hereunder shall survive the termination of this Lease.

(n) This Agreement may be executed and delivered by exchange of facsimile copies showing the signatures of all parties, and signatures need not be affixed to the same copy. The facsimile copies showing the signatures of the parties will constitute originally signed copies of the same agreement.

IN WITNESS WHEREOF the parties hereto have executed this Lease as of the day and year first above written.

LANDLORD:

TENANT:

By: [Signature]

By: [Signature]

Its: Sunrise Real Estate LLC.

Its: South Loop Endoscopy and Wellness



SOUTH LOOP ENDOSCOPY & WELLNESS CENTER, LLC

2334 S. Wabash
Chicago, Illinois 60616

July 14, 2008

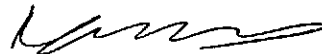
Mr. Jeffrey Mark
Executive Secretary
Illinois Health Facilities Planning Board
525 W. Jefferson Street
2nd Floor
Springfield, IL 62761

Dear Mr. Mark:

This is to certify that the applicant does not own or operate any healthcare facilities.

In addition, this letter authorizes the Illinois Health Facilities Planning Board and its employees to access information in order to verify any documentation or information submitted in response to our application or to obtain any documentation or information that the Planning Board or its employees find pertinent for the purposes of reviewing my background.

Sincerely,



David Chua, M.D.

ATTACHMENT GRC-2

ALTERNATIVES TO THE PROJECT

Applicant considered and rejected the following alternatives.

Do Nothing

Doing nothing would not meet the needs of Dr. Chua's patients. Applicant proposes a single specialty gastroenterology facility. It will have specialized equipment not available at any Chicago ASTC. This equipment will allow performing endoscopic ultrasound and capsule endoscopies. Those procedures are described in more detail in the following section. Articles describing the procedures and benefits of the procedures are included as Attachment GRC-3-1.

This equipment is available in Chicago in a few hospitals. Hospital charges are at least \$1,000 more than applicants proposed charges. Charges for other procedures at the ASTC are estimated to be at least \$100 less than the current facilities. There will be an estimated 1,600 procedures performed the first year. Even using the \$100 per procedure cost savings the savings will total \$160,000 annually.

Doing nothing would save the entire project cost but would offer no benefit to patients and not provide the \$160,000 annual cost savings.

Use Space in Existing Facilities

Existing Chicago ASTCs do not have the equipment to provide capsule endoscopies and endoscopic ultrasounds. Additionally there are scheduling

ATTACHMENT GRC-3

issues for endoscopies at hospitals and multi-specialty ASTCs. Physicians must compete with other physicians for the morning time slots that are best for their patients.

Using existing facilities would save the entire project cost. There would be no benefit to the patients.

Develop an ASTC with One Procedure Room

Applicant is proposing two procedure rooms for operational efficiency. It allows more procedures to be performed in the morning. Endoscopies require patients not to eat the night before. This puts a premium on morning procedure times.

Procedure rooms require time consuming set up and clean up. Having two rooms allows a physician to perform a procedure in one room and then move to the second room while the first room is being cleaned and set up. This provides maximum efficiency for the physician and surgical staff.

Building only one procedure room would reduce space by less than 1000 GSF saving. The cost per square foot is \$176. The savings would be \$176,000. There is no benefit to patients.

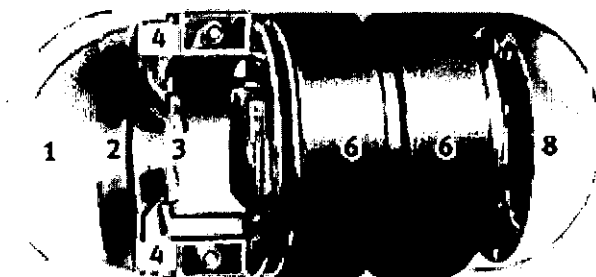


Courtesy of Given Imaging Inc.

Pillcam diagram

Pillcam diagram

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INSIDE THE M2A™ CAPSULE

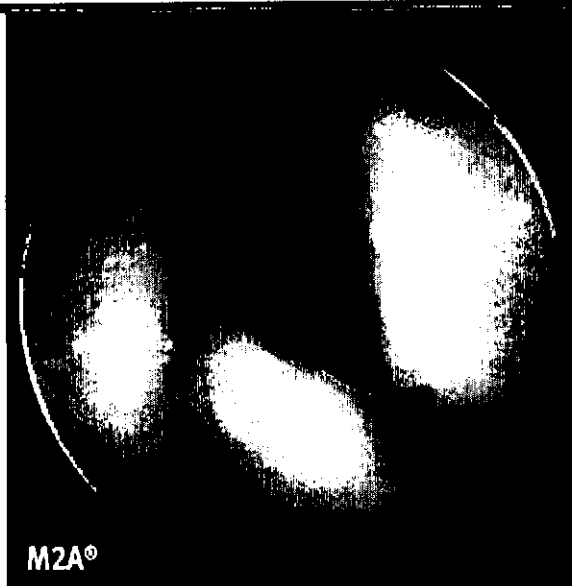
- 1. Optical dome
- 2. Lens holder
- 3. Lens
- 4. Illuminating LEDs (Light Emitting Diode)
- 5. CMOS (Complementary Metal Oxide Semiconductor) imager
- 6. Battery
- 7. ASIC (Application Specific Integrated Circuit) transmitter
- 8. Antenna

Courtesy of Given Imaging Inc.

Duodenal bleeding capsule

Duodenal bleeding

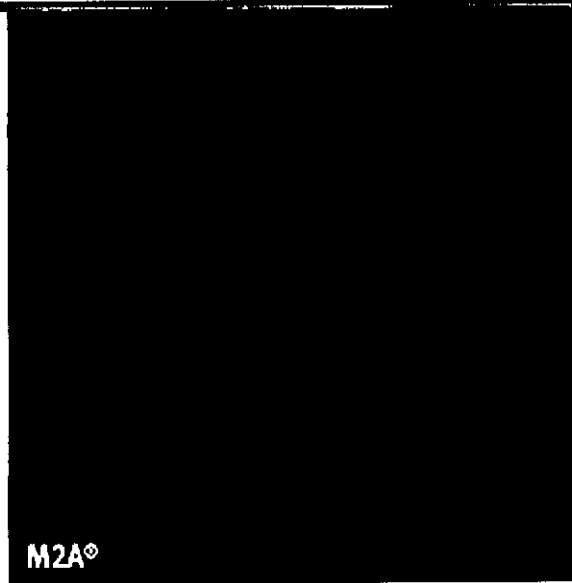
43



Bleeding site in duodenum identified during capsule endoscopy. *Courtesy of Given Imaging Inc.*

Crohns disease capsule

Crohn's disease

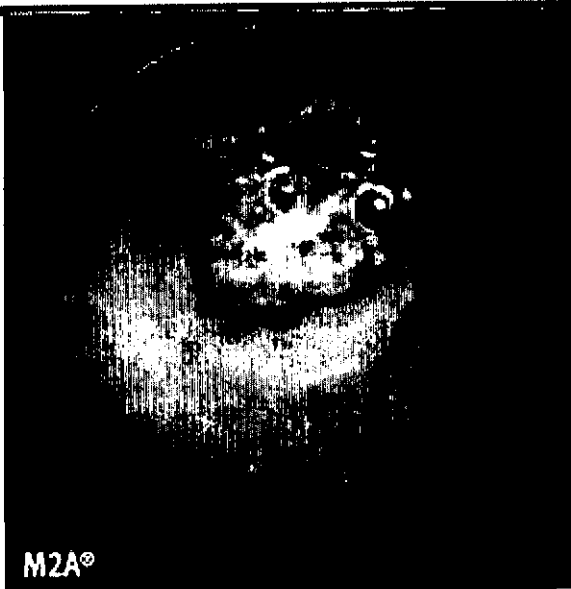


Small bowel ulceration as seen during capsule endoscopy. *Courtesy of Given Imaging Inc.*

NSAIDS stricture capsule

Small bowel stricture

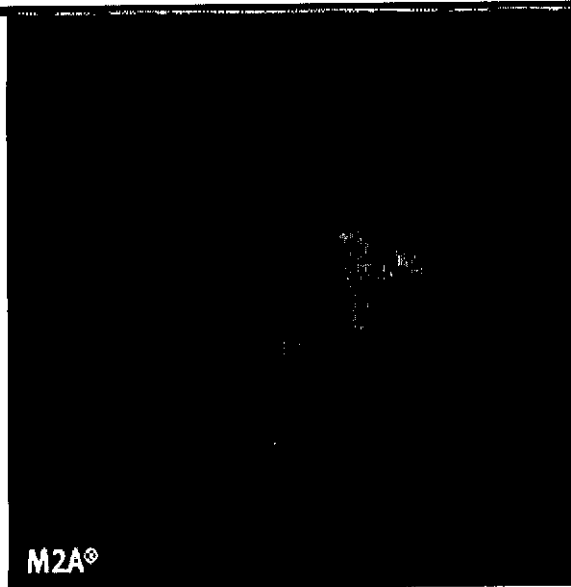
44



An ulcerated small bowel stricture due to nonsteroidal antiinflammatory agents as seen during capsule endoscopy. *Courtesy of Given Imaging Inc.*

Celiac disease capsule

Celiac disease



Small bowel bleeding in an area with villous atrophy in a patient with celiac disease as seen during capsule endoscopy. *Courtesy of Given Imaging Inc.*

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NEED FOR THE PROJECT

Single specialty surgery gastroenterology centers are recognized as being patient friendly, efficient and cost effective. There are more than ten single specialty gastroenterology ASTCs in the state. Only one is located in the City of Chicago. That center is located on West Fullerton Avenue about 10 miles from applicant's proposed site.

The physician owner of the surgery center possesses a unique set of language skills. He speaks both Spanish and Chinese. Applicant is located on the near South side of Chicago just minutes from both Chinese and Spanish speaking areas of Chicago.

The proposed surgery center will offer two procedures not available in any Chicago ASTC., endoscopic ultrasounds and capsule endoscopies. Endoscopic ultrasound combines endoscopy and ultrasound. A small ultrasound transducer is placed at the end of an endoscope. That allows placing the transducer inside the body resulting in better images.

It is a highly accurate technique in the studies of deeper tumors of the gastrointestinal tract, determining the extent and depth of certain cancers, and obtaining tissue samples of some deeper cancers like pancreas, liver and involved lymph nodes in a much safer way than would otherwise be possible. In many instances, it contributes information that lead to decisions in favor or against more invasive treatments including surgery. This is a breakthrough

ATTACHMENT GRC-4

technology that has become indispensable in our care of these patients.

Capsule endoscopies use a small video capsule that is swallowed. A diagram of a "Pillcam" follows this section. It provides improved examination of the small intestine. The procedure is painless and does not require sedation.

In cases where there is unexplained gastrointestinal bleeding, diarrhea, or anemia (meaning no diagnosis was found after doing an upper endoscopy, colonoscopy, and X-ray studies), studying the small intestines with the pill cam capsule have identified diagnoses that led to treatment and cure and alleviation of sickness and suffering. Other applications include Inflammatory Bowel Diseases, small bowel tumors, injury of the small intestines from anti-inflammatory medications, and celiac sprue. It is a cutting edge technology that is continuing to evolve.

Included as Attachments GRC-4-1 are letters of support from the Consul Generals of Honduras, Brazil and the Phillipines. Also included is a support letter from a Chinese charitable foundation attesting to Dr. Chua's support for its charitable medical missions.

In his medical practice Dr. Chua accepts patients who cannot pay or have limited ability to pay. Having an ASTC will allow Dr. Chua to include the facility charge in his free care and reduced fee care for his patients requiring surgical procedures.

The proposed ASTC offers new procedures in an ASTC setting and improves access to care.



CONSULADO GENERAL DE HONDURAS

4439 W. FULLERTON AVE. CHICAGO, IL. 60639

TEL : (773) 342-8281. FAX (773) 342-8293

E-mail: consulchicago@yahoo.com

To
Jeffrey Mark
Executive Secretary
Illinois Health Facilities Planning Board

To whom it may concern:

I am writing to express my full support for Dr. David Chua's application to open the South Loop Endoscopy and Wellness Center. This center will provide much needed medical assistance for the diverse community of Chinese, Filipino and Hispanic immigrants.

Dr Chua has demonstrated years of dedication and the ability to serve this community in a superior way. He has been providing public aid funded and/or charitable services to at least 30% of their patients.

Dr Chua and his staff are sensitive to the ethnic and language needs of the community. This center will truly fill a need that has been lacking for a long time.

I know Dr. Chua personally and I am one of his patients. He is a physician of superior quality. I believe the opening of this Endoscopy Center, will have a lot of my contrymen who are new immigrants and citizens in the city of Chicago.

Sincerely,


Dr. Jose Brazmo Montalvan Hernandez
Consul General

ATTACHMENT GRC-4-1

Consulado Geral do Brasil



Consulate General of Brazil

401 North Michigan Avenue
Suite 3050
Chicago, Illinois 60611
(312) 464-0244
(312) 464-0299 Fax

Jeffrey Mark
Executive Secretary
Illinois Health Facilities Planning Board

To whom it may concern,

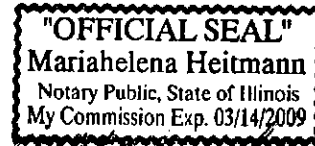
I am please to support Dr David Chua's application for the South loop Endoscopy and wellness center. I believe this center will help residents of Chicago and my countrymen in the community.

Dr.Chua has been in practice for the last 20 years. He has consistently provided quality healthcare to all of his patients, the majority which is Latino and Hispanics. He is also dedicated to serving the less fortunate in the community including those on public aid funding, the uninsured, and the indigent.

I encourage you to give Dr.Chua's application serious and careful consideration. I believe this center will fill an important healthcare need amongst my countrymen.

Sincerely,

Ricardo L. V. de Carvalho
Consul General



04/04/08



台灣佛教慈濟基金會美國芝加哥分會

Taiwan Buddhist Tzu Chi Foundation, U.S.A. Midwest Region

To whom it may concern,

April 2, 2008

Taiwan Buddhist Tzu-Chi Foundation is a charity organization for the last 42 years. Our mission includes charity, medicine, humanitarian, and education. As of today, we have encompassed 64 countries in the world and are a member of the NGO in the United Nation. You are most welcome to visit our website-- (www.us.tzuchi.org).

Dr. David Chua, an Internist and Gastroenterologist, and his wife Dr. Wendy Yeh, a dentist, are well known in the west suburban area of Chicago. They are members of the Tzu-Chi Foundation, and have fully supported the Tzu-Chi medical missions, including medical lectures and outreach clinics serving the underprivileged community. We are excited to learn that Dr. Chua is planning to open a South Loop Endoscopy and Wellness Center in order to provide both high quality and affordable care to the under served, especially to the Chinese, Filipino, and Hispanic, and African-American communities.

This is an important private sector-initiated project that deserves our full support.

Should you have any further question, please do not hesitate to contact us in our office at 630-963-6601.

Thank you for your consideration.

Sincerely Yours,

Dr. Jeng Su


Director of Medical Department

Tzu Chi Foundation U.S.A., Midwest Region

Amy Hsieh


Executive Director

Tzu Chi Foundation U.S.A., Midwest Region



KONSULADO PANLAHAT NG PILIPINAS

CONSULATE GENERAL OF THE PHILIPPINES

CHICAGO

MISC-241-2008

30 April 2008

Dear Mr. Mark,

This refers to the application of Dr. David C. Chua, a Filipino-American Doctor of Medicine, to establish in the Chicago area a Digestive and Endoscopy Center.

Dr. Chua is a noted Digestive and Liver Disease Specialist and has a long history of providing quality medical care to the residents of Chicago, including the Filipino-American community in the State of Illinois.

The proposed Digestive and Endoscopy Center is envisioned to provide quality and affordable care to the residents of Chicago. Dr. Chua and his staff are familiar with and sensitive to the language and needs of the patients of diverse ethnic origins (i.e. Filipinos, Chinese, Hispanic, etc.).

We would highly appreciate your Office's favorable consideration of Dr. Chua's application to open a Digestive and Endoscopy Center in Chicago.

Very truly yours,

Blesila C. Cabrera
BLESILA C. CABRERA
Consul General

Mr. JEFFREY MARK
Executive Secretary and Head
Illinois Health Facilities Planning Board
525 West Jefferson Street
Springfield, IL 62761



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BMJ 2006;332:528-531 (4 March), doi:10.1136/bmj.332.7540.528

Practice

Gastrointestinal capsule endoscopy: from tertiary centres to primary care

Reena Sidhu, specialist registrar in gastroenterology¹, David S Sanders, consultant gastroenterologist¹, Mark E McAlindon, consultant gastroenterologist¹

¹ Royal Hallamshire Hospital, Sheffield S10 2JF

Correspondence to: R Sidhu reena_sidhu@yahoo.com

The first endoscope introduced by Bruening in 1907 was a rigid instrument that allowed inspection of the upper gastrointestinal tract under a general anaesthetic.^{W1} Forty years later the first flexible fiberoptic instrument allowed procedures to be done under local anaesthetic or light sedation. It took a further 20 years for the technological evolution of the first colonoscope. A major advance occurred in 1999, when capsule endoscopy enabled complete visualisation of the small bowel.^{W2} A capsule is swallowed and propelled through the gastrointestinal tract by the action of peristalsis. It contains an imaging device, which transmits images of the intestine to sensors on the abdominal wall.



Fig 1 A capsule endoscope

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Historically the small bowel was considered technically difficult to examine because of its length (3-5 metres), location, and tortuosity.^{W3} Previously the small bowel could be partly assessed by a push anteroscopy, which is longer (about 2 metres) than a standard gastroscope and therefore allows examination of up to 80-120 cm beyond the ligament of Treitz (anatomically the duodenojejunal flexure), while intraoperative enteroscopy required a general anaesthetic and laparotomy. Barium follow through (small bowel meal) and enteroclysis (double contrast small bowel follow through) allow indirect examination of the small bowel but have a low diagnosis rate.^{1 W4 W5} Given the limitations of these other tests, there has been a surge in investigations on the practical diagnostic ability and clinical utility of capsule endoscopy.

Summary points

Capsule endoscopy—a novel method of imaging the small bowel—is safe and can be performed on an outpatient basis in both primary and secondary care

It has a higher positive diagnosis rate in the detection of small bowel pathology than conventional small bowel investigations

Capsule endoscopy can be used to investigate patients with obscure gastrointestinal bleeding and negative results on upper and lower gastrointestinal endoscopy

Sources and selection criteria

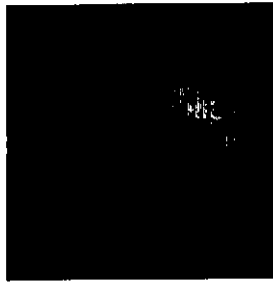
We performed a comprehensive literature search in Medline, Clinical Evidence, the Cochrane library, and Embase with the keywords capsule endoscopy and enteroscopy. We found 50 prospective and peer review studies, six prospective randomised controlled studies, nine retrospective studies, 34 review articles, 21 case studies, 26 letters, 19 editorials, one pooled analysis, and two sets of guidelines (American and European) on capsule endoscopy.

What is capsule endoscopy?

The PillCam SB capsule endoscope (Given Imaging, Yoqneam, Israel), measures 26 mm x 11 mm and weighs 3.7 g. It contains a complementary metal oxide semiconductor imaging chip video camera, six white light emitting diode illumination sources, two silver oxide batteries, and a radio telemetry transmitter^{W2} (fig 1). The image field of view is 140° and the magnification 1:8. Once swallowed, the capsule is propelled by intestinal peristalsis and excreted in the faeces. Video images are captured at two frames per second and are transmitted by radio frequency to a sensor array in a belt placed around the patient's abdomen. The patient wears this digital data recorder for the duration of the battery life (eight hours). The recorded images are then downloaded to a workstation. The software produces a video of these images, which can be reviewed at any time thereafter. The current cost of a single use capsule is £300 (\$522; €439).

Fig 2 Bleeding in the small bowel secondary to angioectasia

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Capsule endoscopy v conventional investigations

Capsule endoscopy has been shown to have a superior positive diagnosis rate (range from 45-76%) for the recognition of small bowel pathology compared with other methods, including push enteroscopy, barium contrast studies, computed tomographic enteroclysis, and magnetic resonance imaging (collective positive diagnosis rate is 21 positive diagnosis rate 1-52%^{1-11 w6}) (table). As a result of these observations, in 2001 capsule endoscopy obtained approval from the Food and Drug Administration in the United States. It is also being used in community gastroenterology practice (primary care) within the US.^{w7} Patients may soon be able to opt for capsule endoscopy as their first line investigation instead of conventional endoscopy, though this is not currently an option in the NHS.

View this table: Studies comparing diagnostic yield of capsule endoscopy with push enteroscopy and radiology for small bowel disease
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Indications for capsule endoscopy

The clinical use of capsule endoscopy is rapidly expanding, and there is now evidence for specific indications. Obscure gastrointestinal bleeding, defined as recurrent gastrointestinal bleeding in the absence of a cause found using standard endoscopic and radiological methods, is the most common. Initial investigations for obscure gastrointestinal bleeding are upper and lower gastrointestinal endoscopy (gastroscopy and colonoscopy). For patients in whom results are normal, the subsequent prevalence of small bowel pathology identified with capsule endoscopy ranges from 45% to 76%.^{2 3 5 8 w8-w11} Commonly detected abnormalities include angiodysplasia, tumours, varices, and ulcers.¹² Recognition of these lesions can lead to therapeutic intervention (adrenalina injection, diathermy, laser therapy, or surgery) and resolution of bleeding (fig 2).⁴ In some patients, however, the source of bleeding is found in the upper gastrointestinal tract proximal to the small bowel.^{1 w4 w10 w11} In such cases a careful second look endoscopy is advisable before capsule endoscopy. In patients with negative results on capsule endoscopy and persistent obscure gastrointestinal bleeding, a second capsule endoscopy should be considered as small studies have shown an additional yield of 35-75%.^{w12 w13} Figure 3 shows a proposed algorithm for the management of patients with obscure gastrointestinal bleeding.

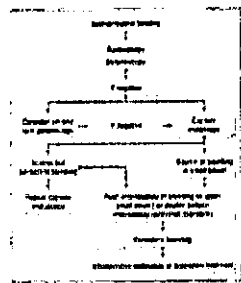


Fig 3 Proposed role of capsule endoscopy in obscure gastrointestinal bleeding

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- Indications for capsule endoscopy**
- Obscure gastrointestinal bleeding (overt/occult)
 - Suspected small bowel Crohn's disease
 - Assessment of coeliac disease
 - Screening and surveillance for polyps in familial polyposis syndromes
 - Assessment of Crohn's disease and gastrointestinal bleeding in children
 - Diagnosis of Barrett's oesophagus

Small bowel Crohn's can be an elusive diagnosis, with the mean time from onset of symptoms to diagnosis ranging from one to seven years.^{w14 w15} Patients with suspected Crohn's disease can present with diarrhoea, abdominal pain, weight loss, or raised inflammatory markers. Results of standard endoscopic or radiological investigations may be equivocal or normal. In such patients, capsule endoscopy can establish the diagnosis in 40-70% of patients by identifying ulcers, erosions, erythema, and mucosal oedema^{13 w16-w20} and is more sensitive than small bowel follow through and computed

tomographic enteroclysis.^{13 w20-w24} It will also allow assessment of the extent of disease, and these findings can then potentially be confirmed by ileocolonoscopy biopsies.

Capsule endoscopy has two reported roles in coeliac disease. Firstly, it can be used to identify complications related to coeliac disease in refractory disease (for example, small bowel lymphoma or ulcerative jejunitis).^{w25 w26} The ability of capsule endoscopy to visualise the entire small bowel allows assessment of the extent of disease and detection of early complications.¹⁴ More recently, some patients are opting for capsule endoscopy with a photograph of small bowel villous atrophy (virtual histology) in conjunction with a positive result for anti-endomysial antibody. Preliminary data indicate that the recognition of coeliac disease with capsule endoscopy is comparable with macroscopic endoscopic appearances. The ability to diagnose coeliac disease with capsule endoscopy may be specific but not sensitive.^{w27} Some patients, however, may prefer this test to a more invasive gastroscopy and small bowel biopsy.

Several small studies have reported the use of capsule endoscopy in the surveillance of polyposis syndromes (n = 20-40).^{w28-w30} Capsule endoscopy is more accurate in the detection of polyps than small bowel follow through and is more likely than magnetic resonance imaging to detect smaller polyps (< 5 mm).¹⁵ Larger follow-up studies are needed to assess whether the use of capsule endoscopy changes the management of these patients. It has also been used in the investigation of functional gastrointestinal disorders, but with less impressive results. An initial small study (n = 20) of capsule endoscopy in the assessment of chronic abdominal pain has shown a low positive diagnosis rate.¹⁶

Capsule endoscopy is being evaluated in children for similar clinical indications.¹⁷ The diagnosis of Crohn's disease not confirmed by standard means has been reported with a similar positive diagnosis rate to that in adults (50-58%).^{17 w31} One of the potential benefits for using capsule endoscopy in children may be the avoidance of gastroscopy and a general anaesthetic.

Use has now extended beyond the confines of the small bowel. The desire for adults to avoid gastroscopy has also led the manufacturers of capsule endoscopy to produce novel prototypes. The PillCam ESO (Given Imaging, Yoqneam, Israel) has been shown to be accurate, safe, and well tolerated for the detection of oesophageal pathology.¹⁸ The conventional PillCam capsule has also been used in the assessment of Barrett's oesophagus by attaching a string to allow controlled movement up and down the oesophagus.^{w32} This technique provides multiple endoscopic images and transforms a physiological process into a procedure that is operator dependent.

Limitations and complications

Capsule endoscopy is contraindicated in patients with known gastrointestinal obstruction and swallowing disorders. The potentially most serious adverse event after capsule endoscopy is intestinal obstruction due to a pre-existing stricture; this may occur in 0.75% of patients (J Barkin, et al, Annual Scientific Meeting, American College of Gastroenterology, Washington, 2002). Risk factors for retention of the capsule include prolonged use of non-steroidal anti-inflammatory drugs, injury from abdominal radiation, and extensive small bowel Crohn's. The capsule may be retained even in the presence of a previously normal barium small bowel radiograph.¹² An alternative safety measure is the Given M2A patency capsule. This is similar in size and shape to the conventional capsule but has a lactose body and contains about 100 mg of barium sulphate. It is excreted intact unless it is impacted in stenosed bowel, in which case it will disintegrate within 40 hours through contact with intestinal fluids.^{w33}

Despite its valuable diagnostic potential, capsule endoscopy can only detect and record small bowel pathology. Currently the device is unable to take biopsies or perform any therapeutic procedures. Interpretation and reading of capsule endoscopy images can be time consuming, especially to the inexperienced. One potentially cost effective strategy is the use of nurse endoscopists for the reporting of images.¹⁹ In addition, general practitioners with a specialist interest in endoscopy may wish to provide a capsule endoscopy service in primary care.

Capsule endoscopy v double balloon enteroscopy

Double balloon enteroscopy (push and pull enteroscopy) is a relatively new technique that allows total enteroscopy by intubation of the small intestine through the oral (extended gastroscopy) or anal (extended ileocolonoscopy) route. Deeper examination of the small intestine is possible with the help of sequential inflation and deflation of the two anchoring balloons at the distal end of the enteroscope (allowing the enteroscope to proceed through a marching effect). Using this novel technique loops are also more easily resolved, which is a distinct advantage over push enteroscopy (the current method most commonly used for endoscopic examination of the small bowel). The procedure can be done under conscious sedation, and the average time for examination for each route is 75 minutes.²⁰ The yield positive diagnosis rate is comparable with that of capsule endoscopy, but early data suggest that it may be superior in its therapeutic yield and ability to perform endoscopic interventions.²⁰ Larger prospective studies are needed to clarify the roles and make cost effective comparisons between double balloon enteroscopy, push enteroscopy, and capsule endoscopy.

Additional educational resources

- www.givenimaging.com
- Rey JF, et al. European Society of Gastrointestinal Endoscopy guidelines for video capsule endoscopy. *Endoscopy* 2004;36: 656-8 [Medline].
- O'Loughlin C, Barkin JS. Wireless capsule endoscopy: summary. *Gastrointest Endosc Clin N Am* 2004;14: 229-37 [CrossRef] [Medline].

Websites for patients

- www.givenimaging.com
- www.gihealth.com
- www.capsuleendoscopy.org

Conclusion

Capsule endoscopy is a procedure that can be performed on an outpatient basis in both primary and secondary care. It has revolutionised the investigation of small bowel disease because it is more sensitive at identifying mucosal lesions than previous small bowel investigations. Capsule endoscopy has now become the investigation of choice in those patients with obscure gastrointestinal bleeding and normal results on gastroscopy and colonoscopy.

Despite this important technological advance, there are still unresolved clinical issues that require further investigation: how do we manage diffuse small bowel vascular abnormalities or obtain histology from observed inflammatory and mass lesions? Real time viewing is now possible (H Ogata et al, American Society of Gastrointestinal Endoscopy, Chicago, 2005), and we anticipate the development of a device whose movement back and forth within the gut can be controlled. The possibility of targeting lesions within the small bowel for real time thermal coagulation or biopsy no longer seems like science fiction.



A full list of references to identified studies is on bmj.com.

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Ethical approval: Not required.

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USE OF VIDEO ENDOSCOPY IN DIAGNOSING SMALL BOWEL DISEASE

P Swain, A Fritscher-Ravens

1866

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The small intestine has been relatively inaccessible to flexible endoscopy until recently.¹ Its length is a challenge to endoscopy. The small intestine accounts for 75% of the total length and 90% of the surface area of the gastrointestinal tract. In adults it measures about 570 cm at post mortem,² which is substantially longer than conventional video gastroscopes. Colonoscopes and gastroscopes measure 100–180 cm. There are features about its position and anatomy which limit the endoscopist's chance of passing longer endoscopes much further than a few centimetres into it, either through the mouth and duodenum or through the ileocaecal valve. The tight curve from the bulb around the head of the pancreas and its relatively fixed retroperitoneal posterior position as it crosses the spine to the ligament of Treitz where it passes downwards as a loosely supported much looped structure on a mesentery is a challenge. If a colonoscope is passed through the mouth into the jejunum and a surgeon pleats the small intestine over the endoscope by hand at laparotomy, the stiffness of the endoscope tends to stretch the mesentery, which is attached posteriorly as the endoscope follows the loops of small intestine and increases the friction exerted by the intestine on the endoscope. Colonoscopists can usually but not always enter the terminal ileum for a few centimetres. Either way, the distance and curved path that a conventional endoscope has to pass to reach the small intestine means that the force for effective forwards propulsion, which can be exerted on the tip of an endoscope, is small. Loops tend to form and enlarge in the stomach or in the colon, which can make deep small intestinal intubation difficult.

Recent technical developments in the design of longer flexible instruments specifically for push enteroscopy have made this examination much more successful.

The advent of wireless video capsule endoscopy³ has released the endoscopist from the requirement to exert force on a long floppy cable-type endoscope to examine relatively short segments of small intestine. This device exploits peristalsis to propel the video endoscope through the small intestine and can usually but not always acquire images from the whole of the small intestine from the pylorus to the caecum.

TECHNICAL ADVANCES

There has been a substantial increase in small intestinal endoscopy in the last 10 years which has followed two technical advances (table 1). The first was the development of specific endoscopes for push enteroscopy (fig 1).^{1–4} Careful attention to the design allowed better transmission of force to the tip and shaft stiffness for use at flexible endoscopy. These instruments were longer than colonoscopes, measuring 200–240 cm, and slimmer, usually measuring 11 mm in diameter but with a 2.8 mm accessory channel. They were initially designed for use with an overtube to aid deep intubation which usually needed x ray control for safe insertion. The overtube appeared to cause some of the complications associated with push enteroscopy—for example, sometimes causing oesophageal trauma.⁵ The addition of video imaging^{4–6} to these instruments allowed very high quality images to be obtained from the oesophagus to the jejunum (fig 2). Despite some evidence that 240 cm enteroscopes do not reach further or find more pathology than those of 200 cm,⁶ some of the newer instruments are longer than the earlier enteroscopes (240–280 cm). Variable stiffness enteroscopes have recently become available.⁷

Most^{8–16} but not all endoscopists⁸ found that these instruments could be used almost as well without an overtube and thus dispensed with the need to perform this procedure under x ray control. There was evidence from two studies that the use of an overtube was associated with a significant increase in depth of insertion into the small intestine by 10–15 cm^{17–18} but in neither of these studies was more pathology found. The whole of the duodenum and some of the jejunum can be examined by video colonoscopes,^{19–20} especially with paediatric colonoscopes, which are more widely available than push enteroscopes. They are of the same diameter but substantially shorter (135 v 200–240 cm).²¹

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Table 1 New and available video methods of small intestinal imaging

- What is new?
- ▶ Wireless capsule endoscope
 - ▶ Double balloon push enteroscopy
- What is available?
- ▶ Push enteroscopy
 - ▶ Paediatric/adult colonoscopes to be used for push enteroscopy
 - ▶ Intraoperative enteroscopy with a colonoscope
 - ▶ Laparoscopic assisted enteroscopy
 - ▶ Ileoscopy at colonoscopy
- What is no longer used?
- ▶ Sonde enteroscopy
- New non-video methods for small intestinal imaging
- ▶ CT enteroclysis and virtual enteroscopy
 - ▶ Ultrasound
 - ▶ MR enterography

CT, computed tomography; MR, magnetic resonance.

It is difficult to be sure how far push enteroscopes are usually advanced into the small intestine because there are no landmarks and it is easy to overestimate the distance examined. A few groups have attempted to measure the distance with or without x rays, which seems rather short (45–70–100 cm).^{11–17, 18}

Wireless capsule video endoscopy was first used in humans in 1999.³ It was able to provide video images from the whole of the small intestine and received FDA approval in 2002 following the demonstration of safety and efficacy as an adjunct to the investigation of patients with suspected small intestinal disease, especially obscure gastrointestinal bleeding. Although this technology has been available for a relatively short period, it has been widely adopted and used in more than 50 000 patients. Table 2 compares the differences between this technology and push enteroscopy.

Over this period another technology—sonde-type enteroscopy—has atrophied and been largely abandoned. This method was usually carried out with a thin (5–7 mm) very long flexible transnasal endoscope with a balloon and a guide thread attached to its tip (fig 1). Once in the stomach, a conventional transoral gastroscope was used to catch the guide thread and push the sonde enteroscope through the pylorus. The balloon was inflated and the endoscope was propelled by peristalsis through the small intestine. After about six hours, an x ray was taken to see how far it had passed and the sonde enteroscope was withdrawn, sometimes recording the image on video.^{21–22}

There has been a recent advance in the ability to image the small intestine. Yamamoto *et al*, in conjunction with Fujinon,²³ have developed a double balloon enteroscope system which can be advanced much further into the small intestine than other push enteroscopes. The balloons are used to plect the small intestine on the overtube, which is cautiously advanced over the enteroscope. This technique takes much longer to perform than a conventional push enteroscopy and needs x ray screening but it can sometimes examine even the whole of the small intestine. The system that has only been used in a few cases^{24–25} may well be an important advance in enteroscopy because it may allow endoscopic directed therapy such as biopsy, snare polypectomy, and thermal treatment of any area in the small intestine.

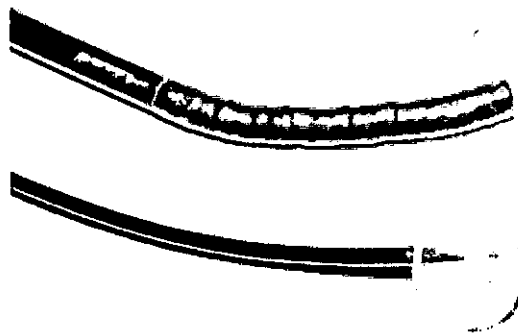


Figure 1 Types of enteroscopes: push enteroscope with bending section at the tip (above) and Sonde enteroscope with a smaller diameter and balloon at the tip.



Figure 2 Push enteroscope video image of an adenomatous polyp in the jejunum.

A side viewing duodenoscope is occasionally helpful in viewing periampullary or duodenal abnormalities,²⁶ which are not well seen with a forward viewing endoscope, or for assessing whether bleeding is from the biliary or pancreatic duct.²⁷

Table 2 Comparison of push and capsule endoscopy

	Push enteroscopy	Capsule endoscopy
Image lesions*	XXX	XX
Biopsy	Yes	No
Therapy	Yes	No
Image quality	XXX	X
Real time viewing	Yes	No
Entire small bowel visibility	No	yes
Sedation	Yes	No
Patient acceptance	X	XXX
Image acquisition time	30 min	8 h
Image assessment time	30 min (as above)	1 h
Value in GI bleeding	XX	XXX
Manual skills needed	Yes	No
Clinical experience needed	Yes	For interpretation only

*In area examined.
XXX, very good; XX, good; X, acceptable.

Diagnostic laparoscopy can be especially valuable in children with suspected small intestinal bleeding²⁸ and probably should be used early in young males with recurrent bleeding as Meckel's diverticulum is the cause in two thirds of male patients under 25 years.²⁹ It is also of some value in middle aged patients when a small intestinal tumour is suspected.³⁰ There has been some interest in using laparoscopy to plect the small intestine over a push enteroscope in order to advance the enteroscope to the ileocaecal valve.^{31, 32}

Open surgical exploration with an endoscope passed through the mouth or through an enterotomy—for example, in the caecum—continues to be an important last resort investigation in some patients with difficult gastrointestinal bleeding.³³

PUSH ENTEROSCOPY

Technique

Push enteroscopes are heavier and longer than standard gastroscopes. They are slightly more difficult to handle during oesophageal intubation and passage across the pylorus but the push characteristics and increased flexibility allow for better handling in the jejunum. The bending section of push enteroscopes are longer, to allow increased angulation in all directions (fig 1).

A complete examination of the oesophagus and stomach should be performed with the instrument before entering the duodenum. Once the scope has been advanced into the second part of the duodenum, as with endoscopic retrograde cholangiopancreatography (ERCP), pulling back will produce "paradoxical" advancement. The ligament of Treitz is usually encountered 85–110 cm from the incisors and usually requires full tip deflection to find the lumen. Once around the ligament, the first jejunal loop can be identified by a straight configuration, which points in a caudal direction if seen on x ray (fig 3).

Overtube

A variety of methods have been used to try to reduce the tendency of the enteroscope to loop in the stomach. These include the use of abdominal pressure, internal stiffening devices,¹¹ and overtubes.^{11, 17, 18} Some have two ring shaped



Figure 3 Fluoroscopic image of a 240 cm long push enteroscope which is introduced to its maximum length into the jejunum.

metal tip markers to facilitate placement under screening and to prevent the overtube tip from being compressed. Others have a more pliable Gortex tip of 10 cm in length, which may limit mucosal trauma when advancing the overtube over the endoscope. The overtube is initially back loaded onto the shaft of the endoscope and advanced down the endoscope through the oesophagus until its distal tip rests within the second portion of the duodenum or beyond the ligament of Treitz. Fluoroscopy is helpful for overtube use as prepyloric placement does little to aid deep intubation. The softer Gortex tipped overtube may buckle in the stomach and fail to provide sufficient rigidity.

Diagnostic applications

The main indication and pressure for improvements in enteroscopy has been obscure gastrointestinal bleeding in patients with a negative gastroscopy and colonoscopy. Push enteroscopy has been performed with published diagnostic yields of 30–50%.¹¹ One surprise has been that in a proportion of such patients having a push enteroscopy—approximately 25%—the cause has been found in the oesophagus, stomach, or duodenum, within reach of a gastroscopist, and was missed on a previous gastroscopy. A list of common missed causes of obscure bleeding is found in table 3.

Push enteroscopy has helped in the diagnosis, biopsy, and management of small intestinal tumours (table 4). Other indications include malabsorption (including coeliac disease), assessment of Cohn's disease, non-steroidal anti-inflammatory drug induced strictures and erosions, abnormalities on barium or computed tomography, and worm infestation.

Therapeutic applications

Push enteroscopes include a standard 2.8 mm biopsy channel that has been used for several therapeutic functions within the proximal small intestine as well as for directed biopsy.¹¹ The more the instrument becomes looped as it advances into the small bowel, the greater the difficulty in getting instruments to emerge from the biopsy channel. This particularly applies to instruments with a long rigid tip such as heater or bipolar probes and balloons, rather than snares and laser fibres.

Biopsy

Endoscopic forceps-type biopsy has now largely replaced the use of a suction fired biopsy capsule as a means of obtaining small bowel biopsies.³⁴ The advantages of the endoscopic method are speed, ease, patient comfort, and reliability. Enteroscopic biopsies can reduce the chances of proximal duodenal inflammation and shorter villi in the bulb causing confusion when examining for coeliac disease. They may offer advantages in the workup of patients with diarrhoea or

Table 3 Common missed causes of bleeding in the upper gastrointestinal tract which may be found during enteroscopy

- ▶ Large hiatus hernia with Cameron erosions
- ▶ Watermelon stomach
- ▶ Dieulafoy exulceratio simplex
- ▶ Varices
- ▶ Ulcers
- ▶ Angiodysplasia

Table 4 Small bowel tumours that may be detected during enteroscopy

- ▶ Lymphangiectatic cysts
- ▶ Gastrointestinal stromal cell tumours (GIST)
- ▶ Neuroendocrine tumours (eg, carcinoid, Zollinger Ellison)
- ▶ Polyps
 - Adenomas
 - Hamartomatous polyps
- ▶ Lipoma/angioliipoma
- ▶ Neurofibromas
- ▶ Duplication cysts
- ▶ Adenocarcinomas
- ▶ Lymphomas
- ▶ Sarcomas
- ▶ Metastases (eg, melanoma, renal cell carcinoma)

malabsorption, particularly if focal specific mucosal abnormalities have been seen in the proximal jejunum on small bowel x ray contrast series.¹⁴ In countries such as the UK where coeliac disease is the commonest cause of malabsorption, enteroscopic biopsy does not add much information that is not acquired by duodenal biopsies taken with a gastroscope as coeliac disease mainly affects the proximal jejunum. It is more useful in assessing coeliac-like syndrome patients with unresponsive sprue or coeliac patients with weight loss when a lymphoma is suspected.³²⁻³⁷ Biopsies from the jejunum were more likely to find a cause of diarrhoea in patients with chronic human immunodeficiency viral related diarrhoea than were duodenal biopsies.³⁸

Jejunal feeding tube placement

Push enteroscopy has also been used in a variety of ways to place jejunal feeding tubes. It has been used to carry a transgastric jejunal tube through a previous gastrostomy into the jejunum.³⁹⁻⁴¹ Nasojejunal feeding tubes have been placed using the Seldinger over the wire technique.⁴² The push enteroscope is placed into the jejunum initially and then a guidewire is advanced. The endoscope is removed, leaving the guidewire in place. A feeding tube is advanced over the wire and then re-routed from the mouth through the nose. This method has been combined with a sewing method for attaching the jejunal feeding tube to the stomach to prevent displacement.¹¹

Direct percutaneous endoscopic jejunostomy placement

By using push enteroscopy, the "pull" technique for placement of percutaneous gastrostomies has been extended to permit direct percutaneous jejunostomies.⁴¹⁻⁴³ This technique has also been used to place jejunal tubes for small bowel enemas⁴⁹ as well as to obtain cholangiograms in patients after Roux-en-Y hepaticojejunostomy.¹¹⁻⁴⁴

Polypectomy

Polypectomy can be performed in the small intestine via the push enteroscope using snares (fig 4A, B).¹¹⁻⁴⁵ Surveillance of patients with a polyposis syndrome can be performed with push enteroscopy, allowing biopsy and polypectomy of larger lesions. Removal of large jejunal hamartomatous polyps in Peutz-Jeghers syndrome has become part of the screening of this autosomal dominant condition with malignant potential (fig 2). The more proximal lesions are relatively easy to

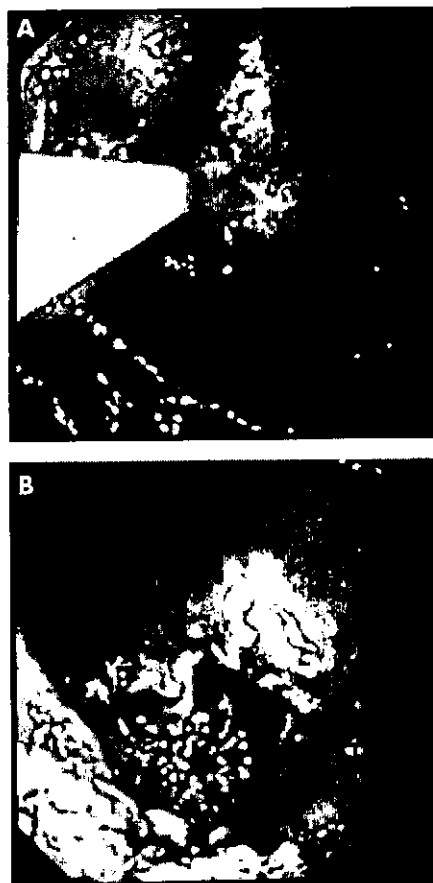


Figure 4 Snare polypectomy during push enteroscopy. (A) The snare is placed around the polyp and removed (B).

remove but endoscopic removal may require an enteroscope and snare used at open surgery: this technique can find and deal with polyps which cannot be identified by surgical palpation and translumination.⁴⁶

Treatment of gastrointestinal bleeding

In addition to diagnosis, push enteroscopy allows cauterisation of bleeding sites. Using bipolar cautery, Foutch *et al* was able to fulgurate angiodysplasias in 11 of 12 patients.¹⁹ Control of bleeding was obtained in 8 of the 11 treated patients. Askin and Lewis⁴⁷ assessed the long term effectiveness of push enteroscopic cauterisation of bleeding arteriovenous malformations in 89 patients. Of these patients, 61 were cauterised and 28 were not. The group that was cauterised required significantly fewer blood transfusions than the non-cauterised group. In another series of 50 patients undergoing therapeutic push enteroscopy, bleeding was terminated in all patients with isolated angiomias and reduced in more than half of the patients with multiple jejunal angiomias as well as in some malignant tumours.⁴⁸ In addition, in 9/50 patients the bleeding source was found within the reach of a gastroscope⁴⁸ and successfully treated. This group had a significantly reduced transfusion requirement when compared with their pre-cauterisation status.

Injection of small intestinal varices

Small intestinal varices, especially in the duodenum and ileum, around anastomoses or adhesions in patients with

mesenteric thrombosis are an uncommon cause of bleeding but can be misdiagnosed and biopsied and may cause torrential bleeding. Successful treatment of bleeding jejunal varices using push enteroscopy to inject a sclerosant has been described.⁴⁹

Complications

Complications are uncommon with push enteroscopy, which is probably nearly as safe as gastroscopy, and most series report that no complications occurred. Some of the complications appear to be associated with the use of a metal tipped overtube. These include a Mallory-Weiss tear, pancreatitis most likely secondary to papillary trauma, a pharyngeal tear, and three cases in which long strips of gastric mucosa were torn off during advancement of the overtube.^{7 12 21} These complications with overtubes occurred prior to the addition of a Gortex tip. Duodenal perforation has been described⁵⁰ but appears less common than with ERCP or endoscopic ultrasound. Some series describe severe patient discomfort, which is usually due to stretching the stomach as a loop is formed along the greater curve while trying to transmit forward pressure to advance the tip in the small bowel.

INTRAOPERATIVE VIDEO ENTEROSCOPY Technique

The endoscope is advanced into the proximal jejunum through the mouth prior to laparotomy as once the abdomen is open it may be difficult to advance the instrument around the ligament of Treitz. With oral intubation using an adult colonoscope, the endotracheal tube cuff may need to be deflated to permit passage of the wide calibre endoscope.

The examination is carried out by an endoscopist and a surgeon; the endoscopist looks at the endoscopic image using minimal air insufflation while the surgeon holds the endoscope tip inside the small bowel so as to inspect a short segment ahead of the endoscope. Once examined both internally and externally, the small bowel is pleated onto the shaft of the endoscope and the next section of bowel is examined. Care has to be taken not to overstreich the mesentery on colonoscopes, which are rather stiff for this use. Active bleeding within the small bowel may diminish the effectiveness of this examination. Visual examination and interpretation has to be performed during intubation and not on pull-back as mucosal trauma occurs with the pleating causing an artefact that may be confused with the appearance of angiodysplasia.⁵¹ A technique of "reverse transillumination" to help differentiate trauma from vascular ectasias in this setting has been described⁵² to allow visualisation of feeding vessel. At the end of the examination, the endoscope is withdrawn and the surgeon can resect the abnormalities identified by the sutures.

An alternative technique is to perform an enterotomy through which a "sterilised" endoscope or an endoscope covered by a sterile plastic sheath is placed. The enterotomy is generally performed in the mid small bowel, allowing both proximal and distal intestinal intubation, but it can be performed in the caecum if vascular ectasias are suspected in this area or distal small bowel. Retrograde intubation of the small bowel can be performed after the caecum has been inspected. The colonoscope is advanced through the ileocaecal valve by the surgeon and up the small intestine.

Diagnostic and therapeutic utility

Intraoperative endoscopy has been used for a variety of indications^{46 47 52-54} but until recently was probably the

endoscopic method most widely used in identifying small intestinal sites of bleeding beyond the proximal jejunum. It can be successful in identifying the site of blood loss in selected patients, with reported yields of 83-100%.⁵²⁻⁵⁴ Vascular ectasias are the most common non-palpable cause of bleeding, but radiation enteritis, ulceration, malignancies, strictures, and polyps (for example, multiple polyps in Peutz-Jeghers syndrome) may require endoscopic identification. Haemostasis can be achieved at intraoperative enteroscopy either by resection of the bleeding lesion or by transendoscopic ablation of the bleeding lesion, usually with a thermal endoscopic method.

Complications

Prolonged ileus, sepsis, and perforations (the surgeon should listen for a hissing sound that indicates that perforation has occurred) are common sequelae of operative enteroscopy.

Outcome studies of the value of video enteroscopy with flexible instruments

Several studies have examined the number of diagnoses, influence on management, and subsequent clinical path of patients who have enteroscopy for suspected small intestinal outcome. Recent prospective studies suggested that management was altered in more than 50% who had push enteroscopy.^{57 58} One study has shown that the costs of investigating and managing patients who bleed from the small intestine are different and substantially more expensive than the costs of patients who bleed from other gastrointestinal sites.⁵⁹ Outcomes studies of the value of push enteroscopy in non-bleeding conditions suggest that it can be of value in malabsorption,^{14 60} Crohn's disease,⁶¹ non-steroidal anti-inflammatory drug toxicity,⁶² and worm infestation.⁶³ It can be usefully performed in non-specialist district general hospitals.⁶⁴

It may be helpful to have some knowledge of the clinical patterns and appearances of the many less common or rare diseases which can affect the small intestine.⁶⁵ Access to an atlas⁶⁶ and book length reviews on enteroscopy in *Gastrointestinal Endoscopy Clinics of North America*⁶⁷ may help.

WIRELESS CAPSULE VIDEO ENDOSCOPY

The development of wireless capsule endoscopy⁶⁸⁻⁷² has changed video endoscopy of the small intestine into a much less invasive and more complete examination.^{71 72-73} It has been particularly successful in finding the cause of obscure gastrointestinal bleeding of suspected small intestinal origin (fig 5).⁷³⁻⁸³

The capsule endoscope (M2A; GivenImaging, Yoqneam, Israel) contains a video imager, transmitter, light source, and batteries in a rounded cylindrical plastic container measuring 11x26 cm.³ There is a clear optical dome shaped window which allows the intestine to be illuminated by an array of six (formerly four) light emitting diodes. The image is captured through a short focal length lens with a wide angle as the optical window of the capsule sweeps past the gut wall, without requiring air inflation of the gut lumen. Video images are transmitted using radiotelemetry to an array of eight aerials attached to the body. They allow image capture and calculation and an indication of the position of the capsule in the body. The capsule transmits images at a rate of two frames per second.

These images are subsequently downloaded from the portable recorder for analysis off line. Currently, the time

needed to evaluate the video sequence takes between 45 minutes and two hours and varies with the experience and concentration of the examiner as well as the number of pathological abnormalities present.

Wireless capsule endoscopy can provide approximately 7-8 hours of continuous video imaging of the gastrointestinal tract. This usually allows image acquisition from the oesophagus, stomach, small intestine, and right colon. The capsule is propelled by peristalsis and is passed through the anus into the toilet usually one or two days after ingestion. Because the gut is a hollow tube it is unimportant whether the capsule points forwards or backwards as it passes through. This form of endoscopy is painless, does not require sedation, and as a consequence the patient is ambulant and does not need to be confined to hospital during the examination.^{3 73-83}

Procedure and technique

Consent should specifically include an explanation that the capsule may become stuck in the small intestine requiring surgical removal, that capsule endoscopy does not always image the whole of the small intestine, that a plain abdominal x-ray may be performed if colonic images are not seen and the capsule is not seen in the toilet by the patient, and that magnetic resonance imaging scans should not be done if the capsule is not known to have emerged.

The patient should have an overnight fast or be nil by mouth for 12 hours prior to ingesting the capsule. Preparation as for colonoscopy may improve the quality of images in the lower small intestine but there are few data to support one regimen against another. It is necessary if images of the right colon are important, as for example in patients with incomplete colonoscopy.

The capsule can then be removed from its packaging which contains a magnet. This action will activate the capsule by releasing an internal magnetic switch and the capsule will start flashing.

The patient can then swallow the capsule, usually with some water. It is helpful to ask the patient to keep an eye on



Figure 5 Bleeding from a jejunal adenocarcinoma.



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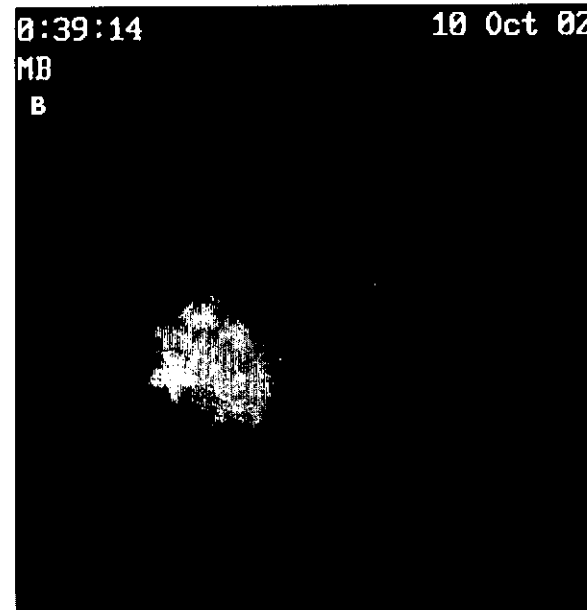


Figure 6 Ulcers in the small bowel. The appearance is non-specific and can be seen in diseases other than Crohn's. (A) Ulcer due to intake of anti-inflammatory drugs. (B) Ulcer due to Crohn's disease.

the flashing light on the recorder and the connection between the aerial and the recorder and to report back if it stops flashing over the next two or three hours.

Patients should be asked not to eat for three hours after swallowing the capsule but told that they can drink clear water. They can have a light meal after this time. The belt and aerial can be removed eight hours after swallowing the capsule or when the recorder has stopped flashing. Patients should return the recorder, aerials, and belt but do not need to find and return the disposable capsule.

The images on the recorder need to be downloaded and processed prior to interpretation. Currently, image analysis of the 50 000 or so images acquired over the eight hour period takes about an hour or more to complete. It is probably unwise to read all the images at the fastest of the three

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Figure 7 Red spot in small bowel representing an angiodysplasia.

available speeds. It is helpful to store any unusual images as well as definite abnormalities as "thumbnails" for more careful subsequent review. Points of entry into the stomach, duodenum, and caecum need to be marked to enable the localisation software to image the passage of the capsule inside the abdomen. Abnormalities detected as blood by the blood sensing algorithm need to be checked. Newer software places two adjacent images side by side to allow faster image analysis. The recording, with marked thumbnails, need to be saved to the hard drive and to a CD-ROM. A typed report with interpretation of the findings needs to be generated.

Interpretation of small intestinal images is not always easy and it may help to go backwards and forwards over some image sequences and to ask another endoscopist for an opinion. There is a wide range of pathologies and numerous rarities are found which can affect the small intestine. Visual appearances are not specific, especially for the wide range of tumours found in the small intestine (see table 4, fig 5). Benign conditions, including Crohn's disease, amyloidosis, and lymphangiectasia, have a wide range of appearances (figs 6, 7). It can be difficult to be sure when a red spot is really an angiodysplasia (fig 7). In young males it may be

helpful to review the lower small intestinal images for a double lumen suggestive of a Meckel's diverticulum and to run over some of the images in the light of the clinical history in most patients.

Most patients believe that wireless capsule endoscopy is good and find it preferable to conventional endoscopy or colonoscopy.^{74, 82} It has been at least as successful as, and sometimes significantly more successful^{75, 82} than, push enteroscopy in finding the cause of obscure gastrointestinal bleeding (table 5) in published series, with yields of 55–70% (table 6). A blood sensing algorithm may assist in alerting the physician to an area of bleeding pathology.⁸⁴ It has been successful in identifying small intestinal tumours (table 4) when multiple other investigations have failed,^{74, 82, 83} but may miss such tumours.⁸⁶ It has been significantly more successful than barium studies⁸⁷ in finding pathology in the small intestine and has outperformed barium meal as well as state of the art enteroclysis^{88, 89} and computed tomographic enteroclysis⁹⁰ in fully published recent studies.

Limitations

Images from the oesophagus, stomach, and colon are less good than those acquired during conventional endoscopy but may show pathology in these areas. Images from the small intestine are somewhat less good than enteroscopic views because the capsule cannot wash or be pulled back to re-examine a possible abnormality. At present, wireless capsule endoscopes cannot take biopsies or deliver therapy. With its current acquisition time of 7–8 hours, the capsule fails to provide images from the caecum approximately 15% of the time. As a consequence, an uncertain length of small intestine remains unexamined. A few patients, especially children, have difficulty swallowing it. Occasional patients retain it for prolonged periods in the stomach as there is a very wide range of "normal" gastric emptying times. Images may be poor in patients with morbid obesity. It can take a long time to interpret the images. Skill and experience are required. A lot of the findings can be of unknown significance. Pathology may only be seen on a single frame. As it may travel looking forwards or backwards, it may not look at pathology in an expected direction. Images in the lower small intestine are often rather dark. The recurring cost of the capsule as a disposable and the relatively lengthy examination times require specific funding and organisational strategies.

The main complication is that the capsule may become impacted in strictures⁹¹ or diverticulae.⁸⁵ Most commonly, capsule impaction is symptomless. Sometimes capsule impaction may be a good outcome, leading to identification of strictures, diverticulae, or ulcers which can be resected. If the capsule can be reached by an endoscope, a snare with a net is the most useful retrieval tool as the capsule is more

Table 5 Possible causes of small bowel bleeding

- ▶ Angiodysplasia and vascular malformations
- ▶ NSAID enteropathy
- ▶ Erosive jejunitis
- ▶ Diverticulae
- ▶ Crohn's disease
- ▶ Jejunal or ileal ulceration: idiopathic, NSAID induced, etc.
- ▶ Intussusception
- ▶ Small intestinal tumours (see table 4)
- ▶ Ischaemic enteropathy
- ▶ Graft versus host disease
- ▶ Cytomegalovirus infection
- ▶ Aortoenteric fistula
- ▶ Blue rubber bleb syndrome

NSAID, non-steroidal anti-inflammatory drug.

Table 6 Comparison of the diagnostic yield of capsule endoscopy and push enteroscopy in the diagnosis of gastrointestinal bleeding

	Capsule	Enteroscopy
Mato ¹⁰⁰	66%	19%
Mylonaki ⁸²	68%	32%
Saurin ¹⁰¹	69%	38%
Lewis ⁷⁴	55%	30%
Ell ⁷⁵	66%	28%

difficult to grasp with a stone basket or simple snare. Inadvertent magnetic resonance imaging may cause complications as the capsule will respond to a magnetic field. If a capsule examination does not provide colonic images and the patient does not see the capsule in the toilet, it might be sensible to take a plain abdominal x ray to check for passage. Pacemakers are probably not a contraindication. Capsule endoscopy has been approved by the FDA for use in children over 10 years.

CLINICAL MANAGEMENT OF PATIENTS WITH OBSCURE GASTROINTESTINAL BLEEDING

Investigation of patients with obscure gastrointestinal bleeding and a suspected small intestinal bleeding source is the commonest indication for video enteroscopy. Angiodysplasia is the commonest finding but there are many other potential causes (table 5). Management still remains demanding despite technological improvements in enteroscopy.

It is assumed that these patients have been investigated with a negative gastroscopy (OGD) and colonoscopy. If review of the reports of gastroscopy and colonoscopy findings suggest that this examination was incomplete or of poor quality, it may be appropriate to repeat OGD and colonoscopy prior to any other examinations.

Clinical history and any other investigations should be reviewed for hints about the possible location of the obscure bleeding. Age, location of any discomfort, length of history, colour of blood seen by the patient, presence of skin abnormalities, unexplained abnormal blood tests, weight loss, hiatus hernia symptoms, and previous history of malignancy (for example, melanoma) should be used to focus the search. Investigation pathways can be constructed based on the age and symptoms of the patients (figs 8, 9).

If male, between 10 and 25 years, a Meckel's scan should be performed early. If positive, surgery should be undertaken without further imaging. Because the scans are frequently negative in such patients and bleeding from a Meckel's diverticula accounts for bleeding in two thirds of this group of patients, capsule examination could be the next step to look for this and other causes of bleeding, such as Crohn's disease. If capsule examination is negative, an early laparoscopy should still be considered (fig 9).

If aged between 40 and 65 years, with a short history of recurrent anaemia, continuous bleeding or transfusion

requirement, or weight loss and raised inflammatory markers, a more intensive investigational algorithm should be followed with early push enteroscopy or capsule examination (figs 8, 9), perhaps followed by laparoscopy or surgical laparotomy and enteroscopy.

If female, and there is doubt that the bleeding is coming from the gastrointestinal tract, consider gynaecological opinions, including pelvic ultrasound and faecal occult blood testing prior to intensive small intestinal investigation.

If there is a short story, active bleeding, transfusion requirement, blood seen coming from the ileocaecal valve, alarm symptoms, or an anxious patient, then capsule examination should be the next examination if available.

An algorithm of examinations for these groups of patients is given in fig 8.

CONCLUSIONS

Recent improvements in push and capsule video enteroscopy has changed the management of patients with small intestinal disease.

Both push and capsule enteroscopy are of proven value in the diagnosis of patients with obscure gastrointestinal bleeding. Because there is a high incidence in most enteroscopic series of lesions missed or their significance not understood on initial gastroscopy (table 3), a case could be made for a repeat gastroscopy by an experienced endoscopist before performing push enteroscopy or wireless capsule examination. There is also a well documented miss rate²² at colonoscopy of polyps and cancers, which may be due to failure to reach the caecum in 10-22% in large colonoscopy series or to incomplete examination on rapid withdrawal of the colonoscope. Repeat colonoscopy should also be considered in patients with persistent difficult gastrointestinal bleeding

In patients with documented malabsorption, push video enteroscopy with biopsy is sometimes of value in establishing a diagnosis when duodenal biopsies are unhelpful. It is more valuable in assessing compliant patients with coeliac disease who have weight loss and diarrhoea and a lymphoma is suspected, and in assessing ulcerating jejunitis. Capsule examination may also prove useful in this subgroup.

Push enteroscopy is frequently disappointing in assessing patients with negative barium studies in whom Crohn's

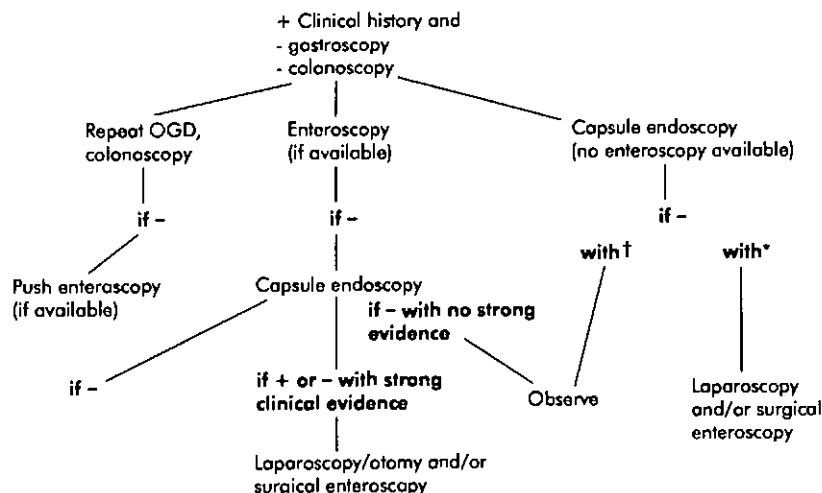


Figure 8 Algorithm for investigation of patients with obscure bleeding. *Short history of bleeding, continued bleeding (transfusion dependent), weight loss, and other abnormal blood tests. †Long history of bleeding, >2 years anaemia corrected with iron, no weight loss, and no other abnormal blood tests.

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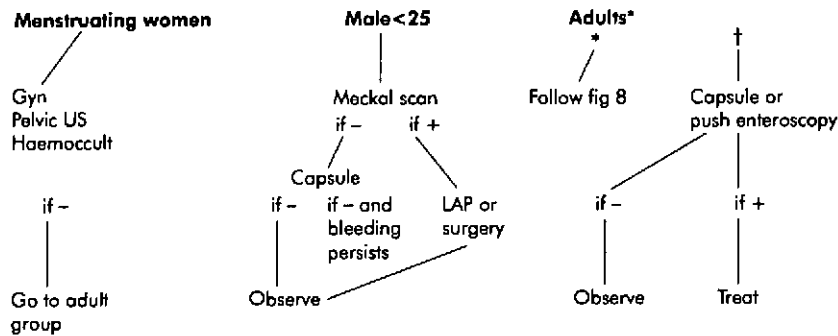


Figure 9 Investigation pathways in different patient groups with obscure bleeding. *Short history of bleeding, continued bleeding (transfusion dependent), weight loss, and other abnormal blood tests. †Long history of bleeding, >2 years anaemia corrected with iron, no weight loss, and no other abnormal blood tests.

disease is suspected,¹¹⁻¹⁴ probably because Crohn's disease less commonly affects the proximal jejunum. Wireless capsule endoscopy has been perhaps surprisingly good at finding evidence of early Crohn's disease⁵³⁻⁵⁶ in patients with negative colonoscopy and barium studies, and is probably the most important advance in imaging for this disease. It has shown that negative ileoscopy does not exclude the diagnosis of Crohn's disease. The fairly common finding of one or a few aphthous ulcers in the small intestine at capsule endoscopy requires further assessment as not all of these patients have Crohn's disease or is the ulceration likely to be the cause of chronic abdominal pain in all of them. The yield of wireless capsule endoscopy in patients with chronic abdominal pain is low but not zero.⁵⁶ Wireless capsule studies have been able to visualise ileal tuberculosis,⁵⁷ worm infestation,⁵¹ and has helped in the management of small bowel transplantation.⁵⁸ It has been suggested that abnormal delays in capsule transit can indicate the presence of small intestinal pathology.⁵⁹

Video enteroscopy has opened up a new world of diagnoses and possibilities to the gastroenterologist. It is a privilege to see images of small intestinal abnormalities at video endoscopy, such as an ulcerated Meckel's diverticulum or active bleeding from a tumour in the middle of the small intestine, which were not possible until recently. The increasing use of this resource and the comfort and ease with which some of these examinations can be performed make it likely that video imaging will have a substantial impact on the management of small intestinal disease.

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Endoscopic Ultrasound (EUS)

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What is Endoscopic Ultrasound?

Endoscopic Ultrasound (EUS) combines endoscopy and ultrasound in order to obtain images and information about the digestive tract and the surrounding tissue and organs. Endoscopy refers to the procedure of inserting a long flexible tube via the mouth or the rectum to visualize the digestive tract (for further information, please visit the [Colonoscopy](#) and [Flexible Sigmoidoscopy](#) articles), whereas ultrasound uses high-frequency sound waves to produce images of the organs and structures inside the body such as ovaries, uterus, liver, gallbladder, pancreas, aorta, etc.

Traditional ultrasound sends sound waves to the organ(s) and back with a transducer placed on the skin overlying the organ(s) of interest. Images obtained by traditional ultrasound are not always of high quality. In EUS a small ultrasound transducer is installed on the tip of the endoscope. By inserting the endoscope into the upper or the lower digestive tract one can obtain high quality ultrasound images of the organs inside the body.

Placing the transducer on the tip of an endoscope allows the transducer to get close to the organs inside the body. Because of the proximity of the EUS transducer to the organ(s) of interest, the images obtained are frequently more accurate and more detailed than the ones obtained by traditional ultrasound. The EUS also can obtain information about the layers of the intestinal wall as well as adjacent areas such as lymph nodes and the blood vessels.

Other uses of EUS include studying the flow of blood inside blood vessels using Doppler ultrasound, and to obtain tissue samples by passing a special needle, under ultrasound guidance, into enlarged lymph nodes or suspicious tumors. The tissue or cells obtained by the needle can be examined by a pathologist under a microscope. The process of obtaining tissue with a thin needle is called fine needle aspiration (FNA).

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When is EUS useful?

Being a relatively new diagnostic tool the uses for EUS are still being developed and, presently, it is being utilized in some of the following situations:

- Staging of cancers of the esophagus, stomach, pancreas and rectum.
- Staging of lung cancer.
- Evaluating chronic pancreatitis and other masses or cysts of the pancreas.
- Studying bile duct abnormalities including stones in the bile duct or gallbladder, or bile duct, gallbladder, or liver tumors.
- Studying the muscles of the lower rectum and anal canal in evaluating reasons for fecal incontinence.
- Studying 'submucosal lesions' such as nodules or 'bumps' that may be hiding in the intestinal wall covered by normal appearing lining of the intestinal tract.

Staging of cancer is becoming an important use of EUS. The prognosis of a cancer victim is related to the stage of the cancer at the time of cancer detection. For example, early stage colon cancer refers to cancer confined to the inner surface of the colon before it is spread to adjacent tissues or distant organs. Therefore early stage colon cancer can be completely resected with good chances for cure. However, if cancer is detected at later stages, the cancer tissues have already penetrated the colon wall and invaded neighboring organs and lymph nodes, or have spread to distant organs such as liver and lungs. Complete surgical excision becomes highly unlikely. EUS can provide information regarding the depth of penetration of the cancer and spread of cancer to adjacent tissues and lymph nodes, information useful for staging.

What is the preparation for EUS?

Your doctor will want to know about your health status especially if you have any allergies, other significant health problems such as heart disease, lung disease, diabetes mellitus, etc. You will also be inquired about allergies to iodine or shellfish as, under certain circumstances, iodine containing contrast material may be used. If there is a possibility of fine needle aspiration (FNA), the doctor will want to check your blood for proper clotting. It is important to inform your doctor of any family history of bleeding problems or if you are taking medications that interfere with blood clotting (such as Coumadin) or platelet function (such as aspirin, Motrin, ibuprofen, Aleve, and other NSAIDs). The wisest is to inform you doctor of any prescription or non-prescription medication you might be taking. Antibiotics are usually not required except in patients with certain heart valve problems.

EUS is performed with sedation so you will not be able to return to work or to drive for 24 hours. It also means that you will need someone to take you home as this is usually an out-patient procedure.

You will need to have an empty stomach that means no oral intake for 6 or more hours. In case of a rectal EUS you will probably need to take some enemas or

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laxatives. In either case, full instructions will be given to you.

How is EUS performed?

Upon arrival at the endoscopy center, the nurse or the doctor will discuss the procedure and answer any questions. You will then be asked to sign a consent form indicating you were informed about the procedure, its alternatives, and its risks. You will undress and put on a hospital gown. An IV will be placed in a vein and kept open with a slow drip of IV fluid. This IV will be used to administer the sedatives or other required medication. Anesthesia is rarely used. You will then be taken into the procedure room and, after the administration of the sedation, the EUS will be carried out. Small electrode patches will be placed on your skin for the monitoring of your blood pressure, pulse, and blood oxygen.

Once sleepy, the special endoscope will be inserted and the procedure started. Because of the sedation, you will only feel minimal discomfort, if any, during the entire procedure. The physician will observe the inside of your intestinal tract on a TV monitor and the ultrasound image on another monitor. The entire procedure generally takes 30 to 90 minutes depending on the complexity and whether fine needle aspiration (FNA) is performed.

After the procedure you will be sleepy for up to one hour and be unable to drink or walk. Once you are fully awake, the doctor will discuss with you and, if desired the person with you, the findings of the procedure. Barring any rare complications, when you are fully awake, your companion will be able to take you home where you should rest for the remainder of the day. Light meals and fluids are allowed. The bloating which you may feel from the insufflated air will only be temporary. Should your throat be mildly sore, for a day or two, salt-water gargles will provide relieve. You should call your doctor if concerned about your progress or having severe pain, vomiting, passage or vomiting of blood, chills or fever. If EUS was particularly difficult or complicated you may be kept in the hospital overnight. The endoscopist will discuss this with you, when you wake up.

What are the risks of EUS ?

Like other endoscopy procedures, EUS is safe and well tolerated. But no procedure is without risk, which with EUS are quite rare. Complication rate for EUS without the fine needle aspiration is about one in two thousand. This is similar to the complication rate of other endoscopy procedures. Sometimes, patients can develop reactions such as hives, skin rash or nausea to the medications used during EUS. A lump may appear in the area of the vein where the IV was placed. This usually resolves over time. Should it persist, you should contact your physician. The main complication of serious note is perforation (making a hole in the intestinal wall) that may require surgical repair. This is quite rare and all precautions are taken to avoid it.

When FNA is performed complications occur more often but are still uncommon (0.5-1.0%). Passing a needle through the gut wall may cause minor bleeding. If unusual bleeding occurs, the patient may be hospitalized briefly for observation,

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but blood transfusions are rarely needed. Infection is another rare complication of FNA. Infection can occur during aspiration of fluid from cysts and antibiotics may be given before the procedure. If the FNA is performed on the pancreas, pancreatitis (inflammation of the pancreas) can rarely occur. Pancreatitis calls for hospitalization, observation, rest, IV fluid, and medication for abdominal pain. It usually resolves spontaneously in a few days.

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ENDOSCOPIC ULTRASOUND UPDATE 2002

William R. Brugge, M.D.

Introduction

The ability to image the gastrointestinal tract with endoscopically placed ultrasound transducers represents a major advance in endoscopic imaging. Although the original instruments were designed to examine areas of the UGI tract not seen with trans-abdominal ultrasound, the effectiveness of endoscopic ultrasound (EUS) has recently been demonstrated for a wide variety of upper gastrointestinal disorders.

The role of EUS has been expanded with the introduction of EUS-guided fine needle aspiration (FNA) of mural, extra-mural, and pancreatic lesions. This technique has also been used for several therapeutic applications.

Instrumentation

Endosonoscopes may be linear or radial in design, depending on the orientation of the ultrasound transducer. Using a rotating 360 degree transducer, radial imaging provides easily interpretable cross-sectional imaging with either a probe or an endosonoscope. In contrast, linear arrayed imaging uses a side-viewing probe to examine sagittally or along a single wall. Although interpretation of linear arrayed images is not as intuitive as that of radial images, linear arrayed imaging offers advantages in the ability to perform EUS-directed biopsies.

Ultrasound transducers can be positioned in the upper gastrointestinal (UGI) tract using dedicated endosonoscopes, non-endoscopic probes, or small probes that can be placed

through the channel of an endoscope. The small probes are designed to provide high resolution imaging of mucosal lesions, intra-mural malignancies, and the wall structure of the UGI tract. Most small probes can be placed through a channel of an endoscope and directed to the area of interest, such as a mural mass. In addition, small flexible probes can be placed into the pancreatic-biliary ducts. Imaging via these probes offers a relatively simple means of determining the type of tissue in mural lesions (fatty, cystic, or vascular) and will be increasing important for guiding endoscopic mucosal resection of early gastric malignancies. Non-endoscopic probes are used solely for esophageal imaging since they cannot be guided into the stomach or duodenum.

Radial endosonoscopes have been used for 15 years and provide high and mid resolution cross-sectional images of the UGI tract. The mechanically-rotating transducers are located at the tip of an oblique-viewing gastroscope and are connected to a dedicated ultrasound console. The direct current motor that drives the rotating shaft is housed between the eyepiece and the tip deflection controls of the gastroscope. The transmission and reception of ultrasound waves from the transducer are enhanced by the use of deaired water contained in a balloon covering the transducer.

Although linear array transducers were originally used on small probes, their use in an endosonoscope is relatively new. The laterally oriented electronic transducers are placed at the tip of an oblique-viewing gastroscope. In contrast to most radial instruments, the ultrasound console for linear endosonoscopes has a range of ultrasound features such as color Doppler, pulse Doppler, and cine-loops. The endoscopic biopsy channel can accommodate a needle aspiration device that can be directed into mural and extra-mural lesions. Recently, an electronic transverse array echoendoscope was approved by the FDA. This device will enable endoscopists to stage tumors with cross sectional imaging, with color Doppler, and an end-viewing echoendoscope.

Clinical Effectiveness

Staging of gastroesophageal masses

Endoscopic ultrasound can readily identify intramural masses of the esophagus and stomach and distinguish them from extrinsic compression. The echo patterns of intramural masses such as cysts, lipomas, and solid masses are quite characteristic and nearly diagnostic. Duplication cysts appear as smooth, round, hypoechoic masses arising from the third layer of the esophagus or stomach. Lipomas also arise from the third layer, and are bright, echo-rich, and smooth. In contrast, the solid intramural tumors of the stomach and esophagus, such as fibromas, leiomyomas, and carcinoids, are difficult to differentiate from each other. Leiomyomas or GI stromal cell tumors (GIST), the most common intramural lesion, may arise from either the inner or the outer muscularis layer and appear as non-homogenous, echo poor round lesions[1]. FNA of stromal cell tumors will provide diagnostic cytology in 75% of cases[2]. A GIST smaller than 5 cm in size with neither a sonolucent area nor an irregular tumor margin strongly suggests a benign lesion[3]. Ancillary techniques such as immunocytochemistry and c-kit gene mutational analysis may aid in the diagnosis of GISTs on FNABs[4].

In addition to evaluating intramural lesions of the esophagus and stomach, EUS can evaluate the cause of thickened gastric folds. After identifying and excluding isolated gastric varices, EUS can define the layers of the stomach that are involved in the fold thickening and suggest the pathologic process. Thickening of the deeper layers is usually associated with malignancy. Agreement by endoscopists was excellent for cystic lesions (kappa = 0.80) and extrinsic compressions (kappa = 0.94), good for lipoma (kappa = 0.65), fair for leiomyoma and vascular lesions (kappa = 0.53 and 0.54, respectively). [5]

Tumor staging is another common indication for EUS. A large number of studies have documented the accuracy (70-90%) of radial EUS in the tumor (T) and nodal (N) staging of gastroesophageal malignancies[6]. EUS can determine if esophageal tumors are localized to the mucosa-submucosa (T1-T2 lesions) or have invaded through the muscularis propria (T3). The invasion of extra-esophageal organs such as the aorta, pericardium, and bronchi, corresponding to stage T4, can be demonstrated with EUS. The staging of advanced lesions may be compromised by the inability of the

endosonoscope to traverse tight malignant strictures and a corresponding increased risk of perforation with stricture dilatation. Careful, graded dilatations prior to EUS have been reported to be safe and the finding of retrogastric (celiac) nodal involvement may have an impact on the decisions for therapy. Small diameter dedicated probes can also be used to stage stenotic esophageal cancers by may tend to understage these malignancies[7].

The accuracy of T staging of esophageal cancer by EUS (80-90%) is significantly higher than that reported for CT scanning (50-60%) and this has been documented in a large number of studies. Preoperative radiochemotherapy downstaged (preoperative EUS stage versus pathologic specimen) 12 of 33 (36%) of patients whereas only 1 patient who did not receive radiochemotherapy[8].

Nodal staging with EUS is not quite as accurate as T staging, but the average accuracy rate of 75% is still substantially higher than the rates reported with CT scanning (54%). Not only the stage grouping of TNM classification but also the number of lymph node metastases determined by ultrasound and endoscopic ultrasound before surgery may be useful for predicting prognosis in patients with esophageal carcinoma[9]. EUS baseline staging results correlate with long term survival in patients with esophageal cancer. Patients with malignant celiac nodal disease as identified by EUS had a significantly worse postoperative survival when compared with patients with malignant celiac adenopathy[10]. Celiac nodes can be better evaluated with EUS, compared to CT imaging[11].

Distant metastasis (M) staging has remained an important role for CT scanning which, when used in combination with EUS, is associated with an overall staging accuracy rate of 86%. Highly accurate staging of esophageal cancers can be used to select patients for a variety of treatments. T1 masses can be endoscopically resected using endoscopic mucosal resection techniques[12]. T2 and T3 masses can be resected after administration of neoadjuvant chemoradiation. T4 lesions have a poor prognosis regardless of the type of treatment and should be treated with palliative therapy.

EUS may also be used to detect anastomotic tumor recurrence, particularly when there is circumferential infiltration of the anastomosis. Although imaging may be obscured by radiation-induced edema, the accuracy of EUS in predicting anastomotic malignancy is 80%. The use of FNA will probably increase the specificity of EUS findings for gastroesophageal anastomotic malignancy.

The staging of gastric cancer with EUS has not been studied as extensively as esophageal cancer because of the smaller number of patients and the uncertain role of EUS. Tumor staging of gastric cancer uses the same principles as that for esophageal tumors. Lesions contained within the gastric wall (T1 - T2) can be identified with accuracy rates of nearly 90% and may be amenable to curative resection. The differentiation between lesions within the mucosa-deep mucosa and those invading the muscularis is increasingly important as endoscopic mucosectomy gains more acceptance. Although CT scanning may be able to provide staging for advanced gastric cancers, it will not be able to stage small lesions with accuracy.

One of the major limitations of EUS is its inability to differentiate between benign peritumor edema and malignant infiltration. This is responsible for the most common error in the staging of gastric cancers and also makes it difficult to use EUS to differentiate between malignant and benign masses of the gastric wall. This problem is particularly evident when attempting to use EUS to differentiate between a benign and malignant gastric ulcer.

The staging of gastric lymphomas is a particularly important role for EUS since much of the therapy is based on the stage of the disease. Lymphoma staging by EUS is similar to the staging of gastric cancer and the accuracy rates are comparable. If MALT lymphomas may be localized to the mucosa and submucosa, they can be successfully (93%) treated with antibiotics[Nakamura, 2001 #23].

Pancreatic - biliary diseases

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The role of endosonography in pancreatic diseases is considerably different than its role in gastroesophageal diseases. EUS may be used as a primary diagnostic procedure in a wide range of benign, malignant, and inflammatory disorders. Endoscopic ultrasound is often used to complement the findings of ERCP and/or CT scanning such as a focal stricture or a suspected mass. The sensitivity (98%) of EUS for diagnosing pancreatic cancer is superior to all other imaging modalities, including US (75%), CT (80%) and angiography (89%).

Although EUS may have high sensitivity rates for detecting pancreatic cancer, the specificity rates have traditionally been lower because ultrasound may not be able to differentiate between focal chronic pancreatitis and cancer. Both lesions appear as focal hypoechoic areas within the pancreatic parenchyma. When other findings such as vessel invasion, adenopathy and duct obstruction are used, the diagnostic accuracy is significantly increased, approaching 80%. Color Doppler imaging may improve the ability of EUS to differentiate between malignancy and inflammation[13].

The recent introduction of EUS-guided biopsies of the pancreas may improve the specificity of EUS for diagnosing pancreatic cancer. In several studies, the sensitivity of EUS biopsies has ranged from 75-88% for the detection of a pancreatic malignancy. Gress has recently defined the accuracy of EUS-guided biopsies and found that the sensitivity was at least 93.5% and a falsely negative predictive rate was 6.9%. [14] EUS FNA was the least costly strategy (\$15,938) compared with CT FNA (\$16,378) and surgery (\$18,723). [15]

In addition to the use of EUS for diagnosing pancreatic cancer, EUS has also been used to stage pancreatic masses. Using the TNM staging classification, EUS can be used to determine what structures have been invaded by a pancreatic mass. Small intra-pancreatic masses (<2 cm) that do not involve the bile duct or duodenum are staged as T1. More commonly, masses are seen involving the bile duct and/or duodenal wall and are staged as T2. Larger lesions extending out of the pancreas, often invading the

arteries and veins adjacent to the pancreas are classified as T3. In a compilation of a large number of studies involving 350 patients, EUS had an accuracy rate of 80% for predicting the T stage and 72% for detecting nodal metastases. These rates for predicting T stage were superior to those obtained with CT scanning (44%) and US (35%). Since evidence of portal venous system invasion by a pancreatic mass is the key determinant for whether a mass can be resected, CT, US, EUS, and angiography have been used extensively for preoperative evaluation. Endoscopic ultrasound is significantly more sensitive than angiography for detecting vascular involvement in patients with pancreatic adenocarcinoma and, thus, may improve patient selection for attempted curative resection[16].

A variety of other pancreatic disorders can be diagnosed with EUS. Chronic pancreatitis can be diagnosed with EUS with greater sensitivity than US, CT, or ERCP by finding parenchymal changes, small pseudocysts, or microcalcifications[17]. Cystic lesions such as cystadenomas are easily seen with EUS[18]. However, EUS imaging alone cannot differentiate between a benign and malignant cyst and fine needle aspiration is required[19]. [20] Pseudocysts may be diagnosed and drained with primary introduction of EUS-guided stents[21]. Intra-ductal tumors are readily diagnosed and staged with EUS, including the use of probes. Main duct type tumors with $>$ or $=10$ mm dilated MPD, branch duct type tumors (>40 mm) with irregular septa, and large mural nodules (>10 mm) strongly suggest malignancy on EUS[22]. FNA will provide evidence of malignancy at a rate similar to other pancreatic lesions[23].

Islet cell tumors, including gastrinomas, can be diagnosed in more than 80% of patients, and EUS is clearly more sensitive than CT scanning. EUS may be the first test used for acute relapsing pancreatitis. EUS, a less invasive test than ERCP, demonstrated an etiology in two-thirds of patients with idiopathic acute pancreatitis. Most patients did not require ERCP during the follow-up period[24].

The staging of ampullary masses with EUS is based on similar principles as used with pancreatic cancer but is technically more difficult. Large lesions are easily localized and the accuracy of staging is 80-90%. Smaller lesions, <2 cm, can also be staged but with a lower accuracy rate, approximately 70%. Since CT scanning is not capable of differentiating between superficial and advanced ampullary masses, EUS plays a critical role in determining the appropriate type of resection. The proper selection of patients for location excision will reduce the need for Whipple resection and its associated costs. EUS is superior to US and CT in the local assessment of periampullary tumors. The staging accuracy of EUS is minimally but not significantly affected by the presence of an endobiliary stent[25].

The ability of EUS to image the biliary tree in detail and without interference by bowel, air or abdominal fat makes it an ideal tool for diagnosis bile duct stones. Several prospective, blinded trials have demonstrated superior sensitivity of EUS over CT and US. EUS is capable of detecting 90-96% of bile duct stones, only missing an occasional stone located high in the intrahepatic ducts. The enhanced ability of EUS was particularly notable in patients with a normal diameter bile duct and with stones <1 cm. In these cases, EUS was clearly superior to US and CT imaging and comparable to ERCP for detecting bile duct stones. EUS is more sensitive than US for detecting bile duct stones[26]. Although EUS will not replace ERCP as the test of choice in high-risk patients -- i.e., with cholangitis and/or pancreatitis -- EUS may be used as the primary diagnostic test in low-risk patients. Using EUS in diagnostic strategies for bile duct stones will reduce cost and morbidity. Recently EUS has been reported in the primary evaluation of patients with a dilated common bile duct[27].

Rectal diseases

Staging of rectal cancers is the most common indication for rectal EUS. There are several staging schema, but TNM staging is often used since it parallel's gastro-esophageal staging. Masses contained within the rectal wall are staged as T1-2 and EUS has an accuracy rate of 73-94 %. Masses extending through the muscularis are staged as T3

and metastatic lesions are staged T4. The accuracy for staging of tumours of the rectum and colon was 81% and 89%, respectively, using a high frequency catheter probe[28]. Masses that are localized to the rectum can be treated with local excision and more advanced lesions can be treated with radiation. Local excision appears to be an effective alternative treatment to radical surgical resection for a highly select subset of patients with T2 and T3 adenocarcinomas of the distal rectum who show a complete pathologic response to preoperative chemoradiation[29]. EUS can also localize an intramural rectal mass such as a carcinoid tumor. Examination of the anal sphincter can detect traumatic tears in the external sphincter and a loss of continuity in the internal sphincter. These findings can be useful in the evaluation of the patients with fecal incontinence. EUS can also be used to evaluate patients with perianal Crohn's, looking for abscesses and fistula[30].

EUS-guided fine needle aspiration

The introduction of linear array imaging has made EUS directed fine needle aspiration (FNA) biopsies possible. Under direct and continuous ultrasound guidance, a 22-gauge needle can be directed into submucosal lesions, lymph nodes, and pancreatic masses. The needle can be extended as far as 5cm, providing access to tissue surrounding the esophagus, stomach and the entire pancreas. Pulse and color Doppler imaging aid in avoiding vessels, contributing to the low complication rates of needle aspiration, <1%. Although the overall diagnostic rate for EUS-guided FNA is 77%, there is considerable variation with the type of tissue. Mediastinal masses and lymph nodes are technically easier to biopsy and the diagnostic yield is quite high, 83-89%. Although the documentation of nodal involvement in gastro-esophageal cancers is important, the finding of malignant (contralateral) nodes in small cell lung cancer can have an even greater impact on whether surgical resection is attempted.

The sensitivity of FNA for malignant pancreatic masses is lower, 75-88%, and the aspirated pancreatic tissue may be diagnostic of adenocarcinoma, islet cell tumors, or cystic neoplasms[31]. EUS guided FNA of pancreatic cancer may have some advantages

over CT guided biopsies, including shorter needle track, smaller diameter needles, and better access to small intra-pancreatic masses. Peritoneal seeding of cells should be even less of a concern than with percutaneous biopsies. Liver metastases, malignant lymph nodes, and ascites can also be aspirated. The complications of pancreatic needle aspiration are very low, but there are isolated reports of pancreatitis and bleeding; the use of a radial instrument may be associated with a higher complication rate because of poor needle imaging. Cystic neoplasms of the pancreas can be aspirated under EUS guidance and the fluid analyzed not only for cytology but also for tumor markers associated with cystic neoplasms. EUS can also be used to assist in the endoscopic drainage of pseudocysts[32]. A site directly adjacent to the pseudocyst and free of intervening vessels can be selected by EUS and long term success with drainage is very good[1].

Therapeutic EUS

The needle aspiration device that is used for biopsies can also be used to inject therapeutic agents under ultrasound guidance. Celiac neurolysis has been performed by injecting local anesthetics or neurolytic agents into the celiac ganglia. In patients with chronic abdominal pain secondary to pancreatic cancer, an ethanol-bupivacaine injection into the celiac ganglia can significantly reduce the severity of pain and the need for chronic narcotic use in more than 80% of patients. Pain scores were lower 2 weeks after EUS celiac plexus neurolysis, an effect that was sustained for 24 weeks when adjusted for morphine use and adjuvant therapy[33]. EUS was superior to CT for the guidance of celiac blockade in benign pancreatic disease. [11]

Indications and the use of EUS

The indications for EUS have evolved as the instrumentation has improved, accuracy of staging has been established, and needle aspiration biopsies have become available. Intramural lesions of the upper gastrointestinal tract should be examined by EUS when there is suspicion of a malignancy. Similarly, enlarged gastric folds should be evaluated when the etiology may be malignant and prior to surgical resection or deep endoscopic biopsies. EUS will readily differentiate between compression by an extrinsic lesion such

as a pseudocyst or an intra-mural mass. EUS can aid in the diagnosis of malignant stromal cell tumors, linitis plastica, and lymphomas while diagnosing benign intramural tumors. The ability of EUS to accurately stage gastro-esophageal cancers after excluding metastatic disease with CT scanning can be used to direct therapeutic strategies. Superficial (T_1) lesions can be locally resected or ablated. Malignancies contained within the GI tract can be resected with a high degree of success and resection of localized lesions ($T_3 N_x$) may be aided by resection after neoadjuvant chemotherapy and radiation.

Although not a common problem after resection of a gastroesophageal malignancy, a refractory or atypical anastomotic stricture is an important indication for EUS since it may be the only means of making a diagnosis of a recurrent malignancy.

Malignant and benign processes of the pancreatic-biliary system can be diagnosed and/or staged with endosonoscopes after CT scanning has excluded metastatic disease. EUS should be used to further stage suspected intra-pancreatic masses. EUS can be used to exclude malignant masses and differentiate between intra-pancreatic masses ($T_{1-2} N_x$) and identify masses involving adjacent structures such as the portal vein ($T_3 N_x$). For patients that require a tissue diagnosis for directing their treatment, EUS can provide pancreatic biopsies with safety and sensitivity comparable to CT scanning.

Non-critically ill patients with suspected bile duct stones can be evaluated with EUS for documenting the presence of stones, or more importantly, excluding stones. EUS is less invasive than ERC and since up to 50% of patients with suspected stones have a normal cholangiogram, EUS may reduce the number and complications of ERC.

Rectal cancers can be staged with EUS but the advantages over staging with CT scanning have not been well documented.

In conclusion, EUS has significantly expanded the imaging capabilities of endoscopy, particularly of the UGI tract. Its ability to provide accurate staging of GI malignancies has provided the basis to several cost effective treatment algorithms.

ENDOSCOPIC ULTRASONOGRAPHY: IMAGING AND BEYOND

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Endoscopic ultrasonography (EUS), introduced into gastroenterological diagnostics more than 20 years ago, has undergone extensive evaluation of its diagnostic capability, probably to a larger extent than most other endoscopic and other imaging techniques in gastroenterology. Almost necessarily, as to be expected with an imaging method being assessed with continuing interest for two decades, initial enthusiasm has waned and questions about its influence on management and outcome have been dealt with, yielding mixed results. Other imaging techniques are usually not burdened by such a self critical approach, mostly due to the fact that technical progress has hindered proper evaluation, and techniques are marketed with only little good evidence of their real value. Methodological questions about study quality in gastrointestinal imaging have attracted limited interest, and only rarely are factors looked into, which may be responsible for divergent study results.¹ However, it happened a few years ago that EUS was revitalised, mainly due to the advent of EUS guided fine needle aspiration (FNA),² and even more recently, several emerging techniques of EUS guided therapy.³ The following does not aim at giving a full overview on the ever rising body of literature on the accuracy of diagnostic EUS, including FNA. For this purpose textbooks and review articles in various journals²⁻⁴ are recommended. Some current trends and possible future tendencies will be outlined.

TECHNICAL FACTORS

Echoendoscopes—with some recent exceptions—are oblique viewing endoscopes which carry a rigid ultrasound transducer at their tip, which either generates a 360° round view perpendicular to the shaft axis or a linear image of variable width parallel to the endoscope axis. Radial scanners have been mechanical scanners but recently electronic scanning—the principle of linear scanners—is being developed for radial scanning also. EUS utilises high ultrasound frequencies (5–20 MHz, 7.5 MHz being the most frequently used ultrasound frequency) which generate a high resolution image in the near field with limited penetration depth, ranging from 1–2 to 5–6 cm, depending of the ultrasound frequency used. EUS is usually done with the patient in the left lateral position, mostly under conscious sedation, and is associated with very low complication rates⁵ with very few exceptions.⁶ Details of the examination technique for the various organs in focus—gastrointestinal tract and immediate surroundings, mainly the pancreatobiliary tract—are described elsewhere.⁷⁻⁸ Miniproboscopes are a further development which mirror the miniaturisation of the technique (they are referred to below).

Linear echoendoscopes are necessary for the performance of EUS guided FNA as only with these instruments can the course of the puncture needle be followed. An average of 2–4 passes is necessary to obtain adequate tissue for cytological smears, and the presence of an in-room cytopathologist seems to improve the yield⁹; some examiners try to obtain small core specimens for histopathological analysis but the relative yield and accuracy of cytological and histological analysis, as well as the best needle diameter (19 or 22 gauge), are still unclear.

ENDOSONOGRAPHIC IMAGING: TUMOUR STAGING STILL THE MAIN INDICATION?

After primary diagnosis of gastrointestinal malignancies by endoscopy and biopsy, EUS is used secondarily for locoregional tumour staging; this applies to oesophageal, gastric, and rectal cancer as well as to gastric lymphoma¹⁰⁻¹¹ (figs 1, 2); the value of EUS in suprarrectal colonic cancer has not yet been established. The use of EUS is limited to patients in whom surgery is considered, either primarily or after neoadjuvant therapy, as EUS is not believed to be useful in inoperable patients or in those with known unresectable disease or distant metastases. The value of EUS in restaging after such neoadjuvant treatment has been burdened with poor results¹² but more elaborate assessment methods such as two dimensional¹³ or even three dimensional volume measurement may fare better. In gastric lymphoma, EUS is clinically useful in selecting patients for *Helicobacter pylori* eradication treatment,¹⁴⁻¹⁵ and restaging after chemotherapy seems to be more successful than in upper gastrointestinal cancer¹⁶

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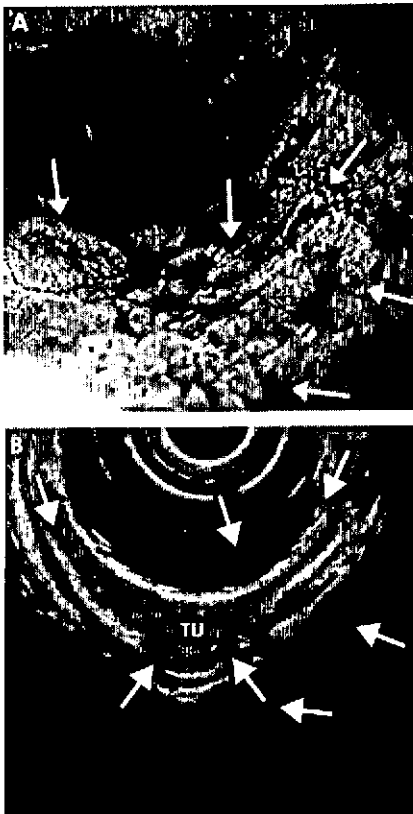


Figure 1 Barrett cancer in stage T1sm; endoscopic view of a large flat tumour with the margins indicated by arrows (A). Endoscopic ultrasonography shows a focal echo poor thickening (TU) of the mucosa with thinned submucosal layer (arrows) due to tumour infiltration (B).

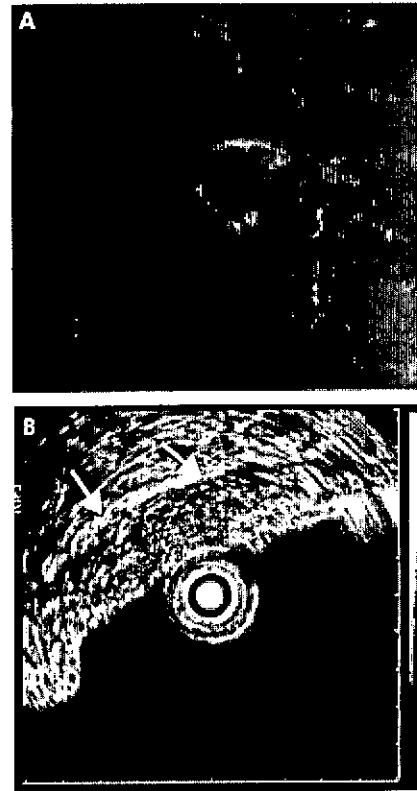


Figure 2 Malignant gastric ulcer (A: endoscopic view). Endoscopic ultrasonography using a miniprobe shows an echo poor wall thickening around the ulcer with smooth outer margins (arrows) (B) indicating stage T2.

In the pancreatobiliary tract the situation is less clear. EUS was repeatedly reported to be the most accurate method for diagnosing small cancers¹⁷ but this was flawed by study designs with a very high disease prevalence, and has not consistently been confirmed by other studies.¹⁸ The value of EUS in "screening" for pancreatic tumours in patients with only a vague suspicion is therefore not established. As with all other imaging tests including, most recently, positron emission tomography (PET),¹⁹ EUS is not useful for differentiating focal chronic pancreatitis from cancer,²⁰ and its accuracy in locoregional staging is seen both enthusiastically²¹⁻²³ as well as more sceptically.²⁴ For pancreatic and biliary cancer staging (fig 3), helical computed tomography (CT) is probably at present the method of choice, merely due to its widespread existence—comparative studies between EUS and helical CT revealing greatly divergent results²⁵⁻²⁷—and EUS might be used as a second-line test in case of uncertainty on CT, or for additional information (FNA) or treatment (plexus neurolysis); these possibilities are discussed below.

In summary, in the year 2003, EUS is still the standard in locoregional staging of oesophagogastric and rectal cancer; the situation in pancreatic cancer being less clear, and EUS may be used as a secondary step in cases with indeterminate CT and/or for FNA or treatment in pancreatic tumours. Recent studies showing less impressive results for EUS in gastrointestinal and pancreatic cancer staging²⁴⁻²⁹ have to be viewed in the perspective of a routine test usually doing less

well under routine circumstances—a fact that is mostly not assessed with other imaging methods but probably applies to them all.

ENDOSONOGRAPHIC IMAGING: USE IN PRIMARY DIAGNOSIS

In the diagnosis of gastrointestinal disorders, EUS plays a substantial role in some areas but has yielded poor results in the differential diagnosis between benign and malignant conditions such as indeterminate ulcers, oesophageal strictures, and pancreatic tumours (both solid and cystic).

In submucosal lesions, EUS is crucial for distinguishing intramural tumours/lesions from extramural compressions³⁰⁻³¹ (fig 4), and in the latter case management is quite different (most impressions are due to normal organs). EUS is also the most important tool to assess the most likely tumour nature and the risk of malignancy³²; again a reliable histological diagnosis cannot be expected. The diagnosis of common bile duct stones is another good indication for EUS, as confirmed by a large number of fairly homogeneous studies from all over the world,³³⁻³⁵ yielding accuracy rates of well over 90%. Direct comparisons with magnetic resonance cholangiopancreatography (MRCP) showed EUS to be superior or equal.³⁶ EUS could therefore be used in patients with low or intermediate risk for common bile duct stones; a negative EUS examination has a very high negative predictive value.³⁷ The diagnosis of pancreatic endocrine tumours is another good indication for EUS, and other tests have repeatedly shown to be inferior to EUS.³⁸

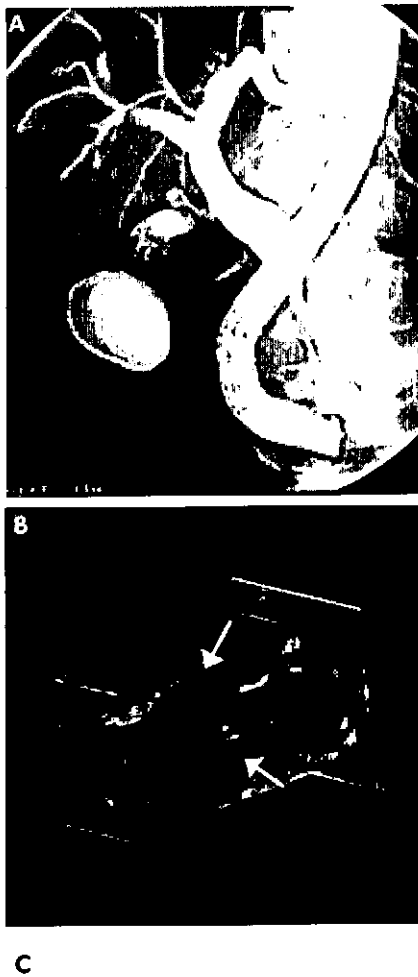


Figure 3 Distal periampullary cancer infiltrating the distal common bile duct (CBD). (A) Endoscopic retrograde cholangiopancreatography image with a 3 cm distal tumour stricture (arrow) and the miniprobe being introduced. (B) Three dimensional reconstruction of the miniprobe picture showing the proximal tumour end (arrows); the full tumour delineation in relation to the pancreatic head is seen on the conventional endoscopic ultrasonography image in (C); the arrows delineate the wall thickening extending from the area of the papilla/duodenal wall up to the CBD.

Due to its good accuracy in detecting common bile duct dilatation, common bile duct stones, pancreatic tumours and, although disputed, chronic pancreatitis,⁴³ EUS has been suggested as a primary tool in patients with a clinical suspicion of pancreatobiliary disease. However, data are mainly from ter-

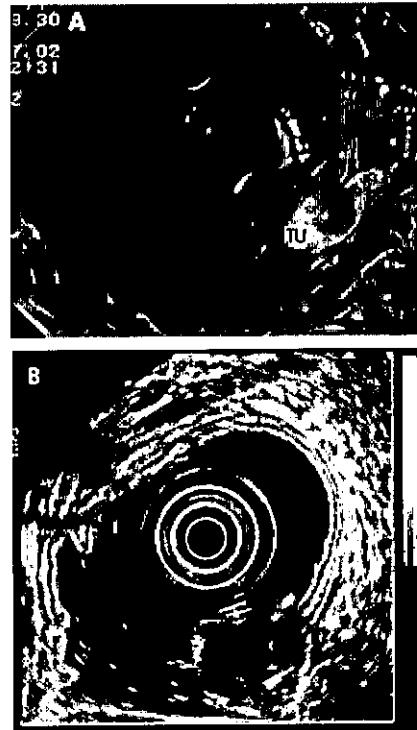


Figure 4 Submucosal tumour (TU) in the gastric body with endoscopic (A) and endosonographic (B) views.

tiary referral centres which see preselected patients and some had a rather high rate of chronic pancreatitis cases.⁴⁰ Large and good outcome studies in patient populations with a low disease prevalence are still lacking. The use of the echoendoscope as an endoscope for upper gastrointestinal tract endoscopic screening, including an endosonographic view of the pancreas, is intriguing but has to be assessed properly. First, data on patients with dyspepsia are appearing.⁴¹

In other areas such as portal hypertension, achalasia, and inflammatory bowel disease, the clinical value of EUS has been less well established. Good results have been described for rectal and anal EUS in detecting fistulas, abscesses, and anal sphincter defects in incontinence.^{42,43}

DIAGNOSTIC EUS WITH MINIPROBES

Simplification of EUS by using small probes (MP, miniprobes) introduced through the working channel of conventional gastroscopes, duodenoscopes, and colonoscopes for use in the gastrointestinal and pancreatobiliary tract has been welcomed but results of these probes have been ambiguous. Good staging results have been shown by one group for oesophageal cancer⁴⁴ but others have limited MP use to small and flat gastrointestinal lesions, again with varying accuracy rates^{45,46} (see fig 2). The advantage of miniprobes over conventional echoendoscopes is their precise placement onto a lesion which is otherwise difficult to localise by conventional EUS. The disadvantage of the gastrointestinal use of MP is that water filling is necessary (although there are balloon types now available) which gives rise to some aspiration risk, at least in the oesophagus.

By and large, MP are mainly used in clinical routine (if available) for staging early cancer prior to planned endoscopic resection using mucosal resection (EMR) techniques. Results in the staging of these early cancers, differentiating between

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mucosal and submucosal invasion, have however been somewhat variable and not consistently over 70–75%.⁴⁹ It is therefore still a matter of debate whether pre-EMR EUS is indispensable or whether the endoscopic impression together with the histopathological examination of the resection specimen is sufficient. According to this approach, EMR starts out as diagnostic EMR and can be regarded as therapeutic only after histopathological review of the resected specimen.

Intrabiliary use of MP has been published in a fair number of studies,^{50–52} but their real value in the diagnosis of biliary strictures and staging of biliary tumours is still limited in clinical practice due to limited durability, costs, expertise, and uncertain accuracy.

DIAGNOSTIC EUS AND OUTCOME

A growing body of evidence deals with the impact of EUS on outcome and management,^{33–37} although it might be difficult to ascribe outcome in complex situations such as gastroenterological tumours to one single imaging test. EUS prediction of advanced tumours has been linked to very poor prognosis in oesophageal and pancreatic cancer.^{34–41} In submucosal tumours, EUS saves a large number of other tests,⁴² with better accuracy, and may save money, but not consistently, depending on the medical reimbursement system.⁴³ Calculations of cost effectiveness in cancer staging,^{44–47} submucosal tumours,⁴⁸ and biliary pancreatitis⁴⁹ have mostly revealed encouraging results but not all of these outcome studies showed huge differences induced by EUS; this however is not to be expected from a merely diagnostic tests, and it has to be mentioned that outcome studies are usually avoided in the field of research dealing with gastrointestinal imaging (endoscopy, radiology, nuclear medicine). A broader application of EUS in patients with abdominal pain/dyspepsia has therefore to be evaluated further.

Application of EUS (echoendoscopes or high frequency MP) prior to endoscopic resection of gastrointestinal tumours has been advocated for early cancer (see above) as well as for submucosal tumours^{54–56}; in submucosal tumours however, endoscopic resection techniques have not yet gained widespread acceptance. In the latter case, EUS would be useful to delineate the layer of origin of the lesion. On the other hand, transabdominal ultrasound may do almost as well in the follow up of endosonographically diagnosed submucosal gastric tumours.⁵⁷ EUS has not been shown to be useful in predicting post-polypectomy bleeding in the colon.⁵⁸

Prior to transluminal endoscopic drainage of pancreatic pseudocysts, EUS was shown to change management in almost 40% of cases.⁵⁹ EUS can diagnose intervening vessels, possibly preventing the blind transluminal approach, and it can guide the way to the best approach and non-bulging cysts. It is however not backed up by study data, whether in pseudocysts with clear bulging, the endoscopic drainage attempt should only be performed after EUS. It is nevertheless only logical that nowadays cyst drainage can be performed under direct EUS guidance (see below)

ENDOSONOGRAPHIC TISSUE ACQUISITION

The addition of guided needle aspiration has clearly widened the spectrum of diagnostic EUS (fig 5). Generally, specificity is close to 100% in all indications but the diagnostic sensitivity somewhat depends on the indications^{60–61}: the highest sensitivity (80–90%) is achieved in mediastinal tumours and lymph node metastases^{62–64} as well as paramural lymph nodes somewhere else, mostly around the coeliac trunk.⁶⁵ In this area,

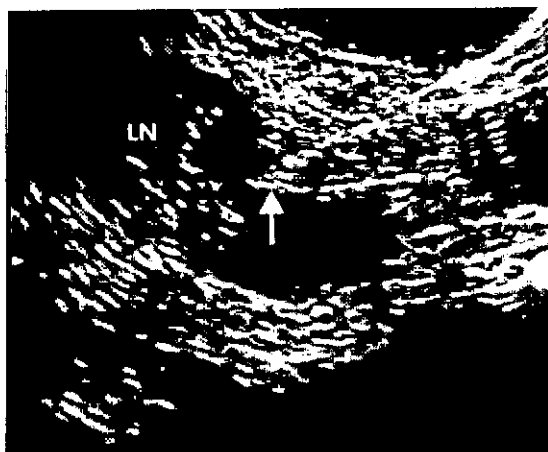


Figure 5 Endosonographic puncture of a large lymph node (LN) in the mediastinum; the needle tip is marked by an arrow.

FNA results may replace more invasive tests such as mediastinoscopy and they have some important impact on outcome—for example, when proving distant metastases in oesophageal cancer and advanced malignancy with contralateral lymph nodes in non-small cell lung cancer. Pancreatic malignancy can be proved with a lower sensitivity, between 70% and 85%, and the influence on outcome is less clear. In irresectable tumours, EUS-FNA is necessary when radiochemotherapy regimens are applied, and can be performed in one step with staging and perhaps coeliac plexus blockade in case of severe pain. In resectable tumours, most would go straight to surgery and a negative FNA result would not change this approach; the minority opinion relies on the fact that resectable tumours may be of different histology than adenocarcinoma and then treated by limited surgery.⁶⁶ In pancreatic cystic lesions, the situation is less clear, and sensitivity of EUS imaging can be improved by FNA results, using cytology and tumour markers, but specificity may be negatively affected.^{67–69} The accuracy in puncturing submucosal tumours has initially been shown to be low but some (not all) recent papers have shown better results, also involving antibodies to diagnose gastrointestinal stroma cell tumours.⁷⁰ In the application of FNA in cystic lesions, infection seems to be a risk⁷ but may have been overestimated.⁶⁸

Other indications are less frequent and include FNA of liver lesions,⁷¹ ascites,⁷² and visible adrenal lesions,⁷³ without clear evidence of clinical impact.

TRAINING AND COMPETENCE

EUS is commonly regarded as the most difficult diagnostic technique in gastrointestinal endoscopy (although high quality diagnostic endoscopic retrograde cholangiopancreatography (ERCP) is by no means easier). Data on acquisition of competence are nevertheless sparse. The respective American and European societies recommend EUS numbers between 50 (oesophageal) and 200 (pancreatobiliary)^{74–76} with actual data usually showing somewhat higher numbers to be necessary.^{77–79} Training courses are held throughout the world, ranging from live demonstrations during larger meetings, small tutorials with the presence of trainees during examinations, and bands on training in biomodels including FNA.⁷⁷ More data however are clearly needed on which to base reliable figures to decide on numbers needed to confirm competence in EUS and FNA.

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Figure 6 Endosonographic access to an infected and necrotic pancreatic pseudocyst, opening the way to further endoscopic treatment (necrosectomy). After endosonographic visualisation of the cyst containing pus and necrotic material, as seen by the echo rich material in the large cyst (A), a catheter [arrows] is introduced after endoscopic ultrasonography guided puncture over a guidewire under endosonographic (B) and radiological control, followed by stenting (C). A few days later, access is dilatated with a large balloon (D), creating a large orifice (E) for introduction of a conventional gastroscope (F) and performance of endoscopic necrosectomy; this view is taken through the gastroscope which is introduced through the large orifice transgastrally into the retroperitoneal space with necrotic material.

ENDOSONOGRAPHIC THERAPY: CURRENT POSSIBILITIES AND FUTURE AREAS OF RESEARCH

A variety of therapeutic possibilities have either been partially explored or are evolving, with some animal data presented. Transmural drainage of pancreatic and peripancreatic fluid collections under direct EUS guidance is one of the most logical applications of therapeutic use, and in a recent series of 35

cases, 20 of whom had infected cysts/abscesses, a 89% initial success rate with three recurrences was reported. Notably, almost all lesions (n=32) did not cause any bulging and would not have been amenable by conventional endoscopic drainage." EUS may open the way to more aggressive therapy, such as direct endoscopic removal of pancreatic necroses" (fig 6). EUS guided coeliac plexus blockade has also been reported

in a variety of studies on pancreatic cancer and chronic pancreatitis pain, with better results in cancer (78%)¹⁰⁰ than in chronic pancreatitis (55%)¹⁰¹; a small randomised study showed the EUS guided technique to be superior to the CT technique.¹⁰² Other indications such as EUS guided botulinum toxin injection, injection treatment for tumours, suprapapillary bile duct drainage, and transgastric approach to the left biliary system have been reported in case reports whereas other techniques such as creation of gastroenterostomy and antireflux techniques are still in the experimental stage.^{2, 103} Nevertheless, some indications will remain and some new ones will evolve which will turn out to be clinically useful.

CONCLUSION

EUS has been used for imaging with clinical impact in gastrointestinal tumour staging and the diagnosis of submucosal tumours and common bile duct stones, based on a large number of prospective controlled studies. In diagnosis and staging of pancreatic lesions, EUS should be used in conjunction with other methods, and most probably after an adequate helical CT. Other potential indications such as search for pancreaticobiliary disease (mainly benign) are not yet fully established and require further studies.

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SIZE OF THE PROJECT

This project is an ambulatory surgical treatment center with two procedure rooms.

The project size is 3,000 GSF.

Allowable size is in excess of 5,500 GSF computed as follows:

ASTC	2,750 GSF/OR	2 OR	5,500
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ATTACHMENT GRC-5

STATEMENT OF PATIENT STATISTICS

	1st YEAR	2ND YEAR
Out-Patient Surgery Patients:	1,600	1,680

Patients are expected to increase in the second year by 5%.

ATTACHMENT GRC-6

SECTION XV. REVIEW CRITERIA RELATING TO NON-HOSPITAL AMBULATORY SURGERY (ASTC)

This section is applicable to all projects proposing to establish or modernize a non-hospital based ambulatory surgical treatment center or to the addition of surgical specialties.

A. Criterion 1110.1540(a), Scope of Services Provided

Read the criterion and complete the following:

1. Indicate which of the following types of surgery are proposed:

- | | | |
|---|---|--------------------------------------|
| a. <input type="checkbox"/> Cardiovascular | f. <input type="checkbox"/> Obstetrics/Gynecology | k. <input type="checkbox"/> Plastic |
| b. <input type="checkbox"/> Dermatology | g. <input type="checkbox"/> Ophthalmology | l. <input type="checkbox"/> Podiatry |
| c. <input checked="" type="checkbox"/> Gastroenterology | h. <input type="checkbox"/> Oral/Maxillofacial | m. <input type="checkbox"/> Thoracic |
| d. <input type="checkbox"/> General/Other | i. <input type="checkbox"/> Orthopaedic | n. <input type="checkbox"/> Urology |
| e. <input type="checkbox"/> Neurology | j. <input type="checkbox"/> Otolaryngology | |

2. Indicate if the project will result in a limited or a multi-specialty ASTC.

B. Criterion 1110.1540(b), Target Population

Read the criterion and provide the following:

1. On a map (8 1/2" x 11"), outline the intended geographic services area (GSA).
2. Indicate the population within the GSA and how this number was obtained.
3. Provide the travel time in all directions from the proposed location to the GSA borders and indicate how this travel time was determined.

APPEND DOCUMENTATION AS ATTACHMENT ASTC-1 AFTER THE LAST PAGE OF THIS SECTION.

C. Criterion 1110.1540(c), Projected Patient Volume

Read the criterion and provide signed letters from physicians that contain the following:

1. The number of referrals anticipated annually for each specialty.
2. For the past 12 months, the name and address of health care facilities to which patients were referred, including the number of patients referred for each surgical specialty by facility.
3. A statement that the projected patient volume will come from within the proposed GSA.
4. A statement that the information in the referral letter is true and correct to the best of his or her belief.

APPEND DOCUMENTATION AS ATTACHMENT ASTC-2 AFTER THE LAST PAGE OF THIS SECTION.

D. Criterion 1110.1540(d), Treatment Room Need Assessment

Read the criterion and provide:

1. The number of procedure rooms proposed.
2. The estimated time per procedure including clean-up and set-up time and the methodology used in arriving at this figure.

APPEND DOCUMENTATION AS ATTACHMENT ASTC-3 AFTER THE LAST PAGE OF THIS SECTION.

E. Criterion 1110.1540(e), Impact on Other Facilities

Read the criterion and provide:

1. A copy of the letter sent to area surgical facilities regarding the proposed project's impact on their workload. NOTE: This letter must contain: a description of the project including its size, cost, and projected workload; the location of the proposed project; and a request that the facility administrator indicate what the impact of the proposed project will be on the existing facility.
2. A list of the facilities contacted. NOTE: Facilities must be contacted by registered mail.

APPEND DOCUMENTATION AS ATTACHMENT ASTC-4 AFTER THE LAST PAGE OF THIS SECTION.

F. Criterion 1110.1540(f), Establishment of New Facilities

Read the criterion and provide:

1. A list of services that the proposed facility will provide that are not currently available in the GSA; or
2. Documentation that the existing facilities in the GSA have restrictive admission policies; or
3. For co-operative ventures,
 1. Patient origin data that documents the existing hospital is providing outpatient surgery services to the target population of the GSA, and
 2. The hospital's surgical utilization data for the latest 12 months, and
 3. Certification that the existing hospital will not increase its operating room capacity until such a time as the proposed project's operating rooms are operating at or above the target utilization rate for a period of twelve full months; and

4. Certification that the proposed charges for comparable procedures at the ASTC will be lower than those of the existing hospital.

APPEND DOCUMENTATION AS ATTACHMENT ASTC-5 AFTER THE LAST PAGE OF THIS SECTION.

G. Criterion 1110.1540(g), Charge Commitment

Read the criterion and provide:

1. A complete list of the procedures to be performed at the proposed facility with the proposed charge shown for each procedure.
2. A letter from the owner and operator of the proposed facility committing to maintain the above charges for the first two years of operation.

APPEND DOCUMENTATION AS ATTACHMENT ASTC-6 AFTER THE LAST PAGE OF THIS SECTION.

H. Criterion 1110.1540(h), Change in Scope of Service

Read the criterion and, if applicable, document that existing programs do not currently provide the service proposed or are not accessible to the general population of the geographic area in which the facility is located.

APPEND DOCUMENTATION AS ATTACHMENT ASTC-7 AFTER THE LAST PAGE OF THIS SECTION.

TARGET POPULATION

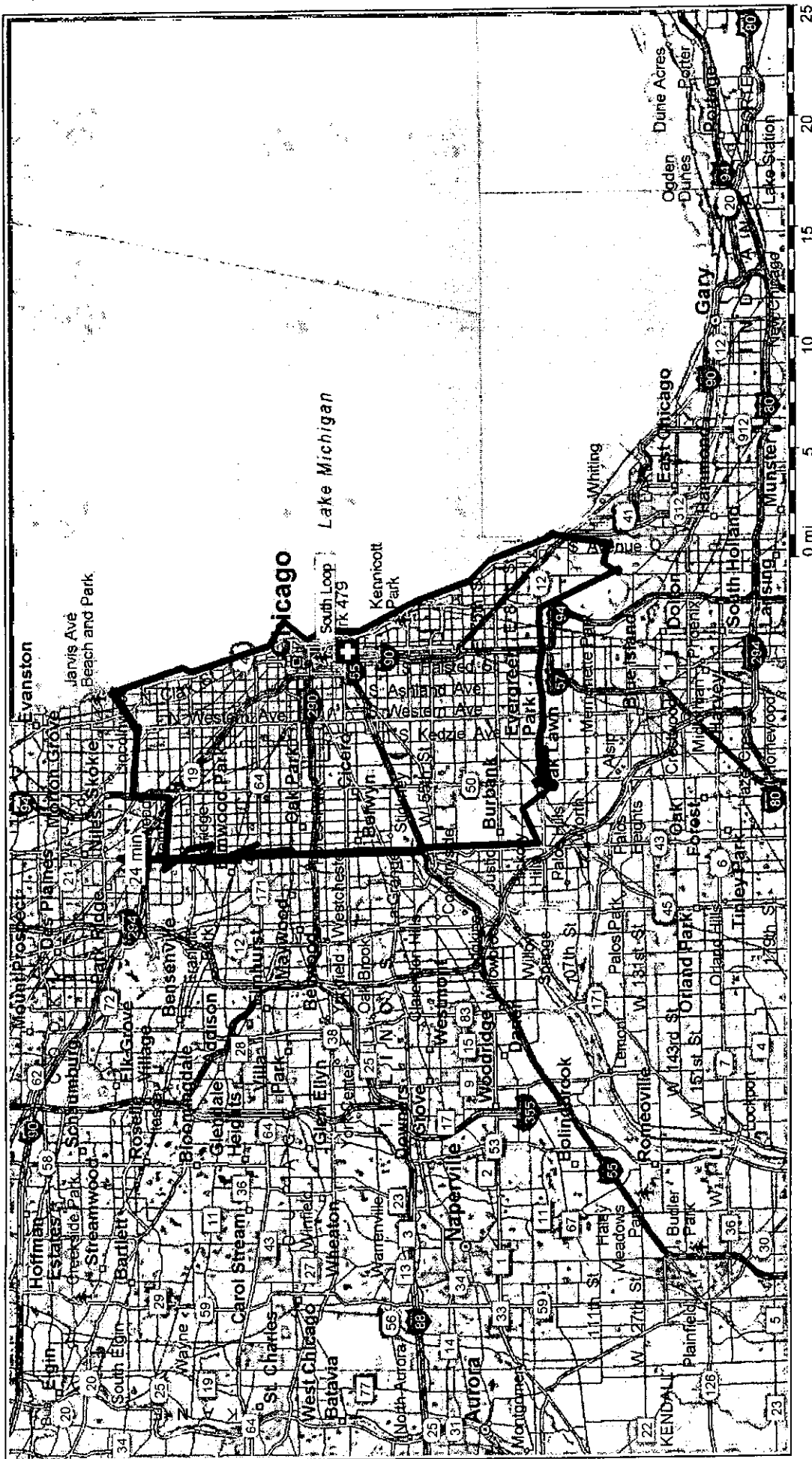
Included as Attachment ASTC-1-1 is a map of the intended geographic services area (GSA). The population for all of the zip codes in the area is approximately 2,800,000 based upon U.S. Census data.

The travel time to the GSA borders is 30 minutes based upon adjusted MapQuest times.

ATTACHMENT ASTC-1

95

2336 s wabash



96

ATTACHMENT GRC-1-1

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PROJECTED PATIENT VOLUME

Attachment ASTC-2-1 is a referral letter from Dr. David Chua, a gastroenterologist. Dr. Chua stated that he will refer 1,600 patients in the first year.

ATTACHMENT ASTC-2

DOCTOR'S OFFICE LETTERHEAD

July 14, 2008

Mr. Jeffrey Mark
Executive Secretary
Illinois Health Facilities Planning Board
525 W. Jefferson Street
2nd Floor
Springfield, IL 62761

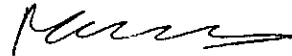
Dear Mr. Mark:

I am a licensed gastroenterologist practicing in the Chicago metropolitan area. Attached is a list of outpatient surgical procedures performed at Saints Mary & Elizabeth Medical Center in Chicago.

I anticipate performing 1,600 of those procedures at South Loop Endoscopy & Wellness Center in Chicago when that facility becomes available. Those patients will come from the proposed service area for the Center.

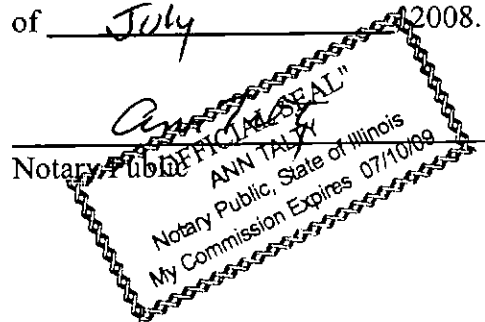
The information contained in this letter is true and correct to the best of my knowledge.

Sincerely,



David Chua, M.D.

SUBSCRIBED AND SWORN TO
before me this 21st day
of July 2008.



ANN TALY
Notary Public, State of Illinois
My Commission Expires 07/10/09

ATTACHMENT ASTC 2-1

Dr. Chua Referrals

Patient Number	Procedure	Zip Code
515203	45385	60477
520773	45385	51
520775	45385	25
516863	45385	57
520852	45385	59
8251	42350	39
9944	45385	18
520395	43239	47
520932	43239	39
520942	45385	56
441	43239	24
4738	43239	39
10294	43239	47
514539	45385	60188
517062	43239	39
520290	43239	40
520548	45385	22
520793	43239	39
520920	45380	51
520930	43239	41
520931	45385	4
520933	45385	9
520934	43239	47
520935	45385	39
9930	43239	47
10260	43239	
14485	43239	18
516427	43239	39
519380	43239	41
519580	45385	47
520499	45380	60139
13488	45385	60501
14858	45385	13
514958	45385	60804
516700	45385	47
520787	45380	41
520836	43239	34
520938	43239	47
520939	45385	18
520940	45385	18
11519	43250	60446
14281	45385	12
514424	43239	47

ZIP CODES ARE ALL 606 UNLESS OTHERWISE INDICATED

99

518617	45385	14
520797	45380	39
520818	43239	22
520952	45385	59
520953	43250	39
520954	45385	25
1635	45380	38
3096	43250	22
9782	45385	60103
10237	43239	32
515488	43239	47
516768	43239	22
520337	45385	47
520339	45380	41
520796	45385	39
520948	45385	51
520949	43250	
512	43239	47
6441	45385	18
7838	45385	
9090	45385	39
517085	43239	52
517222	43239	39
517493	45380	44
520345	43239	
520940	43239	18
520944	45384	18
518517	43239	14
130	45385	39
520997	45385	51
15072	43239	47
521221	45385	8
1019	43239	60439
521234	43239	47
6405	45385	60193
514837	45385	
517042	45385	40
520535	43239	60302
520903	45385	60018
520956	43239	22
521108	45385	47
521220	43239	39
521252	45385	51
521255	43239	47
521384	43239	41
521386	45385	39
521387	43239	47
481	43239	60532
836	45385	60016
6441	43239	18
513655	43239	51
514904	43239	38

518367	43239	60707
520015	45380	22
521194	43239	
521195	43239	18
521378	45380	12
521379	45385	
521380	45385	41
521381	45380	39
13581	45385	23
14667	43239	39
15243	45380	51
15378	43239	47
512197	45385	37
521343	45380	41
521356	45385	41
521390	43239	51
521391	45385	22
6781	45385	47
12566	43250	34
5988	45385	39
11208	43239	39
12566	45385	34
516952	43239	41
521584	45385	47
520910	43239	51
520910	43239	
5205	43239	51
517544	45385	47
521635	43239	39
521502	45385	34
520997	45385	51
516624	43239	29
5465	45385	44
15032	45385	34
5988	43239	39
4838	43239	41
15032	43239	34
15032	45385	
513058	45380	22
3161	45385	22
8791	45380	
8791	45380	
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522206	45385	
517976	43239	25
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521821	43239	29
8244	43239	47
515333	45385	39
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7070	43239	61071
515746	45380	29

518648	43239	22
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521276	43239	39
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521358	45385	22
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522118	45385	12
522120	45385	8
336	43239	47
6141	43239	22
8016	43239	
11971	45385	47
12415	45385	22
514116	45385	60707
516995	45385	18
521901	43239	22
522124	45380	8
5254	43239	22
521178	43239	22
522161	43239	22
522163	43239	
522164	43239	47
522165	43239	22
522166	45380	39
15406	43239	22
513805	45308	28
514231	43239	38
520079	45385	60164
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523632	43239	60025
523634	43239	51
14990	43239	39
519456	45385	39
523152	43239	60804
523155	45385	18
523524	45380	60707
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13235	45385	
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523169	45385	33
523555	43239	39
10084	45385	18
14362	45385	60473

523604	45385	22
523614	43239	22
523648	45385	39
523649	45385	51
523650	45385	25
517348	43239	47
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522307	43239	
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521745	43239	39
513038	43239	
520547	45380	
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12598	43239	47
52212	43239	20
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522463	45385	41
522379	45385	47
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522317	45385	22
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512040	43239	34
519533	43239	
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10015	45385	41
522212	45385	20
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520555	43239	22
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514409	45385	22
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519835	45385	89
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520765	43239	
520766	45380	34
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520921	43239	22
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TREATMENT ROOM ASSESSMENT

There will be 1600 procedures performed during the first year. The average procedure time including preparation and clean up is estimated to be approximately one hour. Those procedures will result in 1600 hours of surgery. That justifies 2 operating rooms based upon the State Standard of 1500 hours per operating room.

Applicant meets the State Standard in proposing two rooms.

ATTACHMENT ASTC-3

IMPACT ON OTHER FACILITIES

The following letters were sent by registered mail to all hospitals and ASTCs on the list that follows this page. No response has been received.

Administrator

Dear Sir or Madam:

South Loop Endoscopy & Wellness Center, LLC proposes to establish a single specialty ambulatory surgical treatment center limited to gastroenterology. It will be located at 2336-40 S. Wabash, Chicago. The facility will contain two procedure rooms located in 3,000 GSF. The estimated project cost is approximately \$1,500,000.

It is estimated that approximately 1,600 patients will be treated during the first year of operation.

The only physician providing a referral letter in support of the application is Dr. David Chua.

Please indicate the impact of the proposed project on your facility.

Sincerely,

ATTACHMENT ASTC-4

MAILING LIST

Administrator
25 East Same Day Surgery
25 E. Washington, Suite 300
Chicago, IL 60602

Administrator
Advanced Ambulatory Surgical Center
2333 N. Harlem Ave.
Chicago, IL 60707

Administrator
Albany Medical Surgery Center
5086 N. Elston Ave.
Chicago, IL 60630

Administrator
American Women's Medical Group
2744 N. Western Ave.
Chicago, IL 60647

Administrator
CMP Surgicenter
3412 W. Fullerton Ave.
Chicago, IL 60647

Administrator
Foot & Ankle Clinics of America, LLC
1644 E. 53rd St.
Chicago, IL 60615

Administrator
Fullerton Surgery Center, Inc.
4849 W. Fullerton
Chicago, IL 60639

Administrator
Hispanic-American Endoscopy Center, LLC
3536 W. Fullerton Ave.
Chicago, IL 60647

Administrator
River North Same Day Surgery Center
One East Erie
Chicago, IL 60611

Administrator
Rush Medical Center
1653 W. Congress Parkway
Chicago, IL 60612

Administrator
Rush Surgicenter – Professional Building
1725 W. Harrison, Suite 556
Chicago, IL 60612

Administrator
Six Corners Same Day Surgery
4211 N. Cicero Ave.
Chicago, IL 60641

Administrator
Southwestern Medical Center, LLC
9831 S. Western Ave.
Chicago, IL 60643

Administrator
Surgicore
10547 S. Ewing Ave.
Chicago, IL 60617

Administrator
The Surgery Center at 900 N. Michigan
60 E. Delaware Ave., 15th Floor
Chicago, IL 60611

Administrator
Water Tower Surgicenter
845 N. Michigan, Suite 994-W
Chicago, IL 60611

Administrator
Advocate Illinois Masonic Medical Center
836 W. Wellington
Chicago, IL 60657

Administrator
Kindred Hospital Chicago North
2544 W. Montrose
Chicago, IL 60618

Administrator
Lincoln Park Hospital
550 W. Webster
Chicago, IL 60614

Louis A. Weiss Memorial Hospital
4646 N. Marine Drive
Chicago, IL 60640

Administrator
Northwestern Memorial Hospital
251 E. Huron
Chicago, IL 60611

Administrator
Thorek Hospital & Medical Center
850 W. Irving Park Road
Chicago, IL 60613

Administrator
Children's Memorial Hospital
2300 N. Children's Plaza
Chicago, IL 60614

Administrator
Loretto Hospital
645 S. Central
Chicago, IL 60644

Administrator
Mount Sinai Hospital Medical Center
2750 W. 15th Street
Chicago, IL 60608

Administrator
Norwegian American Hospital
1044 N. Francisco
Chicago, IL 60622

Administrator
Saint Mary of Nazareth Hospital
2233 W. Division
Chicago, IL 60622

Administrator
Saint Anthony Hospital
2875 W. 19th Street
Chicago, IL 60623

Administrator
Saint Elizabeth Hospital
1431 N. Claremont
Chicago, IL 60622

Administrator
University of Illinois Medical Center at Chicago
1740 W. Taylor St.
Chicago, IL 60612

Administrator
Jackson Park Hospital
7531 S. Stony Island
Chicago, IL 60649

Administrator
Mercy Hospital & Medical Center
2525 S. Michigan Ave.
Chicago, IL 60616

Administrator
Michael Reese Hospital & Medical Center
2929 S. Ellis
Chicago, IL 60621

Administrator
Roseland Community Hospital
45 W. 111th Street
Chicago, IL 60628

Administrator
Saint Bernard Hospital
326 W. 64th St.
Chicago, IL 60621

Administrator
Concord Medical Center
2415 S. Michigan Ave.
Chicago, IL 60616

Administrator
Illinois Eye Institute Ambulatory Surgery Center
3241 S. Michigan Ave.
Chicago, IL 60616

Administrator
Kindred Hospital Chicago Central
4058 W. Melrose Ave.
Chicago, IL 60641

Administrator
Neurologic & Orthopedic Institute of Chicago
4501 N. Winchester Ave.
Chicago, IL 60640

Administrator
John Stroger Hospital of Cook County
1901 W. Harrison
Chicago, IL 60612

Administrator
Sacred Heart Hospital
1101 S. Richmond St.
Chicago, IL 60612

Administrator
Holy Cross Hospital
2707 W. 68th Street
Chicago, IL 60629

Administrator
Provident Hospital of Cook County
500 E. 51st Street
Chicago, IL 60601

Administrator
South Shore Hospital
8012 S. Cranden Avenue
Chicago, IL 60617

Administrator
Trinity Hospital
2320 E. 93rd Street
Chicago, IL 60617

Administrator
University of Chicago Medical Center
1307 E. 60th Street
Chicago, IL 60637

ESTABLISHMENT OF NEW FACILITIES

South Loop Endoscopy and Wellness Center will provide services not now available in Chicago ASTCs. It will offer endoscopic ultrasounds and capsule endoscopies.

Endoscopic ultrasound combines endoscopy and ultrasound. A small ultrasound transducer is placed at the end of an endoscope. That allows placing the transducer inside the body resulting in better images.

It is a highly accurate technique in the studies of deeper tumors of the gastrointestinal tract, determining the extent and depth of certain cancers, and obtaining tissue samples of some deeper cancers like pancreas, liver and involved lymph nodes in a much safer way than would otherwise be possible. In many instances, it contributes information that lead to decisions in favor or against more invasive treatments including surgery. This is a breakthrough technology that has become indispensable in our care of these patients.

Capsule endoscopies use a small video capsule that is swallowed. A diagram of a "Pillcam" follows this section. It provides improved examination of the small intestine. The procedure is painless and does not require sedation.

In cases where there is unexplained gastrointestinal bleeding, diarrhea, or anemia (meaning no diagnosis was found after doing an upper endoscopy, colonoscopy, and X-ray studies), studying the small intestines with the pill cam capsule have identified diagnoses that led to treatment and cure and alleviation

ATTACHMENT ASTC-5

of sickness and suffering.

Offering these services in an ASTC offers significant cost savings. Proposed charges are more than \$1,000 less than the charges in a hospital setting.

Patients find the ASTC experience less stressful and far more convenient than going to a hospital. South Loop Endoscopy will offer new ASTC services at lower costs while providing a better patient experience.

ATTACHMENT ASTC-5

SOUTH LOOP ENDOSCOPY & WELLNESS CENTER, LLC

2334 S. Wabash
Chicago, Illinois 60616

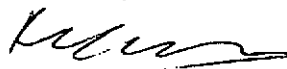
July 14, 2008

Mr. Jeffrey Mark
Executive Secretary
Illinois Health Facilities Planning Board
525 W. Jefferson Street
2nd Floor
Springfield, IL 62761

Dear Mr. Mark:

Attached is a list of charges for South Loop Endoscopy & Wellness Center, LLC. These charges will not be increased during the first two years of operation.

Sincerely,



David Chua, M.D.

ATTACHMENT ASTC-6

CHARGES

\$1,700	Esophagogastroduodenoscopy
\$1,700	Colonoscopy
\$1,800	Capsule Video Small Bowel Endoscopy
\$2,100	Endoscopic Ultrasound of Stomach

A. Criterion 1120.210.a, Financial Viability

1. Viability Ratios

If proof of an "A" or better bond rating has not been provided, read the criterion and complete the following table providing the viability ratios for the most recent three years for which audited financial statements are available. Category B projects must also provide the viability ratios for the first full fiscal year after project completion or for the first full fiscal year when the project achieves or exceeds target utilization (per Part 1100), whichever is later.

Provide Data for Projects Classified as:	Category A or Category B (last three years)			Category B
Enter Historical and/or Projected Years:				2011
Current Ratio				26.48
Net Margin Percentage				46.1%
Percent Debt to Total Capitalization				27.8%
Projected Debt Service Coverage				15.3
Days Cash on Hand				508.2
Cushion Ratio				22.4

Provide the methodology and worksheets utilized in determining the ratios detailing the calculation and applicable line item amounts from the financial statements. Complete a separate table for each co-applicant and provide worksheets for each. Insert the worksheets after this page.

2. Variance

Compare the viability ratios provided to the Part 1120 Appendix A review standards. If any of the standards for the applicant or for any co-applicant are not met, provide documentation that a person or organization will assume the legal responsibility to meet the debt obligations should the applicant default. The person or organization must demonstrate compliance with the ratios in Appendix A when proof of a bond rating of "A" or better has not been provided.

APPEND DOCUMENTATION AS ATTACHMENT FIN-1 AFTER THE LAST PAGE OF THIS SECTION.

B. Criterion 1120.210(b), Availability of Funds

If proof of an "A" or better bond rating has not been provided, read the criterion and document that sufficient resources are available to fund the project and related costs including operating start-up costs and operating deficits. Indicate the dollar amount to be provided from the following sources:

_____ Cash & Securities

Provide statements as to the amount of cash/securities available for the project. Identify any security, its value and availability of such funds. Interest to be earned or depreciation account funds to be earned on any asset from the date of application submission through project completion are also considered cash.

_____ Pledges

For anticipated pledges, provide a letter or report as to the dollar amount feasible showing the discounted value and any conditions or action the applicant would have to take to accomplish goal. The time period, historical fund raising experience and major contributors also must be specified.

_____ Gifts and Bequests

Provide verification of the dollar amount and identify any conditions of the source and timing of its use.

1,211,400 Debt Financing (indicate type(s) OWNER LOAN)

For general obligation bonds, provide amount, terms and conditions, including any anticipated discounting or shrinkage) and proof of passage of the required referendum or evidence of governmental authority to issue such bonds;

For revenue bonds, provide amount, terms and conditions and proof of securing the specified amount;

For mortgages, provide a letter from the prospective lender attesting to the expectation of making the loan in the amount and time indicated;

For leases, provide a copy of the lease including all terms and conditions of the lease including any purchase options.

_____ Governmental Appropriations

Provide a copy of the appropriation act or ordinance accompanied by a statement of funding availability from an official of the governmental unit. If funds are to be made available from subsequent fiscal years, provide a resolution or other action of the governmental unit attesting to such future funding.

_____ Grants

Provide a letter from the granting agency as to the availability of funds in terms of the amount, conditions, and time or receipt.

329,398 Other Funds and Sources

Provide verification of the amount, terms and conditions, and type of any other funds that will be used for the project. Fair Market Value of Lease

1,540,798 TOTAL FUNDS AVAILABLE

APPEND DOCUMENTATION AS ATTACHMENT FIN-2 AFTER THE LAST PAGE OF THIS SECTION.

C. Criterion 1120.210(c), Operating Start-up Costs

If proof of an "A" or better bond rating has not been provided, indicate if the project is classified as a Category B project that involves establishing a new facility or a new category of service? Yes No . If yes is indicated, read the criterion and provide in the space below the amount of operating start-up costs (the same as reported in Section I of this application) and provide a description of the items or components that comprise the costs. Indicate the source and amount of the financial resources available to fund the operating start-up costs (including any initial operating deficit) and reference the documentation that verifies sufficient resources are available.

2 weeks training	\$ 21,400
2 months all expenses	<u>185,000</u>
Total:	\$ 206,400

Start up costs will be funded by the owner.

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SOUTH LOOP ENDOSCOPY AND WELLNESS CENTER

Viability Ratios - end of year

	Year 1	Year 2
Current Ratio:		
Current Portion LT Debt	\$ 32,366	\$ 34,234
Accounts Payable	\$ 26,421	\$ 27,587
Total Current Liabilities	<u>\$ 58,787</u>	<u>\$ 61,821</u>
 Current Assets	 \$ 603,594	 \$ 1,636,837
 Ratio	 10.27	 26.48

Net Margin Percentage:		
Net Ordinary Income	\$ 314,180	\$ 986,367
Net Operating Revenue	\$ 1,425,000	\$ 2,137,500
 Ratio	 22.0%	 46.1%

Percent Debt to Total Capitalization:		
Long Term Debt	\$ 637,035	\$ 602,801
Long Term Debt and Equity	\$ 1,211,002	\$ 2,166,169
 Ratio	 52.6%	 27.8%

Projected Debt Service Coverage:		
Net Income	\$ 314,180	\$ 986,367
Depreciation	\$ 78,076	\$ 36,828
Interest	\$ 38,594	\$ 32,366
Total	<u>\$ 430,850</u>	<u>\$ 1,055,561</u>
 Principal	 \$ 30,599	 \$ 36,828
Interest	\$ 38,594	\$ 32,366
Total	<u>\$ 69,193</u>	<u>\$ 69,193</u>
 Ratio	 6.2	 15.3

Days Cash On Hand:		
Cash	\$ 546,594	\$ 1,551,337
 Total Operating Expenses	 \$ 1,110,820	 \$ 1,151,133
Depreciation	\$ 38,594	\$ 36,828
Total	<u>\$ 1,072,226</u>	<u>\$ 1,114,305</u>
 Total / 365	 \$ 2,938	 \$ 3,053
Ratio	186.1	508.2

Cushion Ratio:		
Cash	\$ 546,594	\$ 1,551,337
Maximum Annual Debt Service	\$ 69,193	\$ 69,193
 Ratio	 7.9	 22.4

SOUTH LOOP ENDOSCOPY & WELLNESS CENTER, LLC

2334 S. Wabash
Chicago, Illinois 60616

July 14, 2008


Mr. Jeffrey Mark
Executive Secretary
Illinois Health Facilities Planning Board
525 W. Jefferson Street
2nd Floor
Springfield, IL 62761

Dear Mr. Mark:

I am a physician licensed to practice in Illinois and am the sole owner of South Loop Endoscopy & Wellness Center, LLC.

I will provide any cash required to fund the project costs and any start up costs from funds that we have on hand.

Sincerely,



David Chua, M.D.

ATTACHMENT FIN-2

SECTION XXV. REVIEW CRITERIA RELATING TO ECONOMIC FEASIBILITY (ECON)

This section is applicable to all projects subject to Part 1120.

A. Criterion 1120.310.a, Reasonableness of Financing Arrangements

Is the project classified as a Category B project? Yes No . If no is indicated this criterion is not applicable. If yes is indicated, has proof of a bond rating of "A" or better been provided? Yes No . If yes is indicated this criterion is not applicable, go to item B. If no is indicated, read the criterion and address the following:

Are all available cash and equivalents being used for project funding prior to borrowing? Yes No

If no is checked, provide a notarized statement signed by two authorized representatives of the applicant entity (in the case of a corporation, one must be a member of the board of directors) that attests to the following:

1. a portion or all of the cash and equivalents must be retained in the balance sheet asset accounts in order that the current ratio does not fall below 2.0 times; or
2. borrowing is less costly than the liquidation of existing investments and the existing investments being retained may be converted to cash or used to retire debt within a 60-day period.

APPEND DOCUMENTATION AS ATTACHMENT ECON-1 AFTER THE LAST PAGE OF THIS SECTION.

B. Criterion 1120.310.b, Conditions of Debt Financing

Read the criterion and provide a notarized statement signed by two authorized representatives of the applicant entity (in the case of a corporation, one must be a member of the board of directors) that attests to the following as applicable:

1. The selected form of debt financing the project will be at the lowest net cost available or if a more costly form of financing is selected, that form is more advantageous due to such terms as prepayment privileges, no required mortgage, access to additional debt, term (years) financing costs, and other factors;
2. All or part of the project involves the leasing of equipment or facilities and the expenses incurred with such leasing are less costly than constructing a new facility or purchasing new equipment.

APPEND DOCUMENTATION AS ATTACHMENT ECON-2 AFTER THE LAST PAGE OF THIS SECTION.

C. Criterion 1120.310.c, Reasonableness of Project and Related Costs

Read the criterion and provide the following:

1. Identify each department or area impacted by the proposed project and provide a cost and square footage allocation for new construction and/or modernization using the following format (insert after this page).

COST AND GROSS SQUARE FEET BY DEPARTMENT OR SERVICE									
Department (list below)	A	B	C	D	E	F	G	H	Total Cost (G + H)
	Cost/Square Foot New Mod.		Gross Sq. Ft. New Circ.*		Gross Sq. Ft. Mod. Circ.*		Const. \$ (A x C)	Mod. \$ (B x E)	
Contingency									
TOTALS									

2. For each piece of major medical equipment included in the proposed project, the applicant must certify one of the following:
 - a. that the lowest net cost available has been selected; or
 - b. that the choice of higher cost equipment is justified due to such factors as, but not limited to, maintenance agreements, options to purchase, or greater diagnostic or therapeutic capabilities.

APPEND DOCUMENTATION AS ATTACHMENT ECON-3 AFTER THE LAST PAGE OF THIS SECTION.

3. List the items and costs included in preplanning, site survey, site preparation, off-site work, consulting, and other costs to be capitalized. If any project line item component includes costs attributable to extraordinary or unusual circumstances, explain the circumstances and provide the associated dollar amount. When fair market value has been provided for any component of project costs, submit documentation of the value in accordance with the requirements of Part 1190.40.

APPEND DOCUMENTATION AS ATTACHMENT ECON-4 AFTER THE LAST PAGE OF THIS SECTION.

D. Criterion 1120.310(d), Projected Operating Costs

Read the criterion and provide in the space below the facility's projected direct annual operating costs (in current dollars per equivalent patient day or unit of service, as applicable) for the first full fiscal year of operation after project completion or for the first full fiscal year when the project achieves or exceeds target utilization pursuant to 77 Ill. Adm. Code 1100, whichever is later. If the project involves a new category of service, also provide the annual operating costs for the service. Direct costs are the fully allocated costs of salaries, benefits, and supplies. Indicate the year for which the projected operating costs are provided.

E. Criterion 1120.310(e), Total Effect of the Project on Capital Costs

Is the project classified as a category B project? Yes No . If no is indicated, go to item F. If yes is indicated, provide in the space below the facility's total projected annual capital costs as defined in Part 1120.130(f) (in current dollars per equivalent patient day) for the first full fiscal year of operation after project completion or for the first full fiscal year when the project achieves or exceeds target utilization pursuant to 77 Ill. Adm. Code 1100, whichever is later. Indicate the year for which the projected capital costs are provided.

F. Criterion 1120.310(f), Non-patient Related Services

Is the project classified as a category B project and involve non-patient related services? Yes No . If no is indicated, this criterion is not applicable. If yes is indicated, read the criterion and document that the project will be self-supporting and not result in increased charges to patients/residents or that increased charges are justified based upon such factors as, but not limited to, a cost benefit or other analysis that demonstrates the project will improve the applicant's financial viability.

APPEND DOCUMENTATION AS ATTACHMENT ECON-5 AFTER THE LAST PAGE OF THIS SECTION.

COST AND GROSS SQUARE FEET BY DEPARTMENT OR SERVICE

<u>Department</u>	<u>Cost/Square Feet</u>	<u>Gross Square Feet Mod.</u>	<u>Total Cost</u>
ASTC	\$ 160	3,000	* 480,000
Contingency	<u>16</u>	<u>3,000</u>	<u>48,000</u>
Totals:	\$ 176	3,000	\$528,000

* Modernization Cost

SOUTH LOOP ENDOSCOPY & WELLNESS CENTER, LLC

2334 S. Wabash
Chicago, Illinois 60616

July 14, 2008

Mr. Jeffrey Mark
Executive Secretary
Illinois Health Facilities Planning Board
525 W. Jefferson Street
2nd Floor
Springfield, IL 62761

Dear Mr. Mark:

South Loop Endoscopy & Wellness Center, LLC, will lease office space for its proposed ambulatory surgical treatment center. We certify that leasing is less costly than constructing a new facility.

Sincerely,



David Chua, M.D.

ATTACHMENT ECON-2


September 26, 2008

Mr. Jeffrey Mark
Illinois Health Facilities Planning Board
525 W. Jefferson Street
Springfield, IL 62761

RE: South Loop Endoscopy & Wellness Center, LLC

Dear Mr. Mark:

The undersigned, being the sole member of the LLC, hereby attests that the selected form of debt financing the project will be at the lowest net cost available.



Signature

David Chua, M.D.

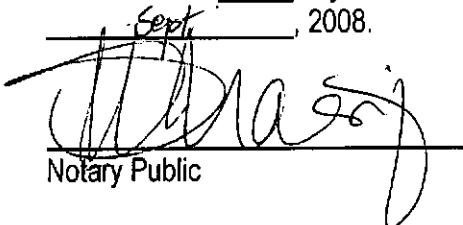
Printed Name

Manager

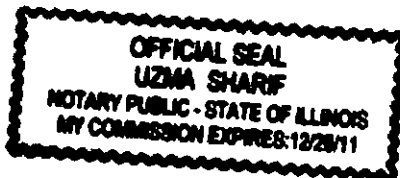
Printed Title

STATE OF ILLINOIS)
) ss
COUNTY OF DuPage)

SUBSCRIBED AND SWORN TO
before me this 25 day of
Sept, 2008.



Notary Public



ATTACHMENT ECON-2

FAIR MARKET VALUE OF SPACE

Square Feet to be Leased	3,000
Terms in Years	5
Discount Rate	8%
Fair Market Value	329,398

ATTACHMENT ECON-4

CONSULTING COSTS

Consulting and other fees include the following items:

CON application fee

IDPH plan review fee

CON consulting fee

Accounting

Space Plan & Cost Estimate

PROJECTED OPERATING COSTS

OPERATING EXPENSES

Salaries	\$470,000
Benefits	86,400
Supplies	<u>185,250</u>

\$741,650

Patients 1,600

Operating Expenses per Patients \$464

ATTACHMENT ECON-5

TOTAL EFFECT OF PROJECT ON CAPITAL COSTS

	2011
Depreciation	\$78,076
Interest	<u>38,594</u>
	\$116,670
Patients	1,600
Capital Cost/patient	\$ 73

ATTACHMENT ECON-5

SHEA, PAIGE & ROGAL, INC.
547 S. LAGRANGE ROAD
LAGRANGE, ILLINOIS 60525
(708) 482-4820

08-078

FAX (708) 482-1091

SPRINGFIELD OFFICE
421 WEST EDWARDS
SPRINGFIELD, IL 62704
(217) 523-2550
FAX (217) 523-2560

October 2, 2008

RECEIVED

Mr. Jeffrey Mark
Executive Secretary
Illinois Health Facilities Planning Board
525 W. Jefferson Street
2nd Floor
Springfield, IL 62761

OCT 07 2008

HEALTH FACILITIES
PLANNING BOARD

RE: South Loop Endoscopy & Wellness Center
2336-40 S. Wabash, Chicago

Dear Mr. Mark:

Enclosed are an original and one copy of South Loop Endoscopy & Wellness Center's application to establish a single specialty surgery center at 2336-40 S. Wabash, Chicago, Illinois.

The facility will include two procedure rooms in approximately 3,000 GSF. The project cost is \$1,540,798.

Dr. David Chua is the manager and sole member of the center.

Very truly yours,


Ira Rogal

IR:khl
Enc

SUMMIT SURGICARE INC.
1 S. 280 SUMMIT AVE.
OAKBROOK TERRACE, IL 60181

BANCO POPULAR NORTH AMERICA
WESTMONT, IL 60559
70-2445/719

5179

8/19/2008

PAY TO THE ORDER OF **ILLINOIS DEPT OF PUBLIC HEALTH**

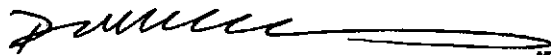
\$**2,500.00

Two Thousand Five Hundred and 00/100*****

DOLLARS

ILLINOIS DEPT OF PUBLIC HEALTH

MEMO *08-078 South Loop Endoscopy + Wellness Center LLC*
CON APPLICATION



AUTHORIZED SIGNATURE

⑈005179⑈ ⑆071924458⑆ 1101002398⑈

Details on Back.

Security Features Included

SOUTH LOOP ENDOSCOPY & WELLNESS CENTER, LLC

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