

Digestive Disease Nursing

An In-Depth Look at Comprehensive Care

FRIDAY, SEPTEMBER 30, 2011



Wireless Capsule Endoscopy

Breakout Session 6

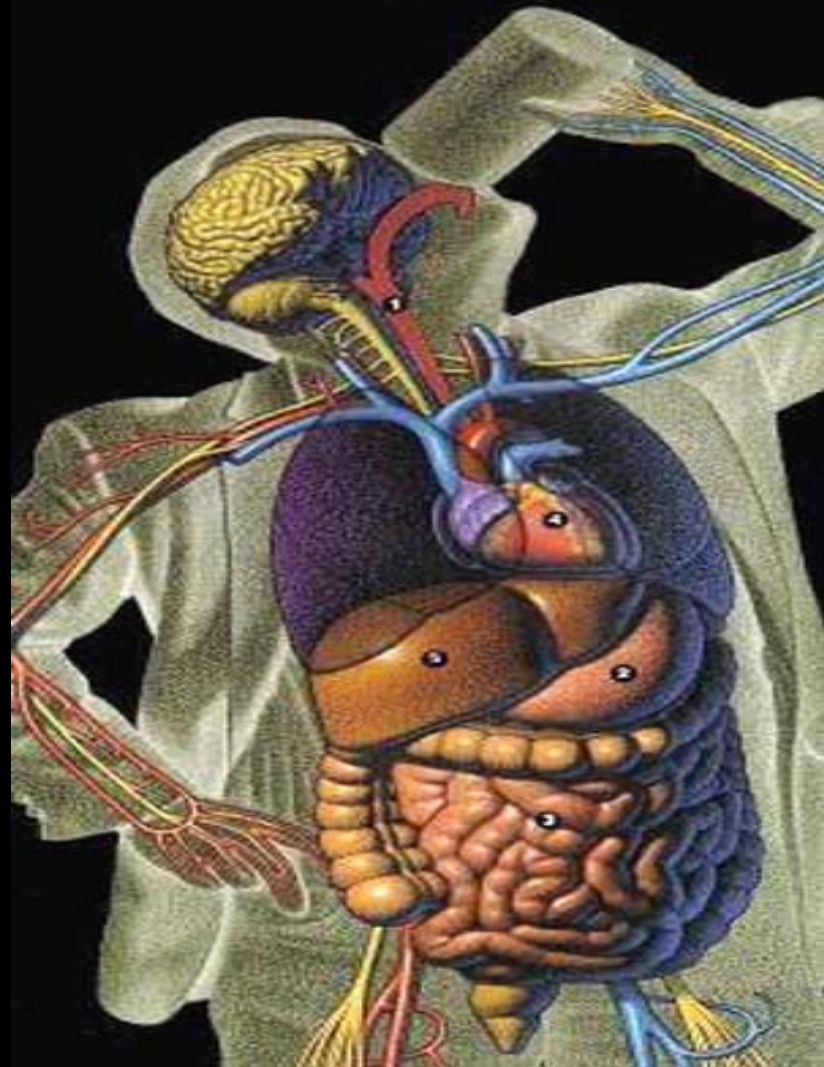
Janice M Santisi, RN
Capsule Endoscopy Coordinator
Digestive Disease Institute
Cleveland Clinic

Session Goals

Attendees will gain knowledge of Capsule Endoscopy of the small bowel including:

- preparation
- pre-procedural considerations
- safety factors
- documentation guidelines
- key nursing components

in current practice of capsule endoscopy for hospitalized and clinic-based patient groups.



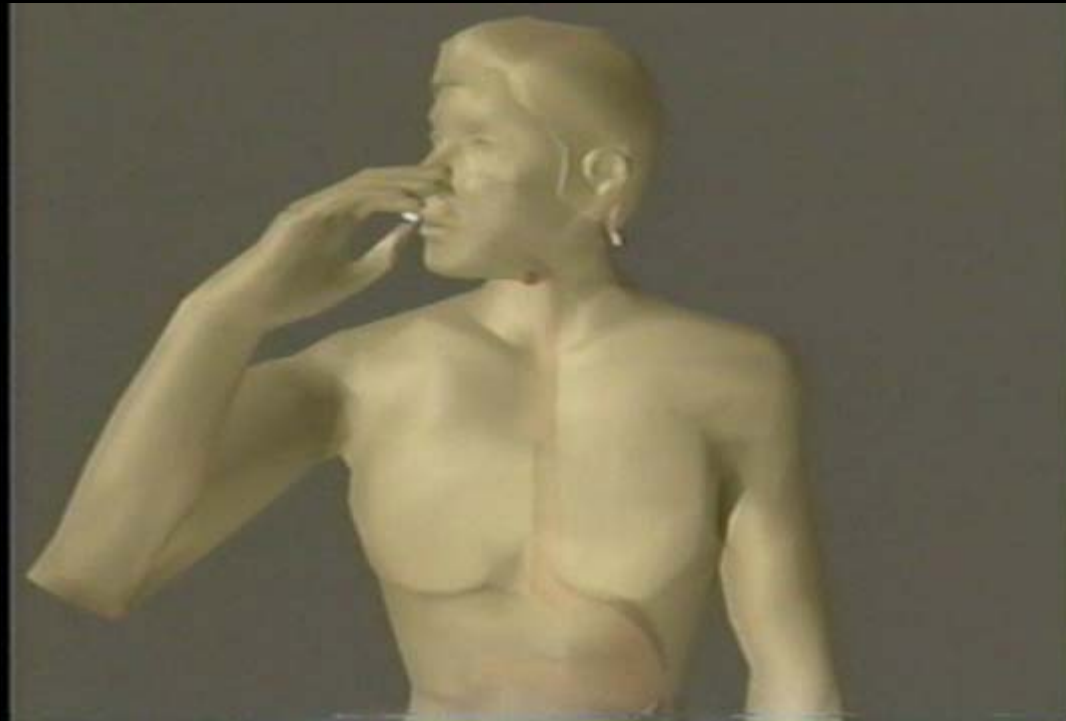
Learning Objectives

- Describe three pre-capsule endoscopy **patient safety** considerations
- Actively discuss parameters of appropriate **patient selection** for capsule endoscopy
- Identify one clinical consideration **difference between a hospitalized and non-hospitalized** capsule endoscopy patient
- Wireless Endoscopy **future** in Digestive Disease
- Recognize **RN scope of practice in interpretive process** of capsule endoscopy video data.

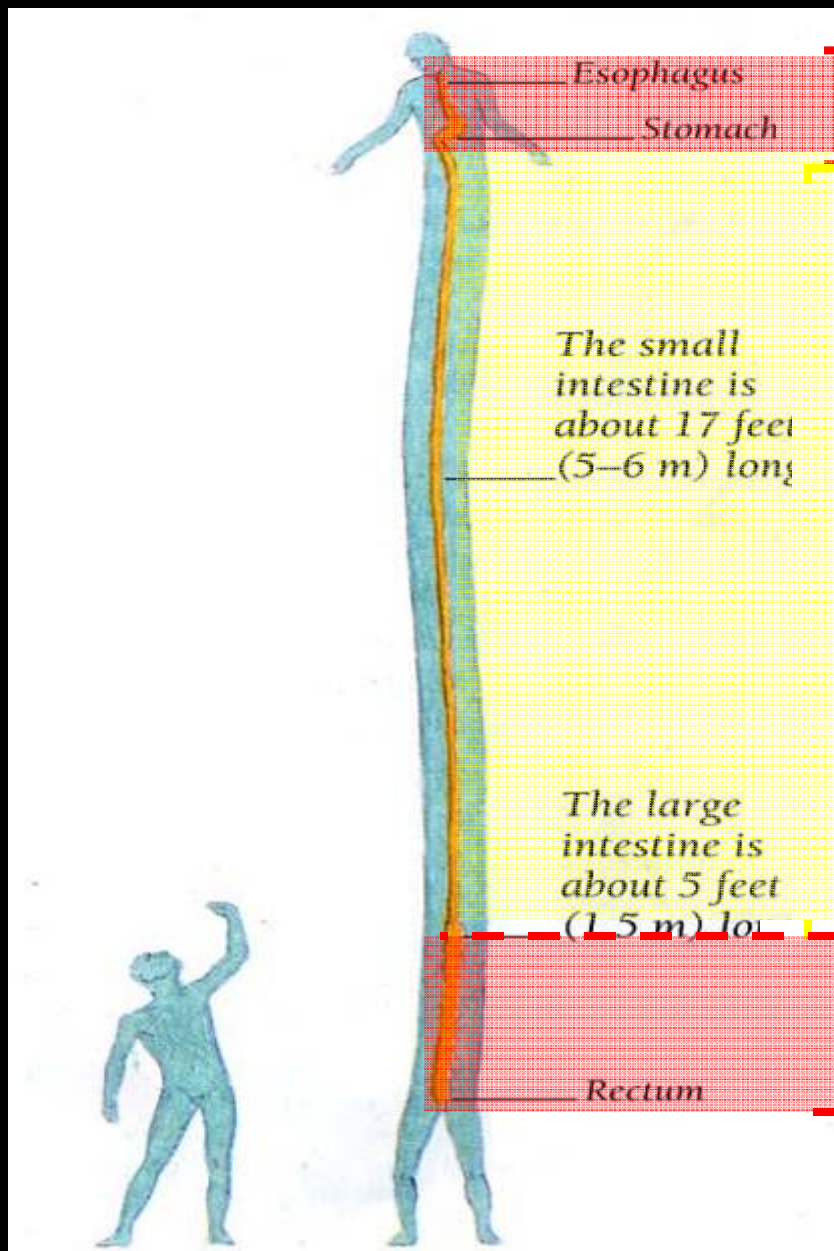
Presentation Agenda

Small Bowel Testing
Capsule Patients





- Non tethered
- Photographic capsule
- Collect 2 images per second
- Moves by peristalsis
- Images converted to RF and are collected and stored for later download
- Capsule “working life” ranges 8-14hrs in current FDA approved devices
- Capsule passes from body naturally in feces
- Specific to examination of the Small bowel but other wireless device that exam remainder of GI tract



Traditional Upper Endoscope

-oral cavity > inches of SB

17-20 feet unexamined by direct visualization

Traditional Lower Endoscope-Colonoscopy

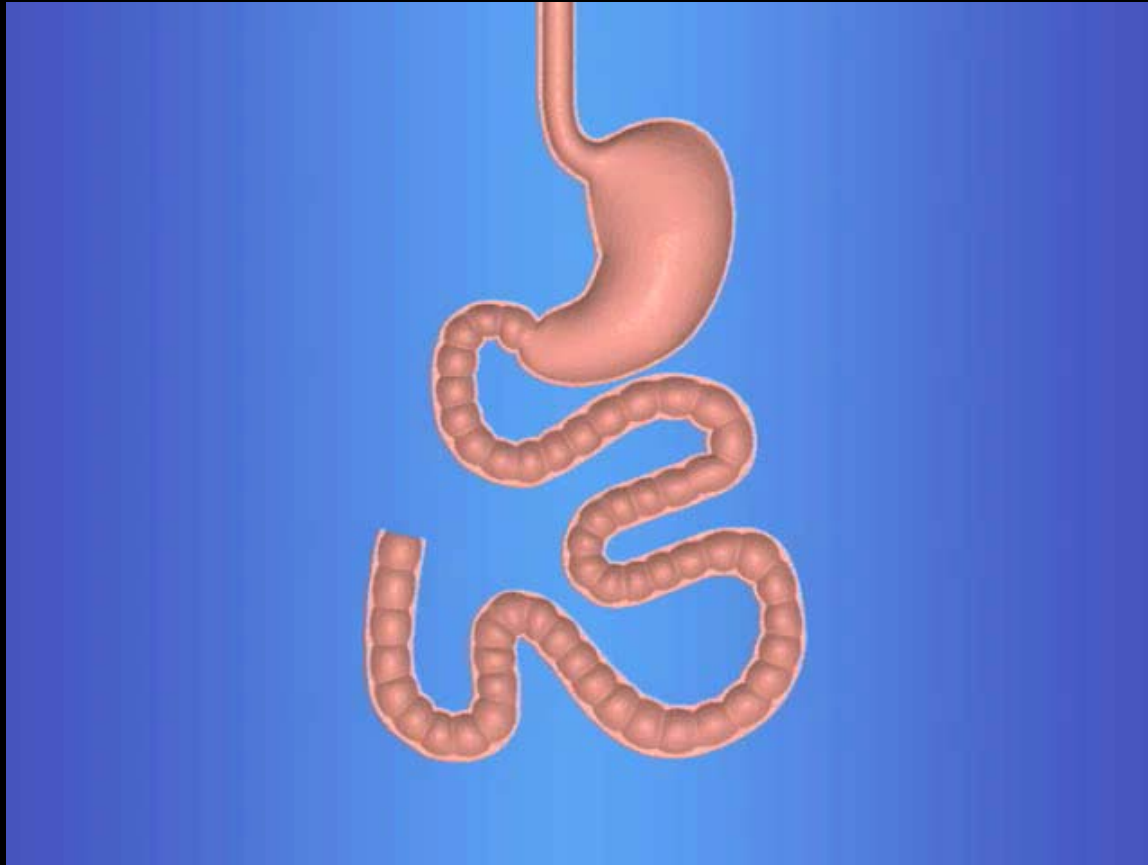
-rectal insertion > 5 feet >
-through Ileal Cecal valve
-From inches-1 foot examined

Intraoperative Enteroscopy



Associated surgical risks-Prolonged recovery-poor diagnostic yield

Balloon Enteroscopy

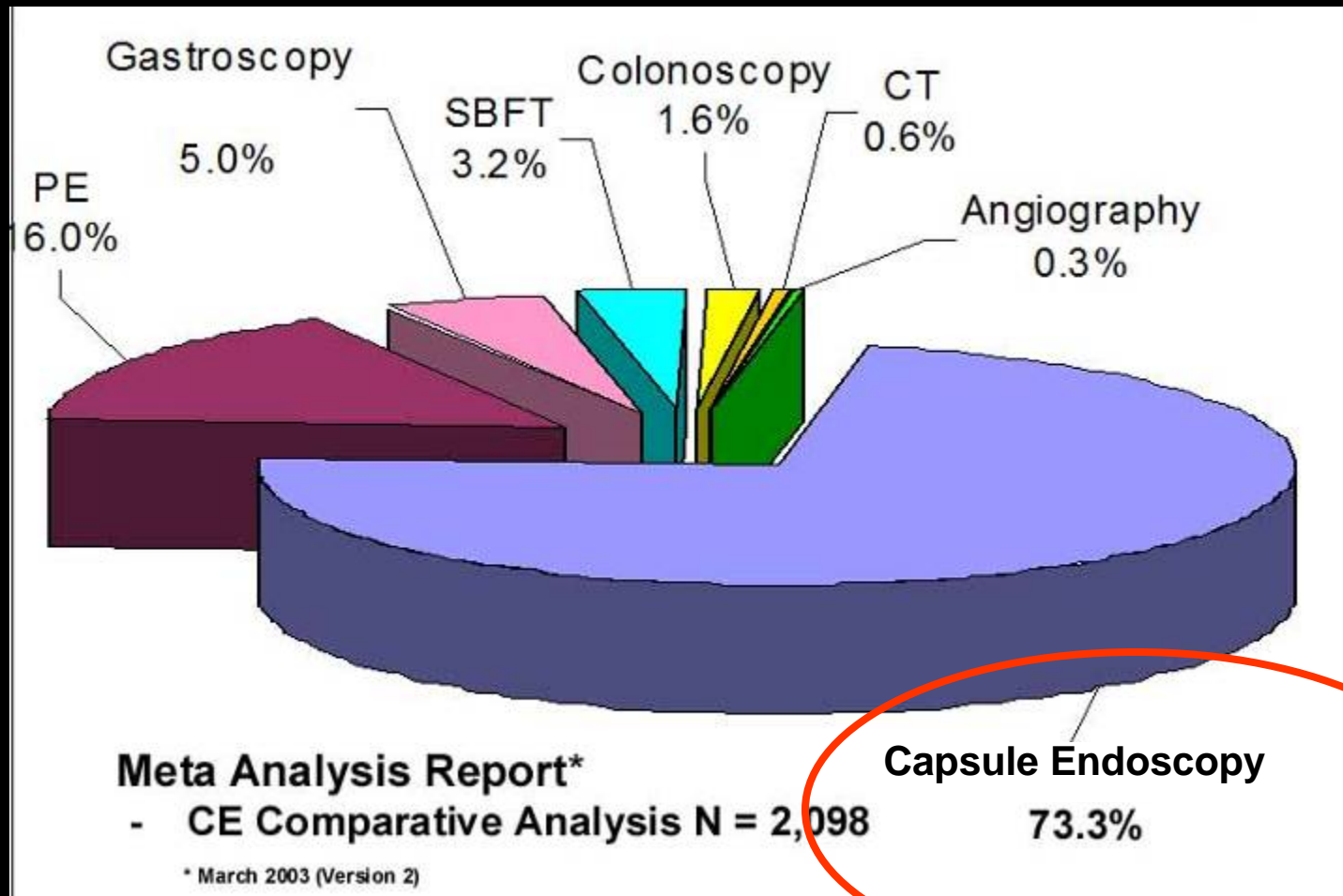


invasive-general anesthesia-risk of perforation
- 2 hour procedure-long recovery -requires
specifically trained team



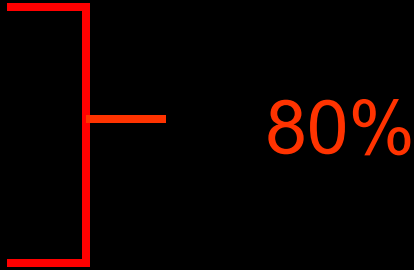
Balloon Enteroscopy primarily used as **treatment modality secondary** to SB lesion diagnosis by capsule endoscopy

Small Bowel Pathology Diagnosis by Procedural Type



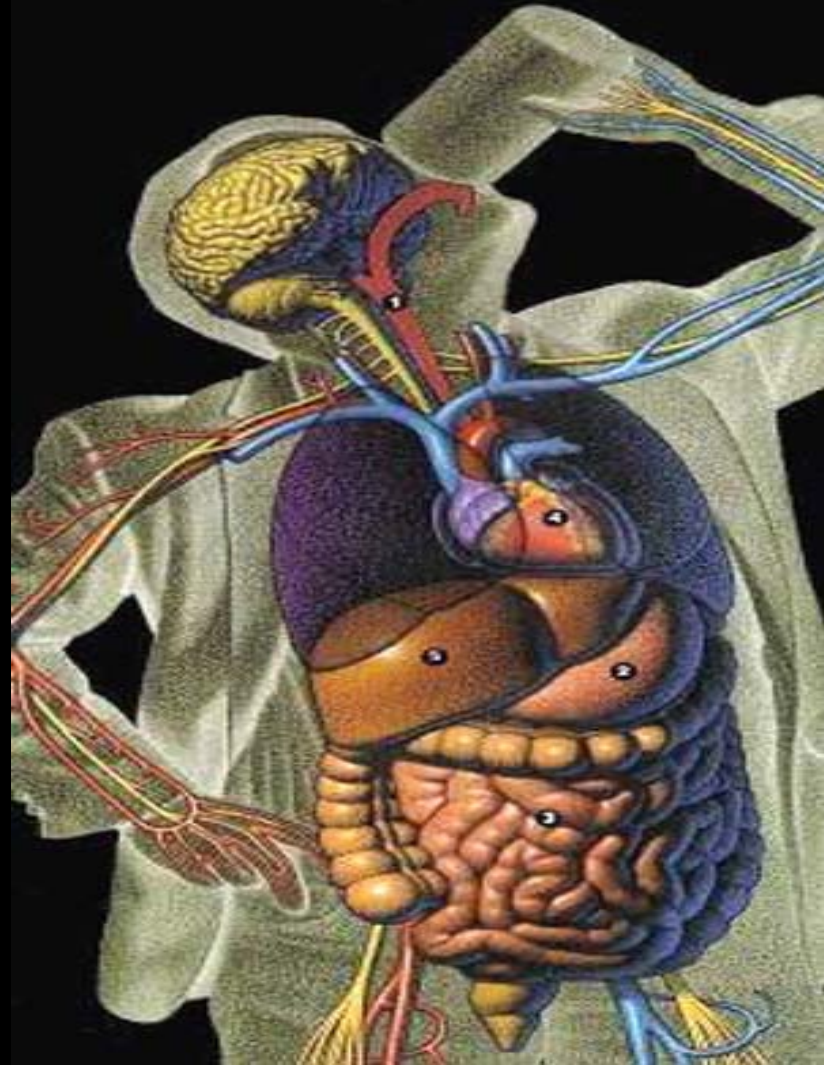
* Does not include CT enterography

What Patients Benefit Most by Diagnostics with SB Capsule Endoscopy

- Blood Loss Anemia
 - Fe Def Anemia
 - Melena
 - Hematochezia
 - Known Crohn's Disease of SB to monitor progress of therapy
 - Indeterminate Crohn's Disease with symptoms of small bowel Disease
 - Malabsorption Syndromes
 - Familial Polyp Syndromes and PJS
 - Abnormal GI X-Ray of the SB –mass suspected
 - Some instances of abdominal pain
- 
- 80%

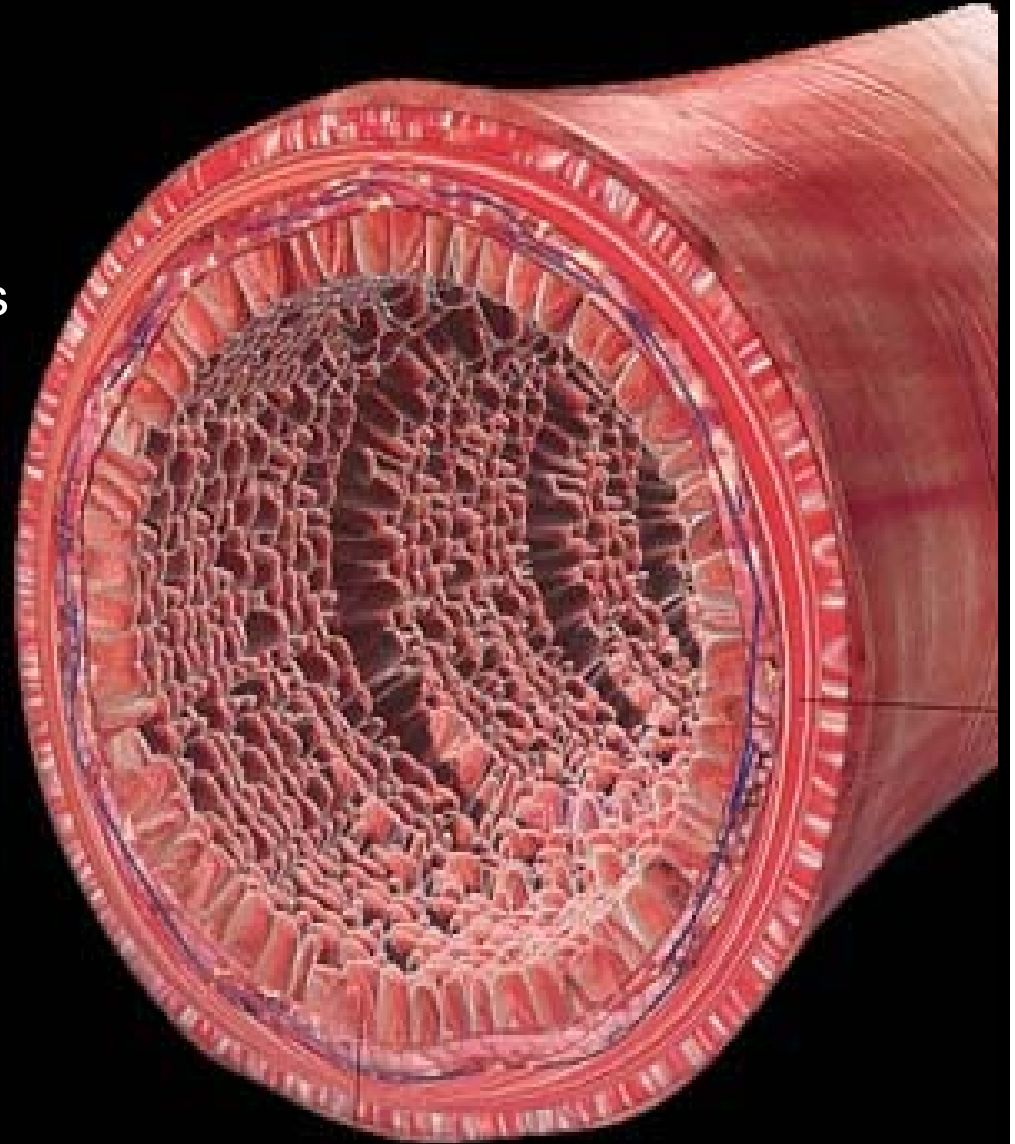
Agenda

Small Bowel Testing
SB Anatomy Review



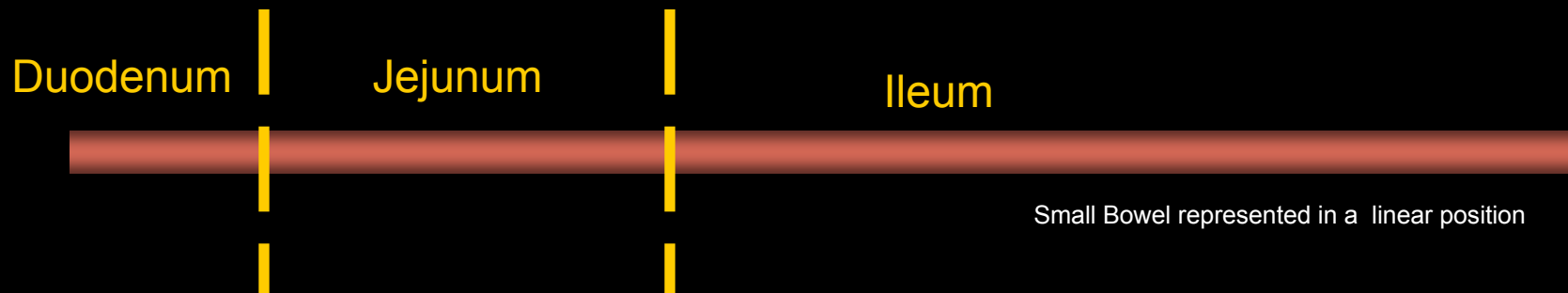
Normal Anatomy of Small Bowel

- Length: **21 feet**
- **Muscular layers** allow for accommodation of various sized bolus and supports bolus to move through the small bowel **via peristalsis**
- Mucosa light pink color –**inner lining-pink** tone varies from patient to patient when imaged by capsule
- **Lumen villi lined giving it a velvet-like appearance**
- **Few structural landmarks- challenge for localization**



Normal Anatomy of Small Bowel

Duodenum: SB-10% shortest of SB
Jejunum: 30% of small bowel
Ileum: 60% small Bowel



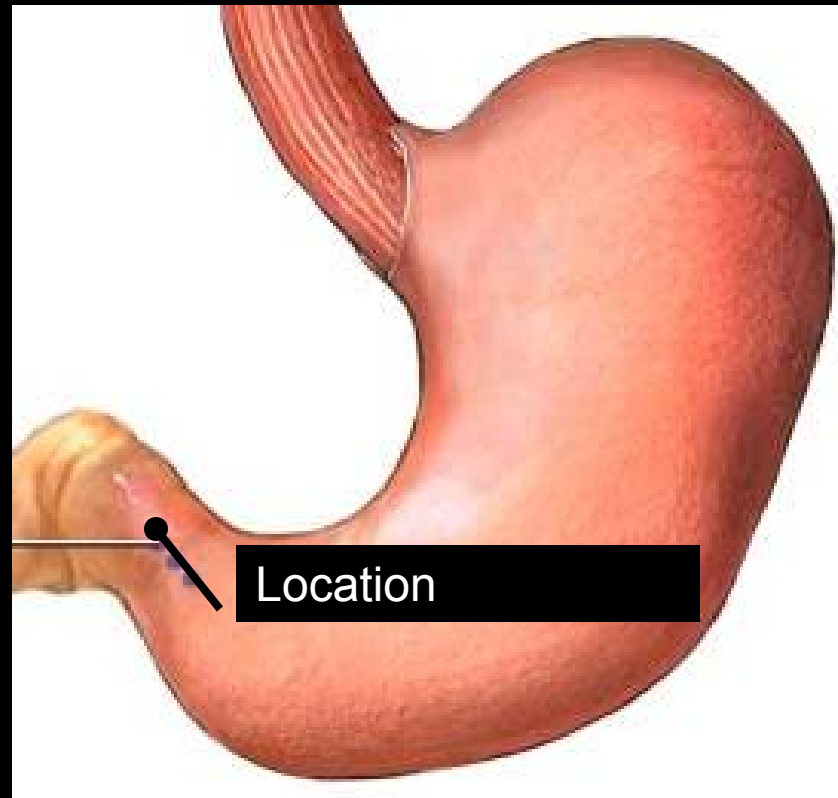
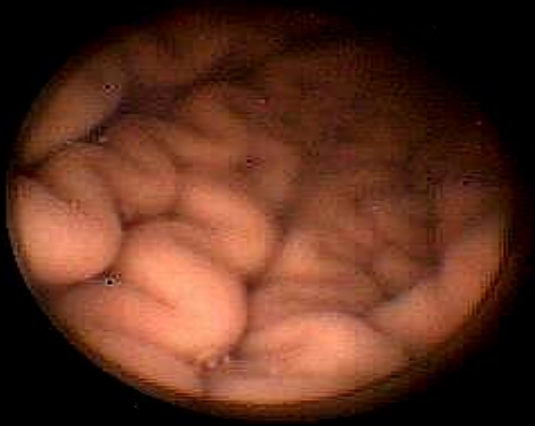
Normal Physiology of Small Bowel



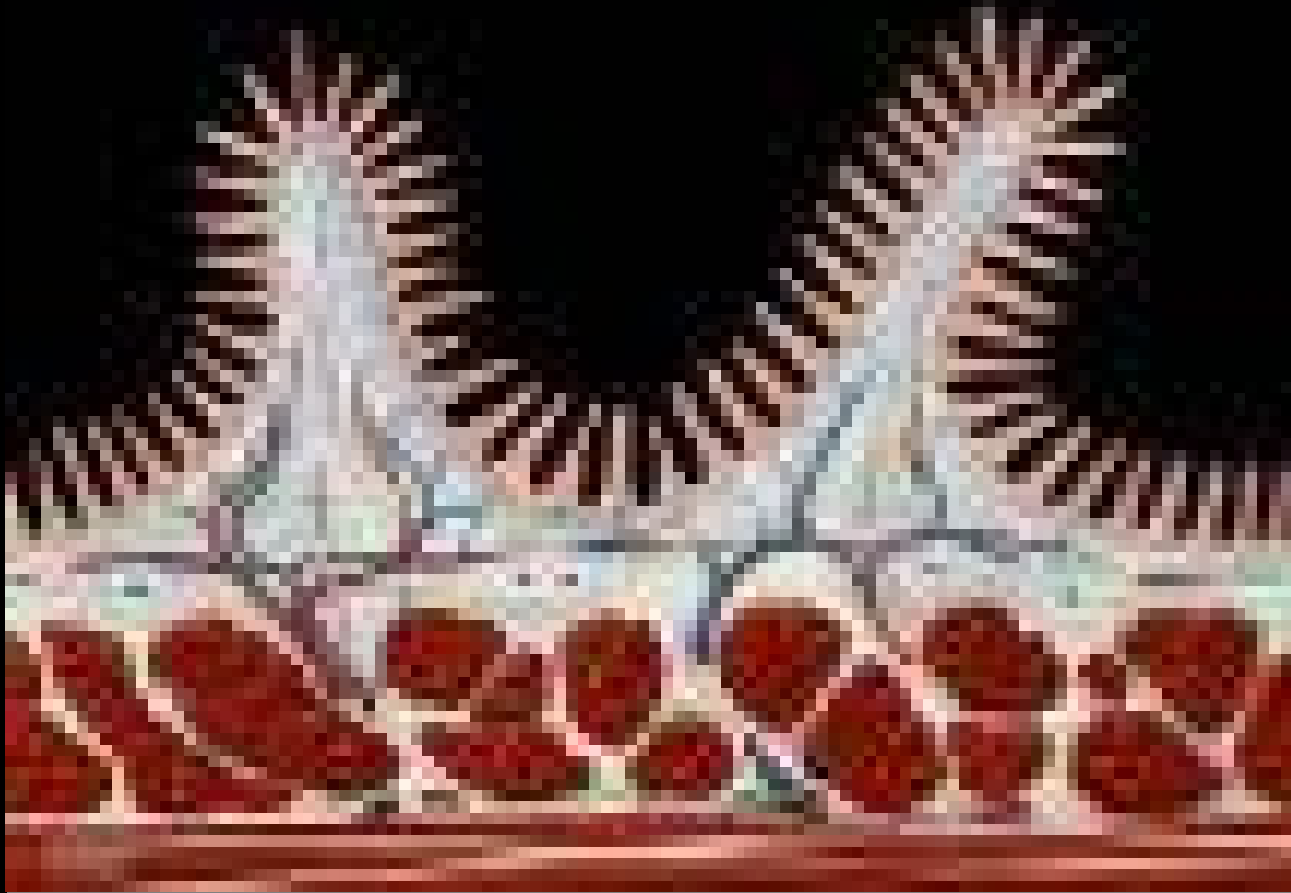
- **Localized Transit Pause**: Capsule endoscope remains static recording same image for $\frac{1}{2}$ hour but no structural obstruction
- **Regional Transit Pause**: Capsule endoscope moves forward and back but remains in same region for greater than $\frac{1}{2}$ hour but no structural obstruction
- **Failure to Traverse**: Phrase used when capsule does not move beyond a point but no structural obstruction

Small Bowel Landmarks: Pylorus

Pylorus



Hallmark of Small Bowel



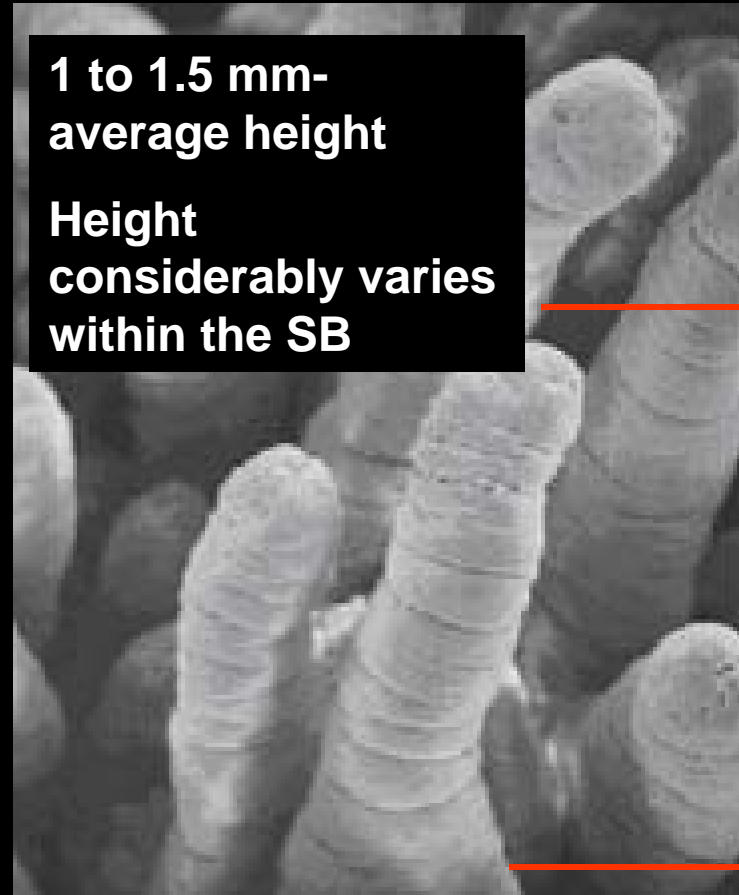
Small Bowel Landmark: Villi

1 biopsy from
medium forcep



1 to 1.5 mm-
average height

Height
considerably varies
within the SB



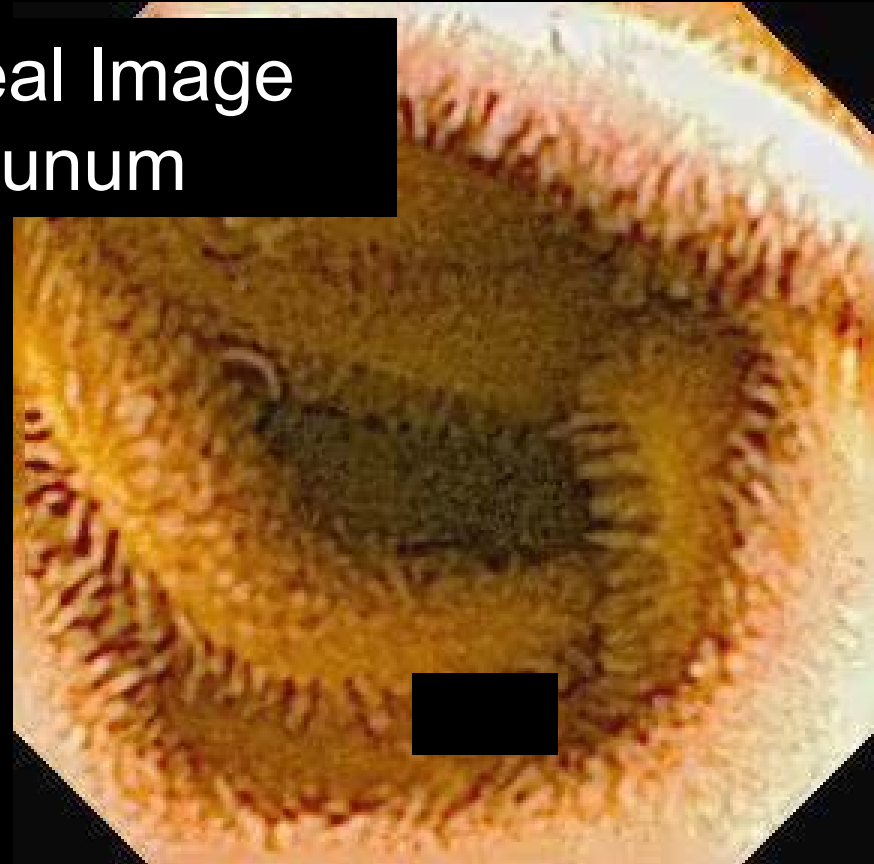
Function: Adds Surface Area

Small Bowel Landmarks: Villi

Ideal Image
Duodenum

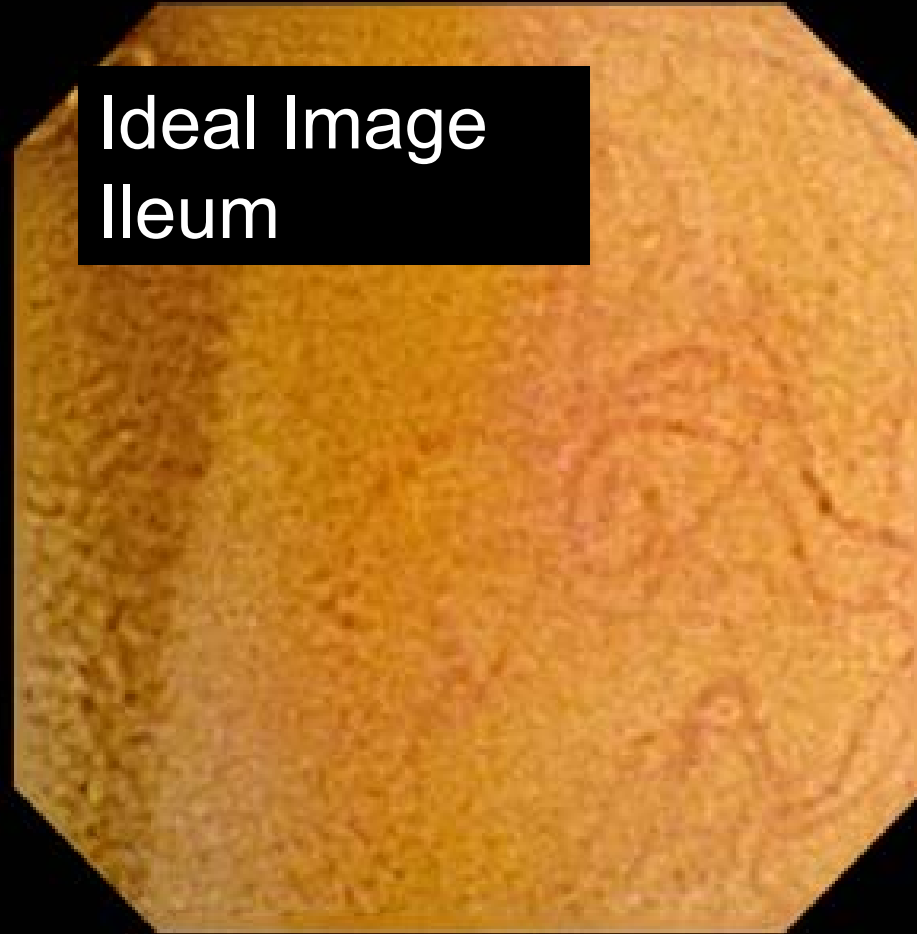


Ideal Image
Jejunum



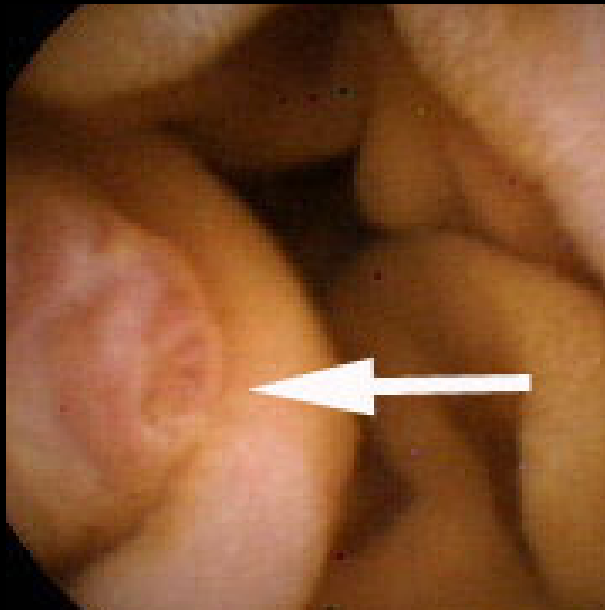
Small Bowel Landmarks: Villi

Ideal Image
Ileum

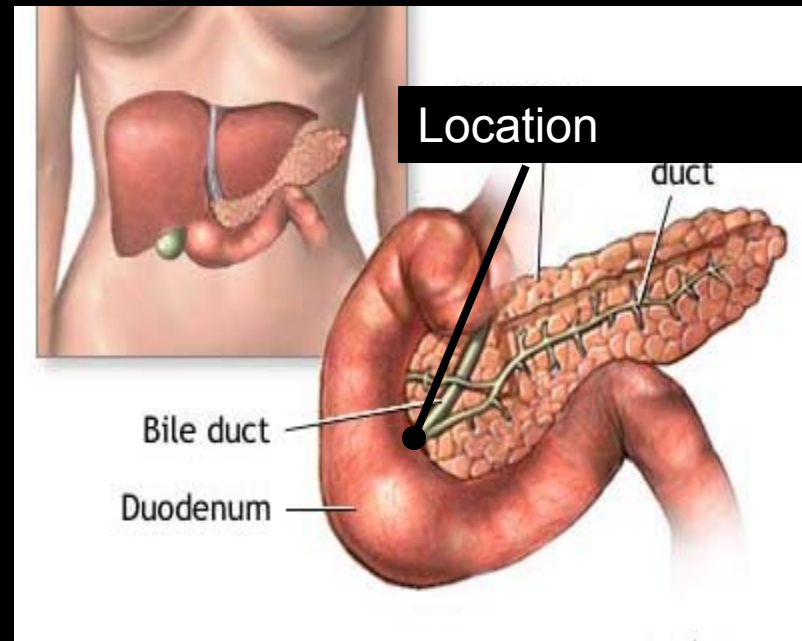


Small Bowel Landmarks

Ampulla's



Capsule Endoscope Image

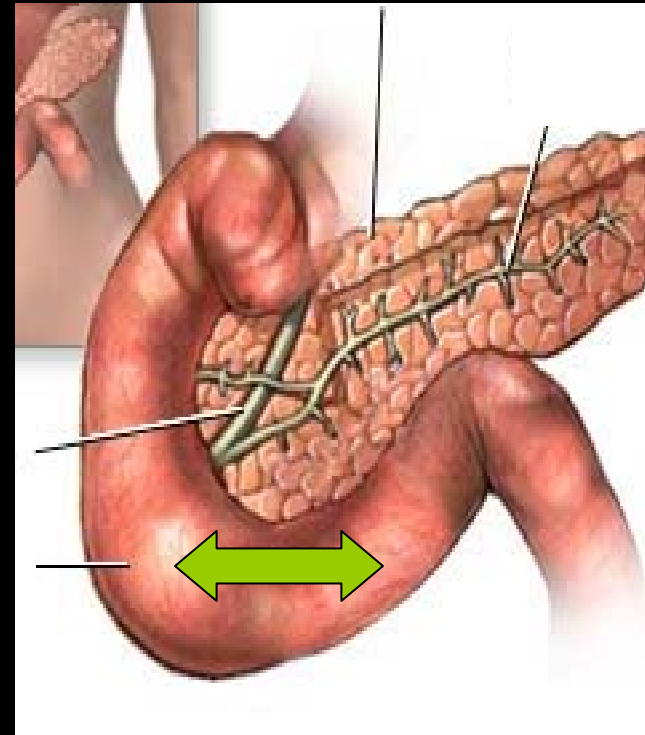


7 to 10 cm below the pylorus

Small Bowel Landmarks

Non-specific-Non-structural landmark:BILE

Caution: not “hard evidence” because bile can reflux into the stomach and actually be seen most anywhere along upper sb



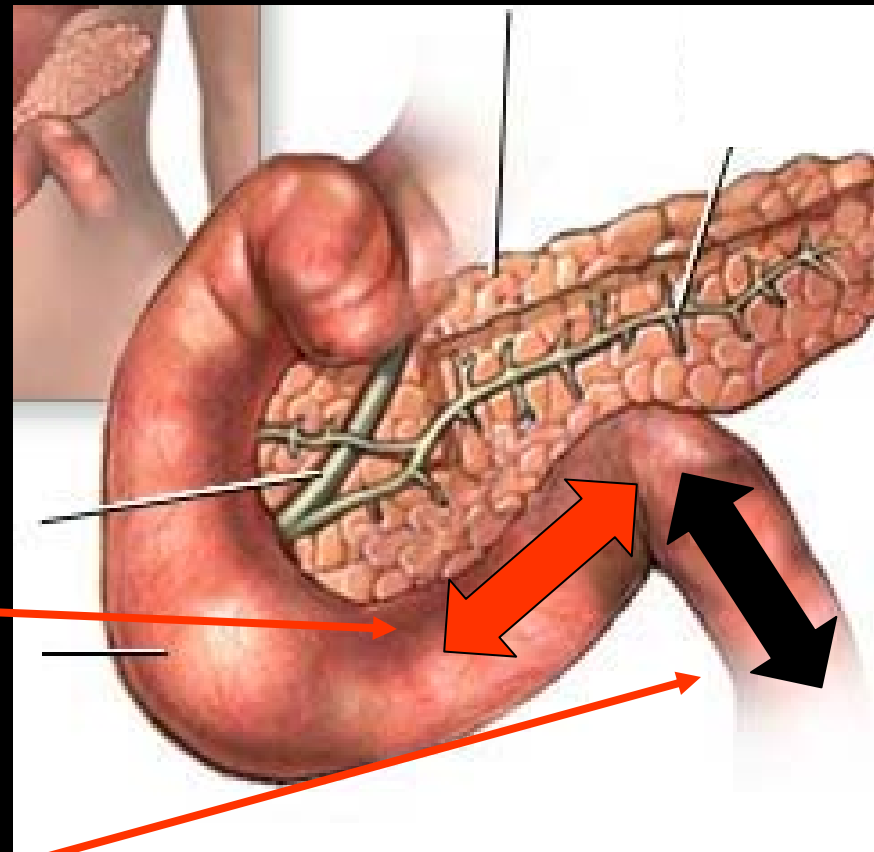
Small Bowel Landmarks

Duodenojejunal flexure
Ligament of Treitz

“C curve”

Capsule often moves forward
And back as it attempts to
round the C-curve

Capsule often speeds in this area
Passing past the flexure



Small Bowel Landmarks

Increased vascularity good visual cue to passing from Jejunum to ileum

Blood supply to the ileum is by way of the **superior mesenteric artery**.

Branched ARCADES of the superior mesenteric artery are prolific in the ileum leading to the luminal –capsule view of increased vascularity.



Small Bowel Landmarks



Increase vascular pattern
in ileum

Relative sparsity of villi in
ileum increasing distally

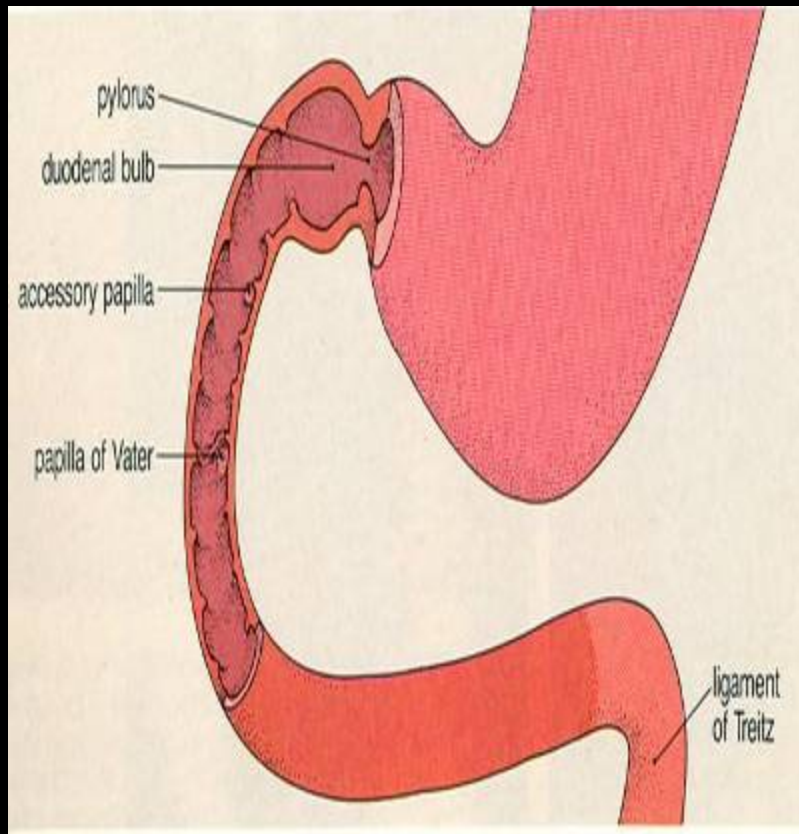


Lymph nodular
hyperplasia



IC valve

Summary: Small Bowel Landmarks



- Pylorus
- Villi length/population
- Ampulla
- Bile
- Movement of capsule with the lumen
- Vascularity
- Lymph nodular hyperplasia
- IC valve

Agenda

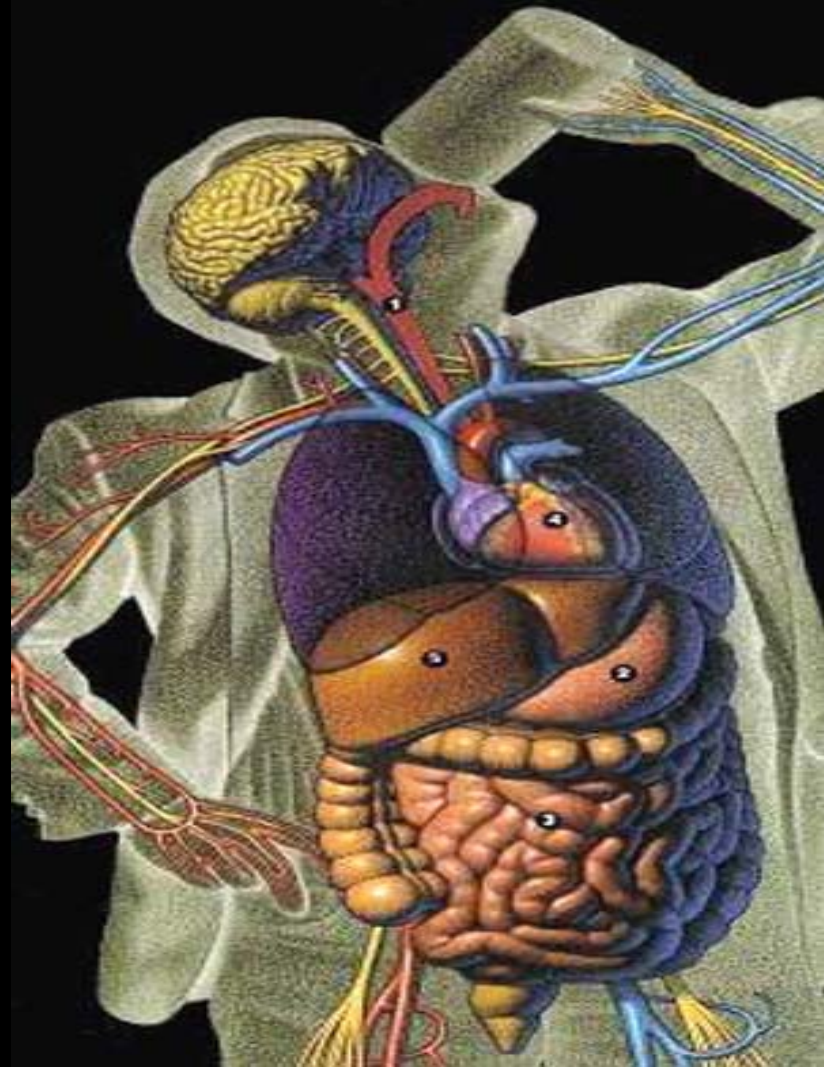
Small Bowel Testing

Anatomy review

Safety Issues in CE

Special Considerations

Patient Selection



Dysphagia

- CVA
- Neuromuscular disease
- Current respiratory distress

Do you have any difficulty swallowing?

- “Can you swallow pills without breaking them in ½ “ or “Can you swallow pills without taking them with pudding or Jell-o”
- Can not ingest capsule but may be a candidate for Endoscopic Assisted Capsule Placement



Rare Risk

Endoscopically Assisted Capsule Placement



Capsule Placed in Duodenum

Also used for some diabetic patients d/t poor gastric emptying

Pregnancy



Not FDA approved for use in pregnancy

Not FDA approved for patient with Implanted Electromedical Device



Not FDA approved for patients with electromedical devices

Implanted Electromedical Device

- Problematic:
 - CPs: 2.4 Million Americans
 - ICDs: 460,000 Americans
 - Population often on anticoag therapy
- Fear:
 - CE electronic features could alter Pacer or ICD function
- Reality:
 - More likely the implanted device would interfere with image capture of the capsule

Published Reports to Date

- Guyomar Y et al. PACE 2004 Cardiac Pacer
- Patel MS, et al. ACG 2004 (Abstract) Cardiac Pacer /ICDs
- Fernandez-Diez S et al. UEGW 2003(Abstract) Cardiac Pacer
- Dubner S et al. ACG 2004 (Abstract) Cardiac Pacer
- Piqueras JP et al ICCE 2004 (Abstract) Cardiac Pacer
- Leighton JA et al. GI Endoscopy 2004 Cardiac Pacer
- Leighton JA et al. Am J of Gastro 2005 Cardiac Pacer
- Bandorski D et al. Zeitschrift fur Gastro 2005 Cardiac Pacer /ICD

No Significant Interactions

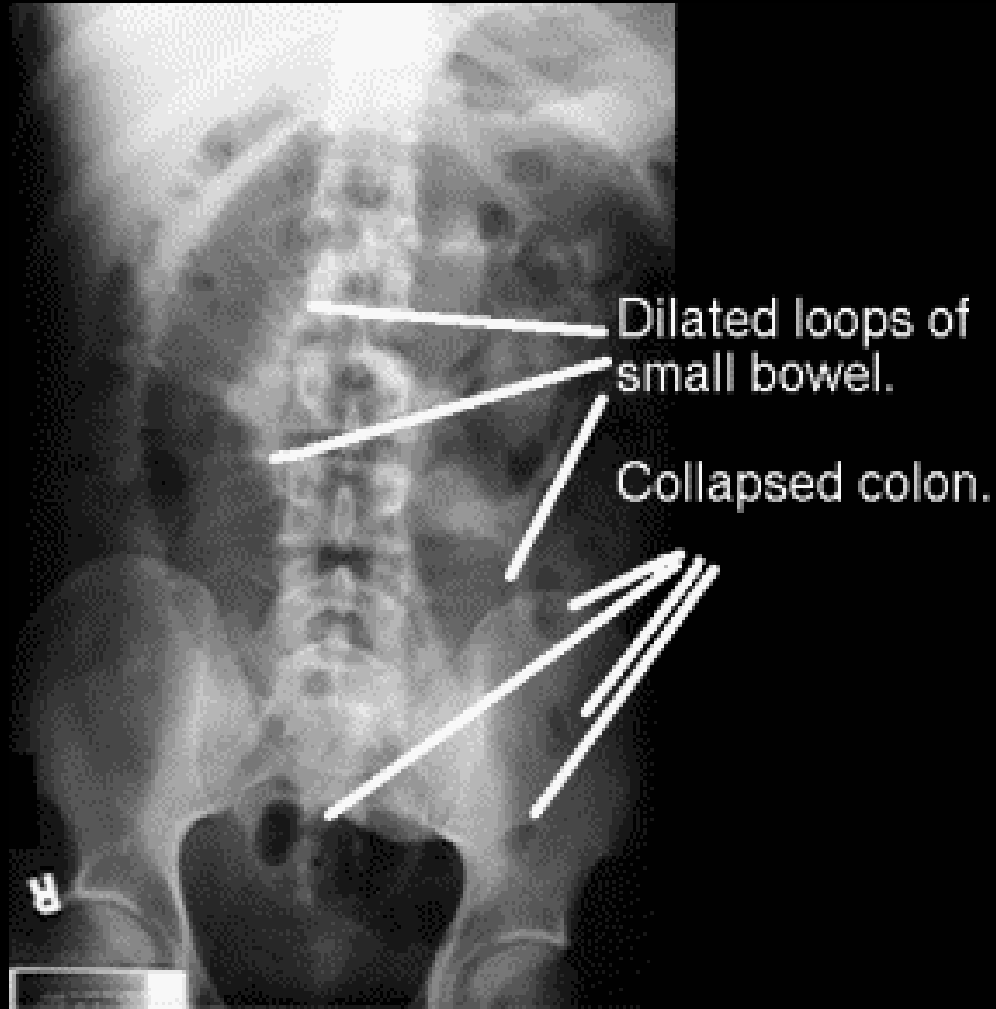
Not FDA approved for patients with
electromedical devices

Current Recommendations

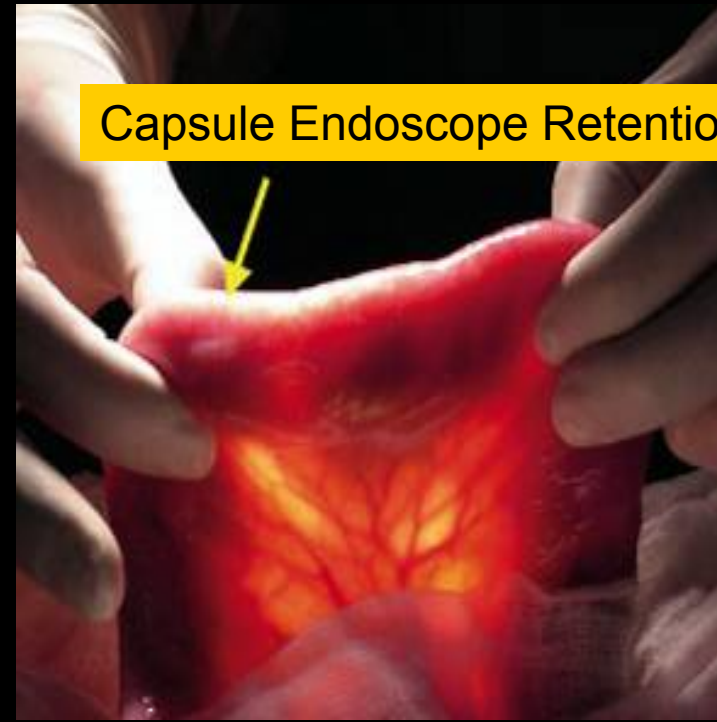
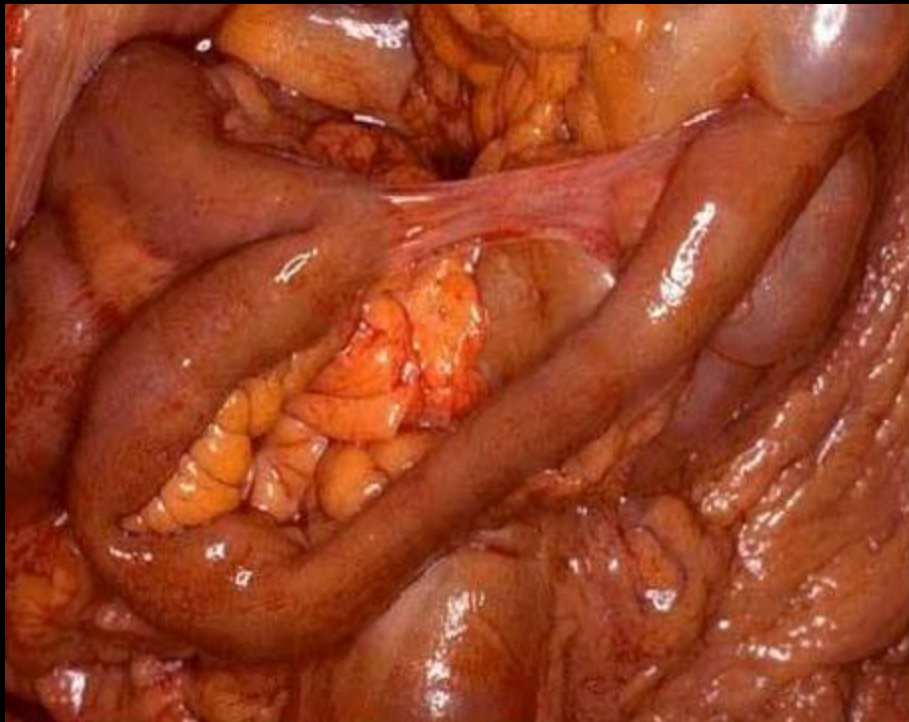
- All Patients with non-dependent pacers and ICDs are off label consented as per Cleveland Clinic Policy and then eligible for CE
- Review literature
- Meet with risk management team
- Follow hospital-medical facility recommendations
- Acknowledge not FDA approved for patients with electromedical devices

Not FDA approved for patients with electromedical devices See manufacturer package insert for complete details

Contraindicated: Known Small Bowel Obstruction



History of Adhesions
Indeterminate Crohn's
History of Abdominal Surgery in past year
Long term Use of NSAIDs



Capsule Retention Treatment

- May be no recommended intervention for an asymptomatic patient with retained capsule. Capsule may pass on its own.
- Serial KUBs and clinical evaluations to monitor progress.
- Steroids have been largely unsuccessful
- Remicade has some reported success but not in large study
- **Treatment of choice: Surgical intervention**

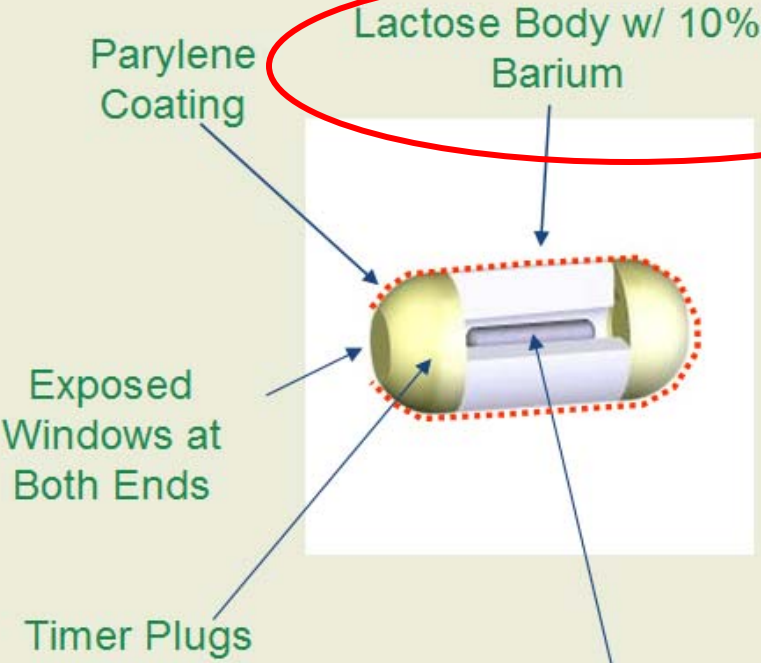
Capsule Retention Treatment

- Capsule retention refers to “small bowel only”.
- Capsule may take 5-10 days to pass from the large bowel. Low risk of retention within the colon.

Agile Patency Capsule

(Biocompatible, food-grade components)

DOES NOT TAKE IMAGES



Principles of Operation

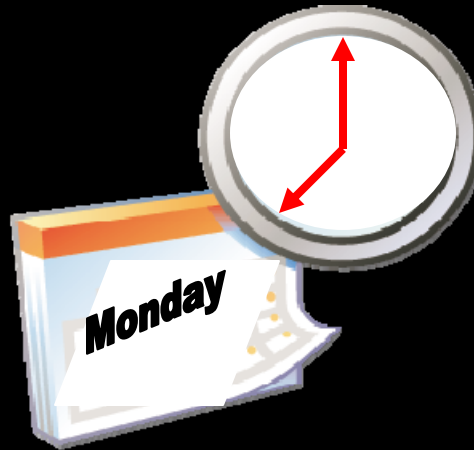
- Stays intact for minimum 30 hours post-ingestion.
- Disintegrates after 30 hours post-ingestion in GI tract.
- Emits electromagnetic waves at 64 KHz when sensing electromagnetic waves at 128 KHz.



Slide acknowledgment Given Imaging, Inc



NPO for 4 hours

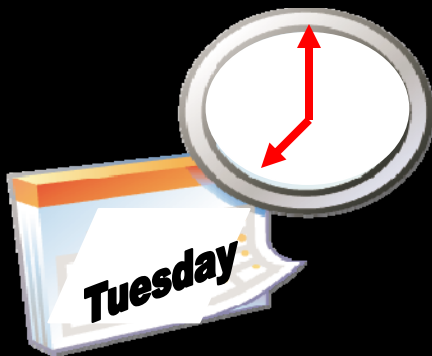


7:00 am Monday



**Ingest Patency Capsule
with glass of water**

24 hours later



7:00 am Tuesday

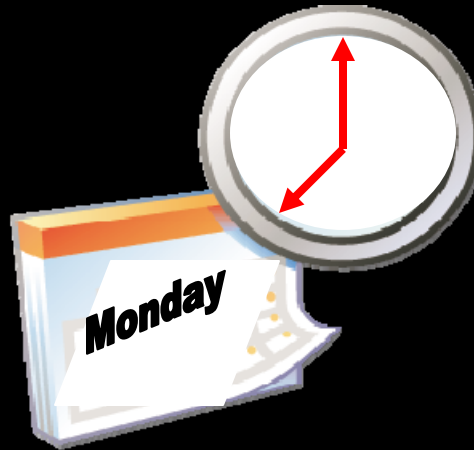


KUB

**No Agile Patency
capsule in small bowel:
CLEARED FOR
PHOTOGRAPHIC
CAPSULE**



NPO for 4 hours

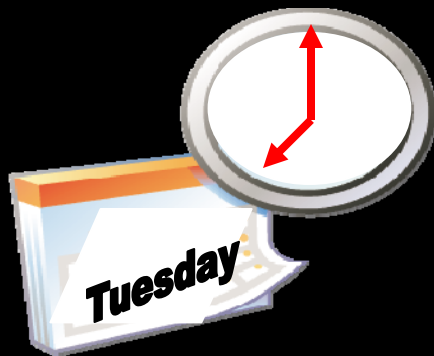


7:00 am Monday



**Ingest Patency Capsule
with glass of water**

24 hours later



7:00 am Tuesday



KUB

**Agile Patency Capsule
noted in small bowel:**

**WAIT 4 HOURS AND
REPEAT X-RAY**

After 4 hours: Scenario 1



Patency Remains in SB



No camera capsule
Agile disintegrates-30hrs

After 4 hours: Scenario 2



No Patency Remains in SB

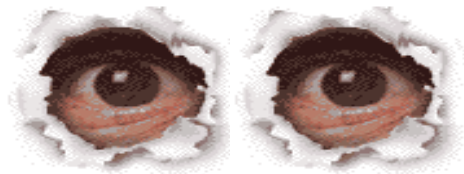
Photographic capsule,
it may be administered

Should this patient have a capsule endoscopy?



Esophageal
Diverticuli

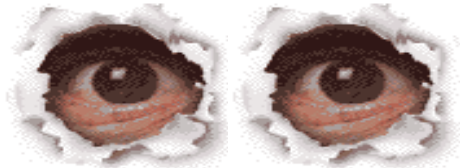
Quiz



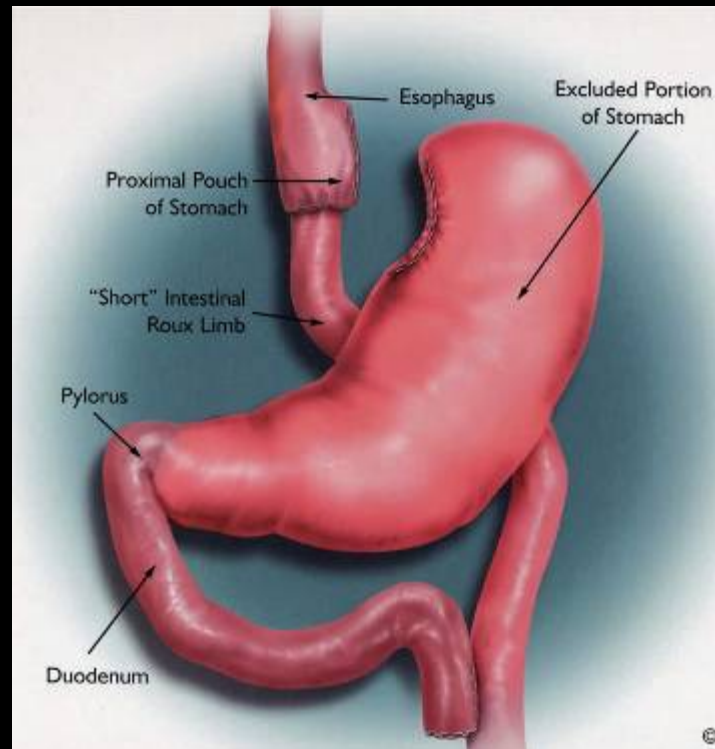
Should this patient have a capsule endoscopy?



Quiz

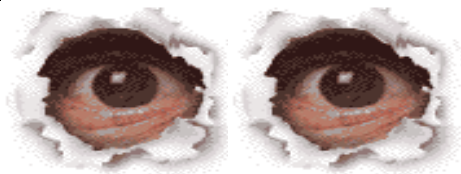


Should this patient have a capsule endoscopy?



Gastric bypass

Quiz

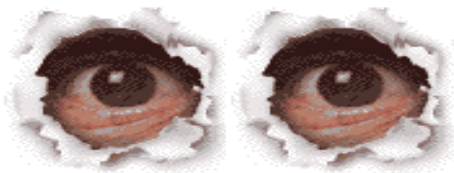


Should this patient have a capsule endoscopy?



Esophageal Candidiasis

Quiz

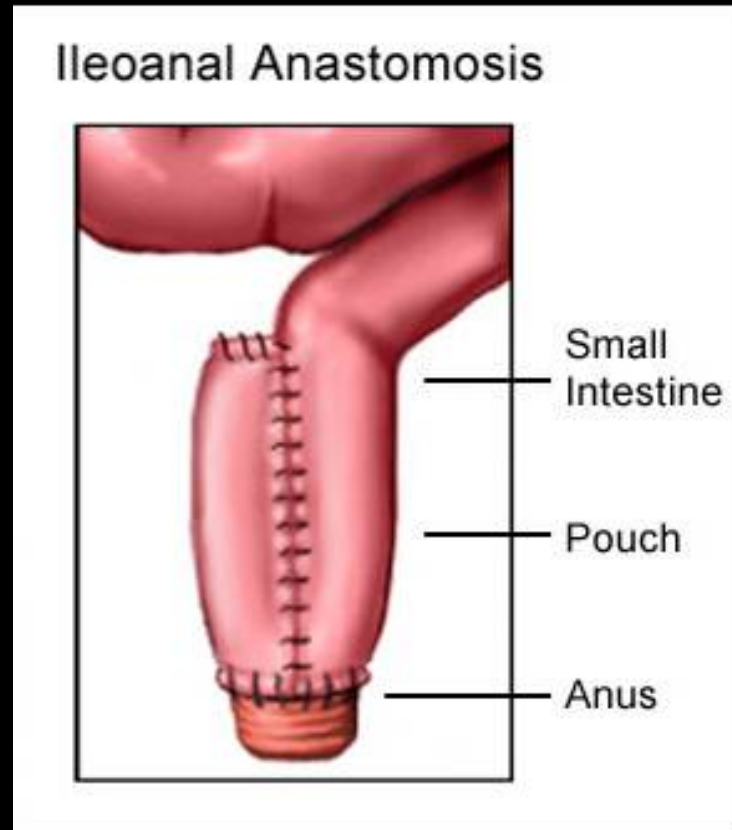


Should this patient have a capsule endoscopy?



Ileostomy

Should this patient have a capsule endoscopy?



J-Pouch

Should this patient have a capsule endoscopy?



- BLOATING
- FEVER
- NAUSEA
- VOMITING
- ABD PAIN
 - INTERMITTENT
 - CONTINUOUS

Should this patient have a capsule endoscopy?



- Aspirin
- Celebrex
- Ibuprofen, Motrin, Tab-Profen
- Vicoprofen
- CHRONIC= >10d/mo

Should this patient have a capsule endoscopy?



Should this patient have a capsule endoscopy?



8 Years old

Patient Perception of Capsule



Vitamin Pill
Motrin 800mg



“Smooth and easily slides down as you swallow as you drink a glass of water”

Should this patient have a capsule endoscopy?



Morbid Obesity

Should this patient have a capsule endoscopy?



Chronic Constipation

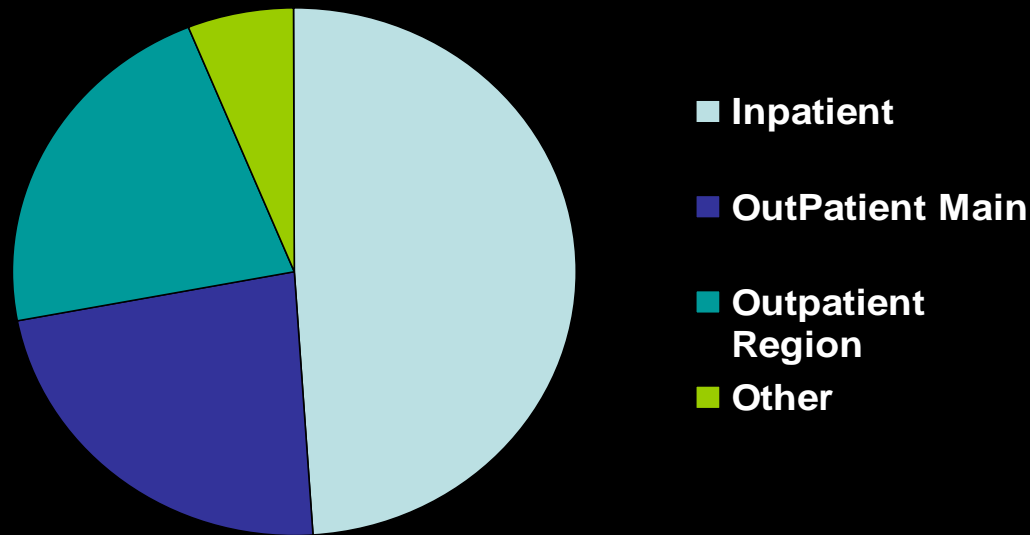
Summary: Safety Issues

- **Dysphagia:** May require endoscopically assisted capsule placement
- **Poor Gastric Emptying/Gastroparesis:** May require endoscopically assisted capsule placement
- **Implanted Electromedical Device:** Non-dependent electromedical device with off label consent. Follow your medical facility policy.
- **Known Bowel Obstruction:** Contraindicated
- **Chronic NSAID use:** Agile Patency Capsule prior to photographic capsule
- **Crohn's Disease:** Possible Patency Capsule prior to photographic capsule
- **Pregnancy:** Contraindicated

Capsule Endoscopy and the Hospitalized Patient



Major Area of Recent Capsule Growth



- Economic: waiting longer to seek care
- Statistical Influence:
 - Outpatients Capsule Endoscopy yield is 30% significant pathology
 - Inpatient Capsule Endoscopy yield in 60% significant pathology

Hospitalized Patient

- Must not share a room with patient also having a capsule endoscopy
- Patients taking narcotic pain medication may have prolonged transit time of SB. Suggestion: Use product with longest battery life recording 14 hours
- Bed rest may slow SB transit time.
- **Dietary preparation:** Clear liquids-nothing red-day- before capsule administration-NPO after midnight: No po meds 2 hours before capsule ingestion

Hospitalized Patient

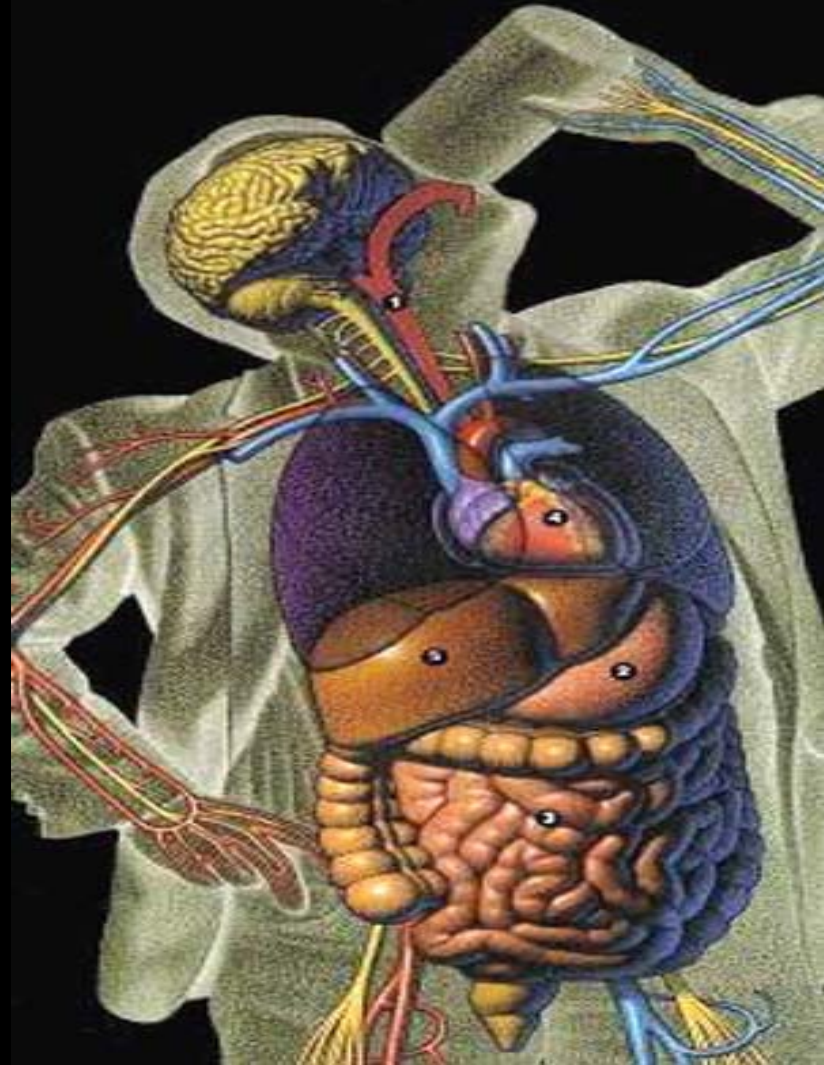
- **NO MRI** until capsule passes from body
- **Do not remove** capsule equipment until designated time. Consider re-scheduling routine x-ray.
- No barium 2-3 days pre- capsule
- No po Fe products for 5 days pre- capsule.
- May consider pre- capsule bowel preparation

Summary of Care of Hospitalized Capsule Patient

- No MRI while capsule in body
- Do not remove equipment
- No Fe for 5 days before procedure
- Adhere is dietary restrictions
- Expect longer transit times
- Avoid other CE patients-no cohorting
- May require bowel prep
- It is not necessary to “save” the capsule when it passes in the stool. Flush down toilet to dispose.

Presentation Agenda

Small Bowel Testing
Anatomy review
Safety Issues in CE
Special Considerations
Patient Selection
Capsule Procedure
Documentation



Assessment Tool



Inpatient Outpatient

Dr:

Date of onset:
Brief recent history:
Transfusions Requirements:
Fe Infusions Requirements:

EGD: 9/14/2009 CCF: Normal study. No bleeding source.
COLONOSCOPY: 9/14/2009 CCF: External hemorrhoids, diverticulosis in cecum
Polyps removed in transverse and descending colon. No bleeding source.
FOET: No
SBS: No
BLEEDING SCAN: No
ANGIOGRAPHY: No
CT: No
MRI: No MRI Planned
H&H: 9/15/2009 8.2 and 27.7
Other: 9/12/2009 Iron studies: Iron 10, Transferrin 3, TIBC 307, Ferritin 2000

Allergies to Latex and/or adhesive: No
Meds: See current
Fe (pg) No
Insulin No
ASA:
NSAIDs Current: History of:
Anticoagulants Current: History of:

Medical History:
Previous diagnosis of angiectasia.
Male Postmenopausal Surgically menopausal LMP:

History of CVA/dementia that may affect ability to ingest capsule:
Surgical history:
Abdominal/bowel/or pelvic surgery for 12 months:

No implanted pacer/ defibrillator or electromedical device
No abdominal or bowel surgery within past 12 months
No pregnancy
No difficulty swallowing
No known or suspected obstruction, No bloating, n/v, abdominal pain, fever
No Mental or Physical condition precluding capsule Endoscopy
No MRI scheduled in the near future
No chronic use of NSAIDs
No history of abdominal radiation and/or chemotherapy
No previous capsule endoscopy

Nursing Plan:

- Meets criteria for capsule endoscopy.
- Patient does not meet criteria
 - Patient has an implanted electromedical device and off label (by contrast) is documented in the EMR and has been discussed with capsule endoscopist.
 - Patient has had surgery in past 12 months without sgx of obstruction. Discussed with capsule endoscopist.
 - Patient has symptoms of intermittent bowel obstruction. Discussed with patient, capsule endoscopist and referring MD. A Patency capsule will be administered prior to photographic capsule endoscopy.
 - Patient has a history of esophageal disease that has potential to inhibit safe ingestion of the capsule. Discussed with referring MD and Capsule endoscopist and the patient is rescheduled for an endoscopic capsule placement.
 - Patient has Alzheimer's Disease and has difficulty following directions. Discussed endoscopically assisted placement of capsule endoscopy with family, referring MD and capsule endoscopist.
 - Patient has continued pg Fe product and has
 - rescheduled pg (date/time)
 - wishes to take bowel preparation and continue scheduled appointment
- Reviewed RBA originally discussed by referring physician with patient. Patient agrees to proceed.
- Pre- intra and post nursing plan reviewed with patient.
- Patient aware CPT code 91110.
- Patient aware diagnosis: example Iron Blood Loss Anemia
- Patient advised to contact insurance company for assured coverage. Pam McDeWell, financial counselor, 216-445-6258 at MAIN Campus for further insurance assistance.
- Capsule endoscopy on: 9/15/2009 RETURN EQUIPMENT: MAIN_RMP_UPS
- Patient concerns or special needs to be addressed at appointment.

Jan Scabi, RN
Clinical Coordinator Capsule Endoscopy
216-444-8836 pager 21536

Assessment Tool



Inpatient

Date: 11-5-2009

Female

Age 62 y

ICD Hematochezia/Melena

Date of onset: 11/17/2009

Brief recent history: Dizziness, fatigue, syncopal episode X1 11-1-2009

Seen CCF ER 11-1-2009-Currently hospitalized

Previous Episode of BRBPR 2007 with negative Structural GI work-up including Capsule Endoscopy.

Transfusion Requirements: 11-1-2009: 4 units in ER

EGD: 11/2/2009 Hiatal hernia. No Bleeding Source. No Bx. CCF

COLONOSCOPY: 11/3/2009 No Bleeding Source. No Bx. CCF

COBT: 11/1/2009

SBS: No

BLEEDING SCAN: 11-3-2009 negative bleeding source

ANGIOGRAPHY: No

CT: 11-3-2009: normal

MRI: No

H&H: 11/9: Hgb: 7.8

Iron Studies: Pending

Other: 11/2/2009: Hemetology: Dr Smith: BMBx: negative

Support decision making for delivery of CE Procedure

Support Insurance claim

Support Interpretation of findings

Allergies to Latex and/or adhesive: No/No

History

Insulin Yes No 0g x 3 days

ASA Yes am/pm

NSAIDS Yes 81mg Qd

Anticoagulants Yes 800mg Qd

Yes Coumadin

Yes am dose

History of: x 2 y

Medical History:

Diabetes

Arthritis

A fib

Hypertension

GERD

Surgical history:

Remote Appi

Remote T/A

Hysterectomy 12/2008

Yes Implanted pacer/ defibrillator or electromedical device

Yes Abdominal or bowel surgery within past 12 months

No Pregnant -postmenopausal

No Difficulty swallowing

No Known or suspected obstruction, No bloating, n/v, abdominal pain, fever

No Mental or Physical condition precluding capsule endoscopy

No MRI scheduled in the near future

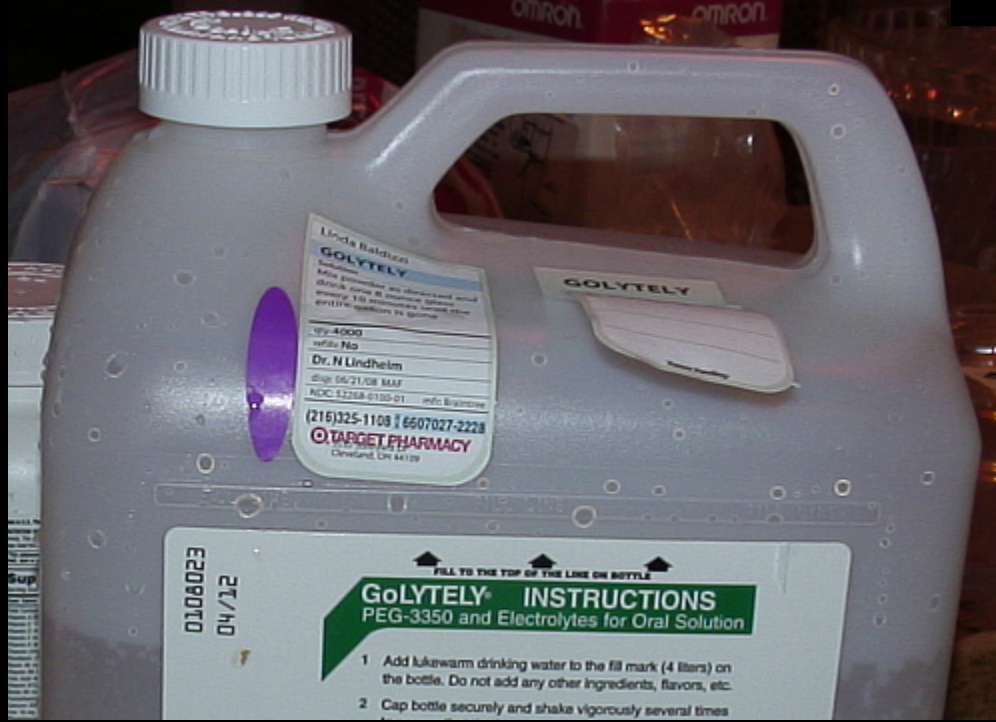
Yes Chronic use of NSAIDs

No Abdominal radiation and/or chemotherapy

No Previous capsule endoscopy

Yes Previous Capsule Endoscopy-passed in stool

To Prep or Not to Prep



Preparation Alternatives

- Diabetics
- Not off Fe for 5-7 days
- Hospitalized patient
- Previous Colonoscopy with poor prep
- Golytely

Pre- Capsule Instructions



Digestive Disease Institute
Capsule Endoscopy
216-444-8636

Capsule Endoscopy Pre- Ingestion Patient Information

ONE WEEK BEFORE YOUR PROCEDURE

1. Do not taking oral iron medication for 5 days before your procedure.
2. It is not necessary to stop taking anticoagulant medication like Coumadin or Plavix before this test.
3. So that you may plan for your capsule endoscopy appointment, you should know:
 1. It is not necessary to have someone drive you to your procedure.
 2. This procedure will take approximately 30 minutes.
 3. You should not schedule other medical procedures on the same day.
 4. If your doctor is not a Cleveland Clinic physician, please be sure that you have a written prescription from your referring doctor for this test.
4. A capsule endoscopy nurse will call you before your procedure to review the preparation, gather health care information specific to this examination and answer your questions. If you have an alternative phone number or cell phone number, please be sure that you have updated your telephone information with Cleveland Clinic at the time of scheduling.
5. Call your insurance provider to assure that you have coverage for this procedure. Your insurance company will want to know the following information:
The name of this procedure: Capsule Endoscopy of the Small Bowel.
The CPT code for this procedure: 91110
The reason for your procedure: Most insurance providers cover Capsule Endoscopy of the Small Bowel for the following reasons:
Blood Loss Anemia
Blood in your stool (bright red)
Blood in your stool (black and tarry stools)
Crohn's Disease
Abnormal GI X-ray
Diseases of poor absorption of nutrients from your small

ONE DAY BEFORE YOUR PROCEDURE

1. The day before your capsule endoscopy procedure, you may have your usual breakfast. After breakfast begin a clear liquid diet. A clear liquid diet consists of:
 - Coffee (without cream or creamer)
 - Tea (without cream or creamer)
 - Cola drinks
 - Apple juice
 - White Grape juice
 - Lemonade (without pulp)
 - Kool-Aid (no red)
 - Beef or Chicken Broth
 - Popsicles (no red)
 - Slush icy Drinks (no red)
 - Jell-O (no red)
 - Ginger Ale

If you are a diabetic, your medication may have to be adjusted to accommodate this preparation. Check with the doctor who monitors your diabetes for further instructions.

2. You may continue your medication as usual the day before your procedure. Do not take any Pepto-Bismol, antacids, Casaflo or medication that may coat your stomach and interfere with the capsule pictures.
3. If you are a male with an abundance of body hair on your abdomen, please shave your abdomen 4 inches above your waist and 4 inches below your waist.

THE DAY OF YOUR PROCEDURE

1. The morning of the procedure, you may take your medication with a sip of water before 7am.
2. Do not eat or drink anything before your procedure.
3. Wear loose fitting two-piece clothing to the procedure. Most patients prefer comfortable slacks or sport pants and a shirt or blouse.
4. Do not wear lotions or powders on your abdomen.

A nurse will be conducting the capsule endoscopy examination. You will have eight (8) adhesive pads placed on your stomach. These adhesive pads look much like EKG pads and hold the sensors close to your body. A wide Velcro belt will be placed around your waist. This belt looks much like the belts you see workers wearing when they are lifting heavy objects in retail stores. There is a pocket in this belt. A small

square electronic device that resembles a CD player will be placed in the belt pocket. This electronic device is specifically labeled with your name and identifying information. You will be asked to swallow a camera capsule. This capsule is about the size of a large vitamin pill. The camera capsule will immediately begin taking pictures. It will continue to move down your gastrointestinal tract in a natural manner capturing images. These images are converted to radio frequency waves and transferred to the electronic box on your side. The pictures are stored in the pocketed data recorder until the end of your procedure. Although the procedure is nine hours long, you will not be required to remain at the health care facility while the imaging takes place. After you have ingested the capsule, a nurse will review with you information regarding your diet, activity and return of equipment.

If you are scheduled for a capsule endoscopy at the Cleveland Clinic Main Campus or a Family Health Center and need further assistance, please contact:

Juanca M. Sandoz, RN
Capsule Endoscopy Co-ordinator
Cleveland Clinic
9500 Euclid Ave-A31
Cleveland, Ohio 44195
216-444-8836
Pager: 216-336 during business hours
sandozj@cc.ohio-state.edu during business hours

Pre- Capsule Instruction Highlights

- One week before Capsule Endoscopy
 - Do not taking oral Iron medication for 5 days before your procedure
 - It is not necessary to stop taking anticoagulant medication like Coumadin or Plavix before this test.
 - So that you may plan for your capsule endoscopy appointment, you should know:

It is not necessary to have someone drive you to your procedure.

This procedure will take approximately 30 minutes.

You should not schedule other medical procedures on the same day

What about the day before?

Pre- Capsule Instruction Highlights

One day before your procedure:

The day before your capsule endoscopy procedure, you may have your usual breakfast. After breakfast begin a clear liquid diet. A clear liquid diet consists of:

Coffee (without cream or creamer)

Tea (without cream or creamer)

Cola drinks

Apple juice

White Grape juice

Lemonade (without pulp)

Kool-Aid (no red)

Beef or Chicken Broth

Popsicles (no red)

Slush Icy Drinks (no red)

Jell-O (no red)

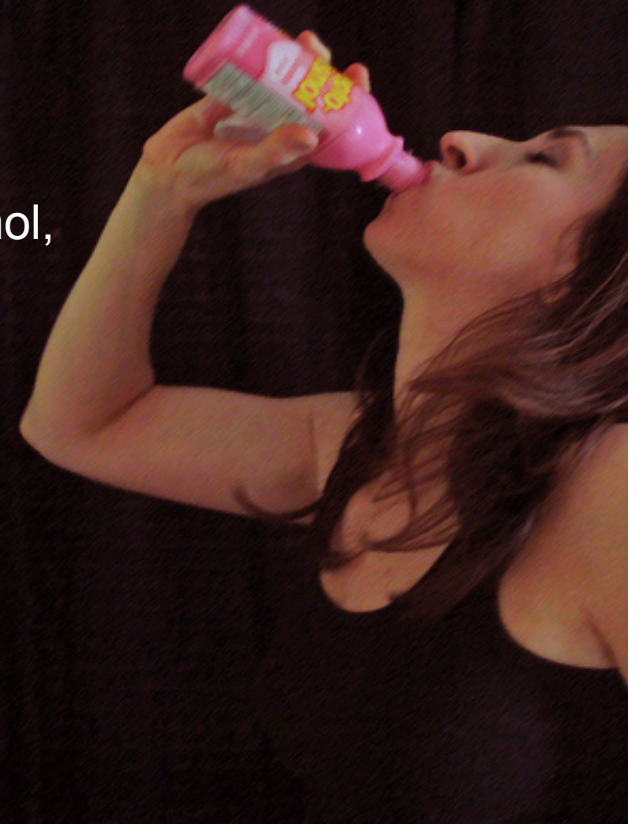
Ginger Ale

Pre- Capsule Instruction Highlights

One day before your procedure:

If you are a diabetic, your medication may have to be adjusted to accommodate this preparation. Check with the doctor who monitors your diabetes for further instructions.

You may continue your medication as usual the day before your procedure. Do not take any Pepto-Bismol, antacids, Carafate or medication that may coat your stomach and interfere with the capsule pictures.



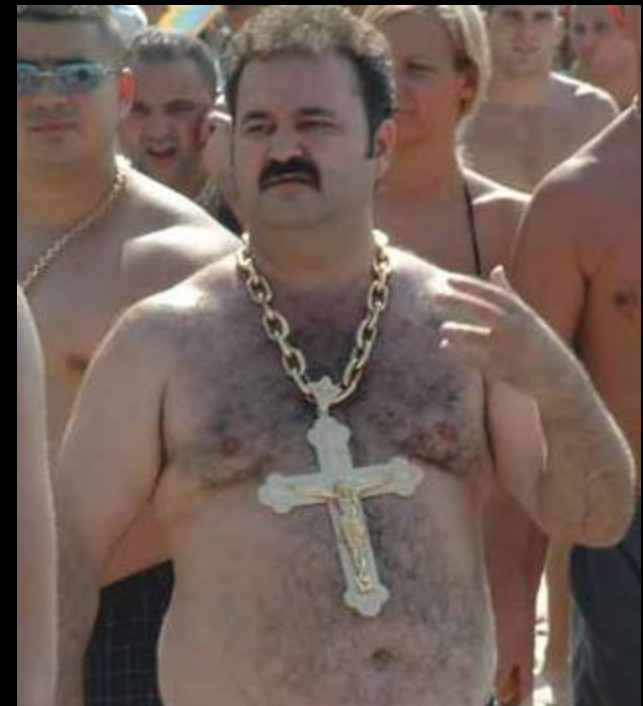
Pre- Capsule Instruction Highlights

One day before your procedure:

If you are a male with an abundance of body hair on your abdomen, please shave your abdomen 4 inches above your waist and 4 inches below your waist.

Leave the body hair issue up to the patient

Generally, no other preparation is required.



Pre- Capsule Instruction Highlights

The day of your procedure:

The morning of the procedure, you **may take your medication with a sip of water before 7am.**

Do not eat or drink anything (other than sip of water with medication) before your procedure. **NPO after midnight.**

Wear loose fitting two- piece clothing to the procedure.

Do not wear **lotions or powders on your abdomen.**

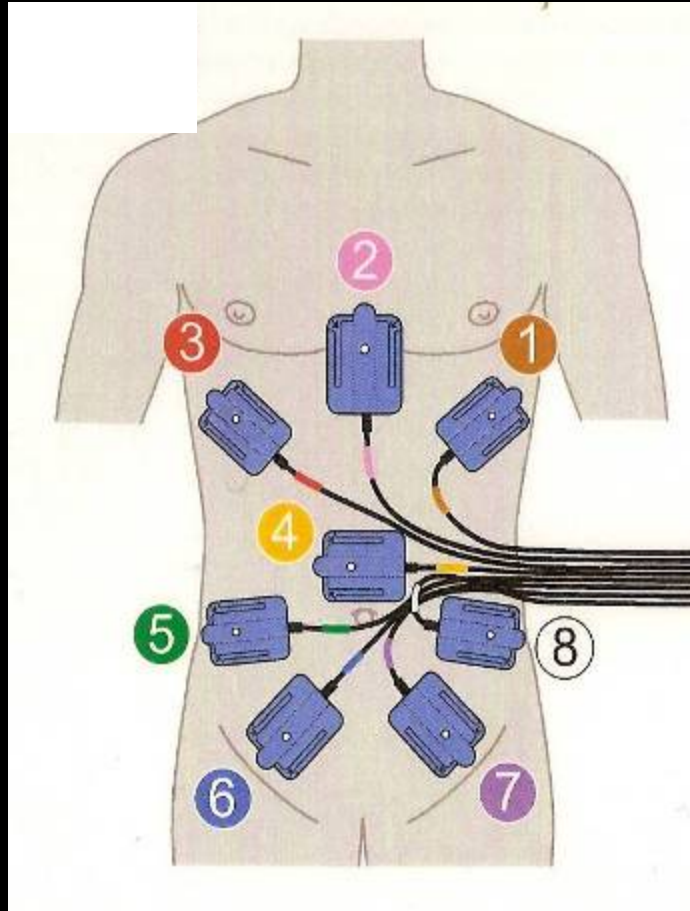
1. Prepared Equipment



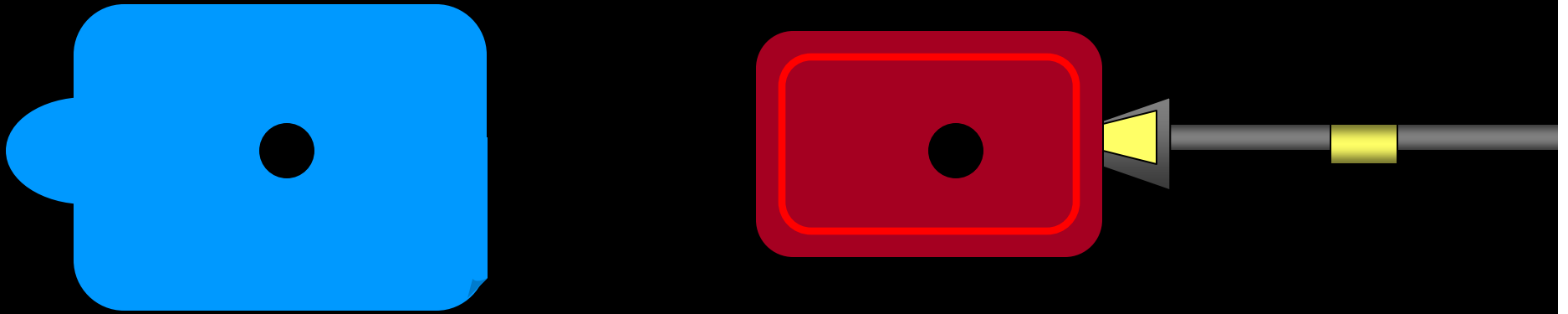
Computer with
Proprietary Software
Endocapsule
Endocapsule
Activator
Data
Recorder/Lithium Ion
Battery
Battery Charging
Device
Sensor
Antenna/Covers
Belt
REAL Time Reader
Upload/Download

Patient information
Patient discharge
information
Return bag
UPS box/ label
Disposable cup
Gloves

2. Attached sensor antenna



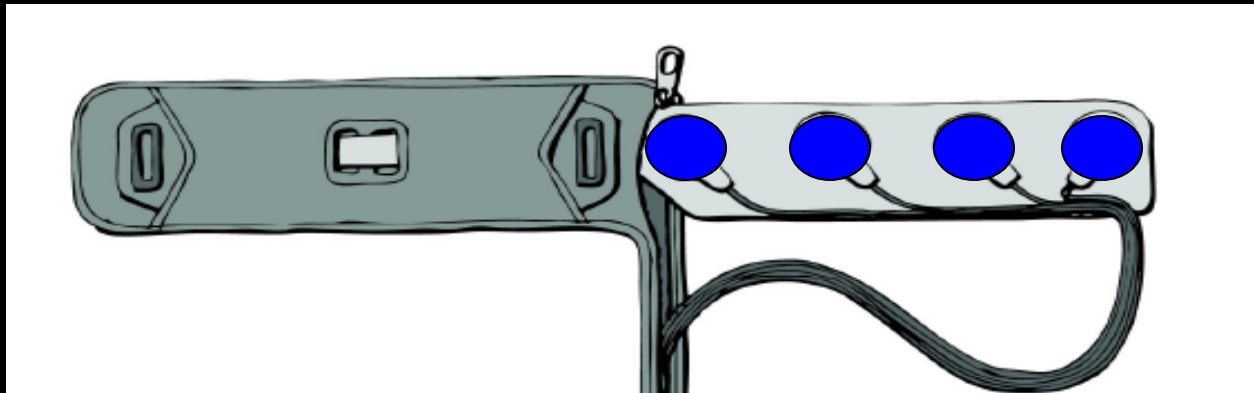
Sensor Adhesive Pads



Purpose:

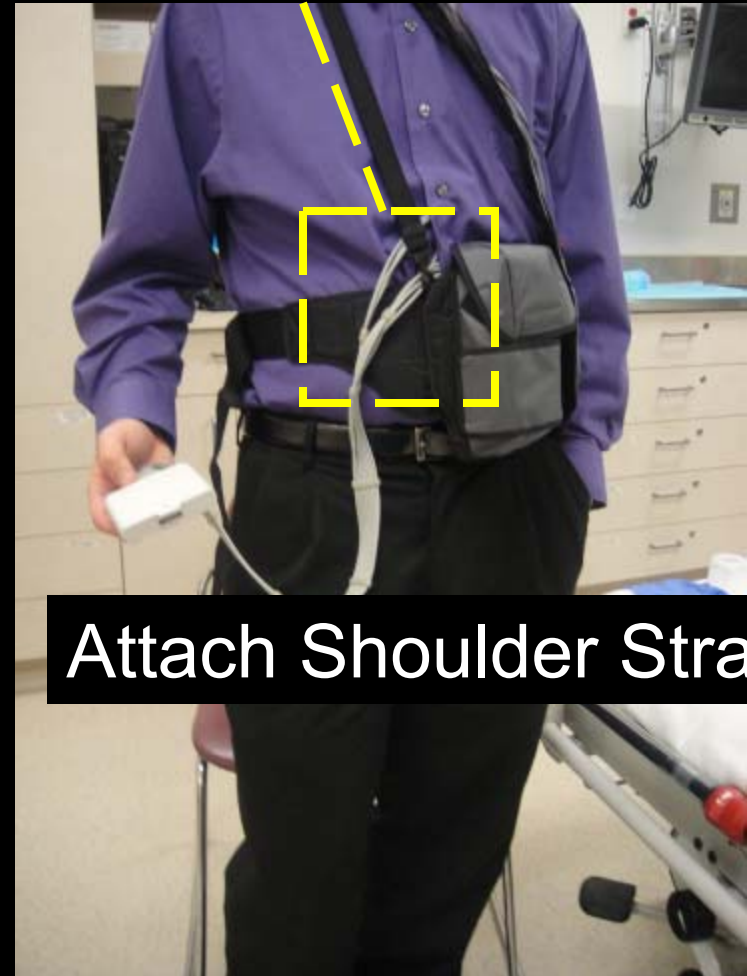
To assure that sensors remain close to abdomen, adhesive pads are placed on the sensors

OR Attached Sensor Belt



3. Apply belt

Attach Belt in Back

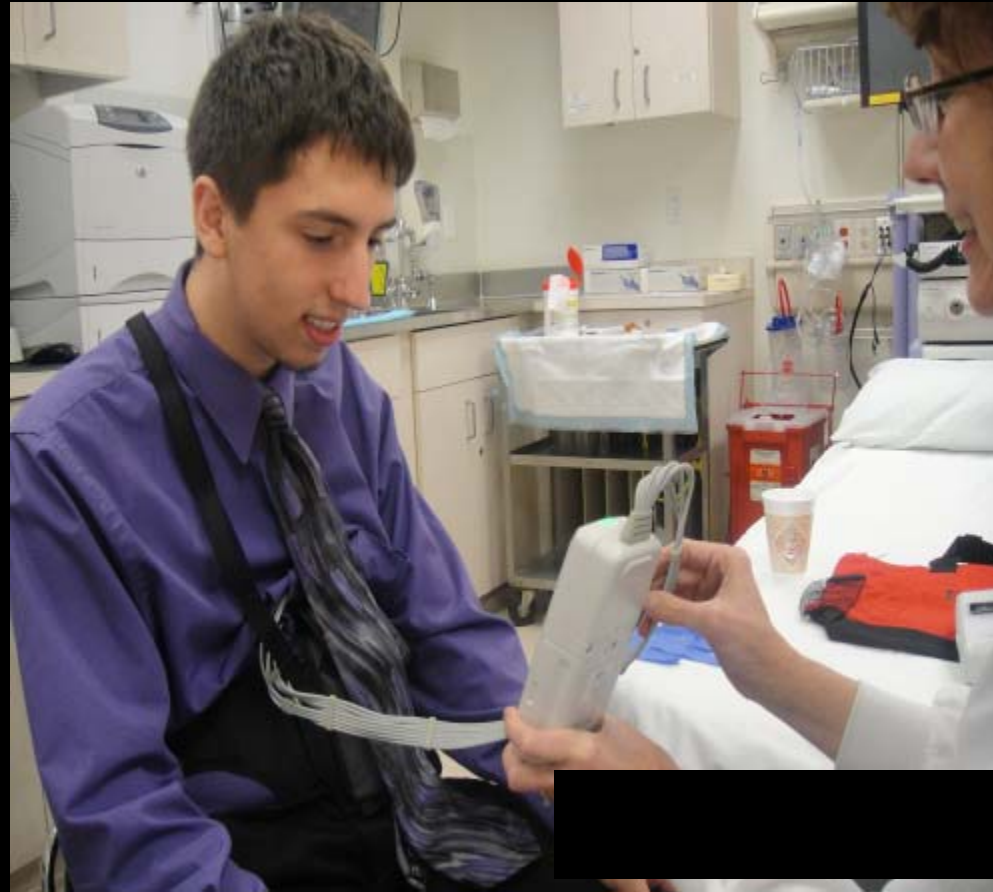


Attach Shoulder Strap

4. Attach Sensor Antenna to DR



5. Confirms Correct Recorder / Correct Patient



6. Place Data recorder in belt pocket

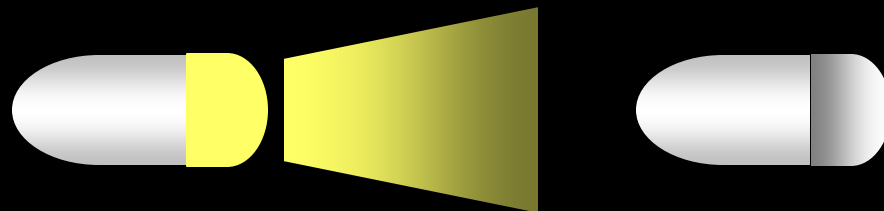
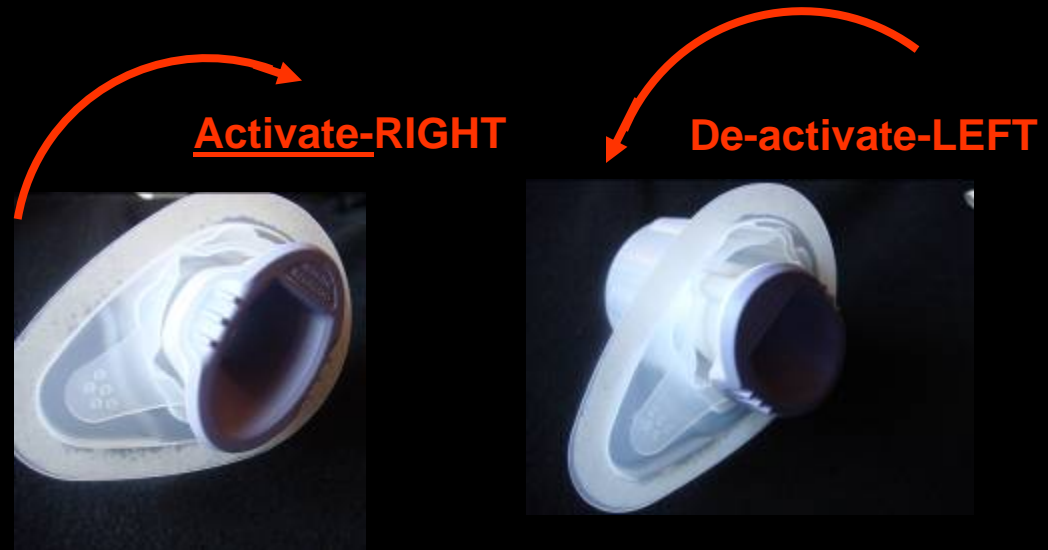


Green lights on Data Recorder and Power light

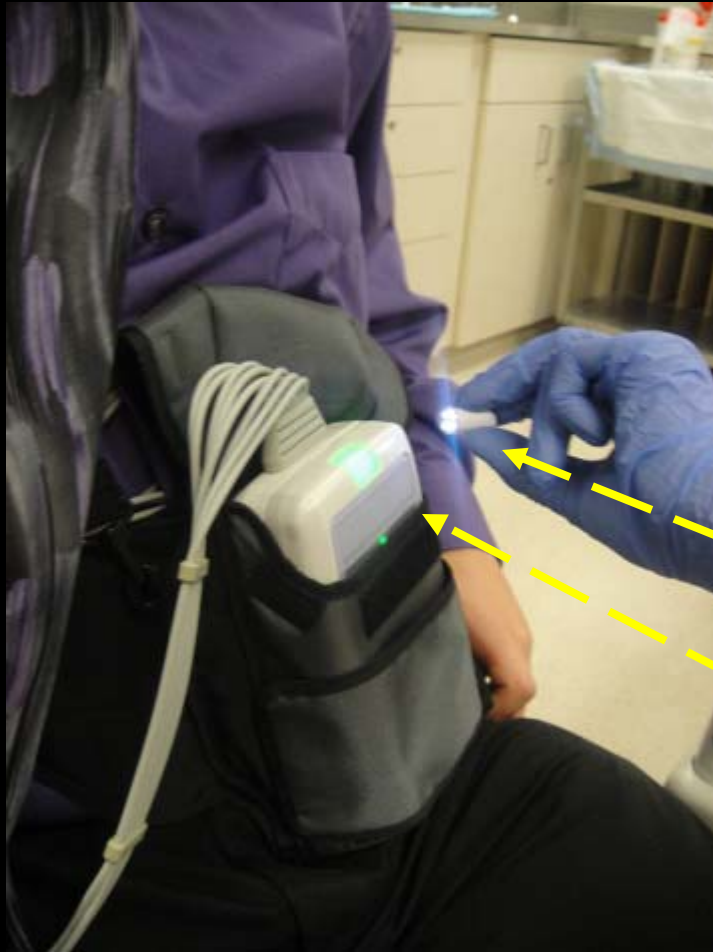
7. Activate the capsule



Activating the Endocapsule



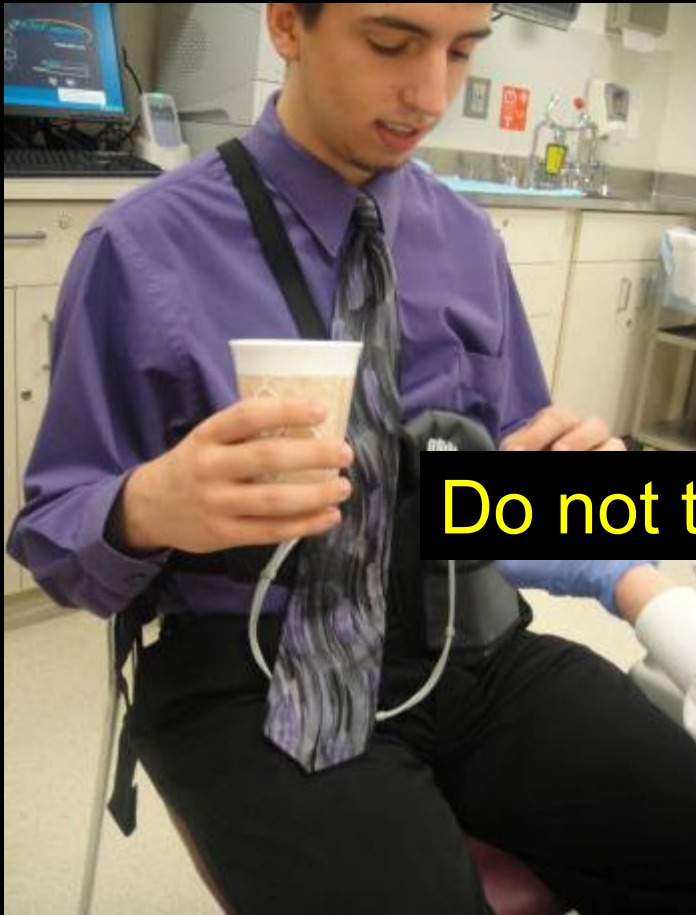
8. Synchronizing



- Hold activated capsule next to data recorder
- Capsule and Data recorder light blink

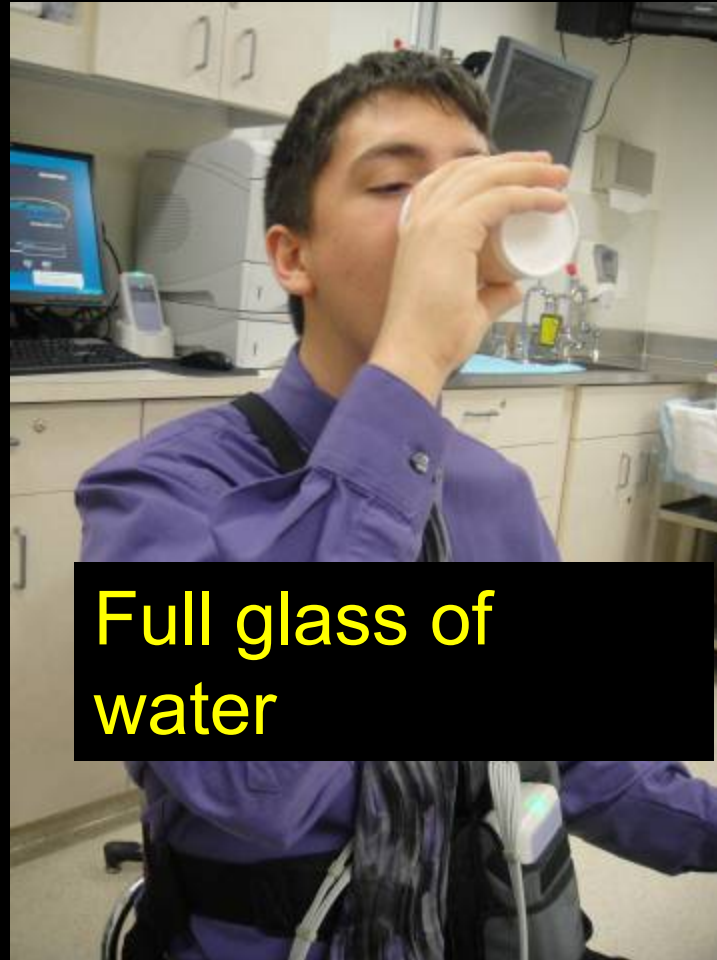


9. Patient ingests capsule



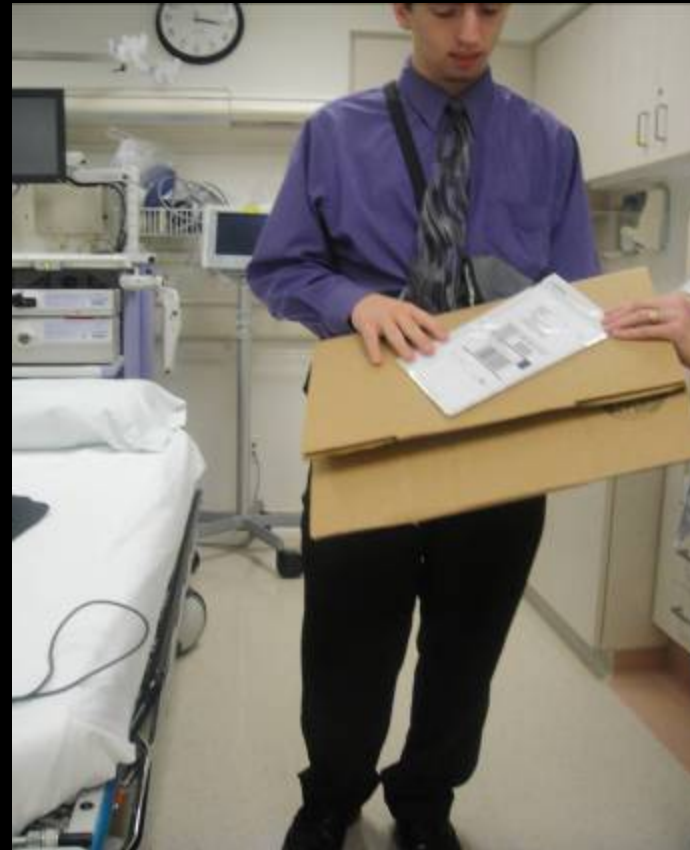
Do not touch lens

10. Ingests with water



Full glass of
water

11. Teaching: return of equipment



Post Ingestion Patient Information



Digestive Disease Institute
Capsule Endoscopy
216 444 8836

Capsule Endoscopy Post Ingestion Patient Information

1. Do not eat or drink for two (2) hours after you have swallowed the capsule endoscope.
2. Three (3) hours after you have swallowed the capsule endoscope you may drink clear liquids like coffee and tea (without cream), cola drinks, apple juice, broth, and eat Jell-O or popsicles. Please do not consume anything red in color. You may also return to taking your routine medications.
3. Four (4) hours after you have swallowed the capsule endoscope, you may return to your usual diet.
4. You may return to your normal activities after ingesting the capsule. Because we want the sensors to remain on your abdomen, please avoid vigorous exercise. If one of the sensors becomes dislodged from your abdomen, simply place the adhesive side back on your abdomen in any position. Do not become concerned. The remaining sensors will transmit the pictures even with several sensors detached.
5. You may operate electrical equipment while undergoing your capsule endoscopy. It is not likely that any household or office equipment will interfere with this examination. You may use cell phones, computers, remote TV appliances, microwaves, MP3 players and digital cameras. Because the capsule endoscopy equipment is somewhat ominous in appearance, we recommend you avoid the airport, bank and government buildings. Many museums use a similar technology for security, it is best to avoid these environments.
6. Avoid other patients also undergoing capsule endoscopy. Although the transmission distance is limited, it is possible that your capsule images could be altered.

V1Sat
5-2008
JMS

- NPO for 2 hours post ingestion
- Two hours after ingestion may have water
- Three hours after ingestion may have clear diet
 - Nothing red
 - Four Hours-Regular diet
- Return to usual activities but avoid activities that could loosen the adhesive pads

Post Ingestion Patient Information



Digestive Disease Institute
Capsule Endoscopy
216 444 8836

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V1Sat
5-2008
JMS

- May operate electrical equipment like cell phones, kitchen appliances, microwave

– Medical Radiofrequency equipment operates on a separate band from household equipment

- Because CE equipment is somewhat ominous in appearance we advice against visiting bank or airport

Post Ingestion Patient Information



Digestive Disease Institute
Capsule Endoscopy
216 444 8836

Capsule Endoscopy Post Ingestion Patient Information

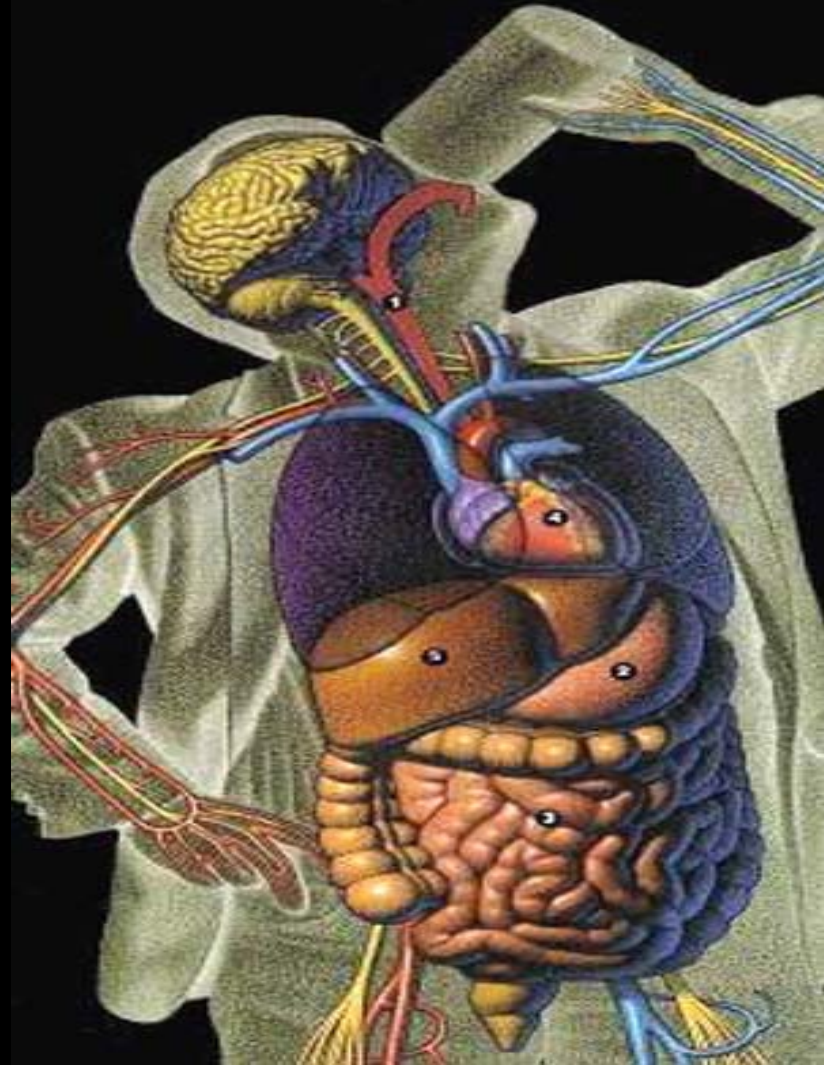
1. Do not eat or drink for two (2) hours after you have swallowed the capsule endoscope.
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V1Sat
5-2008
JMS

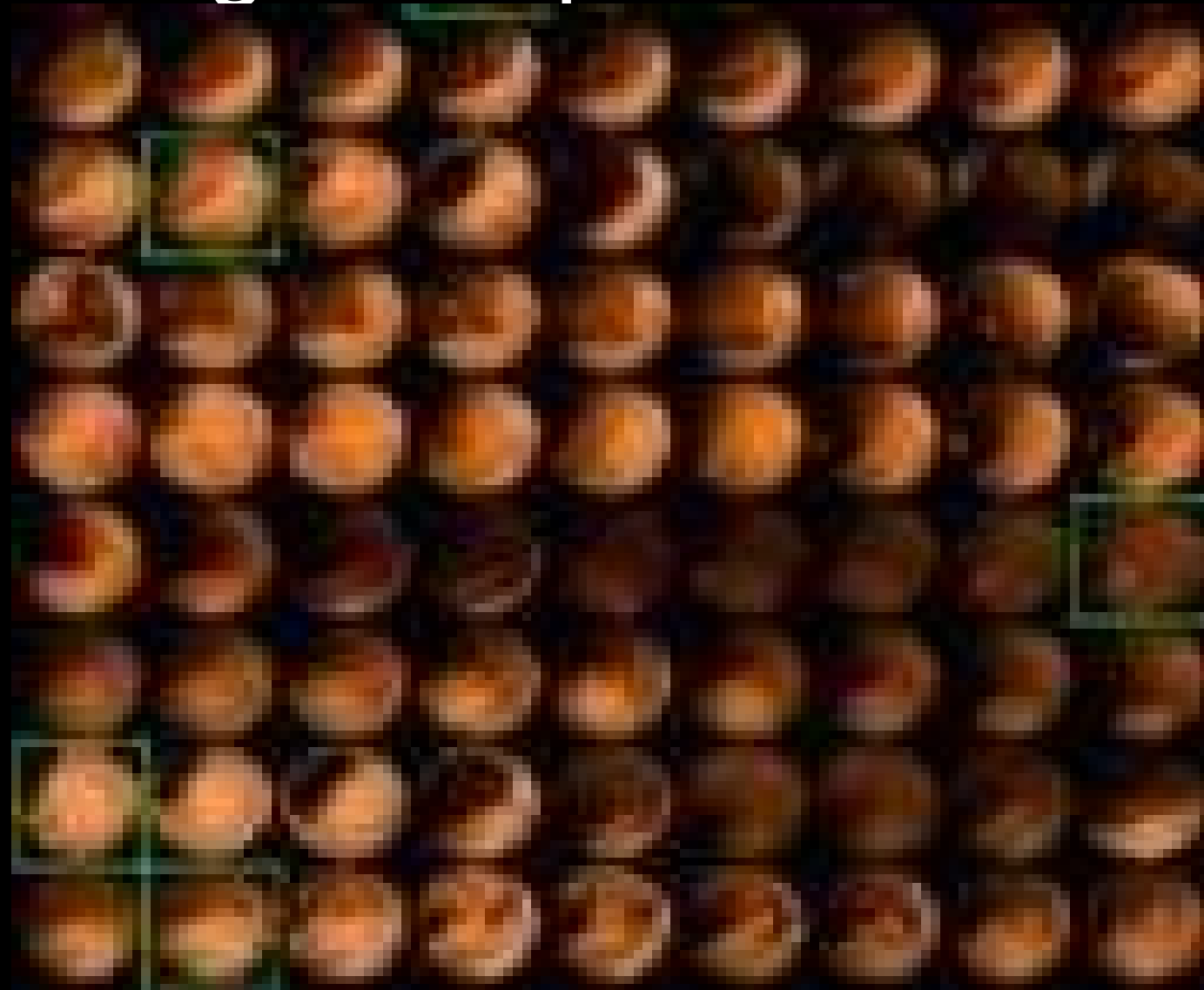
- No MRI until capsule passes from body
- Review symptoms of bowel obstruction

Presentation Agenda

Small Bowel Testing
Anatomy review
Safety Issues in CE
Special Considerations
Patient Selection
Capsule Procedure
Documentation
Video Triage
Interpretation Phase



Triage/Interpretation Phase



- Triage definition: Pre- review. Not a final reading. Pre-reader marks the video for completion and viewability, marks landmarks, points reader to obvious pathology.
- Videos read by Gastroenterologists specialized in capsule endoscopy
- Some mid-level providers reading and finalizing findings.
 - change professional fee reimbursement
 - Some insurance companies stipulate must be read by Board Certified Gastroenterologist
 - Proof of specialized additional education

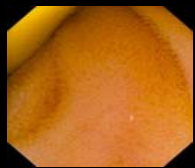
Criteria for image interpretation



Color

Color of mucosa

specific to video
Normal: Pink/Salmon colored



Pattern of mucosa

Pattern:

Normal: No breaks in mucosa



Structure

Structure:

Normal: Specific to region of SB

“No ampulla-like structure just previous to the capsule passing to the cecum “



Debris

Debris:

Normal: some usually apparent likely to increase in volume as capsule moves distally

Sudden onset of debris-watch for pathology -ie adherent to ulcers



Location

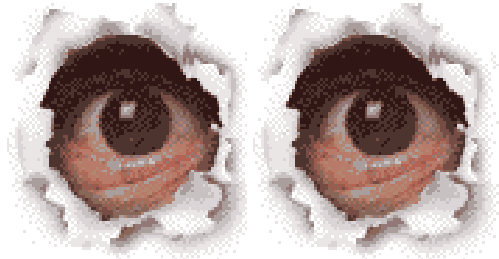
Location:

Use localization function on workstation

Watch villi population and stature

Watch for vascular patterning

Quiz



Stromal tumor



Peristaltic wave



- Color
- Mucosal Integrity
- Structure
- Debris
- Location

MID SMALL BOWEL AS PER LOCALIZATION FEATURE
AND READERS ASSESSMENT

GI Bleeding without a source

Bleeding is considered a finding



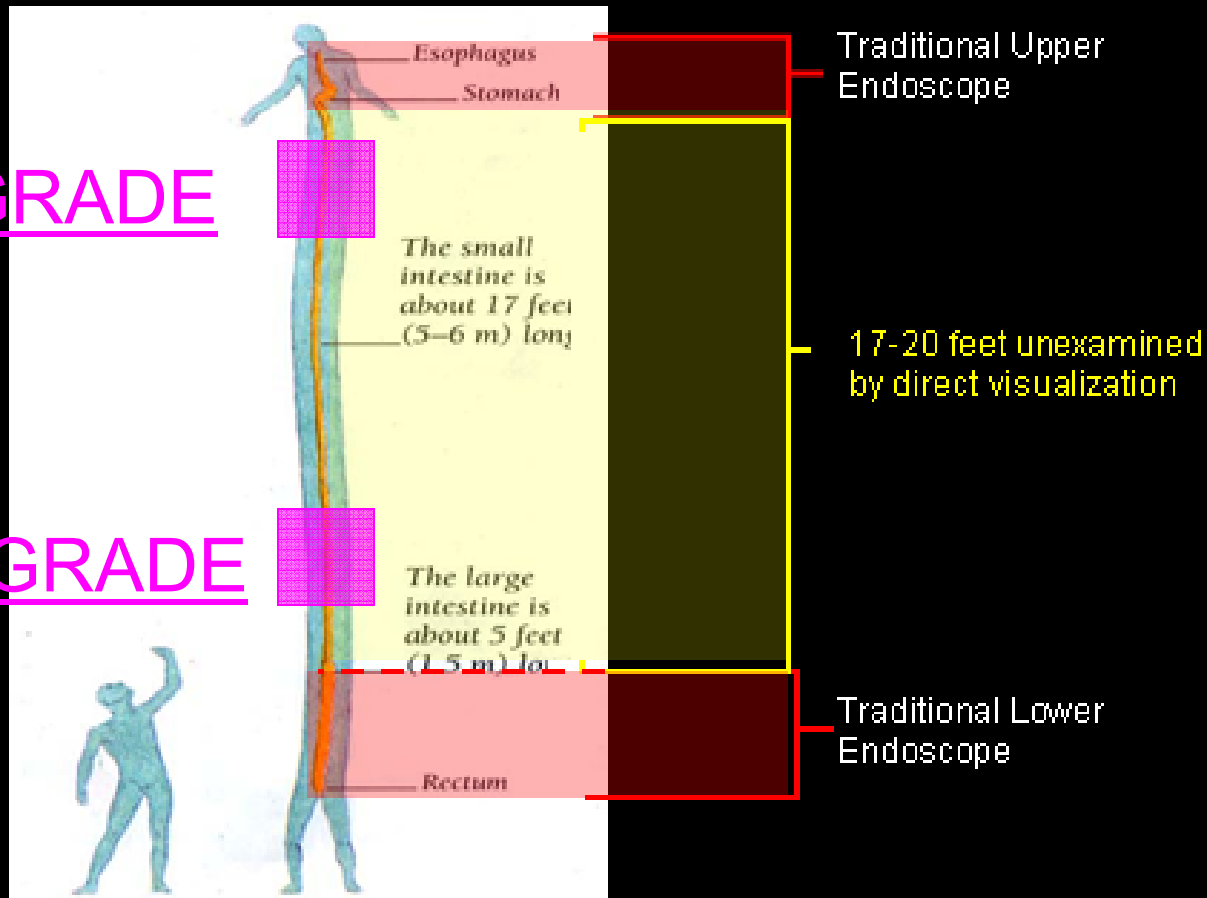
Fulminate



Single frame

ANTEGRADE

RETROGRADE



May not have identified the source

May direct care by indicating therapy by ANTEGRADE versus RETROGRADE Balloon Assisted Enteroscopy

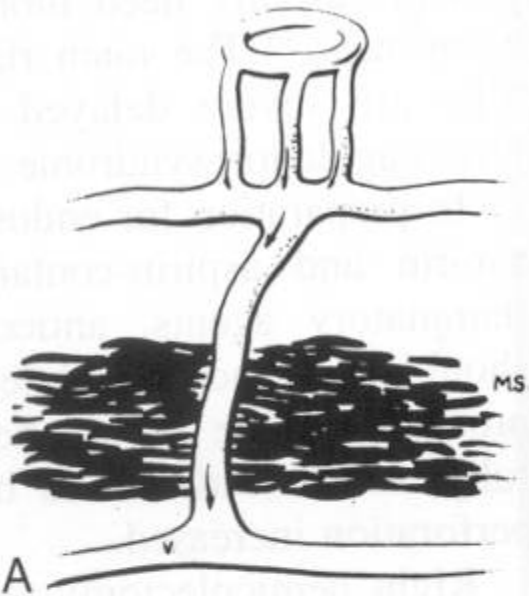
Capsule Findings: Angioectasia

- Feathery appearance
- Bright red
- Feeding vessel
- Singular or multiple
- Star shaped
- Easily identified
- flat- Missed on SBS

Often associated with renal disease, heart disease and anticoagulant therapy



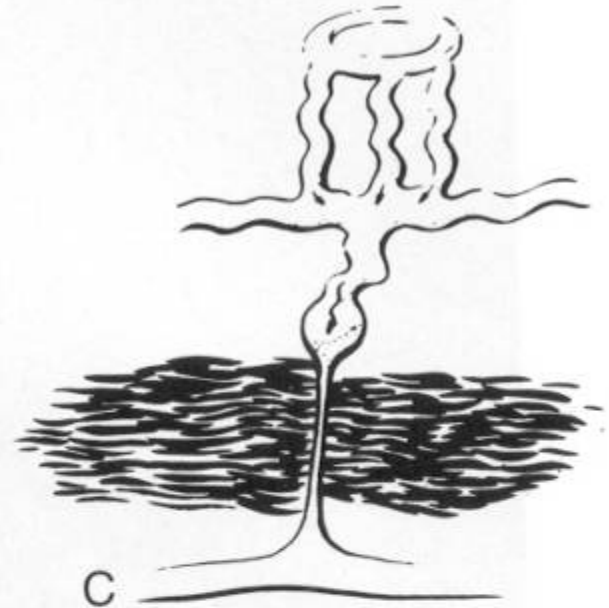
Vascular Congestion



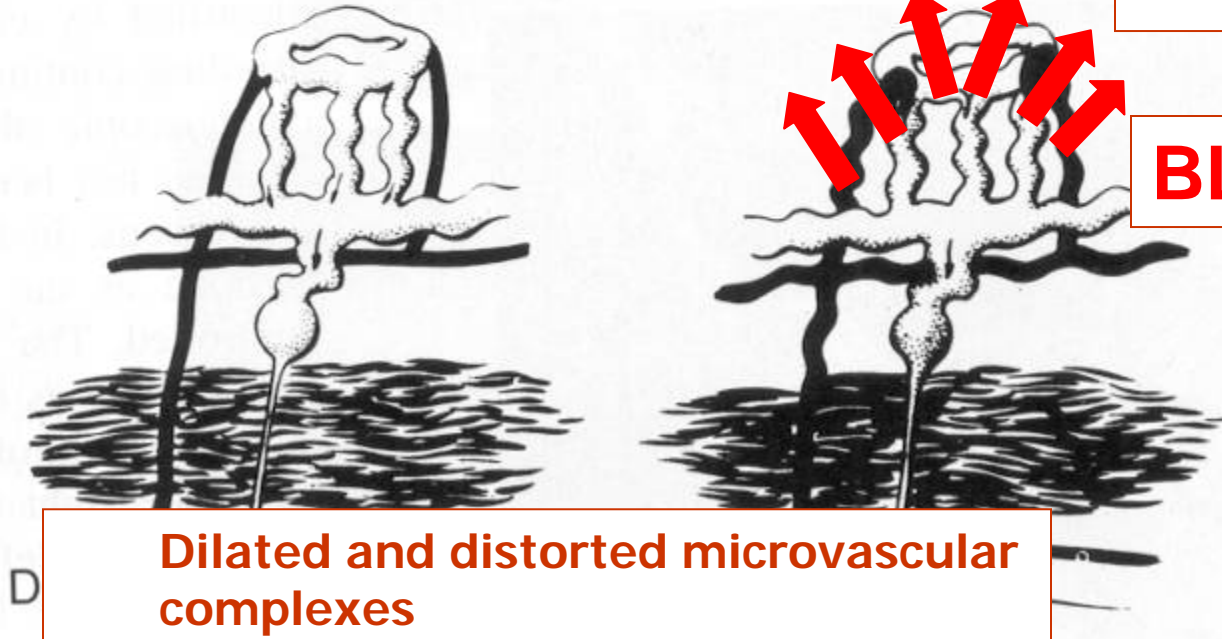
Distal venule fills with blood



Muscle layer contracts

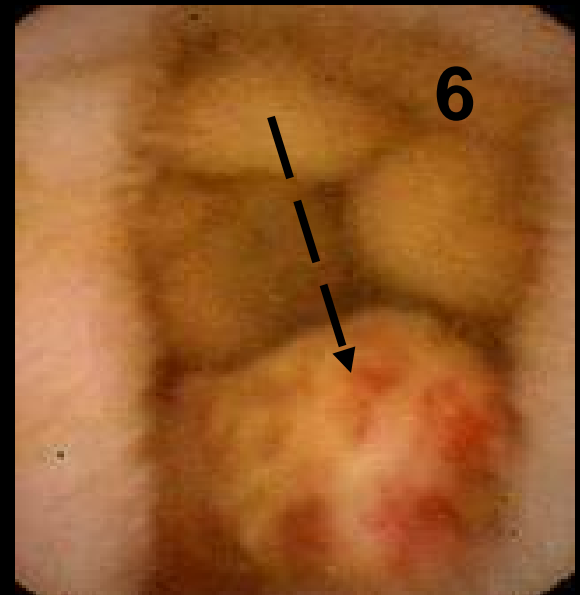
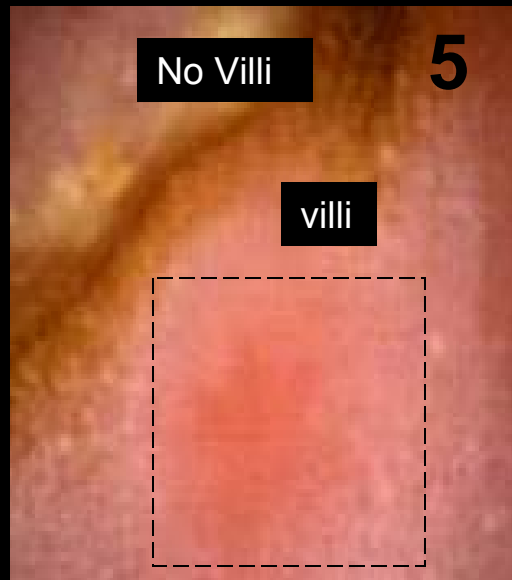
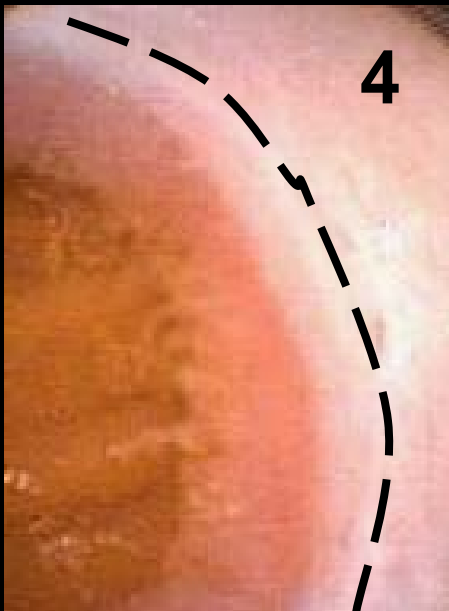


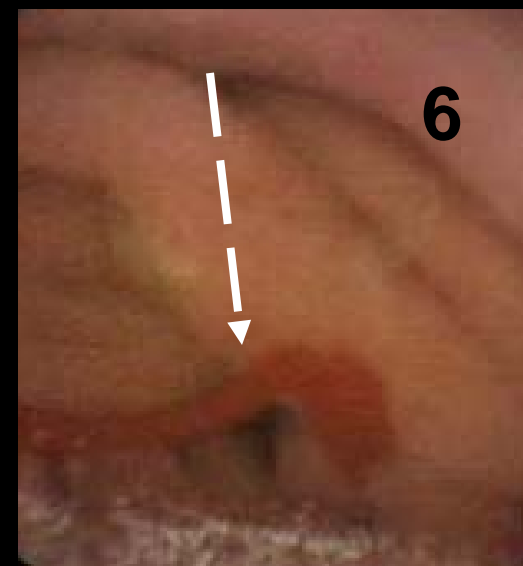
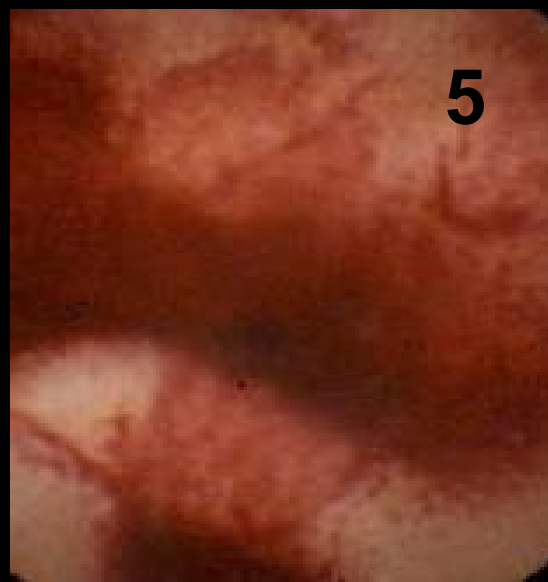
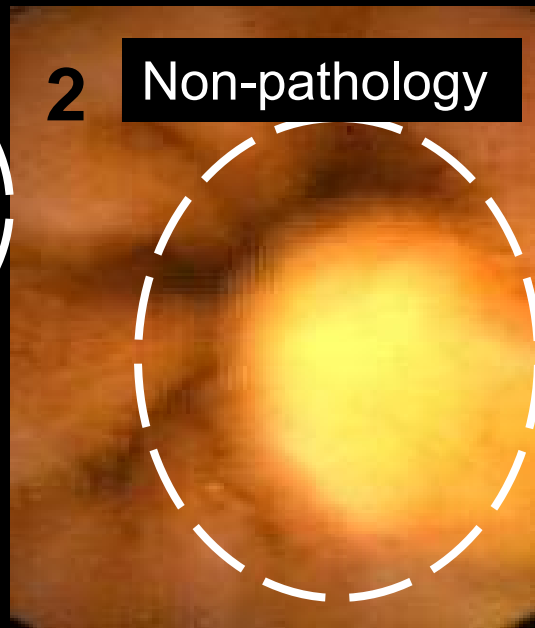
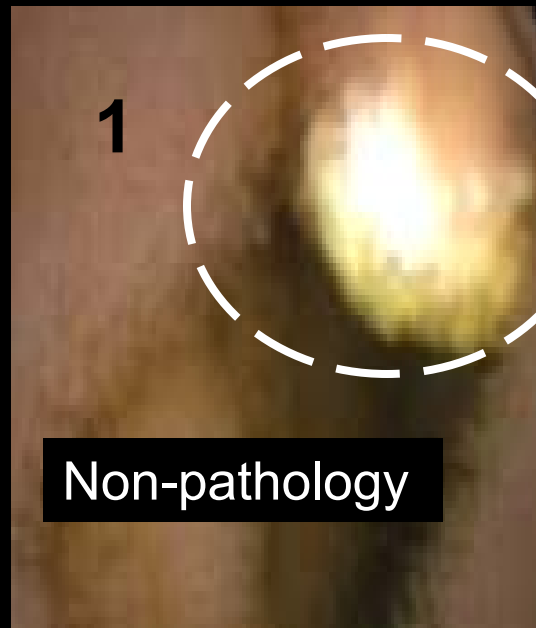
Pressure rises within the venule

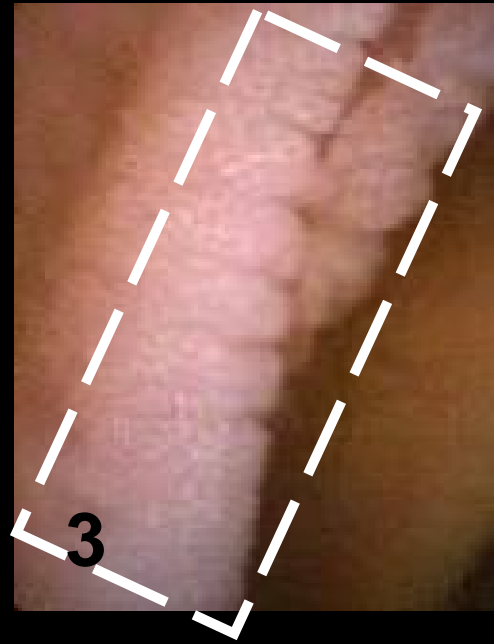


Dilated and distorted microvascular complexes

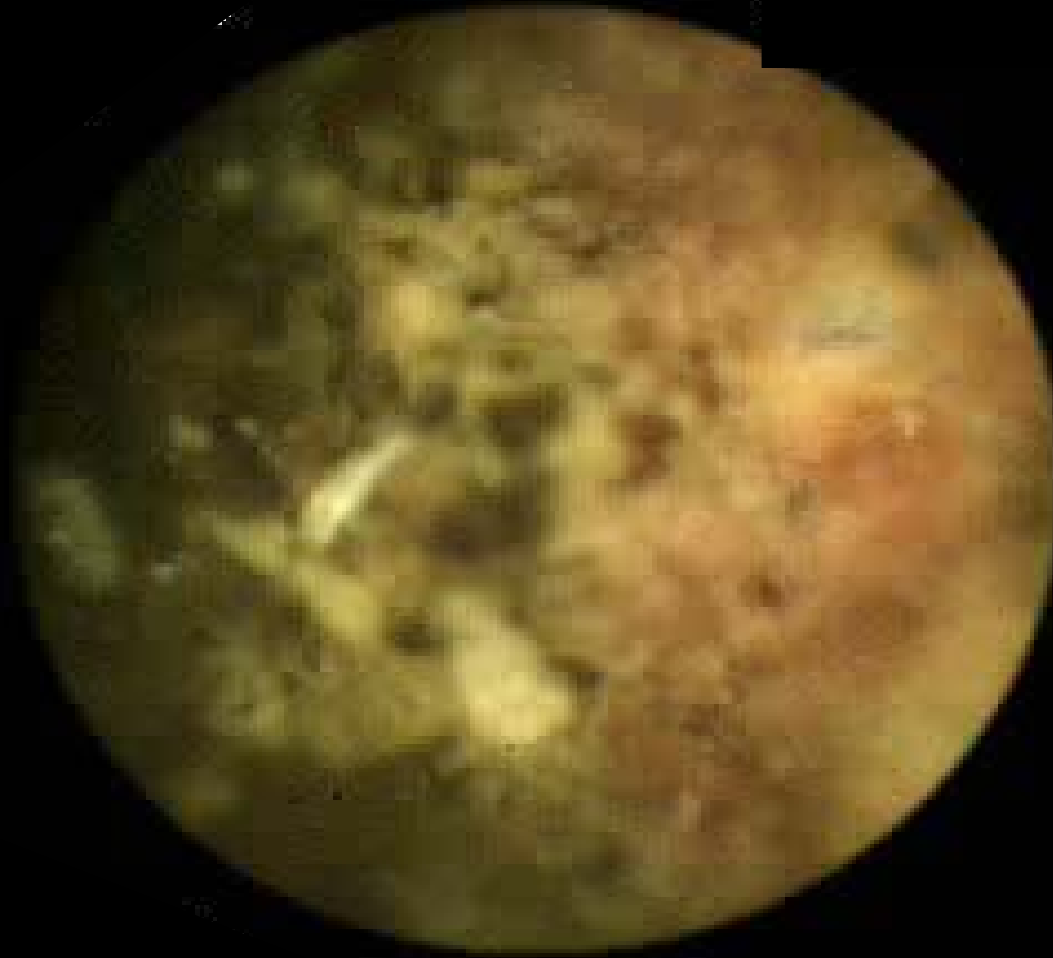
BLEED







Reminder: Debris is not the same
as seeing the cecum



02:28:20

21 Feb 06

il



PillCam™ SB

06:33:14

01 Jul 03

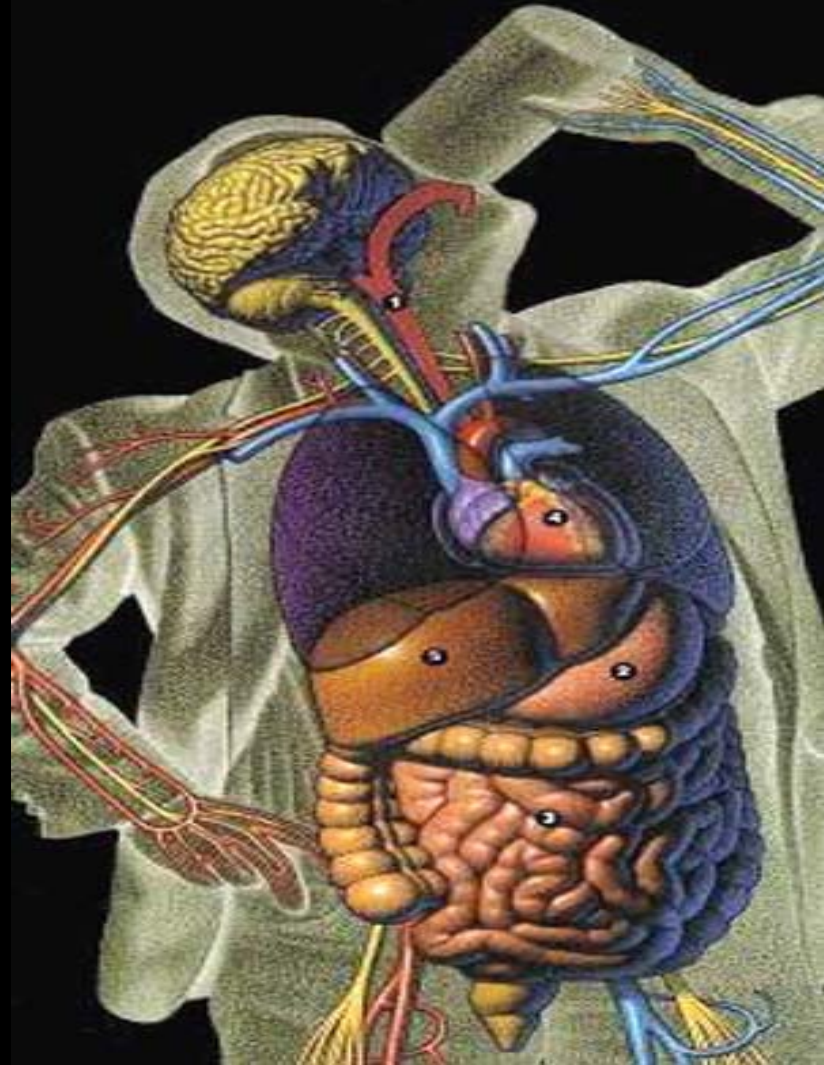
AC

Given®



Presentation Agenda

Small Bowel Testing
Anatomy review
Safety Issues in CE
Special Considerations
Patient Selection
Capsule Procedure
Documentation
Video Triage
Interpretation Phase
Future Technology



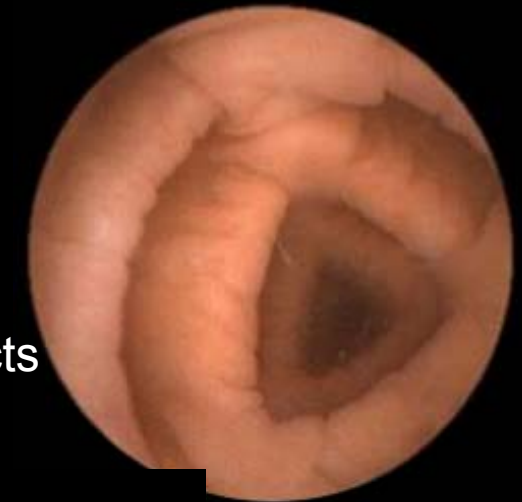
Goals of Capsule Research and Development

Colon Capsule

currently in clinical trials for FDA approval

- In use in Europe
- Did not pass efficacy for FDA approval last year
- Will not doubt be used for screening colonoscopies

Colon Capsule

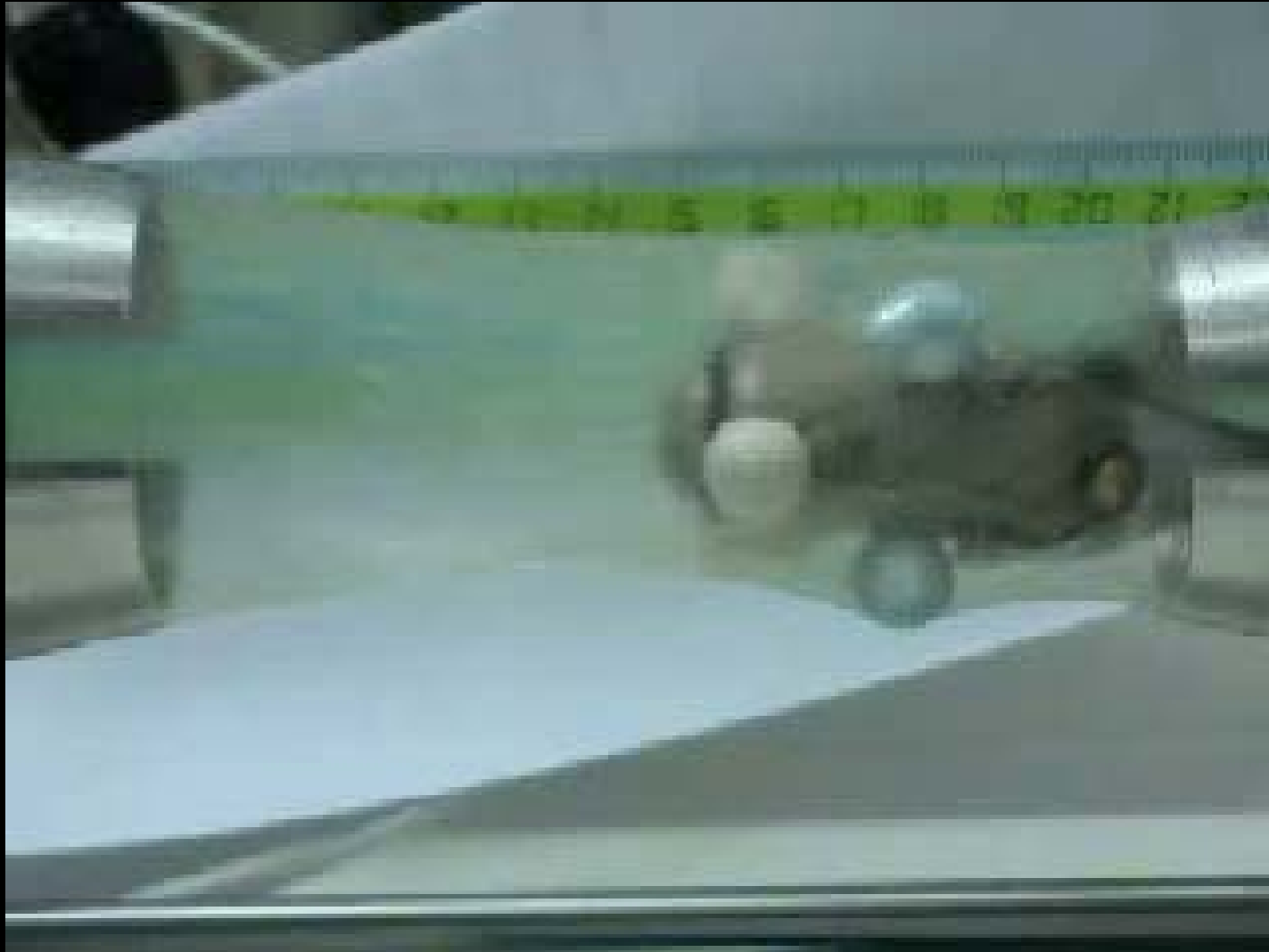


- Slightly larger in size than other Pillcam™ products
- cameras both ends
- Ingested-then sleep mode for 2 hours
- 4 images a second for up to 10 hours
- Belgium small pilot study compared Pillcam Colon™ to Colonoscopy with 77% sensitivity and 70% specificity
- Requires colon prep and prokinetic agent
- Uses same platform DR and sensor arrays as other products

Not FDA Approved



Future Direction



Not FDA Approved

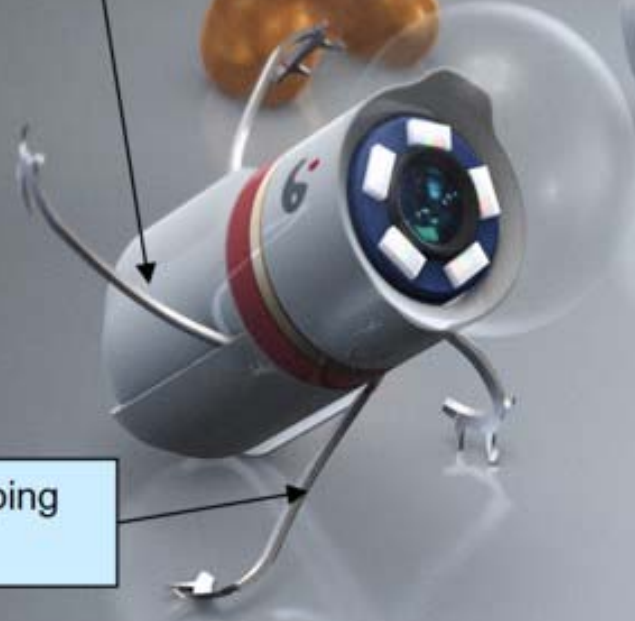
Active locomotion in the colon is feasible with robotic actuators



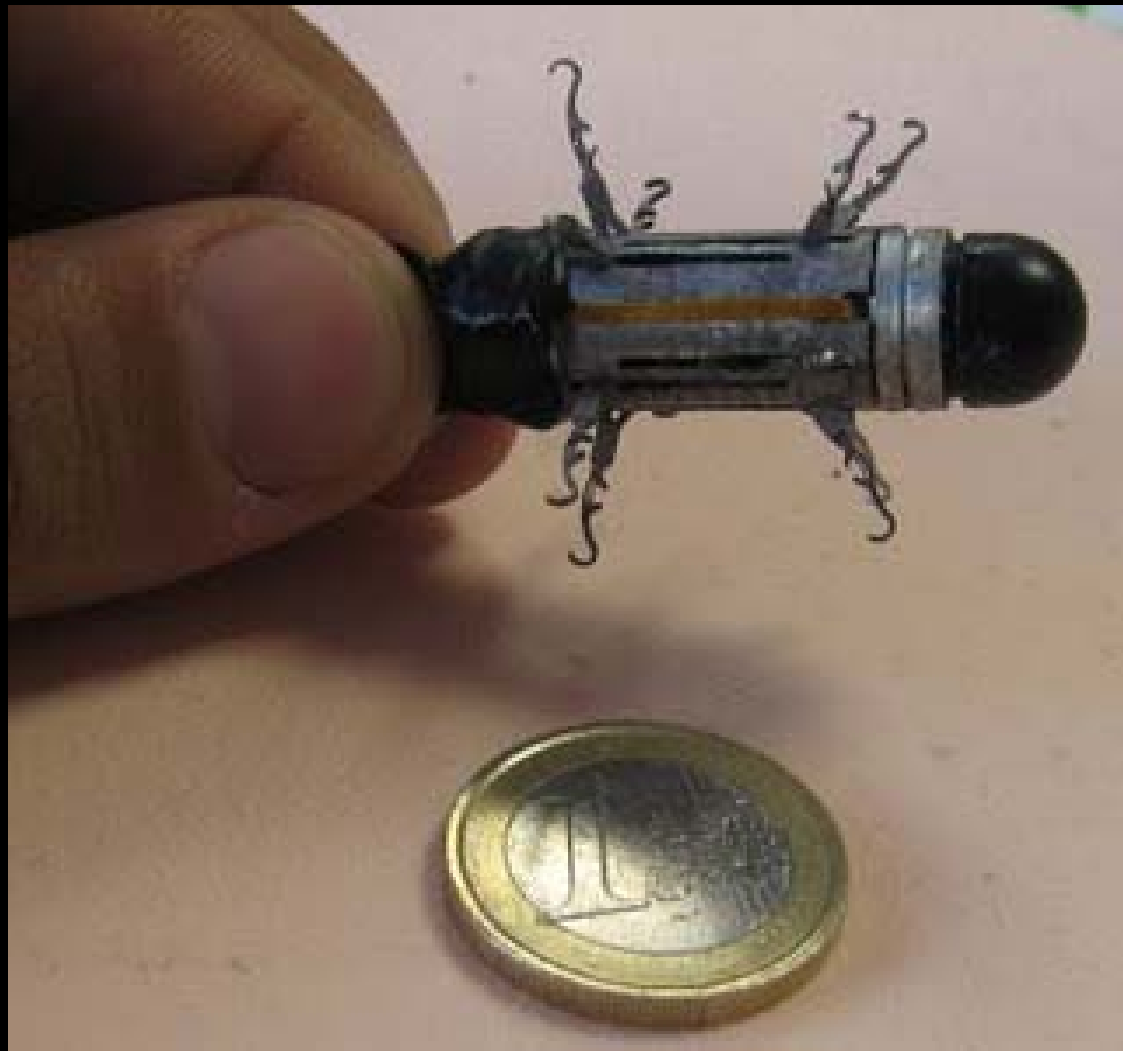
Capsule can passively travel along the esophagus and stop at area of interest



Active stopping with legs



Active direction of the line of sight of the capsule for capsular gastroscopy

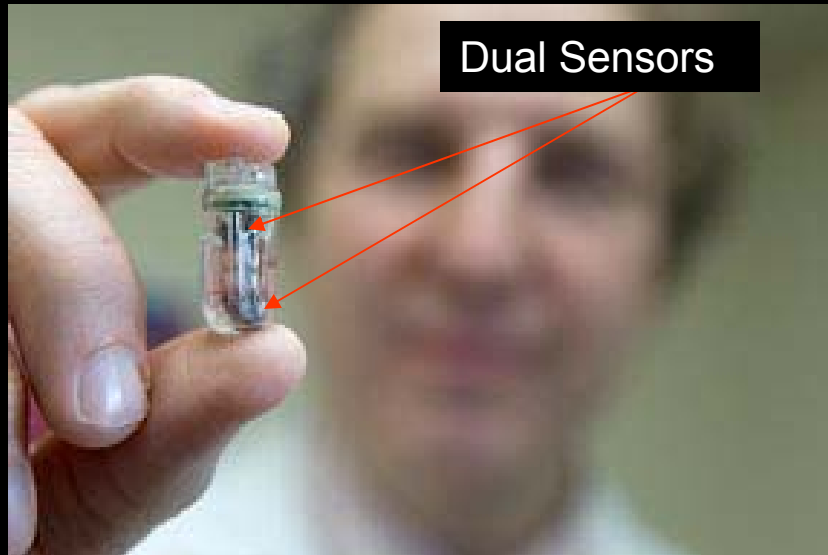


Increase Capsule Rate-Increase battery life



Not FDA Approved

SmartPill



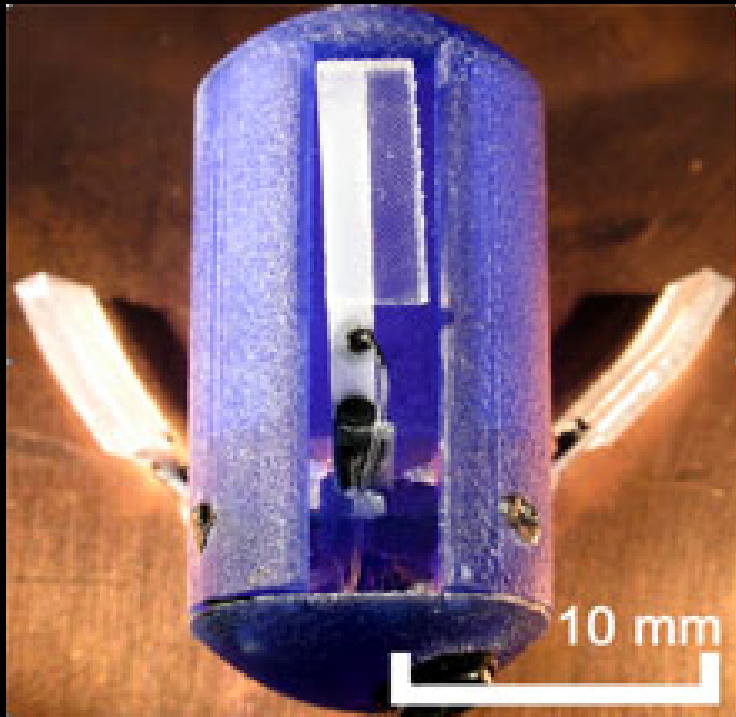
Smart Pill™

FDA approved
CCF Acquired
Gastroparesis

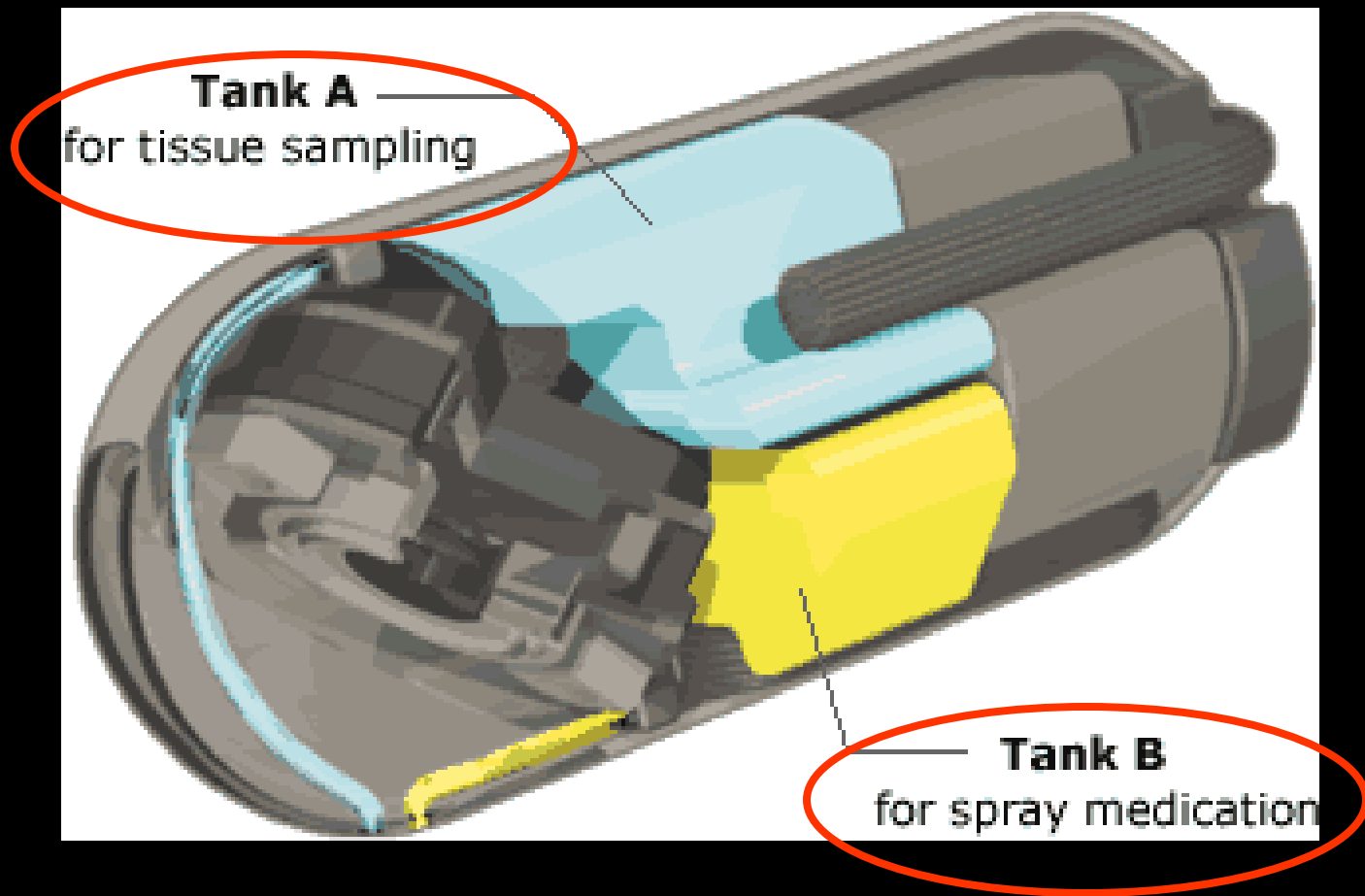
Future uses: IBS

Dyspepsia

- Non-Photographic Capsule
- GI motility disorders
- Accurate biomedical readings as it moves down GI tract
 - gastrointestinal peristaltic pressure
 - pH levels
 - temperature and transit time



Not FDA Approved



Not FDA Approved

05-04-23
14:30:24
SCV-----09



Not FDA Approved

Questions, Thoughts, Concerns

