A Few Words About Endoscopic Advancement

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No Disclosures
Discussion Topics

1. “Through the Scope” Endoscopic Clips
2. “Over the Scope” Endoscopic Clips
3. Submucosal Nodules
4. Active Upper Gastrointestinal Bleeding (non-variceal)
5. Esophago-gastric Varices
6. EUS: A Few Words
7. ERCP: A Few More Words and Cholangioscopy
8. Your Gastrointestinal Consultant
Through the Scope
Endoscopic Clips
Design to provide greater visibility when placing multiple clips.

<table>
<thead>
<tr>
<th>BSC</th>
<th>OLYMPUS</th>
<th>COOK MEDICAL</th>
<th>CONMED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolution™ Clip Device</td>
<td>QuickClip Pro™ Hemostasis Device</td>
<td>Instinct™ Endoscopic HemoClip</td>
<td>DuraClip™ Hemostasis Clip</td>
</tr>
</tbody>
</table>

*Data on file project 0116-005

DuraClip™ Repositionable Hemostasis Clip post-deployed is 40% shorter than the competition.*

This allows for greater visibility and ease of placing multiple clips.

<table>
<thead>
<tr>
<th></th>
<th>Resolution™</th>
<th>QuickClip Pro™</th>
<th>Instinct™</th>
<th>DuraClip™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Clip Height</td>
<td>17.65mm</td>
<td>16.34mm</td>
<td>14.29mm</td>
<td>10.20mm</td>
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<tr>
<td>Jaw Arm Height</td>
<td>5.22mm</td>
<td>4.56mm</td>
<td>5.46mm</td>
<td>5.12mm</td>
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<tr>
<td>Deployed Base Height</td>
<td>12.43mm</td>
<td>11.78mm</td>
<td>8.83mm</td>
<td>5.08mm</td>
</tr>
</tbody>
</table>
# Summary Product Attributes

<table>
<thead>
<tr>
<th></th>
<th>ConMed</th>
<th>Boston Scientific</th>
<th>Olympus</th>
<th>Cook</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repositionable</td>
<td>No limits</td>
<td>Up to 5 times</td>
<td>Up to 5 times</td>
<td>Up to 5 times</td>
</tr>
<tr>
<td>Clip Open Width</td>
<td>11mm</td>
<td>11mm</td>
<td>11mm</td>
<td>16mm</td>
</tr>
<tr>
<td>Leading Arm Width</td>
<td>0.36mm</td>
<td>1.26mm</td>
<td>0.86mm</td>
<td>1.37mm</td>
</tr>
<tr>
<td>Maximum Clip Width</td>
<td>1.41mm</td>
<td>1.87mm</td>
<td>1.14mm</td>
<td>1.79mm</td>
</tr>
<tr>
<td>1:1 Rotation</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>360° Rotation</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Outer plastic sheath</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>MR conditional</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>3 years</td>
<td>3 years</td>
<td>3 years</td>
<td>3 years</td>
</tr>
</tbody>
</table>
MRI Conditional

MR Safety information

Similar to other Hemostasis Clips, The DuraClip is determined to be MR-conditional. Non-clinical testing has demonstrated that the DuraClip is MR Conditional according to ASTM F2503.

A patient with this device can be safely scanned under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla
- Spacial gradient field of 4000 Gauss/cm less
- Maximum whole body averaged specific absorption rate (SAR) of 2 W/kg in
- Normal Operating Mode for a maximum scan time 15min of continuous
- scanning at 1.5T and 3T
Esophageal Ulcers with Bleeding
Duodenal Perforation
Over The Scope Clips
The Padlock Clip™ defect closure system facilitates fast and effective full circumferential tissue closure while still maintaining blood flow to promote healing.

Available in Standard and Pro-Select
The Padlock Clip™ defect closure system is indicated for use in flexible endoscopy and for the compression of tissue in the gastrointestinal tract, for hemostasis, or for treating lesions of the wall of gastrointestinal organs.

The Padlock Clip™ defect closure system is indicated for:

- Hemostasis for:
  - Mucosal/sub mucosal defects
  - Bleeding ulcers
  - Arteries <2mm
  - Polyps <1.5cm diameter
  - Diverticula in the colon
- Closure of GI tract luminal perforations < 20mm that can be treated conservatively
Submucosal Nodules
Esophago-gastric Varices
Active G.I. Bleeding
A different approach to hemostasis.
A different modality

What is Hemospray?
Hemospray is an inert mineral powder developed for endoscopic hemostasis which contains no human or animal proteins or botanicals and has no known allergens.

How does it work?
When Hemospray comes in contact with an actively bleeding site, the powder absorbs water, then acts both cohesively and adhesively, forming a mechanical barrier over the bleeding site.
When to use Hemospray?

Hemospray is a different endoscopic modality that has demonstrated results in a wide range of nonvariceal GI hemorrhage procedures.

Hemospray has also demonstrated successful results with these additional nonvariceal bleed types:

- Gastritis
- Dieulafoy Lesions
- Mallory Weiss Tears
- GAVE/Watermelon Stomach
- Esophagitis
- Gastric Angiodysplasia
- GI Neoplasms
- Post EMR

Reprint and bleed images courtesy of Prof. Joseph Sung, Chinese University of Hong Kong, Hong Kong, China. Duodenal ulcer bleed images courtesy of Dr. Las Kantes, Stavanger University Hospital, Stavanger, Norway. Gastric ESD bleed images courtesy of Dr. David Sierra, Hospital de Luz, Lisbon, Portugal.
Video Courtesy of:
Prof. Joseph Sung
Chinese University of Hong Kong, China
In-hospital mortality rate for upper GI hemorrhage is decreasing over 2 decades in the United States.

Emergency video capsule endoscopy in patients with acute severe GI bleeding and negative upper endoscopy.

Pre-cut sphincterotomy: efficacy for ductal access and the risk of adverse events.

Endoscopic management of pancreatic pseudocysts (with videos).

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Cornerstone of EUS

1. Diagnosis, FNA/FNB, Staging and Treatment, G.I Cancers
2. Cystic Lesions of the Pancreas
3. Biliary Access Procedures
4. Submucosal Nodules and masses
Successful EUS

1. Gastrointestinal Cyto-Pathologist
2. Trained G.I staff knowledgeable of ALL equipment and ability to “Troubleshoot”
3. EUS and Cancer
   a. G.I Interventional Radiologist
   b. Gastrointestinal/Oncologic Surgeons
   c. Tumor Board – Radiation Oncologist, Heme/Oncology
E.R.C.P.
Endoscopic Retrograde Cholangio-Pancreatography
ERCP

1. A procedure available for decades – fiberoptic days
2. Continues to be one of the top leading reasons a G.I. specialist/consultant is named in a lawsuit
3. Continues to be a challenging procedure – even for “seasoned” gastroenterologist
1. G.I. fellowship training in ERCP is extremely variable.
2. F.M.C – ALL new hire fellows are proctored for 200 ERCP’s with an attending
3. F.M.C – Medical Staff Bylaws, for gastrointestinal physicians performing ERCP – 50 procedures per year
Informed Consent Document

1. Risks
2. Benefits
3. Complications
4. Alternatives
5. ALL questions were answered

Informed consent obtained by the physician performing the procedure
SpyGlass™ DS
Direct Visualization System

You’re going to want to see this™

SpyGlass DS System
Overview of Cholangioscopy
SpyGlass™ DS
Direct Visualization System

History and Development of Cholangioscopy

Cholangioscopy was first introduced in the 1970s. Direct visualization of the bile ducts by per-oral cholangioscopy can be of value in the diagnosis of biliary abnormalities, obtaining biopsy specimens, and guiding stone therapy.

Early Cholangioscopy:

Technical limitations of “mother-baby” cholangioscopes:
- High repair costs
- Limited steerability
- Poor irrigation capabilities
- Requires 2 operators

SpyGlass™ Direct Visualization System

- First single-operator cholangioscopy (SOC) system
  - Two dedicated irrigation channels
  - Optic channel
  - 1.2mm diameter therapeutic channel
  - 4-way tip deflection to facilitate steerability through small ducts
- Overcome the limitations of traditional cholangioscopes
- Provide optically-guided therapeutics for targeted stricture and stone management

Disclaimer: Images owned by Boston Scientific
SpyGlass™ DS
Direct Visualization System

You’re going to want to see this.

Large and Difficult-to-Reach Bile Duct Stones

- 85-90% of bile duct stones can be extracted using a retrieval balloon or basket after biliary sphincterotomy
- 15% of patients will have bile duct stones that are difficult to remove

Character and Location of Stones

- Large stone size
- Numerous stones
- Shape of stone
- Intrahepatic stones
- Stones present above a stricture
- Impacted stones
- Bile duct shape and angulation

Anatomical Factors

- Periampullary diverticulum
- Altered anatomy

Patient Factors

- Old age
- Coagulopathy

Disclaimer: Images owned by Boston Scientific
Malignancy Strictures
- Cholangiocarcinoma
- Klatskin’s Tumor
- Extrahepatic Bile Duct Cancer
- Gallbladder Cancer
- Ampullary Cancer
- Pancreatic Cancer
- Primary Sclerosing Cholangitis (PSC)
- Intraductal Papillary-Mucinous Tumors (IPMT)

Benign Strictures
- Postoperative injury after cholecystectomy
- Pancreatitis
- Orthotopic liver transplantation (OLT)
- Mirizzi’s Syndrome
- Radiation
- Blunt abdominal trauma
- Portal biliopathy
- Polyarteritis nodosa and systemic lupus erythematosus (SLE)
- Choledochal cysts
SpyScope™ investigation of the stricture revealed multiple inflammations consistent with PSC
"There is no right way to do the wrong thing."
Your Gastrointestinal Consultant

1. More advanced therapeutic procedures – Less involvement and knowledge of “Routine” gastrointestinal disorders.
2. Your G.I. Consultant – Must become a knowledgeable G.I. radiologist – CT Scans, MRI/MRCP, EUS, Abdominal Ultrasounds all personally reviewed.
3. All therapeutic procedures
   - Plan your procedure
   - Know all equipment needed
   - Discuss anticipated procedure and equipment required with your staff.
4. Time involvement in advanced procedures is critical!
Thank you

Questions during the “Q&A” with Panel

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