The Captivator EMR Device is specifically designed for ligation-assisted Endoscopic Mucosal Resection (EMR) of the Upper Gastrointestinal (GI) tract.

“A device specifically designed for EMR may lead to greater overall efficiency in regards to optimal visualization and device exchange as well as providing a way to consistently handle tissue.”

— Dr. Ram Chuttani,
Beth Israel Deaconess Medical Center

“This is EMR.”
Kit Components

Access Port
Allows passability of 7Fr tools with device in place (Interject™ Injection Therapy Needle Catheter/Resolution™ Clip)

Handle
Blue knob is rotated 120° and is designed with tactile and audible feedback to signal when a band has deployed

Captivator EMR Snare
Stiff snare and band design provides ability to snare where desired (above or below the band)

Captivator EMR Band Ligator
Designed to achieve 360 degree peripheral viewing without obstructions due to the ligator bands, includes 6 bands

Captivator EMR Pathology Kit
Included for histological processing of retrieved tissue samples which may allow for better specimen handling
Endoscopic management of Barrett’s Esophagus may help reduce the potential for an invasive and costly surgical esophagectomy.

The Captivator EMR Device provides potential clinical, economic, efficiency, and patient satisfaction benefits for EMR procedures:

- Delivers a minimally invasive device, for use in the treatment of patients requiring EMR, including Barrett's Esophagus and Esophageal Adenocarcinoma
- Offers significant visualization improvements over other EMR devices with 360 degree unobstructed peripheral viewing
- Designed to help improve physician control in band deployment, tissue capture and complication management with device in place.
- Offers potential for improved pathology handling, with included pathology kit, which may provide the user with greater convenience.
- May help to generate time savings in both establishing visualization and managing complications

"The EMR procedure is the only endoscopic modality which serves the dual function of curative potential and provision of more accurate histological staging."¹
Endoscopic management strategies for Barrett’s esophagus

<table>
<thead>
<tr>
<th>Histology</th>
<th>Intervention Options</th>
</tr>
</thead>
</table>
| Non-Dysplastic Barrett’s Esophagus (NDBE)     | • Consider no surveillance.  
• If surveillance is elected, perform EGD every 3-5 years with 4-quadrant biopsies every 2 cm.  
• Consider endoscopic ablation in select cases.                                                                                                           |
| Indeterminate Grade Dysplasia (IGD)           | • Clarify presence and grade of dysplasia with expert GI pathologist.  
• Increase antisecretory therapy to eliminate esophageal inflammation.  
• Repeat EGD and biopsy to clarify dysplasia status.                                                                                                       |
| Low Grade Dysplasia (LGD)                     | • Confirm with expert GI pathologist.  
• Repeat EGD in 6 months to confirm LGD.  
• Surveillance EGD every year, 4-quadrant biopsies every 1-2 cm.  
• Consider EMR or ablation.                                                                                                                                |
| High Grade Dysplasia (HGD)                    | • Confirm with expert GI pathologist.  
• Consider surveillance EGD every 3 months in select patients, 4-quadrant biopsies every 1 cm.  
• Consider EMR or RFA ablation.  
• Consider EUS for local staging and lymphadenopathy.  
• Consider surgical consultation.                                                                                                                           |
| Esophageal Adenocarcinoma (EAC)               | • EMR is indicated for shorter segment dysplastic BE, nodular dysplasia, superficial (T1a) EAC, and esophageal squamous cell carcinoma (ESC).  
• EMR as an eradication technique for HGD and EAC is successful in 91% to 98% of T1a cancers.                                                              |
Optimal Visualization

The Captivator EMR Band Ligator cap is designed to achieve 360 degree peripheral viewing without obstructions due to the ligator bands.

- Clear visualization plays an important role in the procedure.
- Captivator EMR Device allows the physician to see and assess the tissue/lesion when the EMR device is in place and to see tissue during suction.

When combining the visualization through the opening and the plastic of the cap, the Captivator EMR Device allows visualization of 90% of the endoscopic view directly after mounting the device.4

With Cook Duette® Multi-Band Mucosectomy device, visualization of 90% is not reached until releasing 4 of the 6 rubber bands.4
Features

Complication Management

The Captivator EMR Device offers the ability to manage complications with the device in place

- The types of potential complications during an EMR procedure may include both bleeding and perforation. *

- About 40% of patients who undergo EMR have minor interprocedural bleeding that can be treated endoscopically. ³

- Injection needle can be used for submucosal injection, which may help the physician to assess signs of non-lifting, or to help assess invasion and/or fibrosis

*The Captivator EMR device is compatible with 7Fr devices such as the Interject™ Injection Therapy Needle Catheter and the Resolution™ Clip

Interject Injection Therapy Needle Catheter

Resolution Clip

*Reference the directions for use, for a complete list of potential complications.

"All devices did pass significantly more smoothly with the Captivator EMR."
Consistent and Optimal Tissue Handling

The Captivator EMR pathology kit is included to aid in histological processing of retrieved tissue samples which may allow for better specimen handling.

“Because EMR specimens are larger than biopsy samples, it is helpful for pathologic interpretation to orient and mount the specimen before submerging it in fixative.”
The Captivator EMR device offers clinicians the ability to manage complications with the device in place

- Less time spent switching out devices and less likelihood of needing a 2nd scope and device during the procedure. A potential cost savings of $290 per case*

The Captivator EMR device is designed to achieve 360° peripheral viewing without obstructions

- Offers an efficient way to visualize a complication and may allow more rapid treatment of the complication during the same procedure.

Includes a pathology kit, to incorporate the latest clinical thinking in the handling of specimens and may provide added convenience for endoscopists and pathologists

<table>
<thead>
<tr>
<th>Economic Value</th>
<th>Kit Components</th>
<th>Importance of EMR</th>
<th>Treatment Considerations</th>
<th>Features</th>
<th>Economic Value</th>
<th>Ordering Information</th>
<th>Resources</th>
</tr>
</thead>
</table>

Delivers a minimally invasive treatment option for patients with Barrett’s Esophagus and appears to be less costly to the hospital on a per procedure basis and may be associated with a shorter length of stay versus esophagectomy.6

<table>
<thead>
<tr>
<th></th>
<th>Esophagectomy</th>
<th>EMR</th>
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<tbody>
<tr>
<td>2012 Mean Medicare Hospital Costs</td>
<td>$49,792</td>
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<tr>
<td>2012 Mean Medicare Payment</td>
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<td>Length of Stay (days)</td>
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<td>Outpatient</td>
</tr>
</tbody>
</table>

*Assumes $250 replacement device cost and $40 scope reprocessing cost.
Ordering Information - Captivator EMR

Scope Compatibility

Our Standard Kit (M00561600) is designed to be compatible with gastroscopes with a physical dimension at the distal end of 9.0mm – 9.9mm. While most diagnostic gastroscopes (2.8mm working channel) will fit these dimensions, it is important to verify with the scopes at your hospital.

Our Large Kit (M00561610) is designed to be compatible with gastroscopes with a physical dimension at the distal end of 11.3mm – 11.6mm. While most therapeutic gastroscopes (3.7mm working channel) will fit these dimensions, it is important to verify with the scopes at your hospital.

Captivator EMR Product Codes

<table>
<thead>
<tr>
<th>Captivator EMR Device</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order Number</td>
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Reimbursement and Ordering Information

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<thead>
<tr>
<th>Resolution™ Clip</th>
<th>Code Description</th>
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<tr>
<td>CPT Code</td>
<td>Code Description</td>
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<tr>
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<td>43211</td>
<td>Esophagoscopy, Endoscopic Mucosal Resection (EMR)</td>
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Note: Payer policies will vary and should be verified to treatment for limitations on diagnosis, coding or site of service requirements. The coding option listed within this guide is commonly used but is not intended to be all inclusive. We recommend consulting your relevant manuals for appropriate coding options.
# Resolution™ Clip Product Codes

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<tr>
<th>Resolution Clip</th>
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<th>Minimum Working Channel (mm)</th>
<th>Clip Opening (mm)</th>
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## Interject™ Injection Therapy Needle Catheter Product Codes

### Interject Contrast Single-Use Injection Therapy Needle Catheters*

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<thead>
<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>Sheath Design</th>
<th>Needle Gauge</th>
<th>Maximum Needle Extension Length (mm)</th>
<th>Sheath O.D. (mm)</th>
<th>Working Length (cm)</th>
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*With Star Catheter™ Technology.

### Interject Clear Single-Use Injection Therapy Needle Catheters*

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<tr>
<th>Order Number</th>
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</table>

*With Star Catheter™ Technology.
The Captivator EMR Device

**Pathology Kit**
- Captivator EMR Band Ligator
- Captivator EMR Snare
- Captivator EMR Pathology Kit

**Features**
- Tissue Capture
- Stiff snare and band design allows the physician to snare where desired
- Assessment of the complication for management
- Cap visualization allows physician to see tissue during suction

**Device Set-Up**

**Value Analysis Brief**

**Captivator EMR Device**

**Method**

**Background**

- The value analysis brief provides a comparison of the Captivator EMR Device to a competitive EMR device. The analysis was conducted to determine the cost-effectiveness and clinical outcomes of the Captivator EMR Device compared to a competitive device. The results were obtained through a retrospective analysis of hospital claims data and clinical outcomes.

**Clinical Considerations**

- The Captivator EMR Device is specifically designed for ligation-assisted Endoscopic Mucosal Resection (EMR) of the Upper Gastrointestinal (GI) tract.

**Intended Benefit**

- Treatment of Barrett's Esophagus
- Management of precancerous conditions and superficial cancers of the esophagus

**Clinical Value**

- The Captivator EMR Device provides a minimally invasive management option for Barrett's Esophagus.

**Economic Value**

- The Captivator EMR Device is designed to enable physicians to exchange devices with the device in place.

**Potential Clinical and Economic Benefits**

- Reduces likelihood of using a second scope during the procedure
- Improves passability of 7Fr tools with device in place
- Reduces likelihood of unintended band deployment
- Improves procedural efficiency

**Resources**

- Kit Components
- Importance of EMR
- Treatment Considerations
- Features
- Economic Value
- Ordering Information
- Resources

**View Cart Chart**

**View VAT Sheet**

**View Analysis Brief**

**View Setup Video**
References
2. ASGE, The role of endoscopy in Barrett’s esophagus and other premalignant conditions of the esophagus. Gastrointestinal Endoscopy, 2012 76(6)
5. ASGE Technology Committee, Hwang, J.H. MD, PhD, FASGE, et al. Endoscopic mucosal resection. Gastrointestinal Endoscopy, 2015; 82 (2)
6. 1 Datasource: Medicare’s MedPar 2012 and Medicare’s OPPS 2012 (Outpatient Prospective Payment System) files

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Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.