

# Captivator™ EMR Device

**Boston  
Scientific**  
Advancing science for life™

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

Importance  
of EMR

Treatment  
Considerations

Features

Economic  
Value

Ordering  
Information

Resources

# Kit Components

**Captivator™ EMR**  
Endoscopic Mucosal Resection Device

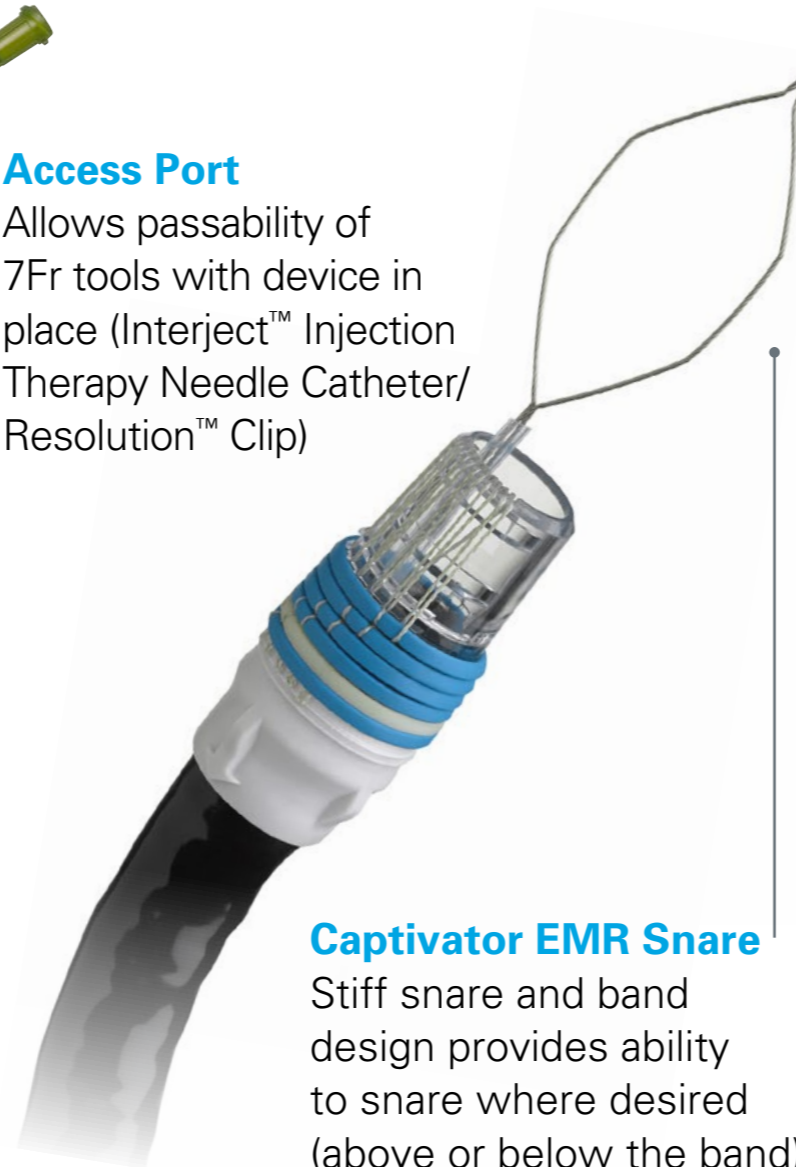


## Handle

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

## Access Port

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



## 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



Kit Components

Importance of EMR

Treatment Considerations

Features

Economic Value

Ordering Information

Resources

# Importance of EMR

**Captivator™ EMR**  
Endoscopic Mucosal Resection Device

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.<sup>1</sup>”



Kit  
Components

Importance  
of EMR

Treatment  
Considerations

Features

Economic  
Value

Ordering  
Information

Resources

# Treatment Considerations

## Endoscopic management strategies for Barrett's esophagus<sup>2</sup>

Histology	Intervention Options
<b>Non-Dysplastic Barrett's Esophagus</b> (NDBE)	<ul style="list-style-type: none"> <li>Consider no surveillance.</li> <li>If surveillance is elected, perform EGD every 3-5 years with 4-quadrant biopsies every 2 cm.</li> <li>Consider endoscopic ablation in select cases.</li> </ul>
<b>Indeterminate Grade Dysplasia</b> (IGD)	<ul style="list-style-type: none"> <li>Clarify presence and grade of dysplasia with expert GI pathologist.</li> <li>Increase antisecretory therapy to eliminate esophageal inflammation.</li> <li>Repeat EGD and biopsy to clarify dysplasia status.</li> </ul>
<b>Low Grade Dysplasia</b> (LGD)	<ul style="list-style-type: none"> <li>Confirm with expert GI pathologist.</li> <li>Repeat EGD in 6 months to confirm LGD.</li> <li>Surveillance EGD every year, 4-quadrant biopsies every 1-2 cm.</li> <li>Consider EMR or ablation.</li> </ul>
<b>High Grade Dysplasia</b> (HGD)	<ul style="list-style-type: none"> <li>Confirm with expert GI pathologist.</li> <li>Consider surveillance EGD every 3 months in select patients, 4-quadrant biopsies every 1 cm.</li> <li>Consider EMR or RFA ablation.</li> <li>Consider EUS for local staging and lymphadenopathy.</li> <li>Consider surgical consultation.</li> </ul>
<p><b>"A distinct advantage of EMR over ablative therapy is the availability of large tissue specimens for pathologic examination and cancer staging."<sup>2</sup></b></p>	
<b>Esophageal Adenocarcinoma</b> (EAC)	<ul style="list-style-type: none"> <li>EMR is indicated for shorter segment dysplastic BE, nodular dysplasia, superficial (T1a) EAC, and esophageal squamous cell carcinoma (ESC).</li> <li>EMR as an eradication technique for HGD and EAC is successful in 91% to 98% of T1a cancers.</li> </ul>

“Multiband mucosectomy is effective in achieving radical removal of early Barrett's neoplasia and does not appear to result in more perforations or bleeding episodes than the endoscopic resection-cap technique, despite the lack of submucosal lifting.<sup>3</sup>”



Kit Components

Importance of EMR

Treatment Considerations

Features

Economic Value

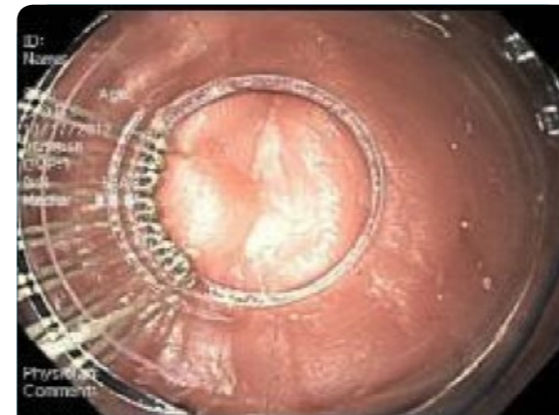
Ordering Information

Resources

## 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



Better Visualization

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.**<sup>4</sup>



Limited Visualization

With Cook Duetto® Multi-Band Mucosectomy device, visualization of 90% is not reached until releasing 4 of the 6 rubber bands.<sup>4</sup>

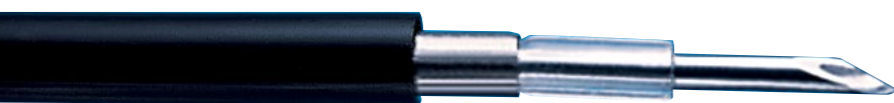
## Complication Management

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.<sup>3</sup>
- 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

“All devices did pass significantly more smoothly with the Captivator EMR.”<sup>4†</sup>”



Interject Injection Therapy Needle Catheter



Resolution Clip

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



Kit  
Components

Importance  
of EMR

Treatment  
Considerations

Features

Economic  
Value

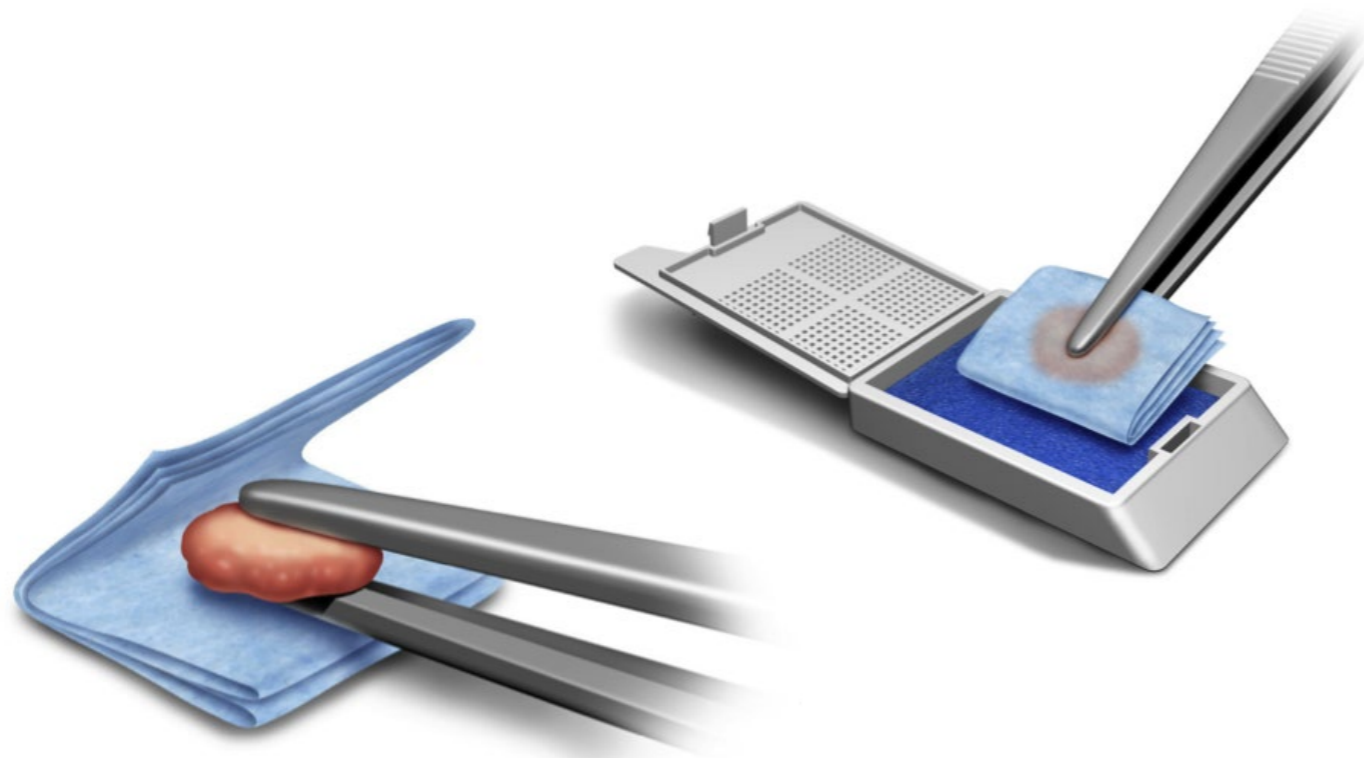
Ordering  
Information

Resources

## Consistent and Optimal Tissue Handling

< 3 of 3

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.”<sup>5</sup>”

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

	Esophagectomy	EMR
2012 Mean Medicare Hospital Costs	\$49,792	<b>\$2,297</b>
2012 Mean Medicare Payment	\$30,040	<b>\$1,776</b>
Length of Stay (days)	12.9	<b>Outpatient</b>

◀ 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.<sup>6</sup>

\*Assumes \$250 replacement device cost and \$40 scope reprocessing cost.



# Ordering Information - Captivator EMR

**Captivator™ EMR**  
Endoscopic Mucosal Resection Device

## Scope Compatibility

1 of 3 >

**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

Captivator EMR Device			
Order Number	GTIN	Product Description	Unit
M00561600	08714729842675	Captivator EMR Device for Standard Gastroscopes	Box 1
M00561601	08714729842682	Captivator EMR Device for Standard Gastroscopes	Box 5
M00561610	08714729842699	Captivator EMR Device for Large Gastroscopes	Box 1
M00561611	08714729842705	Captivator EMR Device for Large Gastroscopes	Box 5



## Reimbursement and Ordering Information

Resolution™ Clip	
CPT Code	Code Description
43254	EGD, Endoscopic Mucosal Resection (EMR)
43211	Esophagoscopy, Endoscopic Mucosal Resection (EMR)

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.



Kit  
Components

Importance  
of EMR

Treatment  
Considerations

Features

Economic  
Value

Ordering  
Information

Resources

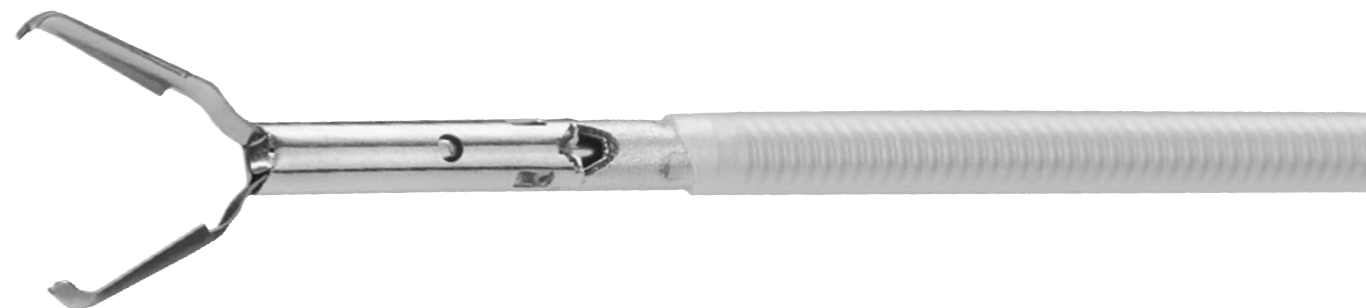
# Ordering Information - Complementary Devices

**Captivator™ EMR**  
Endoscopic Mucosal Resection Device

## Resolution™ Clip Product Codes

< 2 of 3 >

Resolution Clip					
Order Number	GTIN	Working Length (cm)	Minimum Working Channel (mm)	Clip Opening (mm)	Unit
M005 <b>22600</b>	08714729504764	155	2.8	11	Each
M005 <b>22601</b>	08714729504771	155	2.8	11	Box 10
M005 <b>22602</b>	08714729504788	155	2.8	11	Box 20
M005 <b>22610</b>	08714729504795	235	2.8	11	Each
M005 <b>22611</b>	08714729504801	235	2.8	11	Box 10
M005 <b>22612</b>	08714729504818	235	2.8	11	Box 20



Kit  
Components

Importance  
of EMR

Treatment  
Considerations

Features

Economic  
Value

Ordering  
Information

Resources

# Ordering Information - Complementary Devices

**Captivator™ EMR**  
Endoscopic Mucosal Resection Device

## Interject™ Injection Therapy Needle Catheter Product Codes

< 3 of 3

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

Order Number	GTIN	Sheath Design	Needle Gauge	Maximum Needle Extension Length (mm)	Sheath O.D. (mm)	Working Length (cm)	Unit
M005 <b>1815</b> 1	08714729296430	Contrast	23	4	1.8	200	Box 5
M005 <b>1816</b> 1	08714729296447	Contrast	25	4	1.8	200	Box 5
M005 <b>1825</b> 1	08714729296478	Contrast	23	6	1.8	200	Box 5
M005 <b>1826</b> 1	08714729296485	Contrast	25	6	1.8	200	Box 5
M005 <b>1835</b> 1	08714729296522	Contrast	23	4	2.3	240	Box 5
M005 <b>1836</b> 1	08714729296539	Contrast	25	4	2.3	240	Box 5

\*With Star Catheter™ Technology.



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

M005 <b>1810</b> 1	08714729296416	Clear	23	4	1.8	200	Box 5
M005 <b>1811</b> 1	08714729296423	Clear	25	4	1.8	200	Box 5
M005 <b>1830</b> 1	08714729296508	Clear	23	4	2.3	240	Box 5
M005 <b>1831</b> 1	08714729296515	Clear	25	4	2.3	240	Box 5

\*With Star Catheter™ Technology.



Kit  
Components

Importance  
of EMR

Treatment  
Considerations

Features

Economic  
Value

Ordering  
Information

Resources

**Captivator™**  
EMR Device



**The Captivator EMR Device** is specifically designed for ligation-assisted Endoscopic Mucosal Resection (EMR) of the Upper Gastrointestinal (GI) tract. Many physicians are now adopting Upper GI EMR as they recognize the benefits of the procedure to both diagnose and treat precancerous conditions and superficial cancers of the esophagus including Barrett's Dysplasia (LGD, HGD), Mild/Moderate Squamous Cell Neoplasia, and T1a and some T1b cancers.<sup>1</sup> The Captivator EMR Device has \$109k clearance per K140726, for commercialization in the United States.

**The Captivator EMR device includes:**

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



**Economic and Clinical Value**

Clinical Considerations	Intended Benefit
See and assess tissue / lesion with the EMR device in place	The Captivator EMR Band Ligator cap is designed with 360 degree peripheral viewing without obstructions by bands
See and assess complications during the procedure	Passability of 7Fr tools with device in place (Interject™ Needle/Resolution™ Clip)
Assessment of the complication for management	Cap visualization allows physician to see tissue during suction
Tissue Capture	Stiff snare and band design allows the physician to snare where desired (above or below the band)
Standardized tissue handling may assist pathologist's determination of tissue margins	Pathology kit included for histological processing of retrieved tissue samples which may allow for better specimen handling
Economic Considerations	Potential Benefits
Reduce likelihood of using a 2" scope during the procedure	Passability of 7Fr tools with device in place (Interject/Resolution Clip)
Reduce likelihood of unintended band deployment	Handle designed with tactile and audible feedback to signal when a band has deployed
Procedural efficiency	<ul style="list-style-type: none"> <li>• The Captivator EMR Device is designed to enable physicians to exchange devices with the device in place</li> <li>• Designed to allow for adequate suction when both the snare and trip wire are in the working channel</li> </ul>

\*Resolution Clip is compatible with Captivator EMR Device for Large Gastroscopies  
©2018 Boston Scientific

value analysis brief

### Captivator EMR Device

**Method**  
This value analysis brief provides information on the practice of ligation-assisted Endoscopic Mucosal Resection (EMR) of the Upper Gastrointestinal (GI) tract and the potential clinical and economic benefits of the Captivator EMR Device. Many physicians are now adopting Upper GI EMR as they recognize the benefits of the procedure to treat precancerous conditions and superficial cancers of the esophagus including Barrett's Dysplasia (LGD, HGD), Mild/Moderate Squamous Cell Neoplasia, and T1a and some T1b cancers.<sup>1</sup>

**Background**  
Barrett's Esophagus is the central step on the disease continuum from GERD (gastroesophageal reflux disease) to Esophageal Cancer; it begins as a serious complication of GERD. In Barrett's esophagus, the normal squamous epithelium lining of the esophagus is replaced by glandular cells from the stomach. Patients with Barrett's Esophagus have a 50x-100x increase in their risk of developing cancer compared to the general population.<sup>2</sup> Barrett's Esophagus does not just have a negative clinical impact on patients' lives – the economic burden of the disease is also high. Controlling for age, gender, and number of comorbidities, patients with Barrett's Esophagus incur 21.2% higher overall costs than patients with GERD and 62.4% higher overall costs than the general Medicaid population.<sup>3</sup> Endoscopic management of Barrett's Esophagus may help reduce the potential for an invasive and costly surgical esophagectomy.



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

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

**Potential Clinical and Economic Benefits**  
The Captivator EMR Device delivers a minimally invasive treatment option for patients with Barrett's Esophagus.<sup>4</sup> A retrospective claims analysis of Medicare inpatient and outpatient (MedPar and OPPS FY 2012) files was conducted to compare length of stay (LOS), hospital costs and payments between both procedures. Given that upper Gastrointestinal (GI) tract EMR codes did not exist in 2012, various coding combinations utilized by hospitals to report the EMR procedure were identified in the claims file. The mean total hospital costs for esophagectomy were significantly greater than EMR (\$49,702 vs. \$2,267 respectively). Mean postprocedure LOS for esophagectomy was 12.9 days. LOS was not calculated for EMR as the procedure is primarily performed in the outpatient hospital setting. Based on these findings, EMR appears to be less costly to the hospital on a per procedure basis and may be associated with a shorter length of stay than esophagectomy.<sup>5</sup>

	Esophagectomy	EMR
Total Hospitalizations	170	222
2012 Mean Medicare Hospital Costs	\$49,702	\$2,267
2012 Mean Medicare Payment	\$20,040	\$1,716
Length of Stay (days)	12.9	Outpatient

Clear visualization plays an important role in the outcome of the procedure; poor visualization "makes it more difficult to target focal lesions and avoid tissue bridges between multiple resection areas."<sup>6</sup> **The Captivator EMR Band Ligator cap is designed to achieve 360 degree peripheral viewing** without obstructions due to the ligator bands. This allows the physician to see and assess the visualization when the EMR device is in place. To the right is a visualization comparison of Captivator EMR Device and a competitive device.

## Captivator™ EMR Device

### Preparation for Use

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



## Device Set-Up







#### References

1. Jennifer Chennat. Irving Waxman. *Interventional Gastrointestinal Oncology 2. Gastrointestinal Oncology, A Practical Guide* 2011
2. ASGE, The role of endoscopy in Barrett's esophagus and other premalignant conditions of the esophagus. *Gastrointestinal Endoscopy*, 2012 76(6)
3. Pouw, Roos E, et al. Randomized trial on endoscopic resection-cap versus multiband mucosectomy for piecemeal endoscopic resection of early Barrett's neoplasia. *Clinical Endoscopy* 2011; 74 (1)
4. Schölvinc, D.W., Belghazi, K., Pouw, R.E., Curvers, W.L., Wuesten, B.L.A.M., Bergman, J.J.G.H.M., In vitro assessment of the performance of a new multiband mucosectomy device for endoscopic resection of early upper gastrointestinal neoplasia. *Surg Endosc*, 2015
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 OPDS 2012 (Outpatient Prospective Payment System) files

All trademarks are the property of their respective owners.

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.**

**Boston  
Scientific**  
Advancing science for life™

Boston Scientific Corporation  
300 Boston Scientific Way  
Marlborough, MA 01752-1234  
[www.bostonscientific.com/gastro](http://www.bostonscientific.com/gastro)

©2016 Boston Scientific Corporation  
or its affiliates. All rights reserved.

ENDO-338919-AB February 2016