

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.



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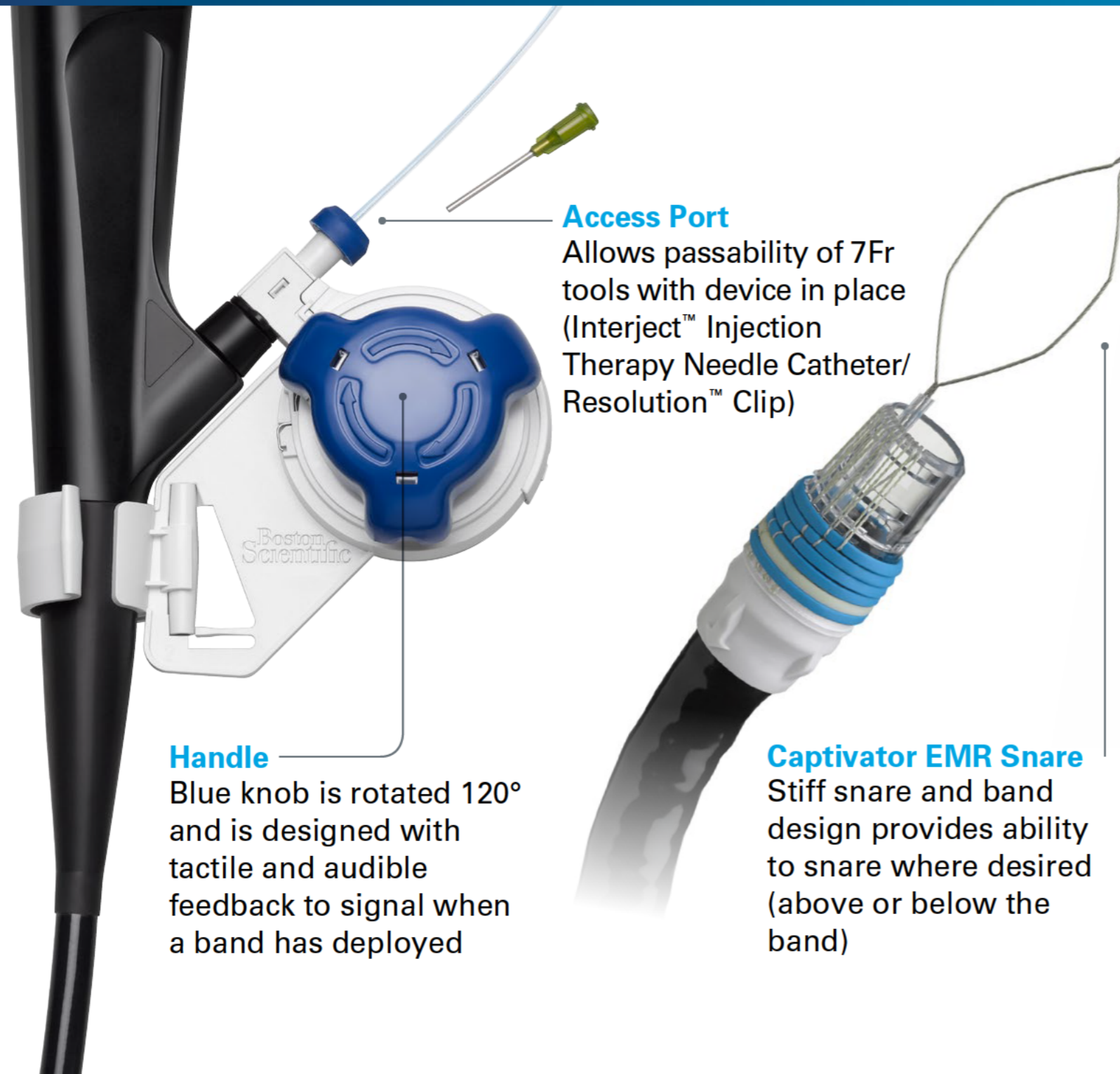
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Kit Components

Captivator™ EMR
Endoscopic Mucosal Resection Device



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 storage of retrieved tissue samples



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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:

- Delivers a minimally invasive device, for use in the treatment of patients requiring EMR, including Barrett's Esophagus and Esophageal Adenocarcinoma [Tap Here](#)
- Designed to achieve 360° peripheral viewing without obstructions from the bands [Tap Here](#)
- Offers clinicians the ability to manage complications with the device in place [Tap Here](#)
- Pathology handling [Tap Here](#)
- Visualization [Tap Here](#)

“The EMR procedure is the only endoscopic modality which serves the dual function of curative potential and provision of more accurate histological staging.¹”



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Treatment Considerations

Endoscopic Management Strategies for Barrett's Esophagus²

Histology	Intervention Options
Non-Dysplastic Barrett's Esophagus (NDBE)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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
<p>"A distinct advantage of EMR over ablative therapy is the availability of large tissue specimens for pathologic examination and cancer staging."²</p>	
Esophageal Adenocarcinoma (EAC)	<ul style="list-style-type: none"> 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

“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.³”



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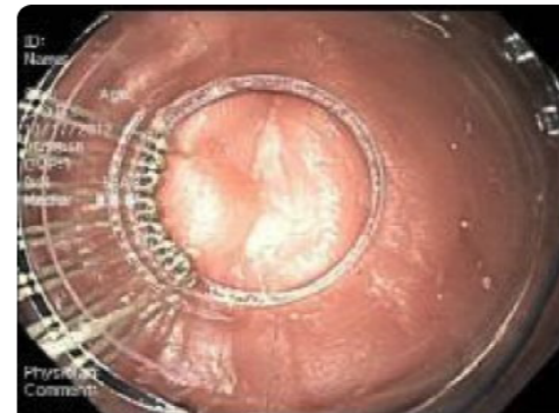
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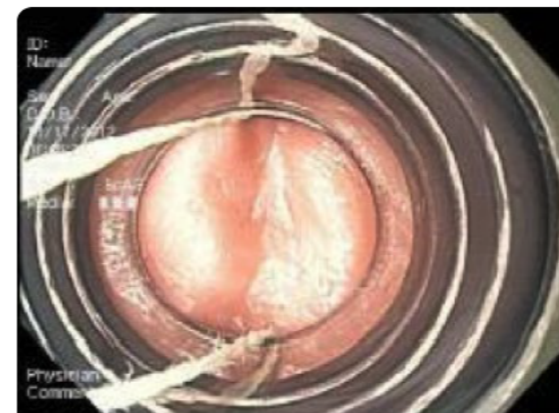
Optimal Visualization

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



Complication Management

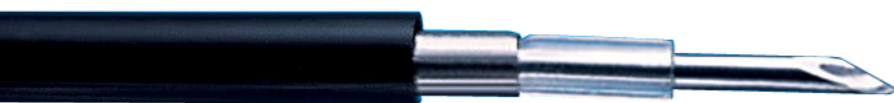
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The Captivator EMR Device offers the ability to manage complications with the device in place

- 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

“All devices did pass significantly more smoothly with the Captivator EMR.”^{4†}

†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.



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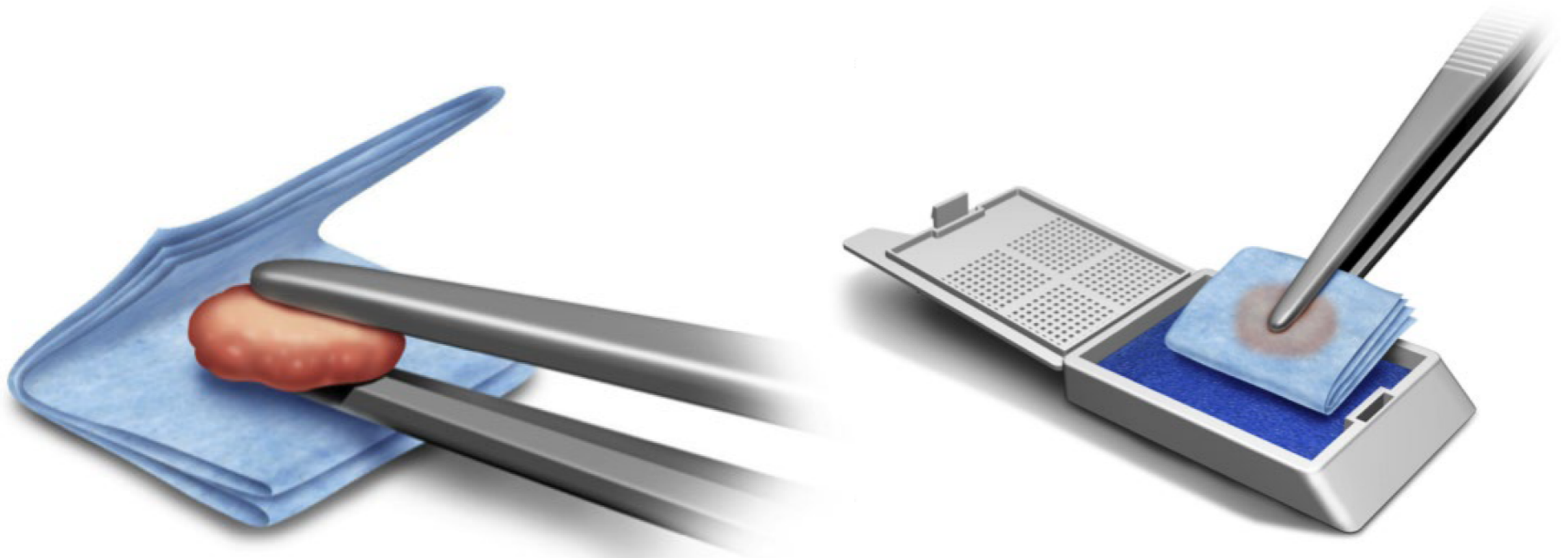
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Tissue Handling

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The Captivator EMR pathology kit is included for storage of retrieved tissue samples.



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- The Captivator EMR device offers clinicians the ability to manage complications with the device in place
- The Captivator EMR device is designed to achieve 360° peripheral viewing without obstructions

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

◀ 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



Ordering Information - Captivator EMR

Captivator™ EMR
Endoscopic Mucosal Resection Device

Scope Compatibility

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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.



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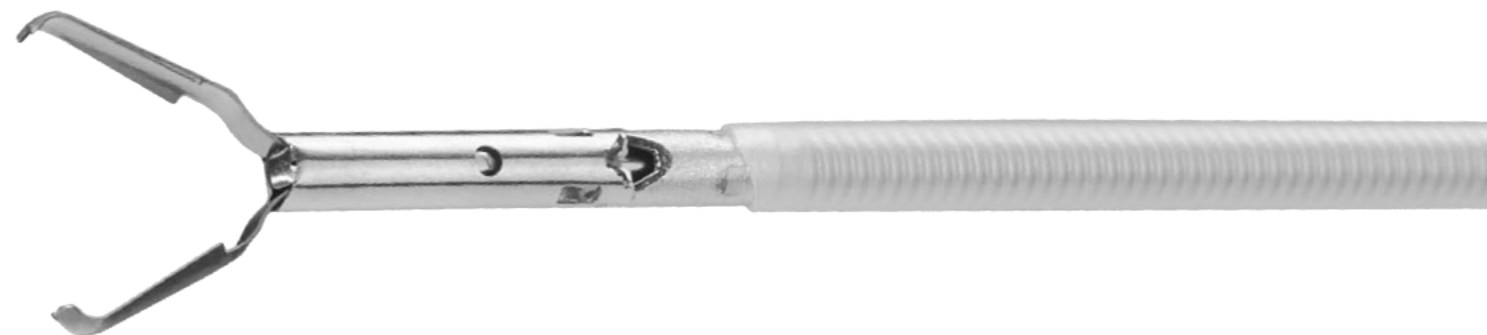
Ordering Information - Complementary Devices

Captivator™ EMR
Endoscopic Mucosal Resection Device

Resolution™ Clip Product Codes

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Resolution Clip					
Order Number	GTIN	Working Length (cm)	Minimum Working Channel (mm)	Clip Opening (mm)	Unit
M00522600	08714729504764	155	2.8	11	Each
M00522601	08714729504771	155	2.8	11	Box 10
M00522602	08714729504788	155	2.8	11	Box 20
M00522610	08714729504795	235	2.8	11	Each
M00522611	08714729504801	235	2.8	11	Box 10
M00522612	08714729504818	235	2.8	11	Box 20



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Interject™ Injection Therapy Needle Catheter Product Codes

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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
M00518151	08714729296430	Contrast	23	4	1.8	200	Box 5
M00518161	08714729296447	Contrast	25	4	1.8	200	Box 5
M00518251	08714729296478	Contrast	23	6	1.8	200	Box 5
M00518261	08714729296485	Contrast	25	6	1.8	200	Box 5
M00518351	08714729296522	Contrast	23	4	2.3	240	Box 5
M00518361	08714729296539	Contrast	25	4	2.3	240	Box 5

*With Star Catheter™ Technology.



Interject Clear Single-Use Injection Therapy Needle Catheters*

M00518101	08714729296416	Clear	23	4	1.8	200	Box 5
M00518111	08714729296423	Clear	25	4	1.8	200	Box 5
M00518301	08714729296508	Clear	23	4	2.3	240	Box 5
M00518311	08714729296515	Clear	25	4	2.3	240	Box 5

*With Star Catheter™ Technology.



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Captivator™ EMR Device

The Captivator EMR Device is specifically designed for incision-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 diagnosis and treat premalignant conditions and to prevent cancer of the esophagus including Barrett's Esophagus (BE), High Grade Intraepithelial Neoplasia (HGIN), and T1a and some T1b cancers. The Captivator EMR Device has 510(k) clearance per K140726 for commercialization in the United States.

The Captivator EMR device includes:

- Captivator EMR Band Ligator
- Captivator EMR Sizer
- Captivator EMR Pathology Kit

Economic and Clinical Value

Clinical Consideration	Interventive Benefit
See and assess tissue lesion with the EMR device in place	The Captivator EMR Band Ligator cap is designed to provide a 360-degree peripheral view of the lesion.
See and assess complete area during the procedure	Flexibility of EMR tools with device in place. Interact/Needle/Resect on Clip.
Assessment of the completion for management	Visualization on a large physician to assess lesion characteristics.
Tissue Capture	Soft snare and band design allows the physician to snare lesions that are below or below the band.
Standardized tissue handling may assist pathologist in diagnosis of tissue resection	Pathology kit included for histological processing of resected tissue samples with an easy-to-use for better specimen handling.
Economic Considerations	Potential Benefits
Reduce likelihood of using a 2nd attempt during the procedure	Flexibility of EMR tools with device in place. Interact/Needle/Resect on Clip.
Reduce likelihood of an extended band deployment	Handle designed with tactile and audible feedback to signal when a band has deployed.
Increased efficiency	<ul style="list-style-type: none"> • The Captivator EMR Device is designed to enable physicians to exchange devices with the device in place. • Designed to allow for adequate suction when both the snare and trap wire are used.

View VAT Sheet
Tap Here

value analysis brief

Captivator EMR Device

Method

This value analysis is a self-study conducted on the part of Boston Scientific Endoscopic Mucosal Resection (EMR) of the Upper Gastrointestinal (GI) Tract and the benefits of the procedure to both diagnosis and treatment of the esophagus including Barrett's Esophagus (BE), High Grade Intraepithelial Neoplasia (HGIN), and T1a and some T1b cancers. The Captivator EMR Device has 510(k) clearance per K140726 for commercialization in the United States.

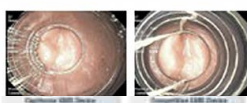
Background

Barrett's Esophagus is the most common form of esophageal adenocarcinoma (EAC) and is associated with a 5-year survival rate of approximately 17%. The incidence of EAC is increasing in the United States, with a 10% increase in the rate of EAC diagnosis compared to the general population. Barrett's Esophagus is a precancerous condition that can lead to EAC. The economic burden of the disease is also high. Cost of care for age, gender, and number of comorbidities. The higher the number of comorbidities, the higher the cost of care. The Captivator EMR Device is a self-study conducted on the part of Boston Scientific Endoscopic Mucosal Resection (EMR) of the Upper Gastrointestinal (GI) Tract and the benefits of the procedure to both diagnosis and treatment of the esophagus including Barrett's Esophagus (BE), High Grade Intraepithelial Neoplasia (HGIN), and T1a and some T1b cancers. The Captivator EMR Device has 510(k) clearance per K140726 for commercialization in the United States.

Potential of Clinical and Economic Benefits

The Captivator EMR Device offers a minimally invasive treatment option for patients with BE. The device is designed to provide a 360-degree peripheral view of the lesion. The device is designed to allow for adequate suction when both the snare and trap wire are used. The device is designed to allow for adequate suction when both the snare and trap wire are used.

Item	Quantity	Unit Price	Total Price
Captivator EMR Device	1	\$2,000	\$2,000
Captivator EMR Band Ligator	1	\$1,000	\$1,000
Captivator EMR Sizer	1	\$1,000	\$1,000
Captivator EMR Pathology Kit	1	\$1,000	\$1,000
Total	4		\$5,000



View Analysis Brief
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Captivator™ EMR Device

Preparation for Use

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

Device Set-Up




View Setup Video
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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 OPSS 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.

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