

Hemostasis Devices





Through innovation and expansion of our therapeutic portfolio, we are proud to offer endoscopy devices to address a variety of **hemostasis situations and improve patient care.**

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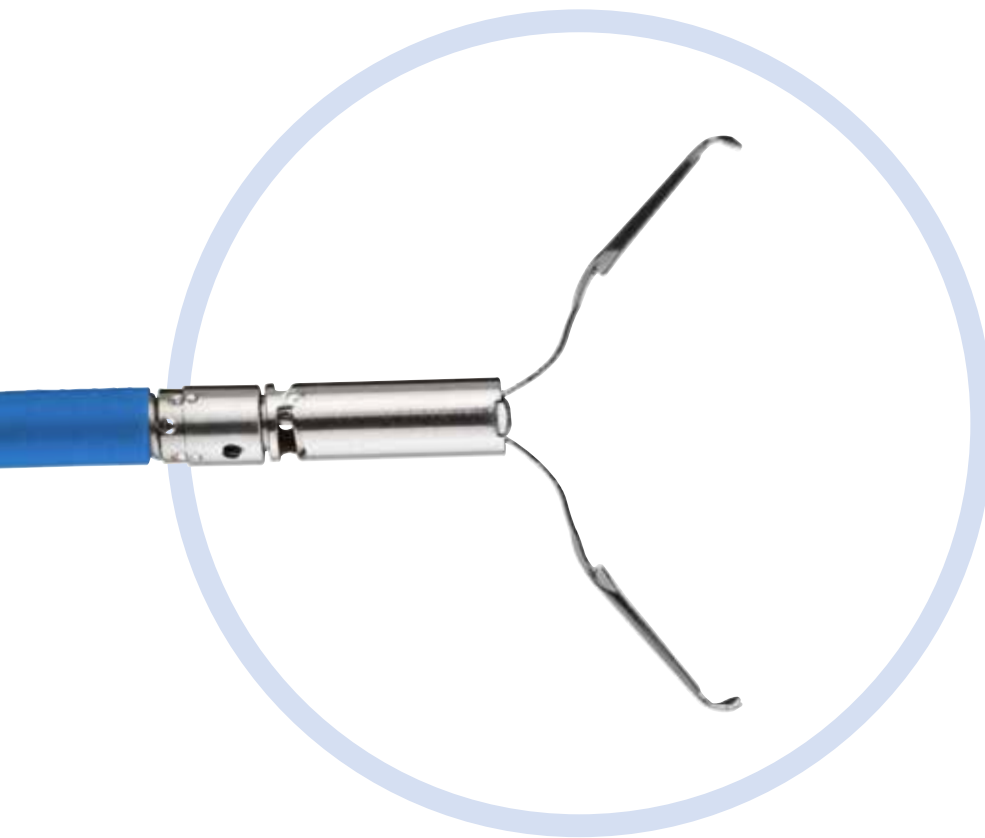
VIPER™ Hemoclip

Portfolio Overview

STERIS offers a complete portfolio of hemostasis clips designed for endoscopic clip placement within the gastrointestinal tract for the purpose of hemostasis, defect closure, endoscopic marking and anchoring.

VIPER Hemoclip:

Available in 4 sizes - all offering a minimal tail length allowing for visualization and maneuverability when deploying multiple clips.



Six VIPER™ Hemoclips closing an esophageal POEM mucosal incision.*



63 day follow up found majority of VIPER™ Hemoclips in place.*

*Photos courtesy of Dr. Sherif Andrawes.

VIPER™ Hemoclip

Features & Benefits



Features	Benefits	VIPER™ Hemoclip
Assistant-controlled adjustment by rotating the handle	Enables accurate clip placement	✓
Minimal tail length	Maneuverability when deploying additional clips	✓
Can be opened/closed multiple times	Facilitates positioning prior to deployment	✓
Design allows for smooth passage through the working channel	Aids in tortuous endoscope positions	✓
Provides audible and tactile feedback on handle	Confirms deployment	✓

VIPER™ Hemoclip								
Product Number	Description	Min. Working Channel (mm)	Catheter Length (cm)	Deployed Length (mm)	Opening Width (mm)	Coated Sheath	Sterile	Units/Box
Removable								
BX00711875	VIPER™ Hemoclip	2.8	230	12.5	11	Yes	Yes	10
BX00711877	VIPER™ Hemoclip	2.8	230	12.5	16*	Yes	Yes	10
BX00711924	VIPER™ Hemoclip	2.8	230	12.5	9	Yes	Yes	10
BX00711925	VIPER™ Hemoclip	2.8	230	12.5	13	Yes	Yes	10
Non-Removable								
BX00711874	VIPER™ Hemoclip	2.8	230	12.5	11	Yes	Yes	10
BX00711876	VIPER™ Hemoclip	2.8	230	14.5	16	Yes	Yes	10
BX00711922	VIPER™ Hemoclip	2.8	230	12.5	11	No	Yes	10
BX00711923	VIPER™ Hemoclip	2.8	230	12.5	16*	No	Yes	10

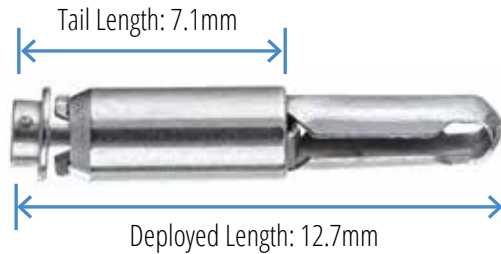


The VIPER™ Hemoclip has a 7.1mm tail length for visibility and maneuverability

Comparison of 16 and 17mm clips*

STERIS

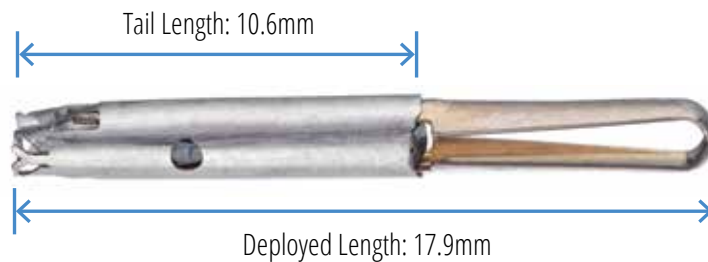
VIPER™ Hemoclip:



Opening Width:
16mm

BOSTON SCIENTIFIC

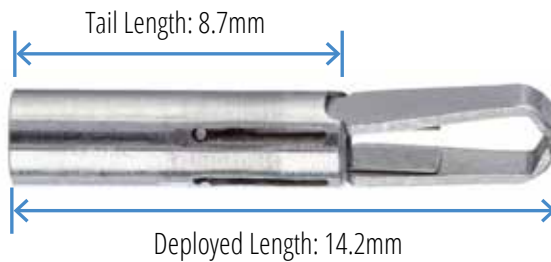
Boston Scientific
Resolution 360™
ULTRA Clip:



Opening Width:
17mm

COOK MEDICAL

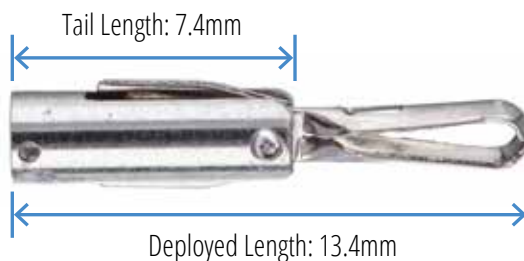
Cook Instinct®
Endoscopic Clip:



Opening Width:
16mm

CONMED

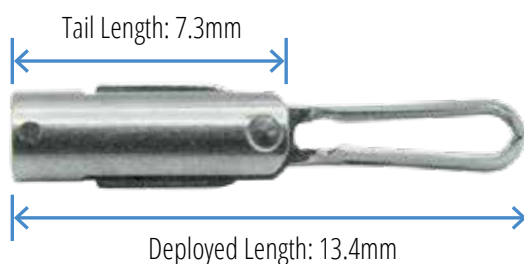
Conmed DuraClip®
Repositionable
Hemostasis Clip:



Opening Width:
16mm

MICRO-TECH

Micro-Tech SureClip™
Hemostasis Clip:



Opening Width:
16mm

*Testing completed October 2021. Data on File. Values may vary or change.
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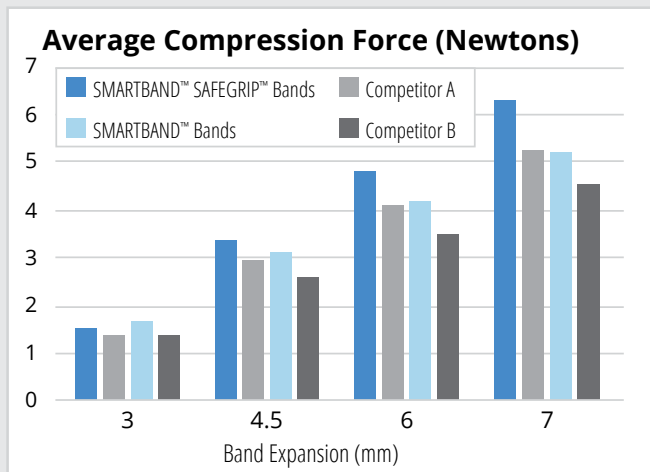
SMARTBAND™ Multi-Band Ligation System

Features & Benefits

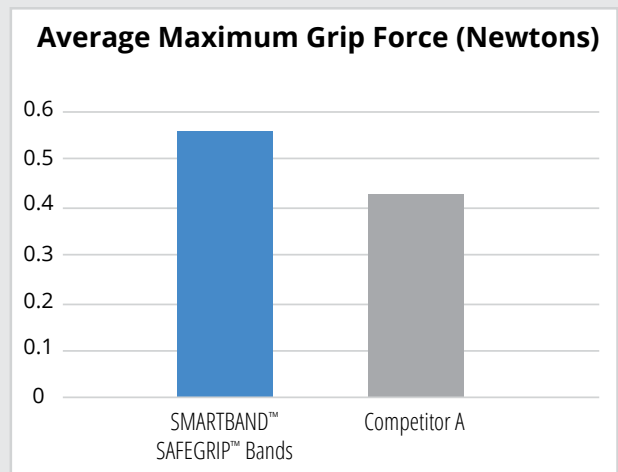
The **SMARTBAND Multi-Band Ligation System** is used to endoscopically ligate esophageal varices at or above the gastroesophageal junction and to ligate internal hemorrhoids.

The ligation bands are...

- Designed to deliver maximum tissue compression and gripping force.
- Manufactured and packaged to enable a 24-month shelf life.



SMARTBAND™ Ligation Bands delivered higher average compression forces than competition during third party testing¹



SMARTBAND™ SAFEGRIP™ Ligation Bands delivered 33% higher gripping force than competition during third party testing¹

1. Third party testing data on file.

SMARTBAND™ Multi-Band Ligation System

Features & Benefits

Features a universal connector that attaches the handle to the endoscope and is compatible with multiple endoscope styles



Offers a 10FR inner diameter handle stem that enables suction capabilities

Includes 6 backloaded bands on a clear, smooth barrel for visualization



Provides a dedicated flush port for clearing the working channel during the procedure.



The SMARTBAND™ Packs offer a reloadable barrel of bands for procedures that require more than 6 bands – helping to reduce costs.

SMARTBAND™ Multi-Band Ligation System			
Product Number	Description	Endoscope Diameter Compatibility (mm)	Unit of Measure
SLK6*	SMARTBAND™ Multi-Band Ligation kit - Components: Ligation Handle with Universal Connector, Loading device, Flush Tube, Pentax Adaptor, and Barrel with 6 Bands	8.6 - 11.6	EA
SLK6LF**	SMARTBAND™ SAFEGRIP™ Multi-Band Ligation Kit - Components: Ligation Handle with Universal Connector, Loading device, Flush Tube, Pentax Adaptor, and Barrel with 6 Bands	8.6 - 11.6	EA
SLP6*	SMARTBAND™ Multi-Band Ligation pack - Components: Deployment Cord with Barrel of 6 Bands	8.6 - 11.6	EA
SLP6LF**	SMARTBAND™ SAFEGRIP™ Multi-Band Ligation Pack - Components: Deployment Cord with Barrel of 6 Bands	8.6 - 11.6	EA

*This product is made with natural rubber latex.

**This product is not made with natural rubber latex.

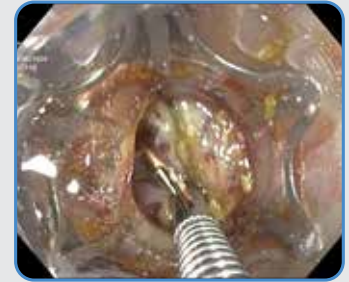
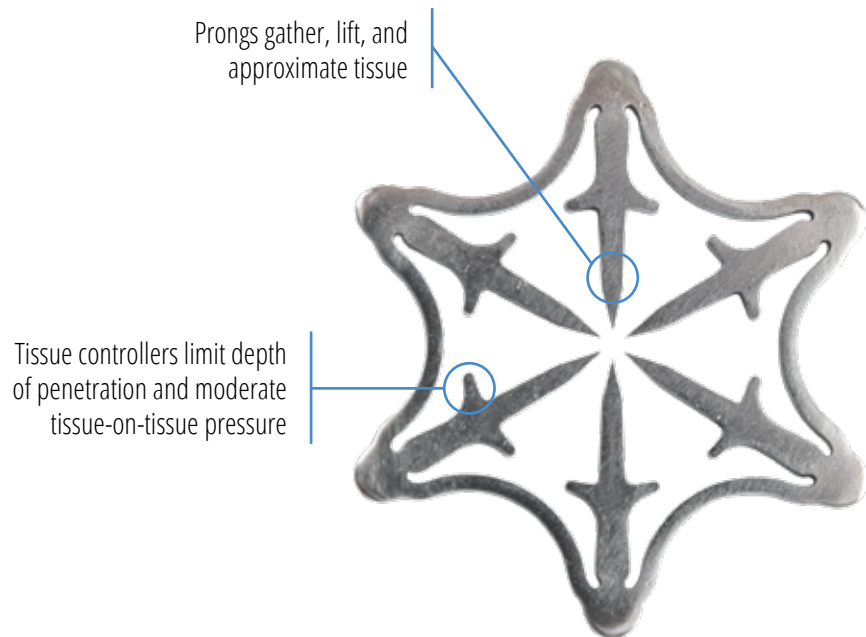
This device is supplied non-sterile and is disposable, single-use only.

PADLOCK CLIP™ Defect Closure System

Features & Benefits

The **PADLOCK CLIP Defect Closure System** facilitates effective full circumferential tissue closure.

- A pre-loaded, self-grasping clip designed to encircle, lift, close, and potentiate the healing of tissue defects
- Attachment to the outside of the endoscope
- Open and free instrument channel for endoscope suction
- “Push of the thumb” deployment
- May be used with the RAPTOR™ Grasping Device to aid tissue recruitment



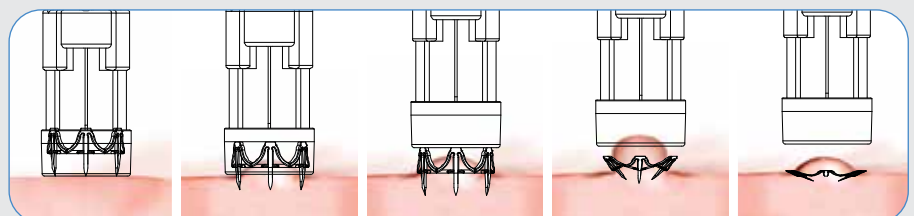
PADLOCK CLIP™ System used with RAPTOR™ Grasping Device to recruit tissue into tissue chamber.



PADLOCK CLIP™ System deployed on colonic EMR site.



The PADLOCK CLIP™ Defect Closure System is made of **flexible, super elastic alloy** and lays flat against the tissue, offering low profile radial compression.



PADLOCK CLIP™ Defect Closure System

Indications & Case Examples

The **PADLOCK CLIP Defect Closure System** is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of: Endoscopic marking of lesions, Closure of GI tract luminal perforations <20mm that can be treated conservatively, and Hemostasis for: Mucosal/Submucosal defects, Bleeding Ulcers, Arteries <2mm, Polyps <1.5cm in diameter, or Diverticula in the Colon. The hemostatic clip has successfully been used in the following clinical situations.

HEMOSTASIS CASES:

- **Rebleeding gastric ulcer** previously treated with epinephrine injection and bipolar cautery. Treated with PADLOCK CLIP System with no further rebleeding.²
- **Bleeding EMR site** successfully treated by the PADLOCK CLIP System and showed persistence of the PADLOCK CLIP System at 3 months follow-up.¹
- **Bleeding rectal ulcer** treated by the PADLOCK CLIP System, resulting in durable hemostasis.¹ Previous unsuccessful treatments included endoclipping and injective therapy.



1. Armellini E, Crinò SF, Orsello M, Ballarè M, Tari R, Saettone S, Montino F, Occhipinti P. Novel endoscopic over-the-scope clip system. World J Gastroenterol 2015; 21(48): 13587-13592.
2. Dr. Mark Prince: "PADLOCK CLIP Defect Closure System - Closure of a large gastric ulcer." Case Study 761675A - STERIS.
3. Dr. David Diehl: "PADLOCK CLIP Defect Closure System - Endoscopic closure of an accidental esophageal perforation during an EMR procedure." Case Study 761685A - STERIS.

PADLOCK CLIP™ Defect Closure System

Indications & Case Examples

FISTULA AND LEAKS:



FISTULA AND LEAK CASES:

- **Tracheo-esophageal fistula** closure with the PADLOCK CLIP System. Previous unsuccessful treatments included surgery, salivary bypass stenting, and endoscopic clipping.¹

PERFORATIONS:



PERFORATION CASES:

- **Esophageal perforation closure.** Perforation occurred during band EMR procedure. Patient was in good condition following the procedure.²

PADLOCK CLIP™ Defect Closure System

Product Number	Description	Length (cm)	Endoscope Distal Tip Diameter (mm)	Tissue Chamber Depth (mm)	Tissue Chamber I.D. (mm)	Housing O.D. (mm)	Units/Box
C910001	PADLOCK CLIP™ Defect Closure System	177	9.5-11	10	11	16	1
C913131*	PADLOCK CLIP™ PRO-SELECT™ Defect Closure System	177	11.3, 12.0, 12.5, 13.0, 13.5, 14.0	4, 8, 11, 13, 15, 19	11	19	1

* Ability to adjust tissue chamber depth based on scope diameter.



SCAN CODE
to view Dr. Diehl
case video.

1. Armellini E, Crinò SF, Orsello M, Ballarè M, Tari R, Saettoni S, Montino F, Occhipinti P. Novel endoscopic over-the-scope clip system. World J Gastroenterol 2015; 21(48): 13587-13592.
2. Dr. David Diehl: "PADLOCK CLIP Defect Closure System - Endoscopic closure of an accidental esophageal perforation during an EMR procedure." Case Study 761685A - STERIS.

PADLOCK CLIP™ Defect Closure System

Clinical Data

STUDY 1: “Novel endoscopic over-the-scope clip system”¹

No.	Age	Etiology	Clinical Condition	Previous Treatment	Treatment Outcome
1	61	Endoscopic mucosal resection	Delayed rectal bleeding	Endoclip, injective therapy	Persistent control of the bleeding
2	80	Solitary rectal ulcer	Rectal bleeding	Endoclip, injective therapy	Persistent control of the bleeding
3	85	Duodenal Dieulafoy lesion	Duodenal bleeding	Injective and thermal therapy	Persistent control of the bleeding
4	53	Mediastinal lymphoma	Broncho-esophageal fistula	Endoclip	New fistulas development
5	66	Post-laryngectomy radio-chemotherapy	Tracheo-esophageal fistula	Endoclip, salivary stent	Fistula healing

CONCLUSION: The new over-the-scope PADLOCK CLIP™ Defect Closure System seems to be simple to use and effective in different clinical settings, particularly in “difficult” scenarios, like recurrent bleeding and respiratory-esophageal fistulas.



STUDY 2: “First clinical experiences with a novel endoscopic over-the-scope clip system”²

No.	Age	Sex	Indication	Technical Success	Outcome	Previous Treatments	Follow-up Months
1	64	M	Rectovesical fistula	Yes	Complete sealing of the fistula. 30-day endoscopic follow-up: clip detached	Ovesco OTSC	7
2	64	M	Rectocutaneous fistula	Yes	Clinical resolution	Ovesco OTSC	8
3	63	M	Persistence of gastrocutaneous fistula after gastrostomy tube removal	Yes	Sealing of the fistula. 30-day endoscopic follow-up: clip detached	TTS clips	18
4	71	F	Closure of gastrocutaneous fistula after removal of infected gastrostomy tube	Yes	Resolution of infection: Sealing of the fistula. 30-day endoscopic follow-up: clip detached	-	5
5	75	F	Iatrogenic duodenal perforation following biliary stent migration	No	Technical failure of clip release. Gastrointestinal perforation was closed by two conventional TTS clips	-	2
6	86	F	Iatrogenic diverticular perforation during diagnostic colonoscopy after failure of conservative management	Yes	Closure of perforation at CT scan. Discharge 7 days after clip placement	Conservative management (6 days)	2
7	76	M	Post-polypectomy intraprocedural bleeding	Yes	Resolution of bleeding. No late rebleeding	Injection hemostasis	3
8	64	M	Post-polypectomy intraprocedural bleeding	Yes	Resolution of bleeding. No late rebleeding	-	10

CONCLUSION: The novel PADLOCK CLIP™ Defect Closure System seems to be an effective and safe tool to treat gastrointestinal fistulas, perforations or post-polypectomy bleeding.



1. Armellini E, Crinò SF, Orsello M, Ballarè M, Tari R, Saettoni S, Montino F, Occhipinti P. Novel endoscopic over-the-scope clip system. World J Gastroenterol 2015; 21(48): 13587-13592.
 2. Marco Dinelli, Barbara Omazzi, Paolo Andreozzi, Nicola Zucchini, Alessandro Redalli, Gianpiero Manes. First clinical experiences with a novel endoscopic over-the-scope-clip system. Endoscopy 2017; 49(04): 407-408.

PADLOCK CLIP™ Defect Closure System

GI Association Guidance on the Use of Over-the-Scope Clips

AGA

- **AGA Clinical Practice Update on Endoscopic Therapies for Non-Variceal Upper Gastrointestinal Bleeding: Expert Review**



Hemostasis using an over-the-scope clip should be considered in select patients with NVUGIB, in whom conventional electrosurgical coagulation and hemostatic clips are unsuccessful or predicted to be ineffective.



ESGE

- **Endoscopic Diagnosis and Management of Nonvariceal Upper Gastrointestinal Hemorrhage (NVUGIH): European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Update 2021**



ESGE recommends that for patients with clinical evidence of recurrent peptic ulcer hemorrhage, use of a cap-mounted clip should be considered.



ACG

- **ACG Clinical Guideline: Upper Gastrointestinal and Ulcer Bleeding**



We suggest over-the-scope clips as a hemostatic therapy for patients who develop recurrent bleeding due to ulcers after previous successful endoscopic hemostasis (conditional recommendation, low-quality evidence).



PERFORATIONS:

ESGE

- **Diagnosis and Management of Iatrogenic Endoscopic Perforations: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement**



ESGE recommends the use of TTS (through-the-scope) endo clips for small holes and OTSCs (over-the-scope clips) for larger ones.



1. Clinical Practice Update: "AGA Clinical Practice Update on Endoscopic Therapies for Non-Variceal Upper Gastrointestinal Bleeding: Expert Review." *Gastroenterology* 2020;159:1120–1128.
2. Gralnek Ian M et al. Endoscopic diagnosis and management of nonvariceal upper gastrointestinal hemorrhage (NVUGIH): European Society of Gastrointestinal Endoscopy (ESGE) Guideline Endoscopy 2021; 53: 300–332. European Society of Gastrointestinal Endoscopy.
3. Guideline: "ACG Clinical Guideline: Upper Gastrointestinal and Ulcer Bleeding." *The American Journal of GASTROENTEROLOGY*. 2021.
4. Paspatis G, Dumonceau JM, et al. "Diagnosis and management of iatrogenic endoscopic perforations: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement *Endoscopy* 2014; 46(08): 693-711 DOI: 10.1055/s-0034-1377531.

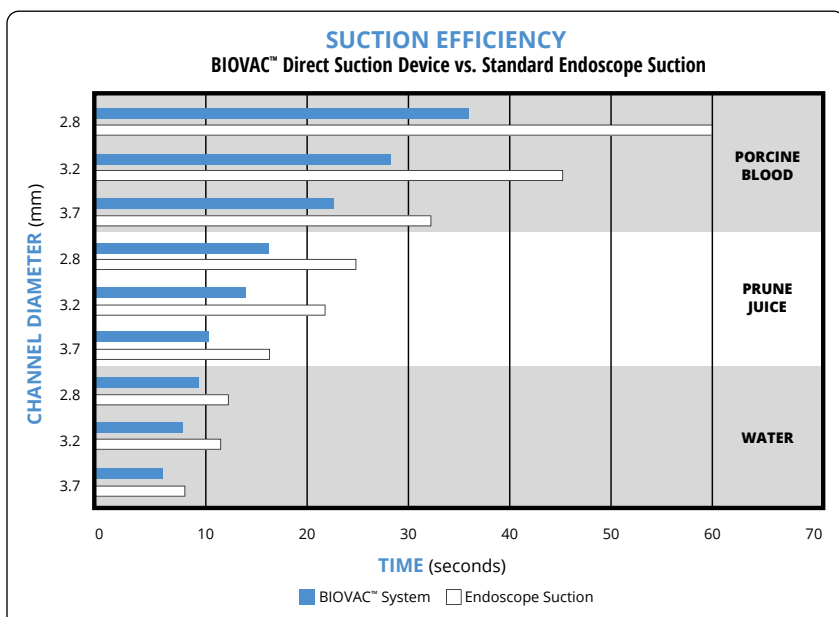
BIOVAC™ Direct Suction Device

Features & Benefits

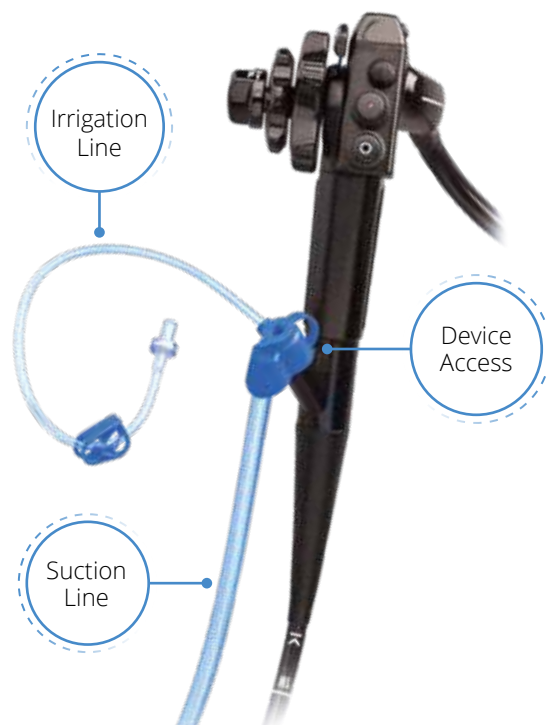
The **BIOVAC Direct Suction Device** is designed to suction hard-to-remove, viscous materials, like gelatinous blood and stringy clots¹, which may otherwise clog the control head of the endoscope. It allows for direct visualization during cleansing and evacuation by empowering the endoscope's own suction capabilities.

The BIOVAC Direct Suction Device offers...

- Suction capabilities, facilitating increased volume¹ and quick, powerful evacuation
- Instrument access, enabling the clinician to utilize suction capabilities as well as provide therapeutic treatment via the accessory channel
- Assistance in dealing with GI bleeds, colonic decompression, poor prep or retained residual food cases



Testing has demonstrated that BIOVAC™ Direct Suction Device can improve evacuation time by 24-40% vs. standard endoscope suction.²



WHITE PAPER:
"Can Endoscopic Suctioning Capabilities Be Improved?" states that there is a 24-40% reduction in evacuation time when using the BIOVAC™ Device. Scan QR code to view complete white paper.

BIOVAC™ Direct Suction Device					
Product Number	Description	Scope Compatibility	Device Access	Y-Port	Units/Box
BX00711511	BIOVAC™ Direct Suction Device	Pentax	Yes	no	5
BX00711512	BIOVAC™ Direct Suction Device	Olympus/ Fujifilm*	Yes	no	5
BX00711513	BIOVAC™ Direct Suction Device	Olympus/ Fujifilm*	Yes	Yes	5

* G5 Series or newer.

1. The size of particles and volume of liquid suctioned is limited to the endoscope's channel size.
 2. Data on file at STERIS.

Injection Therapy Devices

Portfolio Overview

STERIS offers a complete portfolio of dependable options to support your injection needs - from saline assisted polypectomy, esophageal varices, ulcers, and tattooing.

Features	Benefits	CARR-LOCKE Injection Needle	ARTICULATOR™ Injection Needle	FASTFLO™ Injection Needle
Teflon coated spring sheath and pre-load with stop at distal end	<ul style="list-style-type: none"> Helps to ensure consistent and full length needle projection every time Allows for smooth insertion down endoscope channel 	✓		
Stainless steel spring sheath	<ul style="list-style-type: none"> Minimizes sheath kinking especially during challenging procedures 	✓	✓	
Large inner diameter to facilitate injection of viscous solutions	<ul style="list-style-type: none"> Allows for high flow rate and low injection force during use 			✓
Smooth distal metal hub	<ul style="list-style-type: none"> Controls depth of needle insertion; reduces the risk of needle perforations Aids in tamponade 	✓	✓	✓
Luer lock, spring loaded handle	<ul style="list-style-type: none"> Automatically retracts needle to reduce risk of inadvertent needle sticks and/or scope damage 	✓	✓	
Requires less than 1cc of fluid to prime (most needles require 1.5-2.0cc)	<ul style="list-style-type: none"> Less expensive, particularly when using costly injection agents 	✓	✓	



Injection Needles						
Product Number	Description	Sheath Diameter (mm)	Length (cm)	Needle Projection (mm)	Needle Gauge	Units/Box
BX00711807	ARTICULATOR™ Injection Needle	2.5	230	5	25	5
BX00711808*	ARTICULATOR™ Injection Needle	2.5	350	5	25	5
BX00711810	ARTICULATOR™ Injection Needle	2.5	230	5	25	10
BX00711811	CARR-LOCKE Injection Needle	2.5	230	5	25	5
BX00711812	CARR-LOCKE Injection Needle	2.5	230	5	23	5
BX00711813	CARR-LOCKE Injection Needle (Pentax compatible)	2.5	230	5	25	5
BX00711814	CARR-LOCKE Injection Needle	2.5	230	4	23	5
BX00711822	CARR-LOCKE Injection Needle	1.8	230	5	25	5
BX00714000**	FASTFLO™ Injection Needle	2.4	230	4	21	10
BX00714001**	FASTFLO™ Injection Needle	2.4	230	4	23	10
BX00714002**	FASTFLO™ Injection Needle	2.4	230	4	25	10
BX00714004**	FASTFLO™ Injection Needle	2.4	230	6	25	10

* BX00711808 does not have the spring-loaded handle.

** not CE Certified.



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