

# EndoClot<sup>®</sup> Polysaccharide Hemostatic System and Submucosal Injection Solution

The clinical performance you expect driven by AMP<sup>®</sup> Technology to  
offer hemostasis flexibility and higher and longer lifts



# Product Overview

## EndoClot® PHS

### A Different Way to Approach Hemostasis

EndoClot Polysaccharide Hemostatic System (PHS) is an advanced powder hemostat that is applied during a procedure using controlled, consistent air pressure. It is intended for use in large and diffuse bleeds, such as those occurring in peptic ulcers, post-biopsy, polypectomy, tumor bleeding, post EMR and ESD. EndoClot PHS can be used together with other hemostatic techniques, such as clips.

EndoClot PHS can be applied directly to the targeted site without reducing visualization,\* to allow further therapies to continue during the procedure. If needed, EndoClot PHS can be easily irrigated and reapplied multiple times during the procedure as a hemostatic control device, without reducing visualization.

*Performing hemostasis within the GI tract is a technically demanding procedure and use of EndoClot PHS and associated devices may result in patient injury including but not limited to inflammatory reaction, bowel rupture and air embolism.*

### The EndoClot Air Compressor

The EndoClot Air Compressor provides consistent air pressure to propel powder to the bleeding site.

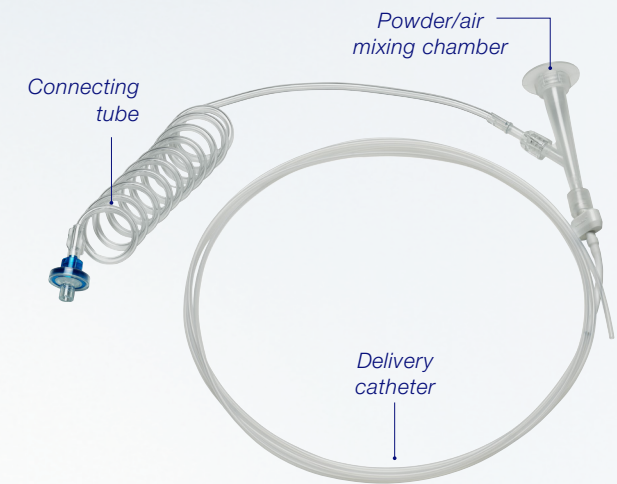
- A consistent flow of air helps prevent the catheter from clogging and creating a white out effect common with CO<sub>2</sub> propellant
- Small and portable so that it can be used anywhere
- Operates on rechargeable battery or A/C power



### Applicator

The applicator is comprised of a powder/air mixing chamber, a delivery catheter, and a connecting tube.

- Anti-reflux design to prevent occlusion
- Provides control of delivery
- Treats hard-to-reach bleeds in difficult procedures\*



### Hemostatic

Hemostatic powder composed of AMP® (Absorbable Modified Polymer) particles

- Indicated for use in oozing to moderate bleeding
- Product is safe to use\*
- Biocompatible
- Starch derived
- 100% absorbable
- Contains no animal or human components
- Hydrophilic
- Absorbs water from blood
- Causes high concentration of platelets, red blood cells and coagulation proteins
- Accelerates clotting cascade



\*data on file with Olympus® as of August 16, 2022



# Product Overview

EndoClot® PHS



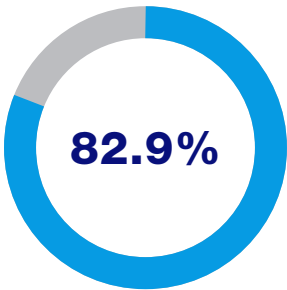
## Comparison of Hemospray® Hemostatic Powder and EndoClot PHS hemostatic powder for the Treatment of Gastrointestinal Bleeding<sup>1</sup>

### Main Outcomes

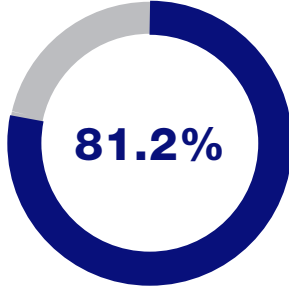
Allows for effective hemostasis with no differences in short term, long term success compared to Hemospray.

### Overall Short Term Success Rate

No statistically significant difference was observed for short term success (hemostasis for 72 h) between Hemospray and EndoClot under primary or salvage therapy.



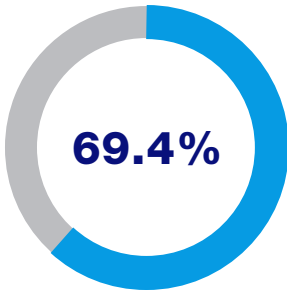
Hemospray



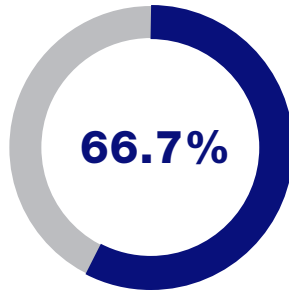
EndoClot

### Overall Long Term Success Rate

As with short term success, there was no statistically significant difference in long term success (hemostasis for a period of 30 days).



Hemospray



EndoClot

## Further Outcomes

### Success Rate in Upper GI

No statistically significant differences for achieving ST or LT hemostasis were detected between HS and EC.

#### Short Term Success



Hemospray



EndoClot

#### Long Term Success



Hemospray



EndoClot

### Success Rate in Lower GI

No statistically significant differences for achieving ST or LT hemostasis were detected between HS and EC.

#### Short Term Success



Hemospray



EndoClot

#### Long Term Success



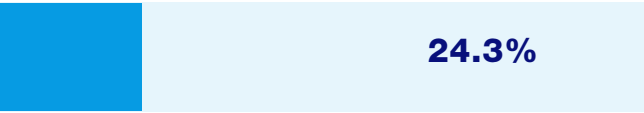
Hemospray



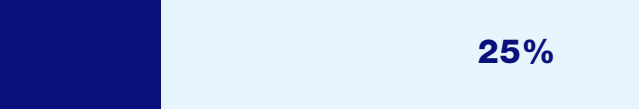
EndoClot

### Re-bleeding Rate

There was no statistically significant difference in re-bleeding rate defined as the number of the patients who showed recurrent bleeding among the patients who underwent follow-up.



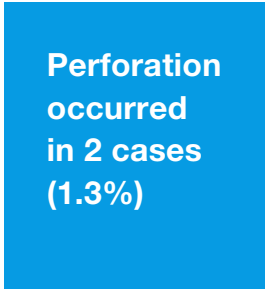
Hemospray



EndoClot

### Major Adverse Events (Complications)

There were no reports of major adverse events other than perforation. To be noted: The Hemospray group had a larger number of patients than the EndoClot group.



Hemospray



EndoClot

# Product Overview

EndoClot® SIS

## A longer and higher way to lift.

EndoClot Submucosal Injection Solution (SIS) is designed to deliver a long-lasting mucosal lift with higher elevation and easy delivery. SIS approaches lifting differently by being composed of Absorbable Modified Polymers (AMP®) derived from plant starch particles.

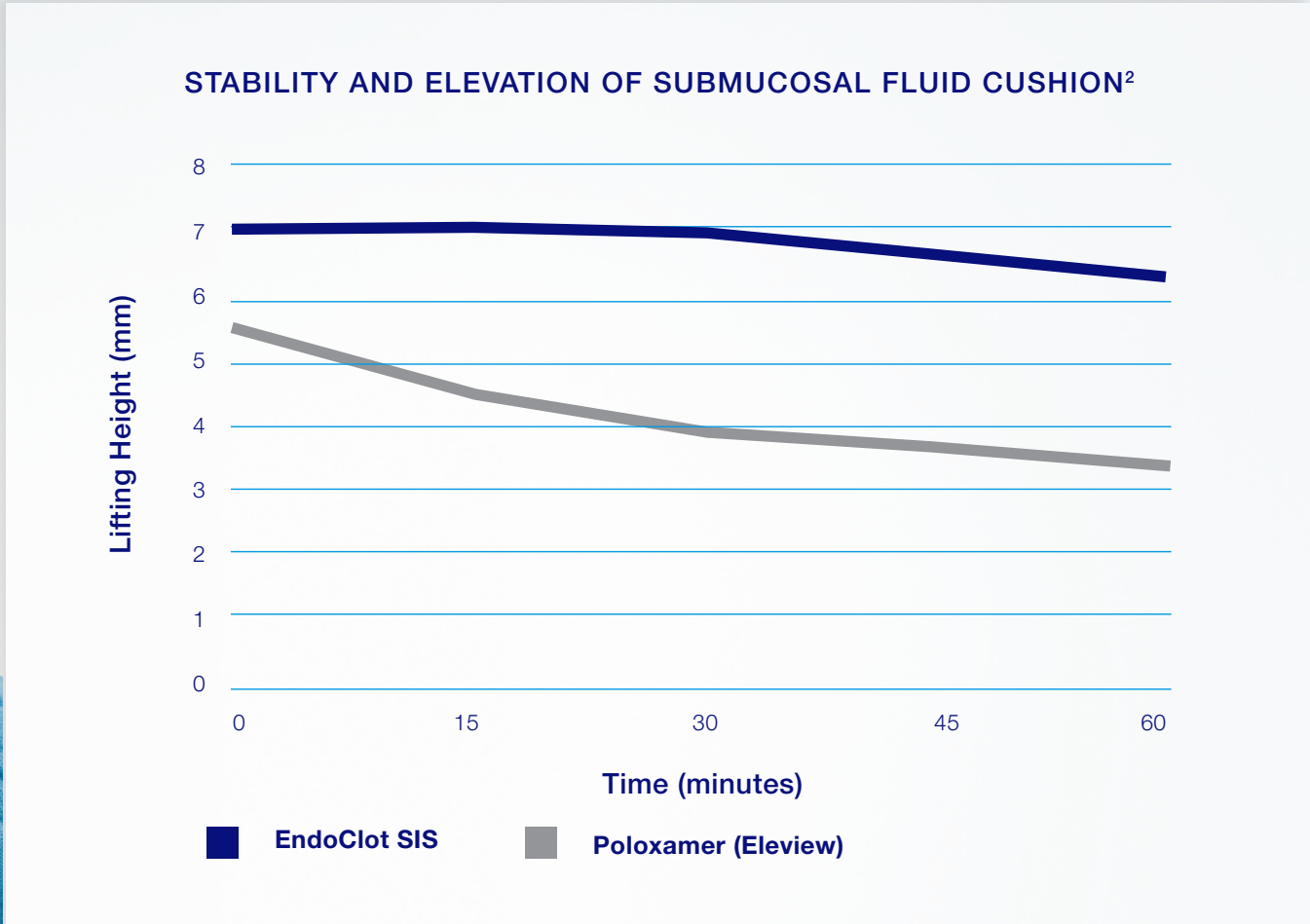
### Features and Benefits\*

- Pronounced Elevation**  
 SIS offers longer and higher lift compared to Eleview® Submucosal Injectable Composition\*
- Easier Dissection**  
 SIS offers a high lift which may create mucosal separation
- Ease of Delivery**  
 With a specifically designed spiral syringe, SIS can deliver to the targeted area accurately
- AMP Technology**  
 SIS uses the same proprietary AMP particles as EndoClot Polysaccharide Hemostatic System (PHS)
- Clean Pathology**  
 SIS does not leave artifacts that may cause abnormalities during pathological investigations

*Use of a lifting agent during EMR/ESD/POEM and difficult polypectomy and the associated devices may result in patient injury, bleeding and/or perforation.*




## A better workflow meets uncompromising performance



Based on animal data, SIS elevation is the highest immediately following injection

**32%** 

higher than Poloxamer (Eleview)

SIS maintained **89%** 

of original height after 60 minutes

\*data on file with Olympus® as of August 16, 2022



## Steps for ESD

### Procedural Steps

#### • Marking

Lateral safety margin is marked with coagulation points around the lesion. (See Figure 1.)

#### • Injection

Solution is injected to create a fluid cushion, elevating tissue to be resected away from the muscle layer.

#### • Incision

First incision is made outside one of the markings, deep enough to see the submucosal layer. This creates a point of access into the tissue and starts the circumferential cut. (See Figure 2.)

#### • Circumferential Cut

A circumferential cut around the perimeter of the lesion is made, just outside of the markings. At the end of the procedure, if the markings are visible on the resected tissue, it indicates the targeted area has been resected completely. (See Figure 3.)

#### • Dissection

Knife is guided through the submucosal space maintaining a cutting plane parallel to the muscle layer until the lesion is resected.

#### • Hemostasis

Blood vessels or active bleeding sites are coagulated during and after resection. (See Figure 4.)

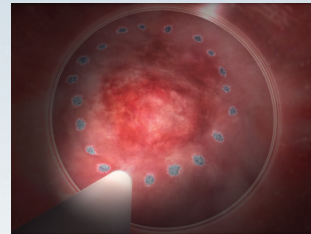


Figure 1

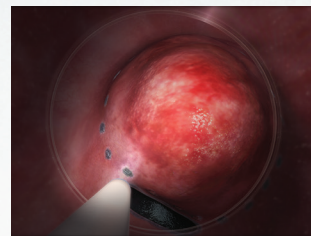


Figure 2

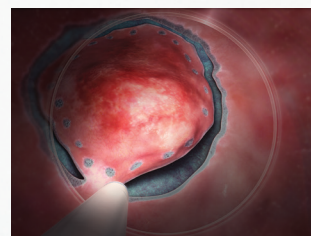


Figure 3

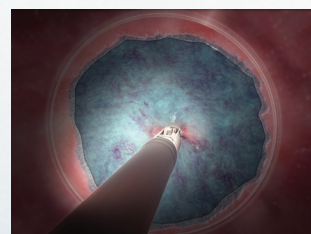
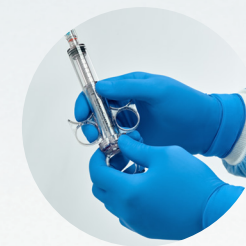


Figure 4

### Commonly Used Applications:



- POEM
- Difficult Polypectomy
- EMR
- ESD

*Use of a lifting agent during EMR/ESD/POEM and difficult polypectomy and the associated devices may result in patient injury, bleeding and/or perforation.*

*The EndoClot SIS solution is injected by rotating the plunger allowing the nurse or technician the ability to watch the endoscopic screen rather than the syringe.*

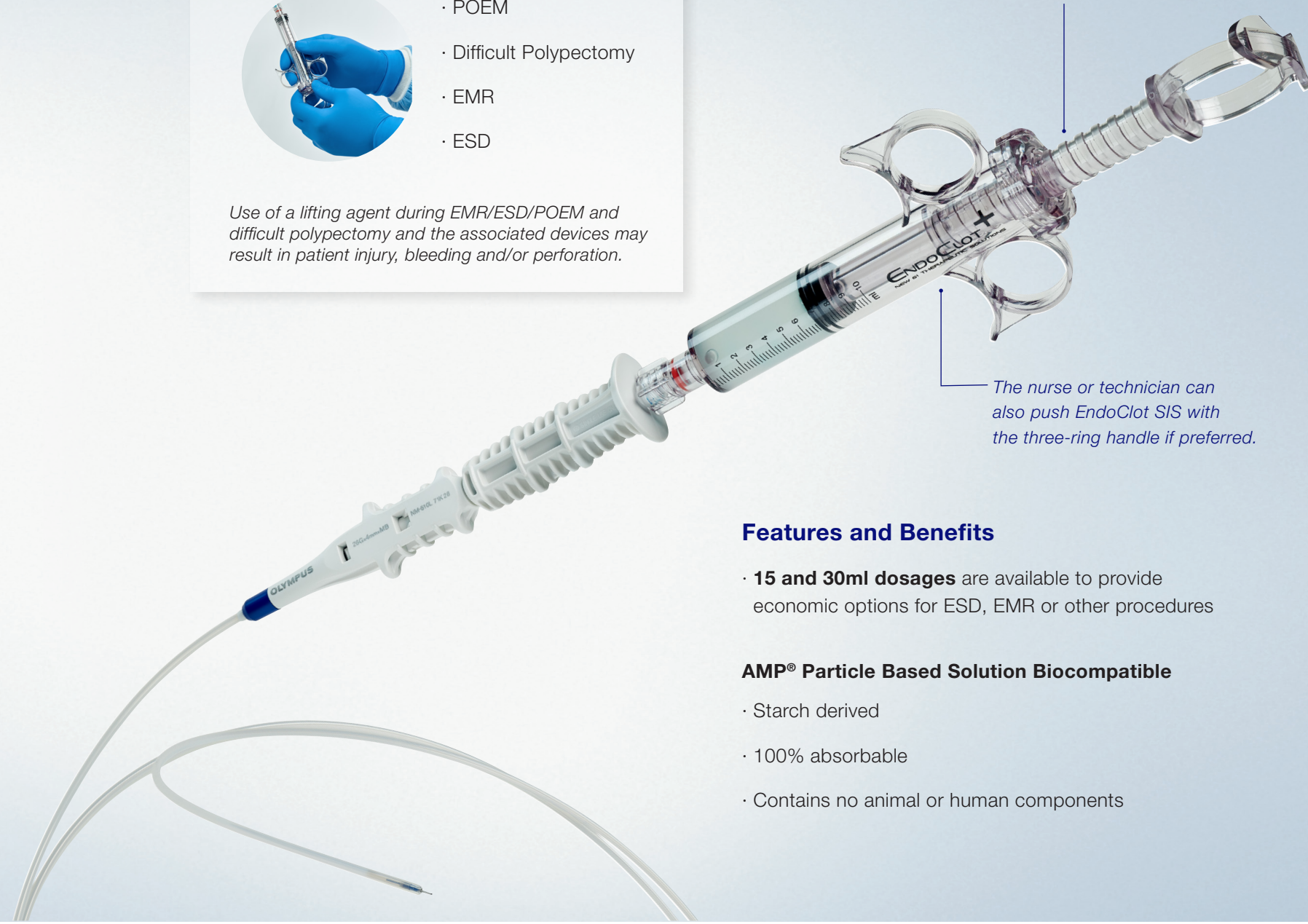
*The nurse or technician can also push EndoClot SIS with the three-ring handle if preferred.*

### Features and Benefits

- **15 and 30ml dosages** are available to provide economic options for ESD, EMR or other procedures

#### AMP® Particle Based Solution Biocompatible

- Starch derived
- 100% absorbable
- Contains no animal or human components



## The EndoClot® family of products are all based on the proprietary AMP® Technology. Derived from plant based starch particles to help improve the overall efficiency of GI procedures.

- EndoClot SIS is designed to deliver a long lasting mucosal lift with higher elevation and easy delivery.<sup>2</sup>
- EndoClot PHS is applied during a procedure using controlled, consistent air pressure. Indicated for use in oozing to moderate bleeding within the GI tract. It is indicated for use in combination with other conventional techniques, such as clips, for bleeding in difficult to reach locations and large bleeding areas. It can also be used to help reduce risks of re-bleeding.

### Ordering Information

#### EndoClot Submucosal Injection Solution (SIS) Specifications

Model #	Description	Packaging
SIS-15-01	EndoClot Submucosal Injection Solution (0.5 g AMP® powder & 1 syringe per unit)	5 units/box
SIS-30-01	EndoClot Submucosal Injection Solution (1 g AMP powder & 1 syringe per unit)	5 units/box

#### EndoClot PHS Order Codes

Product Code	Product Name	Description	Working Length	Minimum Channel	Packaging
EPK2303-01	EndoClot Polysaccharide Hemostatic System (EndoClot PHS) 3g	3 g AMP powder and a delivery applicator	230 cm	2.8	1 unit/box
EPK2305-01	EndoClot Polysaccharide Hemostatic System (EndoClot PHS) 5g	5 g AMP powder and a delivery applicator	230 cm	2.8	1 unit/box
EPAC-2	EndoClot Air Compressor	Reusable Air source for EndoClot PHS	N/A	N/A	1 unit/box
EA230	EndoClot Applicator	Spare delivery applicators for EndoClot PHS/Adhesive	230 cm	2.8	5 units/box
EPAC-1T	EndoClot Air Compressor Connecting Tube	Spare white silicon tube connects between the pump and applicator	N/A	N/A	10 units/box

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1. Vitali F, Naegel A, Atreya R, Zopf S, Neufert C, Siebler J, Neurath MF, Rath T. Comparison of Hemospray® and Endoclot™ for the treatment of gastrointestinal bleeding. World J Gastroenterol. 2019 Apr 7;25(13):1592-1602. doi: 10.3748/wjg.v25.i13.1592. PMID: 30983819; PMCID: PMC6452236. 2. Data on file with Olympus (MED201708154-57).

Manufactured by EndoClot Plus Co., Ltd.

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