# PuraStat®

- Acute GI Bleeds
- Entire GI tract
- Ready and easy to use
- Protective barrier
- Clear & transparent
- Reduces delayed bleeding
- Radiation proctopathy
- Controls intraprocedural bleeding


3-D MATRIX
MEDICAL TECHNOLOGY

# The Effectiveness of PuraStat®

**Injection of diluted adrenalin in the base of the lesion and then resection with a braided polypectomy loop**[1]

Figure 1: Obstructive sigmoid polyp.

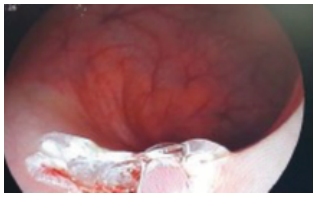


Figure 2: Application of PuraStat® over the bleeding scar

Resection with polypectomy loop[2]

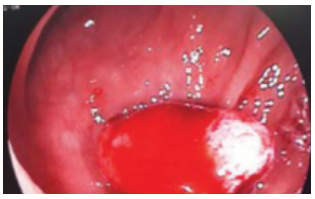


Figure 1: Bleeding polyp in left colon.

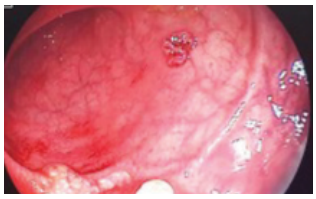


Figure 2: Hemostasis achieved after application of 2ml PuraStat®. There was no remaining active bleeding in the resected area.

*Source 1-2:* ***Dr. Víctor M Aguilar Urbano*** *Hospital El Ángel (Málaga), Spain*

**ESD for 4cm nodule**[3]

Figure 1: Barrett's intramucosal cancer.

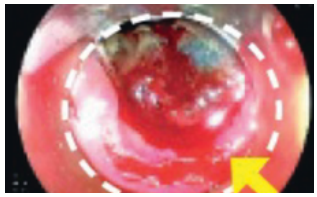


Figure 2: Bleeding during ESD. Yellow arrow indicates bleeding point. White dotted circle indicates resected area.

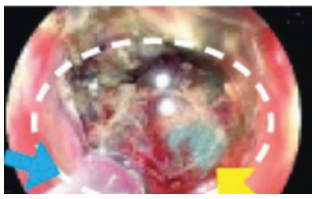
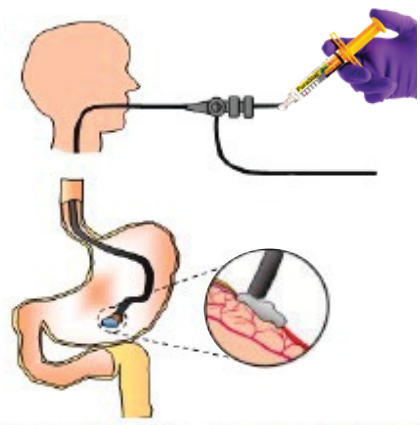


Figure 3: White dotted circle: transparent PuraStat® covered the bleeding site: Yellow arrow: bleeding point; Blue arrow: tip of the catheter.

Figure 4: Hemostasis achieved.

*Source 3:* ***Pradeep Bhandari, Professor*** *Queen Alexandra Hospital, Endoscopy Department Portsmouth, United Kingdom*

## Illustration of endoscopic application of PuraStat®



**Oozing bleed from tissue**
(parenchyma a/o blood vessels)

**Step 1**
Remove as much blood as possible from hemorrhagic site.

**Step 2**
Apply PuraStat® as close as possible to the bleeding point.

**Step 3**
Continue to apply PuraStat® by moving applicator until the product exceeds the margins of the lesion. When potentially re-applying; go through the already present material and apply PuraStat® as close as possible to the bleeding point. Practical experience suggests to work from distal to proximal (Prof. Bhandari). Note: PuraStat® in the lumen of the catheter can be pushed out by e.g. air.

**Hemostasis achieved**

## Advantages

**Transparent Hemostasis**
- Maintains clear sight of bleeding point

**Easy to Use**
- Single, pre-filled, ready-to-use syringe
- No preparation required
- Does not obstruct the applicator

**Flexibility**
- Suitable for endoscopic use
- Can be used in conjuction with sutures and cautery
- Applicable to narrow spaces
- Covers uneven surfaces well

**Synthetic Peptide**
- Inert material
- No risk of contamination

**Procedural Benefits**
- Reduces procedural time
- Easy to use
- Safe and effective
- Wider range of application

## Indications for Use

- of mild, moderate and **acute bleeding**
- Therapy for **intraprocedural** venous bleeding
- Prophylactic therapy to prevent **post procedural** bleeding
- Symptomatic **treatment** of rectal mucositis

## Feedback on PuraStat® Usage

*"We have incorporated Purastat into our therapeutic armamentarium for a variety of hemostatic indications, including topical application for management of post-sphincterotomy bleeding. Our third-space endoscopists are using it regularly in their practice."*

**Todd H. Baron, MD, MASCE**
*Director of Advanced Therapeutic Endoscopy*
*University of North Carolina at Chapel Hill*

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*"PuraStat has really been a gamechanger for us. From easibility of use, the nurses and techs love using it in endoscopy. It's something where, when you have a bleed, it's just something very easy to get, and use it on a variety of applications."*

**Reem Sharaiha, M.D., MSc**
*New York Presbyterian Weill Cornell*
*New York, New York*

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*"Post-ESD stricturing and delayed bleeding commonly occur following extensive circumferential ESD. PuraStat has been shown to reduce the rate of delayed bleeding by forming a synthetic scaffold, mimicking the human extracellular matrix. This mechanism may allow for early healing and reduce structuring associated with extensive resection."*

**Meir Mizrahi, M.D.**
*HCA Florida Largo Hospital*
*Largo, Florida*

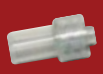
## Economic Benefit = Cost Effective

- Significant time savings during procedures
- Potential cost savings over current modalities
- Strong safety profile to reduce procedural risk and potencially reducing lenght of stay

## PuraStat® Ordering Information

Email **purastat@3dmatrix.com** or call **855.4.3DM.MED (855.433.6633)**


PuraStat – 3ml: 621-062
*1 box = 10 eaches*



Syringe Adapter: 001-099
1 box = 10 eaches

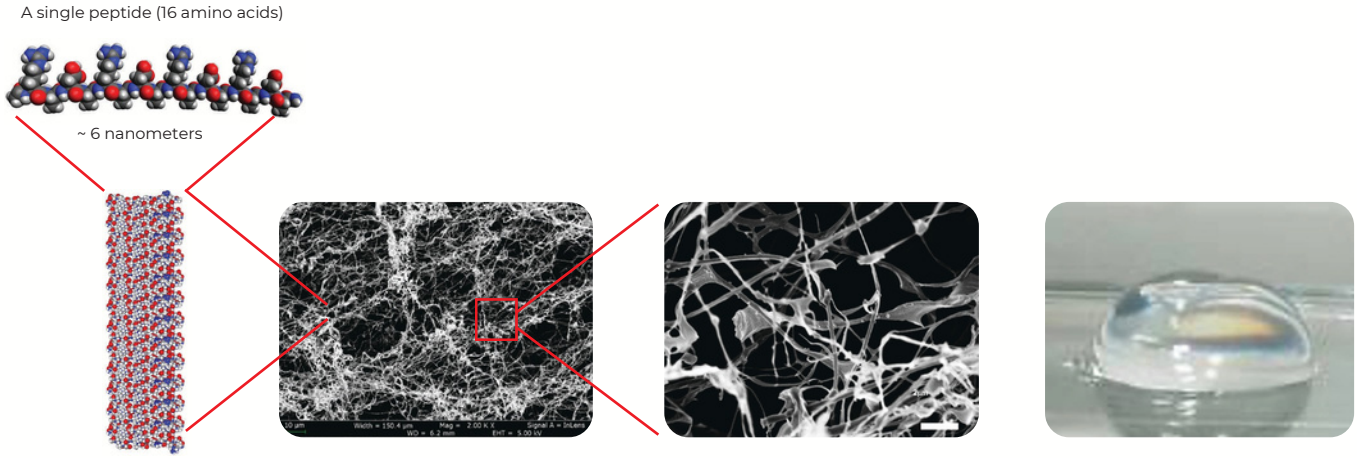
Spray Catheter: WP-18/2200
*Micro-Tech* 1 box = 20 eaches

# The Science behind PuraStat®

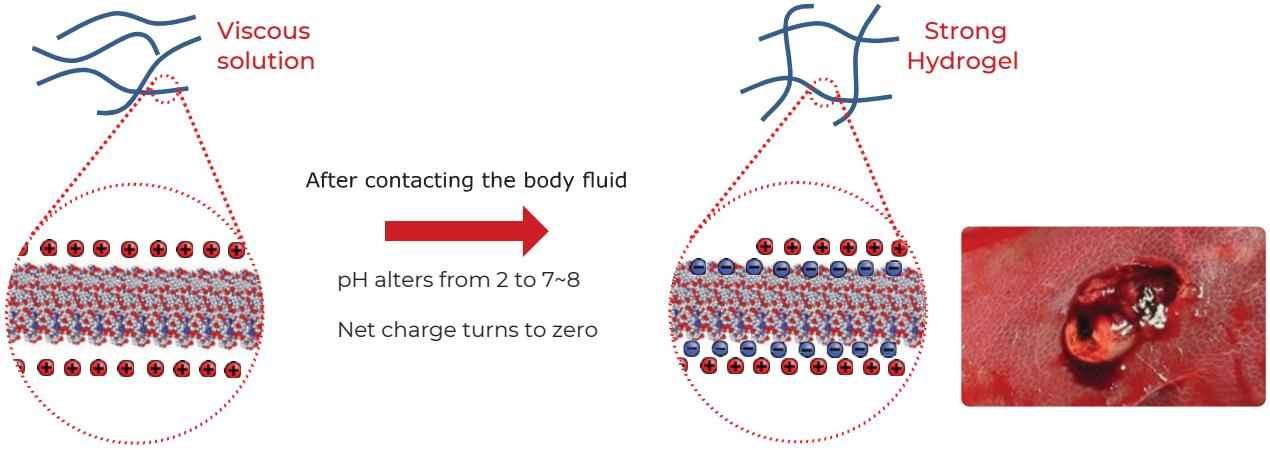
- PuraStat is composed of only two components: 2.5% peptide (RADA16) and 97.5% purified water
- The peptide in PuraStat® is chemically synthesized; no risk of disease transmission and no concerns regarding lot-to-lot variability unlike other biomaterials from animal or human
- The peptides assemble into nanofibers that are smaller than visible light wavelength, so it applies clear and remains transparent
- PuraStat® in a syringe is acidic (pH 2), but upon contact with physiological fluis is immediately neutralized to form a strong and clear hydrogel

## Self-Assembly of RADA16 to nanofibers

- In a liquid state, the peptides self-assemble to nanofibers ionic bond
- The nanofibers are entangled similar to collagen creating an extracellular matrix (ECM) like environment
- This peptide solution is slightly viscous but flows easily




## Gelation in the Body




Before application, positively charged RADA16 nanofibers flow due to weak assembly and electro-repulsion between the nanofibers

After contacting bodily fluid, net charge of RADA16 nanofibers turns to zero resulting in stronger assembly and physical cross-linking between the nanofibers

3-D MATRIX MEDICAL TECHNOLOGY
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