



PuraStat[®]

Clear haemostatic control

Experience in
Gastrointestinal Procedures

The **first haemostat** approved
to **reduce delayed bleeding**,
following ESD in the colon



 3-D MATRIX
MEDICAL TECHNOLOGY

Introduction

PuraStat® fits requirements for a haemostat in endoscopy well and enables **precise work in a narrow space**. It is inert, transparent, deliverable through endoscopic applicator, non-adhesive and not clogging.

"In addition to its efficacy in stopping bleeding, we found more advantageous properties of PuraMatrix, especially during endoscopic surgery. First, PuraMatrix* is a clear material. It does not block the field of view, which is particularly important during endoscopic surgery. Second, PuraMatrix is applied as a solution and only gelsates when in contact with body fluids, making it easy to apply. Good haemostasis was obtained without blocking the field of view"* ⁽²⁾

"PuraMatrix may be a useful alternative to existing haemostatic agents and may improve safety both during surgery for rectal cancer and in the field of endo-surgery in the future" ⁽²⁾

*PuraStat is the tradename of PuraMatrix

Situations Where PuraStat Has Added Value

Recto-Sigmoid- and Colon Polyp Resection

Situation

- Post polypectomy bleeding is the most common complication of colonic polypectomy occurring in 0.3 to 6.1% of polypectomies in various reports ⁽³⁾
- As the complexity of polypectomy increases, a higher risk of adverse events is reported ⁽⁴⁾
- With scarred polyps in the right colon there is a very high risk of bleeding because the scarring causes neovascularization
- Polypectomy in rectum has high risk of post-operative bleedings.

Why PuraStat?

- PuraStat does not compromise endoscopic views after application as compared to other spray powders. This allows endoscopist to apply additional haemostatic therapy if necessary ⁽⁵⁾
- PuraStat can be used in combination with electro-surgical coagulation forceps and clips. Both can be used even after application of PuraStat
- PuraStat is easy to deliver and to handle
- Hemospray is registered for upper GI bleeding ⁽⁶⁾.

Duodenal EMR (Endoscopic Mucosal Resection)

Situation

- Duodenal lesions not involving the major duodenal papilla can be removed with a variety of EMR techniques, but carries an increased risk of bleeding and perforation because the duodenum has increased vascularity and a thin wall ⁽⁷⁾
- Standard therapy for haemostasis control such as electrocautery introduces thermal injury to the wall and carries the risk of perforation
- The risk of later bleeding in this cases is more than 20%.

Why PuraStat?

- PuraStat is suitable to use in delicate/hard to reach areas since it is "fluid" and can flow into tiny niches, even between placed clips
- The transparency of PuraStat maintains a clear view and full control, thereby increasing accuracy
- PuraStat can be used in combination with e.g. clips to deal with the remaining oozing bleeds where placing an additional clip is not possible.

References:

- (1) PuraStat IFU-002 Rev 2.2
- (2) Kondo Y, Nishizaki M, Nagasaka T, Fujiwara T. Puramatrix is a new and useful hemostat in endoscopy surgery. Surg Endosc (2012) 26:S53-S140. P325-Technology S126.DOI 10.1007/s00464-012-2199-2
- (3) Wayne, D.J. Bleeding after colonic polypectomy. <http://cursoenarm.net/UPTODATE/contents/mobipreview.htm?5/2/5152?source=HISTORY>
- (4) Chukmaitov A., MD, PhD., Bradley C.J., PhD, Dahman B., PhD, Siangphoe U, MS, Warren J.L., PhD., Klabunde Carrie N., PhD. Association of polypectomy techniques, endoscopist volume, and facility type with colonoscopy complications. Gastrointest Endosc. 2013 March ; 77(3): 436-446. doi:10.1016/gie.2012.11.012
- (5) Bhandari P., Queen Alexandra Hospital, Endoscopy Department, Portsmouth, United Kingdom. Experience of PuraStat during resection of a large circumferential, recto-sigmoid polyp. Gastrointestinal case report vol 1. CR GI 001 EU EN v2 2019 06 06
- (6) Cook Medical, Hemospray IFU, 2015
- (7) ASGE Technology status evaluation report: EMR, https://www.asge.org/docs/default-source/education/Technology_Reviews/doc-endoscopic_mucosal_resection_aip.pdf?sfvrsn=

Barrett's Esophagus ESD (Endoscopic Submucosal Dissection)

Situation

- Barrett's tumors are well vascularized
- Submucosal oozing and bleeding are likely to occur
- Maintaining a clear view during the procedure is important to assure accuracy
- ESD takes a longer time than EMR because a lot of time is spent controlling bleeding vessels and oozing encountered during the submucosal dissection ⁽¹⁾.

Why PuraStat?

- Usage of PuraStat can make Barrett's ESD safer by reducing the need for coagulation current on the esophageal ESD base ⁽²⁾
- The oozing type of bleeding which often occurs at the resection sites are very well treated with PuraStat
- For haemostasis, value of PuraStat is that it can slow stronger bleeds down even if it cannot stop it immediately; this gives doctor time to put devices down the endoscope, and provide clear sight to use device safely. When there is a pool of blood and the point of bleeding is not clear, this is when people make mistakes and damage may be caused ⁽³⁾.

Gastric EMR (Endoscopic Mucosal Resection)

Situation

- The major risks of these techniques are perforation and bleeding. Haemorrhage is the most common complication of EMR and has been reported in 0.7–24% of cases ⁽⁴⁾
- However, if the response to this bleeding is inappropriate, it can affect the patient's haemodynamic status, leading to further complications requiring transfusion, interventional radiology (IVR), or surgery. Accordingly, the appropriate management of bleeding during the procedure is extremely important for the safe performance of ESD and EMR of gastric cancers ⁽⁵⁾.

Why PuraStat?

- Ready-to-use, no preparation required
- PuraStat is easy to apply during endoscopic procedures and it does not clog the lumen of the applicator or endoscope
- PuraStat does not block the field of view, which is particularly important during endoscopic surgery
- The ability to use PuraStat at the beginning, middle and end of the procedure is an advantage
- Second application of PuraStat is possible and easy.

Angiodysplasia in Colon: Argon Plasma Coagulation

Situation

- Angiodysplasia lesions are probably responsible for 6.0% of cases of lower gastrointestinal (GI) bleeding ⁽⁶⁾
- Lesions in the large bowel occur most often in the right colon ⁽⁶⁾
- After ablation, there may be residual oozing in the affected area
- The risk of rebleeding is a considerable problem ⁽⁷⁾
- In case of secondary angiodysplasia, e.g. due to prostatic cancer treatment: patient with co-morbidities may be more sensitive to any amount of bleeding.

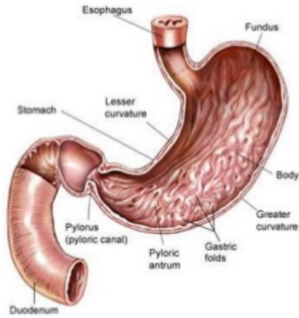
Why PuraStat?

- PuraStat covers well uneven surface
- PuraStat works also in patients with prolonged prothrombin time ⁽⁸⁾
- Transparency of PuraStat maintains a clear view and full control, increasing accuracy and allows checking the efficacy of the application
- As to visibility "A technical challenge associated with all 3 of the haemostatic powders is that by applying them early on in the procedure, the endoscopist may lose his or her landmarks and, thus, not be able to perform additional treatment ⁽⁹⁾".

References:

- (1) Bhandari P. Queen Alexandra Hospital, Endoscopy Department, Portsmouth, United Kingdom. The State of The Art Lecture: Bleeding management. Innovative hemostatic concept PuraStat. Hemostatic Agent During Endoscopic Resection. PuraStat Evening Symposium. 2016; May at DDW. BR GI 001 EU EN V4 2019 07 09
- (2) Bhandari P. Queen Alexandra Hospital, Endoscopy Department, Portsmouth, United Kingdom. Haemostasis with PuraStat during ESD/EMR procedure. Gastrointestinal case report vol 2. CR GI 002 EU EN v2 2019 06 06
- (3) Data on file (Bhandari P. Portsmouth Hospital, United Kingdom. Clinical Use Record GI26, 2015 05 27)
- (4) Gallegos-Orozco J.F., MD., Gurudu S.R., MD. Complex Colon Polypectomy. Gastroenterology & Hepatology. Volume 6, Issue 6 June 2010
- (5) Ono H., Yao K., Fujishiro M., Oda I., Nimura S., Yahagi N., Iishi H., Oka M., Ajioka Y., Ichinose M., Matsui T. Guidelines for endoscopic submucosal dissection and endoscopic mucosal resection for early gastric cancer. Digestive Endoscopy. 2016; 28: 3–15. doi: 10.1111/den.12518
- (6) Gregory F.P. Angiodysplasia of the Gastrointestinal Tract. American Journal of Gastroenterology . Jun1993, Vol. 88 Issue 6, p807-818. 12p.
- (7) Sharma R., MD, Gorbien J.M., MD. Angiodysplasia and Lower Gastrointestinal Tract Bleeding in Elderly Patients. Author Affiliations Arch Intern Med. 1995;155(8):807-812. doi:10.1001/archinte.1995.00430080037005
- (8) Masuhara H, Fujii T, Watanabe Y, Koyama N, Tokuhira K. Novel infectious agent-free hemostatic material (TDM-621) in cardiovascular surgery. Ann Thorac Cardiovasc Surg. 2012;18(5):444-51. Epub 2012 Sep 14. PMID: 22986759
- (9) Barkun A., MD. New Topical Hemostatic Powders in Endoscopy. Gastroenterol Hepatol (N Y). 2013 Nov; 9(11): 744–746. PMID: PMC3995198

Prepyloric GIST (Gastrointestinal Stromal Tumor) Enucleation



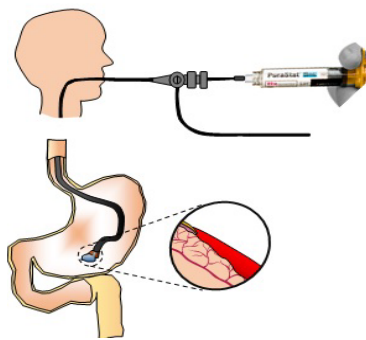
Situation

- Gastrointestinal stromal tumor (GIST) is the most common mesenchymal tumor of the human gastrointestinal tract ⁽²⁾
- The enucleation method for GIST has a high risk of perforation because GIST originates from a proper muscle layer and deeper dissection is necessary for the complete dissection ⁽³⁾
- The principles of surgical treatment for primary resectable GIST are complete resection without causing tumor rupture and to acquire negative margins.

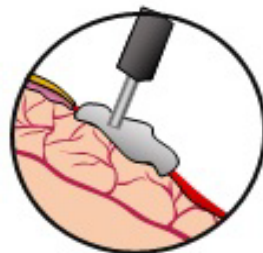
Why PuraStat?

- PuraStat may be used throughout the entire duration of the procedure without effect on visibility of structures in the surgical field, or the material becoming hard or delivery cannula blocked
- Transparency of PuraStat maintains a clear view and full control, increasing accuracy
- Can be used repetitively during the same procedure
- PuraStat is inert and it is broken down to its constituent amino acids that will be absorbed over time although some residue may remain for longer than 30 days ⁽¹⁾.

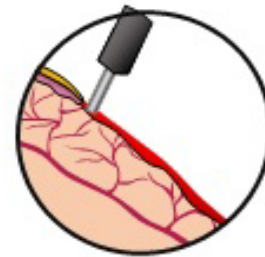
Illustration of endoscopic application of PuraStat



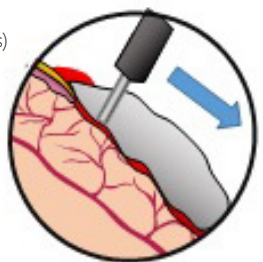
Oozing bleed from tissue (parenchyma a/o blood vessels)



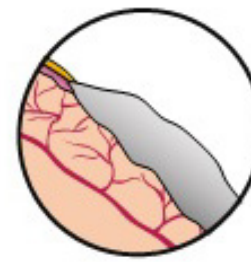
Step 1: Remove as much blood as possible from haemorrhagic site.



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.



Haemostasis achieved.

For application within gastro-enterology, PuraStat is indicated ⁽¹⁾ for

- Achieving haemostasis in bleeding from small blood vessels and oozing from capillaries of the GI tract following surgical procedures [when haemostasis by ligation or standard means is insufficient or impractical]
- Reduction of delayed bleeding following gastrointestinal endoscopic submucosal dissection (ESD) procedures in the colon.

References:

- (1) PuraStat IFU-002 Rev 2.2
 (2) Kitamura Y, Hirota S, Nishida T. Gastrointestinal stromal tumors (GIST): A model for molecule-based diagnosis and treatment of solid tumors. Cancer science. 2003 Apr;94(4):315-20. DOI: 10.1111/j.1349-7006.2003.tb01439.x
 (3) Kong S.H., Yan H.K. Department of Surgery, Cancer Research Institute, Seoul National University College of Medicine, Seoul, Korea. Surgical Treatment of Gastric Gastrointestinal Stromal Tumor. J Gastric Cancer. 2013 Mar; 13(1): 3-18. http://dx.doi.org/10.5230/jgc.2013.13.1.3

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