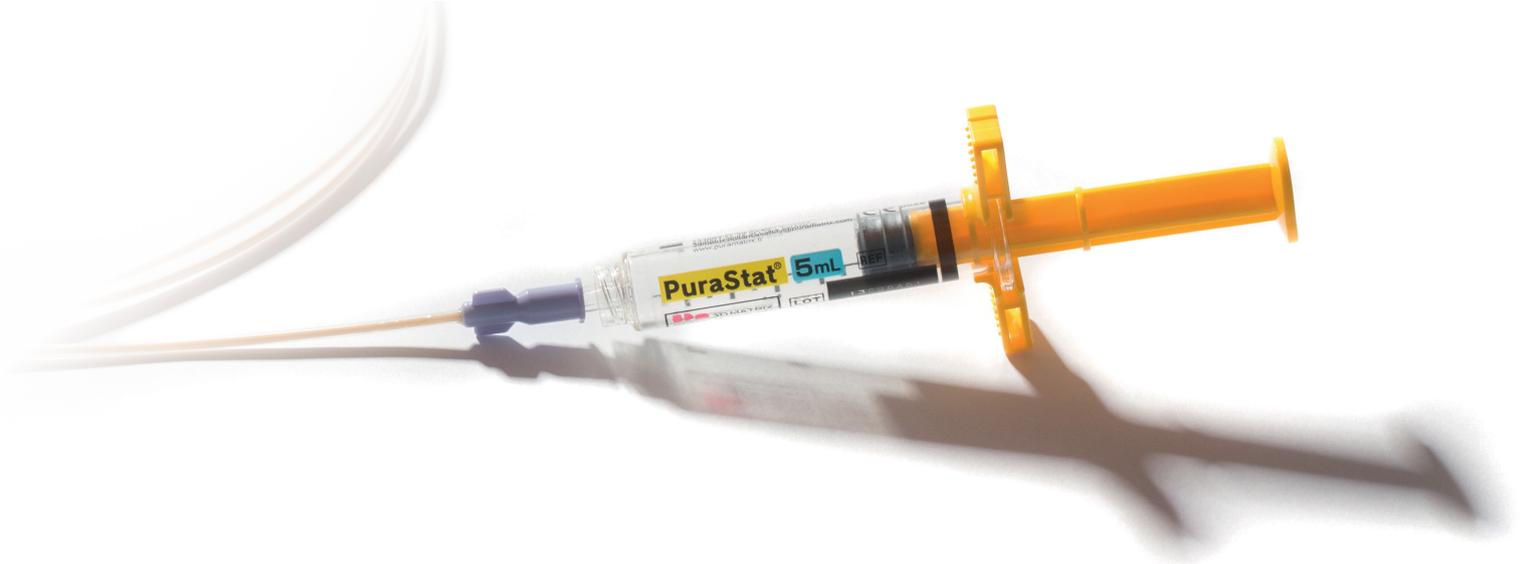




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# Key Studies on the Use of PuraStat for Gastrointestinal Procedures



 3-D MATRIX  
MEDICAL TECHNOLOGY

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## Haemostasis and the prevention of delayed bleeding



JP, 2014

Initial clinical trial of a novel hemostat, TDM-621, in the endoscopic treatments of the gastric tumors

*Yoshida M, Goto N, Kawaguchi M, Koyama H, Kuroda J, Kitahora T, Iwasaki H, Suzuki S, Kataoka M, Takashi F, Kitajima M*

**Aim:** To assess the feasibility of the self-assembling peptide (TDM-621) in haemostasis of the bleeding after endoscopic treatments of the gastric tumours.

**Summary:** N=12. Primary endpoint was the haemostatic effect. The operability was "very easy" in two patients, "easy" in eight patients, "acceptable" in two patients.

**Conclusion and key messages:** No secondary haemorrhage or adverse events. Haemostasis was feasible after endoscopic treatments of gastric tumours.



FR, 2016

**A self-assembling matrix-forming gel can be easily and safely applied to prevent delayed bleeding after endoscopic resection (\*)**

*Pioche M, Camus M, Rivory J, Leblanc S, Lienhart I, Barret M, Chaussade S, Saurin JC, Prat F, Ponchon T*

**Aim:** To assess the safety and efficacy of the self-assembling peptide (SAP) in preventing delayed bleeding after endoscopic resections.

**Results:** N=56 with 65 lesions. PuraStat applied immediately after resection to cover the whole ulcer bed. No adverse events.

**Conclusion:** The use of PuraStat may help to reduce post-endoscopic resection bleedings including high risk patients. PuraStat is easy and safe to use.



UK, 2019

**Haemostasis and prevention of bleeding related to ER: the role of a novel self-assembling peptide (\*)**

*Subramaniam S, Kandiah K, Thayalasekaran S, Longcroft-Wheaton G, Bhandari P*

**Aim:** To investigate the haemostatic efficacy and the use of PuraStat for the prevention of delayed bleeding.

**Summary:** N=100 (ESD=79 cases, EMR=21 cases). Procedures: 48 oesophageal, 31 gastric, 10 duodenal. Mean lesion size 3.7 cm. Intraprocedural bleeding (IPB) occurred in 64 % of cases.

**Conclusion and key messages:** PuraStat is an effective haemostat in 75 % of bleeds (EMR/ESD cases). Works best in mild to moderate bleeds. Low rate of delayed bleeding (3 %) in high-risk cohort patients, No delayed bleeding in colon or duodenum recorded. Safe, easy to use and did not interfere with the procedure.



UK, 2020

**Tu1020 Outcomes From the UK PuraStat registry - a multicentre prospective observational study to evaluate the role of PuraStat in the management of gastrointestinal bleeding (POPS) (\*)**

*Arndtz S, Subramaniam S, Hossain E, Abdelrahim M, Ang YS, Beintaris I, Di Pietro M, Iacucci M, Saunders B, Suzuki N, Bhandari P*

**Aim:** To evaluate the efficacy of PuraStat as a haemostatic agent when used in the prevention and treatment of gastrointestinal (GI) bleeding.

**Summary:** 6 centres across the UK, 141 procedures across 4 endoscopic indications (upper GI bleeds, radiation proctopathy, high-risk endoscopic therapy, delayed iatrogenic bleeds).

**Conclusion and key messages:** PuraStat is safe and effective for a range of indications, with most experience within high-risk therapy. High efficacy in immediate haemostasis, low risk for delayed bleeding. No complications.



UK, 2020

**A novel self-assembling peptide for hemostasis during endoscopic submucosal dissection: a randomized controlled trial (\*)**

*Subramaniam S, Kandiah K, Chedgy F, Fogg C, Thayalasekaran S, Alkandari A, Baker-Moffatt M, Dash J, Lyons-Amos M, Longcroft-Wheaton G, Brown J, Bhandari P*

**Aim:** To assess the reduction in the use of heat therapy for intraprocedural bleeding during endoscopic submucosal dissection when PuraStat is used as a haemostat. Secondary aim was to compare the procedure length, time to haemostasis, delayed bleeding rate, adverse events and wound healing.

**Summary:** N=101. Patients were randomised to the control group where diathermy was used to control bleeding or to an interventional group where PuraStat could be used.

**Conclusion and key messages:** PuraStat reduces the need for cautery by 50 % for IPB during ESD. It is an effective haemostat (92.6 % efficacy in mild-moderate GI bleeds). There were no significant differences in the procedure length, time for haemostasis, and delayed bleeding rate between the groups. At four weeks, 75 % of patients in PuraStat group showed either complete wound healing or scarring, compared with 54 % of patients in control group.

## Acute GI bleeds / Upper GI bleeds



IT, 2020

Efficacy of a novel self-assembling peptide hemostatic gel as rescue therapy for refractory acute gastrointestinal bleeding (\*)

*de Nucci G, Reati R, Arena I, Bezzio C, Devani M, Corte CD, Morganti D, Mandelli ED, mazzi B, Redaelli D, Saibeni S, Dinelli M, Manes G*

**Aim:** To demonstrate the ease of use, safety and efficacy of PuraStat to control acute upper and lower gastrointestinal bleeding, following failure of conventional methods.

**Summary:** N=77 (41 upper bleeds, 36 lower bleeds). There were 13 spurting bleeds, 64 oozing bleeds. 50 patients had iatrogenic bleeding, 27 patients had non iatrogenic bleeding. No adverse events.

**Conclusion and key messages:** High haemostasis (90.1 %), low rebleed rate (10.4 %).



DE, 2021

PuraStat in gastrointestinal bleeding: results of a prospective multicentre observational pilot study (\*)

*Branchi, F., Klingenberg-Noftz, R., Friedrich, K., Bürgel, N., Daum, S., Buchkremer, J., Sonnenberg, E., Schumann, M., Treese, C., Tröger, H., Lissner, D., Epple, H. J., Siegmund, B., Stroux, A., Adler, A., Veltzke-Schlieker, W., Autenrieth, D., Leonhardt, S., Fischer, A., Jürgensen, C., ... Bojarski, C*

**Aim:** To evaluate the feasibility, safety, efficacy, and indication profiles of PuraStat during acute gastrointestinal bleeding, in a clinical setting

**Summary:** N=111, primary and secondary application of PuraStat was evaluated. Primary use in 71 % of cases, with 94 % success to manage bleeding. Secondary use in 29 % cases, with 75 % success to manage bleeding. Rebleeding rate at day 7 follow up was 12 % and at day 30 follow up was 16 %.

**Conclusion and key messages:** Safe to use, no complications as a primary or secondary therapy. Could serve as a bridge to surgery in order to achieve temporary haemostasis in case of refractory severe bleeding, possibly playing a role in prevention of immediate emergency surgery.



IT, 2022

Novel hemostatic gel As rescue therapy for postsphincterotomy bleeding refractory to self-expanding metallic stent placement

*Gagliardi M, Oliviero G, Fusco M, Napoli M, Sica A, Maurano A, Sica M, Zulli C*

**Summary:** In this case report, a patient with choledocholithiasis underwent endoscopic retrograde cholangiopancreatography for stone removal. PuraStat was used as part of the haemostatic strategy in post-endoscopic sphincterotomy (ES) bleeding refractory.

**Results and conclusion:** Haemostasis achieved. Easy preparation, easy to use and low learning curve for physicians.

## Lower GI bleeds



IT, 2021

Endoscopic application of PuraStat in the treatment of solitary rectal ulcer syndrome (\*)

*Gagliardi M, Sica M, Oliviero G, Maurano A, Zulli C*

**Summary:** An independent case that uses PuraStat to treat solitary rectal ulcer syndrome. PuraStat is known for its haemostatic effect and has been hypothesized that it could help with tissue regeneration.

**Results and conclusion:** Four weeks after application of PuraStat, the follow up colonoscopy showed a complete mucosal healing with only mild residual mucosal erythema.



UK, 2021

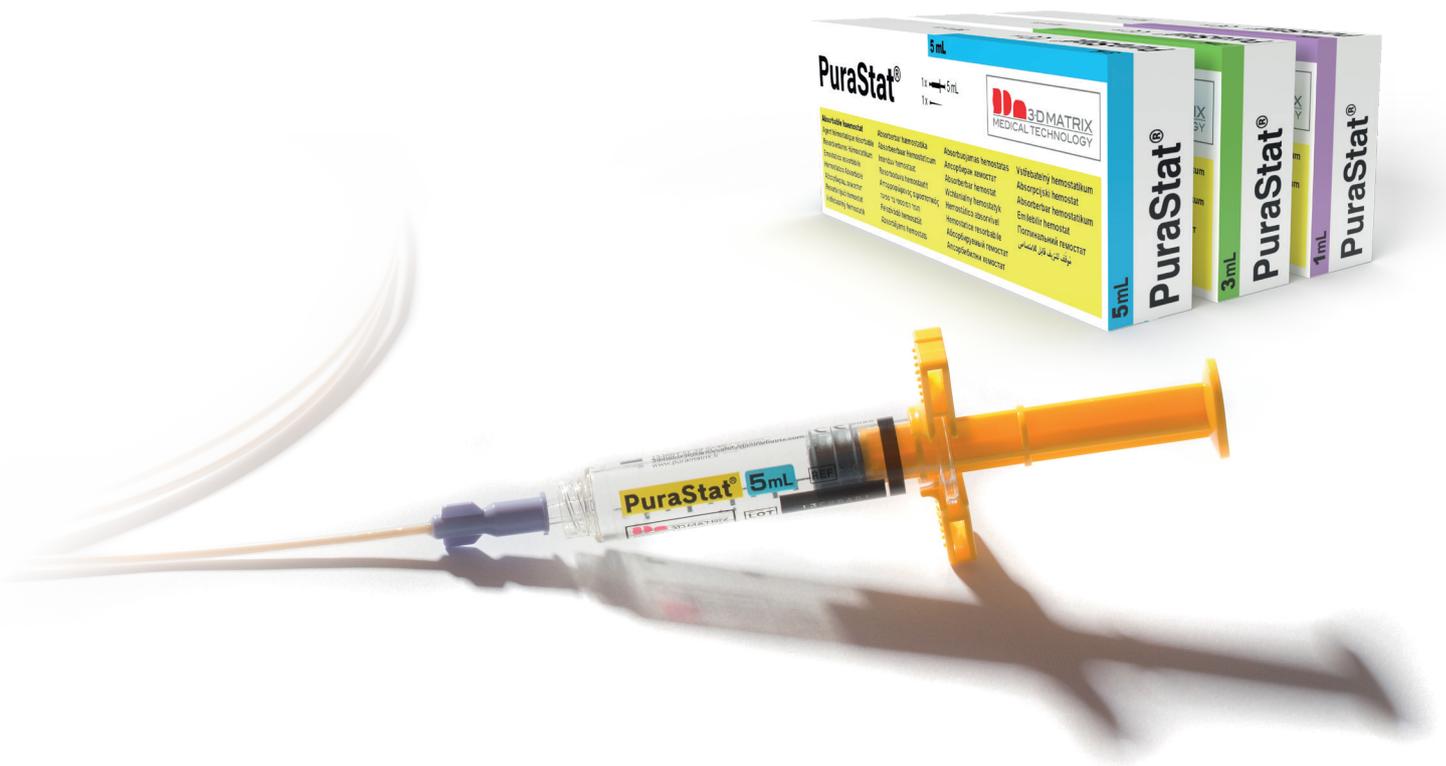
Endoscopically delivered PuraStat for the treatment of severe haemorrhagic radiation proctopathy: a service evaluation of a new endoscopic treatment for a challenging condition

*White K, Henson C*

**Aim:** To report the first experience of the use of PuraStat in haemorrhagic radiation proctopathy (RP)

**Summary:** N=21. PuraStat was applied at four weekly intervals up to three times, with further treatments as determined by symptoms. Median of 3 treatments and 5 mL PuraStat used. No complications.

**Conclusion and key messages:** Improvement in rectal bleeding and endoscopic grade. A randomised controlled trial is planned to determine the safety and efficacy of PuraStat in this patient group.



# Key Studies on the Use of PuraStat for Gastrointestinal Procedures

(\*) These publications contain treatments that are not within PuraStat indications.

For gastroenterology, PuraStat is indicated for haemostasis in the following situations encountered during surgery, when haemostasis by ligation or standard means is insufficient or impractical:<sup>1</sup>

- Bleeding from small blood vessels and oozing from capillaries of the GI tract following surgical procedures and surrounding tissues
- For the reduction of delayed bleeding following gastrointestinal endoscopic submucosal dissection (ESD) procedures in the colon.

## PuraStat



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PuraStat is a class III medical device, CE marked according to European council directive 93/42/EEC on medical devices and its relatives



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Reference

1. PuraStat IFU-007 Rev 2

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