

PuraStat®

Clear haemostatic control (1)

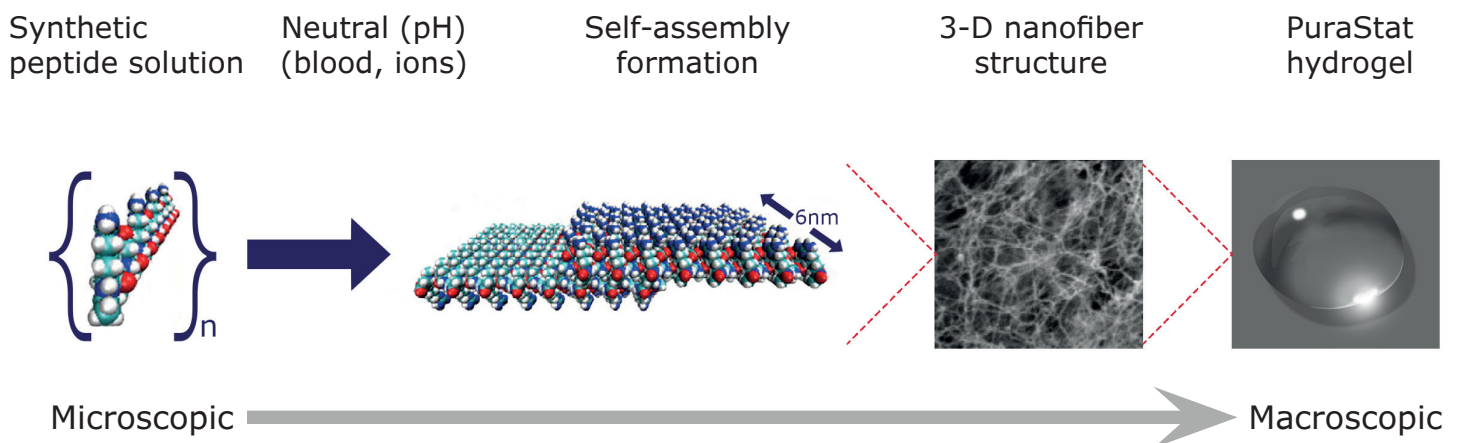


KEY FEATURES

- Transparent soft gel
- No preparation required
- Non-swelling (2)
- Synthetic peptide
- Biocompatible (3)

Mode of Action

PuraStat is a slightly viscous solution of synthetic peptides. Contact between PuraStat and blood causes the acidic peptide solution to be neutralized and exposed to ions, resulting in the formation of β -sheets that then form a 3-dimensional scaffold structure. PuraStat provides a physical barrier to stop bleeding in a variety of surgical indications.



PuraStat provides a physical barrier to stop bleeding. This haemostatic agent is bioresorbable and can be used in a variety of surgical indications.

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Distributed by:

- References:
- (1) PuraStat IFU-007 Rev 2
 - (2) Data on file (Swell Report 2018, Eun Seok Gil 12/06/2018)
 - (3) Biological Safety Report - current version

Please visit for more information:
www.3dmatrix.com

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



PuraStat®

Clear haemostatic control ⁽¹⁾

Indication for Use ⁽¹⁾

PuraStat is indicated for haemostasis in the following situations encountered during surgery, when haemostasis by ligation or standard means is insufficient or impractical:

<p>Bleeding from small blood vessels and oozing from capillaries of the parenchyma and surrounding tissues of solid organs</p>	<p>Oozing from vascular anastomoses to native or artificial vessels, on the surface of blood vessels and surrounding tissues</p>	<p>Bleeding from small blood vessels and oozing from capillaries of the GI tract following surgical procedures and surrounding tissues</p>
<p>Examples</p> <ul style="list-style-type: none"> • Myomectomy • Nephrectomy • Pancreatotomy • Partial hepatectomy • Prostatectomy • Splenectomy 	<p>Examples</p> <ul style="list-style-type: none"> • Coronary bypass • Femoral bypass • Surgery of the aorta or any peripheral arteries 	<p>Examples</p> <ul style="list-style-type: none"> • Endoscopic mucosal resection (EMR) of GI tract • Endoscopic submucosal dissection (ESD) of GI tract • Laparoscopic resection of GI tract organs

PuraStat is also indicated for the **reduction of delayed bleeding** following gastrointestinal endoscopic submucosal dissection (ESD) procedures in the colon.

Please read carefully the Instructions for Use for indications and contra-indications.

Available in 1 ml (621-034), 3 ml (621-035) and 5 ml (621-036)

Advantages



Transparent Haemostat

- Maintains clear sight of bleeding point



Reapplicable & Removable

- Can be used repetitively during the same procedure
- Can be removed easily if desired



Synthetic Peptide

- Inert material
- Well accepted by the body



Easy to Use

- Single prefilled, ready-to-use syringe
- No preparation required
- Does not obstruct the applicator ⁽⁴⁾



Suitability

- Suitable for endoscopic/laparoscopic use
- Possible to place sutures, cauterize
- Applicable to narrow spaces
- Covers well uneven surfaces