3-D MATRIX
MEDICAL TECHNOLOGY

PuraStat®

ABSORBABLE HAEMOSTATIC AGENT

Pre-filled peptide-based biomaterial for clear haemostatic control[1]

PuraStat® is a different kind of haemostat. It is a peptide based haemostatic agent designed to create a 3-dimensional scaffold as a physical barrier that provides atraumatic haemostasis. It is ready without delay. Available in a prefilled ready to use syringe with no preparation required.

PuraStat®
The science behind PuraStat®

PuraStat® is a self-assembling resorbable peptide aqueous solution. The 2.5% aqueous peptide solution is composed of 4 repeating amino acids: R: Arginine, A: Alanine, D: Aspartic Acid -- so the final peptide in PuraStat® is RADA16.

When exposed to physiological fluids such as blood, the aqueous solution neutralises or becomes alkaline. As a result, the ß structure peptide molecules self-assemble into nanofibers on a scale similar to the extracellular matrix , and as a result the peptide molecules quickly form a three dimensional meshwork of nanofibers in the aqueous solution, yielding a peptide hydrogel.

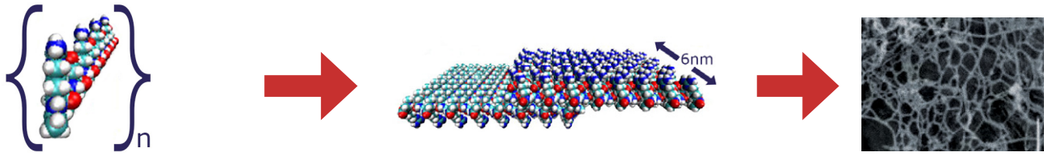
When PuraStat® is applied at the point of bleeding, this ionic exchange and pH balance is instantaneous causing a physical (mechanical) closing of the superficial part of the broken blood vessel, resulting in haemostasis (induces natural blood coagulation).

PuraStat® is fully chemically synthesised and does not contain any animal or human derived substance: and any PuraStat® remaining in the body after haemostasis has been achieved, is absorbed no longer than 30 days after application.

PuraStat®
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 ß-sheets that then form a 3-dimensional scaffold structure that is instantaneous, causing a physical (mechanical) closing of the superficial part of the broken blood vessel, resulting in haemostasis (induces natural blood coagulation).

Synthetic Peptide Solution → **Neutral pH (blood, ions)** → **Self-assembly formation** → **3-D nanofiber structure by the self-assembling of β-sheets**

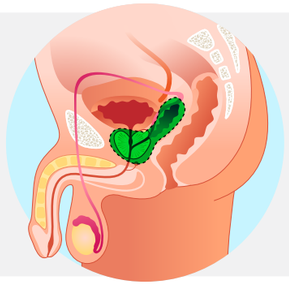


Procedural Applications

Prostatectomy Open, Laparoscopic and Robotic

Potential Bleeding Sites

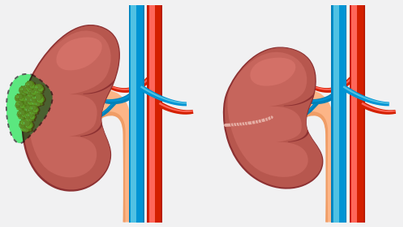
- Prostatic fossa along neurovascular bundles
- Vascular pedicles
- Tissue adherent to the tumor
- Tissue surrounding the prostate
- Along the urethrovesical anastomosis



Partial Nephrectomy

Potential Bleeding Sites

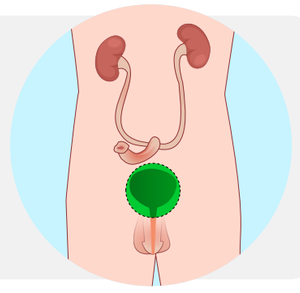
- Renal tissue/capsule following tumor removal
- Suture line oozing
- Soft tissue oozing



Cystectomy & Illeal Conduit

Potential Bleeding Sites

- Neurovascular bundles
- Seminal vesicles structures
- Vascular pedicles
- Tissue adherent to tumor
- Oozing on suture lines
- Anastomotic suture line ooze



PuraStat® 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
- Non-swelling[2]

Easy to Use

- Single prefilled, ready-to-use syringe
- No preparation required
- Does not obstruct the applicator[3]

Suitability

- Suitable for endoscopic/ laparoscopic use
- Can be used in combination with clips, sutures and cautery
- Applicable to narrow spaces
- Covers uneven surfaces

Illustration of Laparoscopic application of PuraStat®

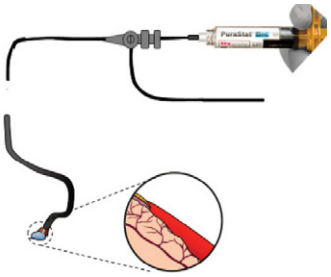


Fig. 1: Oozing bleeding from tissue (parenchyma a/o blood vessels)

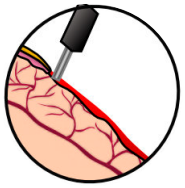


Fig. 2: Remove as much blood as possible from haemorrhagic site (using suction a/o gauze)

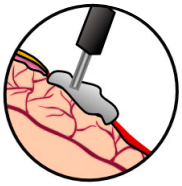


Fig. 3: Apply PuraStat® as close as possible to the bleeding point (also when potentially reapplying)

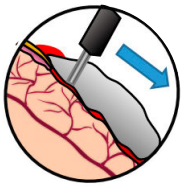


Fig. 4: Continue to apply PuraStat® by moving applicator until the product exceeds the margins of the lesion

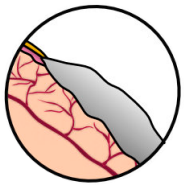
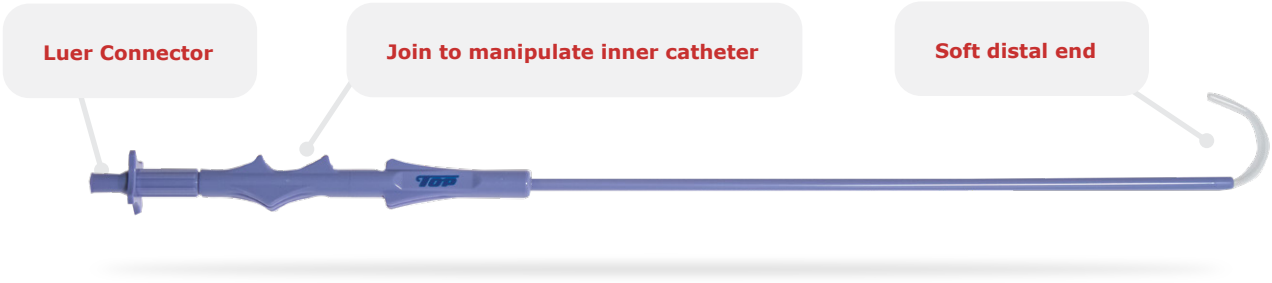


Fig. 5: Haemostasis is achieved

PuraStat® Nozzle System Type-L (Laparoscopic Catheter)



Consists of 2 layers: stiffer inner layer and soft outer layer, creating a soft tip
Flexible and curved tip for precise application
When pushed out, the soft tip of the inner tube articulates, enabling accurate application of PuraStat®

Ordering Information

Product Code	Product Name	Package
621-014	PuraStat® 3mL	1 each
621-015	PuraStat® 5mL	1 each
634163	PuraStat® Nozzle System Type-L	1 box (5 each)
634142	PuraStat® Nozzle System Type-E	1 box (5 each)

Customer Service
australia@3d-matrix.co.jp
1800 3DMATRIX (1800 336 287)

References
1. PuraStat IFU-002 Rev 2.2 2019/04
2. Data on file (Swell Report 2018, Eun Seok Gil 12/06/2018)
3. Risk Management report

PuraStat®

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CE 2797 BSI

Availability of these products may vary from country or region to another, as a result of specific local regulatory approval or clearance requirements for sales in such country or region. Please contact 3-D Matrix Europe should you need any additional information on device classification.

PuraStat® is not available in the US

PuraStat® Nozzle System (Catheter)

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Adachi-ku, Tokyo
120-0035 Japan

CE 0123

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