PuraStat®

The novel, peptide-based hemostat

• Synthetic peptide
• Biocompatible \(^{1}\)
• Ready-to-use, no preparation required
• Physical barrier to stop bleeding
• Easy-to-use material:
  - Slightly viscous solution suitable for endoscopic / laparoscopic use
  - Transparent soft gel
  - PuraStat does not obstruct the applicator \(^{2}\)

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 hemostatic agent is bioresorbable and can be used in a variety of surgical indications.

Available in 1 ml (ref. 621-013), 3 ml (ref. 621-014), 5 ml (ref. 621-015)

References:

(1) Biological Safety Report - current version
(2) Risk Management Report - current version
INDICATIONS FOR USE

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

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<th>Type of bleeding</th>
<th>Examples</th>
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| Exudative haemorrhage from blood vessels and parenchyma of solid organs | • Hepatectomy  
• Splenectomy  
• Cholecystectomy |
| Exudative haemorrhage from vascular anastomoses | • Anastomosis to native or artificial vessel  
• Surgery of the aorta or any peripheral arteries  
• Coronary bypass  
• Femoral bypass |
| Exudative haemorrhage from small vessels and capillary vessels of the GI tract | • Endoscopic mucosal resection (EMR) of GI tract  
• Endoscopic submucosal dissection (ESD) of upper GI tract  
• Laparoscopic resection of GI tract |

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

ADVANTAGES

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<th>Synthetic peptide</th>
<th>• Inert material, no risk of contamination from a biological source</th>
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| Ease of use | • Single prefilled and ready-to-use syringe  
• No preparation required  
• Suitable for endoscopic / laparoscopic use  
• Possible to place sutures, cauterize |
| Transparent hemostat | • Maintains clear sight of bleeding point |
| Re-Applicable and removable | • Can be used repetitively during the same procedure  
• Can be removed easily if desired |
| Slightly viscous solution | • Suitable for endoscopic/laparoscopic use  
• Applicable to narrow spaces  
• Covers well uneven surfaces |

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