3-D MATRIX MEDICAL TECHNOLOGY | PuraStat®

Instructions for Use

Caution: Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

1. PRODUCT DESCRIPTION

PuraStat is a sterile gel composed of a synthetic peptide and sterile water for injection. It is provided as a prefilled syringe (2.5% peptide content) ready for use with the adapter, allowing for delivery of the hemostatic gel with a commercially available luer lock endoscopic catheter.

PuraStat is completely non-animal and non-plant derived and contains no preservatives that might present a risk of allergic reaction or skin irritation.

Exposure to physiological conditions causes the peptide solution to quickly form a transparent hydrogel without expansion in volume. The hydrogel quickly coats the point of bleeding to form a barrier to block blood flow from the bleeding site, thereby resulting in hemostasis.

2. INDICATIONS FOR USE

PuraStat is intended for hemostasis of mild and moderate bleeding post ESD or EMR, as an adjunct, bridge, prophylactic or rescue therapy for intraprocedural venous bleeding or prophylactic therapy to prevent post procedure bleeding, and for primary non-variceal gastrointestinal (GI) bleeding. PuraStat is not indicated for arterial Forrest 1a bleeding.

PuraStat is also indicated for the symptomatic management of Rectal Mucositis (RM), such as radiation proctitis that may be caused by chemotherapy or radiotherapy.

3. CONTRAINDICATIONS

Do not use on patients with a known sensitivity to the gel or any of its components.

4. WARNINGS AND PRECAUTIONS

Do not use on patients with a known sensitivity to the gel or any of its components.

Do not apply excessive pressure to the syringe during application. This may cause the nozzle to detach.

PuraStat is not intended for use on spurting and/or gushing hemorrhages, such as those classified as Forrest 1a (active spurting). For these severe hemorrhages, consider a different type of hemostatic method.

PuraStat exhibits no antimicrobial properties; it is not bacteriostatic toward pre-existing infections, nor does it prevent the occurrence of new infections.

Do not inject intravascularly.

Patients with gastrointestinal bleeding that are on antithrombotic medication may be at an increased risk for rebleeding. Follow the relevant clinical guidelines for the management of antithrombotic agents for endoscopic procedures.

All endoscopic hemostatic therapies, including PuraStat, have an associated risk of rebleeding, particularly in situations where the cause of bleeding is an unresolved underlying disease. After hemostasis has been achieved, monitor patients for rebleeding per relevant clinical guidelines.

Potential complications associated with gastrointestinal endoscopy include, but are not limited to perforation, hemorrhage, aspiration, fever, infection, allergic reaction to the medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

For procedures using an endoscopic knife tip, e.g., endoscopic submucosal dissection, hemostasis of mild and moderate bleeds may be safely achieved with diathermy if the bleeding site is clearly visible and in the immediate vicinity of the knife.

Foreign body reaction may occur as with most surgical adjuvant treatments.

Before applying PuraStat, remove blood and fluids as much as possible from the bleeding site.

Be careful not to contaminate PuraStat during use. Handle PuraStat aseptically.

Use the product promptly after opening the package to prevent contamination.

PuraStat is a sterile product. Do not re-sterilize PuraStat.

Do not expose PuraStat to saline prior to use. Saline exposure prior to application decreases its hemostatic effect.

Do not use PuraStat as the main hemostatic treatment on patients with a blood coagulation disorder.

Instructions for Use Continued

PuraStat is a single-use product and must not be reused. Each syringe and adapter is intended to be used once only for a single patient to achieve hemostasis within a single endoscopic procedure only. Once expressed from the syringe and in contact with fluids such as blood, the PuraStat peptide solution will begin to change character and self-assemble, thereby rendering it non-reusable. Any attempt to retain any unused portion remaining in the syringe after first use has the potential to transfer blood/tissue borne diseases and infection. Any attempt to re-sterilize the product will result in degradation and loss of performance.

Do not connect the PuraStat syringe to any device other than the dedicated adapter. Ensure that adapter does not become detached from the syringe during the endoscopic procedure.

The safety and effectiveness of the use of PuraStat in the setting of inflammatory bowel disease (IBD) has not been evaluated.

5. DIRECTIONS FOR USE

5.1. Before use

- Read these instructions carefully.
- PuraStat is made available in three fill volumes (1, 3, or 5 mL). Select the appropriate volume for the selected bleeding site.
- Before using the product, visually inspect and confirm that there is no damage to the package, or the syringe or product leakage seen. Do not use the product if any damage or leakage is noted.
- For ease of delivery of PuraStat, the inner diameter of the catheter should be greater than or equal to 1.1 mm and the length of the catheter should be less than 240 cm. For these catheter sizes, the maximum required injection force should be 65 Newtons (14.6 lbs.).

5.2. Method of Use

1. Empty the contents of the pouch into a sterile field.
2. Use gel promptly after opening the pouch.
3. Remove the syringe cap and connect the syringe to the adapter. Connect the adapter to a commercially available endoscopic catheter suitable for the endoscope in use and the procedure (e.g., 1600 or 2200 mm length) by turning the catheter clockwise until a secure connection is achieved. Slowly prime the catheter connected to the adapter under direct vision until the gel is noted to have reached the distal end.
4. Confirm that the surgical site is clear of as much blood and fluid as is possible. Blood and fluid should be removed as much as possible prior to the application of PuraStat.
5. Apply an adequate quantity of PuraStat to the bleeding site. For best results, the tip of the catheter should be placed as close as possible to the bleeding site during the application.
6. Do not disturb the self-assembled PuraStat gel until sufficient time has been allowed for hemostasis to occur. Successful hemostasis can be confirmed by the absence of a new blood flow from the original bleeding point.
7. If necessary, repeat the application of PuraStat several times until hemostasis is achieved.
8. After hemostasis is confirmed, excess PuraStat may be left in place.
9. After use, dispose of the syringe and adapter and any unused PuraStat into an appropriate container as clinical waste.

6. STORAGE

- PuraStat should be stored in a refrigerator (from 2 to 8°C). Do not freeze.
- Keep packaging dry.

7. PRESENTATION

PuraStat is provided sterile for single use. If the immediate product packaging is damaged, do not use.

Pack units:

- 1 mL/unit (CAT 621-061)
- 3 mL/unit (CAT 621-062)
- 5 mL/unit (CAT 621-063)

Instructions for Use Continued

8. SYMBOL GLOSSARY

This glossary describes the symbols used on the packaging for PuraStat.

Symbol	Standard and Symbol Reference	Standard Title	Symbol Definition
Rx only	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements.	Prescription only
	ISO 7000-2497	Graphical symbols for use on equipment.	Date of manufacture
	ISO 7000-3082	Graphical symbols for use on equipment.	Manufacturer
CAT	N/A	N/A	Catalog Number
LOT	ISO 7000-2492	Graphical symbols for use on equipment.	Batch code
UDI	N/A	N/A	Unique Device Identifier
STERILE EO	ISO 7000-2501	Graphical symbols for use on equipment.	Sterilized using ethylene oxide treatment
STERILE R	ISO 7000-2502	Graphical symbols for use on equipment.	Sterilized using irradiation
	ISO 7000-2607	Graphical symbols for use on equipment.	Use-by date
	ISO 7000-1641	Graphical symbols for use on equipment.	Consult instructions for use
	ISO 7000-1051	Graphical symbols for use on equipment.	Do not reuse
	ISO 7000-2608	Graphical symbols for use on equipment.	Do not resterilize
	ISO 7000-0632	Graphical symbols for use on equipment.	Temperature limit
	ISO 7000-0626	Graphical symbols for use on equipment.	Keep dry
	ISO 7000-2606	Graphical symbols for use on equipment.	Do not use if package is damaged

3-D Matrix Syringe Adapter

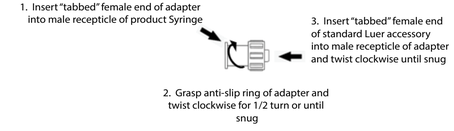
PuraStat Syringe Adapter Instructions For Use:

1. Product Description:

   The PuraStat Syringe Adapter is a transparent plastic (polypropylene) adapter designed to convert the propriatary male fitting on the PuraStat Syringe to a LUER type male receptacle to accomodate LUER female accessories such as suction nozzles, catheters, and irrigator nozzles as needed by medical professionals at their discretion.

2. Directions For Use:
   1. The PuraStat Syringe Adapter should be emptied from sterile pouch in which it is provided onto the sterile surgical tray.
   2. The adapter's tabbed female end should be inserted into the PuraStat syringe's threaded male end and twisted clockwise untila firm seat is established within the Syringe's male sleeve.
   3. The syringe is now ready to receive any LUER accessory by repeating the above instructions while correctly handling that accessory.
   4. Discard the used adapter after each use. Do not resterilize or attempt to reuse.

WARNING: As this medical device uses an alternative small-bore connector design different from those specified in the ISO 80369 series, there is a possibility that a misconnection can occur between this medical device and a medical device using a different alternative small-bore connector, which can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonable foreseeable risks.



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PuraStat®

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