PerClot
POLYSACCHARIDE HAEMOSTATIC SYSTEM

Preparation Instructions

Product Preparation

1

PERCLOT preparation begins with the opening of the outer pouch and the transfer of the inner pouch to the sterile field using aseptic technique. Once the inner pouch has been transferred into the sterile field, the product preparation is as follows.

2

Remove the applicator and the bellows from the package.

3

Remove the cap of the bellows using a counterclockwise turning motion.

4

Connect the bellows firmly to the end of the applicator handle.

5

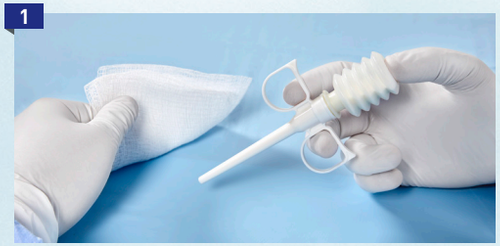
PERCLOT is now ready to be passed off to the surgeon.

PERCLOT in Minimally Invasive Surgery

PERCLOT is compatible with Standard XL 200mm applicator and Laparoscopic 380mm applicator.

Application Technique

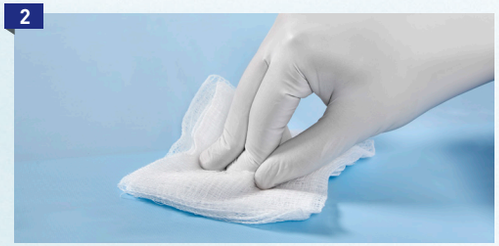
1



Dry

Remove all excess blood from the intended site by blotting or suctioning. Apply a liberal amount of **PERCLOT** Absorbable Modified Polymer (AMP) Particles directly to the source of bleeding to thoroughly cover the bleeding wound.

2



Hold

Apply direct pressure over the wound for several minutes following application.

3

Irrigate

Once haemostasis is achieved, remove excess particles carefully and completely by irrigation and aspiration.

Please see Indication and Detailed Important Risk Information on the reverse side.

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INDICATIONS FOR USE

PERCLOT PHS is indicated for use in surgical procedures (except neurological and ophthalmic) or injuries as an adjunct haemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical.

IMPORTANT SAFETY INFORMATION

Do not apply **PERCLOT** PHS into blood vessels as potential for embolisation and death may exist. **PERCLOT** PHS is contraindicated in patients who are sensitive to starch or starch-derived materials.

PERCLOT PHS is not intended as a substitute for good surgical practice, and in particular, the proper use of conventional procedures (such as ligature) for haemostasis.

PERCLOT PHS is not recommended when an infection is suspected. **PERCLOT** PHS should be used with caution in contaminated areas. If signs of an infection develop in the site where **PERCLOT** PHS has been used, surgery may be necessary to allow adequate drainage. Combined use of **PERCLOT** PHS with other topical haemostatic agents has not been studied in controlled clinical trials. Remove excess AMP particles once haemostasis is achieved. This removal of excess particles is particularly important in and around the spinal cord, areas of bone confine, the optic nerve/chiasm, and foramina of bone because unsaturated particles may swell and compress the surrounding tissues.

PERCLOT PHS should not be mixed with methylmethacrylate or other acrylic adhesives as it may reduce the adhesive strength and compromise the attachment of prosthetic devices to bone tissue. Excess particles should be fully removed from bony surfaces by irrigation prior to the use of adhesives.

Safety and effectiveness of **PERCLOT** PHS have not been clinically evaluated in children and pregnant women. When **PERCLOT** PHS is used in the nasal cavity and laryngopharyngeal, **PERCLOT** PHS should be used with caution to avoid the dry particles being drawn into the trachea or bronchi, which may form a gel that blocks the trachea and bronchi.

PERCLOT PHS is a single use product. Do not use **PERCLOT** PHS in more than a single surgical procedure. **PERCLOT** PHS should not be used for controlling post-partum bleeding or menorrhagia. Safety and effectiveness in neurological and ophthalmic procedures has not been studied in controlled clinical trials.

Ordering Information

PRODUCT	CONTENTS	ORDER NUMBER
PERCLOT Standard 1g	1g dispenser 90mm applicator	STA0001
PERCLOT Standard 3g	3g dispenser 90mm applicator	STA0003
PERCLOT Standard 5g	5g dispenser 90mm applicator	STA0005
PERCLOT Standard XL 3g	3g dispenser 200mm applicator	STA2003
PERCLOT Standard Laparoscopic 3g	3g dispenser 380mm applicator	LAP3803

For questions or ordering information, please contact your Baxter representative.

Advancing the art of healing

Any medical device product quality complaints (including medical device adverse incidents) relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team: In the UK on +44 (0)1604 704603, or by email to UK_SHS_QA_Complaints@baxter.com. In Ireland on +353 (0)1 2065500 or by email to shs_complaints_dublin@baxter.com

Alternatively please report directly to your Baxter Representative, who will take the details and forward to the Baxter Country Quality Assurance Team.

Medical device adverse incidents should also be reported: In the UK to the MHRA.
Reporting forms and information can be found at: www.mhra.gov.uk/safetyinformation/reportingsa fetyproblems/index.htm . In Ireland to the HPRA. Reporting forms and information can be found at: http://www.hpra.ie/homepage/about-us/report-an-issue

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Baxter Healthcare Ltd
Wallingford Road, Compton
Newbury, RG20 7QW
www.baxterhealthcare.co.uk

Baxter Healthcare Ltd
7 Deansgrange Business Park
Blackrock, Co. Dublin
www.baxterhealthcare.ie

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