

PREPARATION INSTRUCTIONS

PRODUCT PREPARATION IN THE STERILE FIELD



1 Remove the applicator and the bellows from the package.



2 Remove the cap using a counterclockwise turning motion.



3 Connect the bellows firmly to the applicator tip using a clockwise turning motion.



4 PERCLOT is now ready to use.

PERCLOT IN MINIMALLY INVASIVE SURGERY



PERCLOT is compatible with the 20cm Extender Tip and the 38cm Laparoscopic Tip.

APPLICATION TECHNIQUE



1 **Dry**
Remove all excess blood from the source of bleeding by blotting, wiping, or suctioning.



2 **Apply**
Immediately apply a liberal amount of PERCLOT granules directly to the source of bleeding to thoroughly cover the bleeding wound.
Apply wound appropriate pressure to the bleeding site until hemostasis is achieved. Amount and duration of pressure is wound dependent.



3 **Irrigate**
Once hemostasis is achieved, remove excess granules carefully and completely by gentle saline irrigation and aspiration. Avoid direct suction or removal of the formed blood clot.

INDICATIONS

PERCLOT Absorbable Hemostatic Powder is indicated in surgical procedures (except neurological and ophthalmic) as an adjunctive hemostatic device to assist when control of suture line bleeding or capillary, venous, and arteriolar bleeding by pressure, ligature, and other conventional procedures are ineffective or impractical.

IMPORTANT RISK INFORMATION

Do not inject or place PERCLOT into blood vessels such as artery or vein as potential for embolization and death may exist.

Do not use PERCLOT for treatment of severe or extreme bleeding.

Do not inject into bladder or ureteral lumen.

Single use only. Do not re-use. Do not re-sterilize. Re-use or reprocessing of a single use device may lead to contamination and compromised device function or structural integrity.

Safety and efficacy of PERCLOT have not been clinically evaluated in children (less than 21 years old) and pregnant or lactating women.

PERCLOT should be used with caution in the presence of infection or in contaminated areas of the body. If signs of infection or abscess develop where PERCLOT has been applied, re-operation may be necessary in order to allow drainage.

Safety and efficacy of PERCLOT in neurological and ophthalmic procedures have not been established.

Safety and efficacy of PERCLOT have not been clinically evaluated for use in controlling post-partum bleeding or menorrhagia.

Once hemostasis is achieved, excess PERCLOT should be removed from the site of application by irrigation and aspiration particularly when used in the pericardial cavity and around foramina of bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm. PERCLOT achieves its maximum swelling within 10 minutes when exposed to blood or other fluids. Dry, white PERCLOT should be removed. The possibility of the product interfering with normal function and/or causing compression of surrounding tissues due to swelling is reduced by removal of excess dry material.

The effect of this product on patients with known sensitivity to starch or starch-derived materials has not been studied.

The efficacy of PERCLOT in achieving hemostasis in cortical bone and spinal bleeding has not been studied in randomized clinical trials.

Blood vessels, suture line gaps, and large needle holes with a diameter of ≥ 2 mm must be ligated prior to PERCLOT application.

Do not apply more than 50g of PERCLOT in diabetic patients as it has been calculated that amounts in excess of 50g could affect the glucose load.

As with other hemostatic agents, do not apply PERCLOT to sites where there is negative peripheral venous pressure as material may be drawn into the vascular system potentially resulting in life-threatening thromboembolic events.

Rx Only. For safe and proper use please refer to full device Instructions for Use for Contraindications, Warnings and Precautions.

ORDERING INFORMATION

PRODUCT	ORDER NUMBER	QUANTITY
PERCLOT 3g - 9cm Standard Tip	PCUS003	5 EA / 1 BX
PERCLOT 20cm Extender Tip	PCET020	5 EA / 1 BX (2 Applicators / Pouch)
PERCLOT 38cm Laparoscopic Tip	PCET038	10 EA / BX

For questions or ordering information, please contact your Baxter representative or call 888-229-0001.
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