Baxter

PerClot
ABSORBABLE HEMOSTATIC POWDER

Instructions for Use

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EXPLANATION OF SYMBOLS

Symbols are referenced from ISO 15223-1:2016 Medical Devices: Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements unless otherwise noted.

Symbol	Symbol Title and Description	Symbol Reference
 http://edocs.baxter.com	Consult instructions for use or consult electronic instructions for use; Indicates the need for the user to consult the instructions for use.	5.4.3
	Do not use if package is damaged and consult instructions for use; Indicates a medical device that should not be used if the package has been damaged or opened. And that the user should consult the instructions for use for additional information.	5.2.8
	Sterilized using irradiation; Indicates a medical device that has been sterilized using irradiation.	5.2.4
	Do not resterilize; Indicates a medical device that is not to be resterilized.	5.2.6
	Temperature limit; Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
	Do not re-use; Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Catalogue number; Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	Batch code; Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Use-by date; Indicates the date after which the medical device is not to be used.	5.1.4
	Caution; Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situations needs operator awareness or operation action in order to avoid undesirable consequences.	5.4.4
	Non-pyrogenic; Indicates a medical device that is non-pyrogenic	5.6.3
	Single sterile barrier system with protective packaging inside; Indicates a single sterile barrier system with protective packaging inside.	5.2.13*
Rx Only	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.	21 CFR 801
MR	MR Safe	ASTM F2503-20
QTY #	Quantity	n/a

* Symbol is referenced from ISO 15223-1:2021 Medical Devices: Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements

DEVICE DESCRIPTION

PerClot Absorbable Hemostatic Powder (hereinafter referred to as PerClot) is a medical device composed of absorbable polysaccharide granules and applicator tip. The granules are biocompatible, non-pyrogenic and derived from purified plant starch. The granules do not contain any human or animal components. PerClot granules have a molecular structure that rapidly absorbs water, forming a gelled adhesive matrix that provides a mechanical barrier against further bleeding and results in the accumulation of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.). The gelled adhesive matrix thus promotes the normal, physiological clotting cascade. PerClot granules are enzymatically degraded by alpha-amylase and glucoamylase and by macrophages. Based on preclinical studies, absorption occurs within 96 hours. Absorption is dependent on the amount of material applied on the wound and the site of use.

PerClot Absorbable Hemostatic Powder Accessory Tips are available separately. The PerClot accessory tips, which include the PerClot 20cm Extender Tip and PerClot 38cm Laparoscopic Tip, are designed to deliver PerClot Absorbable Hemostatic Powder onto surgical wound surfaces consistent with PerClot Absorbable Hemostatic Powder product labeling. The PerClot 20cm Extender Tip is intended only for use in open surgical procedures and the PerClot 38cm Laparoscopic Tip is intended for use in both open and laparoscopic procedures. Please see the Instructions for Use for PerClot Absorbable Hemostatic Powder Accessory Tips for complete information on the tips.

INDICATIONS / INTENDED USE

PerClot Absorbable Hemostatic Powder: 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.

PerClot Accessory Tips: The PerClot Accessory Tips are intended for the application of PerClot® Absorbable Hemostatic Powder onto surgical wound surfaces consistent with the product labeling. The PerClot 20cm Extender Tip is intended only for use in open surgical procedures and the PerClot 38cm Laparoscopic Tip is intended for use in both open and laparoscopic procedures.

CONTRAINDICATIONS ⚠

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

WARNINGS ⚠

- 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 resterilize. Reuse 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.

PRECAUTIONS ⚠

- PerClot is supplied as a sterile product and cannot be re-sterilized. Unused, open containers of PerClot should be discarded.
- PerClot is not recommended as a primary treatment for coagulation disorders.
- PerClot is intended to be used in a dry state. Contact with blood or other fluids prior to application will result in the loss of hemostatic properties.
- Blood vessels with a diameter of ≥2mm, suture line gaps ≥2mm, and large needle holes ≥2mm must be ligated prior to PerClot application.
- Do not use on bone surfaces where adhesives, such as methyl methacrylate or other acrylic adhesives, will be required to attach a prosthetic device.
- When PerClot is used in conjunction with autologous blood salvage circuits, a 40µ cardiotomy reservoir, cell washing, and 40µ transfusion filter, must be used.
- 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.
- In urological procedures, PerClot should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.
- As with other hemostatic agents, do not apply PerClot to sites where there is negative peripheral venous pressure (e.g. due to patient positioning), as material may be drawn into the vascular system potentially resulting in life-threatening thromboembolic events.

PACKAGING / STORAGE

PerClot is supplied as a bellows pre-loaded with hemostatic powder. The bellows contains at least 1, 3, or 5 grams of material.

- 1g: 1.4-1.6 grams
- 3g: 3.4-3.7 grams
- 5g: 5.4-5.8 grams

A 9cm applicator tip is also supplied for application of the hemostatic powder. Contents of the PerClot package are supplied sterile for single-patient use only. Not made with natural rubber latex.

PerClot must be stored between 5°C and 25°C.

ENVIRONMENTAL CONDITIONS MR

PerClot Absorbable Hemostatic Powder is MR safe (i.e., an item that poses no hazards in all MR environments).

PREPARATION ⚠

Inspect the integrity of the product packaging prior to use. If damaged, do not use. Open the outer pouch and remove the inner foil (sterile) pouch. Using the tear notch, open the inner foil pouch. Remove the applicator tip and bellow from its package. Remove the cap using a counter-clockwise turning motion (Fig.1). Firmly connect the threaded end of the applicator tip handle to the threaded portion of the bellow using a clockwise turning motion (Fig. 2). The PerClot Absorbable Hemostat bellow is now ready for use (Fig. 3).

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Figures not to scale.

DIRECTIONS FOR USE

For open surgical use:

1. ⚠ Identify and expose the source of bleeding of the wound. Blot, wipe, or suction the bleeding tissue. It is important to remove the excess blood so PerClot may be applied immediately and directly to the site of active bleeding.
2. ⚠ The applicator tip must be as close to the source of bleeding as possible. Avoid contacting the applicator tip with blood, other fluids and/or tissue surface as this may occlude the applicator. If this occurs, replace the applicator tip, if available. Do not attempt to trim the applicator tip.
3. Invert and pump the bellows directly over the site of bleeding (Fig. 4). Immediately apply a liberal amount of PerClot granules directly to the source of bleeding. Thoroughly cover the lesion with a layer of granules 3 to 4 mm in thickness. Extend the product application to approximately 0.5cm (or 5 mm) beyond the edge of the site of bleeding. The amount of application will depend upon the size of the bleeding site, contour of the bleeding site, and severity of bleeding.
4. Apply wound appropriate pressure to the bleeding site using a non-adhering material until hemostasis is achieved. Amount and duration of pressure is wound dependent.

5. ⚠ If an adherent material is used (i.e. surgical gauze), irrigate the material with saline and carefully remove it from the treated site.
6. ⚠ 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.
7. Repeat steps 1-6 if hemostasis is not achieved.

⚠ When using PerClot Absorbable Hemostatic Powder with Accessory Tips, follow the Instructions for Use for the PerClot Absorbable Hemostatic Powder. The following Accessory Tips may be used with PerClot Absorbable Hemostatic Powder:

- PerClot 20cm Extender Tip (not for laparoscopic use)
- PerClot 38cm Laparoscopic Tip

For endoscopic / laparoscopic surgical procedures ⚠:

Follow all steps above for open surgical procedures. In addition, follow these steps:

- Place the PerClot applicator tip through a 5mm or larger trocar to reach the intended bleeding site. The applicator tip must be as close to the source of bleeding as possible. Maintain direct visualization of the applicator tip at all times in order to minimize the potential for unintended contact with tissue, organs, or fluid which may lead to occlusion of the tip.
- Grasp the 38cm Laparoscopic Tip at the overlapping interface between the distal tip and the extruded tube.

DISPOSAL INSTRUCTIONS

Dispose the used device and any unused material or damaged devices in accordance with accepted medical practice and applicable national, local, or institutional guidelines.

CLINICAL STUDIES

PerClot has an extensive clinical history which includes the clinical trial conducted under IDE (CLOT Trial; G110072) in the US, additional unpublished clinical studies, and supporting clinical literature discussed below.

PRIMARY CLINICAL STUDY - CLOT TRIAL

Study Design

A prospective, multicenter, multidisciplinary, randomized, non-inferiority, controlled clinical trial was conducted (CLOT Trial). Three hundred and twenty-four (324) patients were randomized and treated at 19 investigational centers in the US.

Study Objectives

To evaluate the safety and efficacy of PerClot versus a commercially available absorbable polysaccharide hemostatic powder (Arista™) to control intraoperative bleeding in cardiac, general, and urological surgeries.

Study Product Usage

Sites were supplied with 5 gram bellows of PerClot and physicians could use up to 2 bellows per wound. Physicians used an average of 5.2 ± 3.5 grams to treat each wound.

CLINICAL ENDPOINTS

Primary Endpoint

The primary efficacy endpoint for the clinical investigation was complete hemostasis of the treated bleeding site within 7 minutes.

Secondary Endpoint

The secondary efficacy endpoint for the clinical investigation was complete hemostasis of the treated bleeding site within 5 minutes.

SUBJECTS

A total of 324 subjects were randomized into the study (161 PerClot and 163 Arista subjects). A total of 322 patients were treated and included in the primary endpoint analysis. Follow-up data for 313 subjects were included in the analysis (study attrition included 6 mortalities, 2 lost to follow-up, and 1 voluntary withdrawal). Demographics, surgical procedures, hemostat application sites and baseline surface bleeding severity scale scores were similar between treatment groups. The bleeding severity scale used in the study had 5 bleeding flux levels identified in Table 1. The inclusion criteria for the target bleeding site was Bleeding Severity Score of 1 or 2.

Table 1. Bleeding Severity Scale.

Bleeding Severity Score	Bleeding Flux (g/cm2 per second)
0=No Bleeding	0 – 0.000040
1=Ooze	>0.000040-0.0056
2=Slight Bleeding	>0.0056-0.013
3= Moderate Bleeding	>0.013-0.041
4=Severe Bleeding	>0.041-0.063
5=Life-Threatening Bleeding	>0.063

Patients were randomized only after a suitable bleeding site for treatment with an adjunctive hemostatic device was identified. Complete hemostasis was defined as complete cessation of bleeding.

CLINICAL STUDY RESULTS

PerClot demonstrated performance versus Arista with a comparable complete hemostasis rate at 7 minutes. Comparability was also demonstrated for the secondary endpoint with similar hemostasis rate at 5 minutes for each therapeutic area. Hemostasis for both groups was maintained at a high rate through the 12-minute assessment in all therapeutic areas.

No significant differences were observed in the adverse event rates or supplementary safety measures between PerClot and Arista (Table 2).

Table 2. Reported Adverse Event Summary (rates>5%).

	# Events (#Subjects, % Subjects)		
	All Events		
Adverse Event Category	**All Subjects (N=324)**	**PerClot (N=161)**	**Arista (N=163)**
Hypophosphatemia	46 (45, 13.9%)	22 (22, 13.7%)	24 (23, 14.1%)
Pleural Effusion	38 (38, 11.7%)	20 (20, 12.4%)	18 (18, 11.0%)
Anemia	32 (32, 9.9%)	19 (19, 11.8%)	13 (13, 8.0%)
Hypotension	32 (31, 9.6%)	12 (12, 7.5%)	20 (19, 11.7%)
Constipation	29 (28, 8.6%)	16 (16, 9.9%)	13 (12, 7.4%)
Abdominal Pain	28 (28, 8.6%)	14 (14, 8.7%)	14 (14, 8.6%)
Nausea	27 (27, 8.3%)	13 (13, 8.1%)	14 (14, 8.6%)
Hyperglycemia	26 (26, 8.0%)	14 (14, 8.7%)	12 (12, 7.4%)
Atelectasis	25 (24, 7.4%)	15 (14, 8.7%)	10 (10, 6.1%)
Hypokalemia	24 (23, 7.1%)	12 (11, 6.8%)	12 (12, 7.4%)
Acute Kidney Injury	21 (21, 6.5%)	11 (11, 6.8%)	10 (10, 6.1%)
Dyspnea	21 (21, 6.5%)	12 (12, 7.5%)	9 (9, 5.5%)
Leukocytosis	21 (21, 6.5%)	9 (9, 5.6%)	12 (12, 7.4%)
Atrial Fibrillation	19 (19, 5.9%)	10 (10, 6.2%)	9 (9, 5.5%)
Fever	17 (17, 5.2%)	12 (12, 7.5%)	5 (5, 3.1%)
Total	909 (216, 66.7%)	457 (114, 70.8%)	452 (102, 62.6%)

Other adverse events reported in fewer than 5% of the PerClot treated patients include Activated Partial Thromboplastin Time Increase, Distributive Shock, Gastric Perforation, Hematoma Infection, Hypoxia, Implant Site Fluid Collection, INR Increased, Pericardial Tamponade, Perihepatic Fluid Collection, Pleural Effusion, Pneumonia, Respiratory Failure, and Sepsis.

UNANTICIPATED ADVERSE DEVICE EFFECTS

There were no Unanticipated Adverse Device Effects.

RESULTS BY THERAPEUTIC AREA

For the primary endpoint, the observed PerClot hemostasis rate at 7 minutes post-application is 90.6% versus 92.0% in Arista, a difference of -1.4% for the three therapeutic areas pooled. However, poolability of data across therapeutic areas was not supported by the data due to variability in treatment difference between PerClot and Arista across therapeutic areas. Therefore, primary efficacy data was not pooled across the three therapeutic areas for hypothesis testing. Hemostasis rate at 7 minutes post-application by therapeutic area and treatment group is presented in Table 3.

Table 3. Complete Hemostasis Within 7 Minutes

Primary Efficacy Endpoint	PerClot n/N (%)	Control n/N (%)
Surgical Application	PerClot n/N (%)	Control n/N (%)
Cardiac	85.7% (36/42)	69.0% (29/42)
General	93.3% (70/75)	100.0% (80/80)
Urology	90.7% (39/43)	100.0% (40/40)

For the secondary endpoint, PerClot demonstrated a comparable hemostasis rate at 5 minutes post-application versus Arista. Hemostasis rate at 5 minutes post-application by therapeutic area and treatment group is summarized in Table 4.

Table 4. Complete Hemostasis Within 5 Minutes.

Secondary Efficacy Endpoint	PerClot n/N (%)	Control n/N (%)
Surgical Application	PerClot n/N (%)	Control n/N (%)
Cardiac	83.3% (35/42)	64.3% (27/42)
General	92.0% (69/75)	90.0% (72/80)
Urology	93.0% (40/43)	97.5% (39/40)

Maintenance of Hemostasis

Due to the potential for hemostasis to only be achieved temporarily, a sensitivity analysis was conducted to consider failure to maintain hemostasis through a total of 12 minutes. Table 5 shows the rate of maintenance of hemostasis at 12 minutes for the entire randomized and treated patient population as well as stratified by surgical specialty.

The hemostasis results at 12 minutes demonstrate that the results of the PerClot across the three therapeutic areas are reasonably consistent, with poor performance of Arista in cardiac epicardial cases being the primary reason for variation in performance across therapeutic areas.

Table 5. Additional Efficacy Assessment: Maintenance of Hemostasis at 12 minutes.

Maintenance of Hemostasis (12 min)	PerClot n/N (%)	Control n/N (%)
Surgical Application	PerClot n/N (%)	Control n/N (%)
Cardiac	85.7% (36/42)	69.0% (29/42)
General	92.0% (69/75)	97.5% (78/80)
Urology	90.7% (39/43)	90.0% (36/40)

The study was not powered to evaluate non-inferiority for the individual therapeutic arms. Tables 3, 4, and 5 provide the 5, 7, and 12 minute results by therapeutic area. As shown, there was some variation in the difference between PerClot and Arista by therapeutic area. PerClot and Arista showed comparable safety and efficacy for both Bleeding Severity Score 1 (ooze) and Bleeding Severity Score 2 (slight bleeding) on the bleeding scale, for both men and women, and across different race categories.

These findings suggest that the consistently good performance of PerClot across therapeutic areas at 5, 7, and 12 minutes provides evidence that PerClot affords therapeutic benefit that is anticipated to be comparable to Arista in repeated future use of the product. No safety concerns were identified.

ADDITIONAL STUDIES AND CLINICAL LITERATURE

Four unpublished clinical studies conducted in Europe totaling 119 PerClot subjects and three unpublished clinical studies conducted in China totaling 148 PerClot subjects have been conducted. Nine studies (8 clinical trials and 1 systematic review) totaling 255 PerClot subjects have been reported in the published literature. Published literature shows that PerClot is used in a wide range of real-world applications. No unexpected adverse events were reported in the clinical studies. PerClot was effective in achieving hemostasis with a positive safety profile compared to traditional hemostatic measures.

Additionally, the laparoscopic administration of PerClot was assessed in three clinical studies (one unpublished, two published) totaling 67 subjects which supported the safe and effective use of PerClot in laparoscopic procedures.

The entirety of clinical experience and more than 10 years of commercial use in 50 countries outside the United States further supports the safe and effective use of PerClot for its intended use in open and laparoscopic surgery.

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