PerClot™ Polysaccharide Hemostatic System

CAUTION
PerClot™ should only be used by a physician or other licensed practitioners.

DESCRIPTION
PerClot™ Polysaccharide Hemostatic System (PerClot™ PHS) is a medical device composed of absorbable modified polymer (AMP™) particles and delivery applicators. AMP™ particles are biocompatible, non-pyrogenic and derived from purified plant starch. The device contains no human or animal components. PerClot™ PHS is intended as an absorbable hemostatic system to control bleeding during surgical procedures or following traumatic injuries. For specific surgical procedures, the system is available in following kit configurations: PerClot™ Standard, PerClot™ Laparoscopic, PerClot™ Endoscopic and PerClot™ Express.

ACTION
AMP™ particles have a molecular structure that rapidly absorbs water from the blood. This dehydration process causes a high concentration of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.) which accelerates the normal, physiologic clotting cascade. In contact with blood, AMP™ particles support the formation of a gelled, adhesive matrix which provides a mechanical barrier to further bleeding. Absorption normally requires several days and is dependent on the amount of material applied and the site of use. AMP™ particles are degraded by histaminases, including amylase and glucoamylase.

INDICATIONS
PerClot™ PHS is indicated for use in surgical procedures or injuries as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical.

INSTRUCTIONS FOR USE
The following instructions provide technical direction for the recommended use of ALL PerClot™ PHS models. These instructions do not eliminate the necessity of formal training in the use of PerClot™ PHS. In addition, the techniques and procedures described here do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating specific surgical conditions.

PREPARATION
1. Visually inspect both the sealed AMP™ dispenser and applicator packages. If either package has been previously opened or damaged, discard and replace with a new package.
2. Remove the applicator from the package.
3. Remove the AMP™ particle dispenser (bellows) from its package. Remove the cap using a counter-clockwise turning motion (Fig.1).
4. Connect the AMP™ particle dispenser firmly to the end of the applicator handle (Fig.2 and Fig.3). The system is now ready for use.
5. Pump the dispenser to deliver AMP™ particles directly to the site of bleeding (Fig. 4).

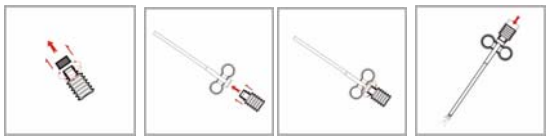


Fig.1 Fig.2 Fig.3 Fig.4

PerClot™ Standard
Intended for management and control of bleeding from open surgical sites.

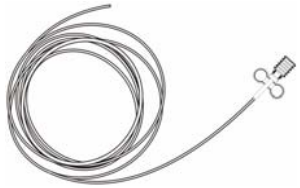
Application Technique
For maximum efficacy, the following techniques are recommended:
1. Remove all excess blood from the intended site by blotting, wiping, or suctioning. Identify and expose the source of bleeding. Removing excess blood is critical to maximizing the hemostatic performance as it allows AMP™ particles direct contact with the site and source of active bleeding.
2. Immediately apply a liberal amount of AMP™ particles directly to the source of bleeding. Thoroughly cover the bleeding wound with AMP™ particles.
3. When managing deep wounds, the applicator tip must be close to the source of the bleeding. In this situation, use caution to avoid contacting the applicator tip with blood as this may occlude the applicator. If this occurs, discard and use a new PerClot™ standard applicator.
4. For profuse bleeding, apply direct pressure over the wound for several minutes. Some materials such as standard gauze may adhere to the formed blood clot. Irrigation with saline before carefully removing the gauze is recommended. The use of a non-adhering substrate to apply pressure is recommended.
5. If bleeding continues, remove excess particles and repeat the procedure.
6. Once hemostasis is achieved, remove excess AMP™ particles carefully and completely by irrigation and aspiration.

PerClot™ Laparoscopic
For use as an adjunct hemostat to control bleeding from capillary, venous, or arteriolar vessels in laparoscopic and laparoscopic-assisted procedures when conventional procedures are ineffective or impractical.

A schematic diagram of The PerClot™ Laparoscopic Applicator

Application Technique
1. Identify the bleeding lesion(s). Removing excess blood from the site of bleeding is essential to achieve maximum hemostatic efficacy.
2. Insert the applicator into the laparoscope and position its tip at the site of bleeding. Deliver the AMP™ particles by pumping the dispenser. Avoid direct contact between the applicator tip and blood to minimize the possibility of applicator tip occlusion. Do not attempt to trim the applicator tip. In the event the tip becomes occluded, use a new applicator.
3. If bleeding continues, remove excess AMP™ particles and re-apply.
4. Once hemostasis is achieved, remove excess AMP™ particles with irrigation and aspiration.
5. Remove the applicator.
6. Following the procedure, insure the laparoscope is completely cleaned by irrigation to avoid laparoscope channel occlusion.

PerClot™ Endoscopic
For use as an adjunct hemostat to control bleeding from capillary, venous, or arteriolar vessels in endoscopic and endoscopic-assisted procedures when conventional procedures are ineffective or impractical.



A schematic diagram of The PerClot™ Endoscopic Applicator

Application Technique
1. Identify the bleeding lesion(s). Removing excess blood from the site of bleeding is essential to achieve maximum hemostatic efficacy.
2. Insert the applicator into the endoscope and position the applicator tip at the site of bleeding. Deliver AMP™ particles by pumping the reservoir. Avoid direct contact between the applicator tip and blood to minimize the possibility of applicator tip occlusion.
3. The endoscopic applicator cannula can be easily trimmed using a sharp scissors.
4. If bleeding continues, remove excess AMP™ particles and re-apply.
5. Once hemostasis is achieved, remove excess AMP™ particles with irrigation and aspiration.
6. Remove the applicator.
7. Following the procedure, insure the endoscope is completely cleaned by irrigation to avoid endoscope channel occlusion.

PerClot™ Express
Used to control capillary, venous, or arteriolar bleeding when conventional procedures are ineffective or impractical. This system is designed to deliver a rapid, precision dosage of AMP™ particles for focal, localized bleeding.

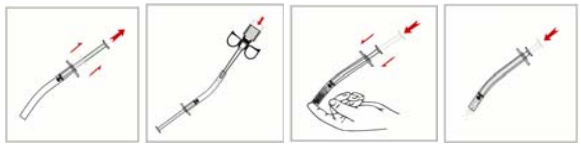


Fig.1 Fig. 2 Fig.3 Fig.4

Application
1. Identify the bleeding site(s). Remove excess blood from the bleeding tissue.
2. Withdraw the syringe plunger (Fig.1) and fill the syringe with AMP™ particles (Fig.2). Place your finger over the syringe tip and advance the syringe plunger (Fig.3).
3. Apply AMP™ particles to the bleeding site by advancing the syringe plunger (Fig.4). Cover the bleeding site(s) completely.
4. If bleeding is profuse, apply direct gauze pressure over the wound.
5. Remove excess AMP™ particles and re-apply if bleeding continues.
6. Once hemostasis is achieved, remove excess AMP™ particles by irrigation and aspiration.

CONTRAINDICATIONS
PerClot™ PHS is contraindicated in patients who are sensitive to starch or starch-derived materials.
Do not inject into blood vessels: extensive intravascular coagulation may occur.
Do not use for controlling post-partum bleeding or menorrhagia.
Do not inject into bladder or ureteral lumen.
Do not inject into eyes.

WARNINGS
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 hemostasis.

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 hemostatic agents has not been studied in controlled clinical trials.

Remove excess AMP™ particles once hemostasis is achieved. This is particularly important in and around the spinal cord, the optic nerve/chiasm, and foramina of the bone since unsaturated particles may swell and compress the surrounding tissues.

When an extracorporeal cardiopulmonary bypass circuit or autologous blood salvage circuit is used in conjunction with PerClot™ PHS, care must be exercised to prevent possible particle entry into the bypass circuit. Entry is prevented by using a 40µ cardio to my reservoir, cell washing, and a 40µ transfusion filter (such as a LipiGuard™).

PerClot™ PHS should not be mixed with methymethacrylate 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.

PRECAUTIONS
PerClot™ PHS is not recommended as a primary treatment for coagulation disorders.

PerClot™ PHS is intended to be used in a dry state. Contact with fluids prior to application will result in the loss of hemostatic properties.

ADVERSE REACTIONS
None reported to date.

DOSAGE AND ADMINISTRATION
Aseptic technique should always be used. A liberal amount of AMP™ particles should be applied to the bleeding site until hemostasis is achieved. For profuse bleeding, apply pressure if necessary. After hemostasis is achieved, AMP™ particles should be removed by irrigation and/or aspiration.

HOW SUPPLIED
PerClot™ Standard
PerClot™ Laparoscopic
PerClot™ Endoscopic
PerClot™ Express

STERILZING METHOD & EXPIRATION DATE
Contents of the PerClot™ PHS package are sterilized by gamma irradiation and should not be re-sterilized. Unused, open packages should be discarded properly.

If stored under the conditions specified in this manual (see Storage and Handling), this product remains sterile for three years from the date of sterilization.

STORAGE AND HANDLING
Do not store in extreme conditions, such as temperatures lower than -40°C or higher than 60°C. PerClot™ PHS should be used immediately after the package is opened.

DISPOSAL
This product shall be disposed of in compliance with pertinent government regulations regarding medical devices.

LIMITED WARRANTY
Starch Medical Inc. warrants that this product is free from defects in workmanship and materials. Liability under this warranty is limited to refund or replacement of any product which has been found by Starch Medical Inc. to be defective in workmanship and materials. Starch Medical Inc. shall not be liable for damages arising from the use, misuse, or abuse of this product or its content in ways that are inconsistent with the specific indications described in these Instructions for Use. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

No employee, agent, or distributor of Starch Medical Inc. has authority to alter this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Starch Medical Inc., and should be reported to Starch Medical Inc. and/or appropriate authorities.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER OBLIGATION OF STARCH MEDICAL INC.

TRADEMARKS
PerClot™ is a registered trademark of Starch Medical Inc.

= Do not reuse

= Use until year & month (Expiration date)

= Reference number (Product code)

= Method of sterilization - Irradiation

= Lot number

= Date of manufacture

= Attention, see Instruction for Use

= CE-mark and identification number of Notified Body. Certified according to MDD (93/42/EEC)

= Manufacturer

= Authorized representative in the EU

= Temperature limitation

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