SuperClot®

Absorbable Polysaccharide Hemostat

Instructions For Use

SuperClot® Absorbable Polysaccharide Hemostat

Caution: SuperClot® should only be used by a physician or other licensed practitioners.

DESCRIPTION
SuperClot® Absorbable Polysaccharide Hemostat (SuperClot®) is a medical device composed of absorbable modified polymer (AMP®) particles and delivery applicator. AMP® particles are biocompatible, non-pyrogenic and derived from purified plant starch. The device contains no human or animal components. SuperClot® is intended as an absorbable hemostatic system to control bleeding during surgical procedures or following traumatic injuries.

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 control 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 amylase and glucoamylase.

INDICATIONS
SuperClot® 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 this device in the management and control of bleeding from open surgical sites and traumatic injuries.

These instructions do not eliminate the necessity of formal training in the use of SuperClot®. In addition, the techniques and procedures described here do not represent all medically acceptable protocols, nor are they intended as a substitute for physician's experience and judgment in treating specific patients.

PREPARATION
1. Visually inspect the sealed SuperClot® package. If the package has been previously opened or damaged, discard and replace with a new package.

2. Remove the AMP® particle dispenser (bellows) and applicator from the package.

3. Remove the cap using a counter-clockwise turning motion (Fig.1).

4. Connect the AMP® dispenser firmly to the end of the applicator handle (Fig.2 and Fig.3). The device is now ready for use (Fig.4).

Fig. 1

Fig. 2

Fig. 3

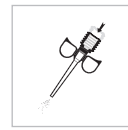

Fig. 4

SuperClot® Standard
Used during open surgical procedure.

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 SuperClot® applicator.

4. For profuse bleeding, apply direct pressure over the wound for several minutes following AMP® particles application. Some materials such as standard gauze may adhere to the clot matrix. 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.

SuperClot® Laparoscopic
Used in laparoscopic and laparoscopic-assisted procedure.

An illustration of the SuperClot® laparoscopic

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 deliberate pumping of the dispenser. Do not attempt to trim the applicator tip. In the event that 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.

CONTRAINDICATIONS
SuperClot® is contraindicated in patients who are sensitive to starch or starch-derived materials.

Do not apply into blood vessels, extensive intravascular coagulation may occur.

Do not use for controlling post-partum bleeding or menorrhagia.

Do not apply into bladder or ureteral lumen.

Do not apply into eyes.

WARNINGS
SuperClot® is not intended as a substitute for good surgical practice, and in particular, the proper use of conventional procedures (such as ligature) for hemostasis.

SuperClot® is not recommended when an infection is suspected. SuperClot® should be used with caution in contaminated areas. If signs of an infection develop in the site where SuperClot® has been used, surgery may be necessary to allow adequate drainage.

Combined use of SuperClot® with other topical hemostatic agents has not been studied in controlled clinical trials.

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

Safety and effectiveness of SuperClot® have not been clinically evaluated in children and pregnant women.

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

SuperClot® 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 the bone tissue. Excess particles should be fully removed from bony surfaces by irrigation prior to the use of adhesives.

All excess SuperClot® must be fully removed during trachea surgery after hemostasis is achieved to avoid potential patient discomfort or trachea blockage.

SuperClot® is a single use product. Do not use SuperClot® in more than a single surgical procedure.

PRECAUTIONS
SuperClot® is not recommended as a primary treatment for coagulation disorders.

SuperClot® is intended to be used in a dry state. Contact with fluids prior to application will result in 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
SuperClot® is available in 0.5g, 1g, 2g, 3g and 5g.

SuperClot® applicators are available in the following lengths:
Standard Applicators: 90mm and 200mm
Laparoscopic Applicator: 380mm

STERILIZING METHOD & EXPIRATION DATE

Contents of the SuperClot® package are sterilized by 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), the unopened and undamaged product remains sterile for three (3) years from the date of sterilization.

STORAGE AND HANDLING
Do not store in extreme conditions, such as a temperature lower than -40°C (-40°F) or higher than 60°C(140°F). SuperClot® should be used immediately after the package is opened.

DISPOSAL
This device 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
SuperClot® and AMP® are registered trademarks of Starch Medical Inc.

LipiGuard® is a registered trademark of Haemonetics Puerto Rico LLC.

 = Do not re-use

 = Use-by date

= Catalogue number

= Sterilized using irradiation

= Batch code

 = Date of manufacture

 = Caution

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

 = Manufacturer

EC REP = Authorized representative in the EC

 = Do not use if package is damaged

= Do not resterilize

 = Consult instructions for use

= This product is not made with natural rubber latex

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