SealFoam® Absorbable Polysaccharide Hemostat

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

DESCRIPTION

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

ACTION

SealFoam® has 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, SealFoam® supports 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. SealFoam® is degraded by amylase and glucoamylase.

INDICATIONS

SealFoam® 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

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

Remove the SealFoam® from the package.

Remove excess blood from the intended site by blotting, wiping, or suctioning. Identify and expose the source of bleeding. Immediately apply SealFoam® directly to the source of bleeding and cover the wound site completely. Apply direct pressure until the SealFoam® adheres to the wound surface. Once hemostasis is achieved, excess SealFoam® may be removed carefully and completely by irrigation.

CONTRAINDICATIONS

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

Do not apply into blood vessels as intravascular coagulation may occur.

Do not use for controlling post-partum bleeding or menorrhagia.
Do not apply into eyes.
Do not apply into bladder, ureteral lumen or renal pelvis.
Do not apply in the brain.

WARNINGS

SealFoam® is not intended as a substitute for good surgical practice, and in particular, the proper use of conventional procedures (such as ligature) for hemostasis.
SealFoam® is not recommended when an infection is suspected. SealFoam® should be used with caution in contaminated areas. If signs of infection develop in the site where SealFoam® has been used, surgery may be necessary to allow adequate drainage.
Combined use of SealFoam® with other topical hemostatic agents has not been studied in controlled clinical trials.
Remove excess SealFoam® 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 SealFoam® may swell and compress the surrounding tissues.
When an extracorporeal cardiopulmonary bypass circuit or autologous blood salvage circuit is used in conjunction with SealFoam®, care must be exercised to prevent foam entry into the bypass circuit.
SealFoam® 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 SealFoam® should be fully removed from bony surfaces by irrigation prior to the use of adhesives.
SealFoam® is a single-use product. Do not use SealFoam® in more than a single surgical procedure.
Safety and effectiveness of SealFoam® have not been clinically evaluated in children and pregnant woman.
Safety and effectiveness in neurological and ophthalmic procedures has not been studied in controlled clinical trials.

PRECAUTIONS

SealFoam® is not recommended as a primary treatment for coagulation disorders.
SealFoam® 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 THAT HAVE BEEN ATTRIBUTED TO OTHER STARCH DERIVED POLYSACCHARIDE HEMOSTATIC PARTICLES

The following adverse events have been reported for other starch derived polysaccharide hemostatic particles and may apply to the use of SealFoam®:
Re-bleeding has been recorded resulting from the unidentified bleeding source during emergency epistaxis and septoplasty.
In laparoscopic or laparoscopic-assisted procedures, infection and bowel obstruction (ileus) resulting from excess and residual hemostatic particles have been observed.
In a randomized prospective, concurrently controlled clinical trial, it was reported for other starch derived polysaccharide hemostatic particles, the most common adverse events were pain related to surgery, anemia, nausea, and lab values out of normal range.

ADVERSE REACTIONS THAT HAVE BEEN ATTRIBUTED TO OTHER NON-STARCH DERIVED HEMOSTATIC AGENTS

The following adverse events have been reported for other non-starch derived hemostatic agents and may apply to the use of SealFoam®:
Paralysis and nerve damage have been reported when hemostatic agents are used in or in proximity to foramina in bone, areas of bone confine, the spinal cord, and/or the optic nerve and chiasm. While most of these reports have been in connection with laminectomy, reports of paralysis have also been received in connection with other procedures.
Compression of the brain and spinal cord resulting from the accumulation of sterile fluid has been observed.

DOSAGE AND ADMINISTRATION

A proper size of SealFoam® should be applied to the bleeding site until hemostasis is achieved.

HOW SUPPLIED

Ref. No.	Model Name	Size (mm) Length x Width	Content(s)/ Unit	Units/ Box	Application
PF432	SealFoam® Standard	40 x 30	1 piece	10	Surgeons can select the specificaitons of SealFoam® according to the bleeding wound site. Details of the application techniques are as per the Instructions for Use.
PD644	SealFoam® HD	60 x 40	1 piece	10	
PD154		100 x 50	1 piece	10	
PFS02	SealFoam® Sternal	120 x 25	2 pieces	10	
PFS03		120 x 25	3 pieces	10	
PFD02	SealFoam® Dental	14 x 7	4 pieces	10	
PFE01	SealFoam® ENT	14 x 7	4 pieces	10	

STERILIZING METHOD & EXPIRATION DATE

Contents of the SealFoam® 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 years from the date of sterilization.

STORAGE AND HANDLING

SealFoam® should be stored at temperatures between 0°C~30°C (32°F~86°F). The extreme temperature is permitted to -20°C (-4°F) or 40°C (104°F) for up to 3 weeks. Once the package is opened, contents are subject to contamination. It is recommended that SealFoam® be used as soon as the package is opened and unused contents discarded.

DISPOSAL

This product shall be disposed of in compliance with pertinent government regulations relating to 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

SealFoam® and AMP® are registered trademarks of Starch Medical Inc.

= Do not re-use

= Use-by date

REF = Catalogue number

STERILE R = Sterilized using irradiation

LOT = Batch code

= Date of manufacture

= Caution

CE 1023 = CE-mark and identification number of Notified Body. Certified according to MDD (93/42/EEC)

= Manufacturer

= Authorized representative in the EC

= Temperature limitation

= Do not use if package is damaged

= Do not resterilize

= Consult instructions for use

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