ARTISS
[Fibrin Sealant (Human)]

How to prepare Artiss

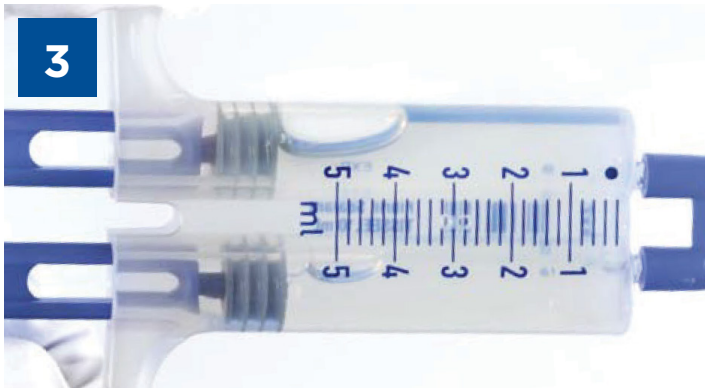
ARTISS is supplied frozen in a sterile two-component fibrin sealant syringe.

Remove Packaging

Remove Artiss Fibrin Sealant from its sterile packaging.

Thaw

Immerse Artiss container with sterile water or saline warmed to 37°C. For 2mL - 5 minutes. For 4mL - 5 minutes. For 10mL - 12 minutes.



Check that Artiss is ready to use

Artiss is ready to use when both solutions are transparent and bubbles have begun to rise.

Assemble Syringe

Remove Artiss syringe from water, remove protective cap, join with connecting piece. Attach the needle and Artiss is ready to use.

Important Points

DO NOT attempt to thaw the frozen solutions in a microwave
DO NOT warm the product to more than 37˚C
DO NOT refreeze or refrigerate the thawed product
USE within 4 hours after thawing (33 -37°C)

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Baxter

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Two-Component Fibrin Sealant, Deep-Frozen, Vapour Heated (VH) and Solvent Detergent (S/D) treated.

Indications

ARTISS is indicated to adhere autologous skin grafts in burn patients.

ARTISS is indicated to adhere tissue flaps during facial rhytidectomy surgery (face-lift).

ARTISS is not indicated for haemostasis.

Contraindications

ARTISS is contraindicated in the case of hypersensitivity to the active substances or to any of the excipients.

ARTISS is contraindicated for intravascular application. Intravascular application may result in life-threatening thromboembolic events.

Soft tissue injection of ARTISS carries the risk of local tissue damage.

Precautions

ARTISS alone is not indicated for the treatment of massive and brisk arterial or venous bleeding. As with any proteincontaining product, allergic type hypersensitivity reactions are possible. Hypersensitivity or allergic/ anaphylactoid reactions may occur with the use of fibrin sealant. In specific cases, these reactions have progressed to severe anaphylaxis.

Sealer protein concentrate and Thrombin are made from human plasma. When medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses or other pathogens.

The standard measures taken (including double virus inactivation by vapor heat treatment and solvent detergent treatment) are considered effective for enveloped viruses such as HIV, HBV, and HCV, and for the non-enveloped virus HAV.

Adverse Effects

Adverse Reactions from Clinical Trials

In a phase 3, multi-centered, prospective, evaluator-blinded, randomized study, where ARTISS was used to affix split thickness sheet skin grafts to excised burn wounds, a total of 8 non-serious adverse reactions were reported. There were no serious reactions.

The eight non-serious adverse reactions occurred in six patients. Five of these reactions were skin graft failures, 4 were graft detachment/nonadherence, and 1 was graft necrosis. The remaining nonserious adverse reactions were pruritus (2) and dermal cyst (1).

Post marketing Adverse Reactions

There are limited post-marketing data available for ARTISS.

Adverse reactions reported from clinical studies as well as from postmarketing surveillance of Baxter´s other fibrin sealants are summarized in the full Product Information.

Dosage and Administration

ARTISS should be administered topically. Do not inject. ARTISS may be denatured by antiseptics (see Interactions with other medicines). Similar to comparable products or Thrombin solutions, the product may be denatured after exposure to solutions containing alcohol, iodine or heavy metals (e.g. antiseptic solutions). Such substances should be removed to the greatest possible extent before applying the product.

The skin graft should be attached to the wound bed immediately after ARTISS has been applied. The surgeon has approximately 60 seconds to manipulate and position the graft prior to polymerization.

After the graft or flap has been positioned, hold in the desired position by gentle compression for at least 3 minutes to ensure ARTISS sets properly and the graft or flap adheres firmly to the underlying tissue.

Please review full Product Information before prescribing. Available from Baxter Medical Information 1300 302 409 or onecall@baxter.com

To order call Baxter Customer Support:

Australia 1800 229 837 **New Zealand** 0800 229 837

ANZ/9/19-0026.

PBS Information: This product is not listed on the PBS

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