Artiss
FIBRIN SEALANT (HUMAN)

Ready to use*
Preparation Guide

*3 Ways to Thaw the Frozen Pre-Filled PRIMA Syringe

**Plan Ahead: Thaw up to 14 days before use. Record the date and time on the sticker provided on the box.*

Thawing / warming - ON sterile field:

Thawing/warming times 33°-37°C

- 2 mL in bath without pouch approximately 5 mins.
- 4 mL in bath without pouch approximately 5 mins.
- 10 mL in bath without pouch approximately 10 mins.

(Ensure the contents of the syringe remain completely submerged throughout thawing.)

Thawing / warming - OFF sterile field:

Thawing/warming times 33°-37°C

- 2 mL in bath with pouches approximately 15 mins.
- 4 mL in bath with pouches approximately 20 mins.
- 10 mL in bath with pouches approximately 35 mins.

(Ensure the pouches remain submerged throughout thawing.)

Thawing / warming - OFF sterile field (Incubator):

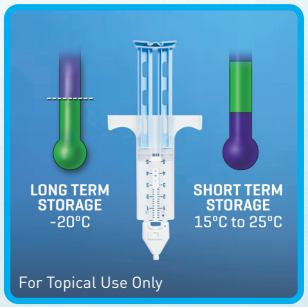
Thawing/warming times 33°-37°C

- 2 mL in pouches approximately 40 mins.
- 4 mL in pouches approximately 50 mins.
- 10 mL in pouches approximately 90 mins.

DO NOT microwave.

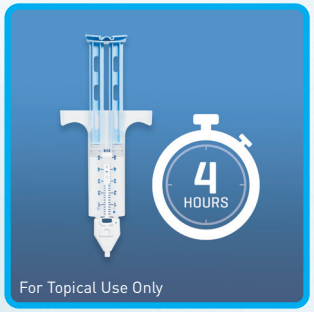
Application of ARTISS Fibrin Sealant [Human] must be completed within 4 hours of warming to 33°C-37°C. Discard any unused product.

Product Storage



Long term: Store at <-20°C

Short term: Unopened pouches, thawed at room temperature, may be stored for up to 14 days at room temperature (15°C to 25°C) after removal from the freezer. **Prior to application, the product must be warmed to 33-37°C.**



Once the package is opened or the product is warmed to 33°C to 37°C, **it must be used within 4 hours.**

DO NOT REFRIGERATE.

Once thawed, DO NOT refrigerate or re-freeze.

DO NOT expose to temperatures above 37°C.

DO NOT use after the expiration date.

Artiss

FIBRIN SEALANT (HUMAN)

PRESCRIBING INFORMATION – ARTISS

(Please consult the Summary of Product Characteristics before prescribing)

Name and composition: ARTISS Solutions for Sealant – one prefilled double chamber syringe containing Sealer Protein Solution (with aprotinin) deep frozen in one chamber and Thrombin Solution (with calcium chloride) deep frozen in the other chamber. Sealer Protein Solution contains 91mg/ml human fibrinogen (clottable protein) and 3000 KIU/ml aprotinin. Thrombin Solution contains 4 IU/ml human thrombin and 40µmol/ml calcium chloride dihydrate. Presentations of 1, 2 or 5ml in each chamber resulting in total volume of 2ml, 4ml or 10ml of total volume of product ready for use. Contains human factor XIII co-purified with human fibrinogen in a range of 0.6 – 5 IU/ml. **Indication:** Hospital use only. A tissue glue to adhere / seal subcutaneous tissue in plastic, reconstructive and burn surgery, replacement or adjunct to sutures or staples. Adjunct to haemostasis on subcutaneous tissue surfaces. **Dosage and Route:** The use of ARTISS is restricted to experienced surgeons who have been trained in the use of ARTISS. For epilesional use. Dose individualised and governed by indication, application methods and number of applications. Guide – 1 pack ARTISS 2ml sufficient for an area at least 10 cm^2. Avoid excess granulation by applying only a thin layer. Surface of the wound should be as dry as possible. **Side effects:** *See summary of product characteristics for detail.* Risk of anaphylactic reaction. Intravascular injection may lead to life-threatening thromboembolic events. Hypersensitivity or allergic reactions. In isolated cases these reactions have progressed to severe anaphylaxis. Pruritus and skin graft failure.

Precautions: Caution applying ARTISS using pressurised air or gas, not to be used with Easy Spray / Spray Set system in enclosed body areas. Any application of pressurised air or gas is associated with a potential risk of air or gas embolism, tissue rupture or gas entrapment with compression, which may be life threatening or fatal. Use spray device pressure within manufacturers recommended range, not exceeding 2.0 bars. Do not spray closer than 10-15 cm from tissue surface. Monitor blood pressure, pulse, oxygen saturation, end tidal CO_2 for possibility of occurrence of air or gas embolism. Not indicated for use where a fast clotting sealant is required, especially in cardiovascular surgery. Not for use in neurosurgery or gastrointestinal or vascular anastomoses. Excessive clot thickness may interfere with efficacy and wound healing. Care to prevent adhesion at undesired sites. Signs of hypersensitivity include hives, urticaria, tightness of chest, wheezing, hypotension, anaphylaxis. Risk of anaphylaxis increased if previous exposure to aprotinin. In event of hypersensitivity or anaphylaxis discontinue use and remove polymerised product from surgical site. Oxycellulose containing preparations may reduce ARTISS efficacy. Infectious diseases due to transmission of infective agents cannot be totally excluded. Use of ARTISS and batch number should be recorded in patient's notes. Carefully evaluate in patients with allergies to bovine proteins. **Contra-indications:** Not indicated to replace sutures intended to close surgical wound. Not for treatment of massive and brisk arterial or venous bleeding. Not for intravascular use. Hypersensitivity to active substances or excipients. Spray application should not be used in endoscopic procedures. **Interactions:** Avoid solutions containing alcohol, iodine and heavy metals. The effects of ARTISS on fertility have not been established. **Overdose:** No cases of overdose have been reported. **Legal Category:** POM Basic NHS price: 2ml kit - £97.50; 4ml kit £195.00; 10ml kit £443.75 **Marketing Authorisation Number and Holder:** ARTISS – PL 00116/0634, Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk. IP24 3SE. **Date of Preparation:** May 2021.

Adverse Events and any suspected defective medicines should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse Events relating to Baxter products can also be reported direct to Baxter Pharmacovigilance on +44 (0)1635 206360, or by email to vigilanceuk@baxter.com
Any drug product quality complaints (including suspected defective medicines) relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team on +44 (0)1604 704603, or by email to UK_SHS_QA_Complaints@baxter.com. Alternatively please report directly to your Baxter Representative, who will take the details and forward to the Baxter Country Quality Assurance Team.

Ordering Information

PRODUCT	ORDER CODE
ARTISS Frozen with PRIMA Syringe 2ML	5500649
ARTISS Frozen with PRIMA Syringe 4ML	5500650
ARTISS Frozen with PRIMA Syringe 10ML	5500651

For questions, please contact your Baxter representative.

Advancing the art of healing

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