ARTISS
[Solutions for Sealant]

ARTISS Product Preparation – Quick Reference Guide

METHOD A

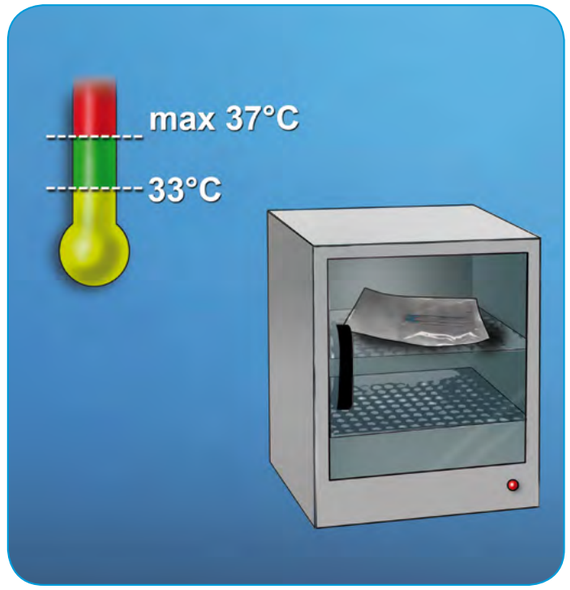
STERILE WATER BATH

Thawing & warming times
at 33-37 °C
(Product removed from aluminum-coated plastic bags)

2 ml – 5 min
4 ml – 5 min
10 ml – 12 min

METHOD B

INCUBATOR



Thawing & warming times
at 33-37 °C
(Product in aluminum-coated plastic bags)

2 ml – 40 min
4 ml – 85 min
10 ml – 105 min

METHOD C

THAWING AT ROOM TEMPERATURE FOLLOWED BY ADDITIONAL WARMING IN AN INCUBATOR JUST BEFORE USE

Thawing times at room temperature
(not exceeding +25°C)

2 ml – 60 min
4 ml – 110 min
10 ml – 160 min

Warming times in incubator
(warm to 33-37°C)

2 ml – 15 min
4 ml – 25 min
10 ml – 35 min

The maximum time ARTISS can be kept (in both aluminum-coated plastic bags) at room temperature is 14 days. If not used within 14 days after thawing, ARTISS has to be discarded.

DO NOT

- Heat above 37 °C
- Microwave
- Thaw the product by holding it in your hands
- Remove cap before use
- Refrigerate
- Refreeze
- Use for more than 4 hours after warming to 37 °C
- Use at room temperature without warming to 37 °C

Baxter

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PRESCRIBING INFORMATION

(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. 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.

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: April 2018.

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.

Baxter

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