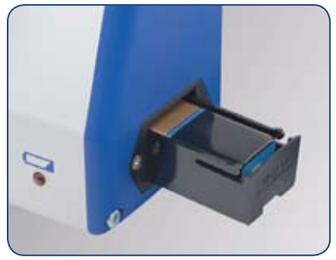
EASYSPRAY Quick Reference Guide

Instructions for Circulating Nurse | EasySpray Pressure Regulator

1



Insert 9V battery into the EASYSPRAY pressure regulator device.

2

Connect EASYSPRAY device to IV pole or cart rail using the clamps on the back of the device.

3

Use suitable connection tube to connect the EASYSPRAY device to medical air (ranging 3.5 – 7 bar / 50 – 100 psi).

4

Connect Spray Set filters to EASYSPRAY device. Connect the blue filter to the blue female luer connector and the clear filter to the male luer connector.

5

Turn the on/off switch on the front side of the EASYSPRAY to the ON position.

6

Check the gauge on the EASYSPRAY device for the appropriate pressure range of 1.5-2.0 bars (21.5-28.5 psi). Adjust pressure setting by turning the black pressure control knob.

Instructions for Scrub Nurse | Spray Set

1

Prepare ARTISS Solution for Sealants according to the instructions in the package insert.

2

Firmly attach the spray head to the nozzle of the syringes.

3

Fasten the pull strap to the double syringe system to assure the spray head is tightly secured.

4

Fit the connection tube of the spray set to the luer-lock connector on the underside of the spray head.

5

Attach the clip (on the end of the sensor line) by sliding it into the grooves located on the top of the syringe plunger.

6

Pass the assembled applicator to the surgeon for spray application. Pass the end of the connection tube with the sterile filters to the circulating nurse.

Instructions for Surgeon

1

Spray from a distance of 10 – 15 cm for optimum results.

2

To activate the flow of gas occlude the opening in the clip center with thumb. To begin application, gently depress the syringe plunger.

The EASYSPRAY device will continue to emit gas for a brief period after the thumb is removed from the clip/plunger. This delay helps to avoid clogging of the spray head.

Please see the ARTISS abbreviated summary of product characteristics (SPC) on the back.

EASYSPRAY Quick Reference Guide

This abbreviated summary of product characteristics (SmPC) is intended for international use. Please note that it may differ from the licensed SmPC in the country where you are practicing.

Therefore, please always consult your country-specific SmPC or package leaflet.

ARTISS, Solutions for Sealant, deep frozen

COMPOSITION: ARTISS consists of: • Human Fibrinogen (as clottable protein) 91 mg1/ml • Synthetic Aprotinin 3000 KIU2/ml • Human Thrombin 4 IU3/ml • Calcium Chloride 40 µmol/ml

INDICATIONS: ARTISS is indicated as tissue glue to adhere/seal subcutaneous tissue in plastic, reconstructive and burn surgery, as replacements or adjuncts to sutures or staples. In addition, ARTISS is indicated as adjunct to hemostasis on subcutaneous tissue surfaces.

CONTRAINDICATIONS: ARTISS is not indicated to replace skin sutures intended to close surgical wound. ARTISS alone is not indicated for the treatment of massive and brisk arterial or venous bleeding. ARTISS can never be applied intravascularly. Hypersensitivity to the active substances or to any of the excipients.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE: For epilesional use only. Do not apply intravascularly. Life threatening thromboembolic complications may occur if the preparation is unintentionally applied intravascularly. Soft tissue injection of ARTISS carries the risk of local tissue damage.

ARTISS is not indicated for hemostasis and sealing in situations where a fast clotting of the sealant is required. Especially in cardiovascular procedures in which sealing of vascular anastomoses is intended ARTISS should not be used. ARTISS is not indicated for use in neurosurgery and as a suture support for gastrointestinal anastomoses or vascular anastomoses as no data are available to support these indications. ARTISS should only be applied as a thin layer. Excessive clot thickness may negatively interfere with the product's efficacy and the wound healing process.

Before administration of ARTISS, care is to be taken that parts of the body outside the designated application area are sufficiently protected/covered to prevent tissue adhesion at undesired sites.

As with any protein-containing product, allergic type hypersensitivity reactions are possible. Signs of hypersensitivity reactions may include hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis. If these symptoms occur, the administration must be discontinued immediately.

ARTISS contains synthetic aprotinin. Even in case of strict local application, there is a risk of anaphylactic reaction linked to the presence of aprotinin. The risk seems to be higher in cases where there was previous exposure, even if it was well tolerated. Therefore any use of aprotinin or aprotinin containing products should be recorded in the patients' records.

In the event of anaphylactic or severe hypersensitivity reactions, administration is to be discontinued and state-of-the-art emergency measures are to be taken. In case of shock, standard medical treatment for shock should be implemented.

Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, 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 measures taken are considered effective for enveloped viruses such as HIV, HBV, and HCV, and for the non-enveloped virus HAV. The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (fetal infection) and for individuals with immunodeficiency or increased erythropoiesis (e.g., hemolytic anemia).

UNDESIRABLE EFFECTS: Inadvertent intravascular injection could lead to thromboembolic events and DIC and there is also a risk of anaphylactic reactions. Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the application site, bradycardia, bronchospasm, chills, dyspnoea, flushing, generalized urticaria, headache, hives, hypotension, lethargy, nausea, pruritus, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing) may occur in rare cases in patients treated with fibrin sealants/hemostatics. In isolated cases, these reactions have progressed to severe anaphylaxis. Such reactions may especially be seen if the preparation is applied repeatedly, or administered to patients known to be hypersensitive to aprotinin or any other constituents of the product.

Even if a first treatment with ARTISS is well tolerated, a subsequent administration of ARTISS or systemic administration of aprotinin may result in severe anaphylactic reactions. Antibodies against components of fibrin sealant may rarely occur. Adverse reactions reported from clinical studies as well as from postmarketing surveillance are summarized in the following. Known frequencies of these adverse reactions are based on a controlled clinical study in 138 patients where skin grafts were fixed to excised burn wounds using ARTISS. None of the events were classified as serious. Unknown frequencies are based on spontaneous reports from postmarketing surveillance of Baxter's fibrin sealants.

The ADRs and their frequencies are: Common (≥1/100 to <1/10): pruritus, skin graft failure; Uncommon (≥1/1000 to <1/100): dermal cyst; Unknown (cannot be estimated from the available data): anaphylactic responses, hypersensitivity, : bradycardia, tachycardia, hypotension, haematoma, dyspnoea, nausea, urticaria, flushing, impaired healing, oedema, pyrexia, seroma.

For the Posology, incompatibilities and interactions, please refer to your locally approved full SmPC.

Medicinal products are subject to medical subscription

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WARNINGS AND PRECAUTIONS

Caution: Pressurized gas supply must be between 3.5 and 7 bar (51-100 psi).

Caution: DO NOT connect to an oxygen source. Failure to follow these instructions can lead to explosion, which could result in serious injury or death.

Prior to operation make sure that the pressure range of the device is adjusted to the range specified in the appropriate spray set instructions for use.

Caution: Any application of pressurized gas may be associated with a potential risk of air embolism, tissue rupture or gas entrapment with compression, which may be life threatening. Be sure to take appropriate measures to address these risks by observing the recommended minimum spraying distance and the maximum pressure provided in the appropriate spray set instructions for use.

Caution: Spraying into enclosed body cavities requires appropriate safety measures to make sure that the above mentioned risks will be avoided.

NOTE: Do not use with rechargeable batteries. The use of accessories of other manufacturers is not permitted.

For detailed information please contact your local representative
www.baxterbiosurgery.com

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