ARTISS
[Fibrin Sealant (Human)]

Baxter

[SPECIFICALLY DESIGNED FOR SKIN GRAFTS IN BURN SURGERY.]

ARTISS is indicated to adhere autologous skin grafts to surgically prepared wound beds resulting from burns in adult and pediatric populations greater than or equal to 1 year of age.

ARTISS is not indicated as an adjunct to hemostasis.

For Topical Use Only

BioSurgery

Please see Detailed Important Risk Information on the back page and the accompanying full Prescribing Information.

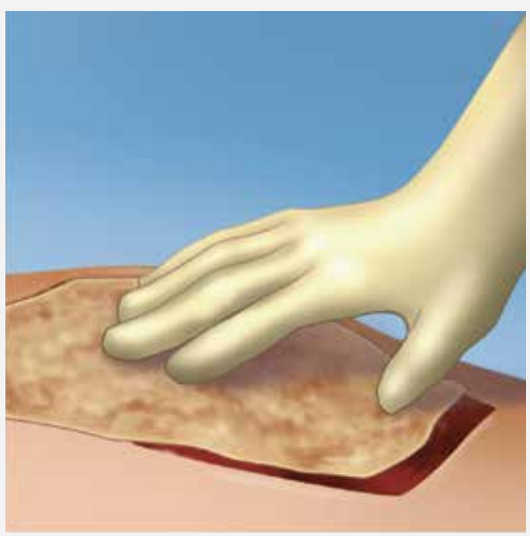
ARTISS
[Fibrin Sealant (Human)]

SPECIFI

Specifically Designed

- **ARTISS [Fibrin Sealant]** is a fibrin sealant that provides **full surface adherence** of the graft to the wound bed[1]
- **ARTISS [Fibrin Sealant]** is indicated to adhere autologous skin grafts to surgically prepared wound beds resulting from burns in adult and pediatric populations greater than or equal to 1 year of age[2]
- **ARTISS [Fibrin Sealant]** is not indicated for hemostasis[2]
- **ARTISS [Fibrin Sealant]** contains 4 units/mL of human thrombin, giving the surgeon up to 60 seconds to manipulate and position the graft prior to polymerization[2]

How ARTISS [Fibrin Sealant] Works



ARTISS [Fibrin Sealant] is a two component fibrin sealant, consisting of human thrombin and human fibrinogen and an antifibrinolytic inhibitor to delay clot degradation.[2]

Upon mixing, soluble fibrinogen is transformed into a fibrin matrix that **adheres to the wound surface and to the skin graft to be affixed.**[2]

Initial polymerization of **ARTISS [Fibrin Sealant]** will take up to 60 seconds; allowing time to manipulate and position the graft prior to polymerization.[2]

The adhesive properties of **ARTISS [Fibrin Sealant] provide full surface adherence** of the graft to the wound bed, closing the space that exists when grafts are attached using point fixation techniques such as staples.[1]

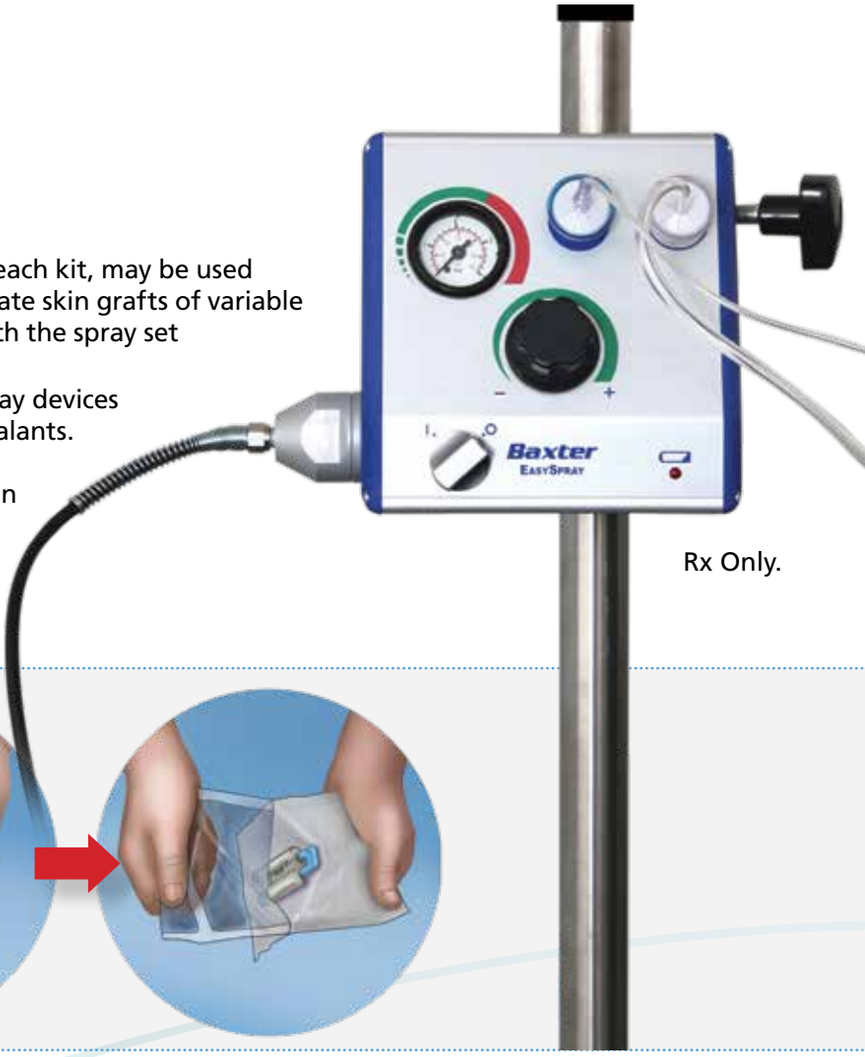
ARTISS [Fibrin Sealant] eliminates the need for staple application or removal.[1]

CALLY DESIGNED

TO MEET THE NEEDS OF BURN SURGERY

Just Thaw and Warm

- **ARTISS [Fibrin Sealant]** comes already prepared in a pre-filled syringe (frozen)
- No mixing or reconstitution required
- Unopened pouches, thawed at room temperature, may be stored for up to 14 days at room temperature (15°- 25°C)[2]
- Prior to use, product should be warmed to 33°- 37°C
  - Do not refrigerate or re-freeze after thawing
  - Do not microwave
  - Do not expose to temperatures above 37°C
- The **ARTISS [Fibrin Sealant]** spray set, included with each kit, may be used along with the EASYSPRAY Pressure Regulator to fixate skin grafts of variable sizes; see additional instructions for use provided with the spray set
- Air or gas embolism has occurred with the use of spray devices employing pressure regulator to administer fibrin sealants. This event appears to be related to the use of spray devices at higher than recommended pressures and in close proximity to the surface of the tissue



Rx Only.

And is Ready To Use

Selected Risk Information for ARTISS [Fibrin Sealant]

- Do not inject ARTISS [Fibrin Sealant] directly into blood vessels; life-threatening thromboembolic events can occur
- Apply only as a thin layer
- Exposure to solutions containing alcohol, iodine, or heavy metals may cause ARTISS [Fibrin Sealant] to be denatured
- Use caution when applying ARTISS [Fibrin Sealant] with pressurized gas

Please see the ARTISS Detailed Important Risk Information on the back page and the accompanying full Prescribing Information.

CALLY DESIGNED

TO MEET THE NEEDS OF BURN SURGERY

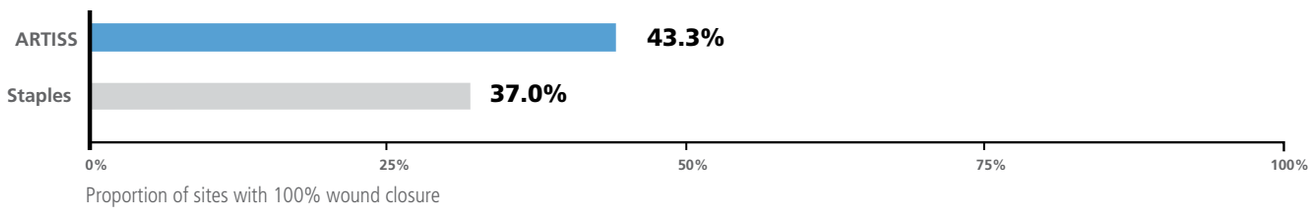
Clinical Evidence / Pivotal Study

The efficacy of ARTISS [Fibrin Sealant] versus staples for skin graft adherence was demonstrated in a phase 3, multicenter, prospective, randomized, evaluator blinded clinical trial in 138 adult and pediatric burn patients. The study was designed to evaluate whether or not complete (100%) wound closure was achieved 28 days after wound excision and skin grafting when ARTISS [Fibrin Sealant] or staples were used.[1]

Efficacy Results

- The proportion of test sites with complete wound closure* was similar between the 2 treatments (ARTISS [Fibrin Sealant], 43.3%; staples, 37%)

Proportion of sites achieving 100% wound closure by Day 28 as assessed by blinded review† of photos



The lower limit of the 97.5% confidence interval of the difference between ARTISS [Fibrin Sealant] and staples was -0.029, which is above the predefined noninferiority margin of -0.1.

Study Conclusion

The pivotal study concluded: ARTISS [Fibrin Sealant] is at least as efficacious as staples at the 97.5% one-sided level for complete wound closure by day 28.[1]

†Blinded Review: reviewers were burn surgeons who were not involved with the study in any other way and who were unaware of treatments used in the study, treatment assignation, time point of assessment, and identity of the patient and operating surgeon

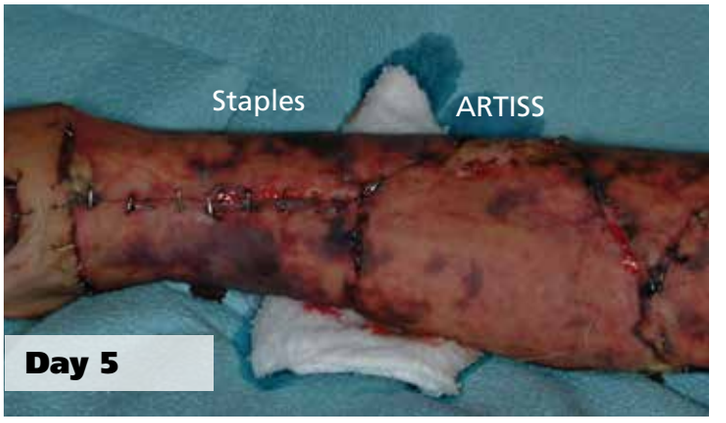
*Full coverage of the wound with a contiguous layer of viable epithelium

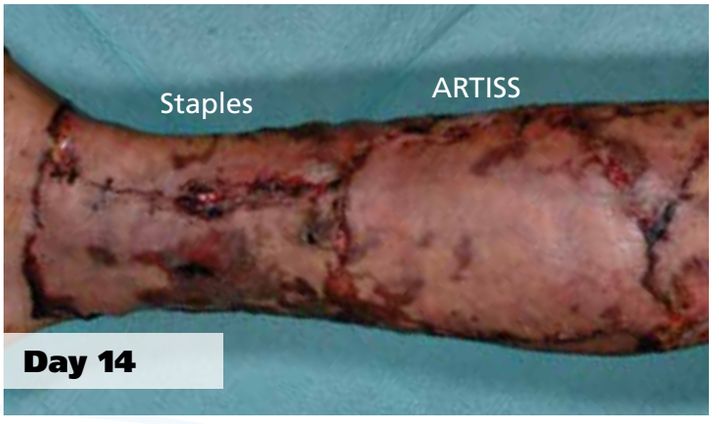
Selected Risk Information for ARTISS [Fibrin Sealant]

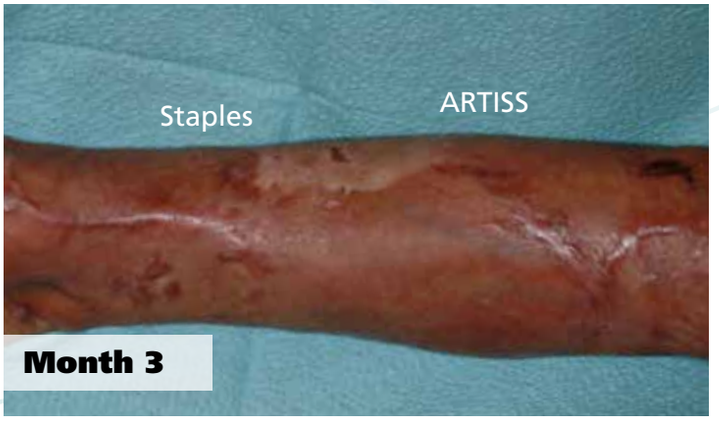
- Do not inject ARTISS [Fibrin Sealant] directly into blood vessels; life-threatening thromboembolic events can occur
- Do not use in individuals with a known hypersensitivity to aprotinin
- Apply only as a thin layer
- Exposure to solutions containing alcohol, iodine, or heavy metals may cause ARTISS [Fibrin Sealant] to be denatured
- ARTISS [Fibrin Sealant] is made from human plasma which theoretically may contain infectious agents
- Use caution when applying ARTISS [Fibrin Sealant] with pressurized gas

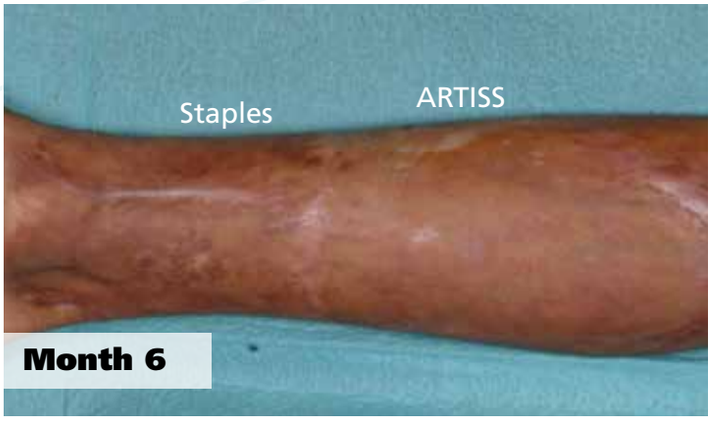
Please see the Detailed Important Risk Information on the back page and the accompanying full Prescribing Information.

Pivotal Study Photographs: Patient #2966[1]









ARTISS
[Fibrin Sealant (Human)]

ARTISS [Fibrin Sealant (Human)] Indication

- ARTISS is indicated to adhere autologous skin grafts to surgically prepared wound beds resulting from burns in adult and pediatric populations greater than or equal to 1 year of age.
- ARTISS is indicated to adhere tissue flaps during facial rhytidectomy surgery (face-lift).
- ARTISS is not indicated as an adjunct to hemostasis.

Important Risk Information for ARTISS

- **For Topical Use Only.** Do not inject directly into blood vessels. Intravascular application can result in life-threatening thromboembolic events.
- Do not use in individuals with a known hypersensitivity to aprotinin and/or hypersensitivity to any of the active substances or excipients.
- Do not spray where the minimum recommended distance from the applicator tip to the target site cannot be assured.
- Hypersensitivity reactions, including anaphylaxis, can occur. Cases have been reported in post-marketing experience with fibrin sealant. Such reactions may especially be seen if ARTISS is applied repeatedly over time or in the same setting, or if systemic aprotinin has been administered previously; however, these reactions may also occur in patients receiving ARTISS for the first time. Symptoms associated with allergic anaphylactic reactions include: flush, urticaria, pruritus, nausea, drop in blood pressure, tachycardia or bradycardia, dyspnea, severe hypotension and anaphylactic shock.
- To reduce the risk of potential life-threatening gas embolism, spray using only the appropriate pressurized gas at the recommended pressure (21.8-29.0 psi) and distance (10-15 cm). Use the EASYSPRAY device connected to CO_2, Medical Air or Nitrogen.
- Discontinue administration in the event of hypersensitivity reactions.
- Exposure to solutions containing alcohol, iodine or heavy metals may cause ARTISS to be denatured.
- ARTISS is made from human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.
- Adverse reactions in the burn studies occurring in greater than 1% of subjects treated with ARTISS were skin graft failure (3%), hematoma (1%) and pruritus (1%).
- Adverse reactions in the facial rhytidectomy studies occurring in greater than 1% of subjects treated with ARTISS were hematoma/seroma (4%).

ARTISS [Fibrin Sealant] Pre-filled (Frozen)	
2 mL	1501651SP
4 mL	1501652SP
10 mL	1501653SP
EASYSPRAY Pressure Regulator Unit	0600012
EASYSPRAY Set (10 pack)	0600065

Rx Only. For safe and proper use of the EASYSPRAY Pressure Regulator and Spray Sets, refer to the appropriate Instructions for Use.

www.artissadherence.com

For more information, contact your local sales representative.

References:
1. Foster K, Greenhalgh D, Gamelli RL, et al.; FS 4IU VH S/D Clinical Study Group. Efficacy and safety of a fibrin sealant for adherence of autologous skin grafts to burn wounds: results of a phase 3 clinical study. *J Burn Care Res*. 2008;29(2):293-303.
2. ARTISS [Fibrin Sealant (Human)] full Prescribing Information.

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Baxter
Baxter International Inc.
One Baxter Parkway
Deerfield, Illinois 60015

www.baxter.com