ARTISS
[Fibrin Sealant (Human)]

For Topical Use Only

PROVIDES TIME FOR THE FINISHING TOUCH

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

ARTISS is not indicated as an adjunct to hemostasis.

SIXTY SECONDS
position and RE-POSITION

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

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Custom Designed –

ARTISS [Fibrin Sealant] is the first and only fibrin sealant FDA approved to adhere autologous skin flaps during face-lift surgery

- ARTISS [Fibrin Sealant] contains between 2.5 to 6.5 units/mL of thrombin, giving the surgeon up to 60 seconds to manipulate and position the flap prior to polymerization[1]

- ARTISS [Fibrin Sealant] provides full surface adherence of the tissue flap to the wound bed eliminating dead space[1]

  – Significantly reduced drainage volume when compared with standard of care[1]

ME FOR
THE FINISHING TOUCH

Easy as 1-2-3 – ARTISS [Fibrin Sealant] is available 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)[1]
- Prior to use, product should be warmed to 33°- 37°C[1]
  - Do not refrigerate or re-freeze after thawing
  - Do not microwave
  - Do not expose to temperatures above 37°C
- ARTISS [Fibrin Sealant] includes an EASYSPRAY spray applicator with each unit that may be used to fixate tissue flaps*

Rx Only.

Selected Important Risk Information for ARTISS [Fibrin Sealant]

- Do not inject ARTISS [Fibrin Sealant] directly into blood vessels; life-threatening thromboembolic events may occur
- Do not use in individuals with a known hypersensitivity to aprotinin

*See additional instructions for use provided with the spray set

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

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How ARTISS [Fibrin Sealant] Works –

ARTISS [Fibrin Sealant] is a two component fibrin sealant consisting of human thrombin and human fibrinogen[1]

Upon mixing of the two components, soluble fibrinogen is transformed into a fibrin matrix that adheres to the wound surface and to the tissue flap to be affixed.[1]

Initial polymerization of ARTISS [Fibrin Sealant] will take up to 60 seconds; allowing time to manipulate and position the flap prior to polymerization. Hold the flap or graft in the desired position by gentle compression for at least 3 minutes to ensure ARTISS sets properly and firmly adheres the skin graft or flap to the underlying tissue.[1]

Adhesive properties of ARTISS [Fibrin Sealant] provide full surface adherence of skin flaps. Full surface adherence minimizes areas of dead space between the wound bed and applied tissues. Elimination of dead space prevents shear irritation upon movement as well as reduces the void space under the skin that can host fluid build-up.[1]

Selected Important Risk Information for ARTISS [Fibrin Sealant]

- Hypersensitivity and allergic reactions may occur with the use of ARTISS [Fibrin Sealant]
- Air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer fibrin sealants
- Apply only as a thin layer
- Adverse reactions in the facial rhytidectomy studies occurring in greater than 1% of subjects treated with ARTISS were hematoma/seroma (4%)

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

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Clinical Evidence

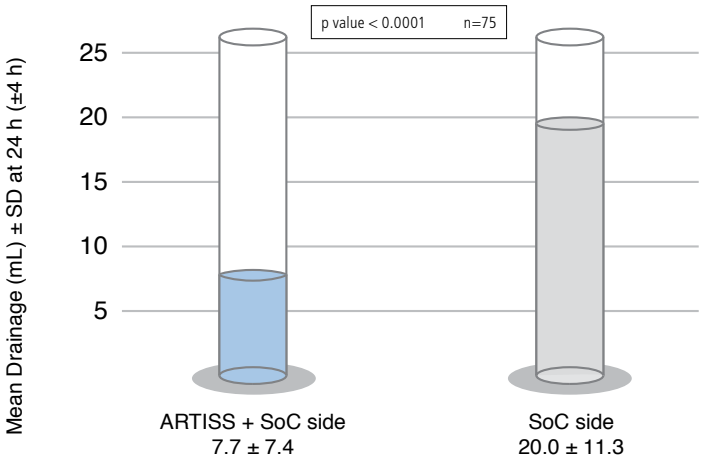
The efficacy and safety of ARTISS [Fibrin Sealant] versus standard of care (SoC), which was the closure of the flap via staples and suturing only, was assessed in a Phase 3, confirmatory, multicenter, prospective, randomized, single-blinded clinical trial in 75 adults with planned facial rhytidectomy. The study was designed to evaluate drainage volumes 24 hours (± 4 hours) post surgery when ARTISS [Fibrin Sealant] along with SoC alone were applied.[1]

Efficacy Results

Drainage volume was significantly reduced, on average, by 62%, when evaluated 24 hours (± 4 h) post surgery, when ARTISS [Fibrin Sealant] was applied along with SoC vs. SoC alone.[1]

Post-rhytidectomy Bilateral Drainage Tube Placement[1]

Drainage Volume Comparison at 24 h Post Operative



Hematoma/Seroma

An integrated analysis of the occurrence of hematoma/seroma in 120 subjects across two studies was performed. A comparison was made of the proportion of subjects experiencing a hematoma/seroma exclusively on the ARTISS [Fibrin Sealant]-treated side or on the SoC side of the face.

Clinical Study	ARTISS [Fibrin Sealant] n (%)	SoC n (%)	Both sides of face n (%)	Total n (%)
Preliminary Study n=45	0	9 (20%)	0	9 (20%)
Confirmatory Study n=75	2 (2.7%)	5 (6.7%)	3 (4%)	10 (13.3%)

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ARTISS [Fibrin Sealant (Human)] Indication

- 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.
- 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.
- Discontinue administration in the event of hypersensitivity reactions.
- Air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer fibrin sealants. This event appears to be related to the use of the spray device at higher than recommended pressures and in close proximity to the tissue surface.
- 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 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

www.artissadherence.com

For more information, contact your local sales representative or call 1-888-229-0001

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

References:
1. ARTISS [Fibrin Sealant (Human)] full Prescribing Information.

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