Provides time for the finishing touch.
ARTISS [SOLUTIONS FOR SEALANT] – FIRST AND ONLY FIBRIN SEALANT CUSTOM DESIGNED FOR SUBCUTANEOUS TISSUE ADHERENCE IN PLASTIC, RECONSTRUCTIVE AND BURN SURGERY

In a pivotal phase 3, multicenter, prospective, randomized, clinical study ARTISS has proven efficacy and safety in facial rhytidectomy.

- Full surface adherence eliminating dead space
- Allows up to 60 seconds to manipulate and to position the flap
- Frozen ready-to-use formulation – no mixing or diluting required

ARTISS is the only slow-setting fibrin sealant with low-concentrated human thrombin (4 IU/mL) and human fibrinogen indicated as a tissue glue to adhere/seal subcutaneous tissue in plastic, reconstructive and burn surgery, as a replacement or an adjunct to sutures or staples. In addition, ARTISS is indicated as an adjunct to hemostasis on subcutaneous tissue surfaces.

- Significantly reduces the drainage volume to standard of care
- May eliminate the need for surgical drains
- Reduces the incidence of hematoma and seroma compared to standard of care
- Adjunctive use of ARTISS did not increase incidence of adverse events compared to standard of care
ARTISS [SOLUTIONS FOR SEALANT] ELIMINATES DEAD SPACE THROUGH FULL SURFACE ADHERENCE¹,⁹

- ARTISS provides consistent flap adherence between the wound bed and the tissue applied by cross-linking with extracellular matrix proteins¹,⁶
- Unlike another fast-setting, hemostatic fibrin sealant, ARTISS contains a mixture of proteins, which play important roles in the wound healing and tissue regeneration process and help to extend clot stability, such as synthetic, non-bovine aprotinin⁶
- ARTISS clots serve as a provisional matrix that has shown in in-vitro studies to encourage adhesion and supports growth of cells involved in soft tissue repair, like keratinocytes⁶

Fig 1 ARTISS Reproduces the Final Stage of the Physiological Clotting¹,⁴

![Fibrinogen, FXIII](#)

![Thrombin 4 IU/mL](#)

![ARTISS](#)

A. The 2-components of ARTISS imitate the last step of the coagulation cascade generating a fibrin clot with physiological clot properties⁴
B. Morphology of human keratinocytes after 24 hours in contact with the ARTISS clot. Red = Actin filaments; Blue = Nuclei⁶

ARTISS was shown to be effective for improved skin flap adherence in facial rhytidectomy in a pivotal phase 3 study compared to standard of care (SoC).¹

Fig 2 Pivotal Study Surgical Set-up and Treatment¹

1. Spray single thin layer of FS VH S/D 4 s-apr on subcutaneous plane (face and neck areas)
2. Position flap over wound
3. Hold for 3 minutes

ARTISS [SOLUTIONS FOR SEALANT] SIGNIFICANTLY REDUCES DRAINAGE VOLUMES¹

- Total mean ± standard deviation of drainage volume at 24 ± 4 hr postsurgery ARTISS + SoC vs SoC alone was: 7.7 ± 7.4 mL vs 20.0 ± 11.3 mL (p < 0.0001)¹
- ARTISS may allow for the elimination of drain placement in facial rhytidectomy (mean drainage volume ≤ 15 mL/side at 24 hr postsurgery)¹

![Fig. 3 Post-rhytidectomy Bilateral Drainage Tube Placement and Treatment at Day 1](#)

![Fig. 4 Pre-op Appearance and Face on Post-op Day 1 after Rhytidectomy with ARTISS](#)

Patient pictures taken from the study described in reference 1. All patients gave their written consent to Baxter to use the pictures.
ARTISS [SOLUTIONS FOR SEALANT] REDUCES THE INCIDENCE OF HEMATOMA AND SEROMA\(^2\)

- On the ARTISS + SoC-treated sides, a total of 7 hematoma/seroma events occurred in 5 subjects vs a total of 17 in 17 subjects on the SoC-treated sides\(^2\)

- In addition, ARTISS significantly reduces the rate of edema compared to SoC alone\(^1\)
- Hematoma can represent up to 70% of all rhytidectomy complications\(^3\)

Fig. 5 Comparison of Hematoma and Seroma Between Sides of the Face (n = 120)\(^2\)

<table>
<thead>
<tr>
<th>Side</th>
<th>Number of Events</th>
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<tr>
<td>ARTISS + SoC</td>
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<tr>
<td>SoC</td>
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ARTISS [SOLUTIONS FOR SEALANT] MEETS INVESTIGATORS’ AND PATIENTS’ EXPECTATIONS\(^1,3\)

- Investigators reported convincing results with ARTISS
  - Higher satisfaction with the treatment on the ARTISS-treated sides at post-operative days 1, 3, 7 and 14 with 63.8%, 73.9%, 82.6%, and 84.1%, respectively\(^3\)
  - Greater confidence for reduced postsurgical complications with the ARTISS-treated sides in 89.4% of patients (Day 1 through 14)\(^2\)

- Patients were highly satisfied with ARTISS
  - Higher preference for the ARTISS-treated sides reporting better appearance at Day 1, 3, 7 and 14 post-operative with 63%, 53%, 59% and 57%, respectively (Fig. 7)\(^1,3\)
  - This preference tended toward statistical significance on all days except Day 3\(^3\)
  - The most common reasons for this preference were less swelling (78.7%) and looks better (74.5%)\(^3\)

Fig. 6 Comparison of Edema Between Sides of the Face (n = 75)\(^1\)

Fig. 7 Proportion of Patients Preferring ARTISS + SoC vs SoC Alone (n = 75)\(^1\)

Modified graph by Rohrich RJ et al., 2011\(^1\)

*Edema was assessed by investigators' visual comparison of sides of the face

\(^1\) Modified graph by Rohrich RJ et al., 2011

\(^2\) Artiss Solutions for Sealant

\(^3\) Hematoma can represent up to 70% of all rhytidectomy complications
**ARTISS [SOLUTIONS FOR SEALANT] IS CONVENIENT AND READY-TO-USE**

- Prefilled syringes – ready-to-use without mixing or dilution required
- Spray application for a single thin layer
- Full surface adherence eliminating dead space
- May eliminate the need for surgical drains

ARTISS slow-setting, vapor-heated and solvent/detergent treated fibrin sealant is developed by Baxter with over 30 years of successful fibrin sealant usage in all surgical specialties with no single case of hepatitis or HIV seropositivity. As with medicinal products manufactured from human plasma the possibility of transmitting infective agents cannot be totally excluded.

### Ordering Information

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<tr>
<th>Product</th>
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<th>Article Code</th>
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<tr>
<td>ARTISS (Solutions for Sealant), frozen</td>
<td>1</td>
<td>please contact your local representative for country-specific codes</td>
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<tr>
<td>EasySpray Pressure Regulator unit</td>
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<tr>
<td>TISSEEL/ARTISS Spray Set (10 pack)</td>
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<td>TISSEEL/ARTISS Spray Set, single</td>
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<td>0600066</td>
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For detailed information please contact your local representative: www.baxterbiosurgery.com

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1 Roehrich RJ et al., ARTISS Improves Flap Adherence Following Rhinectomy Through Full Surface Adherence Between the Wound Bed and Applied Tissue which Eliminates Areas of Dead Space Often Associated with Hematoma and Seroma: Results of a Phase 3, Multicenter, Prospective, Randomized, Clinical Study. *Poster Presented at the American Association of Plastic Surgeons (AAPPS) 2010 Annual Meeting, Boca Raton, FL*, April 9-12, 2011
8 Summary of Product Characteristics for ARTISS, Solutions for Sealant [SIC], Vienna Austria, Baxter International Inc. 2010 9 Foster K 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*