



EVICEL[®] Fibrin Sealant (Human)

Spray Area Coverage / Comparison with Tisseel[®]

ETHICON
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Coverage by Fibrin Sealants (per IFU)

EVICEL Size ^a	Total Volume (CM ³)	Area Covered @ 1 mm Thick
1 ml	2 CM ³	20 CM ²
2 ml	4 CM ³	40 CM ²
5 ml	10 CM ³	100 CM ²

TISSEEL Size ^b	Total Volume (CM ³)	Maximum Coverage using Spray	Maximum Coverage using Cannula
2 ml	2 CM ³	100 CM ²	8 CM ²
4 ml	4 CM ³	200 CM ²	16 CM ²
10 ml	10 CM ³	500 CM ²	40 CM ²

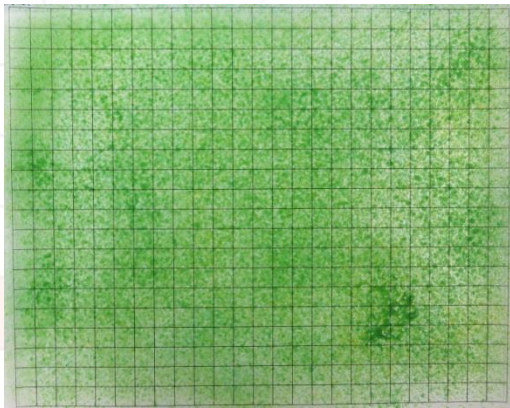
0.2 mm Thick

2.5 mm Thick

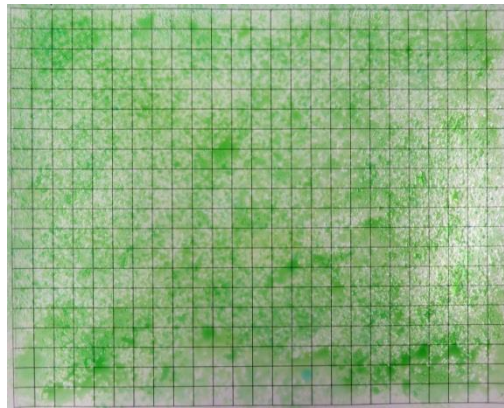
Area Covered (CM²) = Volume (CM³) ÷ Thickness (CM)

^aEVICEL® Fibrin Sealant (Human) PI - Article No. 80FZ00M3D3; ^bTisseel® (Fibrin Sealant) PI- Baxter, Revised 11/2014

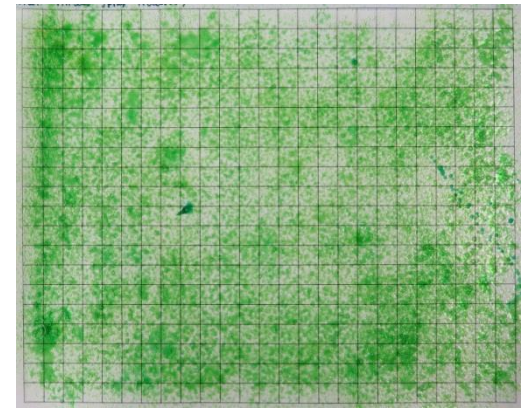
Manual Spray Coverage of a 500 cm² Area¹



TISSEEL® with Gas-Assisted Spray Device
10 mL of Biologics



EVICEL® with Gas-Assisted Spray using 6cm tip
10 mL of Biologics



EVICEL® with Airless Spray Accessory
10 mL of Biologics

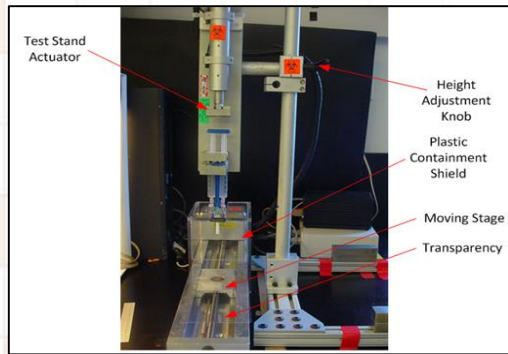


Conclusions: A coverage area of 500 cm² (20x25 cm) was achieved via manual spray with TISSEEL® and EVICEL®. Homogenous mixing of the biologics (separate solutions were yellow and blue) was demonstrated by the green color of the fibrin sealant.

1: Competitive Assessment of Tisseel Spray Coverage Area, O. Moloye-Olabisi, 11/20/2015.

Coverage by Fibrin Sealants - Mechanical Control

Objective: The spray coverage area of TISSEEL® and EVICEL® using CO₂ at 25 psi and with the Airless Spray Accessory (ASA) tip was evaluated using a mechanically controlled delivery system and calibrated target area with 10 ml of total fibrin sealant.



Product	EVICEL® 6 cm tip w. CO ₂	EVICEL® ASA	TISSEEL® w. CO ₂
Average (cm ²)	64.75	69.25	67.38

Conclusion: There was no significant difference in spray coverage area between the groups (analysis of variance; $p=0.092$),¹

1: Competitive Assessment of Tisseel Spray Coverage Area, O. Moloye-Olabisi, 11/20/2015.

CONCLUSION

Evicel using the 6 cm tip with CO₂ or the ASA was able to cover a comparable area as Tisseel when sprayed either manually or with mechanical control in benchtop testing.

Important Safety Information

EVICEL® Fibrin Sealant (Human) IMPORTANT SAFETY INFORMATION

Indication

EVICEL® Fibrin Sealant (Human) is indicated as an adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques (such as suture, ligature, or cautery) is ineffective or impractical.

Contraindications

Do not inject directly into the circulatory system. Intravascular application of EVICEL® may result in life-threatening thromboembolic events.

Do not use in individuals known to have anaphylactic or severe systemic reaction to human blood products.

Do not use for the treatment of severe or brisk arterial bleeding.

Do not use EVICEL® for spraying in endoscopic or laparoscopic procedures where the minimum recommended distance from the applicator tip to the target site cannot be ensured.

Warnings and Precautions

Life-threatening air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer EVICEL®. This event appears to be related to the use of the spray device at pressures higher than recommended and/or at distances closer than recommended to the surface of the tissue.

Warnings and Precautions (continued)

Monitor changes in blood pressure, pulse, oxygen saturation, and end-tidal CO₂ when spraying EVICEL® because of the possibility of gas embolism.

To reduce the risk of potentially life-threatening gas embolism, spray EVICEL® using only pressurized CO₂ gas at the pressures and distances recommended for the specific tips.

Use EVICEL® spray application only if it is possible to accurately judge the spray distance, especially during endoscopic or laparoscopic procedures.

Prior to applying EVICEL®, dry surface areas of the wound by standard techniques (e.g. intermittent application of compresses, swabs, use of suction devices). Prepare and administer EVICEL® according to the instructions and with only devices recommended for this product.

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.

The most common adverse reactions reported in clinical trials are peripheral edema, abdominal abscess, infection, hematoma, incision site hemorrhage, vascular graft occlusion, postoperative wound complication and decreased hemoglobin.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

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