Rely on EVICEL Fibrin Sealant
How are you protecting your patients from potential rebleeding risks?

Achieve rapid and lasting clot adherence regardless of patient coagulation profile—with the EVICEL™ Airless Spray Accessory

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.
In certain situations bleeding may be addressed intraoperatively, but could later develop into more serious complications. Potential bleeding complications are heightened in high-risk clinical situations and patient types. The risk of potential bleeding complications calls for a reliable fibrin clot that is effective independent of the patient coagulation profile—demonstrated in high-risk patients.
For sustained hemostasis, demonstrated in high-risk patients\textsuperscript{2,3}

Effective clot formation regardless of patient coagulation profile\textsuperscript{3,4}

The unique EVICEL fibrin clot is formed when thrombin activates conversion of fibrinogen into fibrin\textsuperscript{1}

Sustained hemostasis demonstrated in more than 800 patients and across 3 randomized controlled trials\textsuperscript{3,7}

- Studied in patients with a wide range of high-risk comorbidities, including patients using anticoagulants/antiplatelets (eg, heparin) and patients with coagulopathies\textsuperscript{3}
EVICEL™ Airless Spray Accessory is designed to deliver a rapid, adherent, and lasting fibrin clot. Inside the grey connector of the EVICEL Airless Spray Accessory (ASA), the biologics are kept separate until they enter the static mixer housed within the white tip. The mixed biologics exit the static mixer through the orifice cup. The ASA is capable of delivering a wide variation in spray pattern—from narrow to broad coverage. The ASA permits spraying at a minimum distance of 2 cm from the bleeding site while allowing control of the spray distance and pressure to create the desired spray pattern.
For a rapid, adherent, and lasting clot with established safety\textsuperscript{3,4,9,10}

No treatment-site bleeding was observed 7 to 14 days postsurgery in pivotal clinical trials\textsuperscript{3,11}

In a prospective, single-arm, observational study of 300 patients, no recurrence of treatment-site bleeding was found for up to 4 weeks post-op\textsuperscript{9}

- All achieved hemostasis\textsuperscript{9}
- 66\% of patients were treated with heparin\textsuperscript{9}
- For those treated with heparin, 88\% did not have heparin reversal with protamine prior to treatment with EVICEL\textsuperscript{9}

The study included patients using antiplatelets and anticoagulants (eg, heparin), patients with coagulopathies, and patients with a wide range of comorbidities, including\textsuperscript{9}:

- Obesity\textsuperscript{9}
- Renal disease\textsuperscript{9}
- Carotid, coronary, and peripheral artery diseases\textsuperscript{9}
Now available with the EVICEL™ Airless Spray Accessory*  

**Designed to deliver a rapid, adherent clot**

**Provides enhanced spraying control**

- Control the spray pattern and distance
- Cover narrow, broad, and challenging areas

**Eliminates the need for external gas sources, reducing setup time**

- No need for pressure regulators, CO₂ tanks, air hoses, trolleys, and tank-top regulators

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<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3921S</td>
<td>Includes 1 gray connector and 3 tips per pouch; 10 pouches per box</td>
</tr>
<tr>
<td>3905ASA</td>
<td>Includes 10 of 3905 and 1 box of 3921S</td>
</tr>
<tr>
<td>3902ASA</td>
<td>Includes 10 of 3902 and 1 box of 3921S</td>
</tr>
<tr>
<td>3901ASA</td>
<td>Includes 10 of 3901 and 1 box of 3921S</td>
</tr>
</tbody>
</table>

*For open procedures only.

†EVICEL Airless Spray Accessory is ONLY included in the price of EVICEL when using codes 3905ASA, 3902ASA, and 3901ASA.
### Ready when you need it

**EVICEL is more convenient to prepare, use, and store compared with TISSEEL**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>TISSEEL&lt;sup&gt;12,b,c&lt;/sup&gt;</th>
<th>EVICEL&lt;sup&gt;33,b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application-ready in &lt;1 minute&lt;sup&gt;11,a&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage options</td>
<td>Frozen</td>
<td>•</td>
</tr>
<tr>
<td></td>
<td>Refrigerator (thawed product)</td>
<td>13,d</td>
</tr>
<tr>
<td>Maximum storage time once thawed</td>
<td>2 days (at 15°C-25°C)</td>
<td>30 days (at 2°C-8°C)</td>
</tr>
<tr>
<td>Thawing conditions</td>
<td>Warm water bath (33°C-37°C)</td>
<td>•</td>
</tr>
<tr>
<td></td>
<td>Room temperature</td>
<td>•</td>
</tr>
<tr>
<td></td>
<td>Refrigerator</td>
<td></td>
</tr>
<tr>
<td>Temperature range for use (average OR temperature: 21°C-24°C)&lt;sup&gt;4&lt;/sup&gt;</td>
<td>33°C-37°C (warm water bath or incubator)</td>
<td>•</td>
</tr>
<tr>
<td></td>
<td>2°C-33°C</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> When stored in refrigerator, after thawing (24 hours).

<sup>b</sup> Comparison is derived from package insert information and is not intended to imply comparative safety or efficacy.

<sup>c</sup> Use within 24 hours of thawing at room temperature.

<sup>d</sup> When at room temperature (20°C-25°C).

<sup>e</sup> EVICEL thaws at 37°C only.

TISSEEL is a registered trademark of Baxter International Inc.
Ready When You Need It
Rely on EVICEL Fibrin Sealant

A full family of solutions with the right tool for the right situation

Available with a wide range of clog-resistant tips for intermittent spray or drip

<table>
<thead>
<tr>
<th>Order code</th>
<th>Description (total volume)</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>3901</td>
<td>1-mL Kit (2 mL)</td>
<td>63713-390-11</td>
</tr>
<tr>
<td>3902</td>
<td>2-mL Kit (4 mL)</td>
<td>63713-390-22</td>
</tr>
<tr>
<td>3905</td>
<td>5-mL Kit (10 mL)</td>
<td>63713-390-55</td>
</tr>
<tr>
<td>3908</td>
<td>35-cm Rigid Tip – Set of 3</td>
<td>N/A</td>
</tr>
<tr>
<td>3909</td>
<td>45-cm Flexible Tip – Set of 3</td>
<td>N/A</td>
</tr>
<tr>
<td>3920</td>
<td>4-cm Control Tip – Set of 10</td>
<td>N/A</td>
</tr>
<tr>
<td>3905PRC</td>
<td>Includes six 5-mL EVICEL Kits and 1 Pressure Regulator</td>
<td>N/A</td>
</tr>
<tr>
<td>EVCCART</td>
<td>Tank Trolley</td>
<td>N/A</td>
</tr>
</tbody>
</table>

To place an order: 1-800-255-2500
For technical support: 1-877-ETHICON (877-384-4266)

Endoscopic Catheter Introducer available via Micromedics, Inc.

SA-3445 | Box of 3 for use with 3909 45-cm Flexible Tip

To place an order: 1-800-624-5662 or fax 1-888-504-0606
Rely on EVICEL Fibrin Sealant

Provides sustained hemostasis for protection from potential rebleeding risks

Bleeding complications often occur in patients who are high risk, taking anticoagulants/antiplatelets, or have coagulopathies

EVICEL provides sustained hemostasis, demonstrated in high-risk patients

EVICEL is proven to effectively form a clot independent of patient’s coagulation profile

• A rapid, adherent, and lasting clot is formed with the use of EVICEL™ Airless Spray Accessory
Overview
Fibrin Sealant
EVICEL
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, ligation, 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 gas embolism has occurred with the use of spray devices employing pressure regulator to administer fibrin sealants. These events appear 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. Follow labeled application instructions regarding pressure range and distance when using a spray device and monitor patients for the possibility of gas embolism.
- To reduce the risk of potentially life-threatening gas embolism, spray EVICEL® using only pressurized CO₂ gas at the recommended pressures and distances.
- Use EVICEL® spray application only if it is possible to accurately judge the spray distance, especially during endoscopic or laparoscopic procedures. Apply as a thin layer.
- 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 only with 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.

Most common adverse events reported in clinical trials (≥5%) are bradycardia, nausea, hypokalemia, insomnia, hypotension, pyrexia, graft infection, vascular graft occlusion, peripheral edema, and constipation.

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

References: