Rely on EVICEL®
Fibrin Sealant

Achieve rapid and lasting clot adherence regardless of patient coagulation status1-4
What are the consequences around potential rebleeding risks?

In certain situations bleeding may be addressed intraoperatively but could later develop into more serious complications.\(^5,6\) Potential bleeding complications are heightened in high-risk clinical situations and patient types.\(^5\)

- Hemotoma (Associated discomfort and swelling)
- A drop in Hemoglobin/Hematocrit levels
- Need for post-op drains
Achieve sustained hemostasis in patients\textsuperscript{2,3} with effective clot formation regardless of patient coagulation profile, demonstrated even in high-risk patients with a fibrin sealant\textsuperscript{3,4}.

The risk of potential bleeding in certain high-risk clinical situations and patient types may call for a reliable fibrin clot that is effective, independent of the patient profile demonstrated in high-risk patients.\textsuperscript{5,6}

\begin{itemize}
  \item Released as a spray to achieve desired coverage.
  \item EVICEL\textsuperscript{®} creates a fibrin clot…
  \item …and sustains hemostasis.\textsuperscript{3,4}
\end{itemize}

**Indication**
EVICEL\textsuperscript{®} 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 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{7}

EVICEL\textsuperscript{®} Airless Spray Accessory is designed to deliver a rapid, adherent clot with control\textsuperscript{4,8}.
**EVICEL® Fibrin Sealant (Human)**

**Application in Total Knee Arthroplasty**

In the presence of active bleeding, below are potential application sites for EVICEL Fibrin Sealant in Total Knee Arthroplasty.

- **Posterior Joint Capsule**
  - Timing for this application is post-pulse lavage and after removal of the trial components, but prior to the final implant placement. With the knee flexed at 90 degrees, spray EVICEL Fibrin Sealant in the posterior capsule between the femur and tibia in the presence of active bleeding.

- **Soft Tissue**
  - Timing for these applications in the presence of active bleeding is after final pulse lavage and after final implant placement, prior to closing arthrotomy.
  - **Spray EVICEL Fibrin Sealant on all exposed soft tissue inside joint capsule.**

- **Boney Edges**
  - **Spray EVICEL Fibrin Sealant along all exposed boney edges around final implant.**

- **DO NOT DISTURB:** It is very important not to disturb the fibrin clots after this application (i.e., pulse lavage or wiping with a lap sponge)

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**Application in Total Hip Arthroplasty**

In the presence of active bleeding, below are potential application sites for EVICEL Fibrin Sealant in Total Hip Arthroplasty.

- **Acetabulum**
  - Timing for this application is after the acetabular component is in place and after pulse lavage.
  - **Spray EVICEL Fibrin Sealant on the soft tissue and expose boney edges around the acetabular component.**

- **Femoral Neck**
  - Timing for this application is after the femoral stem is in place, but before rotation of the femoral head into the acetabular component.
  - **Spray EVICEL Fibrin Sealant on the exposed boney edges around the femoral stem.**

- **Soft Tissue, Muscles**
  - Timing for this application is after the femoral head has been rotated into the acetabular component and after final pulse lavage.
  - **Applying to bleeding sites from deep to superficial, spray EVICEL Fibrin Sealant on all muscles and soft tissue.**
  - **DO NOT DISTURB:** It is important not to disturb the fibrin clots after this application (i.e., pulse lavage or wiping with a lap sponge)
Important Safety Information

Indication
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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
- 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 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.
Eliminate the Need for External Gas Sources with
The EVICEL® Airless Spray Accessory*

Reduces your setup time
• No need for pressure regulators, CO₂ tanks, air hoses, trolleys and tank top regulators

Provides you with improved spraying control
• Control the spray pressure
• Cover narrow to broad areas³

Enables you to deliver a rapid, adherent clot⁴

<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.
³Airless Spray Accessory is ONLY included in the price of EVICEL when using codes 3905ASA, 3902ASA, 3901ASA.
⁴To place an order: 1-800-255-2500
For technical support: 1-877-ETHICON (877-384-4266)

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