Addressing Potential Rebleeding Risk in Bariatric Sleeve Surgery with EVICEL® Fibrin Sealant (Human)

Sustaining hemostasis is key to a successful outcome in open and minimally invasive bariatric sleeve surgery, but bleeding complications can often occur in high-risk patients. When a highly effective and time-efficient approach is necessary, surgeons can rely on the EVICEL™ Airless Spray Accessory.

**Potential bleeding sites**

- Short Gastric Vessels (Small vessels omentum/stomach wall)
- Adhesions (Soft tissue/Visceral organs and Peritoneum/Abdominal wall)
- Staple-Line Bleeding (Stomach wall)

**Is there intraoperative bleeding with a concern of rebleeding?**

YES

**Recommended product**

**EVICEL Fibrin Sealant**

- Minimally invasive bariatric sleeve
  - EVICEL™ Laparoscopic Airless Spray Accessory
- Open bariatric sleeve
  - EVICEL™ Airless Spray Accessory

- Designed to deliver a rapid, adherent, lasting fibrin clot regardless of patient coagulation profile
- Eliminates the need for external CO₂ spraying equipment
- 9 out of 10 clinicians agree that the EVICEL™ Airless Spray Accessory helps drive efficiency in the OR
**Situation**

**Potential Rebleeding Risk**

Bleeding may be addressed intraoperatively but could later develop into more serious complications, especially in high-risk patients.

**Solution**

**EVICEL®**
Part of the **Hemostasis Optimization Program** portfolio of adjunctive hemostats

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**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.
- 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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**References:**
2. ASA Design Validation Marketing Claims, August 2017. Ethicon Inc.
3. STAR ASA coverage area test using corium tissue on a 45 degree tilted plane. September 2014. Ethicon, Inc.

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