SURGICEL® Powder Absorbable Hemostat

SURGICEL Powder is more effective and efficient than ARISTA™ Absorbable Hemostatic Particles

Head-to-head in vivo comparison of SURGICEL Powder vs ARISTA™ AH*

*Based on preclinical testing in a swine acute liver abrasion model.
†Device not shown at actual size.
**SURGICEL® Powder Absorbable Hemostat**

**ARISTA™ AH**

### IMPROVED EFFICACY

- **89%**
  - SURGICEL Powder achieves hemostasis **89% faster** than ARISTA™ AH—that’s **more than 4 minutes!**

- Dual mechanism of action

- Forms a more adherent and durable clot

- Does not increase the incidence of remote adhesions in laparoscopic procedures

- Proven bactericidal in vitro

- Acts only as a dehydrant

- Underperformed in maintaining durable hemostasis following irrigation

- No proven bactericidal properties

### IMPROVED EFFICIENCY

- **2-in-1 laparoscopic tip**

- Innovative delivery device

- Economic advantages over ARISTA™ AH

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Click on the icons above to learn more about the benefits of SURGICEL Powder.

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*Based on preclinical testing in a swine acute liver abrasion model.

†Based on preclinical in vivo animal studies.

‡Methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin-resistant *Staphylococcus epidermidis* (MRSE), vancomycin-resistant *Enterococcus* (VRE), penicillin-resistant *Streptococcus pneumoniae* (PRSP), and *Escherichia coli* (E coli).

§The clinical benefit of these bactericidal claims has not been studied or demonstrated.

||In a propensity score–matched, retrospective review of C-section cases.

SURGICEL® Powder Absorbable Hemostat stops bleeding more than 4 minutes faster than ARISTA™ AH on average\(^1\)*

- SURGICEL Powder is specifically intended for treatment of broad-surface oozing bleeding in open and minimally invasive procedures\(^1\)
- This type of bleeding can be more time-consuming than difficult
- SURGICEL Powder achieves hemostasis 89% faster than ARISTA™ AH \((P<0.001)\)*
  - In real time, that translates to stopping bleeding in **30 seconds vs more than 4.5 minutes**\(^1\)

*Based on preclinical testing in a swine acute liver biopsy model

**SURGICEL® Powder Absorbable Hemostat stops bleeding more efficiently than ARISTA™ AH**

### SURGICEL Powder

**Dual mechanism of action working within the hemostatic cascade**

- SURGICEL Powder oxidized regenerated cellulose (ORC) fragments provide a surface for platelet adhesion and aggregation, working with the patient’s endogenous clotting factors to initiate clot formation.
- The localized reduction in blood pH induces vasoconstriction of blood vessels, reducing blood flow to the area and enabling safe, rapid hemostasis.

**Unique structure breaks the surface tension of the blood** to get to the source of the bleeding.

### ARISTA™ AH

**Acts only as a dehydrant**

- ARISTA™ AH particles concentrate blood solids on the particle surfaces to form a gelled matrix.
- ARISTA™ AH does not contribute to vasoconstriction.

**Particles do not readily penetrate blood,** making them more likely to float on its surface.

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*Based on preclinical testing in a swine acute liver biopsy model.
†Based on surface area and surface energy analyses using inverse gas chromatography in benchtop testing.
SURGICEL® Powder was shown in vivo to form a more adherent and durable clot than ARISTA™ AH1*

SURGICEL Powder achieved hemostasis on 15 out of 15 sites in a diffuse bleeding liver abrasion model.*

SURGICEL Powder sustains hemostasis even when irrigated.*

ARISTA™ AH achieved hemostasis on ONLY 4 out of 15 sites in a diffuse bleeding liver abrasion model.*

Does not increase the incidence of remote adhesions in laparoscopic procedures1,2†

*Based on preclinical testing in a swine acute liver biopsy model.
†Based on preclinical in vivo animal studies.

SURGICEL Powder® has 50+ years of proven safety1:3

- SURGICEL Powder does not increase the incidence of remote adhesions in laparoscopic procedures2,4*
- Like SURGICEL Original Hemostat, SURGICEL Powder demonstrates consistent, safe hemostasis5
- Fully absorbable within 7 to 14 days6,7

*Based on preclinical in vivo animal studies.

SURGICEL® Powder Absorbable Hemostat is proven bactericidal in vitro\(^1\)*

Proven bactericidal in vitro against a broad range of gram-positive and gram-negative organisms\(^1\)
- Including MRSA, MRSE, PRSP, VRE, and \(E\) coli\(^i\)
- The interaction of ORC and blood causes a localized reduction in blood pH, giving SURGICEL Powder proven in vitro bactericidal properties against a broad range of organisms\(^1,2\)

**SURGICEL Powder**

Proven in vitro bactericidal activity against\(^1\)*

- MRSA
- MRSE
- VRE
- \(E\) coli
- PRSP

**ARISTA™ AH**

No bactericidal properties\(^3\)

*The clinical benefit of these bactericidal claims has not been studied or demonstrated.

Have the right tool when you need it with the 2-in-1 SURGICEL™ Endoscopic Applicator

- Flexible inner tube 38 cm (15 in) can be bent for **precise product placement**
- Rigid stainless-steel sheath 31 cm (12.2 in) allows for **one-handed use.** 36 cm (14.2 in) in total length with protrusion of the flexible inner tip from the cannula

**Flexible Tip**
Flexible tip on both the open and endoscopic applicators allows for aspiration in any direction or orientation in open and minimally invasive procedures.

**Rigid Tip**
The rigid component of the endoscopic applicator is designed for one-handed application and enables easy access in MIPs.

**Efficient Aspiration**
Provides a consistent dosage per application for minimal wasted product.

SURGICEL® Powder Absorbable Hemostat innovative device design provides more control and consistency in delivery than ARISTA™ AH

**SURGICEL Powder**
- Provides **consistent expression** regardless of the device orientation
- Chamber design *keeps the powder securely in place* until the user is ready to deploy it
- Delivers **greater control and less waste**, with just 3 g of powder, compared to 5 g of ARISTA™ AH

**ARISTA™ AH**
- In the vertical position, **expresses most of its product in just 2 pumps**, and is empty after 5 pumps
- In the horizontal position, **cannot fully express the remaining one-third of its powder**

References:
SURGICEL® Powder Absorbable Hemostat has economic advantages over ARISTA™ AH

Head-to-head cost-efficiency comparison
In a propensity score–matched, retrospective review comparing SURGICEL Powder to ARISTA™ AH in C-section and open hysterectomy cases, SURGICEL Powder was associated with

$1,933 lower hospital cost per discharge in C-section cases ($8,637 vs $10,977; P<0.005)\(^1\)

$1,955 lower hospital cost per discharge in open hysterectomy cases ($10,488 vs $12,443; P<0.005)\(^1\)

Shorter length of stay in C-section cases (3.36 days vs 4.17 days; P=0.006)\(^1\)

Simplifies inventory with only one SKU each for SURGICEL Powder and the 2-in-1 endoscopic applicator

<table>
<thead>
<tr>
<th>SURGICEL Powder</th>
<th>ARISTA™ AH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Only 1 SKU</strong></td>
<td><strong>4 different SKUs</strong></td>
</tr>
<tr>
<td>• 3 g(^2,3)</td>
<td>• 1 g</td>
</tr>
<tr>
<td><strong>Endoscopic applicator is only 1 SKU</strong></td>
<td>• 3 g</td>
</tr>
<tr>
<td>• 2-in-1 applicator includes both a flexible and a rigid tip</td>
<td>• 5 g</td>
</tr>
<tr>
<td></td>
<td>• 2g ENT kit</td>
</tr>
<tr>
<td></td>
<td>• Flexible tips (2)</td>
</tr>
<tr>
<td></td>
<td>• Rigid tip</td>
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SURGICEL® Powder Absorbable Hemostat Essential Product Information

INDICATIONS
SURGICEL® Powder (oxidized regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective. SURGICEL® Powder can also be applied in laparoscopic or other endoscopic procedures when used with the SURGICEL™ Endoscopic Applicator.

The SURGICEL™ Endoscopic Applicator is intended for use in delivering SURGICEL® Powder absorbable hemostat to bleeding surgical sites through a 5 mm or larger trocar.

CONTRAINDICATIONS
- Do not inject or place SURGICEL® Powder into an open blood vessel. Do not use to treat bleeding from large defects in arteries or veins.
- SURGICEL® Powder should not be used to control hemorrhage from large arteries or veins.
- The SURGICEL® Powder and the SURGICEL™ Endoscopic Applicator devices were not designed for intraluminal procedures.
- When SURGICEL® Powder is used to help achieve hemostasis in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, or the optic nerve and chiasm, it must always be removed after hemostasis is achieved since it will swell and could exert unwanted pressure.
- SURGICEL® Powder should not be used for implantation in bone defects, such as fractures, since there is a possibility of interference with callus formation and a theoretical chance of cyst formation.

WARNINGS
- SURGICEL® Powder is not intended for use on dry (non-bleeding) surfaces or for prevention of bleeding.
- Closing with SURGICEL® Powder in a contaminated wound without drainage may lead to complications and should be avoided.
- SURGICEL® Powder should not be impregnated with anti-infective agents or with other materials such as buffering or hemostatic substances.
- SURGICEL® Powder is dry and there may be difficulties in precise delivery under certain circumstances. Unintentional device placement may result in powder scattering and device migration that may increase the risk of adhesion formation. In preclinical in vivo animal studies it was demonstrated that SURGICEL® Powder does not increase the incidence of remote adhesions in laparoscopic procedures.
- Although SURGICEL® Powder is bactericidal against a wide range of pathogenic microorganisms, it is not intended as a substitute for systemically administered therapeutic or prophylactic antimicrobial agents to control or to prevent postoperative infections.
- To prevent clogging with the SURGICEL™ Endoscopic Applicator Tip, do not touch the tip to wet surface. Be careful to avoid damaging tissue with the rigid tip.
- Do not attempt to trim the applicator tip. Replace the tip if it becomes clogged.

PRECAUTIONS
- SURGICEL® Powder should not be used in conjunction with autologous blood salvage circuits, because its fragments may pass through the transfusion filters of blood-scavenging systems.
- Use only as much SURGICEL® Powder (oxidized regenerated cellulose) as is necessary and apply only where needed for hemostasis. Remove any excess before surgical closure in order to facilitate absorption and to minimize the possibility of foreign body reaction.
- Use minimal amount of SURGICEL® Powder required to achieve hemostasis, and remove excess powder in the area of drains to prevent clogging. In urological procedures, minimal amounts of SURGICEL® Powder should be used and care must be exercised to prevent plugging of the urethra, ureter, or a catheter by dislodged portions of the product.
- Since absorption of SURGICEL® Powder could be prevented in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals.
- If SURGICEL® Powder is used temporarily to line the cavity of open wounds, it should be removed by irrigation with sterile water or saline solution after bleeding has stopped.
- Precautions should be taken in otorhinolaryngologic surgery to ensure that none of the material is aspirated by the patient (e.g., controlling hemorrhage after tonsillectomy and controlling epistaxis).
- The applicator tip provided on the SURGICEL® Powder device is not intended for laparoscopic or other endoscopic use. If laparoscopic or other endoscopic use is desired, remove the existing applicator tip from the SURGICEL® Powder device, and replace with the SURGICEL™ Endoscopic Applicator tip (supplied separately). In laparoscopic or other endoscopic procedures, SURGICEL® Powder should only be applied using the SURGICEL™ Endoscopic Applicator. Consult the SURGICEL™ Endoscopic Applicator Instructions for Use (IFU) for proper assembly and directions for use with the SURGICEL® Powder device.
- The SURGICEL Endoscopic Applicator is supplied with a flexible inner tip inside a rigid cannula. The rigid cannula cannot be used independently.
- The SURGICEL Endoscopic Applicator should only be used by persons having adequate training and familiarity with endoscopic techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any endoscopic procedure.
- To prevent inadvertent device spillage, or unintended contact with tissue, organs, or blood, maintain visualization of the SURGICEL™ Endoscopic Applicator tip at all times.
- Do not compress or excessively bend the flexible inner tip of the SURGICEL Endoscopic Applicator which could obstruct the application of the powder. It is possible that the powder accumulated in the applicator could disperse beyond the target bleeding site upon compression of the bellows, which may require additional irrigation and aspiration.
ADVERSE EVENTS

• Paralysis and nerve damage have been reported when other SURGICEL® products were used around, in, or in proximity to foramina in bone, areas of bony confinement, the spinal cord, and/or the optic nerve and chiasm.
• Blindness has been reported in connection with surgical repair of a lacerated left frontal lobe when other SURGICEL® products were placed in the anterior cranial fossa (see WARNINGS and PRECAUTIONS).
• Foreign body reactions have been reported with other products from the SURGICEL® Family of Absorbable Hemostats.
• Burning has been reported when other SURGICEL® products were applied after nasal polyp removal. Headache, burning, stinging, and sneezing in epistaxis and other rhinological procedures, and stinging when SURGICEL® product was applied on surface wounds (varicose ulcerations, dermabrasions, and donor sites) have also been reported.
• For more information and technical questions, call 1-800-795-0012. For complete information including indications, contraindications, warnings, precautions, adverse reactions, and directions for use, consult the product package insert.

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