



SURGICEL[®] Powder Absorbable Hemostat

**Built to stop continuous,
broad-surface oozing—fast^{1,2}**

The next generation of SURGICEL® Absorbable Hemostats

SURGICEL® Powder Absorbable Hemostat efficiently and effectively controls continuous oozing on broad surfaces^{1,2}

- Ready to use out of the package, with no preparation required³
- Penetrates the surface of the blood to get to the source of bleeding for efficient control of continuous oozing bleeding⁴
- Demonstrated to sustain hemostasis even when it is irrigated^{4*}



Get to the source of the bleed

Unique structure of the powder penetrates the surface of the blood to get to the source of bleeding^{1,4}

1 SURGICEL® Powder Absorbable Hemostat spreads across a large surface area^{2,4}



SURGICEL Powder is an aggregate of small oxidized regenerated cellulose (ORC) fiber fragments³

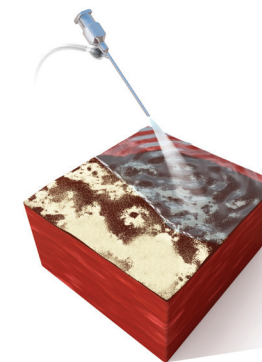
2 Blood saturates the material, providing a surface for platelet adhesion and aggregation, and initiating clot formation^{1,4}



3 Works fast to stop bleeding^{1,4}

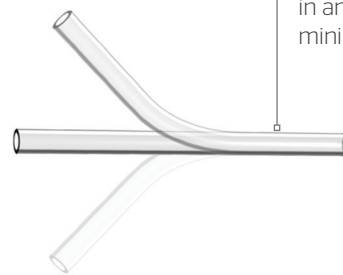


4 Forms a durable clot that maintains hemostasis when irrigated⁴



Flexible Tip

The flexible tip on both the open and endoscopic applicators allows for aspiration in any direction or orientation in open and minimally invasive procedures (MIPs)



Rigid Tip

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

Efficient Aspiration

Provides consistent dosage per application, regardless of orientation, for minimal wasted product⁷



Indication:

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.³

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

Everything you've come to expect from the SURGICEL® Family of Absorbable Hemostats

- Proven in vitro bactericidal activity against five common hospital-acquired pathogens (MRSA, MRSE, VRE, PRSP, *E Coli*)^{3*}
- Fully absorbable within 7 to 14 days^{5,6}
- ORC technology helps control capillary, venous, and small arterial hemorrhage^{2,3}

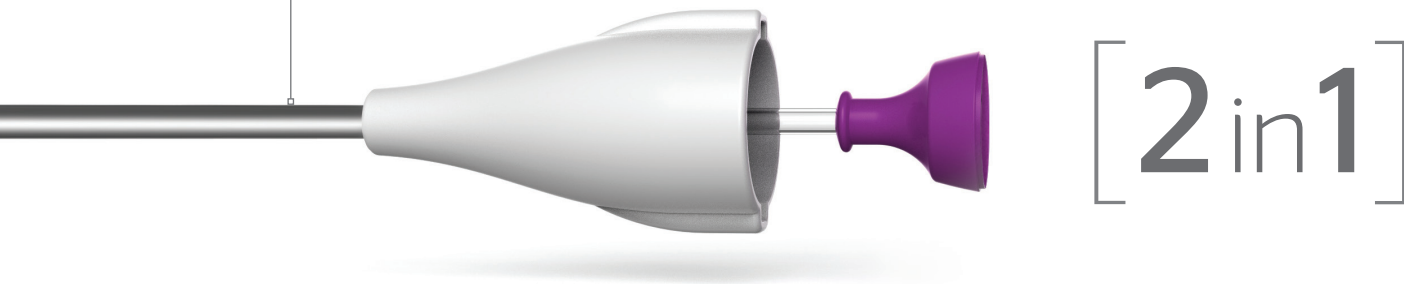
*The clinical benefit of these bactericidal claims has not been studied or demonstrated.

Easy application across both open and laparoscopic procedures²

- The 2-in-1 endoscopic applicator is sold separately and is composed of 2 components, the rigid tip and the flexible tip
- The rigid component of the endoscopic applicator is designed for one-handed application and enables easy access in MIPs
- The flexible tip on both the open and endoscopic applicators allows for aspiration in any direction or orientation in open and MIPs

2-in-1 Endoscopic Applicator:

Sold separately and allows for ease of use in MIPs



Built on a legacy of performance

SURGICEL® Powder Absorbable Hemostat is a unique offering from the SURGICEL® Family of Absorbable Hemostats



Ordering Information

Code	Description	Device Specifications	Quantity (per box)
3013SP	SURGICEL Powder	3.0 grams	5 units
3123SPEA	SURGICEL Endoscopic Applicator	2-in-1 applicator	5 units

Further Information

Please contact our customer support center at 877-ETHICON (384-4266)

SURGICEL Essential Product Information

• INDICATIONS

SURGICEL® Absorbable Hemostat (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® ORIGINAL, SURGICEL® FIBRILLAR™, SURGICEL® NU-KNIT®, and SURGICEL® SNoW™ Absorbable Hemostats can be cut to size for use in endoscopic procedures.

• PRECAUTIONS

Use only as much SURGICEL® Absorbable Hemostat as is necessary for hemostasis, holding it firmly in place until bleeding stops. Remove any excess before surgical closure in order to facilitate absorption and minimize the possibility of foreign body reaction.

In urological procedures, minimal amounts of SURGICEL® Absorbable Hemostat 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® Absorbable Hemostat 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® Absorbable Hemostat is used temporarily to line the cavity of large open wounds, it should be placed so as not to overlap the skin edges. It should also be removed from open wounds by forceps or by irrigation with sterile water or saline solution after bleeding has stopped.

Precautions should be taken in otorhinolaryngologic surgery to assure that none of the material is aspirated by the patient. (Examples: controlling hemorrhage after tonsillectomy and controlling epistaxis.)

Care should be taken not to apply SURGICEL® Absorbable Hemostat too tightly when it is used as a wrap during vascular surgery (see Adverse Reactions section of the complete product package insert).

• ADVERSE EVENTS

“Encapsulation” of fluid and foreign body reactions have been reported.

There have been reports of stenotic effect when SURGICEL® Absorbable Hemostat has been applied as a wrap during vascular surgery.

Paralysis and nerve damage have been reported when SURGICEL® Absorbable Hemostat was used around, in, or in proximity to foramina in bone, areas of bony confine, 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 SURGICEL® Absorbable Hemostat was placed in the anterior cranial fossa.

Possible prolongation of drainage in cholecystectomies and difficulty passing urine per urethra after prostatectomy have been reported.

For more information, please consult your doctor or for product quality and technical questions, call 1-800-795-0012. For complete product information including indications, contraindications, warnings, precautions, and adverse reactions, please reference the individual product package inserts.

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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.

SURGICEL® Powder Absorbable Hemostat Essential Product Information (cont)

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-scravenging 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 confine, 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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SURGICEL® Family of Absorbable Hemostats



One family. **Five products.** 55+ years.



Original

Trust
55+ years of proven safety, efficacy, and in vitro bactericidal properties*



Fibrillar™

Versatile
Easily separated layers are customizable, allowing for precise placement



Powder

Broad Coverage
Efficiently and effectively controls continuous oozing on broad surfaces



Snow™

Innovative
Offers better conformability, handling, and adherence to tissue especially in laparoscopic surgery†



Nu-Knit®

Strength
High tensile strength and thickness allow it to hold suture

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

†Compared to SURGICEL Original Hemostat.

The SURGICEL Family provides a breadth of solutions for all continuous oozing bleeding situations. Continuous oozing: Bleeding that will not stop with compression/simple packing. The solution for this bleeding is more time consuming than it is difficult.

For complete product details, see Instructions for Use.

To order: 1-800-255-2500. For technical support: 1-877-384-4266. Or visit www.surgicel.com.

References: 1. Powder TTH vs Original Final Report. 2015. Ethicon, Inc. 2. Final Report, PSE Accession No. 16-0006. Project No. 16438. Ethicon, Inc. 3. SURGICEL® Powder Absorbable Hemostat. Instructions for Use. Ethicon, Inc. 4. METHOD, Surface Energy/Tension Analysis. Ethicon, Inc. 5. Acceptability and Absorbability of Surgicel. 1995. Ethicon, Inc. 6. Acceptability and Absorbability of Surgicel and Surgicel Nu-Knit. 1993. Ethicon, Inc. 7. SURGICEL® Powder versus ARISTA™ AH and PerClot in a Swine Acute Liver Biopsy Model. Final Report, PSE Accession No. 15-0120, Project No. 16438.