

SURGICEL® Powder Absorbable Hemostat

Optimized Device Performance Quick Guide



Product Overview

Key Features¹

SURGICEL Powder is made from the same raw material as SURGICEL® Original Absorbable Hemostat, by grinding ORC fabric into fiber fragments. SURGICEL Powder 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.

- Ready to use out of the package
- Stored at room temperature (15-30°C/59-86°F)



Mechanism of Action¹

- After SURGICEL Powder has been saturated with blood, it swells into a brownish gelatinous mass, providing a surface for platelet adhesion and aggregation, which aids in the formation of a clot
- SURGICEL Powder is bactericidal in vitro against a wide range of bacteria due to low-pH characteristics



Application

Using the Open Applicator

Step 1

Using sterile technique, open outer foil pouch and transfer SURGICEL Powder delivery device and inner card to sterile field.

Step 2

By holding the body of the applicator, remove SURGICEL Powder delivery device from inner card.

Step 3

Twist to open.

Step 4

SURGICEL Powder is now ready for use. Compress bellows using **light** pressure to apply.

Steps 1 & 2



Step 3



Step 4



Using the Endoscopic Applicator

Step 1

To remove the open tip, simply pull it away from the device; twist to open.

Step 2

Attach the SURGICEL™ Endoscopic Applicator to the SURGICEL Powder Device without pumping the bellows and ensure the connection is secure.

The rigid sheath of the endoscopic applicator allows for one-handed use. ▶

Note: Do not use the rigid tip without the flexible inner tip in place. ▶

Sliding off the rigid sheath reveals a completely flexible inner tip that allows for precise product placement. ▶

Step 1



Step 2



Quick Tips

- If necessary, powder may be held firmly against the tissues until hemostasis is obtained
- Use only as much SURGICEL Powder as is necessary and apply only where needed for hemostasis; although it may be left in situ when necessary, it is advisable to **remove excess powder with irrigation and aspiration once hemostasis is achieved without disturbing the clot**
- Do not disassemble device bellows
- Do not trim the applicator tip
- To prevent clogging, **do not touch the tip to wet surface**
- SURGICEL Powder is not intended for use on dry (non-bleeding) surfaces or for prevention of bleeding.
- In the event of clogging, the tip can be wiped off using dry sterile, surgical gauze to remove the clog. If clog cannot be removed by using dry gauze, use a new SURGICEL Powder delivery device
- **Remove excess powder in the area of drains to prevent clogging**
- Do not inject or place SURGICEL Powder into an open blood vessel; do not use to control hemorrhage from large arteries or veins
- SURGICEL Powder must always be removed after hemostasis is achieved when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, or the optic nerve and chiasm since it could swell and could exert unwanted pressure
- Closing with SURGICEL Powder in a contaminated wound without drainage may lead to complications and should be avoided
- 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
- Precautions should be taken in otorhinolaryngologic surgery to ensure that none of the material is aspirated by the patient
- To view remaining powder in the reservoir or flexible inner tip while using the rigid cannula, partially retract the SURGICEL Powder device and flexible inner tip from the rigid cannula



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 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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Reference: 1. SURGICEL® Powder Absorbable Hemostat Instructions for Use. Ethicon, Inc.