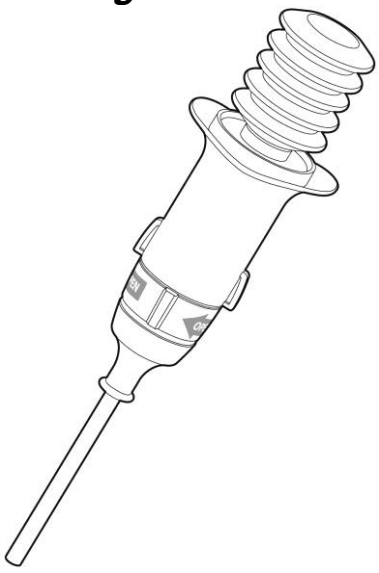
SURGICEL®
Powder
ABSORBABLE HEMOSTATIC POWDER
(oxidized regenerated cellulose)



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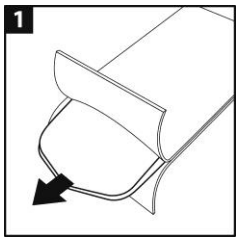
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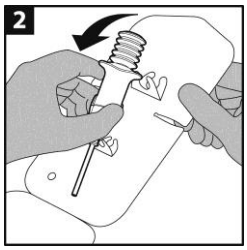
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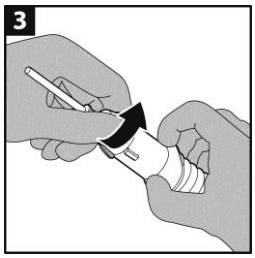
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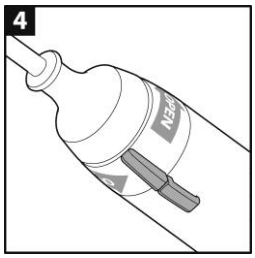
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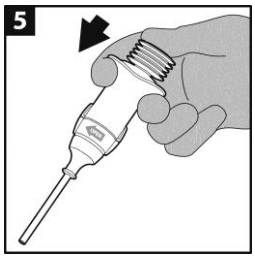
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SURGICEL® Powder
ABSORBABLE HEMOSTATIC POWDER
(oxidized regenerated cellulose)

⚠ Do not pump device intravascularly. Life-threatening embolic events may occur if the product is applied intravascularly.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

DESCRIPTION

SURGICEL® Powder contains Oxidized Regenerated Cellulose (ORC) prefilled in an applicator to dispense on a target bleeding site. SURGICEL® Powder is white with a pale yellow cast and has a faint, caramel-like aroma. It is stable and should be stored at controlled room temperature. A slight discoloration may occur with age, but this does not affect performance. SURGICEL® is bactericidal due to low pH characteristics against a wide range of pathogenic microorganisms.

ACTIONS

The mechanism of action whereby SURGICEL® Powder (oxidized regenerated cellulose) accelerates clotting is not completely understood, but it appears to be a physical effect rather than any alteration of the normal physiologic clotting mechanism. After SURGICEL® Powder has been saturated with blood, it swells into a brownish or black gelatinous mass which aids in the formation of a clot, thereby serving as a hemostatic adjunct in the control of local hemorrhage. When used properly in minimal amounts, SURGICEL® Powder is absorbed from the sites of implantation with practically no tissue reaction. Absorption depends upon several factors, including the amount used, degree of saturation with blood, and the tissue bed.

In addition to its local hemostatic properties, SURGICEL® Powder is bactericidal *in vitro* against a wide range of gram-positive and gram-negative organisms including aerobes and anaerobes. SURGICEL® Powder is bactericidal *in vitro* against strains of species including those of:

- methicillin-resistant *Staphylococcus aureus* (MRSA)
- penicillin-resistant *Streptococcus pneumoniae* (PRSP)
- vancomycin-resistant *Enterococcus* (VRE)
- methicillin-resistant *Staphylococcus epidermidis* (MRSE)
- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Micrococcus luteus*
- *Streptococcus* Group A
- *Streptococcus* Group B
- *Streptococcus salivarius*
- *Branhamella catarrhalis*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Lactobacillus* sp.
- *Salmonella enteritidis*
- *Shigella sonnei*
- *Serratia marcescens*
- *Bacillus subtilis*
- *Proteus vulgaris*
- *Corynebacterium xerosis*
- *Mycobacterium phlei*
- *Clostridium tetani*
- *Clostridium perfringens*
- *Bacteroides fragilis*
- *Enterococcus* sp.
- *Enterobacter cloacae*
- *Pseudomonas aeruginosa*
- *Pseudomonas stutzeri*
- *Proteus mirabilis*

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.

CONTRAINDICATIONS

- Do not inject or place SURGICEL® Powder into an open blood vessel.
- SURGICEL® Powder should not be used to control hemorrhage from large arteries.
- 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 should not be used on non-hemorrhagic serous oozing surfaces, since body fluids other than whole blood, such as serum, do not react with SURGICEL® Powder to produce satisfactory hemostatic effect.
- SURGICEL® Powder is an absorbable hemostat, and should not be used as an adhesion prevention product.

WARNINGS

- SURGICEL® Powder is supplied sterile and as the material is not compatible with autoclaving or ethylene oxide sterilization, SURGICEL® Powder should not be resterilized.
- SURGICEL® Powder is not intended as a substitute for careful surgery and the proper use of sutures and ligatures.
- Closing with SURGICEL® Powder in a contaminated wound without drainage may lead to complications and should be avoided.
- The hemostatic effect of SURGICEL® Powder is greater when it is applied dry; therefore, it should not be moistened with water or saline prior to application.
- SURGICEL® Powder should not be impregnated with anti-infective agents or with other materials such as buffering or hemostatic substances. Its hemostatic effect is not enhanced by the addition of thrombin, the activity of which is destroyed by the low pH of the product.
- Although SURGICEL® Powder may be left *in situ* when necessary, it is advisable to remove excess powder once hemostasis is achieved, without disturbing the clot.
- 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.
- Dislodgement of SURGICEL® Powder could possibly occur by intraoperative manipulation, lavage, exaggerated respiration, etc. With other SURGICEL® products there have been reports that in procedures such as lobectomy, laminectomy, and repair of a frontal skull fracture and lacerated lobe, when the product was left in the patient after closure it migrated from the site of application into foramina in bone around the spinal cord, resulting in paralysis and, in one case, the product migrated into the left orbit of the eye, causing blindness. While these reports cannot be confirmed to be related to SURGICEL® products, special care must be taken by physicians, regardless of the type of surgical procedure. Consider removing SURGICEL® Powder in these

applications (procedures) after hemostasis is achieved.

- 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.
- Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.
- Do not attempt to trim the applicator tip.

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.
- 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).
- This applicator tip is not intended for laparoscopic or other endoscopic use.

ADVERSE REACTIONS

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. While most of these reports have been in connection with laminectomy, reports of paralysis have also been received in connection with other procedures. Blindness has been reported in connection with surgical repair of a lacerated left frontal lobe when SURGICEL® products were placed in the anterior cranial fossa[1] (see WARNINGS and PRECAUTIONS).

Foreign body reactions have been reported with other products from the SURGICEL® Family of Absorbable Hemostats.

There have been reports with other SURGICEL® products, such as possible prolongation of drainage in cholecystectomies and difficulty passing urine per urethra after prostatectomy, and blocked ureter after kidney resection, in which postoperative catheterization was required.

Burning has been reported when other SURGICEL® products were applied after nasal polyp removal and after hemorrhoidectomy. 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.[2]

DIRECTIONS FOR USE

1. Open outer foil pouch and transfer SURGICEL® Powder delivery device and inner card to sterile field (Fig. 1).
2. By holding the body of the applicator, remove SURGICEL® Powder delivery device from inner card (Fig. 2).
3. Twist to open (Figs. 3, 4).
4. SURGICEL® Powder delivery device is now ready for use. Compress bellows using light pressure to apply powder to treatment site (Fig. 5).
5. As an approximate guide, one SURGICEL® Powder delivery device can provide coverage of 10.5 in^2 (3.2 x 3.2 inch area) when applied in one layer at a distance of approximately 2 inches from the bleeding surface. Depending on bleeding intensity and anatomical location, more than one layer may be needed to achieve complete hemostasis at the targeted bleeding surface.
6. If necessary, powder may be held firmly against the tissues until hemostasis is obtained.
7. To prevent clogging, do not touch the tip to wet surface. Do not disassemble device bellows. Do not trim the applicator tip (see WARNINGS).
8. In the event of clogging, the tip can be wiped off using dry sterile, surgical gauze to remove clog. If clog cannot be removed by dry gauze, dispose of the clogged device and use a new SURGICEL® Powder delivery device.

DISPOSAL

Dispose of the device and packaging according to your facility's policies and procedures regarding biohazardous materials and waste.

DOSAGE AND ADMINISTRATION

Sterile technique should be observed in removing the applicator for SURGICEL® Powder (oxidized regenerated cellulose) from its sterile packaging. Apply adequate amount of SURGICEL® powder to cover bleeding area. Use of a non-adhering substrate to apply pressure may prevent adhesion of the formed clot to the surgical glove or other instrumentation.

Unused SURGICEL® Powder should be discarded.

HOW SUPPLIED

The applicator is provided with 3 grams of SURGICEL® Powder (oxidized regenerated cellulose) and should not be resterilized. Sterility guaranteed unless package is opened or damaged.

STORAGE

Store at controlled room temperature 15°C-30°C (59°F-86°F).

CLINICAL STUDIES

No clinical studies have been conducted using SURGICEL® Powder.

REFERENCES:

1. Dutton J, Tse D, Anderson R. Compressive optic neuropathy following use of intra-cranial oxidized cellulose hemostat. *Ophthalmic Surgery.* 1983;14(6):487-490.
2. Huggins S. Control of hemorrhage in otorhinolaryngologic surgery with oxidized regenerated cellulose. *Eye, Ear, Nose and Throat Monthly.* 1969;48(7).

SYMBOLS USED ON LABELING

	Do not reuse		Do not resterilize
	Do not use if package is damaged		Caution
	Use-By Date		Temperature limit
	Manufacturer	REF	Catalogue number
LOT	Batch code		CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner
STERILE R	Sterilized using Irradiation		

[Back cover]

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