SURGICEL®
Powder
ABSORBABLE HEMOSTATIC POWDER
(oxidized regenerated cellulose)

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Made in U.S.A.
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[English Text]
**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.

**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 pyogenes* Group A  
- *Streptococcus pyogenes* Group B  
- *Streptococcus salivarius*  
- *Branhamella catarrhalis*  
- *Escherichia coli*  
- *Klebsiella aerogenes*  
- *Lactobacillus* sp.  
- *Salmonella enteritidis*

Studies conducted in animals show that other SURGICEL® products in contrast to other hemostatic agents do not enhance experimental infection.

**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. 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).

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 (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.14

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 main body of the applicator, remove SURGICEL® Powder delivery device from inner card. (Fig. 2)
3. Twist to open. (Figs. 3, 4) SURGICEL® Powder delivery device is now ready for use. Pump to apply powder to treatment site (Fig. 5). To prevent clogging, do not touch the tip to wet surface. Do not disassemble device bellows.
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. If necessary, powder may be held firmly against the tissues until hemostasis is obtained. 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).

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

CLINICAL STUDIES
No clinical studies have been conducted using SURGICEL® Powder. There have been studies conducted with SURGICEL® Original (oxidized regenerated cellulose) that have been found useful in helping to control capillary or venous bleeding in a variety of surgical applications, including abdominal, thoracic, neurosurgical, and orthopedic, as well as in otorhinolaryngologic procedures. Examples include gallbladder surgery, partial hepatectomy, hemorrhoidectomy, resections or injuries of the pancreas, spleen, kidney, prostate, bowel, breast or thyroid, and in amputations.6,8

SURGICEL® Original has been applied as a surface dressing on donor sites and superficial open wounds, controlling bleeding adequately and causing no delay in healing or interference with epithelialization.9,11 It also has been applied after dermabrasion, punch biopsy, excision biopsy, curettage, fingernail and toenail removal, and to traumatic wounds. In the foregoing applications, bleeding was controlled and the SURGICEL® Original was absorbed from the sites where it was applied.10

In cardiovascular surgery, investigators have found SURGICEL® Original useful in helping to control bleeding from implanted textile grafts, including those of the abdominal aorta.7,11 Such grafts may leak or weep considerably, even when precotted, but this seepage can be controlled by covering the graft with a layer or two of SURGICEL® Original after the graft is in place and before releasing the proximal and distal clamps. When the flow has been reestablished and all the bleeding controlled, the fabric either can be removed or left in situ, since absorption of SURGICEL® Original has been shown to occur without constriction of the graft or other untoward incident when proper wrapping technique is employed.

Otorhinolaryngologic experience with SURGICEL® Original includes adjunctive use in controlling bleeding resulting from epistaxis, tonsillectomy, adenoidectomy, removal of nasal polyps, repair of deviated septum, tympanoplasty, stapes surgery, surgery for sinusitis, and removal of tumors.12,14

SURGICEL® Original has been reported useful as a hemostatic adjunct in such gynecologic procedures as oophorectomy, hysterectomy, conization of the cervix, and repair of cystocoele.6,15

ANIMAL PHARMACOLOGY OF ORC IN FABRIC FORM
The effects of a SURGICEL® product (oxidized regenerated cellulose), absorbable gelatin sponge, and microfibrillar collagen hemostat were compared in a standardized infection model consisting of intra-abdominal and intrahepatic abscesses in mice.
This infection mimics the common characteristics of human infection with nonspore-forming anaerobic bacteria, including a chronic and progressive course. SURGICEL® product did not increase the infectivity of normally subinfectious inocula of mixed anaerobic species in mice. With the other hemostatic agents, microfibrillar collagen hemostat and absorbable gelatin sponge, an enhancement of infectivity of anaerobic mixtures has been shown. SURGICEL® Powder, in contrast to these hemostatic agents, did not enhance or provide a site for bacterial growth.

It was also found that aerobic pathogens did not grow in the presence of SURGICEL® Powder. In these studies,1 SURGICEL® Powder was placed in contaminated incisions of guinea pigs and markedly reduced bacterial growth of three different strains of common pathogens. In a dog model, it was shown that bacterial contamination of implanted Teflon™ patches in the aorta could be reduced by wrapping the area of the patch with SURGICEL® Powder prior to pathogen challenge. Also, in another study,2 SURGICEL® Powder and a gelatin sponge were placed in two splenotomy sites in large mongrel dogs and the animals were then challenged intravenously and the number of organisms from the splenotomy sites were measured over a period of time. The number of organisms at the site of SURGICEL® Powder were significantly lower than those in the control or the absorbable gelatin sponge site.
REFERENCES:
SYMBOLS USED ON LABELING

Do not reuse

Do not use if package is damaged

Do not resterilize

Caution

Use By

Temperature limit

Manufacturer

Catalogue number

Batch code

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

STERILE

Sterilized using Irradiation

[Back cover]

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