SURGICEL® ORIGINAL, SURGICEL® NU-KNIT® and SURGICEL® FIBRILLAR™ Absorbable Hemostats (oxidized regenerated cellulose) FOR SURGICAL USE
(For dental application of this product, reference should be made to the dental use section of this insert.)

DESCRIPTION

SURGICEL® Absorbable Hemostat is a sterile absorbable knitted fabric prepared by the controlled oxidation of regenerated cellulose. The fabric is white with a pale yellow cast and has a faint, caramel-like aroma. It is strong and can be sutured or cut without fraying. It is stable and should be stored at controlled room temperature. A slight discoloration may occur with age, but this does not affect performance. The SURGICEL® FIBRILLAR™ form of the product allows the surgeon to grasp with forceps any amount of SURGICEL® FIBRILLAR™ Hemostat needed to achieve hemostasis at a particular bleeding site. The SURGICEL® FIBRILLAR™ form may be more convenient than the knitted form for hard to reach or irregularly shaped bleeding sites. Although it is easy to pull the desired amount of SURGICEL® FIBRILLAR™ Hemostat from the entire supply, the group of selected fibers continue to cohere to one another and application to the bleeding site is easily controlled. Unwanted dispersal over the operative site does not occur.

ACTIONS

The mechanism of action whereby SURGICEL® Absorbable Hemostat 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® Absorbable Hemostat 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® Absorbable Hemostat 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® Absorbable Hemostat is bactericidal *in vitro* against a wide range of gram positive and gram negative organisms including aerobes and anaerobes. SURGICEL® Absorbable Hemostat 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
Shigella dysenteriae
Serratia marcescens
Bacillus subtilis
Proteus vulgaris
Corynebacterium xerosis
Mycobacterium phlei
Clostridium tetani
Clostridium perfringens
Bacteroides fragilis
Enterococcus
Enterobacter cloacae
Pseudomonas aeruginosa
Pseudomonas stutzeri
Proteus mirabilis

Studies conducted in animals show that SURGICEL® Absorbable Hemostat in contrast to other hemostatic agents does not enhance experimental infection. (1-4)

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™ and SURGICEL® NU-KNIT® Hemostats can be cut to size for use in endoscopic procedures.

CONTRAINDICATIONS

Although packing or wadding sometimes is medically necessary, SURGICEL® Absorbable Hemostat should not be used in this manner, unless it is to be removed after hemostasis is achieved (See WARNINGS and PRECAUTIONS).

SURGICEL® Absorbable Hemostat 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.

When SURGICEL® Absorbable Hemostat 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® Absorbable Hemostat should not be used to control hemorrhage from large arteries.

SURGICEL® Absorbable Hemostat 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® Absorbable Hemostat to produce satisfactory hemostatic effect.

SURGICEL® Absorbable Hemostat is an absorbable hemostat, and should not be used as an adhesion prevention product.

WARNINGS

SURGICEL® Absorbable Hemostat is supplied sterile and as the material is not compatible with autoclaving or ethylene oxide sterilization, SURGICEL® Absorbable Hemostat should not be resterilized.

SURGICEL® Absorbable Hemostat is not intended as a substitute for careful surgery and the proper use of sutures and ligatures.

Closing SURGICEL® Absorbable Hemostat in a contaminated wound may lead to complications and should be avoided.

The hemostatic effect of SURGICEL® Absorbable Hemostat is greater when it is applied dry; therefore it should not be moistened with water or saline.

SURGICEL® Absorbable Hemostat 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® Absorbable Hemostat may be left *in situ* when necessary, it is advisable to remove it once hemostasis is achieved. It must **always** be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm, and in proximity to tubular structures that could become constricted by swelling, regardless of the type of surgical procedure because SURGICEL® Hemostat, by swelling, may exert pressure resulting in paralysis and/or nerve damage. Dislodgement of SURGICEL® Absorbable Hemostat could possibly occur by means such as repacking, further intraoperative manipulation, lavage, exaggerated respiration, etc. There have been reports that in procedures such as lobectomy, laminectomy and repair of a frontal skull fracture and lacerated lobe that SURGICEL® Absorbable Hemostat, when left in the patient after closure, migrated from the site of application into foramina in bone around the spinal cord resulting in paralysis and, in another case, the left orbit of the eye, causing blindness. While these reports cannot be confirmed, special care must be taken by physicians, ***regardless of the type of surgical procedure,*** to consider the advisability of removing SURGICEL® Absorbable Hemostat after hemostasis is achieved.

Although SURGICEL® Absorbable Hemostat 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 prevent post-operative infections.

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, such as encapsulation of the product, which may mimic artifacts on radiographic images, resulting in diagnostic errors and possible reoperation.

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).

Endoscopic procedures should be performed only 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.

A thorough understanding of the principles and techniques involved in laparoscopic laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Refer to appropriate electrosurgical system users manual for use indications and instructions to ensure that all safety precautions are followed. When endoscopic instruments and accessories from different manufacturers are employed together during a procedure, verify their compatibility prior to initiation of the procedure and ensure that isolation or grounding is not compromised.

ADVERSE REACTIONS

"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. Although it has not been established that the stenosis was directly related to the use of SURGICEL® Absorbable Hemostat, it is important to be cautious and avoid applying the material tightly as a wrapping.

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. 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® Absorbable Hemostat was placed in the anterior cranial fossa (5) (See WARNINGS and PRECAUTIONS).

Possible prolongation of drainage in cholecystectomies and difficulty passing urine per urethra after prostatectomy have been reported. There has been one report of a blocked ureter after kidney resection, in which postoperative catheterization was required.

Occasional reports of "burning" and "stinging" sensations and sneezing when SURGICEL® Absorbable Hemostat has been used as packing in epistaxis, are believed to be due to the low pH of the product.

Burning has been reported when SURGICEL® Absorbable Hemostat was applied after nasal polyp removal and after hemorrhoidectomy. Headache, burning, stinging, and sneezing in epistaxis and other rhinological procedures, and stinging when SURGICEL® Absorbable Hemostat was applied on surface wounds (varicose ulcerations, dermabrasions, and donor sites) also have been reported.

DOSAGE AND ADMINISTRATION

Sterile technique should be observed in removing SURGICEL® Absorbable Hemostat from its sterile container. Minimal amounts of SURGICEL® Absorbable Hemostat in appropriate size are laid on the bleeding site or held firmly against the tissues until hemostasis is obtained.

Opened, unused SURGICEL® Absorbable Hemostat should be discarded, because it cannot be resterilized.

HOW SUPPLIED

Sterile SURGICEL® FIBRILLAR™ Absorbable Hemostat is supplied as staple fiber in envelopes of the following sizes.
Code No. 1961 1 in. x 2 in. (2.5 cm. x 5.1 cm.)
Code No. 1962 2 in. x 4 in. (5.1 cm. x 10.2 cm.)
Code No. 1963 4 in. x 4 in. (10.2 cm. x 10.2 cm.)

Sterile SURGICEL® ORIGINAL Absorbable Hemostat (oxidized regenerated cellulose) is supplied as knitted fabric strips in envelopes in the following sizes.
Code No. 1951 2 in. x 14 in. (5.1 cm. x 35.6 cm.)
Code No. 1952 4 in. x 8 in. (10.2 cm. x 20.3 cm.)
Code No. 1953 2 in. x 3 in. (5.1 cm. x 7.6 cm.)
Code No. 1955 0.5 in. x 2 in. (1.3 cm. x 5.1 cm.)

Sterile SURGICEL® NU-KNIT® Absorbable Hemostat
Code No. 1940 1 in. x 1 in. (2.5 cm. x 2.5 cm.)
Code No. 1941 1 in. x 3.5 in. (2.5 cm. x 8.9 cm.)
Code No. 1943 3 in. x 4 in. (7.6 cm. x 10.2 cm.)
Code No. 1946 6 in. x 9 in. (15.2 cm. x 22.9 cm.)

STORAGE

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

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

CLINICAL STUDIES

SURGICEL® Absorbable Hemostat (oxidized regenerated cellulose) has 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® Absorbable Hemostat 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 epithelization. (9,11) It also has been applied after dermabrasion, punch biopsy, excision biopsy, curettage, finger and toenail removal, and to traumatic wounds. In the foregoing applications, bleeding was controlled and the SURGICEL® Absorbable Hemostat was absorbed from the sites where it was applied. (10)

In cardiovascular surgery, investigators have found SURGICEL® Absorbable Hemostat useful in helping to control bleeding from implanted textile grafts, including those of the abdominal aorta. (7,12) Such grafts may leak or weep considerably, even when pre-clotted, but this seepage can be controlled by covering the graft with a layer or two of SURGICEL® Absorbable Hemostat 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® Absorbable Hemostat has been shown to occur without constriction of the graft or other untoward incidents when proper wrapping technique is employed.

Otorhinolaryngologic experience with SURGICEL® Absorbable Hemostat 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. (13,14)

SURGICEL® Absorbable Hemostat has been reported useful as a hemostatic adjunct in such gynecologic procedures as oophorectomy, hysterectomy, conization of the cervix, and repair of cystorectocele. (6,15)

ANIMAL PHARMACOLOGY

The effects of SURGICEL® Absorbable Hemostat, 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® Absorbable Hemostat 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® Absorbable Hemostat, 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® Absorbable Hemostat. In these studies (1), SURGICEL® Absorbable Hemostat was placed in contaminated incisions of guinea pigs and markedly reduced bacterial growth of three different strains of common pathogens. In a dog model (2), 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® Absorbable Hemostat prior to pathogen challenge. Also, in another study (3), SURGICEL® Absorbable Hemostat 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® Absorbable Hemostat were significantly lower than those in the control, or the absorbable gelatin sponge site.

DIRECTIONS FOR USING SURGICEL® ORIGINAL, SURGICEL® NU-KNIT® AND SURGICEL® FIBRILLAR™ ABSORBABLE HEMOSTAT IN ENDOSCOPIC PROCEDURES (see Figures 1–3):

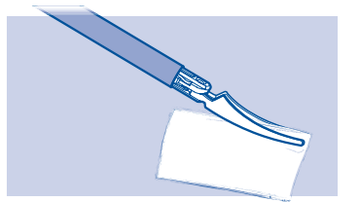

FIGURE 1

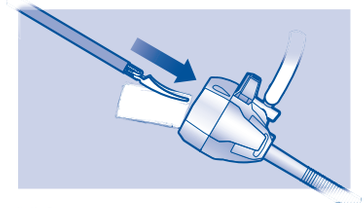

FIGURE 2A

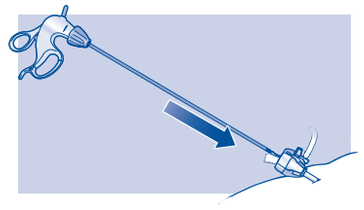

FIGURE 2B

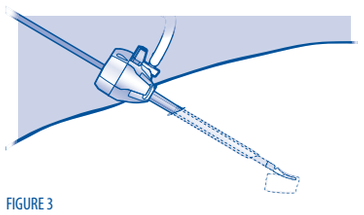

FIGURE 3

Figure 1. SURGICEL® ORIGINAL, SURGICEL® NU-KNIT® AND SURGICEL® FIBRILLAR™ Absorbable Hemostat (oxidized regenerated cellulose) *should be cut to the appropriate size for endoscopic placement. Standard endoscopic procedures should be used up to the point of placement of the absorbable hemostat. Grasp the* SURGICEL® ORIGINAL, SURGICEL® NU-KNIT® AND SURGICEL® FIBRILLAR™ Absorbable Hemostat *at one corner.*

Figure 2A and 2B. *Slowly push the grasping instrument and material into the cavity.*

Figure 3. *With the use of grasping instruments in a second and/or third auxiliary site, placement can be made and the material repositioned as needed.*

SYMBOLS USED IN LABELING

- Do not reuse
- Do not resterilize
- Do not use if package is damaged
- Use by
- Sterilized using irradiation
- Catalogue number
- Batch code
- Manufacturer
- CAUTION! See instructions for use
- Store 15-30°C (59-86°F)
- CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

REFERENCES:

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SURGICEL® ORIGINAL, SURGICEL® NU-KNIT®, and SURGICEL® FIBRILLAR™ Absorbable Hemostats (oxidized regenerated cellulose) For Dental Use
(For surgical applications of this product, reference should be made to the surgical use section of this insert.)

DESCRIPTION

SURGICEL® Absorbable Hemostat is an absorbable knitted fabric prepared by the controlled oxidation of regenerated cellulose. The fabric is white with a pale yellow cast and has a faint, caramel-like aroma. It is strong and can be sutured or cut without fraying. It is stable and can be stored at controlled room temperature. A slight discoloration may occur with age, but this does not affect performance. The SURGICEL® FIBRILLAR™ form of the product allows the physician to grasp with forceps any amount of SURGICEL® FIBRILLAR™ Hemostat needed to achieve hemostasis at a particular bleeding site. The fibrillar form may be more convenient than the knitted form for hard to reach or irregularly shaped bleeding sites. Although it is easy to pull the desired amount of SURGICEL® FIBRILLAR™ Hemostat from the entire supply, the group of selected fibers continue to cohere to one another and application to the bleeding site is easily controlled. Unwanted dispersal over the operative site does not occur.

ACTIONS

The mechanism of action whereby SURGICEL® Absorbable Hemostat 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® Absorbable Hemostat 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® Absorbable Hemostat 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.

INDICATIONS

SURGICEL® Absorbable Hemostat (oxidized regenerated cellulose) is indicated for adjunctive use to assist in the control of bleeding in exodontia and oral surgery. It may also be used to help achieve hemostasis after single or multiple tooth extractions, alveoloplasty, gingival hemorrhage, impactions, biopsies, and other procedures in the oral cavity.

CONTRAINDICATIONS

Although packing or wadding sometimes is medically necessary, SURGICEL® Absorbable Hemostat should not be used in this manner unless it is to be removed after hemostasis is achieved.

SURGICEL® Absorbable Hemostat 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® Absorbable Hemostat is supplied sterile and should not be autoclaved because autoclaving causes physical breakdown of the product.

SURGICEL® Absorbable Hemostat is not intended as a substitute for careful surgery and the proper use of sutures and ligatures.

Closing SURGICEL® Absorbable Hemostat in a contaminated wound may lead to complications and should be avoided.

The hemostatic effect of SURGICEL® Absorbable Hemostat is greater when it is applied dry; therefore it should not be moistened with water or saline.

SURGICEL® Absorbable Hemostat 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® Absorbable Hemostat may be left *in situ* when necessary, it is advisable to remove it once hemostasis is achieved.

PRECAUTIONS

Use only as much SURGICEL® Absorbable Hemostat as is necessary for hemostasis, holding it in place until bleeding stops. Remove any excess before surgical closure in order to facilitate absorption and minimize the possibility of foreign body reaction, such as encapsulation of the product, which may mimic artifacts on radiographic images, resulting in diagnostic errors and possible reoperation. SURGICEL® Absorbable Hemostat should be applied loosely against the bleeding surface. Wadding or packing should be avoided, especially within rigid cavities, where swelling may interfere with normal function or possibly cause necrosis. Precautions should be taken to assure that none of the material is aspirated by the patient.

ADVERSE REACTIONS

Encapsulation of fluid and foreign body reactions have been reported.

DOSAGE AND ADMINISTRATION

Sterile technique should be observed in removing SURGICEL® Absorbable Hemostat from its envelope. Minimal amounts of SURGICEL® Absorbable Hemostat of appropriate size are laid on the bleeding site or held firmly against the tissues until hemostasis is obtained.

Opened, unused SURGICEL® Absorbable Hemostat should be discarded, because it cannot be resterilized.

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for product quality and technical questions,
call 1-877-ETHICON.

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SURGICEL® ORIGINAL ABSORBABLE HEMOSTAT

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