DEVICE SPECS

SURGICEL® Family of Absorbable Hemostats

	 **SURGICEL® Powder** **Absorbable Hemostat**	 **SURGICEL SNoW™** **Absorbable Hemostat**	 **SURGICEL® FIBRILLAR™** **Absorbable Hemostat**	 **SURGICEL® NU-KNIT™** **Absorbable Hemostat**	 **SURGICEL® Original** **Absorbable Hemostat**
Codes	3013SP	2081, 2082, 2083	1961, 1962, 1963	1943, 1946	1951, 1952, 1953, 1955
Description	Fast and durable for broad surface oozing bleeding	Easy handling for MIS and open procedures	Precise for multi-site bleeding in open procedures	Dense for wrapping and suturing in place	Loose knit ORC fabric
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 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 SNoW Absorbable Hemostat can be cut to size for use in endoscopic procedures.	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 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 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.
Size	3.0g	1in x 2in (2081), 2in x 4in (2082), 4in x 4in (2083)	1in x 2in (1961), 2in x 4in (1962), 4in x 4in (1963)	3in x 4in (1943), 6in x 9in (1946)	0.5in x 2in (1951), 4in x 8in (1952), 2in x 3in (1953), 2in x 14in (1954)
Absorption Time	7-14 days	7-14 days	7-14 days	7-14 days	7-14 days
Storage Requirements	Store at controlled room temperature 59°-86°F (15°-30°C)	Store at controlled room temperature 59°-86°F (15°-30°C)	Store at controlled room temperature 59°-86°F (15°-30°C)	Store at controlled room temperature 59°-86°F (15°-30°C)	Store at controlled room temperature 59°-86°F (15°-30°C)
Preparation Time	Ready out of package	Ready out of package	Ready out of package	Ready out of package	Ready out of package
Shelf Life	18 months	2 years	3 years	5 years	5 years
Material/ Composition	Oxidized Regenerated Cellulose with bactericidal properties	Oxidized Regenerated Cellulose with bactericidal properties	Oxidized Regenerated Cellulose with bactericidal properties	Oxidized Regenerated Cellulose with bactericidal properties	Oxidized Regenerated Cellulose with bactericidal properties
Mechanism of Action	Penetrates to the source of bleeding and provides a matrix for platelet adhesion and aggregation	Provides a matrix for platelet adhesion and aggregation	Provides a matrix for platelet adhesion and aggregation	Provides a matrix for platelet adhesion and aggregation	Provides a matrix for platelet adhesion and aggregation
Distributor Code	63713-3013SP	63713-0020-81 (2081) 63713-0020-82 (2082) 63713-0020-83 (2083)	63713-0019-61 (1961) 63713-0019-62 (1962) 63713-0019-63 (1963)	63713-0019-43 (1943) 63713-0019-46 (1946)	63713-0019-51 (1951) 63713-0019-52 (1952) 63713-0019-53 (1953) 63713-0019-55 (1954)
Qty./Box	5	10	10	10 (1943 or 24 (1946)	24

ETHICON

Johnson & Johnson SURGICAL TECHNOLOGIES

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

ESSENTIAL PRODUCT INFORMATION

SURGICEL® Powder Absorbable Hemostat

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 endoscopiic 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 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 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 to control hemorrhage from large arteries or veins.
- 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.
- The SURGICEL Powder and the SURGICEL Endoscopic Applicator devices were not designed for intraluminal procedures.

WARNINGS

- SURGICEL Powder is not intended for use on dry (non-bleeding) surfaces or for prevention of bleeding.
- 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 substance. 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 recommended to remove excess powder with irrigation and aspiration 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.
- 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 minimal amount of SURGICEL Powder required to achieve hemostasis, and remove excess powder in the area of drains to prevent clogging.
- 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, 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® 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.

ETHICON

Johnson & Johnson SURGICAL TECHNOLOGIES

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

SURGICEL® Powder Absorbable Hemostat, continued

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

071582-211105

ETHICON

Johnson & Johnson SURGICAL TECHNOLOGIES

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

ESSENTIAL PRODUCT INFORMATION

SURGICEL®

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.

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 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 ensure 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

- 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
- “Encapsulation” of fluid and foreign body reactions have been reported.
- Burning has been reported when 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.
- There have been reports of stenotic effect when SURGICEL Absorbable Hemostat has been applied as a wrap during vascular surgery.
- 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.

063768-211105

ETHICON

Johnson & Johnson SURGICAL TECHNOLOGIES

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.