SURGICEL™ Powder
Absorbable Haemostat

Presenting SURGICEL™ Powder

Built to stop continuous, broad-surface oozing*—fast**, #, 1-4

*Continuous oozing defined as bleeding that will not stop with compression / simple packing

**TTH study of surgicel powder show average time to haemostasis of 30 seconds

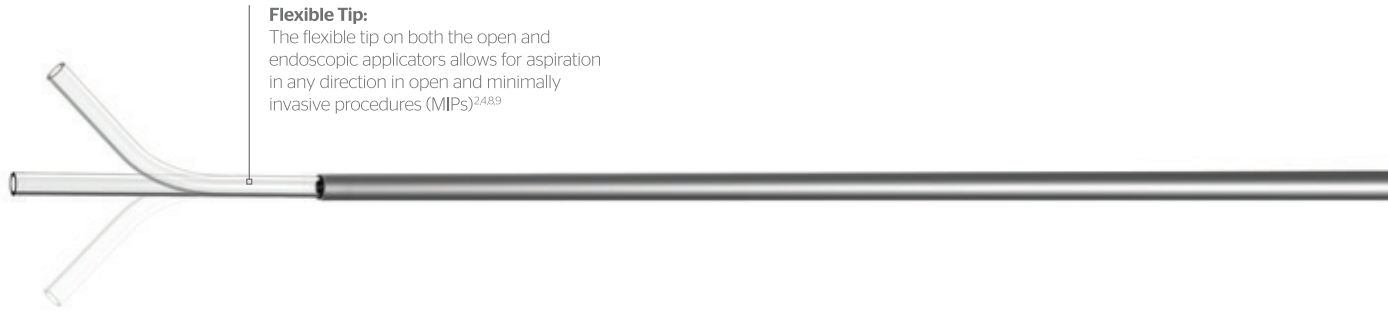
is ready to use out of the package with no preparation required

ETHICON

The next generation of SURGICEL™ Absorbable Haemostats

SURGICEL™ Powder Absorbable Haemostat provides effective control of continuous oozing on broad surfaces[2,5] *

- Ready to use out of the package, with no preparation required[3]
- Penetrates through the blood quickly to stop bleeding right at the source, effectively achieving haemostasis in a wet field[6,7]
- After haemostasis has been achieved, the bleeding site will not rebleed even if SURGICEL™ Powder is irrigated[7] **



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Shaping the future of surgery

*Continuous oozing defined as bleeding that will not stop with compression / simple packing

**Based on a preclinical animal study

Get to the source of the bleed

The structure of the powder allows it to penetrate the surface of the blood to get to the source of bleeding[6,16]

SURGICEL™ Powder
is an aggregate of small oxidized regenerated cellulose (ORC) fiber fragments[2,3]

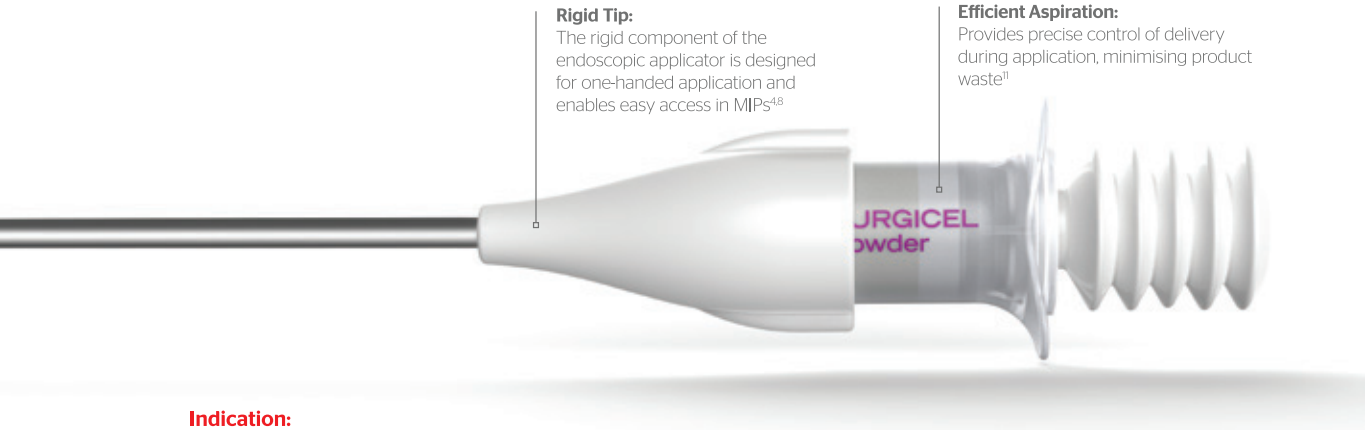
1 **SURGICEL™ Powder**
Absorbable Haemostat provides effective control of continuous oozing on broad surfaces[2,5]*

2 Blood saturates the material, providing a surface for platelet adhesion and aggregation, working with the patients endogenous clotting factors to initiate clot formation[10]

3 Built to stop continuous, broadsurface oozing*—fast**,#,[1-4]

4 Forms a durable clot that won't wash away or rebleed when irrigated[7]†

†based on pre clinical animal study



Indication:
SURGICEL Powder (oxidized regenerated cellulose) contains an aggregate of ORC fibre fragments intended to help control capillary, venous and small arterial haemorrhages or other conventional methods of control are impractical or ineffective.[2,3]

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#is ready to use out of the package with no preparation required

Everything you've come to expect from the SURGICEL™ Family of Absorbable Haemostats

- Proven bactericidal in vitro against a broad range of gram-positive and gram-negative organisms, including various antibiotic-resistant bacteria (*MRSA, VRE, PRSP and MRSE*)[3, 15]
- Contains an aggregate of ORC fiber fragments that help control capillary, venous, and small arterial haemorrhages[2,3]*

Easy application across both open and laparoscopic procedures[2, 4, 9, 17]

- The 2-in-1 endoscopic applicator is sold separately and is composed of 2 components, the rigid tip and the flexible tip
  - The rigid tip allows for one handed use and easy powder delivery in MIPs[4,8]
- The flexible tip allows for aspiration in any direction in open and minimally invasive procedures[2,4,8,9]

2-in-1 Endoscopic Applicator:
Sold separately and allows for ease of use in MIPs

[2 in 1]

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Shaping the future of surgery

Built on a legacy of performance

SURGICEL™ Powder Absorbable Haemostat is an addition to the SURGICEL™ Family of Absorbable Haemostats

For illustration purposes only and may not represent an actual device specification.

Ordering Information

Code	Description	Device Specifications	Quantity (per box)
3013SP	SURGICEL Powder	3.0 grams	5 units
3023SPEA	SURGICEL Endoscopic Applicator	2-in-1 applicator	5 units

Further Information

Please contact your local Ethicon representative.

SURGICEL 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.

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 device was 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. Unlike other SURGICEL® products, SURGICEL® Powder cannot be removed from blood clots and complete removal of the device application may disrupt the clot and increase the risk of re-bleeding.
- 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 not intended for use on dry (non-bleeding) surfaces or for prevention of bleeding.
- 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 recommended to remove excess powder with irrigation and aspiration 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. In preclinical in vivo animal studies it was demonstrated that SURGICEL® Powder does not increase the incidence of remote adhesions in laparoscopic procedures.
- 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.
- 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.

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 fossa1 (see WARNINGS and PRECAUTIONS). Foreign body reactions have been reported with other products from the SURGICEL® Family of Absorbable Hemostats.

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

SURGICEL™
Family of Absorbable Haemostats

One family. **Five products.** 50+ years.

Original | Fibrillar™ | Powder | Snow™ | Nu-Knit®

The SURGICEL™ Family provides a breadth of solutions for all continuous oozing bleeding situations.

Continuous oozing: Bleeding that will not stop with compression/simple packing.
The solution for this bleeding is more time consuming than it is difficult.

References: 1. Ethicon, PSE Accession No. 15-0061, Project No. 16438, Pivotal Study Comparing Performance of SURGICEL® Powder – Absorbable Hemostatic Particles to SURGICEL® Original Absorbable Hemostat in a Swine Acute Liver Abrasion Model, August 2015, Data on File. **2.** Ethicon, PSE Accession No. 16-0006, Project No. 16438, Study Comparing Performance of SURGICEL® Powder – Absorbable Hemostatic Particles to SURGICEL® Original Absorbable Hemostat in a Swine Acute Liver Abrasion Model, March 2016, Data on File. **3.** Ethicon, SURGICEL® Powder Absorbable Hemostat, Instructions for Use. Data on File. **4.** Ethicon, K-5678 Surgicel Endoscopic Applicator Summative Usability Design Validation Surgeon and Nurse Study, December 2016, Data on File. **5.** Ethicon, Market Research on unmet need – Ethicon, Project Pixie Global Positioning Report, Dec 2014, Data on File. **6.** Ethicon, Inc. Surface energy/ tension analysis among ORC Aggregate, ORC Fine Fiber, and Arista – Project PIXIE, March 2017, Data on File. **7.** Ethicon, Inc. SURGICEL® Powder versus ARISTA™ AH. Final Report, PSE Accession No. 15-0120, Project No. 16438, September 2015, Data on File. **8.** Ethicon, Inc. SURGICEL® Endoscopic Applicator, Instructions for Use, Data on File. **9.** Ethicon, 100294016 Rev6, Design Requirements Matrix Project Pixie: SURGICEL Powder, Dec 2016, Data on File. **10.** Ethicon, Inc. SURGICEL Technical Report, 006321-131114, October 2013, Data on File. **11.** Ethicon, Inc. Expression testing- ADAPTIV Document 100293850-1, March 2012, Data on File. **12.** Dineen P. Antibacterial activity of oxidized regenerated cellulose. Surg Gynecol Obstet. 1976;142(4):481-486. **13.** Ethicon. Acceptability and Absorbability of Surgicel. 1995, Data on File. **14.** Ethicon. Acceptability and Absorbability of Surgicel and Surgicel Nu-Knit. 1993,, Data on File. **15.** Ethicon, 100408840-2 ORC Powder Bactericidal Efficacy, Data on File. **16.** Ethicon, US Patent Compacted HaemostaticCellulosic Aggregates Application 20170128618, May 11 2017, Data on File. **17.** Ethicon, VoC Summary Supporting DRM 100179522 May 2015, Data on File.

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Johnson & Johnson Pvt. Ltd. 501, Arena Space, Behind Majas Depot,
JVLR, Jogeshwari East, Mumbai 400060.

183938-210723