GELITA-CEL® X-SORB (DA)

Absorberende gaze-hæmostatikum, fremstillet af oxideret cellulose. Anvendes til alvorlige blødninger.

GELITA-CEL® X-SORB (NO)

Absorberende, oksidert cellulose-gas for større blødninger

GELITA-CEL® X-SORB (SV)

Absorberande gasbinda av oxiderad cellulosa för kraftigare blödning

GELITA-CEL® X-SORB (PL)

Wchłanialny gazik hemostatyczny z utlenioną celulozą do mocniejszych krwawień

GELITA-CEL® X-SORB (AR)

GELITA-CEL® X-SORB (PT)

Hemostático Absorvível de Gaze de Celulose Oxidada para Hemorragia Intensa

GELITA-CEL® X-SORB (ZH)

可吸收性氧化纤维素止血纱布（出血较多时）

GELITA-CEL® X-SORB (SR)

Apsorptivna hemostatska gaza od oksidisane celuloze za obilna krvarenja

GELITA-CEL® X-SORB (BG)

Резорбируем хемостатик от оксидирана целулоза, тип мрежа, за усилено кървотечение

GELITA-CEL® X-SORB (TH)

GELITA-CEL® X-SORB (VI)

Gạc cầm máu tự tiêu dùng cho trường hợp chảy máu nhiều

GELITA-CEL® X-SORB (LT)

Absorbuojanti oksiduotos celiuliozės servetėlė-hemostatas esant stipriam kraujavimui

GELITA-CEL® X-SORB

Absorbable Oxidized Cellulose Gauze Hemostat for Heavier Bleeding

• Instructions for use

GELITA® MEDICAL

Complete Care! Completely Safe!

GELITA-CEL® X-SORB (EN)

Absorbable Oxidized Cellulose Gauze Hemostat for Heavier Bleeding

1. Product Description
GELITA-CEL® X-SORB Absorbable Oxidized Cellulose Gauze Hemostat is a sterile, bio-degradable, high density, thicker knitted gauze, prepared by the controlled oxidation of cellulose. It is intended for use as topical hemostat and serves as a hemostatic adjunct in the control of hemorrhage. GELITA-CEL® X-SORB can be used to control heavier capillary, venous or arteriolar bleeds, owing to its greater density, and tensile strength. The gauze is white and can be sutured or cut without fraying. In use GELITA-CEL® X-SORB swells minimally as blood and other fluids are absorbed.

The bacteriostatic / bactericidal properties of GELITA-CEL® X-SORB inhibit aerobic and anaerobic bacteria cell growth and multiplication. Although the product has demonstrated bacteriostatic / bactericidal properties, it is not intended nor claimed as a substitute for systemically administered therapeutic or prophylactic anti-microbial agent to control or prevent post-operative infections.

It is packaged individually in (double) blister, sterilized by means of Gamma Irradiation, and is for single use only.

2. Indications for use
Topical hemostat for use as an adjunct to hemostasis by tamponade effect, in particular where control of capillary, venous, and arteriolar bleeding, by pressure, ligature, and other conventional procedures, is either ineffective or impractical.

3. Contraindications
GELITA-CEL® X-SORB 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.
GELITA-CEL® X-SORB should not be used in conjunction with methyl methacrylate adhesives, for example in orthopedic surgery, because their presence may reduce the adhesive strength of the bonding agent to bone.
GELITA-CEL® X-SORB should not be used in bleeding from large arteries.
GELITA-CEL® X-SORB should not be used in chemically cauterized areas; its use should not be preceded by application of escharotic chemicals (silver nitrate or any other).
GELITA-CEL® X-SORB should not be used as a surface dressing except for immediate control of bleeding as it inhibits new skin growth.
GELITA-CEL® X-SORB should not be used in closure of skin incisions as it may interfere with healing of the skin edges. This is due to mechanical interposition of oxidized cellulose and not to intrinsic interference with wound healing.

4. Side effects
Occasional reports of "burning" and "stinging" sensations and sneezing when oxidized cellulose has been used as packing in epistaxis, are believed to be due to the low pH of the product. Burning has been reported when oxidized cellulose was applied after nasal polyp removal and after hemorrhoidectomy. Stinging has also been reported where oxidized cellulose was applied on surface wounds (varicose ulcerations, dermabrasions, and donor sites).

5. Directions for use
Sterile technique should be applied.
GELITA-CEL® X-SORB should be applied dry and should not be moistened prior to application.
GELITA-CEL® X-SORB is best employed by loose application against the bleeding surface, where it should adhere.
Remove any excess prior to surgical closure to facilitate bio-degradation and to minimize the possibility of foreign body reaction!
Bio-degradation depends upon several factors including the amount used, degree of saturation with blood and the tissue bed.
GELITA-CEL® X-SORB can be cut to size for use in endoscopic procedures.

Important notice!
GELITA-CEL® X-SORB expands minimally with the absorption of fluids. In radical cavities; laminectomy procedures; around or in proximity to foramina in bone; areas of bony confine; the spinal cord; the optic nerve and chiasm; or closed tissue spaces with presence of bone, GELITA-CEL® X-SORB should be removed when bleeding has stopped, if possible. Failure to do so might result in unintended pressure on neighbouring structures which may cause pain for the patient or could create the potential for nerve damage.

While most reports have been in connection with laminectomy, reports of paralysis have also been received in connection with other procedures.

By absorbing fluid GELITA-CEL® X-SORB may expand and impinge on neighbouring structures. Therefore care should be taken to avoid over-packing, particularly within bony cavities, as it may lead to interference with normal function and may eventually lead to compression necrosis of surrounding tissue.

In cases of postoperative infection, re-operation may be necessary to remove infected material and allow drainage.

Warnings
GELITA-CEL® X-SORB is not intended as a substitute for careful surgery and the proper use of sutures and ligatures. Closing the product in a contaminated wound without drainage may lead to complications and should be avoided.

Avoid use in infected areas.

There have been reports of stenotic effect when oxidized cellulose 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 oxidized cellulose, it is important to be cautious and avoid applying the material tightly as a wrapping.

Care should be taken to avoid the introduction of fragments of the material directly into the circulatory system.

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.

Blindness has been reported in connection with surgical repair of a lacerated left frontal lobe when oxidized cellulose was placed in the anterior cranial fossa.

GELITA-CEL® X-SORB 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.

Special care must be taken by physicians, regardless of the type of surgical procedure, to consider the advisability of removing GELITA-CEL® X-SORB after hemostasis is achieved.

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)

Cell savers
The use of GELITA-CEL® X-SORB with a cell saver is not contraindicated. However, make sure to use proper technique when using GELITA-CEL® X-SORB in conjunction with a cell saver. As with other hemostatic agents, GELITA-CEL® X-SORB should not be aspirated into autologous blood salvage circuits. The technique currently used to ensure that GELITA-CEL® X-SORB is not aspirated into such devices is as follows:

1. Prior to initiating the use of GELITA-CEL® X-SORB, remove blood salvaging suction tips from the surgical wound and exchange for a wall suction device.
2. Apply GELITA-CEL® X-SORB according to the IFU until hemostasis is satisfactory.
3. Gently irrigate excess GELITA-CEL® X-SORB with your preferred irrigation solution, using the wall suction to remove all loosened matrix. All matrix not removed by gentle irrigation/flushing is incorporated into the clot.

6. General storage and handling
GELITA-CEL® X-SORB should be stored dry in its sealed protective outer packaging. Keep away from direct sunlight. For storage temperature conditions please refer to label on box and pouches.

Warning! Browning of the product and tendency to crumble indicate incorrect storage.

Remove the product from the sterile package using sterile technique. Prior to opening, the integrity of the sterile barrier should be confirmed. Discard the product if the packaging is damaged.

Any unused contents should be discarded.

The packaging is subject to and conforms to European & International legislation and other applicable standards. The packaging protects the product from external influences and guarantees its sterility during storage and transport, under normal use.

Do not re-sterilize.

GELITA-CEL® X-SORB (DE)

Resorbierbare hämostatische Gaze aus oxidierter Zellulose für stärkere Blutungen

GELITA-CEL® X-SORB (FR)

Gaze hémostatique résorbable de cellulose oxydée pour saignement important

GELITA-CEL® X-SORB (NL)

Hemostaat van absorbeerbaar gaas van geoxideerde cellulose voor zwaardere bloedingen

GELITA-CEL® X-SORB (IT)

Garza emostatica assorbibile di cellulosa ossidata per emorragie acute

GELITA-CEL® X-SORB (ES)

Hemostático de gasa de celulosa oxidada absorbible para hemorragias mediana intensidad

GELITA-CEL® X-SORB (RO)

Tifon din celuloză oxidată absorbabilă hemostatic pentru sângerări mai grele

GELITA-CEL® X-SORB (RU)

Рассасывающаяся гемостатическая марля из окисленной целлюлозы для остановки тяжелых кровотечений

GELITA-CEL® X-SORB (TR)

Ağır Kanamalar için Emilebilen Okside Selülozlu Gazlı Bez Hemostadı

GELITA-CEL® X-SORB (EL)

Απορροφήσιμη Αιμοστατική Γάζα Οξειδωμένης Κυτταρίνης για Μεγαλύτερη Αιμορραγία

GELITA-CEL® X-SORB (CS)

Zcela resorbovatelná hemostatická gáza z oxidované celulózy pro silnější krvácení

GELITA-CEL® X-SORB (SK)

Absorbovateľná hemostatická gáza z oxidovanej celulózy na silnejšie krvácanie

2. Gázu GELITA-CEL® X-SORB použite podľa Návodu na použitie, až kým nie je dosiahnutá dostatočná hemostáza.
3. Nadbytočnú gázu GELITA-CEL® X-SORB jemne vypláchnite s irigačným roztokom podľa vlastnej voľby a na odstránenie uvoľnenej hmoty použite nástenné odsávanie. Všetka hmota, ktorá nebola odstránená miernym vyplachovaním alebo prepláchnutím, tvorí súčasť zrazeniny.

6. Všeobecné pokyny o uchovávaní a manipulácii
Gázu GELITA-CEL® X-SORB uchovávajte v suchom stave v zatavenom ochrannom vonkajšom obale. Chráňte pred priamym slnečným žiarením. Podmienky týkajúce sa skladovacích teplôt nájdete na štítku škatule a jednotlivých balení.

Varovanie! Zhnednutie výrobku a tendencia rozpadávať sa indikujú nesprávne uchovávanie.

Výrobok vyberte zo sterilného obalu pomocou sterilného postupu. Pred otvorením skontrolujte neporušenosť sterilnej bariéry. Ak je obal poškodený, výrobok znehodnoťte.

Akýkoľvek nepoužitý obsah znehodnoťte.

Balenie podlieha a spĺňa európsku a medzinárodnú legislatívu a ďalšie relevantné normy. Balenie chráni výrobok pred vonkajšími vplyvmi a pri bežnom použití zaručuje jeho sterilitu počas uchovávania a prepravy.

Opakovane nesterilizujte.

These icons give you an indication of the product shapes

Gauze HD

For prescription use only.

GELITA MEDICAL
Complete Care! Completely Safe!

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