

GELITA-CEL® X-SORB

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, fibrin knitted gauze, prepared by the controlled oxidation of cellulose. It is intended for use as topical hemostatic and serves as a hemostat; applied in the control of hemorrhage. GELITA-CEL® X-SORB does not adhere to underlying tissues, does not irritate, does not become friable or brittle, and does not contain any irritants. The gauze will not be saturated or cut without fraying. In use GELITA-CEL® X-SORB weds mainly as blood and other fluids are absorbed.

The bacteriostatic/antibacterial properties of GELITA-CEL® X-SORB inhibit aerobic and anaerobic bacterial cell growth and multiplication. Although the product is not intended for systemic antibiotic use, it is intended for use as a substitute for systemically administered antibiotic or prophylactic anti-microbial agents prior to or prevent post-operative infection.

It is packaged individually in a double sterile, sterilized by means of gamma radiation, and for single use only.

2. Indications for use
Topical hemostat for use as adjunct to hemostasis by tamponade effect. In particular, traction and control of capillary, venous, and arterial bleeding, by pressure, ligation, and other conventional procedures, is effective irrespective of infection.

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 alkalis forming an adhesive character 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 used.
GELITA-CEL® X-SORB should not be used in bleeding from large arteries.
GELITA-CEL® X-SORB should not be used as a dressing or as a substitute for absorbent dressings or bandages.
Use as a substitute for 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 skin grafting.

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 interposi-

tion of oxidized cellulose and not to intrinsic interference with wound healing.

4. Precautions
Occasional reports of "burning" and "stinging" sensations and sneezing when oxidized cellulose was applied as packing in epistaxis, are believed to be due to the low pH of the product. Burning has been reported when oxidized cellulose has been applied after nasal spray removal and after hemostatic therapy. Burning has been reported when oxidized cellulose was applied on surface wounds (varicose ulcers, dermatomas, 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 a surgical sponge by use application against the bleeding surface, where it should adhere.
Remove excess prior to being used to facilitate bio-oxidation and to minimize the possibility of foreign body reaction.

6. Disposal
Dispose of used GELITA-CEL® X-SORB in accordance with local, state, and federal regulations.

GELITA-CEL® X-SORB can be cut to size for use in endoscopic procedures.

Important notices
GELITA-CEL® X-SORB expands mainly with the absorption of fluids. In radical cavities, laminectomy procedures, around or in proximity to brainin bone, areas of or close to the spinal cord, the optic nerve and chiasm, or closed tissue spaces with presence of bone, GELITA-CEL® X-SORB should be removed as soon as possible. Failure to do so may result in unanticipated pressure on neighboring structures which may cause the bone or the cavity to conform to the pressure for nerve damage.

While most reports have been in connection with laminectomy, reports of neurolysis have also been received in connection with other procedures. By absorbing fluid, GELITA-CEL® X-SORB can expand and impinge on neighboring structures. Therefore care should be taken to avoid over-packing particularly in the spine. Care should be exercised with normal saline to compression release 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 intended as a substitute for careful surgery and the proper use of sutures and ligatures. Closing the tract in a contaminated wound without drainage may result in infection.
Avoid use in infected areas.

There have been reports of stenttic effect when oxidized cellulose has been applied as a wrap around vascular surgery. Although it has not been reported that the stentosis 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 intrusion of fragments of the material directly into the circulatory system.

Prophylactic irrigation of drainage in otolaryngology and otitisis passing away per auris after otitis media, has been reported. There has been one report of a patient with a perforated eardrum who had a foreign body reaction to the material.

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

GELITA-CEL® X-SORB should not be irrigated with anti-infective agents when used with oxidized cellulose such as buffering or hemostatic substances. Its hemostatic effect is enhanced by the absorption of fluids, the activity of which is destroyed by the use of the product.

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

When used in connection with otolaryngologic surgery to assure that none of the material is aspirated by the patient (Examples: controlling hemorrhage after tonsillectomy and chondrylaryngitis).

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Gaze hémostatique résorbable de cellulose oxydée pour saignement important

1. Description du produit
GELITA-CEL® X-SORB Gaze hémostatique biodégradable de cellulose oxydée est une gaze tricotée haute densité plus épaisse, stérile et résorbable préparée par oxydation contrôlée de la cellulose. Elle est destinée à être utilisée comme hémostatique local avant ou après le contrôle des hémmorragies. GELITA-CEL® X-SORB ne colle pas aux tissus sous-jacents, ne s'irrite pas, ne devient pas friable ou cassant, et ne contient aucun irritant. La gaze ne sera pas saturée ou coupée sans frayer. En utilisation GELITA-CEL® X-SORB agit principalement en absorbant le sang et d'autres fluides.
Les propriétés bactéricides/antibactériennes de GELITA-CEL® X-SORB inhibent la croissance et la multiplication des cellules bactériennes aérobies et anaérobies. Bien que le produit ait été conçu pour être utilisé comme substitut d'antibiotique systémique, il est destiné à être utilisé comme substitut d'antibiotique prophylactique anti-microbien avant ou après une intervention chirurgicale.

Il est emballé individuellement dans un double emballage stérile, stérilisé par rayonnement gamma.

2. Indications
Hémostatique à usage topique pour réguler ou réduire par effet de tamponade, notamment lorsque le contrôle du saignement au niveau capillaire, veineux ou artériel, est obtenu par pression, ligature, et autres procédures conventionnelles et/ou techniques complémentaires.

3. Contre-indications
GELITA-CEL® X-SORB doit être évité implémenté dans une déformation osseuse telle qu'une fracture en raison de l'interférence éventuelle avec la forme.
GELITA-CEL® X-SORB doit être évité en conjonction avec des adhésifs de méthacrylate de méthyle, par exemple en chirurgie orthopédique, car leur présence peut réduire la force d'adhésion de la colle à base de résine.
GELITA-CEL® X-SORB doit être évité dans le traitement de saignements de grandes artères.
GELITA-CEL® X-SORB doit être évité dans les zones de cicatrisation de grandes artères.
GELITA-CEL® X-SORB doit être évité dans des zones cutanées chagrinées, sans utilisation ne doit pas être précédée de l'application de produits escharotiques (nitrate d'argent ou autre).

GELITA-CEL® X-SORB doit être évité dans le traitement de saignement superficiel excepté pour le contrôle immédiat de saignement car il inhibe la formation de croûtes.

GELITA-CEL® X-SORB doit être évité pour l'usage comme médiation de surface cutanée, car il peut gêner la cicatrisation des bords cutanés. Ceci est dû à l'interposition mécanique de la cellulose oxydée et non à une interférence intrinsèque dans la cicatrisation de la peau.

4. Effets secondaires
Des sensations occasionnelles de "brûlure" et de "picotements" ainsi que d'éternuements lors de l'application de cellulose oxydée comme tamponade, complémentation ou effet de tamponade, sont attribués à la faible valeur de pH du produit. Des brûlures ont été rapportées lorsque la cellulose oxydée a été appliquée après un spray nasal. Des brûlures ont été rapportées lorsque la cellulose oxydée a été appliquée sur des plaies superficielles (ulcères varicelleux, dermatomes, et sites de don). Des brûlures ont été rapportées lorsque la cellulose oxydée a été appliquée sur des plaies superficielles (ulcères varicelleux, dermatomes, et sites de don).

5. Mode d'emploi
GELITA-CEL® X-SORB doit être appliqué sec et ne doit pas être mouillé avant l'application.
GELITA-CEL® X-SORB doit être utilisé de préférence par application légère sur la surface qui saigne, à laquele il doit adhérer.

6. Disposition
GELITA-CEL® X-SORB doit être utilisé conformément aux réglementations locales, étatiques et fédérales.

Important notices
GELITA-CEL® X-SORB expands mainly with the absorption of fluids. In radical cavities, laminectomy procedures, around or in proximity to brainin bone, areas of or close to the spinal cord, the optic nerve and chiasm, or closed tissue spaces with presence of bone, GELITA-CEL® X-SORB should be removed as soon as possible. Failure to do so may result in unanticipated pressure on neighboring structures which may cause the bone or the cavity to conform to the pressure for nerve damage.

While most reports have been in connection with laminectomy, reports of neurolysis have also been received in connection with other procedures. By absorbing fluid, GELITA-CEL® X-SORB can expand and impinge on neighboring structures. Therefore care should be taken to avoid over-packing particularly in the spine. Care should be exercised with normal saline to compression release 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 intended as a substitute for careful surgery and the proper use of sutures and ligatures. Closing the tract in a contaminated wound without drainage may result in infection.

Avoid use in infected areas.

There have been reports of stenttic effect when oxidized cellulose has been applied as a wrap around vascular surgery. Although it has not been reported that the stentosis 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 intrusion of fragments of the material directly into the circulatory system.

Prophylactic irrigation of drainage in otolaryngology and otitis passing away per auris after otitis media, has been reported. There has been one report of a patient with a perforated eardrum who had a foreign body reaction to the material.

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

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

When used in connection with otolaryngologic surgery to assure that none of the material is aspirated by the patient (Examples: controlling hemorrhage after tonsillectomy and chondrylaryngitis).

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

When used in connection with otolaryngologic surgery to assure that none of the material is aspirated by the