CE 2460

INSTRUCTIONS FOR USE (IFU)

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Surgi-ORC®

Oxidized Regenerated Cellulose Haemostat, Sterile, Absorbable

DESCRIPTION

Surgi-ORC® absorbable haemostat is a sterile absorbable knitted fabric prepared by controlled oxidation of regenerated cellulose. The fabric is white to pale yellow in color and has a faint, caramel like aroma. It is stable at room temperature. A slight discoloration may occur with age, but this does not affect its performance. The Surgi-ORC® haemostats are available as Original/Standard, Knit, Fibril and Non-Woven/SNOW, manufactured with the same Oxidized Regenerated
Cellulose.

Surgi-ORC® meets all the requirements of Oxidized Regenerated Cellulose established by United States Pharmacopoeia (USP).

INTENDED USE

The Surgi-ORC® haemostat is used adjunctively in various surgical procedures to assist when control of bleeding from capillary, venous and small arteriolar vessels, by pressure, ligature and other conventional procedures is either ineffective or impractical. The Surgi-ORC® haemostat can be cut to size in endoscopic procedures.

APPLICATIONS

Surgi-ORC® Original/Standard haemostat is suitable for both open and laparoscopic surgeries providing surface contact to bleeding site to that it can absorb blood.

Surgi-ORC® Knit haemostat, the denser knit provides high strength for heavier bleeding. Lightweight and tufted Surgi-ORC® Fibril haemostat can be peeled off easily to hold with forceps. It can be used in any size, as per requirement to obtain haemostasis at a particular bleeding site. It is convenient for hard to reach site or irregularly shaped bleeding site.

The Surgi-ORC® Non-Woven/SNOW, a structured Non-Woven/SNOW fabric, is generally used for minimal to mild bleeding from specific or widespread surgical regions. Surgi-ORC® is used in various type of surgeries for haemostasis e.g. Neurosurgeries, Cardiovascular surgeries, Cardiothoracic Surgery, General Surgery, Obstetrics Surgery, Gynaecology Surgery, Urologic Surgery, Orthopaedic Surgery, Plastic Surgery, ENT Surgery, Dental Surgery etc.

ACTIONS

When Surgi-ORC® haemostat contacts with blood, it forms a brownish or black gelatinous mass, which aids in formation of clot, thereby serving as a haemostatic adjunct in the control of local haemorrhage.

When Surgi-ORC® haemostat is used properly in minimal amounts, it is absorbed from the sites of implantation without tissue reaction. Absorption depends upon several factors including the amount used, degree of saturation with blood and tissue bed.

CONTRAINDICATIONS

- Surgi-ORC® haemostat should not be used for wound packing or wadding. Although if used, it is to be removed after haemostasis is achieved.
- Surgi-ORC® haemostat should not be used for implantation in bone defects, such as fractures, since it may interfere with callus formation and may cause cyst formation.
- When Surgi-ORC® is used to help achieve haemostasis in or around foramina in bone, areas of bony confine, the spinal cord or the optic nerve and chiasm, it must always be removed after haemostasis is achieved, since it will swell and could exert unwanted pressure.
- Surgi-ORC® haemostat should not be used to control haemorrhage from large arteries.
- Surgi-ORC® haemostat should not be used on non-haemorrhagic serious oozing surfaces, since body fluids, except whole blood, such as serum, do not react with Surgi-ORC® haemostat to give satisfactory results.
- Surgi-ORC® haemostat is an absorbable haemostat, and should not be used as .an adhesion prevention product.
- Surgi-ORC® should not be used in patients with known hypersensitivity of Cellulose.

WARNINGS

- Surgi-ORC® haemostat is supplied Sterile and should not be re-sterilized.
- Surgi-ORC®is intended for the single use and it should not be re-used. Re-use of Surgi-ORC® may lead to cross infection.
- Closing Surgi-ORC® haemostat in a contaminated wound without drainage may lead to complications and should be avoided.
- Surgi-ORC® haemostats should not be moistened with water or saline as it may affect the haemostasis effect.
- Surgi-ORC® haemostat should not be impregnated with anti- infective agents or with other materials such as buffering or haemostatic substances.
- Surgi-ORC® haemostat is advisable to be removed once haemostasis 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 regardless of the type of surgical procedure because Surgi-ORC® haemostat may exert pressure resulting in paralysis and/or nerve damage by swelling.
- Dislodgement of Surgi-ORC® haemostat could possibly occur by means such as repacking, further intraoperative manipulation, lavage, exaggerated respiration, etc.
- In procedures such a lobectomy, laminectomy and repair of a frontal skull fracture and lacerated lobe, there is a possibility of migration of Surgi-ORC® from the site of application.
- Special care must be taken by physicians, regardless of the type of surgical procedure, to consider the advisability of removing Surgi-ORC® haemostat after haemostasis is achieved.
- Surgi-ORC® is not intended for the primary treatment of coagulation disorders.
- The safety and effectiveness of Surgi-ORC® is not established in pregnant women.

PRECAUTIONS

- Use only as much Surgi-ORC® haemostats as is necessary for haemostasis, 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.
- In urological procedures, minimal amounts of Surgi-ORC® haemostat should be used and care must be exercised to prevent plugging of the urethra, ureters, or a catheter by dislodged portions of the product.
- Surgi-ORC® haemostats should not be used in chemically cauterized areas.

- If Surgi-ORC® haemostat is used temporarily to line the cavity of large open wounds, it should be placed so as not to overlap the skin edges.
- Surgi-ORC® should 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 otorhinolaryngology surgery to assure that the patient aspirates none of the material.
- Care should be taken not to apply Surgi-ORC® haemostat tightly when it is used as a wrap during vascular surgery.
- Wadding or packing should be avoided, especially within rigid cavities, where swelling may interfere with normal function or possibly cause necrosis.
- Endoscopic procedures should be performed only by persons having adequate training and familiarity with endoscopic techniques.

ADVERSE REACTIONS

- "Encapsulation" of fluid and foreign body reactions have been reported.
- Stenotic effect has been reported when ORC haemostat applied as a wrap during vascular surgery.
- Although it has not been established that the stenosis was directly related to the use of ORC haemostat, it is important to be cautious and avoid applying the material tightly as a wrapping.
- Paralysis and nerve damage have been reported when ORC haemostat 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 ORC haemostat was placed in the anterior cranial fossa.
- Possible prolongation of drainage in cholecystectomies and difficulty in passing urine per urethra after prostatectomy.
- "Burning" and "Stinging" sensations and sneezing can occur when ORC haemostat has been used as packing in epistaxis, are believed to be due to the low pH of the product.

DOSAGE AND ADMINISTRATION

Sterile technique should be observed in removing Surgi-ORC® haemostat from its sterile container. Minimal amount of Surgi-ORC® haemostat in appropriate size is laid on the bleeding site or held firmly against the tissues until haemostasis is achieved. Required amount of Surgi-ORC® haemostat depends on the nature and intensity of the haemorrhage to be stopped. Moistening the material with water or physiological saline solution prior to use is not recommended. Opened, unused Surgi-ORC® haemostat should be discarded, because it cannot be re-sterilized.

STORAGE

Store the product in its Original/Standard packaging in a clean and dry room at the temperature not more than 30°C. Close the outer package of the product immediately after use.

DO NOT REFRIGERATE OR FREEZE.

Expiry date is mentioned on the labels; do not use the product after the expiry date.

SYMBOLS USED


Do not re-use


Caution, Consult instructions

Do not re-sterilize


Do not use if package is damaged


Keep dry


Keep away from sunlight


Consult instructions for use


Use-by date

MD — Medical Device

STERILE R — Sterilized using Irradiation

Do Not Exceed Tempereture 30°C

REF — Catalogue Number

DO NOT REFRIGERATE OR FREEZE.

LOT — Batch code OR Lot number


Manufacturer


Date of Manufacture

CE 2460 — CE-Mark and Identification number of notified body. Product confirms to the essential requirements of the medical device directive 93/42/EEC.

EC REP — **EC Representative**
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