Meril
Endo-Surgery

Meril Endo Surgery Private Limited
Artwork approval

MERIZELLE IFU
(62x400)mm

Date : 27.03.2023

INSTRUCTIONS FOR USE

MERIZELLE™

MANUFACTURED BY

Meril
Endo-Surgery

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MERIZELLE™
OXIDIZED REGENERATED CELLULOSE U.S.P.

DESCRIPTION

MERIZELLE™ Absorbable Hemostat is a sterile absorbable knitted fabric prepared by the controlled oxidation of regenerated cellulose. It is white to pale yellow in colour and has a faint, caramel-like aroma. A slight discoloration may occur with age, but this does not affect performance. Three different types of MERIZELLE™ absorbable haemostat are available : MERIZELLE™ Standard, MERIZELLE™ Woven, MERIZELLE™ Fibre. MERIZELLE™ meets all the requirements for Oxidized regenerated cellulose established by United States Pharmacopeia (U.S.P.).

INDICATIONS

MERIZELLE™ Absorbable Hemostat (oxidized regenerated cellulose) is used 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. These Hemostats can be cut to size for use in endoscopic procedures.

APPLICATION

MERIZELLE™ Standard is suitable for both Open and laparoscopic surgeries providing surface contact to bleeding site so that it can absorb blood. MERIZELLE™ Woven hemostat, the denser knit, provides high strength for heavier bleeding. Lightweight and tufted MERIZELLE™ Fibre hemostat can be peeled off easily to hold with forceps. It can be used in any size, as per the requirement to obtain hemostasis at a particular bleeding site. It is convenient for hard to reach site or irregularly shaped bleeding site.

PERFORMANCE

After MERIZELLE™ Absorbable Hemostat has been saturated with blood, it swells into a brownish or black gelatinous mass which aids in the formation of a clot, thereby serving as a hemostatic adjunct in the control of local haemorrhage. When used properly in minimal amounts, MERIZELLE™ Absorbable Hemostat is absorbed from the sites of implantation with practically no tissue reaction. Absorption depends upon several factors including the amount used, degree of saturation with blood, and the tissue bed. Complete absorption of MERIZELLE™ Absorbable Hemostat takes place in 28 days. In addition to its local hemostatic properties, MERIZELLE™ Absorbable Hemostat is bactericidal in vitro against a wide range of gram positive and gram negative organisms.

CONTRAINDICATIONS

Packing or wadding is not recommended with MERIZELLE™ Absorbable Hemostat. Although if use, it is to be removed after hemostasis is achieved (See WARNINGS and PRECAUTIONS). MERIZELLE™ Absorbable Hemostat is not indicated for implantation in bone defects, such as fractures, because there is a possibility of interference with callus formation and a chance of cyst formation. When MERIZELLE™ 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 be removed after hemostasis is achieved since it will swell and could exert unwanted pressure.

MERIZELLE™ Absorbable Hemostat should not be used to control haemorrhage from large arteries. MERIZELLE™ 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 MERIZELLE™ Absorbable Hemostat to produce satisfactory hemostatic effect. MERIZELLE™ Absorbable Hemostat is an absorbable hemostat, and should not be used as an adhesion prevention product.

WARNINGS

MERIZELLE™ Absorbable Hemostat is supplied sterile and should not be re-sterilized. Closing MERIZELLE™ Absorbable Hemostat in a contaminated wound without drainage should be avoided as it may lead to complications. MERIZELLE™ Absorbable Hemostat should not be moistened with water or saline as it may affect the hemostasis effect. MERIZELLE™ 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.

MERIZELLE™ Absorbable Hemostat is advisable to be removed 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 regardless of the type of surgical procedure because MERIZELLE™ Absorbable Hemostat, by swelling, may exert pressure resulting in paralysis and/or nerve damage. Dislodgement of MERIZELLE™ Absorbable Hemostat could possibly occur by means such as repacking, further intraoperative manipulation, lavage, exaggerated respiration, etc. In procedures such as lobectomy, laminectomy and repair of a frontal skull fracture and lacerated lobe there is possibility of MERIZELLE™ Absorbable Hemostat migration from the site of application. Special care to be taken by physicians, regardless of the type of surgical procedure, to remove MERIZELLE™ Absorbable Hemostat after hemostasis is achieved.

MERIZELLE™ Absorbable Hemostat is not a substitute for careful surgery and the proper use of sutures and ligatures. MERIZELLE™ Absorbable Hemostat is not a substitute for systemically administered therapeutic or prophylactic antimicrobial agents to control or prevent post-operative infections. In dental procedures, MERIZELLE™ Absorbable Hemostat can be applied loosely against the bleeding surface. Wadding or packing should be avoided, especially within rigid cavities, where swelling may interfere with normal functions or possibly cause necrosis.

PRECAUTIONS

Use only as much MERIZELLE™ 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.

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In urological procedures, minimal amounts of MERIZELLE™ 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. MERIZELLE™ Absorbable Hemostat should not be used in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals. If MERIZELLE™ 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 assure that none of the material is aspirated by the patient. Care should be taken not to apply MERIZELLE™ Absorbable Hemostat too tightly when it is used as a wrap during vascular surgery (see Adverse Reactions).Endoscopic procedures should be performed only by persons having adequate training and familiarity with endoscopic techniques.

ADVERSE REACTIONS

Stenotic effect can occur when MERIZELLE™ Absorbable Hemostat is applied as a wrap during vascular surgery. When MERIZELLE™ Absorbable Hemostat is used around, in, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm ,there is a chance of paralysis and nerve damage. When used in lacerated left frontal lobe in the anterior cranial fossa, blindness can occur. Possible prolongation of drainage in cholecystectomies and difficulty passing urine per urethra can occur if used in prostatectomy. When MERIZELLE™ Absorbable Hemostat is used as packing in epistatsis, occassional 'burning' and 'stinging' sensations and sneezing due to low pH of the product is likely to occur.

DOSAGE AND ADMINISTRATION

Minimal amounts of MERIZELLE™ Absorbable Hemostat in appropriate size should be laid on the bleeding site or held firmly against the tissues until hemostasis is obtained. Opened, unused MERIZELLE™ Absorbable Hemostat should be discarded.

STERILITY

MERIZELLE™ Absorbable Hemostat is sterilized by gamma radiation as indicated on the package. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened remaining unused product.

HOW SUPPLIED

Sterile MERIZELLE™ Fibre Absorbable Hemostat is supplied in sterile pack of the following sizes : Code No. ORC F12 (Fibre 1'X2'), Code No. ORC F24 (Fibre 2'X4') and Code No. ORC F44 (Fibre 4'X4').

Sterile MERIZELLE™ Standard Absorbable Hemostat is supplied as knitted fabric strips in the following sizes : Code No. ORC S214 (Std 2'X14'), Code No. ORC S48 (Std 4'X8') and Code No. ORC S23 (Std 2'X3').

Sterile MERIZELLE™ Woven Absorbable Hemostat is supplied in sterile pack of the following sizes : Code No. ORC W11 (Woven 1'X1'), Code No. ORC W135 (Woven 1'X3.5') and Code No. ORC W34 (Woven 3'X4').

STORAGE

MERIZELLE™ should be kept in original packaging under dry, controlled conditions between 15°C to 25°C, and protected from direct sunlight.

SHELF LIFE

The Shelf Life of MERIZELLE™ Absorbable Hemostat is 3 years.

SYMBOLS USED ON LABELLING

= Do not reuse

= Date of Manufacture

= Use by
(Use until Year & Month)

STERILE R = Sterilized using Irradiation

LOT = Batch Code (Number)

= Consult Instruction for use

= Do not resterilize

15°C 25°C = Temperature limit
(Store between 15°C to 25°C)

= Keep away from Sunlight

= Keep Dry

= Do not use if Package is Damaged

= Caution

= Manufacturer

CE 1783 = CE Mark and Identification Number of Notified Body

EC REP = Authorised Representative in the European Community

PANTONE SHADE
C18 M100 Y100 K15
BLACK

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Revision
1. “CE No1783” and obelis address has been added.