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PROFESSIONAL MEDICAL PRODUCTS

CLINICEL®

CELLULOSA OSSIDATA RIGENERATA U.S.P (EMOSTATICO ASSORBIBILE)

OXIDIZED REGENERATED CELLULOSE U.S.P (ABSORBABLE HEMOSTAT)

CELLULOSE OXYDÉE RÉGÉNÉRÉE U.S.P (HÉMOSTATIQUE RÉSORBABLE)

USP (RESORBIERBARES HÄMOSTYPTIKUM) AUS OXIDIERTER REGENERIERTER CELLULOSE

CELULOSA REGENERADA OXIDADA U.S.P (HEMOSTÁTICO ABSORBIBLE)

CELULOSE REGENERADA OXIDADA U.S.P. (HEMOSTATO ABSORVÍVEL)

ΟΞΕΙΔΩΜΕΝΗ ΑΝΑΓΕΝΝΗΜΕΝΗ ΚΥΤΤΑΡΙΝΗ U.S.P. (ΑΠΟΡΡΟΦΗΣΙΜΟ ΑΙΜΟΣΤΑΤΙΚΟ)

Manuale d'uso - User manual - Manuel de l'utilisateur
Gebrauchs- und instandhaltungsanleitung - Guía de uso
Guia para utilização - Οδηγίες χρήσης

ENGLISH

DESCRIPTION

Absorbable Hemostat is a sterile absorbable Fibrillar/ Knitted fabric prepared by the controlled oxidation of regenerated cellulose. The fabric is white with a pale yellow cast. It is strong and can be sutured or cut without fraying. It is stable and should be stored at controlled room temperature. A slight discoloration may occur with age, but this does not affect performance.

ACTIONS

The mechanism of action whereby CLINICEL Absorbable Hemostat accelerates clotting is not completely understood, but it appears to be a physical effect rather than any alteration of the normal physiologic clotting mechanism. After CLINICEL 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 hemorrhage. When used properly in minimal amounts, CLINICEL Absorbable Hemostat is absorbed 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. CLINICEL Absorbable Hemostat should not be used to control hemorrhage from large arteries. CLINICEL Absorbable Hemostat should not be used on no hemorrhagic serous oozing surfaces, since body fluids other than whole blood, such as serum, do not react with CLINICEL Absorbable Hemostat to produce satisfactory hemostatic effect. CLINICEL Absorbable Hemostat is an absorbable hemostat, and should not be used as an adhesion prevention product.

WARNINGS

Absorbable Hemostat is supplied sterile and as the material is not compatible with autoclaving or ethylene oxide sterilization, CLINICEL Absorbable Hemostat should not be resterilized. CLINICEL Absorbable Hemostat is not intended as a substitute for careful surgery and the proper use of sutures and ligatures. Closing CLINICEL Absorbable Hemostat in a contaminated wound without drainage may lead to complications and should be avoided. The fracture and lacerated lobe that CLINICEL Absorbable Hemostat, when left in the patient after closure, migrated from the site of application into foramina in bone around the spinal cord resulting in paralysis and, in another case, the left orbit of the eye, causing blindness. While these reports cannot be confirmed, special care must be taken by physicians, regardless of the type of surgical procedure, to consider the advisability of removing CLINICEL Absorbable Hemostat after hemostasis is achieved.

Although CLINICEL Absorbable Hemostat 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 prevent postoperative infections.

PRECAUTIONS

Use only as much CLINICEL 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. In urological procedures, minimal amounts of CLINICEL Absorbable Hemostat should be 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.

INDICATIONS

Absorbable Hemostat (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.

CONTRAINDICATIONS

Although packing or wadding sometimes is medically necessary, CLINICEL Absorbable Hemostat should not be used in this manner, unless it is to be removed after hemostasis is achieved (See WARNINGS and PRECAUTIONS). CLINICEL Absorbable Hemostat 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.

When CLINICEL Absorbable Hemostat is used to help achieve hemostasis in, around, or in proximity to foramina hemostatic effect of CLINICEL Absorbable Hemostat is greater when it is applied dry; therefore it should not be moistened with water or saline. CLINICEL 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. Although CLINICEL Absorbable Hemostat may be left in situ when necessary, it is advisable to remove 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 CLINICEL Hemostat, by swelling, may exert pressure resulting in paralysis and/or nerve damage. Dislodgement of CLINICEL Absorbable Hemostat could possibly occur by means such as repacking, further intraoperative manipulation, lavage, exaggerated respiration, etc. There have been reports that in procedures such as lobectomy, laminectomy and repair of a frontal skull 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 CLINICEL Absorbable Hemostat could be prevented in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals. If CLINICEL 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 otorhinolaryngology surgery to assure that none of the material is aspirated by the patient.

(Examples: controlling hemorrhage after tonsillectomy and controlling epistaxis.) Care should be taken not to apply CLINICEL 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. Consult medical literature relative to techniques, complications and hazards prior to performance of any endoscopic procedure. A thorough understanding of the principles and techniques involved in laparoscopic laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Refer to appropriate electrosurgical system user's manual for use indications and instructions to ensure that all safety precautions are followed. When endoscopic instruments and accessories from different manufacturers are employed together during a procedure, verify their compatibility prior to initiation of the procedure and ensure that isolation or grounding is not compromised.

ADVERSE REACTIONS

"Encapsulation" of fluid and foreign body reactions have been reported. There have been reports of stenotic effect when CLINICEL Absorbable Hemostat 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 CLINICEL Absorbable Hemostat, it is important to be cautious and avoid applying the material tightly as a wrapping. Paralysis and nerve damage have been reported when CLINICEL Absorbable Hemostat 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. 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 CLINICEL Absorbable Hemostat was placed in the anterior cranial fossa (5) (See WARNINGS and PRECAUTIONS). 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 require Occasional reports of "burning" and "stinging" sensations and sneezing when CLINICEL Absorbable Hemostat has been used as packing in epistaxis, are believed to be due to the low pH of the product. Burning has been reported when CLINICEL Absorbable Hemostat was applied after nasal polyp removal and after hemorrhoidectomy. Headache, burning, stinging, and sneezing in epistaxis and other rhinological procedures, and stinging when

CLINICEL Absorbable Hemostat was applied on surface wounds (varicose ulcerations, dermabrasions, and donor sites) also have been reported.

DOSAGE AND ADMINISTRATION

Sterile technique should be observed in removing CLINICEL Absorbable Hemostat from its sterile container.

Minimal amounts of CLINICEL Absorbable Hemostat in appropriate size are laid on the bleeding site or held firmly against the tissues until hemostasis is obtained. Opened, unused CLINICEL Absorbable Hemostat should be discarded, because it cannot be resterilized.

STORAGE

Recommended storage conditions: Below 30°C away from moisture and direct sunlight. Do not use after expiry date.

CAUTION

Law restricts this device to sale by or on the order of a physician.

	**IT -** Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso **GB -** Caution: read instructions (warnings) carefully **FR -** Attention: lisez attentivement les instructions (avertissements) **DE -** Achtung: Anweisungen (Warings) sorgfältig lesen **ES -** Precaución: lea las instrucciones (advertencias) cuidadosamente **PT -** Cuidado: leia as instruções (avisos) cuidadosamente **GR -** Διαβάστε και ακολουθήστε προσεχτικά τις οδηγίες χρήσης
	**IT -** Codice prodotto **GB -** Product code **FR -** Code produit **DE -** Erzeugniscode **ES -** Código producto **PT -** Código produto **GR -** Κωδικός προϊόντος
	**IT -** Dispositivo monouso, non riutilizzare **GB -** Disposable device, do not re-use **FR -** Ne pas réutiliser **DE -** Für einmaligen Gebrauch, nicht wiederverwenden **ES -** Dispositivo monouso, no reutilizable **PT -** Dispositivo descartável, não reutilizar **GR -** Προϊόν μιας χρήσεως. Μην το χρησιμοποιείται εκ νέου
	**IT -** Numero di lotto **GB -** Lot Number **FR -** Numéro de lot **DE -** Chargennummer **ES -** Número de lote **PT -** Número de lote **GR -** Αριθμός παρτίδας
	**IT -** Data di fabbricazione **GB -** Date of Manufacturing **FR -** Date de fabrication **DE -** Herstellungsdatum **ES -** Fecha de fabricación **PT -** Data de fabrico **GR -** Ημερομηνία παραγωγής
	**IT -** Data di scadenza **GB -** Expiration date **FR -** Date d'échéance **DE -** Ablaufdatum **ES -** Fecha de Caducidad **PT -** Data de validade **GR -** Ημερομηνία λήξεως
	**IT -** Sterilizzato per irradiazione **GB -** Sterilized using irradiation **FR -** Stérilisé par irradiation **DE -** Durch Bestrahlung steril gemacht **ES -** Esterilizado por irradiación **PT -** Esterilizado por irradiação **GR -** Αποστειρωμένο μέσω ακτινοβολίας
	**IT -** Rappresentante autorizzato nella Comunità europea **GB -** Authorized representative in the European community **FR -** Représentant autorisé dans la Communauté européenne **DE -** Autorisierter Vertreter in der EG **ES -** Representante autorizado en la Comunidad Europea **PT -** Representante autorizado na União Europeia **GR -** Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Ένωση
	**IT -** Fabbricante **GB -** Manufacturer **FR -** Fabricant **DE -** Hersteller **ES -** Fabricante **PT -** Fabricante **GR -** Παραγωγός
	**IT -** Non ri-sterilizzare **GB -** Do not resterilize **FR -** Ne pas restériliser **DE -** Nicht erneut sterilisieren **ES -** No reesterilizar - **PT -** Não re-esterilize **GR -** Μην αποστειρώνετε
	**IT -** Conservare in luogo fresco ed asciutto **GB -** Keep in a cool, dry place **FR -** Á conserver dans un endroit frais et sec **ES -** Conservar en un lugar fresco y seco **DE -** An einem kühlen und trockenen Ort lagern **PT -** Armazenar em local fresco e seco **GR -** Διατηρείται σε δροσερό και στεγνό περιβάλλον
	**IT -** Conservare al riparo dalla luce solare **GB -** Keep away from sunlight **FR -** Á conserver à l'abri de la lumière du soleil **DE -** Vor Sonneneinstrahlung geschützt lagern **ES -** Conservar al amparo de la luz solar **PT -** Guardar ao abrigo da luz solar **GR -** Κρατήστε το μακριά από ηλιακή ακτινοβολία
	**IT -** Limite superiore di temperatura **GB -** Upper limit of temperature **FR -** Limites supérieure de température **DE -** Obergrenze der Temperatur **ES -** Limitaciones superiorde temperatura **PT -** Limitação superior de temperatura **GR -** Ανώτερο όριο θερμοκρασίας
	**IT -** Non utilizzare se l'imballaggio è danneggiato **GB -** Don't use if package is damaged **FR -** Ne pas utiliser si le colis est endommagé **DE -** Nicht verwenden, wenn das Paket beschädigt ist **ES -** No usar si el paquete está dañado **PT -** Não use se o pacote estiver danificado **GR -** Μην το χρησιμοποιείτε εάν η συσκευασία παρουσιάζει φθορά
	**IT -** Leggere le istruzioni per l'uso **GB -** Consult instructions for use **FR -** Consulter les instructions d'utilisation **DE -** Gebrauchsanweisung beachten **ES -** Consultar las instrucciones de uso **PT -** Consulte as instruções de uso **GR -** Διαβάστε προσεχτικά τις οδηγίες χρήσης
	**IT -** Dispositivo medico conforme alla Direttiva 93/42/CEE **GB -** Medical Device complies with Directive 93/42/EEC **FR -** Dispositif médical conforme à la directive 93/42 / CEE **DE -** Medizinprodukt gemäß Richtlinie 93/42/CEE **ES -** Dispositivo médico segun a la Directiva 93/42 / CEE **PT -** Dispositivo médico em conformidade com a Diretiva 93/42/CEE **GR -** Ιατρική συσκευή σύμφωνα με την οδηγία 93/42 / CEE

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