



| PAHACEL[®]

Oxidized Regenerated Cellulose



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OXIDIZED REGENERATED CELLULOSE

Pahacel Oxidized Regenerated Cellulose was obtained by controlled oxidation of Regenerated Cellulose fibers with a sterile plain weave fabric which is 100 % organic in nature. The fabric is white / pale yellow cast and has a faint and caramel-like aroma. It is strong and can be sutured or cut without fraying. Pahacel Oxidized Regenerated Cellulose is used adjunctively in surgical procedures to assist in the capillary, venous and small arterial hemorrhage When ligation or other conventional methods of control are impractical or ineffective. Pahacel Standard, Knit, Fibril types of Oxidized Regenerated Cellulose can be cut to size for use in endoscopic procedures. The properties of Pahacel products can be tailored According to customer request with the Approval of 93/42/EEC Medical Device Directives.

General Features

Oxidized Regenerated Cellulose is absorbed in the body within 7-14 days. Provides rapid hemostasis within 2-3 minutes. Do not cause tissue irritation. Exhibits bacteriostatic and bactericidal properties with the effect on growth and multiplication of gram(+) and gram (-) organisms including aerobic, anaerobic bacteria and bacteria showing resistant to antibiotics.

ORC is sterilized by Gamma irradiation technique.



Oxidized Regenerated Cellulose

PAHACEL® Standard

Absorbable Hemostat Standard

For more than 60 years, particularly preferable within the world compared other hemostatic products under the name of different brands. Proven highly effective bactericidal effect.



PAHACEL® Knit

Absorbable Hemostat Knit

PAHACEL Knit with dense weave structure is designed for severe bleeding due to the intense nature and can be easily sutured and stop bleeding 3 times faster compared to the PAHACEL Standard. It is ideal for trauma, sternotomy and solid organ (Such as kidney liver, heart, pancreas) application. Proven highly effective bactericidal effect.

PAHACEL® Fibril

Absorbable Hemostat Fibril

PAHACEL Fibril, could be applied as layer by layer and has soft cotton like nature. On the specific field, making high contact property towards mild bleeding sites. Stop bleeding faster than standard. Ideal for neurosurgery, cardiovascular, orthopedica and vascular application. Proven highly effective bactericidal effect.





Pahacel Oxidized Regenerated Cellulose Instruction for Use
Pahacel Standard Absorbable Hemostat
Pahacel Knit Absorbable Hemostat
Pahacel Fibril Absorbable Hemostat
Pahacel Pillow Type Absorbable Hemostat (For Extra Hemostasis)

Description:

Pahacel Absorbable Hemostats are sterile absorbable knitted fabrics prepared by the controlled oxidation of Regenerated cellulose. The fabric is white with pale yellow cast and has a faint, caramel-like aroma. It is strong and can be sutured or cut without fraying. A slight discoloration may occur with age but this does not affect performance. The Pahacel Fibril form of product allows the surgeon to grasp with forceps any amount of Pahacel Fibril Hemostat needed to achieve hemostasis at a particular bleeding site. The Pahacel Fibril form may be more convenient than the knitted form for hard to reach or irregularly shaped bleeding sites.

Intended Use:

Pahacel 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. Pahacel Standard, Pahacel Knit, Pahacel Fibril hemostats can be cut to size for use in endoscopic procedures.

Contraindications:

Although packing or wadding sometimes is medically necessary, Pahacel Absorbable Hemostat should not be used in this manner, unless it is to be removed after hemostasis is achieved.

Pahacel 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 change of cyst formation.

When Pahacel 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 always be removed after hemostasis is achieved since it will swell and could exert unwanted pressure.

Pahacel Absorbable Hemostat should not be used to control hemorrhage from large arteries.

Pahacel Absorbable Hemostat should not be used on non-hemorrhagic serous oozing surfaces, since body fluid other than whole blood, such as serum, do not react with Pahacel Absorbable Hemostat to produce satisfactory hemostatic effect.

Pahacel Absorbable Hemostat is an absorbable Hemostat, and should not be used as an adhesion prevention product.

Sterility:

The Pahacel Hemostats are sterilized by Gamma irradiation technique. Pahacel Hemostat is for single use only; do not resterilize! Use an aseptic technique in all phases of handling.

Warnings:

Pahacel Absorbable Hemostat is not intended as a substitute for careful surgery and the proper use of sutures and ligatures.

Closing Pahacel Absorbable Hemostat in a contaminated wound without drainage may lead to complications and should be avoided.

The hemostatic effect of Pahacel Absorbable Hemostat is greater when it is applied dry; therefore it should not be moistened with water or saline.

Pahacel 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 Pahacel 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 Pahacel Absorbable Hemostat, by swelling, may exert pressure resulting in paralysis and/or nerve damage. Dislodgement of Pahacel Absorbable Hemostat could possibly occur by means such as repacking, further intraoperative manipulation, lavage, exaggerated respiration, etc. The Pahacel Absorbable Hemostat, when left in the patient after closure, may migrate from the site of application into foramina in bone around the spinal cord resulting in paralysis and may cause the left orbit of the eye, cause blindness. Special care must be taken by the surgeons/physicians, regardless of the type of surgical procedure, to consider the advisability of removing Pahacel Absorbable Hemostat after hemostasis is achieved.

Although Pahacel 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 post-operative infections.

If Oxidized Regenerated Cellulose is inserted on peritoneum to avoid bleeding or in a part where there is no bleeding contact, then the absorption could take a bit more time.

During insertion even should be used as a thin film on the tissue, the product should not be folded.

Laparoscopic- total/partial hysterectomies, severe endometriosis, radical hysterectomies and myomectomy cases as well as Borderline ovarian tumor surgeries, absorption could take a bit more time and the product should not be folded on application area.

EXCESS AMOUNT OF OXIDIZED REGENERATED CELLULOSE AFTER ACHIEVING HEMOSTASIS.

Warranty:

Manufacturer warrants that this medical device is free from defects in both materials and workmanship. The above warranties are in lieu of all other warranties, either express or implied; including any warranty of merchantability or fitness for a particular purpose. Suitability for use of this medical device for any surgical procedure shall be determined by the user. Altaylar Medical Ltd. shall not be liable for incidental or consequential damages of any kind.

Precautions:

Use only as much Pahacel Absorbable Hemostat 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 Pahacel Absorbable Hemostat should be used and care must be exercised to prevent plugging of urethra, ureter, or a catheter by dislodged portions of the product.

Since absorption of Pahacel 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.

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Laparoscopic- total/partial hysterectomies, severe endometriosis, radical hysterectomies and myomectomy cases as well as Borderline ovarian tumor surgeries, absorption could take a bit more time and the product should not be folded on application area.

If Pahacel 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 (controlling hemorrhage after tonsillectomy and controlling epistaxis).

Care should be taken not to apply Pahacel Absorbable Hemostat too tightly when it is used as a wrap during vascular surgery.

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 procedures.

Classification:

PAHACEL® Oxidized Regenerated Cellulose Hemostat is classified as Class III according to Medical Device Directives.

Sterility:

Pahacel® Oxidized Regenerated Cellulose Hemostat is sterilized by Gamma irradiation technique.

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ABSORBABLE HEMOSTATS (Oxidized Regenerated Cellulose)		
Pahacel® Standard Absorbable Hemostat		
Reference	Size	Description
<u>PCS11</u>	<u>1,25 cm x 5 cm</u>	Pahacel® Standard Absorbable Hemostat
PCS12	1,3 cm x 5,1 cm	Pahacel® Standard Absorbable Hemostat
PCS13	1,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS14	2,5 cm x 2,5 cm	Pahacel® Standard Absorbable Hemostat
PCS15	2,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
<u>PCS16</u>	<u>5 cm x 7,5 cm</u>	Pahacel® Standard Absorbable Hemostat
PCS17	5 cm x 35 cm	Pahacel® Standard Absorbable Hemostat
PCS18	5,1 cm x 7,6 cm	Pahacel® Standard Absorbable Hemostat
PCS19	5,1 cm x 35,6 cm	Pahacel® Standard Absorbable Hemostat
PCS20	7,5 cm x 10 cm	Pahacel® Standard Absorbable Hemostat
<u>PCS21</u>	<u>10 cm x 20 cm</u>	Pahacel® Standard Absorbable Hemostat
PCS22	10,2 cm x 20,3 cm	Pahacel® Standard Absorbable Hemostat
PCS23	15 cm x 23 cm	Pahacel® Standard Absorbable Hemostat
PCS24	12,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS25	5 cm x 10 cm	Pahacel® Standard Absorbable Hemostat
Pahacel® Knit Absorbable Hemostat		
Reference	Size	Description
PCK11	2,6 cm x 2,6 cm	Pahacel® Knit Absorbable Hemostat
PCK12	7,6 cm x 10,2 cm	Pahacel® Knit Absorbable Hemostat
PCK13	15,2 cm x 22,9 cm	Pahacel® Knit Absorbable Hemostat
PCK14	2,5 cm x 5,1 cm	Pahacel® Knit Absorbable Hemostat
PCK15	5,1 cm x 10,2 cm	Pahacel® Knit Absorbable Hemostat
PCK16	10,2 cm x 10,2 cm	Pahacel® Knit Absorbable Hemostat
PCK17	5 cm x 7,5 cm	Pahacel® Knit Absorbable Hemostat
Pahacel® Fibril Absorbable Hemostat		
Reference	Size	Description
PCF11	2,6 cm x 5,1 cm	Pahacel® Fibril Absorbable Hemostat
PCF12	7,6 cm x 10,2 cm	Pahacel® Fibril Absorbable Hemostat
PCF13	15,2 cm x 22,9 cm	Pahacel® Fibril Absorbable Hemostat
PCF14	2,5 cm x 5,1 cm	Pahacel® Fibril Absorbable Hemostat
PCF15	5,1 cm x 10,2 cm	Pahacel® Fibril Absorbable Hemostat
PCF16	10,2 cm x 10,2 cm	Pahacel® Fibril Absorbable Hemostat
PCF17	5 cm x 7,5 cm	Pahacel® Fibril Absorbable Hemostat
Pahacel® Pillow Type Absorbable Hemostat (For Extra Hemostasis)		
Reference	Size	Description
PCE11	3 cm x 3 cm	Pahacel® Pillow Type Absorbable Hemostat
PCE12	5 cm x 5 cm	Pahacel® Pillow Type Absorbable Hemostat
PCE13	5 cm x 7,5 cm	Pahacel® Pillow Type Absorbable Hemostat
Polypropylene Mesh – Standard Type		
Order No	Size	
P1010	10x10 cm	