WACOCELL OXIDIZED REGENERATED CELLULOSE INSTRUCTION FOR USE

WACOCELL® STANDARD, WACOCELL® KNITTING®

WACOCELL® LAYER and WACOCELL® PUFYY

(Oxidized Regenerated Cellulose)

FOR SURGICAL USE.

DESCRIPTION:

WACOCELL® Oxidized Regenerated Cellulose is a sterile absorbable knitted fabric prepared by the controlled oxidation of regenerated cellulose. The fabric is white with a pale yellow cast and has a faint, caramel-like aroma. 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.

WACOCELL® Standard and Knitting are in knitted fabric form, WACOCELL® Layer and Puffy are in fiber-cotton form.

The WACOCELL® LAYER form of the product allows the surgeon to grasp with forceps any amount of WACOCELL® LAYER Hemostat needed to achieve hemostasis at a particular bleeding site. The WACOCELL® LAYER form may be more convenient than the knitted form for hard to reach or irregularly shaped bleeding sites. Although it is easy to pull the desired amount of WACOCELL® LAYER Hemostat from the entire supply, the group of selected fibers continue to cohere to one another and application to the bleeding site is easily controlled. Unwanted dispersal over the operative site does not occur.

All WACOCELL® product types can be used in the same areas on the patient. The product in WACOCELL® KNITTING form is recommended to be used in intensive bleeding areas due to its thick and dense knit texture. WACOCELL® LAYER and PUFFY form may be more suitable for hard-to-reach or irregularly shaped bleeding areas than knitted form. Although the difference between the product forms has no effect on the situations in which to use, the decision belongs to the end user.

Thanks to the carboxyl group and acidic structure, the product provides rapid hemostasis and absorption in the body within 14 days.

MECHANISM OF ACTION:

The mechanism of action whereby WACOCELL® Oxidized Regenerated Cellulose 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 WACOCELL® Oxidized Regenerated Cellulose 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, WACOCELL® Oxidized Regenerated Cellulose 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.

In addition to its local haemostatic properties, WACOCELL® Haemostat is bactericidal in vitro against a wide range of gram positive and gram negative organisms including aerobes and anaerobes. WACOCELL® Haemostat is bactericidal in vitro against strains of species including those of:

Staphylococcus aureus
Bacillus subtilis
Staphylococcus epidermidis
Proteus vulgaris
Micrococcus luteus
Corynebacterium xerosis
Streptococcus pyogenes Grup A
Mycobacterium phlei
Streptococcus pyogenes Grup B
Clostridium tetani
Streptococcus salivarius
Clostridium perfringens
Branhamella catarrhalis
Bacteroides fragilis
Escherichia coli
Enterococcus
Klebsiella aerogenes
Enterobacter cloacae
Lactobacillus sp.
Pseudomonas aeruginosa
Salmonella enteritidis
Pseudomonas stutzeri
Shigella dysenteriae
Proteus mirabilis
Serratia marcescens
methicillin-resistant Staphylococcus aureus (MRSA)
penicillin-resistant Streptococcus pneumoniae (PRSP)
vancomycin-resistant Enterococcus (VRE)
methicillin-resistant Staphylococcus epidermidis (MRSE)

The clinical utility of these bacterial claims has not been studied or demonstrated.

Although WACOCELL® Absorbable Hemostat is bactericidal against a wide variety of pathogenic microorganisms, it is not intended to replace systemically administered therapeutic or prophylactic antimicrobial agents to control or prevent postoperative infections.

MODE OF ACTION:
Provides a matrix for platelet adhesion and aggregation and it is Adjunctive Hemostasis.

ABSORPTION:
WACOCELL® Oxidized Regenerated Cellulose is absorbed in body within 14 days.

MECHANISM OF DEGRADATION:
Degradation was rapid, and oligomeric products were evident primarily in the peritoneal fluid from the implantation site, with no apparent accumulation in either the serum or the urine.
A mechanism of degradation consisting of chemical depolymerization, followed by enzymatic hydrolysis mediated by glycosidases endogenous to peritoneal macrophages, is proposed.

INDICATIONS:
WACOCELL® 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. WACOCELL® STANDARD, WACOCELL® LAYER, WACOCELL® KNITTING AND WACOCELL PUFFY Hemostats can be cut to size for use in endoscopic procedures.

Instructions for use in endoscopic procedures:

- WACOCELL® Haemostat should be cut to the appropriate size for endoscopic placement. Standard endoscopic procedures should be used up to the point of placement of the absorbable haemostat. Grasp the WACOCELL® Haemostat at one corner. With a steady backward motion, pull the material into the operating channel until the material is enclosed in the end of the laparoscope.
- Place the laparoscope back into the patient via the sleeve and reposition the scope over the area of desired application. Slowly push the grasping instrument and material into the cavity.
- With the use of grasping instruments in a second and/or third auxiliary site, placement can be made and the material positioned in place

WACOCELL® Haemostat can be used in many areas of surgery, e.g. cardiovascular surgery, haemorrhoidectomy, implantation of vascular prostheses, biopsies, lung operations, surgery to the face and jaw, gastric resection, operations to the throat or nose, liver and gall bladder operations, gynaecological operations, thoracic and abdominal sympathectomies, neurosurgery, especially cerebral operations, thyroid operations, skin transplantations, treatment of superficial injuries.
Dental: WACOCELL® Absorbable Hemostat (oxidized regenerated cellulose) is indicated for adjunctive use to assist in the control of bleeding in exodontia and oral surgery. It may also be used to help achieve hemostasis after single or multiple tooth extractions, alveoloplasty, gingival hemorrhage, impactions, biopsies, and other procedures in the oral cavity.

CONTRAINDICATIONS

Although packing or wadding sometimes is medically necessary, WACOCELL® Oxidized Regenerated Cellulose should not be used in this manner, unless it is to be removed after hemostasis is achieved (See WARNINGS and PRECAUTIONS).
WACOCELL® Oxidized Regenerated Cellulose 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 WACOCELL® Oxidized Regenerated Cellulose 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.
WACOCELL® Oxidized Regenerated Cellulose should not be used to control hemorrhage from large arteries.
WACOCELL® Oxidized Regenerated Cellulose should not be used on nonhemorrhagic serous oozing surfaces, since body fluids other than whole blood, such as serum, do not react with WACOCELL® Oxidized Regenerated Cellulose to produce satisfactory hemostatic effect.
WACOCELL® Oxidized Regenerated Cellulose is an absorbable hemostat, and should not be used as an adhesion prevention product.
Paralysis and nerve damage have been reported when WACOCELL® Oxidized Regenerated Cellulose 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 WACOCELL® Oxidized Regenerated Cellulose was placed in the anterior cranial fossa. Therefore, it is not recommended for use in orthopedics and ophthalmic fields.

WARNINGS

WACOCELL® Oxidized Regenerated Cellulose is supplied sterile and as the material is not compatible with autoclaving or ethylene Oxide sterilization, WACOCELL® Oxidized Regenerated Cellulose should not be resterilized.

The effects WACOCELL® Oxidized Regenerated Cellulose use in children and pregnant women is unknown.

WACOCELL® Oxidized Regenerated Cellulose is not intended as a substitute for careful surgery and the proper use of sutures and ligatures. Closing WACOCELL® Oxidized Regenerated Cellulose in a contaminated wound without drainage may lead to complications and should be avoided. The hemostatic effect of WACOCELL® Oxidized Regenerated Cellulose is greater when it is applied dry; therefore it should not be moistened with water or saline.

WACOCELL® Oxidized Regenerated Cellulose 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 WACOCELL® Oxidized Regenerated Cellulose 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 WACOCELL® Hemostat, by swelling, may exert pressure resulting in paralysis and/or nerve damage. Dislodgement of WACOCELL® Oxidized Regenerated Cellulose 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 fracture and lacerated lobe that WACOCELL® Oxidized Regenerated Cellulose, 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 WACOCELL® Oxidized Regenerated Cellulose after hemostasis is achieved.

An eventual excess of WACOCELL® Oxidized Regenerated Cellulose as a filler during surgeries may cause foreign body reactions.

Although Oxidised Regenerated cellulose products are not appropriate for arteriolar bleeding encountered during surgery, they could help in a quick hemostasis of moderate venous and capillary ooze frequently associated with the excision of intrinsic tumors, lobectomies, or intracerebral hemorrhages. Product is frequently used to stop oozing from the epidural space and to decrease epidural hematoma formation during intracranial surgery (via application to the interface between the dura and the margins of the craniotomy defect).

It is known that any kind of Oxidized Regenerated Cellulose has a tendency to swell once placed, increasing the risk of its use in closed or bone walled spaces. There have been several cases of post-

thoracotomy paraplegia owing to the compressive effects of Oxidized Regenerated Cellulose in adults and children undergoing thoracotomy for pulmonary, esophageal pathologies and resection of mediastinal neuroblastoma. They speculated that pressure differences on closure of the thoracic cavity caused Oxidized Regenerated Cellulose to migrate into the spinal canal through the foramen.
Closure of the thoracotomy with rib approximation could produce a compressive force on the Oxidized Regenerated Cellulose forcing it into the tracheal and esophageal lumen.
An excess of Oxidized Regenerated Cellulose may complicate some surgeries as thoracotomy by migrating through the suture lines into the organs with lumen or foramen.
Therefore, WACOCELL ® Oxidized Regenerated Cellulose should be used judiciously and avoiding the use of an excess of product.

PRECAUTIONS:
Use only as much WACOCELL® Oxidized Regenerated Cellulose 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. If the excess products have not been removed before surgical closure, the product should not be left dry in the tissue.
In urological procedures, minimal amounts of WACOCELL® Oxidized Regenerated Cellulose should be 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 WACOCELL® Oxidized Regenerated Cellulose could be prevented in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals.
If WACOCELL® Oxidized Regenerated Cellulose 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. (Examples: controlling hemorrhage after tonsillectomy and controlling epistaxis.)
Care should be taken not to apply WACOCELL® Oxidized Regenerated Cellulose 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 users 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.
Dental: WACOCELL® Absorbable Hemostat should be applied loosely against the bleeding surface. Wadding or packing should be avoided, especially within rigid cavities, where swelling may interfere

with normal function or possibly cause necrosis. Precautions should be taken to assure that none of the material is aspirated by the patient.

ADVERSE REACTIONS

"Encapsulation" of fluid and foreign body reactions have been reported.

There have been reports of stenotic effect when WACOCELL® Oxidized Regenerated Cellulose 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 WACOCELL® Oxidized Regenerated Cellulose, it is important to be cautious and avoid applying the material tightly as a wrapping.

Paralysis and nerve damage have been reported when WACOCELL® Oxidized Regenerated Cellulose 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 WACOCELL® Oxidized Regenerated Cellulose 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 required.

Occasional reports of "burning" and "stinging" sensations and sneezing when WACOCELL® Oxidized Regenerated Cellulose has been used as packing in epistaxis, are believed to be due to the low pH of the product.

Burning has been reported when WACOCELL® Oxidized Regenerated Cellulose was applied after nasal polyp removal and after hemorrhoidectomy. Headache, burning, stinging, and sneezing in epistaxis and other rhinological procedures, and stinging when WACOCELL® Oxidized Regenerated Cellulose 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 WACOCELL® Oxidized Regenerated Cellulose from its sterile container.

Minimal amounts of WACOCELL® Oxidized Regenerated Cellulose in appropriate size are laid on the bleeding site or held firmly against the tissues until hemostasis is obtained.

The amount required depends on the nature and intensity of the haemorrhage to be stopped. The haemostatic effect of WACOCELL® Haemostat is particularly pronounced when used dry. Moistening the material with water or physiological saline solution is not recommended.

Opened, unused WACOCELL® Oxidized Regenerated Cellulose should be discarded, because it cannot be resterilized.

STORAGE

Store at controlled room temperature 17,5° - 27,5°C.

STERILIZATION

WACOCELL® Oxidized Regenerated Cellulose are sterilized by Gamma irradiation technique.

WACOCELL OXIDIZED REGENERATED CELLULOSE
INSTRUCTION FOR USE

PRODUCT SIZES

	Reference	Size	Thickness		Reference	Size	Thickness		Reference	Size	Thickness
WACOCELL STANDARD TYPE	WA101	1,25*5 cm	0,20-0,30 mm	WACOCELL LAYER TYPE	WA301	2,6*5,1 cm	7 layer	WACOCELL PUFFY TYPE	WA401	2,6*2,6 cm	1 Layer
	WA102	1,3*5,1 cm	0,20-0,30 mm		WA302	7,6*10,2 cm	7 layer		WA402	7,6*10,2 cm	1 Layer
	WA103	1,5*5 cm	0,20-0,30 mm		WA303	2,5*5,1 cm	7 layer		WA403	2,5*5,1 cm	1 Layer
	WA104	2,5*2,5 cm	0,20-0,30 mm		WA304	5,1*10,2 cm	7 layer		WA404	5,1*10,2 cm	1 Layer
	WA105	2,5*5 cm	0,20-0,30 mm		WA305	10,2*10,2 cm	7 layer		WA405	10,2*10,2 cm	1 Layer
	WA106	5*7,5 cm	0,20-0,30 mm		WA306	5*7,5 cm	7 layer		WA406	5*7,5 cm	1 Layer
	WA107	5*35 cm	0,20-0,30 mm	WACOCELL KNITTING TYPE	WA201	2,6*2,6 cm	0,35-0,45 mm				
	WA108	5,1*7,6 cm	0,20-0,30 mm		WA202	7,6*10,2 cm	0,35-0,45 mm				
	WA109	5,1*35,6 cm	0,20-0,30 mm		WA203	15,2*22,9 cm	0,35-0,45 mm				
	WA110	7,5*10 cm	0,20-0,30 mm		WA204	2,5*5,1 cm	0,35-0,45 mm				
	WA111	10*20 cm	0,20-0,30 mm		WA205	5,1*10,2 cm	0,35-0,45 mm				
	WA112	10,2*20,3 cm	0,20-0,30 mm		WA206	10,2*10,2 cm	0,35-0,45 mm				
	WA113	15*23 cm	0,20-0,30 mm		WA207	5*7,5 cm	0,35-0,45 mm				
	WA114	12,5*5 cm	0,20-0,30 mm								
	WA115	5*10 cm	0,20-0,30 mm								

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