

Willocell®

CE-0086

Designed to stop capillary, venous and minor arterial bleeding

Brief product description Willocell®

Intended Use: Willocell® 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. Willocell® Standard, Willocell® Knit, Willocell® Fibril hemostats can be cut to size for use in endoscopic procedures.

Warnings: Although packing or wadding sometimes is medically necessary, Willocell® Absorbable Hemostat should not be used in this manner, unless it is to be removed after hemostasis is achieved. Willocell® 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. The hemostatic effect of Willocell® Absorbable Hemostat is greater when it is applied dry; therefore it should not be moistened with water or saline. Willocell® 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 Willocell® 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 Willocell® Absorbable Hemostat, by swelling, may exert pressure resulting in paralysis and/or nerve damage. The Willocell® 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 Willocell® Absorbable Hemostat after hemostasis is achieved.

Sterility: The Willocell® Hemostats are sterilized by gamma irradiation technique. Willocell® Hemostat is for single use only; do not resterilize! Use an aseptic technique in all phases of handling. Will Pharma will not be responsible for any product that is resterilized,

nor will we accept for credit or exchange any product that has been opened but not used. If you received this product in a sealed pouch package, it will remain sterile until the expiration date printed on the package label or until the package is opened, whichever occurs first. If you received this product in an unsealed pouch paper package and/or as part of a custom procedure pack, the sterilization is (or will be) the responsibility of the pack distributor.

Contra-indications: None known

Side effects: There are no known reactions caused by Willocell® Absorbable Hemostat in literature.

Guarantee: Will-Pharma guarantees that these medical disposables are free of material defects and manufacturing errors. The above guarantees replace all other guarantees, either express or implied, including any guarantee of sale ability or suitability for a specific objective. Suitability for use of this medical device for a surgical procedure is determined by the user. Will-Pharma cannot be held liable for incidental damage or consequential damage of any type whatsoever.

Keep Willocell® Absorbable Hemostat in a dry location, between 15°C and 25°C and out of direct sunlight.

Batch numbering: All Willocell® Absorbable Hemostat packaging has an EAN code and a batch number. Willocell® Absorbable Hemostat is manufactured under ISO 13485 conditions and comply with the guidelines applicable to the CE mark.

Quality: Will-Pharma's quality requirements comply with the ISO 9001 standard, and the manufacturing requirements of Willocell® Absorbable Hemostat comply with the ISO 13485 standard. Regular audits are performed in order to maintain these high quality requirements.

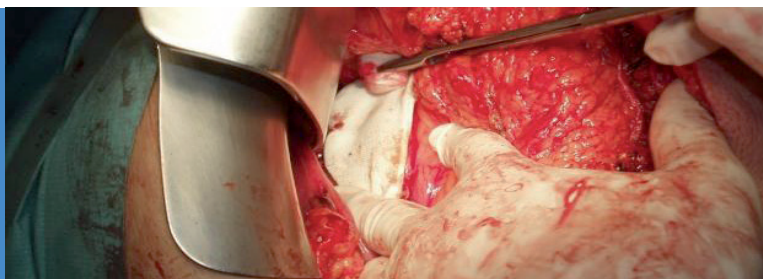
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Local absorbable hemostat Willocell® provides fast and effective local homeostasis within 1-3 minutes. Willocell® has significant antibacterial activity, facilitates in accelerating biochemical processes

Bio-compatible Willocell® is made of 100% oxidized regenerated cellulose and is well tolerated

Biodegradable Willocell® is completely absorbed within 2-14 days

A traumatic Willocell® is perfectly gentle thanks to its complete absorbency

Pliable styptic gauze Willocell® will be used in general and digestive surgery, plastic surgery, orthopaedics, gynaecology, urology, stomatology as well as other surgical branches

Produced under ISO 13845 and CE certified; class 3

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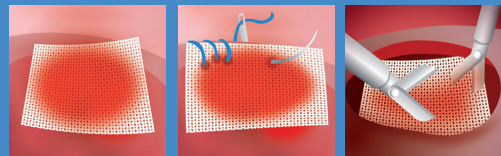
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Its wide range of application enables the product to be used in operations carried out traditionally or laparoscopically, in robotic surgery, for endoscopic operations as well as for one-day surgeries.

- **Willocell®** is a sterile, resorbable, biocompatible, haemostatic oxidized regenerated cellulose gauze designed to assist in the control of capillary, venous and small arterial hemorrhage.
- **Willocell®** provides fast and effective local haemostasis within 1-3 minutes.
- **Willocell®** has significant antibacterial activity due to the pH of 2.2 after 1 to 24 hours, facilitates in accelerating biochemical processes, helps the healing process and minimizes blood loss and complications preoperatively and in the early post-operative stages.
- **Willocell®** is available in the following presentations:

Willocell®:	1,5 x 5 cm, 5 x 7,5 cm, 5 x 35 cm, 10 x 20 cm
Willocell® Knit:	2,6 x 2,6 cm, 7,6 x 10,2 cm, 15,2 x 22,9 cm, 5,1 x 10,2 cm
Willocell® Fibril:	2,6 x 5,1 cm, 5,1 x 10,2 cm



Application of Willocell®

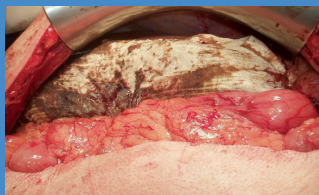
Applying Willocell® is very simple, fast and safe. The haemostatic reticulum is applied directly onto the dried bleeding area or organ. Bleeding usually stops within 1-3 minutes depending on the type of surgery and the intensity of bleeding. It acts locally. The product can either be applied to the required area by gentle pressure, attaching it with a stitch, sewing it onto a tissue or an organ or it can be used as a form of tamponade. Willocell® is perfectly absorbed by the body and does not need to be removed from the place of application.

Description of Willocell®

Willocell® 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 Willocell® Fibril form of product allows the surgeon to grasp with forceps any amount of Willocell® Fibril Hemostat needed to achieve hemostasis at a particular bleeding site. The Willocell® Fibril form may be more convenient than the knitted form for hard to reach or irregularly shaped bleeding sites.



Willocell® is a 100 % oxidized regenerated cellulose, pliable, sterile, resorbable and local haemostatic