

Instruction for BloodSTOP iX Surgical Hemostat (CE)

BloodSTOP[®] iX Absorbable Hemostat is a water soluble sterile absorbable fabric of etherized, oxidized, regenerated cellulose, available in different sizes. It is fully biocompatible. It is stable and sterile in its packaging and should be stored in a cool dry place.

Actions

When BloodSTOP iX Absorbable Hemostat contacts blood and exudates, it transforms to a transparent gel, thereby adhering and creating pressure to seal the wound. BloodSTOP iX also activates the intrinsic coagulation pathway. Once transformed into a gel, its clarity allows for wound monitoring. BloodSTOP iX Absorbable Hemostat is fully absorbable.

BloodSTOP iX Absorbable Hemostat is not intended to be an alternative to the application of antimicrobial agents.

Dosage and administration

Follow sterile handling techniques when removing BloodSTOP iX Absorbable Hemostat from its sterile container.

Use a piece of BloodSTOP iX Absorbable Hemostat slightly larger than the injured area. BloodSTOP iX can be cut to size if necessary.

Place BloodSTOP iX Absorbable Hemostat on the bleeding site. The amount required depends on the nature and intensity of the hemorrhage to be stopped. Apply pressure for approximately 30 seconds with a piece of wet regular cotton gauze.

For small cavity hemostasis, fill cavity loosely with pieces of BloodSTOP iX or a roll of BloodSTOP iX. It is generally not necessary to moisten BloodSTOP iX when used internally. However, sterile saline may be used to moisten BloodSTOP iX if needed.

Indications

BloodSTOP iX Absorbable Hemostat is used in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage.

It can be used in neurosurgery, thoracic surgery, abdominal and gastro-intestinal surgery, plastic surgery, burn treatment, ENT surgery, obstetric and gynecologic surgery, colon-rectal surgery, circumcision, vascular surgery, ulcer wounds and other general surgeries.

BloodSTOP iX Absorbable Hemostat is indicated for use in dental applications to assist in the control of bleeding in exodontia and oral surgery.

Contraindications

BloodSTOP iX Absorbable Hemostat should not be used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, or the optic nerve and chiasm, unless excess gauze is removed after hemostasis is achieved. BloodSTOP iX Absorbable Hemostat should not be used to control bleeding from large arteries.

Symbols Used on Labeling



Single use



Use until year and month



Batch number



See instructions for use



Company Address



Do not use if package is damaged



Sterile unless package is opened or damaged.
Method of Sterilization: Irradiation



CE Mark and identification number of notified body.
Product conforms to the essential requirements of the
Medical Device Directive 93/42/EEC as amended by
2007/47/EEC

Warnings

BloodSTOP iX Absorbable Hemostat is supplied sterile. Do not use if packaging is compromised.

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

Contaminated wounds should be cleaned before closing with BloodSTOP iX Absorbable Hemostat. Do not close a contaminated wound without drainage.

BloodSTOP iX Absorbable Hemostat is not intended as substitute for systemically administered antimicrobial agents to control or prevent post-operative infections.

When packing or wadding of BloodSTOP iX is necessary, excess hemostat should be removed once hemostasis is achieved.

Although BloodSTOP iX Absorbable Hemostat is fully absorbable, it is advisable to remove excess material 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 BloodSTOP iX, by swelling, may exert pressure resulting in paralysis and /or nerve damage.

Special care must be taken by physicians, regardless of the type of surgical procedure, to consider the advisability of removing excess BloodSTOP iX Absorbable Hemostat after hemostasis is achieved.

Do not use this device in conjunction with blood salvage systems as some absorbable hemostatic devices have been reported to fragment and pass through the filters of blood salvage systems, occluding the system and/or the patient's vasculature.

Do not use in conjunction with methylmethacrylate adhesives as some absorbable hemostatic devices have been reported to interfere with these adhesives used to fixate orthopedic prosthetic devices to bone.

Adverse reactions

Paralysis and nerve damage have been reported for other absorbable hemostatic products when used around, in, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm. Although these reports were not in reference to BloodSTOP iX Absorbable Hemostat, it is advisable in these surgical applications to remove the BloodSTOP iX after homeostasis is achieved to eliminate the potential for pressure on neural structures.

Precautions

No more than the necessary quantity of BloodSTOP iX Absorbable Hemostat should be used. Excess gauze should be removed before surgical closure. Care should be taken not to apply BloodSTOP iX Absorbable Hemostat too tightly when it is used as a wrap during vascular surgery.

Opened, unused BloodSTOP iX Absorbable Hemostat should be discarded, as its sterility cannot be guaranteed once the packaging is compromised.

Care should be exercised to ensure that BloodSTOP iX particles do not enter the patient's vasculature. For small cavity hemostasis, care should be taken to fill cavity loosely with BloodSTOP iX.

Shelf-life

BloodSTOP iX Absorbable Hemostat should be stored dry cool place in the original packaging. The expiration date of BloodSTOP iX Absorbable Hemostat is printed on the pack. Do not use after this date.



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