

- Dislodgement of Surgi-ORC® haemostat could possibly occur by means such as repacking, further intraoperative manipulation, lavage, exaggerated respiration, etc.
- In procedures such a lobectomy, laminectomy and repair of a frontal skull fracture and lacerated lobe, there is a possibility of migration of Surgi-ORC® from the site of application.
- Special care must be taken by physicians, regardless of the type of surgical procedure, to consider the advisability of removing Surgi-ORC haemostat after haemostasis is achieved.
- Although Surgi-ORC® haemostat 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.
- Surgi-ORC® is not intended for the primary treatment of coagulation disorders.
- The safety and effectiveness of Surgi-ORC® is not established in pregnant women.

PRECAUTIONS

- Use only as much Surgi-ORC® haemostats as is necessary for haemostasis, 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 Surgi-ORC® haemostat should be used and care must be exercised to prevent plugging of the urethra, ureters, or a catheter by dislodged portions of the product.
- Surgi-ORC® haemostats should not be used in chemically cauterized areas.
- If Surgi-ORC® haemostat is used temporarily to line the cavity of large open wounds, it should be placed so as not to overlap the skin edges.
- Surgi-ORC® should 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 the patient aspirates none of the material.
- Care should be taken not to apply Surgi-ORC® haemostat tightly when it is used as a wrap during vascular surgery.
- Wadding or packing should be avoided, especially within rigid cavities, where swelling may interfere with normal packing or possibly cause necrosis.
- Endoscopic procedures should be performed only by persons having adequate training and familiarity with endoscopic techniques.

ADVERSE REACTIONS

- "Encapsulation" of fluid and foreign body reactions have been reported.
- Stenotic effect has been reported when ORC haemostat applied as a wrap during vascular surgery. Although it has not been established that the stenosis was directly related to the use of ORC haemostat, it is important to be cautious and avoid applying the material tightly as a wrapping.
- Paralysis and nerve damage have been reported when ORC haemostat 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.
- Blindness has been reported in connection with surgical repair of a lacerated left frontal lobe when ORC haemostat was placed in the anterior cranial fossa.

- Possible prolongation of drainage in cholecystectomies and difficulty in passing urine per urethra after prostatectomy.
- "Burning" and "Stinging" sensations and sneezing can occur when ORC haemostat has been used as packing in epistaxis, are believed to be due to the low pH of the product.

DOSAGE AND ADMINISTRATION

Sterile technique should be observed in removing Surgi-ORC® haemostat from its sterile container. Minimal amount of Surgi-ORC® haemostat in appropriate size is laid on the bleeding site or held firmly against the tissues until haemostasis is achieved. Required amount of Surgi-ORC® haemostat depends on the nature and intensity of the haemorrhage to be stopped. Moistening the material with water or physiological saline solution prior to use is not recommended. Opened, unused Surgi-ORC® haemostat should be discarded, because it cannot be re-sterilized.

STORAGE

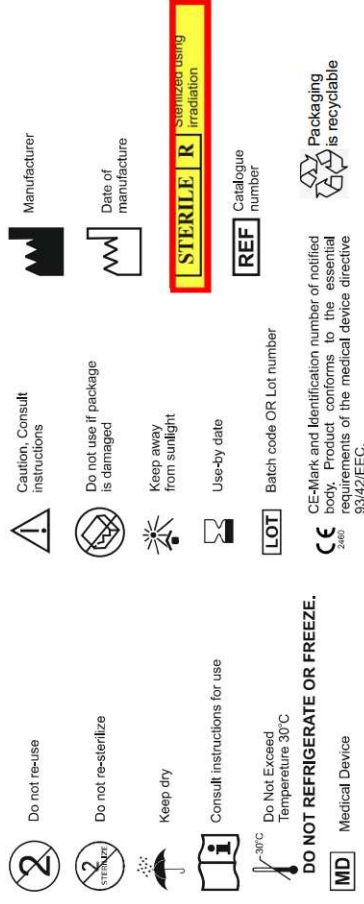
laikomas 15 - 30 laipsnių (Celsijaus) temperatūroje;
Store the product in its original packaging in a clean and dry room at the temperature 15 - 30° C.

Close the outer package of the product immediately after use.

DO NOT REFRIGERATE OR FREEZE.

Expiry date is mentioned on the labels; do not use the product after the expiry date.

SYMBOLS USED



Manufactured by:

AEGIS LIFESCIENCES PVT. LTD.

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EC REP

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AL/IFU/ORC/01; Rev. R8 ; Date- 01-09-2021