ORCA FOAM®

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Absorbable Gelatin Sponge Hemostat, USP

1. Product Description

The **ORCA FOAM®** Absorbable Gelatin Sponge, U.S.P. (Standard) is made of 100% purified porcine gelatin and is of neutral character in nature. **ORCA FOAM®** Absorbable Gelatin Sponge is non-pyrogenic. It is intended for use to control minimal bleeding by tamponade effect, blood absorption and platelet aggregation following ENT surgery. It is insoluble in water and fully absorbable. Its porous structure and interstices enables the product to absorb more than 35 times its own weight of blood and fluids. The absorptive capacity of **ORCA FOAM®** is a function of it's physical size, increasing as the amount of gelatin increases. It is supplied in several sizes. It is packaged individually in (double) blister, pouch or jar/container packaging, sterilized by gamma rays, and is for single use only.

2. Indications

General Indications: the **ORCA FOAM®** is used during and after ENT procedures in intra cranial, middle ear, intra oral, intra nasal, laryngeal, and head & neck soft tissue procedures, to achieve homeostasis by tamponade effect.

3. Contraindications

Allergies to porcine products.
The gelatin sponge should not be used in closures of skin incisions, as it may interfere with wound healing.

4. Side Effects

Formation of tissue granulation during ENT/middle ear procedures has been reported in at least one animal study.

5. Instructions for use

5.1 Gelatin Sponge: The gelatin sponge can be used dry or saturated with a sterile physiological saline solution, if used dry, the sponge is cut into the desired size and is slightly compressed. The sponges must be applied to a bleeding area under light pressure for one or two minutes until bleeding stops.
When used with saline, **ORCA FOAM®** should be soaked in the solution, then withdrawn, squeezed thoroughly between gloved fingers to expel air bubbles present in the interstices, replaced in saline, and kept there until needed.
If bleeding is controlled after (possible multiple) applications of the gelatin sponge the material can be left in situ. The excess should be removed.
Depending on the method of use and the operated site, the total absorption time of the sponge varies from four to six weeks. When applied to bleeding mucosa, it liquefies within 2 to 5 days. It should be noted that the absorption is a process where the volume as well as the absorption characteristics continuously decrease over time.
5.2 ENT Sponge: The gelatin sponge is cut as needed to fit the cavity or defect and inserted to support and separate tissues to prevent adhesions and/or to control bleeding by tamponade effect. The excess should be removed.

6. Precautions

In cases where the gelatin sponge has been compressed (either by the manufacturer or end-user), the gelatin sponge may expand with the absorption of fluids (the sponge will return to its original shape). Where possible excess **ORCA FOAM®** should be removed, because excess product may lead to unintended pressure on neighboring structures which may result in pain for the patient.
The over-packing of **ORCA FOAM®**, particularly within bony cavities, should be avoided.
In cases of postoperative infection, re-operation may be necessary to remove infected material and allow drainage. The product should not be used without antibiotics in infected wounds.

WARNING!

Do not use when the package has been opened or has been damaged.
ORCA FOAM® is a single use product which is not suitable for re-sterilization.
The product should not be used without antibiotics in infected wounds. Embedding the product in a contaminated wound without drainage may lead to complications and should be avoided.
ORCA FOAM® should not be used for controlling postpartum bleeding or menorrhagia.
ORCA FOAM® should not be used in bleeding from large arteries, as this may result in embolization of the blood vessel.
The use of the product in patients on anticoagulant therapy may cause an extended time to hemostasis.
Precautions should be taken in otorhinolaryngology surgery to assure that none of the material is aspirated by the patient. (Examples: controlling hemorrhage after tonsillectomy and controlling epistaxis)
It should be noted when used for packing and supporting in ENT applications, to prevent adhesions at least one study reported that in middle ear it may interfere with both hearing recovery and the healing process of neodrum.

7. General storage and handling

The product should be stored in its sealed protective outer packaging. Prior to opening, the packaging ensuring the integrity of the sterile barrier has to be inspected. Open the package just prior to use in a patient.
The product is for prescription use only.
7.1 Packaging and sterility: The products are packaged sterile.
The packaging consists of:
Storage and transport packaging (secondary packaging)
Sterile Packaging (primary packaging)
The packaging is subject to and conforms to the relevant U.S. regulations and other applicable standards.
The packaging is protecting the product from external influences and guarantees its sterility during storage.
7.2 Handling of the sterile packaging: Remove the product from the sterile package using acceptable aseptic technique.
7.3 Sterilization: The products are sterilized by Gamma radiation.
7.4 Storage: The products should be stored in a dry place in its protective packaging at room temperatures.
Avoid contact with direct sunlight.