ORCA FOAM® POWDER

Absorbable Hemostatic Gelatin Sponge Powder
(Made from Absorbable Hemostatic Gelatin Sponge, USP)

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This package insert is not a reference to surgical techniques.
It is designed to assist in using this product.

DESCRIPTION:
The ORCA FOAM® Powder is a sterile, absorbable gelatin powder intended for hemostatic use by applying to a bleeding surface. The powder is water insoluble and off-white in appearance.

ACTION:
ORCA FOAM® Powder has hemostatic properties. While its mode of action is not fully understood, its effect appears to be more physical than the result of altering the blood clotting mechanism.

INDICATIONS:
ORCA FOAM® Powder, dry or saturated with sterile saline solution, is indicated for Otolaryngology and peripheral / adjunctive Head & Neck surgical procedures (except ophthalmic) for hemostasis when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical.

CONTRAINDICATIONS:
Do not use ORCA FOAM® Powder:
- in closure of skin incisions because it may interfere with the healing of skin edges. This is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.
- in patients with known allergies to porcine collagen (see WARNINGS)
- in intra vascular compartments because of the risk of embolization

WARNINGS:
- Life-threatening anaphylactic reactions, including death, have been reported after exposure to absorbable gelatin sponge powder. Patients with history of allergies to porcine products may be at risk of serious acute hypersensitivity reactions, including anaphylaxis [See Contraindications]. If an anaphylactic reaction is observed, absorbable gelatin sponge powder administration should be immediately discontinued and any applied product removed.
- The overpacking of absorbable gelatin sponge powder should be avoided, since recovering to its initial volume may interfere with normal function and/or could cause possible or eventual compression necrosis of surrounding tissue and nerve damage.
- While packing a cavity for Hemostasis is sometimes surgically indicated, Gelatin Sponge powder should not be used in this manner unless excess product not needed to maintain hemostasis is removed.
- Absorbable gelatin sponge powder should be removed after usage and bleeding has stopped in radical cavities, laminectomy procedures, around or in proximity to foramina in bone, areas of bony confine, the spinal cord and /or the optic nerve and chiasma or closed tissue spaces with presence of bone. This might lead to unintended pressure on neighboring structures which may result in pain for the patient or might create the potential for nerve damage.
- Absorbable gelatin sponge powder should be used with caution in contaminated areas of the body. If signs of infection or abscess develop where Absorbable gelatin sponge powder has been positioned, re-operation may be necessary in order to remove the infected material and allow drainage.
- Do not re-sterilize! Do not use if the package is opened or damaged. This device is designed, tested and manufactured for single use only.
- Absorbable gelatin sponge powder is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis.
- Absorbable gelatin sponge powder should not be used in instances of pumping arterial hemorrhage. It should not be used where blood or other fluids have pooled or in cases where the point of hemorrhage is submerged.

PRECAUTIONS:
- Absorbable gelatin sponge powder should not be placed in the vicinity of the cerebral ventricular space or where there is a possibility of a cerebrospinal fluid fistula to the target bleeding site. Absorbable gelatin sponge powder should also not be used as a tissue substitute to repair tissue defects of the dura or the cranium. Absorbable gelatin sponge powder may migrate from central nervous system (CNS) surgical sites into the cerebral ventricular space and compromise cerebrospinal fluid circulation. Hydrocephalus and cerebrospinal fluid retention, requiring a re-intervention to remove Absorbable gelatin sponge powder residue, have been reported in adult and pediatric patients (see ADVERSE REACTIONS). In some cases, these complications occurred several months after use of Absorbable gelatin sponge powder.
- Use only the minimum amount of Absorbable gelatin sponge powder needed for hemostasis, holding it at the site until bleeding stops and then removing the excess.
- Absorbable gelatin sponge powder should not be used in conjunction with methyl methacrylate adhesives.
- Absorbable gelatin sponge powder should not be used in conjunction with autologous blood salvage circuits.
- Absorbable gelatin sponge powder is not recommended for the primary treatment of coagulation disorders.
- Absorbable gelatin sponge powder should not be used in the presence of infection or should be used with antibiotics in infected wounds.
- Absorbable gelatin sponge powder should not be used for controlling postpartum hemorrhage or menorrhagia.
- Users should be familiar with surgical procedures and techniques involving gelatin sponge powder before employing Absorbable gelatin sponge powder.
- Absorbable gelatin sponge powder sterile sponge is packed in a qualified sterile barrier system which guarantees sterility.
- Once the package is opened, contents are subject to contamination. It is recommended that Absorbable gelatin sponge powder should be used as soon as the package is opened and unused contents discarded.
- Discard any unused Absorbable gelatin sponge powder remaining. Dispose of contaminated devices and packaging materials utilizing standard hospital procedures and universal precautions for bio hazardous waste.
- Positioning of the patient resulting in negative peripheral venous pressure during a procedure has been reported to be a contributing factor resulting in intravascular migration of gelatin and life-threatening thromboembolic events and should be avoided.

HOW SUPPLIED
The ORCA FOAM® Powder comes in a different packaging sterilized by Gamma irradiation.
- 1 gm/ 3 gm/ 5 gm ORCA FOAM® Powder in a container packed within a foil pouch.
- 550mg/1 gm ORCA FOAM® Powder in a sterile prefilled syringe packed within a blister tray with the following sterile components as a kit.

1.550mg/1 gm ORCA FOAM® Powder in a sterile prefilled 25 mL syringe
2.An empty 25 mL syringe.
3.A Luer connector
4.An applicator tip
5.A liquid transfer cup

The sterile ORCA FOAM® Powder in a pre-filled syringe and all the components in the sterile tray are packed in a Tyvek pouch & sterilized by Gamma irradiation.
- 1 gm/ 2 gm/ 3 gm/ 5 gm ORCA FOAM® Powder in a bellow bottle packed within a foil pouch.
- 1 gm/ 2 gm/ 3gm/ 5 gm ORCA FOAM® Powder in a bellow bottle & two pcs. of the applicator (trimmable tip with retainer clip) packed within a foil pouch individually and packed in a Tyvek pouch as a kit.

All products in different packaging contain Instructions for Use and tracking labels.

DIRECTIONS FOR USE
- Before using, inspect the package for signs of damage. If the package or any of the contents are damaged, broken, or wet, sterility cannot be assured and the contents should not be used.
- Sterile technique should always be used to remove the ORCA FOAM® Powder from its packaging.
- Use only the minimum amount necessary to achieve hemostasis.
- ORCA FOAM® Powder can be applied to the bleeding site as a dry powder or saturated with sterile saline solution.
- Open packages of ORCA FOAM® Powder should be discarded since they are not intended for reuse and/or re-sterilization.
- ORCA FOAM® Powder will not act as a tampon or plug in a bleeding site, nor will it close off an area of blood collecting behind a tampon.

When used as ORCA FOAM® Powder (1 gm/ 3 gm/ 5 gm) in a container, add sterile saline solution 3-4 mL/g to prepare a doughy paste, 4-5 mL/g to prepare a paste OR 6-7mL/g to prepare a mousse as following method;
1.Open container, add specified volume of sterile saline solution to container, reattach lid, and shake until a doughy paste, paste or mousse is formed, OR
2.Open container, add specified volume of sterile saline to container, and stir until a doughy paste, paste or mousse is formed, OR
3.Open container, empty contents into sterile beaker, add specified volume of sterile saline solution to the beaker, and stir until a doughy paste, paste or mousse is formed.
The resulting doughy paste, paste or mousse may be smeared or pressed against bleeding surface by hand. When bleeding stops, the excess product should be removed.

When used as ORCA FOAM® Powder 550mg Prefilled Syringe Kit, the desired consistency of hemostat can be achieved by adjusting the volume of hydrating sterile saline up to 3 hours prior to the use using standard sterile technique.
Following the instructions below will yield an average of 7 mL of uniform mixture within the syringe, with a measured minimum delivery volume of 6 mL.
1.Draw 5 mL of sterile, isotonic sodium chloride solution (sterile saline) into an empty 25 mL sterile syringe (diluent not included). Liquid transfer cup may be used (Fig-1)
2.Connect the luer connector to sterile 25 ml syringe containing 5 ml saline and to ORCA FOAM® powder sterile pre filled syringe.(Fig-2)
3.Begin mixing by pushing the sterile saline solution into the ORCA FOAM® Prefilled Syringe. Wait briefly (10-15 seconds) to allow the ORCA FOAM® Sterile Powder to become hydrated with the sterile saline solution. (Fig-3)
4.Push the hydrated gelatin powder back into the sterile saline solution syringe. Continue exchanging the solution between syringes until all components are thoroughly mixed (approximately 10 exchanges) and the consistency is even. If at any point the mixture does not appear uniform, perform additional exchanges between syringes to ensure contents are adequately mixed and the resulting mixture looks homogenous.(Fig-4)
5.Disconnect the syringe without pre attached connector and attach an applicator tip (trimmable) to the syringe containing the hydrated Gelatin powder, if desired. The applicator tip should be cut at a square angle to avoid creating a sharp tip, if desired. The hydrated gelatin powder may also be dispensed directly from the syringe.(Fig-5)
6.The resulting mixture may be smeared, filled, or pressed against the bleeding surface to control bleeding. When bleeding stops, the excess hydrated gelatin powder should be removed.
7.Use only the minimum amount of hydrated gelatin powder necessary to produce hemostasis. The ORCA FOAM® may be left in place at the bleeding site, when necessary. Since ORCA FOAM® causes little more cellular reaction than does the blood clot, the wound may be closed over it. ORCA FOAM® may be left in place when applied to mucosal surfaces until it liquefies.
8.Once the ORCA FOAM™ Sterile Powder in the ORCA FOAM® Powder Kit is hydrated within the syringe, contents are subject to contamination.
9.When used as a ORCA FOAM® Powder 1g Prefilled Syringe Kit, draw 10 mL of sterile, isotonic sodium chloride solution (sterile saline) into an empty 25mL sterile syringe, (diluent not included). Liquid transfer cup may be used. The desired consistency of hemostat can be achieved by adjusting the volume of hydrating sterile saline up to 3 hours prior to the use, using standard sterile technique as described for the ORCA FOAM® Powder 550mg Prefilled Syringe Kit. It will yield an average of 11mL of uniform mixture within the syringe, with a measured minimum delivery volume of 10 ml.

When used as ORCA FOAM® Powder (1 gm/ 2 gm/ 3 gm/ 5 gm)
in Bellow Bottle as a dry powder, follow instructions below:
1.Open the pack, take out the bellow bottle and unlock it by rotating the cap.
2.Remove the cap; pump the desired amount of ORCA FOAM® Powder by holding the neck of bottle by fingers and pressing the mini-vac part of the bottle by thumb. Replace the cap after use.
3.Two pcs. of applicator (trimmable tip with retainer clip) is provided. An applicator may be attached to the bellow bottle, if desired. The trimmable applicator tip should be cut at a square angle to avoid creating a sharp tip. The dry powder may also be dispensed directly from the bellow bottle.(Fig-6)
4.Compress the source of bleeding for 2-3 minutes using dry compress afterwards. When bleeding stops, the excess product should be removed.

ADVERSE REACTIONS:
The following are the potential adverse events that are generally associated with the use of absorbable gelatin hemostat ORCA FOAM® ;
- Life-threatening anaphylactic reactions, including death, have been reported after exposure to porcine absorbable gelatin (see WARNINGS).
- Product migration to the cerebral ventricular space followed by hydrocephalus or cerebrospinal fluid retention leading to secondary intervention, has been reported following neurosurgery in the vicinity of the ventricular space (see PRECAUTIONS).
- There have been reports of fever associated with the use of absorbable gelatin sponge/powder, without demonstrable infection. absorbable gelatin sponge may serve as a nidus of infection and abscess formation, and has been reported to potentiate bacterial growth. Giant cell granuloma has been reported at the implantation site of absorbable gelatin product in the brain, as has compression of the brain and spinal cord resulting from the accumulation of sterile fluid.
- Absorbable gelatin sponge should not be used if there is recurrent massive upper gastrointestinal hemorrhage. It may result in extensive gastric necrosis/massive gastric gangrene and therapeutic transcatheter embolization of the left gastric artery.
- It should not be left in the renal pelvis, renal calyces, bladder, urethra or ureters to eliminate the potential foci for calculus formation.
- After placement, absorbable hemostatic agents may be visible on imaging studies until they are fully absorbed, which could be interpreted as pseudo tumor / pseudo mass appearance.
- Pseudo infection / pseudo abscess has also been reported in the literature.
- Pseudo-tumor / pseudo-mass and pseudo infection / pseudo abscess may result in additional invasive procedures, re-operations, and prolonged hospital stays.
- When absorbable gelatin sponge was used in laminectomy operations, multiple neurologic events were reported, including but not limited to cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.
- Foreign body reactions, encapsulation of fluid and hematoma have also been reported.
- Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin products were used in severed tendon repair.
- Toxic shock syndrome has been reported in association with the use of absorbable gelatin sponge in nasal surgery.
- Fever, failure of absorption, and hearing loss have been reported in association with the use of absorbable gelatin sponge during Tympanoplasty.

Adverse Reactions Reported from Unapproved Uses
- Absorbable gelatin sponge is not recommended for use other than for topical application to bleeding surfaces as a hemostatic agent.
- While some adverse medical events following the unapproved use of absorbable gelatin sponge have been reported (see ADVERSE REACTIONS), other potential harms associated with such use may not have been reported.
- When absorbable gelatin sponge has been used during intravascular catheterization for the purpose of producing vessel occlusion, the following adverse events have been reported; vessel recanalization, intravascular gelatin migration, fever, end organ ischemia and infarction, pancreatitis, post-embolization syndrome, ischemia and infarction at unintended locations (such as duodenum and pancreas), duct stenosis (such as bile duct stenosis), gangrene, infection, necrosis, organ dysfunction, infertility, embolization of extremities, pulmonary embolization, splenic abscess, asterixis, and death.
- The following adverse medical events have been associated with the use of absorbable gelatin sponge for repair of dural defects encountered during laminectomy and craniotomy operations: fever, infection, leg paresthesias, neck and back pain, bladder and bowel incontinence, cauda equina syndrome, neurogenic bladder, impotence, and paresis.
- The following adverse medical events have been associated with the use of absorbable gelatin sponge with or without bone dust for repair of dural and cranial defects encountered during burr-hole operations or craniotomies: cerebrospinal fluid retention and hydrocephalus leading to secondary intervention (see PRECAUTIONS).

STERILIZATION:
ORCA FOAM® is sterilized by gamma radiation. Use of the device with opened and/or damaged packaging; reprocessing and/or re-sterilization; may lead to its failure and subsequent injury and/or create the risk of contamination, patient infection, illness or death.

STORAGE:
ORCA FOAM® Powder should be stored dry in a clean, dry room at the temperature not more than 30°C. It is recommended that ORCA FOAM® Powder be used as soon as the package is opened.
Do not refrigerate or freeze.
Do not use after the expiry date!

STERILE R

ORCA PROFESSIONAL
Innovation. Integrity. Trust.

- Instructions for Use

- **Store at temperature not more than 30° C.**
  Do not refrigerate or freeze.

Absorbable Gelatin Sponge Powder Hemostat, USP

ORCA® FOAM POWDER

Manufacturer | Date of manufacture | 30°C **Store at temperature not more than 30° C. Do not refrigerate or freeze.** | **Keep Dry**

Consult instructions for use | REF **Catalogue number** | **Single use** | **Do not Re-sterilize** | MD **Medical Device**

Do not inject into blood vessels | STERILE R **Radiation sterilisation** | **Warning** | LOT **Batch code** | **Expires**

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Revision: December 2024 0B 10171.05

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