# Embosphere®

English

MICROSPHERES

## INSTRUCTIONS FOR USE

### DESCRIPTION
Embosphere® Microspheres are biocompatible, hydrophilic, non-absorbable, precisely calibrated acrylic polymer microspheres impregnated with porcine gelatin. They are available in a large range of sizes and concentrations. These spheres are designed to offer controlled, targeted embolisation.

### IMPLANTABLE DEVICE MATERIALS TABLE

| Material | Duration of exposure | Level of patient exposure (maximum solid content by vial) |
|---|---|---|
| Trisacryl Copolymer | Long-Term (> 30days) | 159 ± 6 mg |
| Gelatin | Long-Term (> 30days) | 23 ± 1 mg |

### HOW SUPPLIED
8-mL glass vial closed with screw-top cap, individually packaged in blister tray sealed by a peel-away Tyvek® lid.
Contents: 1 mL or 2 mL of microspheres in sterile, pyrogen-free 0,9% NaCl solution. Total volume of saline and microspheres: 5 mL.

### INTENDED PURPOSE
Embosphere Microspheres are designed to occlude arteries for therapeutic or preoperative purposes.

### INDICATIONS FOR USE
Embosphere Microspheres are indicated for arterial embolisation in patients undergoing treatment for the following clinical conditions:
- Hypervascular tumours, including uterine fibroids, meningiomas, and liver tumours.
- Hypervascular processes, including genicular artery embolisation (GAE) in patients with mild-to-moderate knee osteoarthritis who are refractory to standard-of-care first-line conservative treatment (e.g., physical therapy, medical therapy [NSAIDs, opioids], intra-articular corticosteroid injections).
- Benign Prostatic Hyperplasia (BPH) and associated prostate artery embolisation (PAE).
- Arteriovenous malformation (AVM).
- Bleeding/haemorrhage.

### INTENDED PATIENT POPULATION
The intended patient population is as follows:
- Women with diagnosed symptomatic fibroids, who no longer desire fertility but who wish to avoid surgery or are poor surgical or anaesthetic risks.
- Patients with diagnosed meningiomas and who are eligible for embolisation procedure.
- Patients with diagnosed intermediate stage liver tumours who are not eligible for curative treatments.
- Patients with pain and/or disability associated with mild-to-moderate knee osteoarthritis who are refractory to standard-of-care first-line conservative treatment (e.g., physical therapy, medical therapy [NSAIDs, opioids], intra-articular corticosteroid injections).
- Men with mild to moderate to severe lower urinary tract symptoms (LUTS) secondary to diagnosed Benign Prostatic Hyperplasia (BPH).
- Patients with diagnosed resectable or non resectable arteriovenous malformations (AVM).
- Patients with post-partum bleeding, and posttraumatic upper gastrointestinal bleeding secondary to visceral pathology or complicating portal hypertension, hepatic, splenic, pelvic outside the post-partum (complications of gynaecological surgery, prostatic vesicle, inoperable tumours of gynaecological origin or vesico-prostatic).

### INTENDED USER
The Embosphere Microspheres are intended to be used by specialist physicians trained in vascular embolisation procedures.

### DEVICE LIFETIME
The device lifetime for Embosphere Microspheres is defined as time from implantation to patient death.

### CLINICAL BENEFITS
The clinical benefits of embolisation treatment with Embosphere Microspheres for:
- Patients with hypervascular tumours, such as,
  - uterine fibroids, include relief of related symptoms and improved quality of life.
  - meningiomas, include reduction of intraoperative blood loss during resection procedure.
  - liver tumours, include relief of related symptoms and improved clinical outcomes.
- Patients with hypervascular processes, including knee osteoarthritis, relief of pain symptoms and improved quality of life.
- Patients with benign prostatic hyperplasia (BPH) include relief of related lower urinary tract symptoms (LUTS) and improvement of quality of life.
- Patients with arteriovenous malformations (AVM) include relief of related symptoms.
- Patients with haemorrhage include immediate and long-term bleeding control.

For a copy of this device's current European Summary of Safety and Clinical Performance (SSCP), please go to the European database on medical devices (Eudamed), where it is linked to the basic UDI-DI. https://ec.europa.eu/tools/eudamed. Basic UDI-DI: 088445048794EK. Alternatively, download a copy of the SSCP from: https://www.merit.com/sscp

### PERFORMANCE CHARACTERISTICS
Embosphere Microspheres are non-resorbable permanent embolisation microspheres. Their spherical shape, their size and mechanical properties allow making controlled, selective, targeted and complete embolisations. Moreover, their sphericity, their calibration and compressibility, supplemented by hydrophilic properties allow for a facilitated injection through (micro-) catheters. Finally, they have properties of biocompatibility for long-term implantation.

### MAGNETIC RESONANCE IMAGING
Embosphere Microspheres are made of tris-acryl polymer impregnated with porcine gelatin and are magnetic resonance (MR) compatible.

### CONTRAINDICATIONS
All indications
- Patients unable to tolerate vascular occlusion procedures.
- Vascular anatomy or blood flow precluding correct catheter placement or embolic agent injection.
- Presence of arteries supplying the lesion not large enough to accept Embosphere Microspheres.
- Presence of collateral vessel pathways potentially endangering normal territories during embolisation.
- Presence or likely onset of vasospasm.
- Vascular resistance peripheral to the feeding arteries precluding passage of Embosphere Microspheres into the lesion.
- In large diameter arteriovenous shunts (i.e., where the blood does not pass through an arterial/capillary/venous transition but directly from an artery to a vein).
- High-flow arteriovenous shunts or with a diameter greater than the selected microspheres.
- Use in the pulmonary arteries.
- Presence of severe atheromatous disease.
- Patients with known allergy to gelatin.

50-100 µm, 40-120 µm and 100-300 µm microspheres are not recommended for use in the bronchial circulation.

UFE Specific Contraindications
- Pregnant women
- Suspected pelvic inflammatory disease or any other active pelvic infection
- Any malignancy of the pelvic region
- Endometrial neoplasia or hyperplasia
- Presence of one or more submucosal fibroid(s) with more than 50% growth into the uterine cavity
- Presence of pedunculated serosal fibroid as the dominant fibroid(s)
- Fibroids with significant collateral feeding by vessels other than the uterine arteries

GAE Specific Contraindications
- Presence or likely onset of hemorrhage
- Active systemic or local knee infection
- Prior total knee replacement in the target knee
- Excessive vessel tortuosity or severe atherosclerosis

PAE Specific Contraindications
- Active urinary tract infection or prostatitis
- Prostate cancer
- Bladder cancer
- Chronic renal failure
- Bladder atonia, neurogenic bladder disorder, or other neurological disorder impacting bladder function
- Bladder stones
- Urinary obstruction due to causes other than BPH, including urethral stricture
- Excessive vessel tortuosity or severe atherosclerosis

Neurological Specific Contraindications
- Presence of patent extra-to-intracranial anastomoses or shunts
- Presence of end arteries leading directly to cranial nerves
- In any vasculature where Embosphere Microspheres could pass directly into the internal carotid artery, vertebral artery, intracranial vasculature or the above listed vessels

### POTENTIAL COMPLICATIONS
All indications
Potential complications that may be associated with use of the Embosphere Microspheres include, but are not limited to, the following:
- Foreign body reaction necessitating medical intervention
- Allergic reaction due to embolic material
- Cutaneous irritations (e.g. rash), possibly delayed from the time of embolisation

Risks associated with routine embolisation procedures and underlying patient condition include, but are not limited to, the following:
- Complications related to catheterization (e.g. haematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, nerve and/or circulatory injuries which may result in leg injury, infection)
- Vessel or lesion rupture and haemorrhage
- Occlusion of vessels in healthy territories
- Paralysis resulting from untargeted embolisation or ischemic injury from adjacent tissue edema
- Stroke or cerebral infarction
- Ischaemia at an undesirable location, including ischaemic stroke, ischaemic infarction (including myocardial infarction), and tissue necrosis
- Blindness, hearing loss, loss of smell, and/or paralysis
- Capillary bed occlusion and tissue damage
- Death
- Deep vein thrombosis with or without pulmonary embolism
- Undesirable reflux or passage of Embosphere Microspheres into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds, such as the internal carotid artery, pulmonary, or coronary circulations
- Pulmonary embolism due to arterial venous shunting
- Vasospasm
- Recanalisation/neovascularisation
- Foreign body reaction necessitating medical intervention
- Infection necessitating medical intervention
- Allergic reaction to medications (e.g. analgesics)
- Allergic reaction due to contrast media
- Post-embolisation syndrome, such as transient pain, nausea, vomiting, fever, possibly delayed from the time of embolisation.
- Transient hypertensive episode

Additional information is found in the Warnings section

UFE Specific Potential Complications
- The most frequently anticipated post procedure complications are abdominal pain, discomfort, fever and/or nausea, collectively known as "Post-embolisation Syndrome." Some patients may also experience constipation. This is generally managed with prescription or over-the-counter medications.
- Premature ovarian failure (i.e., menopause)

- Amenorrhea
- Infection of the pelvic region
- Uterine/ovarian necrosis
- Phlebitis
- Vaginal discharge
- Tissue passage, fibroid sloughing, or fibroid expulsion post UFE
- Post-UFE intervention to remove necrotic fibroid tissue
- Vagal reaction
- Hysterectomy

GAE Specific Potential Complications
- Skin discoloration (due to non-target embolisation)
- Skin ulceration (due to non-target embolisation)
- Osteonecrosis (bone infarct)
- Paresthesia (toe/leg)

PAE Specific Potential Complications
- The most frequent post-procedure complication includes "Post-PAE Syndrome," which includes nausea, vomiting, fever, pelvic pain, burning sensation, dysuria, and frequent or urgent urination
- Non-targeted embolisation of the rectum, bladder, scrotum, penis, or other areas
- Skin burn (radiation exposure) from prolonged fluoroscopy time
- Blood in urine, semen, or stool
- Bladder spasm
- Urinary tract infection
- Urinary retention
- Constipation
- Urethral obstruction

Neurological Specific Potential Complications
- Ischemic stroke or ischemic infarction
- Neurological deficits, including cranial nerve palsies

**PRECAUTION**

All indications
- Embosphere Microspheres must only be used by specialist physicians trained in vascular embolisation procedures. The size and quantity of microspheres must be carefully selected according to the lesion to be treated, entirely under the physician's responsibility. Only the physician can decide the most appropriate time to stop the injection of microspheres.
- Patients with known allergy to contrast medium may require corticosteroids prior to embolisation.
- Additional evaluations or precautions may be necessary in managing periprocedural care for patients with the following conditions:
  - Bleeding diathesis or hypercoagulative state
  - Immunocompromise
- Do not use if the vial, screw cap, blister tray or peel-away film appear damaged.
- This is a disposable product. Discard opened vials after use.
- For single patient use only - Contents supplied sterile.
- Never reuse, reprocess, or resterilise. Reusing, reprocessing or resterilising may compromise the structural integrity of the device and/ or lead to device failure, which in turn may result in patient injury, illness or death. Reusing, reprocessing or resterilising may also create a risk of contamination of the device and/ or cause patient infection or cross infection including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. All procedures must be performed according to accepted aseptic technique.
- The vial is intended for embolic use only. Do not use for any other application.

UFE Specific Precautions
- There is an increased chance of retro-migration of Embosphere Microspheres into unintended blood vessels as uterine artery flow diminishes. Embolisation should be stopped when the vasculature surrounding the fibroid can no longer be visualized but before complete stasis in the uterine artery.
- UFE should only be performed by specialist physicians who have received appropriate training for treatment of uterine leiomyomata (fibroids).

Liver tumour Specific Precautions
- There is no known incompatibility between Embosphere Microspheres and chemotherapeutics used for the treatment of liver tumours.

GAE Specific Precautions
- Reflux of Embosphere Microspheres into unintended blood vessels could occur as genicular artery flow diminishes. Embolisation should be stopped when appropriate pruning of the neovascularity is visualised, and pathologic hyperemia is resolved.
- Consider the use of ice packs on the skin to minimize transient skin discoloration following the procedure.
- Limited clinical data are available regarding the recommended number of genicular artery branches to be treated during a GAE procedure as well as the number of repeat GAE interventions that may be safely performed for an individual patient.

PAE Specific Precautions
- The PAE procedure should only be performed by specialist physicians who have received appropriate training.
- Collateral circulation may be present and can dilate and supply adjacent arteries as resistance within the prostatic bed increases. Therefore, there is potential for severe complications with nontargeted embolisation.
- There is an increased chance of retro-migration of Embosphere Microspheres into unintended blood vessels as prostatic artery flow diminishes. Embolisation should be stopped when the vasculature surrounding the prostate can no longer be visualized but before complete stasis in the prostatic artery.

Haemostatic indication Specific Precautions
- Embolisation of the splenic artery may be associated with inferior vena cava thrombus.

**WARNINGS**

All indications
- Embosphere Microspheres contain gelatin of porcine origin, and, therefore, could cause an immune reaction in patients who are hypersensitive to collagen or gelatin. Careful consideration should be given prior to using this product in patients who are suspected to be allergic to injections containing gelatin stabilizers.
- Studies have shown that Embosphere Microspheres do not form aggregates, and as a result, penetrate deeper into the vasculature as compared to similarly sized PVA particles. Care must be taken to choose larger sized Embosphere Microspheres when embolising arteriovenous malformations with large shunts to avoid passage of the spheres into the pulmonary or coronary circulation.
- Some of the Embosphere Microspheres may be slightly outside of the range, so the physician should be sure to carefully select the size of Embosphere Microspheres according to the size of the target vessels at the desired level of occlusion in the vasculature and after consideration of the arteriovenous angiographic appearance. Embosphere Microspheres size should be selected to prevent passage from artery to vein.
- Because of the significant complications of misembolisation, extreme caution should be used for any procedures involving the extracranial circulation encompassing the head and neck, and the physician should carefully weigh the potential benefits of using embolisation against the risks and potential complications of the procedure. These complications can include blindness, hearing loss, loss of smell, paralysis and death.
- Serious radiation-induced skin injury may occur to the patient due to long periods of fluoroscopic exposure, large patient diameter, angled x-ray projections, and multiple image recording runs or radiographs. Refer to your facility's clinical protocol to ensure the proper radiation dose is applied for each specific type of procedure performed. Physicians should monitor patients that may be at risk.
- Onset of radiation-induced injury to the patient may be delayed. Patients should be counseled on potential radiation side effects and whom they should contact if they show symptoms.
- Pay careful attention for signs of mistargeted embolisation. During injection carefully monitor patient vital signs to include SaO2 (e.g. hypoxia, CNS changes). Consider terminating the procedure, investigating for possible shunting, or increasing microsphere size if any signs of mistargeting occur or patient symptoms develop.
- Consider upsizing the microspheres if angiographic evidence of embolisation does not quickly appear evident during injection of the microspheres

UFE Specific Warnings

Warnings About UFE and Pregnancy
- The effects of UFE on the ability to become pregnant and carry a fetus to term, and on the development of the fetus, have not been determined. Therefore, this procedure should only be performed on women who do not intend future pregnancy.
- Women who become pregnant following UFE may be at increased risk for postpartum haemorrhage, preterm delivery, cesarean delivery, and malpresentation.
- Devascularization of the uterine myometrium resulting from UFE may theoretically put women who become pregnant following UFE at increased risk of uterine rupture.

Other UFE Warnings
- When using Embosphere Microspheres for uterine fibroid embolisation, do not use microspheres smaller than 500 microns.
- An appropriate gynecologic work-up should be performed on all patients presenting for embolisation of uterine fibroids (e.g., gynecologic history, fibroid imaging, endometrial sampling to rule out carcinoma in patients with abnormal menstrual bleeding).
- The diagnosis of uterine sarcoma could be delayed by taking a nonsurgical approach (such as UFE) to treating fibroids. It is important to pay close attention to warning signs for sarcoma (e.g., rapid tumour growth, postmenopausal with new uterine enlargement, MRI findings) and to conduct a more thorough work-up of such patients prior to recommending UFE. Recurrent or continued tumour growth following UFE should be considered a potential warning sign for sarcoma and surgery should be considered.

GAE Specific Warnings
- A thorough clinical evaluation should be performed on all patients presenting for embolisation of the genicular arteries to rule out localized infection, rheumatoid arthritis, malignancy.
- Embolisation with Embosphere Microspheres for GAE should only be performed by physicians who have received appropriate interventional embolisation training in the region to be treated. Collateral circulation may be present and can dilate and supply adjacent arteries with a potential for severe complications with non-targeted embolisation.

PAE Specific Warnings
- A thorough clinical evaluation should be performed on all patients presenting for embolisation for BPH (e.g., urinalysis, digital rectal exam, symptom scores, prostate imaging, prostate-specific antigen test, transrectal ultrasound) to rule out prostate cancer.
- Because of the tortuous vessels and duplicative feeding arteries in the pelvic area, extreme caution should be used when performing prostatic artery embolisation (PAE). Complications of mistargeted embolisation include ischemia of the rectum, bladder, scrotum, penis or other areas.
- When using Embosphere Microspheres for prostatic artery embolisation, do not use microspheres smaller than 100 microns. It is recommended to use 300-500 microns.

Warnings About PAE and Fertility
- The effects of PAE on fertility have not been determined. Therefore, this procedure should not be performed on men wanting to father a child.

Haemostatic Specific Warnings
- Since Embosphere Microspheres have not been evaluated to control bleeding or haemorrhaging for neurovascular indications, they should not be used for this purpose in the neurovasculature.
- To avoid mistargeted embolisation during bronchial artery embolisation (BAE) procedures, it is recommended to use microspheres larger than 300 microns.

Warnings about use of small microspheres
- Careful consideration should be given whenever use is contemplated of embolic agents that are smaller in diameter than the resolution capability of your imaging equipment. The presence of arteriovenous anastomoses, branch vessels leading away from the target area or emergent vessels not evident prior to embolisation can lead to mistargeted embolisation and severe complications.
- Microspheres smaller than 100 microns will generally migrate distal to anastomotic feeders and therefore are more likely to terminate circulation to distal tissue. Greater potential of ischaemic injury results from use of smaller sized microspheres and consideration must be given to the consequence of this injury prior to embolisation. The potential consequences include: swelling, necrosis, paralysis, abscess and/or stronger post embolisation syndrome.
- Post-embolisation swelling may result in ischaemia to tissue adjacent to target area. Care must be given to avoid ischaemia-intolerant, nontargeted tissue such as nervous tissue.

**INSTRUCTIONS FOR USE**

- Carefully evaluate the vascular network associated with the lesion using high resolution imaging prior to beginning the embolisation procedure.
- Embosphere Microspheres are available in a range of sizes. Because of the potential for misembolisation and the inherent variability in sphere sizes, the physician should be sure to carefully select the size of Embosphere Microspheres according to the size of the target vessels at the desired level of occlusion in the vasculature.
- Carefully select the size of microspheres according to the size of the vessels identified and the catheter used. Embosphere Microspheres are flexible particles that support temporary compression by 20 to 30% microns to facilitate passage through microcatheters. Studies have shown a direct correlation between the size of microspheres and the size of occluded vessels.
- Choose a delivery catheter based on the size of the target vessel and the microsphere size being used. Refer to below table for catheters and Embosphere Microspheres sizes compatibility.
- Embosphere Microspheres are not radiopaque. It is recommended that the embolisation be monitored using fluoroscopic visualization by adding the appropriate amount of non-ionic contrast medium to the physiologic suspension fluid.

**To Deliver Embosphere Microspheres**

- Inspect packaging and vial before use to ensure that they are intact. The external surface of the vial is sterile.
- According to aseptic technique, open the peel-away film beginning at the tip, and peel back the film completely to the base. Gently tip the sterile vial on the sterile field, avoiding contact with any parts previously sealed.
- Gently swirl the opened vial, then pour into a sterile metal / stainless steel cup or a large mixing syringe.
- It is highly recommended to add non-ionic contrast agent to monitor the injection radiologically. Dilute Embosphere Microspheres with non-ionic contrast medium either into a small sterile cup or directly into a large mixing syringe. It is recommended that 50% non-ionic contrast and 50% physiological saline be used for best suspension. To ensure proper suspension, gently agitate the mixture of Embosphere Microspheres and non-ionic contrast and wait 2-3 minutes after mixing, prior to injection.
- Draw up the suspension using a 1 mL or 3 mL injection syringe and attach the syringe to the delivery catheter. Check that the desired quantity and concentration of microspheres are used.
- Inject the Embosphere Microspheres/contrast solution into the delivery catheter under fluoroscopic visualization using a slow pulsatile injection while observing the contrast flow rate. If there is no effect on the flow rate, repeat the delivery process with additional injections of the Embosphere Microspheres/contrast solution. Consider using larger sized Embosphere Microspheres if the initial injections do not alter the contrast flow rate. Always inject under free flow conditions. Reflux of microspheres can induce immediate ischaemia of healthy tissues or vessels.
- Continue infusion until the desired devascularisation is obtained. Studies have shown that Embosphere Microspheres penetrate more distally into the lesion than PVA particles of similar size. Reduction of the arterial blood supply to the lesion is therefore more progressive. Exercise conservative judgment in determining the embolisation endpoint.
- Femoral puncture can result in arterial spasm. This may predispose to femoral thrombosis (e.g. leg injury). Femoral patency should be re-assessed prior to final catheter removal.
- At the end of the infusion, remove the catheter while maintaining gentle suction to avoid dislodging any residual microspheres still within the catheter lumen.
- Apply pressure to the puncture site until haemostasis is complete.
- Discard any open vial or unused Embosphere Microspheres.

Additional UFE Specific Instructions

- When embolising uterine fibroids, choose an Embosphere Microsphere of 500 microns or greater.
- At the discretion of the physician, pneumatic compression devices may be used for patients currently taking hormone therapy, uterine volume >1000cc, and patients that are overweight to lower the risk of deep vein thrombosis.
- Embolisation should be stopped when the vasculature surrounding the fibroid can no longer be visualized but before complete stasis in the uterine artery. There is an increased chance of retro-migration of Embosphere Microsphere into unintended blood vessels as uterine artery flow diminishes.

Additional Meningioma and Liver tumours Specific Instructions

- For embolisation of meningiomas and liver tumours, it is recommended to use 40-120 microns Embosphere Microspheres.

Additional GAE Specific Instructions

- When embolising hypervascularity associated with knee osteoarthritis, only size 100-300 microns Embosphere Microspheres is applicable.

Additional PAE Specific Instructions

- For prostatic artery embolisation, it is recommended to use Embosphere Microspheres 300-500 microns.
- A Foley catheter, with its balloon inflated with a mixture of non-ionic contrast and saline, may be placed prior to PAE for use as a landmark during the embolisation procedure.
- PAE can be performed by either radial or femoral access.

Additional AVM Specific Instructions

- When embolising arteriovenous malformations (AVMs), choose an Embosphere Microsphere size that will occlude the nidus without passing through the AVM.

**CONSERVATION / STORAGE / DISPOSAL**

- Embosphere Microspheres must be stored in a cool, dry and dark place in their original vial and packaging.
- Use by the date indicated on the vial label.
- Do not freeze.
- Do not resterilize.
- After use, Embosphere Microspheres must be disposed as per hospitals contaminated waste circuit.

| Size Range (µm) | Minimum Catheter ID | Color Code | 1 mL | 2 mL |
|---|---|---|---|---|
| 50-100 | 0.016" (0.41 mm) | Grey | V010GH* | V020GH* |
| 40-120 | 0.016" (0.41 mm) | Orange | V110GH* | V120GH* |
| 100-300 | 0.017" (0.43 mm) | Yellow | V210GH* | V220GH* |
| 300-500 | 0.018" (0.46 mm) | Blue | V410GH* | V420GH* |
| 500-700 | 0.020" (0.51 mm) | Red | V610GH* | V620GH* |
| 700-900 | 0.027" (0.69 mm) | Green | V810GH* | V820GH* |
| 900-1200 | 0.038" (0.97 mm) | Purple | V1010GH* | V1020GH* |

*For version, see box label.

**PATIENT COUNSELING INFORMATION**

- Patients should have a clear understanding prior to embolisation of who will provide their post procedure care and whom to contact in case of an emergency after embolisation.
- Embolisation patients should have an understanding of the potential benefits, risks, and adverse events associated with embolisation. In particular, patients should understand that there is a chance their symptoms will not improve following embolisation.

Information on packaging

| | |
|---|---|
| | Manufacturer |
| | Date of manufacture: YYYY-MM-DD |
| | Use by: YYYY-MM-DD |
| LOT | Lot number |
| REF | Catalog number |
| | Do not resterilize |
| | Do not use if package is damaged and consult instruction for use |
| | Keep away from sunlight |
| | Keep dry |
| | Single use |
| | Caution |
| | Non-pyrogenic |
| STERILE | Sterilized using steam |
| 0° C | Lower limit of temperature |
| MD | Medical Device |
| UDI | Unique Device Identifier |
| | Single sterile barrier system with protective packaging inside |
| | Consult Instructions for Use. For electronic copy scan QR Code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within seven calendar days, call U.S.A. or EU Customer Service. |
| BIO | Contains biological material of animal origin |
| CE 2797 | CE mark - Notified body identification: 2797 |

In the European Union, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

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