TauroPace™

Catalogue # TP-08

A. Description and Specification

TauroPace™ contains a disinfecting substance to eradicate environmental microbial contamination on the surface of cardiac implantable electronic devices (CIEDs). The surface of the CIED is moistened with TauroPace™ before the implantation procedure to create a hostile environment on its surface. The antimicrobial substance in TauroPace™ is taurolidine. Other components include water for injection and polyvinylpyrrolidone (PVP). The pH is adjusted with sodium hydroxide. TauroPace™ is supplied as a clear, sterile and nonpyrogenic solution.

B. Purpose

The purpose is to eradicate environmental microbial contamination on the surface of cardiac implantable electronic devices (CIEDs) before implantation.

C. Indications

TauroPace™ is intended to be used by healthcare professionals as a disinfecting solution in any adult patient before implantation of any uncoated or silicon-, epoxy- or polyurethane-coated CIED (including its components, e.g. leads) made of titan or stainless steel.

D. Contraindications

TauroPace™ must not be used if the patient has a known allergy to taurolidine or any of its ingredients. Due to lack of clinical experience in children and adolescents, TauroPace™ should not be used in patients less than 18 years.

E. Cautions

1. Follow the manufacturer's instructions that accompany the particular cardiac device to be implanted.
2. As a consumable TauroPace™ is for single use only.
3. To be efficient, TauroPace™ is to be used as an extracorporeal disinfecting solution as described in the instruction for use. Although no safety issues are to be expected from unintended exposure, any TauroPace™ thereby coming into contact with the implantation pocket (e.g. by rinsing) needs to be removed before suture.
4. TauroPace™ must not be mixed with povidone-iodine, Dakin's solution or hydrogen peroxide (oxidizing agents). When mixing these agents with TauroPace™, taurolidine is degraded to formic acid.
5. The concentration of the antimicrobial compound is near to saturation. If not stored or transported according to the instructions in section H, precipitation can occur in the product. Do not use TauroPace™ solution when particles are visible.

F. Adverse Effects

To date, there are no known adverse effects of TauroPace™ during and after implantation procedure.

G. Application of TauroPace™

- TauroPace™ is intended to be used by healthcare professionals experienced in implantation of CIEDs.
- If the sterile packaging of TauroPace™ is damaged, the product must not be used.
- Before opening the bottle check this product visually for particles. If there are visible particles, do not use.
- Dispose any unused residues of TauroPace™ in accordance with the institutions' waste policy.

Application to CIEDs:

1. A sterile dish is filled with TauroPace™ and sterile surgical compresses are placed in TauroPace™ until thoroughly soaked.
2. Leads and fixing suture are wiped down right before placement with the TauroPace™-soaked compresses.
3. After unpacking of the CIED its complete surface is wiped down with TauroPace™-soaked compresses to keep the CIED's surface moist at any time prior to implantation.
4. Prior to final placement of the CIED and after connection to the leads in place, both leads and CIED as well as suture keeping the CIED in place are wiped down with TauroPace™-soaked compresses.

H. Storage and Shipment

TauroPace™ must be stored and shipped at a temperature between 15 to 25 °C. Do not store it in a refrigerator.

I. Packaging configuration

The following packaging configurations are available for TauroPace™: 10 x 100 mL vials; 10 x 250 mL vials.

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STERILE Sterilized using steam or dry heat.

Read instruction for use.

Do not re-use.

Do not use when package is damaged.

CE 0344 CE acc. MDD 93/42/EEC, notified body: DEKRA Certification B.V.