

PROSTHETIC COMPONENTS: PREMIUM-SHELTA CONICO ABUTMENTS

Instructions For Use:

For detailed information on the specific procedure for the product you are using, please refer to the individual product labels or the appropriate Surgical Manual(s) and/or Catalogue(s) also available on the Sweden & Martina Website.

Description:

Sweden & Martina PREMIUM-SHELTA Conico Abutments are manufactured from biocompatible Gr.5 titanium and polymethylmethacrylate (PMMA). Please refer to product guidelines for use/Surgical Manual for additional device information.

Indications For Use:

PREMIUM-SHELTA Conico Abutments are intended to be used in conjunction with a PREMIUM-SHELTA Implants Systems in fully edentulous or partially edentulous maxillary and/or mandibular arches.

The PREMIUM-SHELTA Conico Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

PREMIUM-SHELTA Conico Abutments are compatible with PREMIUM-SHELTA Implants Systems. Anchorage of dentures retained by taper friction and supported by PREMIUM-SHELTA Implants Systems.

Contraindications:

Placement of Sweden & Martina PREMIUM-SHELTA Conico Abutments are precluded by known patient hypersensitivity to any of the materials listed in the Description section above.

Warnings:

Mishandling of small components inside the patient's mouth carries a risk of aspiration and/or swallowing. Fracture of a restoration may occur when an abutment is loaded beyond its functional capability. Reuse of Sweden & Martina Products that are labelled as single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

Small diameter implants and angled abutments are not recommended for the posterior region.

Precautions:

Sweden & Martina PREMIUM-SHELTA Conico Abutments should only be used by trained professionals. The surgical and restorative techniques required to properly utilize these products are highly specialized and complex procedures. Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration. The PREMIUM-SHELTA Conico Abutments have not been evaluated for safety and compatibility in the Magnetic Resonance environment. The PREMIUM-SHELTA Conico Abutments have not been tested for heating, migration or image artifact in the MR environment. The safety of PREMIUM-SHELTA Conico Abutments in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Sterility:

Non-sterile Prosthetic Components

Non-sterile Prosthetic Components sterilization is to be used for the recommended sterilization parameters. Products provided non-sterile need to be sterilized prior to use; it is the responsibility of the user to establish whether or not their sterilizer has been cleared by the FDA to meet

these recommended parameters, and to use accessories (BIs, CIs, and wraps/pouches/containers) cleared by FDA. Please refer to the individual product labels or Surgical Manual(s) for more information. For products provided non-sterile requiring sterilization prior to use, Sweden & Martina recommends the following sterilization parameters for wrapped items:

- Sterilization parameters
 - autoclave (Dynamic-Air-Removal Cycles) at a temperature of 132°C with a exposure time of 4 minutes and a minimum drying of 20 minutes.

FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters when wrapping the device in a pouch.

Storage and Handling:

Sweden & Martina PREMIUM-SHELTA Conico Abutments should be stored at room temperature. Refer to individual products labels and the Surgical Manual for special storage or handling conditions.

Potential Adverse Events:

Potential adverse events associated with the use of restorative products may include: failure to integrate; loss of integration; dehiscence requiring bone grafting; infection as reported by: abscess, fistula, suppuration, inflammation, radiolucency; gingival hyperplasia; excessive bone loss requiring intervention; fracture; and nerve injury.

Waste Disposal Procedures

Prosthetic components, if removed from the oral cavity, must be treated as organic waste for their disposal, according to the laws that are locally applied. On the other hand, if the implants are sent to Sweden & Martina with a request for execution of a Surf Test, the protocol given on the website www.sweden-martina.com must be followed.

Caution:

U.S. Federal Law restricts this device to sale by or on the order of a dentist.

Manufacturer's details

The Manufacturer of the medical devices is: