sweden & martina
IMPLANTOLOGY

PROSTHETIC COMPONENTS: PRAMA WHITE IMPLANT SYSTEMS

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 Prosthetic Components are manufactured from biocompatible Gr.4 titanium, Gr.5 titanium, polymethylmethacrylate (PMMA), polyoxymethylene (POM), polyetheretherketone (PEEK), zirconium, gold alloy, and cobalt chromium alloy. Please refer to product guidelines for use/Surgical Manual for additional device information.

Indications For Use:
PRAMA White Abutments are intended to be used in conjunction with a PRAMA White Implant Systems in fully edentulous or partially edentulous maxillary and/or mandibular arches.
The PRAMA White 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.
PRAMA White Abutments are compatible with PRAMA White Implant Systems.

Contraindications:
Placement of Sweden & Martina Prosthetic Components 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.
PEEK components, are intended for use to support single- or multiple-unit temporary prostheses in the mandible or maxilla for up to 180 days, at which time definitive prostheses should be inserted.

Precautions:
Sweden & Martina Prosthetic Components should only to 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. Components made from PEEK material are intended for use for up to 180 days.
The PRAMA Implant Systems have not been evaluated for safety and compatibility in the Magnetic Resonance environment. The PRAMA Implant Systems have not been tested for heating, migration or image artifact in the MR environment. The safety of PRAMA Implant Systems 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 Prosthetic Components 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 bon grafting; infection as reported by: abscess, fistula, suppuration, inflammation, radiolucency; gingival hyperplasia; excessive bone loss requiring intervention; fracture; and nerve inquiry.

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:

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Sweden & Martina S.p.A.
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CE 0476 Rx Only NON STERILE

The Symbols glossary is available at:
http://www.sweden-martinainc.com/en_us/ifu/

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