sweden & martina
IMPLANTOLOGY

DENTAL IMPLANT: PREMIUM ONE IMPLANT SYSTEMS

Instructions For Use:
For a detailed explanation of the osteotomy preparation and implant placement guidelines, refers to the appropriate Surgical Manual(s).

Description:
Sweden & Martina Dental Implants are manufactured from biocompatible Gr. 4 titanium. Sweden & Martina dental Implant include various surface treatments. For specific product descriptions refer to individual product labels.

Indications For Use:
Premium One One Implant Systems are intended for both one- and two-stage surgical procedures. Premium One Implant Systems are intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.

Contraindications:
Placement of dental implants may be precluded by both patient conditions that are controindicated for surgery as well as hypersensitivity to commercially pure titanium. Sweden & Martina Dental Implants should not be placed in patients where the remaining jaw bone is too diminished to provide adequate implant stability.

Warnings:
Excessive bone loss or breakage of a dental implant may occur when an implant is loaded beyond its functional capability. Physiological and anatomical conditions may affect the performance of dental implants.
Mishandling of small components inside the patient's mouth carries a risk of aspiration and/or swallowing. Forcing the implants, clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes to the implant's response to percussion or radiographic changes in bone to implant contact along the implant's length. If the implant shows mobility or greater than 50% bone loss, the implant should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible fixture. In addition, the clinician should allow longer periods for osseointegration and avoid immediate loading. Reuse of Sweden & Martina Products that are labelled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended. When tightening the cap screws, post screws or prosthetic screws, you must adhere strictly to the tightening torque recommended in the appropriate Surgical Manual(s) and/or Catalogue(s). A tightening torque which is too high could weaken the mechanical structure of the screw and compromise the prosthetic stability, causing possible damage to the implant connection.

Precautions:
These devices are only to be used by trained professionals. The surgical and restorative techniques required to properly utilize these devices are highly specialized and complex procedures. Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration. When the clinician has determined adequate primary stability is achieved, immediate functional loading can be considered. The following should be taken into consideration when placing dental implants: bone quality, oral hygiene and medical conditions such as blood disorders or uncontrolled hormonal conditions. The healing period varies depending on the quality of the bone at the implantation site, the tissue response to the implanted device and the surgeon's evaluation of the patient's bone density at the time of the surgical procedure. Proper occlusion should be evaluated on the implant restoration to avoid excessive force during the healing period on the implant. The PREMIUM ONE Implant Systems have not been evaluated for safety and compatibility in the Magnetic Resonance environment.The PREMIUM ONE Implant Systems have not been tested for heating, migration or image artifact in the MR environment. The safety of PREMIUM ONE Implant Systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Sterility:
All dental implants are supplied sterile and are labelled "STERILE". All products sold sterile are for single-use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize.

Storage and Handling:
Devices should be stored at room temperature. Refer to individual products labels and Surgical Manual for special storage or handling conditions.

Potential Adverse Events:
Potential adverse events associated with the use of the dental implants may include: failure to integrate, loss of integration, dehiscence requiring bone grafting, perforation of the maxillary sinus, inferior border, lingual plate, labial plate, inferior alveolar canal or gingiva, infection as reported by abscess, fistula, suppuration, inflammation, or radiolucency, persistent pain, numbness, paraesthesia, hyperplasia, excessive bone loss requiring intervention, implant breakage or fracture, systemic infection, nerve inquiry, and aspiration.

Waste disposal procedures:
Fixture implants, if removed from the oral cavity as a result of a biological or mechanical failure, must be treated as organic waste for their disposal, according to the 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:

sweden & martina

Sweden & Martina S.p.A.
Via Veneto 10
35020 Due Carrare (Padova) - Italy
Tel. +39 049.91.24.300 - Fax + 39 049.91.24.290
e-mail: info@sweden-martina.com
Website: www.sweden-martina.com

CE 0476 

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

rev.07-17