

WARNING!!!

Reading and understanding conditions stated in the user guide which given with the product is important for consumers. Users who takes this document, will be agreed terms and conditions.

INSTRUCTION MANUAL

Dental implant treatment involves a complex surgical and restorative procedures. Such operations should be performed by trained dentists in this area. Inadequate training leading to surgical and prosthetic complications and may cause the failure of implant and it's restoration . For a detailed description of the osteotomy preparation and implant placement guidelines , please refer to the appropriate surgical manual / manuals.

DESCRIPTION

Supra Medical Dental Implants are manufactured from biocompatible titanium. Micro structure of Supra Medical Dental Implant surface has passed surface processing to obtain optimal surface. The components included in the box are as down. In the following order ; implants , abutment , internal screw , screw plug and impression cap.

DENTAL IMPLANT SYSTEM PARTS



DENTAL IMPLANT

ABUTMENT

INNER SCREW

CLOSING SCREW

PLASTIC IMPRESSION

INDICATIONS

Parts of Supra Medical Dental Implant System can be used in partially or fully toothless maxillary or mandibular arch, to support multi-teeth or all arc fixed and/or removable dentures.

Also, in the jaw and facial defects, in patients who have difficulty to use removable partial dentures , patients with more expectations than full dentures, in patients with excessive vomiting reflex , as for orthodontic anchorage , conservative treatment request (the patient's request to not interfere with healthy teeth) is indicated in patients .

CONTRAINDICATIONS

Supra Medical Dental Implants , should not be used in patients have jaw osteomyelitis , anatomical defects and deficiencies , TMJ disorders, excessive jaw parafunctions, poor oral hygiene, macroglossia, bruxism, repeated oral mucosal diseases and patients in radiotherapy.

!!Parts of Supra Medical Dental Implant System , systemically; diseases related to bone system, endocrine diseases , and hematopoietic system disorders, rheumatic diseases, chronic kidney diseases, liver cirrhosis, jaw-related allergic disorders, immune system disorders , focal infections, jaw- related tumoral disease conditions should be consulted with the patient's doctor.

WARNINGS

Implants are sterile in package. Products should be used as sterile. The box cover should not be opened any way before using. Surgery kit pieces are not sterile . Before using, kit pieces should be sterile by autoclave method.

Supra Medical Dental Implant system components must only be used with its own system components. Implants must be placed with suitable diameter, sufficient number and on an axis that compatible with dental arch . Length and diameter of burs which according to implant should be used.

Against the risk of contamination, when removed from the sterile package the implant should be placed immediately in the socket with the help of the kit equipment, without touching implant surface.

In the case of overloaded on an implant more than the functional capacity, excessive bone loss or dental implant breakage may occur.

Physiological and anatomic conditions may affect the performance of dental implants. Wrong using of small pieces inside the patient's mouth carry a risk of aspiration and / or swallowing. To try inserting implant in a socket more than its depth may cause bone or implant damage.

If mobility of implant or bone loss indicates more than 50%, removal of the implant should be evaluated .

Reusing of disposable labeled Supra Dental products, may cause of contaminated product, patient infection and / or cause the product to show low performance . Therefore, they are not suitable for second use.

Implants which drops to the ground , the patient's mouth and surgical table should never be used. In case of using these implants can cause contamination.

INFORMATION TO PATIENTS

Surgical site should be kept clean preoperative and postoperative. After the operation, cold compresses should be applied. Patients should be informed about the disinfection of the surgical site. The area that implants placed should not be exposed to load and chewing act early.

SIDE EFFECTS

When using Supra Medical Dental Implants, the following side effects may occur ; opening wound sutures, late healing , numbness, swelling , bleeding, hematoma, infection, inflammation , local or general allergic reactions.

PACKAGING AND STERILIZATION

Supra Medical implants , closing screws , abutments, internal screws and measurements parts are all sterile-packed together. Gamma radiation is used for sterilization of the implant .

Optimal storage temperature is nearly +4 celcius degree. Sterilization is valid until the expiration date stated on the label. Deformed packages and expired products should not be used.

Contaminated implants can not be sterilized again. Re-use of implant can cause clinical failure, infection and lack of integration of the implant, bone resorption and damaging to adjacent structures, and maybe exceed worst complications. Do not touch the surface of the implant by hand , as this may impair its surface properties. Set pieces must be sterilized by autoclave according to the standards of sterilization techniques.

SHELF LIFE

The expiry date is clearly marked on each implant package.

STORAGE AND USING

Products should be stored in its original packaging. In case of damaging the tube of protecting the sterility of the product, it should not be used. Do not store in extremely hot or direct sunlight environment.

TREATMENT PLANNING

Detailed patient examination, pre operation xray's, pre-op diagnosis and treatment planning should be ready before surgery operation. Insufficient planning and diagnosis may cause complications and implant failure.

SURGICAL PROCEDURE

Preparation of the implant area must be prepared with drills, which are in Supra Medical surgical set, with 300-800 rpm processing speed and under good irrigation . Must be very careful about bone overheat.

Avoid the use of drills which has lost its sharpness. It may cause unnecessary trauma and overheat in the bone. Drill procedure shown in next table:

Implant Diameter \ Bone Type	D1	D2	D3	D4
3.7	2 PF 3 3.7	2 PF 3 3.7	2 PF 3	2 PF
4.3	2 PF 3 3.7 4.3	2 PF 3 3.7 4.3	2 PF 3 3.7	2 PF 3

5.0	2 PF	2 PF	2 PF	2 PF
	3	3	3	3
	3.7	3.7	3.7	3.7
	4.3	4.3	4.3	4.3
	5.0	5.0	5.0	5.0

PLACEMENT OF THE IMPLANT

Check the length and diameter of the implant from the product label. There is a label on the product packing to provide traceability. Affix the label to the patient’s file. Open the outer pack and pour out the sterile inner pack to surgical area.

Use the Supra Medical implant carrier to transport implants to surgically prepared implant slot.

Opening the implant package is as follows:

- 1- Tear the area on the top of the carton box to open the top cover.
- 2- Open cover of the plastic packaging which is in box.
- 3- Release slowly colorful plastic box reversing to surgical table.
- 4- Open the cover which is “1” number on the top of the colored plastic box.
- 5- Put implant carrier into implant slowly and fit into implant, then pull implant slowly with counter-clockwise movement
- 6- Put implant in drill socket with clockwise movement by implant carrier and ratchet until implant neck comes same plane bith bone level.
- 7- Pull out the closing screw under the number “1”cap with handle, then put on implant with clockwise movement.

HEALING PROCESS FOR IMPLANTS

Generally depending on the patient's bone quality, type and the overall health status, implants should be allowed to osseointegration for 3-4 months.

Immediate loading can be applied by proven techniques in literature protocols. If immediate loading will be applied, first screwing torque of implant should be more than 35Ncm. Occlusion should be checked. If there is multi implants, they can fix by splints. In total toothless, minimum implant should be placed in maxilla is 6, in mandible is 4.

PLACEMENT

Supra Medikal abutments fix in implants by inner screw. 30-35 Ncm torque is optimal for fixing inner screw, and optimal connection. Supra Medikal implant systems are compatible with Supra surgery kit

Symbols



Refer User Guide



Non-Sterile



Lot Number



Steriled by Radiation



Reference Number



Expiration Date



Manufacturer address



Single use only



do not use damaged packages



Warning