

User Manual

1) Product description

Withmate Implant is made of titanium and grafted in the maxillary or mandibular alveolar bone for surgical treatment. It plays the role of natural dental root. Refer to the manual or the catalogue or our website (www.withmateimplant.com) for detail. See the product label for the product code, specifications, manufacturing date, and expiration date.

2) Use

Should be used in accordance with the general implant guide.

3) Indications

- Generally good health, healthy oral cavity
- Predicted normal healing of wounds
- Jaw bone that has stopped growing
- Good oral cavity hygiene
- Available bone sufficient for vertical, mesio/distal, and buccal/lingual space
- Patient's full recognition of the risk in the course of performing each implant treatment

4) Contraindications

Withmate Implant should not be used in cases where the remaining alveolar bone is too diminished to provide adequate width or height to surround the implant, Lack of osseointegration or subsequent implant, failure may occur in cases where there is insufficient available bone, poor bone quality, poor oral hygiene heavy smoking, tobacco abuse, or medical conditions such as blood disorders or uncontrolled diabetes.

5) Warnings

The selection of inappropriate patients and operation methods can cause implant failure or loss of bone supporting the implant. Withmate implants must not be used for purposes other than the recommended use and must not be remodeled. Implant mobility, bone loss, and chronic infection can result in failure of the implant surgery.

6) Precautions

The surgical technology of dental implant involves an expert, complex procedure. Formal training is required to perform implant surgery. Determine the local anatomy and suitability of the available bone for implant placement. Prepare the implant considering the expected situations and cautions. Visual inspections as well as panoramic and periapical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and the adequacy of the bone. Adequate radiographs, direct palpation, and visual inspection of the implant site are necessary prior to treatment, planning and use of Withmate implant.

7) Adverse reactions

A few problems may occur after the operation (loss of implant stability, damage of prosthesis, etc.) deficient quality and quantity of the remaining bone, infection, inferior oral hygiene or uncooperativeness of patient, implant mobility, partial deterioration of tissue, and improper position or arrangement of implants may cause the above mentioned problems.

8) Surgical complications

The implant procedure has risk, including localized swelling, dehiscence, tenderness of short duration, edema, hematoma, or bleeding. Numbness of the lower lip and chin region following lower jaw surgery, and of the tissue beside the nose following upper jaw surgery, is a possible side-effect of the surgery. Though it would most probably be of a temporary nature, in very rare cases, the numbness has been permanent. Gingival-mucosal (gum tissue) ulceration, tissue reaction, or infection may occur, but generally responds to local care.

9) Sterilization and handling

The implant has been cleaned and sterilized by gamma irradiation and is ready to use. The sterilized product must be used in a sterilized environment with sterilized tools. If the packaging is damaged, or if the expiration date has passed, do not use the product. Expired or contaminated product must not be re-sterilized; they must be disposed of.

10) Storage Condition

Keep the product in a dry place at room temperature (1°C~20°C). Keep away from direct sunlight. This product is valid for 3 years from the date of manufacture, please observe the validity date.

11) Cautions for use

Determine the number, angles, and positions of the implants to be grafted considering a minimum gap of 3mm between implant. Local anesthesia is used; an anesthetic solution should be sufficient to anesthetize the periosteum surface. Conventional implant treatment should be applied. When using engine driver, the recommended speed is 15rpm, and maximum torque, 35Ncm. Once the maximum torque is reached, detach the driver mounted in the hand piece. Afterward, connect the torque wrench and perform grafting while rotating the hand-driver clockwise.

Symbol_Description



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Rx only

For USA only : Federal law restricts this
device to sale by or on the order of a dentist



Reference code



Use by date



Do not reuse



Date of manufacture



Catalogue number



Non sterile



Lot No.



Caution



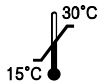
Representative



Manufacture



Keep away
sunlight



Temperature