

precautions and warnings

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CE 0086

Important! Please read

Description Nobel Biocare manufactures dental implants from biocompatible titanium, and abutments from titanium and ceramic materials. The implants are supplied with various titanium and hydroxy apatite surfaces. Accessory restorative components are produced in gold alloy and polymers, as well as titanium.

Indications Nobel Biocare's dental implants are used as the foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to an entire arch of bridgework, as well as retentive elements for overdenture applications. Dental implants are intended to be used in a manner in which they integrate with the bone (osseointegration).

Contraindications Pre-operative patient evaluation is necessary to determine any factors which put the patient at risk from the implant placement procedure itself, or factors that may affect healing capabilities of either the bone or associated soft tissue. Dental implants should not be used in patients who are unfit medically for a general oral surgical procedure. For patients who have localized or systemic factors that could be expected to interfere with the healing process of either bone or soft tissue (e.g. connective tissue disorders, steroid therapy, infections in bone, cigarette smoking) the potential benefits and risks of treatment need to be carefully evaluated.

In addition, the patient needs to have an adequate volume of residual bone for placing sufficient size and numbers of implants to support the anticipated functional loads to which the patient will subject these implants. Insufficient size or numbers of implants to support biomechanical loads or undesirable positioning of implants can lead to mechanical failures including fatigue fracture of implants, prosthetic screws and/or abutment screws. Implant placement and prosthetic design must accommodate individual patient conditions such as bruxism or unfavorable jaw relationships to reduce the risk of overload or fatigue failure, and treatment is contraindicated if adequate accommodation cannot be accomplished. If inadequate bone volume is present, augmentation procedures can be considered. Please consult appropriate clinical manuals and textbooks for information on treatment planning and medical evaluation.

Warning Treatment planning and placement of dental implants requires special considerations compared to dentistry in general. It is recommended that practitioners take courses with hands-on training to learn proper techniques, including biomechanical requirements and radiographic evaluation. Improper technique in either implant placement or restoration can result in implant failure and substantial loss of surrounding bone.

Drilling procedures for implant placement use specific drill measurement systems and reference points unique for each system listed below:

- Replace® Select Tapered
- Replace® Select Straight
- Brånemark System®
- NobelDirect®
- NobelDirect® 3.0
- NobelActive™
- NobelSpeedy™
- NobelReplace™
- NobelPerfect®
- Brånemark System® Zygoma Implants
- Nobel Biocare Immediate Provisional Implant

The practitioner is directed to the measurement description in the appropriate clinical manual, specific to the implant system selected (see above) before any drill preparation takes place around vital structures. Each implant system has unique measuring characteristics to allow full seating of the implant to the desired depth. In some instances, drill length reference lines measure longer than the stated length of the implant. It is recommended that the implant surgeon be thoroughly familiar with the specific measurement system being utilized and provide a suitable safety margin adjacent to any teeth and vital structures. Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures by drilling beyond the depth intended, potentially resulting in permanent numbness to the lower lip and chin from lower jaw surgery or other injury.

Each implant system has specific design characteristics for mating implants, abutments and prosthetic components. Combining components that are not configured or dimensioned for correct mating can lead to mechanical failure of components, damage to tissue, or unsatisfactory esthetic results.

One-hundred percent success cannot be guaranteed. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases are some potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved. Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulation. With respect to children, routine treatment is not recommended until growth has stopped and epiphyseal closure has occurred.

Sterility All implants, and various abutments (see labels) are shipped sterile, and are for single use only prior to the labeled expiration date. Do not use implants if the packaging has been damaged or previously opened. Abutments that are delivered sterile and have never been used in the oral cavity may be re-sterilized. (See manuals listed above). Products not provided sterile by the manufacturer must be cleaned and sterilized (if indicated) according to the instructions in the appropriate manual before intra-oral use (see above). For steam sterilization of kits (not applicable for Try-in Abutment Kit Box and Brånemark System® Zygoma Surgical Kit Box), sterilize at 134°C/274°F, for 6 minutes.

General Precautions Surgical and restorative products used to achieve and maintain osseointegration as described by Professor Brånemark, et al., should be utilized by persons trained in this method. Such training is offered at a number of centers. Please contact manufacturer for information. Each patient must be carefully examined and evaluated to determine radiographic, psychological and physical status. Additionally, the patient's teeth and any associated bone or soft tissue deficits that will influence the final result should also be evaluated. Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for success.

Procedural Precautions, Surgery All efforts must be made to minimize damage to the host tissue, paying special attention to thermal and surgical trauma and to the elimination of contaminants and sources of infection. The surgical procedure requires a high degree of precision and care, and the limits for acceptable tissue handling are much narrower than in general oral surgery. Any divergence from the principle of least possible trauma at implant installation increases the risk of failure to establish osseointegration. Tilting implants – implants may be tilted up to 45°. If the angulation is 30° or more, it is necessary to splint the tilted implants. All drilling procedures should be performed at low speed (approximately 800 rpm for tapered drills and up to 2000 rpm for straight drills). Pre-tapping (threading of the bone) and implant placement should be accomplished at very low speed (~ 25–30 rpm) or manually. All drilling and pre-tapping procedures require the use of dedicated, sharp instruments under constant and profuse irrigation for cooling. Implants are ideally installed in a stable manner; however, excessive insertion torque (greater than 45–50 Ncm) to overcome bone resistance may lead to damage to the implant; fracture or necrosis of the bone site (see appropriate clinical manuals). All instruments used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components. Because of the small size of implant components and instruments, care must be taken that they are not swallowed or aspirated by the patient. After the implant installation, the surgeon's evaluation of bone quality and initial stability will determine when implants may be loaded.

Procedural Precautions, Prosthetics Especially important is proper stress distribution: passive adaptation and fitting of the bridge to the implant abutments; adjusting occlusion to the opposing jaw; avoiding excessive transverse loading forces, particularly in immediate loading cases. If the prosthesis metal substructure is made of gold alloy, this should have a high gold content. Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.

Adverse Effects Implant techniques have normal contraindications and risks. These are extensively documented in the dental literature.

Caution The caution text "Federal (USA) law restricts the sale of this device to, or on the order of, a licensed physician or dentist" is shown on labels with "Rx Only".