Instructions for use

Neoss ProActive® Implants Ø6.5

Description
This Instructions For Use (IFU) is specifically for Neoss ProActive® Implant Ø6.5. The flange diameter on Ø6.5 implants is 6.7 mm. Wide implants can provide additional means of anchorage in certain challenging cases, such as extraction sites and sinus floor elevations, when compared to narrow implants.

Indications
Dental implants from Neoss Limited are used as the means of anchorage between crowns, bridges or dentures and the surrounding bone in the upper or lower jaws. Such prostheses may range from replacement of a single tooth to an entire arch of bridgework and cement or screw retained restorations. The Neoss Implants – Neoss Implant System are also intended for immediate placement and function on single tooth and/or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

Contraindications
Treatment is contraindicated where the patient has a preexisting allergy to the used parts. Use of drills and instruments with other than Neoss products is contraindicated.

Procedures
This Instructions For Use (IFU) is for Neoss ProActive® Implant Ø6.5. For additional information on Neoss implants and detailed information on the other specific Neoss Implant System products you are using, please consult general Instructions For Use (10538) and Neoss Implant System Guidelines (10501).

A specific X-ray Planner is available.

The surgical procedure may entail a range of procedures including minimally invasive surgery and raising a full thickness flap, exposing the bone in the proposed site. A series of increasing diameter drills are used to enlarge the osteotomy for implant placement – this may involve the use of a countersink.

The positions of the implant sites are determined using a round bur, lance drill or 2.2 mm twist drill. Incremental site preparation is carried out as recommended in the chart.

Note: In presence of dense bone, additional care is taken during insertion. The thread cutting and forming design of the implant acts as a screw tap. Use reverse torquing 1/2-1 turn before continuing.

All preparation of the bone tissue is carried out under profuse irrigation with saline and using an intermittent drilling technique. This prevents overheating bone and creates a pumping effect for efficient removal of bone debris.

II

Regular Bone

Ø2.2
Ø3.0
Ø3.6
Ø4.4
Ø5.1
Ø6.0
Recommended speed for drills is 800–2000 rpm using lower speed for larger drills, 800 rpm for countersinks.

**Drill Depth Guide**
This guide shows an 11 mm Neoss ProActive® implant in relation to a twist drill and depth guide. Please note actual distance to drill tip is 0.8 mm longer than the reference line.

**Single Use Drills**
The drills are delivered sterile. Please refer to the Cleaning and Sterilisation section in the Neoss Implant System Guidelines (10501) for re-sterilisation and cleaning recommendations when required.

The drills shall be placed in sterile solution (saline) during surgery if the drills are used for more than one preparation. Ensure sterile handling during preparation and surgery.

Please note instruments that are re-sterilized may not perform as intended by the manufacturer. It is the users’ responsibility to ensure that instruments have not become damaged or worn resulting in decreased performance during cleaning, re-sterilization and handling.

**General Precautions**
Surgical products used to achieve and maintain osseointegration should be utilized by persons trained in this method. Such training is offered at a number of centers. Please contact the manufacturer for information. Pre-operative hard tissue or soft tissue deficits may result in a compromised esthetic outcome or unfavorable implant angulation. Pre-operative patient evaluation and close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for success. Neoss implants, abutments and abutment screws must be used solely on one patient. Single use devices should not be reused due to risks of product contamination, patient/user infection and/or failure of the device to perform as intended. Neoss drills and surgical instruments are used for sole placement of Neoss implants.

The Neoss products are MRI safe. Based on evaluating MR data it can be concluded that dental implants and abutments within the Neoss Dental Implant System will unlikely interfere with patient safety under the MRI conditions up to 7T. Image artefacts still needs to be considered at image analysis. Handling of hazardous material according to established procedures at the hospital/clinic.

**Procedural Precautions**
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. Incorrect clinical placement or loading resulting in loss of implant anchorage or loss of the prosthesis are possible events after surgery. Lack of bone quantity or quality, infections, poor patient hygiene or cooperation, and general diseases are some potential causes for loss of anchorage and function.

**Sterility**
All Neoss implants and related bone cutting instruments are supplied sterile with a given expiry date as indicated by the packaging. For re-sterilization please refer to the Neoss Implant System Guidelines (10501).

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**Caution**
Federal (USA) law restricts the sale of this device to or on the order of a licensed physician or dentist. For additional information, precautions and warnings for Neoss Implants please refer to Instructions For Use for Neoss Implant System (10538).