Instructions for use

Neoss ProActive® Edge Implants

Description
This Instructions For Use (IFU) is specifically for Neoss ProActive® Edge Implant. The flange diameters on ProActive Edge Implants are shown in the table.

<table>
<thead>
<tr>
<th>Implant diameter (mm)</th>
<th>Flange diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø3.5</td>
<td>Ø4.0</td>
</tr>
<tr>
<td>Ø4.0</td>
<td>Ø4.3</td>
</tr>
<tr>
<td>Ø4.5</td>
<td>Ø4.9</td>
</tr>
<tr>
<td>Ø5.0</td>
<td>Ø5.4</td>
</tr>
</tbody>
</table>

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. Please note use of the ProActive Edge Implant for fully guided implant placement, i.e. utilizing the Neoss Guide Implant Mount for placement with a stop through a guide, is contraindicated. Guided preparation of the site, i.e. utilizing the drills and the Drills-Hubs for preparation through a guide, is not contraindicated.

Procedures
This Instructions For Use (IFU) is for Neoss ProActive® Edge Implants. 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).

Specific X-ray Planner and Clinical Organizer are 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.

Note: Take care during the insertion as the large thread pitch allows for fast implant insertion and seating.
Torque control can be used – a maximum of 45 Ncm is recommended. The machine installation of the implant is carried out at low speed – recommended maximum of 20 rpm.

Recommended speed for drills is 800–2000 rpm using lower speed for larger drills, 800 rpm for countersinks.

Debris.

Drilling technique. This prevents overheating bone and creates a pumping effect for efficient removal of bone debris.

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.

Recommended speed for drills is 800–2000 rpm using lower speed for larger drills, 800 rpm for countersinks. The machine installation of the implant is carried out at low speed – recommended maximum of 20 rpm. Torque control can be used – a maximum of 45 Ncm is recommended.

Guidelines
In the chart, identify the appropriate column for the intended implant diameter. Identify the appropriate bone quality marking in the column. This is the last preparation step in the sequence. Starting at the top of the column, all preparations start with the Ø2.2 mm twist drill, move down to the next marking and prepare the site with the drill corresponding to that marking. If a marking is dashed, it is non-mandatory, unless it is the last preparation step. Keep moving down the column until the final preparation is performed at the relevant bone quality marking.

Example: The drill sequence for a Ø4.0 implant in dense bone starts with the Ø2.2 mm twist drill followed by the Ø3.0 T drill. The dashed Ø3.0 T drill step can be omitted.

Use of countersink is not required in situations where under-preparation of the cortical bone is desirable in order to increase cortical anchorage, such as soft bone.

Note: The guiding portion of the Countersink Edge is designed to match the drill for regular bone. If a narrower osteotomy (soft bone) needs countersinking, widening of the cortical part of the osteotomy with the regular bone drill might be required to properly seat the countersink.

Additional notes
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. There are no screw taps for the ProActive Edge implant system. Neoss screw taps are not compatible with the ProActive Edge Implant.

The drills in the ProActive Edge Implant protocol are the same bone cutting instruments as used for the ProActive Tapered implant drill protocol. 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.

Drill Depth Guide
This guide shows an 11 mm Neoss ProActive® Edge 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.

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.

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.