NobelActive®
Instructions for use

Important: Please read.
Disclaimer of liability:
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Description:
NobelActive® implants are endosseous implants intended to be surgically placed in the jaw bone, one must avoid damage the nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

Cautions:
General:
One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure. Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.

Implant:
NobelActive® dental implants are made from bio-compatible commercially pure grade 4 titanium with TiUnite® surface. The NobelActive® WP implant comes with a co-packed Cover Screw made of titanium alloy Ti-6Al-4V.

Tooling:
Nobel Biocare Twist Drills, Twist Step Drills and Screw Taps are made of stainless steel with DLC (Diamond Like Carbon) coating and should be used in conjunction with NobelActive® implants.

Indications for use:
NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.

NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

NobelActive® 3.0 implants are indicated for single unit restorations only.

Contraindications:
It is contraindicated placing NobelActive® in patients:
– who are medically unfit for an oral surgical procedure.
– with inadequate bone volume unless an augmentation procedure can be considered.
– in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or essentially partial functional loads.
– allergic or hypersensitive to commercially pure titanium (grade 4), titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), stainless steel, or DLC (Diamond Like Carbon) coating.
NobelActive® 3.0 implants are not indicated to replace a central incisor, a canine, a premolar or a molar in the maxilla nor to replace a canine, a premolar or a molar in the mandible.
NobelActive® 3.0 implants are not indicated for multiple tooth replacements.

Warnings:
Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mouth.

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

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At surgery:
Particular caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.

All instruments and tooling used during procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient.

NobelActive® implants may be tilted up to 45° relative to the occlusal plane. When used with angulations between 30° and 45°, the following applies: The tilted implant must be splinted; a minimum of 4 implants must be used when supporting a fixed prosthetic in a fully edentulous arch.

After the implant installation, the surgeon’s evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.

After surgery:
To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

Special instructions when placing NobelActive® implants:

Full seating of implant:
The unique thread design of NobelActive® implants allows to redirect the implant during insertion. This feature requires special attention to execute during placement, as the implant will not necessarily stop at the bottom of the prepared site, but may go deeper into the bone.

Insertion speed of implant:
The thread pitch allows the implant to be inserted up to four times faster compared to other implants. This means that significantly less turns are required to fully seat the implant.

Implant tightening:
If a Surgical Driver is used to insert the implant, special care needs to be taken to avoid overtightening.

Special instructions when placing NobelActive® 3.0 implants:

Indications:
NobelActive® 3.0 implants are only intended to be used for replacement of a lateral incisor in the maxilla; lateral and/or central incisor in the mandible. NobelActive® 3.0 implants are indicated only for single unit restorations.

Insertion torque for NobelActive® 3.0:
Due to the narrow implant diameter and narrow implant abutment connection the maximum insertion torque for NobelActive® 3.0 differs from the entire NobelActive® assortment. The maximum insertion tightening torque for the 3.0 implant is 45 Ncm and the maximum prosthetic abutment tightening torque is 15 Ncm.

Caution: Never exceed insertion tightening torque of 45 Ncm for the implant and 15 Ncm prosthetic tightening torque for the abutment screw. Overtightening of implant may lead to damage of the implant, fracture or necrosis of the bone site. Overtightening of the abutment screw may lead to screw fracture.
**Surgical procedure:**

1. During drilling procedures bone quality should be considered (please see table 1: recommended drill sequences based on bone quality to ensure optimal primary stability when applying immediate function).

**Recommended drill sequences based on bone quality. Drill data are stated in mm and the drill diameters listed within brackets denote widening of cortex only.**

<table>
<thead>
<tr>
<th>Implant diameter</th>
<th>Soft Bone Type IV</th>
<th>Medium Bone Type II-III</th>
<th>Dense Bone Type I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø 3.0</td>
<td>1.5</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>(2.4/2.8)</td>
<td>(2.4/2.8)</td>
<td>(2.8/3.2)</td>
</tr>
<tr>
<td>Ø 3.5</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>(2.4/2.8)</td>
<td>(2.4/2.8)</td>
<td>2.4/2.8</td>
</tr>
<tr>
<td>Ø 4.3</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>2.4/2.8</td>
<td>2.4/2.8</td>
<td>2.4/2.8</td>
</tr>
<tr>
<td>Ø 5.0</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
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<tr>
<td></td>
<td>2.4/2.8</td>
<td>2.4/2.8</td>
<td>2.4/2.8</td>
</tr>
<tr>
<td></td>
<td>3.2/3.6</td>
<td>3.2/3.6</td>
<td>3.2/3.6</td>
</tr>
<tr>
<td></td>
<td>3.8/4.2</td>
<td>3.8/4.2</td>
<td>3.8/4.2</td>
</tr>
<tr>
<td>Ø 5.5</td>
<td>2.0</td>
<td>2.0</td>
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<td></td>
<td>2.4/2.8</td>
<td>2.4/2.8</td>
<td>2.4/2.8</td>
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<tr>
<td></td>
<td>3.2/3.6</td>
<td>3.2/3.6</td>
<td>3.2/3.6</td>
</tr>
<tr>
<td></td>
<td>3.8/4.2</td>
<td>3.8/4.2</td>
<td>(4.2/4.6)</td>
</tr>
</tbody>
</table>

Drilling must proceed at high speed (max. 2000 rpm for Twist Step Drills) under constant and profuse external irrigation by sterile saline at room temperature.

**Caution:** Twist Drills and Twist Step Drills extend up to 1 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures (please see image A for drill reference lines).

2. Prepare implant site (B). When using a flapless approach add-on soft tissue height to drill depth.

3. Measure the final depth of implant site for applicable implant length using depth probe with same measurements as Twist Drills and Twist Step Drills.

4. Open the implant package and pick up the implant from inner casing by applying light pressure on the implant driver and carefully turn the implant sleeve counter clockwise until implant driver is fully seated (C). NobelActive® implants are ideally installed with low speed, max 25 rpm, using drilling device or by hand using surgical driver.

5. Place and tighten the implant. For NobelActive® 3.0 use maximum 45 Ncm installation torque (D:1) and for NobelActive® 3.5, 4.3, 5.0 and 5.5 use maximum 70 Ncm installation torque (D:2).

6. For Immediate Function, the implant should be able to withstand a final torque of 35–45 Ncm for NobelActive® 3.0 implant and 35–70 Ncm for NobelActive® 3.5, 4.3, 5.0, and 5.5 implants.

**Caution:** Never exceed insertion torque of 45 Ncm for a NobelActive® 3.0 implant and 70 Ncm for NobelActive® 3.5, 4.3, 5.0 and 5.5 implants.

To ensure ideal prosthetic abutment orientation for internal conical connection implants position one of the internal hexagon flat surfaces in the implant towards buccal/facial.

7. Depending on surgical protocol of choice, place a cover screw or abutment and suture (F).

8. If the implant gets stuck during implant installation or 45 Ncm (NobelActive® 3.0) or 70 Ncm (NobelActive® 3.5, 4.3, 5.0, and 5.5) is achieved before fully seated:

a) rotate the implant counterclockwise approximately ½ turn enabling use of self-tapping capacity of the implant or

b) back out implant and widen the site with a wider drill according to drill protocol or

c) select a NobelActive® Screw tap matching the diameter of the implant. Drill depth for screw tap (E:1 for 3.0, 3.5 and 4.3, E:2 and E:3 for 5.5)

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2 Implant data

<table>
<thead>
<tr>
<th>Platform</th>
<th>Implant diameter</th>
<th>Abutment diameter</th>
<th>Lengths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø 3.0 mm</td>
<td>Ø 3.0 mm</td>
<td>Ø 2.5 mm</td>
<td>10 mm, 11.5 mm, 13 mm, 15 mm</td>
</tr>
<tr>
<td>Ø 3.5 mm</td>
<td>Ø 3.5 mm</td>
<td>Ø 3.0 mm</td>
<td>8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 16 mm</td>
</tr>
<tr>
<td>Ø 3.9 mm</td>
<td>Ø 4.3 mm</td>
<td>Ø 3.4 mm</td>
<td>8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm</td>
</tr>
<tr>
<td>Ø 5.1 mm</td>
<td>Ø 5.5 mm</td>
<td>Ø 4.4 mm</td>
<td>7 mm, 8.5 mm, 10 mm, 11.5 mm, 13 mm, 15 mm</td>
</tr>
</tbody>
</table>

For additional information on surgical procedures please consult the NobelActive® “Procedures & products” treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:
NobelActive® implant: commercially pure titanium grade 4
Cover Screw: titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).
Twist Drills, Twist Step Drill and Screw Taps: stainless steel, DLC (Diamond Like Carbon) coating.

Cleaning and sterilization instructions:
NobelActive® Implants, Twist Drills and Twist Step Drills are delivered sterile for single use only prior to the labeled expiration date.
Caution: Do not use device if the packaging has been damaged or previously opened.
Reprocessed could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.
NobelActive® Screw Taps are delivered sterile but indicated for multiple use. Screw Taps needs to be cleaned and sterilized before re-use.
For USA: Seal single device in a pouch and steam sterilize at 270°F–279°F (132°C–137°C) for 3 minutes.
For outside USA: Seal single device in a pouch and steam sterilize at 132°C–138°C, max. 137°C (270°F–275°F, max. 279°F) for 3 minutes.
Alternative UK: Seal single device in a pouch and steam sterilize at 134°C–136°C, max. 137°C (273°F–275°F, max. 279°F) for 3 minutes.

Full set of recommended parameters are provided in “Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products” available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

MR safety information:
Note: Only the NobelActive® Wide Platform implants have been assessed as MR Conditional. The other platforms and sizes have not been evaluated for safety and compatibility in the MR environment and have not been tested for heating or migration in the MR environment.
MR Conditional:
Non-clinical testing has demonstrated that product is MR Conditional. A patient with this device can be safely scanned in a MR system meeting the following conditions:
- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode)
Under the scan conditions defined above, the product is expected to produce a maximum temperature rise of 4.1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 30 mm from the product when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.
Removal restorations should be taken out prior to scanning, as is done for watches, jewelry etc.
Should there be no MR symbol on the product label, please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration levels into account.
For additional information on Magnetic Resonance Imaging, please consult the “Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products” available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Storage and handling:
The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal:
Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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Canada license exemption: Please note that not all products may have been licenced in accordance with Canadian law.

Prescription device: Rx only
Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

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