Important: Please read.

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Description:
The product is an individualized implant supported bar construction in titanium for edentulous patients.

Intended use:
Nobel Biocare’s NobelProcera® Implant Bar Overdenture is a customized dental implant bar. The Implant bar attaches directly to the endosseous dental implants with clinical screws and provides a platform for restoration. The NobelProcera® Implant Bar Overdenture is designed and made individually to fit the individual requirements for each patient.

Indications:
The NobelProcera® Overdenture Bar is indicated for use as an overdenture bar that attaches to implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

Contraindications:
- Cases with lengths that exceed the maximum limits.
- Bruxism.

Note:
Please refer to the original implant manufacturer’s instruction for use, with regards to the implants contra-indication as well as tooling and torque when restoring.

Cautions:
- Product is made from Titanium alloy 90% Ti, 6% Al, 4% V. May impact patients who are allergic or hypersensitive to Titanium alloy 90% Ti, 6% Al, 4% V.
- It is a must that clinical screws are used when securing the restoration into the patient’s mouth.

Please refer to the original implant manufacturer’s instruction for use, for which compatible clinical screw to use including tooling and torque when restoring the implant. However for Straumann® Standard/Standard Plus (platforms 4.8 and 6.5) the Nobel Biocare developed clinical screws should be used.

- For additional information on clinical screw compatibility please refer to www.nobelbiocare-compy-support.
- It is recommended, that no modifications are made to the implant bar or its seating area as this may affect/hinder its strength or fit.
- It is recommended, that the implant bar is not anodized, as this may affect/hinder the implant bar strength/longevity.

Instruction for clinician:
It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Procedural precautions:
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment. Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.

Impression implant or abutment level open tray technique:
A custom-made open impression tray is essential for an accurate impression and for access to the impression coping guide pins. A wax lid can cover the opening.

Clinical procedure:

Obtaining impression:
Use a custom made rigid impression tray with occlusal screw access holes following an open tray impression protocol.

- Syringe an elastomeric impression material around the impression copings introrally and take an impression.
- After complete setting of the impression material unscrew the impression coping screws and remove the impression tray.
- In addition, take preliminary interocclusal records.
- Inspect the impression for discrepancies and send to the laboratory.

Note: For NobelActive® or NobelReplace® Conical Connection, ensure that Impression Coping Bridge Open Tray Conical Connection is used.

Laboratory procedure:

Fabricating definitive cast, registration records:
Upon receiving impression:

- Confirm the position of the implant level impression coping and carefully screw the implant replica onto the implant impression coping. Pour the impression with low expansion dental stone and fabricate a master model with soft tissue mask. Allow proper curing time of the model to ensure no dimensional changes.
- The soft tissue must be at least 2 mm thick so that the implant replicas stick up at least 2 mm from the plaster model.
- Confirm all implant replicas are set firmly in the model (no movement).

* Note that NobelProcera® Implant Bars are manufactured to very accurate tolerances. It is critical that the proper impression copings, impression materials and laboratory components and are used.

Fabricate model verification jig:
- Make an acrylic framework using non-engaging temporary abutments.
- Send to clinician to place in patient mouth to verify model.
- Use an acrylic resin base (optional: integrate provisional abutment cylinders) and fabricate a wax rim for interocclusal records to properly orient the models in the articulator.

Clinical procedure:

Model verification:
- Place the verification jig into the patient’s mouth to verify fit.

Intraoral jaw relation records:
- Use the wax rim and (optionally a facebow) for jaw relation records.

Laboratory procedure:

Fabricating set-up:
- Upon receiving back the verification jig and wax bite-rim:
  - Articulate models using wax bite-rim (and facebow).
  - Make a diagnostic tooth set-up on the definitive cast and send it to the clinician for try-in and verification.

Clinical procedure:

Intraoral try-in of set-up:
- Try-in the diagnostic tooth set-up to verify functional and esthetic parameters.

Laboratory procedure:

A) Laboratory procedure (in-lab scanning): Design bar:
- Select and carefully mount the appropriate model position locators onto the definitive cast to facilitate the capturing of the correct depth and orientation of the implant into the front-end software, prior to designing the implant bar.
- Scan the diagnostic tooth setup & definitive cast with pre-mounted model position locators using a NobelProcera® scanner (or an approved NobelProcera® System), according to the tutorial found within the software.
- Once scanned, open the relevant CAD module and design your implant bar, following the instructions in the software tutorial, according to the patient’s clinical needs.
- Send scan data file to Nobel Biocare production facility.
- Upon return check for precision of fit on the definitive cast.

Note: Ensure prior to scanning that the scanning position locators are seated flat and securely on the implant replicas.

Recommendations:
- Regularly check scanning position locator for damage/imperfections under a loupe or microscope.
- Confirm they fit properly onto the implant replica.
- Regularly inspect the threads for damage or cross-threading.
- Clean (position locators and replicas) and remove any foreign material (e.g. CAD spray, finger oils, stone chips/dust).

B) Laboratory procedure (centralized scanning): When sending your implant bar case for centralized scanning or design, it is necessary to complete the appropriate order form, and carefully wrap and ship the required materials to Nobel Biocare’s Scan & Design center. For further information and forms visit: www.nobelproceraservices.com
**Clinical procedure:**

**Delivery:**

- Implant bar overdenture must be cleaned or sterilized. Please refer to guidance given below.
  - Implant level – Place the overdenture bar and tighten the clinical screw according to the original implant manufacturer’s instructions. For Nobel Biocare implant systems use UnigrIP™ Screwdriver and Manual Torque Wrench Prosthetic, and verify the tightness of the implant bar to 35 Ncm. For other implant manufacturers please refer to their instruction for use for tooling and torque. See Table 2.
  - Abutment level – Verify the tightness of the abutments according to the original implant manufacturer’s instructions and connect the abutment with the appropriate prosthetic screws. Tighten the screws according to original implant manufacturer’s instructions. For Nobel Biocare implant systems – Verify the tightness of the Multi unit abutments to 35 Ncm – and for angled multi unit abutments to 15 Ncm. See Table 3.
  - Connect the restoration to the abutments with prosthetic screws. Tighten the prosthetic screws to 15 Ncm using the Manual Torque Wrench Prosthetic and UnigrIP™ Screwdriver Machine.
  - Placement of the overdenture. Adjust the retention as necessary. Verify the occlusal relationship; confirm resiliency and possible hinge axis movement.
  - Ensure the implant bar attachments are torqued according to attachment supplier recommendation.

**2 Implant level**

NobelProcare® and Procare® abutment (clinical) screw tightening torque

<table>
<thead>
<tr>
<th>Bar shape</th>
<th>Max. canti-lever</th>
<th>Max. span</th>
<th>Min. diagonal section</th>
<th>Min. bar link height</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dolder® Resilient Regular</td>
<td>Fixed shape</td>
<td>20 mm</td>
<td>40 mm</td>
<td>N/A</td>
</tr>
<tr>
<td>Dolder® Resilient Small</td>
<td>Fixed shape</td>
<td>13.5 mm</td>
<td>35 mm</td>
<td>N/A</td>
</tr>
<tr>
<td>Dolder® Rigid Regular</td>
<td>Fixed shape</td>
<td>20 mm</td>
<td>40 mm</td>
<td>N/A</td>
</tr>
<tr>
<td>Dolder® Rigid Small</td>
<td>Fixed shape</td>
<td>13.5 mm</td>
<td>35 mm</td>
<td>N/A</td>
</tr>
<tr>
<td>Hader</td>
<td>Fixed shape</td>
<td>20 mm</td>
<td>40 mm</td>
<td>N/A</td>
</tr>
<tr>
<td>Milled</td>
<td>Free form</td>
<td>30 mm</td>
<td>45 mm</td>
<td>2.9 mm</td>
</tr>
<tr>
<td>Montreal and Montreal Linguale Metallic</td>
<td>Free form</td>
<td>40 mm</td>
<td>45 mm</td>
<td>2.9 mm</td>
</tr>
<tr>
<td>Round</td>
<td>Fixed shape</td>
<td>10 mm</td>
<td>25 mm</td>
<td>N/A</td>
</tr>
<tr>
<td>Paris</td>
<td>Free form</td>
<td>22 mm</td>
<td>40 mm</td>
<td>2.9 mm</td>
</tr>
<tr>
<td>Wrap Around</td>
<td>Free form</td>
<td>25 mm</td>
<td>50 mm</td>
<td>N/A</td>
</tr>
<tr>
<td>Hybrid</td>
<td>Free form</td>
<td>25 mm</td>
<td>50 mm</td>
<td>2.9 mm</td>
</tr>
</tbody>
</table>

In addition to the basic design parameters in the table above, the following general design parameters should be followed:

- When there is a cantilever with clip, distal cylinders should have a minimum 1 mm wall thickness.
- When using beveled distal cylinders, the minimum thickness point between the inner screw head surface and the external cylinder surface should not be less than 0.25 mm.
- When using micro and macro fixed shape extension links over 10 mm, a 1.5 mm radius reinforcement is required between the cylinder and link.
- When screwed attachments are used there should be a minimum 1 mm wall thickness between the external thread shape and the outside buccal and lingual wall of the bar.

**Clinical procedure:**

**Intraoral verification of framework fit:**

- Control precision of fit of delivered overdenture bar intra-orally. A passive and precise fit is essential to the success of the implants. A forced fit can result in stress concentration on one or more implants, potentially leading to implant failure. Problematic screw loosening or bone loss may result from non-passive bar fit. If the bar does not fit passively, a new bar must be fabricated.

**Laboratory procedure:**

Fabricate overdenture:

- Manufacture overdenture or modify an existing denture according to standard protocol.
- Stability of the restoration can further be reinforced by a non-precious metal framework integrated into the overdenture.
- Integrate the housings of the selected retentive elements in the overdenture.
- Remove the restoration from the definitive cast after complete polymerization and finish the tissue-bearing areas for maximum support of the surrounding tissues and optimal hygiene around the implants.

**Cleaning and sterilization instructions:**

This device is delivered non-sterile and must be cleaned and sterilized prior to use.

For USA: Seal single device in a pouch and steam sterilize at 270°F (132°C) for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132°C-135°C (270°F-275°F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134°C -135°C (270°F-275°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.

**Warning:** Use of non-sterile device may lead to infection of tissues or infectious diseases.

**Caution:** This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

**General pre-cautions:** Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavourable implant angulations.

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.

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., tobacco smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy. In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

Especially important is proper stress distribution: passive adaptation and fitting of the bridge/overdenture bar to the implant or implant abutments; adjusting occlusion to the opposing jaw; avoiding excessive transverse loading forces, particularly in immediate loading cases.

**Magnetic resonance environment:**

This product has been tested to be MR Conditional, where the test is conducted in a non-clinical environment according to the ASTM F 2503-B standard.

After the placement of this product, a patient can be safely scanned under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla only.
- Maximum spatial gradient magnetic field of 270-Gauss/cm or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e. per pulse sequence).
- Normal Operating Mode of operation for the MR system.

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 or request latest printed version from a Nobel Biocare representative.

**Note:** Ensure applicable symbol is depicted on the product label.

**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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