Multi-unit Abutment Plus and Multi-unit Abutment

Instructions for use

**Intended use:**
Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Multi-unit Abutment/Plus in combination with endosseous implants are indicated for multiple-unit reconstructions when screw-retained prosthetics are preferred.

**Indications:**
- Multi-unit Abutment/Plus is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.
- The 45° and 60° Multi-unit Abutment for External Hex are indicated for multi-unit screw retained restorations with NobelZygoma™ 0° implants only.

**Contraindications:**
- It is contraindicated to use Multi-unit Abutment/Plus in:
  - Patients who are medically unfit for an oral surgical procedure.
  - Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
  - Patients who are allergic or hypersensitive to commercially pure titanium or titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), gold alloy (gold, platinum, palladium, iridium) polypropylene or PBT (Polyethylene terephthalate).
- The 45° and 60° Multi-unit Abutment external hex connection are contra-indicated for all other implants other than NobelZygoma™ 0°.

**Cautions:**
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

**Clinical procedure:**
1A. Straight Multi-unit Abutment/Plus:
   1. Place appropriate abutment (A:1). Use plastic holder to facilitate the insertion (B). It is recommended to verify the final abutment seating using radiographic imaging.
   2. Tighten the abutment according to table 1, using Screwdriver Machine Multi-unit and Manual Torque Wrench Prosthetic (C). **Caution:** Never exceed recommended maximum tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

1B. 17° and 30° Multi-unit Abutment/Plus:
   1. Place appropriate angled abutment (A:2). Use the holder to facilitate proper position, as there are several positions available (D). It is recommended to verify the final abutment seating using radiographic imaging.
   2. Unscrew holder (D).
   3. Tighten the abutment to 15 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (E). **Caution:** Never exceed recommended maximum 15 Ncm tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

**Handling instructions:**

**Description:**
A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

The Multi-unit Abutment Plus is made of titanium alloy. The Multi-unit Abutment is made of pure titanium and/or titanium alloy.

**Note:** The 45° and 60° Multi-unit Abutments do not have a holder.

Gold Coping Multi-unit may be used if a casted framework is preferred.

Multi-unit Abutment Plus, straight and angled 17° & 30°
Internal conical connection for: NobelActive®, NobelReplace® CC and NobelParallel™ CC.

Multi-unit Abutment, straight and angled 17° & 30°
Internal trichannel connection for: NobelReplace®, Replace Select™, NobelSpeedy® Replace, NobelReplace® Platform Shift.

External hex connection for: Bränemark System® and NobelSpeedy® Groovy.
Other implant systems: Astra Tech Implant System™, Aqua and Lilac Straumann® Bone Level NC 3.3 and RC 4.1/4.8.

Multi-unit Abutment Non-Engaging, angled 30°
The Multi-unit Abutment Non-Engaging angled 30° is available for use with the All-on-4® treatment concept with guided surgery only.
Internal trichannel connection for: NobelReplace®, Replace Select™, NobelSpeedy® Replace, NobelReplace® Platform Shift.
External hex connection for: Bränemark System® and NobelSpeedy® Groovy.

Multi-unit Abutment, straight
Other implants systems: Straumann® Octagon soft tissue level 4.8 and 6.5.
Ankylos® Implant System 3.5, 4.5, 5.5, 7.0mm. Astra Tech Implant System™ 4.5ST, 5.0ST mm. Cororing® Implant System 3.3, 3.8, 4.3, 5.0/6.0mm.

Multi-unit Abutment angled 45° & 60°
External hex connection for: NobelZygoma™ 0°.

Important: Please read.
Disclaimer of liability:
This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, it is his/her responsibility. Nobel Biocare does not assume any liability whatever for damage arising thereof. Please note that some products detailed in this instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

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Handling instructions:

**Clinical procedure:**

**1. Straight Multi-unit Abutment/Plus:**
   1. Place appropriate abutment (A:1). Use plastic holder to facilitate the insertion (B). It is recommended to verify the final abutment seating using radiographic imaging.
   2. Tighten the abutment according to table 1, using Screwdriver Machine Multi-unit and Manual Torque Wrench Prosthetic (C).
   **Caution:** Never exceed recommended maximum tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

**2. 17° and 30° Multi-unit Abutment/Plus:**
   1. Place appropriate angled abutment (A:2). Use the holder to facilitate proper position, as there are several positions available (D). It is recommended to verify the final abutment seating using radiographic imaging.
   2. Unscrew holder (D).
   3. Tighten the abutment to 15 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (E). **Caution:** Never exceed recommended maximum 15 Ncm tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.
1C. 45° and 60° Multi-unit Abutment:
1. Place appropriate angulated abutment (A:2). It is recommended to verify the final abutment seating using radiographic imaging.
Note: The 45° and 60° Multi-Unit Abutments do not have a holder.
Caution: The screw is not locked by a holder. Ensure that the screw is engaged to the Unigrip™ Screwdriver when placing the abutment.
2. Tighten the abutment to 35 Ncm using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic (C).
Caution: Never exceed recommended maximum 35 Ncm tightening torque for the abutment screw. Over tightening of abutment may lead to a screw fracture.
2. Take impression of abutments using open or closed impression tray technique (F).
Note: Hand tighten only and close impression coping recess prior to impression taking.
Open tray
F:1
Closed tray
F:2
3. Provisionalize or attach healing caps.
Laboratory procedure:
4. Attach abutment replicas to impression copings.
5. Fabricate a working model with removable gingival material (G).
6A. NobelProcera® Implant Bridge Wax-up:
1. Create implant bridge framework using non-engaging temporary cylinders as a foundation and add pattern resin to fabricate desired framework design (H).
2. Scan the acrylic framework using the NobelProcera® Scanner according to the tutorial found within the software.
3. Once precision milled framework is delivered back to lab, veneering material is added.

6B. Laboratory – Casted Framework:
1. Attach Gold Coping Multi-unit to the abutment replicas (I) and reduce the height of the plastic chimney.
2. Wax up framework around gold copings (J).

Clinical procedure:
7. Remove temporary restoration if applicable.
8. Use the Screwdriver Machine Multi-unit and Manual Torque Wrench Prosthetic to verify the tightening of the straight Multi-unit Abutment/Plus according to table 1. Use the Unigrip™ Screwdriver and Manual Torque Wrench Prosthetic to verify tightening of the angulated Multi-unit Abutment/Plus to 15 Ncm and for 45° and 60° Multi-Unit Abutment to 35 Ncm.

1
Abutment (clinical) Screw Tightening Torque

<table>
<thead>
<tr>
<th>Abutment (clinical) Screw Tightening Torque</th>
<th>Straight (17°, 30°)</th>
<th>Angulated (17°, 30°)</th>
<th>Angulated (45°, 60°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nobel Biocare implants</td>
<td>35 Ncm</td>
<td>15 Ncm</td>
<td>35 Ncm</td>
</tr>
<tr>
<td>*Astra Tech Implant System™ Aqua</td>
<td>20 Ncm</td>
<td>15 Ncm</td>
<td>–</td>
</tr>
<tr>
<td>*Astra Tech Implant System™ Lilac</td>
<td>25 Ncm</td>
<td>15 Ncm</td>
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</tr>
<tr>
<td>*Astra Tech Implant System™ 4.5ST, 5.0ST</td>
<td>25 Ncm</td>
<td>15 Ncm</td>
<td>–</td>
</tr>
<tr>
<td>*Straumann® Bone Level, Straumann® Octagon soft tissue level</td>
<td>35 Ncm</td>
<td>15 Ncm</td>
<td>–</td>
</tr>
<tr>
<td>*Ankylos® Implant System</td>
<td>25 Ncm</td>
<td>15 Ncm</td>
<td>–</td>
</tr>
<tr>
<td>*Camlog®</td>
<td>20 Ncm</td>
<td>15 Ncm</td>
<td>–</td>
</tr>
</tbody>
</table>

Note: Always refer to the original implant manufacturer’s instructions for use, with regards to the implant indications and contraindications, as well as tooling and tightening torque.

9. Insert fixed prosthesis and tighten the prosthetic screws by alternating left and right side (K, L). Finally tighten the prosthetic screws according to table 1 using Screwdriver Machine Multi-unit or Unigrip™ Screwdriver, as appropriate, and Manual Torque Wrench prosthetic (M).

10. Close screw access channel.

For additional information on restorative and dental laboratory procedures please consult treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Gold Coping Multi-unit casting specifications: Melting range: 1400–1400° C/ 2550–2720° F. Coefficient of thermal expansion: 12 μm/m°C K.
Recommended casting alloys: Conventional gold alloys: High gold content (min 75% Au + Pt metal) alloys, standard ISO 1622 type 4.
Ceramic bonding alloys: High gold content (min 75% Au) alloys, standard ISO/DIS 9693, NiOM type A. Soldering in the range of 800–890° C/1472–1634° F.
Gold Coping Bar: Soldering in the range of 800–890° C/1472–1634° F.

Materials:
Straight Multi-unit Abutment/Plus for implants with external hex connection and Internal tri-channel connection: commercially pure titanium.
All other Multi-unit Abutment/Plus and Abutment/Prosthetic screws: Titanium alloy 90% Ti, 6% Al, 4%V.
Holder for Multi-unit Abutment/Plus straight: PBT (Polybutylene terephthalate).
Holder for Multi-unit Abutment/Plus angled: Titanium alloy 90% Ti, 6% Al, 4% V.
Gold coping: Gold alloy 60% Au, 19% Pt, 20% Pd, 1% Ir.

Cleaning and sterilization instructions:
Multi-unit Abutment/Plus is delivered sterile for single use only prior to the labelled expiration date.

Warning: Do not use device if the packaging has been damaged or previously opened.
Caution: Multi-unit Abutment/Plus is a single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and / or biological characteristics. Re-use could cause cross contamination.
Gold Coping Multi-unit Abutment and Multi-unit Abutment Non-Engaging 30° are delivered non-sterile for single use.

Final framework with the Gold Coping Multi-unit Abutment and the jig with the Multi-unit Abutment Non-Engaging 30° should be cleaned and disinfected, as applicable per manufacturer’s instructions, before intraoral use.

Warning: Use of non-sterile device may lead to infection of tissues or infectious diseases.
Caution: Gold Coping Multi-unit Abutment and Multi-unit Abutment Non-Engaging 30° are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Re-use could cause cross contamination.
Magnetic Resonance (MR) safety information:

Note: Only the Conical Connection Wide Platform abutments 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.

Non-clinical testing has demonstrated that the 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 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 30mm from the device. Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc. when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

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 in the MR environment.

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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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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