Important – 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-compliance with recommendations 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 this regard to 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, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever 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.

Description:

Replacement parts are defined as prosthetic components and instruments in the Nobel Biocare product range that are essential to maintain existing prosthetic constructions in patients with phasing-out implants and/or abutments i.e. devices no longer placed on the market. Nobel Biocare replacement parts and components are divided into the following categories based on the implant system and their use.
The tables below summarize the available replacement parts and the compatible Nobel Biocare implant systems and/or abutments, screwdrivers and any other relevant information.

Replacement Parts Portfolio for Brånemark System:

The replacement parts portfolio for the Brånemark System is comprised of the following instruments and components (Table 1):

<table>
<thead>
<tr>
<th>Original Implant</th>
<th>Replacement Screw</th>
<th>Tightening Torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Abutment</td>
<td>Abutment Screw</td>
<td>20 Ncm</td>
<td>Multi-unit Screwdriver*</td>
</tr>
<tr>
<td>EstheticCare Abutment</td>
<td>Abutment Screw</td>
<td>EstheticCare</td>
<td>Screwdriver</td>
</tr>
<tr>
<td>Standard Abutment RP or EstheticCare + Gold Cylinder</td>
<td>Prosthetic screw internal hexagon</td>
<td>10 Ncm</td>
<td>Screwdriver Hexagon Machine screw screw screw screw</td>
</tr>
<tr>
<td>Prosthetic screw slot</td>
<td>Screwdriver Medium Screwdriver Slot Machine Screwdriver Slot</td>
<td>Screwdriver</td>
<td></td>
</tr>
<tr>
<td>Low Profile Healing Screw</td>
<td>N/A Hand-tightening</td>
<td>Screwdriver Hex 0.030°</td>
<td></td>
</tr>
</tbody>
</table>

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Multi-unit Screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Replacement Parts Portfolio for Brånemark System Novum:

The replacement parts portfolio for the Brånemark System Novum is comprised of the following components (Table 2):

<table>
<thead>
<tr>
<th>Original Implant</th>
<th>Replacement Screw</th>
<th>Tightening Torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brånemark System Novum</td>
<td>Lower bar screw</td>
<td>35 Ncm</td>
<td>Unigrip Screwdriver*</td>
</tr>
<tr>
<td>Prosthetic screw slot</td>
<td>Screwdriver</td>
<td>Screwdriver Impression Coping to Fixture Novum</td>
<td>Screwdriver</td>
</tr>
</tbody>
</table>

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Unigrip screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Replacement Parts Portfolio for NobelPerfect System:

The replacement parts portfolio for the NobelPerfect System is comprised of the following components (Table 3):

<table>
<thead>
<tr>
<th>Original Implant</th>
<th>Replacement Screw</th>
<th>Tightening Torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td>NobelPerfect</td>
<td>Abutment Screw NobelPerfect</td>
<td>35 Ncm</td>
<td>Unigrip Screwdriver</td>
</tr>
<tr>
<td>Prosthetic screw slot</td>
<td>Screwdriver</td>
<td>Screwdriver Impression Coping to NobelPerfect</td>
<td>Screwdriver</td>
</tr>
</tbody>
</table>

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Replacement Parts Portfolio for SteriOss and Replace External Hex:

The replacement parts portfolio for SteriOss and Replace External Hex is comprised of the following components (Table 4):

<table>
<thead>
<tr>
<th>Original Implant</th>
<th>Replacement Screw</th>
<th>Tightening Torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td>SteriOss External Hex</td>
<td>Abutment Screw NobelPerfect</td>
<td>35 Ncm</td>
<td>Unigrip Screwdriver*</td>
</tr>
<tr>
<td>Replace External Hex</td>
<td>Screwdriver</td>
<td>Screwdriver Impression Coping to NobelPerfect</td>
<td>Screwdriver</td>
</tr>
</tbody>
</table>

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Replacement Parts Portfolio for NobelReplace:

The replacement parts portfolio for NobelReplace is comprised of the following components (Table 9):

<table>
<thead>
<tr>
<th>Original Implant</th>
<th>Replacement Abutment Screw</th>
<th>Tightening Torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td>NobelReplace implant</td>
<td>Abutment Screw PS RP NP</td>
<td>35 Ncm</td>
<td>Unigrip Screwdriver*</td>
</tr>
</tbody>
</table>

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Replacement Parts Portfolio for the Ball Abutment:

The replacement parts portfolio for the Ball Abutment is comprised of the following components (Table 10):

<table>
<thead>
<tr>
<th>Original Implant</th>
<th>Replacement Abutment Screw</th>
<th>Tightening Torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td>NobelPerfect Ball Abutment</td>
<td>Screwdriver Machine Ball Abutment</td>
<td>20 Ncm</td>
<td>Unigrip screwdriver</td>
</tr>
<tr>
<td>NobelReplace implant</td>
<td>Screwdriver Machine Ball Abutment</td>
<td>20 Ncm</td>
<td>Unigrip screwdriver</td>
</tr>
</tbody>
</table>

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Other Replacement Parts Portfolio:

The remaining replacement parts portfolio is comprised of the following components (Table 11):

<table>
<thead>
<tr>
<th>Original Implant</th>
<th>Replacement Screw</th>
<th>Tightening Torque</th>
<th>Screwdriver</th>
</tr>
</thead>
<tbody>
<tr>
<td>NobelPerfect Ball Abutment</td>
<td>Screwdriver Machine Ball Abutment</td>
<td>20 Ncm</td>
<td>Unigrip screwdriver</td>
</tr>
<tr>
<td>NobelReplace implant</td>
<td>Screwdriver Machine Ball Abutment</td>
<td>20 Ncm</td>
<td>Unigrip screwdriver</td>
</tr>
</tbody>
</table>

* Device is part of the Nobel Biocare main portfolio.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the Screwdriver. This IFU is available for download at ifu.nobelbiocare.com.

Intended Use/Intended Purpose:

Clinical/Abutment/Prosthetic Screws:

Intended for use in fastening dental implant system components to a dental implant or to another component.

Screwdrivers:

Intended for use to tighten and/or loosen screws used to connect dental implant system components.
Patients in whom adequate sizes, numbers and desirable positions of implants are not
It is contraindicated to use Nobel Biocare replacement parts in:

- Contraindications:
  - NobelBiocare instruments and components. Use of instruments or components that are not
  - NobelReplace laboratory screw for processing the abutment in the laboratory.
  - NobelReplace screw should be used (for NP article no.36818, for RP and WP article
  - NobelReplace screw is needed for NobelPerfect restoration, a corresponding
  - Clean and disinfect the abutment upon receiving it from the dental laboratory.

- Instructions for Use:
  - Nobel Perfect System:
    - Connect the impression coping into the implant and hand-tighten it using the Unigrip
    - Close cooperation between surgeon, restorative dentist and dental laboratory technician is
    - Send the impression to the dental laboratory.

- Impression Copings:
  - Clinical Procedure:
    - It is recommended to verify the proper seating using radiographic imaging.
    - Do not use device if the packaging has been damaged or previously opened.

- Cautions:

- Clinical Benefits Associated with Nobel Biocare replacement parts:
  - Never exceed maximum tightening torque for the screw. Exceeding the maximum tightening
  - Never exceed recommended maximum tightening torque for the screw. Overtightening of
  - To help ensure a successful long-term-treatment outcome, it is advised to provide comprehensive

- Clinical Benefits and Undesirable Side Effects:
  - Never exceed recommended maximum tightening torque for the screw.
  - Clean and disinfect the abutment and crown upon receiving it from the dental laboratory.

- Handling Procedure:
  - Bränemark System:
    - Bränemark System Novum:
      - Connect the impression coping to the implant. Ensure that the connection is clean and free
  - Blocks out the screwdriver indentation on the impression coping pin.
  - It is recommended to verify the proper seating using radiographic imaging.
  - Select the appropriate screw for the abutment or framework.
  - Block out the screwdriver indentation on the impression coping pin.
  - Canon: Never exceed recommended maximum tightening torque for the screw.
  - Clinical Procedure:
    - Block the clinical screw head using Teflon tape.
  - Notice regarding serious incidents:
    - Block out the screwdriver indentation on the impression coping pin.
    - Clean the final crown using conventional procedures. Remove excess cement.
    - If a replacement screw is needed for NobelPerfect restoration, a corresponding
  - Use the Unigrip screwdriver and hand-tighten the pin.
  - Record the impression.

- Manual Torque Wrench:
  - Manual Torque Wrench:
  - Manual torque wrenches can be used as an alternative to machine torque wrenches.

- Healing Abutments:
  - Healing Abutments:
  - Stop the screws from removing the impression coping using the Unigrip screwdriver.

- Retainer Ring and O-ring Clinical White:
  - Manual torque wrenches can be used as an alternative to machine torque wrenches.
  - Teflon tape can be used to protect the abutment interface.

- Temporary Copings:
  - Temporary Copings:
  - Clinical Benefits Associated with Nobel Biocare replacement parts:
  - Never exceed recommended maximum tightening torque for the screw. Overtightening of

- Impression Copings:
  - Impression Copings:
  - Manual torque wrenches can be used as an alternative to machine torque wrenches.

- Manual Torque Wrench:
  - Manual Torque Wrench:
  - Block the clinical screw head using Teflon tape.
  - Clean and disinfect the abutment and crown upon receiving it from the dental laboratory.

- Clinical Abutment/Prosthetic Screws:
  - Clinical and Abutment Screws are indicated to use for securing a dental abutment or framework
  - Impression Copings:
  - Impression Copings:
  - Clinical Procedure:
    - Block out the screwdriver indentation on the impression coping pin.
    - It is recommended to verify the proper seating using radiographic imaging.

- Clinical Benefits Associated with Nobel Biocare replacement parts:
  - Clinical Benefits Associated with Nobel Biocare replacement parts:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Replace laboratory screw for processing the abutment in the laboratory.
  - Nobel Replace laboratory screw for processing the abutment in the laboratory.
  - Clinical Procedure:
    - Block the clinical screw head using Teflon tape.
  - Notice regarding serious incidents:
    - Notice regarding serious incidents:

- Temporary Copings:
  - Temporary Copings:
  - Clinical Procedure:
    - Block the clinical screw head using Teflon tape.
  - Notice regarding serious incidents:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:

- Nobel Biocare instruments and components. Use of instruments or components that are not
  - After Surgery:
  - Healing Abutments:
  - Healing Abutments:
Clinical Procedure: If necessary, re-tighten the PME abutment to 20 Ncm using dedicated abutment wrench and torque wrench insert as per Table 5. Upon receiving the restoration clean and disinfect it following the restorative material manufacturer’s guidelines.

Laboratory Procedure: Upon receiving the impression, connect the corresponding implant replica to the impression coping. Fabricate a master cast with removable soft tissue.

Clinical Procedure: Connect the gold coping to the replica and fabricate the final restoration with conventional casting technique.

Clinical Procedure: Connect the restoration to the implant with clinical screws using dedicated screwdriver as per Table 5. It is recommended to verify the proper seating of the impression coping using radiographic imaging.

Clinical Procedure: Block off the screwdriver indentation on the impression coping pin.

Clinical Procedure: Never exceed recommended maximum tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

Clinical Procedure: Never exceed maximum recommended tightening torque for the screw. Overtightening of the screw may lead to a screw fracture and/or damage of the component. Tightly tighten the screw using dedicated screwdriver and wrench as per Table 5.

Clinical Procedure: Never exceed recommended maximum tightening torque for the screw. Overtightening of the screw may lead to a screw fracture and/or damage of the component.

Clinical Procedure: Never exceed recommended maximum tightening torque for the screw. Overtightening of the screw may lead to a screw fracture and/or damage of the component. Tightly tighten the screw using dedicated screwdriver and wrench as per Table 5.

Clinical Procedure: Never exceed recommended maximum tightening torque for the screw. Overtightening of the screw may lead to a screw fracture and/or damage of the component. Tightly tighten the screw using dedicated screwdriver and wrench as per Table 5.

Clinical Procedure: Never exceed recommended maximum tightening torque for the screw. Overtightening of abutment may lead to a screw fracture. Unscrew the impression coping pin and remove the impression tray.

Clinical Procedure: Upon receiving the impression, connect the corresponding implant replica to the impression coping. Fabricate a master cast with removable soft tissue. Connect and hand-tighten the Coronal screw set to the replicas using dedicated screwdrivers as per Table 8.

Clinical Procedure: Create a cut-away bar following conventional procedures.

Clinical Procedure: Process the attachments into the overdenture.

Clinical Procedure: Complete and finish the restoration.

Clinical Procedure: Connect the gold coping to the replica and fabricate the final restoration with conventional casting technique.

Clinical Procedure: Block the clinical screw head using Teflon tape and close the screw access hole using Manual and Automated Cleaning: AAMI TIR 12.

Clinical Procedure: Block the clinical screw head using Teflon tape and close the screw access hole using Manual and Automated Cleaning: AAMI TIR 12.

Clinical Procedure: Block the clinical screw head using Teflon tape and close the screw access hole using Manual and Automated Cleaning: AAMI TIR 12.

Clinical Procedure: Block the clinical screw head using Teflon tape and close the screw access hole using Manual and Automated Cleaning: AAMI TIR 12.

Clinical Procedure: Block the clinical screw head using Teflon tape and close the screw access hole using Manual and Automated Cleaning: AAMI TIR 12.

Clinical Procedure: Block the clinical screw head using Teflon tape and close the screw access hole using Manual and Automated Cleaning: AAMI TIR 12.

Clinical Procedure: Block the clinical screw head using Teflon tape and close the screw access hole using Manual and Automated Cleaning: AAMI TIR 12.

Clinical Procedure: Block the clinical screw head using Teflon tape and close the screw access hole using Manual and Automated Cleaning: AAMI TIR 12.

Clinical Procedure: Block the clinical screw head using Teflon tape and close the screw access hole using Manual and Automated Cleaning: AAMI TIR 12.
According to EN ISO 17664, it is the responsibility of the user/processor to ensure that the processing/reprocessing is performed using equipment, materials and personnel which are suitable to ensure the effectiveness of the processes. Any deviation from the following instructions should be validated by the user/processor to ensure the effectiveness of the process.

Note: The manufacturer’s instructions for use for any detergent/cleaning solution and/or equipment and accessories used to clean and/or dry the device(s) must be strictly followed where applicable.

Note: The Abutments NobelPerfect, Abutment Screws, Coping Screws, Converting Screws, Lower Bar Screws, Prosthetic Screws, Capsules Conical Abutment Gold, PME Copings Gold/ Plastic, PME Temporary Caps, Direct Abutments Conical Screw Sets, O-Ring Clinical White Retainer Rings, Impression Copings, Transfer Assemblies, Screwdrivers Manual, Screwdrivers Machine, Torque Wrenches, Transmucosal Abutment Wrenches and O-Ring for Tools have been validated to withstand these cleaning and sterilization procedures.

Initial Treatment at Point of Use Prior to Reprocessing:
1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.
3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:
1. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
2. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store in a closed container to avoid drying of soil and/or debris.

Note: Reusable devices should be reprocessed by instructing the prescribed automated or manual cleaning and drying procedures within 24 hours of use, to ensure the efficacy of the reprocessing. If the device has not been used for an extended period, it must be stored in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Automated Cleaning and Drying (Including Pre-cleaning):
1. Disassemble the Impression Copings prior to cleaning by removing the screw or guide pin from the coping.
2. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. NeoAdhes Medzym) for a minimum of 5 minutes.
3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. NeoAdhes Medzym) using a 20 ml syringe.
4. Brush the outer surfaces with soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds at all visible soil is removed.
5. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 20 seconds at all visible soil is removed.
6. Thoroughly rinse all outer and inner surfaces, lumina and cavities (where applicable) with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Immerse the device in a standardized ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Dakoyzem ASP: NeoAdhes Medzym) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/ maximum 45°C (113°F).
8. Thoroughly rinse the outer surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
9. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes.
10. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:
1. After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracked seals and properly discard any devices that fail the inspection.

Manual Cleaning and Drying:
1. Disassemble the Impression Copings prior to cleaning by removing the screw or guide pin from the coping.
2. Immerse a device for a minimum of 5 minutes in a sterile 0.5% NaCl solution.
3. Scrub the outer surfaces of the device with soft bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
4. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Dakoyzem ASP: NeoAdhes Medzym) for a minimum of 5 minutes at minimum 45°C (113°F) using an irrigation needle connected to a 20 ml syringe.
5. Scrub the inner surfaces, lumina and cavities (where applicable) with appropriately sized brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 10 seconds at all visible soil is removed.
6. Thoroughly rinse the outer surfaces, lumina and cavities of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
7. Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35 kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Dakoyzem ASP: NeoAdhes Medzym) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/ maximum 45°C (113°F).
8. Thoroughly rinse the outer surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.

Note: The inner surfaces, lumina and cavities of Torque Wrenches should be flushed for a minimum of 15 seconds using a water jet pistol.
9. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning solution.
10. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:
1. After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals and properly discard any devices that fail the inspection.

Stereilization:
The following steam sterilizers were used in the Nobel Biocare validation: Systec HK 320 and Selectomat PL/66P-2CL (pre-vacuum cycle), Amso Century Sterilizer and Selectomat PL/66P-2CL (gravity cycle).

Note: It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.
1. Reassemble all multi-piece devices (where applicable), and seal each device in a suitable sterilization pouch. The sterilization pouch should fulfill the following requirements:
   - EN ISO 11607 and/or DIN 58953-7.
   - Suitable for steam sterilization (temperature resistance up to at least 137°C /279°F), sufficient steam permeability.
   - Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.

Table 12 presents examples of suitable Sterilization pouches, pouches, and wraps.

Table 13: Recommended Sterilization Cycles

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Minimum Temperature</th>
<th>Minimum Sterilization Time</th>
<th>Minimum Drying Pressure</th>
<th>Minimum Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vacuum Cycle</td>
<td>132°C (270°F)</td>
<td>10 minutes</td>
<td>10 minutes</td>
<td>≥3042 mbar 5</td>
</tr>
<tr>
<td>Pre-Vacuum Cycle</td>
<td>132°C (270°F)</td>
<td>3 minutes</td>
<td>3 minutes</td>
<td>≥3042 mbar 5</td>
</tr>
</tbody>
</table>

1. Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10^-6 in accordance to EN-ISO 17665-1.
2. Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential MR contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions.
3. Sterilization steam at 132°C as per required by EN ISO 17665-2.
4. As per recommended steam pressure at 132°C (see above).

Note: Autodual/sterilizer design and performance can affect the efficacy of the sterilization process. Healthcare facilities should therefore validate the processes that they use, employing the actual equipment and operators that routinely process the devices. All autoclaves/ sterilizers should comply with the requirements of, and be validated, monitored and checked in accordance to SN EN 14040, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autodual/sterilizer manufacturer’s instructions for use must be strictly followed.

Storage and Maintenance:
1. After sterilization, place the labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

Containment and Transportation/Shipping to Point of Use:
The container and/or outer packaging used to transport or ship the reprocessed device back to the point of use must be suitable to protect and safeguard the devices during transportation, taking the device packaging and the required transportation or shipping process (intrafacility transportation or shipping to an external site) into account.

Magnetic Resonance (MR) Safety Information:
The Replacement Parts such as clinical/abutment/prosthetic screws, abutments, temporary copings, gold copings, impression copings and healing abutments contain metallic materials which can be affected by MRI scanning. Non-clinical testing performed by Nobel Biocare has demonstrated that the Replacement Parts such as screws, abutments, temporary copings, gold copings, impression copings and healing abutments are unlikely to impact patient safety under the following MR conditions:

- Static magnetic field of 1.5 Tesla and 3 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).

Note: Removable restorations should be taken out prior to scanning, as is done for watches, jewellery etc.

Under the conditions defined above, these devices are expected to produce a maximum temperature rise of < 4°C (39.5°F) after 15 minutes of continuous scanning. In the non-clinical testing, the image artifact caused by the devices extends approximately 30 mm from the devices when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system.

Note: Although the non-clinical testing demonstrates that the Replacement Parts such as screws, abutments, temporary copings, gold copings, impression copings and healing abutments are unlikely to interfere with patient safety under the conditions defined above, this testing is insufficient to assert or MR Conditional for the Replacement Parts such as screws, abutments, temporary copings, gold copings, impression copings and healing abutments.

The Replacement Parts such as screwdrivers, wrenches and replicas were not evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Replacement Parts such as screwdrivers, wrenches and replicas is unknown. Scanning a patient who has these devices may result in patient injury.

Table 12: Recommended Sterilization Pouches

<table>
<thead>
<tr>
<th>Method</th>
<th>Recommended Sterilization Pouch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity Cycle</td>
<td>SPSmedical Self-Seal sterilization pouch Sterilization pouch (Wikap)</td>
</tr>
<tr>
<td>Pre-Vacuum Cycle</td>
<td>SterilCLINIC pouch Sterilization pouch (Wikap)</td>
</tr>
</tbody>
</table>

2. Label the sterilization pouch with information necessary to identify the device (for example, the product name with article number and lot/batch number (if applicable)).
3. Place the sealed sterilization pouch into the autoclave/sterilizer. Ensure that the sterilization pouch is oriented in a horizontal position.
4. Sterilize the device. Both the gravity displacement cycle and pre-vacuum (damp dry or removal) cycle can be applied, using the following recommended parameters (Table 13):
### Performance Requirements and Limitations:
To achieve the desired performance, Nobel Biocare replacement parts must only be used with the products described in this Instructions for Use and/or in the Instructions for Use for other compatible Nobel Biocare products, and in accordance with the Intended Use for each product. To confirm the compatibility of products which are intended to be used in conjunction with Nobel Biocare replacement parts, check the color coding, dimensions, lengths, connection type and/or any direct marking as applicable on the products or product labeling.

### Facilities and Training:
It is strongly recommended that both new and experienced users of dental implants, prosthetics, and associated software 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 information please visit www.nobelbiocare.com.

### Storage, Handling and Transportation:
The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

### Disposal:
Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation on packaging and packaging waste, where applicable.

### Manufacturer and Distributor Information:
**Manufacturer:**
Nobel Biocare AB
Box 5940, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

**Distributed in Australia by:**
Nobel Biocare Australia Pty Ltd
Level 4/7 Eden Park Drive
Macquarie Park, NSW 2114 Australia
Phone: +61 1800 804 597

**Distributed in New Zealand by:**
Nobel Biocare New Zealand Ltd
33 Spartan Road
Takanini, Auckland, 2105 New Zealand
Phone: +64 0800 441 657

### Basic UDI-DI Information:

<table>
<thead>
<tr>
<th>Product</th>
<th>Basic UDI-DI Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healing Abutments</td>
<td>733274700000012367T</td>
</tr>
<tr>
<td>PME Temporary Coping</td>
<td></td>
</tr>
<tr>
<td>Abutment Screws RP</td>
<td>73327470000001837D</td>
</tr>
<tr>
<td>Abutment Screws Easy Abutment RPL</td>
<td></td>
</tr>
<tr>
<td>Abutment Screws EsthetiCore</td>
<td></td>
</tr>
<tr>
<td>Abutment Screw PS RP-NT</td>
<td></td>
</tr>
<tr>
<td>Abutment Screws TorqTee</td>
<td></td>
</tr>
<tr>
<td>Converter Screw Titanium UniGrip fit Ø 3</td>
<td></td>
</tr>
<tr>
<td>Coping Screw Hex 2 mm 4/kg</td>
<td></td>
</tr>
<tr>
<td>Coping Screw Slot 16 mm</td>
<td></td>
</tr>
<tr>
<td>Lower Bar Screw UniGrip™ Novum</td>
<td></td>
</tr>
<tr>
<td>Prosthetic Screws Conical/Internal Hexagon</td>
<td></td>
</tr>
<tr>
<td>Prosthetic Screw Slot</td>
<td></td>
</tr>
<tr>
<td>Prosthetic Screw UniGrip™ Novum</td>
<td></td>
</tr>
<tr>
<td>Prosthetic Screws Multi-unit Slot N/YP</td>
<td>73327470000001827B</td>
</tr>
<tr>
<td>Clinical Screw for Straumann</td>
<td>7332747000000206Y6</td>
</tr>
<tr>
<td>PME Coping Gold/Plastic</td>
<td>73327470000001256X</td>
</tr>
<tr>
<td>Abutment NobelPerfect Direct Abutment Engaging/Non-Engaging</td>
<td>733274700000016497K</td>
</tr>
<tr>
<td>Coronal Screw Set</td>
<td>733274700000016497K</td>
</tr>
<tr>
<td>Screwdriver/Activator</td>
<td>73327470000001767G</td>
</tr>
<tr>
<td>PME Impression Coping Open Tray</td>
<td>7332747000000191785</td>
</tr>
<tr>
<td>Impression Coping to Fixture Novum</td>
<td>733274700000019177G</td>
</tr>
<tr>
<td>Transfer Assemblies Hex Open Tray</td>
<td></td>
</tr>
<tr>
<td>Transfer Assembly Hex Open Tray</td>
<td></td>
</tr>
<tr>
<td>Implant Level Impression Copings NobelPerfect NP/YP/WP Thread Timed Transfer Pin 3.25 Non-Hex</td>
<td>73327470000002066G</td>
</tr>
<tr>
<td>Implant Analog/Replicas Replica Fixture Novum</td>
<td>7332747000000191785</td>
</tr>
<tr>
<td>O-Ring Abutment Analog w Spacer 2/kg</td>
<td></td>
</tr>
<tr>
<td>PME Abutment Analog</td>
<td>733274700000019177G</td>
</tr>
<tr>
<td>Analog Conical Abutment</td>
<td>7332747000000206365</td>
</tr>
<tr>
<td>O-Ring Clinical White 12/kg</td>
<td>73327470000001506W</td>
</tr>
<tr>
<td>Retainer Ring 2/kg</td>
<td></td>
</tr>
<tr>
<td>Screwdrivers Hex 0.030&quot;</td>
<td>73327470000001777J</td>
</tr>
<tr>
<td>Screwdrivers Hex 0.050&quot;</td>
<td></td>
</tr>
<tr>
<td>Screwdriver Hexagon 27 mm</td>
<td></td>
</tr>
<tr>
<td>Screwdriver Manual Ball Abutment 22 mm</td>
<td></td>
</tr>
<tr>
<td>Screwdriver Medium 37 mm</td>
<td></td>
</tr>
<tr>
<td>Screwdriver Slot Short 27 mm</td>
<td></td>
</tr>
<tr>
<td>Screwdriver Machine Ball Abutment 24 mm</td>
<td>73327470000001797N</td>
</tr>
<tr>
<td>Screwdriver Machine Slot</td>
<td></td>
</tr>
<tr>
<td>Machine Screwdriver Hex Long</td>
<td></td>
</tr>
<tr>
<td>Machine Screwdrivers Slot Long/Short</td>
<td></td>
</tr>
<tr>
<td>Torque Wrench Inserts</td>
<td>73327470000001897R</td>
</tr>
<tr>
<td>Transmucosal Abutment Wrench</td>
<td>73327470000001917C</td>
</tr>
</tbody>
</table>

### Symbols Glossary:
The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

- **EC:** Authorized representative in the European Community
- **LOT:** Batch code
- **Catalogue number:**
- **Cautions:** Contains hazardous substances
- **Contains or presence of phthalate substances**
- **CE marking:**
- **Consult instructions for use:**
- **Do not re-use:**
- **Do not re-use:** Double sterile barrier system
- **Date of manufacture:**
- **Do not resterilize:**
- **For prescription use only:**
- **Health care centre or doctor**
- **Rx Only:**
- **Keep away from sunlight:**
- **Keep dry:**
- **Link to Online Symbols Glossary and IFU Portal**
- **Magnetic resonance conditional:**
- **Manufacturer:**
- **Medical device:**
- **Non-pyrogenic:**
- **Non-sterile:**
- **Patient identification:**
- **Patient information website:**
- **Patient number:**
- **Single sterile barrier system with protective packaging inside:**
- **Single sterile barrier system with protective packaging outside:**
- **Symbol Glossary Nobel Biocare Ltd**
- **sn/novelbiocare.com**
- **SN:**

### Notes:
Refer to the product label to determine the applicable CE mark for each device.