On1™ Concept
Instructions for use

On1™ Base
On1™ Base Xeal™

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-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, they are/his 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:
The On1™ concept consists of a pre-manufactured, two-piece dental implant base and abutment and restorative components which can be directly connected to an endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

The On1™ concept can be used with internal conical connections (CC) for the NobelActive™ CC, NobelReplace™ CC and NobelParallel™ CC implant systems.

The On1™ concept includes components which are intended for use with RP, RP or WP platforms, the specific On1™ concept components used must have the same platform size as the implant.

The On1™ concept is comprised of the following components:

On1™ Base and On1™ Base Xeal™:
The On1™ concept includes two options for the On1™ Base: the On1™ Base Xeal™ which has the Xeal™ surface, and the On1™ Base with the standard surface. The On1™ Base and On1™ Base Xeal™ is intended to be connected to the implant at time of surgery, and to stay on the implant.

Note: A pre-mounted handle for placement of the On1™ Base, and a pre-mounted On1™ Clinical Screw, are included with the On1™ Base and On1™ Base Xeal™

On1™ Clinical Screw:
The On1™ Clinical Screw is designed to fix the On1™ Base or On1™ Base Xeal™ to an endosseous dental implant.

On1™ Prosthetic Screw:
The On1™ Prosthetic Screw is designed to fix the On1™ abutments to an On1™ Base or On1™ Base Xeal™.

On1™ Temporary Abutment:
The On1™ Temporary Abutment is placed upon the On1™ Base to support the placement of a provisional dental prosthesis. The On1™ Temporary Abutment includes two options: the On1™ Temporary Abutment Engaging which is supporting provisional crowns, and the On1™ Temporary Abutment Non-Engaging which is supporting provisional bridges.

Note: A pre-mounted handle for placement of the On1™ Temporary Abutment and a pre-mounted On1™ Prosthetic Screw are included with the On1™ Temporary Abutment.

On1™ Universal Abutment:
The On1™ Universal Abutment is placed upon the On1™ Base to support the placement of single unit and multi-unit screw-retained prosthetic restorations.

Note: An On1™ Burn-out Coping and On1™ Prosthetic Screw are included with the On1™ Universal Abutment. The On1™ Burn-out Coping is intended for laboratory use only and are not intended for intraoral use.

On1™ Esthetic Abutment:
The On1™ Esthetic Abutment is placed upon the On1™ Base to support the placement of single unit and multi-unit screw-retained dental prostheses.

Note: An On1™ Prosthetic Screw is included with the On1™ Esthetic Abutment.

On1™ Healing Cap:
The On1™ Healing Cap is placed upon the On1™ Base to support healing of the surrounding soft tissue.

On1™ IOS Healing Cap:
The On1™ IOS (Intraoral Scannable) Healing Cap is placed upon the On1™ Base to support healing of the surrounding soft tissue. The On1™ IOS Healing Cap facilitates the digital capturing of an intraoral location of the On1™ Base or On1™ Base Xeal™ from the patient’s jaw to a digital model to facilitate the design and fabrication of a dental restoration in the dental laboratory.

Note: A pre-mounted handle for placement of the On1™ IOS Healing Cap and a pre-mounted On1™ Prosthetic Screw are included with the On1™ IOS Healing Cap.

On1™ Impression Coping:
The On1™ Impression Coping facilitates the transfer of an intraoral location of the On1™ Base or On1™ Base Xeal™ from the patient’s jaw to the relative position on a master cast in the dental laboratory.

On1™ Impression Copings are available for both open-tray and closed-tray impression techniques. The open-tray technique is recommended in cases with multiple implants. The closed-tray technique is recommended in patients with less mouth opening, in limited access areas and with patients with a highly-sensitive gagging reflex.

On1™ Impression Copings Open Tray are co-packaged with a guide pin. On1™ Impression Copings Closed Tray are co-packaged with a screw.

On1™ Screwdriver:
The On1™ Screwdriver Manual and On1™ Screwdriver Machine are used to tighten and loosen the clinical or prosthetic screws which fasten the On1™ concept and prosthetic components to the implant.

On1™ Laboratory Components (Intended for Laboratory Use Only):
The On1™ Base Replica acts as a substitute of the assembly constituted by dental implant and On1™ Base. The On1™ Prosthetic Lab Screw is used for temporary fixation of the restorations, to a replica in a working model.

Intended Use/Intended Purpose:

On1™ Base, On1™ Base Xeal™, On1™ Tempory Abutments, On1™ Universal Abutments, and On1™ Esthetic Abutments:

Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.

On1™ Clinical Screws and On1™ Prosthetic Screws:

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

On1™ Healing Cap and On1™ IOS Healing Cap:

Intended to be temporarily connected to an endosseous dental implant or implant abutment to support healing of the surrounding soft tissue.

On1™ Impression Coping:

Intended for use to transfer the direction, position, or orientation of a dental implant to a patient model.

On1™ Screwdrivers (Manual and Machine):

Intended for use to tighten and/or loosen screws used to connect dental implant system components.

Indications:
The On1™ concept is indicated for single-unit cement and screw-retained restorations, and for multi-unit cement and screw-retained short spanned bridges (2-3 units).

On1™ Base/On1™ Base Xeal™:
The On1™ Base and On1™ Base Xeal™ are indicated for use in the maxilla or mandible for supporting tooth replacements to restore chewing function.

On1™ Clinical Screw:
The On1™ Clinical Screw is indicated for use to secure on an On1™ Base or On1™ Base Xeal™ to a dental implant in the maxilla or mandible for supporting tooth replacements to restore chewing function.

On1™ Prosthetic Screw:
The On1™ Prosthetic Screw is indicated for use to secure a On1™ Universal Abutment, On1™ Esthetic Abutment, or On1™ Temporary Abutment to an On1™ Base or On1™ Base Xeal™ in the maxilla or mandible for supporting tooth replacements to restore chewing function.

On1™ Temporary Abutment:
The On1™ Temporary Abutment Engaging is indicated for use with single unit, screw-retained temporary dental prosthesis placed on the On1™ Base or On1™ Base Xeal™ in the maxilla or mandible, for up to 180 days.

The On1™ Temporary Abutment Non-Engaging is indicated for use with multiple unit, screw-retained temporary dental prosthesis placed on the On1™ Base or On1™ Base Xeal™ in the maxilla or mandible, for up to 180 days.

On1™ Universal Abutment:
The On1™ Universal Abutment is indicated to support the placement of single unit, screw-retained prosthetic restorations in the maxilla or mandible.

The On1™ Universal Abutment Non-Engaging is indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla or mandible for implants with less than 20° overall divergences to allow path of insertion.

On1™ Esthetic Abutment:
The On1™ Esthetic Abutment is indicated to support the placement of single unit and multiple unit, cement-retained restorations in the maxilla or mandible.

On1™ Healing Cap:
The On1™ Healing Cap is indicated for use with the On1™ Base or On1™ Base Xeal™ and the On1™ Clinical Screw in the maxilla or mandible for supporting single unit and multiple unit procedures.

On1™ IOS Healing Cap:
The On1™ IOS Healing Cap is indicated for use with the On1™ Base or On1™ Base Xeal™ and the On1™ Clinical Screw in the maxilla or mandible, for up to 180 days, for supporting single unit and multiple unit procedures.

The On1™ IOS Healing Cap is also indicated for use in combination with an intra-oral scanner to confirm the location, position, and angulation of a On1™ Base or On1™ Base Xeal™, to support creation of the digital model to facilitate the design and fabrication of a dental prosthesis using CAD/CAM technology.

On1™ Impression Coping:
The On1™ Impression Copings are indicated to be connected to the On1™ Base or On1™ Base Xeal™ to be used to transfer the location and orientation of the base from the patient’s partially edentulous jaw to a master cast in the dental laboratory.

On1™ Screwdriver Manual:
Same as Intended Use/Intended Purpose.

On1™ Screwdriver Machine:
Same as Intended Use/Intended Purpose.

Contraindications:
The contraindicated to use the On1™ concept 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 sodium hydrogen phosphate (NaOH, P2O5) or magnesium chloride (MgCl2).
Implant abutments are part of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to those associated with teeth, such as retained cement, calculus, mucositis, ulcer, soft tissue hyperplasia, soft- and hard/tissue recessions. Some patients may experience salivary dilatation in the mucosal area such as grooving. Where required per the European Medical Device Regulation (MDR, EU 2017/745) a Summary of Safety and Clinical Performance document (SSCP) isipplicable_for the On1™ Base, On1™ Base Xeal™, On1™ Clinical Screw, On1™ Prosthetic Screw, On1™ Temporary Abutment, On1™ Universal Abutment, On1™ Esthetic Abutment, and On1™ IOS Healing Cap. The SSCP can be obtained at the following website:
https://ec.europa.eu/tools/eudamed/
Notice regarding serious incidents:

In case of bruxism, other parafunctional habits or unfavorable jaw relationships, (e.g., cigarette 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 prosthesis design must accommodate individual patient conditions. In case of bruxism, other parafunctional habits or unfavorable jaw relationships, (e.g., cigarette 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.

Care and maintenance of sterile instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment. Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield). Aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield). Because the device has not been evaluated in pediatric/adolescent patients and is not recommended for use in children. Routine treatment is not recommended until the end of the juvenile jaw bone growth phase has been properly documented.

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

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

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2. Preparation of the On1™ Burn-out Coping:
   1. Seat the On1™ Burn-out Coping onto the On1™ Universal Abutment.
   2. Adjust the height of the On1™ Burn-out Coping according to the required occlusal plane. Ensure the On1™ Universal Abutment remains fully covered.

3. Prosthetic Lab Screw:
   1. Create a wax-up restoration and use standard procedures to either press or cast a coping or full-contour crown.

4. Finalization and bonding:
   1. Once the restoration is produced, finalize it following the restorative material manufacturer’s instructions.
   2. Connect the On1™ Universal Abutment to a On1™ Baso Replica using the On1™ Prosthetic Lab Screw.
   3. Sandblast the contact surface of the On1™ Universal Abutment with aluminum oxide 50 µm at a maximum of 2 bar.
   4. Clean the bonding surface of the On1™ Universal Abutment using a steam jet or an ultrasonic bath.

Caution: Do not sandblast the seating area. During the blasting procedure, use a On1™ Baso Replica to prevent any modification of the abutment/base interface. The use of wax in the screw channel is to be avoided.

5. Bond the restoration to the On1™ Universal Abutment according to the cement manufacturer’s instructions. Use only self-adhesive dental cement/bonding material suitable for zirconium dioxide ceramics or PMMA (Polymethylmethacrylate).

Caution: The screw channel of the On1™ Universal Abutment needs to be blocked prior to bonding and cleaned thereafter from residues of the bonding material. Follow the bonding material manufacturer’s guidelines.

6. Disconnect the restoration from the On1™ Base Replica and send it to the clinician along with the On1™ Prosthetic Screw.

Clinical Procedure:

Caution: The final restoration and the On1™ Prosthetic Screw must be cleaned and sterilized prior to placement in the patient’s mouth, following the instructions of the material manufacturer.

1. Remove the On1™ Healing Cap, On1™ IOS Healing Cap, or temporary restoration from the On1™ Base/On1™ Base Xeal™ and retract the base if necessary.

Caution: Each time a component is connected to the On1™ Base/On1™ Base Xeal™ ensure the On1™ Clinical Screw is not loosened. Re-tighten the screw to 35 Ncm if necessary.

2. Connect and hand-tighten the On1™ Universal Abutment to the On1™ Base/On1™ Base Xeal™ using the On1™ Prosthetic Screw.

3. Tighten the restoration using the Ungirg™ Screwdriver and Manual Torque Wrench Prosthetic to 35 Ncm.

Caution: Never exceed 35 Ncm prosthetic tightening torque. Over-tightening of the On1™ Prosthetic Screw may lead to a screw fracture.

4. To tighten the abutment, the implant should be able to withstand the recommended tightening torque of the On1™ Prosthetic Screw.

5. Block out the screw head before closing the screw access hole with composite.

6. If removal of the restoration is needed, open the screw access and unthread the screw using the Ungirg™ Screwdriver.

Materials:

- On1™ Base, On1™ Temporaty Abutment, On1™ Universal Abutment, On1™ Esthetic Abutment, Titanium, On1™ Clinical and Prosthetic Screws, On1™ Healing Cap, On1™ Base Replica, and On1™ Impression Coping. Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.
- On1™ Base Xeal™: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3, sodium dihydrogen phosphate (NaH₂PO₄) and magnesium chlorate (Mg(ClO₃)₂).
- On1™ IOS Healing Cap, Handle for placement of On1™ Base/On1™ Base Xeal™/On1™ IOS Healing Cap/On1™ Temporary Abutment: Polyetheretherketone (PEEK).
- On1™ Screwdriver: Stainless Steel AISI 303/AISI 304/403 Mod according to ASTM F899.
- On1™ Universal Abutment Burn-out coping. Polycrystalline (POM).

Sterility and Reusability Information:

The On1™ Base/On1™ Base Xeal™, On1™ Temporary Abutment, On1™ Healing Cap, On1™ IOS Healing Cap, On1™ Prosthetic Screw and On1™ Clinical Screw have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

Warning: Do not use device if the packaging has been damaged or previously opened.

Caution: The On1™ Base/On1™ Base Xeal™, On1™ Temporary Abutment, On1™ Healing Cap, On1™ IOS Healing Cap, On1™ Prosthetic Screw and On1™ Clinical Screw are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

The On1™ Universal Abutment and On1™ Esthetic Abutment are single use and are intended for single use only. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

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

Caution: The On1™ Universal Abutment and On1™ Esthetic Abutment are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

The On1™ Screwdriver and On1™ Impression Coping are delivered non-sterile and are intended for reuse. Prior to first use and reuse clean, disinfect and sterilize using the recommended parameters.

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

The On1™ Screwdriver is a reusable instrument which should be inspected before each use to ensure that the instrument and performance continues to be maintained. Check if any wear, abrasion of the instrument, deforations or corrosion is visible on the component.

If any wear, abrasion of the instrument, deforations or corrosion is visible on the component.

If the impression coping does not seat accurately or has a loose fit on the On1™ Base, or the On1™ Replica.

- If with light pressure the Ungirg™ Screwdriver does not engage or slips in the receptacle of the screw or guide pin.
- If the guide pin is no longer retained in the On1™ Impression Coping, which indicates that the O-ring for the guide pin has been stripped off or has deteriorated.

The On1™ Base Replica and On1™ Prosthetic Lab Screw are used in the dental laboratory only (no intraoral use) and have no cleaning and/or sterilization requirements.

Cleaning and Sterilization Instruction:

The On1™ Universal Abutment and On1™ Esthetic Abutment are delivered non-sterile by Nobel Biocare and are intended for single use. Prior to use, the devices must be cleaned and sterilized by the user.

The On1™ Screwdriver and On1™ Impression Coping are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the devices must be cleaned and sterilized by the user.

The devices can be cleaned manually, or in an automatic washer. Each device must then be individually sealed in a sterilization pouch and sterilized.

The following cleaning and sterilization processes have been validated according to international standards and guidelines as applicable.

Manual and Automatic Sterilization:
- AAMI ST79 and ISO 17665-1.
- Sterilization: AAMI ST79 and ISO 17665-1.

According to EN ISO 17644, 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 the bioburden 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 On1™ Universal Abutment, On1™ Esthetic Abutment, On1™ Screwdriver and On1™ Impression Coping have been validated to withstand the cleaning and sterilization procedures.

Initial Treatment at Point of Use Prior to Reprocessing:

Discard single-use instruments, ensure that instruments are immediately after use.

2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe for soil and debris in cavities.

Caution: All dental debris adhering to the impression copings (such as impression material) must be cleaned away after use. It may not be possible to remove the debris later in the process. Impression copings shall be discarded if dental debris cannot be removed.

3. Rinse the devices with cold running tap water.

Containment and Transportation/Shipping to Reprocessing Area:

If any debris is removed, 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 it in a closed container to avoid drying of soil and/or debris.

Note: Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

3. If the devices are shipped to an outside facility for reprocessing, they must be contained 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):

Detergents:

1. Disassemble the device prior to cleaning by removing the screw from the device, where applicable.

2. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.

3. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.

4. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medasel MED-100 33) for a minimum of 20 seconds until all visible soil is removed.

5. Brush the inner surfaces, lumina and cavities (where applicable) with an appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 20 seconds until 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. Rinse lumina (where applicable) with 20 ml tap water using a 20 ml syringe.

Automated Cleaning and Drying:

The following washer was used in the Nobel Biocare validation: Miele G7836 CD with the Vario TD program.
Perform automatic cleaning. The following parameters are based on the Vario TD program: 1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket) of 11 individual devices. Note: Manual Cleaning and Drying: 1. Reassemble any multi-piece devices (where applicable) and seal each device in a suitable sterilization pouch. 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 (top dynamic air removal) cycle can be applied, using the following recommended parameters (Table 2):

Table 1: Recommended Sterilization Pouches

<table>
<thead>
<tr>
<th>Method</th>
<th>Recommended Sterilization Pouch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum Cycle</td>
<td>SteriCUP® pouch</td>
</tr>
<tr>
<td>Gravity Cycle</td>
<td>SPSimendical Self-Seal sterilization pouch</td>
</tr>
</tbody>
</table>

Table 2: Recommended Sterilization Cycles

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Minimum Temperature</th>
<th>Minimum Sterilization Time</th>
<th>Minimum Drying Time (In Chamber)</th>
<th>Maximum Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity Cycle</td>
<td>120°C (270°F)</td>
<td>15 minutes</td>
<td>20 minutes</td>
<td>&gt;2868.2 mbar*</td>
</tr>
<tr>
<td>Pre-Vacuum Cycle</td>
<td>132°C (270°F)</td>
<td>4 minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Vacuum Cycle</td>
<td>134°C (271°F)</td>
<td>3 minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Vacuum Cycle</td>
<td>134°C (271°F)</td>
<td>18 minutes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Validated sterilization processes to achieve a Sterility Assurance Level (SAL) of 10-6 in accordance to EN ISO 11160-1. 2. Recommendation of the Welsh Health Technical Memorandum (WHTM) O1-01 Part C. 3. Recommendation of the World Health Organization (WHO) for steam sterilization of instruments with potential TSE/CJD contamination. Ensure that the packaging and monitoring systems (chemical/biological indicators) used for this cycle are validated for these conditions. 4. Saturation steam at 123°C as per required by EN ISO 17665-2. 5. Saturation steam at 134°C as per required by EN ISO 17665-2. Note: Autoclave/sterilizer design and performance can affect the efficacy of the sterilization process, and any changes to equipment should therefore validate the processes that they use, employing the actual equipment operators and routines that routinely process the devices. All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked according to EN ISO 11137-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer’s instructions for use must be strictly followed.

Facilities and Training: It is strongly recommended that new and experienced users of Nobel Biocare products always go through special training before using a new product for the first time. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info 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 or policy.

Manufacturer and Distributor Information:

Manufacturer: Nobel Biocare AB
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411 17 Göteborg
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Distributed in New Zealand by:
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Phone: +64 0800 441 657

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

Note Regarding Canadian Device Licensure: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.
**Basic UDI-DI Information:**
The following table lists the Basic UDI-DI information for the devices described in this IFU.

<table>
<thead>
<tr>
<th>Product</th>
<th>Basic UDI-DI Number</th>
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</thead>
<tbody>
<tr>
<td>On1 Bases Conical Connection NP/RP/WP</td>
<td>73327470000001687H</td>
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<td>On1 Bases Xeal™ Conical Connection NP/RP/WP</td>
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<td>On1 Universal Abutments Titanium NP/RP/WP</td>
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<td>On1 Esthetic Abutments Titanium NP/RP/WP</td>
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<tr>
<td>On1 Universal Abutments Non-Engaging NP/RP/WP</td>
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<td>On1 Temporary Abutments Engaging NP/RP/WP</td>
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<tr>
<td>On1 Temporary Abutment Non-Engaging NP/RP/WP</td>
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</tr>
<tr>
<td>On1 Clinical Screws NP/RP/WP</td>
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</tr>
<tr>
<td>On1 Prosthetic Screws NP/RP/WP</td>
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</tr>
<tr>
<td>On1 Healing Caps NP/RP/WP</td>
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<td>On1 IOS Healing Caps NP/RP/WP</td>
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<tr>
<td>On1 Impression Copings Closed Tray NP/RP/WP</td>
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<tr>
<td>On1 Impression Copings Open Tray NP/RP/WP</td>
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<tr>
<td>On1 Impression Copings Open Tray Non-Engaging NP/RP/WP</td>
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<td>On1 Screwdriver Manual</td>
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<tr>
<td>On1 Screwdriver Machine</td>
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</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.

- **Authorized representative in the European Community**
- **Batch code**
- **Catalogue number**
- **Caution**
- **CE marking**
- **Consult instructions for use**
- **Contains hazardous substances**
- **Contains or presence of phthalate**
- **Date**
- **Date of manufacture**
- **Do not re-sterilize**
- **Do not re-use**
- **Do not use if package is damaged**
- **Double sterile barrier system**
- **For prescription use only**
- **Health care centre or doctor**
- **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**
- **Serial number**
- **Single sterile barrier system**
- **Single sterile barrier system with protective packaging inside**
- **Single sterile barrier system with protective packaging outside**

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