Position Locators
Instructions for use

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Description:

Position Locators are premanufactured dental prosthetic components which are connected to an endosseous dental implant placed in the patient's mouth, or to an implant replica embedded in a master cast, to facilitate the design and fabrication of a dental implant restoration.

Position Locators Nobel Biocare N1™ TCC are available in NP/RP platforms, feature a tri-oval conical connection and can be used with Nobel Biocare's Nobel Biocare N1™ implant system.

Position Locators are pre-assembled with a screw which is used to attach the position locator to the implant or implant replica.

Table 1 summarizes the available Position Locators, the compatible implant platforms and associated color coding, compatible screwdriver, and torque specification.

Table 1: Position Locator compatibility

Position Locator for	Available platforms	Color coding	Torque	Screwdriver
Tri-oval conical connection (TCC)	NP RP	O O	hand-tightening	Omnigrip™ mini

Intended Use:

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

Indications for Use:

Position Locators are indicated for use in combination with an intra-oral or desktop scanner to confirm the location, position, and angulation of a dental implant or dental implant replica, to support creation of the digital model to facilitate the design and fabrication of a dental prosthesis using CAD/CAM technology.

Contraindications:

It is contraindicated to use Position Locators 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 titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium) or ZrN (zirconia nitride).

Warnings:

To ensure the accuracy of the scan, the Position Locator must not be modified.
Any modifications may impact the accuracy of the scan.

Cautions:

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

Position Locators must only be used with compatible Nobel Biocare instruments and/or components. Use of instruments and/or components that are not intended to be used in combination with Position Locators can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

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

All components, instruments and tooling 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.

At Surgery:
Because of the small size 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. gauze, dental dam, or throat shield).

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

Handling Procedure:

Caution: do not re-use Position Locators which have been damaged or disassembled.

Intra-oral Scan Workflow:
Note: Before each use inspect the device for scratches and deformation to ensure that the integrity and performance of the position locator is maintained.

1. Connect the Position Locator to the implant by hand-tightening the screw using the Omnigrip Mini™ screwdriver. Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the screwdrivers. This IFU is available for download at ifu.nobelbiocare.com.

Caution: For Position Locators featuring tri-oval conical connection use Omnigrip mini screwdriver only.

2. Verify the seating of the Position Locator using radiographic imaging.
3. Take an intra-oral scan of the patient following the scanner manufacturer's instructions.
4. Remove the Position Locator by untightening the screw.
5. Send the scan file to the laboratory.

Desktop Scanning Workflow:
Note: Before each use visually inspect the device for scratches and deformation to ensure that the integrity and performance of the position locator is maintained.

1. Connect and hand-tighten the Position Locator by tightening the screw to the implant replica embedded in the master cast using the Omnigrip Mini™ screwdriver. Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the screwdrivers.

Caution: For Position Locators featuring tri-oval conical connection use Omnigrip mini screwdriver only.

2. Scan the master cast following the scanner manufacturer's instructions.

Materials:

- Position Locator: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3 and zirconia nitride coating 58% Zr, 42% N.
- Screw: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3.

Sterility and Reusability Information:

Position Locators are delivered non-sterile and are intended for reuse. Prior to use clean and sterilize the product following the manual or automated procedure in the Cleaning and Sterilization Instructions.

Position Locators do not require the disassembly of the screw prior to cleaning and sterilization.

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

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

Position Locators are reusable devices which must be inspected prior to each reuse to ensure that the integrity and performance continues to be maintained. Do not use the Position Locator if it has signs of wear or modifications as this may impact the accuracy of the scan.

Cleaning and Sterilization Instructions:

Position Locators are delivered non-sterile by Nobel Biocare and are intended for reuse. Prior to each use, the device must be cleaned and sterilized by the user.

The device 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 Automated Cleaning: AAMI TIR 12.
- Sterilization: AAMI ST79 and ISO 17665-1.

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: Position Locators 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 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. 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):

Pre-cleaning:
Note: Position Locators do not require disassembly of the screw prior to cleaning and sterilization.

1. Immerse the device in 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes.
2. Fill lumina (where applicable) with 0.5% lukewarm enzymatic cleaning agent (e.g. Neodisher Medizym) using a 20 ml syringe.
3. Brush the outer surfaces with a soft bristled nylon brush (e.g. Medsafe MED-100.33) for a minimum of 20 seconds until all visible soil is removed.
4. 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.

5. 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.
6. 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.

Note: It is recommended to perform the automated cleaning and drying with a maximum load of 11 individual devices.

1. Place the devices in a suitable rack or load carrier (e.g. metal sieve basket).
2. Load the devices into the washer. Ensure the rack or load carrier is oriented in a horizontal position.
3. Perform automatic cleaning. The following parameters are based on the Vario TD program on the Miele G7836 CD washer:
   - Minimum 2 minutes pre-cleaning with cold tap water.
   - Draining.
   - Minimum 5 minutes cleaning with minimum 55°C (131°F) tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean).
   - Draining.
   - Minimum 3 minutes neutralization neutralization with cold desalinated water.
   - Draining.
   - Minimum 2 minutes rinsing with cold desalinated water.
   - Draining.
4. Run drying cycle at minimum 50°C (122°F) for a minimum of 10 minutes.
5. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying cycle.

Note: FDA-cleared washer- disinfectors are to be used for the recommended cleaning parameters.

Visual Inspection:
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:
Note: Position Locators do not require disassembly of the screw prior to cleaning and sterilization.

1. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; maximum 45°C (113°F)) using an irrigation needle connected to a 20 ml syringe.
4. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush (e.g. 1.2 mm/2.0 mm/5.0 mm diameter) for a minimum of 10 seconds until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
6. 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. Cidezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/maximum 45°C (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 ml lukewarm tap water using an irrigation needle connected to a 20 ml syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

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

Sterilization:
The following steam sterilizers were used in the Nobel Biocare validation: Systec HX-320 (pre-vacuum cycle); Amsco Century Sterilizer (gravity cycle).

Note: It is recommended to perform sterilization with a maximum load of 11 devices individually sealed in sterilization pouches.

1. 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 2 presents examples of suitable sterilization pouches.

Table 2: Recommended Sterilization Pouches

Method	Recommended Sterilization Pouch
Gravity Cycle	SPSmedical Self-Seal sterilization pouch
Pre-vacuum Cycle	SteriCLIN® 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.

Gravity Cycle: Steam sterilization at 132°C (270°F) for 15 minutes at saturated steam pressure, followed by drying 15-30 minutes in chamber.

Pre-Vacuum Cycle: Steam sterilization at 132°C (270°F) for 4 minutes at saturated steam pressure, followed by drying 20-30 minutes in chamber.

Note: FDA-cleared sterilization equipment and accessories are to be used for the recommended sterilization parameters.

Note: Autoclave/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, maintained and checked in accordance to SN EN 13060, EN 285, EN ISO 17665-1, and/or AAMI ST79, or to the applicable national standard. The autoclave/sterilizer manufacturer's instructions for use must be strictly followed.

Storage and Maintenance:
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 sterility of 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.

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.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information:

Manufacturer:
Nobel Biocare AB
Box 5190, 402 26
Västra Hamngatan 1
411 17 Göteborg
Sweden
www.nobelbiocare.com

Distributed in USA by:
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, CA, 92887 USA

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

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.

Batch code

Catalogue number

Date


Date of manufacture


Manufacturer

Serial number

Unique Device Identifier


Health care centre or doctor


Patient identification


Patient number


Tooth number


Consult instructions for use

Link to Online Symbols Glossary and IFU Portal


Patient information website


Caution

Do not resterilize


Do not re-use


Do not use if package is damaged and consult instructions for use


Use-by date


Temperature limit


Upper limit of temperature


Keep away from sunlight


Keep dry

Contains biological material of animal origin


Contains hazardous substances

Contains or presence of DEHP phthalate

Contains or presence of natural rubber latex

Contains or presence of phthalate


Non-pyrogenic

Magnetic resonance conditional

Magnetic resonance safe

Non-sterile

Sterilized using Ethylene Oxide

Sterilized using irradiation

Sterilized using steam or dry heat

Single sterile barrier system

Single sterile barrier system with protective packaging inside

Single sterile barrier system with protective packaging outside

Double sterile barrier system

Authorised Representative in Switzerland

Authorized representative in the European Community / European Union

UK Responsible Person

CE mark

CE mark with Notified Body number

EU Importer

Swiss Importer

UKCA mark

UKCA mark with Approved Body number

Medical device

Rx only

For prescription use only