Position Locator

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Description

Position Locators are premanufactured dental prosthetic components which are connected to an endosseous dental implant/abutment placed in the patient's mouth, or to an implant/abutment 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.A new version of Position Locators Nobel Biocare N1™ TCC has been introduced where the screw, which is used to attach the position locator to the implant or implant replica,is co-packed and can be assembled from the side window. Furthermore the screwdriver access has been added also on the upper side and the implant platform/connection information is now engraved on the side. The old version of the Position Locator Nobel Biocare N1TM TCC presents the screw preassembled and has the screwdriver access only through the side window. Nobel Biocare Multi-unit PoLo is available in two different heights and is compatible with the Multi-unit abutments of the corresponding platform. The two heights present a different matching surface and a line at 8mm for an immediate visual feedback of the dimension.The Nobel Biocare Multi-unit PoLo for Multi-unit abutments can be used together with Nobel Biocare Multi-Unit PoLo Link to enhance the scanning capability especially in edentulous cases. The links are available in three different lenghts: 10 mm, 15 mm, 20 mm. Nobel Biocare Multi-unit PoLo is delivered copacked with the prosthetic screw used to attach the device to the Multi-unit abutment.

The following images represents the Nobel Biocare Multi-unit PoLo and Nobel Biocare Multi-unit PoLo Link.

Figure A – Nobel Biocare Multi-unit PoLo 8 mm and Nobel Biocare Multi-unit PoLo 11 mm

Figure B – Nobel Biocare Multi-unit PoLo Link

Figure C – Nobel Biocare Multi-unit PoLo assembled with Nobel Biocare Multi-unit PoLo Link

Figure D – Old (without engraving) and new (with engraving) Position Locator Nobel Biocare N1™ TCC

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

Intended Use

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

Indications

Position Locators Nobel Biocare N1™ TCC and Nobel Biocare Multi-unit Polo are indicated for use in combination with an intra-oral or desktop scanner to confirm the location, position and angulation of a dental implant/abutment or dental implant/abutment 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 the position locators and accessories 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).

Materials

- Position Locator Nobel Biocare N1™ TCC, Nobel Biocare Multi-unit PoLo, and Nobel Biocare Multi-unit PoLo Link: Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3, Zirconia nitride coating 58% Zr, 42% N.
- Screw:
  Titanium alloy 90% Ti, 6% Al, 4% V according to ASTM F136 and ISO 5832-3

Warnings

The devices shall be inspected before each re-use to ensure that the integrity and performance continues to be maintained. Inspect the devices for signs of degradation that may limit the useful life of the devices, such as:

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

Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

Cautions

General

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

Nobel Biocare Multi-unit PoLo, Position Locators Nobel Biocare N1™ TCC and Nobel Biocare Multi-unit PoLo Link must only be used with compatible Nobel Biocare instruments and/or components and/or prosthetic components. Use of instruments and/or components and/or prosthetic components that are not intended to be used in combination with Nobel Biocare Multi-unit PoLo, Position Locators Nobel Biocare N1™ TCC and Nobel Biocare Multi-unit PoLo Link 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

Careful psychological and physiological evaluation, followed by clinical and radiological examination must be performed on the patient prior to surgery to determine the suitability of the patient for treatment.

Special attention must be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g. 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 prosthetic design must accommodate individual patient conditions. In case of bruxism, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

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 tooling used during the clinical and/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

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. gauze, dental dam, or throat shield).

After Surgery

To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform the patient about appropriate oral hygiene.

Intended Users and Patient Groups

Position Locator Nobel Biocare N1™ TCC, Nobel Biocare Multi-unit PoLo, Nobel Biocare Multi-unit PoLo Link are to be used by dental health care professionals.

Position Locator Nobel Biocare N1™ TCC, Nobel Biocare Multi-unit PoLo, Nobel Biocare Multi-unit PoLo are to be used in patients subject to dental implant treatment.

Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB
www.nobelbiocare.com/complaint-form

Handling Procedure

Note Before each use inspect the devices for scratches and deformation to ensure that the integrity and performance of the position locator and link are maintained.

Position Locator Nobel Biocare N1™ TCC Intra-oral Scan Workflow

Assemble the new version of the position locator:

1. Insert the screw from the side slot into the screw hole.

Figure E – Screw assembled through the side window of the new Nobel Biocare N1™ TCC Position Locator

2. Insert the Omnigrip™ Mini screwdriver through the center hole.
3. Engage the screw head and tight the screw into the Position Locator body.
4. Once you see the entire screw thread, the screw is fully inserted.

Figure F – Insertion and screw tightening from the top of Omnigrip™ Mini Screwdriver for the new version of Position Locator Nobel Biocare N1™ TCC

Handling procedure for the old and new version of Position Locator Nobel Biocare N1™ TCC:

5. Connect the Position Locator to the implant by hand-tightening the screw using the Omnigrip™ Mini screwdriver. For the new version of the position locator, it is recommended to use the top hole for the screw tightening whenever the space allows it, as then the screwdriver and the screw are completely aligned. For the old version of the position locator use the side access. Refer to Nobel Biocare Instructions for Use (IFU) IFU1085 for information regarding the screwdrivers.

Figure G – Tightening from the top for the new version and from the side window for the old version of Position Locator Nobel Biocare N1™ TCC

6. Verify the seating of the position locator using radiographic imaging.
7. Take an intra-oral scan of the patient following the scanner manufacturer's instructions. The new position locator present the type of connection and implant platform engraved on the side which can be captured by the scanner.

Engraving	Implant connection	Platform
N1R	(N1) for Nobel Biocare N1™ TCC	(R) for RP
N1N	(N1) for Nobel Biocare N1™ TCC	(N) for NP

Figure H – Example of engraving on the side of the new version of the Position Locator Nobel Biocare N1™ TCC

8. Remove the Position Locator by untightening the screw.

9. Send the scan file to the laboratory.

Position Locator Nobel Biocare N1™ TCC Desktop Scanning Workflow

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.

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

Nobel Biocare Multi-unit PoLo Intra-oral Scan Workflow

1. Select the Appropriate position locator height and link length:
   - Evaluate the specific requirements of the case to determine the ideal position locator height and links length.
   - The links are recommended to be added for edentulous cases and are available in various lengths to accommodate different implant positions.

2. If needed, assemble the links to the position locators:
   - Perform this step extra-orally.
   - Manually tighten the links to the position locators and insert the copacked prosthetic screw into the position locators using the Unigrip™ screwdriver.

3. Placement of Nobel Biocare Multi-unit PoLo on Multi-Unit Abutments:
   - Place the position locators on the Multi-unit abutments.
   - Partially tighten them to ensure stability and align the links toward the next position locator, following the natural arch shape.

For full arch cases, align the links to follow the natural arch shape and position it close to the next position locator. Refer to the provided images for an example setup involving four implants.

Figure I – Example of All-on-4® configuration

4. Hand-Tighten the Screw:
   - Once each position locator and link are aligned, use the Unigrip™ screwdriver to securely fasten the screw.

Caution Avoid excessive force on the link as it may damage the Multi-unit abutment/implant connection.

Note Ensure that the link does not exert pressure on the surrounding soft tissue. A minor non-parallel alignment between the links and the tissues, will not compromise the scan.

5. Intra-Oral Scanning technique:
   - Begin scanning from the posterior position locator. Keep the scanner tip occlusal during scanning.
   - Proceed with a continuous scan from one direction to the other. Aim to capture as much information as possible using linear movements. Slightly tilt the tip of the scanner in order to capture the top of the position locator and the soft tissue paying attention to remove potential scanning gaps between the position locator and the tissue.
   - Once the first scan is completed, if gaps are detected, scan those missing areas individually to ensure comprehensive coverage.

Note Be cautious not to touch the Links during scanning, as any movement could compromise the final result.

6. Save Digital Scan Data:
   - Save the digital scan data files and send the files to the laboratory.

7. Removing Position Locators:
   - Carefully untighten the position locators using the Unigrip™ screwdriver

Additional consideration:
   - For a complete profile of the soft tissue, perform a full arch scan without the position locators in order to capture the whole profile of the soft tissue.
   - Before proceeding with the final restoration, consider testing the passive fit of a prototype.

Nobel Biocare Multi-unit PoLo Desktop Scanning Workflow

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

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

Sterility and Reusability Information

Nobel Biocare 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.

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.

The devices shall be inspected before each re-use to ensure that the integrity and performance continues to be maintained. Inspect the devices for signs of degradation that may limit the useful life of the devices, such as:

- Any sign of wear or modification of the surface.
- Visible corrosion.
- Mechanical wear/damage.

The device shall be disposed if any of these signs of degradation are evident.

Cleaning and Sterilization Instructions

These products are intended to be cleanded and sterilized. For further information refer to Nobel Biocare publication **Cleaning and Sterilization Instructions** by navigating to ifu.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.

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 PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 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 licensed physician or dentist.

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.