

# NobelPearl™ Tapered Dental Implant System

## Instructions for use



### Important: Please read.

#### Disclaimer of liability:

NobelPearl™ Tapered implants are part of an overall concept and may only be used in combination with the appropriate original components and instruments and in compliance with the manufacturer's instructions. The use of non-compliant parts might impair the function of the implants and of the abutments and consequently result in implant failure. Sole responsibility for correct application is assumed by the user and is beyond control of Nobel Biocare and Dentalpoint AG. Nobel Biocare and Dentalpoint AG do not assume any responsibility and liability for damages caused by misuse.

#### Description:

##### Implants:

NobelPearl™ Tapered implants are available in different lengths specified in the current product lists.

**Note:** NobelPearl™ Cover Screw Inter-X included.

Length: The length of NobelPearl™ Tapered implants specified on the package refers to the endosseous length of the implant.

Material: NobelPearl™ Tapered implants are made of biocompatible zirconia / zirconium dioxide. NobelPearl™ Cover Screw Inter-X are made of PEEK (Polyether ether ketone).

Surface: NobelPearl™ Tapered implants feature ZERAFIL™ surface (sandblasted and acid etched).

Implant Platform	Implant Diameter	Implant Length (endosseous)
RP	Ø 4.2 mm	8 mm, 10 mm, 12 mm, 14 mm
WP	Ø 5.5 mm	8 mm, 10 mm, 12 mm

##### Abutments:

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

**Note:** NobelPearl™ Definitive Clinical Screw is included with the NobelPearl™ abutments. NobelPearl™ Temporary Clinical Screw is included with the NobelPearl™ Temporary Abutment.

##### Materials:

– NobelPearl™ Abutments are made of zirconium dioxide

– NobelPearl™ Definitive Clinical Screw is made of VICARBO® (PEEK-CF)

– NobelPearl™ Healing Abutment is made of PEEK

– NobelPearl™ Temporary Abutment is made of PMMA (Polymethyl methacrylate)

– NobelPearl™ Temporary Clinical Screw is made of PEEK-CW30

##### Tooling:

NobelPearl™ Tapered Twist Drill, NobelPearl™ Tapered Drills, NobelPearl™ Tapered Dense Bone Drills and NobelPearl™ Tapered Screw Taps should be used in conjunction with NobelPearl™ Tapered implants. All drills are reusable. Tapered drills are unique for each implant length. The diameter is indicated on each tool by a color code.

##### Materials:

– NobelPearl™ Tapered Twist Drill is made of stainless steel.

– NobelPearl™ Tapered Drills, NobelPearl™ Tapered Dense Bone Drills and NobelPearl™ Tapered Screw Taps are made of stainless steel with DLC (Diamond Like Carbon) coating.

#### Intended Use:

The NobelPearl™ Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore chewing function. It can be used for single or multiple unit restorations.

#### Indications:

The NobelPearl™ Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore esthetics and chewing function. The NobelPearl™ Dental Implant System can be used for single or multiple unit restorations. NobelPearl™ Tapered implants are intended for delayed loading. NobelPearl™ Tapered implants are specially indicated for patients with metal allergies/intolerances and chronic illness due to metal allergies/intolerances.

#### Contraindications:

Implantation is contraindicated in patients with the following conditions:

- Patients who are medically unfit for an oral surgical procedure
- Poor bone quality, i.e. if a stable fit of the implant (primary stability) cannot be assured
- Non-completed bone growth
- Acute or chronic infectious diseases
- Subacute chronic jaw osteitis
- Diseases resulting in microvascular impairments
- Systemic diseases
- General bad medical condition of the patient
- Any kind of substance abuse
- Poor oral hygiene as well as poorly motivated, noncooperative patients
- Vulnerable patient groups (e.g. lactating women)

**Note:** Please consider the general contraindications valid in the field of medical implants. Periodontal problems require appropriate treatment prior to implantation.

#### Side effects, interactions and precautions; complications with NobelPearl™ Tapered implants:

Immediately after the insertion of dental implants, activities that demand considerable physical exertion should be avoided.

Information related to side effects, interactions and precautions, complications with NobelPearl™ Tapered implants should be provided to the patient.

Possible complications following the insertion of dental implants are:

Temporary symptoms: Pain, swelling, phonetic difficulties, gingival inflammation.

More persistent symptoms: Chronic pain in connection with the dental implant, permanent paresthesia, dysesthesia, loss of marginal bone, osteolysis, poor or no osseointegration, localized or systemic infection, oroantral or oronasal fistulae, unfavorably affected adjacent teeth, irreversible damage to adjacent teeth, fractures of implant, jaw, bone or prosthesis, esthetic problems, nerve damage, exfoliation, hyperplasia.

#### Side effects and interactions, complications with NobelPearl™ abutments and accessories:

Failure to follow the procedure outlined in these instructions may harm the patient and/or lead to any or all of the following complications:

- Aspiration of components
- Damage to the implant, abutment, components or tooling
- Loosening of the abutment or other components
- Improper final restoration or malfunction of the crown, bridge, or other final prosthetic
- Impairment of the patient's chewing function
- Failure of the implant and/or
- Removal of the implant

#### Warnings:

One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure.

Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.

Despite the high success rates with NobelPearl™ Tapered implants, failures cannot be excluded. Reasons are case-specific and often not obvious. They should be documented and reported to the manufacturer.

#### Caution / Precautions:

##### Clinical use:

Sterile handling is essential. NobelPearl™ Tapered implants and NobelPearl™ Cover Screw Inter-X are for single use only. A previously used, non-sterile or contaminated implant or cover screw must not be used under any circumstances. Re-use of single use devices may lead to infections, inflammations or loss of the implant.

##### Handling of storage and sterile package:

The storage package is only to be opened shortly before implantation. The sterile package has to be checked for damages prior to opening. Any damage of the sterile package (blister) might affect sterility of the contained products. When taking the implant out of the package, please follow the valid instructions regarding aseptic conditions. NobelPearl™ Tapered implants have to be stored in their original package and in a cool (ambient temperature) and dry environment and have to be protected against direct sunlight.

##### Special caution is advised in patients presenting the following conditions:

- Hypertension
- Myocardial infarction within past six months
- Cerebral infarction and cerebral apoplexy: In cases where the condition of the disease is serious and the patient are concurrently taking anticoagulants.
- Diabetes
- Smoking
- Chronic osteomyelitis
- Bruxism
- Mouth-closing disorder (temporomandibular joint disorder, temporomandibular joint ankylosis, post-tumor resection
- Abnormal anatomical structures, e.g. maxillary sinus, inferior alveolar nerve, that may interfere with implants

#### Cleaning and Sterilization:

NobelPearl™ Tapered implants and NobelPearl™ Cover Screw Inter-X are subjected to steam sterilization.

**Re-sterilization:** If the package is damaged or not tightly closed, NobelPearl™ Tapered implants must not be used or re-sterilized. Same applies to expired implants. The manufacturer does not assume liability for re-sterilized implants.

##### Reprocessing and preparing medical devices / General requirements:

Refer to the legal regulations and guidelines which are valid for medical office practices and hospitals in your country. This applies in particular to specifications for the effective denaturation of prions. Treatment always involves a risk of contamination and infection. Take preventive measures to actively eliminate the risk or to reduce it as much as possible. These measures include:

- Evaluation of the risks that accompany the medical intervention; decision on appropriate protective measures
- Development of systematic procedures for the work flow, in order to prevent contamination and injuries

– Careful recording of each patient’s medical history to be aware of the individual contagion risk.

All medical devices that have been opened and laid out for use are to be considered contaminated and are to be reprocessed in the same way as used equipment. Organize the transport of contaminated devices in such a way that no staff members, co-workers or third parties are endangered. All personnel must wear the appropriate protective clothing and gloves.

Medical products may corrode if they are stored in a physiological saline solution. Instruments are to be submerged fully in the sterilization trays, without air bubbles. The use of demineralized water to rinse instruments after disinfection is absolutely necessary to prevent water spots and the formation of crystals. These disrupt the subsequent sterilization process.

You are responsible for the sterility of the products you use. For this reason, you must use validated procedures for the cleaning, disinfection, and sterilization of your medical devices and products. You must ensure regular maintenance of your equipment, and you must observe all process parameters in every cycle. Please note the shelf life of products in sterile packaging (manufacturer’s data sheet). Reprocessing ends with the release for use. Sterilization indicator and sterilization date must be recorded on every sterile packing.

Important:

- Products that are delivered in non-sterile condition (e.g. drills and abutments) must be sterilized before they are used on a patient the first time.
- After use, all reusable medical devices must be reprocessed in accordance with the described procedure.

#### Automated reprocessing:

For automated cleaning to be effective, it must be preceded by manual cleaning. This removes large impurities (blood, tissue and bone fragments). Rinse instruments under cold, running water immediately after use, and use a fine nylon brush to clean off the large impurities. Then place the instruments in the cleaning tray of your disinfection and cleaning device.

#### Ultrasonic cleaning (optional):

If the instruments are very soiled and it is not possible to remove large impurities manually, cleaning in an ultrasonic bath is recommended.

Important: The cleaning agent must be compatible with the products. Please observe the application times and concentrations specified by the manufacturer.

#### Automated cleaning:

Only use properly suited cleaning and disinfection equipment for your automated cleaning tasks. These should be validated by the user on the basis of established cleaning processes. Place parts in the cleaning tray in accordance with instructions provided by the manufacturer of the equipment. There are commercially available cleaning and disinfection agents. We recommend: „neodisher MediClean“ and „neodisher Z“ as the neutralizing agent (both from Dr. Weigert, Hamburg). Follow the manufacturer’s information on dosage and use. We recommend fully demineralized water to clean instruments and for the final rinsing procedure. The selected cleaning and disinfection program should run with the optimal temperature for removal of blood (45–55°C).

Example of a cleaning program:

- Pre-rinse with cold water: 4 min
- Clean with alkaline cleaning agent at 45–55°: 10 min
- Neutralize: 6 min
- Intermediate rinse: 3 min
- Disinfection: 5 min
- Drying (max. 130°C): 5 min

Before the sterilization process, check the cleaned, dried and disinfected parts for corrosion and damage.

#### Manual reprocessing:

Place the products in a disinfectant solution after use to prevent them from drying out and as a personal protection measure. Remove large impurities (blood, tissue and bone fragments). To do this, take the instruments from the tray and clean them under cold, running water with a fine nylon brush. Never use a metal brush or steel wool for this step!

#### Ultrasonic cleaning (optional):

If the instruments are very soiled and it is not possible to remove large impurities manually, cleaning in an ultrasonic bath is recommended.

Important: The cleaning agent must be compatible with the products. Please observe the application times and concentrations specified by the manufacturer.

#### Cleaning:

Before cleaning the products, rinse them under a flow of cold, demineralized water. Disassemble all products that can be taken apart. A suitable cleaning agent is, for example „neodisher MediClean“ (Dr. Weigert, Hamburg). Place the products in a fresh cleaning bath, in accordance with the manufacturer’s information. Clean the parts with a nylon brush. Rinse the products several times with demineralized water and check for corrosion or damage.

#### Disinfection:

Place the products that need to be disinfected in a fresh disinfectant bath. The liquid must cover them completely. ID 212 instrument disinfection (Dürr System Hygiene) is a suitable disinfectant, for example.

#### Rinsing and drying:

After disinfection of the products, rinse thoroughly with demineralized water. Use residue-free compressed air to dry the instruments.

#### Sterilization:

Re-assemble the dismantled medical devices before you start the sterilization procedure. Sort the separately cleaned and disinfected products into the appropriate sterilization tray. You may also sterilize products individually. Then pack the filled trays and/or the individual products in a non-reusable bag suitable for use in a steam sterilizer (single or double bags) and/or in a sterilization container. The validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79:2010. Two examples are: a non-reusable sterilization bag (single or double bag) with temperature tolerance of at least 137°C (ca. 278.6°F) and vapor permeability that allows adequate protection from mechanical damage, or else a sterilization container, which must undergo regular maintenance according to the specifications of the manufacturer. Instruments such as drills, screw taps and depth gauges have dedicated positions in the NobelPearl™ Tapered Surgery Kit Box, where they can be placed for sterilization. Sterilization is achieved in the autoclave in USA: 132°C for the duration of at least 4 minutes holding time and subsequent 20 minutes drying. Rest of World: 134°C for the duration of at least 7 minutes holding time and subsequent 20 minutes vacuum drying. The parts should then be marked with a sterilization date and placed in dry and dust-free storage. USA: If the parts are stored after sterilization, they must be stored in FDA cleared accessories such as wraps and containers.

#### Procedure:

##### Pre-surgical preparation includes:

- General and local patient history, general medical examination (hemogram, diabetes, etc.), consultation with an internal medicine or general practice doctor as well as the local, clinical and radiological examination
- Patient information on indications, contraindications, possible success and failure
- Pre-surgical and prosthetic preparation and consultation with a dental technician
- Selection of an anatomically suitable implant based on X-ray and other techniques.

**Note:** Anatomic and hygienic conditions of each patient have to be assessed individually. In case of unfavorable conditions implantation is not indicated.

##### Healing time:

For all NobelPearl™ Tapered implants the minimal healing time is considered 3 months in the lower jaw and 6 months in the upper jaw.

##### Surgical procedure:

Image A shows the drill depth marks on the drills with the corresponding depth for a 8 mm implant positioned 1.6 mm supracrestal.

A

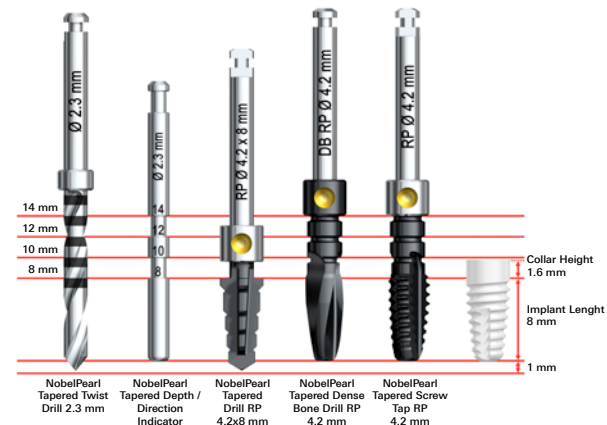
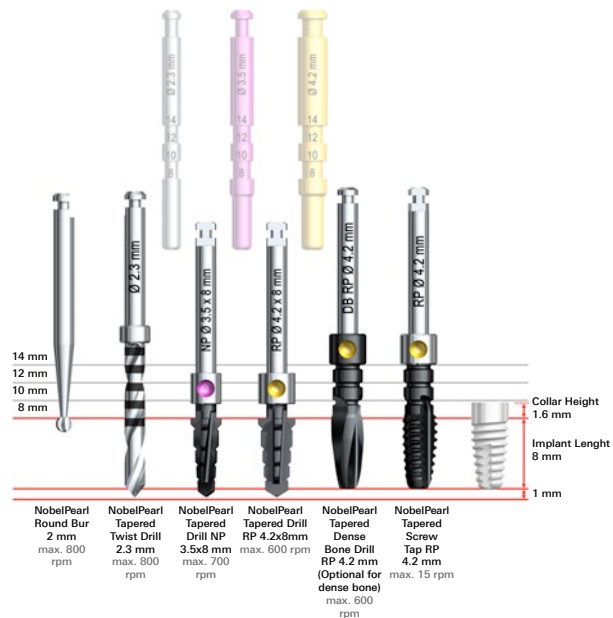


Image B shows protocol steps and “Product Reference line” for NobelPearl™ Tapered RP 4.2 x 8 mm implant positioned 1.6 mm supracrestal. Prepare implant site using NobelPearl™ Tapered Twist Drill 2.3 mm and respective NobelPearl™ Tapered Drill depending on implant to be installed, length and platform.

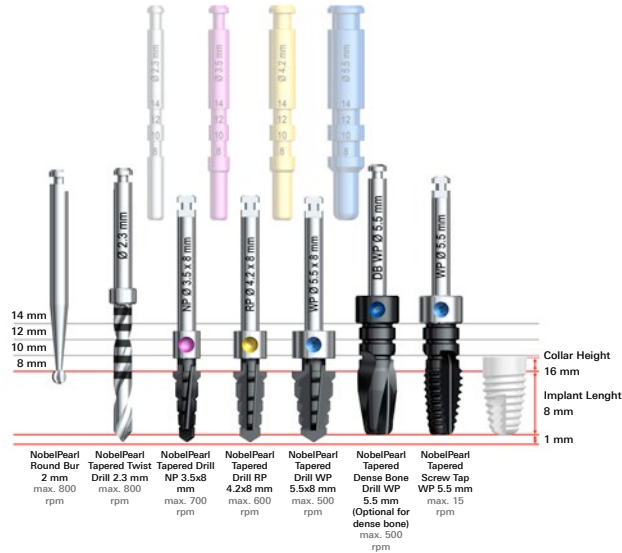
Image C shows protocol steps and “Product Reference line” for NobelPearl™ Tapered WP 5.5 x 8 mm implant positioned 1.6 mm supracrestal. NobelPearl™ Tapered Twist Drill 2.3 mm and respective NobelPearl™ Tapered Drill depending on implant to be installed, length and platform.

**Note:** Different platform sizes have different maximum rpm for the drills. Please refer to the values on Images B & C.

B



C



It is recommended to use the NobelPearl™ Tapered Screw Tap to full-length.

**Caution:** The effective drilling depth is up to 1 mm deeper than the corresponding implant.

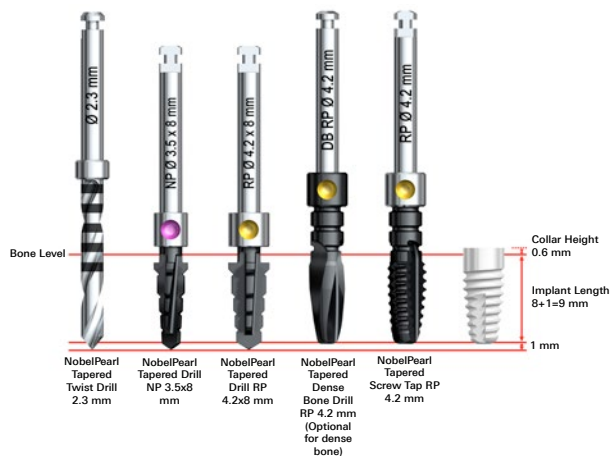
In situations where adjacent structures (natural teeth) would interfere with the angle head and prevent the drill from reaching the desired depth, the Elos Drill Extender may be used.

**Important:** If the drills and instruments are used more than once, place them in the saline solution in the interim.

Alternatively, the implant can also be positioned 0.6 mm supracrestal (instead of 1.6 mm). The NobelPearl™ Tapered Drill and NobelPearl™ Tapered Screw Tap must be inserted 1 mm deeper in this case, as shown on image D.

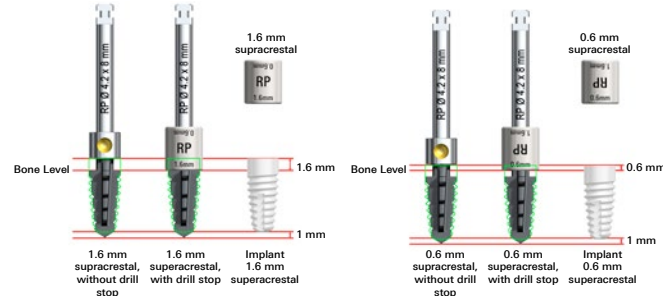
**Note:** For implant lengths of 14 mm, it is recommended that the implant is not placed 0.6 mm supracrestal.

D



Optionally, the NobelPearl™ Tapered Drill Stop can be used to precisely control drilling depth. The NobelPearl™ Tapered Drill Stop is placed on the NobelPearl™ Tapered Drill shaft. It allows for 1.6 mm or 0.6 mm supracrestal placement of the implant (E).

E



Recommended drill spacing between adjacent structures (natural teeth or implants) is shown on image F.

F

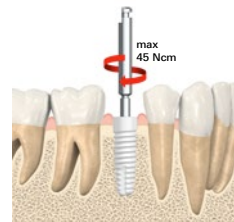


**Insert and cover the implant:**

1. Open the implant package and pick up the implant using the NobelPearl™ Implant Driver Inter-X. Place the implant into the osteotomy. The implants are ideally installed with low speed (maximum 15 rpm).

**Important:** Never use the NobelPearl™ Rescue Driver Inter-X for insertion.

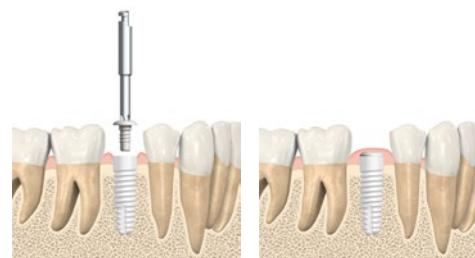
2. Tighten the implant with the Manual Torque Wrench using **20–30 Ncm** insertion torque. The maximum torque for RP and WP implants is **45 Ncm**. Do not exceed this torque. The NobelPearl™ Implant Driver Inter-X has a predetermined fracture point of approximately **50 Ncm**.



3. Connect and tighten the NobelPearl™ Cover Screw Inter-X to the implant using the NobelPearl™ Implant Driver Inter-X or NobelPearl™ Screwdriver. Do not exceed the maximum torque of **5 Ncm**.

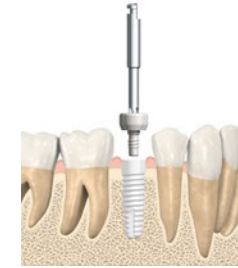
– Option 1: Closed healing (recommended).

– Option 2: Open healing in presence of thick adjacent gingiva.



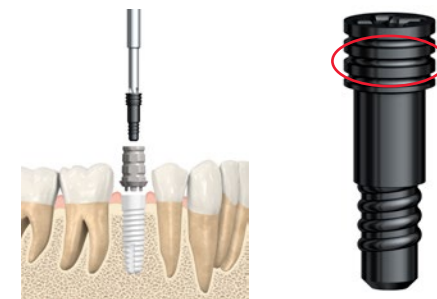
**Healing Abutment:**

Connect and tighten the NobelPearl™ Healing Abutment Inter-X to the implant using the NobelPearl™ Screwdriver. Do not exceed the maximum torque of **5 Ncm**.



**Temporary restoration:**

1. Connect and tighten the NobelPearl™ Temporary Abutment Inter-X to the implant using the NobelPearl™ Screwdriver (max. **15 Ncm**). Make sure to use the NobelPearl™ Temporary Clinical Screw Inter-X. It can be distinguished by three grooves in the screw head (see circle).



2. If necessary, adjust the height of the NobelPearl™ Temporary Abutment Inter-X extra-orally and fabricate a provisional restoration.

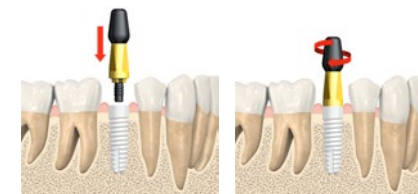
**Processing the provisional restoration:** It is preferable to machine the polymer with fine-grain diamond-coated instruments at a high speed. This is done extra-orally with slight pressure and effective cooling.

**Caution:** The use of NobelPearl™ Temporary Abutment Inter-X is limited to 180 days.

**Closed tray impression taking:**

1. **Clinical procedure:**

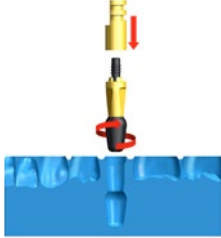
a. Place the NobelPearl™ Impression Coping Closed Tray Inter-X onto the implant. Make sure that the NobelPearl™ Impression Coping Closed Tray Inter-X is fully seated in the implant. To verify this, apply a counter movement. Once the NobelPearl™ Impression Coping Closed Tray Inter-X is seated in the right position, screw in the guide pin. Take an X-ray to verify the proper seating.



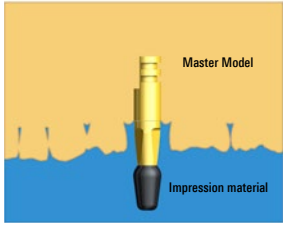
b. Take an impression using a closed tray. Remove the impression. Unscrew the guide pin, remove the NobelPearl™ Impression Coping Closed Tray Inter-X from the implant. Reposition the NobelPearl™ Impression Coping Closed Tray Inter-X with the guide pin in the impression. Send the impression to the dental laboratory.

**2. Laboratory procedure:**

- a. Connect the NobelPearl™ Impression Coping Closed Tray Inter-X to the NobelPearl™ Implant Replica Inter-X. Make sure that the NobelPearl™ Impression Coping Closed Tray Inter-X is fully seated in the NobelPearl™ Implant Replica Inter-X. To verify this, apply a counter movement. Once the NobelPearl™ Impression Coping Closed Tray Inter-X is seated in the right position, screw in the guide pin.



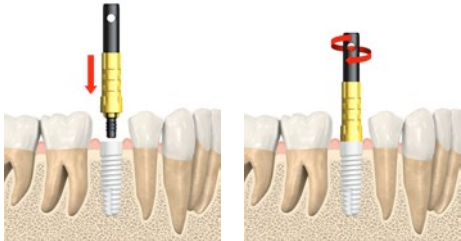
- b. Reposition the NobelPearl™ Impression Coping Closed Tray Inter-X in the impression with the NobelPearl™ Implant Replica Inter-X and make sure that it is fully seated. Create a master model.



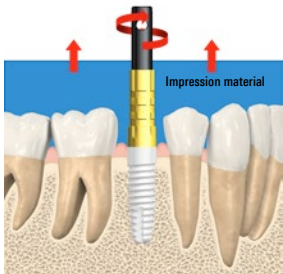
**Open tray impression taking:**

**1. Clinical procedure:**

- a. Place the NobelPearl™ Impression Coping Open Tray Inter-X onto the implant. Make sure that the NobelPearl™ Impression Coping Open Tray Inter-X is fully seated in the implant. To verify this, apply a counter movement. Once the NobelPearl™ Impression Coping Open Tray Inter-X is seated in the right position, screw in the guide pin. Take an X-ray to verify the proper seating.

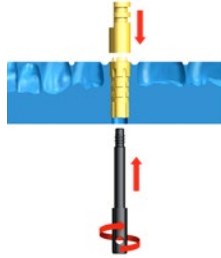


- b. Take an impression using an open tray. Unscrew the guide pin and remove the impression. Send the impression to the dental laboratory, including the guide pin.

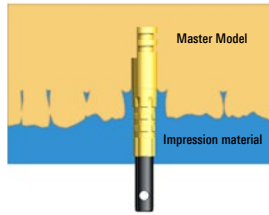


**2. Laboratory procedure:**

- a. Connect the NobelPearl™ Impression Coping Open Tray Inter-X to the NobelPearl™ Implant Replica Inter-X. Make sure that the NobelPearl™ Impression Coping Open Tray Inter-X is fully seated in the NobelPearl™ Implant Replica Inter-X. To verify this, apply a counter movement. Once the NobelPearl™ Impression Coping Open Tray Inter-X is seated in the right position, screw in the guide pin.

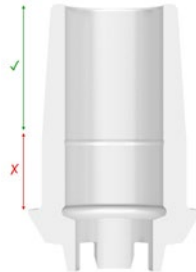


- b. Create a master model. Remove the guide pin before removing the impression.



**Fabrication of the suprastructure in the laboratory:**

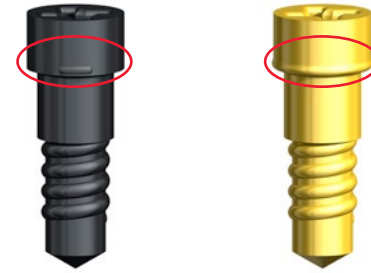
Select an appropriate abutment. If necessary, adjust the height of the abutment. Modifications of the abutments should be performed using sufficient, continuous cooling with slight pressure. Use high speed (turbines) and fine grain size (red-ring diamond, smaller than 50 µm). Local overheating causes micro-fissures and leads to destruction of the abutment. When grinding the abutment, a NobelPearl™ Implant Replica Inter-X can be used as a holder to protect the connection. Only the conical part of the abutment can be shortened.



You can choose a monolithic crown/bridge consisting of a range of optimized polymers or zirconium dioxide or full-ceramic crown/bridge made of layered or pressed ceramic on a zirconium dioxide coping. Make sure to respect the minimum dimensions of the restorative material following the manufacturer's instructions. Do not create a cantilevered restoration.

For work in the laboratory, the NobelPearl™ Lab Screw Inter-X can be used. The maximum torque for the NobelPearl™ Lab Screw Inter-X is **5Ncm**.

**Note:** The NobelPearl™ Lab Screw Inter-X is yellow and has no grooves on the screw head. The NobelPearl™ Definitive Clinical Screw Inter-X is black and also has no grooves on the screw head.



**1. Screw-retained restoration:**

- a. Standard screw channel:

Make sure that the screw channel diameter allows for the NobelPearl™ Definitive Clinical Screw Inter-X to be inserted and removed when the crown/bridge is cemented to the abutment. The minimum diameter of the screw channel for the NobelPearl™ Definitive Clinical Screw Inter-X is  $\varnothing 2.8$  mm.

- b. Reduced-diameter screw channel:

Alternatively, the screw channel can be reduced to  $\varnothing 2.2$  mm. The NobelPearl™ Screwdriver can be utilized to create the screw channel. When using a reduced-diameter screw channel, the NobelPearl™ Definitive Clinical Screw Inter-X must be inserted in the abutment in the laboratory prior to cementing the crown/bridge onto the abutment. Before cementing the crown/bridge, seal the screw channel with wax to prevent the cement from flowing into the screw channel. The NobelPearl™ Definitive Clinical Screw Inter-X cannot be inserted or removed after the crown/bridge has been cemented. If the abutment is shortened, make sure that the NobelPearl™ Definitive Clinical Screw Inter-X has sufficient vertical space to be screwed in and out.

- c. Placement of the restoration:

Connect the restoration to the implant applying slight pressure. Make sure that it is fully seated in the implant. Tighten the restoration to **25Ncm** using the NobelPearl™ Screwdriver and the Manual Torque Wrench. Do not exceed the maximum **25Ncm** tightening torque for the NobelPearl™ Definitive Clinical Screw Inter-X. The NobelPearl™ Definitive Clinical Screw Inter-X may only be tightened once to the maximum torque. It is recommended to verify the abutment seating using radiographic imaging.

**2. Cement-retained restoration:**

If a cement retained restoration is required, fabricate a crown/bridge without the screw channel. Pick up the NobelPearl™ Definitive Clinical Screw Inter-X with the NobelPearl™ Screwdriver and insert it into the abutment until it clicks into the fine groove in the screw channel. Use the NobelPearl™ Screwdriver to transfer the abutment onto the implant. Before tightening the NobelPearl™ Definitive Clinical Screw Inter-X, press it downward. Use the NobelPearl™ Screwdriver and the Manual Torque Wrench. Do not exceed the maximum **25Ncm** tightening torque for the NobelPearl™ Definitive Clinical Screw Inter-X. The NobelPearl™ Definitive Clinical Screw Inter-X may only be tightened once to the maximum torque. It is recommended to verify the abutment seating using radiographic imaging. Cement the crown/bridge onto the fully seated abutment and remove any excess cement.

**Please note:**

The preceding specifications are an outline of the most important operational steps. It is strongly recommended that clinicians go through a briefing by an experienced user. Documentation/Traceability: The manufacturer recommends complete clinical, radiological, photographic and statistic documentation. Traceability of the implants has to be assured. Use the adhesive labels enclosed in the sphere package for documentation in the patient file.

**Availability:**

Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

**For Prescription Use Only. CAUTION:** Federal (United States) law restricts this device to sale by or on the order of a clinician, medical professional or physician.

**Manufacturer:**



Dentalpoint AG, Bodenackerstrasse 5, CH8957 Spreitenbach, Switzerland  
T: +41 (0) 44 388 36 36  
Distributor: Nobel Biocare AB, Box 5190, 402 26 Göteborg,  
Västra Hamngatan 1, 411 17 Göteborg, Sweden



**Rx Only**

Prescription  
use only



Non-sterile



Caution



Date of  
manufacture



Manufacturer



Consult instructions  
for use



Steam sterilized



Do not re-use



Do not use  
if package is  
damaged



Catalogue  
number



Batch code



Use-by date



Keep dry



Keep away from  
sunlight

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