# NobelPearl™ Ceramic Base
## Instructions for use

**Important: Please read.**

**Disclaimer of liability:**
NobelPearl™ Ceramic Base abutments 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:

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 included.

**Materials:**
– NobelPearl™ Ceramic Base abutments are made of zirconium dioxide
– NobelPearl™ Definitive Clinical Screw are made of VICARBO® (PEEK-CF) (Polyether ether ketone – Carbon Fiber)

### Intended use:

Dental implant abutments are to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

### Indications:

The NobelPearl™ Ceramic Base abutment in combination with NobelPearl™ Tapered Inter-X endosseous implants are indicated for single-unit or multiple-unit crowns.

### 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 ostitis
– 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 and interactions, complications with NobelPearl™ Ceramic Base 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™ Ceramic Base abutments, 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:**
NobelPearl™ Ceramic Base abutment is delivered non-sterile and for single use. Final abutment should be cleaned and sterilized, if applicable, before intra oral use.

**Handling of storage and sterile package:**
NobelPearl™ Ceramic Base abutments 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™ Ceramic Base abutments are delivered non-sterile and for single use. Final restoration should be cleaned and disinfected, as applicable per restorative material manufacturer's instructions, before intraoral use.

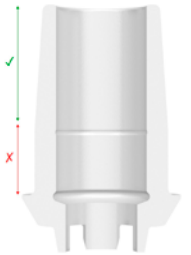
**Warning:** Do not use if package is damaged or previously opened.

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

**Caution:** This is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

### Procedure:

**1. Fabrication of the suprastructure (Laboratory procedure):**
Select the appropriate NobelPearl™ Ceramic Base 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.



**2. Processing options:**
Conventional workflow (Laboratory procedure):
– Connect the NobelPearl™ Ceramic Base to the model using the NobelPearl™ Lab Screw Inter-X. The maximum torque for the NobelPearl™ Lab Screw Inter-X is **5 Ncm**.
– Create a wax-up restoration and use the standard procedure to either press or cast the coping or full-contour crown/bridge. Make sure to respect the minimum dimensions of the restorative material following the manufacturer's instructions. The minimum diameter of the screw channel for the NobelPearl™ Definitive Clinical Screw Inter-X is Ø2.8 mm. Alternatively, the screw channel can be reduced to Ø2.2 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 prior to cementing the crown/bridge onto the abutment. 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.

Digital workflow (DTX Studio/exocad/3Shape) with non-modified abutment (Laboratory procedure):
– Connect the NobelPearl™ Position Locator Inter-X to the model using a maximum torque of **15 Ncm**.
– Scan following the usual scan routines.
– Select the appropriate NobelPearl™ Ceramic Base abutment from the implant library.
  – DTX Studio: The library will be updated automatically to include the NobelPearl™ Ceramic Base abutments.
  – Exocad: The library will be updated automatically to include the NobelPearl™ Ceramic Base abutments. Exception: Systems from Zirkonzahn and Amann Girrbach require files to be imported manually.
  – 3Shape: Please download the files from www.nobelbiocare.com and import them into your system.
– Design the crown/bridge. Make sure to respect the minimum dimensions of the restorative material following the manufacturer's instructions. The minimum diameter of the screw channel for the NobelPearl™ Definitive Clinical Screw Inter-X is Ø2.8 mm. Alternatively, the screw channel can be reduced to Ø2.2 mm. When using a reduced-diameter screw channel, the NobelPearl™ Definitive Clinical Screw Inter-X must be inserted in the abutment prior to cementing the crown/bridge onto the abutment.
– Send the design file to a milling machine accepting exocad/3Shape design files.

Digital workflow with modified abutment (Laboratory procedure):
– Connect the NobelPearl™ Ceramic Base to the model using the NobelPearl™ Lab Screw Inter-X. The maximum torque for the NobelPearl™ Lab Screw Inter-X is **5 Ncm**.
– Scan following the usual scan routines.
– Design the crown/bridge. Make sure to respect the minimum dimensions of the restorative material following the manufacturer's instructions. The minimum diameter of the screw channel for the NobelPearl™ Definitive Clinical Screw Inter-X is Ø2.8 mm.



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Alternatively, the screw channel can be reduced to Ø2.2 mm. When using a reduced-diameter screw channel, the NobelPearl™ Definitive Clinical Screw Inter-X must be inserted in the abutment prior to cementing the crown/bridge onto the abutment. 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.

– Send the design file to a milling machine.

**3. Cementing of the crown/bridge to the NobelPearl™ Ceramic Base (Laboratory procedure):**

– Once the crown/bridge is produced, finalize it following the restorative material manufacturer's instruction.

– Seal the screw channel with wax.

– Clean the surface as recommended by the cementing material manufacturer.

– Cement the crown/bridge to the NobelPearl™ Ceramic Base according to the cement manufacturer's instructions. When using a reduced-diameter screw channel, the NobelPearl™ Definitive Clinical Screw Inter-X must be inserted in the abutment prior to cementing the crown/bridge onto the abutment. The NobelPearl™ Definitive Clinical Screw Inter-X cannot be inserted or removed after the crown/bridge has been cemented.

**4. Final restoration (Clinical procedure):**

Connect the restoration to the implant applying slight pressure to fit the restoration until it snaps into place in the correct position. Tighten the restoration to **25 Ncm** using the NobelPearl™ Screwdriver and the Manual Torque Wrench. Do not exceed the maximum **25 Ncm** 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.

## 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.

## 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.

## Manufacturer and Distributor:


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**Canada license exemption:** Please note that not all products may have been licensed in accordance with Canadian law.

**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.

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Rx Only
Prescription use only

NON STERILE
Non-sterile

Caution

Date of manufacture

Manufacturer

Consult instructions for use

STERILE
Steam sterilized

Do not re-use

Do not use if package is damaged

REF
Catalogue number

LOT
Batch code

Use-by date

Keep dry

Keep away from sunlight

NON STERILE
Non-sterile






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