Anatomical PEEK Healing/Temporary Abutment
Instructions for use

Important: Please read.

Disclaimer of liability:
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Description:

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

Internal conical connection for: NobelActive® CC WP and NobelParallel™ CC WP.

Note: Clinical screw included.

Intended use:

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

The PEEK Healing Abutment is intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue.

The PEEK Temporary Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. It is indicated for single and multiple unit cement retained temporary restorations.

Indications:

The Nobel Biocare anatomical PEEK Healing and Temporary Abutments are premanufactured, adjustable prosthetic components directly connected to endosseous dental implants and are intended for temporary use up to 180 days as an aid in prosthetic rehabilitation.

Contraindications:

It is contraindicated placing PEEK Healing and Temporary Abutments in patients:

– who are medically unfit for an oral surgical procedure.

– in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.

– who are allergic or hypersensitive to PEEK (Polyetheretherketone) or titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium).

Cautions:

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

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.

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Special attention has to 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 or unfavorable jaw relationships reappraisal of the treatment option may be considered.

Never exceed **35 Ncm** prosthetic tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

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

Handling procedure:

Clinical procedure PEEK Healing Abutment

1. Select appropriate healing abutment. Height may be adjusted by use of a rotary instrument (e.g. carbide or acrylic bur).
2. The tissue facing axial contours of the abutment may be modified to achieve the desired shape. If axial modification is done, polishing with silicone points or similar methods is recommended.
3. The modified abutment is seated on the implant and manually tightened using the Unigrip™ Screwdriver.

Clinical procedure PEEK Temporary Abutment

The Nobel Biocare Anatomical PEEK Temporary Abutment may be used for cement retained provisional restorations.

1. Select appropriate temporary abutment. Height may be adjusted by use of a rotary instrument (e.g. carbide or acrylic bur).
2. Cut a small axial 'flat' or 'groove' into the provisional abutment to assist in correct location during cementation.
3. Construct a provisional crown/bridge in conventional manner. It is important to remove and replace the provisional crown/bridge at least once prior to final setting of the restorative material to avoid difficulty in removing the crown/bridge once the restorative material has set.
4. Contour margins and polish modified area.
5. Tighten the PEEK Temporary Abutment to **35 Ncm** using Unigrip™ Screwdriver and Manual Torque Wrench Posthetic.
6. Cement provisional crown/bridge onto PEEK Abutment with preferred temporary cement. Care should be taken to ensure that all excess cement is completely removed.

Materials:

Anatomical PEEK Healing and Temporary Abutment: PEEK (Polyetheretherketone).

Abutment Screw: Titanium alloy 90% Ti, 6% Al, 4% V.

Cleaning and sterilization instructions:

Anatomical PEEK Healing and Temporary Abutments are delivered sterile for single use only prior to the labelled expiration date.

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

Caution: Anatomical PEEK Healing and Temporary Abutments are single use products that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

MR safety information:

MR conditional:

Non-clinical testing has demonstrated that the device is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

– Static magnetic field of 1.5 Tesla and 3.0 Tesla only.

– Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).

– Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of 4.1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the product extends approximately 30 mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

For additional information on Cleaning and Sterilization and Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines for Nobel Biocare Products including MRI Information" available at www.nobelbiocare.com/sterilization or request latest printed version from a Nobel Biocare representative.

Storage and handling:

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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

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

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CE 0086

Rx Only

Magnetic resonance conditional

Sterile using irradiation

Do not resterilize

Consult instructions for use

Use-by date

Do not re-use

Batch code

Do not use if package is damaged

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