PEEK Abutment

Instructions for use

Important: Please read.

1. Disclaimer of Liability

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions recommendation of BIOSTI Implant. Non-recommended use of products made by third parties in conjunction with BIOSTI Implant products will void any warranty or other obligation, express or implied, of BIOSTI Implant.
The user of BIOSTI Implant products has the duty to determine whether or not any product is suitable for the particular patient and circumstances.
BIOSTI Implant disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of BIOSTI Implant products. The user is also obliged to study the latest developments in regard to this BIOSTI Implant product and its applications regularly. In cases of doubt, the user has to contact BIOSTI Implant.
Since the utilization of this product is under the control of the user, it is his/her responsibility. BIOSTI Implant does not assume any liability whatsoever for damage arising thereof.
Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

2. Description

A premanufactured dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.
PEEK Abutments are made of PEEK Material.
PEEK Abutments are available for use with the BIOSTI Implant Systems treatment concept with guided surgery only.

3. 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 abutments in combination with two-stage endosseous implants are used as the foundation for anchoring tooth replacements in either jaw.

Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructions.
PEEK Abutments are intended for use for temporary prosthetic solutions.

4. Material

All PEEK Abutment: Medical PEEK
PEEK Abutment Screws: Grade 5 Titanium.

5. Handling Instructions

Modifications of abutments could be performed using copious water irrigation.
Extra-oral modification of abutment is recommended.

6. Clinical Procedure

1. Select appropriate abutment and check occlusal clearance.
2. Connect and tighten the abutment. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment using Abutment Screw with Driver Torque 1,2 and Adjustable Torque Wrench prosthetic.

Caution: Care should be taken when trying to insert the screw. It is important that it is correctly placed. Never exceed recommended maximum tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Note: Use the appropriate torque values for the abutments. Torque values; Standard 30 Ncm, Mini 20 Ncm, Ultra Mini 15 Ncm.

7. 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.
Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.
Products in damaged packages should not be used on the patient.

8. Indications

PEEK Abutments are pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

9. Contraindications

It is contraindicated to use abutments 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 commercially or Titanium.

10. Users

Dental implant surgery requires appropriate and adequate training.
It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.
Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

11. Cleaning and Sterilization Instructions

PEEK Abutments are delivered non-sterile for single use and must be autoclave sterilization at 121˚C- 20 min prior to use.

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

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

Warning: The Abutment System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Abutment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

12. 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.

13. Disposal

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

	Manufacturer Name/Manufacturer Address		Do not re-use
	Production date	NON STERILE	Non-sterile
MD	Medical device		Caution!
LOT	Batch number	EC REP	European Authorized Representative
REF	Catalog number	eIFU Indicator	Consult electronic instructions for use

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