INSTRUCTIONS FOR USE

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BONECARE
TITANIUM SHOCK ABSORBER

TITANIUM SHOCK ABSORBER SCREW RETAINED/FIXED

Other trade names: Titanium Shock Absorber TSA TF

Important: This document contains the most current instructions for use. Please read & retain.

The Titanium Shock Absorber system includes: Titanium Shock Absorber abutments, ancillary processing components (impression coping, scan body and laboratory analog), a titanium cylinder an interface and tooling (TSA driver)

Intended use: The TITANIUM SHOCK ABSORBER SCREW RETAINED/FIXED or TSA TF is a dental abutment designed to support partial or full arch restorations on endosseous implants in the mandible or maxilla for the purpose of restoring masticatory function of a patient while absorbing masticatory forces.

Intended user: dental technicians, maxilla-facial surgeons, general dentists, orthodontists, periodontists, prosthodontists, and other appropriately trained and experienced dental professionals.

Description: The TITANIUM SHOCK ABSORBER SCREW RETAINED/FIXED or TSA TF is a pre-manufactured abutment on implant level for a resilient connection of partial and full arch bridgework restorations on endosseous implants. The abutment system allows for the bridgework restoration to be screw retained on the abutment.

Indications: indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla or mandible, including full arch dentures.

Implant Compatibility: The product is available for a variety of implant platforms and sizes. For specific platform availability check the references on www.bonecare.be

Contra-indications:

- Patients who are medically unfit or in a poor general state of health for dental implant procedures*
- Patients under the age of 18 (routine treatment is not recommended until the end of the jaw bone growth phase has been properly documented)
- Patients with inadequate bone volume unless an augmentation procedure can be considered.
- Patients in whom adequate sizes, number or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who are allergic for Ti 6-AI 4V (90% titanium, 6% aluminium, 4% vanadium), silicones
- TSA F is not appropriate for single tooth restorations.
- TSA F is not appropriate when a rigid connection is required.
- TSA F is not appropriate for use on an implant with divergence greater than 20 degrees (from vertical)

*Patients with blood disorders, infected implant site, vascular impairment, uncontrolled diabetes, drug or alcohol abuse, chronic high dose steroid therapy, anti-coagulant therapy, metabolic bone disease or radiotherapy treatment.

Warnings & Precautions:
Close cooperation between surgeon, restorative dentist and laboratory technician is essential for a successful implant treatment. It is strongly recommended that Titanium Shock Absorber abutments are only used with compatible BoneCare Dynamics Instruments. Use of instruments that are not intended to be used in combination with the Titanium Shock Absorber can lead to product failure.

When using a new device/treatment for the first time, new and experienced Implant users should do training before using a new system or attempt to do a new treatment method. Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (i.e. poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone and patients who had oro-facial radiotherapy.) Thorough screening of prospective implant candidates must be performed.

Products from damaged packaging must not be used on patients. If the packaging is damaged, the damaged packaging (with the product) must be returned to the manufacturer and a replacement will be provided (if damage to packaging is caused by product shipment from the manufacturer).

Please follow the instructions for use from the manufacturer of each compatible implant system for implant placement and indicated range of divergence for abutments. Components must be assembled and maintained as described in this document. Parafunctional habits, such as bruxism or clenching may result in overloading, loosening or improper fitting of the components, causing them to fracture and/or fail during normal use.

Care should be taken when utilizing small components as they can be dropped and contaminated, ingested or aspirated.

For purposes of traceability we advise the dental professional to record the lot number of the applied products in the patient file.

Content: The Titanium Shock Absorber packaging contains one TITANIUM SHOCK ABSORBER SCREW RETAINED for screw retained bridgework.

Storage and handling: The product in its undamaged, original packaging is not subject to any special considerations for storage or handling.

Single-Use Devices: The TITANIUM SHOCK ABSORBER SCREW RETAINED/FIXED components, with the exception of the scan flag and the tool, are single-use devices and are provided non-sterile. Single-use devices should not be reused or re-sterilized. Reuse of a single-use device may cause harm to the patient in the transfer of blood, tissue or saliva that may contain infectious disease. Single-use devices may not function as intended if re-sterilized and may result in an improper function or failure of the device.

Multi-use Devices: The TITANIUM SHOCK ABSORBER SCREW RETAINED/FIXED Scan flag and Tool are multi-use devices and are provided non-sterile. Reusable instruments must be cleaned and sterilized prior to re-use on patients. If the tool becomes worn or damaged, obtain a replacement tool.

Cleaning & Sterilization Procedure
Containment: as soon as practically possible, remove all visible residue after use (bone, blood or tissue), by immersing the instrument in cold water. Dried soil is difficult to remove.

***Automated cleaning and drying*:** Disassemble instruments from handpieces and all connecting parts from instruments i.e. ratchets, in order to clean soil from obstructed areas. Rinse with 0.5% lukewarm enzynamic cleaning agent (e.g. Neodisher Medizym) for a minimum of 5 minutes, and remove hardened debris with a soft nylon brush (e.g. Medsafe

MED-100.33) for a minimum of 20 seconds until all visible soil is removed. Thoroughly rinse all outer and inner surfaces with cold running tap water for a minimum of 10 seconds to remove all cleaning solution. Avoid mechanical damage during cleaning.

Place the device in a suitable rack or load carrier (e.g. metal sieve basket). Load the devices into the washer (e.g. Miele G7836 CD with the Vario TD program). Ensure the rack or load carrier is oriented in a horizontal position. Perform automatic cleaning bases on Vario TD program:

- Minimum 2 minutes pré-cleaning
- Draining
- Minimum 5 minutes cleaning with minimum 55°C tap water and 0.5% mildly alkaline detergent (e.g. Neodisher Mediclean)
- Draining
- Minimum 3 minutes neutralizatiob with cold desalinated water
- Draining
- Minimum 2 minutes rinsing with cold desalinated water
- Draining

Run drying cycle at minimum 55°C for a minimum of 10 minutes. Dry with compressed air or clean and lint-free single use wipes, if any residual moisture remains after the drying circle.

Manual cleaing and drying: Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution. Scrub the outer surface of the device with soft-brisled nylon brush for a minimum of 20 seconds until all visible soil is removed. Flush the inner surfaces with 20ml lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP; maximum 45°) using an irrigation needle connected to a 20ml syringe Thorougly rinse all outer and inner surfaces with cold running tap water for a minimum of 10 seconds to remove all cleaning solution.
Immerse the device in an ultrasonic bath (e.g. Bandelin; frequency 35kHz; effective ultrasonic power 300 W) containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP) and treat for a minimum of 5 minutes at minimum 40°C/maximum 45°C. Flush the inner surfaces with 20ml lukewarm tap water using an irrigation needle connected to a 20ml syringe. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 10 seconds to remove all cleaning agent. Dry with compressed air or clean and lint-free single use wipes.

Inspection: After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting, or cracking seals and properly discard any devices that fail that inspection.

Packaging**:** Use the correct packaging material as indicated for steam sterilization to ensure sterility is maintained. Double packaging is recommended.

Sterilization**: The Titanium Shock Absorber Abutment, Impression coping, titanium cylinder, interface and tool are supplied non-sterile and should be sterilized prior to use on the patient.**

The following sterilization procedures should be carried out prior to use:

	Gravity Autoclave	Pre-Vacuum Autoclave
Temperature	134°C	134°C
Exposure Time	3 minutes	3 minutes
Dry Time	30 minutes	20 minutes

Storage: Maintain packaging integrity to ensure sterility in storage. Packaging should be completely dry before storage to avoid corrosion and degradation of cutting edges.

Disposal:

safely discard potentially or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislations or policy. Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Prosthetic Procedures:

1. **Placement of abutments (clinical procedure)**

Based on the results of the patient's pre-surgical assessment, the clinician should select and order the appropriate TITANIUM SHOCK ABSORBER SCREW RETAINED/FIXED Abutment based on the type of implant and diameter being used. It is imperative that all bone and soft tissue be removed from the superior aspect of the implant body to guarantee complete seating of the Abutment. Using a calibrated torque wrench, tighten the TITANIUM SHOCK ABSORBER SCREW RETAINED/FIXED Abutment to the torque value that is indicated on the label. It is recommended to verify the final abutment selection and seating using radiographic imaging.

Warning: Use of higher torque values than recommended could cause a fracture of the TITANIUM SHOCK ABSORBER SCREW RETAINED/FIXED Abutment!

2. **Impression Taking (clinical procedure)**

A. Conventional impression

Mount the TSA impression coping (open or closed tray) on the TSA abutment and take a conventional impression on abutment level according to standard clinical procedures for restorative operations. Send the impression to your dental laboratory for making a plaster model. (see step 3.A.).

B. Digital impression with intraoral scanner

Mount the TSA intraoral scan marker on top of the TSA abutment and use an intraoral scanner for digitalizing the oral situation. Send the scan file to the laboratory for making a 3D printed model (see step 3.B.).

3. **Fabricate master model (laboratory procedure)**

A. Plaster model

Fixate the TSA analog into the impression copings inside the impression and fabricate a working master model in plaster using standard conventional laboratory procedures. After this, proceed to step 4.

B. 3D print model

Use the scan data of the dentist and open in the dental CAD software for designing the digital model. Send the design to the 3d printer and print the model. After the model is printed, the TSA digital analog can be placed in the model using the basal screw. After this, proceed to step 5.

4. **Cad/Cam scan of master model with desktop scanner (laboratory procedure)**

Before mounting the TSA extraoral scan marker, ensure that all components are clean and in undamaged condition. Assemble the TSA extraoral scan marker on the TSA analog in the plaster model and visually confirm the fit. Avoid any contact of the TSA extraoral scan marker to the interproximal teeth. Start the scan procedure by following the mandatory scan process. Export the generated scan files.

5. **Prosthesis Fabrication (laboratory procedure)**

Open the dental CAD software and design your restoration in accordance with indications for use, following the instructions in the software and according to the patient's clinical needs. The prosthesis can be restored directly on the TSA abutments, or restored on the TSA interface/cylinder. Upon return check the precision of fit on the model. Finalize the prosthesis using standard laboratory techniques.

6. **Placement of the prosthesis (clinical procedure)**

Verify the seat of the prosthesis following standard restorative clinical procedures. The definitive prosthesis is fixed with a prosthetic screw, using a torque wrench. The torque value for the prosthetic screw is indicated on the label. ***Warning: Use of higher torque values than recommended could cause a fracture of the TITANIUM SHOCK ABSORBER SCREW RETAINED/FIXED Abutment!***

Seal the screw access holes of the restauration using conventional procedures. Verify occlusion and function. If adjustments are made, adequate polishing of occlusal surface must be done.

Patient Care: Good oral hygiene is vital to abutment success. The patient should be made aware of the following:
The TITANIUM SHOCK ABSORBER SCREW RETAINED/FIXED Abutments must be thoroughly cleaned each day to prevent plaque build-up and the patient should use a soft nylon bristle or end-tufted toothbrush with a non-abrasive toothpaste to clean the Abutments. The coarse particles in abrasive toothpaste may scratch the surfaces of the Abutments and cause plaque accumulation. Bruxism may have an impact on the overall restauration and may reduce the longevity. Patients should be instructed to maintain routine follow-up visits for hygiene and abutment function evaluation. Follow-up visits are recommended at 6-month intervals.

Further Information:
Traditional restorative protocols should be followed to process the abutments into the patient's Bridgework. Standard care and maintenance should be followed to ensure the longevity of the restauration.

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Explanation of Outer Packaging Label Symbols

Symbol	Description
	Symbol for "Batch Code" (Lot number)
	Symbol for "Manufacturer"
	Symbol for "UDI number"
	Symbol for the "Catalogue number"
	Symbol for "Consult instructions for use"
	Symbol for "Non-sterile"
	Symbol for "Do not re-use"
	CE Marking
	Medical device

	Symbol for “Production date”