Prodenta 3D

Probase and screw (abutment kit consisting of titanium base and screw)

GENERAL AND PARTICULAR INSTRUCTIONS FOR USE (ENGLISH)

I GENERAL INSTRUCTIONS

MANUFACTURER INFORMATION

All the products that commercialize and distribute PRODENTA have been manufactured in the facilities of PRODENTA.
The website of the company www.prodenta3d.com
The contact telephone number is +37061140554 .
The factory is located in Vytauto st. 42, Marijampolė, LT-68129, Litnuania.

CAUTION – PLEASE READ CAREFULLY

PRODENTA products should only be used by dental specialists with experience in maxillary implantology and other specialities, such as dental diagnosis, planning, dental surgery or prosthetic techniques. If in doubt regarding the product's use, please contact the manufacturer.
PRODENTA products designed for single-use only must never be re-used. If reused, there is a risk that product damage and deterioration of its characteristics could lead to prosthetic solution failure and / or other deterioration of the patient's health like patient tissue infection.
All PRODENTA components must be dry fitted before use to check the correct fitting. The clinician will be responsible for correct application of those restorative products as planning and procedures are under his/her control. This is the reason why only dental specialists with the appropriate experience and training should work with these products. In case of doubt please contact the manufacturer.

INTENDED USE

Probase is premanufactured prosthetic component directly connected to dental implant and is intended for use as an aid in prosthetic rehabilitation reducing the effect of transverse forces on the restoration (in contrast to restorations screwed directly on the implant).
Screw is used to secure the abutment to the implant providing a low friction surface, producing a high clamping force between the abutment and the implant.
PRODENTA abutments are delivered with a dedicated clinical screw that has been optimized for the abutment-implant system that it's part of.

CONTRAINDICATIONS

All materials used are biocompatible however, some patients may present allergies or hypersensitivity to any of the materials and its components (specified in the table).
Neurological, psychiatric, or other disorders where the patient is unable to provide the required daily oral hygiene, contraindicated diseases (e.g. dyscrasia, untreated diabetes, hyperthyroidism, AIDS), contraindicated conditions (e.g. oral cavity infections, cancer diseases, myocardial infarction within the last 12 months) and uncontrolled parafunctions (e.g. bruxism, nocturnal tooth clenching or grinding).

WARNINGS

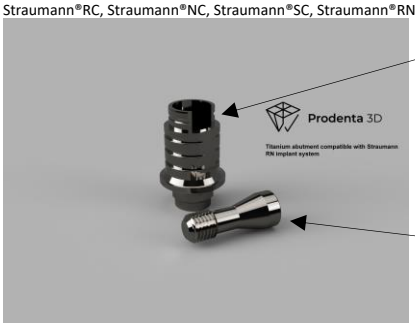
All Abutments and Screws can only be combined with the corresponding compatible implant system. No abutments inappropriate in connection geometry should be used. Any post processing at the connection geometry to the implant may result in fitting inaccuracies prohibiting further use.
The reuse of single-use products carries a possible deterioration of its characteristics, which implies the risk of infection of the tissues and /or deterioration of the patient's health.
The safety and efficacy of the products supplied by PRODENTA, is guaranteed only when trained professionals use them.
Ensure that the abutment angulation is suitable for the respective load. If possible, angled abutments should be avoided in the side tooth area.
Torque values greater than 35 Ncm may result in failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.

RSK ASSOCIATED TO THE USE OF THE PRODUCTS

There is a risk of aspiration or ingestion of the products when used intra-orally, so that appropriate measures be taken to prevent it.

COMPATIBILITY INFORMATION

PRODENTA Probase and screws are compatible with following implant systems:
Straumann®RC, Straumann®NC, Straumann®SC, Straumann®RN, Straumann®RB, Straumann® Multiunit.



Megagen® Anyridge®

Nobel Biocare®I RP, Nobel Biocare® NP, Nobel Biocare® Multi-unit.

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STERILIZATION AND SINGLE USE

All products are supplied NON STERILE. For sterilization, we recommend autoclaving the product at 121°C for 30 minutes, drying time 30 minutes (in accordance with standard EN ISO 17665-1:2006). Devices are marked for "Single use only" because it is difficult or impossible to clean and decontaminate a used device, reuse can lead to cross-infection. Furthermore, any attempt to reuse a device greatly increases the risk of mechanical failure caused by material fatigue. Any warranty claim resulting from the reuse of a single-use device will not be accepted.

ARTICLE	CLASS	MATERIAL	STERILIZATION
Clinical screw	Class IIb	Titanium alloy ELI Ti-6Al-4V	Autoclave before use on the patient
Abutment base	Class IIb	Titanium alloy ELI Ti-6Al-4V	Autoclave before use on the patient

STORAGE AND HANDLING

All products manufactured by PRODENTA should be stored at a temperature between 15-25 ° C and 40-60% humidity. The products must be kept away from direct sunlight and any artificial ultraviolet light. The product is well packaged and sealed. A defect on the packaging may involve the loss of the properties of decontamination and disinfection, it is recommended to avoid their use. The material must not me unpacked and handled if is not going to be immediately used.

Disposal:

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

Please note

Dental specialists must have appropriate knowledge and instruction in the handling of PRODENTA product for using PRODENTA product safely and properly in accordance with these instructions for use.
PRODENTA product must be used in accordance with the instructions for use provided by the manufacturer.
It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation. PRODENTA product is part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by PRODENTA.
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.

MR safety information

Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment. For additional information please contact: justas@prodenta.lt)

II SPECIFIC INSTRUCTION FOR USE

APPLICATIONS AND DIRECTIONS FOR USE – SCREW

Made of Titanium. For fixing on prosthetic implant. Itis imperative the strict compliance with the following conditions:

- For screwing or unscrewing use the appropriate screwdriver.
- The screwdriver must be positioned on the longitudinal axis of the joint prosthesis / implant.
- Both for the first fitting a prosthesis, as for future revisions, new screws should be used.
- For immediate load prosthesis:
  - Hand-tight and avoiding excessive torque
  - Prevent rotation of the implant during this operation
- Do not re-use screws from the dental laboratory for clinical use.
- Be sure to use the appropriate reference for each case.
- The minimum number of turns to ensure a good anchorage between five or six, in case of lower number of turns a longer screw shall be used (for more information contact: justas@prodenta.lt)

APPLICATIONS AND DIRECTIONS FOR USE – PROBASE

Verify the compatibility of the connection, in type and size, between the titanium abutment and the implant. Damage in the connection area of the implant must be avoided. An X-ray in the perpendicular axis to the union interface-implant is recommended in order to ensure the correct adjustment.

*All brand names and trademarks mentioned in this document are the property of their respective holders and are referred to here, for descriptive and reference purposes. PRODENTA has no relationship with the brands proprietors.

EXPLANATION OF THE SYMBOLS THAT APPEAR ON THE LABELS

ISO 15223-1 Symbology	Title of symbol
	Manufacturer
	Date of manufacture
	Serial number
	Catalogue number
	Batch code
	Do not re-use
	Non-Sterile
	Use-by date
	Caution
	Consult instructions for use
	CE marking of conformity (Product conforms to the general, safety and performance requirements of MDR (EU) 2017/745)

Notice:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.