BONE SYSTEM
A Target Ortodonzia Company

CE 0425

# EN: PROSTHETIC COMPONENTS

**PRODUCT IDENTIFICATION**
The prosthetic components related to the implant systems manufactured by Bone System Srl are medical devices intended for use in the oral cavity.
The functions of the prosthetic components are:
- gingival conditioning;
- impression taking;
- anchoring to dental implants for the support of temporary and permanent dental prostheses.

The prosthetic components manufactured by Bone System Srl are designed to be anchored to dental implants also manufactured by Bone System Srl. The use of non-original components limits the liability of Bone System Srl and voids the product warranty.
The prosthetic components must be screwed onto the implants using the appropriate drivers. We are not responsible for the use of non-original instruments.

**DESCRIPTION**
The information contained in these instructions for use supplements the information provided in the catalogues/manuals, which are available on request.
The prosthetic components are designed for the reference implant line. For implant lines featuring a unified prosthetic platform, various emergence profiles are available, as shown in the product catalogue.
The materials used in the production of prosthetic components for dental implants manufactured by Bone System Srl have been selected on the basis of their properties for their intended use, in accordance with Regulation (EU) 2017/745.
Allergy to titanium is very rare but possible, so it is always necessary to check in advance during the patient's medical history that they do not have allergies of this type.
The prosthetic components manufactured by Bone System Srl do not contain materials of human or animal origin, nor phthalates, and are nickel-free.
It is recommended to check with patients for any allergies to the raw materials used;
Bone System Srl can provide technical data sheets on the composition of the materials upon request.
Prosthetic components are divided into the following categories:

**Healing Screws (Gingival Conditioners)**
Description: Direct screw-retained abutments with platform and variable transmucosal height depending on the different implant systems designed to recondition the emergence profiles of the mucosa prior to prosthetic loading.
Intended use: Long-term invasive surgical devices intended for use in the oral cavity.
Raw material: Ti6Al-4V ASTM F136-13 compliant with harmonised standards.

**Transmucosal Collars**
Description: They are inserted into the implant using a press fitting and become an extension of it in the transmucosal section to facilitate the cementation of crowns outside the peri-implant tissues. They are invasive surgical devices with a duration of more than 30 days.
Intended use: Long-term invasive surgical devices intended for use in the oral cavity.
Raw material: Titanium gr. 2 ASTM F67-13 compliant with harmonised standards.

**Temporary Abutments**
Description: Titanium abutments on which an acrylic prosthesis for temporary use is based.
They are sold complete with the relevant fixing screws.
Intended use: Long-term invasive surgical devices for use in the oral cavity.
Raw material: Ti6Al-4V ASTM F136-13 compliant with harmonised standards.

**Titanium Esthetic Abutments**
• Titanium abutments
Description: Preformed straight or angled abutments, millable, with variable transmucosal path heights, available in cemented (press fitting) or complete with prosthetic screws (friction locking) versions.
The final abutments can be gold-coloured, where specified in the catalogue, obtained by anodic oxidation of titanium.
For cementable abutments, use two-component cold metal/metal cement.
Intended use: Long-term invasive surgical devices for the oral cavity.
Raw material: Ti6Al-4V ASTM F136-13 compliant with harmonised standards.
• Ti-Base and Premilled
Description: Abutments equipped with implant connection, available in digital format ('.stl') for CAD systems on the market; they are customised by the dental laboratory or milling centres using CAD-CAM techniques.
Intended use: Long-term invasive surgical devices intended for use in the oral cavity.
Raw material: Ti6Al-4V ASTM F136-13 compliant with harmonised standards.

**Titanium bases for screw-retained prostheses**
Abutments used for screwing prostheses onto multiple implants.
• Titanium base
Description: Titanium base with castable cylinder for modelling the superstructure and tightening screw.
Intended use: Long-term invasive surgical devices for the oral cavity.
Raw material: Ti6Al-4V ASTM F136-13 compliant with harmonised standards.
• Multi Unit Abutments (MUAs)
Description: Abutments for managing large misalignments; they have different shapes and functions depending on whether they are used on parallel or misaligned implants. Straight MUAs are screwed directly onto the implants, while angled MUAs require special fixing screws, which are supplied in the package.
Intended use: Long-term invasive surgical devices for use in the oral cavity.
Raw material: Ti6Al-4V ASTM F136-13 compliant with harmonised standards.

**Customisable cylinders**
Description: The superstructures for MUAs are cylindrical cannulas that are tightened to the abutments using special micro-screws, included in the package with the superstructures themselves, or by means of a truncated cone-shaped Ti-Base to which the digitally manufactured superstructure is bonded.
Please refer to the individual catalogues for detailed specifications.
Intended use: Long-term invasive surgical devices for use in the oral cavity.
Raw material: Ti6Al-4V ASTM F136-13 compliant with harmonised standards.

**Titanium fins**
To connect the hubs together and form a rigid, totally passive reinforcement structure to be incorporated into the temporary device.
Intended use: Medical device accessories. Long-term non-surgical invasive devices intended for use in the oral cavity.
Raw material: Titanium grade 1 ASTM B265/F67-13 compliant with harmonised standards.

**Prosthetic screws**
These are the screws needed to screw abutments and superstructures into place.
They are sold both with the relevant abutments and separately as spare parts.
Since they are used with abutments and superstructures, they are classified in the same class as the reference device.
It is recommended that the screws supplied with the prosthetic components be used only for trial fitting in the mouth and for screwing onto laboratory models. For the final fixation of the restoration in the patient's mouth, it is recommended that new screws be used. Frequent unscrewing and re-screwing of the screw can weaken its structure and cause a loss of precision, resulting in the unscrewing of the components.

Intended use: Medical device accessories. Long-term non-surgical invasive devices intended for use in the oral cavity.
Raw material: Ti6Al-4V ASTM F136-13 compliant with harmonised standards.

**Overdenture components for removable dentures**
Spherical attachments screwed directly onto implants that act as 'buttons' for stabilising a removable full denture. Spherical attachments require a suitable cap (female) to be placed inside the prosthesis, in correspondence with the attachment, which is able to hook onto the spherical heads of the attachments themselves. These polyamide or titanium caps are commercially available, and the hook is standardised (Ø2.5 Normo or Ø2.1 Micro).
Intended use:
Raw material: Ti6Al-4V ASTM F136-13 compliant with harmonised standards and can be coated in TiN depending on the type that meets ISO 10993 standards (biocompatibility).
Please refer to the individual catalogues for detailed specifications.

**INTENDED USE**
For the purposes of Regulation (EU) 2017/745, Bone System Srl declares itself to be the manufacturer of the prosthetic components and identifies their risk class as indicated in the 'CLASSIFICATION' table.
The use and handling of the devices is reserved for medical and dental personnel with the necessary professional qualifications and training (Dental Surgeon).

**IDENTIFICATION OF THE MANUFACTURER**
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**WARNINGS**
Implant prostheses, whether immediate or delayed loading, are a widely tested and reliable technique, capable of solving almost all problems of edentulism, whether functional or aesthetic. An implant prosthesis can replace a single tooth (crown on implant), a group of closely spaced teeth (bridge on implants), or an entire dental arch. Prosthetic components can also be used to stabilise existing full dentures.
Implant prosthetic rehabilitation must meet certain fundamental criteria:
- the presence of a certain amount of bone;
- primary stability of the implant;
- good periodontal (gingival) support;
- the absence of bruxism (teeth grinding) or severe malocclusion;
- the presence of good occlusal balance (correct occlusal plane).

The prosthesis must always be planned in advance and prosthetic planning must be carried out in collaboration with the dental technician.
Prosthetically guided implant placement provides greater guarantees of durability.
It is advisable to collect and archive complete clinical, radiological and radiographic documentation.
Each package bears the code, description of the device and batch number; this information must always be recorded by the doctor in the patient's file.
When handling the devices, both during use and during cleaning and sterilisation, it is recommended to always use the appropriate PPE. Failure to comply with these warnings may result in cross-infection.
The packaging complies with European standards.

**SINGLE-USE DEVICES**
Prosthetic components are single-use. Single-use means that each individual device must be used exclusively for a single patient. It is customary for a prosthetic component to be tried in the mouth several times and then sent back to the dental technician for finalisation. This practice is permissible and does not alter the concept of single use, provided that the same prosthetic component is always used for the same patient. In cases of multiple prostheses, it is important that the same component is always used in the same position and in connection with the same implant, i.e. that components are not interchanged within the same rehabilitation.
Failure to comply with these instructions may compromise the accuracy of the products. Any reuse in different patients must be considered off-label use and in such cases Bone System Ltd. declines all responsibility.

**CONTRAINDICATIONS**
The insertion of implants and implant prostheses is contraindicated in patients who are in poor general health, have poor or inadequate oral hygiene, are unable or unlikely to control their general condition, or have previously undergone organ transplants. Patients who are psychologically unstable, abuse alcohol or drugs, or have poor motivation or insufficient cooperation should also be excluded. Patients with poor periodontal health must be treated and recovered beforehand. In cases of poor bone presence or poor quality of the receiving bone, such that the stability of the implant may be compromised, appropriate guided tissue regeneration must be performed beforehand. Other contraindications include: allergy to titanium or other materials used, acute or chronic infectious diseases, chronic subacute maxillary osteitis, systemic diseases, endocrine disorders, diseases with consequent microvascular disorders, pregnancy, breastfeeding, previous exposure to radiation, haemophilia, granulocytopenia, use of steroids, diabetes mellitus, renal failure, and fibrous dysplasia.
Implants intended to support prostheses are medical devices that are inserted into the oral cavity during surgery and, as such, are subject to additional restrictions on use, for which reference should be made to the relevant instructions for use.

**SPECIAL WARNINGS**
When tightening prosthetic screws, it is recommended to adhere to the following tightening torques:
• Healing screws: 10–15 Ncm
• Prosthetic screws for abutment tightening: 20–25 Ncm
• Direct screw-retained prosthetic components (e.g. ball attachments and straight MUAs): 30 Ncm
Excessive tightening torques can weaken the mechanical structure of the screws and compromise prosthetic stability, with possible damage to the implant connection.
For cemented abutments, use commercially available cold metal/metal cement.
In case of radiation (e.g. to treat oral tumours), remove the movable metal parts.
Do not use toothpastes containing free fluoride as they may corrode the abutment.

**MAINTENANCE**
Complications associated with dental implants are well documented in the literature. These complications can lead to loss of osseointegration and implant failure. Proper maintenance by the patient, regular home hygiene, and periodic check-ups involving professional hygiene sessions extend the useful life of the device. Complications such as the loosening of the screws that secure the prosthesis to the implants, or bone resorption causing loss of mucosal support in removable prostheses, can be easily prevented with regular check-ups.
If it is necessary to tighten the abutment or prosthetic screws, these operations must be performed by the dentist using appropriate devices equipped with torque control. It is advisable to periodically check the calibration of these devices.
If the patient is aware of such occurrences, they should contact their dentist as soon as possible to restore the correct prosthetic function.

Delaying medical intervention can lead to fracture of the locking screw or prosthesis in the first case, and loss of the implant in the second, compromising the rehabilitation outcome. Doctors need to educate patients in this regard.
Complications can be biological (loss of integration) or mechanical (fracture of a component due to excessive load). If there are no complications, the durability of the devices and the entire prosthetic apparatus depends on the mechanical strength in relation to the fatigue accumulated by the device.
Any attempts to remove crowns or bridges cemented with permanent cement, which may cause impact on the implant structures, can lead to their fracture.
Bone System Srl has subjected the implant-abutment-prosthetic screw assembly to fatigue resistance tests using the cycle method. The fatigue tests are performed in accordance with the relevant regulations and validated with finite element calculations.

**CLEANING, STERILISATION AND STORAGE**
All prosthetic components are sold clean and NON-STERILE.
Before use, all prosthetic components must be cleaned, disinfected and sterilised.
Repeating the processes described below does not alter the characteristics of the devices, but failure to follow these instructions may result in cross-infection.

**Cleaning**
There are no specific instructions regarding the type of containers to be used for washing.
When cleaning in an ultrasonic tank, use a suitable detergent solution. We recommend using only neutral detergents without colourants.
Use demineralised water to prevent the formation of stains and marks.
For manual cleaning: use a suitable detergent solution; we recommend using only neutral detergents

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without colourants. Brush the products with soft bristles under plenty of running water. Using the brush, apply the detergent solution to all surfaces. Rinse with double-distilled water.
After rinsing, dry the devices completely and place them in suitable sterilisation bags.
If a drying cycle is performed as part of the washing and disinfection cycle, do not exceed 120°C.

**Sterilisation**

Sterilise in a vacuum autoclave at 121-124°C with a minimum cycle of 20 minutes and a drying cycle of 15 minutes.

**Storage**

After sterilisation, the product must remain in the bags used for sterilisation. The bags must only be opened immediately before use. Sterilisation bags are normally able to maintain sterility inside them unless the packaging is damaged.
Therefore, take care not to use components if the bags in which they were stored are damaged and re-sterilise them in new bags before reuse. The storage period of sterilised products inside the bags must not exceed that recommended by the bag manufacturer.
The product must be stored in a cool, dry place, away from direct sunlight, water and heat sources.

## REGULATORY REFERENCES

The design and manufacture of prosthetic components is carried out in accordance with the relevant harmonised directives and standards with regard to the materials used, manufacturing processes, information provided and packaging.

## DISPOSAL PROCEDURES

Prosthetic components, if removed from the oral cavity due to biological or mechanical failure, must be disposed of as biological waste, in accordance with local regulations.

## LIABILITY FOR DEFECTIVE PRODUCTS AND WARRANTY TERMS

Optimal patient care and attention to their needs are necessary conditions for successful implantology. It is therefore necessary to carefully select patients, inform them of the risks involved and the responsibilities associated with treatment, and encourage them to cooperate with the dentist to ensure the success of the treatment. It is therefore necessary for the patient to maintain good hygiene, which must be confirmed during check-ups and always ensured and documented, just as pre- and post-operative instructions and prescriptions must be observed and documented.
The instructions provided by Bone System Ltd are available at the time of treatment and accepted by the dental practice. They must be observed and applied at all stages of treatment, from the patient's medical history to post-operative check-ups.
The warranty only covers manufacturing defects, subject to the item being sent with its item code and batch number.

## DATE AND VALIDITY OF THESE INSTRUCTIONS FOR USE

These instructions for use are valid from 09/01/2023.

**CLASSIFICATION**

| Device | Classification | Packaging | Rule according to Annex IX | Risk class |
|---|---|---|---|---|
| Healing Screw | Long-term invasive surgical devices intended for the oral cavity | Single use, non-sterile. | 8 | IIb |
| Transmucosal Collars | Long-term invasive surgical devices intended for the oral cavity | Single use, non-sterile. | 8 | IIb |
| Preformed titanium abutments, traditional or CAD-CAM type | Long-term invasive surgical devices intended for the oral cavity | Single use, non-sterile, complete with fixing screws. | 8 | IIb |
| Titanium bases for screw-retained prostheses | Long-term invasive surgical devices intended for the oral cavity | Single use, non-sterile, complete with fixing screws. | 8 | IIb |
| Customisable cylinders | Long-term non-surgical invasive devices intended for the oral cavity | Single use, non-sterile, complete with fixing screws. | 8 | IIb |
| Wings | Medical device accessories. Long-term non-surgical invasive devices intended for use in the oral cavity. | Single use, non-sterile. Sold as standard equipment in single packs. | 5 | IIa |
| Prosthetic Screws | Medical device accessories. Long-term non-surgical invasive devices intended for use in the oral cavity. | Single use, non-sterile. Sold with the respective abutments or in single or multiple packs. | 5 | IIa |
| Overdenture components for removable dentures (Spherical attachments) | Long-term invasive surgical devices intended for the oral cavity | Single use, non-sterile. | 8 | IIb |

**SIMBOLISM**

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|---|---|
|  | Caution! See instructions for use. |
|  | Lot number |
|  | Code |
|  | Manufacturer |
|  | Country of production |
|  | UDI code, Unique Device Identifier |
|  | Medical Device |
|  | Consult the instructions for use. |
|  | CE conformity marking<br>Where applicable: the identification number of the notified body must follow this symbol |
|  | Do not reuse, single-use product |
|  | Do not use if the packaging is damaged. |
|  | Non-sterile product |

**ADDITIONAL SYMBOLS ON THE BOX**

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|---|---|
|  | Keep dry |
|  | Protect from the sun |

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