

INSTRUCTIONS FOR USE - DENTAL ABUTMENTS



Manufacturer
Ritter Implants GmbH & Co.KG
Freiburger Str. 45
66400 Biberach, Germany

R_Xonly



Indications:

The dental superstructures/abutments (hereinafter: the abutments), are intended to be attached/mounted to/on the protruding through gingiva surface (implant/s) and support the substructure that forms the tooth substitute (denture).

Contraindications:

The abutments are intended for mechanical attachment to implants and are meant to be located in Patients oral cavity. Therefore, all the contraindications for implants use are valid for the use of abutments as well. The abutments should not be used in Patient/s who have contraindicating systemic or uncontrolled local diseases such as:



Cardiovascular disorders associated with high endocarditic risk, Coronary insufficiency, Cancers and radiation of the facial region in the past five years, weakened immune system, Diabetes, Bone metabolism disorders, Hemophilia, poor general state of health, inadequate wound healing capacity, maxillary and mandibular growth not completed, unfavorable anatomic bone conditions, Periodontal disease, poor oral hygiene, bruxism, inadequate bone or blood supply, unrealistic Patient expectations or poor Patient motivation, Psychological disorders, smoking, drug abuse or alcoholism, Steroid use, allergy to metals (Titanium, Aluminum, Vanadium and tec.,).

Warnings:

- Carefully read the instructions, prior to abutments use;
- The sale and use of the abutments are restricted to, or by the order of licensed dental Practitioner (or dental prosthetic Specialist, for abutments meant for laboratory use);
- Abutments should be placed only by Practitioners who are licensed and trained to perform the procedures. Adequate preoperative studied are recommended to examine the anatomic structures and to assess the biomechanical, functional and esthetic requirements of each case;
- Consultation between the dental Practitioner and dental laboratory is highly recommended for achieving the best possible results;
- Risks of abutments placement include, but not limited to infection, dislodgement of the

implants, damage to adjacent teeth, and fracture of implants or restorative component;

- Each abutment has a specific design characteristic to mate the implant, prosthetic components, and designated instrumentation. It is recommended that the Performers of the procedures be thoroughly familiar with the system;
- The abutments have not been evaluated for safety and compatibility in the MR environment;
- The abutments installation procedure requires a high degree of precision and care. The Performer must be properly trained and skilled in required processes and procedures;
- The abutments should be installed on the implants in such a way that they are stable and lack of mobility;
- The abutments supplied non-sterile and are meant for single Patient use only;
- The abutments may be modified, as may be needed. The adjustment/modification may be performed by Professionals owning the required knowledge, skills, and abilities – only;

Combination of abutments with implants:

Refer the catalogue for choosing the optimal components.

Abutment Installment Procedure:

Remove the healing abutments or cover screws by using dedicated instrumentation. Make sure the implant attachment area is exposed. Select a required for installation abutment, insert it into the implant, secure it and adjust it by using dedicated instrumentation (screwdriver and hex wrench, ratchet torque 30-35Ncm).

Multi-Unit Abutments:

The Multi-Unit abutments are intended to provide edentulous Patients with an efficient and effective restoration to support full-arch prosthesis.

Sterilization (Autoclaving):

It is recommended that the abutments/superstructures will be autoclaved prior the use on Patients.

The Manufacturer verified the following sequence:

Gravity Displacement, 15min (half cycle – 7 min) at 132°C/207°F.

Dry time – 30min

Note: Use distilled water to avail surface stains

Note: Any changes/deviations from the recommended sequence require sequence verification by the User.

Follow Up Care:

Patients shall be instructed in appropriate oral hygiene. Periodic follow up appointments are recommended to confirm and maintain adequate function of the implants and abutments and the health of surrounding tissue.

Storage:

The superstructures/abutments shall be kept in a dry place at room temperature.







Limited warranty:

In case of failure of an implant, the Company will replace/provide another implant in exchange free of charge, according to following conditions:

Filling in a report with all the information concerning the failure, including any relevant supporting information;

Submitting the report, no later than 6months from the event;

Labelling:

				LOT	EC REP		Rx Only	REF	QTY	STERILE R	CE	
Caution / Attention: See Instructions for Use	Do Not Reuse	Expired by	Manufacturer	Lot Number	Authorized Representative in the European Community	Do Not Use If Package Is Open or Damaged	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician	Catalog Number	Number of units	Sterilized using irradiation	CE Mark	Non-Sterile