RITTER™ IMPLANTS

# Instructions for use
## Implants and prosthetics

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## INTENDED USE
Ritter Implants products are intended only for certified dentists and authorized persons with specific implant training. Ritter Implants are used for two-stage and one-piece implant placement procedures. The implants are made of a titanium alloy and are supplied in sterile, sealed containers. They are supplied with the proviso that only Ritter Implants surgical instruments are used during surgery to complement each implant. If these conditions are not met, the manufacturer declines responsibility.

## APPLICATION NOTES
The Ritter implants are intended for single or multiple replacement of lost teeth and offer a way to insert the prosthetic parts in completely or partially edentulous patients.

## SPECIFIC APPLICATIONS FOR IMPLANTS WITH A DIAMETER OF 3.0 MM
Aufgrund ihrer reduzierten mechanischen Stabilität werden Implantate mit kleinem Durchmesser 3.0 mm nur in Fällen mit geringer mechanischer Belastung verwendet, wie z.B. seitliche Schneidezähne im Oberkiefer oder Schneidezähne im Unterkiefer. Eine Platzierung im Seitenzahnbereich wird nicht empfohlen.

## SPECIFIC APPLICATIONS FOR 6 MM IMPLANTS
Due to the reduced anchoring surface in the bone, these implants should only be used for the following indications:
a) As an additional implant, together with longer implants to support the prosthetic restoration.
b) As an auxiliary implant for implant bar constructions supporting full dentures in a severely atrophied mandible.

## WARNING
For short implants, clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes in the implant's response to percussion, or radiographic changes in the bone to implant contact along the length of the implant. If the implant shows mobility or more than 50% bone loss, the implant should be evaluated for possible removal. If clinicians choose a short implant, then they should consider a two-stage surgical approach by connecting a short implant to an additional implant and placing the widest possible fixture. Longer periods for osseointegration should be planned and immediate loading should be avoided.

**Please observe the safety instructions for MRI examinations on page 24.**

## POTENTIAL ADVERSE EVENTS
Possible adverse events associated with the use of dental implants may include:
Failure to integrate; Loss of integration; Dehiscence requiring bone grafting; Perforation of maxillary sinus, lower margin, lingual plate, labial plate, inferior alveolar canal, gingiva; Infection as reported by: Abscess, fistula, suppuration, inflammation, radiolucency; persistent pain, numbness, paresthesia;

- **Hyperplasia**
- **Excessive bone loss requiring intervention**
- **Implant fracture or breakage**
- **Systemic infection**
- **Nerve injury**

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## CONTRAINDICATIONS:

The usual observations should be made regarding the contraindications associated with the implant materials used in oral surgery. First of all, the patient's general state of health and suitability for oral surgery must be assessed by the attending physician. The placement of dental implants is contraindicated in the following patients:

**1.** Patients who are not medically suitable for oral surgery (patients taking corticosteroids, anticoagulants, anticonvulsants or bisphosphonates, as well as patients receiving radiotherapy or other immunosuppressive therapy).
**2.** Breastfeeding or pregnant women are not candidates, nor are patients with abnormal laboratory values for blood urea nitrogen, creatinine or serum calcium.
**3.** Patients with uncontrolled diabetes, cardiovascular disease, endocarditis and high blood pressure above 170/110 mm Hg.
**4.** Osteoporotic compression fractures, respiratory diseases, thyroid or parathyroid diseases and patients with diagnosed malignant disease or unexplained lumps or masses in the head or neck.
**5.** Patients with uncontrolled diseases such as: Hemophilia, granulocytopenia or other bleeding problems, steroid use, prophylactic antibiotic use, friable diabetes, Ehler-Danlos syndrome, osteoradionecrosis, renal failure, organ transplantation, anticoagulation therapy, unexplained hypersensitivity, fibrous dysplasia, regional enteritis.
**6.** Diseases or treatments that severely impair healing, e.g. including radiotherapy.
**7.** Lack of adequate training of the practitioner.
**8.** Insufficient patient motivation, such as psychiatric disorders affecting the patient's understanding and compliance with the necessary procedures, unrealistic patient expectations, unattainable prosthetic reconstruction, patient's inability to manage oral hygiene, patient's hypersensitivity to certain components of the procedure, e.g. titanium hypersensitivity.
**9.** Electrosurgery: Dental implants are made of a metallic alloy; they are therefore characterized by high conductivity. For this reason, electrosurgery is strictly contraindicated in the vicinity of dental implants.
**10.** The system is not suitable for use with a limited interocclusal distance of less than 7.0 mm. It is not suitable for use if the implants with the 25° angled abutment diverge by more than 45° or if the implants with the 15° angled abutment diverge by more than 30°. The angled abutment must not be excessively prepared. The Narrow Line (NL) of implants has a similar type of abutment. The NL QSI implants (Narrow line) are available in straight and 15° versions. The NL abutments are only intended for the NL-QSI and NL-SNAP* 3.0mm D* and 3.3mm D. Ritter dental implants should not be placed if the volume of the alveolar bone is insufficient to support the implant (at least 2 mm circumferentially and 2 mm apically). Implants placed in the maxilla should not perforate the sinus floor membrane.
**11.** Poor bone quality, poor oral hygiene of the patient, heavy smoking, use of chewing tobacco, uncontrolled systemic diseases (diabetes, etc.), reduced immunity, AIDS, alcoholism, drug addiction, mental instability, aggression, children with underdeveloped bone and bone metabolism disorders may contribute to lack of integration and/or later implant failure. Severe bruxism, teeth grinding and overloading can lead to bone loss, screw loosening, component fracture and/or implant failure. Exposure to radiation and chemotherapy can affect the health and success of the implant.

### Temporary contraindications

**1.** Systemic infections, local oral and respiratory infections, inflammation around the implant
**2.** Anatomical or pathological implications such as;
a) Insufficient alveolar bone width and height to surround the implant with at least 1.5 millimeters of bone
b) Insufficient bone height where proper implant placement would encroach within 2 mm of the mandibular canal, sinus floor, etc.
**3.** Malignant diseases
**4.** Pregnancy
**5.** Insufficient bone volume, unless an augmentation procedure can be considered.
Dental implant patients should be instructed to consult their doctor before undergoing such treatment options.

*Not available in Canada.

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**WARNINGS**
**1.** This system may only be operated by trained specialists. The surgical and restorative techniques required to properly insert the system are highly specialized and complex procedures. Improper technique can lead to implant failure, loss of supporting bone, restorative fractures, screw loosening and aspiration. Therefore, no implant placement should be performed without prior appropriate training by a certified dentist.
**2.** For pediatric patients, routine treatment is not recommended until the end of jawbone growth is properly documented.
**3.** This product is a single-use product. Any attempt to reuse the product may pose a serious health risk, such as product contamination, acute infection, deterioration of mechanical properties, resulting in painful revision surgery to replace the implant.
**4.** Do not use implants if the packaging is opened or damaged, as this may impair sterility or cause the product to malfunction.
**5.** BREAKAGE Implant and abutment fractures can occur when the applied loads exceed the normal functional design tolerances of the implant components. Potential overload conditions may result from deficiencies in the number, length and/or diameter of implants to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interference causing excessive transverse forces, patient parafunction (e.g. clenching), improper casting procedures, inadequate prosthesis seating and physical trauma.
**6.** Do not use excessive force that exceeds the insertion torque of 60Ncm: overtightening an implant can damage the implant and/or the internal connection, lead to fractures or necrosis of the bone area and impair osseointegration.
**7.** Balanced occlusion.
**8.** Correct cementation.
**9.** Aftercare of patients.

**GENERAL DISEASES AND MEDICATIONS**
Cardiovascular disease associated with high endocarditic risk (SBE); coronary insufficiency; blood dyscrasias; immunodeficiency, AIDS; cancer and radiation to the facial region in the last five years; respiratory disease; thyroid or parathyroid disease: Patients with nodular enlargement or unexplained lumps in the head or neck area; metabolic bone disorders; diabetes; hypertension over 170/110 mmHg; drug abuse, alcoholism; titanium hypersensitivity: Patients on corticosteroids, anticoagulants, anticonvulsants, immunosuppressive therapy; patients with abnormal creatine, BUN or serum calcium levels; hemophilia; granulocytopenia; steroid use; prophylactic antibiotics; Ehler-Danlos syndrome; renal failure; organ transplantation; fibrous dysplasia.

**SURGERY PROTOCOL - MANDATORY INITIAL EXAMINATIONS**
Patient examination; Patient history; Clinical examination of patient hygiene, teeth, occlusion, periodontium; Biological observations; X-ray examination: CT scan. Intraoral, X-ray, pan-oral, etc. The lack of adequate practice training is one of the main factors affecting the success of implant surgery and thus the long-term health of patients.

**SURGICAL AND RESTORATIVE PROCEDURES SURGERY**
The hard and soft tissue must be treated carefully to ensure osseointegration. The surgical site must be prepared with the utmost precision. The auxiliary instruments used must be properly sterilized. The surgical procedure requires drilling speeds from 1000 rpm for the first drill to 500 rpm or the last one. Physiologic saline must irrigate the area while the culling sequence must be strictly adhered to. The implant size (height and width) is selected after prior radiography. There must be a distance of 2 mm to anatomical obstacles and a maximum bone height. - The implants are delivered in sterile condition.

**- Implants must not be re-sterilized.**

**- Implants are intended for single use only.**

**- All devices should be placed in a sterile surgical field during surgery.**

**- The shelf life of the devices is 5 years.**



Instructions for use implants

SB/LA
Spiral Implant
SNAP & NL-SNAP

QSI & NL-QSI
Ri-Quadro Spiral
Implant

**GUIDE TO CHOOSING THE RIGHT IMPLANT**
After a preliminary diagnosis, an X-ray and/or CT scan should be used in conjunction with a transparency showing the necessary measurements to determine the appropriate dimensions of the implant for the particular site. As a general rule, the widest and longest implant suitable for a particular site (density and dimensions of the bone, dimensions of the gum) should be used for the most effective rehabilitation. Another general rule is that implant and abutment combinations offer the widest range of rehabilitation possibilities. The use of the integrated implant offers several advantages for the patient The choice of an integrated implant/abutment (one-piece) requires immediate loading and rehabilitation as well as cementation of the restorative appliance. There is no fastening of the abutment by screwing and no choice of the structure of the abutment. This decision is made in advance. For two-stage implant placement, if immediate loading is required, the spiral cone implant (QSI), which has good retention from the start, should be used. In the mandible with type 1 hard bone, the SB/LA SNAP, QSI implants are suitable. In the front, in single-rooted teeth and in the upper teeth between tooth 4 and tooth 7, where the sinus cavity is located, wide conical implants are recommended to reduce the pressure on the base of the sinus. If the bone is very wide and the sinuses are removed, any implant can be used. If the bone is narrow, a wide implant should not be used. After extraction, if the bone is good, a spiral implant (QSI or SNAP) or immediate loading is appropriate.

**SB/LA Spiralimplant (SNAP), QSI & NL-QSI**
A spiral cone implant with deep, wide thread spacing, particularly sharp thread cutting edges and a grooved neck. Its advantages are: The deep threads increase the surface area and thus improve the retention of the implant; while the implant is inserted into the bone by rotation, the sharp thread edges create their path in the bone tissue. The bone is compacted by the conical structure and by these threads; it offers very good primary stability and an excellent initial restoration.

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## DRILLING METHOD

ALL IMPLANTS: after well-planned surgical exposure of the bony surface, the position for the implant should be determined and a guide hole made with our lance drill, which is drilled into the cortical bone to the level of the neck under the drill head. Do not attempt to drill deeper with the marking drill with the guide hole for the position; the color-coded drills are used to drill the hole to the desired depth. The color coding on the bits indicates the diameter of the bit. Almost all drilling should start with the 2.0 millimeter drill bit or lance drill bit. The drills are used in graduated order to slowly increase the diameter of the implant hole until the desired diameter is reached. This allows for safe progression and reduces trauma to the surrounding bone structures. The exact depth of the hole is determined by the length of each implant and indicated by the depth lines around each bit to allow good positioning of the implant in the bone so that its end is flush with the alveolar ridge.
For drills with a stopper function, the drilling depth is limited by the ledge on the respective drill (RIBEU kit).

## QSI/SNAP PROTOCOL

The best conical hole for the planned conical implant is achieved with the intended conical drill. All drills, with the exception of the last regular drill, are inserted one after the other until the desired depth line reaches the alveolar ridge. The last regular drill is gently inserted to a depth of only the necessary situation. The drilling protocols of the conical holes are listed in Table A. Ritter CDEP conical drills have a stopper system that ensures the correct drilling depth and prevents drilling deeper than necessary.

The most efficient drilling method was achieved by using conical drill bits. We strongly recommend our customers to purchase the conical drills. The conical drill for each diameter is suitable for each implant length in that diameter. Where the tapered drills are not available, the desired tapering of the hole can be achieved by re-drilling with two slightly larger drills that are only partially removed. The first drill, which is slightly larger than the drill used to achieve the desired depth of the implant hole, drills only 2/3 of the total depth, and the second, which is slightly larger than the first, drills only 1/3 of the depth, creating a stepped or conical tapered hole.

| **Table A: QSI and SB/LA Spiral Implants -SNAP-** | | | | | | |
|---|---|---|---|---|---|---|
| Implant diameter | NL-3* | NL-3.3 | 3.75 | 4.2 | 5.0 | 6.0 |
| Color coding | white | red | blue | green | black | brown |
| Predecessor of the regular drillings with CDEP | -- | 1 | 1 | 2 | 3 | 4 |
| Conical drill width CDEP (mm) | -- | 2.8 | 3.2 | 3.2-3.65 | 3.2-4.5 | 3.2-5.4 |
| Final regular drill with max. depth / corresponding to the length of the implant (mm) | 2.5 | 2.8 | 3.2 | 3.65 | 4.5 | 5.4 |

*Not available in Canada.



Instructions for use implants

**ATTENTION: As the lance drill bits do not contain a stopper system, the drilling process must be carried out carefully so as not to drill deeper than 6mm!**


## CAUTION

All conical drills are characterized by the fact that they drill through the bone over the entire length of the drill, which is positioned in the gum. This is in contrast to the normal drill, which only drills through the bone with the frontal lower tip.

At the same time, its lateral helical blades slide along the bore wall without any significant radial forces. The use of conical drills causes extreme radial pressure, resulting in the need for gentle, probing drilling rather than constant drilling. This gradual drilling should involve the use of low torque.

The maximum speed (shots per minute) depends on both the type of drill and the drill diameter. Do not exceed 450 rpm and a torque of 35 Ncm. Drilling should be accompanied by intensive watering. First you must drill with bits at a slow incline - first the 2.0 mm bit, then the 2.8 mm bit and so on.

The conical drill is only to be used at the end of the drilling process so that only a small amount of bone has a quicksand effect. The hard bone drills can be used to widen the crestal bone at the end of the drilling sequence (CD 3.75-6.0).

## EXAMPLE

If you wish to insert a 6.0 mm implant, you must use the last regular drill CDEP-5.4 for the 6.0 mm implant.

A periodic pause during drilling allows both the blade and the bone to cool down. It also enables the removal of bone fragments and the necessary control at the appropriate speed.

The drill should be moved up and down during drilling to avoid too much heat and pressure or even microbial formation. (Branemark bone dancing method).

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**SB/LA Spiral Implant -SNAP- IMPLANTATIONS PROTOCOL**
After the implant has been removed from the packaging, its sterility should be maintained. The implant must be inserted directly via Mountdriver (MMIB long or short with ball friction) using a handpiece that can be inserted directly into the implant. MMIB has an SD adapter of the handpiece. Once the MMIB has been inserted into the inner HEX of the implant, the implant should be pulled out of the titanium sleeve as vertically as possible.
After insertion, the implant can be closed at the top with a cover screw (CSI) and the wound must be sutured for the recovery and healing phase. For immediate loading: Install the correct temporary abutment and suture the tissue around the restoration.
**CAUTION:**
**NL-SNAP: requires NL-Narrow Line Instruments Hex-2.0 (NL-RDH, NL-MMIB)**

**QSI IMPLANTATION PROTOCOL**
After the implant has been removed from the double packaging, its sterility should be maintained. The implant is screwed manually via the carrier and/or the SDH and/or HDH tool and/or the RHDI tool and/or the RWH/TRU ratchet or via a handpiece with built-in MMIB adapter, with or without carrier, as required. The recommended position for a perfect restoration is achieved by the exact height of the insertion depth, with one of the sides of the hex running tangentially to the outer jaw bow. The visible outer hex of the carrier is always parallel to the concealed inner hex of the implant. The carrier is separated by a slight pull. You can close the upper part of the implant with a cover screw (CSI), suture it and wait for recovery or load it immediately by attaching the correct abutment and suturing around the tissue.
**CAUTION:**
**NL-QSI: Requires NL-Narrow Line Instruments Hex-2.0 (NL-RDHI, NL-SDH, NL-HDH, NL-HDH & NL-MMIB)**

**STERILIZATION**

Implants should NOT be cleaned and under no circumstances should they be re-sterilized! Do not autoclave hard plastic parts that can melt at approx. 170°C (338°F). Abutments are provided non-sterile and should be sterilized before insertion into the oral cavity. Instructions for sterilization >> see page 11, Sterilization of prosthetic components.

**SPECIAL INSTRUCTIONS FOR THE MAINTENANCE OF SURGICAL TOOLS**

Correct and careful maintenance of surgical instruments is extremely important.
Damage to the drill tips can lead to a considerable impairment of the drilling function. Below you will find detailed instructions for proper maintenance.

Cover screw

Holder

Implant

Internal tube





**INSTRUCTIONS FOR THE MAINTENANCE OF SURGICAL INSTRUMENTS BEFORE FIRST SURGICAL USE**
Information on the surgical kit system, cleaning and sterilization of drills and instruments can be found under Instructions for use I20-0002 "Surgical Kit System".

**RECOMMENDATIONS**
Cutting tools should be used for a maximum of 10 cycles.
Sterilized water should be used to avoid surface stains.

**STORAGE**
The implants should be stored in the original packaging, in a dry area at room temperature (10°C-23°C/ 50°F-73.4°F). The implant should not be used after the expiration date on the package. Light packages should be stacked on top of heavier ones. Do not store implants near hazardous or toxic materials.

**TRANSPORT**
THE IMPLANTS SHOULD BE TRANSPORTED IN THEIR ORIGINAL PACKAGING, AS VIBRATION-FREE AS POSSIBLE.

**WARNINGS** Implant surgery is a very complex procedure and it is recommended that you undergo the necessary training to learn about implant surgery. Improper implant techniques can lead to implant failure and bone loss. Ritter implants are only intended for use according to the protocol described above with Ritter implant drills. Implants placed at sharp angles can lead to implant failure. Bone loss, infection and movement of the implant may indicate that the implant is failing. If any of these are observed, the problem should be treated as soon as possible or the implant should be removed. **Please observe the safety instructions for MRI examinations on page 24.** Risks include: immediate anesthetic and surgical risks psychiatric risks, medical threats of long-term retention, long-term health effects and complications that may include: delayed healing, edema, bleeding, dehiscence, stapling, hematoma, allergic reactions, sinus inflammation, nerve damage, speech problems, and gingivitis long-term problems may include: Nerve damage, bone loss, hyperplasia, local or systemic bacterial infection, endocarditic, long-term pain and fractures. the implant or teeth. The following organ systems may be affected: Cardiovascular-coronary disease; Respiratory - chronic lung disease; Renal - chronic renal failure; Endocrine - diabetes, thyroid disease, pituitary and adrenal disease; Hematologic - anemia, leukemia, blood clotting disorders; Musculoskeletal-arthritis osteoporosis; Neurologic-stroke, paralysis, mental retardation.

**CHANGES IN PERFORMANCE**
It is the physician's responsibility to inform the patient of the side effects, contraindications and precautions if the performance of the implant is in question. If any of the side effects occur, it is the patient's responsibility to consult a trained professional immediately.

**PRECAUTIONARY MEASURES**
Adequate palpation and visual inspection of the future implant site must be performed to determine if there is sufficient bone quality and volume for an implant. After implant failure, the quality and volume of the residual bone must be assessed. The implant is supplied in sterile packaging. Do not re-sterilize. Opened, damaged or defective packaging must be returned to the supplier for replacement free of charge. The use of an implant does not require unusual preoperative antibiotic prophylaxis. In case of unexpected pain, the surgeon must be contacted immediately, as physical exertion should be avoided after surgery.
**Please observe the safety instructions for MRI examinations on page 24.**

**HYGIENE AND MAINTENANCE**
The quality of oral hygiene directly affects the long-term success of the implant. The patient should be educated on the use of proper tools and maintenance of oral hygiene to maintain implant health and visit a dentist for regular check-ups and cleaning. Ritter Implants GmbH & Co. KG high-quality implants are manufactured according to strict international standards. **For this reason, we can offer you a lifetime guarantee for our implant line. In the event of a defect in the implant, implant rejection, fracture or contamination of the product, Ritter Implants GmbH & Co. KG will replace the defective product,** provided that a complaint report has been completed. A complaint report is available from Ritter Implants customer service and will be sent on request.

**LIMITED WARRANTY**
In the event of failure of an implant, Ritter will replace/provide another implant free of charge, subject to the following conditions:
- Completion of a report form provided by Ritter and attachment of an X-ray image before and after implantation.
- Submission of the report no later than 6 months after the start of the event with the failed implant.
This is the full extent of Ritter's warranty for the implantation, which lists the only remedies associated with the implantation. associated with the implantation.

**NOTE**
Regarding serious incidents: The user and/or patient is obliged to report any serious incidents related to the device to the manufacturer and/or the competent authority of the Member State in which the user and/or patient is established.

# Instructions for use - Abutments

Titan

Burn-IT

Zirkon

PEEK

**RITTER IMPLANTAT ABUTMENTS FOR RITTER IMPLANT SYSTEM.**
**APPLICATION NOTES**
Ritter implants are intended for the single or multiple replacement of lost teeth and provide a means of attaching prosthetic components in fully or partially edentulous patients. Surgeons/practitioners should be familiar with all indications, contraindications, recommendations, warnings and instructions as well as all other product-specific information (technical product description, description of the surgical and restorative technique, catalog sheet, etc.) of our system. You should be able to fully comply with these processes. Detailed instructions beyond those contained in these instructions for use regarding the possible combinations, product-specific risks, preparation steps, indications, contraindications, etc. can be found in the product descriptions. This includes the surgical technique and the description of the products as they can be found in the corresponding catalog sheet. Ritter also recommends participation in appropriate training and further education courses. The aforementioned documents and details of the training courses can be carried out on the complications, other negative effects or damage that may occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling with inappropriate use or handling of the instruments, asepsis, etc. The surgeon is responsible for such complications or other consequences. The surgeon is responsible for such complications or other consequences. It is also the responsibility of the surgeon to properly inform the patient about the functions, handling and necessary care of the product and about all known product risks.

**POSITION IN THE MOUTH**
- Straight - Located in all sectors (areas) of the mouth.
- Angled - Located in the anterior sector(s) of the maxilla for 15° angled abutments.
  Sectors in which the existing defects made an implant angled 25° perpendicular to the toocclusal plane impossible.
- Ball attachment/Clicq overdenture/multiple system - Used in all areas of the mouth, but usually used in the anterior region for overdentures.
- Gingiva former/caps - Located in all areas of the mouth.

**Sources of occlusal stress:**
Estevam Barbosa dc LAS CASAS, Andre France de ALMEIDA, Carlos Alberto CIMINI EJUNIOR, Paulo de Tarso VidaGUMES Tulimar Pereira Machado CORNAC- CHIA. Jorge Milton Elian SAFFAR. Determination of tangential and normal components of oral forces Journal of Applied Oral Science.2007;15(1)70-6 - Lucas D. Movement behavior of teeth and dental implants during periotest measurements in ocelusion - an in vitro study, Biomed Tech(Berl). 2001 Nov; 46(11):311-9, PMID: 11778315 [PubMed - indexed for MEDLINE]. - Lyons M.F. y Baxendale R.H. (1990). A preliminary electromyographic study of bite force and jaw-closing muscle fatigue in inhuman subjects with advanced dental attrition. Journal of Oral Rehabilitation 17: 311-318. - Waltime A., Kemppainen P. y Kononen K. (1993). Maximum contraction force and endurance of the human mandibular sphincter during inisometric clenching. Scandinavian Journal of Dental Research l01: 416-421.

**DESCRIPTION**
The restorative abutments have a hex that engages the internal hex of the SNAP, QSI and TFI implants. The abutments are available in several collar heights in straight and offset versions, as well as in 15° and 25° angled versions to allow correction of angle-free implant placement. The abutment is attached to the implant with an abutment retaining screw, which is pre-assembled in the abutment. The abutment screw cannot be removed from the abutment. The abutment has an internal screw access for attaching various restorative components with a separate cap screw. Abutments are packaged with a screw in a blister. The abutment and the fixation screw of the abutment are made of a titanium alloy.

**INSTRUCTIONS**
The straight and angled abutment is used for a terminal or intermediate abutment for screw-retained multi-unit restorations. The 25° angled abutment must be used within 45° of parallelism for a splinted restoration. The 15° angled abutment must be used within 30° of parallelism for a splinted restoration.

**CONTRAINDICATIONS see page 3**

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# Instructions for use - Abutments

**Abutment dimensions & features (material: Ti6AL-4VELI)**

| Abutment Titanium | Length in mm (L) | Shoulder height mm | Characteristic use |
|---|---|---|---|
| Anatomical | 8-10 | 1-3 | Burnout technique |
| Angled 15°/25° | 8-15 | | for the restoration |
| Ball Attachment & Clicq Overdenture | 1-7 | -- | for full dentures |
| Esthetically straight | 8-12 | 1-4 | for the restoration |
| Esthetically angled 15°/25° | 8-10 | 1-3 | for the restoration |
| Esthetic anatomical with platform shifting | 8-12 | 2.5-3.5 | for the restoration |
| Titanium straight | 7-15 | -- | for the restoration |
| Anatomically straight | 8-12 | 1-4 | for the restoration |
| Slim titanium | 5-10 | -- | for the restoration |
| Healing | 2-7 | -- | Healing cap and gingiva shaping |
| Connection of the overdenture | 3-6 | 0.5-2.5 | for full dentures |
| Plastic connection with/without hexagon | 8 | -- | Burnout technique |
| Multi-Units | 7-15 | 1-5 | for the restoration |

| Abutment PEEK / Burn-IT | Length in mm (L) | Shoulder height mm | Characteristic use |
|---|---|---|---|
| Burn-It plastic, laboratory with/without hex | 15.2 | 1 | Burnout technique |
| Burn-It straight anatom. plastic abutment | 10.5-12.5 | 1-3 | Burnout technique |
| Burn-It Estet. angled, plastic abutment | 8.5-11.9 | 1-3 | Burnout technique |
| Straight anatom. Golden titanium | 8-12 | 1-4 | for the restoration |
| Peek-On Peek anatom. straight | 10.5-12.5 | 1-3 | Temporary care |
| Peek-On X-Shape | 8.4-9.4 | 0.5-1 | Temporary care |
| Peek-On Esthet. angled Peek | 8.5-11.9 | 1-3 | Temporary care |
| Peek-On X-Shape angled Peek | 8.4-9.4 | 0.5-1 | Temporary care |

**Abutment Dimension & Charakteristik (Material: Zirconium)**

| Abutment Zirkon | Length in mm (L) | Shoulder height mm | Characteristic use |
|---|---|---|---|
| Zircon | 8 | 2 | for the restoration |
| Zirconium anatom. straight | 10.5-12.5 | 1-3 | for the restoration |
| Zircorite X-Shape straight, zirconium | 8.4-9.4 | 0.5-1 | for the restoration |
| Zircorite Esthet. angled Zircon | 8.5-11.9 | 1-3 | for the restoration |
| Zircorite X-Shape angled zirconium | 8.4-9.4 | 0.5-1 | for the restoration |

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**WARNINGS**
Surgical and restorative techniques required to place dental implants are highly specialized and complex procedures. Surgeons and all physicians should be fully trained in such procedures and be competent in such implant practices. All practitioners should attend courses to familiarize themselves with implantology techniques. Improper technique can lead to bone loss and implant failure. Ritter Dental implant systems are only intended for use with Ritter Dental specially designed bone drills and prostheses. Implants placed at a sharp angle to the existing dentition, or multiple implants placed convergently or divergently, can result in complex restorations that can overload implants. This overloading can lead to implant or prosthesis failure. Thorough diagnostic clarification and the use of a surgical template is recommended to ensure correct positioning of the implant(s). Relative contraindications include the use of steroids, chemotherapeutic agents, bisphosphonates and anticoagulants. These and other medications that may affect the surgical site, the surrounding tissue or the patient's healing function may affect the success of the implant. Careful patient selection, including consultation with the attending physician, is strongly recommended prior to implant treatment for patients on such medications. Placement of an implant adjacent to an infected tooth or a failing root canal-treated tooth may result in implant failure. Excessive mobility, bone loss or infection may indicate that the implant is failing. Any implant that appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site. One can either allow the site to heal as in a traumatic extraction or perform guided tissue regenerative procedures as indicated. Due to metal conductivity, electrosurgery around the implants and intraoral abutment preparations without irrigation can lead to tissue damage and implant failure. **Please observe the safety instructions for MRI examinations on page 24.**

**PRECAUTIONARY MEASURES**
Correct case planning is crucial for the long-term success of the prosthesis and implant. Overloading is one of the main reasons for implant failure. One should ensure that the implant size and abutment angulations are suitable for occlusal loading. Highly angled abutments (>25°) should be avoided and are not recommended. For better support, splinting of off-axis loaded implants may be necessary.

**FRACTURES**
Implant and abutment fractures may occur if the applied loads exceed the normal functional design tolerances of the implant components. Possible overload conditions may result from errors in the number, length and/or length of implants. Other causes of failure may include: improper diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 25 degrees, occlusal interference causing excessive transverse forces, patient parafunction (e.g., bruxing clenching), improper casting procedures, inadequate prosthesis fit, and physical trauma.

**CHANGES IN PERFORMANCE**
It is the responsibility of the clinician to inform the patient of all appropriate contraindications, side effects and precautions, as well as the need to consult a trained dentist in the event of changes in the performance of the implant (e.g. loosening of the prosthesis, infection or exudate around the implant, pain or other unusual symptoms that the patient did not expect).

**HYGIENE & MAINTENANCE**
The long-term health of implants is directly related to the maintenance of oral hygiene. Potential implant candidates should establish proper oral hygiene prior to implant therapy. After implant placement, the clinician should familiarize the patient with proper tools and techniques to ensure long-term maintenance of the implants. The patient should also be instructed to keep routinely scheduled prophylaxis and evaluation appointments.

**TREATMENT PLANNING**
Appropriate imaging techniques should be used to determine if adequate bone is present and to determine the location of important anatomical landmarks such as the mandibular canal, maxillary sinuses and adjacent teeth. A thorough clinical evaluation is essential prior to all implant procedures.

**GENERAL CONSIDERATIONS**
Controlling biomechanical loads is the key to the long-term success of the prosthesis. Even after implant integration, imbalances in occlusal forces can lead to implant failure. Implant patients should be monitored for signs of screw loosening, peri-implant bone loss and tooth wear as signs of occlusal overload.

**UNDESIRABLE EFFECTS**
The following complications may occur in connection with implant placement: Pain, discomfort, dehiscence, delayed healing, paresthesia, hypertonia, edema, bleeding, hematoma, infection, inflammation, local and generalized allergic reactions, lack of integration, damage to adjacent teeth, bone or tooth loss and implant loss. Other adverse effects may also occur as a result of iatrogenic factors and host reactions.

**STERILITY**
Abutments are supplied in a non-sterile condition, packaged under clean room conditions.

**INDIVIDUAL USE**
The reuse of a single-use device that has come into contact with blood, bone, tissue or other body fluids may result in injury to patients or users. Possible risks associated with the reuse of a single-use device include mechanical failure and the transmission of infectious agents.

**EXPIRATION DATE**
The expiration date of the product is indicated by the hourglass symbol on the product label, followed by the year and month of expiration. Caution: Do not use sterile devices if the sterile barrier packaging, including the outer cap, vial or tray, has been damaged or compromised in any way (e.g. torn or crushed).

**PRODUCT PACKAGING**
All implants have been cleaned, packed in double tubes in a controlled clean room and sterilized for convenient and immediate use. The implants are suspended from a titanium shaft carrier to ensure safe transfer to the prepared surgical site without risk of contact contamination. Both the implant and the inner packaging of the tube are sterile. The label on the outer blister packaging for each implant contains a batch number which should be recorded in the patient's file to ensure full traceability of the product. Prosthetic components in sealed blister packs are also pre-cleaned.

**NOTE** regarding serious incidents:
The user and/or patient is obliged to report any serious incidents related to the device to the manufacturer and/or the competent authority of the Member State in which the user and/or patient is established.

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Instructions for use - Abutments

**INFORMATION ON CLEANING/STERILIZATION**
Disinfection and sterilization procedures should be in accordance with OSHA or local guidelines for bloodborne pathogens. Clinically contaminated implants should not be cleaned and resterilized for reuse under any circumstances.

**CLEANING**
Use the following guidelines for cleaning prosthetic components: Disassemble multi-part components (e.g. ratchet) if necessary. Rinse with cool to lukewarm water for two and a half minutes.
For all parts in an ultrasonic cleaner with an enzymatic detergent diluted with tap water according to the manufacturer's guidelines. Ultra-sonic for 10 minutes. Rinse with tap water for three minutes. Clean the parts according to the instructions above. A syringe or pipe cleaner can be used to assist cleaning. Dry the components. Follow the guidelines for sterilization.

**STERILIZATION**
Please unpack the non-sterile prosthetic components from the cardboard and blister box before autoclaving.
Prosthetic components (abutments) should be placed in a suitable autoclave or dry heat bag prior to sterilization. The following sterilization parameters (method, time and temperature) are required to achieve a 10-6 sterilization level (SAL). Local or national specifications should be followed if steam sterilization requirements are more stringent or conservative than those listed in the table. Exceeding these sterilization parameters may result in damage to plastic components. Check the calibration of your device to ensure that the recommended temperatures are not exceeded. To ensure that the autoclave is working effectively, the regular use of biological indicators should be considered. Chemoclave sterilization is NOT recommended for Ritter Implants dental products.

| Sterilization of prosthetic components | Cycle type | Temperature | Time in minutes | Drying time in minutes |
|---|---|---|---|---|
| | Steam | 132°C/270°F | 15 | 15 |

**TECHNICAL INFORMATION**
Procedure for Ritter implants angled abutments.
NOTE: During implant placement, it is recommended to align the plane of the internal hex of the implant so that it is opposite the angle correction. The pre-assembled multipurpose holder can be used to index the internal hex of the implant. The flat side on the wall of the device holder is the same as the flat side of the internal hex. NOTE: To insert the abutment into the mouth, use the HHDA abutment driver. The driver should be hand tightened (max. 25-30 Ncm) to the abutment to confirm adequate attachment of the tool to the abutment.

**Use suitable abutments and angled components that correspond to the implant system to be restored**

1. Remove the angled abutment from the abutment packaging in a sterile area. Hand-tighten the abutment with the HHDA abutment hand screwdriver to confirm attachment to the abutment taper.

2. Thread Dentalfloss through the nostril in the HHDA upper part. Insert the abutment into the mouth using the Abutment Driver. Align the angled abutment in the appropriate orientation for the desired angulation correction.

3. Use 1.27 mm [0.50"] hexagon wrench HHDA to tighten the fixing screw of the abutment by hand (max. 30 Ncm). A contra-angle handpiece with a 1.27 mm0 MMA driver can also be used for initial delivery. The long MMA driver (MMA-28) must be used when the abutment delivery tool is attached to the abutment. The standard MMA driver (MMA-22) can be used when the abutment delivery tool is removed from the abutment.

4. Use a periapical X-ray to check whether the abutment is fully inserted into the implant and has engaged the hexagon socket.

5. Tighten the abutment screw to 30 Ncm using a calibrated torque wrench. The torque wrench TRU/RWH can be used with the abutment driver for the ratchet RDA-L, RDA-M can be used away from the abutment.

6. If the abutments are not immediately restored with a temporary or final restoration, it is recommended to use the healing cap made of titanium. (HC-xx) to avoid irritation of the soft tissue and to prevent the penetration of material into the screw access of the abutment cone.

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# Instructions for use - Ball attachment and Clicq overdenture

**DEVICE DESCRIPTION AND EXPECTED PERFORMANCE:**
Elastic retaining devices for the construction of dentures.

**PRECAUTIONARY MEASURES:**
The choice of the correct attachment is the responsibility of the dentist or dental technician - this applies to all prosthetic projects.

**RESPONSIBILITY AND GUARANTEE:**
Ritter devices and components are manufactured in accordance with European and US standards for medical devices. No undesirable side effects are expected or reported.

**STORAGE, TRANSPORTATION AND CLEANING PROCESS:** If possible, store in a dry and clean place in the original packaging.

**WARNING:** The packaging must not be damaged during transportation. Products do not have an expiration date. The product is sold in NON STERILE packaging, it is recommended to continue the sterilization process of the metal parts by following standard medical procedures (steam autoclave sterilization). All plastic parts (non-castable) should be sterilized by cold sterilization with benzalcynhydrin solution. Technical support: Our technical staff are available to answer any questions you may have regarding the use of Ritter components.
Further information on the use of the Ball Attachment & Clicq Overdenture SYSTEM can be found in our main catalog and our technical data sheets.

**MAINTENANCE AND REGULAR CARE:** Dentists are responsible for ensuring the proper function and storage of the appliances (CAPS AND CLIPS) and for ensuring patient safety through constant care. Guidelines for patients: Patients are advised to follow the dentist's instructions and to attend regular check-ups and or perform them themselves on a daily basis. The kits contain: Single implant attachment: 1 titanium attachment TiN (Ø 2.5), 4 different retentive caps, 1 protective disk.

**TECHNICAL DATA:** Ball attachment & Clicq overdenture on implants: Titanium + TiN single prosthesis attachment for screwing onto endosseous implants, retention is ensured by the elastic cap that runs over the equator of the ball. The vertical dimension of the ball has been reduced in order to obtain a smaller attachment.

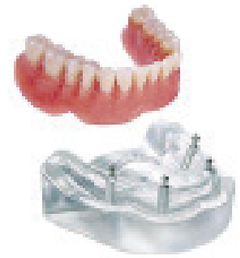
**RETENTIVE CAPS:** Different retentive properties make it possible to choose the right retention. Nylon and acetal copolymer material.

**Prefabricated metal houses or TITAN:** The inner mold is designed to accommodate the elastic retention caps. The outer mould is designed to be inserted into a mobile resin prosthesis or bonded to metal parts, cast reinforcements or metal frames using adhesive, composite materials or self-polymerizing resin.

**UNSCREWING SYSTEMS:** Expanding elastic nylon towel designed to prevent the attachment from unscrewing from the implant (available on request).

**PROTECTIVE DISC:** Disposable disc, plastic and elastic material, transparent color.

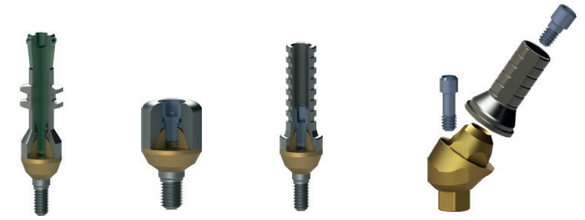
**INSTRUCTIONS FOR USE:** Ball attachment & Clicq overdenture attachment titanium + tin: Screw the attachment onto the implant using the correct square screwdriver, ensuring that the insertion of the metal tip is corrected. Screw the attachment on by hand until the process is complete, then unscrew the attachment and screw it on again. Repeat this process a few times until the thread has the correct shape of the micromodeling of the inner part. Alternatively, the attachment can be screwed on with the correct screw.
Dynamometric drill extension Tool tightening up to 25 N/cm2.



**APPLICATION OF THE PROSTHESIS IN THE PATIENT'S MOUTH:**
Once the Ball Attachment & Clicq Overdenture Attachments are screwed into the implants, proceed with the insertion of the elastic protective disk over the equator of the attachment. Insert the retentive counterpart cap into the metal housing with the correct insertion tool, select the counterpart cap with the correct retainer according to the case, and then place the metal housing over the attachment with precise pressure so that it snaps over the equator. Test the mobile resin prosthesis in the patient's mouth with the correct locations corresponding to the attachments. Ensure that there is sufficient space in case of interference. Enlarge the space with a bur until the interference of the metal housing is eliminated. Fill the spaces with self-polymerizing resin, place the prosthesis in the patient's mouth, check the correct position, have the patient close his mouth and wait until the resin has hardened. Remove the prosthesis, refine and polish any excess material to deliver the prosthesis to the patient. To maintain the high quality standard of the Ball Attachment & Clicq Overdenture line, we recommend the annual replacement of the retentive elastic components. Any use of the Ball Attachment & Clicq Overdenture System and components that does not comply with these instructions or other Ritter literature is considered unauthorized.



# Instructions for use - Multi-Units



Impression | Healing cap | Straight abutment | Angled abutment


**Device description and expected performance:**
Multi-Units are an abutment system that combines many different abutments in one multi-purpose abutment: impression coping, healing cap, straight abutment, angled abutment for the final restoration.

**Precautionary measures:**
The choice of the correct attachment is the responsibility of the dentist or dental technician.
according to the prosthetic project. Safety, responsibility and warranty: Ritter devices and components are manufactured in accordance with European and US standards for medical devices.
No undesirable side effects are expected or reported. Storage, transportation and cleaning process: If possible, store in a dry and clean place in the original packaging.

**WARNING:**
The packaging must not be damaged during transportation. Products do not have an expiration date. The product is sold in NON STERILE packaging, it is recommended to continue the sterilization process of the metal parts by following standard medical procedures (steam autoclave sterilization). All plastic parts (non-castable) should be sterilized by cold sterilization with benzalcynhydrin solution. Technical support: Our technical staff are available to answer any questions you may have regarding the use of Ritter components.
Further information on the use of the Multi-Unit-SYSTEM can be found in our main catalog and our technical data sheets.
Guidelines for patients: Patients are advised to follow the dentist's instructions, attend regular check-ups and carry out accurate daily hygiene.

**TECHNICAL DATA:**
Multi Units on implants: Titanium base grade 5 abutment attachment for screwing onto endosseous implants.

**INSTRUCTIONS FOR USE:**
Multi-unit base attachment: Place the multi-unit with the metal handle MU-HD in the correct position on the implant. Screw it onto the implant using the correct square-head screwdriver, ensuring that the insertion of the metal tip is corrected. Tighten by hand (up to 25 NCM) until the process is complete. Use angled Multi Units Angled Base for angle adjustment from 17° to 30°. Also applies to working with bar restorations for all on 4 / all on 6.

**APPLICATION OF THE PROSTHESIS IN THE PATIENT'S MOUTH:**
Once the multi-unit attachments are screwed into the implants, proceed with the insertion of the final laboratory crown. Fill the spaces with self-polymerizing resin, place the prosthesis in the patient's mouth, check the correct position, have the patient close their mouth and wait for the resin to set. Remove the prosthesis, refine and polish any excess material to deliver the prosthesis to the patient. Any use of the Multi Units and components not in accordance with these instructions or other Ritter literature is considered unauthorized.

# CORRESPONDING ABUTMENTS FOR RITTER IMPLANTS STANDARD PLATFORM

SNAP-3.75-8
SNAP-3.75-10
SNAP-3.75-11.5
SNAP-3.75-13
SNAP-3.75-16

SNAP-4.2-8
SNAP-4.2-10
SNAP-4.2-11.5
SNAP-4.2-13
SNAP-4.2-16

SNAP-5-6
SNAP-5-8
SNAP-5-10
SNAP-5-11.5
SNAP-5-13
SNAP-5-16

SNAP-6-6
SNAP-6-8
SNAP-6-10
SNAP-6-11.5
SNAP-6-13

QSI-3.75-8
QSI-3.75-10
QSI-3.75-11.5
QSI-3.75-13
QSI-3.75-16
QSI-4.2-8
QSI-4.2-10
QSI-4.2-11.5
QSI-4.2-13
QSI-4.2-16

QSI-5-6
QSI-5-8
QSI-5-10
QSI-5-11.5
QSI-5-13
QSI-5-16
QSI-6-6
QSI-6-8
QSI-6-10
QSI-6-11.5
QSI-6-13

## HEALING CAPS

HC-2 Standard Line H 2 mm | Ø 4.5 mm
HC-3 Standard Line H 3 mm | Ø 4.5 mm
HC-3C Standard Line H 3 mm | Ø 4.5 mm C= 1.5 mm Collar

HC-3N Standard Line slim H 3 mm | Ø 3.8 mm
HC-3W Standard Line wide H 3 mm | Ø 5.5 mm
HC-3WC Standard Line wide H 3 mm | Ø 5.5 mm C= 1.5 mm Collar

HC-3EW Standard Line extra wide H 3 mm | Ø 6.3 mm
HC-3EWC Standard Line extra wide H 3 mm | Ø 6.3 mm C= 1.5 mm Collar

HC-4 Standard Line H 4 mm | Ø 4.5 mm
HC-5 Standard Line H 5 mm | Ø 4.5 mm
HC-5C Standard Line H 5 mm | Ø 4.5 mm C= 1.5 mm Collar

HC-5N Standard Line slim H 5 mm | Ø 3.8 mm
HC-5W Standard Line wide H 5 mm | Ø 5.5 mm
HC-5WC Standard Line wide H 5 mm | Ø 5.5 mm C= 1.5 mm Collar

HC-5EW Standard Line extra wide H 5 mm | Ø 6.3 mm
HC-5EWC Standard Line extra wide H 5 mm | Ø 6.3 mm C= 1.5 mm Collar

HC-6 Standard Line H 6 mm | Ø 4.5 mm
HC-7 Standard Line H 7 mm | Ø 4.5 mm

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## IMPRESSION COPINGS

### Closed Tray transfer

ACT-15 Standard Line – 15° angled H 11 mm | Ø 4.4 mm,
ACT-25 Standard Line – 25° angled H 10.9 mm | Ø 4.4 mm

CTT-10.8N Standard Line slim H 10.9 mm | Ø 3.8 mm
CTT-13.8N Standard Line slim H 13.9 mm | Ø 3.8 mm
CTT-13N Standard Line slim H 13 mm | Ø 3.8 mm

### Open Tray transfer

OTT-10.8N Standard Line slim H 10.8 mm | Ø 4 mm
OTT-13.8N Standard Line slim H 13.9 mm | Ø 4 mm
OTT-13N Standard Line slim H 13 mm | Ø 3.8 mm
OTT-13.8W Standard Line wide H 13.9 mm | Ø 5.5 mm

### Scan Abutment

3DSPA-8C 5 mm Abutment-body, 1.6 mm Shoulder C= 1.5 mm Vertical Platform switching

## TITANIUM ABUTMENTS

### Smooth

SLTA-5 L 5 mm | ø 3.8 mm
SLTA-7 L 7 mm | ø 3.8 mm
SLTA-9 L 9 mm | ø 3.8 mm

### Slim

SLTA-6 L 5 mm | ø 3.8 mm
SLTA-8 L 7 mm | ø 3.8 mm
SLTA-10 L 9 mm | ø 3.8 mm

### Standard

STA-5 L 5 mm | ø 4.5 mm
STA-7 L 7 mm | ø 4.5 mm
STA-9 L 9 mm | ø 4.5 mm
STA-12 L 12mm | ø 4.5mm
STA-15 L 15 mm | ø 4.5 mm

### Wide

STA-9W L 9 mm | ø 5.5 mm
STA-12W L 12 mm | ø 5.5 mm

### Standard 15° angled

EATA-15-1 G1 1mm | L 9 mm
EATA-15-2 G1 2mm | L 10 mm
EATA-15-3 G1 3mm | L 11 mm

### Standard 25° angled

EATA-25-1 G1 1mm | L 9 mm
EATA-25-2 G1 2mm | L 10 mm
EATA-25-3 G1 3mm | L 11 mm

### Angled

ATA-15N L 9 mm
ATA-15 L 9 mm
ATA-15L L 11,5 mm

### Angeld

ATA-25N L 9 mm
ATA-25 L 9 mm
ATA-25L L 11,5 mm

### Straight Anatomic Emergency Profile

SATA-1 G1 1 mm | L 8.9 mm | Ø 4.5 mm
SATA-2 G1 2 mm | L 9.9 mm | Ø 4.5 mm
SATA-3 G1 3 mm | L 10.9 mm | Ø 4.5 mm

### Straight Anatomic Emergency Profile GOLD

SAGA-1 G1 1 mm | L 8.9 mm | Ø 4.5 mM
SAGA-2 G1 2 mm | L 9.9 mm | Ø 4.5 mm
SAGA-3 G1 3 mm | L 10.9 mm | Ø 4.5 mm

### Straight Emergency Profile

ESPS-1 G1 1 mm | Ø 4.8 mm
ESPS-2 G1 2 mm | Ø 4.8 mm
ESPS-3 G1 3 mm | Ø 4.8 mm

### Straight Traditional Emergency Profile

SSTA-1 G1 1 mm | Ø 4.8 mm
SSTA-2 G1 2 mm | Ø 4.8 mm
SSTA-3 G1 3 mm | Ø 4.8 mm
SSTA-4 G1 4 mm | Ø 4.8 mm

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## ABUTMENTS FOR CASTING

| | |
|---|---|
| AZA | Titanium Abutment<br>with Plastic Sleeve<br>Titanium base for accurate<br>restorations. |
| AZA-CC | Cobalt Chrome Abutment<br>with Plastic Sleeve<br>Cobalt Chrome base for<br>accurate restorations. |
| AZA-L | Titanium Abutment<br>with Plastic Sleeve |
| AZA-CC-L | Cobalt Chrome Abutment<br>with Plastic Sleeve |

| | |
|---|---|
| PACA | Plastic Connection Abutment<br>without Hex |
| PAC | Burn-It Plastic Sleeve<br>for Laboratory, Rotational |
| PAC-H | TBurn-It Plastic Sleeve<br>for Laboratory, Anti-Rotational |
| PA-H | Burn-It Plastic Sleeve for Laboratory,<br>with Hex, Anti-Rotational |
| PA-N | Burn-It Plastic Sleeve Abutment<br>for Laboratory, without Hex, Rotational |

## PUT SYSTEM

| | |
|---|---|
| PUT-1S | 4 mm \| 1.1 mm Shoulder |
| PUT-1SC | 4 mm \| 0.6 mm Shoulder<br>C= 0,5 mm Vertical Platform switching |
| PUT-1M | 6 mm \| 1.1 mm Shoulder |
| PUT-1MC | 6 mm \| 0.6 mm Shoulder<br>C= 0.5 mm Vertical Platform switching |
| PUT-1L | 8 mm \| 1.1 mm Shoulder |
| PUT-1LC | 8 mm \| 0.6 mm Shoulder<br>C= 0.5 mm Vertical Platform switching |

| | |
|---|---|
| PUT-2S | 4 mm \| 2.1 mm Shoulder |
| PUT-2SC | 4 mm \| 1.1 mm Shoulder<br>C= 1 mm Vertical Platform switching |
| PUT-2M | 6 mm \|2.1 mm Shoulder |
| PUT-2MC | 6 mm \| 1.1 mm Shoulder<br>C= 1 mm Vertical Platform switching |
| PUT-2L | 8 mm \| 2.1 mm Shoulder |
| PUT-2LC | 8 mm \| 1.1 mm Shoulder<br>C= 1 mm Vertical Platform switching |
| PUT-3S | 4 mm \| 3.1 mm Shoulder |
| PUT-3SC | 4 mm \| 1.1 mm Shoulder<br>C= 2 mm Vertical Platform switching |

| | |
|---|---|
| PUT-3M | 6 mm \| 3.1 mm Shoulder |
| PUT-3MC | 6 mm \| 1.1 mm Shoulder<br>C= 2 mm Vertical Platform switching |
| PUT-3L | 8 mm \| 3.1 mm Shoulder |
| PUT-3LC | 8 mm \| 1.1 mm Shoulder<br>C= 2 mm Vertical Platform switching |
| PUT-4L | 8 mm \| 4.1 mm Shoulder |
| PUT-5S | 4 mm \| 5.1 mm Shoulder |
| PUT-5L | 8 mm \| 5.1 mm Shoulder |

| | |
|---|---|
| PUT-15-1M | 15° angles<br>6 mm \| 1 mm Shoulder |
| PUT-15-2M | 15° angles<br>6 mm \| 2 mm Shoulder |
| PUT-15-3M | 15° angles<br>6 mm \| 3 mm Shoulder |

| | |
|---|---|
| PUT-25-1M | 25° angles<br>6 mm \| 1 mm Shoulder |
| PUT-25-2M | 25° angles<br>6 mm \| 2 mm Shoulder |
| PUT-25-3M | 25° angles<br>6 mm \| 3 mm Shoulder |

## TEMPORARY ABUTMENTS

### PEEK Abutments

| | |
|---|---|
| PASA-1 | 1 mm Shoulder \| L 11.1 mm |
| PASA-2 | 2 mm Shoulder \| L 12.1 mm |
| PASA-3 | 3 mm Shoulder \| L 13.1 mm |

### Titanium Abutments

| | |
|---|---|
| TTA-ZI-H ø 4.5 mm | L 9.5 mm Anti-Rotational |
| TTA-ZI-R ø 4.5 mm | L 9.5 mm Rotational |

### Angled white PEEK Abutment 15°

| | |
|---|---|
| EAPA-15-1 | G1 1mm \| L 9 mm |
| EAPA-15-2 | G1 2mm \| L 10 mm |
| EAPA-15-3 | G1 3mm \| L 11 mm |

### Angled white PEEK Abutment 25°

| | |
|---|---|
| EAPA-25-1 | G1 1mm \| L 9 mm |
| EAPA-25-2 | G1 2mm \| L 10 mm |
| EAPA-25-3 | G1 3mm \| L 11 mm |

## TI-BASE

### Rotational

| | |
|---|---|
| TBC-0.5R | H 4.7 mm \| ø 4.2 mm<br>C= 0,5 mm |
| TBC-1.5R | H 4.7 mm \| ø 4.2 mm<br>C= 1,5 mm |
| TBC-3R | H 4.7 mm \| ø 4.2 mm<br>C= 3 mm |

### Anti-Rotational

| | |
|---|---|
| TBC-0.5R | H 4.7 mm \| ø 4.2 mm<br>C= 0,5 mm |
| TBC-1.5 | H 4.7 mm \| ø 4.2 mm<br>C= 1,5 mm |
| TBC-3 | H 4.7 mm \| ø 4.2 mm<br>C= 3 mm |





## OVERDENTURE ABUTMENTS

### Removable Ball Abutments

| | |
|---|---|
| BA-1 | 1 mm Shoulder |
| BA-2 | 2 mm Shoulder |
| BA-3 | 3 mm Shoulder |
| BA-4 | 4 mm Shoulder |
| BA-5 | 5 mm Shoulder |
| BA-6 | 6 mm Shoulder |
| BA-7 | 7 mm Shoulder |

### Clicq™ straight

| | |
|---|---|
| COD-0.5 | 0.5 mm Shoulder |
| COD-1 | 1 mm Shoulder |
| COD-2 | 2 mm Shoulder |
| COD-3 | 3 mm Shoulder |
| COD-4 | 4 mm Shoulder |
| COD-5 | 5 mm Shoulder |
| COD-6 | 6 mm Shoulder |
| COD-7 | 7 mm Shoulder |

### Clicq™ 18° angled

| | |
|---|---|
| COD-18-1 | G1 1 mm, G2 2.5 mm \| Ø 3.85 mm |
| COD-18--2 | G1 2 mm, G2 3.5 mm \| Ø 3.85 mm |
| COD-18-3 | G1 3 mm, G2 4.5 mm \| Ø 3.85 mm |
| COD-18-4 | G1 4 mm, G2 5.5 mm \| Ø 3.85 mm |

### Clicq™ 30° angled

| | |
|---|---|
| COD-30-1 | G1 1 mm \| G2 3.5 mm \| Ø 3.85 mm |
| COD-30-2 | G1 2 mm \| G2 4.5 mm \| Ø 3.85 mm |
| COD-30-3 | G1 3 mm \| G2 5.5 mm \| Ø 3.85 mm |
| COD-30-4 | G1 4 mm \| G2 6.5 mm \| Ø 3.85 mm |

### Clicq™ PLUS straight

COD-0.5P COD-1P COD-2P COD-3P COD-4P COD-5P COD-6P

### Clicq™ PLUS 18° angled

| | |
|---|---|
| COD-18-0.5P | G1 0.5 mm \| G2 2.1 mm \| Ø 5.2 mm |
| COD-18-1P | G1 1 mm \| G2 2.6 mm \| Ø 5.2 mm |
| COD-18-2P | G1 2 mm \| G2 3.6 mm \| Ø 5.2 mm |
| COD-18-3P | G1 3 mm \| G2 4.6 mm \| Ø 5.2 mm |

### Clicq™ PLUS 30° angled

| | |
|---|---|
| COD-30-0.5P | G1 0.5 mm \| G2 3.1 mm \| Ø 5.2 mm |
| COD-30-1 | G1 1 mm \| G2 3.6 mm \| Ø 5.2 mm |
| COD-30-2 | G1 2 mm \| G2 4.5 mm \| Ø 5.2 mm |
| COD-30-3 | G1 3 mm \| G2 5.6 mm \| Ø 5.2 mm |

## MULTI UNIT ABUTMENTS

### Straight

| | |
|---|---|
| MU-KS10 | 1 mm Shoulder |
| MU-KS20 | 2 mm Shoulder |
| MU-KS30 | 3 mm Shoulder |
| MU-KS40 | 4 mm Shoulder |
| MU-KS50 | 5 mm Shoulder |

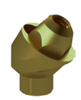
### 17° angled

| | |
|---|---|
| MU-KS1710 | 17° angled Multi Unit<br>1.1 mm \| 2.5 mm Shoulder |
| MU-KS1720 | 17° angled Multi Unit<br>2.1 mm \| 3.5 mm Shoulder |
| MU-KS1730 | 17° angled Multi Unit<br>3.1 mm \| 3.5 mm Shoulder |
| MU-KS1740 | 17° angled Multi Unit<br>4.1 mm \| 3.5 mm Shoulder |

| | |
|---|---|
| MU-KS1710H | 17° angled Multi Unit anti-rotation<br>1.1 mm \| 2.5 mm Shoulder |
| MU-KS1720H | 17° angled Multi Unit anti-rotation<br>2.1 mm \| 3.5 mm Shoulder |
| MU-KS1730H | 17° angled Multi Unit anti-rotation<br>3.1 mm \| 3.5 mm Shoulder |
| MU-KS1740H | 17° angled Multi Unit anti-rotation<br>4.1 mm \| 3.5 mm Shoulder |

### 30° angled

| | |
|---|---|
| MU-KS3010 | 30° angled Multi Unit<br>1.1 mm \| 3.5 mm Shoulder |
| MU-KS3020 | 30° angled Multi Unit<br>2.1 mm \| 4.5 mm Shoulder |
| MU-KS3030 | 17° angled Multi Unit<br>3.1 mm \| 3.5 mm Shoulder |
| MU-KS3040 | 30° angled Multi Unit<br>4.1 mm \| 3.5 mm Shoulder |



| | |
|---|---|
| MU-KS3010H | 30° angled Multi Unit anti-rotation<br>1.1 mm \| 3.5 mm Shoulder |
| MU-KS3020H | 30° angled Multi Unit anti-rotation<br>2.1 mm \| 4.5 mm Shoulder |
| MU-KS3030H | 30° angled Multi Unit anti-rotation<br>3.1 mm \| 3.5 mm Shoulder |
| MU-KS3040H | 30° angled Multi Unit anti-rotation<br>4.1 mm \| 3.5 mm Shoulder |

# CORRESPONDING ABUTMENTS FOR RITTER IMPLANTS NARROW LINE

NL-SNAP-3-10
NL-SNAP-3-11.5
NL-SNAP-3-13
NL-SNAP-3-16

NL-SNAP-3.3-10
NL-SNAP-3.3-11.5
NL-SNAP-3.3-13
NL-SNAP-3.3-16

NL-QSI-3.0-10
NL-QSI-3.0-11.5
NL-QSI-3.0-13
NL-QSI-3.0-16

NL-QSI-3.3-10
NL-QSI-3.3-11.5
NL-QSI-3.3-13
NL-QSI-3.3-16

## HEALING CAPS

| | |
|---|---|
| NL-HC-2 | Narrow Line<br>H 2 mm \| Ø 4.5 mm |
| NL-HC-2N | Narrow Line slim<br>H 2 mm \| Ø 3.8 mm |
| NL-HC-3 | Narrow Line<br>H 3 mm \| Ø 4.5 mm |
| NL-HC-3C | Narrow Line<br>H 3 mm \| Ø 4.5 mm<br>C= 1.5 mm Collar |

| | |
|---|---|
| NL-HC-3N | Narrow Line slim<br>H 3 mm \| Ø 3.8 mm |
| NL-HC-4 | Narrow Line<br>H 4 mm \| Ø 4.5 mm |
| NL-HC-4N | Narrow Line slim<br>H 4 mm \| Ø 3.8 mm |

| | |
|---|---|
| NL-HC-5 | Narrow Line<br>H 5 mm \| Ø 4.5 mm |
| NL-HC-5C | Narrow Line<br>H 5 mm \| Ø 4.5 mm<br>C= 1.5 mm Collar |
| NL-HC-5N | Narrow Line slim<br>H 5 mm \| Ø 3.8 mm |
| NL-HC-6 | Narrow Line<br>H 6 mm \| Ø 4.5 mm |
| NL-HC-6N | Narrow Line slim<br>H 6 mm \| Ø 3.8 mm |





## IMPRESSION COPINGS

### Closed Tray transfer

| | |
|---|---|
| NL-ACT-15 | Narrow Line - 15° angled<br>H 11 mm \| Ø 4.8 mm |
| NL-ACT-25 | Narrow Line - 25° angled<br>H 11 mm \| Ø 4.8 mm |

| | |
|---|---|
| NL-CTT-10.8N | Narrow Line slim<br>H 10.9 mm \| Ø 3.8 mm |
| NL-CTT-13.8N | Narrow Line slim<br>H 13.9 mm \| Ø 3.8 mm |
| NL-CTT-13N | Narrow Line slim<br>H 13 mm \| Ø 3.8 mm |

### Open Tray transfer

| | |
|---|---|
| NL-OTT-10.8N | Narrow Line slim<br>H 10.8 mm \| Ø 3.8 mm |
| NL-OTT-13.8N | Narrow Line slim<br>H 13.9 mm \| Ø 3.8 mm |
| NL-OTT-13N | Narrow Line slim<br>H 13 mm \| Ø 3.8 mm |
| NL-OTT-13.8C | Narrow Line slim<br>H 13.9 mm \| Ø 4.5 mm<br>C= 1.5 mm Emergence Profile |

### Scan Abutment

| | |
|---|---|
| NL-3DSPA-8C | 5 mm Abutment-body,<br>1.6 mm Shoulder<br>C= 1.5 mm Vertical Platform switching |

## TITANIUM ABUTMENTS

### Standard

| | |
|---|---|
| NL-STA-10 | L 10 mm |

### Angled

| | |
|---|---|
| NL-ATA-15 | |

### Straight Traditional Emergency Profile

| | |
|---|---|
| NL-SSTA-1 | G1 1 mm, Ø 4.8 mm |
| NL-SSTA-2 | G1 2 mm, Ø 4.8 mm |
| NL-SSTA-3 | G1 3 mm, Ø 4.8 mm |

## ABUTMENTS FOR CASTING

| | |
|---|---|
| NL-AZA | Titanium Abutment<br>with Plastic Sleeve<br>Titanium base for accurate restorations. |
| NL-AZA-CC | Cobalt Chrome Abutment<br>with Plastic Sleeve<br>Cobalt Chrome base for accurate restorations. |

| | |
|---|---|
| NL-PAC-H | TBurn-It Plastic Sleeve<br>for Laboratory, Anti-Rotational |

## TI-BASE

### Rotational

| | |
|---|---|
| NL-TBC-0.5R | H 4.7 mm \| ø 4.2 mm<br>C= 0,5 mm |
| NL-TBC-1.5R | H 4.7 mm \| ø 4.2 mm<br>C= 1,5 mm |
| NL-TBC-3R | H 4.7 mm \| ø 4.2 mm<br>C= 3 mm |

### Anti-Rotational

| | |
|---|---|
| NL-TBC-0.5R | H 4.7 mm \| ø 4.2 mm<br>C= 0,5 mm |
| NL-TBC-1.5 | H 4.7 mm \| ø 4.2 mm<br>C= 1,5 mm |
| NL.TBC-3 | H 4.7 mm \| ø 4.2 mm<br>C= 3 mm |

## PUT SYSTEM

| | |
|---|---|
| NL-PUT-1S | 4 mm, 1.1 mm Shoulder |
| NL-PUT-1M | 6 mm, 1.1 mm Shoulder |
| NL-PUT-1MC | 6 mm, 0.6 mm Shoulder<br>C= 0.5 mm Vertical Platform switching |
| NL-PUT-1L | 8 mm, 1.1 mm Shoulder |
| NL-PUT-1LC | 8 mm, 0.6 mm Shoulder<br>C= 0.5 mm Vertical Platform switching |

| | |
|---|---|
| NL-PUT-2S | 4 mm, 2.1 mm Shoulder |
| NL-PUT-2SC | 4 mm, 1.1 mm Shoulder<br>C= 1 mm Vertical Platform switching |
| NL-PUT-2M | 6 mm, 2.1 mm Shoulder |
| NL-PUT-2MC | 6 m, 1.1 mm Shoulder<br>C= 1 mm Vertical Platform switching |
| NL-PUT-2L | 8 mm, 2.1 mm Shoulder |
| NL-PUT-2LC | 8 mm, 1.1 mm Shoulder<br>C= 1 mm Vertical Platform switching |

| | |
|---|---|
| NL-PUT-3S | 4 mm, 3.1 mm Shoulder |
| NL-PUT-3SC | 4 mm, 1.1 mm Shoulder<br>C= 2 mm Vertical Platform switching |
| NL-PUT-3M | 6 mm, 3.1 mm Shoulder |

| | |
|---|---|
| NL-PUT-3MC | 6 mm, 1.1 mm Shoulder<br>C= 2 mm Vertical Platform switching |
| NL-PUT-3L | 8 mm, 3.1 mm Shoulder |
| NL-PUT-3LC | 8 mm, 1.1 mm Shoulder<br>C= 2 mm Vertical Platform switching |
| NL-PUT-4L | 8 mm, 4.1 mm Shoulder |

| | |
|---|---|
| NL-PUT-15-1M | 15° angles<br>6 mm, 1 mm Shoulder |
| NL-PUT-15 -2M | 15° angles<br>6 mm, 2 mm Shoulder |
| NL-PUT-15 -3M | 15° angles<br>6 mm, 3 mm Shoulder |

| | |
|---|---|
| NL-PUT-25-1M | 25° angles<br>6 mm 1 mm Shoulder |
| NL-PUT-25-2M | 25° angles<br>6 mm, 2 mm Shoulder |
| NL-PUT-2 5 -3M | 25° angles<br>6 mm, 3 mm Shoulder |

## OVERDENTURE ABUTMENTS

### Removable Ball Abutments


NL-BA-1


NL-BA-2


NL-BA-3


NL-BA-4

### Clicq™ straight


NL-COD-0.5


NL-COD-1


NL-COD-2


NL-COD-3


NL-COD-4


NL-COD-5


NL-COD-6

### Clicq™ 18° angled

| | |
|---|---|
| NL-COD-18-1 | G1 1 mm, G2 2.5 mm, Ø 3.85 mm |
| NL-COD-18--2 | G1 2 mm, G2 3.5 mm, Ø 3.85 mm |
| NL-COD-18-3 | G1 3 mm, G2 4.5 mm, Ø 3.85 mm |
| NL-COD-18-4 | G1 4 mm, G2 5.5 mm, Ø 3.85 mm |

### Clicq™ 30° angled

| | |
|---|---|
| NL-COD-30-1 | G1 1 mm, G2 3.5 mm, Ø 3.85 mm |
| NL-COD-30-2 | G1 2 mm, G2 4.5 mm, Ø 3.85 mm |
| NL-COD-30-3 | G1 3 mm, G2 5.5 mm, Ø 3.85 mm |
| NL-COD-30-4 | G1 4 mm, G2 6.5 mm, Ø 3.85 mm |

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### Clicq™ PLUS straight

NL-COD-0.5P

NL-COD-1P

NL-COD-2P

NL-COD-3P

NL-COD-4P

NL-COD-5P

NL-COD-6P

NL-COD-7P

### Clicq™ PLUS 18° angled

| | |
|---|---|
| NL-COD-18-0.5P | G1 0.5 mm, G2 2.1 mm, Ø 5.2 mm |
| NL-COD-18-1P | G1 1 mm, G2 2.6 mm, Ø 5.2 mm |
| NL-COD-18-2P | G1 2 mm, G2 3.6 mm, Ø 5.2 mm |
| NL-COD-18-3P | G1 3 mm, G2 4.6 mm, Ø 5.2 mm |

### Clicq™ PLUS 30° angled

| | |
|---|---|
| NL-COD-30-0.5P | G1 0.5 mm, G2 3.1 mm, Ø 5.2 mm |
| NL-COD-30-1P | G1 1 mm, G2 3.6 mm, Ø 5.2 mm |
| NL-COD-30-2P | G1 2 mm, G2 4.5 mm, Ø 5.2 mm |
| NL-COD-30-3P | G1 3 mm, G2 5.6 mm, Ø 5.2 mm |

## MULTI UNIT ABUTMENTS

### Straight

| | |
|---|---|
| NL-MU-KS10 | 1 mm Shoulder |
| NL-MU-KS20 | 2 mm Shoulder |
| NL-MU-KS30 | 3 mm Shoulder |
| NL-MU-KS40 | 4 mm Shoulder |
| NL-MU-KS50 | 5 mm Shoulder |

### 17° angled

| | |
|---|---|
| NL-MU-KS1710 | 17° angled Multi Unit<br>1.1 mm \| 2.5 mm Shoulder |
| NL-MU-KS1720 | 17° angled Multi Unit<br>2.1 mm \| 3.5 mm Shoulder |
| NL-MU-KS1730 | 17° angled Multi Unit<br>3.1 mm \| 3.5 mm Shoulder |
| NL-MU-KS1740 | 17° angled Multi Unit<br>4.1 mm \| 3.5 mm Shoulder |

| | |
|---|---|
| NL-MU-KS1710H | 17° angled Multi Unit anti-rotation<br>1.1 mm \| 2.5 mm Shoulder |
| NL-MU-KS1720H | 17° angled Multi Unit anti-rotation<br>2.1 mm \| 3.5 mm Shoulder |
| NL-MU-KS1730H | 17° angled Multi Unit anti-rotation<br>3.1 mm \| 3.5 mm Shoulder |
| NL-MU-KS1740H | 17° angled Multi Unit anti-rotation<br>4.1 mm \| 3.5 mm Shoulder |

### 30° angled

| | |
|---|---|
| NL-MU-KS3010 | 30° angled Multi Unit<br>1.1 mm \| 3.5 mm Shoulder |
| NL-MU-KS3020 | 30° angled Multi Unit<br>2.1 mm \| 4.5 mm Shoulder |
| NL-MU-KS3030 | 30° angled Multi Unit<br>3.1 mm \| 3.5 mm Shoulder |
| NL-MU-KS3040 | 30° angled Multi Unit<br>4.1 mm \| 3.5 mm Shoulder |

| | |
|---|---|
| NL-MU-KS3010H | 30° angled Multi Unit anti-rotation<br>1.1 mm \| 3.5 mm Shoulder |
| NL-MU-KS3020H | 30° angled Multi Unit anti-rotation<br>2.1 mm \| 4.5 mm Shoulder |
| NL-MU-KS3030H | 30° angled Multi Unit anti-rotation<br>3.1 mm \| 3.5 mm Shoulder |
| NL-MU-KS3040H | 30° angled Multi Unit anti-rotation<br>4.1 mm \| 3.5 mm Shoulder |

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# MRI safety information

Ritter titanium implants are made of grade 5 titanium (Ti). These materials are considered paramagnetic and therefore interact only weakly with magnetic fields.

Ritter abutments such as abutments, caps, cover screws and healing caps are made of titanium 5, PEEK or ceramic ($ZrO_2$). These materials are either paramagnetic or non-magnetic.

It can be concluded from the literature that the components of the Ritter Dental Implant System are unlikely to interfere with patient safety. Scientific articles have shown that the magnetic displacement of dental implant system components is less than the force exerted by gravity on the medical device, and RF heating results in a maximum temperature rise below the heat pain threshold of 8°C - 10°C, without taking into account the cooling effect of the surrounding tissue and blood flow [1]. However, image artifacts are to be expected and must be taken into account during image analysis [2], [3] and [4].

Note that this literature is not sufficient to assign a rating of MR Safety to the components of the Ritter Dental Implant System. Scanning a patient fitted with these components may result in injury to the patient.

Due to the wide variety of MRI scanners available on the market, Ritter cannot make any predictions regarding the safety or behavior of our implants and components in a particular MRI system. Patients should consult with their physician and imaging technologist prior to undergoing an MRI procedure. Removable restorations should be removed prior to scanning, as is customary for watches, jewelry, etc.

Finally, Ritter cannot take responsibility for the composition and behavior of third party products (including the crown, bridge, bar, prosthesis, etc.) that are not distributed by Ritter and may contain materials that are not compatible with MRI imaging.

Following the launch of the new European database for medical devices (Eudamed), the Summary of Safety and Clinical Performance (SSCP) can be accessed on the Eudamed website at https://ec.europa.eu/tools/eudamed.

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*[1]*
*Sherin Jose Chockattu, Deepak Byathnal Suryakant, Sophia Thakur, "Unwanted effects due to interactions between dental materials and magnetic resonance imaging: a review of the literature", Restorative Dentistry & Endodontics 2018 Nov;43(4):e39*

*[2]*
*Margit-Ann Geibel, Benjamin Gelißen, Anna-Katinka Bracher, Volker Rasche "Artifact Properties of Dental Ceramic and Titanium Implants in MRI", Georg Thieme Verlag KG, Published online: 2018-11-12*

*[3]*
*Chalakuzhiyl Abraham Mathew, Sudhakara Maller, Maheshwaran, „Interactions between magnetic resonance imaging and dental material" Journal of Pharmacy & BioAllied Sciences. 2013 Jun; 5(Suppl1): S113–S116*

*[4]*
*Ralf Smeets, Maximilian Schöllchen, Tobias Gauer, Ghazal Aarabi, Alexandre T. Assaf, Carsten Rendenbach, Benedicta Beck-Broichsitter, Jan Semmusch, Jan Sedlacik, Max Heiland, Jens Fiehler, Susanne Siemonsen "Artefacts in multimodal imaging of titanium, zirconium and binary titanium–zirconium alloy dental implants: an in vitro study" Dentomaxillofacial Radiology (2017) 46, 20160267*




Medical devices - Symbols to be used on labels for medical devices, Labeling and information to be provided - Part 1: General requirements

| Symbol | Symbol Title | Explanatory Text | Standard, Reference Number |
|---|---|---|---|
| STERILE R | Sterilized by irradiation | Indicates a medical device that has been sterilized by irradiation. | ISO 15223-1 Reference #5.2.4<br>FDA approval # 5-117 |
| Single Use | Do not reuse | Refers to a medical device that for single use or use on a single patient use on a single patient during a single treatment is intended. | ISO 15223-1 Reference #5.4.2<br>FDA approval # 5-117 |
| CAUTION | Caution | Indicates the need for the user to read the instructions for use for important safety-related information, such as warnings and precautionswhich, for a variety of reasons, are not reasons cannot be placed on the medical device on the medical device itself. | ISO 15223-1 Reference #5.4.4<br>FDA approval # 5-117 |
| www.ritterimplants.com/IFU | Observe the electronic instructions for use | Refers to the necessity for the user to consult the instructions for use for advice. | ISO 15223-1 Reference #5.4.3<br>FDA approval # 5-117 |
| | If the packaging is damaged<br>Do not use | Indicates a medical device that should not be used if the packaging is damaged or opened. | ISO 15223-1 Reference #5.2.8<br>FDA approval # 5-117 |
| | Can be used until | Indicates the date after which the medical medical device may no longer be used. | ISO 15223-1 Reference #5.1.4<br>FDA approval # 5-117 |
| REF | Item number | Displays the manufacturer's order number, so that the medical device can be identified. | ISO 15223-1 Reference #5.1.6<br>FDA approval # 5-117 |
| LOT | Batch code | Displays the batch designation of the manufacturer so that the batch or lot or the lot can be identified. | SO 15223-1 Reference #5.1.5<br>FDA approval # 5-117 |
| STERILIZE | Do not re-sterilize | Indicates a medical device that must not be re-sterilized. | ISO 15223-1 Reference #5.2.6<br>FDA approval # 5-117 |
| XXXX-XX-XX | Manufacturer with date of manufacture | Indicates the manufacturer of the medical device | ISO 15223-1 Reference #5.1.1<br>FDA approval # 5-117 |
| CE<br>CE 0483 | CE marking / with reference of the notified body ##### | Means the European conformity mark (CE) / Indicates the conformity of products for which the notified body carried out the conformity assessment. Notified body reference # is displayed | NA |
| Rx only ** | Explanation of the prescription | Caution: US federal law restricts the sale this product for sale. Use by healthcare professionals only | 81 FR 38911<br>FDA Reference # 2016-13989 |
| NON STERILE | Non-sterile | Indicates a medical device that has not been sterilization process has not been sterilized. | ISO 15223-1 Reference #5.2.7<br>FDA approval # 5-117 |
| 10°C/ 50°F<br>23°C/ 73.4°F | Temperature limitation<br>Storage condition<br>10°C-23°C/ 50°F-73.4°F | The temperature limits to which the medical device can be safely can be safely exposed to. | ISO 15223-1 Reference #5.3.7<br>FDA approval # 5-117 |
| 20%<br>75% | Humidity, limitation<br>Storage condition 20-75% | Indicates the humidity range to which the medical device can be safely exposed to. | ISO 15223-1 Reference #5.3.8<br>FDA approval # 5-117 |
| | Simple sterile barrier system with internal protective packaging | Shows a simple sterile/barrier system with internal protective packaging on | ISO 7000-3708 2019-10-18 |
| MD | Medical device | Indicates that the article is a medical device | ISO 15223-1 Reference #5.7.7 |
| | Protect from sunlight | Indicates a medical device that must be protected from light sources | ISO 7000-0624<br>2014-06-04 |
| | Keep dry store | Indicates a medical device that must be protected from moisture | ISO 7000-0626<br>2014-06-04 |



** Only for the scope of the FDA