Instructions for the Use of Meoplant® Medical Dental Implants

Meoplant® Medical dental implants are double-blistered sterile (gamma sterilised). Prior to use, check the packaging for damage. The implants must be stored dry and at room temperature. The implants may no longer be used if the expiration date has elapsed.

1. Product Description

The Meoplant® Medical Implant System is manufactured from pure grade T4 CP titanium. It is an integrated system of enossal dental implants with corresponding secondary parts. The surface of the Meoplant® implant is blasted and acid-etched (CellTex® surface structure). The apically, tapered implant body has a cylindrical, parallel-walled shape in the mid-section with a macro-thread and a micro-thread in the crestal bone area. The three spirals ensure a self-centering insertion. The outer areas of the thread are designed so that a self-cutting effect occurs, as long as the recommended drill protocol is maintained. The thread pitch and furrow-like interruptions in the thread have the function of harvesting bone chips with vital bone cells, transporting them to the implant body, thus concentrating them in order to biologically optimise primary stability and osseointegration. The implant tip is shaped like a lens; its convex design protects anatomically challenged structures such as the maxillary sinus mucous membrane, such as in the case of a sinus-lift. The internal hex is responsible for insuring a rotation-resistant, permanently congruent connection between the implant and the abutment. The cone connection provides for a close metal connection that reduces the micro-gap between the abutment and the implant and insures a better adhesion. Instead of a internal hex, the reduced-diameter MeoMini® implant has an additional extended, tulip-shaped polished neck that transitions into an external hex. The Meoplant® Medical Implant System comprises implants of various diameters and lengths intended for different indications. Nevertheless, please note that compliance with the prescribed drill protocol is mandatory. The Meoplant® Implant System has its own separate components such as cover screws, gingiva formers, impression copings, MeoLock®, MeoMulti® and Meoplant® prosthetic components for utilization.

Implant	Diameter	Length	Material	Color Coding
MeoMini®	2.9mm	8mm / 10mm / 12.5mm	Titanium Grade 4 CP	White
Meoplant®	3.5mm	8mm / 10mm / 12.5mm / 15mm	Titanium Grade 4 CP	Yellow
Meoplant®	3.8mm	8mm / 10mm / 12.5mm / 15mm	Titanium Grade 4 CP	Red
Meoplant®	4.2mm	8mm / 10mm / 12.5mm / 15mm	Titanium Grade 4 CP	Green
Meoplant®	4.8mm	8mm / 10mm / 12.5mm / 15mm	Titanium Grade 4 CP	Blue
Meoplant®	6.0mm	8mm / 10mm	Titanium Grade 4 CP	Black

2. Safety Instructions:

Prior to using the Meoplant® Medical dental implant system, carefully read the Instructions for use of Meoplant® Medical Dental Implants. The user is responsible when failing to comply with these instructions. Notwithstanding these instructions, all rules regarding dental surgical procedures, as well as occupational safety and accident prevention regulations, must generally be observed for all indications specified. Incorrect use of surgical and/or prosthetic parts can cause damage to the implant as well as the abutment, and as a consequence can result in bone loss or even implant loss.
Only adequately qualified dentists trained in implantology with reference to diagnostics, planning and surgical techniques may use the Meoplant® Medical dental implant system.
The Meoplant® Medical dental implant system is a fully synchronised and coordinated implant system that may not be combined with the components and instruments of other implant manufacturers. In our terms of delivery we guarantee the perfect condition and perfect functionality of our products, as long as the above rules are observed.
Prior to the use of the Meoplant® Medical dental implant system, the practitioner has to ensure that all necessary system components are in good condition, and are protected against suction and swallowing during the treatment protocol. If there are any outstanding questions regarding the utilization or indication parameters prior to surgery, the operation may not be performed until all questions are answered. The practitioner is solely responsible for any damage caused through the use of Meoplant® Medical products. The abutments/secondary components may only be used as indicated IAW the rules regarding dental surgical procedures, as well as occupational safety and accident prevention regulations. Implants with a reduced diameter and angulated abutments are not intended for use in the posterior region. Consultations regarding the use of Meoplant products are held on a regular basis and are strongly recommended.

3. Indications:

The Meoplant® medical implant is intended solely for the use in dental implantology and OMF surgery. For single crowns and bridges, both screw-retained and cemented; to support partial prostheses, full prostheses and epitheses. For all applications, taking into account bone quality, the aim is for a load distributed across the axis and a sufficient implant length, which may not exceed 1:1 with regard to the crown length. The Meoplant® implant system is intended for use in immediate, delayed and late implantation surgical procedures; both single-stage and two-stage; edentulous spaces; reduced rows of teeth and toothless jaws.
The reduced diameter MeoMini® implant (O 2.9 mm) is not suited for use for single-tooth restoration of central incisors of the upper jaw, nor for canines, pre-molars or molars in the lower and upper jaw. In this region (upper jaw), implant sizes with diameters of 4.2 mm, 4.8 mm, and 6.0 mm are to be used. In the lower jaw, the 3.8 mm diameter can also be used in the side tooth area. However, the implant length should not be less than 10 mm, or blocked if the implant is shorter. The MeoMini® implant is suited to increase posts for support of prostheses and bridges, as well as for use in orthodontics as a counter-bearing.

4. Contraindications:

Wound healing disorders, endocrine diseases, osteomyelitis, systemic diseases of the bones, immune system or haematopoietic system, rheumatoid diseases, liver disease, diabetes that is uncontrolled or difficult to control, mental illness. Temporary contraindications: Nicotine and alcohol abuse, poor oral hygiene, acute inflammation of the surgical area, insufficient available bone and risk to critical anatomical structures, recurring diseases of the mucus membranes in the mouth, acute parafunctional habit, failure to obtain patient compliance, insufficient interocclusal space, insufficient soft tissue coverage, steroidal therapy, radiation therapy in the head area, chemotherapy, medications that affect calcium levels, anticoagulation therapy.

5. Side Effects:

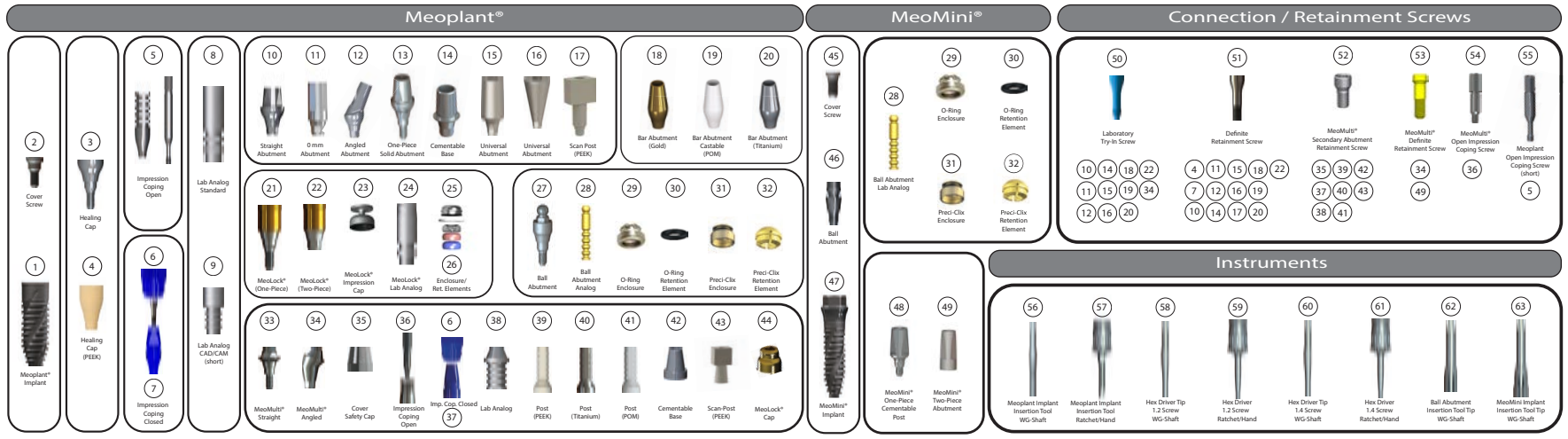
The common accompanying symptoms of surgical interventions such as swelling, haematoma, oedema and post-operative pain, restrictions of mouth opening and chewing, and sensory loss are possible.

6. Complications:

The following operative complications can occur in rare cases: infections of the surgical area; suture dehiscence; insufficient primary stability; unwanted trauma; post-surgical bleeding due to vascular injury; injuries to critical anatomical structures; screw breaks; stripping of cover screws or gingiva formers; breaks or fractures of the implant neck or body; suctioning or swallowing of small parts.

7. Delivery State / Intended Use / Shelf Life:

The implants are gamma sterilised in their packaging and are intended for one-time use only. They must not be resterilised. The implants may no longer be used if their packaging is damaged or open, or if the sterilisation expiration date has elapsed. The manufacturer will not be held responsible in the case of violations. All instruments and abutments/secondary components are unsterilised when packaged, and must be sterilised prior to use (IAW Autoclave EN DIN 554). Items intended for one-time use were not tested to determine whether repeated cleaning and sterilisation procedures would have an affect on the materials, thus impacting function and/or accuracy of fit. Therefore, repeated use of these items is not recommended.



8. Surgical Guidelines:

Each and every implantation is a surgical procedure that requires clarification, planning, sterile conditions and careful treatment of soft and hard tissue. This includes drilling with sufficient cooling at no more than 400 RPM, with intermittent movement and slight pressure. Avoid the repeated use of drills due to the risk of bone overheating if the drill is dull; this will prevent healing (osseointegration) as a result of heat necrosis. After preparing the bone cavity, the Meoplant implant ① is inserted with the insertion tool ⑯ | ⑰ and the MeoMini® Implant ㊼ is inserted with the insertion tool ㊸ at 10–15 RPM. The insertion torque when inserting the implant should not exceed 50 Ncm and must never be higher, in order to prevent pressure necroses and thermal damage. Likewise, ensure that the insertion torque is not less than 15 Ncm. Generally, the instruments used to insert the implants should fit the implant inner geometry precisely, in order to prevent damage to the inner geometry of the implant. The implant surface is specially produced as an SLA-compatible surface and is highly active. All contact with the implant surface prior to insertion should be avoided.
The Meoplant® Implant ① is designed so that the implant edge should be flush with the edge of the crestal bone after insertion. In addition, the precise prosthetic position of the subsequent super-structure should match the position of the implant in the horizontal and saggittal axes through precise surgical planning that takes into account the available bone. An implantation can take place with the creation of the mucoperiosteal flap; or transgingivally -- which requires precise knowledge of the available bone. With the transgingival procedure, soft tissue entrapment by the implant has to be avoided. Closed healing can commence after inserting a cover screw ②and suturing the incision site; or open healing after inserting a healing cap ③|④ or a ready-made, possibly previously customized abutment, as a or with a long-term provisional (temporary) fabricated for either a tissue-punched (with a gingival punch), or a surround-sutured incised flap. There must not be approximal or occluding contact to neighboring teeth.

9. Re-Entry / Impression-Taking / Prosthetic Selection:

In a single-stage implantation, after being inserted, the implant ① receives a healing cap/gingiva former ③|④ or an abutment ⑩ - ⑯ | ⑰ - ㉒ | ㉗ | ㉝ | ㉞. An immediate loading with a temporary on a prepared abutment after taking an impression can also be effected. Accordingly, ensure that there is no approximal or occluding contact with neighboring teeth. In a two-stage procedure, after being inserted, the implant ① recieves a cover screw ②. After the prescribed healing time has elapsed, a re-entry, the removal of the cover screw ②, insertion of a healing cap/gingiva former ③|④or an abutment (see above single-stage procedure) and subsequent closure/suturing takes place under anaesthesia. At this time, if so chosen, an impression can take place with selected open ⑤ or closed ⑥/⑦ impression copings, tightened with no more than 5-10 Ncm; bearing in mind that an exact seating is mandatory to insure the precise fit of the future restoration. For an open impression ⑤, openings for the impression posts ⑨are made in the individual impression trays, so that the impression posts can later be released from the implant after having taken the impression. For further processing a laboratory implant analog ⑧|⑨ that has the same inner geometry as the implant ① is attached to the impression coping ⑤ located in the tray. After the model is poured and cured, the screw connection from the laboratory analog is loosened and the tray is removed from the casted model. For a closed impression ⑥+⑦, the respective impression coping is connected to the implant ①. A transfer cap ⑥ is audibly/tactilely snapped onto the impression coping ⑦. An impression is taken with a conventional closed tray. After removal of the tray, the transfer cap ⑥ is embedded in the impression mass of the tray. The impression post ⑦ is now released from the implant ①, connected with a laboratory analog ⑧|⑨ and repositioned into the transfer cap ⑥ located in the tray. The model is created the same way as for the open impression technique.
After a lab-fabricated custom abutment/temporary, or the definite restoration, follows the provisional restoration therewith. Maturation of the peri-implant tissue can take up to six months and serves as a long-term prognosis for the implant. A blue anodised laboratory screw ㊿ especially designed for this process must be used for all retainment-work in the laboratory. When inserting the final prosthetic restoration, the definitive retainment screw ㊶ that is part of the corresponding abutment package must be used. Either the abutment or the entire crown-assembly is torqued IAW recommended values (see Recommended Abutment/Secondary Component Torque Table. Cementing may be used as an alternative to screw retainement for crowns, bridges and other prosthetic assemblies. When selecting the abutment, the height of the gingiva, the diameter of the implant, as well as its angulation, have to be considered. Breakage of the retainment screw can be prevented by maintaining the maximum torque of 30 Ncm. Should a screw break however, the fractured screw is removed using a specially designed recovery kit. The adhesive labels in the packaging provide for a method of documenting each components pertinent specifications.

The Meoplant® Medical abutments are to be used once only and are not sterile upon delivery. They must be sterilised prior to use, in particular if used during the surgical phase of implantation. The abutments should be kept in a clean and dry location.

Instructions for the Use of the Meoplant Medical® Dental Implant System Abutments / Secondary Components

1. General Safety Instructions:

Prior to using the components of the Meoplant® Medical dental implant system, carefully read the Instructions for the Use of the Meoplant® Medical Dental Implant System Abutments/Secondary Components. Observe the instructions. The user (dental practitioner/implantologist) is responsible for following and complying with these instructions. The rules and regulations of dental implant surgery, occupational safety and accident prevention guidelines in all of the cited/subsequent implant indications/protocols, must be upheld. It is recommended that only qualified dental practitioners trained in implantology, as well as in diagnostics, planning and surgical techniques, use the Meoplant® Medical dental implant system. The Meoplant® Medical dental implant system is a fully synchronised and coordinated dental implant system that may not be combined with the components and instruments of other implant manufacturers. In our terms of delivery we guarantee the perfect condition of our products, as long as the rules above are observed. Meoplant® Medicals Advanced Training Academy, Dental Centers of Excellence and Dental Hospitation Practices offer the opportunity to gain visual/practical experience that demonstrates the exact use of this implant system in the form of seminars/tutorials/workshops. Prior to the implementation/use of the Meoplant® Medical dental implant system, the practitioner must ensure that all necessary system components are in good condition and are protected against suction and swallowing during the treatment protocol. If there are any open/unanswered questions prior to the implant surgery relating to use in terms of benefit/purpose, or with regard to the protocol, the procedure may not be performed until all of these questions are fully answered/clarified.

2. Sterilisation:

CAUTION: The packaging that abutments and instruments are delivered in, is not suitable for sterilisation. Abutments and instruments must be removed from their packaging and repackaged IAW EN 868 or ISO 11607 for sterilization. Make sure that the seal (weld seam) is hermetic, undamaged and free of strain. The packaging must be large enough for the respective abutment or instrument. The sterilisation procedure must be validated and carried out IAW RKI guidelines.

3. Subgingival (Closed) Healing:

1. **Implant Insertion:**
Before suturing, close the inner geometry of the implant ①| ㊼ using a cover screw ②| ㊺, which is tightened manually with a maximum of 2–4 Ncm with hex instrument ⑱ | ⑲ / ⑳ | ㉑. NOTE: Overtightening will make subsequent loosening during re-entry, difficult if not impossible.
2. **Re-Entry:**
After re-entry using hex instrument 1.2 ⑱ | ⑲ for the MeoMini® implant ㊼, or hex instrument 1.4 ⑳ ㉑ for the Meoplant® implant ① to remove the cover screw ②| ㊺ and insert a healing cap/gingiva former ③| ④for soft-tissue conditioning; prior to or after which an impression can take place. NOTE: The MeoMini® implant is pre-mounted with a H=1 mm ball abutment, has no proprietary healing cap/gingiva former and seldomly reuqires a cover screw.

a.) Open Impression:
Impression coping ⑤ whiches long or short fixation screw ㊺ is used depending on the location and the available space, is torqued with a maximum of 5-10 Ncm. Ensure there is no tissue or paticulate matter in the implants ①internal geometry, in order to facilitate an exact seating and a firm fit. A previously prepared custom impression tray with perforations for the fixation screw ㊺, so that the impression coping can be disengaged from the implant once the impression material cures is required for this procedure.

b.) Closed Impression:
There are two three-piece impression copings: ⑥ + ⑦ + ㊶ for the Meoplant® implant platform ① and ⑥+ ㊼ + ㊷ for the Meoplant® implant with a MeoMulti® abutment platform ㉝ | ㉞, available for the closed impression technique. The impression copings are attached respectively with a maximum torque of 5-10 Ncm. Correspond- ingly the transfer cap ⑥ audibly/tactilely snaps onto each impression coping. A conventional impression can be taken with a closed tray. NOTE: Alginate is not suited for implant impressions. The impression/transfer cap ⑥ remains in the cured impression material. After the fixation screw of the impression coping is loosened, the impression tray is removed from the patients mouth. Now the impression coping is removed from the implant and along with the tray, is sent or given to the dental laboratory technician for further processing.theconnected with a respective laboratory implant analog ⑧|⑨| ㊽ and repositioned into its respective impression/transfer cap.

3. **Laboratory – Model Fabrication:**
The technician again verifys the seating of the embedded impression/transfer cap ⑥; then selects the appropriate laboratory implant analog ⑧|⑨| ㊽; connects it to the corresponding impression coping ⑦| ㊼ and repositions it back into the the tray accordingly. After applying a gingival mask material and pouring the tray with alginate, the model is ready to be separated from the tray by loosening the fixation screw of the impression coping.
4. **Laboratory – Abutment Selection and Customization:**
Depending on the requirement or axis of the set implant, an abutment ⑩ - ⑯ | ⑱ - ㉒ | ㉗ | ㉝ | ㉞ | ㊻ | ㊽ | ㊾ from the selection offered, can be chosen and customised. A standard abutment ⑩ | ⑫ will usually suffice when the implant is ideally axis-aligned. A one-piece abutment ⑬ can be adapted to the implant/tooth axis by the practitioner, chairside, with minor customization, within the oral cavity. NOTE: When customizing one-piece abutments in situ (the patients mouth) insure to use a rubber dam. A universal abutment ⑮ | ⑯ is to be customised in the dental laboratory.

4. Transgingival (Open) Healing:

If there is a deficit of soft tissue or a good to excellent primary stability, the transgingival method of implantation can be chosen by inserting a titanium healing cap/gingiva former ③ of suitable height and diameter with a torque of 2-4 Ncm; or a customizable PEEK healing cap/gingiva former ④+ ㊶ of suitable height and diameter, with a torque of 15 Ncm to form the peri-implant soft tissue to maturation. Impressions are taken as described in 2. a) and 2. b).

5. Transgingival (Open) Healing with Abutment & Temporary/ Long-Term Provisional without Immediate Loading

A frequent change of abutments is not conducive in enabling the soft tissue to mature without interruption. In this case it makes sense to immediately insert an abutment/temporary, or long-term provisional emulating the final restoration, or crown. Straight abutments ⑩ | ⑪ / ⑬ - ⑮ can be customized depending on the implant position and placed in non-occlusion for the duration of the soft-tissue conditioning phase.

6. Transgingival (Open) Healing with Abutment & Final Restoration with Immediate Loading

The only difference when compared to 6. (above) is in the fabrication of the restoration. Scan abutments/posts ⑰ + ㊶ | ㊸ + ㊷ are positioned directly into a placed implant, torqued with 15 Ncm and digitally scanned in a patients mouth. The resulting STL-file and the matching CAD/CAM planning software enables the dental technician to fabricate and the practitioner to install a crown, bridge, partial or full denture restoration of unsurpassed precision and perfection in the shortest amount of time with the greatest of ease, dependability and satisfaction.

MeoLock®

With respect to an edentulous jaw, the Meoplant® Medical MeoLock® abutment system serves to offer a method of securing cover dentures/prosthesis against vertical extraction forces during matication. Single-piece ㉑ and two-piece ㉒ + ㊶ MeoLock® abutments are available in heights of 1–6 mm. After re-entry, either a one-piece, non-hex MeoLock® abutment ㉑ is inserted into the implant ① using the MeoLock® insertion tool with a torque of 30 Ncm; or a two-piece, hexed MeoLock® abutment ㉒ is affixed to the implant ① with retainment screw ㊶ and torqued with 30 Ncm. Impression cap ㉓ is snapped onto the MeoLock® abutment for the closed tray impression technique. After taking the impression, the dental technician places the MeoLock® abutment analog ㉔ into the impression cap ㉓ retained within the tray and pours the model. The cover denture/prosthesis is fabricated over the MeoLock® abutments ㉑ | ㉒ by polymerising the MeoLock® matrix ㉕ in their respective position. This can be done chairside or articulated in the lab. The retention (patrix) elements ㉘ are color-coded and available in various retention strengths. They can be replaced when necessary.

Ball Abutments:

The MeoMini® implant ㊼ is delivered pre-mounted (25 Ncm) with a H=1 mm ball abutment ㊹; there are two further ball abutments with a height of 2 and 3 mm and a cover screw available. The Meoplant® implants have their own ball abutments in a height range of 1-4 mm. The ball-part has a standardized Ø 2.25 mm. The ball abutment insertion/removal tool ㊷ is used to insert (torque)/remove all ball abutments. Ball abutments for MeoMini® are torqued with 25 Ncm; and 30 Ncm for all Meoplant® implants. Impressions are taken conventionally with a closed-tray directly over the ball abutment. After removing the impression tray, a ball abutment analog ㉘ is inserted into the tray and the master model is fabricated in the laboratory. There are two retention element possibilities: the O-ring ㉙ + ㉚ and the Preci-Clix ㉛ + ㉜; both housings are polymerized into the denture/prothesis and have interchangable retention elements.

MeoMini® Abutments:

There are two post abutments available for the MeoMini® implant ㊼. A one-piece solid abutment ㊽ and a calssical two-piece abutment ㊾ + ㊸; both of which are torqued with 25 Ncm using hex driver ㊵ | ㊶. Impressions are made with a closed tray directly over the abutments.

Bar Abutment System:

There are three bar abutments available for the laboratory fabrication of a bar. A gold bar abutment ⑱ which is castable/pourable. A plastic (POM) bar abutment ⑲ which is castable/burned out. A titanium bar abutment ⑳ which is laser-weldable. All abutments are affixed in the laboratory using the try-in screw ㊿. Once the final restoration is ready for installation, regardless of the abutment used, the definite fixation screw ㊶ is used and torqued with 30 Ncm.

Recommended Torque for Abutments / Secondary Components	
Meoplant® Straight and Angled/Angulated	30 Ncm
Meoplant® One-Piece Solid / Ball System / Bar System	
MeoLock® One-Piece and Two-Piece	
MeoMulti® Straight and Angled/Angulated	27 Ncm
Cementable Base	
MeoLock® Cap	
MeoMulti® Abutment (Secondary, Titanium)	
MeoMulti® Safety Cap	25 Ncm
MeoMini® One-Piece and Two-Piece / Ball Abutment	
PEEK & PEKK (High-Performance Thermoplastics)	15 Ncm
Impression Copings / POM Abutment (Plastic)	5-10 Ncm
Cover Screw	2-4 Ncm
Gingiva Former/Healing Cap	

Contraindications:

Components that are not part of the Meoplant® Medical dental implant system may not not be used, as this can cause damage.
Side effects and interactions: Allergic reactions to titanium are extremely rare, but cannot be excluded. This is particularly the case with various titanium (metal) alloys in constitution, hence occlusion within/between superstructures. This can aggregate galvanic reactions within the oral cavity, adversely impacting patient wellness. The dental practitioner/implantologist/referring dentist must ensure that complications such as these are precluded.

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Explanation of Symbols:

Use by:
Follow the instructions for use.
REF Order Number
Keep away from direct sunlight.
Keep away from moisture.
STERILE R Gamma sterilised
Temperature limits.
Do not use if packaging is damaged.
LOT Batch Number
Do not re-sterilise.
For one-time use only.

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