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DITRON DENTAL
Instructions for Use
for Dental Implants and Abutments

1. Intended Purpose:

Indications

DITRON DENTAL (hereinafter: 'Ditron') implants and abutments are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Dental implants are intended to be used in a manner to integrate the bone (osseointegration).

Patient Populations

Edentulous or partially edentulous adult patients' population (from 22 years of age) who require tooth replacement in dental rehabilitation and to whom none of the specified contraindications apply.

2. Products and materials

The IFU covers the components in this table:

Component	Sterilization	Biocompatible Materials	Use
Implant and Cover Screw	Sterile	Titanium Alloy	Single Use
Healing Cap	Non Sterile	Titanium Alloy	Single Use
Abutments / Temporary Abutment	Non Sterile	Titanium Alloy	Single Use
PEEK Temporary Abutment	Non Sterile	Ti + PEEK	Single Use
Casting Abutment – Titanium Base-Plastic Sleeve	Non Sterile	Titanium Alloy	Single Use
Casting Abutment – Cobalt Chrome Base and Plastic Sleeve	Non Sterile	CoCr	Single Use

The label on the single-use implant package is color-coded. Each implant is labeled to indicate size i.e, Implant Diameter and Implant Length. The implant size (diameter and length) labels are visible on both the exterior of the pages and the inner implant plastic tube.

3. Symbols - Glossary

Symbol	Description	Symbol	Description
REF	Catalog number	LOT	Batch code/number
MD	Medical Device	MR Conditional	MR Conditional
	Use-by date		Date of manufacture
	Do not reuse		Do not re-sterilize
STERILE R	Sterilized using irradiation		Do not use if package is damaged and consult instructions for use
NON STERILE	Non-sterile		Single sterile barrier system with protective packaging inside
CE	CE-Mark	EC REP	Authorized representative in the European Community / European Union
	Keep away from sunlight	RX only	Prescription Device
	Keep dry		Manufacturer
	Importer		distributor
	Consult instructions for use or consult electronic instructions for use		

4. Storage

The Implant system parts should be kept in their original package.
The sterile products should be stored in the sterilization package until required for use. During storage, make sure the packaging barrier is maintained. Before use, check the packaging for any opening or damages that might cause compromising of sterility.
The device must be stored and transported in clean and dry condition in the original packaging and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure. Store at room temperature. Note: 5 years shelf life was validated under temperature of 20°C-25°C at 60%±10RH.

5. Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy. Separation, re-cycling, or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

NOTE 1. This document applies to Ditron Dental's Implants and Abutments. Users are advised to consult packaged instructions for use and the technical support sections of our website for assistance.
NOTE 2. Inform Ditron and the competent authority (details below) in case of life threatening or any serious incident that has occurred in relation to the device.
NOTE 3. A summary of the safety and clinical performance (SSCP) for Ditron's implantable products will be available at Eudamed Database (under https://ec.europa.eu/tools/eudamed).

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DITRON DENTAL
Instructions for Use for Dental Implants

1. Description

Ditron's implants are screw shaped fixtures, meant to be used as substitutes for missing dental roots. The implants are made of biocompatible Titanium alloy grade 23 (Ti6Al4V ELI) per the ASTM F136 standard followed by surface treatment which is widely used for dental and medical purposes. Ditron's restorative components are similarly made of the same Titanium alloy. The product does not contain phthalates and endocrine disruptors.

2. Indications

Ditron's implants and abutments are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

• Two stage Internal Hex: MPI, ULT, API, CPI models to be used only with corresponding Ditron's Internal Hex abutments and Internal Hex tools and accessories.

• One stage: OPI model

The 3.3 and 3.0 mm diameter models for One stage OPI, Two stage MPI, and API implants are intended only for the incisors and cuspids of the maxilla and mandible. They are also indicated for denture stabilization using multiple implants.

Two stage and One stage implants for temporary or long-term use are self-tapping Titanium threaded screws indicated for long term intra bony applications. They permit immediate splint stability and long-term fixation of new or existing crowns, bridges and prosthesis and protection of graft sites.

MPI, ULT, API, CPI, and OPI are indicated for immediate loading (except for 6mm length implants) in single tooth restorations when good primary stability is achieved with appropriate occlusal loading.

The 30° multi-unit abutments must be used within 45° of parallelism for a splinted restoration. The 17° multi-unit abutments must be used within 32° of parallelism for a splinted restoration.

3. Contra Indications

Ditron's implants should not be placed in patients suffering from physiological, medical, and/or anatomic conditions (such as: uncontrolled diabetes, uncontrolled blood pressure, unstable respiratory diseases, patients who are exposed to radiation treatments, lactating or pregnant women, abnormal laboratory values for BUN, endocrine disruption, creatinine, CMR vulnerable or, serum calcium patients with diabetes, cardiovascular disease, hypertension above 110/170 mm Hg, osteoporotic crush fracture, respiratory disease, should be excluded as well as patients with diagnosed malignancy in the past five years and those with nodular enlargement, tenderness, or unexplained lump or masses of the head or neck. etc) that may negatively affect healing. Following current accepted knowledge and technology, dental implants should not be placed in patients with active osteolytic, inflammatory or infectious processes in the implanting site. Nor in patients suffering from bone disease, insufficient alveolar bone width and height surrounding the implant or who are using anti bone turnover medications, hypersensitivity or allergy to Titanium, Stainless Steel, Chrome-Cobalt or Polyetheretherketone (PEEK), Physiological, medical and anatomic conditions may negatively affect the implant performance.

ELECTROSURGERY & MR (Magnetic Resonance) ENVIRONMENT (Safety Information)
Dental implants are made of a metallic alloy; therefore, they are characterized by high conductivity. For this reason, electro-surgery is strictly contraindicated near dental implants. A patient with Ditron's dental implants and abutments can be scanned safely in an MR system under the following conditions:

Device Name	Dental Implants and Abutments (Dental Implant System)
Static Magnetic Field Strength (B0)	≤ 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

4. WARNING & PRECAUTIONS:

• CAUTION Rx only: US Federal law restricts this device for sale by or on the order of a dental professional. These devices are intended for use only by certified dentists and authorized personnel with specific implant training. Lack of adequate training may pose a major risk to the patient and may compromise the clinical success of the implant. Product availability may vary between countries according to regulations approvals.

• Single Use Products - In order to avoid contamination or product malfunction, DO NOT reuse and DO NOT re-sterilize implants or any other products marked with symbol. All products marked with symbol are intended for SINGLE USE ONLY!

• Implant failure, bone loss, nerve injury, damage to vital blood vessels and/or perforation of the maxillary sinus may occur as a result of lack of careful planning or inappropriate surgical procedure.

• Excessive load during placement or restoration may result in damage to implant, tools or components, and may even cause breakage of implant. Aggressive placement may result in damage to the bone lining the osteotomy or placement that is deeper than the pre-planned depth. Please note that maintenance of surgical instruments is crucial for a successful treatment.

• Do not use sterile parts if package is opened or damaged as sterility might be compromised.

• Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth. The implants are not intended for re-sterilization.

• Small diameter implants (Ø3.3mm, Ø3.5mm) and angled abutments (15°,17°, 25°, 30°) are not recommended for use in the posterior region (maxilla, and mandibular) of the mouth. Specific Indications Ø3.3mm implants must be used exclusively for: Single tooth replacement of the lateral incisors in the maxilla or single tooth replacement of the lateral and central incisors in the mandible.

•For short implants (6mm), clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes to implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length. If the implant shows mobility or bone loss greater than 50%, the implant should be evaluated for possible removal. If the clinicians choose a short implant, then clinicians should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible fixture. Allow longer periods for osseointegration and avoid immediate loading.

• The Ditron Implants must be used only in conjunction with the corresponding original components and instruments by Ditron Dental Ltd. Use with non-Ditron parts is not recommended and will void any warranty or other obligation of Ditron Dental Ltd.

5. Risks and Potential Adverse Events

The dental literature indicates that the following are potential adverse events related to the placement and restoration of dental implants: nerve injury, perforation of maxillary sinus, perforation of maxillary or mandibular bone, loss of integration, failure of implant, dehiscence, delayed healing, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, implant breakage or fracture of implant or components. Although some of these adverse events are incurable, many may require additional surgical procedure for their resolution. Implant placement procedure is a surgical procedure performed in the oral cavity, and as such, the patient is exposed to the risks associated with intraoral surgical procedures. Such as Allergic or hypersensitivity reactions to materials used, Patients must be informed of all potential risks and provide a conscious, written consent for the procedure.

6. Sterilization

Ditron's implants are supplied STERILE and are sterilized by gamma irradiation and validated method. All sterile products are sold and labelled "STERILE". All sterile products are a single use and are to be used before the expiration date printed on the product label. When removing the implant from the sterile packaging, the rules of asepsis must be observed. The sterile packaging must not be opened until immediately prior to insertion of the implant. Do not reuse, do not re-sterilize and do not use products if the packaging has been damaged or opened. Previously used or opened implants should be discarded and not be reused under any circumstances. due to risk of contamination. It is recommended to have a replacement implant on hand.

7. Treatment Planning

Comprehensive clinical and radio graphical evaluations of each case and a full diagnosis are mandatory prior to treatment planning.
If the treatment plan aims to utilize dental implants, the following factors should be considered: patient's medical and psychological condition, bone quality and quantity, esthetics and available soft tissues, quality of oral hygiene, smoking, habits (such as Bruxism, clenching). Special care should be given to the identification of vital anatomical landmarks such as the mandibular canal, maxillary sinuses and adjacent teeth.

8. Change in Performance

It is the obligation of the surgeon and the restorative dentist to inform patients of all potential risks, contraindications and adverse events related to the surgical placement of dental implants and their restoration. If needed, it is the responsibility of the surgeon or restorative dentist to seek advice and help from trained dental professionals in case of inability to resolve a problem.

9. Loading Protocols

Immediate loading protocols and delayed loading protocols are conventional loading protocols established in the dental literature. However, in order to maximize success and minimize risk for implants, it is advisable to consider the following guidelines:

9.1 Initial stability is found to be the primary factor for implant success.
9.2 Splinting implants may be advisable, whenever possible, in immediate loading cases.
9.3 Wide diameter implants may bear loads better than small diameter ones.
9.4 Occlusal forces including transverse loading forces should be controlled carefully to prevent excessive forces.
9.5 In case of doubt, consult the Ditron Surgical Manual.

10. Breakage

Fractures may occur due to excessive loads, excessive transverse loading forces or forces transferred to the implant or abutment. Such forces may be a result of (but not only) the following: inappropriate number of implants, inappropriate implant length and/or diameter, inappropriate cantilever lengths, habits and para function, a restoration that does not present a "passive fit" to the abutments, acute angle of implant (greater than 25°), occlusal instability and trauma.

11. Product Packaging

Implants are cleaned and packed in a double vial package. Packaging takes place in a clean room using bacterial barrier materials in order to maintain sterility. Sterilization is achieved using validated methods and protocols. Implants should be connected to the insertion tool (hand-key or motor-key), which enables easy transfer of the implant from the vial to the osteotomy, and then removed from the implant. All implants are supplied with labels specifying implants' data, lot number, expiration date and additional relevant data. This information should be kept in patients' records for future reference. Sterile Package includes: 1 dental implant, 1 cover screw, SHELF LIFE: 5 Years, year and month of expiration is indicated by the hourglass symbol on the product label. Do not use the product after the labeled expiry date and/or if the bacterial barrier package is opened or damaged! Note: 5 years shelf life was validated under temperature of 20° - 25°C at 60%±10RH.

12. Insertion Procedure

STEP 1 - Prepare the case thoroughly: Analyze the patient's medical and dental conditions, arrange a complete prosthetic and surgical treatment plan, including the number and locations of the planned implants. Plan the length and diameter of implants to be used per location based on clinical assessment and necessary radiographs (including CT scans, when required).

STEP 2 - Record the data of each implant placed: Locate the label in the implant's packaging and record the lot number and product description in the patient's chart. Arrange a complete prosthetic and surgical treatment plan, including the number and locations of the planned implants. Plan the length and diameter of implants to be used per location, based on clinical assessment and necessary radiographs (including CT scans, when required).

STEP 3 - Preparation of the osteotomy: Gradually create the suitable osteotomy/osteotomies in respect to the implant length and diameter. It is recommended that the implant surgeon be thoroughly familiar with the specific measurement and provide a suitable safety margin adjacent to any teeth and vital structures. Failure to recognize the difference between the actual length of the drill and radiographic measurements can result in permanent injury to the nerves or other vital structures by drilling beyond the depth intended, potentially resulting in permanent numbness to the lower lip and chin or other injuries.

STEP 4 - Handling of the implant package: The implant and cover screw are sealed inside a vial (tube). Sterility is assured unless the vial is damaged or opened. All Ditron's products should be received in intact packages. Damaged packages or products should not be used and should be discarded. Labeling information is located on the outer surface of the vial and on the outer cardboard box.

STEP 5 - Seating implant into osteotomy: Carry the implant to the appropriate site by the implant insertion tool and insert the implant into the prepared osteotomy. Screw the implant into place by using the torque wrench attached to the implant insertion tool. Do not use a high torque or high speed when inserting the implant (do not exceed 15 rpm) Torque should not exceed 35Ncm.

13. Healing Phase

According to traditional protocols, implants are allowed to heal a minimum of three (mandible) to six (maxilla) months before prosthetic loading, depending upon placement site and quality of bone. However, more recent protocols allow implant loading after a period of 2-3 months in both jaws. In addition, immediate loading protocols may also be used when indicated. When implants are placed in conjunction to bone augmentation procedures, a longer healing time may be required. In any case, and because of the rapid changes in acceptable surgical protocols, the dentist who places or restores the implants should be updated in current relevant literature. Protocol recommendations offered by Ditron should not supersede the clinical knowledge, experience, and judgment of the clinician.

DITRON DENTAL
Instructions for Use for Abutments and Prosthetic Non-Sterile Components

1. Training

Implant restoration involves complex procedures and should be performed by dental professionals who have received implantology training in proper techniques. Inadequate training may result in failure of the restoration and further complications.

2. Packaging

All abutments and prosthetic parts are cleaned and packaged in a clean environment and are supplied Non-Sterile unless they are explicitly marked as Sterile. Sterilization is required for all prosthetic components prior to being used Intraorally.

3. Non-Sterile Prosthetic Components

Prosthetic components are provided cleaned but Non-Sterile therefore must be sterilized prior to use. **WARNING:** The Non-Sterile prosthetic parts are labelled as Non-Sterile and are intended for Single use only after sterilization! Therefore, in order to avoid any part's malfunction or adverse reaction, DO NOT attempt to reuse. Note: Only one sterilization process is allowed for non-sterile provided parts. DO NOT attempt to re-sterilize. It is recommended that Steam Sterilization will be performed in accordance to the following instructions:

4. Steam Sterilization Instruction

• General instructions: These sterilization instructions are applicable to DITRON DENTAL Non-Sterile Prosthetic components that are provided and labelled as 'Non-Sterile'. No sterilization before use is required for products that are labelled as 'STERILE'. In the US, FDA-Cleared sterilization accessories are to be used for the recommended sterilization parameters.

• Packaging before steam sterilization: Place the product before sterilization in a standard polyethylene/Tyvec (or equivalent) sterilization pouch, compatible with steam sterilization process. Sets of instruments may be loaded into dedicated instrument trays or general purpose trays for steam sterilization.

• The following steam sterilization process is recommended: Follow the autoclave manufacturer's instructions to sterilize the products. In particular, care must be taken **not to exceed** the maximum recommended load for the autoclave.

Sterilization in an autoclave without a pre-vacuum cycle (gravity displacement type) should be performed for a holding time of ten (10) minutes at a temperature of 135°C (275°F). Holding time of at least six (6) minutes at a temperature of at least 134°C (273°F) is also applicable if your sterilizer can be programmed accordingly. The holding time is the minimum time for which the minimum temperature is sustained. Allow drying time of 30 minutes if products are sterilized wrapped. If devices are sterilized unwrapped, the sterilized devices are for immediate use. Do not store after sterilization. NOTE: Local infection control practice may recommend a different combination of holding time and temperature.

5. Insertion Procedures for Abutments

5.1 Patient Information: Peel off removable label from the package container and place the label in the patient's chart.
5.2 Remove Abutments from Packaging:
5.3 Proceed with sterilization instructions as detailed in item above.
5.4 Insertion of Abutments: Abutments are initially seated using a Ø1.25mm Hex Tool in conjunction with either a fixation screw (straight, and angled abutments) or by accessing the hex portion of the abutment top (over denture and ball abutments). To ensure fixation between mating components abutments should then be fastened to the abutment with the provided screw using a recommended torque value as per the table below:

Prosthetic	Torque Value (Ncm)
Healing Cap	15
PEEK Abutment	15
Multi-Unit Abutments to implant	30
Multi-Unit Screw	15
Multi-Unit Healing Cap	15
Locator / Liberator	30
Ball Abutment	30
Cemented abutment (straight & angulated)	30

5.5 The Healing Cap for Multi-unit abutments should only be tightened using prosthetic Keys 1.25mm. Do not exceed a tightening torque value of 15 Ncm.
5.6 For multi-unit loaded restoration, abutment models with post-height of less than 4mm above the shoulder may be used.
5.7 For users in the US only: Single-unit loaded restoration, abutment models with post-height of less than 4mm (screw retained abutment), should NOT be used unless used in combination with extending prosthetic allowing at-least 4mm. Consult Ditron's accompanied surgical manual.
5.8 Small diameter implants (Ø3.3mm, Ø3.5mm) and angled abutments (15°,17°, 25°, 30°) are not recommended for use in the posterior region (maxilla, and mandibular) of the mouth. Implants with OD smaller than Ø3.75mm should always be used with abutments angulation below 25°.
5.9 **Implants with length of 6mm should always be used with straight abutments only.**
5.10 Do not perform additional angular corrections to Multi-Unit and Liberator Abutments labelled as post-height of less than 4mm.
5.11 For users in the US only: Do not perform additional angular corrections to the Milled Abutment models.
5.12 For users in the US only: No CAD/CAM design and fabrication is allowed for the Milled Abutment models. Only hand-milling or casting may be used for abutment modification.

6. Post-Restorative Care

It is recommended that patients use a suitable mouth rinse for the first 7 to 10 days following implant restoration. Subsequently, patients should perform regular oral hygiene and maintain regular dental prophylaxis.