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DITRON DENTAL
Instructions for Use for Dental Instruments Class I

1. Product Description:

This user instructions are only applicable for the products specified below:

Instrument	Material	Number of Uses Cleaning Procedure
Insertion Drivers – allow Implant pick up and insertion	SS420 or Titanium	20 uses. Clean and sterilize per section 10
Tool Extractor – used to extract guided mount		
Guided Insertion Mounts - Implant pick up and insertion		
Guided Sleeves – allow a Guided Surgery Insertion path	Titanium	Single-use - Clean and sterilize per section 10
Guided Anchoring Screw – allow the fixation of the guided template	SS420 or Titanium	
Guided Lateral Fixation Pin - – allow the fixation of the guided template	Titanium	
Overdenture Processing Components – allow the connection of overdenture to liberator or ball abutment	SS316, silicon, Ti6Al4V, Polyethylene and NYLON	Single-use –Clean and disinfect per section 9
Casting Abutments – used to cast individual abutments	PMMA (Poly Methyl Methacrylate)	Single-use – cleaning not applicable
Impression Coping Analog – Implant replicas of dental implant fixtures	SS420 or SS316 or Titanium	
Prosthetic Screwdrivers – allow connection of abutment mating part.	SS420 or Titanium	Dispose after the instrument loses its functionality. Clean and sterilize per section 10
Depth Guides and Probe – used to assess osteotomy depth and angulation		
Wrench /Ratchet – used to transfer torque to driver, mounts, or screwdrivers.	SS420 or SS316 or SS304	
Lab Accessories Handle – allow controlled sleeve placement		
Lab Insertion/Extraction Tool – used to assist with Overdenture Processing Components		
Impression Coping – Transfer – impression-taking instrument	SS420 or Titanium and PEEK	Single-use - Clean and sterilize per section 10

* For Multi-loc refer to IFU ID#DD118 recent Version

* For Ratchet torque - refer to Ditron Dental IFU ID# DD124 recent version

2. Intended use:

Ditron Dental Instruments are intended to be used for:

- Dental implant placement procedures in the bone of the upper or lower jaw arches,
- Dental implant placement via a template, allowing for the insertion on the dental implant/s in a controlled way.
- Additionally, Ditron instruments are intended to be used for impression coping in a standard or digital form
- Ditron Instruments are intended for prosthetic restorations procedures.

3. Intended clinical benefits:

The correct use of Dental Instruments allows for the insertion of the dental implant/s in a controlled and stable way. Additional Dental Instruments are used during the prosthetic restoration procedures.

4. Target population:

4.1. Patient population: Edentulous or partially edentulous adult patients' population who require tooth replacement in dental rehabilitation and to whom none of the specified contraindications apply.

4.2. Intended users: Ditron Dental Instruments are to be used only by a licensed dentist (DMD/DDS) who has the specialization, skills and appropriate training in dental implants and restoration in order to assure successful treatment. Rx Only. Federal law restricts this device for sale by or on the order of a dentist or a licensed practitioner

5. Indication:

DITRON DENTAL Tools and accessories (hereinafter: 'Instruments') are indicated for use in restorative applications for implant 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. using a template in dental rehabilitation and to whom none of the specified contraindications apply.

6. Contraindications:

Ditron Dental Instruments should not be used in patients suffering from: physiological, medical and/ or anatomic conditions (such as: cleft of the alveolus and palate, uncontrolled diabetes, uncontrolled blood pressure, unstable respiratory diseases, patients who are exposed to radiation treatments and patient with bleeding disorders, Patient on anticoagulation, immune-suppression, bleeding issues, active treatment of malignancy, drug abuse, psychiatric illness, intravenous bisphosphonate use, recent myocardial infarction and cerebrovascular accident, valvular prosthesis surgery etc. that may negatively affect healing. Following current accepted knowledge and technology, Dental Instruments should not be used in patients suffering from bone disease, insufficient alveolar bone width and height surrounding the implant site or who are using anti bone turnover medications, hypersensitivity or allergy to : Titanium, Stainless Steel, silicon, peek, plastics and Nylon. Physiological, medical, and anatomic conditions may negatively affect the implant placement procedure and implant performances. These devices are intended for use only by certified dentists and authorized personnel with specific implant training. **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. Product availability may vary between countries according to regulations approvals.

7. Warning & Precautions:

- Ditron Dental's Instrument are to be used only by licensed dentists and authorized personnel, who has the specialization, skills and appropriate training in dental implants and restoration in order to assure successful treatment. Lack of adequate training of the practitioner is a major risk factor for the success of the implant procedure and may endanger patient health.
- Failure to plan and prepare implant and/or fixation site position and depth correctly can result in harm to nerves, blood vessels, teeth, or other sensitive structures. Incorrect instrument settings or excessive installation torque can result in failed implant or fracture of the jawbone.
- Before using the product, it is advisable to tie a safety thread (e.g.: dental floss) to the instrument in order to avoid the risk of the patient swallowing or inhaling it.
- Always wear Gloves when handling contaminated Instruments. Eye protection must be worn to protect against ejected particles. A surgical mask must be worn to avoid inhalation of aerosol or dust generated.
- Inspect the Instruments for damage or wear before each use and discard/return to manufacturer defective Instruments.
- Before using the product, make sure the selected instrument is correlated to the implant connection platform i.e. Hex Connection or Conical Connection.
- The products are provided non-sterile. Clean and sterilize the Instruments in accordance with the directions below before first use and before each reuse, in order to avoid contamination. Use of non-sterile components may lead to infection of tissues or infectious diseases.
- If the sterile packaging of products (after being sterilized by the user) is damaged, the products should not be used and must undergo another repreparation according to these specific instructions
- Over time, repeat sterilizations may affect Instruments' efficiency and color appearance. Functional edges should present a continuous edge and appear sharp. If inspection reveals signs of wear, damage, or unrecognizable color identification, replace immediately.
- Instruments should be replaced after a specified number of uses per the Product Description table. Blunt or damaged Instruments must be replaced immediately. Inspect the Instrument for damage or wear before each use and discard/return to manufacturer defective Instrument/s.
- Worn Instruments must be disposed /discarded according to local environmental authority regulations (be aware of physical hazards -due to sharp edges).
- Ensure that the tool is fully seated and gripped before use.
- Avoid contact when cleaning, disinfecting and sterilizing Instruments from different materials Use only specifically formulated for dental cleaning and disinfectant agents.
- Clean disinfect and sterilize the Instruments in accordance with the directions below before first use and before each reuse.

8. 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 the maxillary sinus, perforation of maxillary or mandibular bone, loss of integration, failure of the 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 procedures for their resolution. The implant placement procedure is 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

9. Cleaning instructions for Overdenture Processing Components

Male retention caps, silicon ring for processing, metal housing, are delivered non-sterile and must be disinfected prior to use.

Disinfection

- Immerse the components completely, eliminating air pockets, in a high-level neutral/mild pH disinfectant according to the instructions for use, such as CIDEX OPA (Johnson & Johnson) solution for a minimum of 12 minutes at 20°C or higher, to destroy all pathogenic microorganisms.
- Remove the component from the disinfectant solution.
- Rinse it thoroughly with highly purified sterile water.
- A final rinse using a 70% alcohol solution may be used to speed the drying process.
- Air-dry completely and immediately use or seal in a clean pouch to minimize recontamination.

10. Cleaning and sterilization instructions for reusable Instruments:

Correct and careful maintenance of Ditron Dental Instruments is extremely important. Cleaning per the Product Description table to the left. Cleaning can be done manually or by using automated washer unit.

10.1. **Manual cleaning**:

- Never let residues (blood, debris) dry on Instrument, clean immediately after procedure.
- Prepare a neutral/mild pH enzymatic detergent (Deconex® POWER ZYME concentration of 5ml/l or equivalent) according to manufacturer's instructions.
- Rinse the instrument under running lukewarm tap water for one (1) minute.
- Immediately soak in a detergent solution for ten (10) minutes.
- Use soft-bristled, nylon brush to gently scrub the instrument during detergent soaking to remove any remaining blood or debris for one (1) minute. While brushing, particular attention should be made to the grooves in the reachable exterior surfaces.
- Rinse the instrument under running tap water for (2) minutes.
- Fully dry on a clean cloth before sterilization. Prevent contact between Instruments.

10.2. **Automatic cleaning (Using automated washer unit):**

- Never let l residues (blood, debris) dry on an instrument, clean immediately after procedure:
- pH Neutral Enzymatic detergent will be prepared according to manufacturer's instructions, at the lowest recommended concentrations and lowest recommended temperature.
- (Note: Deconex Power Zyme detergent manufacturer indicate recommended working
- temperature of 45-55° C for 10 min).
- Place the instrument in the automatic washer
- Run the automatic wash cycle – short cycle parameters:
  - 2 min cold prewash at 30 ±5°C with tap water
  - 10 min main wash with neutral pH detergent and tap water at 45 ±5°C
  - 10 min rinse 70°C (tap water)
  - 20 min. air drying phase at high temperature of 100°C
  - Place the Instruments on a clean cloth to dry for a least 10 minutes

10.3. **Sterilization:**

- Wrap the instrument for sterilization with approved microbial barrier wraps (FDA Clearance in the US and CE Mark in EU
- Sterilize the Instruments by steam according to the autoclave's instructions.
- 134°C/275°F for up to a maximum 6 minutes followed by a 30 minutes dry cycle. Distilled water should be used in order to avoid surface stains. Make sure before use that the elements, inside the autoclave, are not rusted.
- Chemiclave is NOT recommended.
- The sterilized devices are for immediate use. Do not store after sterilization.
- Inspect the parts after each preparatory treatment/cycle (cleaning, sterilization) to ensure proper functionality and safety. If you suspect a problem, do not use the instrument.

11. Storage and Disposal:

Storage: The Instruments 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. **Disposal:** Worn Instruments must be disposed /discarded according to local environmental authority regulations (be aware of physical hazards due to sharp edges).

12. Symbols: interpretation: Symbols on the product package should be interpreted as follows:

Symbol	Description	Symbol	Description
MD	Medical Device	RX only	Prescription device (US only)
REF	Catalogue number		
LOT	Lot number/Batch number	NON STERILE	Non-sterile
	Use-by date		Keep dry
	Date of manufacture		Keep away from sunlight
	Manufacturer	CE	CE-Mark
	Consult instructions for use or consult electronic instructions for use	EC REP	Authorized representative in the European Community / European Union

NOTE 1. This document applies to Ditron Dental's Instruments. 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.

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