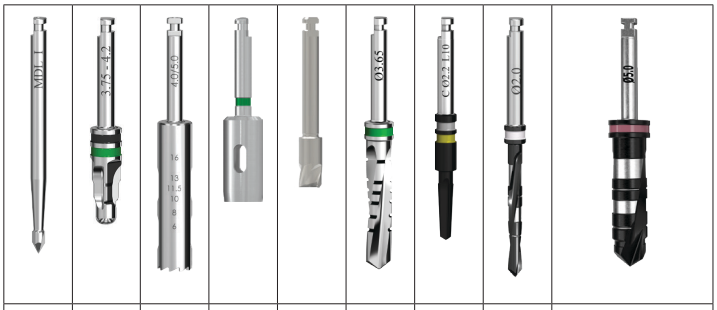
EN

DITRON DENTAL
Instructions for Use
for Dental Implant Drills

1. Product Description and variations - The drill variations are as follows:



Marking Drill	Countersink Drill	Trephine Bur	Tissue Punch	(Bone) Mill Drill	Twist Drill	Coated Twist Drill	Coated Step Drill	(Integral) Stopper Twist Drill standard and coated Guided Step Drill

Dental Drills	
(Bone) Mill Drill	To flatten the alveolar ridge prior to drilling, A flat surface allows for a more controlled use of the marking and pilot drills.
Marking Drill	Marking drills: use marking drill in order to create a reference point to mark the location for further drilling.
Pilot Drill	Use a pilot drill to allow visualization of the actual implant position at the beginning of the drilling procedure.
(Integral) Stopper Twist Drill standard and coated	Drills that have a built stopper (an integral part of the Drill and cannot be removed). These drills prevent over drilling as they block the drill from exceeding the stated drill length.
Guided Step Drill	Similarly, to the stopper twist drills the guided drills are used to drill the osteotomy through a guiding sleeve. The drill shank allows a controlled drill angle and depth as the drill stops on top of the sleeve. available in stainless steel or carbon coated.
Countersink Drill	Countersink drills can be used upon completion of the drilling procedure according to the dentist's decision. The countersink drill can be used in all bone types. In cases of soft bone (bone type 3 & 4) the countersink drill may be used instead of the last drill in the drilling procedure to enlarge the crestal area of the implant site, in order to minimize the excessive pressure on the crestal bone.
Drill Extender	For use, attach the handpiece and the dental drill to the drill extender.
Trephine Bur	Use a trephine bur in cases when an implant has to be removed and is difficult to pull out. Drill around the implant in order to facilitate its removal.
Tissue Punch	Place the Tissue punch on the gingiva and press gently. Turn the tool either manually or by motor (max 25 RPM). Manually remove punched gingiva.
Twist Drill – standard and coated	Attach the drill to the handpiece and set the drilling mode and the drilling speed according to the drilling procedure. Position the drill on the drilling site; make sure that the drill rotates clockwise, while activating a light pressure in the drilling direction. Proceed and extract the drill from the cavity allowing the extraction of debris from the drilling site. Repeat the described procedure until reaching the desired drilling depth or width (using depth marks visual indication). Coated drills are covered with DLC coating (which confers to black color to the drill). This coating is used to increase the cutting ability and decrease the friction coefficient with the bone.
Step Drill - standard and coated	
Surgical Kit Boxes are intended to organize and contain the dental drills during use	
Stopper Drill Full Kit	DISKit Contains: Marking drill and (Integral) stopper twist drill standard and coated in DISKit-C.
Stopper Drill Tube	D-Tube Contains: Marking drill and (Integral) stopper twist drill standard and coated in DC-Tube.
Full Surgical Kit	Contains: Marking drill, Countersink, Drill Extender, and twist drill in FSBOX-001 and Coated drills in FSBOX-001C.
Surgical Tube	Contains: Marking drill and twist drill MMBOX -003 and Coated drills in MMBOX-003C.
Mini Surgical Kit	Contains: Marking drill, Countersink, Drill Extender, and twist drill in MSBOX002 and Coated drills in MSBOX002C.

* Each variation may be provided separately or integrated in a kit according to user preference.

2. Color Coding: The drills have been marked with sizes and color coded for ease of identification

White : Ø2.0	Blue : Ø3.2	Purple : Ø5.0
Yellow : Ø2.5	Green : Ø3.8	Brown : Ø5.2
Red : Ø2.8	Black : Ø4.5	
White/Brown : Ø5.0X6.0	Black/Green : Ø3.75X4.2	

3. Indications

Dental drills intended purpose is to prepare the implant bedding in both the maxilla and mandibula, according to a predefined drilling sequence. Implant shape and bone quality are the main factors determining the drilling sequence.

Auxiliary drills might be used during the preparation according to the user's discretion: marking/ crestal drills for marking the drilling location, burs for ridge alignment, countersink drill for cortical layer preparation, trephine drills in cases when implant removal is necessary and milling drill for ridge alignment prior to drill sequence.

4. Contraindications

Ditron Dental drills 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 Drills should not be used in patients suffering from bone disease, insufficient alveolar bone width and height surrounding the drill site or who are using anti bone turnover medications, hypersensitivity or allergy to Titanium, Stainless Steel, Physiological, medical, and anatomic conditions may negatively affect the drill procedure and implant performances. These devices are intended for use only by certified dentists and authorized personnel with specific implant training.

5. General Precautions

Before using Ditron Dental products, the operating surgeon/practitioner in charge should carefully study the 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.) and fully comply with them. Ditron products are not liable for complications, other negative effects, or damages that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the Drills, asepsis, and so on. The operating surgeon is responsible for any such complications or other consequences.

6. General Information

All drills must be cleaned and sterilized prior to use. The drills have been marked with sizes and color coded for ease of identification. Size marking and color coding should be used to select the proper drill for each surgical procedure.

Implant Drills are susceptible to damage and wear and should be inspected before use.

The number of uses per drill will vary and depend on a variety of factors including bone density encountered, proper handling, and cleaning. Over time, repeat sterilizations may affect cutting efficiency and color appearance. Cutting edges should present a continuous edge and appear sharp. Check the latch lock shank for wear to ensure the connection is not damaged. If the inspection reveals signs of wear, damage, or unrecognizable color identification, replace the drill accordingly. We advise 10 uses at the maximum.

7. Intended Purpose / Intended Use

Ditron Dental's Implant Drills are intended for use in the dental implant surgery application preparing the jawbone for a dental implant. The Implant Drill Accessories assist the Implant Drill in its use.

8. Target Population

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

8.2. **Intended Users:** Ditron Implant Drills are to be used only by a licensed dentist (DMD/ DDS) who is licensed and qualified to perform dental implantation procedures. Rx Only. Federal law restricts this device for sale by or on the order of a dentist or a licensed practitioner.

9. Intended clinical benefits

The use of Dental Drills is considered to be beneficial for dental implantation procedure: For those patients, who needs to prevent further tooth loss, or at those patients, who looks for tooth restoration and improvement of esthetics (for any reason).

10. Undesirable Side Effects and risks

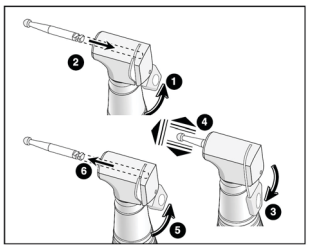
Events which may occur during the surgical procedure (disregarding their probability and severity): local anesthetic complications, bleeding including uncontrolled perforation of the nasal and maxillary sinus, perforation of soft tissue spaces, nerve injuries, perforation of bone plates, perforation of adjacent teeth, difficulties with stabilization of the implant in its osteotomy, components in the patient's mouth may be swallowed or aspirated, immediate implant dislocation in the maxillary sinus, perforation of the maxillary sinus, mandibular base, lingual plate and the inferior alveolar canal, immediate fracture of the jaw bone.

11. Caution and Warnings

- Lack of adequate training of the practitioner is a major risk factor for the success of the implant procedure and may endanger patient health. Therefore, no implantation shall be performed without prior adequate training by a certified institute.
- Failure to plan and prepare implant site position and drill depth correctly can result in harm to nerves, blood vessels, teeth or other sensitive structures.
- Allergy or hypersensitivity to chemical ingredients of material used. Patient's health history must be carefully assessed.
- Always wear Gloves when handling contaminated drills.

- Eye protection must be worn to protect against ejected particles.
- A surgical mask must be worn to avoid inhalation of aerosol or dust generated.
- Do not use if the Ditron package has been damaged or opened. Inspect the drill for damage or wear before each use and immediately discard/ return to Ditron Blunt, damaged or defective drills. Particular attention should be paid to design features such as channels, blind holes, threads, undercuts, and mating surfaces. Cutting instruments and drills should be replaced after 10 cycles of use.
- Ensure that the drill is fully seated and gripped in the handpiece collet before use.
- Maintain the handpiece in good working order and correctly lubricated.
- Do not exceed the maximum speeds indicated in this leaflet.
- Avoid excessive drilling speed and/or drilling duration in order to avoid overheating and associated complications.
- Move the drill continuously when in use to avoid localized heating.
- The products are provided non-sterile. Clean and sterilize the drills in accordance with the directions below before first use and before each reuse, in order to avoid contamination. The use of non-sterile components may lead to infection of tissues or infectious diseases.
- Check the coolant flow at the drilling tip of the instrument frequently, before and during the drilling. Make sure that drills and milling tools are adequately cooled during preparation.
- Drilling should be intermittent, under moderate pressure. Waiting for the bone to cool, and use of pilot drills in successively increasing sizes is essential. Do not attempt to reach the target depth in a single drilling step.
- A maximum speed of 1500 rpm must not be exceeded at any step of the preparation. Higher drilling speeds and/or improper external cooling may cause local overheating of the bone, resulting in bone necrosis. These undesired consequences will jeopardize the osseointegration process and proper healing of peri-implant bone.
- All drills are operated in a clockwise direction, unless explicitly stated otherwise.
- Remove bone chips from the drill tip before every drilling step.

12. Connection To Handpiece and Disconnection from Dental Drill



12.1 Open the latch.

12.2 Insert the dental drill up to the limit stop and turn until it engages.

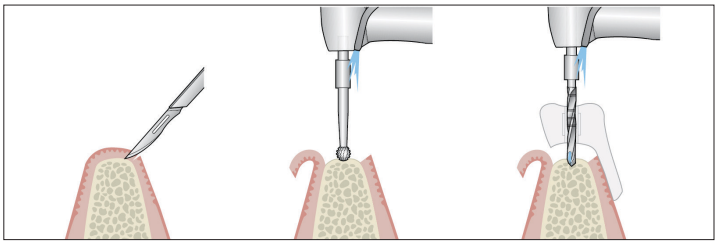
12.3 Close the latch.

12.4 Check the dental drill in held securely pulling on it in an axial direction.

12.5 Open the latch.

12.6 Remove dental drill.

13. Implant Bed Preparation



13.1. **Alveolar Ridge Preparation**

- Use a large, sterile, externally irrigated bone mill drill bur to prepare the alveolar ridge for implantation.
- A narrow, tapering ridge should be reduced and smoothened with the bur – providing a wide and flat bone surface suitable for implantation.

  IMPORTANT WARNING: Take into account the amount of vertical reduction when choosing the proper implant length and adjust accordingly.

13.2. **Implantation Site Marking and Pilot Drilling**

- Mark the implantation site determined during the treatment planning with the marking drill.
- Widen and correct the position of the mark with a round bur, if necessary.
- With the pilot drill, mark the implant axis by drilling to a depth of about 6 mm (according to depth marks on the drill itself).
- Insert the parallel pin to check for correct implant axis orientation.
- Pre-drill the bed to the final preparation depth with the pilot drill. Minor corrections of the implant axis, if necessary, are made at this step.

14. Cleaning and Sterilization Instructions

Correct and careful maintenance of Ditron Implants Drills is extremely important. Cleaning can be done manually or by using an automated washer unit.

14.1. **Manual Cleaning:**

- Soak the drills in a mild, pH-neutral (Action 201 or equivalent) detergent according to manufacturer's instructions for 2.5 minutes or until cleaning can be performed. Avoid contact with phenol alcohol, chlorine, acid, or quaternary Ammonia.
- Rinse the drills under a hard stream of water. Avoid water with high concentration of chlorine. Warning: Use sterile water (from a sterile labeled container/bag), unless the potable water is of low contamination and meets all applicable local laws and regulations.
- Flush the drill flutes/channel with a hypodermic needle.
- Use a soft nylon brush to rid the drill of additional debris caught in the dental drill flutes/channel.
- Never clean drills or surgical kits with metal brushes or steel wool. This can cause corrosion, deposition of metal particles, oxidation etc.

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

- Flush the drill lumen with a hypodermic needle.
- Use a soft nylon brush to rid the drill of additional debris caught in the dental drill flutes/channel.
- Never clean drills or surgical kit with metal brushes or steel wool. This can cause corrosion, deposition of metal particles, oxidation, etc.
- Run the automatic wash cycle using neutral pH enzymatic detergent according to manufacturer's instructions (such as Deconex Powerzyme or equivalent).

  Per minimum/maximum cycle parameters:

  » 4 min cold prewash at 30 ±5°C

  » 10 min cleaning wash at 55 ±5°C

  » 1 min rinse at 30 ±5°C (tap water)

  » 10 min rinse at 30 ±5°C (distilled water)

  Note: At the end of the cleaning process, only distilled water should be used, in order to avoid surface stains or corrosion. Warning: Use sterile water (from a sterile labeled container/bag), unless the potable water is of low contamination and meets all applicable local laws and regulations.

14.3 **Sterilization:**

- Wrap the drill for sterilization with approved microbial barrier wraps (FDA Clearance in the US and CE Mark in EU
- Sterilize the drills 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. After sterilization, the products need to be transported to the point of use stored in sterilization wrapping, kept dry and not exposed to direct sunlight.
- 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 drills.

15. Storage

The device must be stored and transported in clean and dry condition in the original packaging and not exposed to direct sunlight. Store at room temperature. The user must avoid all effects that could affect the product marking or shelf-life of the drills, the drill surface, or the drill geometry such as unnecessary motion, strains, heat, UV radiation, moisture, etc.

16. Disposal

Disposed reusable surgical instruments should be handled as potentially contaminated products unless conclusive evidence exists to the contrary. Disposed surgical instruments and packaging must be disposed/discarded according to local environmental authority regulations (be aware of physical hazards due to sharp edges).

17. Symbols Interpretation

Symbols on the product package should be interpreted as follows:

Symbol	Description	Symbol	Description
MD	Medical Device	RX only	Prescription device
REF	Catalog number		Do not use if package is damaged or opened
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

DISCLAIMER OF LIABILITY

The users of Ditron Dental products must determine whether or not a particular product is suitable for a particular application and circumstance. Ditron Dental disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages arising out of or in conjunction with any errors in professional judgment or practice in the use of Ditron Dental products. The devices are intended for use only by certified dentists and authorized personnel with specific implant training. Users are advised and obliged to study the latest news and developments in implant dentistry for any updates to products and/or specifications. Ditron Dental has no control over the use of its products, which are the responsibility of the user. Ditron Dental will assume no liability whatsoever for damage arising thereof.

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