INSTRUCCTIONS FOR USE

DRILLS AND TAPS

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1. Product:

Drills and taps.
The two terms are distinguished because it is the nomenclature used by the intended user.
It is considered a generic group of products because both (drills and taps) are the same type of devices, dental instruments with the same intended use, the same principles of operation, the same patient populations, the same intended user, the same parts of the body /tissues contacted by the device, the same duration of use or contact with the body, the same contraindications.

Types:

Instruments to use with the MPI Privilege® implant system:		
Drills		
Reference	Laser depth marks (mm)	Speed (rpm)
DPEC210	7, 8.5, 10 , 11.5	900-1200
DPEC215	7, 8.5, 10 , 11.5, 13, 15	900-1200
DPEC220	7, 8.5, 10 , 11.5, 13, 15, 7.5, 20	900-1200
DPEC2710	7, 8.5, 10 , 11.5	500-700
DPEC2715	7, 8.5, 10 , 11.5, 13, 15	500-700
DPEC2720	7, 8.5, 10 , 11.5, 13, 15, 7.5, 20	500-700
DPEC310	7, 8.5, 10 , 11.5	400-700
DPEC315	7, 8.5, 10 , 11.5, 13, 15	400-700
DPEC320	7, 8.5, 10 , 11.5, 13, 15, 7.5, 20	400-700
DPEC32610	7, 8.5, 10 , 11.5	400-700
DPEC32615	7, 8.5, 10 , 11.5, 13, 15	400-700
DPEC32620	7, 8.5, 10 , 11.5, 13, 15, 7.5, 20	400-700
DPEC42610	7, 8.5, 10 , 11.5	400-600
DPEC42615	7, 8.5, 10 , 11.5, 13, 15	400-600
DPEC42620	7, 8.5, 10 , 11.5, 13, 15, 7.5, 20	400-600
PD2310	7, 10	800
PD3410	7, 10	800
CS24510	4.35, 5.35, 6.35, 7.35	200-400
LD3317	No depth marks	1200
LD3310	No depth marks	1200
Taps		
TAP3	7, 8.5, 10 , 11.5	25
TAP4	7, 8.5, 10 , 11.5	25
TAP5	7, 8.5, 10 , 11.5	25

Instruments to use with the MPI Excellence® and MPI All-In® implant systems:		
Drills		
Reference	Laser depth marks (mm)	Speed (rpm)
LD3310 DLC	No depth marks	1200
CD 3	7, 8.5, 10 , 11.5, 13, 15	800-1200
CD 37	7, 8.5, 10 , 11.5, 13, 15	800-1200
CD 4	7, 8.5, 10 , 11.5, 13, 15	800-1200

Instruments to use with the MPI Excellence® and MPI All-In® implant systems:		
Drills		
Reference	Laser depth marks (mm)	Speed (rpm)
CD 5	7, 8.5, 10 , 11.5, 13, 15	800-1200
PDC 3	4, 4.25, 5, 5.25, 6, 6.25, 7, 7.25	800
PDC 37	4, 4.25, 5, 5.25, 6, 6.25, 7, 7.25	800
PDC 4	4, 4.25, 5, 5.25, 6, 6.25, 7, 7.25	800
PDC 5	4, 4.25, 5, 5.25, 6, 6.25	800
D215	7, 8.5, 10 , 11.5, 13, 15	900-1200
Taps		
TAPC 3	7, 8.5, 10 , 11.5	25
TAPC 37	7, 8.5, 10 , 11.5	25
TAPC 4	7, 8.5, 10 , 11.5	25
TAPC 5	7, 8.5, 10 , 11.5	25

Instruments to use with the MPI Short® implant system:		
Drills		
Reference	Laser depth marks (mm)	Speed (rpm)
SD2	6.3, 7.3, 8.8, 10.3	900-1200
SD3	6.3, 7.3, 8.8, 10.3	400-700
SD4	6.3, 7.3, 8.8, 10.3	400-600
SD48	6.3, 7.3, 8.8, 10.3	400-600
SD48S	6.3, 7.3, 8.8, 10.3	400-600

The tolerance of all the laser depth marks is ± 0.20 mm.

2. Description and material:

They are medical devices (dental, surgical and reusable), mechanical instruments for cutting, made in stainless steel, that are used with a handpiece (contra-angle) of the implant motor to activate its rotation.
They are medical devices class IIa.

3. Intented use/purpose:

They are intended to be used in dental surgery to create channels of appropriate depth and diameter in bone (osteotomy) of the oral cavity to facilitate the implantation of a dental implant in the jaw or maxilla.

4. Medical purpose/indication:

Placement of a dental implant through bone perforation in edentulous patient.

5. Intended user:

The intended user is a medical professional, responsible for the appropriate surgical procedures and restorative techniques, who should assess the suitability of the procedure used, based on their personal medical knowledge, education, training and experience (at least 1 year of documented experience in dental surgeries with these devices).

6. Intended patient:

Adult patients (in general 17-18 years and older) with jaw/maxilla growth complete, to be treated with a dental implant system and who are not contraindicated.
See the chapter "contraindications".

7. Indications for use:

-It is recommended to follow the instructions for use recommended by the manufacturer, as well as to adopt the necessary protective and clothing measures. Inadequate use of the instruments may result in patient damage.
-They are indicated to be used sequentially to form a cavity with the appropriate measures for the placement of the dental implants indicated in point 1, both in diameter and in depth. The depth of the drilling will depend on the height of the dental implant to be placed, following the depth marks of the instruments. The drilling protocol indicated in this document and also in the catalogue and on the website must be followed.
-The instruments must be used connected to a compatible handpiece (contra-angle) for instruments designed according to ISO 1797: 2017. (Depending on the instrument geometry, it must be connected directly to the contra-angle, or connected to the contra-angle using an intermediate connector).
-Before using the instruments, once verified their good condition, the intended user must disinfect, clean and sterilize them by autoclave moist heat. The intended user is responsible for the disinfection, cleaning and sterilization of them.
-The devices must be replaced after a maximum of 10 uses (the drilling use chart is recommended to control the number of uses of the instruments), with their corresponding sterilizations. If before the 10 uses: oxidation marks appear on its surface, and/or the laser marks lose color, and/or wear is noticed, and/or the cutting efficiency is reduced, do not use the devices and replace them.
-When deciding to replace the instruments, the intended users should dispose them following the protocol for disposal of medical devices defined in the dental clinic, to ensure their safe disposal.

8. Contraindications:

It is contraindicated to use the instruments in patients:
-Not suitable for an oral surgical procedure (for example, patients who have undergone radiotherapy or who have been treated with bisphosphonates, should contact the specialist who has treated them to verify the risks and contraindications).
-Allergic or hypersensitive to the materials used.
-Contraindicated for treatment with dental implants or restorative components.
-With periodontal diseases, limited bone availability and density, diabetics and / or smokers.
The intended user must inform the intended patient about these contraindications.

9.Possible adverse reactions and risks:

-Mishandling/inadequate use of devices, inadequate drilling protocol/surgical technique, and if the drills or taps are not replaced after the maximum recommended uses, can cause the injury of dimensional and ergonomic features of the shank connection, the wear of cutting edges and/or the device fracture that can cause bone damage.
-Also, the bone can suffer necrosis by thermal effects, due to lack of irrigation (no cooling of the devices with sterile saline solution during drilling) or applying a speed of rotation higher than the recommended ones.
-Unqualified or untrained user who use the devices without planning clinical cases and/or in contraindicated patients can cause patient harm.
-Inappropriate environment in which the devices are intended to be used, inappropriate/incorrect disinfection, cleaning and sterilization of devices and incorrect storage conditions can cause device contamination, infection of the patient, and/or wear effect such as laser marks discoloration that can cause nerve damage.

To date, no other possible significant adverse effects caused by these products are known. The intended user must inform the intended patient about the importance of maintaining good dental hygiene, and about these possible adverse reactions/risks.

10.Cleaning, disinfection and sterilization:

-The instruments are delivered non-sterile and are intended to be reused.
-The cleaning, disinfection and sterilization stages must be respected before the first use and each time the instruments are reused. The intended user is responsible for its correct cleaning, disinfection and sterilization.
-Before sterilization by autoclave moist heat, to guarantee the elimination of contaminating microorganisms, the instruments must be disinfected and cleaned with cleaning and disinfection agents with CE certificate, with bactericidal, fungicidal and virucidal properties, according to the instructions manufacturer.
Step1: Pre-disinfection
-After using the instruments in the surgery, to eliminate the residues and remains of blood, and to prevent that the blood will be dried on its surface and thus facilitate their subsequent cleaning, immerse them in a disinfectant solution (with EC certificate, with bactericidal, fungicidal and virucidal properties, with any substance not compatible with the drills), according to the manufacturer's instructions (pay attention to concentrations and immersion time; excessive concentration may cause corrosion of the products).
-Disinfectant solutions containing substances not compatible with the instruments should not be used.
-Rinse the instruments with purified water. If they have visible impurities, it is recommended to brush them manually.
Step 2: Manual cleaning and disinfection
-Immerse the instruments in a cleaning and disinfectant solution (with EC certificate, with bactericidal, fungicidal and virucidal properties), in an ultrasonic bath, according to the manufacturer's instructions.
-Immerse the instruments in an ultrasonic bath for 15 min at 35°C, maintaining a maximum temperature of 45°C to avoid protein coagulation.
-Repeat the process again with new purified water, to make a total of two rinses. Remove the instruments and rinse them (immerse them, shake them and keep them for 1 minute in purified water).
-Dry the products with filtered air.
Step 3: Inspection
-Inspect the instruments and discard those that have defects that may affect their resistance, safety or performance.
-Wash and disinfect dirty instruments again.
Step 4: Sterilization
-To ensure the complete elimination of all life forms, including spores, the intended user must perform the sterilization of the instruments before using them.
-To sterilize the instruments, store them in a suitable sterilization package, seal it, and sterilize them in autoclave moist heat at 134ºC for 18 minutes.
-To ensure that the sterilizer maintains adequate working conditions, it is important to inspect and clean it regularly. It is recommended periodic tests, cleaning and calibration following the instructions for use and maintenance of the sterilizer.

11.Precautions:

-Check that the handpieces (contra-angles) where the instrument will be connected are in perfect hygienic and operating conditions.
-Check that the instrument has been correctly anchored to the contra-angle.
-Check the correct rotation of the instrument and check the speed of rotation as it is specified in point 1.
-Do not use the instruments after a maximum of 10 uses, with their corresponding cleanings, disinfections and sterilizations to guarantee their functions.
-The intended user who uses the product must have experience to use it safely and adequately to these instructions for use.
-It is recommended that the intended user consult the surgical protocols, receive personalized assistance and attend special training before using the instruments.

MPI offers courses for different levels of knowledge and experience.
For more information, please see our website. [*]

12.Warnings:

-After each use, clean and disinfect the instruments. Improper cleaning can lead to improper sterilization. The use of hydrogen peroxide or other oxidizing agents will damage the surface of the instruments. Use disinfectant solutions approved for their effectiveness.
-Dry heat sterilization is not allowed, as it directly affects the performance of the instruments.
-Ensure that the instruments are completely dry. If they do not dry completely during sterilization, they can remain wet and cause discoloration and oxidation. The oxidized instruments can contaminate the water circuit, and the oxide particles can cause the initial oxidation of the intact instruments in all future sterilization cycles.
-Do not use the instruments if the sealed package in which the instrument is shipped is damaged or opened.
-These instruments are intended to be used in a sterile environment.
-Any serious incident related to the device must be notified to the manufacturer and to the competent authority of the Member State in which the intended user and / or the patient is established.
-For best results, these instruments should only be used with the indicated implant systems.

13.Handling:

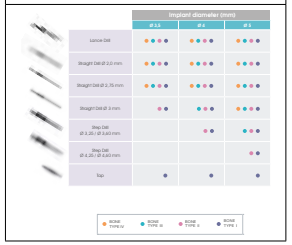
-To activate the rotation of the instruments, they must be connected to the handpiece (contra-angle) of the implant motor.
-Drill the bone following the rotation speeds indicated in point 1 and the drilling protocol indicated in this document and also in the catalogue and the website. [*]
-In case of using a tap – to facilitate the placement of the implants in a bone with high density D1 and D2 (Lekholm & Zarb, 1985)-, place it inside the previously drilled implant bed, apply apical pressure and begin threading in the clockwise direction. The tap must be removed reversing the rotation at the same speed.
-To accurately measure the perforation performed, it is recommended to verify the perforation by using calibrated measuring probes.
-To avoid mechanical and thermal risks, use irrigation with sterile saline solution to cool the instruments when they are being used.

14.Storage and transport:

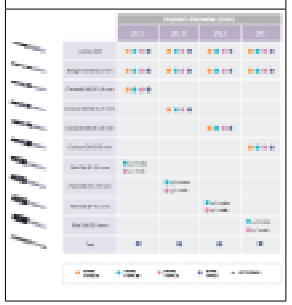
The original packaging has been validated simulating transport and storage conditions to guarantee the cleanliness of the devices packaged, and its protection against impacts. After sterilization, keep the instruments in the sterilization packaging, storing them in a clean and dry environment (40-60% humidity) at room temperature (15-25ºC), not exposed to direct sunlight. Incorrect storage during transport can influence the characteristics of the device and lead to its failure.

15. Drilling protocol:

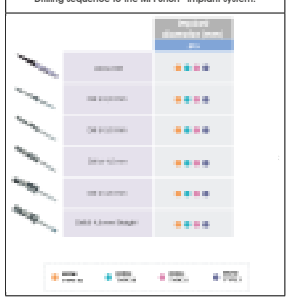
Drilling sequence to the MPI Privilege® implant system:



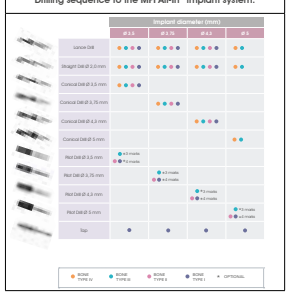
Drilling sequence to the MPI Excellence® implant system:



Drilling sequence to the MPI Short® implant system:



Drilling sequence to the MPI All-In® implant system:



16.Labelling symbols:

	Manufacturer
LOT	Batch code
REF	Catalogue number
NON STERILE	Non-sterile
	Keep away from sunlight
	Keep dry
	Consult instructions for use
	Caution
	Do not use if package is damaged or opened
CE 1639	CE symbol with the notified body number 1639

[*] For more information, please consult the catalogue and website: www.mpimplants.com

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