0. Manufacturer

These instructions for use contain the information regarding the TOLTAC® SYSTEM product manufactured by:

PMP MULTITASK S.r.l.

Via Mirabella, 2a

46040 Cavriana (MN) – ITALIA

www.pmpmultitask.com

1. Product Description and Intended Use

The product **TOLTAC® SYSTEM** (code "TS001"), which is the subject of these instructions for use, is a single-use drill guide device for dental implant surgery. It consists of a GUIDE and a DRIVER:

- ✓ GUIDE: TOLTAC® GUIDE (codice "DT005")
- ✓ DRIVER (available in 4 versions/models, all compatible with the DT005 guide
  - TOLTAC® STD DRIVER 2.55 (code "DT003")
  - TOLTAC® FLAT DRIVER 2.55 (code "DT004")
  - TOLTAC® STD DRIVER 5.5 (code "DT007")
  - TOLTAC® FLAT DRIVER 5.5 (code "DT006")

The **TOLTAC® SYSTEM medical device** can be used for patients of any gender aged 16 years and older who are undergoing dental implant surgery that requires surgical drills. Pediatric use is at the discretion of the dental surgeon, who determines whether the accessory is necessary for the procedure. Typically, intervention is avoided before skeletal growth is complete. **The device must not be used on pregnant or breastfeeding women.**

The **TOLTAC® SYSTEM** consists of two separate components — the TOLTAC® GUIDE and the TOLTAC® DRIVER — which are designed to be used only in combination with each other, never individually. There are two different versions of the TOLTAC® DRIVER ("standard" and "flat") that the clinician may choose from depending on the clinical scenario.
As a whole, the system allows accurate directional guidance of dental implant surgical drills.
The TOLTAC® GUIDE (Figure 1) includes two longitudinal protrusions for precise, unique placement into designated seats of 3D-printed surgical templates, and a groove that allows the longitudinal movement of a TOLTAC® standard DRIVER (Figure 2) once inserted into the guide structure.
The TOLTAC® DRIVER features a portion with a hole matching the diameter of the drill shank (universal) and an elongated structure that runs parallel to the axis of the hole, allowing minimal-clearance longitudinal sliding within the groove of the TOLTAC® GUIDE.

Figure 1
3D View of the TOLTAC® GUIDE

Figure 2
3D View of the TOLTAC® Standard DRIVER

The components are designed so that the axis of the insertion hole for the surgical drills in each TOLTAC® DRIVER, once inserted into the sliding groove of the TOLTAC® GUIDE, is positioned at a precise, fixed distance from the TOLTAC® GUIDE.
A specific template design protocol allows for the placement of one or more TOLTAC® GUIDES — one for each implant planned in the procedure — in such a position that a drill inserted into a TOLTAC® DRIVER, which in turn is placed into

the groove of the TOLTAC® GUIDE fixed to the surgical template, will be aligned in the exact direction intended for the implant site preparation, and can move precisely along that axis.

The elongated structure of the TOLTAC® DRIVER extends asymmetrically from the drill coupling portion, allowing the clinician, if desired, to reverse the orientation of the TOLTAC® DRIVER in relation to the drill. This makes it possible to guide the drill earlier or later in relation to its contact with the bone, depending on operative needs.

Both versions of the TOLTAC® DRIVER share the same coupling structure to the drill shank and have the same height for the guiding structure, but they differ in the shape of the guide structure itself.

The guide structure of the TOLTAC® standard DRIVER is precisely complementary to the groove of the TOLTAC® GUIDE, allowing only longitudinal sliding within the groove.

In contrast, the guide structure of the TOLTAC® flat DRIVER (Figure 3) is flat and has the maximum width compatible with lateral insertion into the TOLTAC® GUIDE groove.

Because it can be inserted from the side, the TOLTAC® flat DRIVER eliminates the need to access the GUIDE from above. This makes it the preferred option when, during the procedure, the clinician encounters limited patient mouth opening that prevents insertion of the TOLTAC® standard DRIVER.

The TOLTAC® flat DRIVER provides passive drill guidance only in the mesio-distal direction, while in the bucco-lingual direction the device must be manually guided by the clinician along the bottom of the TOLTAC® GUIDE groove, thus still maintaining the planned drilling direction.

Figure 3

3D View of the TOLTAC® Flat DRIVER

The two components are manufactured through CNC milling using PEEK (polyetheretherketone) certified for medical use and sterilizable.

The TOLTAC® trademark is registered in Italy under No. 302016000009166, registered on June 27, 2017, filed on January 29, 2016, and expiring on January 29, 2026. It refers to medical and veterinary apparatus and instruments; radiotherapy apparatus; dental instruments and devices; dental prostheses [Class 10].

The devices in question are protected by Italian patent No. 102017000138179, granted by the Italian Patent and Trademark Office on February 18, 2020, and by European patent No. EP3716884, granted on June 22, 2022.

2. Checks Before Use

The product is intended to be used exclusively by a surgeon in the field of dental implantology.
The user must first verify the correct labeling. The symbols present on the packaging are listed on the last page.

Before use, ensure that the TOLTAC® SYSTEM is intact and free of damage or foreign bodies.

3. Preparation and Use

Preparation of the surgical guide for using the TOLTAC system

After completing virtual planning using implant planning software and producing the surgical guide via 3D printing, fix a TOLTAC® GUIDE into each of the dedicated seats on the guide, in a position appropriate for the preparation of each planned implant site.

Carefully verify the seating accuracy of the guide, first on the patient's plaster model, then in the patient's mouth, to ensure that the guide can remain correctly and stably positioned during surgery. This will allow each implant site to be prepared exactly in the location defined during virtual planning.

Operation in case of limited mouth opening If the patient, due to fatigue or anatomical limitations, is unable to open their mouth wide enough to allow the insertion of the TOLTAC® standard DRIVER (mounted on the drill shank) into the TOLTAC® GUIDE, remove the TOLTAC® standard DRIVER from the drill shank and use a TOLTAC® flat DRIVER instead.

Thanks to its flat sliding portion, the flat DRIVER allows side access to the TOLTAC® GUIDE.

Complete the procedure using the planned sequence of drills, guided by the TOLTAC® flat DRIVER.

4. Warnings and Precautions

WARNING TOLTAC® DRIVERS constrain the drills to move only in the direction corresponding to the planned implant axis, but they do not provide any depth stop mechanism.

As a result, reaching the planned drilling depth is entirely the responsibility of the surgeon, who must stop drilling at the appropriate moment to avoid the risk of damaging underlying anatomical structures.

WARNING When using a TOLTAC® flat DRIVER, the drills are accurately guided in the mesio-distal direction by the interaction between the TOLTAC® GUIDE and the TOLTAC® DRIVER. However, in the bucco-lingual direction, the drill is free to assume various inclinations.

Therefore, the clinician must actively guide the drill in the correct direction by applying appropriate pressure on the TOLTAC® flat DRIVER against the bottom of the TOLTAC® GUIDE groove, and sliding it along the groove.

Mechanical assistance is thus partial, but still sufficient to allow the procedure to be successfully completed, even in cases of limited mouth opening.

The TOLTAC® flat DRIVER also does not provide any depth control, meaning that achieving the planned drilling depth is entirely up to the surgeon, who must stop drilling at the appropriate point to avoid the risk of injury to underlying structures.

WARNING

The TOLTAC® SYSTEM is a single-use device, but it is not supplied sterile. It is intended to be sterilized before use, either by cold sterilization or in an autoclave at 121°C.

The component known as TOLTAC® GUIDE is intended for single use and should be cold sterilized together with the 3D-printed surgical guide in which it is inserted.

The component known as TOLTAC® DRIVER may be sterilized either by cold sterilization or in an autoclave at 121°C before use.

It is noted that autoclave cycles at 121°C typically run according to preset programs, generally lasting 15–20 minutes.

WARNING: For cold sterilization, strictly follow the instructions and technical data sheets of the product used, both regarding the method of application (e.g., dosage) and the duration of treatment.

WARNING: For autoclave sterilization, strictly follow the instructions and technical data sheets provided by the autoclave manufacturer, both for the usage procedure and the treatment duration.

Precautions

- ✓ Must not be used for purposes or indications other than those specified in these instructions for use;
- ✓ Must not be used if any damage is present;
- ✓ Must not be used if the packaging does not bear the CE marking label;
- ✓ Must not be used by personnel other than a surgeon specialized in dental implantology;
- ✓ Must not be reused;
- ✓ Must be sterilized according to the manufacturer's instructions;
- ✓ Must be used exclusively according to the manufacturer's instructions;
- ✓ Do not dispose of in the environment.

Any serious incidents occurring in relation to this medical device must be reported to the Manufacturer and to the Competent Authority of the country where the user or patient is located, as required by European Regulation 745/2017.
Do not use the TOLTAC® SYSTEM in ways other than those specified in these instructions for use.
In case of doubt, contact the manufacturer.

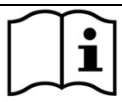
5. Disposal

The **TOLTAC® SYSTEM** must be disposed of as medical waste, in accordance with the procedures in place at the dental clinic where the surgical procedure was performed.
No special instructions or precautions are required for its disposal.

6. Storage

Store the device inside its original packaging until use.
No special environmental conditions are required.
It is recommended to keep it in a dry, cool place, away from light and heat sources.

Pictogram (if applicable)	Meaning / Explanation	Wording Present on the Labeling
	Unique Product Code	**TOLTAC® SYSTEM** (code "TS001") with specification of whether it is a guide or a driver: ✓ guide: TOLTAC® GUIDE (code "DT005") ✓ driver (available in 4 versions/models, all compatible with the DT005 guide): ○ TOLTAC® STD DRIVER 2.55 (code "DT003") ○ TOLTAC® FLAT DRIVER 2.55 (code "DT004") ○ TOLTAC® STD DRIVER 5.5 (code "DT007") ○ TOLTAC® FLAT DRIVER 5.5 (code "DT006")
	Type of Device	Class I Medical Device
/	Device Description	Drill Guide Device for Dental Implant Surgery
	his is the mark that certifies CE conformity of the surgical mask	CE Marking is present
	Manufacturer Information	PMP MULTITASK S.r.l. Via Mirabella, 2A 46040 Cavriana (MN) – ITALIA www.pmpmultitask.com
	Date of Manufacture (indicated by year and month)	E.g. 2023/01
	Batch Number (composed of digits)	E.g. 23025
	The product must be stored away from sunlight (UV) and light sources	/
	The product must be stored in a cool, dry place	/

Pictogram (if applicable)	Meaning / Explanation	Wording Present on the Labeling
	The product is supplied non-sterile	/
	Indicates the need for the user to consult the instructions for use for important safety information such as warnings and precautions	/
	Refer to the instructions for use provided by the manufacturer	/
Q.TY	Quantity / Number of Pieces	1 pc Means that the package contains 1 piece