

GDT (TADs) Temporary Anchorage Device Orthodontic Tools Kit

INSTRUCTIONS FOR USE

Case containing the necessary tools suitable for the installation and removal of GDT Orthodontic Micro Implants, designed specifically for this application.

Handling:

Spear Tip – Drilling the bone plate: Select the Micro Implant installation site and use the “Spear Tip Point Drill” (ORTSTP) to demarcate and puncture the bone board.



Attention: the Spear Tip does not allow use in contra-angle.

Driver Handle Holder Tool (ORTHTL) – Inserting and Removing the Micro Implants: Handle with freedom of rotation from the body of the key that allows for the effort to be applied with the fingertips only, which offers more sensitivity during clinical procedures.

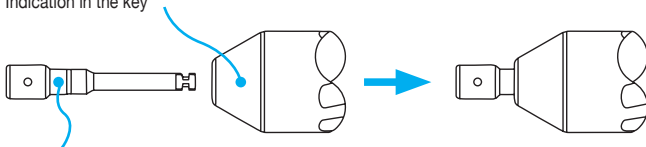


The body is grooved to prevent finger slippage during the application of the key turning efforts. It has coupling system to prevent the improper disassembly of the assembly.

To use the interchangeable tips safely we advise:

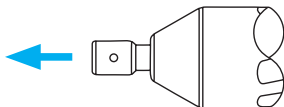
Place the interchangeable tip in the key hole (except for the **“Hand Finger Key”** (ORTHFG), which cannot be used in conjunction with the interchangeable tips), align the tip marking with the position mark on the key body, rotate the tip pressing against the wrench body until the markings align and the assembly locks.

Indication in the key



Marking in the interchangeable tip

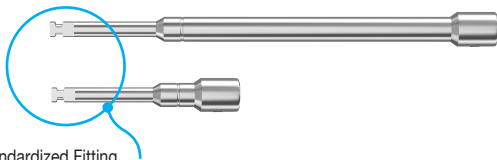
After use remove the tip by pulling it in the opposite direction of placement.



To facilitate the placement of the Micro Implant the key head has two engravings that project the position of the through hole present in the Micro Implant head.



The **“Hexagonal Keys”** (ORTHKS and ORTHKL) are manufactured with standard fit for contra-angle coupling allowing other installation options for the Micro Implants. Two key lengths are available to fit different points in the mouth.

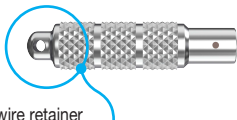


Standardized Fitting

Tip handling advice in conjunction with the Hand Key:

For safety, the interchangeable tips can be detached from the Hand Key when it is removed if there is misalignment with respect to the Micro Implant.

Hand Finger Key (ORTHFG) – Micro Implant Insertion and Removal:



Hole wire retainer

This component does not engage to the others, being a safe option for installing or removing miniscrews in areas of difficult access to the Hand Key. Its small size allows installation only with the use of fingertips. The Hand Finger Key fits snugly into the Hexagonal region of the Micro Implants and has a clamping system that prevents the Micro Implant from loosening before installation or removal to prevent accidental drops.

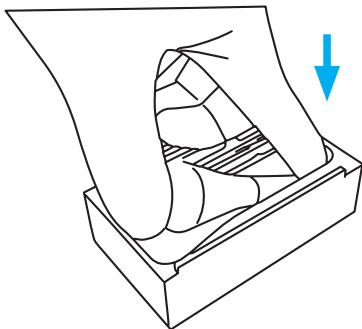
Warning: The Hand Finger Key has a hole for the string/dental floss to avoid accidental swallowing or aspiration during the procedure.

Tools kit Case – Storage and sterilization of the toolset: The Case is intended for storage and sterilization of the fixing tools of the Micro Implants.



Case Handling:

Press the end of the keys to remove from the case.

**Procedure for cleaning the tools:**

For safe reuse of the Orthodontic Tools Kit, it is recommended to perform the following cleaning sequence:

- Prewash by immersion in enzymatic detergent at the concentration and time specified by the manufacturer.
- Ultrasonic washing with the use of enzymatic detergent, or manual washing with soft plastic bristle brush.
- Air jet drying of areas subject to chlorinated water accumulation.
- Sterilize the kit by autoclaving for 15 minutes at 134 °C, the kit must be pre-packed in surgical grade paper.

Cleaning Warnings:

Storage of material without proper cleaning and drying will cause oxidation.

Do not use hydrogen peroxide, chlorine-based liquids and steel wool to decontaminate tools or clean the case.

The use of descaling products tends to darken the instruments and cause oxidation.
The use of enzymatic detergents in concentration above 10% favors oxidation.

The use of salt-containing common water can cause staining on the surface of the tooling as well as unregulated autoclaves with residual moisture.

Tools are reusable and supplied non-sterile and must be sterilized prior to use to prevent possible contamination to users.

Autoclave sterilizable product up to 134 °C.

Non-sterilizable oven product (dry heat).

Contraindications:

The Toolkit is part of the necessary resources for handling the Orthodontic Micro Implants, and there are no contraindications related to its use.

Side effects:

It is the responsibility of the professional to identify any possible risk of damage and / or contraindications that may arise during treatment, notify the patient the possibility of any unwanted side effect, however they are not expected side effects to the use of the Tools kit.

Composition / information about components:

Hand Key Cable: Polyetherimide.

Case box: Polypropylene / Cover: Polyphenyl Sulfone.

Metal Components: Stainless Steel (Cr = Máx 19% / Ni = Máx 10% / C = Min 0.15% / Mn = Máx 2.0 % / Si = Máx 1% / P = Máx 0.2% / S = Min 0.15% / Mo = Máx 0.15%).

General Warnings: All components, including the Case, are reusable and autoclavable.

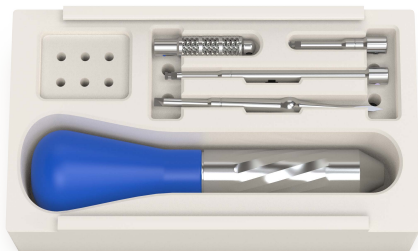
Use the interchangeable tips only with the Hand Key or reducing contra-angle (Max. 50 RPM).






This product contains nickel and chrome. A small percentage of the population is allergic to these metals. If allergic reactions occur, advise the patient to seek medical advice.

Do not use the product if its packaging is damaged or opened in order to minimize possible dangers related to the transmission of microorganisms or possible falsification of products.

Product for exclusive application by qualified professional.

Considering that the product is used in contact with mucous membranes and body fluids, it is recommended to the professional to apply the sanitary norms applicable for the disposal of medical products according to current sanitary regulations.



| Content | Type | Code |
|-----------------------------------------------------------------------------------|---------------------------|--------|
|  | Spear Tip Point Drill | ORTSTP |
|  | Hexagonal Key Long | ORTHKS |
|  | Hexagonal Key Short | ORTHKL |
|  | Hand Finger Key | ORTHFG |
|  | Driver Handle Holder Tool | ORTHTL |
| FULL KIT IN AUTOCLAVABLE BOX | | ORTKIT |



Rx Only

Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material.

The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.