


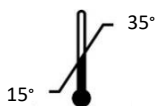
B3-FO-01-012	Business Development – Engineering	 Technology
	Formulary	
Version: 02	Instruction for Use	

Implant Tool



English

Instructions for Use



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1 System Description

Implant tools are intended to tighten and loosen prosthetic screws in laboratories or Dental offices. These screws are used to maintain the abutments in the implants. Temporary or definitive prostheses are fixed on the abutments.

Implant tools or drivers have an ISO or square shanks. These interfaces are used with an adapted torque wrench to tighten the screws at good torque values. The values are set according to the manufacturer's recommendation.

Implant tools are delivered in kits or individually non-sterile.

1.1 Intended Use

Implant Tool is intended to be used with screws and torque wrench to fix and remove dental prosthesis in the mouth.

1.2 Intended user

The assembly of the components with the prosthesis must be performed by a properly trained professional. Cleaning and maintenance of the prosthesis must be advised by the dental practitioner.

1.3 Indications for use and patient population

- Implant tools are intended for dental professionals.
- Implant tools are used with screws and torque wrenches.
- Implant tools are used for the replacement or modification of a dental prosthesis or a set of prosthetic elements.
- For fully or partially edentulous jaws.

1.4 Contra-indications

Do not use the devices if the drivers or the screws have deteriorated.

1.5 Warnings/ Precautions








It is important to check the following points before use.

- Make sure the retreatment (disinfection and sterilization) has been carried out before each use.
- To have chosen the good driver according to the screws.
- To respect the recommendations of the Implant manufacturer concerning the tightening torque.

2 Components:

All the components described below can be found as a kit (Implant Buddy) or separately.

2.1 Tools

1	Body	
2	Manual Adapter	
3	Hex Screwdriver 0.9 mm	
4	Hex Screwdriver 1.2 mm	
5	Hex Screwdriver 1.25 mm	
6	Hex Screwdriver 1.3 mm	
7	Angled Screwdriver	
8	SCS Screwdriver	
9	Unigrip Screwdriver	

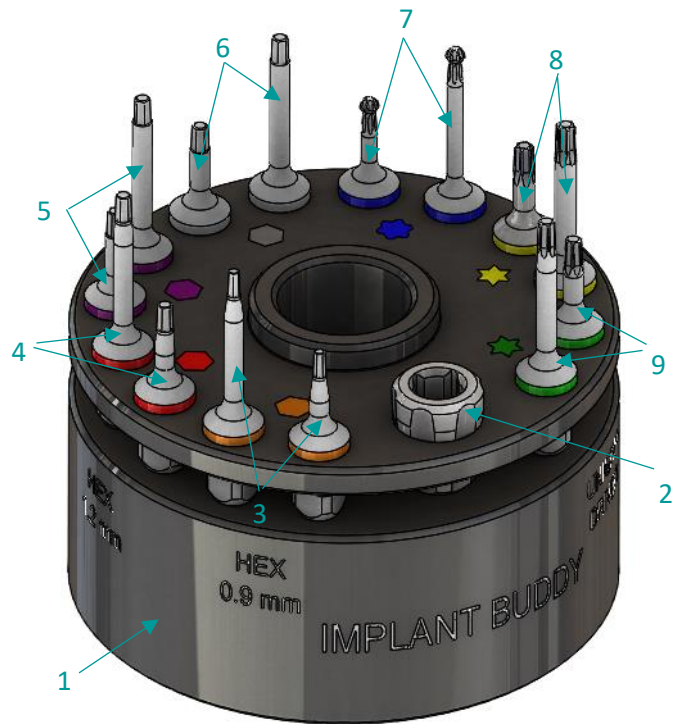









FIG.1 : Implant Buddy Dental

1	Body	
2	Manual Adapter	
3	Multi-Unit Driver	
4	Hex Screwdriver 0.9 mm	
5	Hex Screwdriver 1.2 mm	
6	Hex Screwdriver 1.3 mm	
7	Angled Screwdriver	
8	Straight Driver	
9	SCS Screwdriver	
10	Unigrip Screwdriver	

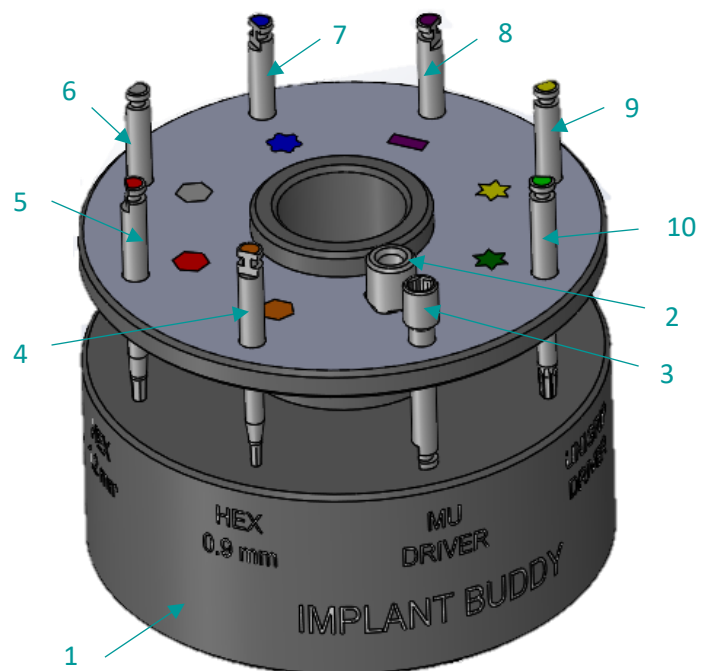



FIG.2 : Implant Buddy Latch

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2.2 Procedure for use

During tightening operations, the screws must be tightened with a torque limiter, which is compatible with the screwdriver.

For all use of the device, its components must be used according to the method described below:

2.2.1 Screwdriver Adapter Insertion For Manual Use

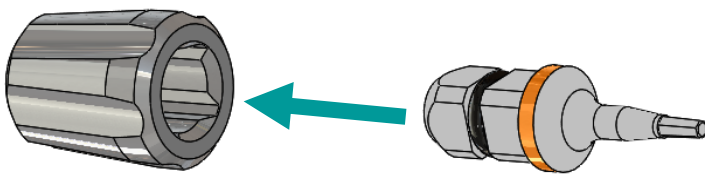


FIG.3 : Screwdriver Adapter Mounting



FIG.4 : Screwdriver Adapter Mounted

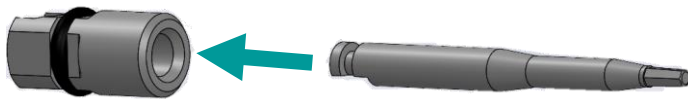


FIG.5 : Screwdriver Adapter Mounting

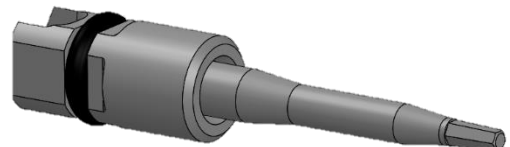


FIG.6 : Screwdriver Adapter Mounted

2.2.2 Screwdriver Insertion into the Torque Limiter

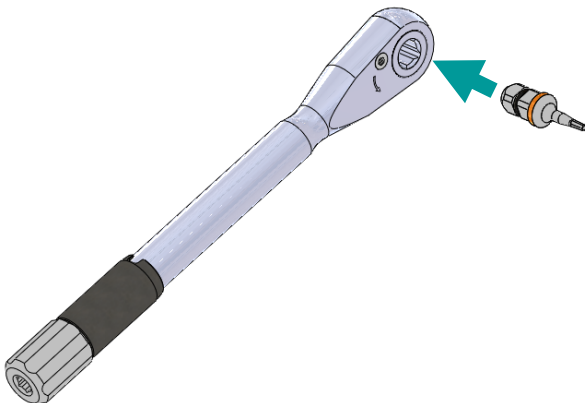



FIG.7: Mounting the screwdriver into the torque limiter



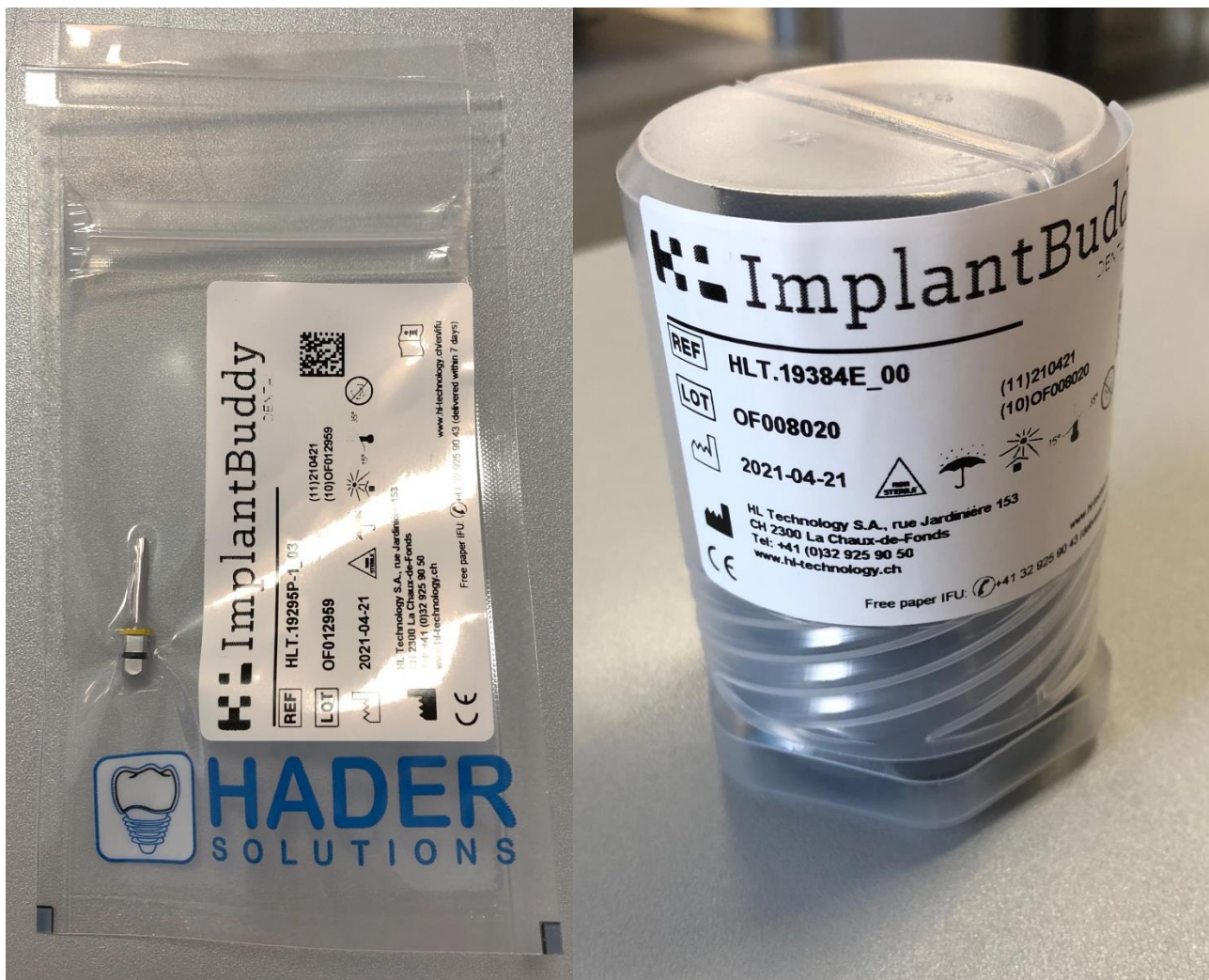
FIG.8: The screwdriver in the mounted position

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3 Packaging / Storage

The parts are delivered in a vacuum-sealed plastic bag. If the pouch is no longer sealed or under vacuum upon receipt of the parts, they must be returned to the distributor. The kits Implant Buddy are delivered in tube/rigid plastic packaging.

The parts should be kept in a clean, dry place and protected from direct sunlight. The temperature of the storage conditions must remain at room temperature.

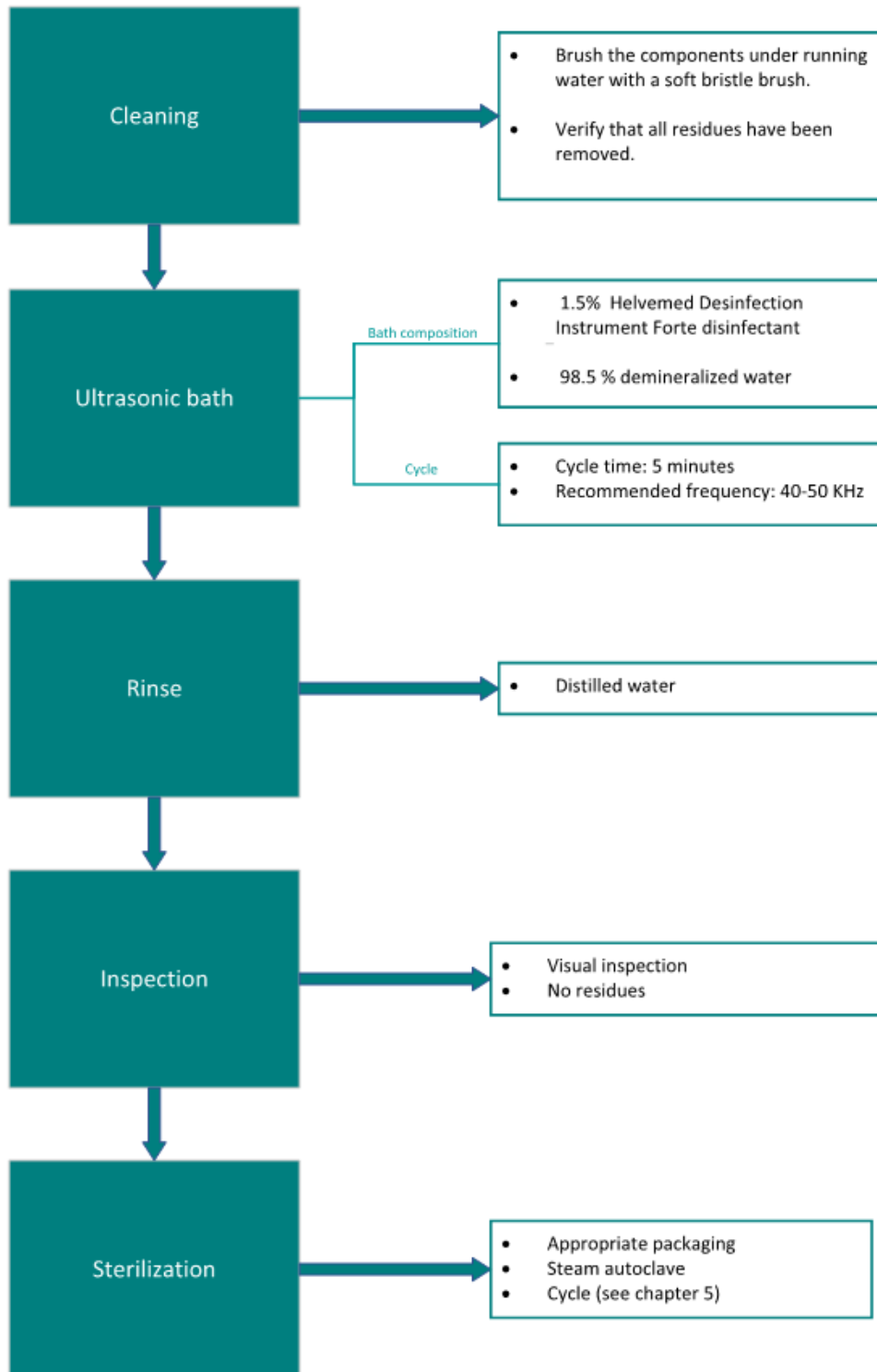



Left picture: plastic bag for drivers.

Right picture: plastic tube for the support.

4 Treatment:

4.1 Disinfection




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4.2 Sterilization

US Market	
Method	Steam sterilization according to the EN ISO 17665 norm and ANSI/AAMI ST79
Cycle	
1) Pre-vacuum	
2) Sterilisation	4 minutes at 132°C / 270°F
3) Drying time	60 minutes
4) Cooling time	60 minutes at ambient temperature

EU Market	
Method	Steam sterilization according to the EN ISO 17665 norm
Cycle	
1) Pre-vacuum	
2) Sterilisation	18 minutes at 134°C / 273°F at 2 bars
3) Drying time	20 minutes

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5 Recommendations for use

- It is recommended to use the screwdrivers always with a torque wrench to avoid over or under-tightening of the abutments screws.
- Always follow the tightening recommendations provided by the implant manufacturers.
- Never exceed the tightening values shown in the table below.

Driver	Torque max
Hex Screwdriver 0.9 mm	15N/cm
Hex Screwdriver 1.2 mm	32N/cm
Hex Screwdriver 1.25 mm	30N/cm
Hex Screwdriver 1.3 mm	30N/cm
SCS Screwdriver	35N/cm
Unigrip Screwdriver	35N/cm
Straight Driver	15N/cm
Angled Driver	30N/cm

6 Disposal

Disposal must be done following the regulations applied in the country of use.