

BIO MATERIALS KOREA	Technical Construction File	No. of Document	TCF-INS-8
		Date of Rev.	2018.05.24
	8. Labeling & Packaging	No. of Rev.	- 8 -

Instructions for Use (Handle)

Rev. No. 4 / Issued Date : 2017. 12. 08

As screw driver for implant orthodontic anchor screw that hexagonal-type screw head, it made of corrosion-resistant Ti alloy and stainless steel, it is no-sterile product that consists of handle portion and blade.

Materials: Titanium Alloy, Super Stainless Steel, Stainless Steel

Performance and Purpose of Use

- Performance** : As screw driver that is used to implant orthodontic anchor screw that hexagonal-type screw head. After implant, cleaning is easy because appearance is simple and can be added a lot of force to axial.
- Purpose of Use** : Instrument that is used to care dental implant(or dental orthodontic anchor screw).

Instructions

1. Precautions

- ① The high-pressure steam sterilization for 30 min at 121℃ before use.
- ② Check whether or not tightly connected handle portion with blade.

2. Directions

- ① Combine handle portion with blade.
- ② Put combined screw driver set in screw head of dental orthodontic anchor screw.
- ③ Situate screw on the site that you want to care and tighten it to use driver.
- ④ After use, disassembly handle region and blade and disinfection and drying.

3. Storage and maintenance after use

- ① Store at room temperature.
- ② Store at drying place.
- ③ Disassembly handle region and blade and store them.

4. Cautions

- ① Don't apply excessive force.

Packaging Unit:

Outer case: PE vinyl bag

Expiration Date: Not applicable

Storage: Keep under the room-atmospheric condition

Expiration date: Semi-permanent

Notice: Medical Device

* Products with any noticeable deformations, flaws or damages will be exchanged.

Correct devices or tool : refer to a catalog

* If the instruction manual that is an official language of the European other than English is required, is provided through a variable easily if necessary.

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Instructions for Use (Blade)

Rev. No. 4 / Issued Date : 2015. 2. 13

This device is the blade for implanting orthodontic anchor screw.
The instruments were made of stainless steels with high corrosion resistance.
This device is non-sterile and re-use product.

Materials: Super Stainless Steel, Stainless Steel

Performance and Purpose of Use

- Performance** : Blade used to combine with handle part to insert orthodontic anchor screw. After implant, cleaning is easy because appearance is simple and can be added a lot of force to axial.
- Purpose of Use** : Instrument that is used to care dental implant(or dental orthodontic anchor screw).

Instructions

1. Precautions and warnings

- Screw driver should be sterilized before use.
Sterilization Method : High temperature steam autoclave sterilization
Temperature : 121℃ Exposure time : 30 min
- Check whether or not tightly connected handle part with blade.
- Should be operated only by a specialist with fully understanding of the instructions.

2. Operation procedure

- Connect handle part with blade.
- Combined head part of blade with head of orthodontic anchor screw or bone screw.
- Place the screw on the site to be treated, and insert the screw with driver.
- After use, disassemble driver and blade, and should clean and dry them.

3. Storage and maintenance

- Keep under the room atmospheric (dry) condition.
- After use, should be disassembled driver and blade, and keep under the room atmospheric (dry) condition.

4. Cautions

- Don't apply excessive force.

Packaging Unit:

Outer case: PE vinyl bag

Expiration Date: Not applicable

Storage: Keep under the room-atmospheric condition

Expiration date: Semi-permanent

Notice: Medical Device

* Products with any noticeable deformations, flaws or damages will be exchanged.

Correct devices or tool : refer to a catalog

* If the instruction manual that is an official language of the European other than English is required, is provided through a variable easily if necessary.

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Instructions for Use (Ratchet Wrench)

Rev. No. 1 / Issued Date : 2017.12.08

Materials: Stainless Steel

Instructions

1. Precautions and warnings

- ① Ratchet Wrench should be sterilized before use.
Sterilization Method : High temperature steam autoclave sterilization
Temperature : 121℃ Exposure time : 30 min
- ② Confirm the deformation, scratch and damage in appearance before use.
- ③ Should be operated only by a specialist with fully understanding of the instructions.

2. Operation procedure

- ① Before use, choose the proper instrument in accordance with its intended use.
- ② Fix the connection part of instrument with connection of Ratchet Wrench.
- ③ After use, instrument should clean and dry under the room atmospheric (dry) condition.

3. Storage and maintenance

- ① Keep under the room atmospheric (dry) condition.

4. Cautions

- ① Should be operated only by a specialist with fully understanding of the instructions.
- ② Confirm the deformation, scratch and damage in appearance before use.
- ③ Fix the connection part of instrument with connection of Ratchet Wrench.
- ④ Should be careful for the deformation around the connection part.
- ⑤ Shouldn't have user limit in age or gender.

Expiration Date: Not applicable

Storage: Keep under the room-atmospheric condition

Expiration date: Semi-permanent

Notice: Medical Device

* Products with any noticeable deformations, flaws or damages will be exchanged.

Correct devices or tool : refer to a catalog

* If the instruction manual that is an official language of the European other than English is required, is provided through a variable easily if necessary.

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* Note : Graphical symbols for use in the labelling



symbol for "Caution"



symbol for "Consult instructions for use"

REF

symbol for "Catalogue number" or "Model"



symbol for "do not reuse" are "single use", "use only once"



symbol for "batch code" or "Lot Number"



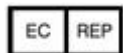
symbol for "date of manufacture"



symbol for "Non-Sterile" product



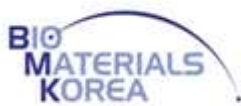
symbol for "manufacturer"



symbol for "authorized representative in the european community"



symbol for "federal law (usa) restricts this device to sale, distribution, or use by or on the order an orthodontist"



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