

**Instructions for Use**
Orthodontic Crimpable Hooks


- Please read these instructions carefully before using this product.
- Keep these instructions for reference.
- In case of any serious incident please report it to the manufacturer and your competent authority.
- These instructions for use are based on experience from physicians and/or their published literature. It is intended to assist in using this device. It is not a reference to surgical techniques.

**1. PRODUCT NAME**

Orthodontic Crimpable Hooks

**2. DESCRIPTION/INDICATIONS**

The orthodontic hooks are accessory of orthodontic treatment and are used together with other orthodontic materials, e.g. orthodontic brackets, bands, tubes, archwires and elastomerics, etc. for movement of teeth. They are intended for maintaining wire positioning or limiting tooth movement. They are fixed on the arch wires inserted structure and fit round or rectangular wire.

Orthodontic hooks are divided into orthodontic crimpable hook and orthodontic power hook. The device consists of a hook body and a base tube. Orthodontic crimpable stop is a special type of the orthodontic crimpable hook. It contains only the base tube. The hook body aids in the seating and positioning of band as well as accepting maxillary and mandibular appliances such as palatal bars and quad helix appliances. The hook body of orthodontic crimpable hook has a ball shape, while the hook body of orthodontic power hook is a hook with the shape of a question mark. This type increases acceptable tractive power. In comparison, the orthodontic crimpable hook is more flexible, and can be curved to the left or right.

Crimpable archwire hooks allow quick and simple placement of the hooks in the desired position with the archwire in or out of the mouth. It can be placed mesial to the cuspid anywhere on the arch without having to remove or replace the archwire.

The orthodontic crimpable hooks / orthodontic power hooks are made of stainless steel 06Cr19Ni10 acc. to EN ISO 7153-1.

Orthodontic crimpable hooks are used temporarily and are removed after orthodontic treatment has been completed.

**Intended Purpose**

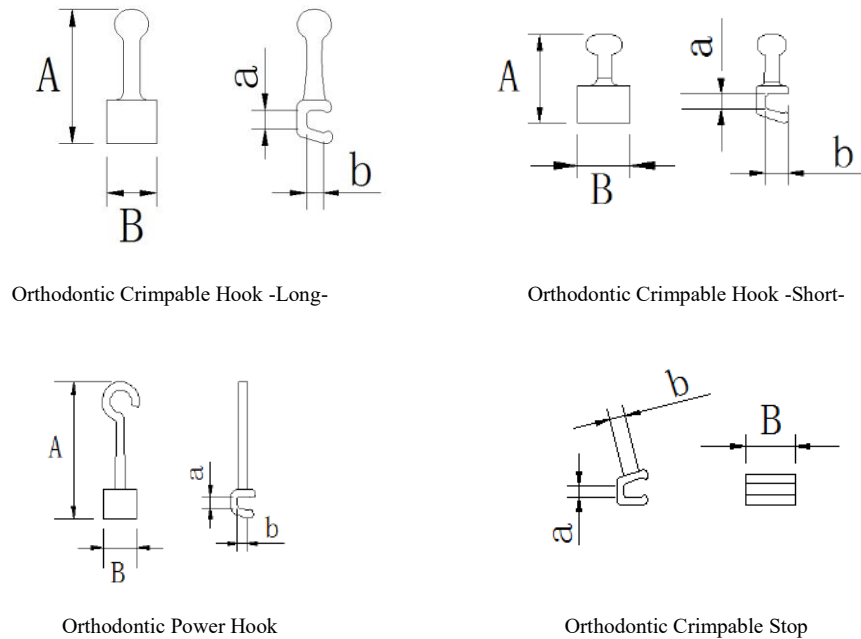
The orthodontic crimpable hooks are intended for orthodontic movement of teeth. It is used for correction of twisted and crooked teeth.

The device is intended to be used together with orthodontic bracket, bands, tubes, archwires and elastomerics, etc, to move the teeth to desired positions. They are indicated for orthodontic treatment in patients of all ages when prescribed by an orthodontist.

This is a single-use device. A reprocessing and re-use of the device are not allowed.

**3. SPECIFICATION**

Product Type	Variants	A±0.5	B±0.5	a	b
Orthodontic Crimpable Hook	Long	5.5	2.2	0.64±0.10	0.65±0.10
	Medium	4.2	2.2		
	Short	3.7	2.2		
Orthodontic Power Hook	Long	8.5	2.2		
	Short	7.1	2.2		
Orthodontic Crimpable Stop	--	—	2.2		



**Figure 1 Schematic Diagram of Orthodontic Hooks**

#### 4. CONTRAINDICATIONS

Orthodontic crimpable hooks should not be used for persons with periodontitis.  
Orthodontic crimpable hooks are contraindicated for those who are allergic to chromium and nickel.

#### 5. CAUTIONS and WARNINGS

- The orthodontic crimpable hooks can only be operated by dentists that have taken professional training;
- Pay attention to keep the mouth hygiene;
- Do not bite hard or sticky food, do not chew gum;
- This is single-use device. A reprocessing and re-use of the device is not allowed. An infection or transmission of diseases could occur, if the device were to be re-used.
- After use this device may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and with applicable local, state and federal laws and regulations.

#### 6. POTENTIAL COMPLICATIONS

Complications of Orthodontic Crimpable Hooks are documented. These complications may include:

- Allergic reactions
- Pain during the orthodontic treatment
- Tooth discolorations
- Decalcification
- Root resorption
- Periodontal complications

#### 7. DIRECTIONS FOR USE

- 1) This device should be used together with orthodontic brackets, orthodontic buccal tubes, orthodontic archwires, orthodontic bands, orthodontic elastomers, etc.
- 2) The orthodontic crimpable hooks should be routinely cleaned prior to use, e.g. with water or ethanol.
- 3) The hook body aids in the seating and positioning of band as well as accepting maxillary and mandibular appliances such as palatal bars and quad helix appliances.

- 4) Crimpable archwire hooks allow quick and simple placement of the hooks in the desired position with the archwire in or out of the mouth. It can be placed mesial to the cuspid anywhere on the arch without having to remove or replace the archwire.
- 5) For placement of the device, a plier has to be used. Please refer also instructions for use of the plier.
- 6) The free hook jaws are mounted outwardly on the slot for the hook, and are clamped at the position where the archwire needs to be clamped.
- 7) The end of the hook after clamping is not allowed to contact the gums to avoid inflaming the patient's gums.

**8. EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE:**



Catalogue number



Caution



Batch code



Consult instructions for use



Do not re-use



Keep away from sunlight



Use-by date



Keep dry



Do not use if package is damaged



Fragile, handle with care



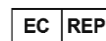
UDI code



Manufacturer



Medical device



Authorized representative in the European Community



Importer



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