

Instructions for extrusion eyelet and Caplin hook with gold chain

Intended purpose: It is the orthodontic accessories of fixed appliance to correct malocclusion and dentofacial deformity for human beings

Indication for use: Dental malocclusion. Orthodontic treatment.

Contra-indications: Patient who has the periodontal disease should not be accepted for orthodontic treatment until curing. Pregnant woman and child before dental transitional period should not be permitted for orthodontic treatment.

Patient target group: Any individual with malocclusion undergoing orthodontic treatment.

Intended user: Healthcare professional: dentist or orthodontist.

Sterilization instructions

Before use on patient the Extrusion eyelet and Caplin hook should be sterilized in an Autoclave or in Glutaraldehyde disinfectant solution.

Sterilizing with autoclave

- Place the Extrusion eyelet/ Caplin hook in a sterilization bag
- Autoclave for a minimum of 3 minutes at a temperature of 134°C-137°C
- Minimum dry time 15 minutes

Sterilizing with Glutaraldehyde disinfectant

- Place the Extrusion eyelet/ Caplin hook in a container with Glutaraldehyde disinfectant for 10 minutes

The Extrusion eyelet/ Caplin hook may also be washed in an automated washer/disinfector at a temperature of 90°C, or via a hand wash method prior to the sterilization process.
PH neutral detergent only.

Bonding instructions

Bond the mesh base on appropriate location of the teeth surface (use qualified orthodontic adhesive) according to the instruction for use by supplier, when the joint between the traction chain and the teeth crown has a certain strength, adapt the elastic ring through the hole of the chain.

After finishing, debond the Extrusion eyelet/ Caplin hook with removing pliers.

Transportation and storage requirements

Gold plated traction chain should be stored indoor which is less than 80% RH, ventilation and without corrosive material.

Precautions and warnings

1. This product is for single use only, not reusable.
2. This product is only operated by qualified professional orthodontic doctor for clinic practice.



Precautions and warnings

3. During the first clinical treatment, the patient should be warned by clinicians that some individuals may have an allergic reaction to the material of the traction chain. Patients should be timely treated once oral allergy occurred.
4. Clinicians should warn the patient against rigid and sticky food after the clinical treatment (such as corn, apples, etc.), and keep good oral hygiene.
5. Do not use if the packing breaks.
6. After use, the gold plated chain should be processed as medical solid wastage.
7. The maximum force shall not exceed 2,5N during orthodontic treatment.
8. Device contains nickel and chromium.
9. Report any serious incidents that have occurred in relation to the device to the manufacturer or to the competent authority of the Member State in which you are resident.

Symbols:

