

## Instructions for use



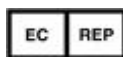
Manufacturer:



Astar Orthodontics Inc.

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Zhongshan Road Section 1, Shanghai 200023, China

SRN code: CN-MF-000028647



whose single Authorized Representative:

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### 【PRODUCT NAME】 Orthodontic Lingual Cleats

【MODEL】 Bondable; Weldable; Small, Big

【INTENDED USE】 For orthodontic treatment only.

【CLEANING】 All products supplied non-sterile. Before used, the product is recommended to be cleaned by 75% alcohol. The procedures recommended for cleaning of the materials are intended only to products themselves and not to packages containing.

【PRODUCT LIFT TIME】 The device is made of stainless steel and has no specific shelf life if the recommended storage requirements are followed. The orthodontic treatment cycle varies from patients, and general period would be around 5 years.

Check the product appearance prior to use to ensure that the device has no stains or corrosion during storage, otherwise, discard the device.

【CONTRAINDICATION】 Prohibition of use that the patients: ① Nickel allergies, ② Patients with periodontal disease, ③ Hyperthyroidism, ④ Diabetes, ⑤ Tuberculosis, ⑥ Mental illness, ⑦ Severe malnutrition, ⑧ Pregnant women.

### 【DIRECTION FOR USE】

#### Bondable Lingual Cleats:

#### 1. Select the adhesive

Bondable cleats can be bonded with all standard orthodontic adhesives. Either no-mix or mix adhesive is applicable.

## 2.Operation

Use bracket tweezers to hold and place.

Refer to the instruction of orthodontic adhesive, the etchant will be used on tooth surface to be bonded with brackets, as well as the base of cleat. Then, rinse, apply primer and adhesive paste etc., completely remove any excess exuding around the side of the button base. This is particularly important for easy de-bonding at the end of treatment.

To finish the treatment, the bonded cleat can be removed by a bracket removing pliers or other tools. The practice should be carefully to avoid the possible tooth injury and damage of tooth surface.

### Weldable Lingual Cleats:

1. The weldable cleats can be used independently in clinic. Usually it has to be welded to band in laboratory, or by a technician in clinic.
2. Suggest to use the spot welder in clinic to weld the cleat onto the lingual side of bands. here is the picture of the spot welder and the parameters for reference. the drs must study well of the operating manual of the machine.



The following parameters are only for the user's reference

Energy Selection	00~02	03~17	18~29
Welding Thickness	<0.2mm	0.2~1.6mm	>1.8mm


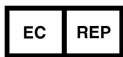














\*\*\*The data is provided by YAJIE company, only for the user's reference.  
The doctors must study well the IFU which supplied by the manufacturer.

### 【PRECAUTIONS】

1. When welded and before using in clinic, The product should be cleaned before used. 75% alcohol is recommended. no impact to the treatment.
2. Single use, discarded after using, do not re-use. Repeated use can cause mechanical performance failure and cause cross-infection.
3. For professional use only.
4. Single use to the correspondent tooth only. Please follow the advice on the product label. Mixed or wrongly placement of the brackets might lead to unexpected problem in clinic .
5. The product contain Nickel and chromium, Nickel Allergies are prohibited !
6. Patients are prohibited who are with periodontal disease, dental caries, Hyperthyroidism, diabetes mellitus, tuberculosis, psychosis, Severe malnutrition and pregnant women.

【STORAGE】 Be stored in dry and room temperature. Avoid the contact of corrosive airs.

### Symbols for use in the labeling:

Item	Symbols	
1		Symbol for "MANUFACTURER"
2		Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"
3		Symbol for "DO NOT REUSE"
4		Symbol for "BATCH CODE"
5		Symbol for "CATALOGUE NUMBER"
6		Symbol for "USE BY"
7		symbol for "DATE OF MANUFACTURE"
8		Symbol for "CAUTION"
9		Symbol for "CONSULT INSTRUCTIONS FOR USE"
10		Symbol for "NON-STERILE"
11		Symbol for "CE mark" acc. Directive 93/42/EEC by Notified Body 0197
12		Symbol for "MEDICAL DEVICE"
13		Country of manufacture
14		Do not use if package is damaged and consult instruction for use
15		Key dry
16		Unique device identifier