

Zhejiang Risheng Medical Technology Co.,Ltd	CE Technical Documentation	Document No.	TCF-01-07
	IFU of Orthodontic bracket	Version	08

Instruction for use



Please read and study the following directions carefully so as to use this product at the best for you and your patients. The written instructions cannot cover all eventualities during operation. Please ask us for any more other questions or ideas if there is any more doubt.

1. [TYPE AND SIZE]

No.	Types	Description		Size	Product code
1.	ligating	Edgewise	no hooks	0.018"/ 0.022"	BE1/BE2
		Roth	3 teeth with hooks		BR1/BR2
		MBT	345 teeth with hooks		BM1/BM2
2.	Self-ligating	MBT	no hooks 3 teeth with hooks 345 teeth with hooks	0.018"/ 0.022"	SMM1/SMM2
		High torque			SMH1/SMH2
		low torque			SML1/SML2
		Standard torque			SMQ1/SMQ2

2. [STRUCTURE]



F1.Ligating Bracket



F2.Self-Ligating Bracket

3.[DESCRIPTIONS]

3.1 The intended purpose:the orthodontic brackets are one of the most important parts of the fixed orthodontic appliance, Orthodontic brackets belongs to the fixed appliance to correct malocclusion or dentofacial deformity.

3.2 Indication: 1) Lock jaw. 2) Patients with teeth gap. 3) Posterior Cross-bite. 4) Crowding teeth. 5) Overbite. 6) Anterior Cross bite. 7) Double jaw thrust forward. 8) Deep bite.

3.3 The intended user: Orthodontist or professional doctors.

3.4 Patient population: The patient population with malocclusion or dentofacial deformity, except for who has the periodontal disease would not be accepted for orthodontic

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treatment until curing,

3.5 When the orthodontic bracket is combined with other devices during the using, the devices should meet the requirement of product standard or the device made in Zhejiang Risheng Medical Technology Co.,Ltd.

4.[OPERATING PROCEDURE]

1). Tooth surface cleaning

Using a goblet rubber dipped in polishing powder, rapid removal of tartar and teeth stains, then rinse with water and dry with alcohol. And lastly, using a mouse-gag with sliver and a saliva pump to prevent teeth wet again.

2). Tooth surface acid etching

Applying the dental etching agent on the teeth surface, the acid etching area is slightly larger than the bracket base board area. Acid etching time is (60-90)s , but dental fluorosis is (2-3) min.

3). Cleaning and drying

The tooth surface must be washed by pure water after acid etching to avoid acid and debris residues, then drying the tooth with hot winds or compressed air. After the above steps, the tooth are chalk color, at this time it should be to prevent pollution again.

4). Positions

Use a bracket placement gauge to marking a reference line on the surface of the teeth.

5). Apply the orthodontic adhesive

Prepare the orthodontic adhesive according to the manufacturer's instructions. Apply only a small amount of the adhesive to the center of the bracket base, but enough to cover the adhesive surface. This will produce an optimum bonding strength.

6). Placing the brackets

After applying the adhesive, place the bracket on the tooth in the usual way, align the bracket and press it on. Before the adhesive hardens (hardening time according to the adhesive manufacturer's instructions), completely remove any excess exuding around the side of the bracket base. This is particularly important for easy de-bonding at the end of treatment. When the self-ligating orthodontic bracket' adhesive hardened, open the cover with a special opening tool, push the orthodontic wire into the wire slot, and then close the cover.

7). Bracket De-bonding

Brackets can be de-bonded with bracket remover or Weingart pliers. Grip the brackets at the

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mesial and distal and loosen the base of the bracket carefully from the tooth by closing the pliers and bending the brackets. Then, if necessary, remove the bracket from the tooth without pulling by twisting the bracket briefly to the right or left.

Remind : No special precautions have to be taken when disposing of brackets after treatment.

5.[PRECAUTIONS]

- 1) When the adhesive begins to solidify, do not move the bracket, otherwise it will affect the bonding effect.
- 2) The orthodontic bracket should be operated only by professional orthodontists and qualified dentists.
- 3) The orthodontic bracket belongs to disposal product; no special requirement to deal with them after use.
- 4) Always ask the patients to keep good oral sanitary during treatment.
- 5) The products should not be worn when patient is undergoing an MRI
- 6) The qualified and validity device was used on combination with orthodontic bracket by professional orthodontists and qualified dentists.

6.[CONTRAINDICATION]

- 1) Patient who has the periodontal disease would not be accepted for orthodontic treatment until curing.
- 2) Do not use for patients with nickel-chromium allergies.

7.[PACKAGE]

Packed with plastic bag and middle box, 20 pcs×1kit/box. Or in accordance with the requirements of customers.

8.[STORAGE AND TRANSPORT]

Packaged brackets should be stored under the ventilated clean room without corrosive air.

9.[VALIDITY PERIOD]

Follows the appropriate transport and storage conditions, this product can be stored for 4 years.

10.[MANUFACTURER]

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11.[EUROPEAN COMMUNITY REPRESENTATIVE]

EU Authorised Representative Name: Lotus NL B.V.

Address:Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

12.[Definition of symbol]

No	Symbol	Definition	No	Symbol	Definition
1		Keep dry	10		Use-by Date
2		Keep away from sunlight	11		Batch code
3		Country of manufacture, Date	12		Unique Device Identifier
4		Do not re-use	13		Caution
5		CE marking of conformity, and Notified Body Code	14		Manufacturer
6		Do not use if package is damaged and consult instructions for use	15		Authorized representative in the European Community / European Union
7		Medical device	16		Consult instructions for use or consult electronic instructions for use
8		Non-sterile	17		MR unsafe
9		Medical device	18		Date of manufacture