

Instructions for Use
Orthodontic Lingual Buttons


- 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 Lingual Buttons

2. DESCRIPTION/INDICATIONS

The orthodontic lingual button is an accessory of orthodontic treatment and is used together with other orthodontic materials, e.g. orthodontic brackets, bands, tubes, archwires and elastomers, etc for movement of teeth.

Orthodontic lingual buttons aid in the seating and positioning of band as well as accepting maxillary and mandibular appliances such as palatal bars and quad helix appliances.

The orthodontic lingual button can be directly bonded to the lingual side of the crown or is used together with the buccal tube. The main function of the device is to use the orthodontic elastic accessory to cooperate with the lingual side buckle to adjust the position of the tooth through a certain sustained external force, so as to restore the correct occlusion relationship or consolidate the treatment effect after the completion of the tooth deformity treatment.

The orthodontic lingual button is principally composed of a lingual button body and base plate. Both parts are integrally formed. The base plate has a net pattern.

Orthodontic lingual buttons are divided into bondable and weldable types. Bondable orthodontic lingual buttons have three variants: button bondable type, double wing bondable type and guide plate bondable type. From the weldable orthodontic lingual button, only one variant is available: hook weldable type.

Intended Purpose

The orthodontic lingual button is intended for orthodontic movement of teeth.

The device is intended to be used together with orthodontic bracket, bands, tubes, archwires and elastomers, etc, to move the teeth to desired positions. It is used for correction of twisted and crooked teeth.

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

3. SPECIFICATION
Table 1 Types and Dimension of Orthodontic Lingual Buttons

	l (mm)	w (mm)	h (mm)	Φ (mm)	Θ (°)
Button bondable type	2.0±0.2	0.9±0.2	2.1±0.2	3.5±0.2	/
Double wing bondable type	5.0±0.2	1.0±0.2	1.7±0.2	4.1±0.2	/
Guide plate bondable type	3.5±0.2	1.0±0.2	3.8±0.2	4.1±0.2	72±5
Hook weldable type	7.0±0.2	1.0±0.2	1.0±0.2	--	--



4. CONTRAINDICATIONS

Orthodontic lingual buttons should not be used for persons with periodontitis.

Orthodontic lingual buttons are contraindicated for those who are allergic to chromium and nickel.

5. CAUTIONS and WARNINGS

- The orthodontic lingual buttons should only be operated by dentists that have taken professional training;
- Pay attention to keep the mouth hygiene. During use, use a soft toothbrush to gently brush up and down under the guidance of a dentist;
- Do not bite hard or sticky food, do not chew gum;
- Do not use such devices after exceeding the shelf life;
- 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 lingual buttons 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 lingual button should be routinely cleaned prior to use, e.g. with water or ethanol.
- 3) Bonding method (applicable to the bondable orthodontic lingual button)
 - Clean the tooth surface: use a cup-shaped rubber wheel to finely grind the tooth surface to remove the tartar, color stains, then rinse the surface with water and dry it with alcohol. Blow the tooth for drying. Using mouth opener and pad cotton and sucking saliva to facilitate acid etching by separating the operation area from the wet. Those with enamel dysplasia should properly erase the tooth surface.
 - Tooth surface etching treatment: directly coat the acid etchant on the tooth surface, on which the orthodontic lingual button should be placed, the area is slightly larger than the area of the base plate. the acid treatment time is 60-90 seconds, and for the dental fluorosis the time is 2-3 minutes.
 - Rinsing and drying: After acid etching, the tooth surface must be thoroughly rinsed with water. Rinse off the acid and debris, and then dry the tooth surface with warm air or compressed air. At this time, the tooth surface is dull and white etched. Strictly prevent re-contamination of the treated tooth surface by saliva.
 - Affixing orthodontic lingual button: modulate the adhesive material as required. Firstly, apply the primer to the surface of the etched tooth, then use the air pistol to gently blow the primer to form a thin layer on the tooth surface. Apply an appropriate amount of adhesive onto the base plate. Put the orthodontic lingual button on the respective tooth surface and press it slightly. Remove the residual adhesive in time and keep the tooth surface around the orthodontic lingual button smooth.
 - Curing: After placing the orthodontic lingual button on the correct position, cure the adhesive by a light curing machine, so that the device is firmly attached to the crown surface.
- 4) Welding method (for Weldable Orthodontic Lingual Button): welding the orthodontic lingual button onto the tongue side of the orthodontic band for use with the orthodontic band.
 - Clean the tooth surface: use a cup-shaped rubber wheel to finely grind the tooth surface to remove the tartar, color stains, then rinse the surface with water (> 3 times) and dry it with alcohol.
 - Placement: Place the weldable orthodontic lingual button on the optimal position of the tooth surface with a loop.

- Engagement: The weldable orthodontic lingual button is engaged on the surface of the crown with special tongs for orthodontics.

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



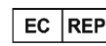
UDI code



Manufacturer



Medical device



Authorized representative in the European Community



Importer



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