

Instructions for UseOrthodontic Buccal Tubes

- 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 Buccal Tubes

2. DESCRIPTION/INDICATIONS

Orthodontic tubes are devices used in orthodontics that align and straighten teeth and help position them with regard to a person's bite, while also aiming to improve dental health. Orthodontic tubes also fix gaps. They are often used to correct underbites, as well as malocclusions, overbites, open bites, deep bites, cross bites, crooked teeth, and various other flaws of the teeth and jaw. Orthodontic Tubes are often used in conjunction with other orthodontic appliances to help widen the palate or jaws and to otherwise assist in shaping the teeth and jaws.

Orthodontic tube is a time-tested part of major and minor orthodontic treatment. These tubes are fabricated from durable stainless steel in order to provide the strength required to move teeth. The tubes are placed on the patient's teeth with an adhesive and then connected to each other via wires and bands in order to provide the precise teeth movements the patients require.

Orthodontic tube consists of tube body and base plate. There is a hook attached to the tube body.

According to clinical treatment techniques, orthodontic tubes can be divided into three types: ROTH, Edgewise and MBT. These three tubes differ in the torque angle (θ) and the angulation (α) of the tube design. According to the width of product slot, it can be divided into: 18 (0.018" or 0.46mm) and 22 (0.022" or 0.56mm) variants.

The Tube body and the cover are made of stainless steel 05Cr17Ni4Cu4Nb and the base plate is made of stainless steel 06Cr19Ni10.

There is a horizontal square slot in the middle of the tube body to accommodate the arch wire. The base plate of the orthodontic tube is intended to be adhered onto the surface of the crown, and the base has a mesh-type structure that increases the adhesion and retention.

Orthodontic tubes provide with a well-designed, reliable and predictable orthodontic solution, offering a better experience both chairside and in treatment. Metal-injection molded for dimension consistency and rounded surfaces, the tubes have a contoured shape and hook designed for both practicality and comfort. Funneled features allow for easier mesial wire insertion, and deep distal notch provides more effective wire crimping. Multiple torque and angulation options meet the varied treatment needs of different patients.

Orthodontic tubes are compliant to EN ISO 27020.

Orthodontic tube is used temporarily and is removed after orthodontic treatment has been completed.

Intended Purpose

Orthodontic tube is intended for orthodontic movement of teeth.

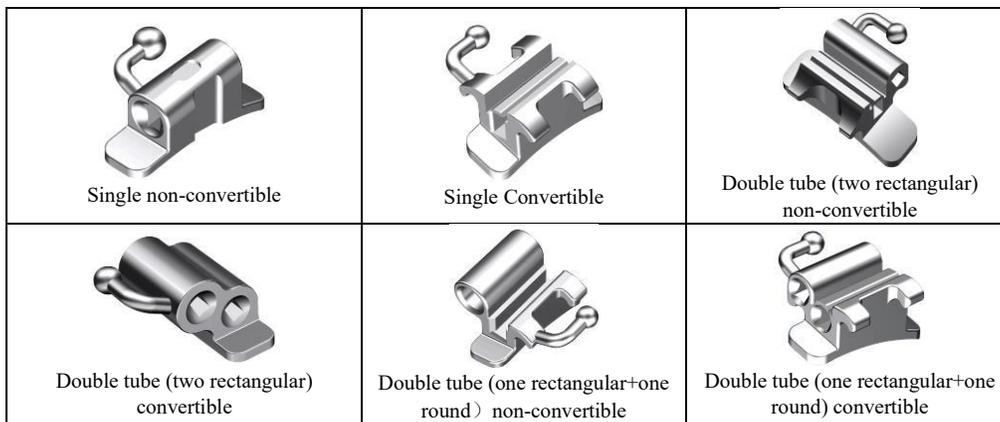
They are indicated for orthodontic treatment in patients of all ages when prescribed by an orthodontist.

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

3. SPECIFICATION

Table 1 Specification of Orthodontic Tube Types

Type	Tooth Position	Torque Angle θ	Angulation	Length M/D
ROTH	16	-14°	10°	4.0 mm
	26	-14°	10°	4.0 mm
	36	-30°	4°	4.0 mm
	46	-30°	4°	4.0 mm
	17	-14°	10°	3.5°
	27	-14°	10°	3.5°
	37	-30°	4°	3.5°
	47	-30°	4°	3.5°
Edgewise	17	-14°	10°	3.5°
	27	-14°	10°	3.5°
	37	-10°	0°	3.5°
	47	-10°	0°	3.5°
MBT	17	-14°	10°	3.5°
	27	-14°	10°	3.5°
	37	-10°	0°	3.5°
	47	-10°	0°	3.5°


Figure 1 Schematic Diagram of Orthodontic Tubes

4. CONTRAINDICATIONS

Orthodontic Tubes are contraindicated for those who are allergic to chromium and nickel. The device should not be used for patients with periodontitis.

5. CAUTIONS and WARNINGS

- Prior to use, soaking the device with 75% alcohol for 20 to 30 minutes;
- When the adhesive begins to cure, the orthodontic tube should no longer be moved, otherwise the bonding would be affected;
- Pay attention to keep the mouth hygiene;
- Do not bite hard or sticky food, do not chew gum;
- This is single-use device. A re-use is not allowed. An infection or transmission of diseases could occur, if the device were to be re-used.

6. POTENTIAL COMPLICATIONS

Complications of orthodontic buccal tubes 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) 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.
- 2) Tooth surface etching treatment: directly coat the acid etchant on the tooth surface, on which the orthodontic tube should be placed, the area is slightly larger than the area of the bracket base plate. The acid treatment time is 60-90 seconds, and for the dental fluorosis the time is 2-3 minutes.
- 3) 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.
- 4) Positioning: Draw the positioning reference line of the orthodontic tube attachment position on the tooth surface by using a bracket locator.
- 5) Affixing orthodontic tube: 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 tube on the respective tooth surface and press it slightly. Remove the residual adhesive in time and keep the tooth surface around the orthodontic tube smooth.
- 6) Curing: After placing the orthodontic tube in the correct position, cure the adhesive by a light curing machine, so that the orthodontic tube is firmly attached to the crown surface.

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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