



Instructions for Use

Orthodontic Ceramic Brackets



- 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 Ceramic Brackets

2. DESCRIPTION/INDICATIONS

Orthodontic brackets 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 brackets 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 brackets 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 ceramic bracket consists of bracket body, bracket wing and base plate. According to clinical treatment techniques, orthodontic ceramic brackets can be divided into three types: ROTH, Edgewise and MBT. These three brackets differ in the torque angle (θ) and the angulation (α) of the bracket design. The type ROTH don't have pre-formed slots in the bracket. During the use, three series of bending are bent on the archwire; the types Edgewise and MBT have pre-formed slots in the bracket. For these types, three series of bending are used to the pre-formed slots in the bracket. 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. Due to the locking equipment of the device, they are divided into: standard bracket and bracket with self-locking. According to the availability of hook on the tooth position #3/4/5 the devices can be divided into 3 groups: no hook, hook on tooth #3 and hook on tooth #345.

Orthodontic ceramic brackets are compliant to EN ISO 27020. They are made of aluminium oxide (Al_2O_3) ceramic.

Intended Purpose

Orthodontic ceramic bracket is intended for orthodontic movement of teeth.

The device is intended to be bonded to teeth, upon which an orthodontic wire is placed to move the teeth to desired positions. 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 Dimensions of Orthodontic Ceramic Brackets, Type ROTH (0.018"/0.022")

Tooth Position	Bracket in-out l_i (mm)	Slot depth d (mm)	(0.018") Slot width h (mm)	(0.022") Slot width h (mm)	Slot length l_s (mm)	Angle of torque θ (°)	Angulation α (°)	Basal arc R (mm)	Bracket bottom thickness H(mm)
(1 \perp 1)	1.10 ± 0.2 0	$0.70_{0}^{+0.30}$	$0.46_{0}^{+0.06}$	$0.56_{0}^{+0.06}$	3.50 ± 0.30	$12 \pm 1^\circ$	$5 \pm 1^\circ$	$3 - \infty$	0.7 ± 0.07
(2 \perp 2)	1.20 ± 0.2 0	$0.70_{0}^{+0.03}$	$0.46_{0}^{+0.06}$	$0.56_{0}^{+0.06}$	3.20 ± 0.30	$8 \pm 1^\circ$	$9 \pm 1^\circ$	$3 - \infty$	0.7 ± 0.07
(3 \perp 3)	1.00 ± 0.2 0	$0.70_{0}^{+0.30}$	$0.46_{0}^{+0.06}$	$0.56_{0}^{+0.06}$	3.20 ± 0.30	$-2 \pm 1^\circ$	$10 \pm 1^\circ$	$3 - \infty$	0.7 ± 0.07
(54 \perp 45)	1.00 ± 0.2 0	$0.70_{0}^{+0.30}$	$0.46_{0}^{+0.06}$	$0.56_{0}^{+0.06}$	3.20 ± 0.30	$-7 \pm 1^\circ$	$0 \pm 1^\circ$	$3 - \infty$	0.7 ± 0.07
(21 \perp 12)	1.20 ± 0.2 0	$0.70_{0}^{+0.30}$	$0.46_{0}^{+0.06}$	$0.56_{0}^{+0.06}$	3.00 ± 0.30	$-1 \pm 1^\circ$	$0 \pm 1^\circ$	$3 - \infty$	0.7 ± 0.07



(3┐3)	1.00 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$-11 \pm 1^\circ$	$7 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(4┐4)	1.00 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$-17 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(5┐5)	1.00 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$-22 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07

Table 2 Dimensions of Orthodontic Ceramic Brackets, Type Edgewise (0.018"/0.022")

Tooth Position	Bracket in-out l_i (mm)	Slot depth d (mm)	(0.018") Slot width h (mm)	(0.022") Slot width h (mm)	Slot length l_s (mm)	Angle of torque θ (°)	Angulation α (°)	Basal arc R (mm)	Bracket bottom thickness H(mm)
(1┐1)	1.40 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.50 ± 0.30	$0 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(2┐2)	1.40 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$0 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(3┐3)	1.00 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$0 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(54┐45)	1.10 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$0 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(21┐12)	1.30 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.00 ± 0.30	$0 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(3┐3)	1.00 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$0 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(4┐4)	1.10 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$0 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(5┐5)	1.10 ± 0.2 0	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$0 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07

Table 3 Dimensions of Orthodontic Ceramic Brackets, Type MBT (0.018"/0.022")

Tooth Position	Bracket in-out l_i (mm)	Slot depth d (mm)	(0.018") Slot width h (mm)	(0.022") Slot width h (mm)	Slot length l_s (mm)	Angle of torque θ (°)	Angulation α (°)	Basal arc R (mm)	Bracket bottom thickness H (mm)
(1┐1)	1.10 ± 0.20	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.50 ± 0.30	$17 \pm 1^\circ$	$4 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(2┐2)	1.20 ± 0.20	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$10 \pm 1^\circ$	$8 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(3┐3)	1.00 ± 0.20	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$-7 \pm 1^\circ$	$8 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(54┐45)	1.00 ± 0.20	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$-7 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(21┐12)	1.20 ± 0.20	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.00 ± 0.30	$-6 \pm 1^\circ$	$0 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(3┐3)	1.00 ± 0.20	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$-6 \pm 1^\circ$	$3 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(4┐4)	1.00 ± 0.20	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$-12 \pm 1^\circ$	$2 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07
(5┐5)	1.00 ± 0.20	$0.70_0^{+0.30}$	$0.46_0^{+0.06}$	$0.56_0^{+0.06}$	3.20 ± 0.30	$-17 \pm 1^\circ$	$2 \pm 1^\circ$	$3-\infty$	0.7 ± 0.07

4. CONTRAINDICATIONS

Orthodontic ceramic brackets are contraindicated for patients with tooth tissue dysplasia. The device should not be used for patients with periodontitis.

5. CAUTIONS and WARNINGS

- Select correct size of orthodontic ceramic brackets according to the orthodontic method used;
- Prior to use, soaking the device with 75% alcohol for 20 to 30 minutes for disinfection;
- When the adhesive begins to cure, the buccal tube with the ring should no longer be moved, otherwise the bonding would be affected;
- 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 re-use 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














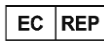

Complications of orthodontic ceramic brackets are documented. These complications may include:

- 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 bracket 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 bracket attachment position on the tooth surface by using a bracket locator.
- 5) Soak the device for 20-30 minutes with 75% alcohol for disinfection, then rinse the residual disinfectant with sterile water (more than three times, 1 minute each time).
- 6) Select brackets with correct angulation (α) for each tooth position.
- 7) Affixing bracket: 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 bracket on the respective tooth surface and press it slightly. Remove the residual adhesive in time and keep the tooth surface around the bracket smooth.
- 8) Curing: After placing the bracket in the correct position, cure the adhesive by a light curing machine, so that the bracket 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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