

## Product information

Product Name : Spa Orthodontic Ceramic Bracket



Brand Name : Spa Orthodontic Ceramic Bracket

GMDN CODE : 58937

GMDN TERM : Orthodontic bracket

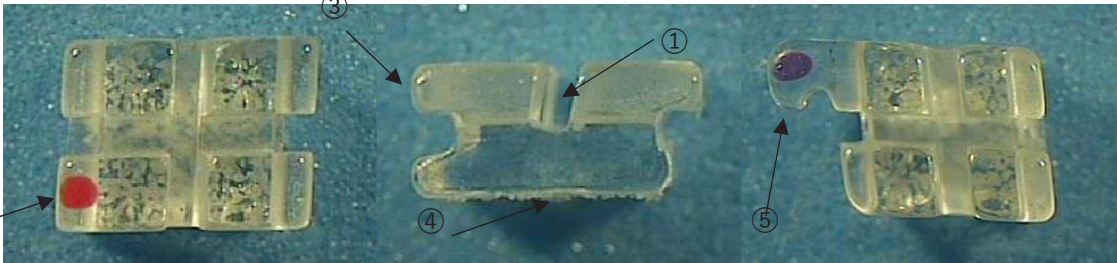
## 1. General Description

Ceramic Spa Orthodontic Ceramic Bracket is made of monocrystalline (Al<sub>2</sub>O<sub>3</sub>) intended to be placed on teeth to straighten the teeth.

## 2. Key performance claims

- ✓ Transparent material, single crystal sapphire provides aesthetic satisfaction Unique heat treatment technology provides the powerful strength and bonding strength (Avg. 15 mpa) to the bracket. The special base surface
- ✓ minimizes damage to the enamel surface during debonding
- ✓ Low profile (2.0~2.2 mm) and smooth surface for maximum patient comfort

## 3. Product composition

		
No	Part name	Description
①	Slot	Space where orthodontic archwires are inserted
②	Marking	Colour dots for easy identification of teeth position
③	Tie wing	Parts that hold the archwires inserted into the bracket using elastics or ligature wire
④	Base	The part that attaches directly onto the surface of the teeth. (For bonding process, orthodontic adhesive, curing light, and etching gel could be used together.)
⑤	Hook	The part that attaches the rubber bands needed to move the tooth to the ideal position

## 4. Intended use

Spa Orthodontic Ceramic Bracket is attached to the surface of the teeth for the treatment of malocclusions.

## 6. Contraindications

- ✓ Heavy smoker, Drug / Alcohol abuser
- ✓ Patient with poor oral hygiene
- ✓ Patient who is uncooperative in an orthodontist's treatment plan
- ✓ Any illness and/or underlying conditions that preclude orthodontic treatment.

## 7. Preparation before use

- Keep a clean working environment without saliva or contamination.
- Check if the product is defective.
- The base of the bracket shall be kept clean to ensure the best bonding performance.
- Disinfect the bracket with a suitable solvent for disinfect/cleaning and dry thoroughly before use.

## 8. Bonding

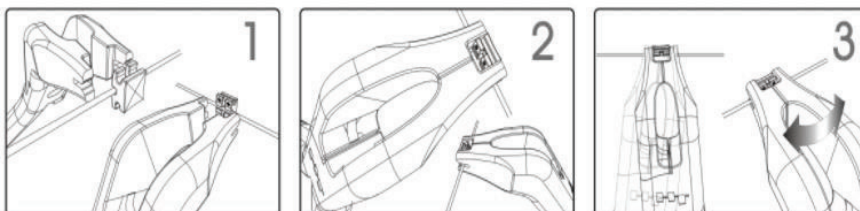
Orthodontic adhesives and various dental instruments are required for bonding or de-bonding the orthodontic brackets to/from the patient's teeth. Other ancillary orthodontic materials generally available to the orthodontic industry, such as archwires, elastics, power chain, and closed/open coil springs, can be used for orthodontic treatment in conjunction with the Spa Orthodontic Ceramic Bracket.

For bonding, DB Orthodontics recommend using light curing type orthodontic adhesive.

- 1) Perform the etching process before attaching the bracket. If a third party's etching gel is used, it shall be possible to follow the manufacturer's instruction of the product for proper use.
- 2) Apply adhesive to the surface of the teeth, take out the bracket from the product case and attach it to the appropriate position of the teeth by referring to the guide shown on the inside of the case.
- 3) Finishing bonding of brackets using a curing light.

## 9. De-Bonding

To minimize damage to the enamel, use a suitable de-bonding instrument. Gently hold the bracket with a de-bonding instrument, and remove the bracket properly. Each of the de-bonding instruments has its own shapes and methods of use, so be sure to comply with the manufacturer's instructions.



## 10. Warnings and Precautions for use

- Chewing on hard or harsh foods may cause the brackets attached to the teeth to fall off or the product to deteriorate.
- The Spa Orthodontic Ceramic Bracket is single-use only. If the bracket is distorted or broken, discard and attach a new bracket.
- Orthodontic brackets should be used in conjunction with appropriate orthodontic materials or equipment for safe and effective orthodontic treatment.
- Remove colour dot after bonding
- For use by dentists and orthodontists only.
- Bracket already used for treatment of other patients is prohibited from being reused.  
(The manufacturer is not responsible for intra-oral infections, product deformation and degradation of bonding performance caused by reuse.)
- For third-party devices or accessories for orthodontic treatment, we recommend using certified products (CE, ISO, FDA, etc).
- Use or storage in contaminated environments can cause biological toxicity (e.g. cytotoxicity).

## 11. Storage

- Do not expose products to high temperatures or intense light.
- Please store in a well-ventilated, shady and dry place.
- Please store at room temperature

## 12. Shelf life

5 Years from manufacture.











### 13. Warranty and Limitation of liability








DB Orthodontics Ltd. warrants Spa Orthodontic Ceramic brackets defects by the manufacturer only. DB Orthodontics Ltd. will replace defected products immediately or refund the purchase price. DB Orthodontics Ltd. is not liable for any loss or damages arising from Spa Orthodontic Ceramic brackets, whether direct, indirect, special, incidental or consequential, regardless of the theories asserted, including warranty, contract, negligence or strict liability. These limitations do not apply to third party personal injury claims.

### 14. Chemical composition

Raw Material	Monocrystalline Alumina	Criteria	Test results
Composition	Al <sub>2</sub> O <sub>3</sub>	≥ 98.4	99.85
	SiO <sub>2</sub>	≤ 0.06	0.042
	Fe <sub>2</sub> O <sub>3</sub>	≤ 0.03	0.017
	Na <sub>2</sub> O	≤ 0.70	< 0.010
Hazardous Elements Information	Ni	≤ 0.1	< 0.001
	Cd	≤ 0.1	< 0.001
	Pb	≤ 0.1	< 0.001
	Be	≤ 0.1	< 0.001

### 15. Symbols Glossary

Symbols	Symbol Title – Explanatory Text
	<b>Manufacturer</b> Indicates the medical device manufacturer as defined EU Directives and Regulations
	<b>Authorized Representative in the European Community</b> Indicates the Authorized representative in the European Community
	<b>Caution</b> Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	<b>CE Marking / EU Notified Body Number</b> In compliance with 93/42/EEC Directive on Class IIa or IIb medical devices
	<b>Consult Instructions for Use</b> Indicates the need for the user to consult the instructions for use
	<b>Catalog Number</b> Indicates the manufacturer's catalogue number so that the medical device can be identified
	<b>Batch Code</b> Indicates the manufacturer's batch code so that the batch or lot can be identified
	<b>Date of Manufacture</b> Indicates the date on which a product was manufactured
	<b>Use-by Date</b> Indicates the date after which the medical device is not to be used
	<b>Keep away from sunlight</b> Indicates a medical device that needs protection from light sources

	<b>Do Not Re-use</b> Indicates a medical device that is intended for one use, or for use on a single-patient during a single procedure
	<b>Non-Sterile</b> Indicates a medical device that has not been subjected to a sterilization process
	<b>Medical Device</b> Indicates that the device is a medical device
	<b>Keep Dry</b> Indicates a medical device that needs to be protected from moisture
	<b>Damaged Packaging</b> Do not use if packaging is damaged
	<b>Model Number</b> Indicates manufacturer's model number
	<b>Use-by-date</b> Indicates the date after which the medical device is not to be used

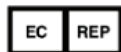
## 16. Information of Manufacturer, EU Representative



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