

- 3) If the bracket has been contaminated (e.g., moisture), rinse the bracket in isopropyl alcohol and allow to dry.
- 4) Prepare the tooth surface and bond the bracket using the procedure as described by the adhesive manufacturer.
- (6) Storage and maintenance after use
 - 1) This product is a disposable medical device and should not be reused.
 - 2) Any product removed after teeth correction completes and disjoined one due to shock during the correction should be immediately discarded.

Physical and Chemical Characteristics

- (1) A declaration of chemical composition
 - 1) Bracket : Stainless steel (SUS 630) 100%
 - 2) Clip : Stainless steel (SUS 304) 100%
- (2) Hazard elements
 - 1) Nickel(Ni) : clip : 8.1 ~ 8.5% & body : 3.0 ~ 5.0 %
 - 2) Beryllium(Be) : 0.02% or below
 - 3) Cadmium(Cd) : 0.02% or below
 - 4) Lead(Pb) : 0.02% or below

(3) Range of Dimension

Item	ZEUS Bracket & ACTFIA METAL SL & ProSlide™ active	META Bracket
In-out(mm)	0.6mm ~ 1mm	0.6mm ~ 1.18mm
Slot height(mm)	0.5mm ~ 0.6mm	0.5mm ~ 0.6mm
Slot depth(mm)	0.47mm ~ 0.61mm	0.47mm ~ 0.61mm
Slot length(mm)	2.5mm ~ 3mm	2.2mm ~ 3.1mm
Angulation(°)	0° ~ 11°	0° ~ 11°
Angle of torque(°)	-17° ~ 17°	-17° ~ 17°

STORAGE CONDITIONS

Keep at room temperature out of direct sunlight.











DISPOSAL METHOD

Disposal of all orthodontic appliances must follow regional and national regulations.

CONTACT

Tel : +82-505-600-8880
 Fax : +82-505-333-8880
 Homepage : <http://www.gniortho.com>

[Pictograms]

	MANUFACTURER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	DATE OF MANUFACTURE		KEEP AWAY FROM SUNLIGHT
	DO NOT REUSE		CONSULT INSTRUCTIONS FOR USE
	LOT NUMBER		CATALOGUE NUMBER
	CAUTION		CE Marking



GNI Co., Ltd.

5F 501, 63-12, Dongtanchheomdansaneop 1-ro, Hwaseong-si, Gyeonggi-do, Korea



E.M.23-Konsident Ltd.

62 Deyan Belshiki str. 1404 Sofia, Bulgaria



Instructions for use

ProSlide™ active mini

Rhodium

 OrthoDepot™

[Instructions for Use]

DESCRIPTION

This product is an orthodontic bracket attached to teeth to recover aesthetics and function of malocclusion. Made with metal materials, it is attached to teeth and straightens irregular teeth with orthodontic wire installed through the wire's elasticity.

(1) ZEUS Bracket & ACTFIA METAL SL & ProSlide™ active

It is made with metal materials and seeks smooth movement of orthodontic wire for straightening irregular teeth and it has self-ligating Clip to fix Wire.

(2) META Bracket

It is made with metal materials and seeks smooth movement of orthodontic wire for straightening irregular teeth and it requires additional rubber ring or ligating wire to fix Wire.

INTENDED USE

This product is an orthodontic bracket attached to teeth for straightening irregular teeth.

INDICATIONS : Malocclusion

CONTRAINDICATIONS

- (1) Known allergies to Nickel when applying for ZEUS bracket only.
- (2) Patients with uncontrolled diabetes.
- (3) Patients with active periodontal disease.
- (4) Instruct patients not to chew or bite on hard substances such as hard candy, ice, carrots, etc.

SIDE EFFECTS

Discomfort, gum disease, bleeding of the gums, tooth decay, marking/staining of the teeth around the brackets, root resorption, degeneration of the nerve inside the tooth, ankylosis, injuries, earaches, headaches, orthodontic relapse, pain, pulpal change, gingivitis, alveolar bone loss, loss of attached gingival support, decalcification of enamel, masticatory muscle pain, internal derangement of the temporomandibular joint disc and degenerative temporomandibular joint disorders.

INTENDED USER : Dentist

Cautions for use

(1) Warning

- 1) The product should be used only by medical experts and it should not be used for any purposes other than its intended use.
- 2) It should be confirmed whether a patient is nickel-allergic before use as it may cause nickel allergy.
- 3) A product whose packaging is damaged should not be used.
- 4) Instruct patients not to chew or bite on hard substances such as hard candy, ice, carrots, etc. Careful and thorough patient instruction is a key to avoiding appliance or enamel damage.

(2) General cautions

- 1) Do not apply excessive power upon use.
- 2) Replace any disjoined product and attach a new one.
- 3) Upon reattachment, place the product on a right place for tooth correction in accordance with a dentist's judgments and directions.
- 4) Discard an exchanged product.
- 5) A dentist's judgments and directions should be followed whenever the product is used.
- 6) Discard the product immediately after using it.
- 7) Consult a specialist if a bioincompatible reaction occurs after our product is used.
- 8) Contact our company if there is any question about our product.

INSTRUCTIONS FOR USE

(1) Preparations before use

- 1) Check whether a product's name is identical with what one intends to use.
- 2) Check whether there is any crack, fracture or impurity on product.
- 3) Remove moisture and foreign substance on teeth's surface.
- 4) Teeth correction using this product should be performed under a dentist's judgments and directions.
- 5) Stop using the product immediately and contact us if there is any problem with product appearance.

(2) How to use

- 1) Check whether teeth and product's contact surfaces are clean.
- 2) Check the product's packaging and any abnormality and then treat it with universal tools like tweezers, etc.
- 3) Apply proper amount of bonding agent to make it adhere to the crown and follow rules for fixation based on adhesive type used.

- 4) After universal adhesive hardens, ligate universal wire inside the bracket slot.
- 5) Follow a dentist's treatment method and directions for teeth correction and surgical procedures.

(3) Bracket Bonding Method

- 1) GNI brackets can be used with traditional direct or indirect bonding methods. No change in bonding technique is necessary. For bonding procedures please follow the adhesive manufacturer's.
- 2) GNI brackets can be bonded using any standard bracket adhesive. Please note that it is absolutely necessary to adhere to the manufacturer's instructions for use of the relevant bracket adhesive, regarding the bonding of brackets.
- 3) When placing GNI brackets, it is suggested that the bracket be placed in a sliding motion, occlusal to gingival, forcing excess adhesive to the incisal edge of the bracket for easier clean-up.
- 4) Care must be taken when cleaning up adhesive flash so as not to disturb the final positioning before adhesive curing.
- 5) Before placing the archwire, patient should brush to remove the reference markers.

(4) Bracket Debonding Method

- 1) Remove adhesive flash around base of bracket to be debonded.
 Note: Failure to remove flash around bracket base, especially on the mesial-distal sides, may result in incomplete debonding.
- 2) Place the centering guide of the Self-Ligating Bracket Debonding Instrument vertically into the center of the bracket, perpendicular to the archwire slot. Be sure that the inner ledges of the instrument are symmetrically positioned against the tie-wings of the bracket.
- 3) Gently squeeze instrument handles until the GNI bracket collapses. Gently rock the bracket in the mesial or distal direction to completely separate the bracket from the enamel, if necessary.
 Note: Extra caution should be taken when debonding without the archwire in place.
 Maintain the hold on the bracket to keep the debonded bracket parts in the instrument tips.

(5) Bracket Rebonding Method

- 1) Carefully inspect the bracket for any damage. Brackets that have fractured through the vertical debonding slot cannot be rebonded and must be replaced. If a tie-wing is cracked, replace the bracket.
- 2) Remove any excess adhesive. Extra care must be taken to prevent chipping or breaking of the bracket. Use a hand scaler to remove any excess flash from around the edges of the bracket. Do not use a bur. Do not attempt to scrape adhesive from the base of the bracket or attempt to micro-etch the adhesive as this may damage the bracket's bonding surface.