

English

Instruction for Use:IFU-00060 -0006

MS/ANVISA No.:10396830037

ANVISA Technical Name:Components for Orthodontics

Comercial Name in ANVISA:BRÁQUETES, BANDAS E TUBOS

Important: To consult the Instruction for Use, check the version indicated on the product label along with the code, and access the digital file at www.morelli.com.br/IFU. To get the printed Instruction for Use, without cost, please let us know through our Customer Service at +55(15)3328-8200 or send us an email at sac@morelli.com.br. For chemical compositions request Security Datasheet of the product.



Fabricado por:

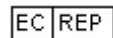
Dental Morelli Ltda.

Alameda Jundiá, 230/250 – Jardim Saira

CEP/ ZIP Code: 18085-090 Sorocaba – SP Brazil

Tel.: +55(15)3328-8200 / 0800 0121455 / 0800 7031455

Technical Responsible: Roger Morelli CREA-SP 5060214985



Representante Europeu

Nuno Flores

Al. Bonifácio Lázaro Lozano, 3 Piso / Floor O - C

Oeiras – Portugal – 2780125

Tel.: 351 21 4439292

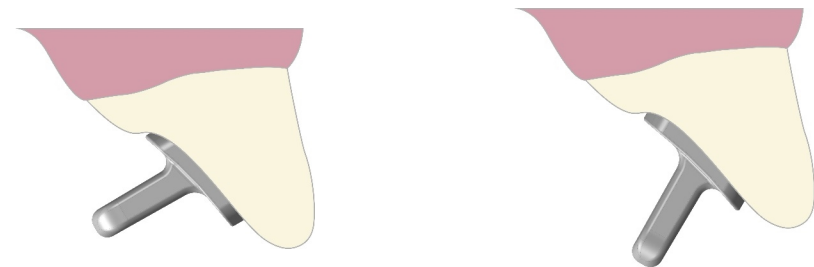
Stop and Bite Guide



The Stop and Bite Guide is an orthodontic device designed to compose the dental appliance. They are uniquely sized and are installed by bonding on the lingual surface of the Upper Central Incisors teeth, associated with the use of orthodontic adhesives.

In this regard, its installation basically requires procedures and care similar to those applied in the installation of orthodontic brackets. Its main function is to decrease the contact and / or impact of the Upper Teeth with the Brackets installed in the Lower Teeth, since it works by opening the bite, at the same time as it provides the reeducation and the muscular rest.

The Stop and Bite Guide, as its name suggests, is a device that makes it possible to use two functions: stop function and guide function. These functions are obtained by varying the installation position of the device. The following figure is intended to exemplify such positions:



On the left, device positioned in stop function; to the right, device positioned in the guide function.

Use indication:

The most common clinical situations are:

- Accelerates overbite correction (deep bite), with posterior extrusion, when associated with the use of intermaxillary elastics;
- Prevention of upper teeth touching the lower brackets;
- Intrusion of incisors (upper/lower);
- Neuromuscular deprogramming.

Patient Indication: all ages with indication for orthodontic treatment.

Intended User: use and installation by a qualified professional.

Bonding:

Use **Orthoprimer** and **Orthobond** for effective bonding.

Bonding warning:

All products intended for bonding are sandblasting and undergo a thorough decontamination of the bases.

Do not touch the bonding surfaces before applying primer/adhesive, as any contact can cause contamination causing adhesive interface failures.

Do not use disinfection and sterilization methods to the base as they can contaminate or compromise them, causing the restraint system to fail.

Do not blast, clean or apply other types of silane to the base of any part, as the ideal surface treatment is already carried out during manufacturing. Therefore, only Orthoprimer should be applied to the enamel or base of the piece before gluing.

In case of base contamination, discard and replace the part.

Proceed with adequate insulation at the time of bonding, avoiding contamination by blood or saliva.

It is recommended to glue one tooth at a time. Preparing teeth simultaneously increases the risk of failure due to saliva contamination, early photopolymerization of the primer on adjacent teeth, etc.

In bonding always use orthodontic adhesives, which promote better adhesion and facilitate the removal of residual adhesive from the tooth, preserving its enamel. Non-orthodontic resins are denser, penetrate less at the base and are difficult to remove from the tooth and consume more drills.

It is recommended to apply a minimum film sufficient to cover the surface of the enamel and the base of the pieces. Remove any excess Orthoprimer with an air jet, in the gingival direction, avoiding compromising the bonding area with saliva. Excess orthoprimer compromises the bonding and can cause the part to move out of position until light-cured.

Prior photopolymerization of Orthoprimer compromises its adhesion to the adhesive.

Debonding:

Use bracket removal instrument.

Contraindications:

Morelli supplies the products only to qualified professionals. It is the responsibility of the orthodontist to identify conditions that may be contraindicated for treatment, such as:

- Patients with poor oral hygiene.
- Patients unable to cooperate with treatment.
- Patients with propitious oral environment to dental enamel demineralization.
- Allergy to any of the materials of the orthodontic appliance.
- Diseases or other pre-existing conditions that may hinder orthodontic treatment.
- Root resorption.
- Existing bone resorption.
- Existing Decalcification in dental enamel;
- Use in a Magnetic Resonance environment.

Side effects:

It is the responsibility of the qualified professional to identify any possibility of risk and/or contraindication that may arise during treatment, communicate to the patient the possibility of any unwanted side effect.

During treatment, unwanted side effects may include:

- Damage to oral mucosa and tongue;

- Difficulty in speaking or chewing;
- Tooth discoloration;
- Decalcification;
- Root resorption;
- Periodontal complications;
- Allergic reactions;
- Difficulties in maintaining oral hygiene;
- Pain;
- Discomfort;
- Sensitivity.

Expiry date:

120months.

Warnings:

During the first few days, using the device may make eating difficult as it reduces chewing efficiency for a certain period. In this case, it may be temporarily recommended to eat soft foods.

Misalignment of the devices can promote undue intrusion of the incisor(s).

Occlusion force can generate intrusive components, which requires case-by-case assessment.

If the device detaches, it is recommended that the patient seeks the qualified professional who installed it.

Orient the patient NOT TO CHEW OR BITE HARD FOOD during orthodontic treatment to prevent premature detachment.



The presence of this product may produce an image artifact in a Magnetic Resonance Imaging exam in the head and/or neck region. Some manipulation of the scanning parameters may be necessary to compensate for the artifact or remove it, as determined by the healthcare professional, laboratory or hospital.



This product contains Nickel and Chromium. A small percentage of the population is allergic to these metals. In case of allergic reactions, advise the patient to seek medical attention.



Non-reusable product, as its reuse may cause cross infection, reduced bonding efficiency and loss of mechanical properties due to natural wear.

The product is supplied in unsterile condition, however has proven biocompatibility, not being necessary cleaning, disinfection or sterilization measures, since the package has not been violated. If the product comes into contact with surfaces or substances other than its intended purpose prior to use, it is recommended to discard the product. The product should not be reused or reprocessed.

Do not use the product if its packaging has been damaged or opened, in order to minimize possible dangers related to the transmission of microorganisms or possible falsification of products.

It is up to the qualified professional to guide their patients from the risk of aspiration and deglutition in the hypothesis of breakage / detachment of the pieces, should not be underestimated the possible immediate or late complications resulting from this type of accident and must adequately inform the patient and / or their legal guardians about the risks inherent in the event and what actions to take.

Product for exclusive application by a qualified professional, the use by person without the necessary technical knowledge may cause unwanted tooth movement, bone loss, loss of the dental element, fenestration, gingival recession or root dehiscence.

It is up to the qualified professional to guide the patient about correct oral hygiene, to avoid the appearance of plaque and tartar or diseases such as gingival inflammation (gingivitis), periodontitis or even endocarditis.

Considering that the product is used in contact with mucous membranes and body fluids, it is recommended to the professional to apply the sanitary norms applicable for the disposal of medical products in according to current sanitary regulations.

ATTENTION:

Morelli is not responsible for the results obtained by applying the product without the due precautions or non-observance of the warnings.

Reference:

¹ Notified Body

Code	Quantity	CE	NB ¹
30.60.001	10	-	-

Revision	Alterations
0	Elaboration and availability on the Morelli website.
1	Review of contraindications, side effects, warnings and inclusion of Orthobond Plus.
2	Review of bonding indication.
3	Review of the alerts regarding the use of the products in environment of MRI by image, inclusion of the contraindication and revision of the warning. Included Notify body number
4	Mask update, warnings and language adjustment.
5	Language adjustment.
6	Bonding review and bonding warning.