English

Instruction for Use: IFU-00033 -0005

MS/ANVISA No.: 10396830038

ANVISA Technical Name: Componentes para Ortodontia

Commercial Name in ANVISA: APARELHOS PARA ORTOPEDIA FUNCIONAL DOS MAXILARES

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.

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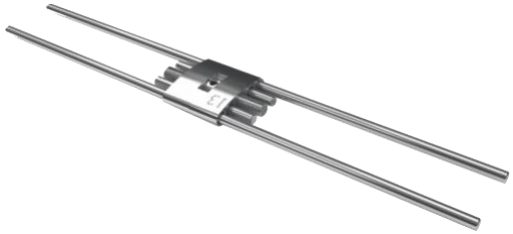
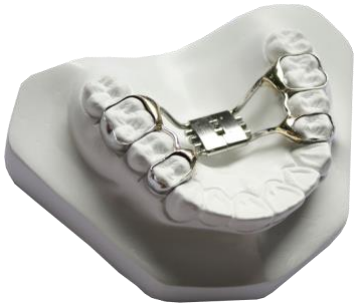
Expansion Screw for Palatal Split



These devices are designed to correct the occlusion of certain maxillomandibular regions, usually employed in the maxillary functional orthopedics, to:

To widen the dental arch in its transversal direction through the lateral forces application against the maxillary posterior teeth, producing the mesopalatine suture separation, having as result, the increase in the transverse dimension of the basal bones of maxilla employing orthopedic movements.

Such devices are fixedly employed in the patient and conjunction with orthodontic bands devices. After placement, the patient or sponsor, may be activation of the expansion screw according to the orthodontist guidance.

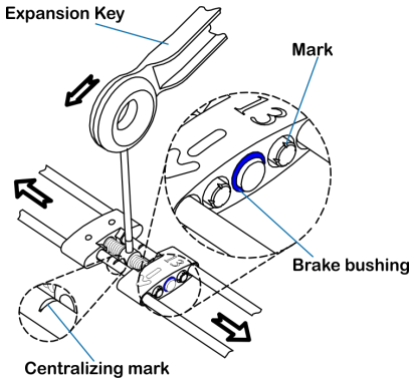


Use indication:

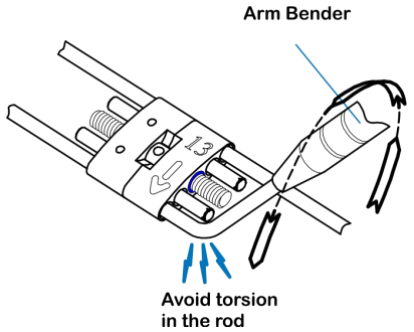
The most common clinical situations are:

- Correction of deficient maxillomandibular relationships;
- Cases of mixed/early permanent dentition;
- Posterosuperior bilateral crossbite, as a result of deficiency of the apical base of the maxilla;
- Anterior or posterior crossbite that are not too severe.

Installation:

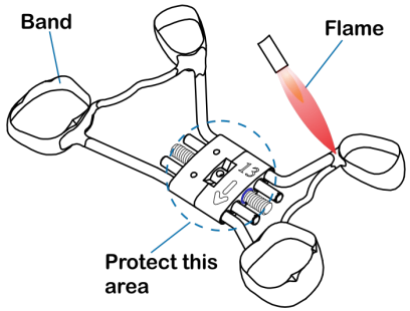


The Morelli expansion screws has a brake bushing designed to prevent the return of the screw during its activation. This bushing is made of high quality polymer. In cases where welds are performed close to the bushing region, it is recommended to protect the bushing to avoid material overheating, ensuring the product effectiveness. This protection can be performed by applying specific paste, gypsum, alginate or cotton dampened in water.



When shaping the expansion screw rods use suitable tools, such as the Arm Bending for bows (cod. 75.02.001) and the trident pliers.

Perform the needed folds with the desired angulation, avoiding to subject the rods to torsional stresses, which can weaken the rod as well as the weld, causing the fracture thereof.



When preparing the expansion screw avoid directing the flame on the expansion screw's body during the welding, avoiding to affect the product.

Activation:

For the activation, the appropriate key's, specifically designed for this application must be used.

The main characteristic of the Expansion Screws are the activation of a central screw, using a specific key* (ref.75.01.038), which promotes the movement of metallic bodies.

Single patient, multiple use.

*All expansion screws are accompanied by an activation key Ref. 75.01.038.

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:

60months.

Warnings:

For patient safety, in intraoral activation applications, use only the long key Ref. 75.01.038.

The excessive rod heating may compromise the structure of the material, reducing its mechanical properties leading it to fracture.

The Hyrax Type Expander is intended for palate expansion through dental anchorage, and uses outside the intended indication, such as distalization and expansion with skeletal anchorage, are not recommended.

This product must not be used in a Magnetic Resonance environment as it may cause interference with the images during the examination. It is up to the orthodontic practitioner to warn the patient about this contraindication and arrange for removal of the device if necessary.

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.

Single patient use, multiple use.

Non reusable product, as its reuse may cause cross infection 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 before 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, 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.

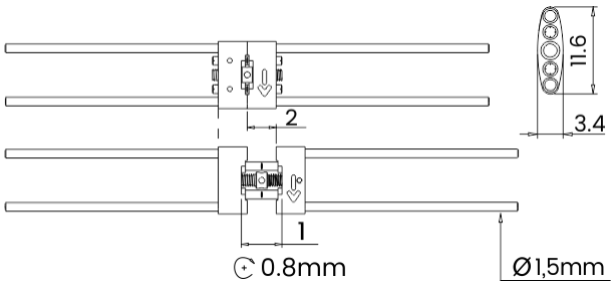
Considering that the product is used in contact with mucous membranes and body fluids, it is recommended to the professional to apply the sanitary norms applicable for the disposal of medical products in according to current sanitary regulations.

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	Model	Opening	Quantity	CE	NB[1]
65.05.010	Hyrax Palatal Split Screw	7mm	01 UN.	C E	2797
65.05.011	Hyrax Palatal Split Screw	9mm	01 UN.	C E	2797
65.05.012	Hyrax Palatal Split Screw	11mm	01 UN.	C E	2797
65.05.013	Hyrax Palatal Split Screw	13mm	01 UN.	C E	2797



1 - Opening

2 - Expansion = Opening less 2 mm

Revision	Date	Alterations
0	08/2017	Elaboration and availability on the Morelli website.
1	09/2019	Review of the alerts regarding the use of the products in environment of magnetic resonance by image, inclusion of the contraindication and revision of the warning.
2	06/2021	Removal of the composition and alteration of the mask.
3	06/2021	Revision of the warning about the intraoral activation key.
4	08/2021	Mask update, warnings and language adjustment.
5	10/2022	Language adjustment.