Hyrax Type Expander for Palatal Disjunction

English

Instruction for Use:IFU-00033 -0006

MS/ANVISA No.:10396830038

ANVISA Technical Name: Components for Orthodontics

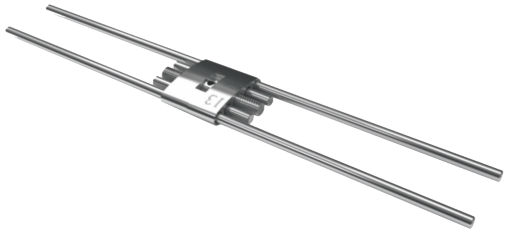
Comercial Name in ANVISA:APARELHOS PARA ORTOPEDIA FUNCIONAL DOS MAXILARES

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.

Fabricado por:
Dental Morelli Ltda.
Alameda Jundiaí, 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

EC REP
Representante Europeu
Nuno Flores
Al. Bonifácio Lázaro Lozano, 3 Piso / Floor O - C
Oeiras – Portugal – 2780125
☎Tel.: 351 21 4439292

Expansion Screw for Palatal Split



They are devices designed to correct the occlusion of certain maxillomandibular regions, generally used in functional jaw orthopedics, with the purpose of:

Expand the dental arch in its transverse direction through the application of lateral forces against the posterior dentition of the maxilla, producing the separation of the mesopalatine suture, having as an effect, the increase in the transverse dimension of the maxillary basal bone through orthopedic movements.

Such devices are used fixedly on the patient and together with orthodontic bands. After placement, the patient or guardian can activate the expander as instructed by the orthodontist.

Use indication:

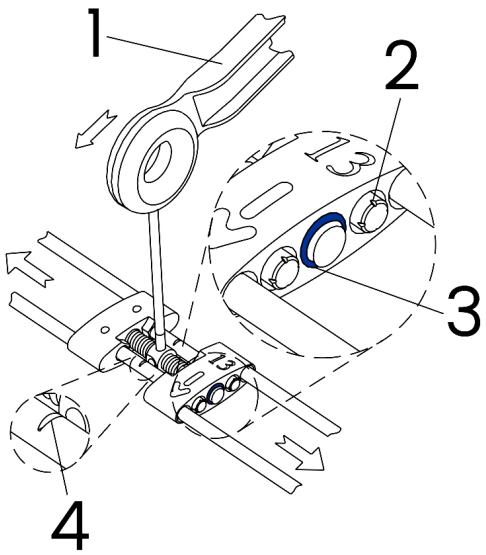
The most common clinical situations are:

- Correction of deficient maxillomandibular relationships;
- Early mixed/permanent dentition cases;
- Posterosuperior bilateral crossbite, as a result of maxillary apical base deficiency;
- Anterior or posterior crossbites that are not too severe.

Patient Recommendation: all ages with indication for orthopedic and/or orthodontic treatment.

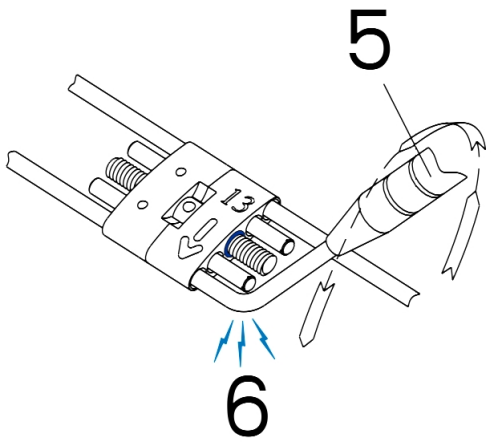
Intended User: use and installation by a qualified professional.

Installation:



1 - Expander Key; 2 - Carnation; 3 - Brake bushing; 4 - Centralizing nail;

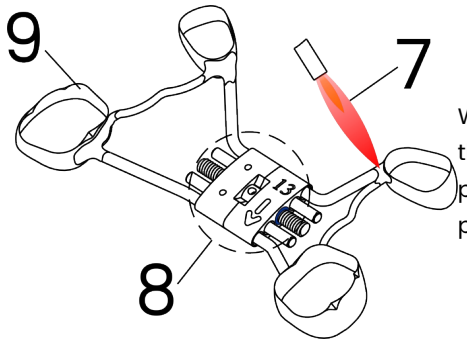
Morelli expanders have a brake bushing designed to prevent the screw from returning during activation. This bushing is manufactured with high quality polymer. In cases where welds are carried out close to the bushing region, it is recommended to protect it, in order to avoid excessive heating of the material, guaranteeing the effectiveness of the product. This protection can be performed by applying a specific paste, plaster, alginate or cotton dampened in water.



5 - Wire bender; 6 - Avoid twisting the rod;

When shaping the expander rods, use suitable tools, such as the arch bender (code 75.02.001) and trident pliers.

Perform the necessary bends with the desired angle, avoiding subjecting the rods to torsion efforts, which can weaken the rod as well as the weld, causing their fracture.



7 - Flame; 8 - Protect this area; 9 - Band.

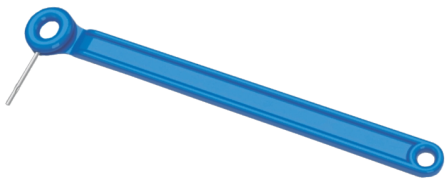
When preparing the expander, avoid directing the flame over its body during the welding process, thus avoiding compromising the product.

Activation:

The patient should only activate the expander in accordance with the guidance of a qualified professional.

For activation, the appropriate keys, designed specifically for this application, must be used.

Expanders' main operating characteristic is the activation of a central screw, using a specific key* (ref. 75.01.038), which promotes the movement of metallic bodies.



Use on a single patient, multiple times.

*All expanders come with 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:

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

Excessive heating of the rod can compromise the structure of the material, reducing its mechanical properties, leading to fracture.

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

Incorrect activation by the patient, outside of what is specified by a qualified professional, may cause activation key failure, pain, discomfort, sensitivity, difficulty speaking and chewing, fenestration, unwanted tooth movement and/or Brodie's bite.

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.

Single patient use, multiple use.

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

In case of serious problems arising from the use of the product, it is important that the qualified professional and/or patient inform the manufacturer or the competent authority in the country in which they reside.

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 profissional to apply the sanitary norms applicable for the disposal of medical products in according to current sanitary regulations.

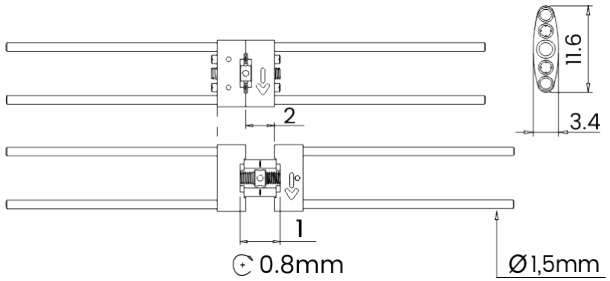
ATTENTION:

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	NB¹
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	Alterations
0	Elaboration and availability on the Morelli website.
1	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	Removal of the composition and alteration of the mask.
3	Revision of the warning about the intraoral activation key.
4	Mask update, warnings and language adjustment.
5	Language adjustment.
6	Review of MRI warning and activation key usage, and inclusion of intended patients and users