

English

Instruction for Use:IFU-00030 -0007

MS/ANVISA No.:10396830015

ANVISA Technical Name:Orthodontic Elastics

Comercial Name in ANVISA:Orthodontic Elastics

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:

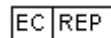
Dental Morelli Ltda.

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

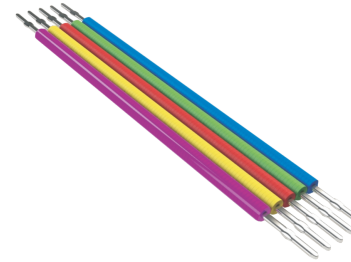
Nuno Flores

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

Oeiras – Portugal – 2780125

Tel.: 351 21 4439292

Elastic Ligature



They are orthodontic elastomers, used for fixing orthodontic wires or arches to the bracket slots, promoting the transfer of the forces applied by the arches / wires to the teeth.

Use indication:

- Fixation of orthodontic wires or arches to bracket slots, to transfer the forces applied by arches/wires to teeth.

Handling:

Insertion and removal of bandages must be carried out using tools intended for this purpose, such as: **Elastic Ligature Applicators** (ref. 75.01.001), (ref. 75.01.002), (ref. 75.01.003), (ref. 75.01.004) or **"Plic" Tweezers** (ref. 75.01.028).

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:

36months.

Warnings:

Store in a cool and airy place. Avoid exposure to high temperature or intense light, in order to avoid the decrease of the useful life of the product and loss of the mechanical properties.

Elastomeric ligatures are inherent to color change in the oral environment: Consider replacing them for shorter periods to maintain the desired aesthetic effect.

The product follows the dimensional patterns, initial strength (F_0) and residual after 24h (F_{24}), as established in the norms ABNT NBR ISO 21606 and DIN EN ISO 21606.

Keep the product in its original packaging and always closed in order to avoid drying.



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 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.

Internal Diameter (Di); External Diameter (Do); Cutting thickness in cross section (t); Initial force (F0); Residual force after 24 hours (F24).

Cane (Di - $\varnothing 1.4^{+0.1/-0.05}$); (Do - $\varnothing 3.0^{+0.1/-0.1}$); (t - $0.70^{+0.05/-0.05}$); (F_0 - $350gf^{+150gf} / 3.4N^{+1.5N}$); ($F_{24} \rightarrow = 50\%$)

Modular (Di - \varnothing 1.4 ^{+0.1/-0.1}); (Do - \varnothing 3.1 ^{+0.05/-0.05}); (t - 0.85 ^{+0.05/-0.05}); (F₀ - 350gf ^{±102gf} /3.4N ^{±1.0N}); (F₂₄ -> = 45%)

Reference:

¹ Notified Body

Code	Model	Color	Quantity	CE	NB ¹
60.03.300	Elastic Ligature in Canes	CRYSTAL	1000 UNITS	C E	-
60.03.301	Elastic Ligature in Canes	GRAY	1000 UNITS	C E	-
60.03.302	Elastic Ligature in Canes	ASSORTED	1000 UNITS	C E	-
60.03.304	Elastic Ligature in Canes	BABY BLUE	1000 UNITS	C E	-
60.03.305	Elastic Ligature in Canes	YELLOW	1000 UNITS	C E	-
60.03.307	Elastic Ligature in Canes	MOSS GREEN	1000 UNITS	C E	-
60.03.308	Elastic Ligature in Canes	BLUE	1000 UNITS	C E	-
60.03.310	Elastic Ligature in Canes	RED	1000 UNITS	C E	-
60.03.311	Elastic Ligature in Canes	BLACK	1000 UNITS	C E	-
60.03.312	Elastic Ligature in Canes	ROSE	1000 UNITS	C E	-
60.03.313	Elastic Ligature in Canes	PURPLE	1000 UNITS	C E	-
60.03.315	Elastic Ligature in Canes	SEA GREEN	1000 UNITS	C E	-
60.03.316	Elastic Ligature in Canes	MARINE BLUE	1000 UNITS	C E	-
60.03.317	Elastic Ligature in Canes	SILVER	1000 UNITS	C E	-
60.03.319	Elastic Ligature in Canes	BABY ROSE	1000 UNITS	C E	-
60.03.320	Elastic Ligature in Canes	IVORY	1000 UNITS	C E	-
60.03.322	Elastic Ligature in Canes	WINE	1000 UNITS	C E	-
60.03.324	Elastic Ligature in Canes	PEARL GREEN	1000 UNITS	C E	-
60.03.326	Elastic Ligature in Canes	PEARL ROSE	1000 UNITS	C E	-
60.03.327	Elastic Ligature in Canes	WHITE	1000 UNITS	C E	-
60.03.328	Elastic Ligature in Canes	LILAC	1000 UNITS	C E	-
60.03.350	Elastic Ligature in Canes	CRYSTAL LEMON	1000 UNITS	C E	-
60.03.351	Elastic Ligature in Canes	CRYSTAL RED	1000 UNITS	C E	-
60.03.352	Elastic Ligature in Canes	CRYSTAL ORANGE	1000 UNITS	C E	-
60.03.353	Elastic Ligature in Canes	CRYSTAL GREEN	1000 UNITS	C E	-
60.03.354	Elastic Ligature in Canes	CRYSTAL BLUE	1000 UNITS	C E	-
60.03.355	Elastic Ligature in Canes	CRYSTAL PINK	1000 UNITS	C E	-
60.03.358	Elastic Ligature in Canes	CRYSTAL ASSORTED	1000 UNITS	C E	-
60.03.359	Elastic Ligature in Canes	CRYSTAL GRAPE	1000 UNITS	C E	-
60.03.700	Elastic Ligature in Canes	CRYSTAL	5000 UNITS	C E	-

Code	Model	Color	Quantity	CE	NB ¹
60.03.701	Elastic Ligature in Canes	GRAY	5000 UNITS	C E	-
60.06.100	Elastic Ligature in Modules	CRYSTAL	1000 UNITS	C E	-
60.06.101	Elastic Ligature in Modules	GRAY	1000 UNITS	C E	-
60.06.103	Elastic Ligature in Modules	BABY BLUE	1000 UNITS	C E	-
60.06.104	Elastic Ligature in Modules	YELLOW	1000 UNITS	C E	-
60.06.106	Elastic Ligature in Modules	MOSS GREEN	1000 UNITS	C E	-
60.06.107	Elastic Ligature in Modules	BLUE	1000 UNITS	C E	-
60.06.109	Elastic Ligature in Modules	RED	1000 UNITS	C E	-
60.06.110	Elastic Ligature in Modules	BLACK	1000 UNITS	C E	-
60.06.111	Elastic Ligature in Modules	ROSE	1000 UNITS	C E	-
60.06.112	Elastic Ligature in Modules	PURPLE	1000 UNITS	C E	-
60.06.114	Elastic Ligature in Modules	SEA GREEN	1000 UNITS	C E	-
60.06.115	Elastic Ligature in Modules	MARINE BLUE	1000 UNITS	C E	-
60.06.117	Elastic Ligature in Modules	SILVER	1000 UNITS	C E	-
60.06.118	Elastic Ligature in Modules	ASSORTED	1000 UNITS	C E	-
60.06.119	Elastic Ligature in Modules	BABY ROSE	1000 UNITS	C E	-
60.06.120	Elastic Ligature in Modules	IVORY	1000 UNITS	C E	-
60.06.122	Elastic Ligature in Modules	WINE	1000 UNITS	C E	-
60.06.124	Elastic Ligature in Modules	PEARL GREEN	1000 UNITS	C E	-
60.06.126	Elastic Ligature in Modules	PEARL ROSE	1000 UNITS	C E	-
60.06.127	Elastic Ligature in Modules	WHITE	1000 UNITS	C E	-
60.06.128	Elastic Ligature in Modules	LILAC	1000 UNITS	C E	-
60.06.150	Elastic Ligature in Modules	CRYSTAL LEMON	1000 UNITS	C E	-
60.06.151	Elastic Ligature in Modules	CRYSTAL RED	1000 UNITS	C E	-
60.06.152	Elastic Ligature in Modules	CRYSTAL ORANGE	1000 UNITS	C E	-
60.06.153	Elastic Ligature in Modules	CRYSTAL GREEN	1000 UNITS	C E	-
60.06.154	Elastic Ligature in Modules	CRYSTAL BLUE	1000 UNITS	C E	-
60.06.155	Elastic Ligature in Modules	CRYSTAL PINK	1000 UNITS	C E	-
60.06.158	Elastic Ligature in Modules	CRYSTAL ASSORTED	1000 UNITS	C E	-
60.06.159	Elastic Ligature in Modules	CRYSTAL GRAPE	1000 UNITS	C E	-

Revision	Alterations
0	Elaboration and availability on the Morelli website.
1	Review of contraindications, side effects and warnings.
2	Review of contraindications, side effects and warnings.
3	Review of template, composition and specification.
4	Mask update, warnings and language adjustment.
5	Language adjustment.
6	Adjustment of the maximum tolerance of the inner diameter of the elastic cane.
7	Update of warnings.