

Hangzhou DTC Medical Apparatus Co., Ltd	Documentation No.	HZDTC/CE-12-B-03
	IFU	English
Orthodontic Elastics	Date:2024-03-25	Rev.C/0

Hangzhou DTC Medical Apparatus Co., Ltd

CE Technical Files

Orthodontic Elastics

Instruction For Use(Product Introduction)

说明书（产品介绍）

Originator		Issued Date	
Reviewer		Effective Date	
Approver			
Manufacturer	Hangzhou DTC Medical Apparatus Co., Ltd		
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Revision History

Rev No.	Issued date	Description of Change	Author	Approved by
C/0	2024/03/25	1.First edition。		

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Instruction for Use

Orthodontic Elastics



Rev. C/0, Effective: 2024.03.25

Description :

Ligature: A device intended to securely tether an orthodontic archwire to an orthodontic bracket, or securely hold the archwire in the archwire slot of an orthodontic bracket (or brace). It is in the form of a small single tie, or a circular band made of elastomeric . This is a single-patient device intended to be replaced regularly during orthodontic treatment (single-use).

Separator: A non-surgical orthodontic device typically in the form of a loop or ring intended to be placed between adjacent teeth to slowly move them apart to help achieve improved positioning and/or appearance of the teeth; it is not intended for separation of tooth roots. This is a single-patient device intended to be used for the duration of the treatment (single-use) before being discarded.

Chain: A non-sterile device intended to be used during orthodontic treatment to function as an archwire/bracket ligature on several adjacent teeth and/or to exert a continuous light force to close the spaces between the teeth. It is also known as a power chain and is in the form of a series of connected loops made of an elastomeric material. This is a single-patient device intended to be replaced regularly during orthodontic treatment (single-use).

Elastic: A non-sterile circular band intended to be used during orthodontic treatment to exert a continuous light force to adjust bite and jaw position for correcting malocclusions (e.g., overbite, underbite). It is made of an elastomeric material and is secured to hooks on orthodontic brackets across non-opposing mandibular and maxillary teeth. This is a single-patient device intended to be replaced regularly during orthodontic treatment (single-use).

Indication for Use :

Orthodontic elastics is used with orthodontic brackets and orthodontic wires to exert orthodontic force on all kinds of teeth through orthodontic bracket, so that the teeth can rotate or move predetermined.

Product Composition :

The Orthodontic Elastics is made of polyurethane (TPU).

Specification:

1. The orthodontic elastics shall comply with the requirements of ISO 21606: 2022(E) and be manufactured in accordance with the drawings and technical d

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- ocuments approved by the prescribed procedure.
- The orthodontic elastics shape structure, the basic size shown in Figure 1, Table 1.
 - appearance: Product surface should be smooth, round, uniform, no burr, l eading edge, crack, fall off and other defects.
 - The initial extension force shall meet the requirements specified by the ma nufacturer.
 - the 24 h residual force should be no less than 50% of the specified initial extension force value of the corresponding specification.
 - the ultimate extension of the Separator should not be less than 400%.
- The structure diagram of the orthodontic Orthodontic Elastics is shown below.

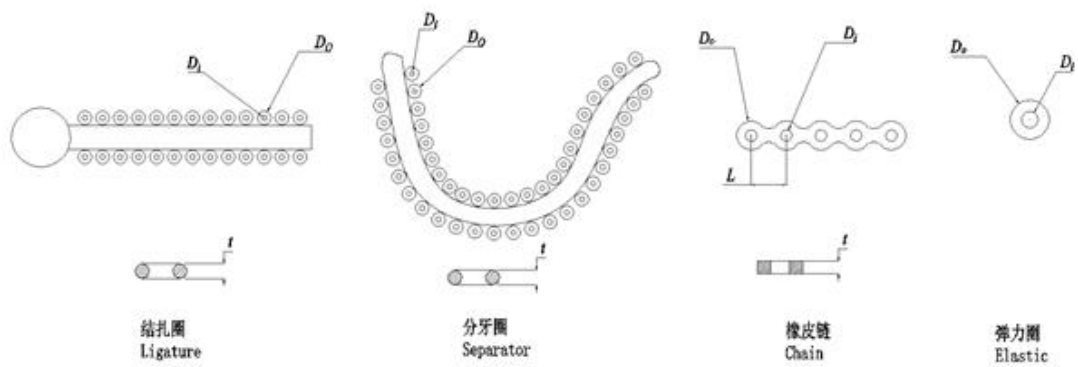


Figure 1 orthodontic elastics

Table1 Size of orthodontic elastics					Unit: mm
		Di	Do	L	t
Ligature		1.30±0.20	3.20±0.20	/	0.80±0.10
Separator		1.80±0.20	4.50±0.20	/	1.20±0.10
Chain	Closed	1.30±0.20	2.90±0.20	2.80±0.20	0.70±0.10
	Short	1.30±0.20	2.90±0.20	3.50±0.20	0.70±0.10
	Long	1.30±0.20	2.90±0.20	4.00±0.20	0.70±0.10
Elastic	3/8	9.50±0.20	11.50±0.20	/	/
	5/16	8.00±0.20	10.00±0.20	/	/
	1/4	6.00±0.20	8.00±0.20	/	/
	3/16	5.00±0.20	7.00±0.20	/	/
	1/8	3.00±0.20	5.00±0.20	/	/
Note: Other models of tube can be developed according to customer requirements.					

The specific specifications and models are shown in the following table:

Table 2. Specification and model list of Orthodontic Elastics

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No	Designation	Code	Type			Pack	
1	Power Chains	E631-01	Open long			1roll/pk(4.5m)	
2		E631-02	Closed continuous				
3		E631-03	Open short				
4	Ligature rings	E632-02	Normal			40 branches/bag 26pcs/branch	
5		E632-03	Flower shape			20 branches/bag 16pcs/branch	
6		E632-04	Heat shape			20 branches/bag 16pcs/branch	
7		E632-05	Ring clear			10 branches/bag 10pcs/branch	
8	Orthodontic Rotation Wedges	E633-01	Normal			20 branches/bag 10pcs/branch	
9	Orthodontic Chewies	E633-02	6 flavors:Original Orange Mint Mango Strawberry Grape			2pcs/bag	
10	Separators	E632-01	Blue			15 branches/bag 70pcs/branch	
No	Designation	Size	Light Force 2.5Oz	Light Force 3.5Oz	Light Force 4.5Oz	Light Force 6.5Oz	
11	O RING	1/8(3.2mm)	A641-32	A642-32	A644-32	A643-32	
12		3/16(4.8mm)	A641-48	A642-48	A644-48	A643-48	
13		1/4(6.4mm)	A641-64	A642-64	A644-64	A643-64	
14		5/16(8.0mm)	A641-79	A642-79	A644-79	A643-79	
15		3/8(9.5mm)	A641-95	A642-95	A644-95	A643-95	
No	Designation	Size	Light Force 3.5Oz		Light Force 4.5Oz		Light Force 6.5Oz
16	O RING Without Latex	1/8(3.2mm)	A642-32-Si		A644-32-Si		A643-32-Si
17		3/16(4.8mm)	A642-48-Si		A644-48-Si		A643-48-Si
18		1/4(6.4mm)	A642-64-Si		A644-64-Si		A643-64-Si
No	Designation	Code	Type	Help fit and remove elastic bands on braces		Pack	
19	O RING Placed	E634-01	4 Colors			100pcs/bag	
No	Designation	Code	Type			Diameler Inch/mm	
20	Elastomeric Thread	E636-11	Length 25feet			0.020"	
21		E636-12				0.025"	
22		E636-13				0.030"	
No	Designation	Code	Size				
23	Orthodontic Archwire Sleeve 5M	E635-01	5m				

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Contraindication:

People allergic to rubber should use with caution.

Usage:

1. Size selection: according to the orthodontic method used in the corresponding size of the elastic.
2. This product is a non sterile product, it is recommended to disinfect before use, with 75% alcohol soak for 20-30 minutes for disinfection, and then the residual disinfectant with sterile water rinse repeatedly (more than three times, each time 1 minute).
3. Use a special tool to place the elastics on the bracket, tube or other accessories.

Warning:

1. According to the use of orthodontic methods used in the corresponding size of the elastics.
2. This product is a one-time use of goods, is strictly prohibited cross-use.
3. Warned the wearer to maintain oral hygiene.
4. Use with caution if you are sensitive to rubber.
5. More than the warranty period, is strictly prohibited. (See the product packaging label for the date of manufacture)
6. The elastics attached to the tooth surface, the adversary must not bite hard or sticky food, not chewing gum.
7. This product is non-sterile medical device, and the professional physician must sterilize the product before use. should make strict disinfection processing for the orthodontic elastic ring, with 75% alcohol immersion disinfection of 20 to 30 minutes, and then the residual disinfectant with sterilized water rinse repeatedly (more than three times, each time 1 minute) (note: used for the first time to flush times and time of verification, should ensure that when disinfection washing times and time value is higher than the validation, verification methods: The sterilized water for the last rinse tested to be zero alcohol).
8. The orthodontic elastics are disposable products and cannot be reused. The finished orthodontic elastics is treated as a medical solid.

Packaging:

Packed in plastic bag, or as per customer's requirement.

Storage:

After packing, the Lingual Buttons shall be stored in a clean room with a relative humidity of no more than 80%, free of corrosive gases and well ventilated.

Shelf-life:

Sixty months from the date of delivery.

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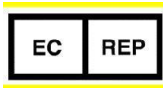
Symbols:



Do Not Reuse



Manufacturer



Authorised Representative In The European Community



Consult Instructions For Use

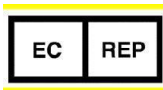


Caution



Manufactured by:

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