CENDRES+ MÉTAUX

esthetic.line

Wires

Instructions for Use Wires

1 Scope of application of Instructions for Use

These Instructions for Use apply to the products listed under Section 29. The issuing of these Instructions for Use renders all previous versions invalid. The manufacturer rejects any liability for damages resulting from non-compliance with these Instructions for Use.

2 Trade name

See Section 29.

3 Intended use

The products are intended for prosthetic restorations and to support procedures in the dental clinic or laboratory.

4 Expected clinical benefit

Restoration of chewing function and improved aesthetics.

The Summary of Safety and Clinical Performance, SSCP for the implantable devices covered by these Instructions for Use, is available on our website and accessible at this address: www.cmsa.ch/docs.

5 Product description

The wires in precious metal alloys are used in removable dentures.

Material and delivery forms:

Round wires		
	Diameter mm	Length mm
Elasticor	1.15	200

6 Indications

Holding elements (clasps).

7 Contraindications

– Patients who are unable to keep the regularly required check-up appointments for health reasons.
– Patients with bruxism or other para-functional habits.
– Patients with allergies to materials used in the product, see Section 19.
– Existing clinical picture in the patient's mouth does not permit the correct application of the products.

8 Compatible products

N/A

9 Qualification of the specialist

Expertise in professional dentistry and dental technology is assumed. The current Instructions for Use must be available at all times and be completely read and understood before the first application. The fabrication of dentures and their maintenance may only be performed by qualified specialists.

Important information for the specialist

⚠ Warning symbol for increased caution

10 Prescription

Federal laws in the USA prohibit the use by or sale to unlicensed dentists.

11 Side effects

⚠ This product must not be used in patients with allergies or suspected allergies to materials used in the product (see Section 19), or only after prior allergological clarification.
Auxiliary instruments may contain nickel.
If applied as intended, side effects can be excluded.

12 Warnings

⚠ **Magnetic resonance (MR) environment**
The device has not been evaluated for safety and compatibility in the MR environment.
The product has not been tested for heating or migration in the MR environment.

13 General information

N/A

14 Preventive measures

– The product components are supplied non-sterile. For more information see Section 16 "Reprocessing".
– For your own safety, always wear suitable protective clothing. In particular when grinding, we recommend wearing protective goggles and a dust mask as well as the use of a suction unit.

15 Single use

Products that are intended for single use and are labelled "single-use" accordingly are subject to a certain amount of stress, increased wear, and even loss of functionality during their use.

⚠ Multiple application of products labelled «single use» was not tested. This can impair the safety, function and performance of the products as well as increase the risk of transmitting infections.

16 Reprocessing

The prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised prior to each work step. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation. With the exception of Pekkton®, components made of plastics are not suitable for steam sterilisation.
Consider published national guidelines when selecting a disinfection and sterilisation process and the Instructions for Use “Reprocessing of surgical and prosthetic products” (www.cmsa.ch/docs).

17 Scope of application

Removable dentures.

18 Procedure

18.1 Cold-forming

Bending wires supplied in a soft state (cold-forming) deforms their structure and is accompanied by hardening. If the wire reaches the stage where it is difficult to bend, it must be intermediate-annealed (soft-annealed).

18.2 Bending technique

When bending the wire with tools such as pliers, make sure that the wire is not damaged, e.g. notches, which could cause the wire to fracture at these points.

Once the clasps have been completed and soft annealed, they have to be hardened to give them their optimum mechanical properties.

18.3 Soft-annealing

Soft-annealing is carried out in a porcelain furnace – Elasticor at 700 °C for 10 mins. followed by quenching in water.

18.4 Hardening

This is achieved by glowing the wire in a porcelain furnace at 400 °C for 15 mins. followed by bench cooling to room temperature.

18.5 Pickling

After heat treatment (soldering, soft annealing or hardening), the wire should be pickled in warm, clean 10 % (by volume) sulphuric acid (H_2SO_4).

When using other pickling agents, follow their manufacturers’ instructions.

18.6 Polishing

After finishing and hardening the wire, any areas of exposed metal must be polished to a high lustre to remove the oxide layer completely.

19 Materials

19.1 Composition in weight %

Physical properties

Alloys	Colour	Au + Pt-Met.	Au	Pt	Pd	Ag	Cu	Zn	Ir
Elasticor	Yellow	74.5	61.0	13.5		16.5	9.0		

Mechanical properties

Alloys	Melting range	Hardness HV 5				Young’s Modulus
	°C	soft		hardened		
Elasticor	950 – 1050	700 °C / 10’ / H_2O	HV 205	400 °C / 15’ / air	HV 285	96

More detailed information on the materials as well as their compositions can be found in the product-specific material data sheets, the product information as well as the product list compiled in Section 29. All relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

20 Notes on storage

Insofar as no specific information on storage is given on the packaging of the product, we recommend storing the product in its original packaging, in a dry place, at room temperature and without direct sunlight. Improper storage can influence the product properties and lead to failure of the restoration.

21 Patient information

On the day of insertion of the dentures at the latest, the patient must be informed that regular follow-up care is necessary to maintain the health of the entire masticatory system and the functionality of the denture. Ensure that the patients are motivated and instructed with regard to caring for their teeth as well as dentures.

Permanent and removable dentures are subject to considerable stress. Signs of wear are normal and cannot be avoided, only reduced. The amount of wear depends on the overall system.

22 Ordering information

The information relevant to your order can be found in the product list in Section 29 of this document. The product information is also helpful. This and other relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

23 Availability

Some of the products described in this document may possibly not be available in all countries.

24 Traceability of the lot number

The lot numbers of all parts used must be documented to ensure traceability.

25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product. To do this, please contact your customer advisor or send us your message by e-mail to the address complaints-cmbrand@cmsa.ch. In serious cases, also send a report to the competent authority where you are domiciled.

26 Safe disposal

The products must be disposed of in accordance with local laws and environmental regulations, taking into account the level of contamination. Cendres+Métaux Lux SA would be very pleased to accept precious metal waste. For information and additional details, please contact your Cendres+Métaux SA representative.

27 Trademarks

Registered trademarks of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland include:

N/A

Unless explained specifically, all products marked with "®" are not registered trademarks of Cendres+Métaux Holding SA, but registered trademarks of the respective manufacturer.

28 Disclaimer

The manufacturer rejects any liability for damages resulting from non-compliance with these Instructions for Use. Cendres+Métaux SA products are parts of an overall concept and may only be used or combined with the appropriate original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the lot number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products mentioned in the product list in Section 29 will void any warranty or other express or implied obligation of Cendres+Métaux SA.

Responsibility regarding the suitability of a product for the specific patient case is at the discretion of the specialist.

Cendres+Métaux SA disclaims any express or implied liability and shall not be responsible for any direct, indirect, punitive or other damages arising from or in connection with errors in professional judgement or practice in the use of Cendres+Métaux SA products.

The specialist is obliged to regularly study the latest developments of the products mentioned in the product list in Section 29 and their applications.

It should be noted that the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Expertise in dentistry, dental technology and instructions by an experienced specialist in the use of the products mentioned in the product list under Section 29 is always necessary.

In case of inconsistencies in translations, the English language version shall prevail.

29 Product list

Cat. No.	Product name	Single use	Labelling	UDI-DI	Basic UDI-DI
01000365	Elasticor Ø 1.15 mm	No	CE 0483	97640173082463	764016651000044E3

30 Labelling on packaging / symbols

	Date of manufacture
	Manufacturer
REF	Catalogue number
LOT	Lot number
QTY	Quantity
 www.cmsa.ch/docs	Observe the Instructions for Use, which are available in electronic form at the address specified.
Rx only	Attention: According to US federal law, this product may only be sold by or on behalf of a physician.
CE 0483 CE	Cendres+Métaux products with CE labelling meet the requirements of the relevant European requirements.
	Do not re-use
	Non-sterile
	Protect from sunlight
	Attention, observe accompanying documents
UDI 	Clear product identification
EC REP	European Authorised Representative
	Importer
MD	Medical device

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