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## Wires for laser welding

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# Instructions for Use Wires for laser welding

## 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](http://www.cmsa.ch/docs).

## 5 Product description

When welding the laser wire material is melted selectively with a laser so that it can be alloyed with the connected parts. This method is a weld in which the alloy can be easily melted.

## 6 Indications

Precious metal laser wires are used for laser joining precious metal alloys.

## 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

### Assignment of laser welding wires to alloys

LW N° 1	Estetecor® Helvetica	V-Gnathos Plus	Estetecor® Ideal H	Estetecor® Avenir	BioEthic						
LW N° 2	Estetecor® Royal H	Estetecor® Cosmor H	V-Classic	Estetecor® Economic	Estetecor® Plus	Estetecor® Accurate 40	Cerapall 6	Cerapall 2	Estetecor® CC	Ceradelta	V-Supra- gold
LW N° 3	V-Deltaloy	V-Delta Special	V-Delta SF	Estetecor® N2	Estetecor® Blancor	Ceradelta 2	Estetecor® Actual	Estetecor® NewStart	Estetecor® Implant 76	Estetecor® Implant 58	Estetecor® Implant 32
	EcoDelta										
LW N° 4	Estetecor® Ecologic	DGVO8 H									
LW N° 5	Opticast	Aurofluid 2 PF	Pontor MPF	Neocast 3	Protor 3	Aurofluid 3					
LW N° 6	Dentalor 60	Solaro 3	Medior 3	Solaro 4	Yellow Special	Solaro Special					
LW N° 7	Pallorag 33	Pagalin 2	Pallorag 35								

To fabricate the finished denture, a number of general laboratory supplies are required in addition to the products listed under Section 29. The following gives a selection of materials that Cendres+Métaux SA offers in its portfolio.

08052138	Polyurock Kit	08055014	Livento® invest Powder (50 x 100 g)
08052135	Polyurock Catalyst	083739	Livento® invest Liquid (1000 ml)
08052137	Polyurock Mixer	08052160	uniVest® Plus Powder (30 x 150 g)
08052149	ABF Wax Universal	08052161	uniVest® Plus Liquid (1000 ml)
08052150	ABF Wax Creativ light	08052162	uniVest® Rapid Powder (30 x 150 g)
08052151	ABF Wax Creativ dark	08052163	uniVest® Rapid Liquid (1000 ml)
08052154	ABF Wax Special	080181	CM soldering investment (4 kg)
08052148	ABF Wax Margin	080229	CM soldering paste
08052153	ABF Wax Position	08052307	Legabril Diamond (50 g)
08052152	ABF Wax Tecno		

**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**

Whenever working with a laser welder, the safety precautions recommended by the manufacturer must be taken to protect the user.



– 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](http://www.cmsa.ch/docs)).

**17 Scope of application**

Fixed and removable dentures.

**18 Procedure****18.1 Optimum joints**

To create optimum joints, the laser welder must be adjusted for precious metal alloys as recommended by its manufacturer.

The relevant working parameters listed below overleaf have been established for x-shaped connections with the use of filler material. These parameters have been established with the laser welding unit DL 3000 (Dentaurum).

Wires for laser welding	Focus ∅ mm	Voltage V	Impulse ms	Frequency Hz
LW N° 1	0.9	280	8	2
LW N° 2	0.8	270	8.5	2
LW N° 3	0.9	255	7	2
LW N° 4	0.9	285	6	2
LW N° 5	0.8	295	9	2
LW N° 6	0.9	315	6.5	2
LW N° 7	0.9	285	6	2



These parameters can only serve as basic values for your orientation, due to differing welding results between laser welding units. Therefore, they must be considered as basic values.

**18.2 Testing the base values with your own laser welding unit**

We recommend the correct adjustment of your laser welding unit by test welding on a piece of casting sprue (rubber-polished), consisting of the alloy you want to join.

Depending on the results, the welding parameters should then be adjusted before the real joining of the dental restoration takes place.

**18.3 Laser welding wire specifications**

The laser welding wires do not contain additives such as flux etc. Flooding the area with protective gas (approx. 8 l/min) during the laser impulse effectively prevents oxidation of the welding area and welding wire. The welding wires are 0.4 mm in diameter and 200mm long when supplied.

**18.4 Thermal treatments of cast metal frameworks**

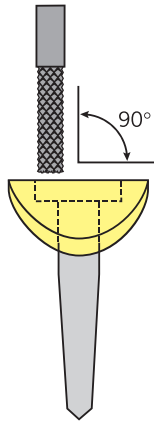
All cast metal frameworks should be heat-treated before the laser welding process in order to eliminate possible tensions, especially when rejoining separated bridgework. In the case of metal ceramic alloys, their specific indications for the oxide firings can be employed. Crown and bridge alloys should first be annealed, then hardened according to the manufacturers indications.

**18.5 Thermal treatments of bars**

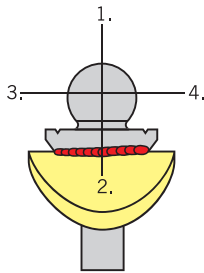
The Elitor® versions of the Cendres+Métaux Dolder® bars and Cendres+Métaux round bars are delivered in an annealed state. Thus, after the laser welding the root caps, the bars E and the weld must be thermally treated in order to achieve their maximum mechanical properties:  
 1. Annealing: 700 °C 10 min. / then quench in H<sub>2</sub>O and  
 2. hardening: 400 °C 15 min. / benchcool slowly

**18.6 Example of use**

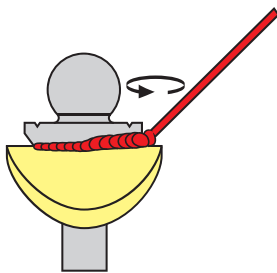
Prepare the surface of the root cap (Protor 3) right-angled to the direction of insertion.



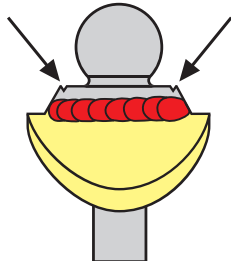
Position the laser welding male part (Elitor) in the desired area, fix it with 4 welds (over crossing), then weld it circularly.

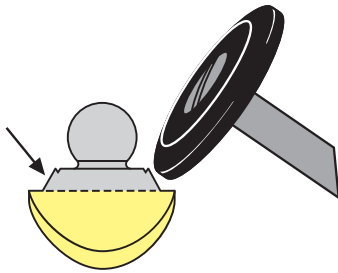


Circular filling of the undercut of the laser welding male part E using the laser welding rod LW N° 5 as filler material.



Burnish the weld circularly.  
 Note: Avoid the removal of too much material by not exceeding the marking groove on the base plate (towards the centre).





Refining the surface of the weld. In order to guarantee the stability of the laser-welded joint, avoid grinding off too much material.

The welded area has a hardness of about HV5 190 because it has cooled very rapidly. This hardness can be increased up to HV5 260, by heat-treating the whole work as follows:

1. Annealing: 700 °C/10 min. then quench in H<sub>2</sub>O and
2. hardening: 400 °C/15 min., then benchcool slowly.

## 19 Materials

### 19.1 Composition of the laser welding wires in weight %

Laser welding wires	Melting range °C															
		Au- + Pt-Met.	Au	Pt	Pd	Ag	Cu	Sn	Zn	In	Ir	Ru	Rh	Fe	Ta	Mn
LW N° 1	1045–1205	98.00	84.50	13.30					1.90		0.10		0.10	0.10		
LW N° 2	1120–1250	94.00	75.10		18.85	1.00	0.50	2.00	0.50	2.00	0.05					
LW N° 3	1165–1290	96.90	76.80	1.35	18.60			2.90	0.20		0.15					
LW N° 4	975–1090	83.50	75.10	8.30		13.80			2.30	0.20	0.10				0.10	0.10
LW N° 5	890–935	75.40	71.60	3.75		12.70	10.80		1.10		0.05					
LW N° 6	870–920	66.50	63.00	0.50	3.00	20.00	12.00		1.50			<1.00				
LW N° 7	915–1005	79.90	69.90	9.50		13.30	2.90		1.90	2.00	0.10		0.40			

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](http://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](http://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](mailto: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
01000363	LW N° 1	Yes	CE 0483	97640173082449	764016651000043DZ
01000358	LW N° 2	Yes	CE 0483	97640173082395	764016651000043DZ
01000359	LW N° 3	Yes	CE 0483	97640173082401	764016651000043DZ
01000360	LW N° 4	Yes	CE 0483	97640173082418	764016651000043DZ
01000361	LW N° 5	Yes	CE 0483	97640173082425	764016651000043DZ
01000362	LW N° 6	Yes	CE 0483	97640173082432	764016651000043DZ
01000364	LW N° 7	Yes	CE 0483	97640173082456	764016651000043DZ

**30 Labelling on packaging/symbols**

-  Date of manufacture
-  Manufacturer
-  Catalogue number
-  Lot number
-  Quantity
-  Observe the Instructions for Use, which are available in electronic form at the address specified.  
[www.cmsa.ch/docs](http://www.cmsa.ch/docs)
-  Rx only  
Attention: According to US federal law, this product may only be sold by or on behalf of a physician.
-  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
-  Clear product identification
-  European Authorised Representative
-  Importer
-  Medical device