

esthetic.line

Alloys

Pallorag 35, Strator 3, Pallorag 33, Pagalin 2

DE	Gebrauchsanweisung	Deutsch	1
FR	Mode d'emploi	Français	8
EN	Instructions for Use	English	15
IT	Istruzioni d'uso	Italiano	22
ES	Instrucciones de uso	Español	29
DA	Brugsanvisning	Dansk	36
FI	Käyttöohje	Suomi	43
SV	Bruksanvisning	Svenska	50
HU	Használati utasítás	Magyar	57
ZH	使用说明书	简体中文	64
JA	取扱説明書	日本語	70
KO	사용 설명서	한국어	77

Instructions for Use Alloys

Pallorag 35, Strator 3, Pallorag 33, Pagalin 2

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

These casting Ag-Pd-Au alloys have a narrower processing tolerance than high gold content and reduced gold content alloys. The group includes alloys with different mechanical and physical properties. It is therefore possible to select an alloy on the basis of its composition which is best suited to the type of work to be performed. The alloys can be soldered without difficulties and are also suitable for the cast-on technique.

6 Indications

Alloys							
	Typ (ISO 22674)	a	b	c	d	e	f
Pallorag 35	4						
Strator 3	3		●	●	●	●	●
Pallorag 33	4		■	■	■	■	
Pagalin 2	4	■	■	■			

a Inlays, onlays, crowns ¾
 b Single crowns
 c Short-span bridgework
 d Long-span bridgework
 e Milled work
 f Clasps, lingual bars, palatal plates

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

Solders and Laser welding wire

Alloys	Solders		Laser welding wire
	First solder	Second solder	
Pallorag 35	S.G 810	S.G 750	LW N° 7
Strator 3	S.G 810	S.G 750	not weldable
Pallorag 33	S.G 810	S.G 750	LW N° 7
Pagalin 2	S.G 880	S.G 750	LW N° 7

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

- Mixing of different alloys or alloys of similar types is not allowed!
- Wear darkened eye protection and protective gloves when melting.
- Protect eyes, hands and breathing when pickling.

 – 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

Fixed and removable dentures.

18 Procedure

18.1 Modelling

Usual modelling technique for ceramic-fused-to-metal works. Minimal wall thickness 0.4 mm. With bridgework the connections must have a minimum section of 6–9 mm². Modelling of garlands or inlay shaped reinforcements in the palatal region will give added stability. The application of air and cooling vents improves casting results.

18.2 Spruing

Wax sprues of no less than Ø 3.5 mm are required. Direct (Ø 3.5 mm) and cross bar (Ø 5 mm) spruing produce excellent results. Feeder sprues to heavy pontics should be of at least Ø 4 mm.
Air vents (Ø 1 mm) may be used to advantage. Wax patterns should be set outside the thermal centre, i.e. near the casting ring wall and about 5 mm from the end. For individual copings and small bridges (up to three units), use of the circular sprue provides ideal positioning of the wax patterns and ensure controlled solidification of the frameworks.

18.3 Investing

When using steel casting rings always use refractory liner in order to allow free expansion of the investment.

The following investment materials from Cendres+Métaux are suitable for this alloy type:
uniVest Plus: universal phosphate-bonded, graphite- and gypsum-free investment material
uniVest Rapid: graphite-free, phosphate-bonded investment material

Livento® invest: Special investment material for lithium disilicate and other pressable ceramics. Fabrication of refractory stumps. Metal casting technique.

When using plaster based investment compounds care has to be taken not to exceed a preheating temperature of 700°C in order to prevent an embrittlement of the alloy by the uptake of sulphur.

Pd-based alloys absorb carbon in the melted condition. Therefore graphite based investment compounds should not be used. Also, these alloys should only be melted in ceramic or vitrified carbon crucibles to prevent embrittlement of the alloy during frequent remelting.



Rapid preheating technique: the use of burn-out plastic parts can lead to spalling in the investment material.

18.4 Preheating

Observe manufacturer's recommendations with regard to setting times, temperature levels etc. On reaching the end temperature a soaking period of 20 to 45 min. is advisable depending on the size of the cylinder.

Alloys			
	Preheating °C	Crucible	Casting temperature °C
Pallorag 35	700	② ③	1060–1110
Strator 3	700	② ③	1010–1060
Pallorag 33	700	② ③	1120–1170
Pagalin 2	630–680	②	1270

- ① = Graphite crucible
- ② = Universal ceramic crucible
- ③ = Vitrified carbon crucible



Re-use of alloy

Only use perfectly cleaned (by sand-blasting with aluminium oxide) buttons and sprues and add at least 1/3 of new alloy.

18.5 Melting

It is important, when using a torch for melting that the recommended propane (approx. 0.5 bar or 7.25 psi) / oxygen (approx. 1.0 bar or 14.5 psi) mixture and pressure are observed. Before melting add a pinch of flux to the alloy.

Flux: boric acid

Recommended casting systems (not compulsory)

Alloys					
	Propane-oxygen flame	Vacuum-pressure casting with electric resistance furnace	Centrifugal casting with electric resistance furnace	High frequency induction in atmosphere	High frequency induction in protective gas atmosphere
	Post-melting time 5–10 s	Post-melting time 40–60 s	Post-melting time 40–60 s	Post-melting time 5–10 s	Post-melting time 5–10 s
Pallorag 35	✓	✓	✓		
Strator 3	✓	✓	✓		
Pallorag 33	✓	✓	✓		
Pagalin 2	✓	✓	✓		

Particular instructions for use

Alloys			
	Annealing	Hardening	Sandblasting with glass beads 50 µm
Pallorag 35	700 °C / 10 min / H ₂ O	400 °C / 15 min / air*	✓
Strator 3	700 °C / 10 min / H ₂ O	400 °C / 15 min / air*	✓
Pallorag 33	700 °C / 10 min / H ₂ O	400 °C / 15 min / air*	✓
Pagalin 2	700 °C / 10 min / H ₂ O	450 °C / 15 min / air*	✓

* Annealing before hardening



Surface quality of cast objects

In order to prevent corrosion the cast object must have a surface free of shrink holes and porosities after trimming and polishing.

18.6 Cooling of castings

Do not quench the casting cylinder after casting, but bench cool to room temperature.

18.7 Finishing

Trim the framework first preferably using carbide burs and then fine grinding points at low speed.

18.8 Soldering

We recommend using a propane/oxygen torch for soldering and a flux like CM soldering paste. During soldering wear dark goggles for protection. The design of the soldering block is a compromise between minimising its thermal mass whilst retaining sufficient strength to avoid its fracturing during soldering. Leave a parallel gap of 0.1–0.2 mm between surfaces to be soldered and sufficient area to ensure adequate strength of the joint.

18.9 Pickling

After firing or soldering pickle in a warm, freshly prepared (clean) solution of 10 vol. % sulphuric acid (H₂SO₄)

 When using other pickling agents follow the instructions for use of the respective manufacturer.

18.10 Thermal treatments (not compulsory)

After casting, some of the high gold metal alloys have not yet obtained their maximal mechanical properties. For long-span bridgework and for works with attachments in combustible plastic which will not be veneered with ceramic, a simulation firing of the work in the as cast condition (cleaned frameworks, sprues not yet removed) in the ceramic furnace can be done.

This procedure has the following advantages: The hardness increase allows easier and faster trimming of the frameworks. Grinding overlaps are prevented. Possible tensions due to the casting process are reduced.

18.11 Gilding of frameworks

Gilding is carried out at the user's own risk.

18.12 Polishing

Thorough rubberwheeling ensures easy prepolishing. For best polishing results, soft brushes, felts and cotton wheels are employed using Legabril Diamond diamond-paste. «Whiting chalk» (chalkpowder) mixed with water on soft brushes or cotton wheels may be used for final high polish.

19 Materials

19.1 Composition %

Alloys															
	Au + Pt group metals	Au	Pt	Pd	Ag	Cu	Sn	Zn	In	Ga	Ir	Ru	Rh	Fe	Others
Pallorag 35	46.50	35.00	1.00	10.50	41.00	12.00			0.50						
Strator 3	40.00	20.00		19.95	40.00			4.00	16.00			0.05			
Pallorag 33	30.00	10.00		20.00	59.50	9.50		1.00							
Pagalin 2	26.05	3.00		23.00	65.00	6.45		0.50	2.00		0.05				

19.2 Physical properties

Alloys			
	Density g/cm ³	Melting range °C	Young's Modulus GPa
Pallorag 35	12.4	880–960	98
Strator 3	11.4	855–900	75
Pallorag 33	10.9	935–1020	95
Pagalin 2	10.8	975–1070	95

19.3 Mechanical properties

Alloys												
	Hardness HV5			Proof stress Rp 0.2% MPa			Tensile strength (Rm) MPa			Elongation A5 %		
	As cast	Soft	Hardened	As cast	Soft	Hardened	As cast	Soft	Hardened	As cast	Soft	Hardened
Pallorag 35	235	165	280*	535	350	720	690	520	860	17	37	6*
Strator 3	175	125	165*	315	230	305*	535	465	530*	5	7	5*
Pallorag 33	170	135	230	430	280	615	575	505	810	15	24	9
Pagalin 2	175	135	230*	390	250	400*	580			22	20	7*

* 100% selfhardening after cooling in the cylinder or soldering block, otherwise particular instructions for use.

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:

Livento®.

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.	Packing (gram)	Product name (Material)	Single use	Labelling	UDI-DI	Basic UDI-DI
01000341	10.0	Pallorag 35	No	CE 0483	97640173082227	764016651000041DV
01000342	30.0		No	CE 0483	97640173082234	764016651000041DV
01000313	10		No	CE 0483	97640173081947	764016651000041DV
01000314	25	Strator 3	No	CE 0483	97640173081954	764016651000041DV
01000315	10.0		No	CE 0483	97640173081961	764016651000041DV
01000316	30.0		No	CE 0483	97640173081978	764016651000041DV
01000306	10	Pallorag 33	No	CE 0483	97640173081879	764016651000041DV
01000307	25		No	CE 0483	97640173081886	764016651000041DV
01000278	10	Pagalin 2	No	CE 0483	97640173081596	764016651000041DV
01000279	25		No	CE 0483	97640173081602	764016651000041DV

30 Labelling on packaging/symbols

	Date of manufacture
	Manufacturer
	Catalogue number
	Lot number
	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.
	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