


INSTRUCTION OF USE: NOVOSin

Material information and manufacturer data

Name, trade name	NOVOSin				MD	<input checked="" type="checkbox"/> Medical Device
Classification	Classification:	Ila	Labelling:	CE 0483		<input type="checkbox"/> Technical Device
Data	Article No.:	F09<>		Basis UDI:	763029670009P	
Variants	Powder		Liquid		Colours	
	200g, 500g, 1KG, 5KG		100ml, 250ml, 500ml, 1L, 2.5L		C, Blue, Yellow, Red, Violet, Orange, Green, Rose	
Allowed equipment	Force distribution anchors, expansion screws, metal clasps and metal primer systems approved for orthodontic appliances.					
Manufacturer data	SRN:		LI-MF-000000633			
	Anschrift:		NOVODENT Ets., Industriestrasse 32, 9487 Bendorf, Liechtenstein			
General information	For professional use only (dental technicians/dentists). Document product name and LOT no. Follow the instructions for use. All serious incidents occurring in relation to the product shall be reported to the manufacturer and the competent authority of the Member State.					
Intended purpose	For the manufacture/repair of orthodontic appliances (basic)					
Indication	Orthodontic plastic for the production of orthodontic appliances to fix brace elements / screws to correct malpositioned teeth.					
Contraindication	Avoid direct contact of non-polymerised material in the intraoral area. In case of hypersensitivity of the patient to any of the ingredients, refrain from use.					



Use of the product

Properties

Absolutely easy to process, high mechanical values, absolutely colour-stable, catalyst system free of non-colour-stable tertiary amines.

Environment of use		Shelf life and storage instructions
Applicable at room temperature. Keep away from sources of ignition.		Avoid direct sunlight. Always keep containers closed. The shelf life is 3 Years. Do not use the product after the expiry date. Keep out of reach of children. Store at room temperature min. + 2°C, max. 25°C.
Material composition		
Powder	Polymethyl methacrylate	
Liquid:	Methylmethacrylate	
Skin protection	Disposable gloves butyl rubber, layer thickness 0.7mm, penetration time (min) >480 Disposable gloves nitrile rubber, layer thickness 0.4mm, penetration time (min) >120 The exact penetration time must be obtained from the manufacturer of the protective gloves and must be observed.	
Transport	For regulations on the transport of the raw material, please refer to the NOVOSin safety data sheets.	
Specifications	For specific product specifications, please refer to the NOVOSin technical data sheet.	

Danger notice

	Liquid contains methyl methacrylate (MMA). Highly flammable. Flash point +10°C. Liquid is irritating to eyes, respiratory system and skin. May cause sensitisation by skin contact. Keep container in a well-ventilated place. Keep away from sources of ignition - do not smoke. Completely emptied containers can be returned to the local material cycle. Residual quantities must be disposed of as hazardous waste in compliance with the hazardous waste regulations. Take measures against electrostatic charging. Avoid direct skin contact. Take protective gloves made of special nitrile, handle only with spatula, use suction equipment, as well as mouth protection and work goggles. No systematic side effects.
	

Instructions for use

Mixing ratio	2 parts by weight powder to 1 part by weight liquid. (e.g. 2g powder to 1g liquid)							
Polymerisation	Device	Pressure pot	Pressure	2-4 bar	Duration	20 Minutes	Temperature	45- 50°C
Processing	<p>Preparation and use The plaster model is to be insulated with a suitable insulation such as Seperator CC or HC Universal. Insulation containing formaldehyde should be avoided. The following information refers to a room temperature of 22°C. At a lower room temperature the times are longer and at a higher room temperature they are shorter.</p> <p>In the <u>sprinkling method</u> (Salt&Pepper), the powder is sprinkled onto the insulated plaster model starting from one side and then the powder is wetted with the liquid. The liquid must completely absorb the amount of powder, after which the next layer can be applied in the same way until the targeted thickness is reached.</p> <p>In the <u>dough modelling process</u>, the liquid must be placed in the mixing cup, the approximate amount of powder added quickly and stirred immediately. Further addition of powder should only be done in small quantities and quickly. The mixing bowl should be swayed to remove air bubbles. The NOVODur dough is pourable for 2 minutes after mixing. Afterwards a plastic phase (duration approx. 4 min.) is reached.</p> <p><u>Polymerisation</u> in the pressure pot should take place after 4-7 min. at the earliest, the dough surface must look matt. The finishing is done according to the current state of the art (grinding in, finishing).</p> <p>Note on polishing Pre-polish with an emery mandrel or rubber attachment. Then polish with a pumice stone, a goat hair brush and a small polishing fork. Polish carefully with a polishing fork. Auxiliaries such as approved polishing agents for dental acrylics can be used.</p>							















Liability notice

The information is based on the current state of our knowledge, but does not constitute a guarantee of product properties and does not establish a contractual legal relationship. The product is normally delivered stabilised. However, it may polymerise under heat development if the storage time and/or storage temperature are significantly exceeded. No liability is accepted for damage resulting from failure to observe the instructions for use and the area of application. This also applies if the product is mixed or processed together with products from competitors.

Contact details of the manufacturer

Address:	NOVODENT Ets., Industriestrasse 32, 9487 Bendern, Liechtenstein						
Contact:	Phonel.:	+423 377 1500	Fax:	+423 377 1509	E-Mail:	frontoffice@novodent.com	
Websites::	Webshop:	www.novodent.dental			Main page:	www.novodent.com	

Note about the symbols ⓘ

	<input checked="" type="checkbox"/> Lot/Batch No.		<input checked="" type="checkbox"/> Manufacturer		<input checked="" type="checkbox"/> Unique Device Identification 
	<input checked="" type="checkbox"/> Expiry date		<input checked="" type="checkbox"/> Storage temperatures		<input checked="" type="checkbox"/> Observe operating instructions
	<input checked="" type="checkbox"/> Articlenuumber		<input type="checkbox"/> Protection from sunlight		<input checked="" type="checkbox"/> Medical Device *
	<input checked="" type="checkbox"/> Attention (GHS)		<input checked="" type="checkbox"/> Danger Flammable (GHS)		<input checked="" type="checkbox"/> Do not reuse
SRN	<input checked="" type="checkbox"/> Single Registration Number (EUDAMED)				<input checked="" type="checkbox"/> MP- European conformity *

ⓘ Symbols used on the labelling of this product are marked with . *Not applicable for non-medical products