



## INSTRUCTION OF USE: NOVOTray (763029670011P,763029670012P)



### Material information and manufacturer data

<b>Name, trade name</b>	NOVOTray				<input checked="" type="checkbox"/> Medical Device
<b>Classification</b>	<b>Classification:</b>	I	<b>Labelling:</b>		CE
<b>Data</b>	<b>Article No.:</b>	F11 / F12<>		<b>Basis UDI:</b>	763029670011P,763029670012P
<b>Variants</b>	<b>Powder</b>		<b>Liquid</b>		<b>Colours</b>
	500g, 1KG, 5KG		250ml, 500ml, 1L, 2.5L		
<b>Allowed equipment</b>	Impression silicon Class I				
<b>Manufacturer data</b>	<b>SRN:</b>		LI-MF-000000633		
	<b>Anschrift:</b>		NOVODENT Ets., Industriestrasse 32, 9487 Bendorf, Liechtenstein		
<b>General information</b>	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.				
<b>Intended purpose</b>	For the production of a custom impression tray				
<b>Indication</b>	To enable the manufacturing of custom impression trays tailored precisely to the oral anatomy of the patient, facilitating the creation of accurate impressions of the oral cavity.				
<b>Contraindication</b>	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

<b>Properties</b>	Absolutely easy to process, high mechanical values, absolutely colour-stable, catalyst system free of non-colour-stable tertiary amines.
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<b>Environment of use</b>	Applicable at room temperature. Keep away from sources of ignition.	<b>Shelf life and storage instructions</b>	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.
<b>Material composition</b>	<b>Powder</b> Polymethyl methacrylate <b>Liquid:</b> Methylmethacrylate		
<b>Skin protection</b>	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.		
<b>Transport</b>	For regulations on the transport of the raw material, please refer to the NOVOTray safety data sheets.		
<b>Specifications</b>	For specific product specifications, please refer to the NOVOTray technical data sheet.		

<b>Danger notice</b>	  <p>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.</p>
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## Instructions for use

<b>Mixing ratio</b>	4 parts by weight powder to 1 part by weight liquid. (e.g. 4g powder to 1g liquid)							
<b>Polymerisation</b>	<b>Device</b>	-	<b>Pressure</b>	-	<b>Duration</b>	<10 Minutes	<b>Temperature</b>	Roomtemp.
<b>Processing</b>	<p><b><u>Preparation and use</u></b> The plaster model is to be insulated with a suitable insulation. Insulations containing formaldehyde should be avoided.</p> <p>The following instructions are based on a room temperature of 22°C. In colder temperatures, the timeframes will be extended, while in warmer temperatures, they will be shortened. Begin by placing the liquid in the mixing vessel, then swiftly add the powder quantity and immediately stir. Additional powder should only be added in small amounts and quickly. The mixing vessel should be agitated to remove air bubbles. The NOVOTray dough is workable for 5 minutes after mixing. Polymerization occurs in the air on the model and completes in 10-15 minutes. Finishing is carried out according to current state-of-the-art techniques.</p> <p><b><u>Note on polishing</u></b> The product is not intended for polishing.</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

<b>Address:</b>	NOVODENT Ets., Industriestrasse 32, 9487 Bendern, Liechtenstein						
<b>Contact:</b>	<b>Phonel.:</b>	+423 377 1500	<b>Fax:</b>	+423 377 1509	<b>E-Mail:</b>	<a href="mailto:frontoffice@novodent.com">frontoffice@novodent.com</a>	
<b>Websites::</b>	<b>Webshop:</b>	<a href="http://www.novodent.dental">www.novodent.dental</a>			<b>Main page:</b>	<a href="http://www.novodent.com">www.novodent.com</a>	
<b>SSCP-Rapport</b>	not applicable, due to its Class I product						

### 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"/> Articulenumber		<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	
<b>SRN</b>	<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