

QUALITY SYSTEM FORM

The purpose of this document is to show how to prevent and solve problems related to the use of Villacryl Opaker as opaque material for crowns and bridges and frame dentures.

Problem	Potential impact on patient/product	Probable cause	Recommended action
Allergic reaction	-	<i>Patient sensitive to allergens contained in the product</i>	<i>Use a different material that is appropriate for the patient</i>
	-	<i>Increased Residual monomer content</i>	<i>Strictly adhere to powder to liquid ratios. Use IFU-recommended residual monomer reduction measures.</i>
Material falling off the metal, changing the color, bubble formation.	<i>Making a final device free of defects is not possible. Toxicological risk to the patient</i>	<i>Overheating of the material during curing. polymer decomposition</i>	<i>Follow the Instruction for Use. Avoid long-term curing of the material in one place, do not exceed temperatures above 250°C</i>
Pores in the acrylic resin after polymerization	<i>Increased roughness - may cause color changes and bacteria to settle on the surface, which may cause inflammation. Lower mechanical properties of the final device</i>	<i>Wrong mixing ration powder/ liquid</i>	<i>Use the recommended mixing ratios of powder and liquid</i>
		<i>Incorrect consistency of the acrylic mass (too thick) when pouring into the mold</i>	<i>Reducing waiting time after mixing powder and liquid Reducing workshop temperature</i>
		<i>Wrong polishing methods of the veneer acrylic part</i>	<i>Use a milling cutter, pumice stone and polishing paste</i>
		<i>Too fast polymerization process</i>	<i>Use the polymerization recommendations polymerization flask fixed in the frame in water at a temperature of 80-90 °C and heat for 30 minutes</i>
		<i>Dry gypsum model</i>	<i>Before working with acrylic resin, soak the gypsum model during 5 minutes in to water</i>
Low mechanical properties of the crown after polymerization	<i>Delamination of the veneer from the metal substructure</i>	<i>Wrong mixing ratio powder/ liquid</i>	<i>Use the recommended powder-liquid mixing ratio</i>
		<i>Missing of retention elements</i>	<i>Project retention elements, sandblast with aluminum oxide and use Villacryl Opaker Primer (follow the instruction for use)</i>
		<i>Wrong polymerization process</i>	<i>Use the polymerization recommendations polymerization in hot air or flame, not burn the material (color change chalky)</i>
Wrong color of the final restoration	<i>The aesthetics of the prosthesis are not acceptable</i>	<i>Wrong powder/ liquid mixing ratio</i>	<i>Use the recommended powder-liquid mixing ratio</i>
		<i>Improperly cured metal masking agent</i>	<i>Follow the instructions for the metal masking agent. Acrylic polymerization is possible after the above agent has completely cured..</i>
		<i>To high temperature during polymerization</i>	<i>Heat the material evenly over a stream of hot air or a flame until the material is no longer shiny on the surface. Move the filling in the stream of warm air so that it heats evenly</i>
Changes in color and discoloration of the denture during use	<i>The aesthetics of the prosthesis are not acceptable</i>	<i>Wetting the technician's hands with water / using moisturizing creams while processing the material</i>	<i>Use HDPE gloves</i>

PREVENTION AND PROBLEM SOLVING		
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		<i>Using aggressive denture cleaning agents containing oxidizing substances</i>	<i>Recommend the patient to use alternative, less aggressive agents given in the IFU.</i>
		<i>remains from smoking, drinking coffee, dyes contained in consumed foods or spices, taken medications</i>	<i>Use of IFU recommended denture cleaning products</i>
<i>The veneer did not connect with the metal elements</i>	<i>Increased affinity for the accumulation of fungi and bacterial flora - possible irritations and microbial infections</i>	<i>Incorrectly designed metal element</i>	<i>Acrylic does not chemically bond with metals. The metal element must be modeled so that the acrylic part can be retained in the prosthesis.</i>
		<i>Improperly cured metal masking agent</i>	<i>Follow the instructions for the metal masking agent. Acrylic polymerization is possible after the above agent has fully cured.</i>
		<i>Silane as adhesion promotor is missing</i>	<i>Use silane spread it on the metal surface, wait few minutes until it evaporates and apply Villacryl Opaker tin layer on such surface</i>
<i>The crown or bridge is not adhering properly to the model</i>	<i>Problem with the cementation</i>	<i>Wrong project of the metal superstructure</i>	<i>Follow the recommendations of the metal alloy manufacturers.</i>

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