



TECHNICAL DATA SHEET

Product:	Alpha-Crown™ Crown & Bridge Material	
Product Description:	Alpha-Crown™ is an auto-mix (catalyst and base) polymer-based temporary crown & bridge material with fluorescence which allows for naturally aesthetic, life-like temporaries. It contains 23% by volume of a blend (barium-alumino-silicate, quartz and silica) of fillers. The material is compatible with light cure flowable composites for repairs and is radiopaque for easy identification in radiographs.	
Indications for Use:	For use in temporary crowns and bridges, temporary inlays and onlays, and long term temporaries.	
Appearance:	1:1 ratio, 2-paste system Catalyst: glossy, white Base: glossy, natural Shades: A1, A2, A3, and B1	
Curing Mechanism:	Self cured by mixing base and catalyst together.	
Shelf-Life:	30 months	
Filler Type:	Barium-alumino-silicate, quartz and silica	
	Filler % by Volume:	22.70
	Filler Particle Range (µm):	0.02 – 5.00
	Average Filler Particle Size (µm):	3.09
Main Composition (%w/w):		
	Catalyst paste:	% w/w
	Inorganic filler	35 – 45
	Methacrylate and bisacrylate monomers	55 – 65
	Initiator	<1
	Inhibitor	<1
	Base paste:	
	Inorganic filler	35 – 45
	Methacrylate and bisacrylate monomers	55 – 65
	Accelerator	<1
	UV stabilizer	<1
	Colorants	<1
Physical /Mechanical Properties:		
	Working time:	≥90 sec. at 23.5°C
	Setting time:	≤5.5 min. at 23.5°C
	Flexural strength:	≥50 MPa
	Water sorption:	≤32 µg/mm ³
	Solubility:	≤5 µg/mm ³
	Color Stability:	Stable



Regulatory Classification:

This product is in conformity with the following standard(s) or other normative documents:

Code of Federal Regulations CFR 21 Part 820 – Medical Device Quality System Regulation
Code of Federal Regulations CFR 21 Part 872.3770 Temporary Crown and Bridge Resin
International Standard ISO 10477:2018/ Polymer-based crown and bridge materials

Signature/ Date:

 / 7/16/19

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ISO 13485

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Associated Documents: NR 676, DCN 1787, 3473, 4880, 6333, 6405, 6843