Affinity™

Hydroactive Impression Material

INTENDED USE: A vinyl poly siloxane material to be used as a medical device for the purposes of creating, via impression, a reproduction of tooth and gum structure.

Hydroactive Affinity™ V.P.S. from Clinician's Choice® Dental Products Inc. is the first 3rd generation vinyl poly siloxane impression material. Affinity's advanced 3rd generation chemistry provides true hydroactive properties, higher tear strength and dimensional stability. In addition, each viscosity is matched to all others resulting in a superior impression, regardless of the technique utilized. Affinity also exhibits the most efficient working and set times to minimize chair time and the potential for inaccuracies. Affinity's dispensing is even advanced in that Affinity flows more easily through a conventional mixing tip as compared to previous generation impression materials, regardless of the viscosity. 3rd generation Affinity will consistently provide you with the most efficient and accurate impression.

INSTRUCTIONS FOR AUTO-MIX CARTRIDGES

1) Insert the flange at the rear of the cartridge into the space provided at the front of the impression gun – depress the gun lever to lock the cartridge in place.
2) Twist off and dispose of the cartridge shipping cap.
3) Attach a mixing tip and twist 1/4 turn to lock it into position; the mixing is done automatically inside the mixing tip.
4) Before filling the tray, it is recommended to discard the initially mixed (pea-sized) amount of the material. Check to ensure both base and catalyst are expressing freely.
5) Gently squeeze the impression gun handle to mix and dispense the impression material. Release handle to stop the flow.
6) Leave the used auto-mix tip on the cartridge as a self sealer after each use. For subsequent dispensing remove and discard the sealer tip. Proceed with steps 3 through 6.

MIXING INSTRUCTIONS FOR PUTTY

1) Using the color coded scoops provided, dispense equal portions of base and catalyst from the jars.
2) Using fingertips, mix the base and catalyst until a homogeneous mixture is achieved (approximately 30-45 seconds). Slight variations in the relative amounts of base and catalyst will not alter the work and set times.
3) Place the mixed putty into an adhesive coated impression material tray.

MIXING/SETTING TIMES

AFFINITY V.P.S. HYDROACTIVE	COLOR	AVAILABLE WORKING TIME	MINIMUM INTRAORAL SET TIME	MAXIMUM TOTAL CURE TIME FROM START OF MIX
LIGHT H.F. REGULAR SET	**LIGHT BLUE**	**1:45 min.**	**2:30 min.**	**4:15 min.**
LIGHT H.F. FAST SET	**LIGHT BLUE**	**1:10 min.**	**1:45 min.**	**2:55 min.**
LIGHT R.F. REGULAR SET	**LIGHT GREEN**	**1:45 min.**	**2:30 min.**	**4:15 min.**
LIGHT R.F. FAST SET	**LIGHT GREEN**	**1:10 min.**	**1:45 min.**	**2:55 min.**
LIGHT BODY XL	**ORANGE**	**1:45 min.**	**2:30 min.**	**4:15 min.**
MONOPHASE	**MAUVE**	**2:15 min.**	**2:45 min.**	**5:00 min.**
HEAVY BODY REGULAR SET	**TEAL**	**1:45 min.**	**2:30 min.**	**4:15 min.**
HEAVY BODY FAST SET	**DK. GREEN**	**1:10 min.**	**1:45 min.**	**2:55 min.**
INFLEX REGULAR SET	**DK. BLUE**	**1:45 min.**	**2:30 min.**	**4:15 min.**
INFLEX FAST SET	**DK. BLUE**	**1:10 min.**	**1:45 min.**	**2:55 min.**
QUICK BITE	**PURPLE**	**0:15 min.**	**0:45 min.**	**1:00 min.**
AFFINITY CRYSTAL	**CLEAR**	**0:45 min.**	**1:30 min.**	**2:15 min.**
PUTTY *	**TEAL**	**1:45 min.***	**3:15 min.**	**5:00 min.**

* TIME IS IN ADDITION TO A 30-45 SECOND MIX TIME. THESE PROCEDURE TIMES REFLECT IDEAL CONDITIONS. FLUCTUATIONS IN TEMPERATURE AND HUMIDITY MAY REDUCE OR EXTEND THESE TIMES. PLEASE CALL FOR QUESTIONS OR CONCERNS.

AFFINITY REGULAR SET MATERIALS HAVE A FASTER TOTAL CURE TIME COMPARED TO PREVIOUS GENERATION FAST SET MATERIALS.

AFFINITY FAST SET MATERIALS ARE RECOMMENDED FOR SINGLE PREPARATIONS ONLY.

VINYL POLY SILOXANE IMPRESSION MATERIAL CONSIDERATIONS

1) Allow impression material to reach room temperature prior to use.
2) Handling retraction cord with latex gloves may subsequently prevent the setting of the impression material if direct contact occurs.
3) Prior to taking impression, use Detail Pre-Impression Cleansing Gel to decontaminate the preparation site.

PLEASE NOTE

- **Sulpha-based drugs may inhibit the set time of VPS material.**
- **When handling Affinity Putty, certain gloves will inhibit the set. It is suggested the operator mix a small amount of putty to confirm proper setting prior to impression procedure, to test for compatibility. Keep jars closed when not in use.**
- **Very high viscosity (putty) materials are not suitable for detailed impressions when used alone.**
- **For model fabrication, Affinity is ideally poured two hours after the impression has been taken. However, Affinity can be poured sooner if the impression is placed in hot water for ten minutes to allow for degassing to occur.**

STORAGE

Vinyl Poly Siloxane impression material should be stored at room temperature (65º-75ºF/18º-24ºC) and at minimum relative humidity. Ensure adequate ventilation of the premises where this product is handled and stored.

WARRANTY

Clinician's Choice® Dental Products, Inc. will replace any Affinity Hydroactive Impression Material, free of charge, if proven to be defective, and when stored according to the manufacturer's specifications. Clinician's Choice Dental Products Inc. does not accept liability for any loss or damage, direct or consequential, arising out of the use of or the inability to use these products. Before using, the user shall determine the suitability of the product(s) for its intended use and the user assumes all risk and liability whatsoever in connection therewith.

Clinician's Choice®

Distributed by Clinician's Choice, a division of Den-Mat Holdings, LLC
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℞ only

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Affinity

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SAFETY DATA SHEET

SECTION 1: MATERIAL IDENTIFICATION & INFORMATION

MATERIAL NAME: Affinity™ V.P.S.

USE OR PREPARATION: Impression Material

COMPANY: Distributed by Clinician's Choice, a division of Den-Mat Holdings, LLC
1017 W. Central Avenue, Lompoc, CA 93436 USA

TELEPHONE: For emergencies or product information
800.433.6628 or email info@clinicianschoice.com

DATE OF ISSUE: March 2015

DATE OF REVISION: February 2024

SECTION 2: HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to Regulation (EC) 1272/2008: Void

Information concerning particular hazards for human and environment: The product does not have to be labeled due to the calculation procedure of the "General classification guideline for preparations of the EU" in the latest valid version.

LABEL ELEMENTS:

Labeling according to Regulation (EC) 1272/2008: Void

Labeling according to EU guidelines: Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

OTHER HAZARDS

RESULTS OF PBT AND VPVB ASSESSMENT

PBT: Not applicable

vPvB: Not applicable

SECTION 3: COMPOSITION/INFORMATION OF INGREDIENTS

CHEMICAL CHARACTERIZATION:

Description: Mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica

Hazardous components: None

SECTION 4: FIRST AID MEASURES

General information: No special measures required

After skin contact: Wash with plenty of water and soap

After eye contact: Rinse with plenty of water and consult a doctor

After swallowing: If symptoms persist consult a doctor

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing media: CO_2, water

Protective equipment: No special measures required

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Not required

Environmental precautions: No special measures required

Methods for cleaning up: Pick up mechanically

Additional information: None

SECTION 7: HANDLING AND STORAGE

HANDLING:

Information for safe handling: For dental use only. No special measures required.

Recommendation for fire and explosion protection: No special measures required

STORAGE:

Requirements at storerooms and containers: No special measures required

Requirements for storage with other products: Not required

Further information on storage conditions: None

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with limits of values to be supervised at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace

Additional information: The lists valid during the making were used as basis.

PERSONAL PROTECTIVE EQUIPMENT:

General measures of protection and hygiene: Normal hygienic measures

Respiratory protection: Not required

Protection of hands: Not required

Eye protection: Not required

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE:

Form: Paste

Color: Different

Odor: Odorless

INFORMATION ON CHANGE IN THE PHYSICAL STATE	Value	Unit	Method
Melting point/melting range:	n.a.	°C	
Boiling point/boiling range:	n.a.	°C	
Flash point:	n.a.	°C	
Autoignition temperature:	n.a.		
Danger of explosion:	none		
Density:			
Heavy Body MegaMix	1,5	(20°C)	g/cm³
Heavy Body RS/FS	1,46	(20°C)	g/cm³
InFlex RS/FS/MegaMix	1,49	(20°C)	g/cm³
Light Body HF RS/FS	1,24	(20°C)	g/cm³
Light Body RF RS/FS	1,33	(20°C)	g/cm³
Light Body XL	1,20	(20°C)	g/cm³
Monophase	1,41	(20°C)	g/cm³
Putty	1,53	(20°C)	g/cm³
Quick Bite	1,52	(20°C)	g/cm³
Vapor pressure:	n.a.		mbar
Viscosity:	paste		
pH:	neutral		
Solubility in/miscibility with:	Partially soluble in toluene, petrol ether		
Water:	insoluble		
Content of solvents:	none		
Organic solvents:	-----		
Water:	-----		
Content of solids:	n.a.		

SECTION 10: STABILITY AND REACTIVITY

Conditions to avoid: No decomposition if used according to specification

Hazardous decomposition products: None under normal conditions of storage and use

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

PRIMARY IRRITATION:

Skin: No irritating effect

Eye: No irritating effect

Additional toxicological information: When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

SECTION 12: ECOLOGICAL INFORMATION

General information: Avoid transfer into environment

Classification of water endangerment: WGK 1 (German regulation) slightly hazardous for water

SECTION 13: DISPOSAL CONSIDERATIONS

PRODUCT:

Recommendation: Small quantities can be disposed of with household waste. Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

UNCLEANED PACKAGING:

Recommendation: Disposal must be made according to official regulations.

SECTION 14: TRANSPORT INFORMATION

Land transport ADR, RID: Not subject to transport regulations

Maritime transport: IMDG-Code: Not subject to transport regulations

Air transport ICAO-TI/IATA-DGR: Not subject to transport regulations

SECTION 15: REGULATORY INFORMATION

Classification according to EC-guidelines: The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Changes compared with the previous version: Adaptation according to 1907/2006/EG, Article 31

Prepared by: Peter G. Jordan

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

N/D: NOT DETERMINED N/A: NOT APPLICABLE