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 gingival tissues.

AFFINITY™ MULTI-PREP® Extended Working Time Impression Material from CLINICIAN'S CHOICE® is a hydroactive vinyl poly siloxane formulation. AFFINITY MULTI-PREP uses advanced 3rd generation chemistry to provide true hydroactive (hydrophilic) properties, a higher tear strength, and superior dimensional stability. AFFINITY MULTI-PREP Tray Material is closely matched to the AFFINITY MULTI-PREP Wash Material to prevent overdisplacement, resulting in more wash material being left on the tooth preparation for improved accuracy. AFFINITY MULTI-PREP working time is extended to allow for use in cases with multiple preparations, helping to prevent impression distortion.

INSTRUCTIONS FOR AUTOMIX 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) Squeeze the gun handle to engage the plunger into the cartridge, making sure the cartridge and plunger are aligned.

4) Before attaching the automix tip to the cartridge, extrude 1/4 inch of impression material by gently squeezing the handle. Check to ensure both base and catalyst are expressing freely. Wipe the end of the cartridge clean.

5) Attach an automix tip to the cartridge and twist 1/4 turn to lock it into position.

6) Gently squeeze the impression gun handle to mix and dispense the impression material. Release handle to stop the flow.

7) Leave the used automix tip on the cartridge as a self sealer after each use. For subsequent dispensing remove and discard the sealer tip. Proceed with steps 4 through 7.

MIXING/SETTING TIMES

AFFINITY MULTI-PREP V.P.S.	COLOR	AVAILABLE WORKING TIME	MINIMUM INTRAORAL SET TIME	MAXIMUM TOTAL CURE TIME FROM START OF MIX
WASH MATERIAL	**DARK BLUE**	**2:40 minutes**	**4:30 minutes**	**7:10 minutes**
TRAY MATERIAL	**YELLOW**	**2:40 minutes**	**4:30 minutes**	**7:10 minutes**

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

- Sulphur-based drugs may inhibit the set time of VPS material.
- Very high viscosity materials are not suitable for detailed impressions when used alone.
- For model fabrication, AFFINITY MULTI-PREP is ideally poured at least 30 minutes after the impression has been taken. However, AFFINITY MULTI-PREP 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-78ºF/18º-25ºC) 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 MULTI-PREP 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®
DENTAL PRODUCTS INC.
1-800-265-3444 • Phone: (519) 641-3066 • www.clinicianschoice.com

EC REP EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

112017
981201

CE

PRODUCT SPECIFICATIONS & DIRECTIONS FOR USE

CLINICIAN'S CHOICE®
DENTAL PRODUCTS INC.

SAFETY DATA SHEET

SECTION 1: MATERIAL IDENTIFICATION/PREPARATION/COMPANY UNDERTAKING

Material name: Affinity™ Multi-Prep® Extended Working Time Impression Material

Clinician's Choice® Dental Products Inc.
167 Central Avenue, London, ON, Canada, N6A 1M6

For U.S. Distribution: Brookfield, CT, USA, 06804

Telephone: For emergencies or product information
1-800-265-3444 or (519) 641-3066 (8:00am - 5:00pm ET)

Date reviewed: October 2017

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

Chemical characterization: Mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica

Hazardous components: None

SECTION 4: FIRST-AID MEASURES

First-aid measures: 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/°F	
Boiling point/boiling range:		n.a.	°C/°F	
Flash point:		n.a.	°C/°F	
Autoignition temperature:		n.a.		
Danger of explosion:		none		
Density:	Tray Material	1,50 (20°C/68°F)	g/cm³	
	Wash Material	1,24 (20°C68°F)	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 CONSIDERATION

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: No subject to transport regulations
Maritime transport: IMDG-Code: No subject to transport regulations
Air transport ICAO-TI/IATA-DGR: No 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

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.

Preparation by: Peter G. Jordan

Product Inquireies & Ordering

CLINICIAN'S CHOICE®
DENTAL PRODUCTS INC.

1-800-265-3444 • Phone: (519) 641-3066 • www.clinicianschoice.com