CounterFit™ II

Multi-Purpose Replication Silicone

INDICATION FOR USE

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

DESCRIPTION OF MATERIAL

CounterFit™ II is an addition-vulcanising impression silicone especially for situation impressions. A short setting time in the mouth, easily removed from the mouth, unlimited shelf life of the impressions, and a highly detailed reproduction make CounterFit II an advantageous alternative to alginates.

TECHNICAL DATA ACCORDING TO DIN EN ISO 4823

Consistency: medium viscosity - type 2

Maximum Working Time: 1:10 minutes

Minimum Intraoral Set Time at 37ºC/98.6ºF: 1:30 minutes

Total Set Time: ≤2:30 minutes

Polymerization shrinkage after 24h: 0.05-0.3%

Elastic recovery: ≥98.8%

Strain in compression: 4.9-7.1%

Shore-A Hardness (24 hours): 40-47

The mixing and processing times refer to a room temperature of 23°C/73°F and a relative air humidity of 50%. Lower temperatures prolong, higher temperatures shorten these times.

INSTRUCTIONS FOR USE

MIXING 50ML CARTRIDGES

When using 50mL cartridges, insert the cartridge into the impression gun and attach a mixing tip; the mixing is done automatically inside the mixing tip. **Before filling the tray, it is recommended to discard the initially mixed (pea-sized) amount of the material. Leave the used mixing tip attached to the cartridge to act as a seal between uses.**

380ML CARTRIDGE LOADING

Hold the cartridge with the sealed outlet openings facing upwards. Take the handle of the sealing cap and remove the sealing cap upwards. Avoid excessive force. Insert the cartridge into the mixing machine (according to manufacturer's instructions). Attach a new mixing tip to the cartridge. After the mixing tip is correctly seated (the central hexagonal socket at the lower end of the tip must be properly aligned with the hexagonal drift shaft), place the Bayonet ring over the mixing tip and push it down completely. Turn the ring clockwise (1/4 turn) to lock the mixing tip securely in place. Check to ensure the hexagonal drift shaft engages when starting. The spiral in the mixing tip must rotate when starting.

NOTE: Discard the first 3cm of impression material extruded from newly filled cartridges. Store used cartridge with fixed/used mixing tip in place. It serves as a cap. To remove the used mixing tip turn the Bayonet ring counter-clockwise and draw it off.

CHOOSING THE IMPRESSION TRAY

When using a plastic or metal, perforated or non-perforated metallic tray, we recommend using a vinyl poly siloxane tray adhesive. CounterFit II will work with all commonly used impression trays.

IMPRESSION TRAY

The impression tray should be cleaned and dried carefully before use.

COUNTER-FIT II SINGLE-PHASE IMPRESSION TECHNIQUE

CounterFit II should be mixed to a uniform color and consistency, then immediately placed into the impression tray followed by immediate intraoral placement. The working time is approximately 1:10 minute. The recommended intraoral removal time is at least 1:30 minutes, for a total set time of 2:30 minutes. Afterward, the material can be demolded. The flexible recovery processes are finished after approximately 30 minutes. The impression should be stored at room temperature (max. 25ºC/77ºF). CounterFit II is best poured up with dental stone after 30 minutes (degassing process). CounterFit II remains stable indefinitely.

DISINFECTING

For disinfecting, the impression should be immersed in disinfecting solution. The use of a 2% glutaraldehyde solution is recommended. Please make sure that the disinfecting solution is compatible with addition-reaction silicones. After removing the impression from the mouth it should be rinsed with water for 15 seconds. The disinfecting process time for the impression is about 10-15 minutes, afterwards it must be rinsed with water for another 15 seconds.

CASTING AND GALVANIZATION

After disinfecting, dry the impression and store it at normal room temperature (max. 25ºC/77ºF). The impression should be poured 30 mins. at the earliest after removal from the mouth. Using special purpose hard plaster (ISO 6873, type 3) respectively an ultra hard plaster (ISO 6873, type 4) for the forms is recommended. CounterFit II can be copper or silver galvanized.

IMPORTANT ADVICE

- When using 50mL cartridges, the mixing tip should remain on after use to seal the cartridge.
- CounterFit II is not to be used in combination with condensation impression materials.
- Residues from hemostatic agents must be removed by water spray prior to taking an impression. Polymerization may be inhibited by use of latex gloves, creams, cleaning agents, resins, etc.

KEEP AWAY FROM CHILDREN!

ONLY FOR DENTAL USE!

STORAGE CONDITIONS

At room temperature <25ºC/77ºF.

DURABILITY

See date of expiry. CounterFit II is not to be used when expiry date has passed.

WARRANTY

Clinician's Choice® Dental Products, Inc. will replace CounterFit II, 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 this product. 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.

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Clinician's Choice®

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Multi-Purpose Replication Silicone

800.433.6628

www.clinicianschoice.com

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SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIER
Trade name: CounterFit II Multi-Purpose Replication Silicone

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST
No further relevant information available.
APPLICATION OF THE SUBSTANCE/THE MIXTURE: Impression material

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET
Manufacturer/Supplier:
Distributed by Clinician's Choice, a division of Den-Mat Holdings, LLC
1017 W. Central Avenue, Lompoc, CA 93436 USA
Emergency Telephone Number: 800.433.6628
info@clinicianschoice.com

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 ON 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 with a doctor.
After swallowing: If symptoms persist, consult 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 applicable.
Eye protection: Not absolutely required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:
Form: Paste
Color: Purple
Odor: Odorless

	Value	Unit	Method
Information on change in the physical state			
Melting point/melting range:	N.A.	ºC/ºF	
Boiling point/boiling range:	N.A.	ºC/ºF	
Flash point:	N.A.	ºC/ºF	
Autoignition temperature:	N.A.		
Danger of Explosion:	None		
Density:	1,46 (20ºC/65ºF)	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

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.