

VersaFio® Syringe

INSTRUCTIONS FOR USE

Light-Activated Flowable Composite Resin

10°C - 24°C
50°F - 75°F



English

33052X / 6 x 2g + 30 Needles; 33053X / 1 x 2g + 5 Needles

Light-cure flowable composite

- 1) Prepare tooth and apply composite bonding agent.
- 2) Bend needle if required. Squeeze syringe with a slow, steady pressure. Test on pad first.
- 3) Syringe in layers no more than 2mm thick. Light-cure each layer for a minimum of 30 seconds each.
- 4) After use, remove tip from syringe and dispose of properly. Disinfect syringe.

Dansk

33052X / 6 x 2g + 30 Needles; 33053X / 1 x 2g + 5 Needles

Flydende lyshærdende komposit

- 1) Forbered tanden og stryg kompositbindemiddel på den.
- 2) Bøj nålen efter behov. Tryk på sprøjten med langsomt, jævnt tryk. Prøv på pladen først.
- 3) Indsprøjt i lag, der ikke er over 2 mm tykke. Lyshærd hvert enkelt lag minimum 30 sekunder.
- 4) Efter anvendelsen fjernes spidsen fra sprøjten og den kasseres iflg. vedtægterne. Sprøjtehåndtaget steriliseres.

Español

33052X / 6 x 2g + 30 Needles; 33053X / 1 x 2g + 5 Needles

Compuesto fluido de fotocurado

- 1) Prepare el diente y aplique el agente adhesivo del compuesto.
- 2) Doble la aguja si es necesario. Presione la jeringa con una presión lenta y constante. Pruebe primero en un recipiente.
- 3) Aplique con la jeringa en capas no mayores a 2 mm de espesor. Cure con luz cada capa durante un mínimo de 30 segundos cada una.
- 4) Luego de usar, quite la punta de la jeringa y deséchela en forma adecuada. Esterilice el asidero de la jeringa.

Nederlands

33052X / 6 x 2g + 30 Needles; 33053X / 1 x 2g + 5 Needles

M.b.v. licht uithardende stromende composietvulling

- 1) Bereid de tand voor en breng een bindmiddel voor de composietvulling aan.
- 2) Buig de naald indien vereist. Druk langzaam en gestadig op de injectiespuit. Eerst op het kussentje testen.
- 3) In lagen injecteren die niet dikker zijn dan 2 mm. Elke laag m.b.v. licht uit laten harden voor minstens 30 seconden per laag.
- 4) Na gebruik het uiteinde van de injectiespuit verwijderen en in de juiste afvalton weggoien. Steriliseer de hendel van de injectiespuit.

Italiano

33052X / 6 x 2g + 30 needles; 33053X / 1 x 2g + 5 Needles

Composito fluido fotoattivato

- 1) Preparare il dente ed applicare l'agente legante del composito.
- 2) Piegar l'ago a piacimento. Premere lentamente lo stantuffo della siringa esercitando una pressione uniforme. Effettuare una prova iniziale su un tampone.
- 3) Iniettare strati spessi non più di 2 mm. Fotoindurire ciascuno strato per non meno di 30 secondi.
- 4) Dopo l'uso, rimuovere la punta dalla siringa e smaltirla opportunamente. Sterilizzare l'impugnatura della siringa.

Français

33052X / 6 x 2g + 30 needles; 33053X / 1 x 2g + 5 Needles

Composé versable photopolymérisant

- 1) Préparez la dent et appliquez l'agent adhésif du composé.
- 2) Orientez l'aiguille si nécessaire. Appuyez lentement sur la seringue en maintenant une pression constante. Testez tout d'abord sur un morceau de gaze.
- 3) Utilisez la seringue pour appliquer des couches d'un maximum de 2 mm d'épaisseur. Photopolymérisez chaque couche pendant au moins 30 secondes.
- 4) Après utilisation, retirez l'extrémité de la seringue et jetez-la de manière appropriée. Stérilisez la poignée de la seringue.

Portuguese

33052X / 6 x 2g + 30 Needles; 33053X / 1 x 2g + 5 Needles

Composto fluido de fotocurado

- 1) Prepare o dente e aplique o agente de união composto.
- 2) Curve a agulha se necessário. Aperte a seringa com uma pressão lenta e uniforme. Teste primeiro no bloco.
- 3) Aplique a seringa em camadas com menos de 2 mm de espessura. Deixe fazer o fotocurado de cada camada por pelo menos 30 segundos.
- 4) Após o uso, retire a ponta da seringa e descarte-a adequadamente. Esterilize a seringa.

Svenska

33052X / 6 x 2g + 30 Needles; 33053X / 1 x 2g + 5 Needles

Ljushärdande flytande komposit

- 1) Förbered tanden och påför kompositbindemedlet.
- 2) Böj vid behov kanylen. Tryck ihop sprutan i en jämn och långsam rörelse. Utför först prov på plattan.
- 3) Spruta på i högst 2 mm tjocka skikt. Ljushärda varje skikt i minst 30 sekunder.
- 4) Efter avslutad användning skall sprutspetsen avlägsnas och deponeras på lämpligt sätt. Sterilisera spruthandtaget.

Deutsch

33052X / 6 x 2g + 30 Needles; 33053X / 1 x 2g + 5 Needles

Fließfähiges Komposit, lichthärtend

Gebrauchsanleitung

- 1) Zahn wie gewohnt präparieren und Adhäsiv aufbringen
- 2) Kanülenansatz - falls nötig - in den gewünschten Winkel biegen. Material mit leichtem gleichmäßigem Druck ausdrücken. Materialfluß evtl auf einem Mischblock prüfen.
- 3) Nicht in Schichtdicken von mehr als 2 mm aufbringen. Jede Schicht mit handelsüblichen Halogenlampen 30 sec. belichten.
- 4) Nach Gebrauch C-R Tip entfernen und verwerfen. Dosierpistole desinfizieren.

SAFETY DATA SHEET (SDS)

In accordance with Hazard Communication Standard (HCS), 29CFR 1910.1200(g), 2012 revision

SECTION I - PRODUCT / COMPANY IDENTIFICATION

Product Name: VERSAFLO®
Synonyms: Light-Activated Flowable Composite Resin
Recommended Use: Dental Material
Part (Item) Number: 330520, 330521, 330522, 330523, 330528,
330530, 330531, 330532, 330533, 330538
Company Name: Centrix Inc.
Address: 770 River Road
City, State, Zip: Shelton Ct, 06484
Emergency Telephone Number: 203-929-5582
Information Telephone Number: 800-235-5862

SECTION II – HAZARDS IDENTIFICATION

For potential health hazards: SEE Section 11 below.
No other significant hazards to man or the environment are reasonably foreseen.

SECTION III - COMPOSITION / INFORMATION ON INGREDIENTS

Product Contents: Flowable Light-Cure Composite Restorative / Veneer Cement
Hazardous Ingredients: None listed.
Exact % content withheld due to trade secret restrictions.

SECTION IV - FIRST AID MEASURES

Inhalation: No harm anticipated.
Skin Contact: Wash with soap and water.
Eye Contact: Flush immediately with copious amounts of water.
Ingestion: Induce vomiting if large amount of material is swallowed.

SECTION V - FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Water contact acceptable.
Extinguishing Media which should not be used: None.
Special exposure hazards from combustion products: None specific.
Special protective equipment for fire-fighters: None.

SECTION VI - ACCIDENTAL RELEASE MEASURES

Personal Precautions: Avoid contact of skin or eyes.
Wash hands with soap and water if contact occurs.
Environmental Precautions: Dispose of in accordance to all federal, state, local regulations.
Methods for Cleaning Up: Wipe up with soap, water and paper towels.

SECTION VII - HANDLING AND STORAGE

Handling Precautions: None.
Safe Storage Conditions: Store at temperatures not exceeding 75°F (24°C).
Other Restrictions or Recommendations: Avoid exposure to moisture and light.

SECTION VIII - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection & Ventilation: Not required.
Protective Clothing or Equipment: Not required under normal handling.
Unusual Work/Hygienic Practices: Avoid prolonged contact skin; wash with soap and water.

SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Thin paste. Odor: Negligible odor. pH: Not Applicable.
Boiling Point / Range: Not Applicable. Melting Point / Range: Not Applicable.
Flash Point: Not Applicable. Auto-Ignition Temperature: Not Applicable.
Flammability: No. Explosive Limits in Air: Not Applicable.
Oxidizing Properties: None. Vapor pressure (mm Hg): Negligible
Other Data: Not available or none.

SECTION X - STABILITY AND REACTIVITY

Stability: Generally stable.
Conditions of Instability: Avoid exposure to light.
Incompatibility with Various Substances: None.
Hazardous Decomposition Products: None.
Hazardous Polymerization: May occur upon exposure to elevated temperatures when large quantities of material are involved.
Conditions to Avoid: Avoid exposure to light and temperatures above 80°F.

SECTION XI - TOXICOLOGICAL INFORMATION

Potential Acute Health Effects: Possibility of skin irritation or sensitization if not washed off promptly.
Potential Chronic Health Effects: Possibility of skin sensitization or irritation upon prolonged or repeated exposure.
Signs and Symptoms of Exposure: Skin/eye irritation.
Medical Conditions Generally Aggravated by Exposure: None known.
Carcinogenic or Potential Carcinogenic Effects: No ingredient listed as a carcinogen.
Other Potential Health Effects: None known.
SECTION XII - ECOLOGICAL INFORMATION
No ecological damage or impact anticipated when handled as indicated.

SECTION XIII - DISPOSAL CONSIDERATIONS

Waste Disposal: Do not dispose into sink.
Dispose of in accordance with all federal, state, and local regulations.

SECTION XIV - TRANSPORT INFORMATION

UN Classification: Not Applicable. Identification: Not Applicable.
Special Provisions for Transport: Avoid elevated temperatures and high intensity light.

SECTION XV - REGULATORY INFORMATION

U.S. FDA Dental Device: Class II product
EC Medical Device Directive: Class IIa product

SECTION XVI - OTHER INFORMATION

Product handling exclusively by dental specialists per instructions for use.

CAUTION

The above information is based on presently available data and to our best knowledge for handling the product under normal conditions. Any use of this product in any way not indicated on this document or using it together with any other process/procedure will be exclusively under the user's responsibility.

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Making Dentistry Easier.™

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