Instructions for Use (IFU)

Rapid Set Pickup Acrylic

Manufactured For:

Smart Denture Conversions, LLC
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Suite 104
Apex NC, 27523
855-550-0707
www.SmartOnX.com



Training:

It is strongly recommended that clinicians, new as well as experienced implant and abutment users, always go through special training before undertaking a new treatment method. Smart Denture Conversions offers a wide range of courses for various levels of knowledge and experience. For more information, please visit www.SmartOnX.com.

Product Description:

The Rapid Set Pickup Acrylic is a self curing, fast setting acrylic resin for use in a variety of dental applications.

Name	Flammable?	Material
Rapid Set Pickup Acrylic Liquid Monomer	Yes	Methyl Methacrylate Blend
Rapid Set Pickup Acrylic Powdered Polymer	No	Methacrylate Copolymer

Directions for Use

The recommended mixing ratio is 1cc of Acrylic Powder to 0.5cc of Liquid Monomer.

For Denture Pickup using the SDC protocol

1. Prior to performing a pickup using the SDC protocol, a dam material should be used to help reduce to the risk of overheating tissue. Also, ensure that irrigation and suction are available to help reduce the heat of the acrylic during curing.
2. Pour the required amount of Acrylic Powder into a graduated measuring cup. A standard size denture that has been channeled out will use approximately 15cc of powder. Adjust the amount for the size of the denture and how much filling needs to be done.
3. Pour the Liquid Monomer into a separate graduated measuring cup, filling to only half the volume of the powder. (i.e. 7.5cc of Liquid Monomer for 15cc of Powder Acrylic).
4. Pour the Acrylic Powder into the cup with the Liquid Monomer and mix thoroughly for 10-20 seconds.
5. As the acrylic starts to thicken, it can be poured into the intaglio of the denture.
6. Once the mixture reaches a dough-state (00:20 - 01:30 min:sec), the denture can be properly seated in the mouth.
7. Use irrigation and suction to help reduce the heat generated from the Acrylic during the cure time (1:30 - 3:00 min:sec).
8. Finish and polish in the usual manner.

For adding small amounts of acrylic (Precoating and minor Backfilling)

1. Pour a small amount of Acrylic Powder into a graduated measuring cup.
2. Pour a small amount of Liquid Monomer into a separate graduated measuring cup.
3. Using a disposable brush, dip into the Liquid Monomer and apply to all the surfaces that need acrylic added.
4. Dip the brush back into the Liquid Monomer, allowing a ball of liquid to form on the end.
5. Dip the brush into the Acrylic Powder, allowing it to stick to the monomer ball.
6. Apply the liquid/powder ball to the surface needing to be filled, ensuring all powder changes to the darker color, showing that it has mixed with the liquid monomer.
7. Repeat steps 3-6 until all the required acrylic has been added.

8. The denture can be placed in hot water or a pressure pot to improve the acrylic structure and accelerate curing time.
9. Finish and polish in the usual manner.

Indications for Use:

For TiBase pickups, repair of dentures, construction of temporary crowns, impression trays for individual teeth and orthodontic plates, splints, check bite and other general purposes.

Contraindications:

It is contraindicated to use Rapid Set Pickup Acrylic if:

- Operator or Patient shows signs of allergy or hypersensitivity to the chemical components of the materials listed in the chart above.

Warning:

- The supplied Rapid Set Pickup Acrylic is intended for laboratory use by a trained technician.
- Surgical masks must be worn to avoid inhalation of aerosol or dust.
- If the indication or the nature of use is not clear, do not use until all points have been clarified.
- Do not use if package is damaged.
- Smart Denture Conversions is not liable for damage resulting from use outside the intended use of the product.

Cautions/Precautions:

The following precautions are required before or during procedure:

- The liquid is HIGHLY FLAMMABLE. Avoid sources of ignition.
- In case of contact with eyes, flush immediately with water and seek medical attention.
- Personal Protective Equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.
- Do not use Smart Denture Conversion components after the expiration date indicated on the packaging.
- Before every procedure make sure that all required components, instruments and auxiliary equipment are complete, in operating order and available in the required quantity.
- Position the patient such that the danger of aspiration of components is minimized.
- All components used in the patient's mouth must be secured to prevent aspiration and swallowing.

Cleaning and Disinfecting Recommendation for Multi-Use Delivery Systems:

To avoid cross-contamination between patients, the bottles and measuring devices require mid-level disinfection. Immediately after use inspect the bottles, measuring devices and label for deterioration. Discard if damaged. DO NOT IMMERSE. Thoroughly clean bottles and measuring devices to prevent drying and accumulation of contaminants. Disinfect with a mid-level registered healthcare-grade infection control product according to regional/national guidelines.

Cleanup:

Remove residual resin with a dry gauze after each application. Mop up liquid spills with a dry cloth.

Storage, Handling and Transportation:

The devices must be stored in a dry place in their original packaging at room temperature and protected from direct sunlight (2-37°C/36-98°F). Improper storage may compromise essential material and design characteristics, leading to device failure.

Disposal:

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy. Separation, recycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging

waste, where applicable. If there is no current legislation, pack them in a perforating waste/sharps disposal container and dispose of them in hospital waste.

Validity:

Upon publication of these instructions for use, all previous versions are superseded.

Availability:

Some items of Smart Denture Conversions are not available in all countries.

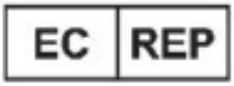
Warranty:

Please visit www.SmartOnX.com for the most up to date warranty information.

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Symbols Glossary:

The following Symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

	Manufactured for/ Distributor		Date of Manufacture
	Use By Date		Serial Number
	Batch Code		Catalog Number
	Unique Device Identifier		Medical Device
	CE Mark		UK Representative
	United Kingdom Conformity Assessment Mark		United Kingdom Conformity Assessment Mark with Approved Body Number
	European Representative		Non-Sterile
	Do Not Reuse		Do Not Resterilize
	Do Not Use if Packaging is Damaged		Consult Instructions for Use
	Keep Dry		Keep Away from Sunlight
RX Only	For Prescription Use Only		Caution, Consult Accompanying Documents