

Advertencias, precauciones y restricciones:



PELIGRO / ATENCIÓN

Exclusivo para uso odontológico. Uso profesional. Manipular el producto en local ventilado, utilizando espátula, ropa de protección, guantes desechables de protección y tapa bocas. Se recomienda la manipulación del producto en temperatura ambiente (20°C a 25°C). Realizar los controles habituales para el control microbiológico durante la manipulación. Los recipientes, instrumentos y las manos deben estar libres de contaminantes para evitar la contaminación de las piezas y del paciente con microorganismos. Los recipientes, instrumentos, las piezas y las manos deben estar libres de cera o grasa para obtener una adecuada unión química entre las resinas. Seguir las instrucciones de uso para evitar residuos de monómero en la pieza rebasada, alteración de color, desgaste acelerado o rotura. El no cumplimiento de las instrucciones de uso puede afectar el desempeño del producto. Puede ocurrir pigmentación en el Glaze en pacientes fumadores. En caso de alergia comprobada del paciente a cualquiera de los componentes de este producto, el mismo no deberá ser utilizado. No es recomendable la manipulación de este producto por parte de gestantes y lactantes. No reutilizar los embalajes del producto. Conservar el envase herméticamente cerrado. **Resina:** Puede formar mezclas aire/pólvora inflamable. **Eliminación:** Los residuos, contenido/recipiente deben ser eliminados en basureros industriales o sanitarios, de acuerdo a la legislación vigente. No descartar los residuos en la tubería de desagüe, cloacas, en ríos, cursos de agua, o junto a los residuos domésticos. La Ficha de Seguridad para Productos Químicos de este producto puede ser obtenida por teléfono. Producto inflamable. Temperatura de ignición del líquido: 421,4°C. Punto de inflamación: 10°C. Conservar alejado de fuentes de ignición – No fumar. **Líquido / Polvo / Glaze / Kit:** Evitar inhalar el polvo, las neblinas y los vapores. Lavarse bien las manos después del manoseo. Quitar cualquier ropa contaminada y lavar antes de volver a usarla. **Líquido / Polvo / Kit:** Puede causar reacciones alérgicas en la piel. Tóxico para los organismos acuáticos, con efectos nocivos duraderos. La ropa de trabajo contaminada no puede salir del lugar de trabajo. Evite la liberación al medio ambiente. EN CASO DE CONTACTO CON LA PIEL: lava abundantemente con agua y jabón. En caso de irritación o erupción cutánea: Consultar a un médico. Recoge el material derramado. **Líquido / Glaze / Kit:** Líquidos y vapores altamente inflamables. Provoca irritación ocular grave. Mantener alejado del calor, chispa, llama abierta y superficies calientes. - No fumar. Mantener el recipiente herméticamente cerrado. Estabiliza el vaso contenedor y el receptor del producto durante transferencias. Utilizar equipamiento eléctrico, de ventilación y de iluminación a la prueba de explosión. Utilizar solamente herramientas que no generan chispas. Evitar el acumulo de cargas electrostáticas. EN CASO DE CONTACTO CON LA PIEL (o el cabello): retira inmediatamente toda la ropa contaminada. Enjuga la piel con agua o toma una ducha. EN CASO DE INHALACIÓN: remueve la persona para un lugar ventilado y la mantiene en reposo en una posición que no obstaculice la respiración. Si la irritación ocular persiste: consulta a un médico. En caso de incendio: para la extinción utilizar polvo químico, dióxido de carbono (CO2), Halon, neblina de agua, o espuma para alcohol. **Polvo / Glaze / Kit:** Puede causar irritación respiratoria. Utilice solamente al aire libre o en lugares bien ventilados. EN CASO DE INHALACIÓN: remueve la persona para un lugar ventilado y la mantiene en reposo en una posición que no obstaculice la respiración. Caso se sienta mal, entrar en contacto con un CENTRO de INFORMACIÓN TOXICOLOGICA o un médico. **Líquido / kit:** Causa irritación de la piel. Se sospecha que perjudica la fertilidad o para el feto. Obtener instrucciones específicas antes de su uso. No manipule el producto antes de haber leído y comprendido todas las precauciones de seguridad. EN CASO DE exposición o sospecha de exposición: Consulta un médico. **Glaze / kit:** Puede ser nocivo en caso de ingestión. Puede causar somnolencia o mareos. Cualquier incidente grave relacionado con el producto debe comunicarse al fabricante y a la autoridad competente del Estado miembro en el que estén establecidos el usuario y/o el paciente.

Almacenamiento: **Polvo:** Almacenar el producto en un lugar seco, fresco, bien ventilado y bajo protección de la luz solar. **Líquido / Kit / Glaze:** Almacenar el producto en local seco, fresco, bien ventilado y bajo protección de la luz solar. No almacenar en temperaturas superiores a 35°C.

Composición: **Polvo:** PEMA y pigmentos orgánicos. **Líquido:** MMA, DBP, DMPT y HEMA. **Glaze:** PEMA, acetato de etilo y esencia de menta.

Material de apoyo: Medidores.

Presentación:

Código	Contenido
0012303404	Kit Soft Rebase 30g - Rosa
0012303405	Kit Soft Rebase 30g - Incoloro

Código	Contenido
0012303416	Kit Soft Rebase 120g - Rosa
0012303417	Kit Soft Rebase 120g - Incoloro

EN

Soft Rebase

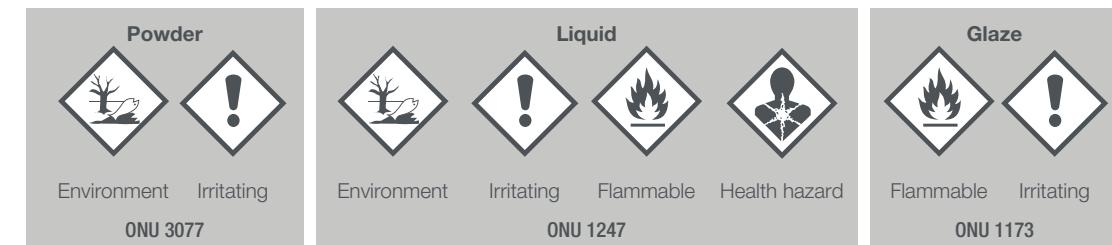
Soft Rebase TDV is a soft self-curing acrylic resin for temporary relining, which allows the patient more adaptation time to the full denture. Its formulation allows the maintenance of the soft state for up to 9 months protecting the patient in sensitive areas. For intraoral and extraoral application because the polymerization does not generate heat and the monomer does not cause irritation in the oral mucosa. Easy handling and application, the kits comes with a measuring device for the adequate control and use of the material. Soft Rebase TDV meets the requirements of ISO 20795-1, Type 2, Class 1, ensuring high quality results. The product is available in colorless and pink colors. The kit comes with Glaze and measuring cup. Glaze is suitable for waterproofing of the resin, promoting brightness and protection against pigmentation and accumulation of bacteria, since it seals the porous surface of the pieces.

Indication: Indicated for functional molding, relining of total and removable partial dentures, relining of plaques and orthodontic appliances and creation of artificial gingiva in implant models. It absorbs the masticatory load over the total or partial prosthesis, which generates less tension on the hard base of the prosthesis and avoids localized areas of tension concentration on the alveolar ridge. Soft Rebase TDV is also indicated for relining surgical areas in tissue reconditioning, post implants and surgeries, with the objective of greater protection of these tissues. However, for surgical areas that requires greater care of the tissues and implants it is recommended to use the TDV Soft Provisional.

Use: Soft denture, plaques and orthodontic braces rebasing: **Preparation:** Proceed with an induced relief of the denture to be rebased, removing approximately 1.5mm of resin, with the assistance of, low rotation burs or strips. Clean and dry the piece. For extraoral procedures, coat buccal and labial surfaces, interproximal areas and occlusal surfaces of teeth and any opposing full or partial denture with insulation. Do not apply coating within 3mm (1/8 inch) of the peripheral border. **Resin Mixing:** Shake the powder bottle before use. First place the liquid in the Dappen cup, then add the powder, gradually. The proportion of Soft Rebase TDV resin components is 2 parts powder to 1 part liquid (v/v). Mix it for 30 seconds tops, avoiding the formation of bubbles (it is recommended to use the Spatula 36). Wait for the plastic stage to be applied to the part.

Application in prosthesis: Cover the teeth, gingival and palatine surface, with insulation. Do not apply recoating in more than 3mm from the peripheral edge. Spread Soft Rebase TDV resin over the area to be covered. Insert the prosthesis onto patient's mouth and ask him to close his mouth gently until occlusion. Wait 3 minutes and ask the patient to move the lips and maxillae in order to obtain a muscular adaptation in the peripheral area. Remove the prosthesis from patient's mouth and rinse it with cold water. Remove excess material using scalpel or dental burs. Insert the prosthesis onto patient's mouth and ask him to firmly close the mouth in occlusion, hold this position steady for 5 minutes. Remove the prosthesis from patient's mouth and rinse it with cold water. **Application in plaques and orthodontic braces:** Spread Soft Rebase TDV resin over the area to be covered. Insert the piece onto patient's mouth, keeping the piece in steady position for 4 minutes. Remove it from the patient's mouth and rinse it with cold water. Remove material residues. **Finishing and Polishing:** After completion of the polymerization (10 to 15 minutes), proceed with molding of the work piece. Proceed the finishing in the conventional way. It is recommended to give the first finishing using a tungsten dental bur and then use a sandpaper discs to smooth the surface. Clean the piece with detergent and water. Dry the entire surface of the acrylic using oil-free compressed air. Carry out the polishing in the conventional fashion with the assistance of a polishing paste or abrasive rubbers. Apply two to three layers of glaze on the piece. Wait for 2 to 3 minutes. Wash the piece with water and detergent. In case of complete or partial prosthesis, do not pass the glaze over the thermoplastic resin. **Gingival mask under implant-assisted prosthesis molding:** **Preparation and mixing:** Place the implants into the molding transfer. Isolate the molding material around the implants. Shake the powder bottle before use. First place the liquid in the Dappen cup, then add the powder, gradually. The proportion of Soft Rebase TDV resin components is 2 parts powder to 1 part liquid (v/v). Mix it for 30 seconds in maximum, avoiding the formation of bubbles (it is recommended to use the Spatula 36). Wait for the plastic stage to be applied. **Application:** Spread Soft Rebase TDV resin over the implant area. Shape it with a spatula assisted the monomer. Wait for 3 minutes in order to pour the plaster. **For functional moldings:** Shake the powder bottle before use. First place the liquid in the Dappen cup, then add the powder, gradually. The proportion of Soft Rebase TDV resin components is 2 parts powder to 1 part liquid (v/v). Mix it for 30 seconds in maximum, avoiding the formation of bubbles (it is recommended to use the Spatula 36). Wait for the plastic stage to be applied. Apply the resin to the customized tray keeping an uniform thickness. Bring the tray to the mouth and proceed with the functional molding technique. **Reassembly of surgical areas in tissue reconditioning:** **Preparation:** Make an internal prosthesis relief, compatible with the operated region. An additional relief (margin of safety) of 3 to 5 mm is suggested for greater tissue protection. **Mixing and Application:** Proceed according to guidelines for general prosthesis relining. **Glaze:** After finishing the surface, apply two to three layers of glaze over the rebased area. Wait for 2 to 3 minutes. Rinse before use.

Warnings, precautions and restrictions:



DANGER / WARNING

For dental use only. Professional use. Handle the product in a ventilated place, using a spatula, protective clothing, disposable gloves, goggles and a mask. The product is recommended to be handled at room temperature (20°C to 25°C). Follow the usual procedures for microbiological control during handling. Containers, instruments and hands must be free of contaminants in order to avoid contamination of the parts and the patient with micro-organisms. Containers, instruments, parts and hands must be free of wax or grease in order to provide an adequate chemical bond between the resins. Follow the instructions for use to avoid monomer residue on the manufactured part, color change, wear and tear or breakage. The failure in complying with the instructions for use may affect product performance. Glaze pigmentation may occur in smokers. If there is proven allergy to any of its components, the product must not be used. The product handling is not recommended for pregnant and lactating women. Do not reuse containers. Store in a locked place. **Resin:** It may produce flammable air / powder mixtures.

Disposal: Waste material, content and container must be disposed in an industrial or sanitary landfill according to local legislation enforcement. Do not dispose the captioned waste in sewers, waterways or regular household waste. The Chemical Products Safety Data Sheet for such product may be requested by phone. Flammable product. Ignition temperature of the liquid: 421,4°C. Flash point: 10°C. Keep away from any sources of ignition - Do not smoke. Liquid / Powder / Glaze / Kit: Avoid inhaling dust, vapors and mists. Wash hands thoroughly after handling. Remove all contaminated clothing and wash before its reuse. **Liquid / Powder / Kit:** May cause allergic skin reactions. Toxic to aquatic organisms with long lasting effects. Contaminated clothing must not leave from its workplace. Avoid release to the environment. IN CASE OF CONTACT WITH SKIN: Wash with plenty of soap and water. In case of skin irritation or rash: Get medical advice / attention. Put away the spilled material. **Liquid / Glaze / Kit:** Highly flammable liquids and vapors. Causes serious eye irritation. Keep away from heat, sparks, naked flames and hot surfaces. - Do not smoke. Keep container tightly closed. Proceed with grounding on containers and product receiver during shipment. Use explosion-proof electrical, ventilation, and lighting equipment. Only use anti-sparking tools. Avoid the accumulation of electrostatic charges. IN CASE OF CONTACT WITH SKIN (or hair): Immediately remove all contaminated clothing. Rinse skin with water or take a shower. IN CASE OF INHALATION: Remove the person to a ventilated area and keep at rest in a comfortable breathing position. If eye irritation persists: Search for medical advice. In case of fire: For extinguishing it use chemical powder, carbon dioxide (CO2), Halon, water mist, or alcohol foam. **Powder / Glaze / Kit:** May cause irritation of the respiratory tract. Use only outdoors or in a well-ventilated area. IN CASE OF INHALATION: Remove the person to a ventilated area and keep at rest in a comfortable breathing position. If you feel unwell, please contact a TOXICOLOGICAL INFORMATION CENTER or a doctor. **Liquid / kit:** Causes skin irritation. Suspected of damaging fertility or fetus. Obtain specific instructions before use. Do not handle the product until you have read and understood all safety precautions. IN CASE OF exposure or suspected exposure: Search for medical advice. **Glaze / kit:** May be harmful if swallowed. May cause drowsiness or dizziness. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Storage: **Powder:** To be stored in a cool and dry place, protected from sunlight. **Liquid / Glaze:** To be stored in a cool and dry place, protected from sunlight. Do not store the product in temperature above 35°C.

Composition: **Powder:** PEMA and organic pigments. **Liquid:** MMA, DBP, DMPT and HEMA. **Glaze:** PEMA, ethyl acetate and mint essence.

Support material: Measuring devices

Presentation:

Code	Content	Code	Content
0012303412	Kit Soft Rebase 30g - Pink	0012303416	Kit Soft Rebase 120g - Pink
0012303413	Kit Soft Rebase 30g - Colorless	0012303417	Kit Soft Rebase 120g - Colorless

Manufacturer: TDV Dental Ltda.
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PT/ES: Dispositivo Médico
EN: Medical Device