

INSTRUCTIONS FOR USE

GENERAL CHARACTERISTICS
Renamel® Microfill is the only composite that truly mimics the enamel surface. Where enamel is to be replicated, Renamel Microfill is the composite resin of choice. Renamel Microfill has been and continues to be the number one rated microfill for more than two decades. When applied, sculpted, finished and polished accurately, no other composite resin can match its lifelike, natural appearance. In essence, it is the artistic dentist's dream material. Renamel Microfill is intended for the replacement of tooth substance and is used solely by the dentist in the dental practice.

DESCRIPTION
Renamel Microfill is a light-cured, microfilled, highly polishable dental filling material, according to EN ISO 4049 (Type 1/Class 2/Group 1). Renamel Microfill cures with an LED or Halogen light with a light intensity more than 500mW/cm² at wave-length range of 400 - 500 nm. Renamel Microfill has a compressive strength of >320 MPa, flexural strength of > 80 MPa and 2 mm depth of cure.

CREATING AN ENAMEL-LIKE SURFACE
Renamel Microfill is a pure microfill, and as such can be polished as highly as glass. Using the appropriate instruments, a dentist can shape and texture the surface to exactly duplicate the surrounding dentition. This step should not be taken lightly, for this is the part that gives you the ultimate in esthetic dentistry. Renamel Microfill has the best refractive and reflective index of any product in the marketplace. When finished and polished properly, Renamel Microfill will create results that are so beautiful and long-lasting, that both the dentist and the patient will be astounded.

COMPOSITION
Renamel Microfill contains UDMA and 1,4-Butanediol dimethacrylate (28 - 30%). The fillers contain silicon dioxide and prepolymerized composite (70% by weight and 60% by volume). Initiators, stabilizers and pigments are additional ingredients (< 1%). The particle size of the filler range from 0.04 - 0.2 micron.

Renamel Microfill has been in the marketplace for more than twenty-five years, and its handling, color stability, and long term polishability is unsurpassed.

LONG-TERM COLOR STABILITY
Renamel composites offer color stability that is unmatched in the marketplace. Renamel Microfill holds its shade and polish so that you can rest assured that your patient will be happy for many years.

INDICATIONS FOR USE

- Direct anterior veneers
- Top layer of Class I and II restorations
- Anterior Class III and IV restorations
- Class V restorations (cervical caries, root erosion, wedge-shaped defects)
- Closing of diastemas
- Repair of composite and ceramic veneers
- Reshape, lengthen and restoratively reposition anterior teeth

CONTRAINDICATIONS
Renamel Microfill is contraindicated if patient is known to be allergic to any of the ingredients of Renamel Microfill. No other patient restrictions apply.

SIDE EFFECTS
Can cause irritation in sensitive patients.

INTERACTIONS
Do not use Renamel Microfill in combination with eugenol containing materials, as these can impede the polymerization process.

NOTICE
During time-consuming procedures, avoid overexposure from the operatory light to protect against premature polymerization of the material.

The curing unit must be maintained and calibrated according to the manufacturer's specifications.

WARNING
Contains skin sensitizing substances (acrylates, Skin Sens. 1 > 0,1%). Observe safety data sheet.

Applies to the uncured material. May cause an allergic skin reaction. Avoid contact with the uncured material. Wear protective gloves/protective clothing/eye protection.

If on skin: Wash with plenty of water and soap. If skin irritation or rash occurs: Get medical advice/attention. The uncured material is hazardous to the environment. Avoid release to the environment.

Always observe the relevant country-specific health and safety regulations and legal requirements when handling hazardous substances.

Any deviation from the processing process described here can jeopardize the biocompatibility, functionality and safety of the final product.

DISPENSING COMPOSITE MATERIAL
Syringe delivery:

- Extrude composite onto a mixing pad by turning the handle slowly in a clockwise manner. Slice an increment of proper size with a sterile instrument onto the mixing pad.
- Immediately replace syringe cap to prevent polymerization. If the extruded material is not used right away, cover the composite with a light protecting box such as our ResinKeeper™.

Unit dose delivery

- Insert unit dose into dispensing gun and dispense composite material. Dispose of unit dose after use.

PLACEMENT DIRECTIONS

Prior to the application of Renamel Microfill, the use of opaques or microhybrids, or a combination of both may be necessary to achieve excessive color blackout. If replacing dentin, place a micro-hybrid or nanofill composite first for strength and opacity. Polymerize before the addition of your microfill layer.

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- Extrude composite onto a mixing pad by turning the handle slowly in a clockwise manner. Slice an increment of proper size with a sterile instrument onto the mixing pad.
- Immediately replace syringe cap to prevent polymerization. If the extruded material is not used right away, cover the composite with a light protecting box such as our ResinKeeper™.

Unit dose delivery

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COSMEDENT® www.cosmedent.com | 1.800.621.6729
RenameL® Microfill | COMPOSITE DE MICRORRELLENO FOTOPOLIMERIZADO

SELEÇÃO DE TONALIDADE
Ao selecionar uma tonalidade, deve-se lembrar que os dentes são geralmente policromáticos, com três zonas: incisal translúcida mais escura, porção central mais clara do corpo e área cervical mais escura. A avaliação da tonalidade em um dente limpo e úmido usando a ampliação ajudará a identificar facilmente essas áreas.

As tonalidades do corpo no Renamel Restorative System correspondem à zona central do corpo da superfície do dente. A seleção de tonalidade primária deve ser feita contra a área do corpo do dente. Uma boa sugestão é remover a porção incisal e gengival em cada abra de tonalidade, o que pode ajudar a obter uma correspondência mais precisa com a área do corpo. É possível também criar um guia de tonalidade próprio a partir do material compósito.

Algumas dicas adicionais sobre seleção de tonalidades:
- Entender como a luz afeta o aspecto geral da seleção de tonalidades. Avaliar a tonalidade em luz fluorescente (onde podemos ver uns outros na maioria das vezes) e aumentar com outros tipos de luz, ou seja, luz de combinação de tonalidade, como Rite-Lite™ 2° (do Cosmedent) ou visualização em luz natural.
- Os materiais devem corresponder exatamente a uma escala de cores existente. Caso contrário, convém criar um guia de tonalidades própria.
- É possível incluir o paciente na mudança de tonalidade, mas nunca inclui-lo na correspondência de tonalidades.

DICAS ÚTEIS PARA COLOCAÇÃO

- ① O uso de um dente enluvado limpo e seco é muito eficaz para formar rapidamente a superfície desejada antes das técnicas de escultura.
- ② O uso de instrumentos revestidos de titânio é indicado para evitar o recuo do compósito.
- ③ Usar um instrumento 8A ou 8AL (lámina longa ou curta) ou G3 da Cosmedent para aplicação e modelagem geral do material, e o IPCL ou IPCL (lámina longa ou curta) para refinamentos finitos.
- ④ O uso do instrumento Multi-Purpose do Cosmedent é muito eficaz para a colocação de lóbulos e sulcos incisais, o que permite espaço suficiente para a adição do material incisal.
- ⑤ Usar um calibrador para medições.
- ⑥ Para evitar a contaminação, lavar e secar bem as luvas antes de colocá-las. Não usar luvas poliviniladas.
- ⑦ Certificar-se de que o paciente remove toda a maquiagem antes do tratamento.
- ⑧ Ao aplicar o compósito, colocar a forma de conveniência em uma peça, esculpir o excesso. Isto é muito mais fácil do que colocar pouco demais e adicionar mais depois.

HIGIENE E DESINFECÇÃO

- Não reusar uma dose unitária.
- A desinfecção da seringa e do dosador de unidade pode ser feita com uma solução desinfetante disponível no mercado.
- Todos os instrumentos usados devem ser cuidadosamente lavados e autoclavados.
- ARMAZENAMENTO**
- Depois de aberto, não refrigerar.
- Manter o Renamel Microfill à temperatura ambiente (aproximadamente 4 a 24 °C).
- Não usar o produto após a data de validade.
- Manter longe da luz do sol.
- Manter fora do alcance das crianças.
- Nota:** O produto foi desenvolvido para utilização em Medicina Dentária e tem de ser utilizado nos termos das instruções de utilização. Os incidentes graves têm de ser comunicados à DeltaMed GmbH e à autoridade competente. Para obter o Resumo de segurança e desempenho clínico (SSCP), consulte a base de dados Eucomed (<https://ec.europa.eu/tools/eudamed>).

INSTRUÇÕES DE DESCARTE
Descartar o conteúdo/recipiente de acordo com a regulamentação local.

EMBALAGEM
Renamel Microfill está disponível em seringas de 4 g ou 20 embalagens de doses unitárias de 0,2 gramas cada.

TONALIDADES
A1, A1.5, A2, A2.5, A3, A3.5, A4, A5, A6, B-Zero, B1, B2, B3, B4, C1, C2, C3, C4, C5, D2, D3, D4, Body White, Light Opaque, Light Incisal, Medium Incisal, Dark Incisal, Opalite.

Tonalidades SuperBrite: SuperBrite 1, SuperBrite 2, SuperBrite 3

Brazil Registration Holder:

HAIAT BAZZI LTDA

Rua Julia Wandrey, 1045, Sala 02

Centro - Ponta Grossa - PR

Cep: 84010-170 Brazil

Responsável Técnico: Cristine F. Bazzi

Registro: 8044450008

COINCIDÊNCIA DE COLORES
2ºHay algo más difícil que hacer que coincida el color de un diente con los dientes existentes! El sistema de restauración Renamel Restorative System™ está pensado para dejar de hacer conjeturas al respecto del color. Reconoce que hay zonas distintas de color y translucidez. Entiende que la selección del color debe consistir en lograr el matiz correcto del esmalte con previsibilidad.

O sistema restaurador Renamel Restorative System de Cosmedent lo ayudará a obtener fácilmente unos resultados uniformemente fiables al seleccionar un color.

LA COINCIDENCIA DE COLORES ES UNA CIENCIA DIFÍCIL Y MUCHAS PERSONAS TIENEN PROBLEMAS CON LA SELECCIÓN DEL COLOR.

2ºCuales son los problemas?

- Muchos materiales existentes en el mercado no coinciden con sus guías de tonos.

Preste atención a la hoja de datos de seguridad.

Aplicable al material sin polimerizar: Puede provocar una reacción cutánea alérgica.

Evitete el contacto con el material no polimerizado. Utilice guantes/ropa protectora/protección ocular.

En caso de contacto con la piel: Lavar con agua y jabón abundantes.

En caso de irritación o erupción cutánea: Consultar a un médico.

El material no polimerizado es perjudicial para el medio ambiente.

Evitete su liberación al medio ambiente.

Cumpla siempre las normas vigentes específicas en cada país relativas a seguridad y salud, así como los requisitos legales durante la manipulación de sustancias peligrosas.

Cualquier desviación del procedimiento de procesamiento descrito puede afectar a la biocompatibilidad, funcionalidad y seguridad del producto final.

DISPENSACIÓN DE MATERIAL DE COMPOSITE
Administración con la jeringa:
- Extraiga el compósito y colóquelo en un bloque de mezcla, girando lentamente el mango el sentido de las agujas del reloj. Corte un incremento de tamaño adecuado con un instrumento estéril y colóquelo en un bloque de mezcla.

- Vuelva a colocar inmediatamente el tapón de la jeringa para evitar la polimerización. Si se usa inmediatamente el material extraído, cubra el compósito con una caja fotoprotectora, por ejemplo, nuestra ResinKeeper™.

Cosmedent ha desarrollado de manera uniforme unos materiales fiables y de color estable, que coinciden de manera precisa entre sí y la guía de tonos Clásica VITA® Shade Guide.

Los compuestos Renamel han coincidido con los tonos VITA® shades con mayor precisión que cualquier otro material del mercado. Los 16 tonos distintos de la guía de tonos VITA shade guide comprenden cuatro intervalos de tonos.

Cosmedent ha añadido varios otros tonos útiles para proporcionarle al dentista más opciones para desarrollar el color correcto. Entre estos, se cuentan algunos tonos gástricos más oscuros para restauraciones cervicales (A5, A6 y C5) y tonos SuperBrite® (SB1, SB2 y SB3) para que

LOT	Número do lote
REF	Número do artigo
MD	Dispositivo médico
	Durabilidade
	Observar as instruções de utilização
	Distribuidor
	Límite de temperatura
	Fabricante
	Proteger do sol
	CE 0124
	Contém substâncias que sensibilizam a pele
	Não reusar

INSTRUCCIONES DE EMPLEO

CARACTERÍSTICAS GENERALES

Renamel® Microfill es el único composite que realmente se asemeja a la superficie del esmalte. En los casos en los que hay que imitar el esmalte, Renamel Microfill es la resina de elección. Renamel Microfill ha sido y sigue siendo el microrrelleno mejor valorado durante más de dos décadas. Si se aplica, terrena y rítmico con precisión, ninguna otra resina de composite puede igualar su aspecto realista y natural. En esencia, es el material soñado por los dentistas artistas. Renamel Microfill se utiliza para sustituir la sustancia dental y lo aplica exclusivamente el dentista en la consulta.

INSTRUCCIONES DE APLICACIÓN

Antes de la aplicación de Renamel Microfill, puede ser necesario el uso de opacadores, microfibra o una combinación de ambos para lograr el bloqueo del exceso de color. Si se sustituye dentina, coloque primero un composite de microfibra o nanofibra para obtener resistencia y opacidad. Polimerice antes de añadir la capa de microrrelleno.

① Prepare el diente, grabe y sequé según las instrucciones del fabricante.

② Coloque el adhesivo dental preferido, por ejemplo, Complete™ de Cosmedent, y polímerice.

③ Se debe colocar Renamel Microfill en una caja fotoprotectora, por ejemplo, ResinKeeper™, en el fin de evitar la prepolimerización por la luz ambiental. Corte un incremento de tamaño adecuado y enrrolle el compósito para formar una bola, un cilindro o una forma elíptica (forma cómoda), según la necesidad.

④ Coloque un instrumento metálico limpio en la zona que se va a restaurar y moldear. Unos instrumentos excelentes para la colocación son 8A y 8AL (de lámina larga y corta) y G-3 de Cosmedent.

Nota. Para la instrumentación, se recomiendan los instrumentos de composite recubiertos de titanio, porque evitarán que el material de composite se adhiera al instrumento.

⑤ Si, aun así, la resina se sigue adhiriendo al instrumento, este puede estar arrañado o sucio. Si la sala es demasiado caliente y se produce cierta adherencia, limpie el instrumento con un hisopo levemente empapado en alcohol y ello disminuirá la adherencia.

⑥ Tómese su tiempo y esculpa con cuidado. Sobrecontornee ligeramente cada restauración salvo en las zonas interproximales. Esculpa exactamente para moldear en estas zonas y ello ayudará mucho a obtener el contorno final de su restauración, y acortará el tiempo de acabado y pulido. Los instrumentos IPC de Cosmedent son excelentes para el esculpido interproximal.

⑦ Si se está colocando un color incisal, el uso de un instrumento recubierto de titanio, por ejemplo, un instrumento Multi-Purpose de Cosmedent, resulta muy eficaz para la colocación de lóbulos y surcos de titanio.

⑧ Para evitar la contaminación, lave y seque bien los guantes antes de la colocación. No uses luvas poliviniladas.

⑨ Certificar-se de que o paciente remove toda a maquiagem antes do tratamento.

⑩ Ao aplicar o compósito, colocar a forma de conveniência em uma peça, esculpir o excesso. Isto é muito mais fácil do que colocar pouco demais e adicionar mais depois.

COMPOSIÇÃO

Renamel Microfill contiene UDMA y dimetacrilato de 1,4-butandiol (al 28 - 30 %). Los empastes contienen óxido de silicio y compuesto prepolimerizado (al 70 % peso y al 60 % por volumen). Otros componentes son iniciadores, estabilizadores y pigmentos (< 0.1%). El tamaño de las partículas de los empastes oscila entre 0,04 y 0,2 µm.

Renamel Microfill ha estado en el mercado durante más de veinticinco años, y su manipulación, estabilidad del color y durabilidad de pulido son insuperables.

ESTABILIDAD PROLONGADA DEL COLOR

Los compuestos Renamel ofrecen una estabilidad del color que no tiene parangón en el mercado. Renamel Microfill mantiene su tono y pulido de manera que puede estar seguro de que su paciente estará feliz durante muchos años.

INDICACIONES DE EMPLEO

- coronas anteriores directas;

- restauraciones de clases I y II de la capa superior;

- restauraciones anteriores de clases III y IV;

- restauraciones de clase V (caries cervical, erosión de la raíz, defectos cuneiformes);

- cierre de diastemas;

- reparación de coronas de composite y cerámica;

- remoldado, alargado y recolocación restauradora de los dientes anteriores.

CONTRAINDIQUACIONES

Renamel Microfill está contraindicado si se tiene conocimiento de que el paciente es alérgico a alguno de los componentes de Renamel Microfill. No se aplican otras restricciones para los pacientes.

EFEKTOS ADVERSOS

Puede causar irritación en los pacientes sensibles.

INTERACCIONES

No se debe usar Renamel Microfill en combinación con materiales que contienen eugenol, ya que estos pueden impedir el proceso de polimerización.

AVISO

Durante las intervenciones prolongadas, se debe evitar la exposición excesiva a la luz operativa, a fin de proteger contra la polimerización prematura del material.

Se debe mantener y calibrar la lámpara de fotopolimerización según las especificaciones del fabricante.

ADVERTENCIA

Contiene sustancias sensibilizantes para la piel (acrílicos, sens. piel I > 0,1%).

Preste atención a la hoja de datos de seguridad.

Aplicable al material sin polimerizar: Puede provocar una reacción cutánea alérgica.

Evitete el contacto con el material no polimerizado. Utilice guantes/ropa protectora/protección ocular.

En caso de contacto con la piel: Lavar con agua y jabón abundantes.

En caso de irritación o erupción cutánea: Consultar a un médico.

El material no polimerizado es perjudicial para el medio ambiente.

Evitete su liberación al medio ambiente.

Cumpla siempre las normas vigentes específicas en cada país relativas a seguridad y salud, así como los requisitos legales durante la manipulación de sustancias peligrosas.

Cualquier desviación del procedimiento de procesamiento descrito puede afectar a la biocompatibilidad, funcionalidad y seguridad del producto final.

DISPENSACIÓN DE MATERIAL DE COMPOSITE

Administración con la jeringa:

- Extraiga el compósito y colóquelo en un bloque de mezcla, girando lentamente el mango el sentido de las agujas del reloj. Corte un incremento de tamaño adecuado con un instrumento estéril y colóquelo en un bloque de mezcla.

- Vuelva a colocar inmediatamente el tapón de la jeringa para evitar la polimerización. Si se usa inmediatamente el material extraído, cubra el compósito con una caja fotoprotectora, por ejemplo, nuestra ResinKeeper™.

Cosmedent ha desarrollado de manera uniforme unos materiales fiables y de color estable, que coinciden de manera precisa entre sí y la guía de tonos Clásica VITA® Shade Guide.

Los compuestos Renamel han coincidido con los tonos VITA® shades con mayor precisión que cualquier otro material del mercado. Los 16 tonos distintos de la guía de tonos VITA shade guide comprenden cuatro intervalos de tonos.

Cosmedent ha añadido varios otros tonos útiles para proporcionarle al dentista más opciones para desarrollar el color correcto. Entre estos, se cuentan algunos tonos gástricos más oscuros para restauraciones