

# CHARISMA® Bulk Flow ONE

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## CHARISMA® Bulk Flow ONE

### Instructions for use ⓑ

**Medical Device – for use by dental health care professionals only.**

**Intended purpose**
CHARISMA Bulk Flow ONE is a flowable, light-curing, radio-opaque nano-hybrid composite. Prosthetic indications include adhesive, tooth-coloured restorations for the anterior and posterior region, including the occlusal surfaces. The radiopacity of the product corresponds to an aluminium layer measuring 3.0 – 3.5 mm (dentine = 1 mm, enamel = 2 mm). Due to its properties, it flows well into the cavity walls during application. The universal colour ensures curing of up to a layer measuring 4 mm in thickness with low shrinkage tension. A topcoat with a universal composite material is not needed. This dental material is suitable for patients requiring dental treatment for the following indications with consideration of the contraindications. For pregnant and nursing women, the treatment risks must be weighed carefully against the benefits taking into consideration the unborn child or infant.
Kulzer medical devices ensure the rehabilitation of oral functions such as chewing, speaking and aesthetics. They stabilize the remaining dentition and/or the avestior ridge restoratively or prosthodontically, or they are accessories in the rehabilitation process.

**Indications**
• Class-I, II, III and -V direct restorations
• First-layer lining for class I and II cavities
• Repair of direct and indirect restorations in combination with a suitable adhesive
• Splitting loosened teeth resulting from trauma or periodontal associated events
• Extended fissure sealing

**Contraindications**
In case of known or suspected allergy to components of the product, its use is contraindicated. Do not use this product in case of known or suspected allergies against (meth)acrylate compounds. Do not use on dentine close to the pulp (layer thickness < 1 mm).

**Potential side effects**
Hypersensitivities to the product or its components cannot be excluded in individual cases.

**Product properties**
**Package sizes / delivery forms**
2.0 g cartridges

**Accessories**
• Application cannulas are intended for single use.
• Application cannulas must be disposed of after single use to avoid cross-contamination between patients.

## CHARISMA® Bulk Flow ONE

### Instrucciones de uso ⒺS

**Producto sanitario: sólo destinado al uso por profesionales de la salud dental.**

**Finalidad prevista**
CHARISMA Bulk Flow ONE es un compuesto, fotoresistible, radiopaco y nanohíbrido. Entre sus indicaciones terapéuticas se incluyen las restauraciones adhesivas de dientes de diferentes tonos para los sectores anterior y posterior, incluyendo las superficies oclusales. La radiopacidad del producto se corresponde con la de una capa de aluminio de 3.0–3.5 mm (dentina = 1 mm, esmalte = 2 mm). Por sus características, penetra con fluidez hacia las paredes de las cavidades durante la aplicación. El color universal asegura la polimerización de una capa de hasta 4 mm de grosor, con tensión de retracción reducida. No es necesario aplicar una capa final de compuesto universal. Este material dental es adecuado para pacientes que necesitan tratamiento para las siguientes indicaciones, teniendo en cuenta las contraindicaciones. En el caso de mujeres embarazadas o en período de lactancia, deben valorarse cuidadosamente los riesgos del tratamiento con respecto a los beneficios, teniendo en cuenta la salud del feto o el bebé.
Los productos sanitarios de Kulzer garantizan la creación de las funciones bucales, como la masticación, el habla y la estética. Estabilizan las piezas dentales existentes o la resaca alveolar de forma restauradora o protésica o son accesorios en el proceso de rehabilitación.

**Indicaciones**
• Restauraciones directas de clases I, II, III y V
• Primera capa de revestimiento para cavidades de clases I y II
• Reparación de restauraciones directas e indirectas en combinación con un adhesivo adecuado
• Fertilización de dientes con movilidad por traumatismo o enfermedad periodontal
• Sellado de fisuras dentales.

**Contraindicaciones**
El uso del producto está contraindicado si existe o se sospecha una alergia a sus componentes. El uso de este producto está contraindicado en caso de alergia conocida o sospechada a los componentes del (met)acrilo. No debe usarse en la dentina próxima al tejido pulpar (grueso de capa < 1 mm).

**Efectos secundarios posibles**
En casos aislados, este producto o sus componentes pueden causar reacciones de hipersensibilidad.

**Características del producto**
**Tamaños de envase / formatos de entrega**
Terapias de 3x2x0 g

**Accesorios**
• Las cánulas de aplicación son para un solo uso.
• Es necesario desechar las cánulas de aplicación después de cada uso para evitar la contaminación cruzada entre pacientes.

## CHARISMA® Bulk Flow ONE

### Instruções de utilização ⓅT

**Produto para saúde – Para uso exclusivo de profissionais de odontologia.**

**Finalidade**
O CHARISMA Bulk Flow ONE é uma resina composta nano-híbrida, radiopaca, fluida e fotopolimerizável. As indicações terapêuticas incluem restaurações adesivas de dentes de diferentes tons para os setores anterior e posterior, incluindo as superfícies oclusais. A radiopacidade do produto corresponde a uma camada de alumínio medindo 3,0–3,5 mm (dentina = 1 mm, esmalte = 2 mm). Devido a suas propriedades, ele apresenta uma boa fluidez em direção às paredes das cavidades durante a aplicação. A cor universal garante a polimerização em uma camada de até 4 mm de espessura com baixa contração de retração. Não há necessidade de camada superior universal. Este material odontológico é adequado para pacientes com necessidade de tratamento odontológico para as indicações a seguir, levando-se em consideração as contraindicações. Para gestantes e lactantes, os riscos do tratamento devem ser cuidadosamente ponderados em relação aos benefícios, sempre levando-se em consideração o bebê.
Os produtos sanitários de Kulzer garantem a criação e a manutenção das funções bucais, como mastigação, fala e estética. Estabilizam a dentição remanescente e/ou o rebordo alveolar em caráter restaurativo ou protético, ou são acessórios no processo de reabilitação.

**Indicações**
• Restaurações diretas classes II, III, II e V
• Revestimento de primeira camada para cavidades classes I e II
• Reparo de restaurações diretas e indiretas em combinação com um adesivo adequado
• Fertilização de dentes abalotados resultantes de trauma ou eventos periodontais associados
• Selamento de fissuras

**Contraindicações**
O uso deste produto é contraindicado no caso de suspeita de alergia ou sensibilidade conhecida aos componentes do produto. Não use este produto em caso de suspeita ou confirmação de alergia a compostos de acrílateo e metacrilato. Não use em dentina próxima à póps (espessura da camada < 1 mm).

**Efeitos colaterais potenciais**
Em alguns casos, pode ocorrer hipersensibilidade ao produto ou aos seus componentes.

**Propriedades do produto**
**Tamanhos de embalagem/apresentação**
Serings de 2,0 g

**Accesórios**
• As cânulas de aplicação são descartáveis.
• As cânulas de aplicação devem ser descartadas após o uso para evitar contaminação cruzada entre pacientes.

## CHARISMA® Bulk Flow ONE

### Lietošanas instrukcija ⓁV

**Medicīniskā ierīce – Lietošanai tikai zobārstniecības speciālistiem.**

**Paredzētāis nolūks**
CHARISMA Bulk Flow ONE ir plūstošs, gaismā cietējamais, rentgenstarus necaurlaidīgs nanohibrids kompozīts. Terapeitiskās indikācijas ir adhēzīvas restaurācijas zoba krāsā piekšājamā un auzmuguram reģionam, ieskaitot okluzālas virsmas. Produkta rentgenstaru necaurlaidīgums atbilst alumīnija slānim, kura izmēri ir 3,0–3,5 mm (dentīns = 1 mm, emalja = 2 mm). Sava īpašību dēļ materiāls uzklāšanas laikā labi iekļaujas kavētos dentīnos. Universālā krāsā nodrošina caursīšiānu līdz pat slānīn, kura biezums ir 4 mm, turklāt ar savu sarūsāšanās spriem, kur no nepieciešama virskārta ar universālu kompozitmateriālu. Šīs zobārstniecības materiāls ir piemērots pacientiem, kuri nepieciešama zobārstniecības terapija tālāk minētās indikācijās gadījumā, ņemot vērā kontraindikācijas. Grūtniecēm un sievietēm, kuras bāro bērnu vai krūti, ir uzmanīgi jāapsver iespējamie risks, salīdzinot ar priekšrocībām, ņemot vērā nedrošību bērnu vai zīdaiņiem.
Kulzer medicīniskās ierīces nodrošina lielu mūles funkciju kā veidošana, runāšana un estētiska rehabilitācija. Tās stabilizē atbilstoši vārus un/vai atbalvēn kor restoratīvi vai prozūtiķi formā vai arī ir rehabilitācijas procesa piederības.

**Indikācijas**
• II, III un IV klases tiešās restaurācijas
• Pirmā slāņa odere I un II klases kavītātmē
• Tiešo un netiešo restaurāciju remonta kopā ar piemērotu adhēzīvu līdzekli
• Traumas vai periodontoloģiskā noikuma rezultātā kustušu zobu nostiprināšana
• Paplašināšanas pārisu noliktuvēšana

**Kontraindikācijas**
Izstrādājuma lietošana ir kontrindicēta, ja ir zināma alerģija pret (met)akrila sāienveidīgiem vai zidomas par to. Nelietojiet uz dentīna pulpas tuvumā (slāņa biezums < 1 mm).

**Iespējamās blakusparādības**
Paaugstināta jutība pret produktu vai tā sastāvdaļām atsevišķos gadījumos nevar tikt izslēgta.

**Produkta īpašības**
**Iepakojumu lielumi/iegādāties veidi**
2,0 g širces

**Piederumi**
• Uzklāšanas kanīles ir paredzētas vienreizējai lietošanai.
• Uzklāšanas kanīles ir jālikvidē pēc vienas lietošanas reizes, lai novērstu šķērskontamināciju starp pacientiem.

## CHARISMA® Bulk Flow ONE

### Naudojimo instrukcija ⓁT

**Medicinos priemonė – naudoti tik dantų specialistams.**

**Paskirtis**
„CHARISMA Bulk Flow ONE“ yra takus, šviežioji kietėjantis, spinduliuotes nepažeidžiamas nanohibridinis kompozitas. Terapinės indikacijos apima priekines ir užpakalines sritis dantų, įskaitant skandžio-židų paviršių, klavimą, dantų restauracijas pagal dantų spalvą. Produktas nepažeidžiamas spinduliuotės atžaliu, 3,0–3,5 mm (dantinas = 1 mm, emalis = 2 mm) storio sluoksniu. Savo savybių dėka medžiaga užklāmas laiką labi įkūta kavėtose dantiniuose. Universalioje krāse nodrošina lūdz pat slānīn, kurā biezums ir 4 mm, turklāt ar savām sarūsāšanās spriemām, kurās nepieciešama virskārta ar universālu kompozitmateriālu. Šīs zobārstniecības materiāls ir piemērots pacientiem, kuri nepieciešama zobārstniecības terapija tālāk minētajās indikācijās gadījumā, ņemot vērā kontraindikācijas. Grūtniecēm un sievietēm, kuras baro bērnu vai krūti, ir uzmanīgi jāapsver iespējamie risks, salīdzinot ar priekšrocībām, ņemot vērā nedrošību bērnu vai zīdaiņiem.
Kulzer medicīniskās ierīces nodrošina lielu mūles funkciju kā veidošana, runāšana un estētiska rehabilitācija. Tās stabilizē atbilstoši vārus un/vai atbalvēn kor restoratīvi vai prozūtiķi formā vai arī ir rehabilitācijas procesa piederības.

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**Produkta īpašības**
**Pakuoties veidi / pristatymo būdai**
2,0 g širvīkstas

**Priedai**
• Naudojimo kanūles yra skirtos naudoti vieng kartą.
• Naudojimo kanūles būtina išmesti po kiekvieno naudojimo, siekiant išvengti křížkontaminacijos tarp pacientų.

**Galimas šalutinis poveikis**
Atskleidžiamas negalima atseviškai padidėjęs jautrumas produktui arba jo komponentams galimybė.

**Produkto savybės**
**Pakuoties veidai / pristatymo būdai**
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Importado e Distribuído no Brasil por
Kulzer South America Ltda.
CNPJ 48.708.010/0001-02
Rua Cennno Strighi, 27 – cj. 42
São Paulo – SP – CEP 05036-010
sac@kulzer-dental.com
Resp. Técnica: Dra. Regiane Marton –
CRO 70.705
Nº ANVISA: vide embalagem

Manufacturer:
Kulzer GmbH
Leipzigser Straße 2
63450 Hanau (Germany)
Made in Germany

**Composiçao**
CHARISMA Bulk Flow ONE é a light-curing methacrylate based formulation with the following ingredients: Barium aluminum borate, barium fluoride, silane, E48ADMA, UDMA, ytterbium fluoride, silicon dioxide, titanium dioxide, BHT, aminobenzoinic acid ester, camphorquinone, fluorescent pigments, metal oxide pigments, organic pigments. CHARISMA Bulk Flow ONE contains approx. 41% filler by vol., the particle size is 20µm – 5µm.

**Color**
CHARISMA Bulk Flow ONE is a flowable, light-curing, radio-opaque nano-hybrid composite. Prosthetic indications include adhesive, tooth-colored restorations for the anterior and posterior region, including the occlusal surfaces. The radiopacity of the product corresponds to an aluminium layer measuring 3.0 – 3.5 mm (dentine = 1 mm, enamel = 2 mm). Due to its properties, it flows well into the cavity walls during application. The universal colour ensures curing of up to a layer measuring 4 mm in thickness with low shrinkage tension. A topcoat with a universal composite material is not needed. This dental material is suitable for patients requiring dental treatment for the following indications with consideration of the contraindications. For pregnant and nursing women, the treatment risks must be weighed carefully against the benefits taking into consideration the unborn child or infant.
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CHARISMA Bulk Flow ONE is a flowable, light-curing, radio-opaque nano-hybrid composite. Prosthetic indications include adhesive, tooth-colored restorations for the anterior and posterior region, including the occlusal surfaces. The radiopacity of the product corresponds to an aluminium layer measuring 3.0 – 3.5 mm (dentine = 1 mm, enamel = 2 mm). Due to its properties, it flows well into the cavity walls during application. The universal colour ensures curing of up to a layer measuring 4 mm in thickness with low shrinkage tension. A topcoat with a universal composite material is not needed. This dental material is suitable for patients requiring dental treatment for the following indications with consideration of the contraindications. For pregnant and nursing women, the treatment risks must be weighed carefully against the benefits taking into consideration the unborn child or infant.
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## CHARISMA® Bulk Flow ONE

**의료器材 – 仅限牙科医疗专业人士使用本品。**

CHARISMA Bulk Flow ONE 是一种可流动、光固化、X射线阻射的纳米混合型复合树脂材料。适用于前牙和后牙 (包括咬合面) 的牙色材料粘接修复。产品的X射线阻射性相当于 3.0–3.5 毫米的铝片 (牙本质 = 1 毫米, 牙釉质 = 2 毫米)。由于其材料特性, 产品无需使用通用复合材料做表面覆盖。可确保形成最大厚度为 4 毫米、具有低聚合收缩应力的固化层, 从而无需使用通用复合材料做表面覆盖。在考虑到相应禁忌症的前提下, 该牙科材料适用于需要针对以下适应症的患者。对于孕妇和哺乳期妇女而言, 必须谨慎权衡治疗风险与益处, 并考虑未出生婴儿或动物。

Kulzer 医疗器械能够实现咀嚼、语言等口腔功能的康复和美学效果的恢复。产品通过修复或重建的方式稳定剩余的牙列和/或牙槽嵴, 或者用作康复过程中的附件。

**适应症**

- I、II、III 和 V 类洞的直接修复
- I 类和 II 类洞的底层材料
- 配合合适的粘接剂修补直接/间接修复体的缺损
- 微牙周炎板对松动牙 (由创伤或牙周疾病导致) 进行固定
- 窝沟封闭

**禁忌症**

如果已知或怀疑对产品中所含的成分过敏, 则禁止使用本产品。如果已知或怀疑对 (甲基) 丙烯酸酯复合材料过敏, 则禁止使用该产品。请勿用于靠近牙髓的牙本质 (层厚 < 1 毫米)。

**潜在副作用**

在个别情况下不排除发生对产品或其组分的过敏反应。

**产品特性**

**包装尺寸 / 供货量**

2.0g 注射器装

**附件**

- 牙科输送头为一次性使用产品。牙科输送头在单次使用后必须废弃处理, 以免患者之间的交叉污染。

## CHARISMA® Bulk Flow ONE

**외로기기-치과 의료전문기관 사용.**

**사용 목적**
CHARISMA Bulk Flow ONE은 광중합형 방사선 불투과성의 나노-하이브리드 플로우 복합레진입니다. 치로 적용층은 고품질을 포함한 전치부 및 구치부에 대한 적합형 치아색 수복을 포함합니다. 본 제품의 방사선 불투과성은 두께 3.0-3.5mm의 알루미늄 레이어에 상응합니다.(덴틴 = 1mm, 에나멜 = 2mm). 제품의 색상 사용 시 외층벽으로 잘 흘러 들어갑니다. 일반적인 색상은 낮은 수축 응력으로 4mm 레이어 이하의 경층을 보장합니다. 전구치 전용 복합레진 재료 면 적층을 도모할 필요가 없습니다. 이 치과 재료는 금/사랑의 고리 하에 다음과 같은 적용층에 대해 치과 치료가 필요한 환자에게 적합합니다. 임 신부 및 수유부의 경우, 태아 또는 유아를 고려하여 치료 이익이 반하는 위험을 신중하게 평가해야 합니다.

Kulzer 의 의료기기 제품은 저작, 발음 및 심미성과 같은 구강 기능의 재건을 보장합니다. 둘 제품은 잔존 치아 이외에는 치조bones을 수복적 또는 보철적으로 안정화시켜주거나, 또는 재건 과정에서의 부수 제품을 합니다.

**적용층**

- I, II, III, V급 직접 수복 시
- I급 외층에서 최종 레이어의 이장 시
- 적절한 접착제와 함께 직접 및 간접 수복을 수리
- 외상이나 치주 관련 사고에 의해 느슨해진 치아의 고정(Splinting)
- 확장된 임플루 친 수

**금지 사항**

제품의 성분에 대하여 알레르기가 있거나 있을 것으로 의심되는 경우 사용하지 마십시오. 메타크릴레이트 또는 아크릴레이트 합성물에 대하여 알레르기가 있거나 있을 것으로 의심되는 경우 이 제품을 사용하지 마시오. 치수에 가까운 덴틴에는 사용하지 마십시오(레이어 두께 1mm 미만).

**접착제 부착**

일반적인 경우에서 제품 또는 구성 성분에 대한 개인 반응을 배제할 수 없습니다.

**제품 특성**

**포장 크기 / 배송 형태**

2.0g 시린지 형

**역사/키워드**

- 적용 케블러 팁은 일회용입니다.
- 적용 케블러 팁은 환자간 교차 오염을 방지하기 위해 1회 사용 후 반드시 폐기해야 합니다.

## CHARISMA® Bulk Flow ONE

**Meditsiniseade – Ainult hambaarstide jaoks kasutamiseks.**

**Sihetstarve**
CHARISMA Bulk Flow ONE on valguksõuvalgu röntgenkontraste nanohübriidkomposiit. Ravinäidustused on adhesiivsed hamba värviga restaursatsioonid anteriorseos ja posterioorseos piirkonnas, sh okulaasetel pindadel. Toote röntgen-kontrastsus vastab alumiiniumkihilte pakuseguga 3,0–3,5 mm (dentin = 1 mm, email = 2 mm). Tänu oma omadustele, voolab toote apliteerimisel hästi kaitsele seintele. Universaalse värvuse tagab kuni 4 mm pakuse kihil valguksõuvalguise vihesse kahanemispinge. Pealiskihit universaalse komposiitmaterjaliga ei ole vajalik. See hambamaterjal sobib kasutamiseks järgmistele näidustustega patsientidel, võttes arvesse vastunäidustusi. Rasedatele ja imetavatel naistel peab raviriske kaaluma hoolikalt kasutegurite suhtes, arvestades esajärgse sünnitatu või vastundündu lappaga. Kulzeri meditsiniseadmed taastavad suuõone funktsioone, nagu närimine, kõnelmine ja esteetika. Need stabiliseerivad restaaratsioonit või proteseetist (lejaläinud hambaid ja/või avelasteid harja või saab neid kasutada tarkutena taastusrasv.

**Näidustused**

- I, II, III ja V klassi direktsed restaursatsioonid
- I ja II klassi kaitselehelte aluskihid
- Direktsed ja indirektsed restaursatsioonid parandus sobiva adhesiiviga
- Trauma või peridontaalsete haiguste tõttu liikuvalte hammaste lahastamine
- Fissuuride ulatlik hermeetiseerimine

**Vastunäidustused**

Teadolava või kahtlastud allergia korral toote koostisosade suhte osas selle toote kasutamine vastunäidustatud. Ärge kasutage (metakrülaadidesthente sisalde teadaoleva allergia või allergia kahtluse korral. Ärge kasutage publi lähedal asuval dentinile (kõhi pakkus < 1 mm).

**Võimalikud kõrvaltoimed**

Ülitundlikkus toote või selle koostisainete vastu ei saa kõigil juhtudel välistada.

**Tootekomadused**

**Pakendi suurus / tarnevorm**

2,0g süstla

**Tarvikud**

- Aplikatsioonikanüülid on ette nähtud ühekorkeks kasutuseks.
- Aplikatsioonikanüülid tuleb pärast ühte kasutatut kälbelt kõrvaldada, et vältida patsientide vahelist ristsaastumist.

**Coosto**
CHARISMA Bulk Flow ONE on valguskõuvalgu metakrülaadil põhinev preparaat, mis sisaldab järgmisi koostisosi: baarium-alumiinium fluori-fluori-silikaat klaas, E4BADAMA, UDMA, triürümfuoriid, rändioksiidid, titaandoksiidid, BHT, aminobensoehape etne, kamperkinn, fluoreneeruvad pigmendid, metaküllidid, pigmendid, orgaanilised pigmendid. CHARISMA Bulk Flow ONE sisaldab umbes 41% liiteseadmis muhi kohta ja osakeste suurus on 20nm–5µm.

**Värv**

**Toote apliteerimine**

Enne kasutamist vasikade toode kahjustuste suhtes üle. Kahjustatud tooted ei tohi kasutada. Patsiendil soovitatakse kasutada kaitsefilmi.

1. Eemaldage hambalajuga ja prepareriga hambahas struktuuri säilitamiseks vastavalt adhesiivse restauraativri üldistele reeglitele. Pärast seda loputage, puhastage ja kuivatage kaitsele välides hambah prima liigest kuivatamist. Kui hamba pinda ei töödelda temperatuuril mis ümbrusest instrumentidiga, tuleb pinda enne restauraiooni pagaidamist puhastada pimsi või fluoriidivaba viimistuspastaga. Kontrolli apliteerimiseks ja vormimiseks sobib mittekeevup instrumnt.

2. Kinnitage kofereedid (nt Ivory Rubber Dam) ja kalista rindavälja piirkonda saastumisest eest. Järgige tootja juhiseid.

3. Kasutage matrisiisüsteemi, et kujundada proksimaalsel külkkõnnakutekad. Kõlluga matrisist kasutamiseks on kaoks põhi-juht. Matrisist hamba vastu surudes tuleb hermeetiline sülg ja teie ei jää üle rippuma. Lisaks tagab see sõltumatu matrisist pakusest hambahaste vahete väikesed vahed, aidates luua tiheda koostisainetega lõpliku restaursatsiooni ja kõrvalhamba vahel. Sel põhjusel on soovitatav kasutada õhuke matrisist. Koostis on sile ja sellise kujuga, mis võimaldab head kontaktimist hamba pinna. Matrisist kuju tuleb musta vastava instrumendiga, sest CHARISMA Bulk Flow ONE ei suuda komposiidil pagaidamisel survet taluda.

4. Enne restauraativmaterjalist siemast tüübi emalle ja dentinile apliteerimist sobivad adhesiivi vastavalt tootja juhisteid (nt GLUMA® adhesiivisüsteemid). Muu adhesiivi kasutamine eest vastutab arst. Adhesiiviga töödeldud kaitsele ei tohi saastuda niiskuse, vere või siljaga.

5. Kui süstideel kasutatud suuse, kasutage saastumisest vältimiseks tavalla hügieenilist kaitsevarrakkid. Pärast saastumist ärge korduskasutage.

6. Apliteerige CHARISMA Bulk Flow ONE'i, alustades sügavaimast kohast otse ettevõimastatud kaitsele ja hoidke otsakut pidevalt materjal suhtes. Veenduge apliteerimisel, et materjal voolab aeglaselt ja ühtlaselt, vältimaks õhulimide teket. Hoidke süstla otsakut materjal ja tihke kaitsele alt (alles maksimaalselt 4 mm pakusest). Vajadusel eemaldage õhulim-ild või üliilangne materjal enne polimerisatsiooni küretil või mikroharjaga.

7. Teise võimalusena saab CHARISMA Bulk Flow ONE'i apliteerida õhukesse aluskihina katmata dentinile või kasutada direktselt või indirektselt restaursatsioonid parandamiseks, kasutades sobivat adhesiivi (nt GLUMA® adhesiivisüsteemi, apliteerimiseks) või tootja kasutusjuhendit.

**成分**
CHARISMA Bulk Flow ONE 是一种基于光固化甲基丙烯酸酯的配方, 含有以下成分: 钡铝硼硅酸盐玻璃, E4BADAMA, UDMA, 氟化硅, 二氧化硅, 二氧化钛, BHT, 氨基苯甲酸酯、樟脑酚、荧光染料、金属氧化物颜料、有机颜料。CHARISMA Bulk Flow ONE 含有约 41% 的填料 (体积比), 填料粒径为 20nm–5µm。

**色泽**

**ONE**

**产品的使用**

使用前, 请通过目视检查是否有破损之处, 不得使用破损产品。建议为患者佩戴眼罩。

1. 按照粘接修复治疗的通用规则去除龋坏组织并进行牙体预备, 尽可能地保存牙体组织。之后, 冲洗、清洁并干燥窝洞, 但不要使牙齿窝洞表面过度干燥。充填修复前, 如牙面未经金属磨砂车针或其他研磨器械处理, 则需用浮石或无氟抛光膏对患牙表面进行清洁。不粘性器械适用于复合树脂的应用和塑形。

2. 建议使用橡皮障 (例如 Ivory 型橡皮障) 以保护治疗区域免受污染。橡皮障的应用请参照制造商的使用说明。

3. 建议在腔内使用注射器时, 请使带有时间限制的成形系统有两个原因, 以确保与后续充填复合树脂的结合。使用通用复合材料做表层覆盖并非必要的步骤。

11. 金剛鋼車針適用於打磨修飾。最好使用細粒金剛砂和多刃碳化鈣鋼頭進行最終成型和輪廓修整。可使用拋光砂紙對於牙體接觸面的充填體進行最終修飾。纖維金剛砂、柔性拋光盤、硅酸拋光器械 (例如 Charisma EasyShine) 和拋光刷等都適用於精細拋光。

12. 治療結束時, 從注射器上取下注射器保護套。

13. 將用過的牙科輸送頭廢棄處理, 並提供提供的密封槽小心地重新密封注射器。

14. 如果有證據表明复合材料已被口腔液体污染, 请勿重复使用该材料。

**产品使用说明**

- CHARISMA Bulk Flow ONE 应在 23°C (73°F) 的环境下温度下使用。
- 上述聚合时间为最短时间。在任何情况下都不应缩短聚合时间, 以确保聚合更完全及获得相应的物理性能。
- 对较大的窝洞进行充填时, 由于操作所需时间较长, 建议关闭牙科治疗椅的顶灯, 或将顶灯转向, 以避免对治疗区域过度照射, 导致材料过热固化。
- 对于近髓或小部分已经暴露牙髓的深窝洞, 必须间接或直接用氢氧化钙产品进行局部覆盖处理。在将 CHARISMA Bulk Flow ONE 注入窝洞之前, 应使用玻璃离子水门汀衬垫氢氧化钙产品。制备过的牙髓和牙本质表面不得与含有丁香酚的产品接触, 否则可能会影响复合材料达到最佳聚合效果。

**一般信息**

请遵守以下安全指示以及其他章节的所有处理说明。请务必严格按照说明书使用本产品。任何违反这些说明的使用均由牙科专业人员自行决定并全权负责。

7. CHARISMA Bulk Flow ONE은 노출된 덴틴의 이장제로서 많은 레이어로 적용하거나, 또는 적절한 접착제(예: GLUMA® 접착시스템, 적용은 제조사의 사용설명서 참조)와 함께 직접 및 간접 수복물을 수리하는 데 사용될 수도 있습니다.

8. 적절한 정형성 중합 펄프 (최대 파장 450–480nm; 광속력: 1550–600mW/cm²; 예: Kulzer Translux)를 이용하여 아래 표에 따라 CHARISMA Bulk Flow ONE의 레이어(최대 4mm)를 중합하십시오.

오, 중합 펄프는 중합 강도와 방출되는 스펙트럼 출력 면에서 상당한 차이를 갖고 있을 것을 주의해야 합니다. 따라서 명시된 모든 중합 시간은 최소 시간입니다. 의문점이 있는 경우 펄프 제조사로부터 정답을 받아 보시고, 환자에게 사용하기 전에 광중합하기 in vitro 기능을 반드시 확인해야 합니다.

**CHARISMA Bulk Flow ONE: Translux® 광중합기 또는 타사 정형성 중합기의 권장 중합 시간 및 최대 레이어 두께.**

ONE	20초	4mm
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9. 중합 시에 표면이 분산층이 형성되는데, 추가 복합레진 층이 최적으로 적용될 수 있도록 이를 만지거나 제거해서는 안 됩니다.

10. 전구치 경우 복합레진 재료로 면 적층을 도포 하지 않아도 됩니다.

11. 다이아몬드 또는 기타 피니싱에 적합합니다. 최종 성형 및 연마 작업은 미세 입자 다이아몬드 스톤과 달리 불려서 사용해야 합니다. 적용하는 것이 가장 좋습니다. 인질면 표면은 폴리싱 스톤으로 마무리할 수 있습니다. 피니싱 다이아몬드, 폴리싱 블록 디스크, 실리콘 폴리시(예: Charisma Easy-Shine)와 폴리싱 브리시는 마무리에 적합합니다.

12. 치료가 종료되면 시린지 하에서 하부 보호 커버를 벗겨 제거하십시오.

13. 사용용 마친 적용 케블러 팁은 폐기하고, 재사용 가능한 시린지 중합을 방지하기 위하여 1회 사용 후 폐기하십시오.

14. 복합레진이 액체로 오염된 중합기가 있으면 시린지를 재사용하지 마십시오.

**제품 사용에 대한 팁**

- CHARISMA Bulk Flow ONE은 주변 온도가 23°C(73°F)인 곳에서 적용해야 합니다.
- 위에 명시된 중합 시간은 최소 시간입니다. 최적의 중합 속도와 관련 재료의 물성을 확실하게 알기 위하여 이러한 상황에서도 중합 시간을 단축해서는 안 됩니다.
- 광 수복물이 또는 한 번 시간이 긴 수복물을 적용하는 경우, 복합레진이 사전 중합을 방지하기 위하여 더러운 의복을 일시적으로 끄거나 또는 작업 부위를 비추지 않도록 다른 곳을 향해 해야 합니다.
- 치수 위에 최소한의 덴틴 층만 있거나 또는 치수의 작은 영역이 이미 노출된 깊은 외층은 수산할랄수 제품을 이용하여 직접 또는 간접적으로 국소적으로 치수 복원해야 합니다. CHARISMA Bulk Flow ONE은 외층에 형성되기 전에 수산할랄수 제품을 글래스 아이언노어 시멘트로 도포해야 합니다.

CHARISMA Bulk Flow ONE이 접착제로 합착된 프렛한 에나멜과 덴틴 표면은, 복합레진의 최적 중합이 적절될 수 있으므로 유지할 이 포함된 제품과 절차로 다루어는 안됩니다.

8. Polimeriseerige CHARISMA Bulk Flow ONE kihtide kaupa (kuni 4 mm) vastavalt alltoodud tabelile, kasutades sobivat sinise valgusega polimeriseerimislampi (max kiirteavaldus 450–480nm, võimsus: 1550–600 mW/cm²; nt Kulzer Translux®). Tuleb märkida, et polimeriseerimislampide valguse intensiivsus ja spekter võib vahel olla oluliselt erinev. Seega on kõik polimeriseerimisajad minimaalväärtused. Kahtluse korral tuleb kasutajal hankida teavet lambi tootjalt ja kontrollida valguseadme funktsionaalsust enne patsiendil kasutamist.

**CHARISMA Bulk Flow ONE: Translux® polimeriseerimislambi või muude sinise valgusega polimeriseerimis-lampide soovitatav kõvastumisaeg ja maksimaalsed kõvastatava kihhi pakused.**

ONE	20s	4mm
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9. Polimeriseerimisel tekib pinnal disperioonikiht, mida ei tohi puustatada ega eemaldada, et oleks võimalik lisada täiendavaid komposiidkihte.

10. Pealiskihit universaalse komposiitmaterjaliga ei ole vajalik.

11. Karakas polimeriseerimiseks sobivad teemantpõhised. Lõpliku kuju ja kontuuri saab anda peenteerlaste teemantkihtidega ja mitme teraga voltimist karbidipõhised. Proksimaalsaid pindu võib viimistleda polimerimistbadega. Viimistluseks sobivad viimistlustemant, pinduvad kettad, silikoonpõeerijad (nt Charisma EasyShine) ja poeerimistarjad.

12. Pärast ravi lõppu eemaldage süstallt hügieeniliste kaitsekatte ja visake see ära.

13. Kõrvakivade kasutatud apliteerimiskannulil kasutusele ja pange süstla otsakule vastav kott tagasi peale.

14. Kui esineb märke, et komposiit on saastunud suuveduikidega, ärge süstla teemantkihtidele kasutage.

**Näidatud toote kasutamisel**

- CHARISMA Bulk Flow ONE'i tuleb töödelda temperatuuril 23°C (73°F).
- Ülaõudude polimeriseerimisajad on miinimumväärtused. Neid ei tohiks mingil tingimusel vähendada, et tagada optimaalne polimeriseerimiskiirus ja materjali füüsilised omadused.
- Suurte või ajamuhukalte restaursatsioonide ettevalmistamisel tuleb pea kohal asetsev valgust ei justid tüüta tüüta või löögikaitsest eemale suunada, et vältida komposiidil eneseaegset kõvastumist.
- Silgivate kaitselehelte korral, kus puubi kohal on dentinikiht minimaalne või kus on väike osa pulpi juba katmata, tuleb need katta kaltsiumhüdroksiidil põhise tootlega kas indirektselt või direktselt. Kaltsiumhüdroksiidil põhine toode tuleb katta kassiannonneersemendiga enne CHARISMA Bulk Flow ONE'i isamist kaitsele. Preparaentud emall- ja dentinipind- nulle tuleb emandatakse adhesiiviga CHARISMA Bulk Flow ONE'i, et tohi kokku puutuda eugenioli sisaldavate toode- tega, kuna need võivad häirida komposiidil optimaalset polimerisatsiooni.

**Üldine teave**

Pöörake tähelepanu järgnevale ohutusjuhtele ja teiste jaoksle kõigile lõõtusjuhtele. Seda toodet võib kasutada vaid vastavalt kasutusjuhtele. Kasutus, mis ei järgi neid juhiseid, on hambaharvõtõttaja vastutada ja otsustada.

8. 根据下表使用合适的光固化光固化灯 (最大波长在 450–480nm 之间; 光功率: 1550–600mW/cm²; 例如 Kulzer Translux®) 对 CHARISMA Bulk Flow ONE 进行分层聚合 (最大层厚可达4mm)。应注意的, 光固化灯有时在强度和发射光谱功率上存在相当大的变化。因此, 所有指定的聚合时间都是最短时间。如有疑问, 执业者应联系光固化灯制造商处查询, 并在对患者使用之前在体外检查灯的功能性。

**CHARISMA Bulk Flow ONE: 使用 Translux® 光固化灯或其它光固化灯所推荐的聚合时间和最大单层材料厚度。**

ONE	20s	4mm
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9. 在聚合过程中, 固化表面会形成一层氧阻聚层, 严禁触碰或去除, 以确保与后续充填复合树脂的结合。使用通用复合材料做表层覆盖并非必要的步骤。

11. 金剛鋼車針適用於打磨修飾。最好使用細粒金剛砂和多刃碳化鈣鋼頭進行最終成型和輪廓修整。可使用拋光砂紙對於牙體接觸面的充填體進行最終修飾。纖維金剛砂、柔性拋光盤、硅酸拋光器械 (例如 Charisma EasyShine) 和拋光刷等都適用於精細拋光。

12. 治療結束時, 從注射器上取下注射器保護套。

13. 將用過的牙科輸送頭廢棄處理, 並提供提供的密封槽小心地重新密封注射器。

14. 如果有證據表明复合材料已被口腔液体污染, 请勿重复使用该材料。

**产品使用说明**

- CHARISMA Bulk Flow ONE 应在 23°C (73°F) 的环境下温度下使用。
- 上述聚合时间为最短时间。在任何情况下都不应缩短聚合时间, 以确保聚合更完全及获得相应的物理性能。
- 对较大的窝洞进行充填时, 由于操作所需时间较长, 建议关闭牙科治疗椅的顶灯, 或将顶灯转向, 以避免对治疗区域过度照射, 导致材料过热固化。
- 对于近髓或小部分已经暴露牙髓的深窝洞, 必须间接或直接用氢氧化钙产品进行局部覆盖处理。在将 CHARISMA Bulk Flow ONE 注入窝洞之前, 应使用玻璃离子水门汀衬垫氢氧化钙产品。制备过的牙髓和牙本质表面不得与含有丁香酚的产品接触, 否则可能会影响复合材料达到最佳聚合效果。

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8. 적절한 정형성 중합 펄프 (최대 파장 450–480nm; 광속력: 1550–600mW/cm²; 예: Kulzer Translux)를 이용하여 아래 표에 따라 CHARISMA Bulk Flow ONE의 레이어(최대 4mm)를 중합하십시오.

오, 중합 펄프는 중합 강도와 방출되는 스펙트럼 출력 면에서 상당한 차이를 갖고 있을 것을 주의해야 합니다. 따라서 명시된 모든 중합 시간은 최소 시간입니다. 의문점이 있는 경우 펄프 제조사로부터 정답을 받아 보시고, 환자에게 사용하기 전에 광중합하기 in vitro 기능을 반드시 확인해야 합니다.

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ONE	20 초	4mm
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9. 중합 시에 표면에 분산층이 형성되는데, 추가 복합레진 층이 최적으로 적용될 수 있도록 이를 만지거나 제거해서는 안 됩니다.

10. 전구치 경우 복합레진 재료로 면 적층을 도포 하지 않아도 됩니다.

11. 다이아몬드 또는 기타 피니싱에 적합합니다. 최종 성형 및 연마 작업은 미세 입자 다이아몬드 스톤과 달리 불려서 사용해야 합니다. 적용하는 것이 가장 좋습니다. 인질면 표면은 폴리싱 스톤으로 마무리할 수 있습니다. 피니싱 다이아몬드, 폴리싱 블록 디스크, 실리콘 폴리시(예: Charisma Easy-Shine)와 폴리싱 브리시는 마무리에 적합합니다.

12. 치료가 종료되면 시린지 하에서 하부 보호 커버를 벗겨 제거하십시오.

13. 사용용 마친 적용 케블러 팁은 폐기하고, 재사용 가능한 시린지 중합을 방지하기 위하여 1회 사용 후 폐기하십시오.

14. 복합레진이 액체로 오염된 중합기가 있으면 시린지를 재사용하지 마십시오.

**제품 사용에 대한 팁**

- CHARISMA Bulk Flow ONE은 주변 온도가 23°C(73°F)인 곳에서 적용해야 합니다.
- 위에 명시된 중합 시간은 최소 시간입니다. 최적의 중합 속도와 관련 재료의 물성을 확실하게 알기 위하여 이러한 상황에서도 중합 시간을 단축해서는 안 됩니다.
- 광 수복물이 또는 한 번 시간이 긴 수복물을 적용하는 경우, 복합레진이 사전 중합을 방지하기 위하여 더러운 의복을 일시적으로 끄거나 또는 작업 부위를 비추지 않도록 다른 곳을 향해 해야 합니다.
- 치수 위에 최소한의 덴틴 층만 있거나 또는 치수의 작은 영역이 이미 노출된 깊은 외층은 수산할랄수 제품을 이용하여 직접 또는 간접적으로 국소적으로 치수 복원해야 합니다. CHARISMA Bulk Flow ONE은 외층에 형성되기 전에 수산할랄수 제품을 글래스 아이언노어 시멘트로 도포해야 합니다.

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**警告和安全說明**

可能引起皮膚和眼睛刺激。避免接觸皮膚。接觸皮膚可能會引起過敏。操作時須佩戴適合的防護手套。如本產品與皮膚接觸, 則則使用大量清水和肥皂清洗接觸部位。避免接觸眼部。如本品與眼睛接觸, 請用清水沖洗數分鐘。如症狀仍持續存在, 請查詢眼科醫生。存在損害生育能力的可能性。

**特別建議**

對於 SSCP (安全性和臨床表現總結), 請參閱 EUDAMED 數據庫 (https://ec.europa.eu/tools/eudamed) 或联系 sscp-service@kulzer-dental.com。如需在 EUDAMED 中查找 SSCP (安全性和臨床表現總結), 請使用附在產品包裝上的 UDI 代碼。

**儲存**

- 請勿使用過期材料。• 开封后, 请在保质期内使用。• 存储温度不得高于 25°C (77°F)。• 避免阳光直射。• 在干燥环境下储存。• 防止电离辐射。

**废弃处理信息**

建议在产品的所有通信中引用批号 和产品编号 或 UDI。产品在包装 和批号 或 UDI: 参见注射器/包装上的说明。

**附加信息**

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根据《欧盟医疗器械法规》, 用户有责任义务向制造商和国家主管部门报告医疗器械已发生的安全事故以及严重事故。

**特别建议**

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可能引起皮肤和眼睛刺激。避免接触皮肤。接触皮肤可能会引起过敏。操作时须佩戴适合的防护手套。如本产品与皮肤接触, 则则使用大量清水和肥皂清洗接触部位。避免接触眼部。如本品与眼睛接触, 请用清水冲洗数分钟。如症状仍持续存在, 请咨询眼科医生。存在损害生育能力的可能性。

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**警告和安全说明**

可能引起皮肤和眼睛刺激。避免接触皮肤。接触皮肤可能会引起过敏。操作时须佩戴适合的防护手套。如本产品与皮肤接触, 则则使用大量清水和肥皂清洗接触部位。避免接触眼部。如本品与眼睛接触, 请用清水冲洗数分钟。如症状仍持续存在, 请咨询眼科医生。存在损害生育能力的可能性。

**特别建议**

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**废弃处理信息**

建议在产品的所有通信中引用批号 和产品编号 或 UDI。产品在包装 和批号 或 UDI: 参见注射器/包装上的说明。

**附加信息**

建议在产品的所有通信中引用批号 和产品编号 或 UDI。产品在包装 和批号 或 UDI: 参见注射器/包装上的说明。

根据《欧盟医疗器械法规》, 用户有责任义务向制造商和国家主管部门报告医疗器械已发生的安全事故以及严重事故。

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**特别建议**