

EN

INTENDED PURPOSE: PINK CAD/CAM disc is suitable for milling full and partial dentures and temporary immediate load implant supported dentures.

COMPOSITION: PMMA material with embedded pigments and residual methyl methacrylate less than 1%

INDICATION: Edentulism, partial edentulism

CONTRAINDICATIONS: Do not use the product in case of known allergies or hypersensitivity to acrylic materials.

WEARING TIME: The recommended wearing time is up to 5 years.

INSTRUCTIONS FOR USE

NOTE! Before use of the disc carefully read the label of the disc to choose the correct height of the disc and shade.

Design rules to consider within CAD software for the design of denture bases

Design the denture base with suitable CAD dental software.

Fix the disc in the milling machine holder. Pay attention to the orientation of the multilayer PINK CAD/CAM disc. The lighter shade should be on top. Load the CAM-file on the milling machine. Milling strategies for PMMA must be considered according to the milling machine instructions. The denture is separated from the disc with standard grinding tools for PMMA resin after milling.

Bonding of denture teeth

Bond the artificial teeth to the denture base with PMMA resin or light curing composite material according manufacturer's instructions. The artificial teeth must be roughened and prepared according to manufacturer's instructions.

The denture base does not require special treatment in case of PMMA bonding resin but usually requires a primer treatment in case of composite bonding material according to manufacturer's instructions. The denture can be finished with standard grinding and polishing tools for PMMA resin after the bonding of artificial teeth.

Tools for acrylic are used for finishing and final adjustments. For polishing use grinding paper, polishing rubbers, pumice stones, pastes and soft polishing brushes suitable for acrylic resins to achieve glossy surface.

CLEANING: Make sure to thoroughly clean the restoration to remove any residue of the milling and finishing processes using common dental laboratory practice (e.g. steam et joli soap/detergent).

INFORMATION FOR DENTIST: In accordance with standard dental medicine practice, the dentist must clean medical device before inserting it into the oral cavity. The dentist must provide the patient with instructions for adequate cleaning of the medical device and follow up the patient at regular appointments to assess the condition of the medical device. We recommend cleaning with soft brushes and mild soap for removable medical device and non-abrasive tooth pastes for fixed restorations.

STORAGE: Keep away from direct sunlight!
DISPOSAL: Disposal should be made in accordance with local, state and national legislation.
CAUTION! US users only: Federal law restricts this device to sale by or on the order of a dentist.
WARNINGS: Professional use only! Dental CAD/CAM skills are required to properly process the product. The discs must be milled using a compatible CAD/CAM system.
It is important not to overheat the material!
Do not use the material after expiry date. Expiry date is printed on the packaging.
PMMA dust may develop during the milling process, leading to mechanical irritation of the eyes, skin, and respiratory tract. Make sure to use the extraction system in the workplace. When processing PMMA discs, wear personal protective equipment (protection mask for dust, safety glasses, ...).
To ensure traceability and assignment of the product as well as the LOT numbers for the patient at any time, it is recommended to store the milling blank in the original packaging during two milling operations.
Further safety-relevant information can be found in the material safety data sheet available on request.

In case that any serious incident has occurred i: relation to the device it should be reported to the manufacturer (Polident d.o.o.; vigilanca@polident.si) and the competent authority of the Member State, where the user is established
DE VERWENDUNGSZWECK: Die PINK CAD/CAM Disc eignet sich zum Fräsen von Voll- und Teilprothesen sowie von sofort belastbarem, implantatgetragenem Überzugs Zahnsatz.

ZUSAMMENSETZUNG: PMMA-Material mit eingebetteten Pigmenten und einem Restgehalt an Methylmethacrylat von weniger als 1%

INDIKATION: Zahnlösigkeit, teilweise Zahnlösigkeit

KONTRAINDIKATIONEN: Bei bekannten Allergien oder Hypersensibilität gegenüber Acrylmaterialien das Produkt nicht anwenden.

TRAGEDAUER: Die empfohlene Tragedauer beträgt bis zu 5 Jahre.

GEBRAUCHSANWEISUNG

HINWEIS! Lesen Sie vor der Verwendung das Etikett der Scheibe sorgfältig durch, um die richtige Scheibenfarbe und Scheibenfarbe auszuwählen.

Bei der Konstruktion von Prothesenbasen in der CAD-Software zu berücksichtigende Designregeln

Konstruieren Sie die Prothesenbasis mit einer geeigneten CAD-Dentalsoftware. Fixieren Sie die Scheibe im Halter der Fräsmaschine. Achten Sie auf die Ausrichtung der mehrschichtigen PINK CAD/CAM Disc. Die hellere Farbe muss oben sein. Laden Sie die CAM-Datei in die Fräsmaschine. Frästechnologien für PMMA sind entsprechend der Anleitung der Fräsmaschine zu beachten. Die Prothesen wird nach dem Fräsen mit handelsüblichen Schleifwerkzeugen für PMMA-Kunststoff ja von der Scheibe getrennt.

Verkleben von Prothesenzähnen

Befestigen Sie die künstlichen Zähne mit PMMA-Harz oder lichthärtendem Verbundharz gemäß den Anweisungen des Herstellers an der Prothesenbasis. Die künstlichen Zähne müssen entsprechend den Herstellerangaben aufgeraut und vorbereitet werden. Die Prothesenbasis bedarf bei PMMA-Verbundkunststoff keiner besonderen Behandlung, es ist jedoch in der Regel eine Grundierung gemäß den Anweisungen des Herstellers erforderlich. Nach dem Aufkleben der künstlichen Zähne erfolgt die Endbearbeitung mit handelsüblichen Schleif- und Polierwerkzeugen für PMMA-Kunststoff.

Endbearbeitung

Zur Endbearbeitung und für letzte Anpassungen werden Werkzeuge für Acrylat verwendet. Zum Polieren verwenden Sie Schleifpapier, Polergummie, Bimssteine, Pasten und weiche, für Acrylharze geeignete Polierbürsten, um eine glänzende Oberfläche zu erzielen.

REINIGUNG: Achten Sie darauf, dass der Zahnersatz gründlich gereinigt wird, und entfernen Sie Rückstände der Fräse- und Fertigungsprozesse mit den üblichen zahnärztlichen Verfahren (z. B. Dampfstrahler oder milde Seife/ Reinigungsmittel).

INFORMATION FÜR DEN ZAHNARZT: Gemäß der üblichen Zahnmethodischen Praxis muss der Zahnarzt ein Medizinprodukt reeinigen, bevor er es in die Mundhöhle einführt. Der Zahnarzt muss dem Patienten Anweisungen zur ordnungsgemäßen Reinigung des Medizinproduktes geben und ihn bei regelmäßigen Terminen nachbeobachten, um den Zustand des Medizinprodukts zu beurteilen. Für herausnehmbare Medizinprodukte empfehlen wir die Reinigung mit weichen Bürsten und milder Seife und feststellenden Zahnersatz nicht scheuernde Zahnpasten.

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verpakking gedrukt.

Tijdens het freesproces kan zich PMMA-stof ontwikkelen, wat leidt tot mechanische irritatie van de ogen, huid en luchtwegen. Zorg ervoor dat u het atuzgemaal op de werkplek gebruikt. Draag bij het werken met PMMA-schijven persoonlijke beschermingsmiddelen (beschermingsmasker tegen stof, veiligheidsbril, ...).

Om de traceerbaarheid en toekenning van de productgegevens en de LOT-nummers voor de patiënt op elk moment te garanderen, wordt aanbevolen om het freesstuk tijdens twee freesbewerkingen in de originele verpakking te bewaren.

Verdere veiligheidsrelevante informatie kunt u vinden in het veiligheidsinformatieblad dat op aanvraag verkrijgbaar is.

Als zich een ernstig incident heeft voorgedaan met betrekking tot het hulpmiddel, moet dit worden gemeld aan de fabrikant (Polident d.o.o.; vigilanca@polident.si) en de bevoegde autoriteit van de lidstaat waar de gebruiker is gevestigd

NO
TILTEKTET FORMÅL: PINK CAD/CAM disc-skive er egnet for freseing av hel- og delproteser samt midlertidige implantatstøtte proteser.

SAMMENSETNING: PMMA-materiale med innebygde pigmenter og rester av metylemetakrylat mindre enn 1 %

INDIKASJON: Tannloset, delvis tannloset
KONTRAINDIKASJONER: Produktet skal ikke brukes ved kjente allergier eller overfølsomhet overfor akrylmateriale.

BRUKSTID: Anbefalt brukstid er opp til fem år.

INSTRUKSJONER FOR BRUK
MERK! For du bruker skiven, les etiketten på skiven nøyde for å velge riktig heyre på skiven samtidig med å følge instruksjonene.

Designregler á hennin til innen CAD-programvare for design av protesbaser
Design protesbaser med egnet CAD-tannprogramvare.

Fest skiven i fresemaskinholderen. Vær obs på retningene til den flerlags PINK CAD/CAM disc-skiven. Den lysere nyansen skal være øverst. Last CAM-filen på fresemaskinen. Prosesstrategier for PMMA må vurderes i henhold til fresemaskinvansnringene. Protesen separeres fra skiven med standard slipesverktøy for PMMA-harpiks etter fresing.

Limming av protesetester
Fest de kunstige tennene til protesbasen med PMMA-harpiks eller lyserhende kompositmateriale etter produsentens instruksjoner. De kunstige tennene må være rør og klarliggende i henhold til produsentens instruksjoner. Protesebasen krever ikke spesiell behandling ved PMMA-bindeharpiks, men krever vanligvis en grunningsbehandling i tillegg til kompositbindningsmateriale i henhold til produsentens instruksjoner. Protesen kan etter liming av kunstige tennetetter behandles med standard slipe- og poleringsverktøy for PMMA-harpiks.

Etterbehandling
Verktøy for akrylat brukes til etterbehandling og sluttjustering. Til polering bruk slipespaper, poleringssummi, pimpest, pastør og myke poleringsterster egnet for akrylharpiks for en blånk fot.

RENGØRING: Sør for å rengjøre konstruksjonen grundig før å fjerne eventuelle rester fra frese- og etterbehandlingsprosessen ved å bruke vanlig tannlegelabopraksis (f.eks. dampstøler eller mild såpe/vaskemiddel).

INFORMASJON TIL TANNELEGE: I samsvar med standard tannlegepraksis må tannlegen rengjøre den medisinske enheten for den blir satt inn i munnen. Tannlegen må gi pasienten instruksjoner for riktig rengjøring av den medisinske enheten og følge opp pasienten ved faste avtale for å vurdere tilstanden til den medisinske enheten. Vi anbefaler å rengjøre med myke børster og mild såpe for avtakbare medisinske enheter og ikke-slipende tannpastører for faste konstruksjoner.

OPPBÆRING: Hold unna direkte sollys!

AVHENDING: Avhending skal gjøres i samsvar med lokal og nasjonal lovgivning.

ADVARSLER: Kun til profesjonell bruk! CAD/CAM-tannegeferdigheter kreves for å behandle produktet på riktig måte. Skivene må fresses med et kompatibelt CAD/CAM-system.

Materialelet må ikke overopphøres!

Ikke bruk materialelet etter utløpsdatoen. Utløpsdato er trykket på emballasjen. PMMA-stov kan utvikles under freseprosessen, noe som fører til mekanisk irritasjon av øyne, hud og luftveier. Sør for at avtrekkssystemet på arbeidssplassen er i orden. Ved behandling av PMMA-skiver, bruk personlig verneutstyr (vernemaske for øyer, vernebriller, ...).

For å sikre sporbarhet og tilordning av produktdata samt LOT-numre for patient til enhver tid, anbefales det å oppbevare freseemnet i originalemballasjen under freseoperasjoner.

Sikkerhetsrelaterte tilleggsinformasjon finnes i sikkerhetsdatabladet som er tilgjengelig på forespørsel. Ved en alvorlig hendelse i forhold til enheten, bør den rapporteres til produsenten (Polident d.o.o.; vigilanca@polident.si) og de kompetente myndighetene i medlemsstaten der brukeren er etablaert.

PL
PRZECIĘWKAZANIA: Krażka PINK CAD/CAM DISC nadaje się do frezowania protez całkowitych i częściowych oraz protez tymczasowych na implantach z natychmiastowym obciążaniem.

SKŁAD: Material PMMA z wbudowanymi pigmentami i pozostałościami metylemetakrylu ponizej 1%

WSKAZANIE: Bezbezpiecze, częściowe bezbezpiecze

PRZECIĘWKAZANIA: Nie stosować produktu w przypadku stwardzonej alergii lub nadwrażliwości na materię akrylową.

CZAS NOŚNIAZ: Zalecaný čas noszenia wynosi do 5 lat.

INSTRUKCJA UŻYWANIA
UWAGA! Przed użyciem krażki należy dokładnie przeczytać jego etykietę, aby wybrać odpowiednią wysokość i odcięcie.

Zasady przy projektowaniu płyt protetycznych w oprogramowaniu CAD
Płyty protetyczne należy zaprojektować za pomocą odpowiedniego stomatologicznego oprogramowania CAD.

Zamocować krażkę w uchwycie frezarki. Należy zwrócić uwagę na orientację wielotorowego krażka CAM/PINK CAD/CAM DISC. Jaśniejszy odcięcie powinien znajdować się na górze. Zalecać plik CAM do frezarki. Strategie frezowania dotyczące PMMA należy uwzględniać zgodnie z instrukcją obsługi frezarki. Protrząza oddziała się na krażkę za pomocą standardowych narzędzi do szlifowania zywicy PMMA po frezowaniu.

Wiązanie żebów protetycznych

Związać sztuczne żebą do płyty protetycznej za pomocą żywicy PMMA lub światłotwardzalnego materiału kompozytowego zgodnie z instrukcjami producenta.

Sztuczne żebę należy zmatkować i przygotować zgodnie z zaleceniami producenta. Płyta protetyczna nie wymaga specjalnego przygotowania w przypadku żywicy PMMA, ale zwykle wymaga zastosowania podkładu w przypadku kompozytowego materiału właściwego zgodnie z zaleceniami producenta. Proteza można wykonywać standardowymi narzędziami do szlifowania i polerowania w żywicy PMMA po związaniu sztucznych żebów.

Wykonanie

Narzędzia do akrylu służą do wykańczania i ostatecznych poprawek. Do polerowania należy używać papieru śliwego, gumek polerskich, pumeksu, pasti i miękkich szczoteczek polerskich odpowiadających do żywic akrylowych, aby uzyskać błyszczącą powierzchnię.

Verdere veiligheidsrelevante informatie kunt u vinden in het veiligheidsinformatieblad dat op aanvraag verkrijgbaar is.

Als zich een ernstig incident heeft voorgedaan met betrekking tot het hulpmiddel, moet dit worden gemeld aan de fabrikant (Polident d.o.o.; vigilanca@polident.si) en de bevoegde autoriteit van de lidstaat waar de gebruiker is gevestigd

CYZSZCZENIE: Należy pamiętać o dokładnym wyczyszczeniu uzupełnienia w celu usunięcia wszelkich pozostałości po frezowaniu i wykańczaniu. W tym celu należy zastosować powszechnie stosowaną praktykę w pracowni dentystycznej (np. strumień powietrza lub lagodne mydło/detergent).

INFORMACJA DLA STOMATOLOGA: Zgodnie ze standardowymi praktykami stomatologicznymi stomatolog ma obowiązek czyszczania wyrobu medycznego przed wprowadzeniem go do jamy ustnej. Stomatolog jest zobowiązany przekazać pacjentowi instrukcję dotyczące odpowiedniego czyszczania wyrobu medycznego i wykonywanie badania kontrolne pacjenta podczas regularnych wizyt w celu oceny stanu wyrobu. Zalecamy czyszczenie miękkimi szczoteczkami i lagodnym mydlem do wyjmowanych wyrobów medycznych oraz nieścisłymi pastami do żebów do uzupełnienia stałych.

SESTAVA: PMMA materiał z wkładem pigmentu i prosty monomeru manj kot 1%.

INDIKACJE: Edentulizem, delni edentulizem

KONTRAINDIKACJE: Izdeka ne uporabljajte v primeru znanih alergij ali preobčitljivosti na akrilatne materiale.

CAS UPORABE: Priporočeni čas uporabe pri pacientu je do 5 let

NAVODILA ZA UPORABO
POMEMBNA: Pred uporabo diskova pozorno preberite oznake na disku, da izberete pravilo višino in brava.

Pravila: Kražka, ki jih je potrebno upoštevati pri načrtovanju protetnih žeb:
Protetno žeb je potreben narisati v ustremnem dentalnem CAD programu.

W procesie frezowania może powstawać pył PMMA, który może powodować mechaniczne podrażnienie oczu, skóry i głowy odczuciem drażenia. Wszystko zależy od konstrukcji systemu odrysowania w miejscu pracy. Podczas obróbki tarczki PMMA należy posieć środki ochrony indywidualnej (maskę chroniącą przed kurzem, okulary ochronne itp.).

Aby w każdym momencie móc zapewnić pacjentowi identyfikowalność i przypisanie danych produktu oraz numerów LOT, zaleca się przechowywanie szablonu do frezowania w oryginalnym opakowaniu podczas dwóch operacji frezowania.

Dalsze informacje istotne dla bezpieczeństwa można znaleźć w karcie charakterystyki produktu dostępnego na żądanie.

W przypadku wystąpienia poważnego zdarzenia związanego z wyrobem należy zgłosić je producentowi (Polident d.o.o.; vigilanca@polident.si) oraz właściwemu organowi państwa członkowskiego, w którym użytkownik ma siedzibę.

PT

FINALIDADE PREVISTA: O PINK CAD/CAM disc é adequado para fresar protes dentárias totais e parciais e próteses provisórias de colocação imediata suportadas por implantes.

COMPOSIÇÃO: Material à base de PMMA com pigmentos incorporados e metacrilato de metilo residual a menos de 1%

INDICAÇÃO: edentulismo, edentulismo parcial

CONTRAINDICAÇÕES: Não utilize o produto em caso de alergias conhecidas ou hipersensibilidade a materiais acrílicos.

TEMPO DE USO: O tempo de uso recomendado é de até 5 anos.

INSTRUÇÕES DE UTILIZAÇÃO

NOTA! Antes de utilizar o disco, leia atentamente a etiqueta do disco para escolher a altura e a tonalidade corretas do mesmo.

Regras de desenho e considerar em software CAD para o desenho de bases de próteses dentárias

Desenhe a base da prótese dentária com um software dental CAD adequado. Fixe o disco no suporte da frezadora. Preste atenção à orientação do PINK CAD/CAM disc multilayer. A tonalidade mais clara deve ficar em cima. Carregue o ficheiro CAM na frezadora. As estratégias de frezagem da frezadora. Após a frezagem, a prótese dentária é separada do disco com ferramentas de refinação padrão para resina de PMMA.

Colagem dos dentes de prótese dentária

Cole os dentes artificiais a base da prótese dentária com resina de PMMA ou material compósito fotopolimerável, de acordo com as instruções do fabricante. Os dentes artificiais devem ser desbastados e preparados de acordo com as instruções do fabricante. A base da prótese dentária não requer tratamento especial no caso de resina de colagem de PMMA, mas normalmente requer um tratamento de primário no caso de material de colagem compósito, de acordo com as instruções do fabricante. O acabamento da prótese dentária pode ser realizado com ferramentas normais de refinação e polimento para resina de PMMA após a colagem dos dentes artificiais.

SHRANJEVANJE: Hraniti zaščitenno pred sončno svetlobo!

ODSTRANJEVANJE: Z odpadki ravnjate v skladu z lokalnimi/ regionalnimi nacionalnimi predpisi.

Kontrola: Za manjše popravke se uporablja obdelovalna sredstva za akrilat.

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