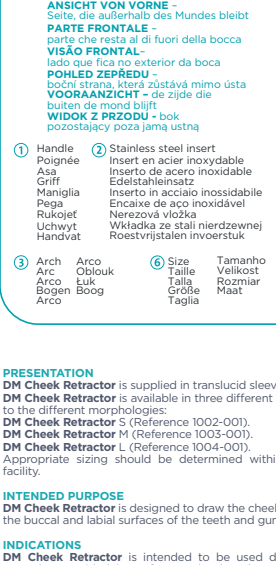


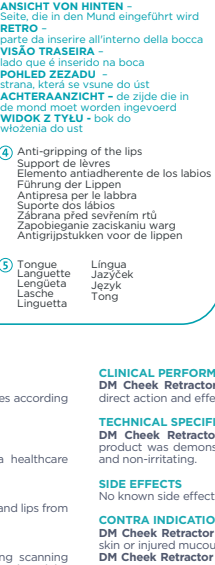
# Summary

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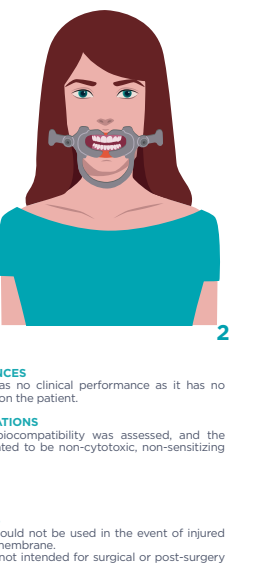
**FRONT VIEW** – side remaining outside the mouth  
**VUE FRONTALE** – côté restant à l'extérieur de la bouche  
**VISTA FRONTAL** – parte che resta fuori della bocca  
**ANSICHT VON VORNE** – Seite, die außerhalb des Mundes bleibt  
**PARTE FRONTAL** – parte che resta fuori della bocca  
**VISO FRONTAL** – lado que fica no exterior da boca  
**POHLED ZEPŘEDU** – část, která zůstává mimo ústa  
**VOORAAANZICHT** – de zijde die buiten de mond blijft  
**WIDOK Z PRZODU** – bok pozostający poza jamą ustną

|                                                                                 |                                                                                                                                                                                                                                                             |                                                |
|---------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| ① Handle<br>Poignée<br>Asa<br>Griff<br>Maniglia<br>Rungloj<br>Uchwyt<br>Handvat | ② Stainless steel insert<br>Insert en acier inoxydable<br>Inserto de acero inoxidable<br>Edelstahleinsatz<br>Inserto in acciaio inossidabile<br>Incausa de oțel inoxidabil<br>Nerezová vložka<br>Wkładka ze stali nierdzewnej<br>Roestvrijstalen invoerstuk |                                                |
| ③ Arch<br>Arco<br>Arco<br>Bogen<br>Arco                                         | ④ Size<br>Taille<br>Größe<br>Taglia                                                                                                                                                                                                                         | ⑤ Tongue<br>Langue<br>Zazyček<br>Język<br>Tong |



**BACK VIEW** – side to be inserted in the mouth  
**VUE DE L'ARRIÈRE** – côté devant être inséré dans la bouche  
**VISTA POSTERIOR** – parte que se introduce en la boca  
**ANSICHT VON HINTEN** – Seite, die in den Mund eingeführt wird  
**RETRO** – parte da inserir all'interno della bocca  
**VISO TRASEIRA** – lado que é inserido na boca  
**POHLED ZE ZADU** – strana, která se vsune do úst  
**ACHTERAAANZICHT** – de zijde die in de mond moet worden ingevoerd  
**WIDOK Z TYŁU** – bok do włożenia do ust

|                                                                                                                                                                                                                                                                 |                                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| ④ Anti-gripping of the lips<br>Support de lèvres<br>Elemento antiadherente de los labios<br>Führung der Lippen<br>Antipresa per le labbra<br>Suporte dos lábios<br>Zabrana pred sevanjem rtu<br>Zapobieganie zaciskaniu warg<br>Antigrijpstukken voor de lippen | ⑤ Tongue<br>Langue<br>Zazyček<br>Język<br>Tong |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|



**DESCRIPTION / DESCRIPTION / DESCRIPCIÓN / BESCHREIBUNG / DESCRIZIONE / DESCRICÃO / POPIS / BESCHRIJVING/ OPIS**

**PRESENTATION**  
The **DM Cheek Retractor** is supplied in translucent sleeve.  
**DM Cheek Retractor** is available in three different sizes according to the different morphologies:  
**DM Cheek Retractor S** (Reference 1002-001).  
**DM Cheek Retractor M** (Reference 1003-001).  
**DM Cheek Retractor L** (Reference 1004-001).  
Appropriate sizing should be determined within a healthcare facility.

**INTENDED PURPOSE**  
**DM Cheek Retractor** is designed to draw the cheeks and lips from the buccal and labial surfaces of the teeth and gums.

**INDICATIONS**  
**DM Cheek Retractor** is intended to be used during scanning procedures guided by software, developed, and marketed by Dental Monitoring.

**TARGET GROUPS**  
Target population: **DM Cheek Retractor** is indicated for use for patients over the age of 6.

Intended users: **DM Cheek Retractor** is intended to be used by: Healthcare professional in professional healthcare facilities, such as a dental practice.  
Lay persons, patients themselves or third parties, in a non-healthcare environment, such as the patient's own home.

Type of use/reuse: **DM Cheek Retractor** is reusable and can be used:  
Single patient multiple use.

**CLINICAL BENEFITS**  
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**NOTES**  
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**DIRECTIONS FOR USE**  
**INSERTING THE DM CHEEK RETRACTOR IN YOUR MOUTH**  
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Slightly fold the retractor towards you by bringing closer the left and right side.  
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In the event of pain, refer to your healthcare facility to check you have the appropriate retractor size.

**INSTRUCTIONS FOR REUSABLE DEVICES**  
Clean the **DM Cheek Retractor**.  
Before and after each use, clean with soap, such as Sanex 0%, and cold water.  
If necessary, gently brush the surface with a soft bristle brush and

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Rinse with cold water at least 15 seconds.  
Let the **DM Cheek Retractor** air dry.  
Then store it in the provided sleeve protection, in a dry and clean place, avoiding compression of the **DM Cheek Retractor** with other objects.

**INSTRUCTIONS FOR DAMAGED PACKAGING**  
If the packaging is damaged before use, return the pack to your healthcare facility.

**STORAGE**  
The retractor should be stored in its sleeve away from solar radiation and moisture.

**DISPOSAL**  
Once your retractor is no longer required, dispose of it in accordance with your local recycling regulations.

**LIST OF REQUIRED NON-RECYCLING PRODUCTS**  
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Dental Monitoring (REF 2001-001)

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# APRESENTAÇÃO

O **DM Cheek Retractor** é fornecido numa bolsa translúcida. O **DM Cheek Retractor** destina-se a ser usado durante procedimentos de digitalização guiada por um software desenvolvido e comercializado pela Dental Monitoring.

# FINALIDADE PREVISTA

O **DM Cheek Retractor** foi concebido para afastar as bochechas e os lábios das superfícies vestibular e labial dos dentes e das gengivas.

# INDICAÇÕES

O **DM Cheek Retractor** destina-se a ser usado durante procedimentos de digitalização guiada por um software desenvolvido e comercializado pela Dental Monitoring.

# GRUPOS-ALVO

População-alvo O **DM Cheek Retractor** está indicado para pacientes com mais de 6 anos de idade.

Utilizadores previstos O **DM Cheek Retractor** destina-se a ser usado por:

profissionais de saúde em clínicas e consultórios profissionais, como consultórios dentários;

leigos, os próprios pacientes ou terceiros, em ambientes não relacionados com cuidados de saúde, como a própria residência do paciente.

Tipo de utilização/reutilização O **DM Cheek Retractor** é reutilizável e pode ser usado:

Para múltiplas utilizações por um só paciente.

# BENEFÍCIOS CLÍNICOS

Não há benefícios clínicos diretos do uso do **DM Cheek Retractor**. O **DM Cheek Retractor** destina-se a ser usado durante procedimentos de digitalização realizados com o software Dental Monitoring.

# DESEMPENHOS CLÍNICOS

O **DM Cheek Retractor** não apresenta desempenhos clínicos, uma vez que não tem qualquer ação ou efeito diretos no paciente.

# ESPECIFICAÇÕES TÉCNICAS

Foi avaliada a biocompatibilidade do **DM Cheek Retractor**, e ficou demonstrado que o produto não é citotóxico e não produz sensibilização nem irritação.

# EFEITOS SECUNDÁRIOS

Não se conhecem efeitos secundários.

# CONTRAINDICAÇÕES

O **DM Cheek Retractor** não deve ser utilizado caso existam ferimentos na pele ou nas membranas mucosas.

O **DM Cheek Retractor** não se destina a uma utilização cirúrgica ou pós-cirúrgica, nem a captar fotografias intraorais com outros produtos que não os comercializados pela Dental Monitoring.

# ADVERTÊNCIAS, PRECAUÇÕES, AVISOS

## Advertências

Não se conhecem quaisquer advertências.

## Precauções

Quando o **DM Cheek Retractor** apresenta-se em forma não estéril. Limpe o **DM Cheek Retractor** antes e depois de cada uso (consulte as instruções para dispositivos reutilizáveis). Consulte o procedimento de limpeza para determinar o procedimento adequado a seguir de acordo com o uso do produto. Mantenha abrigado de fogo.

Não utilize o **DM Cheek Retractor** numa máquina de lavar a loiça ou noutra máquina automatizada.

Siga o procedimento de limpeza para evitar qualquer contaminação.

Não utilize o **DM Cheek Retractor** se este estiver partido.

# INSTRUÇÕES PARA DISPOSITIVOS REUTILIZÁVEIS

Limpe o **DM Cheek Retractor**:

antes e depois de cada utilização, lave com sabão, como Sanex 0%, e água fria.

Se necessário, escove suavemente a superfície com uma escova de cerdas macias e assegure-se de que está completamente limpo.

Enxague com água fria durante, pelo menos, 15 segundos.

Deixe o **DM Cheek Retractor** secar ao ar.

Em seguida, guarde-o na luva de proteção fornecida, em local limpo e seco, evitando a compressão do **DM Cheek Retractor** contra outros objetos.

# INSTRUÇÕES PARA EMBALAGENS DANIFICADAS

Se a embalagem se apresentar danificada antes da utilização, devolva a embalagem à sua clínica ou consultório.

# ARMAZENAMENTO

O afastador deve ser guardado na bolsa respetiva, protegido de radiação solar e humidade.

# ELIMINAÇÃO

Quando já não precisar do afastador, elimine-o de acordo com a regulamentação local relativa a reciclagem.

# LISTA DE PRODUTOS NECESSÁRIOS NÃO INCLuíDOS NA EMBALAGEM

ScanBox Dental Monitoring (1001-001); acessório opcional Dental Monitoring (REF 2001-001)

# GARANTIA

Um ano a partir da data de compra original.

# VIAGENS

No caso de viagem, o afastador deve ser mantido na respetiva bolsa. Assegure-se de que o afastador não fica embalado sob pressão, para evitar qualquer deformação durante o transporte.

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Não utilize o **DM Cheek Retractor** se houver sinais de desgaste, como fissuras visíveis ou fraturas.

Não utilize o **DM Cheek Retractor** se detetar alguma descoloração ou deformação.

As seguintes pessoas devem ser auxiliadas por terceiros ao utilizar o dispositivo:

crianças até aos 12 anos de idade;

adultos ou crianças com deficiência visual;

adultos ou crianças com deficiência auditiva;

adultos ou crianças com qualquer outro problema que possa impedir que o paciente utilize o dispositivo de forma adequada.

No caso dos pacientes com dentes deciduais, é necessária vigilância pelo responsável pelo paciente para assegurar que os dentes deciduais não caem na colocação do **DM Cheek Retractor**.

**Avisos**

Este dispositivo não é um brinquedo. As crianças devem ser supervisionadas para assegurar que não brincom com o dispositivo.

# INSTRUÇÕES ANTES DE UTILIZAR

Antes de utilizar, deve lavar as mãos com água e sabão ou gel hidroalcoólico. Tem igualmente de limpar o **DM Cheek Retractor** (segundo as recomendações do fabricante) antes de cada utilização. Consulte nas Instruções para dispositivos reutilizáveis as etapas adequadas a seguir.

# INSTRUÇÕES DE UTILIZAÇÃO

## INTRODUÇÃO DO DM CHEEK RETRACTOR NA SUA BOCA

Segure no afastador utilizando ambas as pegas 1, com o arco para baixo 3 e os encaixes de aço inoxidável afastados da boca 2. Incline ligeiramente o afastador na sua direção, aproximando o lado esquerdo e o direito.

Insira primeiro um lado e depois o outro. Certifique-se de que as linguas ficam corretamente inseridas na boca 5.

Verifique se o afastador está corretamente aplicado: os dentes e as gengivas devem ser visíveis, sem dor nem desconforto. Caso sinta dor, consulte a sua clínica ou consultório para verificar se tem o tamanho de afastador adequado.

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**PREZENTACE**

O **DM Cheek Retractor** se dodává v průsvitném pouzdru. **DM Cheek Retractor** je k dispozici ve třech různých velikostech s ohledem na různou morfologii pacientů.

**DM Cheek Retractor**, S (ref. č. 1002-001).

**DM Cheek Retractor**, M (ref. č. 1003-001).

**DM Cheek Retractor**, L (ref. č. 1004-001).

Vhodnou velikost stanoví zdravotnické zařízení.

## ZAMÝŠLENÝ ÚČEL

**DM Cheek Retractor** slouží k odtažení tváří a rtů od bukalních a labiálních plošek zubů a dásní.

## INDIKACE

Používání **DM Cheek Retractor** je určen k použití při postupech skenování navigačních softwarem vyvinutým a dodávaným společností Dental Monitoring.

## CILOVE SKUPINY

Cílová populace: **DM Cheek Retractor** je indikován u pacientů starších 6 let.

Zamýšlení uživatelé: **DM Cheek Retractor** je indikován k použití následujícími osobami:

Zdravotníci na profesionálních zdravotnických pracovištích jako např. stomatologické praxe.

Leigové, os próprios pacientes ou terceiros, em ambientes não relacionados com cuidados de saúde, como a própria residência do paciente.

Typ použití / opakovaného použití: **DM Cheek Retractor** je opakovane použitelný a lze jej používat: Opakované použití / jedním pacientem.

## KLINICKÉ VÝHODY

Používání **DM Cheek Retractor** nemá žádné přímé klinické výhody. **DM Cheek Retractor** je určen k použití při postupech skenování pomocí softwaru společnosti Dental Monitoring.

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dospělí nebo děti se zdravotním postižením dospělí nebo děti se sluchovým postižením dospělí nebo děti s jiným zdravotním stavem, kvůli němuž nedokážou s prostředkem správně zacházet

U pacientů s mléčnými zuby musí být při vkládání **DM Cheek Retractor** přítomn zákonný zástupce, který dohlédne na to, aby tyto zuby nevypadly.

## Poznámky

Tento výrobek není hračka. Dohlédněte na to, aby si děti s prostředkem nehrály.

## NÁVOD PŘED POUŽITÍM

Před použitím si umyjte ruce vodou a mýdlem nebo hydroalkoholovým gelem. **DM Cheek Retractor** je také třeba před každým použitím vyčistit (dle doporučení výrobce). Postupujte podle pokynů pro opakované použití nástroje.

## POKYNY K POUŽITÍ

### VLOŽENÍ DM CHEEK RETRACTOR DO ÚST

Retraktori uchopte za obě rukojeti 1 oboukolem dólů 3 a vločkami z nerostové oceli směrem od sebe 2.

Retraktori musí být vložen s příklonem levé a pravé strany. Nejprve vložte jednu stranu, pak druhou. Dbejte, aby byly jazyčky správně vloženy do út 5.

Zkontrolujte, že je retractor správně vložen: zuby a dásně musí být viditelné, aniž byste cítili bolest nebo nepohodlí.

V případě bolesti požádejte ve zdravotnickém zařízení, aby ověřili, zda máte retractor vhodné velikosti.

## POKYNY K OPAKOVANÉ POUŽITELNÝM PROSTŘEDKŮM

**DM Cheek Retractor** čistíte následovně:

Před každým použitím i po něm omýjte retractor studenou vodou a mýdlem, jako je například Sanex 0%.

Podle potřeby povrch zlepkla očistíte měkkým kartáčkem a zkontrolujete, že je zcela čistý.

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**PRESENTATIE**

O **DM Cheek Retractor** wordt geleverd in een doorzichtige hoes. De **DM Cheek Retractor** is in drie maten verkrijgbaar, passend bij de verschillende gezichtsmorfieën.

**DM Cheek Retractor**, S (referentie 1002-001).

**DM Cheek Retractor**, M (referentie 1003-001).

**DM Cheek Retractor**, L (referentie 1004-001).

De juiste maat dient in een zorginstelling te worden bepaald.

## BEOOGD DOEL

De **DM Cheek Retractor** is bedoeld om de wangen en lippen weg te duwen van de buccale en labiale oppervlakken van de gebitselémenten en het tandvlees.

## INDICATIES

De **DM Cheek Retractor** is bedoeld voor gebruik tijdens softwaregestuurde scanprocedures met software die door Dental Monitoring is ontwikkeld en op de markt gebracht.

## DOELGROEPEN

Doelgroep: De **DM Cheek Retractor** is geïndiceerd voor gebruik door patiënten ouder dan 6 jaar.

Beoogde gebruikers: De **DM Cheek Retractor** is bedoeld voor gebruik door:

Tandheelkundige professionals in professionele zorginstellingen, zoals een tandartspraktijk.

Niet-professionals, patiënten zelf of derden, in een niet-zorgomgeving, zoals bij de patiënt thuis.

Type gebruik/hergebruik: De **DM Cheek Retractor** is herbruikbaar en geschikt voor:

Herhaald gebruik door één patiënt.

## KLINISCHE VOORDELEN

Gebruik van de **DM Cheek Retractor** levert geen direct klinisch voordeel op. De **DM Cheek Retractor** is bedoeld voor gebruik

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beschadiging, zoals zichtbare scheuren of breken. Gebruik de **DM Cheek Retractor** niet als deze vervormd of verkleurd is.

De volgende populatie dient bij gebruik van het hulpmiddel door een derde te worden geholpen:

kinderen tot 12 jaar;

slechtziende volwassenen of kinderen;

volwassenen met kinderen met een aandoening waardoor de patiënt het hulpmiddel mogelijk niet goed kan gebruiken.

Bij gebruik moet er meer aandacht zijn op het plaatsen van de ouder/voogd geboden om te voorkomen dat melktanden of -kiezen bij plaatsing van de **DM Cheek Retractor** uitvallen.

## Aandachtspunten

Dit is geen speelgoed. Houd toezicht op kinderen om te voorkomen dat ze met het hulpmiddel spelen.

## INSTRUCTIES VOÓR GEBRUIK

Was uw handen vóór gebruik met water en zeep of een desinfecterende handgel. Reinig ook de **DM Cheek Retractor** (volgens de instructies van de fabrikant ervan) vóór elk gebruik.

Volg de instructies voor het herbruikbare hulpmiddelen voor de stappen die u moet volgen.

## GEBRUIKSAANWIJZINGEN

### DE DM CHEEK RETRACTOR IN UW MOND PLAATSEN

Houd de spreider aan beide handvatten 1 vast, met de boog 3 naar beneden en de roestvrijstalen inzetstukken 2 van u af. Buig de spreider licht naar u toe door de linker- en rechterkant naar elkaar toe te brengen. Plaats eerst de ene, en dan de andere kant in de mond. Zorg dat de tongen 5 correct in de mond worden geplaatst.

Controleer of de spreider goed is geplaatst: tanden en tandvlees moeten zichtbaar zijn zonder dat er sprake is van pijn of ongemak. Bij pijn of ongemak neem u contact op met uw behandelaar om na te gaan of u wel de juiste maat spreider hebt.

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## PREZENTACJA

**DM Cheek Retractor** jest dostarczany w przezroczystej tulei.

**DM Cheek Retractor** jest dostępny w trzech różnych rozmiarach, zgodnych z różnymi morfologiami:

**DM Cheek Retractor**, rozmiar S (nr kat. 1002-001).

**DM Cheek Retractor**, rozmiar M (nr kat. 1003-001).

**DM Cheek Retractor**, rozmiar L (nr kat. 1004-001).

Właściwy rozmiar powinien być ustalony w placówce ochrony zdrowia.

## PRZEZNACZENIE

**DM Cheek Retractor** został stworzony z myślą o odcigananiu policzków i warg od powierzchni wargowych i podniebiennej żębow i dąsael.

## WSKAZANIA

**DM Cheek Retractor** jest przeznaczony do stosowania podczas procedur skanowania kierowanych przez oprogramowanie opracowane i sprzedawane przez firmę Dental Monitoring.

## GRUPY DOCELOWE

Populacja docelowa: **DM Cheek Retractor** jest przeznaczony dla pacjentów w wieku powyżej 6 lat.

Planowani użytkownicy: **DM Cheek Retractor** jest przeznaczony do stosowania przez następujące osoby:

Pracownicy ochrony zdrowia w profesjonalnych placówkach ochrony zdrowia, np. w gabinecie dentystycznym.

Inne osoby, sami pacjenci lub osoby trzecie w środowisku niezwiązanym z opieką zdrowotną, np. w domu pacjenta.

Typ użytkowania / ponownego użytkowania: **DM Cheek Retractor** to wielokrotnego użytku i może być używany: Wieloakownego użytku u jednego pacjenta.

## ZALETY KLINICZNE

Nie występuje bezpośrednie zalety kliniczne użytkowania wyrobu **DM Cheek Retractor**. **DM Cheek Retractor** jest przeznaczony do

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Nie używaj urządzenia **DM Cheek Retractor**, jeśli jest ono uszkodzone.

Nie używaj urządzenia **DM Cheek Retractor** w przypadku śladów zużycia, takich jak widoczne pęknięcia lub zlamania.

Następujące grupy użytkowników powinny skorzystać z pomocy osób trzecich przy obsłudze wyrobu:

dzieci w wieku poniżej 12 lat;

niedowidzące osoby dorosłe i dzieci;

niedosłyszące osoby dorosłe i dzieci;

osoby dorosłe i dzieci z jakimikolwiek innymi dolegliwościami, które mogą uniemożliwić pacjentowi prawidłową obsługę wyrobu.

W przypadku pacjentów z zębami mlecznymi opiekun musi uważać, aby zęby mleczne nie wypadły podczas umieszczania **DM Cheek Retractor**.

## Uwagi

Urządzenie nie jest zabawką. Dzieci powinny być nadzorowane, aby nie bawiły się urządzeniem.

## INSTRUKCJA PRZED ROZPOCZĘCIEM UŻYTKOWANIA

Przed użyciem należy umyć ręce wodą z mydłem lub żelem hydroalkoholowym. Przed każdym użyciem należy również wyčystić wyrob **DM Cheek Retractor** (zgodnie z zaleceniami producenta). Odpowiednie kroki można znaleźć w instrukcji wyrobów wielokrotnego użytku.

## PODCZAS UŻYTKOWANIA

### WKLADANIE DM CHEEK RETRACTOR DO UST

Chwyć retractor za oba uchwyty 1, z kółkiem 3 skierowanym w dół i z wkładkami ze stali nierdzewnej 2 od siebie. Delikatnie złóż retractor do siebie, zbliżając stronę lewą i prawą. Najpierw włoż jedną stronę, a następnie drugą stronę. Upewnij się, że języki 5 zostały prawidłowo umieszczone w jamie ustnej. Sprawdź, czy retractor jest prawidłowo założony; języki i dąsłowa powinny być widoczne bez odczuwania bólu lub dyskomfortu.

W przypadku wystąpienia bólu lub dyskomfortu należy

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