Medtronic

DLP®

Perfusion Adapter
Adaptateur de perfusion
Perfusionsadapter
Adaptador de perfusión
Perfusie-adapter
Adattatore per perfusione
Perfusjonsadapter
Perfuusiosovitin
Perfusionsadapter
Προσαρμογέας έγχυσης
Perfusionsadapter
Łącznik do perfuzji
Adaptador de perfusão
Perfüzyon Adaptörü
Perfúzní adaptér
Perfúziós adapter
Переходник для перфузии

Instructions for Use • Mode d'emploi • Gebrauchsanweisung • Instrucciones de uso
Gebruiksaanwijzing • Istruzioni per l'uso • Bruksanvisning • Käyttöohjeet
Bruksanvisning • Οδηγίες χρήσης • Brugsanvisning • Instrukcja użytkowania
Instruções de utilização • Kullanım Talimatları • Návod k použití • Használati útmutató
Инструкция по эксплуатации

USA **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

CE 0123

Explanation of symbols on package labeling / Explication des symboles des étiquettes sur l'emballage / Erläuterung der Symbole auf dem Verpackungsetikett / Explicación de los símbolos que aparecen en el etiquetado del envase / Verklaring van de symbolen op de verpakkingslabels / Spiegazione dei simboli sulle etichette della confezione / Forklaring av symboler på emballasjen / Pakkauksen symbolien selitykset / Förklaring av symboler på förpackningsetiketten / Επεξήγηση των συμβόλων στην ετικέτα της συσκευασίας / Forklaring af symboler på emballagens mærkater / Objaśnienie symboli znajdujących się na etykietach opakowania / Explicação dos símbolos nas etiquetas da embalagem / Ambalaj etiketindeki sembollerin açıklamaları / Vysvětlení symbolů uvedených na štítcích balení / A csomagoláson látható szimbólumok jelentése / Объяснение символов на маркировках упаковки

Refer to the outer package label to see which symbols apply to this product / Se référer à l'étiquette sur l'emballage extérieur pour savoir quels symboles s'appliquent à ce produit / Welche Symbole für dieses Produkt gelten, entnehmen Sie bitte dem Etikett auf der Verpackung / Consulte la etiqueta del envase exterior para comprobar qué símbolos son aplicables a este producto / Controleer het label op de buitenverpakking om te zien welke symbolen op dit product van toepassing zijn / Vedere l'etichetta sulla confezione esterna per sapere quali simboli si applicano a questo prodotto / Se på etiketten utenpå pakningen for å fastslå hvilke symboler som gjelder for dette produktet / Katso ulkopakkauksesta, mitkä symbolit koskevat tätä tuotetta / Se etiketten på ytterförpackningen för de symboler som gäller denna produkt / Ανατρέξτε στην ετικέτα της εξωτερικής συσκευασίας για να δείτε ποια σύμβολα εφαρμόζν αυτό το προϊόν / Se mærkaten på den ydre emballage for de symboler, der gælder for dette produkt / Należy zapoznać się z etykietą na zewnętrznym opakowaniu, aby określić, które symbole dotyczą niniejszego produktu / Consultar as etiquetas exteriores da embalagem para ver que símbolos se aplicam a este produto / Hangi sembollerin bu ürün için geçerli olduğunu görmek için ambalaj etiketine bakınız / Podle štítků na vnější straně balení zjistíte, která symboly se týkají tohoto produktu / A termékre vonatkozó szimbólumok a külső csomagoláson találhatók / См. на упаковке, какие символы применимы к данному продукту

CE 0123 — Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Council Directive 93/42/EEC. / Conformité Européenne. Ce symbole signifie que l'appareil est entièrement conforme à la Directive 93/42/CEE du Conseil de l'Union Européenne. / Conformité Europäenne (Europäische Konformität). Dieses Symbol besagt, dass das Gerät allen Vorschriften der Richtlinie 93/42/EWG des Europäischen Rates entspricht. / Conformidad Europea. Este símbolo indica que el dispositivo cumple totalmente la Directiva del Consejo Europeo 93/42/CEE. / Conformité Européenne (Europese Conformiteit). Dit symbool betekent dat het apparaat volledig voldoet aan de Europese Richtlijn 93/42/EEG. / Conformità Europèenne (Conformità Europea). Questo simbolo significa che l'apparecchio è conforme alla Direttiva del Consiglio Europeo 93/42/CEE. / Conformité Européenne (samsvar med europeisk norm). Dette symbolet betyr at utstyret er fullstendig i samsvar med EU-direktiv 93/42/EØF. / Conformité Européenne (eurooppalainen vaatimustenmukaisuus). Tämä symboli tarkoittaa, että laite on kokonaan Euroopan unionin neuvoston direktiivin 93/42/ETY mukainen. / Conformité Européenne (EU-standard). Denna symbol betyder att utrustningen helt följer rådets direktiv 93/42/EEG. / Conformité Européenne (Ευρωπαϊκή Συμμόρφωση). Το σύμβολο αυτό σημαίνει ότι η συσκευή συμμορφώνεται πλήρως με την οδηγία του Ευρωπαϊκού Συμβουλίου 93/42/ΕΟΚ. / Conformità Europèenne (Europæisk Standard). Dette symbol betyder, at enheden fuldt ud overholder det Europæiske Råds Direktiv 93/42/EØF. / Conformité Européenne (Zgodność z normami Unii Europejskiej). Symbol ten oznacza, że produkt spełnia wszystkie wymogi dyrektywy Unii Europejskiej 93/42/EWG. / Conformité Européenne (Conformidade Europeia). Este símbolo significa que o dispositivo está em total conformidade com a Directiva do Conselho Europeu 93/42/CEE. / Conformité Européenne (Avrupa Normlarına Uygunluk). Bu sembol, cihazın Avrupa Konseyi Direktifi 93/42/EEC ile tamamen uyumlu olduğu anlamına gelir. / Conformité Européenne (Shoda s EÚ). Tento symbol znamená, že toto zařízení zcela splňuje požadavky evropského nařízení 93/42/EEC. / Conformité Européenne (Európai Megfelelőség). Ez a szimbólum azt jelenti, hogy az eszköz teljes mértékben megfelel az Európai Tanács 93/42/EGK irányelve követelményeinek. / Conformité Européenne (Европейское соответствие). Этот символ обозначает, что устройство полностью соответствует требованиям директивы Европейского Совета 93/42/EEC.

PYROGEN — Nonpyrogenic / Apyrogène / Pyrogenfrei / Apirógeno / Niet-pyrogeen / Non pirogeno / Pyrogenfri / Pyrogeeniton / Icke-pyrogen / Μη πυρετογόνο / Non-pyrogen / Produkt niepirogenny / Apirogénico / Non Pirojenik / Nepyrogenní / Nem pirogén / Апирогенно

STERILE EO — Sterilized Using Ethylene Oxide / Stérilisation par oxyde d'éthylène / Sterilisiert mittels Ethylenoxid / Esterilizado mediante óxido de etileno / Gesterilisseerd met ethyleenoxide / Sterilizzato con ossido di etilene / Sterilisert med etylenoksid / Steriloitu etyleenioksidilla / Steriliserad med etylenoxid / Αποστειρωμένο χρησιμοποιώντας οξείδιο του αιθυλενίου / Steriliseret med etylenoxid / Produkt sterylizowany tlenkiem etylenu / Esterilizado com óxido de etileno / Etilen Oxalite Sterilize Edilmiştir / Sterilizováno etylenoxidem / Etilén-oxiddal sterilizálva / Стерилизовано этиленоксидом

Do Not Reuse / Ne pas réutiliser / Nicht wiederverwenden / No reutilizar / Voor éénmalig gebruik / Non riutilizzare / Bare for engangsbruk / Kertakäyttöinen / Får inte återanvändas / Μην επαναχρησιμοποιείτε / Må kun bruges én gang / Produkt do jednorazowego zastosowania / Não reutilizar / Yeniden Kullanmayın / Nepoužívejte opakovaně / Nem újrafelhasználható / Не использовать повторно

Use By / A utiliser jusqu'au / Zu verwenden bis einschließlich / No utilizar después de / Te gebruiken tot en met / Data di scadenza / Siste forbruksdato / Viimeinen käyttöpäivä / Får användas till och med / Ημερομηνία λήξης / Kan anvendes til og med / Data ważności / Não utilizar depois de / Son Kullanma Tarihi / Použít do / Lejárat / Использовать до

Do Not Resterilize / Ne pas restériliser / Nicht resterilisieren / No reesterilizar / Niet hersteriliseren / Non risterilizzare / Skal ikke sterliseres på nytt / Ei saa steriloida uudellisen / Får inte omsterliseras / Μην επαναποστειρώνετε / Må ikke re-steriliseres / Nie należy resteryilizować / Não reesterilizar / Yeniden Sterilize Etmeyin / Neprovádět resterilizaci / Nem újrasterilizálható / Не стерилизовать повторно

LOT — Lot Number / Numéro de lot / Chargennummer / Número de lote / Partijnummer / Numero di lotto / Lotnummer / Erätnumero / Lotnummer / Αριθμός παρτίδας / Partinummer / Numer partii / Número de lote / Lot Numarası / Číslo šarže / Gyártási szám / Номер партии

Quantity / Quantité / Menge / Cantidad / Aantal / Quantità / Antall / Määrä / Mängd / Ποσότητα / Antal / Ilość / Quantidade / Miktar / Množství / Mennyiség / Количество

Caution, Consult Accompanying Documents / Attention, se référer aux documents joints / Achtung, Begleitdokumentation beachten / Precaución, consulte la documentación que se incluye / Let op, zie bijgevoegde documentatie / Attenzione, vedere i documenti allegati / Obs! Se medfølgende dokumenter / Huomio, katso oheiset asiakirjat / OBS! Se medföljande dokument / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Forsigtig! Se medfølgende dokumentation / Przestroga: Należy się zapoznać z dołączoną dokumentacją / Atenção, consulte os documentos em anexo / Dikkat, Ürünle Verilen Belgelere Bakın / Upozornění, viz přiložená dokumentace / Figyelem! Tanulmányozza a mellékelt dokumentumokat / Внимание! Ознакомьтесь с сопроводительной документацией

! USA — For US Audiences Only / Ne s'applique qu'aux États-Unis / Gilt nur für Leser in den USA / Sólo aplicable en EE. UU. / Alleen van toepassing voor de VS / Esclusivamente per il mercato statunitense / Gjelder bare i USA / Koskee vain Yhdysvaltoja / Gäller endast i USA / Mövo yia πελάτες εντός των Η.Π.Α. / Gælder kun i USA / Dotyczy tylko klientów w USA / Apenas aplicável aos E.U.A. / Yalnızca ABD'deki Kullanıcılar İçin / Pouze pro uživatele z USA / Csak egyesült államokbeli felhasználóknak / Только для США

Upper Limit of Temperature / Limite maximale de la température / Obere Temperaturgrenze / Límite superior de la temperatura / Maximale temperatuur / Limite superiore di temperatura / Øvre temperaturgrense / Lämpötilan yläraja / Övre temperaturgräns / Ανώτατο όριο θερμοκρασίας / Højeste tilladte temperatur / Górna granica dopuszczalnej temperatury / Limite máximo de temperatura / Sıcaklık Üst Sınırı / Horní limit teploty / Legmagasabb tárolási hőmérséklet / Температура не выше

REF — Catalog Number / Numéro de référence / Katalognummer / Número de catálogo / Catalogusnummer / Numero di catalogo / Katalognummer / Luettelonumero / Katalognummer / Αριθμός καταλόγου / Katalognummer / Numer katalogowy / Número de catálogo / Katalog Numarası / Katalogové číslo / Katalógusszám / Номер по каталогу

Manufacturer / Fabricant / Hersteller / Fabricante / Fabrikant / Produttore / Produsent / Valmistaja / Tillverkare / Κατασκευαστής / Fabrikant / Producent / Fabricante / Imalatçı / Výrobce / Gyártó / Производитель

PVC DEHP — Contains di(2-ethylhexyl)phthalate (DEHP) / Confient di(2-éthylhexyl)phtalate (DEHP) / Enthält Bis(2-ethylhexyl)phthalat (DEHP) / Contiene di(2-etilhexil)ftalato (DEHP) / Bevat di(2-ethylhexyl)ftalaat (DEHP) / Contiene ftalato di bis(2-etilesile) (DEHP) / Inneholder di(2-etylheksyl)ftalat (DEHP) / Sisältää di(2-etyyliheksyyli)ftalaattia (DEHP) / Innehåller di(2-ethylhexyl)ftalat (DEHP) / Περιέχει αβουλικό δι(2-αιθυλεξυλ)εστέρα (DEHP) / Indeholder di(2-ethylhexyl)phthalat (DEHP) / Zawiera ftalan di(2-etyloheksylu) (DEHP) / Contém ftalato de bis(2-etil-hexilo) (DEHP) / Di(2-etilheksil)ftalat (DEHP) içerir / Obsahuje di(2-ethylhexyl) ftalát (DEHP) / Di-(2-etilhexil)-ftalát (DEHP) tartalmaz / Содержит ди(2-этилгексил)фталат (ДЭГФ)

...ecial policy.
...nly:

...RODUCT" HAS BEEN
...DTRONIC HAS NO CONTROL

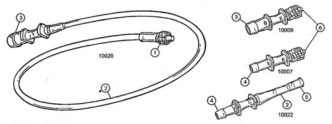

Figure 1 / Figure 1 / Abbildung 1 / Figura 1 / Afbeelding 1 / Figur 1 / Figur 1 / Kuva 1 / Figur 1 / Εικόνα 1 / Figur 1 / Rycina 1 / Figura 1 / Şekil 1 / Obrázek 1 / 1. ábra / Рисунок 1

1. Locking male luer fitting / Verrouillage luer mâle / Luer-Lock-Anschluss, männlich / Conector de bloqueo luer macho / Mannelijke luerlockfitting / Raccordo luer lock maschio / Hann-luerlock-kobling / Luer-urosliitin / Luerlockbeslag, hane / Αρσενικός σύνδεσμος ασφάλισης luer / Låsende han-luerfitting / Męskie złącze typu luer lock / Encaixe de bloqueio tipo luer macho / Kilitli erkek luer bağlantısı / Spojka s vnější koncovkou typu Lock Luer / Menetes apaluer-csatlakozó / Охватывающий винтовой люэровский разъем
2. Flexible tubing / Tubulure flexible / Flexibler Schlauch / Tubo flexible / Flexibele tubing / Tubo flessibile / Fleksibel slange / Joustava letku / Mjuk slang / Εύκαμπτη σωλήνωση / Bøjelig slange / Elastyczny dren / Tubagem flexível / Esnek boru / Pružná hadička / Hajlékony cső / Гибкая трубка
3. 0,95 cm (3/8 in) barbed connector / Connecteur cranté de 0,95 cm (3/8 pouce) / 0,95-cm-Schlauchtülle (3/8 Zoll) / Conector de lengüeta de 0,95 cm (3/8 pulg.) / Gegroefde connector van 0,95 cm (3/8 inch) / Connettore dentato da 0,95 cm (3/8 di pollice) / 0,95 cm (3/8 tommer) kontakt med mothaker / 0,95 cm (3/8 tuuman) väkäsellinen liitin / 0,95 cm (3/8 in) räfflad kopplingsdel / Σύνδεσμος 0,95 cm (3/8 ίντσες) με σκέβες / 0,95 cm (3/8") modhagekonnektor / Karbowany konektor 0,95 cm (3/8 cala) / Conector farpado de 0,95 cm (3/8 pol.) / 0,95 cm (3/8 ing) kancalı konektör / Ozubený konektor 0,95 cm (3/8 palce) / 0,95 cm-es (3/8 hüvelykes) bordázott csatlakozó / Разъем с бородкой диаметром 0,95 см (3/8 дюйма)
4. 0,64 cm (1/4 in) barbed connector / Connecteur cranté de 0,64 cm (1/4 pouce) / 0,64-cm-Schlauchtülle (1/4 Zoll) / Conector de lengüeta de 0,64 cm (1/4 pulg.) / Gegroefde connector van 0,64 cm (1/4 inch) / Connettore dentato da 0,64 cm (1/4 di pollice) / 0,64 cm (1/4 tommer) kontakt med mothaker / 0,64 cm (1/4 tuuman) väkäsellinen liitin / 0,64 cm (1/4 in) räfflad kopplingsdel / Σύνδεσμος 0,64 cm (1/4 ίντσες) με σκέβες / 0,64 cm (1/4") modhagekonnektor / Karbowany konektor 0,64 cm (1/4 cala) / Conector farpado de 0,64 cm (1/4 pol.) / 0,64 cm (1/4 ing) kancalı konektör / Ozubený konektor 0,64 cm (1/4 palce) / 0,64 cm-es (1/4 hüvelykes) bordázott csatlakozó / Разъем с бородкой диаметром 0,64 см (1/4 дюйма)
5. Locking female luer fitting / Verrouillage luer femelle / Luer-Lock-Anschluss, weiblich / Conector de bloqueo luer hembra / Adluitbare vrouwelijke luerfitting / Raccordo luer lock femmina / Hunn-luerlock-kobling / Luer-naarasliitin / Koppling med honkuerlock / Θηλυκό εξάρτημα ασφάλισης luer / Låsende hun-luerfitting / Żeńskie złącze typu luer lock / Encaixe de bloqueio tipo luer fêmea / Kilitli dişi luer bağlantısı / Uzamykací přípojka s vnitřní koncovkou luer / Menetes anyaluer-csatlakozó / Охватывающий винтовой люэровский разъем
6. Locking male luer spin nut / Écrou de verrouillage luer mâle à montage libre / Luer-Lock-Anschluss, Gewinde / Tuerca de bloqueo luer macho / Mannelijke luerlock draaimoer / Dado luer lock maschio / Roterende mutter for hann-luerlock-kobling / Luer-uromuttari / Hanluerlock, spinnmutter / Περιστροφικό παξιμάδι ασφαλούς συνδέσμου ασφάλισης luer / Låsende han-luer drejematrik / Męskie złącze typu luer lock z nakrętką / Porca giratória tipo luer macho / Kilitli erkek luer burgulu somunu / Otočná matka s vnější koncovkou Lock Luer / Menetes apaluer-csavar / Закручивающаяся гайка охватывающего винтового люэровского разъема

DLP®

Perfusion Adapter

Product Description

Models 10007 and 10008 are designed to prevent inadvertent separation of tubing connections during perfusion. These adapters have a free spinning nut on one end that locks the male luer fitting to a locking female luer fitting. On the opposite end is a barbed connector for attachment to an open-ended tube.

Model 10020 is a 61.0 cm (24 in) tubing adapter designed to convert from a 0.95 cm (3/8 in) ID line to a locking female luer fitting. On one end of the tubing is a barbed connector; the other end has a locking male luer fitting.

Model 10022 is 8.3 cm (3.25 in) long. On one end is a barbed connector; the other end has a locking female luer fitting.

Sterile, nonpyrogenic, single use.

Indications for Use

These adapters are intended for use in conjunction with cardiopulmonary bypass surgery. The purpose of Models 10007 and 10008 is to connect a 0.95 cm (3/8 in) or 0.64 cm (1/4 in) ID tube to a locking female luer fitting. The purpose of Model 10020 is to connect a 0.95 cm (3/8 in) ID tube to a locking female luer fitting. The purpose of Model 10022 is to connect cardioplegia lines during open heart surgery.

Contraindications

This device is not intended for use except as indicated above.

Precautions

Note: Proper surgical procedures and techniques are the responsibility of the medical professional. The described procedure is furnished for information purposes only. Surgeons must evaluate the appropriateness of the procedure based on their own medical training and experience, the type of surgical procedure, and the type of delivery and suction systems utilized.

When infusing cardioplegia solution use the lowest possible pressure consistent with surgical techniques to minimize the chance of hemolysis or damage to the vessels.

Purge all air from adapter before using.

This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Applicable where phthalates are identified on product label: Due to the presence of phthalates in the product, the clinician must weigh the medical benefits of product use against the drawbacks of phthalate exposure for male children and pregnant or nursing women.

Adverse Effects

This device, as do all extracorporeal blood system devices, has possible side effects which include, but are not limited to, infections, blood loss, thrombus formation, embolic events, and dislocation. Vessel damage and complications at the puncture site may occur if the Instructions for Use are not followed.

Instructions for Use

1. Inspect the package and product for damage and expiration date. If undamaged and unexpired, open the package and transfer the product onto the sterile field utilizing an aseptic technique.
2. Push tubing completely over the barbed connector.
3. Prime all tubing and the adapter with cardioplegia solution.
4. Connect the adapter to the cannula or administration line by using one of the following methods:
   a. **Models 10007 and 10008:** Connect the locking male luer spin nut to a locking female luer fitting and turn the nut until the connection is secure.
   b. **Model 10020:** Connect the locking male luer fitting to a locking female luer fitting.
   c. **Model 10022:** Connect the locking female luer fitting to a locking male luer fitting.
5. Remove all air from the system before using.
6. Upon completion of the procedure, disconnect the adapter and dispose of it according to hospital policy.

The following disclaimer of warranty applies to United States customers only:

Disclaimer of Warranty

ALTHOUGH THE PERFUSION ADAPTER, HEREAFTER REFERRED TO AS "PRODUCT" HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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The following disclaimer of warranty applies to customers outside the United States:

Disclaimer of Warranty

ALTHOUGH THE PERFUSION ADAPTER, HEREAFTER REFERRED TO AS "PRODUCT" HAS BEEN CAREFULLY DESIGNED, MANUFACTURED AND TESTED PRIOR TO SALE, THE PRODUCT MAY FAIL TO PERFORM ITS INTENDED FUNCTION SATISFACTORILY FOR A VARIETY OF REASONS. THE WARNINGS CONTAINED IN THE PRODUCT LABELING PROVIDE MORE DETAILED INFORMATION AND ARE CONSIDERED AN INTEGRAL PART OF THIS DISCLAIMER OF WARRANTY. MEDTRONIC, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT. MEDTRONIC SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, OR FAILURE OF THE PRODUCT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

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