



Medtronic

Aligning Pain - Restoring Health - Extending Life

Europe

Europe/Africa/Middle East Headquarters

Medtronic International Trading Sàrl
Route du Molliau 31
Case Postale
CH - 1131 Tolochenaz
Switzerland
Internet: www.medtronic.co.uk
Tel. 41-21-802-7000
Fax 41-21-802-7900

Medtronic E.C. Authorized Representative/Distributed by

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel. 31-45-566-8000
Fax 31-45-566-8668

Asia-Pacific

Japan

Medtronic Japan
Cornodio Shiodome 5F
2-14-1 Higashi-Shimbashi, Minato-ku
Tokyo 105-0021
Japan
Tel. 81-3-6430-2011
Fax 81-3-6430-7140

Australia

Medtronic Australasia Pty. Ltd.
Business Address:
97 Waterloo Road
North Ryde NSW 2113
Mailing Address:
PO Box 945
North Ryde NSW 1670
Australia
Tel. 61-2-9857-9000
Fax 61-2-9878-5100

Asia

Medtronic International Ltd.
Suite 1602 16/F, Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel. 852-2891-4068
Fax 852-2591-0313

Americas

Latin America

Medtronic Latin America
3750 NW 87th Avenue
Suite 700
Miami, FL 33178
USA
Tel. 305-500-9328
Fax 786-709-4244

Canada

Medtronic of Canada Ltd.
6733 Kitimat Road
Mississauga, Ontario L5N 1W3
Canada
Tel. 905-826-6020
Fax 905-826-6620
Toll-free in Canada:
1-800-268-5346

United States

Manufacturer:
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
Internet: www.medtronic.com
Tel. 763-514-4000
Fax 763-391-9100
Toll-free in the USA:
1-800-328-2518
(24-hour consultation service)



Medtronic

DLP®

Tourniquet Kit
Kit de tourniquet
Tourniquet-Set
Equipo de torniquete
Tourniquetset
Kit emostático
Tornikésæt
Kirstyssidepakkkaus
Tourniquet-sats
Kit αλιοστατικής ταινίας
Tourniquetsæt
Zestaw krepulca
Kit de torniquete
Turnike Kiti
Turniketová sada
Kantilörgzítő készlet
Кровоостанавливающий турникет

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

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

CE

0123

© Medtronic, Inc. 2009
All Rights Reserved
M934625A001 Rev. A

Explanation of symbols on package labeling / Explication des étiquettes sur l'emballage / Erläuterung der Symbole auf der Verpackung / Explicación de los símbolos que aparecen en el etiquetado del envase / Verklaring van de symbolen op de verpakkinglabels / Spiegazione dei simboli sull'etichetta 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 emballagen mærkat / Objaśnienie symboli znajdujących się na etykietach opakowania / Explicação dos símbolos nas etiquetas da embalagem / Ambalaj etiketindeki sembollerin açıklaması / Vysvětlení symbolů uvedených na štítcích obalu / A csomagolásdon látható szimbólumok jelentése / Объявление символов на маркировках упаковок

Refer to the outer package label to see which symbols apply to this product / Se referer à l'étiquette sur l'emballage extérieur pour savoir quels symboles s'appliquent à ce produit / Welche Symbole für dieses Produkt zutreffen, 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 al prodotto / Se på etiketten utenpå pakningen for å fastslå hvilke symboler som gjelder for dette produktet / Katso ulkopakkauksesta, mikä symbolit koskevat tätä tuotetta / Se etiketten på ytterförpackningen för de symboler som gäller denna produkt / Avgränsa utrycket utpå etiketten för att bestämma vilka symboler som gäller för detta produkt / Należy zapoznać się z etykietą na zewnętrznym opakowaniu, aby określić, które symbole dotyczą niniejszego produktu / Consulte as etiquetas exteriores da embalagem para ver que símbolos se aplicam a este produto / Hangi szimbollal bu úrten için gereelli oldugunu görmek için ambalaj etiketlerine başvurun / Podľa štítku na vnější strane balení zjistíte, které symboly se týkají tohoto produktu / A termékre vonatkozó szimbólumok a külső csomagolásdon találhatóak / См. на упаковке, какие символы применимы к данному изделию



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 européenne 93/42/CEE du Conseil de l'Union Européenne. / Conformité Européenne (Europäische Konformität). Dieses Symbol besagt, dass das Gerät allen Vorschriften der Richtlinie 93/42/EWG des Europäischen Rates entspricht. / Conformité Européenne (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. / Conformité Européenne (Conformità Europea). Questo simbolo indica che l'apparecchio è conforme alla Direttiva del Consiglio Europeo 93/42/CEE. / Conformité Européenne (saansvar med europeisk standard). Dette symbolet betyr at utstyret er fullstendig i samsvar med EU-direktiv 93/42/EØF. / Conformité Européenne (eurooppaläinen vaatimustenmukaisuus). Tämä symboli tarkoittaa, että laite on kokonaan Euroopan unionin neuvoston direktiivin 93/42/ETY mukainen. / Conformité Européenne (Europeisk Standard). Denna symbol betyder att utrustningen helt följer Rådets direktiv 93/42/EEG. / Conformité Européenne (Európai Biztonsági Szabványok). Ez a szimbólum azt jelenti, hogy az eszköz teljes mértékben megfelel az Európai Tanács 93/42/EGK számú irányelvének. / Conformité Européenne (Европейское соответствие). Этот символ обозначает, что устройство полностью соответствует требованиям Директивы Европейского Совета 93/42/ЕЕС.

Nonpyrogenic / Apyrogeen / Pyrogenfrei / Apyrogeen / Niet-pyrogeen / Non-pyrogeno / Ikke-pyrogen / Pyrogenation / Ikke-pyrogen / Μη πυρογόνο / Non-pyrogen / Produkt nerpjrogeny / Não pirogênico / Non Pyrogenik / Nerpjrogenl / Nøtt pirogøn / Aπυρογενno

PYROGEN

Nonpyrogenic / Apyrogeen / Pyrogenfrei / Apyrogeen / Niet-pyrogeen / Non-pyrogeno / Ikke-pyrogen / Pyrogenation / Ikke-pyrogen / Μη πυρογόνο / Non-pyrogen / Produkt nerpjrogeny / Não pirogênico / Non Pyrogenik / Nerpjrogenl / Nøtt pirogøn / Aπυρογενno

STERILE EO

Sterilized Using Ethylene Oxide / Stérilisation par oxyde d'éthylène / Mit Ethylenoxid sterilisiert / Esterilizado mediante óxido de etileno / Gesteriliseerd met ethyleenoxide / Sterilizzato con ossido di etilene / Steriliseret ved ethylenoxid / Steriloitu etyleenoksidilla / Steriliserad med etylenoxid / Αποστειρωμένο με ηθρήον ατβήλενοξείδιο / Steriliseret med ethylenoxid / Produkti sterylizowany tiemklem ethylen / Esterilizado com óxido de etileno / Etileen Oksit ile Sterilize Edilmisdir / Sterilizovano etylenoxidem / Etileen-oxididai 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 ikke genbruges / Produkt do jednorazowego zastosowania / Nào reutilizar / Yeniden kullanmayın / Nepoužívat opakovaně / Kizárólag egyszeri használatra / Не использовать повторно

Use By / A utilizar jusqu'au / Zu verwenden bis einschließlich / No utilizar después de / Te gebruiken tot en met / Utilizzare entro / Siste forbrúksdato / Vilmäinen käyttöaika / Får användas till och med / Ημερομηνία λήξης / Kan användes til og med / Data ważności / Não utilizar depois de / Son Kullanma Tarihi / Datum použitelnosti / Lejárati / Истечение срока до

Do Not Resterilize / Ne pas restériliser / Nicht reesterilisieren / No reesterilizar / Niet hersteriliseren / Non ristertilizzare / Skäl ikke steriliseres på nytt / Ei saa uudelleensteriloida / Får inte omsteriliseras / Μην επαναστειρωθείτε / Må ikke re-steriliseres / Nie należy resterylizować / Não reesterilizar / Yeniden Sterilize Etmeyin / Neprovádět resterilizaci / Nem újraszterilizálható / Не стерилизовать повторно

Lot Number / Numéro de lot / Chargennummer / Número de lote / Partijnummer / Numero di lotto / Lotnummer / Etánummer / Lotnummer / Αριθμός παρτίδας / Partinummer / Numero partii / Numero de lote / Lot Numarası / Číslo šarže / Tételszám / Номер партии

Quantity / Quantité / Menge / Cantidad / Aantali / Quantità / Antal / 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 ohjeiset asiakirjat / OBS! Se medföljande dokument / Προσοχή, συγβουλευτείτε τα συνοδευτικά έγγραφα / Forsigtigt! Se medfølgende dokumentation / Pozostoga: Należy zapoznać się z dołączoną dokumentacją / Atenção, consulte os documentos anexos / Díkka! Ürüne Birlikte Verilen Belgelere Bakın / Upozorněni, viz příložená dokumentace / Figyelni! Tanulmányozza a mellékelt dokumentumokat / Внимание! Ознакомьтесь с сопроводительной документацией

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 / Gelder bare i USA / Koskee vain Yhdysvaltoja / Galler endast i USA / Μόνο για τρέχουσες ετρώς Η.Π.Α. / Gælder kun i USA / Dotyczy tylko Klientów w USA / Apenas aplicável aos E.U.A. / Yalnızca ABD'deki Kullanıcılar için / Pouze pro uživatele z USA / Csak egyesült államokbeli felhasználóknak / Только для США

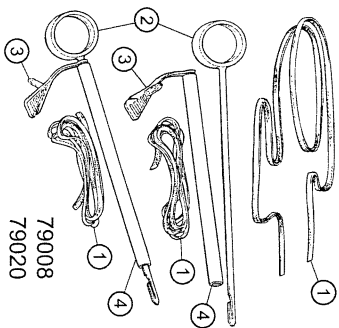
Upper Limit of Temperature / Limite maximale de la température / Obere Temperaturgrenze / Limite superior de la temperatura / Maximale temperatuur / Limite superiore di temperatura / Øvre temperaturgrense / Lämpötilan yläraja / Øvre temperaturgräns / Avvörat öpio bepluokpooitoc / Højeste tilladte temperatur / Górna granica dopuszczalnej temperatury / Limite máximo de temperatura / Ust. Sıcaklık Sınırı / Horní limit teploty / Legmagasabb tárolási hőmérséklet / Температура не выше

REF

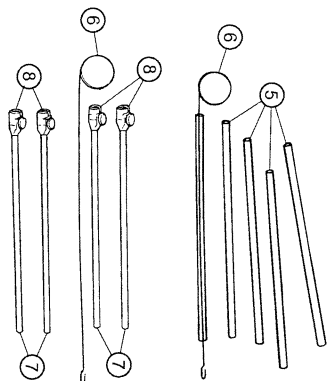
Catalog Number / Numéro de référence / Katalognummer / Número de catálogo / Catalognummer / Numero di catalogo / Katalognummer / Luettelonumero / Katalognummer / Αριθμός καταλόγου / Katalognummer / Numer katalogowy / Número de catálogo / Katalog Numarası / Katalogové číslo / Katalogszám / Номер каталога / Manufacturer / Fabricant / Hersteller / Fabricante / Fabrikant / Produttore / Producent / Valmistaja / Tiljverkare / Κατασκευαστής / Fabrikant / Producent / Fabricante / Imatıcı / Výrobce / Gyártó / Производители

**USA**

79003, 79004, 79005, 79006,
79009, 79015, 79016, 79019,
79022, 79023, 79026, 79027



79008
79020



79010
79011
79012
79013
79014

Figure 1 / Figura 1 / Abbildung 1 / Figura 1 / Figure 1 / Kuva 1 / Figure 1 / Etkova 1 / Figur 1 /
Рисина 1 / Figura 1 / Şekil 1 / Obrázek 1 / 1. ábra / Рисунок 1

1. Umbilical tape / Bande ombilicale / Versorgungsband / Cinta umbilical / Navelstrengband / Nastro ombelcale / Navlestrengstape / Napanoranauha / Karband / Оупдана тавда / Umbilicalband / Tašma ohrivuljczna / Fila umbilical / Umbilical band / Puceňkova páska / Káldkkszalag / Кровооснанаваашуашый жрыт
2. Plastic snare / Anse en plastique / Kunststoffschlinge / Lazo de plástico / Plastic klem / Ansa a caprio in plastica / Plastsnare / Muovisilmukka / Plastsnara / Пластиковá проóос / Plastšylngje / Plastikova pelta / Laço de plástico / Plastik kiskaq / Plastové otko / Mltanyag hurok / Пластикова петля
3. Plug / Obturateur / Verschluss / Tapon / Plug / Tappo / Kobling / Tulipa / Propp / Büoqua / Prop / Wtyczka / Dispositivo de bloqueio / Tapa / Kolček / Dugó / Бтупка
4. Tapered bronze tube / Tube biseauté de couleur bronze / Konisch zulaufender bronzefarbener Schlauch / Tubo cónico color bronce / Taps toelopende bronznen buis / Tubo rastematno di colore bronzno / Konisk bronzefariget slange / Kapa pronssinháinen putki / Avsmalhande bronzfárgad slang / Kuvnikós kqkqktrivos souhlyos / Konisk bronzfarvet slange / Zwežany brázowy dren / Tubo bronzze cónico / Konik bronz túp / Zašpicátáá bronzová trubka / Elvékonyodó bronzszíni csó / Конусовидная трыбка бронзового цвета
5. Color-coded tubes / Tubes de couleur / Farbkodierte Schläuche / Tubos codificados por colores / Buisjes met kleurcode / Tubi codificati a colori / Fargekodede slanger / Varikooditud pükett / Farigkodade slanger / Souhlyes je xpoumatiké kuódkoditrotrn / Farvekodede slanger / Róznokolorowe dreny / Tubos com código de cores / Renk kodlu tüpler / Barvnyé označené trubky / Színkódolt csóvek / Трыбки с цветной маркировкой
6. Wire snare / Anse métallique / Drahtschlinge / Lazo de alambre / Draadklem / Ansa a caprio in filo metallico / Snare av metalltrád / Lankasilmukka / Snara av metalltrád / Συρματινός βρόχος / Trádsylngje / Druciana pelta / Lazo metallico / Tel kiskaq / Drátene otko / Dróthurok / Проволочная петля
7. Bronze tubes / Tubes de couleur bronze / Bronzefarbene Schläuche / Tubos color bronce / Bronzen buisjes / Tubi di colore bronzno / Bronzefariget slange / Pronssinháiset pükett / Bronzefárgade slanger / Καρεκτρινοι σωhlyes / Bronzefarvet slange / Brázowe dreny / Tubos bronzze / Bronz tüpler / Bronzová trubka / Bronzszíni csóvek / Трүбки бронзового цвета
8. Quick tie / Raccord rapide / Schnellfixiervorrichtung / Dispositivo de apriete rápido / Snelhechting / Fasceta per serraggio rapido / Hurlrigeste / Píkalimlike / Snabbhætering / Пíhуоро óéоjuo / Lynbinding / Element dou szylbkého navijánia tášmy ohrivuljcznej lub nici szwu / Encaixe rápido / Hizli bađ / Rychloupevnení / Gyorstógzító / Фиксатор нити

DLP®

Tourniquet Kit

Product Description

The tube-style tourniquets are plastic color-coded tubes packaged with a wire snare. The tourniquet tubes are color coded: red for arterial; blue for venous; and clear, bronze, or white radiopaque for caval use. The Tournikwik™ style tourniquets are bronze tubes with a quick-tie device for securing the suture. They are also packaged with wire snares.

The Sure-Snare™ and plug-style tourniquets consist of a bronze tourniquet tube with an attached plug device for securing the umbilical tape or suture strands. Two plastic snares and two umbilical tapes are provided with the Sure-Snare™ style tourniquet. A wire snare is provided with the plug-style tourniquet.

Sterile, nonpyrogenic, single use.

Indications for Use

These products are intended for securing cardiopulmonary bypass cannulae used during cardiopulmonary bypass surgery.

Contraindications

These devices are not intended for use except as indicated above. The tube, Tournikwik™, and plug styles should not be used for securing caval tapes.

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, and the type of surgical procedure.

These tourniquets and snares are designed and intended for single use only. **DO NOT REUSE.**

Adverse Effects

None known.

Instructions for Use

1. Package 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. Slide the snare through a tourniquet tube. Place the purse string suture ends through the hook of the snare. Pull the snare with the suture strands in the hook of the snare back through the tourniquet tube.
3. Pull the suture taut and clamp the tourniquet with a hemostat (tube style), or wrap the sutures around the knob twice (Tournikwik™ style) and pull through grooves, or secure by pushing the plug into the end of the tube (Sure-Snare™ and plug styles).
4. Tie a holding suture around the tourniquet tube and the cannula to keep the cannula in place.
5. To remove the cannula, cut the holding suture from around the tourniquet tube and cannula, unclamp the tourniquet, and pull the tourniquet tube off the purse string suture strands.
6. Remove the cannula and tie the purse string.

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

Disclaimer of Warranty

ALTHOUGH THE TOURNIQUET KIT, 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.

The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law, by a court of competent jurisdiction, the validity of the remaining

portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

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

Disclaimer of Warranty

ALTHOUGH THE TOURNIQUET KIT, 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.

The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held by any court of competent jurisdiction to be illegal, unenforceable or in conflict with applicable law, the validity of the remaining portion of the Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.