REF	LOT	(Use by date symbol)	(Manufacturer symbol)
Catalogue number	Batch code	Use by date	Manufacturer
Référence du catalogue	Numéro de lot	A utiliser jusqu'au	Fabricant
Bestellnummer	Chargenbezeichnung	Verwendbar bis	Hersteller
Número de catálogo	Número de lote	Caducidad	Fabricante
Referência	Número de lote	Data limite de uso	Fabricante
Codice prodotto	Numero di lotto	Utilizzare entro	Fabbricante
Catalogus nummer	Lotnummer	Gebruiken voor	Fabrikant
Artikelnummer	Batchkod	Används före	Tillverkare
Varenummer	Batchnummer	Udløbsdato	Producent af
Artikkelnummer	Batch nummer	Brukes før-dato	Produsent
Tuotekoodi	Eränumero	Eräpäivä	Valmistaja
Κωδικός Προϊόντος	Αριθμός παρτίδας	Ημερομηνία λήξης	Κατασκευαστής
Каталожный номер	Номер партии	Годен до	Изготовлено
Kod produktu	Numer serii	Użyć przed datą	Wytwórca
Termékkód	Tételszám	Felhasználható	Gyártó
Kód výrobku	Číslo výrobní série	Použít do	Vyrobeno
Kód výrobku	Identifikačné číslo	Použiť do	Výrobca
Ürün kodu	Lot numarası	Son kullanım tarihi	Üretici firma
Kood	Partii nr.	Säilivusaeg	Tootetud
Koda Nr.	Sērijas Nr.	Derīguma termiņš	Ražots
Katalogo Nr.	Partijos kodas	Sunaudoti iki	Gamintojas
Koda izdelka	Številka serije	Uporabno do	Izdelovalec
Šifra proizvoda	Serijska oznaka	Upotrebljivo do	Proizvođač
Codul produsului	Număr lotului	Data de expirare.	Fabricat de
Каталожен номер	Партиден номер	Срок на годност	Произведено от
Номер за каталогом	Код партії	Використати до	Виробник

Do not use if package is damaged

Do not use if package is damaged
Ne pas utiliser si l'emballage est endommagé
Inhalt beschädigter Packung nicht verwenden
No usar si el paquete está dañado
Não usar se a embalagem estiver danificada
Non utilizzare se la confezione risulta danneggiata
Niet gebruiken wanneer de verpakking beschadigd is
Använd inte om förpackningen är skadad
Må ikke anvendes, hvis pakningen er beskadiget
Må ikke brukes hvis forpakningen er ødelagt
Älä käytä jos pakkaus on vahingoittunut
Μην το χρησιμοποιήσετε εάν η συσκευασία είναι κατεστραμμένη
Не использовать, если упаковка повреждена
Nie stosować w przypadku uszkodzenia opakowania
Ne használja, ha a csomagolás sérült
Nepoužívejte, bylo-li balení poškozeno
Nepoužívajte, ak je obal poškodený
Paket hasarlıysa kullanmayınız
Ärge kasutage, kui pakend on kahjustatud
Nelietot, ja sterilais iepakojums ir bojāts
Jei pakuotė pažeista, nenaudoti
Ne uporabljajte ga, če je ovojnina poškodovana
Ne upotrebljavati ukoliko je pakovanje oštećeno
A nu se utiliza în cazul în care ambalajul este deteriorat
Не използвайте, ако опаковка е повредена
Не використовувати якщо пакування пошкоджено

Contents

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Tartalom
Obsah
Obsah
İçindekiler
Sisu
Saturs
Sudėtis
Vsebina
Sadržaj
Conţinut
Съдържание
Зміст

Do not reuse

Do not reuse
Ne pas réutiliser
Nicht zur Wiederverwendung
No reutilizar
Não reutilizar
Monouso
Niet opnieuw gebruiken
Ingen återanvändning
Må ikke genbruges
Må ikke gjenbrukes
Kertakäyttöinen
Μόνο για μια χρήση
Не использовать повторно
Nie używać powtórnie
Csak egyszeri használatra
Nelze použít opakovaně
Na jednorázové použitie
Tek kullanımlık
Ainult ühekordseks kasutuseks
Tikai vienreizējai lietošanai
Pakartotinai nenaudoti
Samo za enkratno uporabo
Samo za jednokratnu upotrebu
Doar pentru unică folosinţă
Само за еднократна употреба
Використовувати повторно заборонено

STERILE EO

Sterilized using ethylene oxide
Stérilisé à l'oxyde d'éthylène
Sterilisation mit Ethylenoxid
Esterilizado con óxido de etileno
Esterilizado com óxido de etileno
Sterilizzato con ossido di etilene
Gesteriliseerd met ethyleenoxide
Steriliserad med etylenoxid
Ætylenoxid steriliseret
Sterilisert med etylen oksid
Steriloitu etyleenioksidilla
Αποστειρωμένο με αιθυλενοξείδιο
Стерилизовано окисью этилена
Sterylizowane tlenkiem etylenu
Etilénoxiddal sterilizálva
Sterilizováno ethylenoxidem
Sterilizované etylénoxidom
Etilen Oksitle sterilize edilmiştir
Steriliseeritud etüleenoksiidiga
Sterilizēts ar etilēna oksīdu
Sterilizuota naudojant etileno oksidą
Sterilizirano z etilen oksidom
Sterilisano etilen oksidom
Sterilizat cu oxid de etilenă
Стерилизирано с етилен оксид
Простерилізовано за допомогою оксиду етилену

®: Registered Trademark
®: Marque Enregistrée
®: Eingetragenes Warenzeichen
®: Marca Registrada
®: Marca registada
®: Marchio Registrato
®: Geregistreerd Handelsmerk
®: Registrerat Varumärke
®: Registreret varemærke
®: Registrert varemerke
®: Rekisteröity tavaramerkki
®: Κατοχυρωμένο Εμπορικό Σήμα
®: зарегистрированный товарный знак
®: Zastrzeżony znak towarowy
®: Bejegyzett védjegy
®: Registrovaná obchodní značka.
®: Registrovaná obchodná známka
®: Tescilli Marka
®: Registreeritud kaubamärk
®: Reģistrēta tirgzīme
®: Registruotas prekės ženklas
®: Registrirana zaščitena znamka
®: Registrovana robna marka
®: Marcă înregistrată
®: Регистрирана търговска марка
®: Зареєстрована Торгівельна Марка

TERUMO CORPORATION
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151-0072, JAPAN MADE IN VIETNAM

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TERUMO® CE 0197

2012 - 07

RADIFOCUS®

RADIFOCUS® GUIDE WIRE M

Guide Wire	Prowadnik
Guide	Vezetődrót
Führungsdraht	Vodicí drát
Guía	Vodiaci drôt
Fio-guia	Kılavuz Tel
Guida	Juhtetraat
Voerdraad	Vadītājstīga
Guidewire	Kreipiamoji viela
Guidewire	Vodilna žica
Guidewire	Žica vodič
Ohjainvaijeri	Ghid
Συρμάτινος Οδηγός	Водач
Проводник	Провідник

CE 0197

RG34M1501AV

Consult instructions for use

Consult instructions for use
Lire le mode d'emploi
Gebrauchsanweisung beachten
Consulte las instrucciones de uso
Consultar instruções de uso
Consultare le istruzioni per l'uso
De gebruiksaanwijzing raadplegen
Läs bruksanvisningen
Læs brugsanvisningen
Les bruksanvisning før bruk
Lue käyttöohjeet
Διαβάστε τις οδηγίες χρήσης
Прочитайте инструкцию по применению
Sprawdzić w instrukcji stosowania
Olvassa el a használati útmutatót
Postupujte podle pokynů
Prečítajte si návod na použitie
Kullanma talimatına başvurunuz.
Tutvu kasutusjuhendiga
Pirms lietošanas izlasiet instrukciju
Skaitykite naudojimo instrukciją
Glej navodila za uporabo
Pogledaj instrukcije za upotrebu
A se consulta instrucţiunile de folosinţă
Прочетете указанията за употреба
Ознайомитися з інструкціями для застосування

L:

Usable length
Longueur
Länge
Longitud
Comprimento utilizável
Lunghezza
Lengte
Längd
Brugbar længde
Brukbar lengde
Pituus
Χρησιμοποιήσιμο μήκος
Используемая длина
Długość użytkowa
Hasznos hossz
Použitelná délka
Použiteľná dĺžka
Kullanılabilir uzunluk
Kasutatav pikkus
Lietojamā garums
Naudojamas ilgis
Uporabna dolžina
Upotrebljiva dužina
Lungime utilizabilă
Използваема дължина
Робоча довжина

Guide wire diameter

Guide wire diameter
Diamètre du guide
Führungsdrahtdurchmesser
Diámetro guía
Diâmetro do fio-guia
Diametro della guida
Voerdraaddiameter
Guide wire diameter
Guidewire diameter
Guidewire diameter
Ohjaimen läpimitta
Διάμετρος συρμάτινου οδηγού
Диаметр проводника
Średnica prowadnika
Vezetődrót átmérő
Průměr drátu
Priemer vodiaceho drôtu
Kılavuz tel çapı
Juhtetraadi diameeter
Vadītājstīgas diametrs
Kreipiamosios vielos diametras
Premer vodilne žice
Prečnik žice vodiča
Diametrul ghidului
Диаметър на водача
Діаметр провідника

FLEX L:

Flexible length
Longueur flexible
flexible Länge
Longitud flexible
Comprimento flexível
Lunghezza flessibile
Flexibele lengte
Böjlig längd
Bøjelig længde
Fleksibel lengde
Taipuisan pituus
Εύκαμπτο μήκος
Длина гибкой части
Elastyczna długość
Hajlékony hossz
Délka flexibilní části
Dĺžka flexibilnej časti
Esnek kısım uzunluğu
Painduva osa pikkus
Lokanas daļas garums
Lankstus ilgis
Upogljiva dolžina
Dužina fleksibilnog dela
Lungimea porţiunii flexibile
Дължина на гъвкавата част
Довжина гнучкої частини

Do not resterilize

Do not resterilize
Ne pas restériliser
Nicht wieder sterilisieren
No reesterilizar
Não re-esterilizar
Non risterilizzare
Niet hersteriliseren
Omsterilisera inte
Må ikke steriliseres flere gange
Må ikke re-steriliseres
Älä steriloi uudelleen
Να μην επαναποστειρωθεί
Не стерилизовать повторно
Nie sterylizować ponownie
Nem sterilizálható újra
Nesterilizujte opakovaně
Nesterilizujte
Yeniden sterilize etme
Mitte steriliseerida
Nesterilizēt atkārtoti
Pakartotinai nesterilizuoti
Ne resterilizirati
Nemojte ponovo sterilisati
A nu se resteriliza
Не стерилизирайте втори път
Повторно не стерилізувати

Do not use with metal entry needle.

Do not use with metal entry needle.
Ne pas utiliser avec une aiguille de ponction métallique.
Eine Punktionsnadel aus Metall darf nicht benutzt werden.
No utilizar con una aguja de inserción metálica.
Não usar com uma agulha de entrada em metal.
Non usare una guida di plastica con un ago introduttore metallico.
Niet gebruiken met een metalen introductienaald.
Använd inte med punktionsnål av metall.
Må ikke bruges med metal punktur nål.
Skal ikke benyttes med en punksjonsnål av metall.
Älä käytä metallisia punktioneuloja.
Μην χρησιμοποιείτε με μεταλλική βελόνα εισαγωγής.
Запрещается использовать с металлической пункционной иглой.
Nie używać z metalową igłą wprowadzającą.
Ne használja fém bevezető tűvel!
Nepoužívejte kovovou kanylu.
Kovovú kanylu nepoužívajte.
Uç kısmı metal kanül kullanmayınız.
Kasutada koos metallist punktsiooninõelaga
Nelietot ar metāla ievadīšanas adatu
Nenaudokite su metaline adata
Ne uporabljati s kovinsko vstopno iglo
Ne koristiti zajedno sa metalnom iglom
A nu se utiliza cu un ac de puncţie metalic.
Да не се използва с метална пункционна игла
Не використовувати з металічною голкою

ENGLISH

GUIDE WIRE M

GUIDE WIRE

INSTRUCTION FOR USE

Read the following warnings, precautions and directions for use carefully.

INDICATION FOR USE

The Radifocus GUIDE WIRE M is designed to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures.

CONTRAINDICATIONS

No contraindications are known when using guide wires in vascular procedures. Carefully read the list of Contraindications in the instructions for use accompanying the other interventional devices to be used with the guide wire.

COMPLICATIONS

Complications that may be related to the use of guide wire can include but may not be limited to the following:

•Tissue trauma •Infection •Vessel perforation •Hematoma •Embolism
•Allergic reaction •Thrombus formation •Hemorrhage

Carefully read the list of Complications in the instructions for use accompanying the other interventional devices to be used with the guide wire.

WARNINGS

Failure to abide by the following warnings might result in damage to the vessel, shearing of the GUIDE WIRE M, and release of plastic fragments from the GUIDE WIRE M. Such pieces or fragments from the wire may have to be removed from the vessel.

- Do not manipulate or withdraw the GUIDE WIRE M through a metal entry needle or a metal dilator. Manipulation and/or withdrawal through a metal entry needle or a metal dilator may result in destruction and/or separation of the outer polyurethane coating requiring retrieval. A plastic entry needle is recommended when using this wire for initial placement.
- Do not use the GUIDE WIRE M with devices which contain metal parts such as atherectomy catheters, laser catheter, or metal introduction devices as they may cause the GUIDE WIRE M plastic coating to shear and/or sever the wire.
- Do not reshape the GUIDE WIRE M by any means. Attempting to reshape the wire may cause damage, resulting in the release of wire fragments into the vessel.
- When exchanging or withdrawing a catheter over the GUIDE WIRE M, secure and maintain the guide wire in place under fluoroscopy to avoid unexpected guide wire advancement, otherwise damage to the vessel wall by the wire's tip may occur.
- A retrieving device, such as a gripper or basket forceps, can only be used after the GUIDE WIRE M has been removed from the patient's vessel. Using a retrieving device while the GUIDE WIRE M is in the vessel may cause the GUIDE WIRE M to break.
- Manipulate the GUIDE WIRE M slowly and carefully in the vessel while confirming the behavior and location of the wire's tip under fluoroscopy. Improper manipulation of the GUIDE WIRE M without fluoroscopic confirmation may result in vessel perforation.
- Do not apply repetitive bending force to one specific point of the device as this may cause damage to the GUIDE WIRE M.
- If any resistance is felt or if the tip's behavior and/or location seems improper, stop manipulating the GUIDE WIRE M and/or the catheter and determine the cause by fluoroscopy. Continuing to manipulate or rotate the GUIDE WIRE M or failure to exercise proper caution may result in bending, kinking, separation of the guide wire's tip, damage to the catheter, or damage to the vessel.
- Do not attempt to use the GUIDE WIRE M if it has been bent, kinked or damaged. Use of a damaged wire may result in damage to the vessel or the release of wire fragments into the vessel.
- Consider the use of systemic heparinization to prevent or reduce the possibility of thrombus formation on the surface of the GUIDE WIRE M.

PRECAUTIONS

- The GUIDE WIRE M should be used by a physician, who is well trained in manipulation and observation of guide wires under fluoroscopy.
- Sterile in an unopened and undamaged unit package. Do not use if the unit package or the guide wire is broken or soiled. The GUIDE WIRE M should be used immediately after opening the package and be disposed of safely and properly after use, following local regulations for medical waste management.
- When using a drug or a device concurrently with the GUIDE WIRE M, the operator should have a full understanding of the properties/characteristics of the drug or device so as to avoid damage to the GUIDE WIRE M. For example when using the GUIDE WIRE M with any device that emits energy (laser, pressure, ultrasound, etc.) confirm that the GUIDE WIRE M is retracted into a position where it will not be impacted by the energy.
- Consider the use of systemic heparinization.
- The surface of the GUIDE WIRE M is not lubricous unless it is wet. Before taking it out of its holder and inserting it through a catheter, fill the holder and the catheter with heparinized physiological saline solution.
- When reinserting the GUIDE WIRE M back into the holder, take care not to damage the wire's hydrophilic polymer coating with the edge of the holder.
- Do not use a metal torque device with the GUIDE WIRE M. Use of a metal torque device may result in damage to the GUIDE WIRE M.
- Do not slip a tightened up torque device or Y-connector over the wire, as this may result in damage to the wire.
- Due to the slippery nature of the hydrophilic coating on the GUIDE WIRE M, the operator may encounter some difficulties in handling the wire. A RADIFOCUS TORQUE DEVICE, sold separately, is recommended for easier handling/manipulation of the wire.
- Due to variations of certain catheter tip inner diameters, abrasion of the hydrophilic coating may occur during manipulation. If any resistance is felt during introduction of the catheter, it is advisable to stop using such catheters.
- Do not manipulate the GUIDE WIRE M through a tightened up rotating hemostasis valve, as this may result in damage to the wire.
- After removal from the patient's vessel, and prior to reinserting it into the same patient during the same catheterization, the GUIDE WIRE M should be rinsed in a bowl full of heparinized physiological saline solution. Any blood residues still adhering to the wire can be removed by wiping once with a gauze moistened with heparinized physiological saline solution. Use of alcohol, antiseptic solutions or other solvents must be avoided, because they may adversely affect the surface of the GUIDE WIRE M.
- The GUIDE WIRE M contains a metallic core, do not use with any inappropriate equipment (e.g. MRI).
- The entire operation should be carried out aseptically.
- This product has been sterilized by ethylene oxide gas. For single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
- Avoid exposure to water, direct sunlight, extreme temperatures and high humidity during storage. Store under controlled room temperature.

DIRECTIONS FOR USE

1. Remove the GUIDE WIRE M and the holder together from the package.
2. Fill the holder with heparinized physiological saline solution through the hub of the holder using a syringe.
3. Remove the GUIDE WIRE M from the holder and inspect the GUIDE WIRE M prior to use, to verify that it is lubricated. If the GUIDE WIRE M can not be easily removed from the holder, inject more heparinized physiological saline solution into the holder and try again.
4. Prior to use, prime the catheter with heparinized physiological saline solution to ensure smooth movement of the GUIDE WIRE M within it.
5. The GUIDE WIRE M may slide entirely into the catheter or slip out of the catheter because of its low sliding friction.
6. Keep at least 5 cm. of the wire extended out of the hub of the catheter during introduction.