

CE 0123

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JUL 2018

Crusade

Dual lumen catheter

Cathéter à double lumière

Dual-Lumen-Katheter

Catéter de doble lumen

Cateter de Lúmen Duplo

Catetere a doppio lume

Dubbellumenkatheter

Kateter med dubbel lumen

Dobbeltlumenkateter

Dobbellumen-kateter

Kaksoisluumenkatetri

Καθετήρας διπλού αυλού

Двухпросветный катетер

Cewnik dwuświatłowy

Két lumenes katéter

Katétr se dvěma lumeny

Katéter s dvojíým lúmenom

Çift Lümenli Kateter

Kahe valendikuga kateeter

Dubulta lūmena katetrs

Dvigubo spindžio kateteris

Dvolumenski kateter

Dvolumenski kateter




Cateter cu lumen dublu


Катетър с двоен лумен


Двопросвітний катетер

Dvolumenski kateter

 **KANEKA
MEDICAL
PRODUCTS**

REF	SN	LOT	
Catalogue number Référence du catalogue Bestellnummer Número de catálogo Referência Codice prodotto Catalogusnummer Artikelnnummer Varenummer Artikkelnummer Tuotekoodi Κωδικός Προϊόντος Каталожный номер Kod produktu Termékkód Kód výrobku Kód výrobku Ürün kodu Kood Koda Nr. Katalogo Nr. Koda izdelka Šifra proizvoda Codul produsului Каталожен номер Номер за каталогом Kataloški broj	Serial number Numéro de série Seriennummer Número de serie Número de série Numero di serie Seriennummer Seriennummer Seriennummer Seriennummer Sarjanumero Αριθμός παραγωγής Серийный номер Numer serii Sorozatszám Výrobní číslo Sériové číslo výrobku Seri Numarası Seerianumber Sērijas Nr. Serijos Nr. Serijska številka Serijski broj Număr de serie. Сериен номер Серійний номер Serijski broj	Lot number Numéro de lot Chargenbezeichnung Número de lote Número de lote Numero di lotto Lotnummer Batchkod Batchnummer Batch nummer Eränumero Αριθμός παρτίδας Номер партии Numer serii Tételszám Číslo výrobní serie Identifikačné číslo Lot numarası Partii nr. Sērijas Nr. Partijos kodas Številka serije Serijska oznaka Număr lotului Партиден номер Код партії Šifra serije	Use by A utiliser jusque Verwendbar bis Caducidad Data limite de uso Utilizzare entro Gebruiken voor Användes före Udløbsdato Brukes før-dato Eräpäivä Ημερομηνία λήξης Годен до Użyć przed datą Felhasználható Použit do Použit do Son kullanım tarihi Säilivusaeg Derīguma termiņš Sunaudoti iki Uporabno do Upotrebljivo do Data de expirare Срок на годност Використати до Upotrijebiti do
STERILEEO			
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<p>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 инструкции по применению Sprawdź w instrukcji stosowania Olvassa el a használati útmutatót! Postupujte podle pokynů Prečítajte si návod na použitie Kullanna talimatina başvurunuz Tutvu kasutusjuhendiga. Pirms lietošanas izlasiet instrukciju Skaitykite naudojimo instrukciją Glej navodila za uporabo Pogledaj instrukcije za upotrebu A se consulta instrucțiunile de folosință Прочетете указанията за употреба Ознайомтеся з інструкціями для застосування Pogledati upute za upotrebu</p>	<p>Contents Contenu Stück Unidades Conteúdo Unità Stuks Styck Indhold Innhold Sisältö Περιεχόμενα Содержание Zawartość Tartalom Obsah Obsah İçindekiler Sisu Saturs Sudēti Vsebina Sadržaj Conținut Зміст Вміст Sadržaj</p>
	<div>EC REP</div>
<p>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 käyttää 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 sterlais 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 Ne upotrebljavati ako je pakiranje oštećeno</p>	<p>Authorized Representative in the European Community Rep. CE (Mandataire européen) Bevollmächtigter in der Europäischen Gemeinschaft Representante autorizado de la Comunidad europea Representante autorizado na CE Rappresentante autorizzato nella comunità europea Gemachtigde vertegenwoordiger in de EU (Europese Unie) Auktoriserad återförsäljare inom EU-området Autoriseret forhandler indenfor EU området Autoriseret representant i Det europeiske Fællesmarked EY edustaja Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα Авторизованный представитель Европейского сообщества Autoryzowany przedstawiciel w Unii Europejskiej Az Európai Közösségből a képviselőre jogosult Zástupce Evropského společenství Predstaviteľ Európskej únie Yetkili AB temsilcisi Esindaja EL-s ES pārstāvis Įgaliotas atstovas Europos bendrijose Zastopnik v Evropski Skupnosti Predstavník v Evropskej Uniji Reprezentant UE Упълномощен представител в ЕС Уповноважений представник в Европейському Союзи Ovlašteni predstavnik u europskoj zajednici</p>

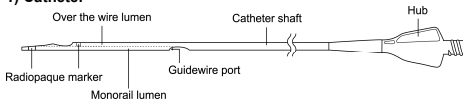
		
<p>Do not resterilize Ne pas restériliser Nicht wieder sterilisieren No reesterilizar Não re-esterilizar Non risterilizzare Niet hersteriliseren Får ej omsteriliseras Må ikke resteriliseres Må ikke re-steriliseres Ei uudelleen steriloimista Να μην επαναποστειρωθεί Не стерилизовать повторно Nie sterylizować ponownie Nem sterilizálható újra! Nesterilizujte opakovane Neresterilizujte Yeniden sterilize etmeyin Ärge steriliseerige uuesti Nesterilizēt atkārtoti Pakartotina nesterilizuoti Ne reesterilizirati Ne resterilisati Nu resterilizați Да не се стерилизира повторно Повторно не стерилизувати Ne ponovo sterilizirati</p>	<p>Manufacturing Site Site de fabrication Herstellungsort Lugar de fabricación Site do fabricante Sito di produzione Productielocatie Tiliverkningsplats Produktionssted Produksjonssted Valmistuspaikka Τόπος Κατασκευής Произведено Miejsce produkcji Gyártóhely Místo výroby Miesto výroby Üretim Yeri Tootmiskoht Ražotne Gamybos vieta Proizvodno mesto Mesto proizvodnje Locul de Productie Място на производство Виробнича дільниця Mjesto proizvodnje</p>	<p>Keep dry Conserver au sec Vor Nässe schützen Mantener seco Manter seco Conservare in luogo asciutto Droog bewaren Håll torrt Holdes tør Holdes tørt Pidä kuivassa Διατηρήστε το στεγνό Бережь от влаги Przechowywać w miejscu suchym Nedvességtől védett helyen tartandó Udržujte v suchu Udržujte ja suchom mieste Kuru tutunuz Holda kuivas Sargāt no mitruma Laikyti sausoje vietoje Izogibajte se dežju Čuvati na suvom mestu A se păstra în locuri ferite de umezeală Съхранявайте на сухо Зберігати в сухому місці Držati suho</p>
		
<p>Keep away from sunlight Craint la chaleur Vor Sonnenlicht schützen Mantener alejado de la luz solar Manter ao resguardo da luz solar Tenere lontano da fonti di calore Niet blootstellen aan zonlicht Aktas för solljus Må ikke udsættes for sollys Unngå sollys Suojattava auringonvalolta Φυλάξτε το μακριά από το ηλιακό φως Избегать прямого солнечного света Chronić przed bezpośrednim działaniem promieni słonecznych Napfénytől védett helyen tartandó Chraňte před slunečním zářením Udržujte mimo slnečného žiarenia Güneş ışığından uzak tutunuz Kaitsta otsese päikesevalgus eest Sargāt no saules stariem Saugoti nuo saulės šviesos Izogibajte se sončni svetlobi Ne izlagati sunčevoy svetlosti A se păstra la umbră Пазете от слънчева светлина Зберігати подалі від сонячного проміння Držati dalje od sunčevog svjetla</p>		<p>Temperature limit Limite de température Temperaturbegrenzung Limite de temperatura Limite de temperatura Limiti di temperatura Temperatuurlimiet Temperaturgräns Temperaturgrænse Temperaturbegrensning Lämpötilarajoitus Όριο θερμοκρασίας Допустимая температура Ograniczenie temperatury Hőmérsékleti korlát Teplotní omezení Teplotné obmedzenie Sıcaklık sınırı Temperatuuriipiirang Temperatūras ierobežojums Temperatūros ribinės vertės Temperatūra omejitėv Ograničenje za temperaturu Limită de temperatură Температурно ограничение Обмеження температури Ograničenje temperature</p>

[Contraindications]

1. For single use only. Do not reuse, reprocess or resterilize.
2. These components are contraindicated in the following patients:
 - 1) Patients with unprotected lesions in the left main coronary trunk without bypass or collateral circulation.
 - 2) Patients with histories of coronary artery spasm
 - 3) Patients non eligible for coronary artery bypass graft surgery

[Shape and structure]

1) Catheter



2) Flushing Needle



[Indication for use]

1. Intended use

Crusade is intended to be used for;

- guide wire support for crossing side branch
- exchange of guide wires, during percutaneous coronary intervention (PCI).

2. Indications

Coronary artery disease (CAD) patients who undergo PCI.

3. Specifications

- Recommended guidewire outer diameter
- Maximum diameter: 0.014 inch (0.36mm)
- Minimum guiding catheter I.D.: 0.056 inch (1.44mm)

[Operation method and instructions for use]

1. After aseptically removing this catheter from the package container, detach the protective materials such as sheath.
2. Inject heparinized saline into the monorail and over-the-wire lumens via the guidewire port and hub and allow the saline to fill both lumens.
3. Insert the handheld end of the guidewire advanced to the distal end of the lesion into the monorail lumen through the tip of this catheter.
4. Advance this catheter along the guidewire until its tip reaches the target site.
5. Insert another guidewire into the over-the-wire lumen through the hub. Advance the guidewire until it reaches the distal end of the stenotic lesion in the side branch.
6. After verifying that the guidewire has reached and passed the distal end of the target site, remove this catheter taking care not to pull out the guidewire.

[Precautions related to procedures]

1. The catheter shaft is highly elastic and easily bounces. When storing this catheter in a tray filled with heparinized saline, be careful not to allow the catheter to jump out of the tray.
2. Precautions should be taken to prevent any damage to the soft tip of this catheter.
3. Handle this catheter carefully to prevent the catheter shaft from kinking when removing it from the package container, filling its two guidewire lumens with heparinized saline, or inserting it into the Y connector (not included in this kit).
4. When filling the two guidewire lumens with heparinized saline, take care not to puncture the wire lumen with the flushing needle.
5. As for the medical devices used in conjunction with this catheter, follow the package inserts of such devices.

[Precautions during usage]

[Important basic precautions]

1. This catheter should be used only by physicians skilled in percutaneous vascular therapy.

2. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Duration of use or contact with the body : Transient

3. Do not use if packaging is damaged.
4. Do not use agents containing organic solvents or oleaginous contrast media. Contact with these agents may lead to damage to Crusade.
5. Since serious complications might arise when using this catheter, operation should be done in the medical institution where emergency procedure can be executed.
6. Heparinized saline should be infused for anti-coagulation while this catheter is inserted in the blood vessel.
7. Operate the catheter carefully in the blood vessel verifying the location and movement of its tip under fluoroscopy.
8. Do not use this catheter if its shaft is bent or broken.
9. Precautions should be taken to prevent any damage to the catheter by the surgical knife or scissors.
10. Do not connect too tightly while connecting the other device to the Hub of this catheter.
11. When exchanging the guidewire while this catheter is inserted in the blood vessel, insert the guidewire carefully. (Inserting a highly penetrating guidewire while this catheter is left in a tortuous region may break the catheter shaft resulting in blood vessel injury.)
12. Do not advance this catheter with the guidewire placed in the trunk and side branch. (Doing so may injure the bifurcation.)
13. If any abnormality such as strong resistance is experienced during the operation of this catheter, the operation should be discontinued immediately. Then, the cause for such abnormality should be verified and appropriate measures should be taken. (Continuing the operation may apply excessive force resulting in damage to this catheter or vascular wall injury.)
14. After use, dispose of product and packaging in accordance with hospital, administrative and/or relevant national regulations.

[Adverse events]

Adverse events related to Crusade include, but are not limited to, infarction caused by occlusion of distal vessels or side branch, vasospasm, stripping of vascular endothelium, dissection of vascular intima, re-occlusion, vascular perforation, blood pressure fluctuation, stroke, shock, reaction to drugs, reaction to contrast media, renal insufficiency, transient ischemia, air embolism, thromboembolism, internal bleeding, hematoma, infection, etc. These adverse events may cause emergent coronary bypass surgery, myocardial infarction, re-stenosis, cardiac tamponade, hemorrhage, emergent brain surgery cerebral infarction, formation of vessel fistula, aneurysm, arrhythmia, and even death.

[Additional precautions]

1. Do not use if the product or package is suspected to be damaged.
2. Use immediately after the sterile package is opened. Dispose as medical waste after use.

[Storage, care and expiration date]

1. Store in a cool, dark, and dry place avoiding exposure to water and direct sunlight, extreme temperature, or high humidity.
2. The expiration date is indicated on the box. Do not use after the expiration date.

[Package]

- 1 set / box
- <Content>
 - Catheter (Crusade) x 1 piece
 - Flushing needle x 1 piece

[Name and address of manufacturer or representative]



Manufacturer :

KANEKA CORPORATION

Address: 3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city,
OSAKA, 530-8288 JAPAN

Tel. No.: (+81)-(0) 6-6226-5256

Fax No.: (+81)-(0) 6-6226-5143

EC	REP
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EC Representative :

KANEKA PHARMA EUROPE N.V.

Address: Nijverheidsstraat 16, 2260 Westerlo-Oevel, BELGIUM

Tel. No.: (+32)-(0) 14-256-297

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