

KANEKA PTCA Balloon Dilatation Catheter

Device Documentation

Chapter 4 Annex 3

Instructions for Use of IKAZUCHI Zero

(No.: 3216-2)

IKAZUCHI Zero

(KANEKA PTCA Catheter CO-R7)

Instructions for use

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EN Do not re-use
FR Ne pas réutiliser
DE Nicht wiederverwenden
ES No reutilizar
PT Não reutilizar
IT Non riutilizzare
NL Niet opnieuw gebruiken
SE Får ej återanvändas
DK Må ikke genbruges
NO Ikke til gjenbruk
GR Να μην επαναχρησιμοποιείται
RU Не использовать повторно
PL Nie używać ponownie
HU Ne használja újra
CZ Nepoužívejte opakovaně

SK Nepoužívajzte opakovane
TR İkinci kez kullanmayın
LV Neizmantoj atkārtoti
LT Nenaudoti pakartotinai
SI Ne uporabite ponovno
RS Nemojte koristiti više puta
RO A nu se reutiliza
BG Не използвайте повторно.
HR Nemojte ga ponovno koristiti
BA Ne koristiti ponovo
BY Не выкарыстоўваць паўторна
ET Mitte korduskasutada.
FI Ei saa käyttää uudelleen
UK Не використовувати повторно
KR 재사용 금지



EN Do not resterilize
FR Ne pas re-stériliser
DE Nicht resterilisieren
ES No reesterilizar
PT Não re-esterilizar
IT Non risterilizzare
NL Niet opnieuw steriliseren
SE Får ej resteriliseras
DK Må ikke gensteriliseres
NO Må ikke resteriliseres
GR Μην επαναποστειρώνεται
RU Не стерилизовать повторно
PL Nie sterylizować ponownie
HU Ne sterilizálja újra
CZ Neresterilizujte

SK Nesterilizujte opakovane
TR Tekrar sterilize etmeyin
LV Nesterilizēt atkārtoti
LT Nesterilizuoti pakartotinai
SI Ne sterilizirajte ponovno
RS Nemojte ponovo sterilisati
RO A nu se resteriliza
BG Не стерилизирайте повторно.
HR Nemojte ga ponovno sterilizirati
BA Ne sterilizirati
BY Не стэрылізаваць паўторна
ET Mitte kordussteriliseerida
FI Ei saa steriloida uudelleen
UK Не стерилізувати повторно
KR 재살균 금지

STERILE EO

EN Sterilized using ethylene oxide
FR Stérilisé à l'oxyde d'éthylène
DE Mit Ethylenoxid sterilisiert
ES Esterilizado con óxido de etileno
PT Esterilizado com óxido de etileno
IT Sterilizzato mediante ossido di etilene
NL Gesteriliseerd met ethyleenoxid
SE Steriliserad med etylenoxid
DK Steriliseret med ethylenoxid
NO Sterilisert med etylenoksid
GR Αποστειρωμένο με αιθυλενοξείδιο
RU Стерилизовано этиленоксидом
PL Produkt sterylizowany tlenkiem etylenu
HU Etilén-oxiddal sterilizálva
CZ Sterilizováno etylénoxidem

SK Sterilizované etylénoxidom
TR Etilen oksitle sterilize edilmiştir
LV Sterilizēts, izmantojot etilēna oksīdu
LT Sterilizuota etileno oksidu
SI Sterilizirano z etilenoksidom
RS Sterilisano pomoću etilen oksida
RO Sterilizat cu oxid-etilen
BG Стерилизиран с етиленов оксид.
HR Steriliziran etilen-oksidom
BA Sterilizirano etilen oksidom
BY Стэрылізавана з дапамогай этыленаксіду
ET Steriliseeritud etüleenoksiidiga.
FI Steriloitu etyleenioksidilla
UK Стерилизовано етиленоксидом
KR 에틸렌 옥사이드를 사용하여 살균됨



EN Balloon Diameter
FR Diamètre du ballonnet
DE Ballondurchmesser
ES Diámetro del balón
PT Diâmetro do balão
IT Diametro del palloncino
NL Ballondiameter
SE Ballongdiameter
DK Diameter på ballon
NO Ballongdiameter
GR Διάμετρος μπαλονιού
RU Диаметр баллона
PL Średnica balonu
HU A ballon átmérője
CZ průměr balónku

SK Priemer balónika
TR Balon Çapı
LV Balona diametrs
LT Balionėlio skersmuo
SI Premer balona
RS Prečnik balona
RO Diametrul balonului
BG Диаметър на балона
HR Promjer balona
BA Prečnik balona
BY Дыяметр балона
ET Ballooni diameeter
FI Pallon halkaisija
UK Диаметр балона
KR 풍선 직경



EN Balloon Length
FR Longueur du ballonnet
DE Ballonlänge
ES Longitud del balón
PT Comprimento do balão
IT Lunghezza del palloncino
NL Ballonlengte
SE Ballonglängd
DK Længde på ballon
NO Ballonglengde
GR Μήκος μπαλονιού
RU Длина баллона
PL Długość balonu
HU A ballon hossza
CZ délka balónku

SK Dĺžka
TR Balon Uzunluğu
LV Balona garums
LT Balionėlio ilgis
SI Dolžina balona
RS Dužina balona
RO Lungimea balonului
BG Дължина на балона
HR Duljina balona
BA Dužina balona
BY Даўжыня балона
ET Ballooni pikkus
FI Pallon pituus
UK Довжина балона
KR 풍선 길이



EN Catheter Effective Length
FR Longueur utile du ballonnet
DE Effektive Länge des Katheters
ES Longitud efectiva del catéter
PT Comprimento efetivo do cateter
IT Lunghezza effettiva del catetere
NL Effectieve katheterlengte
SE Effektiv kateterlängd
DK Kateters effektlængde
NO Kateter effektiv lengde
GR Πραγματικό μήκος καθετήρα
RU Эффективная длина катетера
PL Efektywna długość cewnika
HU A katéter munkahossza
CZ účinná délka katétru

SK Efektívna dĺžka katétra
TR Etkili Kateter Boyutu
LV Katetra aktīvais garums
LT Veiksmingasis kateterio ilgis
SI Efektivna dolžina katetra
RS Efektivna dužina katetera
RO Lungimea efectivă a cateterului
BG Эффективна дължина на катетъра
HR Efektivna duljina katetera
BA Efikasna dužina katetera
BY Эфектыўная даўжыня катэтару
ET Katetri efektiivne pikkus
FI Katetrin käyttöpituus
UK Робоча довжина катетера
KR 카테터 유효 길이



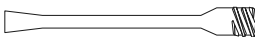
EN Maximum Guidewire Outer Diameter
FR Diamètre externe maximal du guide
DE Maximaler Außendurchmesser des Führungsdrahts
ES Diámetro máximo externo de la guía
PT Diâmetro exterior máximo do fio-guia
IT Diametro esterno massimo del filo guida
NL Maximale buitendiameter van voerdraad
SE Maximal ytterdiameter för ledare
DK Guidewirens maks. ydre diameter
NO Maximum Guidekabel Ytre Diameter
GR Μέγιστη εξωτερική διάμετρος συρμάτινου οδηγού
RU Максимальный наружный диаметр проводника
PL Maksymalna średnica zewnętrzna przewodnika
HU A vezetődórt maximális külső átmérője
CZ maximální vnější průměr vodičho drátu

SK Maximálny vonkajší priemer vodiaceho drôtu
TR Maksimum Kılavuz Tel Dış Çapı
LV Vadītājstīgas maksimālais ārējais diametrs
LT Didžiausias kreipiamosios vielos išorinis skersmuo
SI Maksimalni zunanji premer vodilne žice
RS Maksimalan spoljašnji prečnik vodič žice
RO Diametrul extern maxim al firului de ghidare
BG Максимален външен диаметър на водещата тел
HR Maksimalni vanjski promjer žice vodilje
BA Maksimalni vanjski prečnik žice vodilice
BY Максімальны знешні дыяметр драцянога накіравальніка
ET Juhtetraadi maksimaalne välisdiameeter
FI Ohjauslangan maksimiuulkohalkaisija
UK Максимальний зовнішній діаметр провідника
KR 최대 유도선 외경



EN Pressure
FR Pression
DE Druck
ES Presión
PT Pressão
IT Pressione
NL Druk
SE Tryck
DK Tryk
NO Press
GR Πίεση
RU Давление
PL Ciśnienie
HU Nyomás
CZ tlak

SK Tlak
TR Basınç
LV Spiediens
LT Slėgis
SI Tlak
RS Pritisak
RO Presiune
BG Налягане
HR Tlak
BA Pritisak
BY Ціск
ET Rõhk
FI Paine
UK Тиск
KR 압력



EN Flushing tool (with re-wrapping function)
FR Outil de rinçage (avec fonction de ré-enduction)
DE Spülwerkzeug (mit Rückfaltungsfunktion)
ES Herramienta de enjuagado (con función de replegado)
PT Dispositivo de limpeza de cateter (com a função de voltar a enrolar)
IT Strumento di irrigazione (con funzione di riavvolgimento)
NL Spoelinstrument (met functie voor opnieuw opwikkelen)
SE Spolinstrument (med omslagningsfunktion)
DK Skyllerværktøj (med gen-indpakningsfunktion)
NO Spyllingsverktøy (med re-innpakningsfunksjon)
GR Εργαλείο έκπλυσης (με λειτουργία επαναδίπλωσης)
RU Инструмент для промывания (с функцией свертывания баллона)
PL Narzędzie do przepłukiwania (z funkcją ponownego zawijania)
HU Öblítő eszköz (újracsomagolási funkcióval)
CZ proplachovací nástroj (s funkcí opětovného zatažení)

SK Oplachovací nástroj (s funkciou opakovaného balenia)
TR Temizleme aracı (tekrar sama özelliğine sahip)
LV Skalošanas instruments (ar atkārtotu ietīšanas funkciju)
LT Plovimo įrankis (su pakartotinio suvyniojimo funkcija)
SI Orodje za izpiranje (s funkcijo ponovnega ovijanja)
RS Alat za ispiranje (sa funkcijom za ponovno pakovanje)
RO Instrumentul de clătire (cu funcție de re-pliere)
BG Инструмент за промиване (с функция за повторно увиване)
HR Alat za ispiranje (s funkcijom ponovnog omatanja)
BA Instrument za ispiranje (s funkcijom ponovnog umotavanja)
BY Прылада для прамывання (з функцыяй перакладвання)
ET Loputusriist (uesti mähkimise funktsiooniga)
FI Huuhtelutyökalu (uudelleenkääritätoiminnolla)
UK Пристрій для промивання (з функцією повторного упакування)
KR 세척기구(재감기 기능 포함)

NP

EN Nominal Pressure
FR Pression nominale
DE Nenndruck
ES Presión nominal
PT Pressão nominal
IT Pressione nominale
NL Nominale druk
SE Nominellt tryck
DK Nominelt tryk
NO Nominelt trykk
GR Ονομαστική πίεση
RU Номинальное давление
PL Ciśnienie nominalne
HU Névleges nyomás
CZ nominální tlak

SK Nominálny tlak
TR Nominal basınç
LV Nominālais spiediens
LT Nominalusis slėgis
SI Nazivni tlak
RS Nominalni pritisak
RO Presiune nominală
BG Номинално налягане
HR Nazivni tlak
BA Nominalni pritisak
BY Наминальны ціск
ET Nimirõhk
FI Nimellispaine
UK Номинальний тиск
KR 공칭압

RBP

EN Rated Burst Pressure
FR Pression nominale de rupture
DE Nennberstdruck
ES Presión de rotura nominal
PT Pressão Nominal de Rótura
IT Pressione di scoppio nominale
NL Maximale barstdruk
SE Bristningstryck
DK Nørmerede sprængningstryk
NO Nominelt sprengningstrykk
GR Ονομαστική πίεση διάρρηξης
RU Номинальное давление разрыва
PL Znamionowe ciśnienie rozerwania
HU Névleges felszakítási nyomás
CZ vypočtený tlak protřetí

SK Menovitý tlak pri pretrhnutí
TR Anma Patlama Basıncı
LV Nominālais pārpļīšanas spiediens
LT Vardinis trūkimo slėgis
SI Nazivni tlak pred razpočenjem
RS Nominovani pritisak pucanja
RO Presiune nominală de spargere
BG Номинално налягане за спукване
HR Nazivni tlak prsnuća
BA Nominalni pritisak pucanja
BY Разліковы ціск разрыву
ET Nimilõhkemisrõhk
FI Nimellinen halkeamispaine
UK Розрахунковий тиск розриву
KR 정격파열압



EN Catheter clip
FR Attache du cathéter
DE Katheterklemme
ES Clip del catéter
PT Clipse para cateter
IT Clip del catetere
NL Katheterklem
SE Kateterclips
DK Kateterklemme
NO Kateter klipp
GR Κλιπ καθετήρα
RU Зажим катетера
PL Klips cewnika
HU Katétercsipesz
CZ svorka katétru

SK Svorka katétra
TR Kateter klipsi
LV Katetra spaile
LT Kateterio spaustukas
SI Sponka za kateter
RS Štipaljka katetera
RO Clema pentru cateter
BG Щипка на катетъра
HR Kopča katetera
BA Stezaljka katetera
BY Зажым катэтару
ET Katetri klamber
FI Katetrin nipistin
UK Kniuca katetepa
KR 카테터 클립



<i>EN</i>	Balloon catheter	<i>SK</i>	Balónikový katéter
<i>FR</i>	Cathéter à ballonnet	<i>TR</i>	Balon kateter
<i>DE</i>	Balloonkatheter	<i>LV</i>	Balonkatetrs
<i>ES</i>	Catéter de balón	<i>LT</i>	Balioniinis kateteris
<i>PT</i>	Cateter de balão	<i>SI</i>	Balonski kateter
<i>IT</i>	Catetere a palloncino	<i>RS</i>	Kateter sa balonom
<i>NL</i>	Balloonkatheter	<i>RO</i>	Cateter cu balon
<i>SE</i>	Ballongkateter	<i>BG</i>	Балонен катетър
<i>DK</i>	Ballonkateter	<i>HR</i>	Balonski kateter
<i>NO</i>	Ballongkateter	<i>BA</i>	Balonski kateter
<i>GR</i>	Καθετήρας με μπαλόνι	<i>BY</i>	Балонны катэтар
<i>RU</i>	Баллонный катетер	<i>ET</i>	Balloonkateteer
<i>PL</i>	Cewnik balonowy	<i>FI</i>	Pallokatetri
<i>HU</i>	Balloonkatéter	<i>UK</i>	Балонний катетер
<i>CZ</i>	balónkový katétr	<i>KR</i>	풍선 카테터

RX

<i>EN</i>	Rapid exchange	<i>SK</i>	rýchla výmena
<i>FR</i>	échange rapide	<i>TR</i>	hızlı değişim
<i>DE</i>	Rapid-Exchange	<i>LV</i>	ātrā apmaiņa
<i>ES</i>	intercambio rápido	<i>LT</i>	sparčiojo pakeitimo
<i>PT</i>	troca rápida	<i>SI</i>	hitra izmenjava
<i>IT</i>	scambio rapido	<i>RS</i>	brza zamena
<i>NL</i>	rapid exchange	<i>RO</i>	schimb rapid
<i>SE</i>	snabbt utbyte	<i>BG</i>	бърза смяна
<i>DK</i>	hurtig udskiftning	<i>HR</i>	brza zamjena
<i>NO</i>	Rask utveksling	<i>BA</i>	brza zamjena
<i>GR</i>	γρήγορη αλλαγή	<i>BY</i>	хуткая замена
<i>RU</i>	быстрая смена	<i>ET</i>	kiirvahetatus
<i>PL</i>	szybko wymieniany	<i>FI</i>	pikavaihto
<i>HU</i>	gyorsan cserélhető	<i>UK</i>	швидкозмінний катетер
<i>CZ</i>	rychlá změna	<i>KR</i>	급속 교환

MFG

<i>EN</i>	Manufacturing Site	<i>SK</i>	Miesto výroby
<i>FR</i>	Site de fabrication	<i>TR</i>	Üretim Tesisi
<i>DE</i>	Produktionsstandort	<i>LV</i>	Ražošanas vieta
<i>ES</i>	Planta de fabricación	<i>LT</i>	Gamybos vieta
<i>PT</i>	Local de fabrico	<i>SI</i>	Mesto izdelave
<i>IT</i>	Sito di produzione	<i>RS</i>	Mesto proizvodnje
<i>NL</i>	Fabricagelocatie	<i>RO</i>	Locul fabricației
<i>SE</i>	Tillverkningsplats	<i>BG</i>	Фабрика
<i>DK</i>	Fremstillingssted	<i>HR</i>	Mjesto proizvodnje
<i>NO</i>	Produksjonsnettsted	<i>BA</i>	Mjesto proizvodnje
<i>GR</i>	Εργοστάσιο κατασκευής	<i>BY</i>	Сайт вытворцы
<i>RU</i>	Место производства	<i>ET</i>	Tootmiskoht
<i>PL</i>	Zakład produkcyjny	<i>FI</i>	Valmistuspaikka
<i>HU</i>	Gyártási hely	<i>UK</i>	Місце виробництва
<i>CZ</i>	místo výroby	<i>KR</i>	제조 공장



EN Caution
FR Attention
DE Vorsicht
ES ¡Atención!
PT Atenção
IT Attenzione
NL Let op!
SE Försiktigt
DK Forsigtig
NO Forsiktig
GR Προσοχή
RU Внимание!
PL Uwaga
HU Figyelem
CZ Pozor

SK Pozor
TR Dikkat
LV Uzmanību!
LT Perspėjimas!
SI Svarilo
RS Pažnja
RO Atenție
BG Внимание
HR Oprez
BA Oprez, koristite prateću dokumentaciju
BY Аццярожна! Уважліва праглядаце прыложаныя дакументы
ET Ettevaatust! Lugege saatedokumente!
FI Huomio, perehdy oheisiin asiakirjoihin
UK Увага! Див. супровідні документи
KR 주의사항



EN Consult instructions for use
FR Consulter le mode d'emploi
DE Gebrauchsanleitung heranziehen
ES Consultar las instrucciones de uso
PT Consultar as Instruções de utilização
IT Consultare le istruzioni per l'uso
NL Raadpleeg de gebruiksaanwijzing
SE Se bruksanvisningen
DK Konsulter brugsanvisning
NO Se bruksanvisningen
GR Συμβουλευθείτε τις οδηγίες χρήσης
RU Ознакомьтесь с инструкцией по применению
PL Patrz instrukcja obsługi
HU Olvassa el a használati utasítást
CZ Prostudujte si návod k použití

SK Pozrite návod na používanie
TR Kullanma talimatlarına bakın
LV Skatīt lietošanas instrukcijas
LT Žr. naudojimo instrukcijas
SI Glejte navodila za uporabo
RS Pogledajte uputstva za upotrebu
RO Consultați instrucțiunile de utilizare
BG Прочетете инструкциите за употреба.
HR Konzultirajte upute za uporabu
BA Koristite uputstva za upotrebu
BY Глядзіце інструкцыю па выкарыстанні
ET Vaadake kasutusjuhendit.
FI Noudata käyttöohjeita
UK Ознайомтеся з інструкцією з використання
KR 사용 지침 참조



EN Do not use if package is damaged
FR Ne pas utiliser si l'emballage est endommagé
DE Bei beschädigter Verpackung nicht verwenden
ES No utilizar si el paquete está dañado
PT Não utilizar se a embalagem estiver danificada
IT Non utilizzare se la confezione è danneggiata
NL Niet gebruiken als de verpakking beschadigd is
SE Om förpackningen är skadad får produkten ej användas
DK Må ikke anvendes, hvis emballagen er beskadiget
NO Må ikke brukes hvis emballasjen er skadet
GR Μην χρησιμοποιηθεί αν η συσκευασία είναι κατεστραμμένη
RU Запрещается использовать, если упаковка повреждена
PL Nie używać, jeśli opakowanie jest uszkodzone
HU Ne használja, ha a csomag sérült
CZ Nepoužívejte, pokud je balení poškozeno

SK Nepoužívajte, ak je balenie poškodené
TR Paket hasar görmüşse kullanmayın
LV Nelietot, ja iepakojums ir bojāts
LT Nenaudoti, jei pakuotė pažeista
SI Ne uporabljajte, če je embalaža poškodovana
RS Nemojte koristiti ako je pakovanje oštećeno
RO Nu utilizați dacă ambalajul este deteriorat
BG Не използвайте, ако опаковката е повредена.
HR Nemojte koristiti kateter ako je ambalaža oštećena
BA Ne koristiti ako je pakovanje oštećeno
BY Не выкарыстоўвайце, калі ўпакоўка пашкоджана
ET Mitte kasutada, kui pakend on vigastatud.
FI Ei saa käyttää, jos pakkaus on vahingoittunut
UK Не використовувати, якщо упаковку пошкоджено
KR 포장이 손상된 경우 사용하지 마십시오



EN Keep away from sunlight	SK Chránite pred slnečným žiarením
FR Conserver à l'abri de la lumière	TR Güneş ışığından koruyun
DE Vor Sonneneinstrahlung schützen	LV Sargāt no saules gaismas
ES Mantener alejado de la luz solar	LT Saugoti nuo saulės spindulių
PT Manter afastado da exposição solar	SI Ne hranite na svetlobi
IT Conservare al riparo dalla luce solare	RS Držite van uticaja sunčeve svetlosti
NL Uit het zonlicht houden	RO A se feri de expunerea la soare
SE Förvaras skyddad från solljus	BG Дръжте далеч от слънчева светлина.
DK Må ikke udsættes for sollys	HR Držite podalje od sunčevog svjetla
NO Holdes vekk fra sollys	BA Zaštite od sunčeve svjetlosti
GR Κρατήστε το προϊόν μακριά από το ηλιακό φως	BY Трымайце здаля ад сонечнага святла
RU Беречь от воздействия солнечного света	ET Hoida eemal päikesevalgusest
PL Chronić przed promieniowaniem słonecznym	FI Älä altista auringonpaisteelle
HU Napfénytől távol tartandó	UK Тримати подаль від сонячних променів
CZ Chraňte před slunečním světlem	KR 직사광선을 피하십시오



EN Keep dry	SK Udržujte v suchu
FR Garder au sec	TR Kuru ortamda saklayın
DE Trocken lagern	LV Uzglabāt sausu
ES Mantener seco	LT Laikyti sausoje vietoje
PT Manter seco	SI Hranite na suhem
IT Mantenere asciutto	RS Чувати на сувом месту
NL Droog houden	RO A se păstra uscat
SE Förvaras torrt	BG Съхранявайте на сухо
DK Holdes tør	HR Čuvati na suhom
NO Hold tørt	BA Zaštite od vlage
GR Διατηρήστε στεγνό	BY Трымайце здаля ад дажджу
RU Хранить в сухом месте	ET Hoida vihma eest varjul.
PL Chronić przed wilgocią	FI Älä altista sateelle
HU Tartsa szárazon	UK Тримати подаль від дощу
CZ Udržujte v suchu	KR 건조한 상태를 유지하십시오



EN Temperature limit	SK Teplotné obmedzenie
FR Limite de température	TR Sıcaklık sınırı
DE Temperaturbegrenzung	LV Temperatūras ierobežojums
ES Límite de temperatura	LT Temperatūros ribinės vertės
PT Limite de temperatura	SI Temperaturna omejitev
IT Limiti di temperatura	RS Ograničenje za temperaturu
NL Temperatuurlimiet	RO Limită de temperatură
SE Temperaturgräns	BG Температурно ограничение.
DK Temperaturgrænse	HR Ograničenje temperature
NO Temperaturbegrensning	BA Raspon temperature
GR Όριο θερμοκρασίας	BY Тэмпературнае абмежаванне
RU Допустимая температура	ET Temperatuuripiirang
PL Ograniczenie temperatury	FI Lämpötilarajoitus
HU Hőmérsékleti korlát	UK Обмеження температури
CZ Teplotní omezení	KR 온도 제한

IKAZUCHI Zero

(KANEKA PTCA Catheter CO-R7)

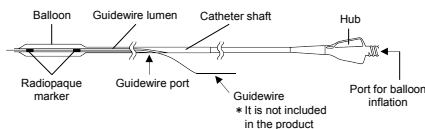
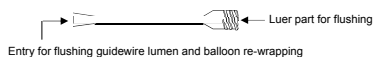
PTCA Balloon Dilatation Catheter

[Contraindications]

1. For single use only. Do not reuse, reprocess or resterilize.
2. These components are contraindicated in the following patients:
 - Patients with unprotected lesion in the left coronary trunk
 - Patients with coronary artery spasm in the absence of significant stenosis
3. Do not inflate the balloon exceeding the diameter of the blood vessel in the vicinity of the stenotic lesion.
(The blood vessel may be damaged or ruptured.)
4. Do not inflate the balloon to a pressure exceeding the rated burst pressure. (The balloon may burst and the debris may remain inside the body.)
5. The catheter is contraindicated for hand crimping of stent components and as a stent delivery system.
6. The product is contraindicated to patients who cannot tolerate antiplatelet therapy and anticoagulant therapy.

[Shape and structure]**1. Balloon catheter**

<Representative schematics>

**2. Flushing tool (with re-wrapping function)****Note**

Flushing tool is used for flushing guidewire lumen of this product. In case of re-insertion after removing out from the body, balloon may be inserted to Flushing tool to make balloon wrap in slender shape.

For appropriate use of the Flushing tool, follow the procedures described in 3) of "1.Preparations" in [Operation method or instructions for use].

3. Catheter clip**Note**

Catheter clip is used for binding up catheter shaft of this product.

[Indication for use]

This product is intended to be used for dilating the stenosis lesion in the coronary artery when performing percutaneous transluminal coronary angioplasty (PTCA).

[Product Specifications]

1. Balloon Compliance
 - Nominal Pressure (NP) : 0.6 MPa
 - Rated Burst Pressure (RBP) : 1.4 MPa
2. Maximum diameter of the guidewire
0.36 mm (0.014 inch)

[Operation method or instructions for use]**1. Preparations**

- 1) After aseptically removing this catheter from the package container, detach the protective materials such as a balloon protective sheath. Carefully remove the catheter, and check that there are no defects, such as a rupture.
- 2) Remove the air in the balloon and balloon inflation lumen according to the following procedures.
 - (a) Attach the inflation device filled with the contrast media diluted with sterilized physiological saline in the ratio of 1:1 (hereinafter, the inflation fluid) onto the balloon inflation port (hereinafter, the inflation port), and place this catheter with the distal tip facing downward.
 - (b) After applying the negative pressure using the inflation device for approximately 15 seconds, release the negative pressure gradually allowing the inflation fluid to fill the balloon and the balloon inflation lumen and to expel the air.
 - (c) Repeat the procedures (b) to expel the air completely.
 - (d) Remove the inflation device from the inflation port and expel all the air in the inflation device.
 - (e) Reattach the inflation device to the inflation port and apply negative pressure. After checking that the air no longer returns to the inflation device, release the negative pressure gradually. (a syringe can be used in place of the inflation device for the procedures (a)-(e).)
 - (f) Prior to inflation, immerse the balloon in sterilized physiological saline for at least one minute.
- 3) Flush the guidewire lumen by the Flushing tool according to the following procedures.
 - (a) Withdraw appropriate amount of heparinized saline into the syringe and connect the Flushing tool to luer part for flushing.
 - (b) Insert the distal tip of the product into entry for balloon re-wrapping until the product come to a stop inside the tool.
 - (c) Flush the guidewire lumen with heparinized saline using the syringe and fill up the lumen with the saline.

2. Insertion and removal of the balloon catheter

- 1) Insert this catheter along the guidewire advanced to the distal end of the lesion. Use a guiding catheter of 6 French or larger with the catheter. Under fluoroscopy, advance the catheter to make the radiopaque marker at the distal end of

the catheter reach the target site. Balloon should be deflated during this procedure.

- 2) Determine the position of this balloon catheter and screw the haemostatic valve tight enough to prevent blood leakage. Be careful not to overtighten the valve when tightening the valve. (This may restrict the flow of contrast media into the inflation lumen and slow down the inflation and deflation of the balloon.)
- 3) Inflate the balloon to the appropriate pressure for the lesion.
- 4) When the procedure is finished, deflate the balloon completely and loosen the haemostatic valve.
- 5) After checking that the balloon is completely retracted into the guide catheter under fluoroscopy, remove this catheter.

3. Exchanging PTCA catheter

- 1) Loosen the haemostatic valve.
- 2) Grasp the guidewire and the haemostatic valve with one hand to prevent the dislocation of the guidewire from the position in the coronary artery. Grasp the handheld part of this balloon catheter with another hand and start pulling this catheter out of the guide catheter. The position of the guidewire should be monitored under fluoroscopy during this procedure.
- 3) Withdraw this balloon catheter gradually until its guidewire port comes out. While maintaining the position of the guidewire passing through the coronary artery lesion, pull this balloon catheter carefully out of the guidewire.
- 4) Close the haemostatic valve.
- 5) Referring to its package insert, prepare a rapid exchange catheter and insert it in place.

[Precautions related to procedures]

1. Prior to use, expel all the air in the balloon and balloon inflation lumen and replace it with the inflation fluid. (In case of incomplete air removal, balloon inflation state can not be observed under fluoroscopy.)
2. Use the inflation fluid to inflate the balloon. No gaseous body such as air should be used for inflation.
3. Always immerse the balloon in sterilized physiological saline for at least one minute before inflation as the strength of the balloon may sometimes decrease.
4. Do not move this catheter while the balloon is inflated in the blood vessel. (Moving the catheter with the balloon inflated may lead to blood vessel injury, balloon burst, and catheter breakage.)
5. The insertion and withdrawal of the catheter should be performed slowly with caution. (If this procedure is performed too fast, it may lead to kinking of or damage to the catheter shaft.)
6. As for the medical devices used in conjunction with this catheter, follow the package inserts of such devices.
7. Proceed with care to prevent PTCA dilatation catheter kinking and collapse when forming loops of catheter.
8. Proceed with care to prevent shaft kinking and collapse while removing the catheter clip.
9. If reinsertion of the catheter is necessary, flush the guidewire lumen before insertion.
10. Secure the PTCA dilatation catheter with the catheter clip at the stiffer, proximal end. Do not use the catheter clip on

the flexible, distal shaft or catheters, it may damage the PTCA dilatation catheter.

11. Medical devices used with the product should be operated in accordance with the instructions for use of each individual device. (Refer to the Instructions for use of the stent products in case of usage for post-dilatation after stenting.)

[Precautions during usage]

[Important basic precautions]

1. This catheter may be used only by physicians skilled in percutaneous transluminal angioplasty.
2. The product should not be used in patients who are pregnant or suspected for pregnancy unless it is determined that the benefit to treat with the product may exceed the risk to use the product.
3. 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.
4. Do not use if the product or package is believed to be damaged.
5. Use immediately after the sterile package is opened. Device is to be regarded as contaminated waste after use.
6. Do not use agents containing organic solvents or oleaginous contrast media. Contact with these agents may lead to damage of the catheter.
7. Since PTCA procedure may induce dangerous complications, perform the procedure only after having prepared for emergency coronary artery bypass grafting (CABG).
8. Since serious complications might arise when using this catheter, operation should be done in the medical institution where emergency procedure can be executed.
9. The physician in charge of the procedure should determine the duration and number of balloon inflations based on his/her past experiences.
10. Heparinized and sterilized physiological saline should be infused for anti-coagulation while this balloon catheter is inserted in the blood vessel.
11. This catheter can only be inserted with the use of a guidewire. (Insertion of this catheter alone may lead to damage to the vascular wall or perforation of vessels.)
12. Operate the catheter carefully in the blood vessel verifying the location and movement of its tip under fluoroscopy.
13. Do not twist or turn this balloon catheter or the guidewire during operation. (The catheter may be tangled increasing the resistance.)
14. If abnormal or strong resistance is experienced during the operation, the cause for such abnormality or resistance should be verified and appropriate measures should be performed before proceeding. (If such abnormality or

resistance is ignored and excessive force is applied, it may lead to damage of the vessels or to the catheter shaft breaking and remaining inside the body).

15. During usage, the catheter shaft should be replaced for any bend, break or kink. (If the catheter continues to be used and such occurrence is ignored, the catheter shaft may be damaged and remain inside body).
16. If a great resistance is encountered during insertion, movement, or pulling out of this catheter, it should be verified that the guidewire is not tangled. If so, the tangling of the guidewire should be removed. (Since the guidewire lumen of this catheter is short, the guidewire may wind around the catheter shaft. In addition, while drawing this catheter back into the guiding catheter inside vessels, the wide-angle separation between the catheter shaft and guidewire may occur. Under this circumstance, a forced withdrawal may lead to damage to the guidewire or catheter.)
17. A catheter with any sign indicating damage should not be used.
18. Due to the lack of conductivity of twist forces, the catheter shaft should not be twisted (If twisted, the catheter shaft may be damaged and then remain inside the body).
19. Challenging lesions such as calcified or tortuous lesions may not be crossed with this catheter. The physician in charge of the procedure should determine whether this catheter is applicable based on his/her past experiences.
20. Precautions should be taken to prevent any damage to the catheter by the surgical knife or scissors.
21. During the usage of this catheter, the temperature, blood pressure, pulse, and respiration of patients should be monitored. In case of any abnormality, the procedure should be stopped or appropriate measures taken based on the physician's judgment.
22. After use, dispose of product and packaging in accordance with hospital, administrative and/or relevant national regulations.
23. If any abnormalities are detected during inflation of the balloon, apply negative pressure immediately and interrupt the operation.
24. Do not immerse the catheter in hot water or chemicals such as disinfectants [This may adversely affect its function.]

[Adverse events]

Adverse events related to the product 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 or rupture, unstable angina, 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 for cerebral infarction, formation of vessel fistula, aneurysm, arrhythmia, and even death.

[Storage, care and expiration date]

1. Store in a cool, dark, and dry place between 5°C and 30°C (41°F and 86°F) 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 (one primary packaging) / box
- Contents)
- 1) Balloon catheter x 1
 - 2) Flushing tool x 1
 - 3) Catheter clip x 1

[Names and Addresses of Manufacturer, Manufacturing Site and EC Representative]

[Manufacturer]

Name: 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

[Manufacturing Site]

Name: KANEKA CORPORATION OSAKA PLANT
 Address: 5-1-1, Torikai-Nishi, Settsu-city, OSAKA,
 566-0072 JAPAN

[EC Representative]

Name: KANEKA PHARMA EUROPE N.V.
 Address: Nijverheidsstraat 16, 2260 Westerlo-Oevel,
 Belgium
 Tel. No.: (+32)-(0) 14-256-297
 Fax No.: (+32)-(0) 14-256-298

[Compliance chart]

Diameter of balloon inflated by recommended inflation pressure (NP)				Diameter of balloon inflated by maximum inflation pressure (RBP)					
Balloon Diameter (mm)		Balloon Inflation Pressure						RBP	
		NP							
		MPa	0.2	0.4	0.6	0.8	1.0		1.2
		atm	2	4	6	8	10	12	
1.00		0.97	0.98	1.00	1.02	1.05	1.07	1.09	
1.20		1.18	1.20	1.20	1.22	1.24	1.26	1.28	
1.50		1.44	1.47	1.50	1.53	1.55	1.58	1.61	
1.75		1.65	1.70	1.75	1.79	1.82	1.85	1.89	
2.00		1.86	1.93	2.00	2.05	2.09	2.12	2.16	
2.25		2.08	2.16	2.25	2.31	2.35	2.40	2.44	
2.50		2.29	2.39	2.50	2.57	2.62	2.67	2.72	
2.75		2.53	2.64	2.75	2.83	2.88	2.93	2.99	
3.00		2.77	2.88	3.00	3.09	3.15	3.20	3.25	
3.25		2.99	3.12	3.25	3.34	3.41	3.48	3.53	
3.50		3.20	3.35	3.50	3.60	3.68	3.75	3.81	
3.75		3.44	3.59	3.75	3.88	3.97	4.04	4.11	
4.00		3.67	3.82	4.00	4.15	4.26	4.34	4.41	

This data is reference value, not guaranteed value.