CE 0123

# IKAZUCHI Zero

（*KANEKA PTCA Catheter CO-R7*）

**Instructions for use**



KANEKA
MEDICAL
PRODUCTS

***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*** Nepoužívajte opakovane
***TR*** İkinci kez kullanmayın
***LV*** Neizmantot 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


***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 ethyleenoxide
***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*** Стерилізовано етиленоксидом
***KR*** 에틸렌 옥사이드를 사용하여 살균됨

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

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


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

***EN*** Non-pyrogenic
***FR*** Apyrogène
***DE*** Nicht-pyrogen
***ES*** Apirógeno
***PT*** Não pirogénico
***IT*** Apirogeno
***NL*** Niet-pyrogeen
***SE*** Icke-pyrogent
***DK*** Ikke-pyrogent
***NO*** Ikke-pyrogen
***GR*** Μη πυρογενές
***RU*** Апирогенно
***PL*** Wyrób apirogenny
***HU*** Nem pirogén
***CZ*** Nepyrogenní
***SK*** Nepyrogénne
***TR*** Pirojenik değildir
***LV*** Nepirogēns
***LT*** Nepirogeninis
***SI*** Apirogeno
***RS*** Није пирогено
***RO*** Apirogen
***BG*** Непирогенно
***HR*** Nepirogeno
***BA*** Nije zapaljiv
***BY*** Непіраагенны
***ET*** Mittepürogeenne
***FI*** Ei-pyrogeeninen
***UK*** Апірогенний
***KR*** 비발열성


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

***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 prowadnika
***HU*** A vezetődrót maximális külső átmérője
***CZ*** maximální vnější průměr vodicího 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 maksimiulkohalkaisija
***UK*** Максимальний зовнішній діаметр провідника
***KR*** 최대 유도선 외경


***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*** Діаметр 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*** Ефективна дължина на катетъра
***HR*** Efektivna duljina katetera
***BA*** Efikasna dužina katetera
***BY*** Эфектыўная даўжыня катэтара
***ET*** Kateetri efektiivne pikkus
***FI*** Katetrin käyttöpituus
***UK*** Робоча довжина катетера
***KR*** 카테터 유효 길이

| | | | |
|---|---|---|---|
| ***EN*** | Pressure | ***SK*** | Tlak |
| ***FR*** | Pression | ***TR*** | Basınç |
| ***DE*** | Druck | ***LV*** | Spiediens |
| ***ES*** | Presión | ***LT*** | Slėgis |
| ***PT*** | Pressão | ***SI*** | Tlak |
| ***IT*** | Pressione | ***RS*** | Pritisak |
| ***NL*** | Druk | ***RO*** | Presiune |
| ***SE*** | Tryck | ***BG*** | Налягане |
| ***DK*** | Tryk | ***HR*** | Tlak |
| ***NO*** | Press | ***BA*** | Pritisak |
| ***GR*** | Πίεση | ***BY*** | Ціск |
| ***RU*** | Давление | ***ET*** | Rõhk |
| ***PL*** | Ciśnienie | ***FI*** | Paine |
| ***HU*** | Nyomás | ***UK*** | Тиск |
| ***CZ*** | tlak | ***KR*** | 압력 |

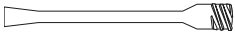
**NP**

| | | | |
|---|---|---|---|
| ***EN*** | Nominal Pressure | ***SK*** | Nominálny tlak |
| ***FR*** | Pression nominale | ***TR*** | Nominal basınç |
| ***DE*** | Nenndruck | ***LV*** | Nominālais spiediens |
| ***ES*** | Presión nominal | ***LT*** | Nominalusis slėgis |
| ***PT*** | Pressão nominal | ***SI*** | Nazivni tlak |
| ***IT*** | Pressione nominale | ***RS*** | Nominalni pritisak |
| ***NL*** | Nominale druk | ***RO*** | Presiune nominală |
| ***SE*** | Nominellt tryck | ***BG*** | Номинално налягане |
| ***DK*** | Nominelt tryk | ***HR*** | Nazivni tlak |
| ***NO*** | Nominelt trykk | ***BA*** | Nominalni pritisak |
| ***GR*** | Ονομαστική πίεση | ***BY*** | Намінальны ціск |
| ***RU*** | Номинальное давление | ***ET*** | Nimirõhk |
| ***PL*** | Ciśnienie nominalne | ***FI*** | Nimellispaine |
| ***HU*** | Névleges nyomás | ***UK*** | Номінальний тиск |
| ***CZ*** | nominální tlak | ***KR*** | 공칭압 |

**RBP**

| | | | |
|---|---|---|---|
| ***EN*** | Rated Burst Pressure | ***SK*** | Menovitý tlak pri pretrhnutí |
| ***FR*** | Pression nominale de rupture | ***TR*** | Anma Patlama Basıncı |
| ***DE*** | Nennberstdruck | ***LV*** | Nominālais pārplīšanas spiediens |
| ***ES*** | Presión de rotura nominal | ***LT*** | Vardinis trūkimo slėgis |
| ***PT*** | Pressão Nominal de Rotura | ***SI*** | Nazivni tlak pred razpočenjem |
| ***IT*** | Pressione di scoppio nominale | ***RS*** | Nominovani pritisak pucanja |
| ***NL*** | Maximale barstdruk | ***RO*** | Presiune nominală de spargere |
| ***SE*** | Bristningstryck | ***BG*** | Номинално налягане за спукване |
| ***DK*** | Normerede sprængningstryk | ***HR*** | Nazivni tlak prsnuća |
| ***NO*** | Nominelt sprengningstrykk | ***BA*** | Nominalni pritisak pucanja |
| ***GR*** | Ονομαστική πίεση διάρρηξης | ***BY*** | Разліковы ціск разрыву |
| ***RU*** | Номинальное давление разрыва | ***ET*** | Nimilõhkemisrõhk |
| ***PL*** | Znamionowe ciśnienie rozerwania | ***FI*** | Nimellinen halkeamispaine |
| ***HU*** | Névleges felszakítási nyomás | ***UK*** | Розрахунковий тиск розриву |
| ***CZ*** | vypočtený tlak protržení | ***KR*** | 정격파열압 |

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



***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 ominslagsfunktion)
***DK*** Skylleværktøj (med gen-indpakningsfunktion)
***NO*** Spylingsverktøy (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 sarma 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 (uuesti mähkimise funktsiooniga)
***FI*** Huuhtelutyökalu (uudelleenkäärintätoiminnolla)
***UK*** Пристрій для промивання (з функцією повторного упаковування)
***KR*** 세척기구(재감기 기능 포함)

***EN*** Catheter clip
***FR*** Attache du cathéter
***DE*** Katheterklemme
***ES*** Clip del catéter
***PT*** Clipe 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 катэтара
***ET*** Kateetri klamber
***FI*** Katetrin nipistin
***UK*** Кліпса катетера
***KR*** 카테터 클립

## REF

*EN* Catalogue Number
*FR* Référence du catalogue
*DE* Bestellnummer
*ES* Número de catálogo
*PT* Referência
*IT* Codice prodotto
*NL* Catalogusnummer
*SE* Artikelnummer
*DK* Varenummer
*NO* Artikkelnummer
*GR* Κωδικός Προϊόντος
*RU* Каталожный номер
*PL* Kod produktu
*HU* Termékkód
*CZ* Kód výrobku
*SK* Kód výrobku
*TR* Ürün kodu
*LV* Koda Nr.
*LT* Katalogo Nr.
*SI* Koda izdelka
*RS* Šifra proizvoda
*RO* Codul produsului
*BG* Каталожен номер
*HR* Kataloški broj
*BA* Kataloški broj
*BY* Нумар па каталогу
*ET* Kood
*FI* Tuotekoodi
*UK* Номер за каталогом
*KR* 카탈로그 번호

## LOT

*EN* Lot Number
*FR* Numéro de lot
*DE* Chargenbezeichnung
*ES* Número de lote
*PT* Número de lote
*IT* Numero di lotto
*NL* Lotnummer
*SE* Batchkod
*DK* Batchnummer
*NO* Batch nummer
*GR* Αριθμός παρτίδας
*RU* Номер партии
*PL* Numer serii
*HU* Tételszám
*CZ* Číslo výrobní serie
*SK* Identifikačné číslo
*TR* Lot numarası
*LV* Sērijas Nr.
*LT* Partijos kodas
*SI* Številka serije
*RS* Serijska oznaka
*RO* Număr lotului
*BG* Партиден номер
*HR* Šifra serije
*BA* Broj šarže
*BY* Нумар партыі
*ET* Partii nr.
*FI* Eränumero
*UK* Код партії
*KR* **로트 번호**

## SN

*EN* Serial Number
*FR* Numéro de série
*DE* Seriennummer
*ES* Número de serie
*PT* Número de série
*IT* Numero di serie
*NL* Serienummer
*SE* Serienummer
*DK* Serienummer
*NO* Serienummer
*GR* Αριθμός παραγωγής
*RU* Серийный номер
*PL* Numer serii
*HU* Sorozatszám
*CZ* Výrobní číslo
*SK* Sériové číslo výrobku
*TR* Seri Numarası
*LV* Sērijas Nr.
*LT* Serijos Nr.
*SI* Serijska številka
*RS* Serijski broj
*RO* Număr de serie.
*BG* Сериен номер
*HR* Serijski broj
*BA* Serijski broj
*BY* Серыйны нумар
*ET* Seerianumber
*FI* Sarjanumero
*UK* Серійний номер
*KR* 일련 번호

| | | | |
|---|---|---|---|
| *EN* | Manufacturer | *SK* | Výrobca |
| *FR* | Fabricant | *TR* | Üretici firma |
| *DE* | Hersteller | *LV* | Ražots |
| *ES* | Fabricante | *LT* | Gamintojas |
| *PT* | Fabricante | *SI* | Izdelovalec |
| *IT* | Fabbricante | *RS* | Proizvodjač |
| *NL* | Fabrikant | *RO* | Fabricat de |
| *SE* | Tillverkare | *BG* | Произведено от |
| *DK* | Produceret af | *HR* | Proizvođač |
| *NO* | Produsent | *BA* | Proizvođač |
| *GR* | Κατασκευαστής | *BY* | Вытворца |
| *RU* | Изготовлено | *ET* | Toodetud |
| *PL* | Wytwórca | *FI* | Valmistaja |
| *HU* | Gyártó | *UK* | Виробник |
| *CZ* | Vyrobeno | *KR* | 제조사 |

**MFG**

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

**EC REP**

| | | | |
|---|---|---|---|
| *EN* | Authorized representative in the European Community | *SK* | Predstaviteľ Európskej únie |
| *FR* | Rep. CE (Mandataire européen) | *TR* | Yetkili AB temsilcisi |
| *DE* | Bevollmächtigter in der Europäischen Gemeinschaft | *LV* | ES pārstāvis |
| *ES* | Representante autorizado de la Comunidad europea | *LT* | Įgaliotas atstovas Europos bendrijoje |
| *PT* | Representante autorizado na CE | *SI* | Zastopnik v Evropski Skupnosti |
| *IT* | Rappresentante autorizzato nella comunità europea | *RS* | Predstavnik u Evropskoj Uniji |
| *NL* | Gemachtigde vertegenwoordiger in de EU (Europese Unie) | *RO* | Reprezentant UE |
| *SE* | Auktoriserad återförsäljare inom EU-området | *BG* | Упълномощен представител в ЕС |
| *DK* | Autoriseret forhandler indenfor EU området | *HR* | Ovlašteni predstavnik u europskoj zajednici |
| *NO* | Autorisert representant i Det europeiske Fellesmarked | *BA* | Ovlašćeni predstavnik u Evropskoj uniji |
| *GR* | Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα | *BY* | Упаўнаважаны прадстаўнік у Еўрапейскай супольнасці |
| *RU* | Авторизованный представитель Европейского сообщества | *ET* | Esindaja EL-s |
| *PL* | Autoryzowany przedstawiciel w Unii Europejskiej | *FI* | EY edustaja |
| *HU* | Az Európai Közösségben a képviseletre jogosult | *UK* | Уповноважений представник в Європейському Союзі |
| *CZ* | Zástupce Evropského společenství | *KR* | 유럽 연합의 법정 대리인 |

| | | | |
|---|---|---|---|
| ***EN*** | Use-by-date | ***SK*** | Dátum spotreby |
| ***FR*** | Utiliser avant le | ***TR*** | Son kullanma tarihi |
| ***DE*** | Verfallsdatum | ***LV*** | Izlietošanas termiņš |
| ***ES*** | Fecha de caducidad | ***LT*** | Galiojimo data |
| ***PT*** | Validade | ***SI*** | Uporabiti do |
| ***IT*** | Utilizzare entro la data | ***RS*** | Датум рока употребе |
| ***NL*** | Uiterste houdbaarheidsdatum | ***RO*** | Data expirării |
| ***SE*** | Förbrukningsdatum | ***BG*** | Срок на годност |
| ***DK*** | Sidste anvendelsesdato | ***HR*** | Rok upotrebe |
| ***NO*** | Bruk innen | ***BA*** | Datum roka upotrebe |
| ***GR*** | Χρήση έως ημερομηνία | ***BY*** | Тэрмін прыдатнасці |
| ***RU*** | Срок годности | ***ET*** | Realiseerimise ja tarvitamise lõpptähtpäev |
| ***PL*** | Termin ważności | ***FI*** | Viimeinen käyttöpäivä |
| ***HU*** | Felhasználhatóság dátuma | ***UK*** | Термін придатності |
| ***CZ*** | Datum použitelnosti | ***KR*** | 유효 기간 |

EN

Instructions for use

# IKAZUCHI Zero

（KANEKA PTCA Catheter CO-R7）

PTCA Balloon Dilatation Catheter

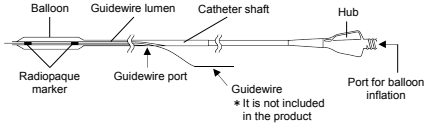
## [Contraindications]

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.

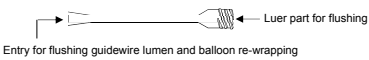
## [Shape and structure]

**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]

**1. Indications**

This product is indicated for patients suffering from myocardial infarction or angina pectoris.

**2. Intended 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℃ and 30℃ (41℉ and 86℉) 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

EN

**[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 | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | NP | | | | RBP |
| | MPa | 0.2 | 0.4 | 0.6 | 0.8 | 1.0 | 1.2 | **1.4** |
| | atm | 2 | 4 | 6 | 8 | 10 | 12 | **14** |
| 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.

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IKAZUCHI Zero

(KANEKA PTCA Catheter CO-R7)

APR 2019