

JELCO

Jelco IntuitIV Safety IV Catheter™ (Side Port)

| | |
|------------------------------------|------------------------------|
| en INSTRUCTIONS FOR USE | nl GEBRUIKSAANWIJZING |
| fr MODE D'EMPLOI | sv BRUKSANVISNING |
| de GEBRAUCHSANWEISUNG | da BRUGSANVISNING |
| it ISTRUZIONI PER L'USO | no BRUKSANVISNING |
| es INSTRUCCIONES DE USO | fi KÄYTTÖOHJEET |
| pl INSTRUKCJE DE UTILIZAÇÃO | el ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ |

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0086


















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| en English | fr Français | de Deutsch | it Italiano | es Español | pt Português | nl Nederlands | sv Svenska | da Dansk | no Norsk | fi Suomi | el Ελληνικά |
|---|--|--|---|--|---|---|--|---|--|---|---|
|  Caution | Précaution | Achtung | Cautela | Aviso | Aviso | Let op | Försiktighetsåtgärd | Forsigtig | Forsiktig | Varoitus | Προσοχή |
|  Do not re-use | Ne pas réutiliser | Nicht zur Wiederverwendung | Non riutilizzare | No reutilizar | Não reutilizar | Niet opnieuw gebruiken | Får inte återvändas | Må ikke genanvendes | Til engangsbruk | Ei saa käyttää uudelleen | Μην επαναχρησιμοποιείτε |
|  Do not re-sterilize | Ne pas restériliser | Nicht reesterilisieren | Non risterilizzare | No reesterilizar | Não reesterilizar | Niet opnieuw steriliseren | Får ej omsteriliseras | Må ikke reesteriliseres | Skal ikke reesteriliseres | Älä steriloitua uudelleen | Μην επαναστεριώνετε |
|  Catalogue Number | Numéro de catalogue | Bestellnummer | Numero di catalogo | Número de catálogo | Número de catálogo | Catalogusnummer | Katalognummer | Katalognummer | Katalognummer | Luettelonumero | Αριθμός καταλόγου |
|  Batch code | Numéro de lot | Chargenbezeichnung | Codice del lotto | Código de lote | Código de série | Batchcode | Batchkod | Batchkode | Kode for parti | Eräkoodi | Κωδικός партиδας |
|  Date of manufacture | Date de fabrication | Herstellungsdatum | Data di fabbricazione | Fecha de fabricación | Data de fabrico | Fabricagedatum | Tillverkningsdatum | Fremstillingsdato | Produksjonsdato | Valmistuspäivä | Αριθμός партиδας |
|  Use by | Utiliser avant le | Verwendbar bis | Utilizzare entro | Fecha de caducidad | Utilizar até | Te gebruiken voor | Använd före | Anvendes inden | Brukes innen | Käytettävä ennen | Ημερομηνία λήξης |
|  Manufacturer | Fabricant | Hersteller | Fabbricante | Fabricante | Fabricante | Fabrikant | Tillverkare | Fabrikant | Produsent | Valmistaja | Κατασκευαστής |
|  Does not contain Natural Rubber Latex | Ne contient pas de latex de caoutchouc naturel | Enthält keinen Latex aus Naturkautschuk | Non contiene lattice di gomma naturale | No contiene látex de caucho natural | Não contém látex de borracha natural | Bevat geen natuurlijke rubberlatex | Innehåller inte naturligt latexgummi | Indeholder ikke naturgummitæx | Inneholder ikke naturlig gummitæx | Ei sisällä luonnonkumi lateksia | Περιέχει φυσικό ελαστικό λατέξ ή υπάρχει παρουσία φυσικού ελαστικού λατέξ |
|  Quantity | Quantité | Menge | Quantità | Cantidad | Quantidade | Aantal | Kvantitet | Antal | Antall | Määrä | Ποσότητα |
|  Sterilized using ethylene oxide | Stérilisé à l'oxyde d'éthylène | Sterilisiert mit Ethylenoxid | Metodo di sterilizzazione con ossido di etilene | Método de esterilización utilizando óxido de etileno | Esterilizado utilizando óxido de etileno | Gesteriliseerd met ethyleenoxide | Steriliserad med etylenoxid | Steriliseret med etylenoxid | Sterilisert med etylenoksid | Steriloitu etyleenioksidilla | Αποστειρώθηκε με χρήση οξειδίου του αιθυλενίου |
|  Fluid path components non-pyrogenic | Éléments de trajet du liquide non pyrogéniques | Komponenten des Flüssigkeitssystems nicht pyrogen | Componenti del percorso del fluido apirogeni | Los componentes de los conductos del fluido son apirógenos | Componentes da via de passagem do fluido apirógenos | Onderdelen vloeistofpad niet-pyrogeen | Vätskeledarkomponenter är ej pyrogena | Væskebanens komponenter er ikke-pyroge | Ikke-pyrogene væskebanekomponenter | Nestepolun osat ei-pyrogeenisia | Εξαρτήματα διέλευσης υγρού μη πυρεταγόνα |
|  Temperature Limitation | Limite de température | Temperaturbereich | Limiti di temperatura | Limite de temperatura | Limites de temperatura | Temperatuurlimiet | Temperaturbegränsning | Temperaturbegrænsning | Temperaturgrense | Lämpötilarajoitus | Περιορισμός θερμοκρασίας |
|  This way up | Haut | Oben | Alto | Este lado hacia arriba | Este lado para cima | Deze kant boven | Denna sida upp | Denne vej op | Denne siden opp | Tämä puoli ylös | Επάνω πλευρά |
|  Fragile, handle with care | Fragile ; manipuler avec soin | Vorsicht, zerbrechlich | Fragile, maneggiare con cura | Frágil, manipúlese con prudencia | Frágil, manusear con cuidado | Breekbaar, voorzichtig behandelen | Bräcklig, hanteras varsamt | Forsigtig | Skjøre saker, håndteres forsiktig | Hölpösti särkynnä, käsiteltävä varovasti | Ευθραστο, ο χειρισμός του πρέπει να γίνεται με προσοχή |
|  Do not use if package is damaged | Ne pas utiliser si l'emballage est endommagé | Inhalt bei beschädigter Verpackung nicht verwenden | Non utilizzare se la confezione è danneggiata | No utilizar si el envase está dañado | Componentes da via de passagem do fluido apirógenos | Niet gebruiken indien de verpakking beschadigd is | Får inte användas om förpackningen är skadad | Må ikke anvendes, hvis emballagen er beskadiget | Må ikke brukes hvis emballasjen er ødelagt | Ei saa käyttää, jos pakkaus on vahingoittunut | Μην το χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά |
|  Keep dry | Conserver au sec | Trocken aufbewahren | Tenere all'asciutto | Manténgase en lugar seco | Manter seco | Droog houden | Förvaras torrt | Oppbevares tørt | Oppbevares tørt | Pidettävä kuivana | Να διατηρείται στεγνό |
|  Keep away from sunlight | Conserver à l'abri de la lumière du soleil | Vor Sonnenlicht schützen | Tenere al riparo dalla luce solare | Manténgase lejos de la luz solar | Manter afastado da luz solar | Niet blootstellen aan zonlicht | Skyddas för solljus | Må ikke udsættes for sollys | Oppbevares utenfor direkte sollys | Suojattava auringonvalolta | Διατηρείται μακριά από το ηλιακό φως |

English

Jelco IntuitIV Safety IV Catheter™ (Side Port)

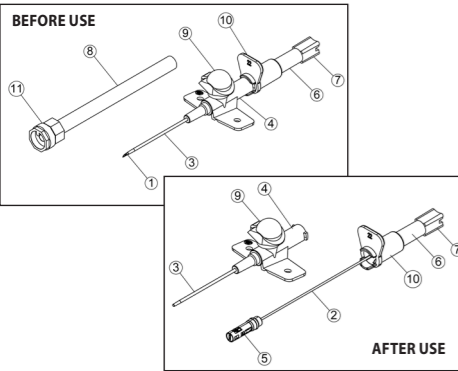
INSTRUCTIONS FOR USE

These instructions apply to the use of the following Jelco® products:
7114 to 7122 Jelco IntuitIV Safety IV Catheter™ FEP 14G to 22G
7214 to 7222 Jelco IntuitIV Safety IV Catheter™ PUR 14G to 22G

These instructions contain important information for safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient and/or clinician.

NOTE: DISTRIBUTE THIS INSERT SHEET TO ALL PRODUCT LOCATIONS.

1. DESCRIPTION:
Each Jelco IntuitIV Safety IV Catheter™ consists of an introducer needle with an integral tip-protector. Key parts are (1) needle bevel, (2) needle, (3) catheter, (4) catheter hub, (5) tip-protector, (6) flash chamber, (7) flash plug assembly, (8) sheath, (9) snap cap, (10) thumb tab, and (11) Luer lock cap.



CATHETER GAUGE AND REFERENCE CHART

| Gauge | 14G | 16G | 18G | 20G | 22G |
|--------|--------|------|-------|------|------|
| Colour | Orange | Grey | Green | Pink | Blue |

This device is intended for single use only and is provided sterile and non-pyrogenic. The materials used to manufacture this radiopaque IV catheter do not contain latex and are PVC and DEHP free.

- 2. INDICATIONS:**
- 2.1** A properly placed Jelco IntuitIV Safety IV Catheter™ provides access to a vein or artery to sample blood, monitor blood pressure, or administer fluids.
- 2.2** The tip-protector that locks over the needle as the needle is withdrawn helps reduce the risk of accidental needlesticks.
- 2.3** These catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused and duration of the therapy.
- 3. CONTRAINDICATIONS:**
None known.
- 4. WARNINGS:**
- 4.1 For proper use, CLINICIANS MUST BE TRAINED IN THE PRACTICE OF VENIPUNCTURE and follow the INSTRUCTIONS For Use. Failure to follow these instructions could result in death or serious injury to the patient and/or clinician.**
- 4.2 To avoid the potential of an embolus:**
DO NOT CUT THE CATHETER or use sharp instruments near the catheter.
• Never reinsert the introducer needle inside the catheter as it may sever it.
- 4.3 To avoid an accidental needlestick:**
• DO NOT BEND THE NEEDLE during insertion, threading, or removal of the catheter assembly.
• If venipuncture is not successful, engage the safety mechanism and discard both the needle and the catheter.
• In the unlikely event that the device does not lock out; dispose of the sharp immediately into an approved sharps container.
- 4.4 Needle is not intended to be used with a guidewire - use will prevent activation of safety tip-protector**
- 4.5 Do not manipulate the tip-protector assembly before or after use.**
- 4.6 Do not use under high pressure conditions. To avoid leakage, maximum pressure for side-port catheters is 45 psi.**
- 5. CAUTIONS:**
- 5.1** Product is sterile, non-toxic and non-pyrogenic unless package is open, wet, or damaged. Discard if open, wet, or damaged.
- 6. PRECAUTIONS:**
- 6.1** This device is designed to help reduce the risk of accidental needlesticks. In addition to these instructions for use, it is recommended that the health care professional follow the recommendations set forth by the CDC and OSHA standards (USA) or local equivalent for bloodborne pathogens when starting, maintaining, or discarding any IV catheter to avoid the risk of exposure to blood.
- 6.2** Follow current institutional policies and procedures for catheter insertion, maintenance and removal.
- 6.3** The catheter is shorter than the introducer needle. Therefore, blood flashback may occur before the catheter tip is fully in the blood vessel. If necessary, slightly advance the catheter and needle together to assure full catheter entry into the blood vessel lumen. To avoid inadvertently puncturing the posterior wall of the vessel, lower the needle until it is parallel to the skin.
- 6.4** Ensure fluid administration/hub connection is secure in order to prevent leaking.

- 6.5** Ensure stabilization of catheter to the patient. Improper stabilization may lead to loss of vascular access.
- 7. INSTRUCTIONS FOR USE:**
Due to the risk of bloodborne pathogen exposure, follow Standard Precautions during placement, use and removal of an IV catheter.
- 7.1** Select and prepare site per institutional policy. Apply tourniquet.
- 7.2** Remove sheath in straight outward motion and inspect device. Ensure snap cap is closed and the catheter hub is fully seated and verify the needle bevel is in the up position.
- 7.3** Find a stable position to hold the Jelco IntuitIV Safety IV Catheter™ by holding the wings with index and middle finger and place the thumb at the flash plug assembly.
- 7.4** Anchor the blood vessel with gentle skin traction and insert the needle into the skin and blood vessel at an appropriate angle.
- 7.5** Blood flashback into the flash chamber confirms blood vessel entry.
- 7.6** Decrease angle and insert device slightly to assure catheter entry into the blood vessel.
- 7.7** Remove tourniquet.
- 7.8** Before removing needle, apply digital pressure to the blood vessel distal to the catheter tip and secure the catheter hub, remove the needle by pulling straight back. The tip-protector will automatically engage over the needle tip.
Note: A slight resistance will occur as the protected needle is removed from the catheter hub.
- 7.9 Note: Do not reinsert the tip-protector into the hub after it has been removed.**
- 7.10** Connect IV administration line and dress site per institutional policy.
- 7.11** Immediately discard unit into a puncture resistant, leak-proof, disposable sharps container.

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en

Single use.

Do Not Reuse: Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

Sterile unless unit container is opened or damaged.

Destroy after single use. Do not resterilize.

fr

A usage unique.

Ne pas réutiliser: Les dispositifs médicaux requièrent des caractéristiques matérielles spécifiques pour être utilisés comme prévu. Ces caractéristiques ont été avérées uniquement en cas d'usage unique. Toute tentative de retraitement du dispositif en vue d'une réutilisation peut gravement compromettre son intégrité ou ses performances.

Sterile sauf si l'emballage est ouvert ou endommagé.

A détruire après usage unique. Ne pas restériliser.

de

Einwegpackung.

Nicht zur Wiederverwendung: Medizinische Produkte erfordern bestimmte Materialeigenschaften, um ihre vorgesehene Funktion erfüllen zu können. Diese Eigenschaften wurden nur für eine einmalige Anwendung validiert. Jeder Versuch der Wiederaufbereitung für weitere Anwendungen kann die Integrität des Produktes beeinträchtigen oder zu einer schlechteren Funktion führen.

Steril, wenn die Verpackung nicht geöffnet oder beschädigt wurde.

Nach einmaligem Gebrauch vernichten. Nicht erneut sterilisieren.

it

Monouso.

Non riutilizzare: Per funzionare correttamente, i dispositivi medici devono rispondere a caratteristiche specifiche del materiale. Queste caratteristiche sono state verificate esclusivamente nel caso di singolo utilizzo del dispositivo. Qualsiasi tentativo di riprocessare il dispositivo per il riutilizzo successivo può alterare in maniera avversa l'integrità del dispositivo stesso o condurre a un deterioramento delle prestazioni.

Sterile a meno che il contenitore dell'unità non risulti aperto o danneggiato.

Distruggere dopo l'uso. Non risterilizzare.

es

De un sólo uso.

No reutilizar: El material de los dispositivos médicos debe reunir características específicas para funcionar como es debido. Dichas características únicamente se han verificado para un solo uso. Cualquier intento de reprocesar el dispositivo para su ulterior reutilización puede afectar negativamente a la integridad del mismo o dar lugar a fallos en su funcionamiento.

Estéril a menos que el envase unitario esté abierto o dañado.

Destruir después de un sólo uso. No volver a esterilizar.

pt

Utilização única.

Não reutilizar: É necessário que determinadas características do material de dispositivos médicos tenham o desempenho pretendido. Estas características foram validadas para uma utilização única. Qualquer tentativa de reprocessar o dispositivo para subsequente reutilização pode afectar adversamente a integridade do dispositivo ou levar à alteração do seu desempenho.

Esterilizado enquanto a embalagem não for aberta ou danificada.

Destruir após utilização única. Não reutilizar

nl

Voor eenmalig gebruik.

Niet opnieuw gebruiken: Voor een beoogde werking moeten medische hulpmiddelen over specifieke materiaaleigenschappen beschikken. Deze eigenschappen zijn na verificatie alleen voor eenmalig gebruik geschikt verklaard.

Probeer niet het hulpmiddel opnieuw te bewerken met hergebruik als doel. Zulke pogingen kunnen een ongunstige invloed op de integriteit van het hulpmiddel hebben of kunnen een verslechterde werking van het hulpmiddel veroorzaken.

Steriel tenzij de doos geopend of beschadigd is. Vernietigen na eenmalig gebruik.

Mag niet opnieuw worden gesteriliseerd.

sv

Engångsartikel.

Får inte återvändas: Medicintekniska utrustningar kräver specifika egenskaper hos materialet för att de ska fungera såsom avsett. Dessa egenskaper har endast verifierats för engångsbruk. Varje försök att uppabeta utrustningen för efterföljande återanvändning kan förorsaka skador på utrustningen eller leda till försämrad funktion.

Steril tills förpackningen öppnats eller skadats.

Förstör efter en användning.

Sterilisera inte på nytt.

da

Til engangsbrug.

Må ikke genanvendes: Medicinsk udstyr kræver specifikke materialegenskaber for at fungere som tilsigtet. Disse egenskaber er kun kontrolleret til engangsbrug. Ethvert forsøg på at behandle udstyret til efterfølgende genbrug kan påvirke perfekt tilstand af udstyret negativt eller medføre forringet funktionsevne.

Steril med mindre enhedens beholder åbnes eller beskadiges.

Bortskaf efter engangsbrug. Må ikke steriliseres igen.

no

Til engangsbruk.

Til engangsbruk: Medisinsk utstyr krever særskilte materialegenskaper for å fungere etter hensikten. Disse egenskapene er kun verifisert for engangsbruk. Eventuelle forsøk på å gjenprosessere utstyret for gjentatt bruk vil kunne ha negativ effekt på utstyret eller føre til at funksjonsevnen forringes.

Steril så lenge enheten er uåpnet og uskadd.

Destrueres etter engangsbruk.

Må ikke resteriliseres.

fi

Kertakäyttötuote.

Ei saa käyttöä uudelleen: Lääkinnälliset tarvikk eet vaativat materiaalin erityisomaisuuksia toimiakseen halutulla tavalla. Näitä ominaisuudet on vahvistettu vain yhtä käyttökertaa varten. Yritykset käsitellä tarvike uudelleenkäyttöä varten voi vaurioittaa tarviketta tai johtaa toiminnon huonontumiseen.

Steriili kunnes yksittäispakkaus avataan tai vaurioituu.

Hävitetävä yhden käyttökerran jälkeen. Älä steriloi uudestaan.

el

Μίας χρήσης.

Μην επαναχρησιμοποιείτε: Τα ιατροτεχνολογικά προϊόντα απαιτούν συγκεκριμένα χαρακτηριστικά υλικών για να έχουν την προβλεπόμενη απόδοση. Τα χαρακτηριστικά αυτά έχουν επαληθευτεί για μία μόνο χρήση. Οποιαδήποτε απόπειρα επανεπεξεργασίας του οργάνου για επικόλουθη επαναχρησιμοποίηση μπορεί να επηρεάσει αρνητικά την ακεραιότητα του οργάνου ή να οδηγήσει σε υποβάθμιση της απόδοσης.

Αποστειρωμένο εκτός εάν η συσκευασία στην οποία περιέχεται είναι ανοιχτή ήκατεστραμμένη.

Καταστρέφεται μετά από μία χρήση. Δεν αποστειρώνεται πάλι.