

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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

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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 steriloit 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	Nestepulun 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	Höpsligt särkynn, 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	Opbevares 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	Opbevares utenfor direkte sollys	Suojattava auringonvalolta	Διατηρείται μακριά από το ηλιακό φως

English

Jelco IntuitIV Safety IV Catheter™ (Side Port)

INSTRUCTIONS FOR USE

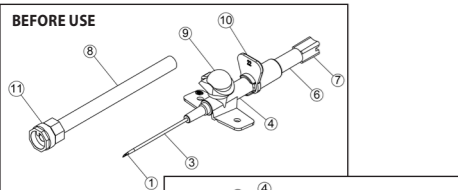
These instructions apply to the use of the following Jelco® products:
7114 to 7122 Jelco IntuitIV Safety IV Catheter™ FEP 14G to 22G
7214 to 7222 Jelco IntuitIV Safety IV Catheter™ PUR 14G to 22G

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.

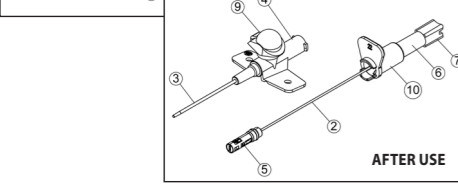
NOTE: DISTRIBUTE THIS INSERT SHEET TO ALL PRODUCT LOCATIONS.

- 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.

BEFORE USE



AFTER USE



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.

- 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.
- CONTRAINDICATIONS:**
None known.
- 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.**
- CAUTIONS:**
- 5.1** Product is sterile, non-toxic and non-pyrogenic unless package is open, wet, or damaged. Discard if open, wet, or damaged.
- 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.
- INSTRUCTIONS FOR USE:**
 - 7.1** **Due to the risk of bloodborne pathogen exposure, follow Standard Precautions during placement, use and removal of an IV catheter.**
 - 7.2** Select and prepare site per institutional policy. Apply tourniquet.
 - 7.3** 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.
 - 7.4** 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.
 - 7.5** Anchor the blood vessel with gentle skin traction and insert the needle into the skin and blood vessel at an appropriate angle.
 - 7.6** Blood flashback into the flash chamber confirms blood vessel entry.
 - 7.7** Decrease angle and insert device slightly to assure catheter entry into the blood vessel.
 - 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 återanvändas: 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.

Steriiilii 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 επανεξεργασίας του οργάνου για επακόλουθη 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.