BD Connecta™ Stopcock with extension tube Sterile
394995 – 394997 – 394926 – 394951 – 394961 – 394982 - 394983

BD Switzerland Sàrl
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TDS number: V201-033 – Rev.02
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1. General Information

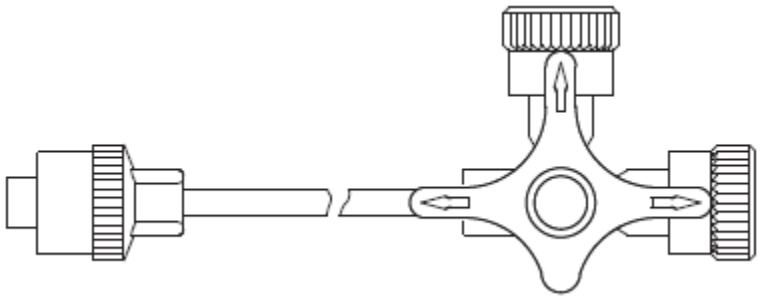
1.1 Intended use

BD Connecta™ Stopcock with extension tube is designed to supply the blood system with fluids or medication coming from one or two different sources via an IV cannula or extension tube. The product can also be used in different combinations in several applications of nutrition administration.

BD Connecta™ Stopcock with Low Volume Extension tube (for pediatric use) is designed to supply the blood system with fluids or medication from one or two different sources via an IV cannula or an extension tube. Alternatively, one of the connections can be used for injections or sampling. The product can also be used in various combinations for several nutrition administration applications.
BD Connecta™ Stopcock with Low Volume Extension is suitable for applications where a stopcock is preferably placed at some distance from the insertion site.

1.2 General description

BD Connecta™ Stopcock with extension tube has a transparent housing with a white or blue tap. The housing has two female Luer-lock fittings with white plugs, and one fitting to which an extension line or a low volume extension tube is assembled. The luer cone at the end of the extension line is protected by a white protection cap. The rotating tap has closed and open position indicators when snap turned (ON-OFF). The rotating tap shows which ports are open. The tap rotation is 360°.



BD Catalog Number	BD Product Description	Tube Length (cm)	Tap color
394995	CONNECTA PLUS3 10CM WHITE	10	White
394997	CONNECTA PLUS3 10CM BLUE	10	Blue
394926	CONNECTA WHT 360DEG TB 25CM	25	White
394951	CONNECTA WHT 360DEG TB 50CM	50	White
394961	CONNECTA WHT 360DEG TB 100 CM	100	White
394982	CONNECTA WHT 360DEG LOW VOLUME TB 15CM	15	White
394983	CONNECTA WHT 360DEG LOW VOLUME TB 30CM	30	White

Please check BD catalog number availability in your country.

Further features: N/A

1.3 Certification

BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
394995 394997 394926 394951 394961 394982 394983	**Address:** Becton Dickinson Infusion Therapy AB Florettgatan 29C PO Box 631 SE-251 06 Helsingborg Sweden **ISO 13485** Certificate No.: MD 597883	CE certified with BSI (2797) Certificate No.: CE 597884	**Address:** Becton Dickinson Infusion Therapy systems Inc. S.A. de C.V. Periferico Luis Donaldo Colosio #579 Nogales, Sonora C.P. 84048 Mexico **ISO 13485** Certificate No: FM 673986	N/A

1.4 Materials

Component	Material
Housing	Polycarbonate
Tap	Polyethylene
Tube	Polyvinylchloride
Nut	Polycarbonate
Plug	Polypropylene
Protection cap	Polyethylene Master batch white
Silicone liquid	Polydimethylsiloxane
Peg	Polyethylene

1.5 Materials of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

Material	Comment
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per 13 March 2019, BD has not identified any • Bis(2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), • Dibutyl phthalate (DBP) (CAS# 84-74-2), • Benzyl butyl phthalate (BBP) (CAS# 85·68-7), • Bis(2-methoxyethylj phthalate (DMEP) (CAS# 117·82-8), • Diisobutyl phthalate (DIBP) (CAS# 84-69-5), • Diisopentyl phthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CAS# 131-18-0), • Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), or • N-pentyl-isopentylphthalate (CAS# 776297-69-9) in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w). Furthermore, these products are not designed to contain any phthalates.
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 02 February 2019, the articles with the product numbers above are not formulated with natural rubber latex.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per 13 March 2019, BD has not identified any • 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w). There are polycarbonate components in these products. Bisphenol A (BPA), CAS# 80-05-7, is an organic compound that is a chemical building block for polycarbonate. Based on information from our suppliers and BD test results, the BPA level is less than 0.1% wt/wt «1000 ppm). These levels are below a de minimis concentration with no demonstrable clinically significant exposure nor toxicity. No labeling for California Prop 65 is needed. No REACH SVHC declaration is required.
Substances of animal origin BSE/TSE	The raw materials used in the manufacture of these devices do not contain any animal tissue but may contain very small amounts of chemicals that are derived from animal-derived raw materials. These products are manufactured using polymer resins which may contain very small amounts of stearic acids and related substances derived from tallow derivatives. Our resin suppliers have confirmed that these tallow-derived materials have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN 22442-1 and Section 6 of EMA 410/01 Rev. 3. Therefore, these raw materials meet or exceed the requirements of EN ISO 22442-1 and EMA 410/01 Rev. 3. Based on this information, these products are considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, as recognized by MEDDEV 2.4/1, such derivative chemicals produced in accordance with the aforementioned standards and guidelines are considered irrelevant when determining the classification of a medical device (per MDD 93/42/EEC and EU No 722/2012).
Polyvinyl chloride (PVC)	The medical devices referenced above do contain PVC which is not formulated with any regulated phthalates.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 13 March 2019, BD has not identified any chemicals in the articles and packaging of BD Connecta™ Stopcock with extension, in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate list" published by the European Chemical Agency (ECHA) on 27 June 2018 according to Art. 59 (1,10) of the Regulation (EC) N°1907/2006 (REACH).

1.7 Biocompatibility

BD Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices.

1.8 Sterilization method

Sterilization method: **Radiation** (EN ISO 11137-1 "Sterilization for Healthcare products-Radiation –Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices).

1.9 Shelf life and storage conditions

The BD Connecta™ Stopcock with extension tube shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Connecta™ Stopcock with extension tube have a shelf life of 3 years.

Store in a dry and warm place, not exposed to strong light.

1.10 Standards

As per extract from the Declaration of Conformity:

Harmonized Standards	
EN 556-1:2001	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices.
EN 20594-1:1993	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

Harmonized Standards	
EN ISO 11137-1:2006	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2013	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
EN ISO 11737-1:2006	Sterilization of medical devices – Microbial methods- Part 1 : Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
EN 980:2008	Symbols for use in the labelling of medical devices
EN 62366:2008	Medical devices. Application of usability engineering to medical devices
Non-Harmonized Standards	
ISO 14644-1:1999	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
ISO 594-2:1998	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment –Part 2: Lock Fittings
EN ISO 15223-1:2012	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements

Note:
The above standards reflect the status at the time of drafting this document. More information or updates are available on request in the Declaration of Conformity.

1.11 Classification

The products have been classified in accordance with the Medical Devices Directive Annex IX as amended. Rule 2 is applicable and the products belong to Class IIa.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Connecta™ Stopcock with extension are referenced as follows:
GMDN Code: 32172
GMDN Term: Infusion Stopcock

1.13 Manufacturing practices

The entire manufacturing and testing processes are following the Manufacturing Practices as specified below:

- Incoming raw materials are verified via material inspection and testing and our suppliers are approved via our vendor management system.
- In addition to the automatic on-line inspections, in-process inspections are performed in addition to final product testing to ensure compliance with approved specifications.
- The manufacturing and testing details of each batch of product are recorded on a batch record which is retained in accordance with our document control procedures.
- BD operates a system of internal and external audits to maintain compliance.
- BD confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact *(Commission Regulation EU 1183/2012 on "plastic materials and articles intended for contact with food" and Directive 2002/72/CE (as amended) "relating to plastic materials and articles intended to come into contact with foodstuffs")* is not required as BD products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
- Good Manufacturing Practices as defined by the FDA Pharmaceutical is not applicable for Medical Devices.

2. Packaging

2.1 Packaging configuration

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
394995	CONNECTA PLUS3 10CM WHITE	1	50	250	Yes
394997	CONNECTA PLUS3 10CM BLUE	1	50	250	Yes
394926	CONNECTA WHT 360DEG TB 25CM	1	20	100	Yes
394951	CONNECTA WHT 360DEG TB 50CM	1	20	100	Yes
394961	CONNECTA WHT 360DEG TB 100 CM	1	20	100	Yes
394982	CONNECTA WHT 360DEG LOW VOLUME TB 15CM	1	50	250	Yes
394983	CONNECTA WHT 360DEG LOW VOLUME TB 30CM	1	50	250	Yes

*"No": IFU may be available but not as an insert.

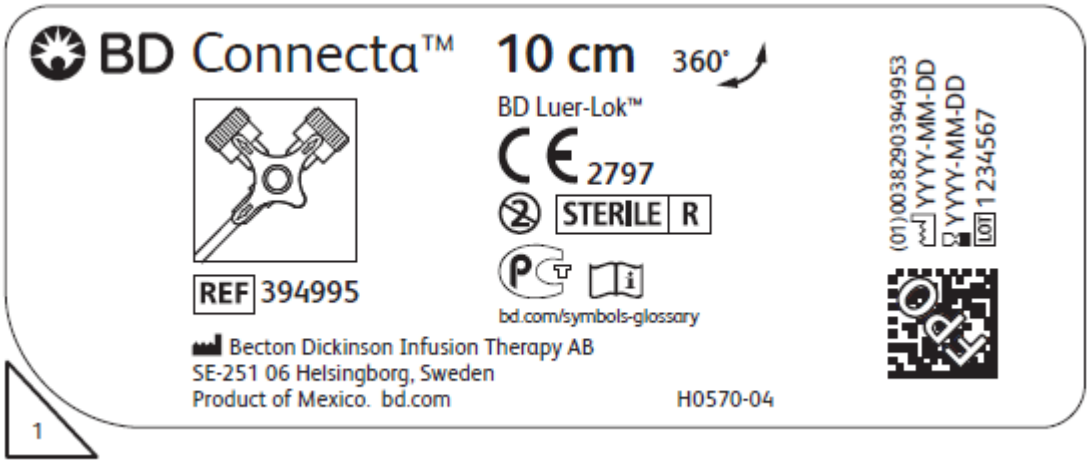
2.2 Packaging material

Component	Material
Unit Pack	Plastic film and medical grade paper
Shelf Box	Cardboard
Shipping Case	Cardboard
IFU	Paper

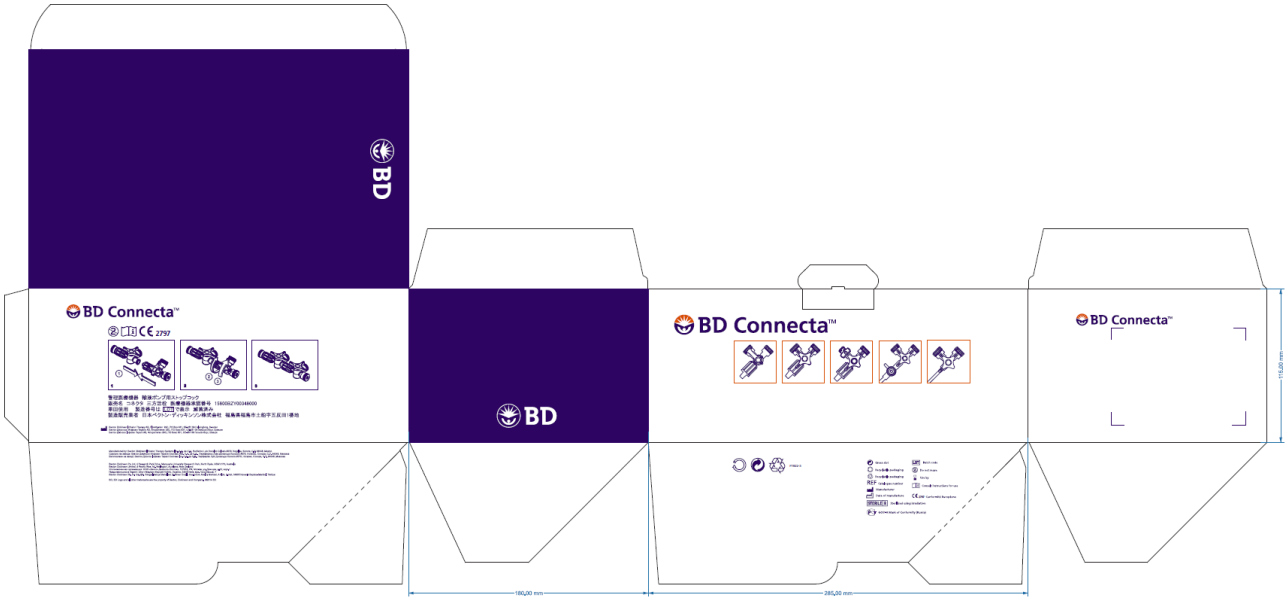
2.3 Examples of labeling

Labels: According to European Medical Device directive, labels are multilingual.

Primary Packaging Label (Top Web) extracted from document H0570 related to reference 394995:

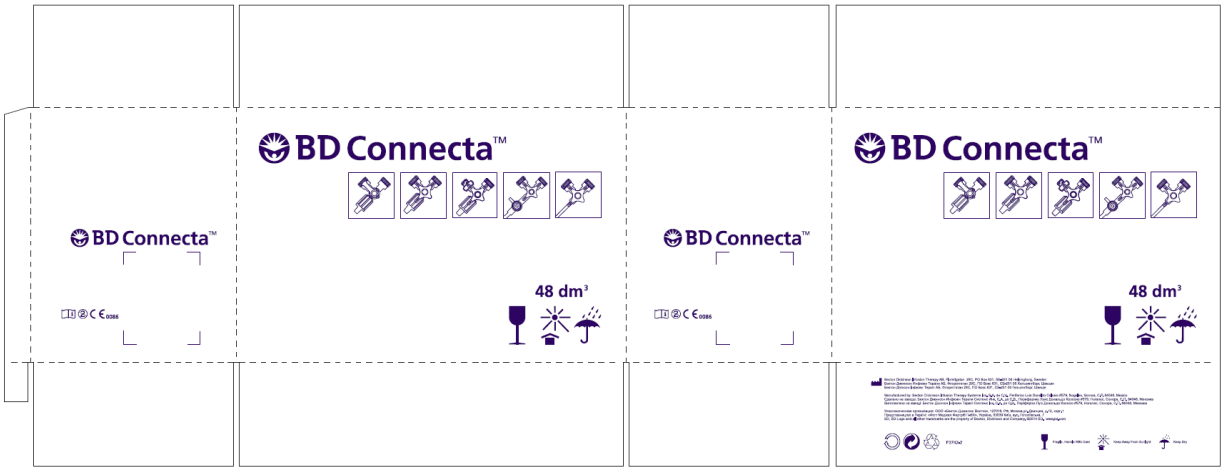


Shelf Box extracted from document F1922 related to reference 394995:

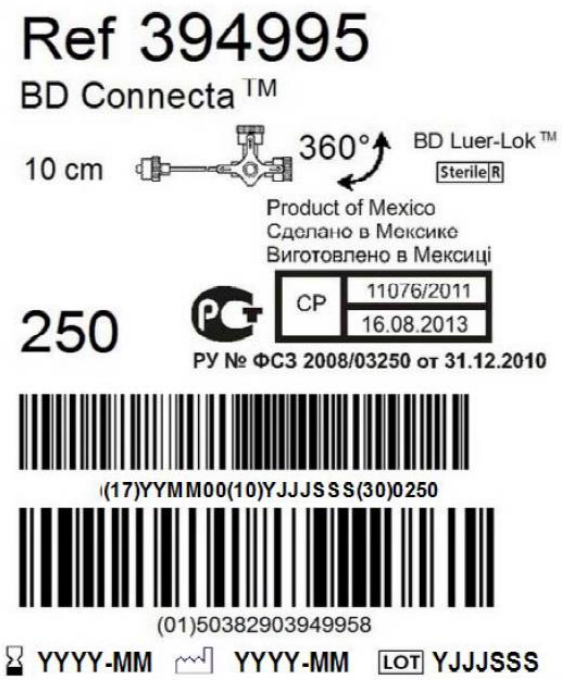


Shelf label extracted from document D16662 related to reference 394995:

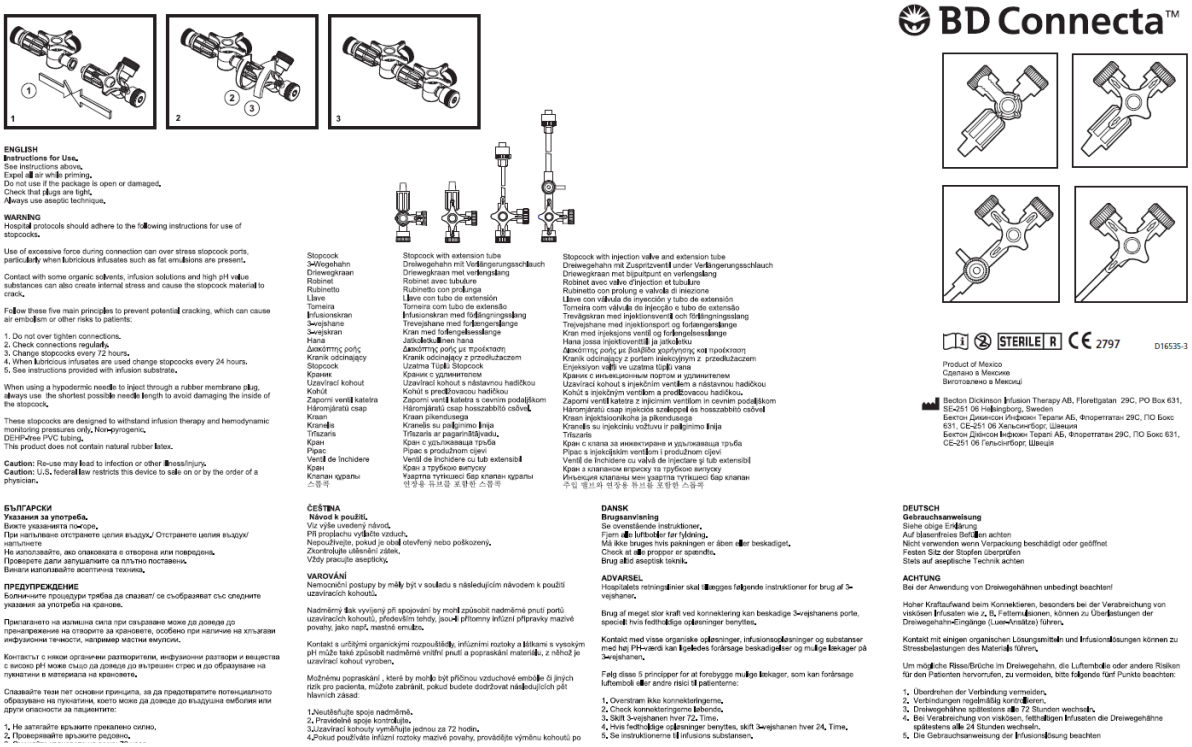
Shipping Case extracted from document F3742 related to reference 394995:



Case Label extracted from document D16663 related to reference 394995:



IFU insert extracted from document D16535 related to reference 394995:



ENGLISH
Instructions for Use.
See instructions above.
Expel all air while priming.
Do not use if the package is open or damaged.
Check that plugs are tight.
Always use aseptic technique.

WARNING
Hospital protocols should adhere to the following instructions for use of stopcocks.

Use of excessive force during connection can over stress stopcock ports, particularly when lubricious infusates such as fat emulsions are present.

Contact with some organic solvents, infusion solutions and high pH value substances can also create internal stress and cause the stopcock material to crack.

Follow these five main principles to prevent potential cracking, which can cause air embolism or other risks to patients:

1. Do not over tighten connections.
2. Check connections regularly.
3. Change stopcocks every 72 hours.
4. When lubricious infusates are used change stopcocks every 24 hours.
5. See instructions provided with infusion substrate.

When using a hypodermic needle to inject through a rubber membrane plug, always use the shortest possible needle length to avoid damaging the inside of the stopcock.

These stopcocks are designed to withstand infusion therapy and hemodynamic monitoring pressures only. Non-pyrogenic.
DEHP-free PVC tubing.
This product does not contain natural rubber latex.

Caution: Re-use may lead to infection or other illness/injury.
Caution: U.S. federal law restricts this device to sale on or by the order of a physician.

Stopcock
3-Wegehahn
Driewegkraan
Robinet
Rubinetto
Llave
Torneira
Infusionskran
3-vejshane
3-vejskran
Hana
Διακόπτης ροής
Kranik odcinający
Stopcock
Краник
Uzavírací kohout
Kohút
Zapomi ventil katetra
Háromjáratú csap
Kraan
Kranelis
Trīsceļu
Кран
Pipac
Ventil de închidere
Кран
Кланан құралы
스톱콕

Stopcock with extension tube
Dreiwegehahn mit Verlängerungsschlauch
Driewegkraan met verlengslang
Robinet avec tubulure
Rubinetto con prolunga
Llave con tubo de extensión
Torneira com tubo de extensão
Infusionskran med förlängningsslang
Trevejshane med forlængerslange
Kran med forlengelsesslange
Jatkeletkullinen hana
Διακόπτης ροής με προέκταση
Kranik odcinający z przedłużaczem
Uzatma Tüplü Stopcock
Краник с удлинителем
Uzavírací kohout s nástavnou hadičkou
Kohút s predĺžovacou hadičkou
Zapomi ventil katetra s cevnim podaljškom
Háromjáratú csap hosszabbító csővel
Kraan pikendusega
Kranelis su pailginimo linija
Trīsceļu ar pagarinātāju
Кран с клапа за инжектиране и удължаваща тръба
Pipac s produžnom cijevi
Ventil de închidere cu tub extensibil
Кран з трубкою випуску
Кранан қуралы
연장용 튜브를 포함한 스톱콕

Stopcock with injection valve and extension tube
Dreiwegehahn mit Zusprtzventil under Verlängerungsschlauch
Driewegkraan met bijsputpunt en verlengslang
Robinet avec valve d'injection et tubulure
Rubinetto con prolunga e valvola di iniezione
Llave con válvula de inyección y tubo de extensión
Torneira com válvula de injecção e tubo de extensão
Trevägskran med injektionsventil och förlängningsslang
Trevejshane med injektionsport og forlængerslange
Kran med injeksjons ventil og forlengelsesslange
Hana jossa injektioventtiili ja jatkoletku
Διακόπτης ροής με βαλβίδα χορήγησης και προέκταση
Kranik odcinający z portem iniekcyjnym z przedłużaczem
Enjeksiyon valfi ve uzatma tüplü vana
Краник с инъекционным портом и удлинителем
Uzavírací kohout s injekčním ventilem a nástavnou hadičkou
Kohút s injekčným ventilom a predĺžovacou hadičkou
Zapomi ventil katetra z injicirnim ventilom in cevnim podaljškom
Háromjáratú csap injekciós szeleppel és hosszabbító csővel
Kraan injektsioonikoha ja pikendusega
Kranelis su injekciniu vožtuvu ir pailginimo linija
Trīsceļu
Кран с клапа за инжектиране и удължаваща тръба
Pipac s injekcijskim ventilom i produžnom cijevi
Ventil de închidere cu valvă de injectare și tub extensibil
Кран з клапаном впрыску та трубкою випуску
Инъекция клапаны мен ұзартпа түтікшесі бар кранан
주입 밸브와 연장용 튜브를 포함한 스톱콕

BD Connecta™

STERILE R CE 2797 D16535-3

Product of Mexico
Сделано в Мексике
Виготовлено в Мексиці

Becton Dickinson Infusion Therapy AB, Floretigatan 29C, PO Box 631, SE-251 06 Helsingborg, Sweden
Бектон Дикинсон Инфюжн Терапи АБ, Флоретгатан 29С, ПО Бокс 631, СЕ-251 06 Хельсингборг, Швеция
Бектон Дікінсон Інфюжн Терапі АБ, Флоретгатан 29С, ПО Бокс 631, СЕ-251 06 Гельсінборг, Швеція

БЪЛГАРСКИ
Указания за употреба.
Вижте указанията по-горе.
При напълване отстранете целия въздух./ Отстранете целия въздух/ напълнете
Не използвайте, ако опаковката е отворена или повредена.
Проверете дали запушалките са плътно поставени.
Винаги използвайте асептична техника.

ПРЕДУПРЕЖДЕНИЕ
Болничните процедури трябва да спазват се съобразяват със следните указания за употреба на кранове.

Прилагането на излишна сила при свързване може да доведе до пренапрежение на отворите за кранчетата, особено при наличие на хлъзгави инфузионни течности, например мастни емулсии.

Контактът с някои органични разтворители, инфузионни разтвори и вещества с високо pH може също да доведе до вътрешен стрес и до образуване на пукнатини в материала на крановете.

Спазвайте тези пет основни принципа, за да предотвратите потенциалното образуване на пукнатини, което може да доведе до въздушна емболия или други опасности за пациентите:

1. Не затягайте връзките прекалено силно.
2. Проверявайте връзките редовно.

ČEŠTINA
Návod k použití.
Viz výše uvedený návod.
Při proplachu vyhněte vzduch.
Nepoužívejte, pokud je obal otevřený nebo poškozený.
Zkontrolujte utěsnění zátek.
Vždy pracujte asepticky.

VAROVÁNÍ
Nemocniční postupy by měly být v souladu s následujícím návodem k použití uzavíracích kohoutů.

Nadměrný šlak vyvíjený při spojování by mohl způsobit nadměrné pnutí portů uzavíracích kohoutů, především tehdy, jsou-li přítomny infúzní přípravky mazivé povahy, jako např. mastné emulze.

Kontakt s určitými organickými rozpouštědly, infúzními roztoky a látkami s vysokým pH může také způsobit nadměrné vnitřní pnutí a popraskání materiálu, z něhož je uzavírací kohout vyroben.

Možnému popraskání , které by mohlo být příčinou vzduchové embolie či jiných rizik pro pacienta, můžete zabránit, pokud budete dodržovat následujících pět hlavních zásad:

1.Neutěsňujte spoje nadměrně.
2. Pravidelně spoje kontrolujte.
3.Uzavírací kohouty vyměňujte jednou za 72 hodin.
4.Pokud používáte infúzní roztoky mazivé povahy, provádějte výměnu kohoutů po

DANSK
Brugsanvisning
Se ovenstående instruktioner.
Fjern alt luftboble før fyldning.
Må ikke bruges hvis pakningen er åben eller beskadiget.
Check at alle propper er spændte.
Brug altid aseptisk teknik.

ADVARSEL
Hospitalets retningslinier skal følgeges følgende instruktioner for brug af 3-vejshaner.

Brug af meget stor kraft ved konnektering kan beskadige 3-vejshanens porte, specielt hvis fedtholdige opløsninger benyttes.

Kontakt med visse organiske opløsninger, infusionsopløsninger og substanser med høj PH-værdi kan ligeledes forårsage beskadigelser og mulige lækager på 3-vejshanen.

Følg disse 5 principper for at forebygge mulige lækager, som kan forårsage luftemboli eller andre risici til patienterne:

1. Overstram ikke konnekteringerne.
2. Check konnekteringerne løbende.
3. Skift 3-vejshanen hver 72. Time.
4. Hvis fedtholdige opløsninger benyttes, skift 3-vejshanen hver 24. Time.
5. Se instruktionerne til infusions substansen.

DEUTSCH
Gebrauchsanweisung
Siehe obige Erklärung
Auf blasenfreies Befüllen achten
Nicht verwenden wenn Verpackung beschädigt oder geöffnet
Festen Sitz der Stopfen überprüfen
Stets auf aseptische Technik achten

ACHTUNG
Bei der Anwendung von Dreiwegehähnen unbedingt beachten!

Hoher Kraftaufwand beim Konnektieren, besonders bei der Verabreichung von viskösen Infusaten wie z, B, Fettemulsionen, können zu Überlastungen der Dreiwegehahn-Eingänge (Luer-Ansätze) führen.

Kontakt mit einigen organischen Lösungsmitteln und Infusionslösungen können zu Stressbelastungen des Materials führen,

Um mögliche Risse/Brüche im Dreiwegehahn, die Luftemboile oder andere Risiken für den Patienten hervorrufen, zu vermeiden, bitte folgende fünf Punkte beachten:

1. Überdrehen der Verbindung vermeiden,
2. Verbindungen regelmäßig kontrollieren,
3. Dreiwegehähne spätestens alle 72 Stunden wechseln,
4. Bei Verabreichung von viskösen, fetthaltigen Infusaten die Dreiwegehähne spätestens alle 24 Stunden wechseln,
5. Die Gebrauchsanweisung der Infusionslösung beachten

REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	Product picture added. Correction of Product description for 394983 and additional information added for Low Volume Extension tube. Updated label extracts.