BD Venflon™ Pro Safety,
I.V. Cannula
Sterile, Single use

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1. General Information

1.1 Intended use

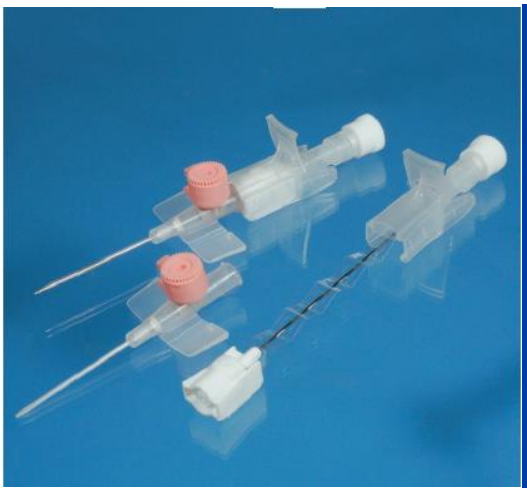
The BD™ Venflon Pro Safety is designed to access the peripheral veins of the patient's blood system for rehydration, parenteral nutrition, medication delivery, blood transfusion and monitoring purposes. A special product feature is the needle tip protection device, which is activated when the steel needle is withdrawn. It covers the steel needle tip and protect against accidental needle stick.

The catheters are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa) with the maximum flow rate as shown below:

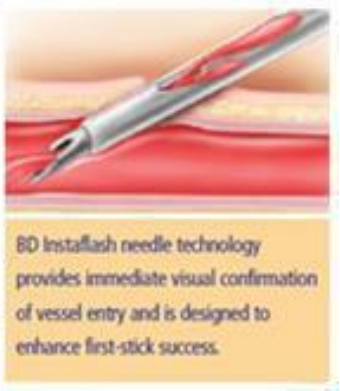
Gauge x Length	Maximum Power injector Flow Rate for Contrast Media Viscosity ≤11.8 cP (mPa s)	Maximum Power injector Flow Rate for Contrast Media Viscosity ≤ 27.5 cP (mPa s)	Maximum Power Injector Pressure Limit Setting
18GA 1.3mm x 45mm	18 mL/s	14 mL/s	325 psi (2240 kPa)
18GA 1.3mm x 32mm	18 mL/s	14 mL/s	
20GA 1.1mm x 32MM	12 mL/s	9 mL/s	
22GA 0.9mm x 25mm	7 mL/s	5 mL/s	

1.2 General description

The BD Venflon Pro Safety Needle Protected I.V. Cannula with Vialon™ catheter and injection port is a single-use disposable device in the Becton Dickinson Infusion Therapy AB range of peripheral I.V. Catheters.



BD Venflon Pro Safety catheter with gauge size of 18GA, 20GA and 22GA are also available with BD Instaflash Needle Technology features, which serves for earlier visualization of flashback via a notch in the cannula.



Catheter Dwell Time - BD does not specify a minimum or maximum in situ dwell time for this catheter family. Catheter dwell times must be dictated by healthcare organization procedures, national clinical guidelines, each clinical environment and the clinical status of each patient.

BD Catalog Number	BD Product Description	Gauge Size	Length (mm)	Color Code	Flow rate (ml/min)
BD Venflon™ Pro Safety I.V. Cannula					
393222	VENFLON PRO SAFETY 22GA 0.9MM OD 25MM L	22	25	Blue	42
393224	VENFLON PRO SAFETY 20GA 1.1MM OD 32MM L	20	32	Pink	67
393226	VENFLON PRO SAFETY 18GA 1.3MM OD 32MM L	18	32	Green	103
393227	VENFLON PRO SAFETY 18GA 1.3MM OD 45MM L	18	45	Green	103
393228	VENFLON PRO SAFETY 17GA 1.5MM OD 45MM L	17	45	White	133
393229	VENFLON PRO SAFETY 16GA 1.8MM OD 45MM L	16	45	Grey	236
393230	VENFLON PRO SAFETY 14GA 2.0MM OD 45MM L	14	45	Orange	270
393242	VENFLON PRO SAFETY 22GA INDIA	22	25	Blue	42
393244	VENFLON PRO SAFETY 20GA INDIA	20	32	Pink	67
393246	VENFLON PRO SAFETY 18GA 32MM L INDIA	18	32	Green	103
393247	VENFLON PRO SAFETY 18GA 45MM L INDIA	18	45	Green	103
393248	VENFLON PRO SAFETY 17GA INDIA	17	45	White	133
393249	VENFLON PRO SAFETY 16GA INDIA	16	45	Grey	236
393250	VENFLON PRO SAFETY 14GA INDIA	14	45	Orange	270
BD Venflon™ Pro Safety I.V. Cannula with Instaflash™ Needle Technology					
393280	VPS 22GA 0.9MM OD 25MM L INSTAFLASH	22	25	Blue	42
393281	VPS 20GA 1.1MM OD 32MM L INSTAFLASH	20	32	Pink	67
393282	VPS 18GA 1.3MM OD 32MM L INSTAFLASH	18	32	Green	103
393283	VPS 18GA 1.3MM OD 45MM L INSTAFLASH	18	45	Green	103
393284	VPS 22GA INDIA INSTAFLASH	22	25	Blue	42
393285	VPS 20GA INDIA INSTAFLASH	20	32	Pink	67
393286	VPS 18GA 32MM L INDIA INSTAFLASH	18	32	Green	103
393287	VPS 18GA 45MM L INDIA INSTAFLASH	18	45	Green	103

Note: Please check BD catalog number availability in your country.
The BD Product Description can slightly differ from the Declaration of Conformity; please always refer to the BD Catalog Number.

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)
393222 393224 393226 393227 393228 393229 393230 393242 393244 393246 393247 393248 393249 393250 393280 393281 393282 393283 393284 393285 393286 393287	**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 Medical Pte Ltd. 30 Tuas avenue 2 Singapore 639461 Singapore **ISO 13485** Certificate No.: MD 81426	N/A

1.4 Materials

Component	Material
Cannula hub	Polypropylene
Needle hub	Polypropylene
Flow control plug	Polypropylene
Plug	Polypropylene with white master batch
Protection cap	Polypropylene with colored master batch
Protection hub	Polyethylene
V-Clip	Stainless steel
Foil	Clear printable polyester
Valve	Methyl vinyl polysiloxane
Catheter tubing	Polyurethane Vialon
Catheter bushing	Polyetherimide
Cannula	Stainless steel
Silicone liquid	Polydimethylsiloxane

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 June 2020, BD has not identified any • 1,2-Benzendicarboxylic acid, dihexyl ester (branched & linear) (CAS#68515-50-4), • 1,2-Benzendicarboxylic acid, di-C6-8-branched alkyl esters (CAS#71888-89-6), • 1,2-Benzendicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS#68515-42-4), • 1,2-Benzendicarboxylic acid, di-C6-10 alkyl esters (CAS#68515-51-5), • 1,2-Benzendicarboxylic acid, mixed decyl, hexyl, and octyl diesters (CAS#68648-93-1), • Benzyl butyl phthalate (BBP) (CAS# 85-68-7), • Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), • Bis (2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), • Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), • Dibutyl phthalate (DBP) (CAS# 84-74-2), • Diisobutyl phthalate (DIBP) (CAS# 84-69-5), • Diisopentylphthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CAS# 131-18-0), • N-pentyl-isopentylphthalate (CAS# 776297-69-9), or • Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7) in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w).
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per June 2020, 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 June 2020, BD has not identified any Bisphenol A (BPA), CAS# 80-05-7, in the articles with the Product Numbers as referenced above. It is not a building block of any of the raw materials utilized and is not intentionally added. BD has not done any testing to evaluate levels of this chemical in these products.
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 chemicals have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN ISO 22442-1:2015 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 have not been designed nor intentionally manufactured with any additives or raw materials that contain PVC. No PVC is intentionally added to these medical devices.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per June 2020, BD has not identified any chemicals in the articles and packaging with the Product Numbers as referenced above, 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 15 January 2019 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

All references could be sterilized by either (sterilization method is indicated on the labels):

- **Ethylene Oxide Sterilization** method validated in compliance with EN ISO 11135 *(Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices).*

- **Radiation sterilization** method validated in compliance with EN ISO 11137-1 *(Sterilization of health care 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 Venflon™ Pro Safety shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time. BD Venflon™ Pro Safety have a shelf life of 3 years.

There are no specific transportation and storage conditions associated with these devices, but it is recommended to maintain products at conditions of transportation and storage between 0-46°C targeting 25°C

1.10 Standards

As per extract from the Declaration of Conformity (document number TF010HEL-DOC) linked to CE certificate number CE 597884:

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 10555-1:2009	Sterile, single use intravascular catheters – General Requirements
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
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 ISO 11135-1:2014	Sterilization of health care products. Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices
Non-Harmonized Standards	
ISO 594-2:1998	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment –Part 2: Lock Fittings
ISO 14644-1:1999	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness
ISO 9626:1991	Stainless steel needle tubing for the manufacture of medical devices
ISO 10555-1:2013	Sterile, single use intravascular catheters – General Requirements
ISO 10555-5:2013	Sterile, single use intravascular catheters – Over needle peripheral catheters
ISO 23908:2011	Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
EN ISO 15223-1:2016	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

BD Venflon™ Pro Safety products are classified as Class IIa medical device as defined in the Medical Devices Directive (93/42/EEC) Annex IX, section 2.3, Rule 7.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Venflon™ Pro Safety is referenced as follows:
GMDN Code: 64574
GMDN Term: Peripheral intravenous catheter

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*
BD Venflon™ Pro Safety I.V. Cannula					
393222	VENFLON PRO SAFETY 22GA 0.9MM OD 25MM L	1	50	500	Yes
393224	VENFLON PRO SAFETY 20GA 1.1MM OD 32MM L	1	50	500	Yes
393226	VENFLON PRO SAFETY 18GA 1.3MM OD 32MM L	1	50	500	Yes
393227	VENFLON PRO SAFETY 18GA 1.3MM OD 45MM L	1	50	500	Yes
393228	VENFLON PRO SAFETY 17GA 1.5MM OD 45MM L	1	50	500	Yes
393229	VENFLON PRO SAFETY 16GA 1.8MM OD 45MM L	1	50	500	Yes
393230	VENFLON PRO SAFETY 14GA 2.0MM OD 45MM L	1	50	500	Yes
393242	VENFLON PRO SAFETY 22GA INDIA	1	50	500	Yes
393244	VENFLON PRO SAFETY 20GA INDIA	1	50	500	Yes
393246	VENFLON PRO SAFETY 18GA 32MM L INDIA	1	50	500	Yes
393247	VENFLON PRO SAFETY 18GA 45MM L INDIA	1	50	500	Yes
393248	VENFLON PRO SAFETY 17GA INDIA	1	50	500	Yes
393249	VENFLON PRO SAFETY 16GA INDIA	1	50	500	Yes
393250	VENFLON PRO SAFETY 14GA INDIA	1	50	500	Yes
BD Venflon™ Pro Safety I.V. Cannula with Instaflash™ Needle Technology					
393280	VPS 22GA 0.9MM OD 25MM L INSTAFLASH	1	50	500	Yes
393281	VPS 20GA 1.1MM OD 32MM L INSTAFLASH	1	50	500	Yes
393282	VPS 18GA 1.3MM OD 32MM L INSTAFLASH	1	50	500	Yes
393283	VPS 18GA 1.3MM OD 45MM L INSTAFLASH	1	50	500	Yes
393284	VPS 22GA INDIA INSTAFLASH	1	50	500	Yes
393285	VPS 20GA INDIA INSTAFLASH	1	50	500	Yes
393286	VPS 18GA 32MM L INDIA INSTAFLASH	1	50	500	Yes
393287	VPS 18GA 45MM L INDIA INSTAFLASH	1	50	500	Yes

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

2.2 Packaging material

Component	Material
Unit Pack	Top Web: Medical grade Paper Bottom Web: APET foil
Shelf Box	Bleached folding duplex boxboard
Shipping Case	Case Carton
IFU	Paper

2.3 Examples of labeling

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

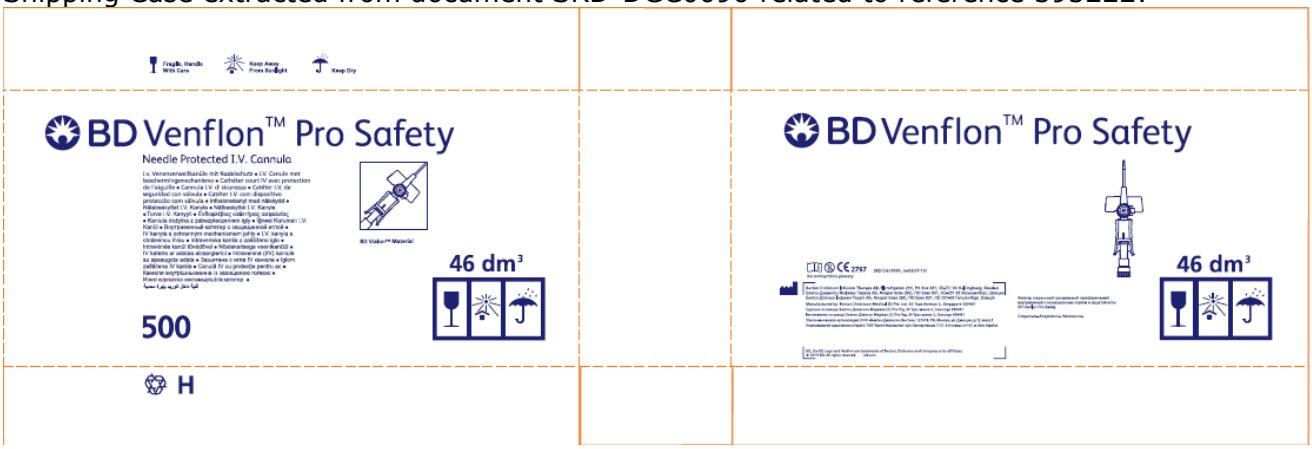
Primary Packaging Label (Top Web) extracted from document SRD-DGW0160 related to reference 393222 (EO sterilized):

Variable information prints as shown within a 25.4mm x 25mm area.

Shelf Box extracted from document SRD-DGF0083 related to reference 393222:

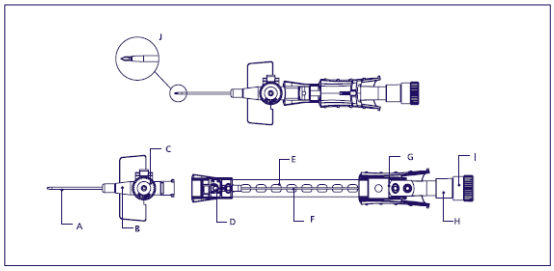
Shelf Box label extracted from document SRD-DGL0352 related to reference 393222 (EO sterilized):

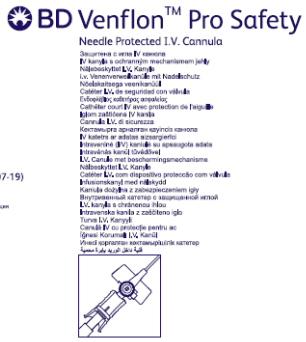
Shipping Case extracted from document SRD-DGC0090 related to reference 393222:



Case Label extracted from document SRD-DGL0383 related to reference 393222:

IFU insert (English part only) extracted from document SRD-DGP0037 (EO sterilized)





	Maximum Power injector Flow Rate for Contrast Media Viscosity ≤11.8 cP (mPa s)	Maximum Power injector Flow Rate for Contrast Media Viscosity ≤ 27.5 cP (mPa s)	Maximum Power Injector Pressure Limit Setting
18GA 1.3mm x 45mm	18 mL/s	14 mL/s	325 psi(2240 kPa)
18GA 1.3mm x 32mm	18 mL/s	14 mL/s	
20GA 1.1mm x 32mm	12 mL/s	9 mL/s	
22GA 0.9mm x 25mm	7 mL/s	5 mL/s	

English
Maximum Power Injector Flow Rate for Contrast Media Viscosity. Maximum Power Injector Pressure Limit Setting.

Български
Максимален дебит на инжектирането под налягане според вискозитета на контрастното вещество. Настройка на максимална гранична стойност на налягането на уреда за инжектиране.

Čeština
Maximální rychlost průtoku automatického injektoru s ohledem na viskozitu kontrastní látky. Nastavení maximálního mezního tlaku automatického injektoru.

Dansk
Maksimal højtryksinjektorgennemstrømning for kontrastmiddelviskositet. Maksimal indstilling for højtryksinjektorens trykbegrænsning.

Deutsch
Maximale Flussrate des Hochdruckinjektors für Viskosität der Kontrastmittel. Maximale Druckbegrenzungseinstellung für Hochdruckinjektor.

Eesti
Voolujaoturi maksimaalne voolukiirus kontrastaine viskoossuseks. Voolujaoturi maksimaalse piirväärtuse säte.

Español
Caudal máximo de servoinyector correspondiente a la viscosidad del medio de contraste. Ajuste del límite de presión máxima del servoinyector.

Ελληνικά
Μέγιστη παροχή εγχυτήρα ισχύος για ιξώδες μέσου αντίθεσης. Ρύθμιση ορίου πίε
ισχύος εγχυτήρα.

Français
Débit maximum de l'injection à pression pour la viscosité du produit de contraste. Limite maximale de la pression de l'injecteur à pression.

Hrvatski
Najveća snaga protoka injektora za viskoznost kontrastnog sredstva. Ograničenje najvećeg tlaka injektora

Italiano
Portata massima del flusso dell'iniettore a pressione per la viscosità del mezzo di Impostazione del limite di pressione massimo dell'iniettore a pressione.

Қазақша
Контрасты құрал тұтқырлығына арналған максималды қуат инжекторы ағын
Максималды қуат инжекторы қысымы шегінің параметрі.

Latviešu
Automātiskās injicēšanas ierīces pīkšmas ātrums kontrastvielas viskozitātei. Mak
automātiskās injicēšanas ierīces spiediena ierobežojuma iestatīšana.

Русский
Максимальный расход инфузионного насоса для вязких контрастных препар
Установка ограничения максимального давления инфузионного насоса.

ENGLISH

BD Needle Protected I.V. Cannula

Instructions for Use.
Read before use.

(A) BD Vialon™ Catheter, (B) Catheter Hub, (C) Injection Port with Flip Cap, (D) Needle Cap, (E) Tether, (F) Needle, (G) Needle Grip, (H) Flashback Chamber, (I) Plug

Although this device is designed to help prevent accidental needle stick injury when used in accordance with its instructions, effective, safe working procedures and Universal Precautions must be maintained during its use and disposal.

Clinicians must be trained in the practice of venipuncture and catheter insertion and be aware of inherent dangers.
Aseptic technique, proper skin preparation and continued protection of the site are essential.

NON PYROGENIC-STERILE: Do not use if the package is open or damaged.

This product does not contain natural rubber latex. This product is DEHP free.

CAUTIONS
- Caution: Re-use may lead to infection or other illness/injury.
- Holding or obstructing the plastic tether during use may result in failure of the protection mechanism to activate.
- Do not try to detach the needle protection mechanism from the plastic tether.
- Do not detach the needle protection mechanism from the catheter hub with fingers, release by fully withdrawing the needle as normal.
- Minimise blood exposure by applying finger-tip pressure to occlude the vein above the catheter tip during needle withdrawal.
- Check insertion site regularly and remove device immediately if signs of phlebitis are present.
- DO NOT use scissors at or close to the insertion site.
- Never reinsert the needle into the catheter.
- Always visually check that the safety mechanism has fully activated.
- If the needle protection mechanism fails, do not attempt to manually activate it. Doing so may cause needlestick injuries. Discard the needle immediately into a sharps collector.
- To minimize the risk of contamination, observe Universal precautions on ALL patients.
- REPORT NEEDLESTICKS IMMEDIATELY AND FOLLOW ESTABLISHED PROTOCOL. Exposure to blood, either through percutaneous puncture with a contaminated needle or via mucous membranes may lead to serious illnesses such as hepatitis, HIV (AIDS), or other infectious diseases.
- DO NOT resheath contaminated needles. Resheathing needles is hazardous.

Directions for Use:
1. Carefully remove needle cover in a straight outward motion and inspect the catheter unit.
2. Needle and catheter tip should be properly aligned.
3. Ensure that needle bevel is facing upward on insertion (see J above). Perform venipuncture. (18-22Ga with BD Instaflash™ Needle Technology: blood return will be visible in the catheter)
4. Observe for flashback in flashback-chamber.
5. Upon visualization of blood return, lower and advance the entire catheter and needle unit slightly to ensure the catheter tip is within the vessel.
6. Holding the flash chamber stationary, advance the catheter off the needle into the vein. When removing the needle occlude vein just above cannula tip and withdraw needle holding needle grip.
7. Do not bend the needle during withdrawal.
8. As the catheter slides off the needle a plastic tether will begin to extend over the needle from the needle grip.
9. Once the needle is fully released the needle-tip protector will cover the tip of needle.
10. Immediately discard the needle in an approved sharps container.
11. Ensure that the protective cap of the port is closed.
12. Secure the catheter and apply sterile dressing as per protocol.

Indications for Use:
These devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa).
Power Injection
NOTE: If power injecting through an access port, ensure access port is capable of power injection.
1.Ensure catheter patency according to your facility protocol immediately before power injection.
WARNING: Failure to ensure patency of the catheter may result in catheter failure and/or extravasation.
2.Avoid kinking or obstructing the catheter during power injection.
WARNING: In the event of an occlusion, power injector pressure-limiting features may not prevent catheter failure.

REVISION	CHANGE SUMMARY
01	Initial release according to new template