Document Number: EMEA-SOP039-F1	Rev. Lev.: 02
Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

BD® Venflon™ Pro Safety Needle Protected IV Cannula
Sterile, Single-use
Product codes: 393222, 393224, 393226, 393227, 393228, 393229, 393230

BD® Venflon™ Pro Safety Needle Protected IV Cannula with BD® Instaflash™ Needle Technology
Sterile, Single-use
Product codes: 393280, 393281, 393282, 393283

Becton Dickinson
Infusion Therapy Systems Inc.
9450 South State Street
Sandy, Utah
84070 USA

TDS number: V201-057 – Rev. 03
Veeva Vault number: BD-134334
2026-April

1. General Information

1.1 Intended purpose

Venflon™ Pro Safety Needle Protected IV Cannula and **Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology** are designed to access the peripheral vasculature of the patient's blood system for rehydration, parenteral nutrition, medication delivery, blood transfusion, and monitoring purposes. The 22-18 G (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa).
Risk of reuse statement: Devices referenced in this document are intended for single use only. Reuse may lead to infection or other illness/injury. All product labelling bears the single use symbol, and the risk of reuse statement shown above has been included in the product Instructions For Use per MDR (EU) 2017/745, Annex I, GSPR 23.2 (n).

1.2 Intended User

Clinicians must be trained in the practice of venipuncture and catheter insertion and be aware of inherent dangers.

1.3 General Medical Devices description

Venflon™ Pro Safety Needle Protected IV Cannula is an over-the-needle, intravascular (IV) catheter. This device has a BD Vialon™ Catheter Material, a needle grip, a passive safety needle shield, and a flash chamber with a removable flow control plug. The wings attached to the catheter hub can be used for securement after catheter insertion. The needle and catheter are protected by a needle cover.
The flash chamber provides confirmation that the device has entered the vessel. The removable flow control plug can be removed and connected to the IV cannula hub after catheter insertion (optional).
A separate injection port is located on the catheter hub. The injection port can be used for immediate intravenous injection using a syringe without a hypodermic needle. In addition, the injection port can be used for intermittent injections even when a continuous infusion is connected to the IV cannula hub.

The injection port is protected by a cap. The injection port cap is color codes to indicate catheter gauge size (22G (0.9 mm) = Blue, 20G (1.1 mm) = Pink, 18G (1.3 mm) = Green, 17G (1.5 mm) = White, 16G (1.8 mm) = Grey, 14G (2.0 mm) = Orange).

Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology is an over-the-needle, intravascular (IV) catheter. This device has BD Vialon™ Catheter Material, a needle grip, a passive safety needle shield, a flash chamber with a removable flow control plug, and BD Instaflash™ Needle Technology. Two wings attached to the catheter hub can be used for securement after catheter insertion. The needle and catheter are protected by a needle cover.
The flash chamber provides confirmation that the device has entered the vessel. BD Instaflash™ Needle Technology allows for immediate visualization of blood along the catheter.

Instaflash™ Needle Technology is clinically demonstrated to significantly improve first-attempt insertion success*.

The removable flow control plug can be removed and connected to the IV cannula hub after catheter insertion (optional).
A separate injection port is located on the catheter hub. The injection port can be used for immediate intravenous injection using a syringe, without a hypodermic needle. In addition, the injection port can be used for intermittent injections even when a continuous infusion is connected to the IV cannula hub. The injection port is protected by a cap. The injection port cap is color coded to indicate catheter gauge size (22G (0.9 mm) = Blue, 20G (1.1 mm) = Pink, 18G (1.3 mm) = Green).

*Compared to a non-notched needle.[1,2]

1. Van Loon FH, Timmerman R, den Brok GP, et al. The impact of a notched peripheral intravenous catheter on the first attempt success rate in hospitalized adults: Block-randomized trial. J Vasc Access. 2021. DOI: 10.1177/1129729821990217.
2. Seetharam AM, Raju U, Suresh K. A randomized controlled study to compare first stick success with Instaflash technology: The FIRSST study. J Vasc Access. 2022:11297298221080369.

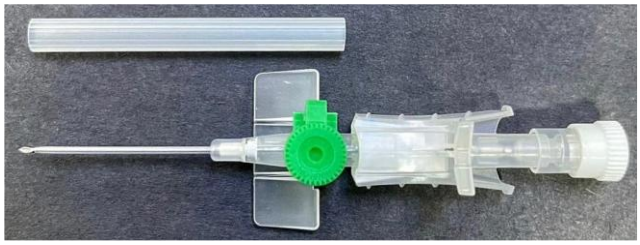

Figure 1: Venflon™ Pro Safety Needle Protected IV Cannula (18GA)

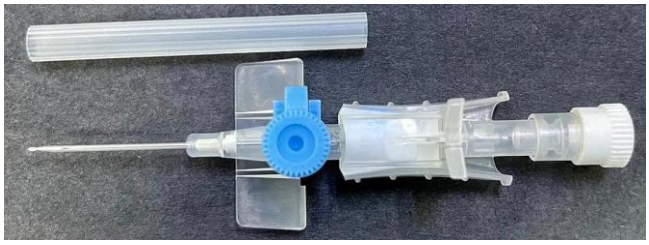

Figure 2: Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology (20GA)

Note: colour code to indicate the catheter gauge size, as per General Medical Device description

BD Catalogue Number	BD Product Description	Gauge	Size (mm)	Inner Diameter - ID (mm)	Outer Diameter - OD (mm)	Gravity Flow Rate (mL/min)	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
393222	Venflon™ Pro Safety Needle Protected IV Cannula	22GA	0.9 x 25.0	0.66	0.93	42.0	7.0 mL/sec	5.0 mL/sec	325 psi (2240 kPa)
393224	Venflon™ Pro Safety Needle Protected IV Cannula	20GA	1.1 x 32.0	0.83	1.13	67.0	12.0 mL/sec	9 mL/sec	
393226	Venflon™ Pro Safety Needle Protected IV Cannula	18GA	1.3 x 32.0	1.00	1.32	103.0	18.0 mL/sec	14.0 mL/sec	
393227	Venflon™ Pro Safety Needle Protected IV Cannula	18GA	1.3 x 45.0	1.00	1.32	103.0			
393228	Venflon™ Pro Safety Needle Protected IV Cannula	17GA	1.5 x 45.0	1.14	1.48	133.0	N/A (Not for use with power injectors)		
393229	Venflon™ Pro Safety Needle Protected IV Cannula	16GA	1.8 x 45.0	1.45	1.81	236.0			
393230	Venflon™ Pro Safety Needle Protected IV Cannula	14GA	2.0 x 45.0	1.62	2.00	270.0			
393280	Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology	22GA	0.9 x 25.0	0.66	0.93	42.0	7.0 mL/sec	5.0 mL/sec	325 psi (2240 kPa)
393281	Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology	20GA	1.1 x 32.0	0.83	1.13	67.0	12.0 mL/sec	9.0 mL/sec	
393282	Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™	18GA	1.3 x 32.0	1.00	1.32	103.0	18.0 mL/sec	14.0 mL/sec	

BD Catalogue Number	BD Product Description	Gauge	Size (mm)	Inner Diameter - ID (mm)	Outer Diameter - OD (mm)	Gravity Flow Rate (mL/min)	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
	Needle Technology								
393283	Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology	18GA	1.3 x 45.0	1.00	1.32	103.0			

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

1.4 Certification

BD Catalogue Number	BD Legal Manufacturer and ISO 13485 Certification	CE/UKCA Certificate Number And Notified Body Acronym and Number	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative/ CH Representative/ (if applicable)
393222, 393224, 393226, 393227, 393228, 393229, 393230, 393280, 393281, 393282, 393283	Name and Address: Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah, 84070 USA ISO 13485 Certificate No.: FM 71665	CE Certified with BSI (2797) MDR Certificate No.: MDR 731353 UKCA certified: N/A	Becton Dickinson Medical (s) Pte Ltd. 30 Tuas Avenue 2 Singapore 639461 ISO 13485Certificate No.: MD 81426	EC Representative: Becton Dickinson Ireland Ltd. Donore Road Drogheda, Co. Louth A92 YW26, Ireland CH Representative: BD Switzerland Sàrl Terre Bonne Park – A4 Route de Crassier 17 1262 Eysins, Switzerland

1.5 UDI-DI and Basic UDI-DI

BD Catalogue Number	UDI-DI		Basic UDI-DI
393222	Primary Packaging	00382903932221	038290TBSJGPELDD
	Shelf Box	30382903932222	
	Shipping Case	50382903932226	
393224	Primary Packaging	00382903932245	
	Shelf Box	30382903932246	
	Shipping Case	50382903932240	
393226	Primary Packaging	00382903932269	
	Shelf Box	30382903932260	
	Shipping Case	50382903932264	
393227	Primary Packaging	00382903932276	
	Shelf Box	30382903932277	
	Shipping Case	50382903932271	
393228	Primary Packaging	00382903932283	
	Shelf Box	30382903932284	
	Shipping Case	50382903932288	
393229	Primary Packaging	00382903932290	
	Shelf Box	30382903932291	
	Shipping Case	50382903932295	
393230	Primary Packaging	00382903932306	
	Shelf Box	30382903932307	
	Shipping Case	50382903932301	
393280	Primary Packaging	00382903932801	038290EJACFUASXJ
	Shelf Box	30382903932802	
	Shipping Case	50382903932806	
393281	Primary Packaging	00382903932818	
	Shelf Box	30382903932819	
	Shipping Case	50382903932813	
393282	Primary Packaging	00382903932825	
	Shelf Box	30382903932826	
	Shipping Case	50382903932820	
393283	Primary Packaging	00382903932832	
	Shelf Box	30382903932833	
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1.6 Materials

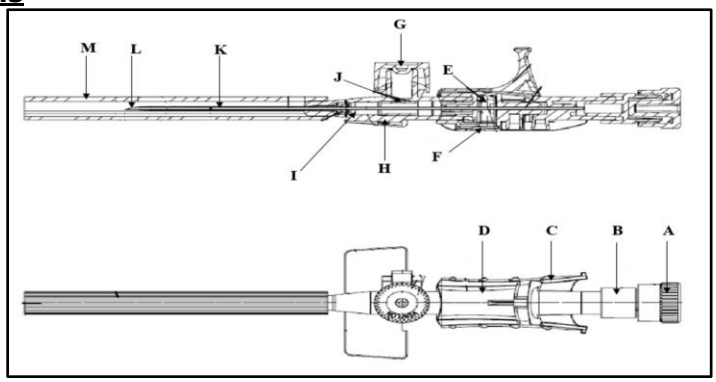


Figure 3: Key Functional Components of Venflon™ Pro Safety Needle Protected IV Cannula

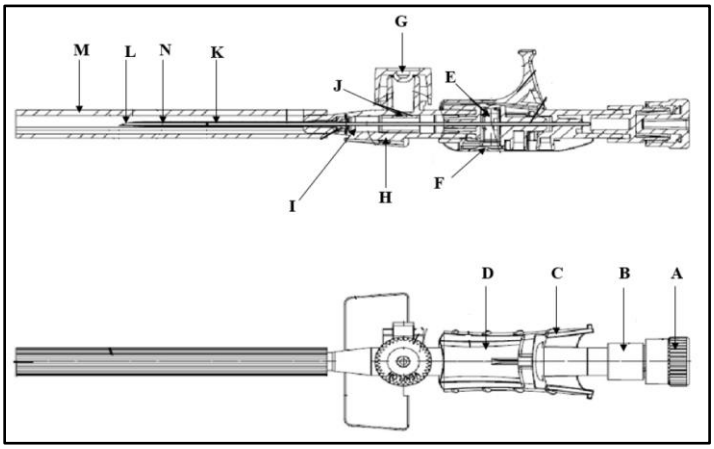


Figure 4: Key Functional Components of Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology

Component		Material
A	Plug	Polypropylene (PP)
*NS**	Plug – White color Masterbatch	PP Color Concentrate 12105 White
B	Flow Control Plug	PP
C	Needle Hub	PP
D	Needle Cap	PP
*NS**	Needle Cap – White color Masterbatch	PP Color Concentrate 12105 White
E	V-Clip	Stainless Steel
F	V-Clip Housing Cover	PP
*NS**	V-Clip Housing Cover - White color masterbatch	PP Color Concentrate 12105 White
G	Protection Cap Flip-Top	PP
*NS**	Protection Cap Flip-Top –colored Masterbatch	PP Color Concentrate 15817 Orange
		PP Color Concentrate 13055 Grey
		PP Color Concentrate 12105 White
		PP Color Concentrate 182499 Green

		PP Color Concentrate 14320 Pink
		PP Color Concentrate 19183 Blue
H	Cannula Hub	PP
I	Catheter Bushing	Polyetherimide
J	Valve	Methyl vinyl polysiloxane
K	Catheter Tubing	Polyurethane Vialon™
L	Cannula	Stainless Steel
M	Protection Hub/Tube	Polyethylene
*NS**	Foil	Clear printable polyester
	Cannula Lubricant	Polydimethylsiloxane
	Catheter Lubricant	Polydimethylsiloxane
	Catheter Tipping Lubricant	Polydimethylsiloxane

Refer to Figures 3 and 4 above.
** NS – Not Shown*

1.7 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 10 March 2025, BD has not identified any 1,2-Benzenedicarboxylic acid, dihexyl ester (branched & linear) (CAS# 68515-50-4), 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters (CAS# 71888-89-6), 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS# 68515-42-4), 1,2-Benzenedicarboxylic acid, di-C6-10 alkyl esters (CAS# 68515-51-5), 1,2-Benzenedicarboxylic 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), Diisopentyl phthalate (DIPP) (CAS# 605-50-5), Dipentyl phthalate (DPP) (CAS# 131-18-0), N-pentyl-isopentyl phthalate (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% w/w.
Latex (euMDR Annex I Sections 13.3 and 23.4(s))	Based on our ongoing data collection efforts and/or information received from our suppliers as per 10 March 2025, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced above.
Bisphenol A (BPA)	Based on our ongoing data collection efforts and/or information received from our suppliers as per 10 March 2025, BD has not identified any 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the article and packaging with the product numbers as referenced above, in an individual concentration above 0.1% (w/w). There is a polyetherimide component in this product. Bisphenol A (BPA), CAS# 80-05-7, is an organic compound that is a chemical building block for polyetherimide. Based on

Material	Comment
	information from our suppliers and BD test results, the BPA level is less than 0.1% w/w (<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.
Animal Derivatives	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. This product is manufactured using polymer resins which may contain very small amounts of stearic acid 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 22442-1:2020 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, this product is considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, 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, MDR 2017/745, and EU No 722/2012).
Animal and Human Cells and Tissue (euMDR Annex I Section 13.1 and 13.2)	The raw materials used in the manufacture of this device (these devices) do not contain animal nor human tissue.
Blood and Blood Derivatives (euMDR Annex I Sections 13.1, 13.2, 23.2(e), and 23.4(s))	The medical devices referenced above have not been designed nor intentionally manufactured with human or animal blood derivatives, and thus EU Directive 2002/98/EC is out of scope.
Medicinal Substances (euMDR Annex I Sections 12.0 and 23.4(s))	The medical devices referenced above have not been designed nor intentionally manufactured with medicinal substances, and thus both European Directive 2001/83/EC and its amendment, 2004/27/EC, are out of scope.
Polyvinyl chloride (PVC)	Based on our ongoing data collection efforts and/or information received from our suppliers as per 10 March 2025, 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.
Class 1A and 1B Carcinogenic, Mutagenic and Reprotoxic (CMR) and Endocrine-Disrupting Substances (ED) (euMDR Annex I Section 10.4.1a, and 10.4.1b)	BD has been gathering data on Class 1A and Class 1B CMR and endocrine-disrupting (ED) chemicals to meet Medical Device Regulation (MDR) 2017/745. For the above-listed BD products, cobalt, classified as a Class 1B carcinogen (C) and reprotoxin (R), may be present at trace levels in various grades of stainless steel. In this case, cobalt is not intentionally added, but may be present in quantities above 0.1% w/w. Relevant ISO 10993 biocompatibility studies have found satisfactory performance for the stainless steel containing products. Based on the information received from our suppliers, as per 17 November 2021, we have not been made aware of any other Class 1A or Class 1B carcinogenic (C), mutagenic (M), reprotoxic (R), or endocrine-disrupting (ED) substances in the components that are either invasive and/or (re)administer medicines, body liquids or other substances, including gases, to/from the body at concentrations greater than 0.1% w/w. This includes endocrine disruptors covered by Article 5(3) of Regulation EU 528/2012. <u>Cobalt Justification</u> This device [or: one or more components of this device] contains the following substance defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

Material	Comment
	Current scientific evidence supports that medical devices manufactured from stainless-steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.* ** This sentence is provided voluntarily to highlight to the users the safety of the device; it is not an MDR requirement.*
RoHS Directive, Heavy Metals and Brominated Flame Retardants	It is BD's view that the above-referenced products do not meet the definition of electrical and electronic equipment as stated in Art. 3(1) of Directive 2011/65/EU ("EU RoHS") and, therefore, do not fall within the scope of the EU RoHS Directive. Based on our ongoing data collection efforts and/or information received from our suppliers as of 10 March 2025, there is no intentionally added lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ether in the above-listed products.
Heavy Metals in Packaging	Based on our ongoing data collection efforts and/or information received by our suppliers as per 10 March 2025, the product (devices & packaging) listed above conform with the requirements of TPCH/CONEG and Section 1.2 of RL 94/62/EC (2004).
Tris(4-nonylphenyl) phosphite (TNPP)	Based on our ongoing data collection efforts and/or information received from our suppliers as per 17 November 2021, BD has not identified any Tris(4-nonylphenyl) phosphite branched or linear (TNPP) (CAS 3050-88-2) in Venflon™ Pro Safety IV Cannula, in an individual concentration above 0.1% weight by weight (w/w).

1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 10 March 2025, 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 14 June 2023 according to Art. 59 (1,10) of the Regulation (EC) No 1907/2006 (REACH).

1.9 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.

1.10 Sterilisation method

Sterilisation method: **Beta irradiation (E-Beam sterilisation)**.
Do not re-sterilise.

1.11 Shelf life and storage conditions

The Venflon™ Pro Safety Needle Protected IV Cannula (and with Instaflash™ Needle Technology) shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
Those Medical Devices have a shelf life of **3 years**.

BD recommends to store in a dry and warm place, not exposed to strong light.

1.12 Applied Standards

As per the Technical Documentation:

Standard reference number	Title	Standard applied (Full or Partial)
Quality Standard		
EN ISO 13485:2016/ A11:2021/ ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes	Full
Risk Management Standard		
EN ISO 14971:2019/ A11:2021 / ISO 14971:2019	Medical devices – Application of risk management to medical devices	Full
Device Specific Standards		
ISO 594-1:1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements	Full
ISO 594-2:1998	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings	Full
ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications Part 1: General requirements	Full
ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications	Full
ISO 10555-1: 2013/ AMD 1:2017	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements – Amendment 1	Full
ISO 10555-5:2013	Intravascular Catheters – Sterile and single-use catheters – Part 5: Over-needle peripheral catheters	Full
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	Full
Biocompatibility Standards		
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Full
ISO 10993-2:2022	Biological evaluation of medical devices - Part 2: Animal welfare requirements	Full
ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Full
ISO 10993-4:2017/Amd.1:2025	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	Full
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity	Full
ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	Full
EN ISO 10993-10:2023 / ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization	Full
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Full
EN ISO 10993-12:2021 / ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	Full
EN ISO 10993-17:2023 / ISO 10993-17:2023	Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents	Full

Standard reference number	Title	Standard applied (Full or Partial)
EN ISO 10993-18:2020/ A+1:2023 / ISO 10993-18:2020/A1:2022	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process	Full
EN ISO 10993-23:2021 / ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation	Full
Labeling Standards		
ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer	Full
EN ISO 15223-1:2021 / ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, Labelling and information to be supplied – Part 1: General requirements	Full
Packaging/Distribution Standards		
EN ISO 11607-1:2020 / ISO 11607-1:2019	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	Full
EN ISO 11607-2:2020 / ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	Full
Sterilization Standards		
EN 556-1:2024	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	Full
EN ISO 11737-1:2018 +A1:2021 / ISO 11737-1:2018/Amd.1:2021	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products – Amendment 1	Full
EN ISO 11737-2:2020 / ISO 11737-2:2019	Sterilization of health care products - Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	Full
EN ISO 11137-1:2015 / ISO 11137-1:2006/Amd 1:2013	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 1	Full
EN ISO 11137-2:2015 / ISO 11137-2:2013/Amd 1:2023	Sterilization of health care products – Radiation –Part 2: Establishing the sterilization dose	Full
Other Standards		
IEC 62366-1:2015+AMD1:2020	Medical devices – Part 1: Application of usability engineering to medical devices	Full
ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management	Full (Annex C.5)
ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration	Full
ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Full
ISO 14001:2015	Environmental Management System	Full
Other Guidelines		
EMA 410/01	Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products	Full (Section 6)
MEDDEV 2.7/1 Rev 4	Clinical Evaluation: A guide for manufacturers and notified bodies Under directives 93/42/EEC and 90/385/EEC	Full
MDCG 2018-1 rev.4	Guidance on basic UDI-DI and changes to UDI-DI	Full

Standard reference number	Title	Standard applied (Full or Partial)
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies April 2020	Full
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies April 2020	Full
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies April 2020	Full
MDCG 2021-5 rev.1	Guidance on standardisation for medical devices	Full
MDCG 2021-24	Guidance on classification of medical devices October 2021	Full
MDCG 2021-12 rev.1	FAQ on the European Medical Device Nomenclature (EMDN)	Full
MDCG 2022-16	Guidance on Authorised Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746	Full
MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745	Full
Other Regulations		
(EU) 2021/2226	Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices	Full

Note:
The above standards reflect the status at time of document release.

1.13 Classification

Medical Devices referenced in this document are classified as **Class IIa** medical device under Rule 7 as defined in the MDR (EU) 2017/745 Annex VIII and no other rules apply.

1.14 Medical Device Nomenclature

GMDN Code: 64574
GMDN Term: Peripheral Intravenous Cannula

EMDN Code: C0101010201
EMDN Description: Peripheral venous access catheter needles, with safety systems, with injection valve

1.15 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.

1.16 Other information

- 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 EU Pharmaceutical is not applicable for Medical Devices.
- MRI Safety Information: **MR Safe (per IFU, extract below):**

MRI SAFETY INFORMATION

MR Safe

BD Venflon™ Pro Safety Needle Protected IV Cannula and BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology are MR Safe.

2. Packaging

2.1 Packaging configuration

BD Catalogue Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
393222	Venflon™ Pro Safety Needle Protected IV Cannula	1	50	500	Yes
393224	Venflon™ Pro Safety Needle Protected IV Cannula	1	50	500	Yes
393226	Venflon™ Pro Safety Needle Protected IV Cannula	1	50	500	Yes
393227	Venflon™ Pro Safety Needle Protected IV Cannula	1	50	500	Yes
393228	Venflon™ Pro Safety Needle Protected IV Cannula	1	50	500	Yes
393229	Venflon™ Pro Safety Needle Protected IV Cannula	1	50	500	Yes
393230	Venflon™ Pro Safety Needle Protected IV Cannula	1	50	500	Yes
393280	Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology	1	50	500	Yes
393281	Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology	1	50	500	Yes
393282	Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology	1	50	500	Yes
393283	Venflon™ Pro Safety Needle Protected IV Cannula with Instaflash™ Needle Technology	1	50	500	Yes

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

2.2 Packaging material

Component	Material
Top Web	Reinforced Paper
Bottom Web	Amorphous Polyethylene Terephthalate (APET) foil
Shelf Package	Bleached folding duplex boxboard
Case Carton	Corrugated Case Carton

2.3 Recycled material in packaging

-Recycled Content:

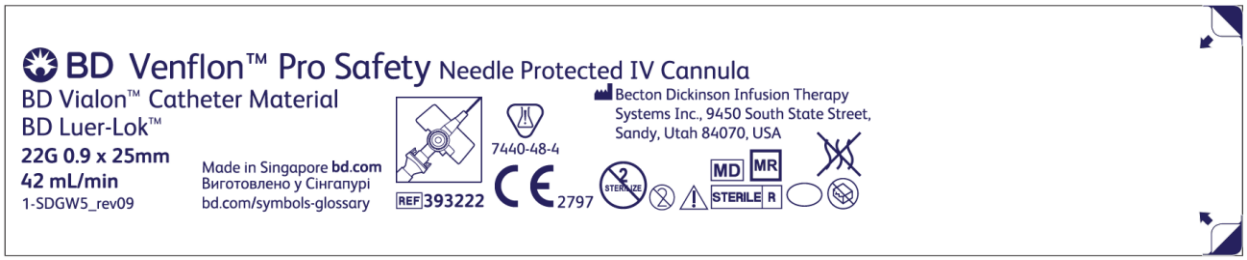
BD Product Numbers	Secondary Packaging Recycled Content (Shelf Carton)	Tertiary Packaging Recycled Content (Case Carton)
393222, 393224, 393226, 393227, 393228, 393229, 393230, 393280, 393281, 393282, 393283	100%	100%

-Recyclability of Packaging: The secondary and tertiary portions of the packaging are recyclable. Some portions of the primary packaging may only be recyclable in the communities that have appropriate recycling facilities, and some portions of the package may not be recyclable.

BD Catalogue Number	Packaging Type	Recyclability
393222, 393224, 393226, 393227, 393228, 393229, 393230, 393280, 393281, 393282, 393283	Primary Packaging: Multilayer laminate plastic and paper	Two materials – designed to be peeled apart
		This grade of paper is not suitable for current mechanical recycling processes. It may be disposed in other non-regulated mixed waste streams, as permitted by local regulation.
		Multilayer laminate is recyclable through monomer recovery recycling methods
	Secondary Packaging: Shelf Carton	Cardboard is recyclable
	Tertiary Packaging: Carton Case	Cardboard is recyclable

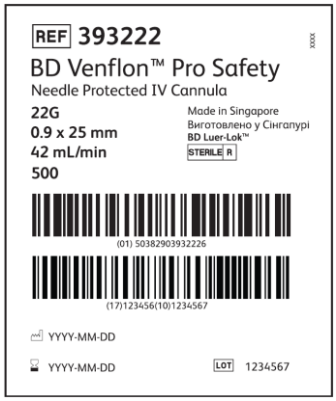
2.4 Examples of labelling

Primary Packaging (Top Web) extracted from document **SDGW5_Rev.09** related to reference *393222*:

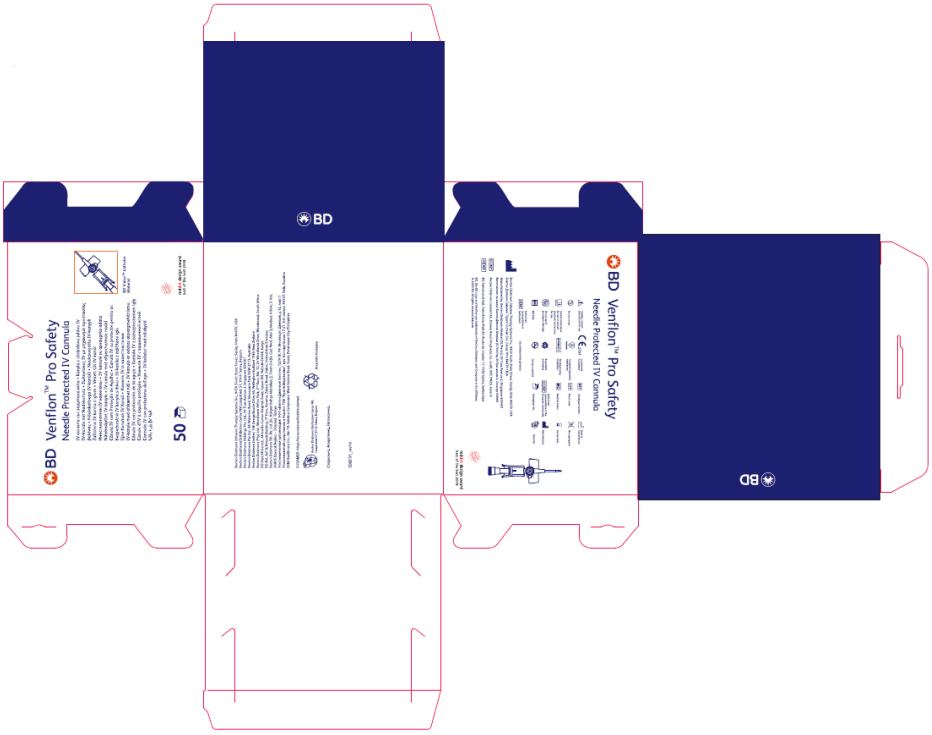


Shelf Box label, extracted from document**SRD-DGL0188_Rev.07** related to reference *393222*:

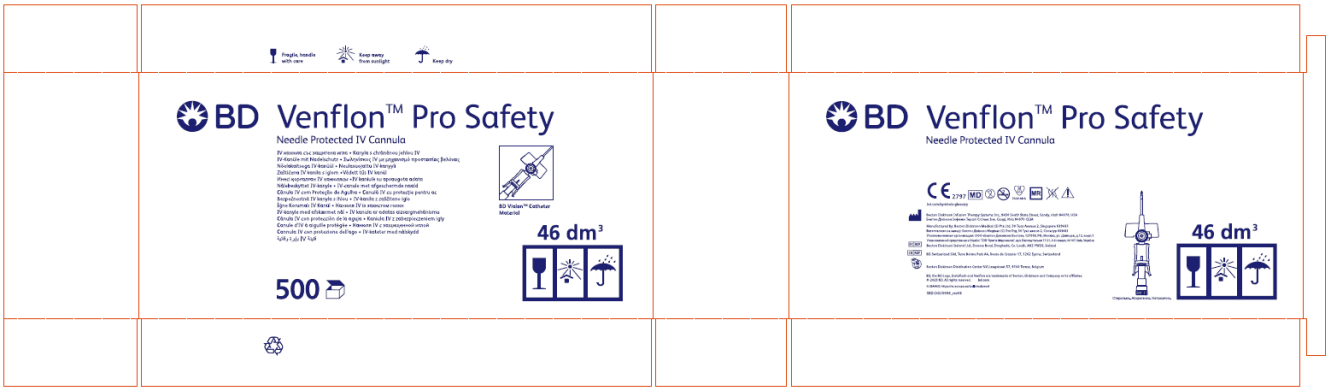
Shipper Box label, extracted from document **SRD-DGL0222_Rev.07** related to reference *393222*:



Shelf box, extracted from document **SDGF31_Rev.10** related to reference *393222*:



Shipper box, extracted from document **SRD-DGC0090_Rev.06** related to reference *393222*:



IFU insert (English parts only), extracted from document **SDGP2_Rev.11** related to reference *393222*:
For the whole document, where other languages are included, please refer to: eifu.bd.com

BD

BD Venflon™ Pro Safety

Needle Protected IV Cannula

BD Venflon™ Pro Safety

Needle Protected IV Cannula
with BD Instaflash™ Needle Technology

IV канюла със защитена игла	Kanyla s chráněnou jehlou IV
IV-Kanüle mit Nadelschutz	Σωληνίσκος IV με μηχανισμό προστασίας βελόνας
Nõelakaitsega IV-kanüül	Neulasuojattu IV-kanyyli
Zaštićena IV kanila s iglom	Védett tűs IV kanül
Инесі қорғалған IV канюлясы	IV kaniulė su apsaugota adata
Nålebeskyttet IV-kanyle	IV-canule met afgeschermde naald
Cânula IV com Proteção de Agulha	Canulă IV cu protecție pentru ac
Bezpečnostná IV kanyla s ihlou	IV-kanila z zaščiteno iglo
İğne Korumalı IV Kanül	Канюля IV із захистом голки
IV-kanyle med afskærmet nål	IV kanula ar adatas aizsargmehānismu
Cánula IV con protección de la aguja	Kaniula IV z zabezpieczeniem igły
Canule d'IV à aiguille protégée	Канюля IV с защищенной иглой
Cannula IV con protezione dell'ago	IV-kateter med nålskydd
قنية IV بإبرة وقائية	

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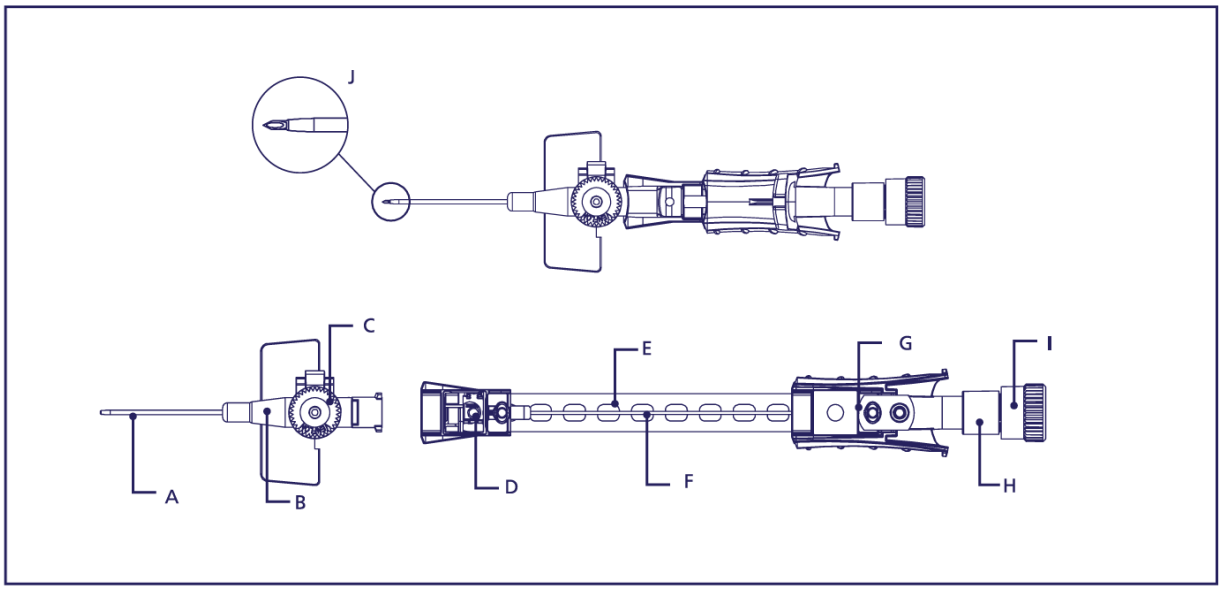
SDGP2_rev11



en
Gravity Flow Rate. Maximum Power injector Flow Rate for Contrast Media Viscosity. Maximum Power Injector Pressure Limit Setting. Not for use with power injectors.

es
Velocidad del flujo gravitatorio. Velocidad de flujo máxima de la bomba de infusión para la viscosidad de los medios de contraste. Configuración del límite de presión máxima de la bomba de infusión. No utilizar con bombas de infusión.

	Gravity Flow Rate (mL/ min)	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
22G 0.9 mm x 25 mm	42 mL/min	7 mL/s	5 mL/s	325 psi (2240 kPa)
20G 1.1 mm x 32 mm	67 mL/min	12 mL/s	9 mL/s	
18G 1.3 mm x 32 mm	103 mL/min	18 mL/s	14 mL/s	
18G 1.3 mm x 45 mm	103 mL/min	18 mL/s	14 mL/s	
17G 1.5 mm x 45 mm	133 mL/min	Not for use with power injectors		
16G 1.8 mm x 45 mm	236 mL/min			
14G 2.0 mm x 45 mm	270 mL/min			

en

BD Needle Protected IV Cannula

INSTRUCTIONS FOR USE

READ BEFORE USE

(A) BD Vialon™ Catheter Material, (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.

DEHP or Natural Rubber Latex are not part of the material formulation.

INTENDED PURPOSE

BD Venflon™ Pro Safety Needle Protected IV Cannula and BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology are designed to access the peripheral vasculature of the patient's blood system for rehydration, parenteral nutrition, medication delivery, blood transfusion, and monitoring purposes. The 22-18 G (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 325 psi (2240 kPa).

INTENDED PATIENT POPULATION

BD Venflon™ Pro Safety Needle Protected IV Cannula and BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology may be used for any patient population with consideration given to patient size, appropriateness for solution being infused and duration of therapy.

CLINICAL BENEFITS

- Ability to provide rehydration.
- Ability to provide parenteral nutrition.
- Ability to provide medication delivery.
- Ability to provide blood transfusion.
- Ability to monitor blood pressure.
- Ability to power inject contrast media at a maximum pressure of 325 psi/2240 kPa with 22-18GA (0.8-1.2mm) devices.
- Passive safety mechanism: The needle tip is passively protected when the needle is removed.

CONTRAINDICATIONS

None Known

PRECAUTIONS

- Precaution: 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.
- Use only with ISO compliant Luer connections. Non-ISO compliant Luer connections may cause leakage.
- Potential complications related to the insertion and use of PIVC include but are not limited to: delay or interruption of treatment, unsuccessful insertion, needle stick injury, catheter breakage / embolization, needle breakage / embolization, air embolism, blood loss / leakage, infusate leakage, exposure to non-hazardous / hazardous drugs, slow flow rate infusion, inaccurate dose, localized infection, hematoma, blood stream infection, choking, particulate infusions, vessel infiltration / extravasation, hemolysis during blood draw, wrong medication dose / type, syncope / fainting, blood exposure, thrombosis, hemorrhage, death.
- EU Only: Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.

MRI SAFETY INFORMATION

MR MR Safe

BD Venflon™ Pro Safety Needle Protected IV Cannula and BD Venflon™ Pro Safety Needle Protected IV Cannula with BD Instaflash™ Needle Technology are MR Safe.

HAZARDOUS SUBSTANCES INFORMATION

7440-48-4 Contains Hazardous Substances

This device contains the following substances defined as CMR 1B in a concentration above 0.1% weight by weight:
Cobalt; CAS No. 7440-48-4; EC No. 231-158-0. Current scientific evidence supports that medical devices manufactured from stainless-steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

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. Attach Luer adapter of injection syringe, extension set, or infusion system to flush or begin infusion. There are no known non-compatible medicinal products or IV fluids.
12. Ensure that the protective cap of the port is closed.
13. Secure the catheter and apply sterile dressing as per protocol.
14. To remove catheter, first disconnect from infusion system, remove sterile dressing, and then gently pull catheter out from insertion site.
15. Upon removal, examine catheter to ensure it is intact and discard according to your facility policy.

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.

Recyclable Packaging	Рециклируема опаковка
Recyklovatelný obal	Genanvendelig pakning
Recyclingfähige Verpackung	Ανακυκλώσιμη συσκευασία
Envase reciclable	Taaskasutatav pakend
Kierrätettävä pakkaus	Emballage recyclable
Ambalaža koja se može reciklirati	Újrahasznosítható csomagolás
Confezione riciclabile	Қайта пайдалануға болатын қаптама
Grąžinamajam perdirbimui tinkama pakuotė	Pārstrādājams iepakojums
Resirkulerbar emballasje	Recyclebare verpakking
Opakowanie nadaje się do recyklingu	Embalagem reciclável
Ambalaj reciclabil	Перерабатываемая упаковка
Recyklovateľný obal	Embalaža, primerna za recikli-ranje
Återvinningsbar förpackning	Geri Dönüştürülebilir Ambalaj
Упаковка, що підлягає повторній обробці	العبوات القابلة لإعادة التدوير

eifu.bd.com	Consult instructions for use or consult electronic instructions for use
STERILE R	Sterilized using irradiation
REF	Catalogue Number
	Open here
	Do not resterilize
	Do not use if package is damaged
CE 2797	Conformité Européene
7440-48-4	Contains Hazadous substances
MR	MR Safe
	Date of Manufacture
	Use-by date
	Importer
MD	Medical Device

	Do not re-use
LOT	Batch code
	Single Sterile Barrier System
	Caution, consult instructions for use
	Fragile, handle with care
	Keep dry
	Packaging unit
	Keep away from sunlight
	Non-pyrogenic
	Manufacturer
CH REP	Authorized representative in Switzerland
EC REP	Authorized representative in European Community
	bd.com/symbols-glossary

Becton Dickinson Infusion Therapy Systems Inc., 9450 South State Street, Sandy, Utah 84070, USA
Бектон Дікінсон Інфюжн Терапі Сістемс Інк. Санді, Юта 84070 США

Becton Dickinson Distribution Center NV, Laagstraat 57, 9140 Temse, Belgium

CH REP BD Switzerland Sàrl, Terre Bonne Park A4, Route de Crassier 17, 1262 Eysins, Switzerland

EC REP Becton Dickinson Ireland Ltd., Donore Road, Drogheda, Co. Louth, A92 YW26, Ireland

Manufactured by: Becton Dickinson Medical (S) Pte Ltd, 30 Tuas Avenue 2, Singapore 639461
Виготовлено на заводі: Бектон Дікінсон Медікал (С) Пте Лтд 30 Туас авеню 2 Сінгапур 639461

Made in Singapore
Виготовлено у Сінгапурі

Becton Dickinson Pty Ltd, 66 Waterloo Road, Macquarie Park NSW 2113, Australia
Becton Dickinson Limited, 14B George Bourke Drive, Mt. Wellington Auckland 1060, New Zealand
Becton Dickinson Infusion Therapy Systems Inc., 9450 South State Street, Sandy, Utah 84070, USA
Becton Dickinson/Distribution Center NV, Laagstraat 57, 9140 Temse, Belgium
Becton Dickinson Holdings Pte. Ltd., 30 Tuas Avenue 2, Singapore 639461
Becton Dickinson (Pty) Ltd., Woodlands Office Park, 2nd floor, Bld. 12, 20 Woodlands Drive, Woodmead, South Africa
BD East Africa Ltd., Africa Re-Center Hospital Road, Upper Hill, Nairobi 00508, Kenya
BD B.V., Arif & Bintoak Building, 1st floor, Karama, Zabeel Road, Dubai, United Arab Emirates
Becton Dickinson İth. İhr. Ltd. Şti., Rüzgarlıbahçe Mahallesi, Ş. Sinan Eroğlu Cad. No:6, Akel İş Merkezi, A Blok, 3. Kat, 34805 Kavacık Beykoz – İstanbul, Türkiye
Уполномоченная организация: ООО «Бектон Дикинсон Восток», 127018, РФ, Москва,ул. Двинцев, д.12, корп.1
Уповноважений представник в Україні: ТОВ "Кратія Медтехніка", вул. Багговутівська 17-21, 6-й поверх, 04107, Київ, Україна
KSM Healthcare Inc., Km 19, Sabrina Compound, West Service Road, Sucat, Paranaque City, Philippines

EUDAMED: https://ec.europa.eu/tools/eudamed

REVISION	CHANGE SUMMARY
01	Initial release according to new template – December 2020
02	TDS revised according to new template *EMEA-SOP039-F1_Rev.01* as per PIV-STED-006-Rev.A/Ver.A – September 2024
03	April 2026: - TDS revised according to new template EMEA-SOP039-F1_Rev.02 as per PIV-STED-006-Rev.B/Ver.B – released in October 2025 - Update of: o General Medical Devices description (section 1.3) o Certification (section 1.4) o UDI-DI and Basic UDI-DI (section 1.5) o Materials (section 1.6) o Materials of concern (section 1.7) o REACH information (section 1.8) o Shelf life and storage conditions (section 1.11) o Applied Standards (section 1.12) o Other information (section 1.16) o Recycled material in packaging (section 2.3) o Examples of labelling (section 2.4)