BD® Neoflon™ Pro IV Cannula

Sterile, single-use

Product codes: 391379, 391380

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

TDS number: V201-001 – Rev. 03
Veeva Vault number: BD-134654
2024-September

1. General Information

1.1 Intended purpose

Neoflon™ Pro IV Cannula is intended for infusions/injections and is designed to gain access to the peripheral vessels of the vascular system for IV therapy, blood transfusion, and pressure monitoring.

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

Neoflon™ Pro IV Cannula is for use by clinicians that are qualified through training and experience to perform insertion of peripheral intravenous catheters.

1.3 General Medical Devices description

Neoflon™ Pro IV Cannulas are over-the-needle, intravascular (IV) catheters. These catheters include BD® Vialon™ Catheter Material, needle grip, removable wing cover, flash chamber with a removable flow control plug and BD® Instaflash™ Needle Technology. Two flexible 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 Instaflash™ Needle Technology allows for immediate visualisation 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 can be connected to the IV cannula hub after catheter insertion (optional).

The catheter hub and wings are colour coded to indicate the catheter gauge size (24 GA (0.7 mm) = Yellow, 26 GA (0.6 mm) = Violet).

*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.

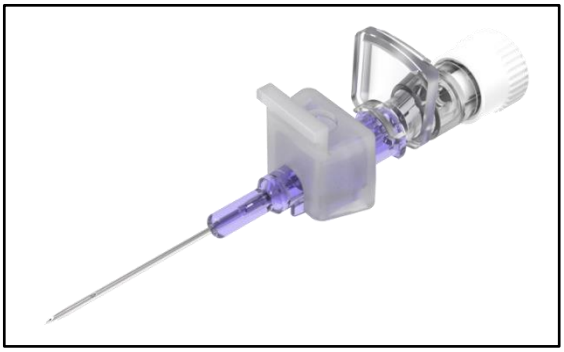


Figure 1: Neoflon™ Pro IV Cannula (26GA)

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

BD Catalogue Number	BD Product Description	Gauge	Size (mm)	Gravity Flow Rate (mL/min)	Needle Penetration Force (N)	Catheter Penetration Force (N)	Catheter Aver. Drag Force (N)	Flashback in Catheter/ Chamber
391379	Neoflon™ Pro IV Cannula	26GA	0.6 x 19.0	14.0	0.25	0.34	0.10	<5 sec / N/A
391380	Neoflon™ Pro IV Cannula	24GA	0.7 x 19.0	19.0	0.29	0.34	0.10	<3 sec / <7 sec

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 Certificate Number and Notified Body (acronym)	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	Authorised Representatives
391379, 391380	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah, 84070 USA ISO 13485:2016 Certificate No.: FM 71665	CE Certified with BSI (Notified body number 2797) Certification number: MDR 731353	Becton Dickinson Medical (S) Pte Ltd, 30 Tuas Avenue 2 Singapore 639461 Singapore ISO 13485:2016 Certificate No.: MD 81426 (Manufacturing, Sterilisation and Final Testing Site)	EU Representative: Becton Dickinson Ireland Ltd. Donore Road Drogheda, Co. Louth A92 YX26, 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

Product Trade Name	BD product code	UDI-DI		Basic UDI-DI
Neoflon™ Pro IV Cannula	391379	Unit	(01)00382903913794	038290ZCNOSRXLMV
		Shelf	(01)30382903913795	
		Case	(01)50382903913799	
	391380	Unit	(01)00382903913800	
		Shelf	(01)30382903913801	
		Case	(01)50382903913805	

1.6 Materials

Component		Material
A	Notched Cannula (Needle with Instaflash™ Needle Technology)	Stainless Steel (SS 304)
B	Catheter Hub	Polypropylene (PP) + Polypropylene-based violet (26GA) or Yellow (24GA) colourant masterbatch
C	Flow Control Plug (FCP)	Polypropylene (PP)
D	Plug White Luer-lock (LL)	Polypropylene (PP) + Polypropylene-based white colourant masterbatch
E	Catheter Tubing (Vialon™ Catheter Material)	Polyurethane Vialon™ Catheter Material
F	Protection Tube (Needle Cover)	Low-density Polyethylene (LDPE)
G	Hold for Cannula Hub Wings (Wing Holder)	High-density Polyethylene (HDPE)
H	Needle Hub (Flash chamber)	Polypropylene (PP)
I	Metal Wedge	Stainless Steel (SS 305)
*NS**	Cannula (Needle) Lubricant	Polydimethylsiloxane (PDMS)
	Catheter Lubricant	
	Metal Wedge Lubricant	
	Tipping Lubricant	

** NS – not shown*

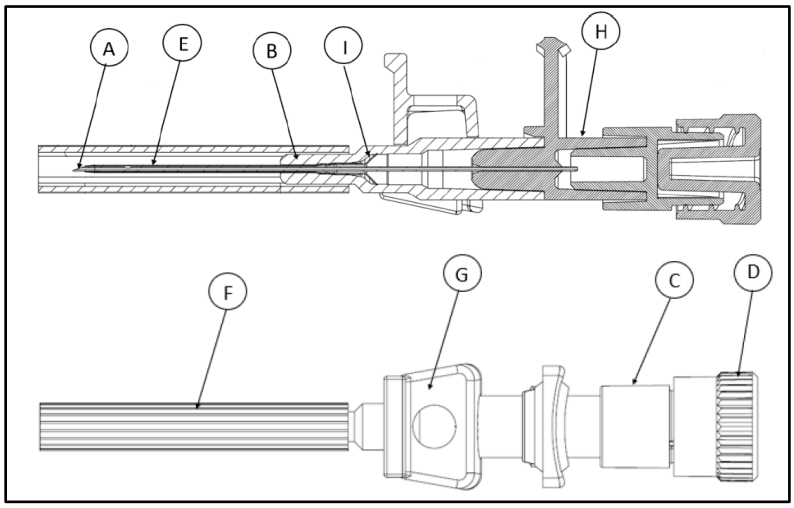


Figure 2: Key functional components of Neoflon™ Pro IV Cannula

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
DEHP/Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per 17 June 2024, 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	Based on our ongoing data collection efforts and/or information received from our suppliers as per 17 June 2024, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced above.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per 17 June 2024, 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% (w/w).
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. These products are 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, these products are 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 devices (per MDD 93/42/EEC, euMDR 2017/745 Annex VIII, and EU No 722/2012).
Blood and Blood Derivatives	Neoflon™ Pro IV Cannula has not been designed nor intentionally manufactured with human blood or blood derivatives, and thus EU Directive 2002/98/EC is out of scope.
Polyvinyl chloride (PVC)	The medical devices and packaging 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.

Material	Comment
Class 1A and 1B Carcinogenic, mutagenic and reprotoxic (CMR) and Endocrine-Disrupting (ED) Substances	BD has been gathering data on Class 1A and Class 1B CMR and ED chemicals to meet Medical Device Regulation (MDR) 2017/745 and 2017/746. For the above-listed BD products, cobalt, classified as a Class 1B carcinogen (C) and reprotoxin (R) under CLP regulation (EC 1272/2008), 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 June 2024, 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. Cobalt Justification Neoflon™ Pro IV Cannula [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 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, brominated flame retardants, and phthalates	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 17 June 2024, there is no intentionally added lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ether in the above-listed products. Furthermore, based on our ongoing data collection efforts and/or information received from our suppliers as of 17 June 2024, BD has not identified any bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) or diisobutyl phthalate (DIBP) in an individual concentration above 0.1% w/w in the above-listed products.
REACH Restricted list	N/A

1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 17 June 2024, 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 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

1.10 Sterilisation method

Ethylene Oxide (EO). Do not re-sterilise.

1.11 Shelf life and storage conditions

Neoflon™ Pro IV Cannula requirements are verified for the period of declared shelf-life. Based on stability and shelf-life testing, Neoflon™ Pro IV Cannula has a shelf-life of **3 years**. Store at room temperature and not exposed to strong light.

1.12 Applied Standards

As per Technical Documentation:

Standard reference number	Title
Quality Standard	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
Risk Management Standard	
EN ISO 14971:2019	Medical Device – Application of risk management to medical devices
Biocompatibility Standards	
EN ISO 10993-1:2020 / ISO 10993-1:2018, corrected Version 10/2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-2:2006 / ISO 10993-2:2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements
EN ISO 10993-3:2014 / ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4:2017 / ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood.
EN ISO 10993-5:2009 / ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016 / ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
EN ISO 10993-9:2009	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-9:2019	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products
EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitisation
EN ISO 10993-11:2018 / ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
BS EN ISO 10993-12:2021 / ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-13:2010 / ISO 10993-13:2010	Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices
EN ISO 10993-15:2009	Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys
ISO 10993-15:2019	Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys
EN ISO 10993-17:2009 / ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable

Standard reference number	Title
EN ISO 10993-18:2020/AM1:2022	Biological evaluation of medical devices – Part 18: Chemical Characterisation of Materials
EN ISO 10993-23:2021 / ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation
Labelling Standards	
BS EN 1041:2008	Information supplied by the manufacturer of medical devices
ISO 15223-1:2016 corrected version 2017-03	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
Packaging/Distribution Standards	
ISO 11607-1:2019	Packaging for terminally sterilised medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilised medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
Sterilisation Standards	
BS EN 556-1:2001	Sterilisation of Medical Devices for terminally sterilised product labelled "sterile" – Part 1: Requirements for terminally sterilised medical devices
ISO 11135:2014	Sterilisation of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilisation process for medical devices
EN ISO 10993-7:2008/AC:2009/AM 1: 2022 / ISO 10993-7:2008/ COR 1:2009/AM 1:2019	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilisation residuals
EN ISO 11737-1:2018/A1:2021	Sterilisation of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products – Amendment 1
EN ISO 11737-2:2020	Sterilisation of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilisation process
Device Specific Standards	
ISO 594-1:1986*	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements
ISO 594-2:1998*	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings
ISO 10555-1: AMD1:2017	Sterile, single-use intravascular catheters–Part 1: General requirements
ISO 10555-5:2013	Intravascular catheters - Sterile and single-use catheters – Part 5: Over-needle peripheral catheters
ISO 80369-1:2010	Small-bore connectors for liquids and gases in healthcare applications – Part 1: General Requirements
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
Clinical Investigation Standard	
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
Other Standards	
IEC/EN 62366 1:2015+AMD1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
EN ISO 14644-1:2015 / ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2:2015 / 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

Standard reference number	Title
EN ISO 22442-1:2020	Medical devices utilising animal tissues and their derivatives – Part 1: Application of risk management
Other Guidelines	
EMA 410/01	Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products
MEDDEV 2.7/1 Rev 4	Clinical Evaluation: A guide for manufacturers and notified bodies Under directives 93/42/EEC and 90/385/EEC
MDCG 2020-5	Clinical Evaluation – Equivalence A guide for manufacturers and notified bodies April 2020
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
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template – A guide for manufacturers and notified bodies April 2020
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template – A guide for manufacturers and notified bodies April 2020
MDCG 2021-24	Guidance on classification of medical devices – October 2021
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

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

*Luer components used in Neoflon™ Pro IV Cannula are being qualified for BS EN ISO 80369-7 and are currently in the phase of component qualification. The Luer components currently comply with ISO 594-1 and 594-2.

1.13 Classification

Neoflon™ Pro IV Cannula is classified as **Class IIa** medical device under Rule 7 of MDR (EU) 2017/745 Annex VIII, to which the exceptions do not 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

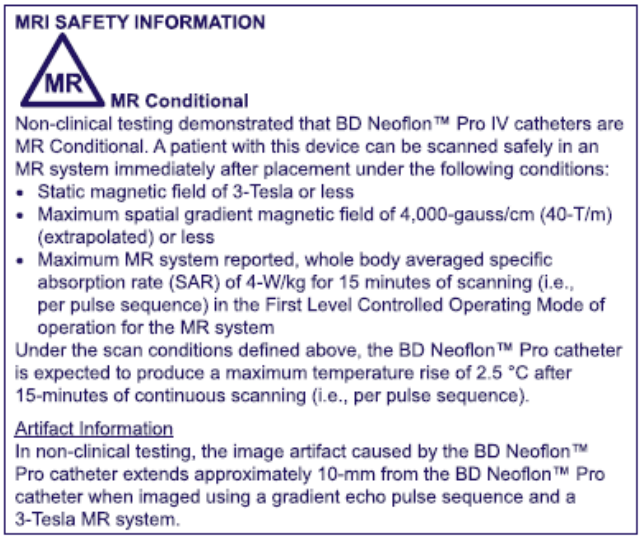
The entire manufacturing and testing processes are following the Manufacturing Practices as specified below:

- 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.
- BD reserves the right to use the internal change control procedure to change raw material suppliers and production process.

1.16 Other information

- Material Data Safety sheets are not required for this product.
- Certificate of Food Contact (*COMMISSION REGULATION (EU) No. 10/2011 of January 14th, 2011 concerning materials and plastic objects intended to get in touch 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.
- General Precaution: Replace catheter according to your facility policy, relevant guidelines, or if the integrity of the device has been compromised (per IFU).
- MRI Safety Information: **MR Conditional (per IFU, extract below):**



MRI SAFETY INFORMATION

MR

MR Conditional

Non-clinical testing demonstrated that BD Neoflon™ Pro IV catheters are MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m) (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system

Under the scan conditions defined above, the BD Neoflon™ Pro catheter is expected to produce a maximum temperature rise of 2.5 °C after 15-minutes of continuous scanning (i.e., per pulse sequence).

Artifact Information

In non-clinical testing, the image artifact caused by the BD Neoflon™ Pro catheter extends approximately 10-mm from the BD Neoflon™ Pro catheter when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

2. Packaging

2.1 Packaging configuration

BD Catalogue Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert
391379, 391380	Neoflon™ Pro IV Cannula	1	50	500	Yes

2.2 Packaging material

Component	Material
Top Web	Medical Grade Paper
Bottom Web	Amorphous Polyethylene Terephthalate (APET) Film
Shelf Package	White duplex treated wood pulp board with grey back
Case Carton	Natural Kraft

2.3 Recycled material in packaging

Packaging recycled content:

BD Product Numbers	Secondary Packaging Recycled Content (Shelf Carton)	Tertiary Packaging Recycled Content (Case Carton)
391379, 391380	100%	100%

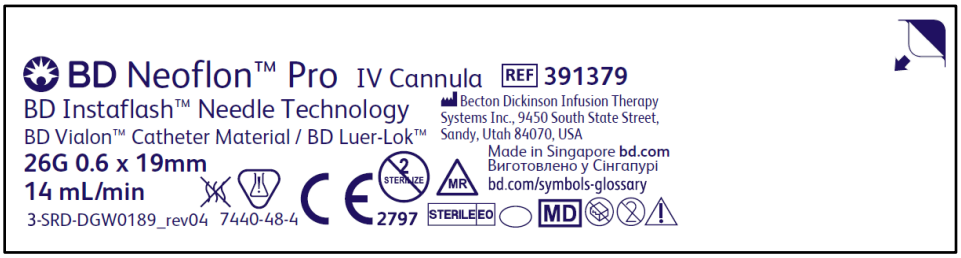
Packaging recyclability:

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.

- Primary Packaging: 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 Box) cardboard is recyclable.
- Tertiary Packaging: (Shipper Box) cardboard is recyclable.

2.4 Examples of labelling

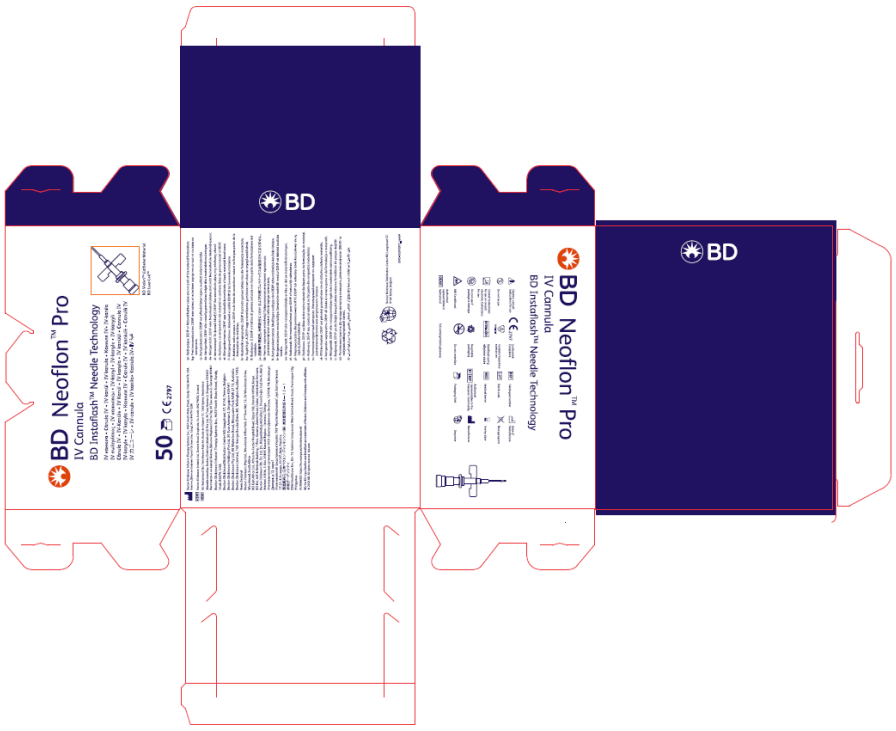
Neoflon™ Pro IV Cannula Unit label, extracted from document **SRD-DGW0189_Rev.04** (example for product *391379*):



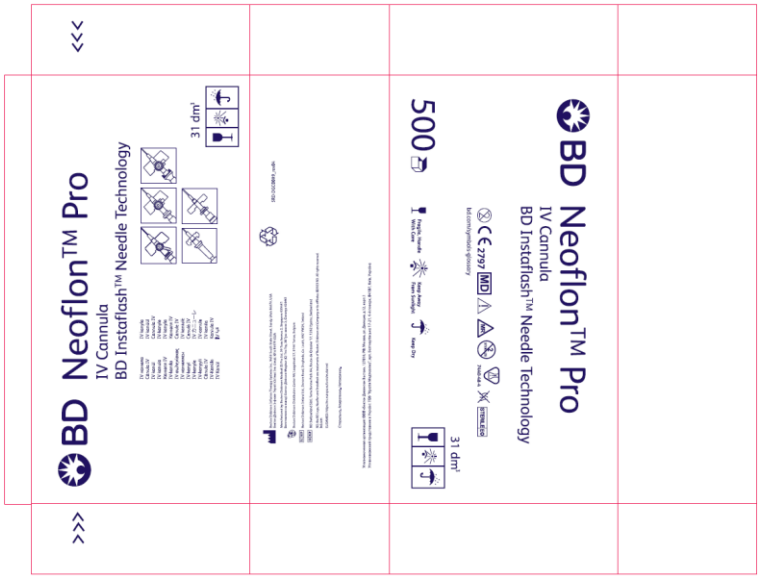
Neoflon™ Pro IV Cannula Shelf label, extracted from document **SRD-DGL0423_Rev.02** (example for product *391379*):

Neoflon™ Pro IV Cannula Shipper label, extracted from document **SRD-DGL0427_Rev.02** (example for product *391379*):

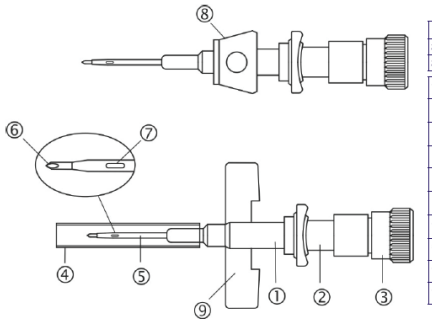
Neoflon™ Pro IV Cannula Shelf box, extracted from document **SRD-DGF0077_Rev.04**:



Neoflon™ Pro IV Cannula Shipper box, extracted from document **SRD-DGC0089_Rev.04**:



Neoflon™ Pro IV Cannula IFU (English parts only), extracted from document **SRD-DGP0041_Rev.01**:



	Gravity Flow Rate (mL/min)
24 GA (0.7 X 19mm)	19 mL/min
26 GA (0.6 X 19mm)	14 mL/min

en Gravity Flow Rate	fi Painovoimavirtausnopeus	fr Débit par gravité
ru Скорость самотека	cs Gravitační průtok	sl Hitrost gravitacijskega pretoka
hr Gravitacijska stopa protoka	it Portata a gravità	sv Gravitationsflöde/hastighet
no Gravitasjonsstrøm	ro Flux gravitațional	sk Prietok pri gravitácii
bg Гравитационен дебит	pt Taxa de fluxo por gravidade	nl Stroomsnelheid door zwaartekracht
uk Швидкість безнапірного потоку	es Velocidad del flujo gravitatorio	tr Ağırlıksal Akış Hızı
el Ρυθμός έγχυσης βαρύτητας	hu Gravitációs áramlási sebesség	lv Gravitācijas plūsmas ātrums
sk Rýchlosť gravitačného toku	sk Гравітаційний потік жидкості	ja 重力流量
et Loovedu kiirus	pl Prędkość przepływu grawitacyjnego	ar معدل تدفق الجاذبية
de Massenflussstärke	de Schwerkraft-Flussrate	

BD **Neoflon™ Pro**

IV Cannula

with BD Instaflash™ Needle Technology

IV канюля	IV kanyla	IV-kanyle
Cánula IV	IV kanüül	IV-kanyyli
IV kanül	Cannula IV	IV カニューレ
IV kanula	IV-kanyle	IV-canule
Канюля IV	IV kanyla	Cânula IV
IV-kanüla	Канюля IV	IV-Kanüle
IV σωληνάκος	Canule IV	IV kanila
IV канюлясы	IV kaniulė	Kaniula IV
IV-kanyl	Canulă IV	IV Kanül
	IV قنية	

en

IV Cannula – Instruction for Use

DEVICE DESCRIPTION

The BD Neoflon™ Pro IV Cannula are over-the-needle, intravascular (IV) catheters. These catheters include BD Vialon™ Catheter Material, needle grip, removable wing cover, flash chamber with a removable flow control plug and BD Instaflash™ Needle Technology. Two flexible 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 BD Instaflash™ Needle Technology allows for immediate visualization of blood along the catheter. The removable flow control plug can be removed and connected to the IV cannula hub after catheter insertion (optional).

The catheter hub and wings are color coded to indicate the catheter gauge size (24 GA (0.7 mm) = Yellow, 26 GA (0.6 mm) = Violet).

INTENDED PURPOSE

The BD Neoflon™ Pro IV Cannula is intended for infusions / injections and is designed to gain access to the peripheral vessels of the vascular system for IV therapy, blood transfusion, and pressure monitoring.

CLINICAL BENEFITS

- Provides short term access to the peripheral vessels of the vascular system to facilitate infusions/injections to aid in patient treatment, management, and diagnosis.
- Provides short term access to the peripheral vessels of the vascular system to facilitate IV therapy to aid in patient treatment, management, and diagnosis.
- Provides short term access to the peripheral vessels of the vascular system to facilitate blood transfusion to aid in patient treatment, management, and diagnosis.
- Provides short term access to the peripheral vessels of the vascular system to facilitate blood pressure monitoring to aid in patient treatment, management, and diagnosis.

CONTRAINDICATIONS

None known.

GENERAL WARNINGS

- Intended for single patient use only.
- Do not resterilize.
- DO NOT RE-USE. Re-use may lead to infection or other illness/injury.
- Exposure to blood, either through percutaneous puncture with a contaminated needle or via mucous membranes or non-intact skin, may lead to serious illness such as hepatitis, HIV (AIDS), or other infectious diseases.
- Do not leave Luer slip connections unattended as they may become disconnected and result in blood exposure or blood loss.
- Small parts are a potential choking hazard. After use, discard small parts according to your facility policy.
- Potential complications related to the insertion and use of PIVC (peripheral intravenous catheter) include but are not limited to: abscess, air embolism, arterial irritation, blood exposure, blood loss/leakage, blood stream infection, bruising, catheter breakage/embolization, choking, death, delay/interruption of treatment, discomfort, edema, exposure to non-hazardous/hazardous drugs, hematoma, hemolysis, hemorrhage, infusate leakage, localized infection, needle stick injury, needle breakage/embolization, pain at injection site, particulate infusion, permanent ischemic damage, persistent pain, phlebitis, pseudoaneurysm, thrombosis, unsuccessful insertion, vessel infiltration/extravasation and wrong medication dose.

GENERAL PRECAUTIONS

- For proper use, clinician should be trained in vascular access and use of these catheters.
- Use these catheters in conjunction with your facility policy.
- Ensure aseptic technique, proper skin preparation, and continued protection of the site consistent with accepted standards of practice and your facility policy.
- Replace catheter according to your facility policy, relevant guidelines, or if the integrity of the device has been compromised.
- Follow Universal/Standard Precautions when inserting, maintaining, and removing these catheters to prevent exposure to bloodborne pathogens.
- Adhere to all contraindications, warnings, precautions, and instructions for all infusates, as specified by their manufacturer.
- Do not bend the needle before or during use.
- Do not use scissors or other sharp instruments at or near the insertion site.
- Use only with ISO compliant Luer connections. Non-ISO compliant Luer connections may cause leakage.
- Do not overtighten ISO Luer connections as damage may occur.
- EU Only: Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.

MRI SAFETY INFORMATION

MR **MR Conditional**

Non-clinical testing demonstrated that BD Neoflon™ Pro IV catheters are MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m) (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system

Under the scan conditions defined above, the BD Neoflon™ Pro catheter is expected to produce a maximum temperature rise of 2.5 °C after 15-minutes of continuous scanning (i.e., per pulse sequence).

Artifact Information

In non-clinical testing, the image artifact caused by the BD Neoflon™ Pro catheter extends approximately 10-mm from the BD Neoflon™ Pro catheter when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

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.

INSTRUCTIONS

Catheter Insertion and Removal

1. Examine unit package before opening to confirm its integrity. **PRECAUTION:** Do not use if package is damaged or opened or if the expiration date has passed.
2. Open package and remove device.
3. Inspect device for damage before insertion. **PRECAUTION:** Do not use if device is damaged. **NOTE:** The white luer lok plug (3) can be removed and attached to the catheter hub (1) after the catheter is placed in the vessel.
4. Holding the wing cover (8) remove needle cover (4) in a straight, outward motion and inspect the catheter unit for damage before insertion. Discard the needle cover according to your facility policy.
5. Ensure that the needle (6) bevel is facing upside on insertion.
6. Access vessel. **WARNING:** If the needle (6) is partially or completely withdrawn from the catheter tubing (5) during insertion, do not attempt to reinsert the needle (6) into the catheter tubing (5) as damage may occur.
7. Observe immediate blood return along the catheter tubing (5) -BD Instaflash™ Needle Technology (7).
8. Upon visualization of blood return, decrease the angle of insertion and advance the entire catheter and needle slightly to ensure the catheter tip is within the vessel.
9. Holding the flash chamber (2) stationary, advance the catheter off the needle (6) into the vessel. **PRECAUTION:** Do not pull back on the needle during catheter advancement.
10. Release tourniquet
11. Apply vessel compression before pulling the needle out of the catheter. Do not bend the needle during withdrawal.
12. Discard the needle into a puncture-resistant, leak-proof sharps container.
13. Attach Luer adapter of injection syringe, extension set, infusion tubing or white Lure plug (3) to flush or begin infusion. There are no known non-compatible medicinal products or IV fluids.
    - **WARNING:** Blood leakage from the catheter hub (1) may occur unless a secure Luer connection is made. Do not leave the catheter hub (1) exposed without connecting to an accessory device.
    - **WARNING:** During ARTERIAL use, DO NOT INFUSE THERAPEUTIC FLUIDS OR MEDICATIONS. Only infuse fluids required for maintenance of blood pressure monitoring and catheter patency after blood withdrawal.
14. Secure the catheter, flatten the wings (9), and apply a sterile dressing according to your facility policy.
15. To remove catheter, first disconnect from infusion system, remove sterile dressing, and then gently pull catheter out from insertion site.
    - **WARNING:** Upon removal of ARTERIAL catheter, apply direct pressure to insertion site while ensuring distal circulation until hemostasis achieved per your facility guidelines and policies.
16. Upon removal, examine catheter to ensure it is intact and discard according to your facility policy.

REVISION	CHANGE SUMMARY
01	Initial release according to new template – April 2019
02	Rev.02 – March 2021 Update of 1.5: Material of concern Update of 1.6: REACH information Update of 1.12: GMDN code – The GMDN code has changed Update of 2.3: Examples of labelling
03	General update according to new procedure and new MDR requirements, as per PIV-STED-011_Rev.A/Ver.A, with change of Legal Manufacturer – September 2024