BD Product NeoflonTM Pro Peripheral IV Catheter, Sterile, Single use
391379 – 391380

BD Switzerland Sàrl
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TDS number: V201-001 – Rev. 02
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1. General Information

1.1 Intended use

BD Neoflon™ Pro IV catheter device 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. These catheters may be used for any patient population with consideration given to patient size, appropriateness for solutions being infused and duration of therapy.

1.2 General description

The BD Neoflon™ Pro IV catheters consist of a straight, over the needle peripheral IV catheter with flexible wings that can be used with tape or adhesive for securement of the catheter after insertion. They are all devices for use by suitably trained health care professionals. The product is provided with a protection hub to protect against contamination of the catheter.
No separate instructions for use are provided with these devices as they are can be used safely without instructions. The labelling states that the user shall not reinsert a partially or fully withdrawn needle.
The BD Neoflon™ Pro catheter is available in both 24 and 26 gauge (GA), with a catheter length of 19 millimeters (mm) or 0.75 inches (IN). The product is delivered sterile and is non-pyrogenic.

BD Neoflon™ Pro IV catheter might be connected to other devices through a luer-lock connection

BD Neoflon™ Pro 24GA

BD Neoflon™ Pro 26GA

BD Catalog Number	BD Product Description	Gauge Size (GA/MM)	Cannula Length (MM)	Color Code
391379	Neoflon™ Pro 26GA	26/0.6	19	Purple
391380	Neoflon™ Pro 24GA	24/0.7	19	Yellow

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)
391379 391380	**Address:** Becton Dickinson Infusion Therapy AB Florettgatan 29C PO Box 631 SE-251 06 Helsingborg Sweden **ISO 13485** Certificate No.: 597883	CE certified with BSI (2797) Certificate No.: CE 597884	**Address:** Becton Dickinson Medical (S) Pte Ltd. 30 Tuas Avenue 2 Singapore 639461 Singapore **ISO 13485** Certificate No.: MD 81426	N/A

1.4 Materials

Component	Material
Catheter Hub	Polypropylene + Colorant
Needle Hub	Polypropylene
Flow Control Plug	Polypropylene
Plug	Polypropylene + Colorant
Hold housing	High Density Polyethylene
Protection Hub	Low Density Polyethylene
Catheter Tubing	BD Vialon™ (Polyurethane with radiopaque stripes)
Catheter Bushing	Stainless Steel
Cannula (Steel needle)	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 22 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 22 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 22 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	Based on our ongoing data collection efforts and/or information received from our suppliers as per 22 June 2020, BD has not identified any intentionally incorporated animal tissue or animal derived materials in the articles and packaging with the Product Numbers as referenced above. We have not conducted any tests for animal-derived materials in the above-listed products.
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 22 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

Sterilization method is validated per EN ISO 11135-1:2007 - "Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices"; and per EN 556-1 – "Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices"

1.9 Shelf life and storage conditions

The BD Neoflon™ Pro shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Neoflon™ Pro 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 TF013HEL-DOC linked to CE certificate number CE 597884:

Harmonized Standards	
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 ISO 20594-1:1993	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – General Requirements
EN ISO 10555-1:2014	Sterile, single use intravascular catheters – General Requirements
EN ISO 10555-5:2013	Sterile and single-use catheters - Part 5: Over-needle peripheral catheters
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
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 556-1:2001	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
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 1041:2008	Information supplied by the manufacturer of medical devices
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 – Lock Fittings
ISO 14644-1:1999	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
ISO 9626	Stainless steel needle tubing for the manufacture of medical devices
ISO 10555-1:2013	Sterile, single use intravascular catheters – General Requirements
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare — Part 7: Connectors for intravascular or hypodermic applications

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 Neoflon™ Pro are Class IIa medical devices as defined in the Medical Devices Directive (93/42/EEC) Annex IX, section 2.3, Rule 7: Surgically invasive devices intended for short-term use, to which the exceptions do not apply.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Neoflon™ Pro 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*
391379	Neoflon™ Pro 26GA	1	50	500	No
391380	Neoflon™ Pro 24GA	1	50	500	No

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

2.2 Packaging material

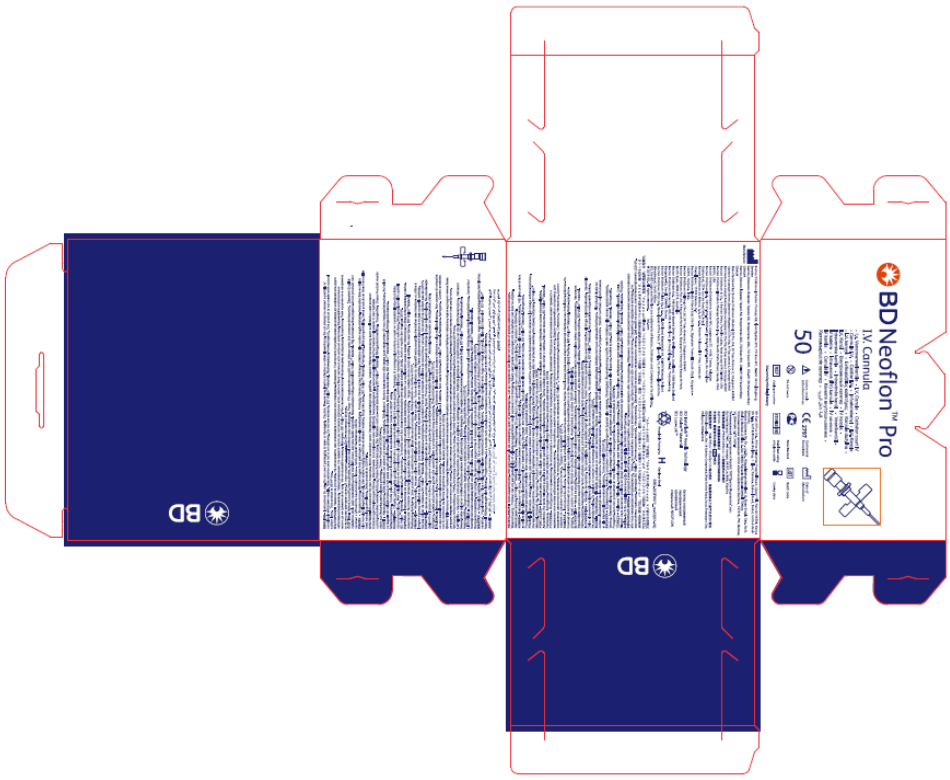
Component	Material
Unit Pack	Top Web: Medical paper – APET foil
Shelf Box	Bleached folding duplex boxboard
Shipping Case	Corrugated Case Carton

2.3 Examples of labeling

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

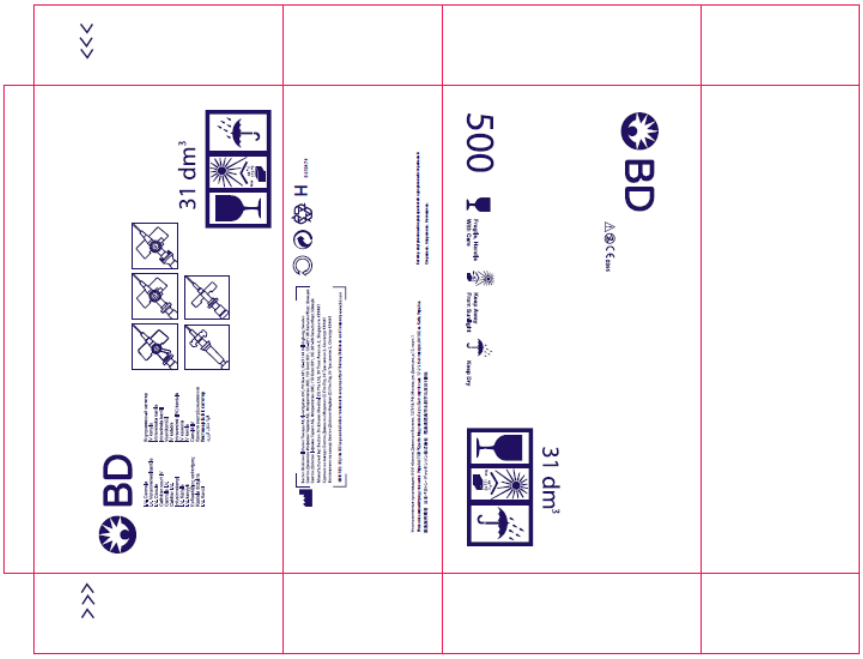
Primary Packaging Label (Top Web) extracted from document SRD-DGW0189 related to reference 391379:

Shelf Box extracted from document SRD-DGF0077 related to reference 391379:



Shelf Box label extracted from document SRD-DGL0423 related to reference 391379:

Shipping Case extracted from document SDGC2 related to reference 391379:



Case Label extracted from document SRD-DGL0427 related to reference 391379:

REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	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