BD Venflon™,
Sterile,
391451 – 391452 – 391453 – 391454 – 391455
391456 – 391457

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1. General Information

1.1 Intended use

BD Venflon™ I.V. Cannula Luer-Lock with a plug attached to the flow control plug, are disposable devices in the BD IT AB assortment of peripheral I.V. Cannula. The products are designed to gain access to peripheral veins of the patient's blood system for rehydration, parenteral nutrition, medication delivery, blood transfusion, and monitoring purposes.

1.2 General description

The BD Venflon™ product has a stainless steel cannula provided with a soft siliconized catheter of PTFE over it. The catheter is fixed in a cannula hub with a patented bushing design. The cannula hub has a canal running from the catheter fixation to a Luer-Lock fitting at the opposite end, intended for further connection.

The cannula hub also has a separate injection port which, by a patented automatic valve, is connected to the canal. Through this port it is possible to give an immediate intravenous, eventually repeated injection with a syringe (without using a hypodermic needle) during infusion or as intermittent injections. In the latter case the Luer- Lock fitting of the cannula hub is sealed with a plug. When the injection port is not used it is protected by a cap, which is fixed to the cannula hub and in that way impossible to lose. The protection cap is colored according to the ISO color coding system for different catheter sizes.

The flexible wings of the cannula hub can, with a piece of adhesive, be used for fixation of the product, once it is inserted into a vein. The stainless steel needle runs through the whole length of the catheter and the cannula hub and ends up fixed in a grip, which fits in the Luer-Lock fitting of the cannula hub. The other end of the grip has a female cone, in which a flow control plug (FCP) is placed. When puncturing a vein, blood flows through the steel needle to the FCP. In this way, it indicates when the steel needle has entered the vein. At the same time, the blood leakage is prevented and, thereby, the risk of contamination.

A plug is assembled onto the FCP. The fixation is designed in such a way that, when the grip with the FCP has been removed from the I.V. Cannula, the plug is disassembled for intended use with a simple one-hand-operation. The tapered and beveled tip of the catheter fits tightly to the steel needle. This minimizes friction during skin and vein puncture.

The I.V. Cannula is provided with a protection hub to protect against contamination.
The BD Venflon™ catheter is available in various gauge (G) sizes ranging from 14 to 22G and lengths ranging from 1 to 1.8 inch (IN) (25 to 45 millimeters).

BD Catalog Number	BD Product Description	Gauge Size	Length	Color Code	Flow rate mL/min	Penetration Force (N)
391451	VENFLON 2 BL 22GA IV CANNULA	22	25	Blue	31	0.5
391452	VENFLON 2 PNK 20GA IV CANNULA	20	32	Pink	54	0.6
391453	VENFLON 2 GN 18GA IV CANNULA	18	45	Green	80	0.6
391454	VENFLON 2 WH 17GA IV CANNULA	17	45	White	125	0.7
391455	VENFLON 2 GR 16GA IV CANNULA	16	45	Grey	180	0.7
391456	VENFLON 2 BR 14GA IV CANNULA	14	45	Orange	270	0.8
391457	VENFLON 2 GN 18GA IV CANNULA	18	32	Green	80	0.6

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)
391451 391452 391453 391454 391455 391456 391457	**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 India Pvt. Ltd. Plot No.1, Sector 3 IMT Bawal, District Rewari Haryana 123501, India **ISO 13485** Certificate No.: 247911-2017-AQ-IND-NA-PS	N/A

1.4 Materials

Component	Material
Cannula Hub	Polypropylene
Needle Hub	Polypropylene
Flow Control Plug	Polypropylene
Plug	Polypropylene with white master batch
Color coded protection cap	High Density Polyethylene with colored master batch
Protection hub	Low Density Polyethylene
Valve	Methyl Vinyl Polysiloxane
Catheter tubing	Polytetrafluoroethylene
Catheter Bushing	Polycarbonate white
Cannula	Stainless steel
Silicone liquid	Polydimethylsiloxane

1.5 Materials of concern

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

Material	Comment
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per June 2020, BD has not identified any • 1,2-Benzendicarboxylic acid, dihexyl ester (branched & linear) (CAS#68515-50-4), • 1,2-Benzendicarboxylic acid, di-C6-8-branched alkyl esters (CAS#71888-89-6), • 1,2-Benzendicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS#68515-42-4), • 1,2-Benzendicarboxylic acid, di-C6-10 alkyl esters (CAS#68515-51-5), • 1,2-Benzendicarboxylic acid, mixed decyl, hexyl, and octyl diesters (CAS#68648-93-1), • Benzyl butyl phthalate (BBP) (CAS# 85-68-7), • Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), • Bis (2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), • Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), • Dibutyl phthalate (DBP) (CAS# 84-74-2), • Diisobutyl phthalate (DIBP) (CAS# 84-69-5), • Diisopentylphthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CAS# 131-18-0), • N-pentyl-isopentylphthalate (CAS# 776297-69-9), or • Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7) in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w).
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per June 2020, the articles with the Product Numbers above are not formulated with natural rubber latex.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per June 2020, BD has not identified any 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w). There is a polycarbonate component in these products. Bisphenol-A (BPA) is an organic compound that is a chemical building block for polycarbonate. Based on information from

	our suppliers and BD test results, the BPA level is less than 0.1% wt/wt (<1000 ppm). These levels are below a de minimis concentration with no demonstrable clinically significant exposure nor toxicity. No labeling for California Prop 65 is needed. No REACH SVHC declaration is required.
Substances of animal origin BSE/TSE	The raw materials used in the manufacture of these devices do not contain any animal tissue but may contain very small amounts of chemicals that are derived from animal-derived raw materials. These products are manufactured using polymer resins which may contain very small amounts of stearic acids and related substances derived from tallow derivatives. Our resin suppliers have confirmed that these chemicals have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN ISO 22442-1:2015 and Section 6 of EMA 410/01 Rev. 3. Therefore, these raw materials meet or exceed the requirements of EN ISO 22442-1 and EMA 410/01 Rev. 3. Based on this information, these products are considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, as recognized by MEDDEV 2.4/1, such derivative chemicals produced in accordance with the aforementioned standards and guidelines are considered irrelevant when determining the classification of a medical device (per MDD 93/42/EEC and EU No 722/2012).
Polyvinyl chloride (PVC)	The medical devices referenced above have not been designed nor intentionally manufactured with any additives or raw materials that contain PVC. No PVC is intentionally added to these medical devices.
Blood Derivatives	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.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per June 2020, BD has not identified any chemicals in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on 15 January 2019 according to Art. 59 (1,10) of the Regulation (EC) N° 1907/2006 (REACH).

1.7 Biocompatibility

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

1.8 Sterilization method

Ethylene Oxide sterilization method validated in accordance with EN ISO 11135-1 (Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices).

1.9 Shelf life and storage conditions

The BD Venflon™ shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Venflon™ have a shelf life of 5 years.

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

1.10 Standards

As per extract from the Declaration of Conformity (document number TF001HEL-DOCVenflon) linked to CE certificate number CE 597884:

Harmonized Standards	
EN 556-1:2001	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 15223-1:2016	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 20594-1:1993	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.
EN 980:2008	Symbols for use in the labelling of medical devices
EN ISO 10555-1:2014	Sterile, single use intravascular catheters – General Requirements
EN ISO 10555-1:2013	Sterile, single use intravascular catheters – General Requirements
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 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 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
EN ISO 11137-1:2006	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2009	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
EN 62366:2008	Medical devices. Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
Non-Harmonized Standards	
ISO 15223-1:2012	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – 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 14644-1:1999	Clean rooms and associated controlled environments – Part 1: Classification of air cleanliness
ISO 9626:1991	Stainless steel needle tubing for the manufacture of medical devices
ISO 10555-1:2013	Sterile, single use intravascular catheters – General Requirements
ISO 10555-5:2013	Sterile, single use intravascular catheters – Over needle peripheral catheters

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

1.11 Classification

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

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Venflon™ is referenced as follows:
GMDN Code: 64574
GMDN Term: Peripheral vascular 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*
391451	VENFLON 2 BL 22GA IV CANNULA	1	50	500	N/A
391452	VENFLON 2 PNK 20GA IV CANNULA	1	50	500	N/A
391453	VENFLON 2 GN 18GA IV CANNULA	1	50	500	N/A
391454	VENFLON 2 WH 17GA IV CANNULA	1	50	500	N/A
391455	VENFLON 2 GR 16GA IV CANNULA	1	50	500	N/A
391456	VENFLON 2 BR 14GA IV CANNULA	1	50	500	N/A
391457	VENFLON 2 GN 18GA IV CANNULA	1	50	500	N/A

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

2.2 Packaging material

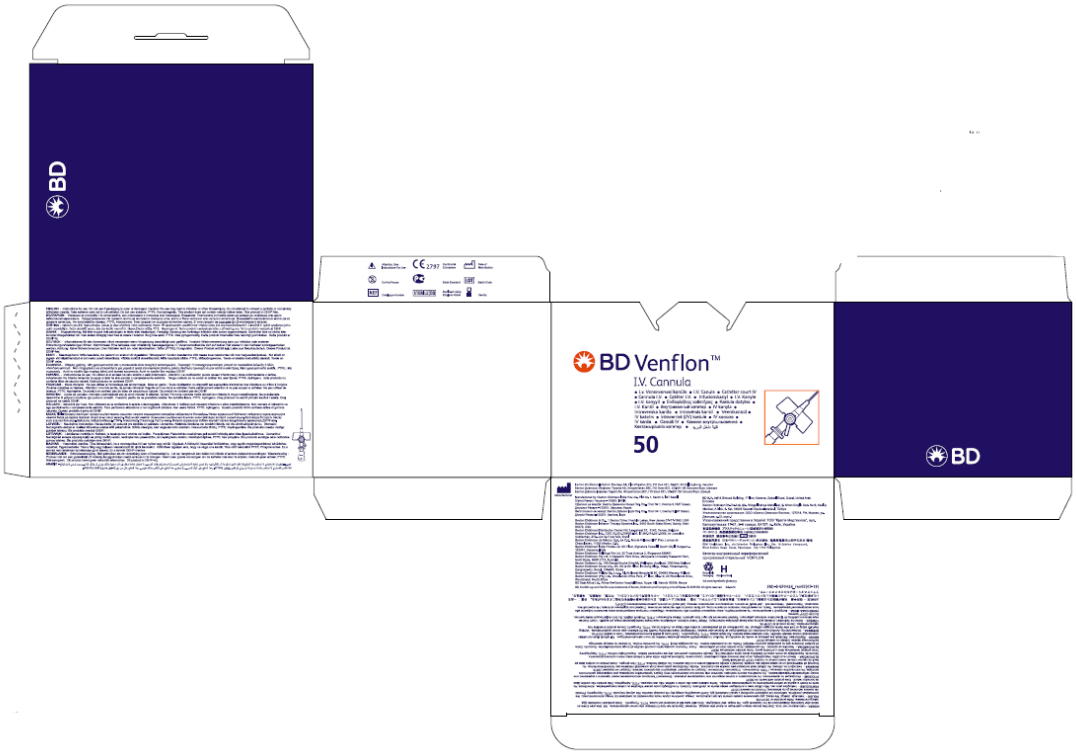
Component	Material
Unit Pack	Top web: Medical paper or Tyvek Bottom web: APET foil
Shelf Box	Bleached folding duplex boxboard
Shipping Case	Corrugated Case Carton

2.3 Examples of labeling

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

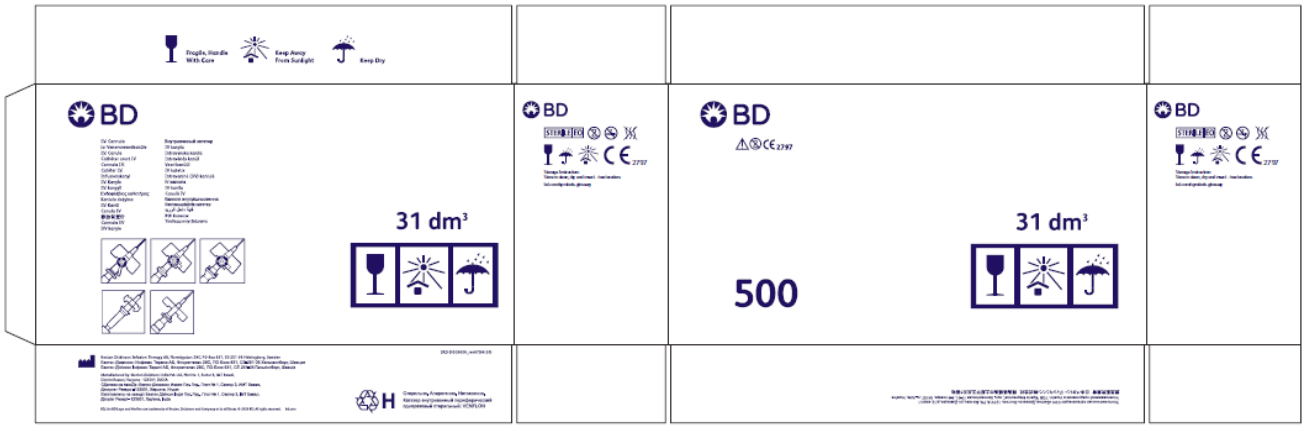
Primary Packaging Label (Top Web) extracted from document SRD-DGW0056 related to reference 391451:

Shelf Box extracted from document SRD-DGF0026 related to reference 391451:



Shelf Box label extracted from document SRD-DGL0199 related to reference 391451:

Shipping Case extracted from document SRD-DGC0030 related to reference 391451:



Case Label extracted from document SRD-DGL0233 related to reference 391451:

REVISION	CHANGE SUMMARY
01	Initial release according to new template