Becton Dickinson and Company
BD Medical,
BD Medication Delivery Solutions

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Version 01 – May 2020

TECHNICAL DATA SHEET
BD Arterial Cannula with Flow switch
Peripheral IV Catheter
Sterile, Single Use

1. General Information

1.1. Intended use

The Arterial Cannula is a sterile, non-pyrogenic, disposable catheter designed to allow peripheral access to the human circulatory system. It is indicated for patients requiring continuous direct blood pressure monitoring and arterial blood gas sampling.

1.2. General description

BD Arterial Cannula is a sterile, non-pyrogenic, disposable (single use), over the needle, single lumen peripheral catheter , which specifically is intended for insertion into the radial artery and is indicated for patients requiring arterial pressure monitoring and serial arterial blood gas determinations.

The BD Arterial Cannula hub has an integral on/off flow control device to prevent back-flow and blood spillage, a luer-lock connection for accessory attachment, and wings to facilitate securement. The flow control device is operated by a positive action by moving a red button to or from a position allowing flow through the device. The catheter tubing is polytetrafluoroethylene (PTFE), which is widely accepted as nonreactive and resistant to a broad range of drugs. Peripheral IV catheters made of FEP-polymer have been available for over 50 years.

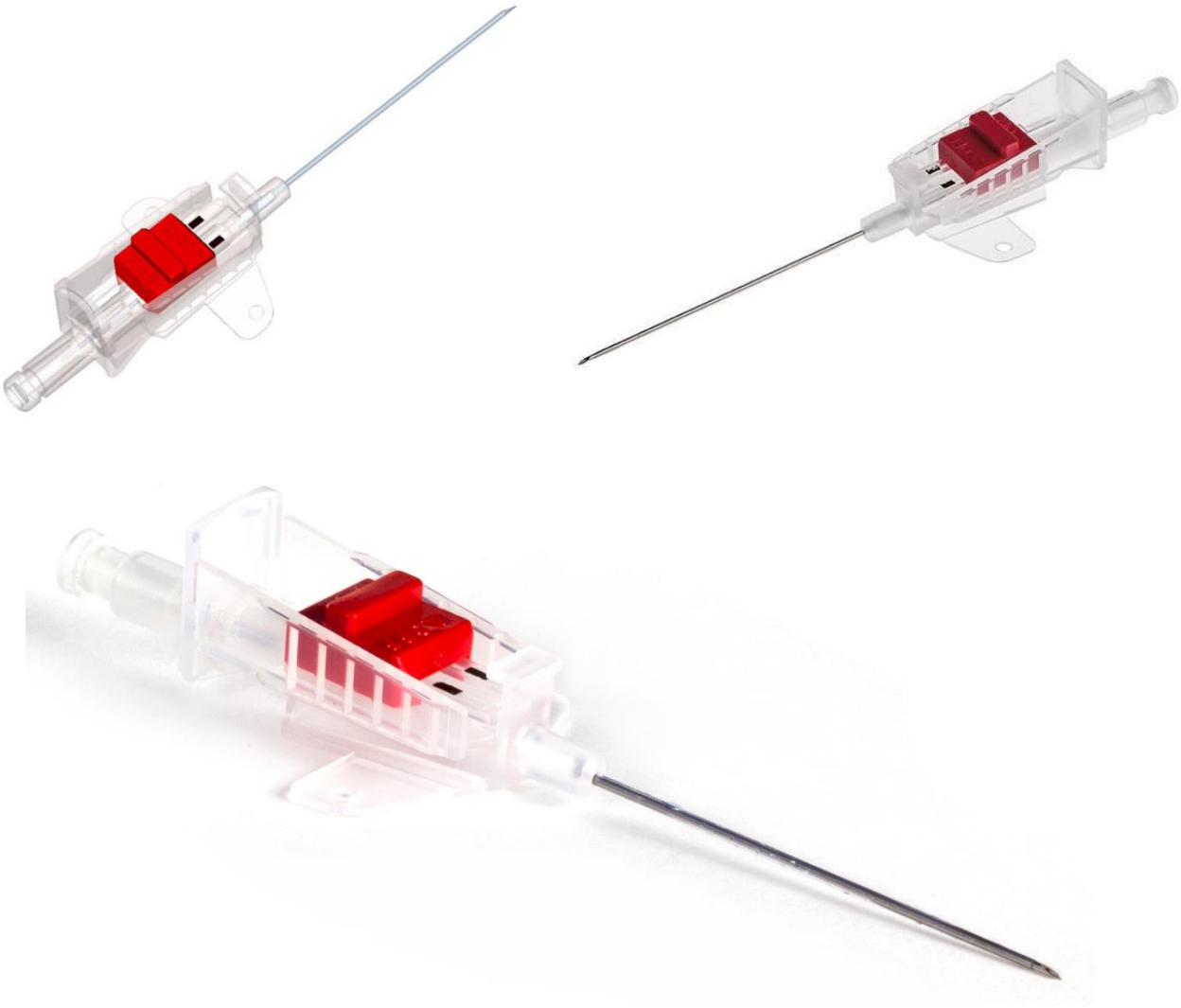
The product is available in a:

- Standard outer diameter of 1.1mm

- Standard length of 45mm

The product is individually packed in a pre-formed blister plastic foil with a sealed pre-printed medical grade paper.

The sealed unit packs are sterilized using Ethylene Oxide gas and are given a shelf life of 5 years from the date of sterilization.



Catalogue No	Product Description
682245	BD Arterial Cannula 20G / 1.10mm x 45mm 49mL/mi

1.3. Certification

BD Legal Manufacturer	CE Marking	BD Manufacturing Site	EC Representative
Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah 84070, USA. ISO 13485:2016 Certification No.: FM71665	BSI 2797 Certificate: CE 01738	**Becton Dickinson Medical (S) Pte Ltd** 30 Tuas Avenue 2 Singapore 639461 Singapore. EN ISO 13485: 2016 & ISO 13485:2016 Certification No.: MD 81426	**Becton Dickinson Distribution Center NV** Laagstraat, 57 Temse 9140 Belgium

1.4. Material

Component	Material
Flow Control Switch Button	Polyphenylene Oxide
Flow Control Switch Housing	Polypropylene
Needle Grip	Polypropylene
Guide Bush	Polycarbonate
Catheter Bush	Polycarbonate
Flow Control Switch Housing	Polypropylene
Catheter Tube	PTFE
Protection Tube	Polyethylene
Valve	Silicone
Flow Control Plug	Body Material: Polypropylene Membrane Material: Acrylic Copolymer
Steel Needle	Stainless Steel
Steel Ball	Stainless Steel
Lubricant	Silicone
Printing Foil	Polyester Foil
Bottom Web	Polyester/Polyethylene
Top Web	Medical Grade Paper

IFU	Paper
Shelf Box	Cardboard
Shipper Box	Corrugated Carton

1.5. Material of concern

Material	Present (No/Yes)
DEHP/Phthalate	No
Latex	No
Substances of animal origin BSE/TSE	No
PVC	No

1.6. REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 25 June 2020, BD has not identified any chemicals in the articles and packaging with the Product Number 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) No 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

1.8.1. Sterilization Process

The product is sterilized by Ethylene Oxide at the contract sterilization facilities listed below:

Sterile Services (Singapore) Pte. Ltd.
No. 47A Jalan Buroh,
Module 6,
CWT Distripark
619492
Singapore.

Becton Dickinson Medical (S) Pte. Ltd.
30 Tuas Avenue 2
Singapore 639461
Singapore

and tested at the manufacturing facility
Becton Dickinson Medical (S) Pte Ltd.
30 Tuas Avenue 2
Singapore 639461
Singapore

Sterile Services (Singapore) Pte Ltd is ISO 13485:2016 certified for the provision of ethylene oxide sterilization in accordance with EN ISO 11135:2014.

Their sterilization process is validated in compliance with EN ISO 11135:2014 "Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices".

1.8.2. Product Release

Sterilization certificates are signed by BD microbiologist prior to product release.

In the event of sterilized product not meeting the release criteria, it is put on hold immediately and will be handled per disposition of non-conformance product procedure.

After which the microbiologist (along with BD Medical Surgical Systems personnel if needed), review the sterilization process records and determines if it is acceptable for release, re-sterilization or if it must be scrapped.

1.9. Shelf life

The BD Arterial Cannula shelf life of 5 years was justified by conducting stability studies in order to verify the functionality, physic-chemical and microbial properties over time.

The 5-year shelf life is substantiated by the accelerated aging test:

Report-BD Arterial Cannula DVT Device Verification Testing Study, Report No: 295006-132-157 Rev No.:2.0

1.10. Standards

The products/procedures comply with the following standards:

Standard Reference No	Year / Revision	Name of Standard
EN ISO 13485 (ISO 13485)	2012 2003	Quality Systems- Medical Devices- System Requirements for Regulatory Purpose
ISO 9001	2008	BSI British Standards: Quality Management Systems- Requirements
21 CFR Part 820	2010	Federal Register- Quality System Regulation

EN ISO 10555-1 ISO 10555-1	2009 1995	Sterile, Single-use Intravascular Catheters Part 1: General Requirement
ISO 10555-5	1995	Sterile, Single-use Intravascular Catheters- Part 5: Over-needle Peripheral Catheters
EN 20594-1 ISO 594- Part 1	1993 1986	Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 1: General Requirements
ISO 594- Part 2	1998	Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 2: Lock Fittings
EN ISO 10993-1 ISO 10993-1	2009 2009	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing I
EN ISO 11737-1 ISO 11737-1	2006 2006	Sterilization of medical devices – Microbiological Methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11135-1 ISO 11135-1	2007 2007	Sterilization of Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization
BS EN 980	2008	Symbols for Use in the Labelling of Medical Devices
EN ISO 10993-7 ISO 10993-7	2008 2008	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

BS EN ISO 14644-1	1999	Cleanrooms and Associated Controlled Environments- Part 1: Classification of Air Cleanliness
EN 1041	2008	Information Supplied by the Manufacturer with Medical Devices
EN ISO 14971 ISO 14971	2012 2007	Medical Devices - Application of Risk Management to Medical Devices
USP 33 <788>	2010	USP- Particulate Matter in Injections

1.11. Classification

BD Arterial Cannula is intended for short-term (less than 30 days), invasive medical device, which is intended for insertion into the radial artery and is indicated for patients requiring arterial pressure monitoring and serial arterial blood gas determinations. Therefore, the product is classified as a Class IIa device per Annex IX, Section 2.3 (Rule 7) of the Medical Device Directive 93/42/EEC.

1.12. GMDN code

GMDN Code: 10689

GMDN Term: Arterial blood pressure catheter

Definition: A thin, flexible tube designed for passage into arteries, usually for arterial infusion/aspiration. The device is typically interfaced with a parent device (e.g., an oscilloscope) for the continuous measurement of arterial blood pressure. This is a single-use device.

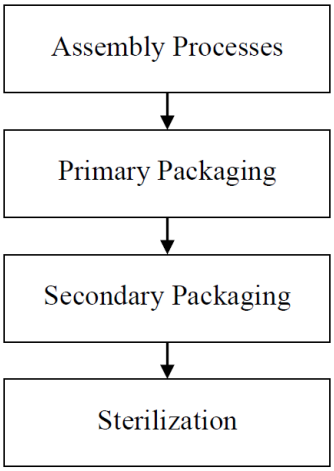
1.13. Good Manufacturing practices

BD Arterial Cannula is manufactured and assembled step by step in ISO Class 8 Cleanroom. The assembly processes is automated.

The devices are packaged and labelled in their single unit pack, after which the unit packed devices are placed into shelf cartons, followed by shipper cartons, and palletized and forwarded to sterilization.

The products are held quarantined until final release by QA Department.

Below is the simplified manufacturing flow of the BD Arterial Cannula:



Detailed manufacturing flowchart is located in MFC-009.

1.14. Others

Arterial catheters have been used clinically since the 1960s both in the United States and in Europe. The BD Arterial Cannula is a mature device that has been used successfully since the start of distribution in 1980.

The clinical evaluation is based primarily on clinical expert opinion and BD's long term experience with these devices. The value of clinical experience data is that it provides real world experience obtained in larger, heterogeneous and more complex populations with a broader range of end-users than is usually

the case with clinical investigations. At this time, clinical investigation or a systematic review of the published literature are not considered necessary to demonstrate that these devices continue to perform safely and as intended.

The clinical evaluation also considered supporting data such as existing risk and health hazard analysis, risk mitigation strategies, and a review of product labelling and Instruction for Use.

For further details of the Clinical Evaluation Report of BD Arterial Cannula, refer to RTF63.

2. Packaging

The device labeling incorporates a form, fit and seal blister plastic foil with a sealed pre-printed lid, printed product shelf box and shipper box, printed label affixed to the shelf box and shipper box and instructions for use. The printed information includes the name and address of manufacturer, product description, graphical symbols in accordance with BS EN 980, precautionary statements, the name and address of the EU representative(s), the CE mark, and other relevant symbols, such as DEHP-Free symbol, that are specific to the product.

Labeling and IFU checklists with reference to the Medical Device Directive Essential Requirements Section 13.3 and 13.6 can be found in Tables 1 and 2.

Table 1: Labelling Checklist as per Essential Requirements Section 13.3

SUBSECTION	APPLICABLE	INFORMATIONAL ELEMENT	PRESENT
13.3 (a)	Yes	Name and address of manufacturer and Name and address of authorized representative in Europe	Yes
13.3 (b)	Yes	Identification of device	Yes
13.3 I	Yes	The word 'STERILE'	Yes
13.3 (d)	Yes	The batch code preceded by 'LOT'	Yes
13.3 (e)	Yes	Expiration date	Yes
13.3 (f)	Yes	Indication that the device is for single use	Yes
13.3 (g)	No	The words 'custom-made device'	N/A

13.3 (h)	No	The words 'exclusively for clinical investigations'	N/A
13.3 (i)	No	Special Storage and handling conditions	N/A
13.3 (j)	Yes	Special Operating Instructions	N/A
13.3 (k)	Yes	Warnings and/or precautions	N/A
13.3 (l)	No	Year of manufacture (for active devices)	Yes
13.3 (m)	Yes	Method of sterilization	Yes
13.3 (n)	No	Indication that the device contains human blood derivative	N/A

Table 2: IFU Checklist as per Essential Requirements Section 13.6

SUBSECTION	APPLICABLE	INFORMATIONAL ELEMENT	PRESENT
13.6 (a)	Yes	Name and address of manufacturer and Name and address of authorized representative in Europe	Yes
13.6 (a)	Yes	Identification of device	Yes
13.6 (a)	Yes	The word 'STERILE'	Yes
13.6 (a)	Yes	Indication that the device is for single use	Yes
13.6 (a)	No	The words 'custom-made device'	N/A
13.6 (a)	No	The words 'exclusively for clinical investigations'	N/A
13.6 (a)	No	Special Storage and handling conditions	N/A
13.6 (a)	Yes	Special Operating Instructions	Yes
13.6 (a)	Yes	Warnings and/or precautions	Yes
13.6 (a)	No	Year of manufacture (for active devices)	N/A
13.6 (a)	Yes	Method of sterilization	Yes
13.6 (a)	No	Indication that the device contains human blood derivative	N/A
13.6 (b)	Yes	Performance Information	Yes
13.6 (c)	No	Identification of connected devices	N/A
13.6 (d)	No	Installation, maintenance, calibration	N/A
13.6 (e)	No	Risks of implantation of device	N/A
13.6 (f)	No	Risks of reciprocal interference	N/A
13.6 (g)	Yes	Instructions for damaged packaging	Yes
13.6 (h)	Yes	Instructions for re-use and warning for re-use of device for single use	Yes
13.6 (i)	No	Handling needed prior to use	N/A
13.6 (j)	No	Details of radiation emitted	N/A
13.6 (k)	No	Performance change precautions	N/A

13.6 (l)	No	Environmental precautions necessary	N/A
13.6 (m)	No	Medicinal products administered	N/A
13.6 (n)	No	Precautions for device disposal	N/A
13.6 (o)	No	Medicinal substances or human blood incorporated into device as an integral part	N/A
13.6 (p)	No	Accuracy of measuring functions	N/A
13.6 (q)	Yes	Date of issue or the latest revision of IFU	Yes

Labelling Artwork List

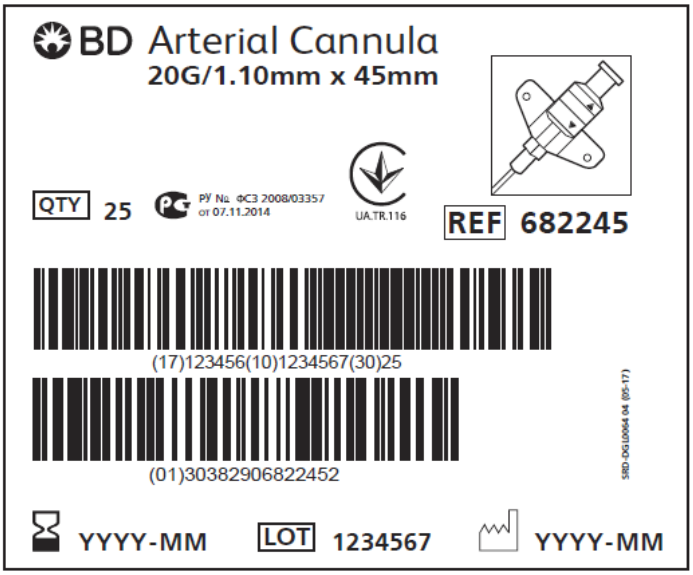
Packaging Level	Artwork Drawing No.
Unit Label	SRD-DGW0051
Unit Label (4 x 2 Lane)	SRD-DGW0240
Shelf Box	SRD-DGF0079
Shelf Label	SRD-DGL0064
Shipper Label	SRD-DGL0063
Shipper Box	SRD-DGC0083
Instruction for Use	SRD-DGP0009

2.1. Packaging material

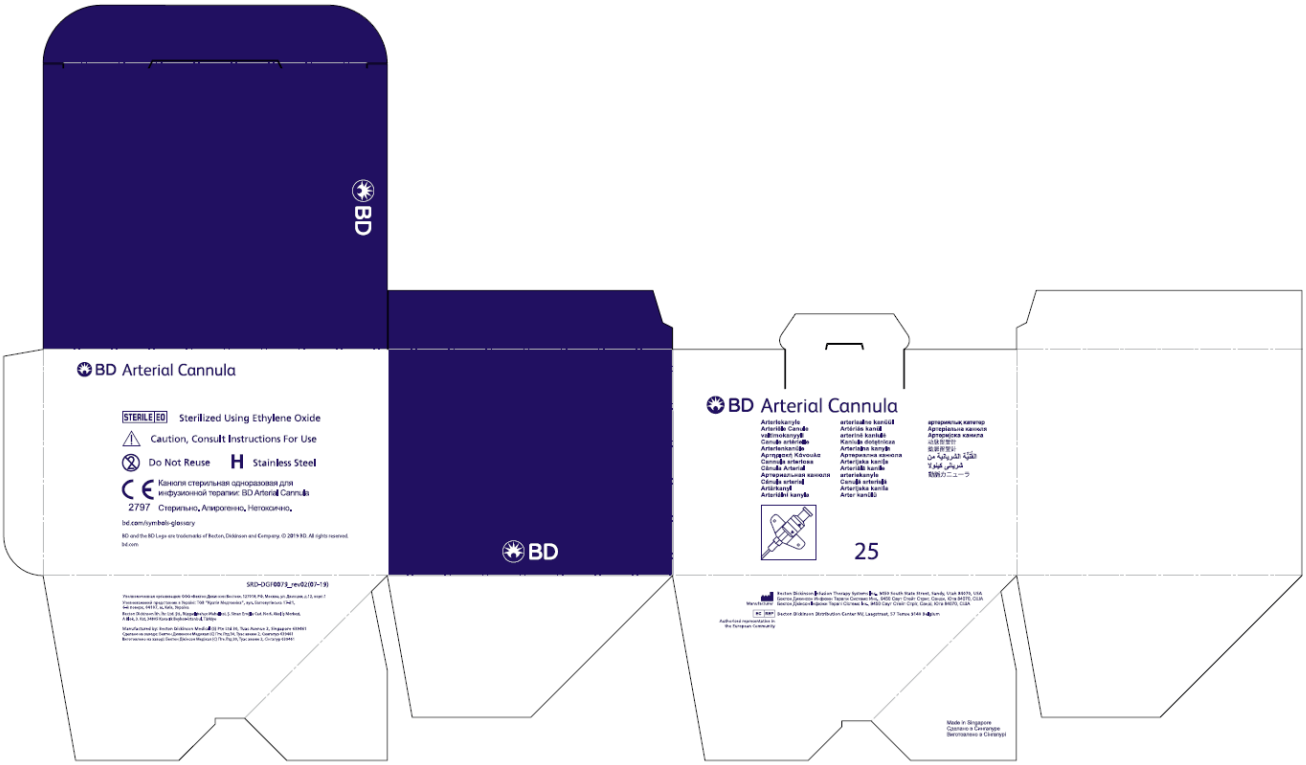
Packaging Level	Material
Bottom Web	Polyester/Polyethylene
Top Web	Medical Grade Paper
IFU	Paper
Shelf Box	Cardboard
Shipper Box	Corrugated Carton

2.2. Example labeling

Shelf Label, extracted from document SRD-DGL0064



Shelf box, extracted from document SRD-DGF0079



Shipping label, extracted from document SRD-DGL0063

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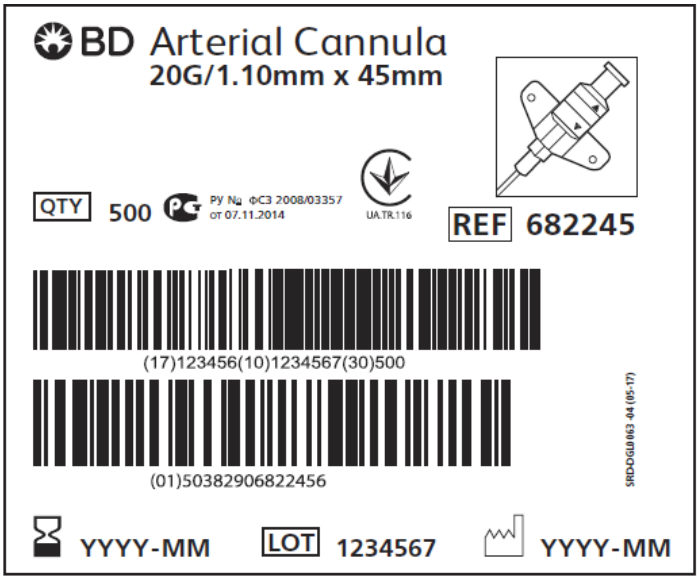
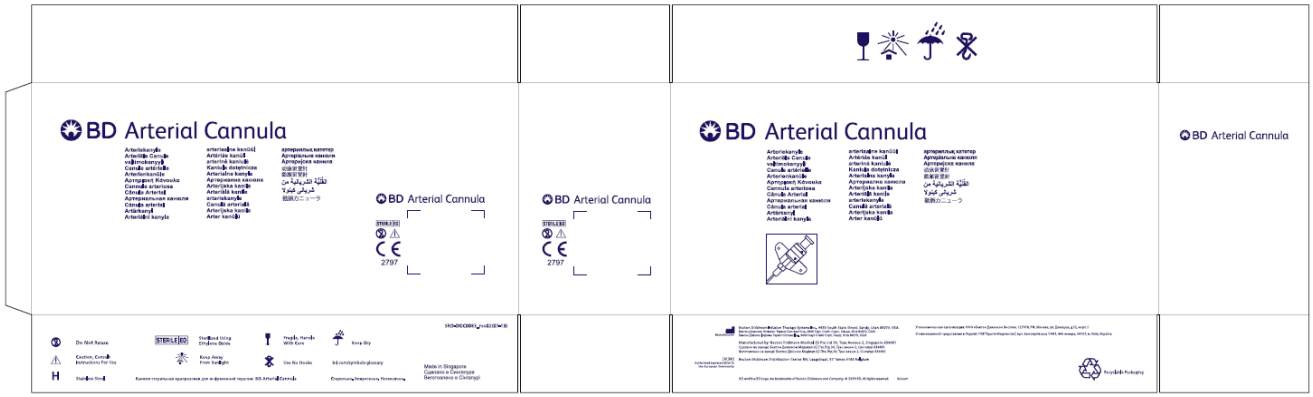


Shipping carton, extracted from document SRD-DGC0083



Unit label, extracted from document SRD-DGW0051

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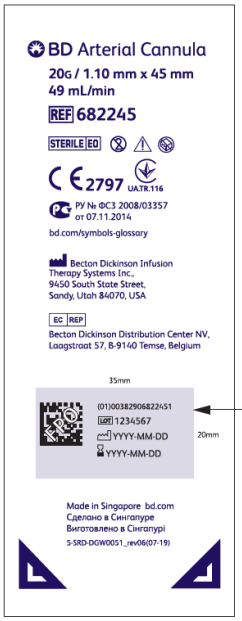

Variable information prints as shown within a 35mm x 20mm area.

End of TDS