BD Pressure Rated Catheter Extension sets
Sterile, Single-use
20019E7DS / 20038E7DS / 20039E7DS

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com

TDS number: V201-113 – Rev. 01
BD-104990 – Rev. 01
2023-October

1. General Information

1.1 Intended use

1.1.1 Intended purpose

The BD Pressure Rated Catheter extension sets are sterile, single use devices intended to be attached to an IV catheter to decrease movement /manipulation of the catheter hub and provide extra length, and functionality. Pressure Rated Catheter Extension Sets can be used for direct injection, intermittent infusion, and/or continuous infusion of fluids and/or medications.

1.1.2 Intended User

The BD Pressure Rated Catheter Extension Sets are intended to be used by healthcare professionals who are experienced in IV infusion therapy.

1.2 General Medical Devices description

The BD Pressure Rated Catheter Extension Sets are used for infusion therapy. The extension sets vary in length, configuration, power injection capability and priming volume. The pressure rating is specified on the product label.

Figure 1. 20019E7DS
BD SmartSite™ 'Y' Extension
Set. 2 Needle Free Valves

Figure 2. 20038E7DS
BD SmartSite™ Extension
Set. 3 Needle Free Valves

Figure 3. 20039E7DS
BD SmartSite™ Extension
Set. One Needle Free Valve

BD Catalog Number	BD Product Description	Tube Length (cm)	Total Length (cm)	Priming Volume (ml)	Tube Inner Diameter (mm)	Tube Outer Diameter (mm)
20019E7DS	BD SmartSite™ 'Y' Extension Set. 2 Needle-Free Valves	17.5	24	0.40	1	2.1
20038E7DS	BD SmartSite™ Extension Set. 3 Needle Free Valves	7.5	14	0.51	1	2.1
20039E7DS	BD SmartSite™ Extension Set. One Needle Free Valve	10	16	0.13	1	2.1

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:

BD Catalog Number	Gravity Use	Pressure	Ventilation Spike	Back Check Valve	Filter Size	Change Interval*	Lipid Resistant*
20019E7DS	Yes	325 psi	No	No	N/A	7d	24h
20038E7DS	Yes	325 psi	No	No	N/A	7d	24h
20039E7DS	Yes	325 psi	No	No	N/A	7d	24h

* For infusions of blood, blood products or lipid emulsions replace every 24 hours. For further information please see Instructions for Use placed in the shipper box.

1.3 Certification

BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number and Norified Body Brief Name	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
20019E7DS	**Address:** Sendal S.L., Ctra. Nacional Madrid-Cáceres s/n, 10350 Almaraz, Cáceres, SPAIN **ISO 13485** Certificate No.: Q5 064670 0025	CE certified with TÜV SÜD Certificate No.: G10 064670 0026 Rev.00	**Address:** Sendal S.L., Ctra. Nacional Madrid-Cáceres s/n, 10350 Almaraz, Cáceres, SPAIN Country of Origin: Spain **ISO 13485** Certificate No.: Q5 064670 0025	N/A
20038E7DS				
20039E7DS				

1.4 UDI-DI

The UDI-DI is:

SKU.No	UDI_DI
20019E7DS	Primary DI: 08428820007757
	Package Level 2 DI: 58428820007752
	Package Level 3 DI: None
20039E7DS	Primary DI: 08428820007771
	Package Level 2 DI: 58428820007776
	Package Level 3 DI: None
20038E7DS	Primary DI: 08428820007764
	Package Level 2 DI: 58428820007769
	Package Level 3 DI: None

1.5 Eudamed Registration

- Manufacturer Single Registration Number (SRN): ES-MF-000016981
- EU Authorised Representative Single Registration Number (SRN): N/A

1.6 Person Responsible for Regulatory Compliance

The information about the Person Responsible for Regulatory Compliance (PRRC) can be found on Eudamed website:

https://ec.europa.eu/tools/eudamed/#/screen/home

1.7 Materials

Component	Material
BD SmartSite™	Acrylic (body), Polyurethane (cap), Silicone (piston)
Slide clamp	PE
Y connector	PVC (not made with DEHP)
Rotating luers	ABS
Protective cap at luers	PE
Tubing	PVC (not made with DEHP)

1.8 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	DEHP or other phthalates are not part of material formulation of the products presented in this technical data sheet
Latex	Natural rubber latex is not part of material formulation of the products presented in this technical data sheet.
Bisphenol A	The products presented in this technical data sheet do not contain bisphenol A.
Substances of animal origin BSE/TSE	The products in this technical data sheet are not made with substances of animal origin.
Polyvinyl chloride (PVC)	The products in this technical data sheet contain polyvinyl chloride, however not made with added DEHP.

1.9 REACH information

We recognize that while our products, as mixtures, are exempt from REACH obligations, some of the individual substances within these mixtures require Registrations. We wish to assure you that we have assessed our product portfolio and will remain in compliance with all relevant obligations pertaining to the REACH Regulation for all nonexempt substances which BD import or manufacture within the European Economic Area (EEA) in total quantities above 1 tonne per annum (tpa). Please note that not all of the substances within our product portfolio require Registration.

1.10 Biocompatibility

The 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.

1.11 Sterilization method

Ethylene Oxide Sterilization

1.12 Shelf life and storage conditions

The BD SmartSite™ shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
The BD SmartSite™ references 20019E7DS / 20038E7DS / 20039E7DS has a shelf life of 47 months.
BD recommends storing in a dry and warm place, not exposed to strong light.

1.13 Standards

As per extract from the Declaration of Conformity (ALM-STED-03) linked to CE certificate number G10 064670 0026:

Standards	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 13485: 2016/A11:2021	
EN ISO 14971:2019	Medical Device – Application of risk management to medical devices
EN ISO 14971:2019/A11: 2021	
ISO 8536-4:2019	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
ISO 8536-9:2015	Infusion equipment for medical use - Part 9: Fluid Lines for single use with pressure infusion equipment
ISO 8536-10:2015	Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment
ISO 8536-11:2015	Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-2:2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements
ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood.
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 10993-17: 2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable
ISO 10993-18: 2020	Biological evaluation of medical devices – Part 18: Chemical
	Characterization of Materials
EN ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Test for Irritation
EN ISO 15223-1:2021	Symbols to be used with medical device labels, labeling, and information to be supplied
ISO 20417: 2021	Information Supplied by the Manufacturer with the Medical Device
ISO 11607-1:2019	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
ASTM F1980-07:2011	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
EN ISO 11135:2014	Validation and Routine Control of Ethylene Oxide Sterilization
EN ISO 11135:2014/A1:2019	
556-1:2001	Sterilization of Medical Devices for terminally sterilized product labeled "sterile"
EN ISO 11737-1:2018	Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
EN ISO 11737-1:2018/A1:2021	
EN ISO 11737-2:2010	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 11138-1:2006	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
ISO 11138-2:2009	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization process

ISO 10993-7:2008	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
ISO 14155:2011	Clinical Investigation of Medical Devices

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.

1.14 Classification

Risk Classification and Rule as per Medical Devices Regulation MDR (EU) 2017/745 of the European Parliament and of the Council: IIa, Rule 2

1.15 Medical Device Nomenclature

According to ALM-STED-03 Section 1. Device description and specification, including variants and accessories, BD Pressure Rated Catheter Extension sets is referenced as follows:

GMDN Code: 58977
GMDN Term: Basic Intravenous Administration Set

EMDN code: A03020102
EMDN Term: High Pressure Extension Lines

1.16 Manufacturing practices

The entire manufacturing and testing processes are following the Good 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-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.

1.17 Other information

- (Material) Safety Data 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.
- 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)
20019E7DS	BD SmartSite™ 'Y' Extension Set. 2 Needle-Free Valves	1	N/A	100	Yes
20038E7DS	BD SmartSite™ Extension Set. 3 Needle Free Valves	1	N/A	100	Yes
20039E7DS	BD SmartSite™ Extension Set. One Needle Free Valve	1	N/A	100	Yes

2.2 Packaging material

Component	Material
Unit Pack	Medical grade paper 60g & 80µm film
Shipping Case	Carton
IFU	Paper

2.3 Examples of labeling

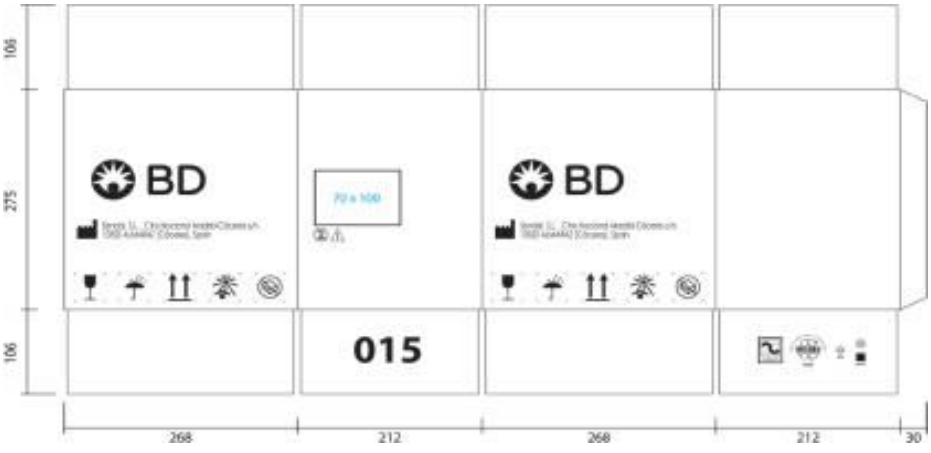
Labels: According to European Medical Device directive, labels are multilingual.

Primary Packaging Label (Top Web) extracted from document EUP31-ES-ET-402 and shipping case label extracted from document EC30-ES-ET-402:

Unit Label:

Case Label:

Shipping Case extracted from document 015BD-RC:



Instruction for use extracted from document EUI30-ES-ET-402 (example of English text):

en BD Pressure Rated Catheter Extension Sets

Product Description
BD Pressure Rated Catheter Extension Sets are used for infusion therapy. The extension sets vary in length, configuration, power injection capability (≥22.5 bar) and priming volume. Some variations contain slide clamps, pinch clamps, check valves, anti-siphon valves, and needle-free connectors. The pressure rating is specified on the product label.

Intended Purpose
BD Pressure Rated Catheter extension sets are sterile, single use devices intended to be attached to an IV catheter to decrease movement /manipulation of the catheter hub and provide extra length, and functionality. Pressure Rated Catheter Extension Sets can be used for direct injection, intermittent infusion, and/or continuous infusion of fluids and/or medications.

Intended User
BD Pressure Rated Catheter Extension Sets are intended to be used by healthcare professionals who are experienced in IV infusion therapy.

Target Patient Population
BD Pressure Rated Catheter Extension Sets are intended to be used with all patient populations, with consideration given to the procedure being performed and fluids being infused.

Warnings
- Failure to properly prime the device can result in an air embolism to the patient or occlude IV catheter.
- Trace lines before connection. Verify the extension set is being connected to the appropriate intravenous therapy line.
- DO NOT REUSE. Intended for single use only. Reuse and/or repackaging may compromise the safety and efficacy of the device, which may lead to device failure, and/or patient injury, infection, or illness.
- DO NOT use if package is damaged, opened, or the expiration date has passed. Do not use if package or device contains any foreign material. Examine the package carefully before opening to confirm its integrity.
- DO NOT use if device is damaged or has missing components.
- DO NOT use if protective caps located over luer lock are not in place.
- During use, if the device is damaged or leaks, stop use and replace immediately.
- If infusing lipids, ensure that the primary set or administration set has a 1.2 micron filter.
- To minimise reflux of blood into the vascular access catheter, clamp after each disconnection.
- Disinfection of the device is not complete until the disinfectant is allowed to dry. Connecting to access points while disinfectant is still wet can make disconnection difficult.
- DO NOT use sharp instruments if there is a difficult disconnection. Replace device.

Precautions
- Follow all instructions, contraindications, warnings, and precautions for all infusates, IV pumps, IV sets, and IV extension sets used with this device, as specified by its manufacturer.
- Connection of BD Pressure Rated Catheter Extension Sets to non-ISO luers or use of ISO luers with visible defects can cause fluid leakage, damage, and/or failure of the device.
- Ensure all connections are secure before each use. Disconnections or loose connections can result in air embolism, fluid loss, and infection due to leakage.
- The NFC should not be used with needles, blunt cannula systems, non-ISO luer connections, or luer connections with visible defects. Doing so may result in leakage and/or failure of the device. Do not alter the NFC in any way.
- Luer-slip connections should not be left unattended due to potential for unintentional disconnection.
- When using the product, avoid over-threading. Excessive threading may damage the integrity of the product.
- The BD Pressure Rated Catheter Extension sets can be used for up to 96 hours (excepting for the product code which ends in E7DS, where is 7 days) or 200 activations of the NFC whichever occurs first.
- For infusions of blood, blood products or lipid emulsions replace every 24 hours.
- Do not leave open packages or discarded devices within reach to prevent ingestion of the device or its components. Ingestion of the device or its components may pose a choking hazard.
- Follow recognised standards and institution policies on securement of vascular access devices and extension sets to reduce the risk of accidental catheter dislodgment.

Instructions for Use
Directions: Use aseptic no touch technique (ANTT)
1. Remove set from packaging, close clamps.
2. Remove protective caps from distal end(s).
3. Attach the Catheter Extension Set to the primary IV line.
4. Carefully check connections before starting treatment.
5. Open clamps.
6. Prime the set. When priming is complete, close the clamp.
7. Remove protective cap from proximal end.
8. Connect the set to vascular access device.
9. Open the clamp to allow flow. Initiate infusion.
10. If applicable, prior to every access to the Y-site, swab with 70% isopropyl alcohol and allow to dry. Flush Y-site or after each use.
11. When the infusion is complete, ensure all clamps are closed, disconnect from vascular access device and dispose in accordance with local and/or other governing regulations for medical device and/or chemical and biohazardous waste disposal.
12. When disconnecting a luer-lock or luer-slip syringe or tubing set from the Needle Free Connector, carefully rotate the luer counterclockwise a 360 degree turn or until disconnected using a controlled motion to minimize fluid escaping. Wipe connector surface dry by swabbing surface after disconnection.

Notes
EU Only: Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.
To dispose of this device, adhere to local and/or other governing regulations for medical device and/or biohazardous waste disposal.
The formulation of the product materials does not contain Latex or DEHP.

REVISION	CHANGE SUMMARY
01	Initial release according to new template.