BD Pressure Rated Extension Sets
Sterile, Single-use
PA-XXX / PA-XXX-G / PA-XXX-GC

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com
TDS number: V201-115 – Rev. 01
2023-October

1. General Information

1.1 Intended use

1.1.1 Intended purpose

The BD Pressure Rated Extension Sets are sterile, single use devices intended to be attached to the IV line or catheter to lengthen and/or provide additional IV access ports. Pressure Rated 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 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 Extension Sets are used for infusion therapy. The extension sets vary in length, configuration, power injection capability and priming volume.

Figure 1: BD Pressure Rated Extension Sets (PA-XXX & PA-XXX-G)

Figure 2: BD Pressure Rated Extension Sets PA-XXX-GC

BD Catalog Number	BD Product Description	Tube Length (cm)	Priming Volume (ml)	Pressure (bar)	Tube Inner Diameter (mm)	Tube Outer Diameter (mm)
PA-50	MICROBORE EXT.SET 50 CM	50	0.49	≤ 40 Bar	1	2.5
PA-100	MICROBORE PRES.EXT.SET 100 CM	100	0.89	≤ 40 Bar	1	2.5
PA-150	MICROBORE EXT.SET 150 CM	150	1.29	≤ 40 Bar	1	2.5
PA-200	MICROBORE EXT.SET 200 CM	200	1.69	≤ 40 Bar	1	2.5
PA-50-G	MICROBORE PRES.EXT.SET 50CM-ROT.L.LOCK	50	0.57	≤ 40 Bar	1	2.5
PA-100-G	MICROBORE PRES.EXT.SET 100CM-ROT.L.LOCK	100	0.97	≤ 40 Bar	1	2.5
PA-150-G	MICROBORE PRES.EXT.SET 150CM-ROT.L.LOCK	150	1.37	≤ 40 Bar	1	2.5
PA-200-G	MICROBORE PRES.EXT.SET 200CM-ROT.L.LOCK	200	1.77	≤ 40 Bar	1	2.5
PA-250-G	MICROBORE PRES.EXT.SET 250CM-ROT.L.LOCK	250	2.17	≤ 40 Bar	1	2.5
PA-80-GC	PRESSURE EXT. SET 80 CM. W/ CLAMP	80	0.79	≤ 40 Bar	1	2.5
PA-150-GC	MICROBORE EXT.SET 150 CM.W/CLAMP,ROT.LL	150	1.37	≤ 40 Bar	1	2.5
PA-200-GC	MICROBORE EXT.SET 200 CM.W/CLAMP,ROT.LL	200	1.77	≤ 40 Bar	1	2.5

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	BD Product Description	Amber tubing	Spiral tubing	Slide clamps	Roller clamps	Y-sites	Anti-siphon valves
PA-50	MICROBORE EXT.SET 50 CM	No	No	No	No	No	No
PA-100	MICROBORE PRES.EXT.SET 100 CM	No	No	No	No	No	No
PA-150	MICROBORE EXT.SET 150 CM	No	No	No	No	No	No
PA-200	MICROBORE EXT.SET 200 CM	No	No	No	No	No	No
PA-50-G	MICROBORE PRES.EXT.SET 50CM-ROT.L.LOCK	No	No	No	No	No	No
PA-100-G	MICROBORE PRES.EXT.SET 100CM-ROT.L.LOCK	No	No	No	No	No	No
PA-150-G	MICROBORE PRES.EXT.SET 150CM-ROT.L.LOCK	No	No	No	No	No	No
PA-200-G	MICROBORE PRES.EXT.SET 200CM-ROT.L.LOCK	No	No	No	No	No	No
PA-250-G	MICROBORE PRES.EXT.SET 250CM-ROT.L.LOCK	No	No	No	No	No	No
PA-80-GC	PRESSURE EXT. SET 80 CM. W/ CLAMP	No	No	**Yes**	No	No	No
PA-150-GC	MICROBORE EXT.SET 150 CM.W/CLAMP,ROT.LL	No	No	**Yes**	No	No	No
PA-200-GC	MICROBORE EXT.SET 200 CM.W/CLAMP,ROT.LL	No	No	**Yes**	No	No	No

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/ CH Representative/ UK Representative (if applicable)
PA-50 PA-100 PA-150 PA-200 PA-50-G PA-100-G PA-150-G PA-200-G PA-250-G PA-80-GC PA-150-GC PA-200-GC	**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 (0123) Certificate No.: G10 064670 0026	**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	**EC REP**: N/A **CH REP:** BD Switzerland Sàrl Terre Bonne Park – A4 Route de Crassier, 17 1262 Eysins-Switzerland **UK REP**: Not assigned yet

1.4 UDI-DI

The UDI-DI is:

PA-50	Primary DI: 08428820017459
	Package Level 2 DI: 58428820017454
	Package Level 3 DI: None
PA-100	Primary DI: 08428820017435
	Package Level 2 DI: 38428820017436
	Package Level 3 DI: 58428820017430
PA-150	Primary DI: 08428820017411
	Package Level 2 DI: 58428820017416
	Package Level 3 DI: None
PA-200	Primary DI: 08428820029117
	Package Level 2 DI: 58428820029112
	Package Level 3 DI: None
PA-150-G	Primary DI: 08428820034241
	Package Level 2 DI: 38428820034242
	Package Level 3 DI: 58428820034246
PA-200-G	Primary DI: 08428820034265
	Package Level 2 DI: 58428820034260
	Package Level 3 DI: None
PA-250-G	Primary DI: 08428820034319
	Package Level 2 DI: 58428820034314
	Package Level 3 DI: None
PA-100-G	Primary DI: 08428820034197
	Package Level 2 DI: 58428820034192
	Package Level 3 DI: None
PA-50-G	Primary DI: 08428820034364
	Package Level 2 DI: 58428820034369
	Package Level 3 DI: None
PA-80-GC	Primary DI: 08428820039871
	Package Level 2 DI: 58428820039876
	Package Level 3 DI: None
PA-150-GC	Primary DI: 08428820039284
	Package Level 2 DI: 58428820039289
	Package Level 3 DI: None
PA-200-GC	Primary DI: 08428820039291
	Package Level 2 DI: 58428820039296
	Package Level 3 DI: None

1.5 Eudamed Registration

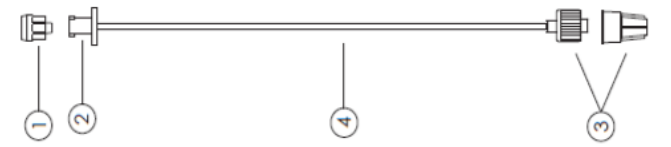
- Manufacturer Single Registration Number (SRN): ES-MF-000016981
- EU Authorised Representative Single Registration Number (SRN): N/A

1.6 Person Responsible for Regulatory Compliance

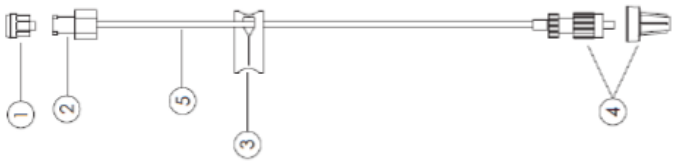
The information about the Person Responsible for Regulatory Compliance (PRRC) can be found on Eudamed website:

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

1.7 Materials



PA-XXX PA-XXX-G



PA-XXX-GC

Figure 3: Components of BD Pressure Rated Extension Sets

PA-XXX PA-XXX-G:

Component	Material
PF0949B	Screwing Cap
559181NDL	Female Luer
3831L/382L	Male Luer Lock and cap
TNDG25XXX	Tubing 1 x 2.5 x XXXX*

*XXXX= Length of the tubing, in mm

PA-XXX-GC:

Component	Material
PF0949B	Screwing Cap
559181NDL	Female Luer
PF0532	Slide Clamp
233AL/382AL	Rotating Male Luer Lock and cap
TNDG25XXX	Tubing 1 x 2.5 x XXXX*

*XXXX= Length of the tubing, in mm

Joint #	Joining Group 1	Joining Group 2
860	Luer lock female PVC Elcam Microbore external side	Transparent microbore tube (900/75S)
882	Luer lock male ABS Terlux Elcam Microbore external side	Transparent microbore tube (900/75S)

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
ABS Lustran (Screwing Cap)	*Pending
ABS Terlux Polyethylene (Male Luer Lock and cap)	*Pending
PVC (Female Luer)	PVC Rigid- LATEX Free- NO BPA- NO ESB RISK- No Phthalates BPB and PCB free
PVC (Tubing 1 x 2.5 x XXXX*)	The compound does not contain phthalates as DEHP, DBP, BBP, DINP, DIDP and DNOP.

1.9 REACH information

Based on BD's ongoing data collection efforts and/or information received from BD's suppliers, BD has not identified any chemicals in the articles and packaging of PA-XXX / PA-XXX-G / PA-XXX-GC references (BD Pressure Rated Extension Sets), 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 27 June 2018 according to Art. 59 (1.10) of the Regulation (EC) N° 1907/2006 (REACH).).

1.10 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.

1.11 Sterilization method

Ethylene Oxide Sterilization

1.12 Shelf life and storage conditions

The BD Pressure Rated Extension Sets shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Pressure Rated Extension Sets following references 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 (Technical Documentation for BD PRESSURE RATED EXTENSION SETS ALM-STED-03-FRM06) linked to CE certificate number G10 064670 0026:

Quality Standards	Standard Title
EN ISO 13485:2016 EN ISO 13485: 2016/A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes
Risk Management Standards	
EN ISO 14971:2019 EN ISO 14971:2019/A11: 2021	Medical Device – Application of risk management to medical devices
Device Specific Standards	
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 8536-12:2021	Infusion equipment for medical use - Part 12: Check Valves
Biocompatibility Standards	
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, EN ISO 11135:2014/A1:2019	Validation and Routine Control of Ethylene Oxide Sterilization
556-1:2001	Sterilization of Medical Devices for terminally sterilized product labeled "sterile"

EN ISO 11737-1:2018 EN ISO 11737-1:2018/A1:2021	Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
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-FRM-02 "Section 1. Device description and specification, including variants and accessories", BD Pressure Rated Extension Sets is referenced as follows:

EMDN code: PA-XXX / PA-XXX-G / PA-XXX-GC
EMDN Term: A03020102

GMDN code: PA-XXX / PA-XXX-G / PA-XXX-GC
GMDN Term: 58977

1.16 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.

1.17 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)	Unit Pack (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
PA-50	MICROBORE EXT.SET 50 CM	25	8	200	Yes
PA-100	MICROBORE PRES.EXT.SET 100 CM	25	8	200	Yes
PA-150	MICROBORE EXT.SET 150 CM	25	8	200	Yes
PA-200	MICROBORE EXT.SET 200 CM	25	8	200	Yes
PA-50-G	MICROBORE PRES.EXT.SET 50CM ROT.L.LOCK	25	8	200	Yes
PA-100-G	MICROBORE PRES.EXT.SET 100CM-ROT.L.LOCK	25	8	200	Yes
PA-150-G	MICROBORE PRES.EXT.SET 150CM-ROT.L.LOCK	25	8	200	Yes
PA-200-G	MICROBORE PRES.EXT.SET 200CM-ROT.L.LOCK	25	8	200	Yes
PA-250-G	MICROBORE PRES.EXT.SET 250CM-ROT.L.LOCK	25	8	200	Yes
PA-80-GC	PRESSURE EXT. SET 80 CM. W/ CLAMP	25	8	200	Yes
PA-150-GC	MICROBORE EXT.SET 150 CM.W/CLAMP,ROT.LL	25	8	200	Yes
PA-200-GC	MICROBORE EXT.SET 200 CM.W/CLAMP,ROT.LL	25	8	200	Yes

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

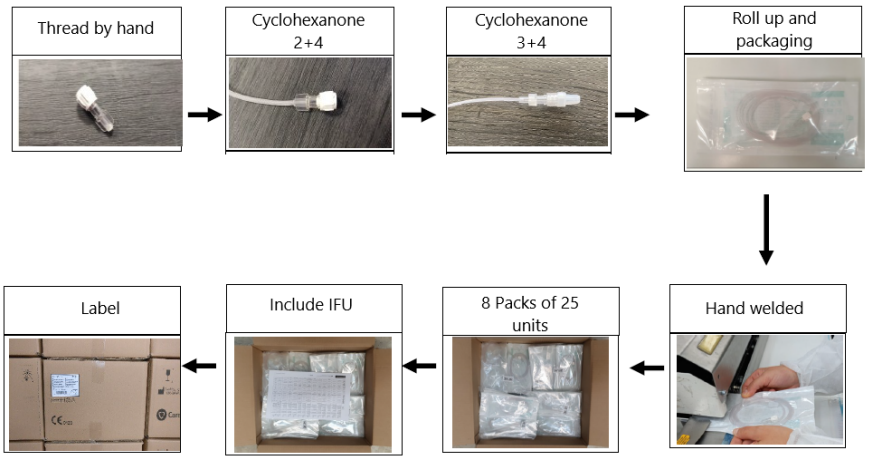


Figure 4: Packaging configuration (example PA-100-G WI)

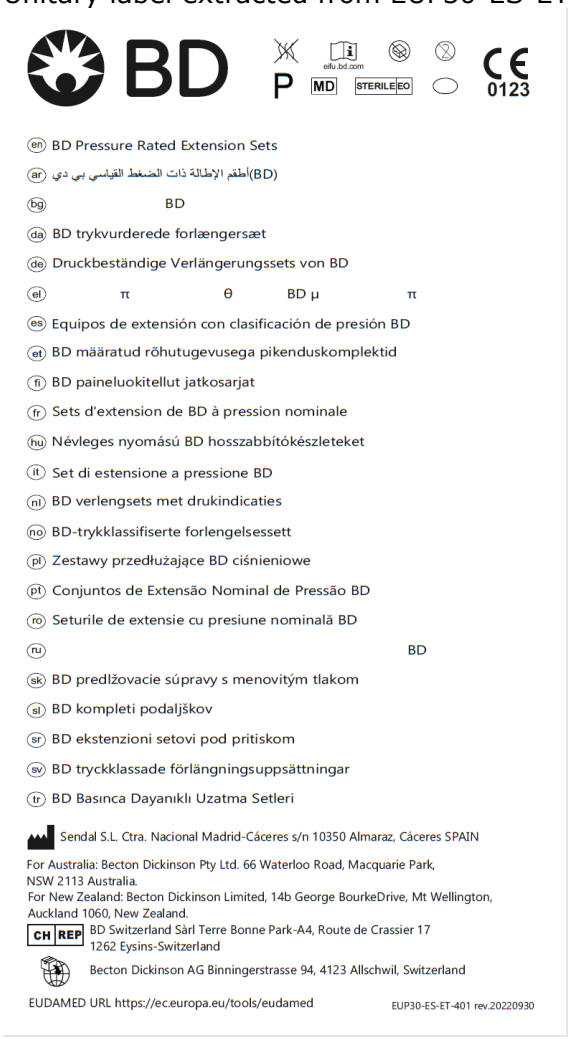
2.2 Packaging material

Component	Material
Unit Pack	PP Copolymer/ Polyester/ PP/PE/PA
Transparent PE pouch for 25 units	PE
Shipper box	Carton
IFU	Medical grade paper

2.3 Examples of labeling

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

Unitary label extracted from EUP30-ES-ET-401 rev.20220930:



BD

P MD STERILE EO 0123

(en) BD Pressure Rated Extension Sets
(ar) أطقم الإطالة ذات الضغط القياسي بي دي(BD)
(bg) BD
(da) BD trykvurderede forlængersæt
(de) Druckbeständige Verlängerungssets von BD
(el) π θ BD μ π
(es) Equipos de extensión con clasificación de presión BD
(et) BD määratud rõhutugevusega pikenduskomplektid
(fi) BD paineluokitellut jatkosarjat
(fr) Sets d'extension de BD à pression nominale
(hu) Névleges nyomású BD hosszabbítókészleteket
(it) Set di estensione a pressione BD
(nl) BD verlengsets met drukindicaties
(no) BD-trykklassifiserte forlengelsessett
(pl) Zestawy przedłużające BD ciśnieniowe
(pt) Conjuntos de Extensão Nominal de Pressão BD
(ro) Seturile de extensie cu presiune nominală BD
(ru) BD
(sk) BD predlžovacie súpravy s menovitým tlakom
(sl) BD kompleti podaljškov
(sr) BD ekstenzioni setovi pod pritiskom
(sv) BD tryckklassade förlängningsuppsättningar
(tr) BD Basınca Dayanıklı Uzatma Setleri

Sendal S.L. Ctra. Nacional Madrid-Cáceres s/n 10350 Almaraz, Cáceres SPAIN

For Australia: Becton Dickinson Pty Ltd. 66 Waterloo Road, Macquarie Park, NSW 2113 Australia.
For New Zealand: Becton Dickinson Limited, 14b George BourkeDrive, Mt Wellington, Auckland 1060, New Zealand.

CH REP BD Switzerland Sàrl Terre Bonne Park-A4, Route de Crassier 17 1262 Eysins-Switzerland

Becton Dickinson AG Binningerstrasse 94, 4123 Allschwil, Switzerland

EUDAMED URL https://ec.europa.eu/tools/eudamed EUP30-ES-ET-401 rev.20220930

Unitary label extracted from EUP31-ES-ET-401 rev.20220930:

(en) BD Pressure Rated Extension Sets
(ar) أطقم الإطالة ذات الضغط القياسي بي دي(BD)
(bg) BD
(da) BD trykvurderede forlængersæt
(de) Druckbeständige Verlängerungssets von BD
(el) π θ BD μ π
(es) Equipos de extensión con clasificación de presión BD
(et) BD määratud rõhutugevusega pikenduskomplektid
(fi) BD paineluokitellut jatkosarjat
(fr) Sets d'extension de BD à pression nominale
(hu) Névleges nyomású BD hosszabbítókészleteket
(it) Set di estensione a pressione BD

(nl) BD verlengsets met drukindicaties
(no) BD-trykklassifiserte forlengelsessett
(pl) Zestawy przedłużające BD ciśnieniowe
(pt) Conjuntos de Extensão Nominal de Pressão BD
(ro) Seturile de extensie cu presiune nominală BD
(ru) BD
(sk) BD predlžovacie súpravy s menovitým tlakom
(sl) BD kompleti podaljškov
(sr) BD ekstenzioni setovi pod pritiskom
(sv) BD tryckklassade förlängningsuppsättningar
(tr) BD Basınca Dayanıklı Uzatma Setleri

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CH REP BD Switzerland Sàrl Terre Bonne Park-A4, Route de Crassier 17 1262 Eysins-Switzerland

Becton Dickinson AG Binningerstrasse 94, 4123 Allschwil, Switzerland

EUDAMED URL https://ec.europa.eu/tools/eudamed

EUP31-ES-ET-401 rev.20220930

Ship box label extracted from EC-30-ES-ET-401:

IFU extracted from EUI-30-ES-ET-401 rev.20220930

en BD Pressure Rated Extension Sets

Product description:
BD Pressure Rated 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 amber tubing, spiral tubing, slide clamps, roller clamps, Y-sites, 0.2 and 1.2 micron filters, check valves, and anti-siphon valves. The pressure rating is specified on the product label.

Intended purpose:
BD Pressure Rated Extension Sets are sterile, single use devices intended to be attached to the IV line or catheter to lengthen and/or provide additional IV access ports. Pressure Rated Extension Sets can be used for direct injection, intermittent infusion, and/or continuous infusion of fluids and/or medications.

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

Intended Patient Population:
BD Pressure Rated 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 extension set 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
To minimize reflux of blood into the vascular access catheter, clamp after each disconnection.
Disinfect the device prior to each use. Disinfection of the mating device is not complete until the disinfectant is 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, and 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 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.
When using the product, avoid over-threading. Excessive threading may damage the integrity of the product.
The BD Pressure Rated Extension Sets can be used for up to 96 hours.
For infusions of 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 recognized 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 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 after each use.
11. When the infusion is complete, ensure all clamps are closed, disconnect from vascular access device and dispose.

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.