

TECHNICAL DATA SHEET

MaxZero™ Pressure Rated Extension Sets

DEHP and natural rubber latex are not part of the material formulation.

Sterile, for Single Use

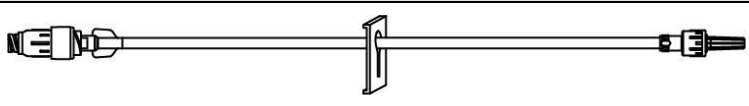
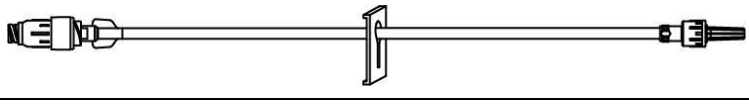
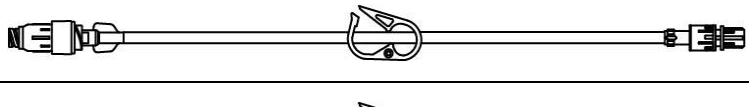
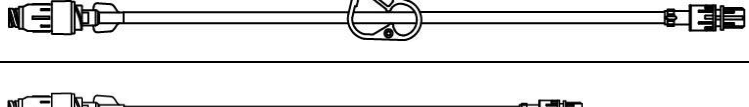
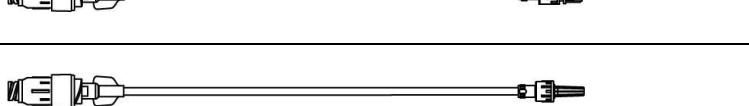
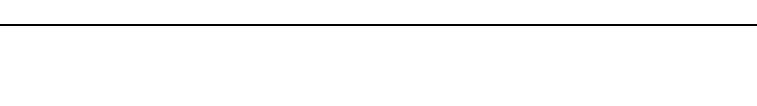
Product references presented in this Technical Data Sheet:

MZ5301, MZ5302, MZ5303, MZ5304, MZ5305, MZ5306, MZ5307, MZ5309, MZ5310

1. General Information

1.1 General

The MaxZero™ extension sets with needle-free connector(s) are intravascular extension sets intended for single patient use, including pediatrics (neonates, infants, children, adolescents) and immunocompromised patients for direct injection, intermittent infusion, continuous infusion, or aspiration of drugs, blood and fluids. These sets may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10 mL per second. MaxZero pressure rated extension sets with needle-free connector(s) allow thorough and easy disinfection due to a solid, flat smooth surface and eliminate the risk of needle stick injuries. The MaxZero connector on each set features positive displacement, which helps reduce reflux into the catheter at disconnect. Intended use specific to individual products are stated in the directions for use supplied with each device. The “MaxZero needle-free connector” description is equivalent to “MaxZero needleless connector” in this Technical Data Sheet.

Product Code	Product Image
MZ5301	
MZ5302	
MZ5303	
MZ5304	
MZ5305	
MZ5306	

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Product Code	Product Image
MZ5307	
MZ5309	
MZ5310	

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1.2 Features

DOA = Dioctyl adipate NA = Not Applicable, NFC = Needle-free Connector, PR = Pressure Rated, PVC = Polyvinyl chloride

Product Reference	Product Description	Type of Needle-free Connector	Total Length		Average Gravity Flow Rate (Liters/Hour)	Priming Volume (mL)
			cm	inches		
MZ5301	Minibore PR ext set, IV connector	MaxZero	18	7	4.01	0.4
MZ5302	Minibore PR ext set, IV connector	MaxZero	18	7	3.34	0.4
MZ5303	PR ext set, IV connector	MaxZero	18	7	6.20	0.5
MZ5304	PR ext set, IV connector	MaxZero	18	7	6.20	0.5
MZ5305	PR ext set, IV connector	MaxZero	18	7	6.35	0.5
MZ5306	Minibore PR ext set, IV connector	MaxZero	18	7	4.14	0.4
MZ5307	Minibore bi-fuse PR ext set, 2 IV connectors	MaxZero	18	7	3.17	0.8
MZ5309	PR ext set, IV connector	MaxZero	18	7	6.20	0.5
MZ5310	PR ext set, IV connector	MaxZero	18	7	6.20	0.5

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Product Reference	Tubing Diameter Inner/Outer		Tubing Material	Plasti-cizer	Number of Lines (Fuses)	No. of NFC	Bonded (B) or Removable (R) NFC	Number of T ports	Number of Y ports
	Inner mm/in.	Outer mm/in.							
MZ5301	1/0.042	2/0.079	PVC	DOA	1	1	B	0	0
MZ5302	1/0.042	2/0.079			1	1	R	0	0
MZ5303	1.5/0.06	3.7/0.144			1	1	B	0	0
MZ5304	1.5/0.06	3.7/0.144			1	1	R	0	0
MZ5305	1.5/0.06	3.7/0.144			1	1	B	0	0
MZ5306	1/0.042	2/0.079			1	1	B	0	0
MZ5307	1/0.042	2/0.079			2	2	B	0	0
MZ5309	1.5/0.06	3.7/0.144			1	1	B	0	0
MZ5310	1.5/0.06	3.7/0.144			1	1	R	0	0

Product Reference	Change Interval	Pressure Rating	Drug Compatibility	Disinfectant Compatibility	Quantity per smallest shipper box
MZ5301	7 days/200 activations	325 PSI @ 10 mL per second	Lipid and harsh infusates compatible	70% Isopropyl alcohol, Chlorhexidine gluconate, Iodine	50
MZ5302					
MZ5303					
MZ5304					
MZ5305					
MZ5306					
MZ5307					
MZ5309					
MZ5310					

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Product Reference	Type of Male Luer	Filter Size	Stopcocks	Back Check Valve(s)	Anti-Siphon Valve(s)
MZ5301	Spin Lock	NA	NA	NA	NA
MZ5302					
MZ5303					
MZ5304					
MZ5305					
MZ5306					
MZ5307					
MZ5309					
MZ5310					

Product Reference	Clamp type(s)	Gravity Use	Pump Use	Drip Chamber: Approximate Drops per 1 mL	Drip Chamber/Spike: Vented or Non-Vented
MZ5301	Slide	Yes	Yes	NA	NA
MZ5302	Slide				
MZ5303	Pinch				
MZ5304	Pinch				
MZ5305	None				
MZ5306	None				
MZ5307	Slide				
MZ5309	Slide				
MZ5310	Slide				

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1.3 Certification

Product Reference	Legal Manufacturer	Manufacturing Site	ISO Certificate Number	Notified Body	
MZ5301	BD Switzerland Sàrl Route de Crassier 17, Business Park Terre- Bonne, Batiment A4, Eysins, CH-1262, Switzerland	Sistemas Medicos Alaris. de C.V. Blvd. Insurgentes No 20351Parque Industrial El Florido Seccion Vistas 1Tijuana Baja California Mexico CP 2224	ISO 13485: 2003& BS EN ISO 13485:2012 Certificate number MD 71300 (BSI)	(BSI) Notified Body No. 0086	
MZ5302					
MZ5303					
MZ5304		EC Certificate Number	CE 502238	EU Authorized Representative	BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, Eysins, CH- 1262, Switzerland
MZ5305					
MZ5306					
MZ5307					
MZ5309					
MZ5310					

1.4 Needle-Free Connector, Components and Packaging Material

ABS = Acrylonitrile butadiene styrene, HDPE = High-density polyethylene

MaxZero Needle-free Connector and Extension Set	
COMPONENT	MATERIAL
Clear Top	Polycarbonate
Clear Base	Polycarbonate
Blue Piston	Silicone
Protective Cap	Polyethylene
Silicone lubricant	Silicone MED-460
Tubing	PVC with DOA Plasticizer
Male Luer	Clear ABS
Female Luer	Copolyester
Clamp	Polypropylene and HDPE
PACKAGING	MATERIAL
Unit Packaging	Nylon and Flashspun HDPE
Shelf Packaging	NA
Box (Shipper) Packaging	Carton

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1.5 Material 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 the material formulation used in the MaxZero extension sets.
Latex	Natural rubber latex is not part of the material formulation used in the MaxZero extension sets.
Bisphenol A	The polycarbonate used to manufacture the clear top and base of the MaxZero needle-free connector contains trace amounts of BPA. The residual BPA is less than 50 parts per million.
Substances of animal origin BSE/TSE	The raw materials used in the manufacture of this device are not made with animal tissue, residue or derivatives.
Polyvinyl chloride (PVC)	The MaxZero extension sets contain polyvinyl chloride.

1.6 REACH information

BD maintains an active REACH compliance program and work closely with their supply base on an ongoing basis with a view to obtaining information on REACH Substances of Very High Concern ("SVHC") through regular communication and exchange.

1.7 Biocompatibility

BD medical products contained within this technical data sheet comply with the requirements of the standard for biocompatibility of medical devices, ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

1.8 Sterilization

Sterilization Method: Electron Beam sterilization

Standard: ISO 11137-1: 2015 (Sterilization for Healthcare products - Electron Beam Sterilization – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices).

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1.9 Shelf life

Shelf life is 3 years for all product references in this technical data sheet. For storage and transportation condition please check the information on the packaging and labeling. Recommendations are to store at room temperature, in a dry and warm place and not exposed to strong light. The storage temperature range is between -40 °C/ °F and +52 °C/125 °F.

1.10 Standards

Refer to Declaration of Conformity document attached in Appendix I for the list of standards to which products comprised of Technical Data Sheet is compliant. For current Declaration of Conformity refer to your local representative.

1.11 Classification

Class IIa Medical Device under Rule 2, Annex IX of Medical Devices Directive 93/42/EEC as amended.

1.12 GMDN or UMDNS code

GMDN code: 12170, Description: Intravenous administration tubing extension

1.13 Good Manufacturing Practices

- 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 and final product testing is completed to ensure compliance with approved specifications.
- The manufacturing and testing details of each product batch 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 adheres 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 processes.

1.14 Others

- 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.
- (Material) Safety Data Sheets are not required for this product.

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2. Packaging

All packaging sizes have company, product, lot number, sterilization, and expiration date details printed on them.

2.1 Example Unit Package Labeling

Unit Container Labeling printed with 21 Languages: Arabic, Chinese, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Slovenian, Spanish, Swedish and Turkish.

Example product reference: MZ5301

BD MaxZero™

en- Minibore pressure rated extension set, IV connector
cs - Tlaková prodlužovací souprava s minipříměrem, konektor IV
da- Trykklificeret forlængersæt med minimal, indvendig diameter, IV-konnektor
de- Druckresistentes Minibore Verlängerungsset, Konnektor
el - Σετ επέκτασης minibore με κλίμακα πίεσης, ενδοφλέβιο συνδετικό
es - Alargadera minicalibre resistente a la presión, conector IV
fi - Minibore-jatkosarja paineistettuun käyttöön, laskimoliitin
fr - Tubulure d'extension résistante à la pression Minibore, connecteur IV
hu- Minifuratú nyomásbesorolásos bővítőkészlet, infúziós csatlakozó
it - Set prolunga minibore con pressione nominale, connettore EV
lv - Minikanāla augstspiediena pagarinājuma komplekts, IV tipa savienotājs
nl - Minibore drukbestendige uitbreidingsset, IV-connector
no- Minibore trykksertifisert forlængelsessett, IV-kobling
pl - Linia przedłużająca Minibore do zastosowań ciśnieniowych, złącze do wlewów dożylnych
pt - Prolongamento de pressão registada de diâmetro míni, conector IV
ro - Set de extensie Minibore cu presiune normată, conector IV
ru - Удлинительный комплект Minibore для высокого давления с соединителем для инфузионной системы
sl - Podaljšek Minibore za uporabo pod tlakom, intravenski konekt
sv - Minibore tryckklassificerat förlängningsaggregat, IV-anslutning
tr - Minibore basınçlı uzatma seti, IV konnektörü
ar - أداة تمديد Minibore تتحمل معدل ضغط معين، وصلة داخل الوريد

REF MZ5301
≈ 0.40 m; ≈ 18 cm (7 in)
≤ 325 psi; 10 mL/s

(01) 10885403230547
17) 9999-12-31

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Appendix I Declaration of Conformity



**EC Declaration of Conformity to:
Medical Devices Directive 93/42/EEC**

Legal Manufacturer:	BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, Eysins, CH-1262, Switzerland
Manufacturing Site (s):	Sistemas Medicos Alaris SA de C.V. Blvd. Insurgentes No 20351, Parque Industrial, El Florido Seccion Vistas 1, Tijuana, Baja California, CP 22244, Mexico.
Device Description/Family:	MaxZero™ Extension Sets <i>(See attached Product Schedule)</i>
EC Product Classification:	Class IIa, Annex IX, Rule 2
GMDN:	12170 – <i>Intravenous administration tubing extension set</i> A collection of tubing and connectors intended to establish an extension of tubing where the standard length of the tubing in an Intravenous (IV) administration set is insufficient. This is a single-use device.

We herewith declare that the product(s) listed above and detailed in the attached Product Schedule meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Applied Directives:	85/374/EEC - Product Liability 2006/121/EC – REACH 94/62/EC - Packaging and Packaging Waste Directive
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Applied Standards	BS EN 556-1:2001/AC:2006 BS EN 1041:2008 +A1:2013 BS EN ISO 1135-4: 2016 BS EN ISO 1135-5:2015 BS EN ISO 8536-4:2013 +A1:2013 BS EN ISO 8536-8:2015 BS EN ISO 8536-9:2015 BS EN ISO 8536-10:2015 BS EN ISO 10993-1:October 2009 BS EN ISO 10993-2:2006 BS EN ISO 10993-4:2017 BS EN ISO 10993-5:2009 BS EN ISO 10993-10:2013 BS EN ISO 10993-11:2009 EN ISO 10993-12:2012
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	EN ISO 10993-17:2009 BS EN ISO 11137-1:2015 BS EN ISO 11137-2:2015 BS EN ISO 11607-1:2009 +A1:2014 BS EN ISO 11607-2:2006 +A1:2014 EN ISO 11737-1:2006 EN ISO 11737-2:2009 BS EN ISO 13485:2012 BS EN ISO 14644-1:2015 BS EN ISO 14644-2:2015 BS EN ISO 14644-5:2004 BS EN ISO 14971:2012 BS EN ISO 15223-1:2016 BS EN 15986:2011 BS EN ISO 80369-7:2017 ISTA-1A - 2014 Edition ISTA-2A - 2012 Edition
Notified Body:	BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, United Kingdom Notified Body Number: 0086
CE Certificate Number:	Annex II (EC Certificate No. 502238)
Date of issuance of original CE certificate:	16 November 2005

STED File: 308

Issue Level: 14

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Product Schedule MaxZero™ Extension Sets

Sistemas Medicos, Mexico.

Part Number	Description	EC Product Class	GMDN
MZ5301	BD MaxZero™. Minibore pressure rated extension set, IV connector	II a	12170
MZ5302	BD MaxZero™. Minibore pressure rated extension set, removable IV connector	II a	12170
MZ5303	BD MaxZero™. Pressure rated extension set, IV connector	II a	12170
MZ5304	BD MaxZero™. Pressure rated extension set, removable IV connector	II a	12170
MZ5305	BD MaxZero™. Pressure rated extension set, IV connector, no clamp	II a	12170
MZ5306	BD MaxZero™. Minibore pressure rated extension set, IV connector, no clamp	II a	12170
MZ5307	BD MaxZero™. Minibore bi-fuse pressure rated extension set, 2 IV connectors	II a	12170
MZ5309	BD MaxZero™. Pressure rated extension set, IV connector	II a	12170
MZ5310	BD MaxZero™. Pressure rated extension set, removable IV connector	II a	12170
MZ8001	BD MaxZero™. Administration set, microbore tubing, 3 IV connectors, 20 drop drip chamber, filter, check valve, anti-siphon valve	II a	12170
MZ8002	BD MaxZero™. Administration set, microbore tubing, IV connector, 20 drop drip chamber, filter, check valve, anti-siphon valve	II a	12170
MZ9226	BD MaxZero™. Microbore extension set, IV connector, filter	II a	12170
MZ9265	BD MaxZero™. Microbore bi-fuse extension set, 2 IV connectors	II a	12170
MZ9266	BD MaxZero™. Microbore tri-fuse extension set, 3 IV connectors	II a	12170
MZ9267	BD MaxZero™. Microbore extension set, IV connector	II a	12170
MZ9270	BD MaxZero™. Microbore tri-fuse extension set, 3 IV connectors, filter	II a	12170
MZ9271	BD MaxZero™. Microbore bi-fuse extension set, 2 IV connectors, filter	II a	12170
MZ9272	BD MaxZero™. Microbore tri-fuse extension set, 3 IV connectors, filter	II a	12170
MZ9273	BD MaxZero™. Microbore tri-fuse extension set, 3 IV connectors, filter	II a	12170
MZ9274	BD MaxZero™. Microbore tri-fuse extension set, 3 IV connectors, 2 filters	II a	12170
MZ9275	BD MaxZero™. Microbore quad-fuse extension set, 4 IV connectors	II a	12170

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Part Number	Description	EC Product Class	GMDN
MZ9276	BD MaxZero™. Microbore tri-fuse extension set, 3 IV connectors, filter	II a	12170
MZ9277	BD MaxZero™. Microbore extension set, IV connector	II a	12170
MZ9278	BD MaxZero™. Microbore tri-fuse extension set, 3 IV connectors, 3 check valves	II a	12170
MZ9279	BD MaxZero™. Minibore bi-fuse extension set, 2 IV connectors, 2 check valves	II a	12170
MZ9281	BD MaxZero™. Minibore tri-fuse extension set, 3 IV connectors, 3 check valves	II a	12170
MZ9283	BD MaxZero™. Minibore quad-fuse extension set, 4 IV connectors, 4 check valves	II a	12170
MZ9287	BD MaxZero™. Microbore extension set, IV connector	II a	12170
MZ9288	BD MaxZero™. Microbore extension set, removable IV connector	II a	12170
MZ9289	BD MaxZero™. Microbore extension set, removable IV connector, filter	II a	12170
MZ9290	BD MaxZero™. Microbore bi-fuse extension set, 2 removable IV connectors	II a	12170
MZ9292	BD MaxZero™. Microbore bi-fuse extension set, 2 removable IV connectors, check valve	II a	12170
MZ9293	BD MaxZero™. Microbore bi-fuse extension set, 2 removable IV connectors, filter, check valve	II a	12170
MZ9294	BD MaxZero™. Microbore bi-fuse extension set, 2 removable IV connectors, filter	II a	12170
MZ9295	BD MaxZero™. Microbore bi-fuse extension set, 2 IV connectors, check valve	II a	12170
MZ9296	BD MaxZero™. Microbore bi-fuse extension set, 2 IV connectors, filter, check valve	II a	12170
MZ9300	BD MaxZero™. Microbore quad-fuse extension set, 4 IV connectors, filter	II a	12170
MZ9301	BD MaxZero™. Microbore extension set, IV connector	II a	12170
MZ9302	BD MaxZero™. Microbore extension set, IV connector, filter	II a	12170
MZ9322	BD MaxZero™. Microbore quad-fuse extension set, IV connector, 2 check valves, filter	II a	12170
MZ9323	BD MaxZero™. Minibore quad-fuse extension set, IV connector, 2 check valves, filter	II a	12170
MZ9324	BD MaxZero™. Minibore quad-fuse extension set, 2 IV connectors, 2 filters	II a	12170
MZ9325	BD MaxZero™. Minibore tri-fuse extension set, IV connector, 2 filters	II a	12170
MZ9326	BD MaxZero™. Minibore tri-fuse extension set, IV connector	II a	12170
MZ9327	BD MaxZero™. Microbore tri-fuse extension set, IV connector	II a	12170
MZX5305	BD MaxZero™. MaxZero Pressure rated extension set, IV Connector, needleless Y-site.	II a	12170

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Part Number	Description	EC Product Class	GMDN
MZX5306	BD MaxZero™. MaxZero Pressure rated extension set, removable IV connector, T-connector.	II a	12170
MZXT5304	BD MaxZero™. MaxZero Pressure rated extension set, IV Connector, T-connector.	II a	12170
MZXT5306	BD MaxZero™. MaxZero Pressure rated extension set, removable IV Connector, T-connector.	II a	12170
MZXT9001	BD MaxZero™. Microbore extension set, IV connector, T-connector	II a	12170

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