Becton Dickinson and Company
BD Medical

Business Park Terre-Bonne,
Batiment A4,
CH-1262 Eysins
Switzerland
bd.com

TECHNICAL DATA SHEET

MaxZero™ Needle-free Connector

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

Sterile, for Single Use

Product references presented in this Technical Data Sheet: MZ1000, MaxZero Needle-free Connector

1. General Information

1.1 General

The MaxZero™ needle-free connector is a sterile single patient use connector for needle-free access to the IV line and/or catheter during IV therapy. The MaxZero can be used for direct injection, intermittent infusion and continuous infusion or aspiration

The MZ1000 connector provides a solid, sealed, surface for effective disinfection in three seconds. This patented solid, sealed surface is intended to reduce the possibility that the intraluminal fluid pathway of the device may become microbial contaminated. Upon disconnection of a male Luer from the MZ1000 connector fluid is expelled from the catheter tip, preventing blood from entering back into the catheter, thus preventing reflux. The clear housing and fluid filled design of the MZ1000 connector enhances flushing practices. There is no interstitial or dead space internal to the connector. The MZ1000 connector may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10 mL per second. Change according to facility protocol or in accordance with current recognized guidelines for IV therapy, such as every 7 days or 200 activations. The MaxZero connector is an accessory to an Intravascular Administration Set and used as a secondary sterile injection site for delivery of fluids to a patient's vascular system through a cannula inserted in a vein or artery. The MZ1000 positive displacement at disconnection of a male Luer is 0.018 mL. The "MaxZero needle-free connector" description is equivalent to "MaxZero needleless connector" in this Technical Data Sheet.

Product Number	Device Picture
MZ1000	

1.2 Features

NFC = Needle-free Connector

Product Reference	Product Description		Type of Needle-free Connector		Average Flow Rate (L/Hr)	Priming Volume (mL)	
MZ1000	MaxZero Needle-free Connector		MaxZero		8.5	0.19 mL	
	Tubing Diameter (mm)		Tubing Material	Plasticizer	Bonded (B) or Removable (R)NFC	No. of T ports	No. of Y ports
	Inner (ID)	Outer (OD)					
	NA	NA	NA	NA	NA	NA	NA

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Product Reference	Change Interval	Pressure Rating		Drug Compatibility	Disinfectant Compatibility	Quantity per smallest shipper box
MZ1000	7 days/200 activations	325 PSI @ 10 mL per second		Lipid and harsh infusates compatible	70% Isopropyl alcohol, Chlorhexidine gluconate, Iodine	100
	Type of Male Luer	**Filter Size**		**Back Check Valve(s)**	**Anti-Siphon Valve(s)**	
	Locking	NA		NA	NA	
	Clamp Type(s)	**Gravity Use**	**Pump Use**	**Drip Chamber: Approximate Drops per 1 mL**	**Drip Chamber/Spike: Vented or Non-Vented**	
	NA	Yes	Yes	NA	NA	

1.3 Certification

Product Reference	Legal Manufacturer	Manufacturing Site	ISO Certificate Number	Notified Body
MZ1000	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
		EC Certificate Number	**EU Authorized Representative**	**Country of Origin**
		CE502238	BD Switzerland Sàrl, Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins Switzerland	Mexico

1.4 Needle-free Connector and Packaging Material

MZ1000 MaxZero Needle-free Connector	
COMPONENT	**MATERIAL**
Clear Top	Polycarbonate
Clear Base	Polycarbonate
Blue Piston	Silicone
Protective Cap	Polyethylene
Silicone lubricant	Silicone MED-460

COMPONENT	**MATERIAL**
Male Luer	NA
Female Luer	NA
Clamp	NA

PACKAGING	**MATERIAL**
Unit Packaging	Nylon and Flashpun HDPE
Shelf Packaging	NA
Box (Shipper) Packaging	Carton

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	DEHP or other Phthalates are not part of the material formulation used in the MaxZero MZ1000.
Latex	Natural rubber latex is not part of the material formulation used in the MaxZero MZ1000.
Bisphenol A (BPA)	The polycarbonate used to manufacture the clear top and base of the MaxZero MZ1000 contains trace amounts of BPA. The residual information of 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 MZ1000 MaxZero needle-free connector does not contain polyvinyl chloride.

1.6 REACH information

BD and CareFusion maintain 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 and CareFusion Medical products 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).

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 dry and warm place and not exposed to strong light. 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

42727- Positive-pressure-needleless valve-connector

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1.13 Good Manufacturing Practices

The manufacturing and testing processes follow 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 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

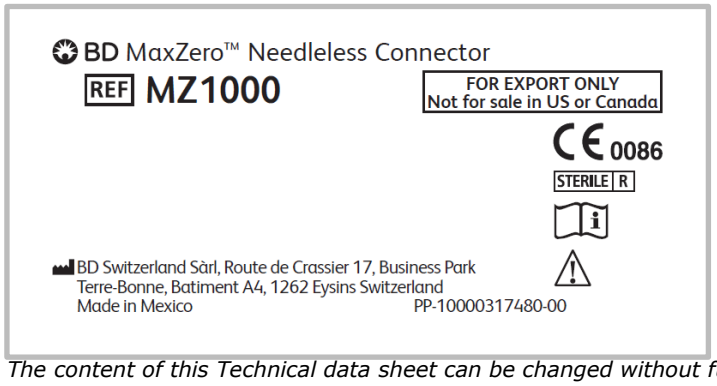
- Certificate of Food Contact (*COMMISSION REGULATION (EU) No. 10/2011 of January 14th, 2011 concerning materials and plastic objects intended to get in touch with foodstuffs)* is not required as BD products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
- Safety (Material) Data Sheets are not required for this product.

2 Packaging

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

2.1 Example Unit package labeling

Unit Container Labeling printed with 24 Languages: 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.



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2.2 Shipper Label

2.3 Shelf box graphic

There is no shelf box for MZ1000 product.

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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™ Needleless Connectors *(See attached Product Schedule)*
EC Product Classification:	Class IIa, Annex IX, Rule 2
GMDN:	*42727 – Positive-pressure needleless valve-connector* *A small, sterile, stand-alone, Luer-activated needleless plastic valve intended to mate two related intravenous (IV) line devices [e.g., hypodermic syringe and catheter port or tubing from an IV administration set] and hold them in a secured, sealed, locked position until disconnection, at which point positive pressure from the device causes a small volume of fluid to be expelled from the catheter/tubing. It is intended to eliminate the use of needles for IV administration of medications. 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

Applied Standards	BS EN 556-1:2001/AC:2006 BS EN 1041:2008 +A1:2013 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

	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: 307 Issue Level: 09

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Product Schedule
Needleless Connectors

GMDN Number: 42727

Part Number	Description	EC Product Class
MZ1000	MaxZero™ needleless connector	II a

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