Technical Data Sheet
PowerLoc Max Power Injectable Infusion Set

1. General Information

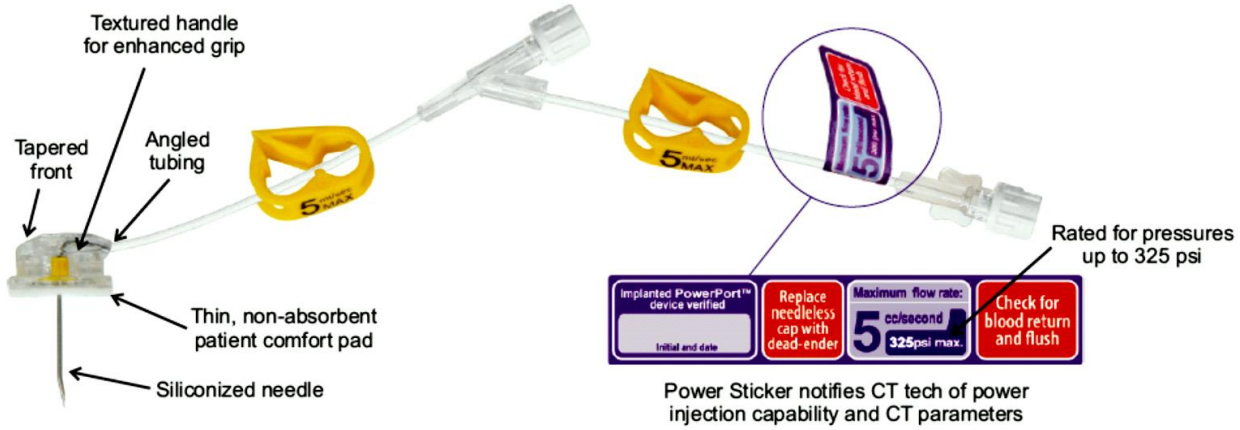
1.1. Indication for Use

The POWERLOC™ MAX Power Injectable Infusion Set is an intravascular infusion set with a non-coring right angle needle and manually activated needle stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by shielding the needle. The needle is used to access surgically implanted vascular ports.

The POWERLOC™ MAX Power Injectable Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

When used with ports that are indicated for power injection of contrast media into the central venous system, the POWERLOC™ MAX Power Injectable Infusion Set is also indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate at 11.8 cPs is 5 mL/s for 19 gauge and 20 gauge needles, and 2 mL/s for 22 gauge needles.

1.2. General Description



Power Sticker notifies CT tech of power injection capability and CT parameters

The PowerLoc™ MAX Power-Injectable Infusion Set device is an intravascular administration set with a non-coring right angle needle and manually activated needlestick prevention safety mechanism which reduces the risk of accidental needlestick injuries by shielding the needle. The device is used to access surgically implanted vascular ports.

1.3. Available Product Codes

Product Code	Description	With Y-Site	Without Y-Site
0141910	PowerLoc Max Power-Injectable Infusion Set 19G x 1.0 in (25 mm)		X
0141915	PowerLoc Max Power-Injectable Infusion Set 19G x 1.5 in (38 mm)		X
0141975	PowerLoc Max Power-Injectable Infusion Set 19G x 0.75 in (19 mm)		X
0142010	PowerLoc Max Power-Injectable Infusion Set 20G x 1.0 in (25 mm)		X
0142015	PowerLoc Max Power-Injectable Infusion Set 20G x 1.5 in (38 mm)		X
0142075	PowerLoc Max Power-Injectable Infusion Set 20G x 0.75 in (19 mm)		X
0142210	PowerLoc Max Power-Injectable Infusion Set 22G x 1.0 in (25 mm)		X
0142215	PowerLoc Max Power-Injectable Infusion Set 22G x 1.5 in (38 mm)		X

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0142275	PowerLoc Max Power-Injectable Infusion Set 22G x 0.75 in (19 mm)		X
0131910	PowerLoc Max Power-Injectable Infusion Set 19G x 1.0 in (25 mm)	X	
0131915	PowerLoc Max Power-Injectable Infusion Set 19G x 1.5 in (38 mm)	X	
0131975	PowerLoc Max Power-Injectable Infusion Set 19G x 0.75 in (19 mm)	X	
0132010	PowerLoc Max Power-Injectable Infusion Set 20G x 1.0 in (25 mm)	X	
0132015	PowerLoc Max Power-Injectable Infusion Set 20G x 1.5 in (38 mm)	X	
0132075	PowerLoc Max Power-Injectable Infusion Set 20G x 0.75 in (19 mm)	X	
0132210	PowerLoc Max Power-Injectable Infusion Set 22G x 1.0 in (25 mm)	X	
0132215	PowerLoc Max Power-Injectable Infusion Set 22G x 1.5 in (38 mm)	X	
0132275	PowerLoc Max Power-Injectable Infusion Set 22G x 0.75 in (19 mm)	X	

Product Information:

Product Attributes	
Storage Conditions	There are no special storage requirements. Store dry at room temperature.
Shelf Life	3 years
Pyrogenicity	Non-Pyrogenic
Use	Single Use
Sterilization	Ethylene Oxide (SAL of 10^{-6})
Biocompatibility	Tested to ISO 10993-1 per device classification of externally communicating, blood path indirect for prolonged exposure (≥ 24 hours, not to exceed 30 days)
DEHP	Product does not contain DEHP
Latex	Not made with Natural Rubber Latex

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2. Technical Product Information

Description		Power-injectable	Max Flow Rate*	Max Power Injector Pressure	Priming Volume	Sterilization Method
	19G	Yes	5 mL/sec	325 psi (2241 kPA)	0.4 mL (w/Y-site) 0.3 (without Y-site)	EO
	20G	Yes	5 mL/sec	325 psi (2241 kPA)	0.4 mL (w/Y-site) 0.3 (without Y-site)	
	22G	Yes	2 mL/sec	325 psi (2241 kPA)	0.4 mL (w/Y-site) 0.3 (without Y-site)	
*Flow rate values are based on testing with a contrast media viscosity of 11.8 cP						

MR Information:
Non-clinical testing has demonstrated the device is MR conditional. It can be scanned safely under:

- A static magnetic field of 3 Tesla or less
- A maximum specific absorption rate (SAR) of 4.09 W/kg for 15 minutes of scanning
- A spatial gradient field of 2300 Gauss/cm or less

In non-clinical testing, the POWERLOC™ MAX Power Injectable Infusion Set produced a temperature rise of 2.0°C at a maximum whole body averaged specific absorption rate (SAR) of 4.09 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3 tesla General Electric Medical Systems HDx MRI scanner running version HD 16.0_V01_1108.b software and a Bruker 7T/20 cm BioSpec animal imaging system.

MR image quality may be compromised if the area of interest is within 6.6 cm of the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

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Device Materials:

Component	Material	Patient Contact?	PVC?	DEHP?	Latex?	BPA?	Animal Derivatives	Blood Derivatives	Medicinal Substances
Tubing, Microbore	PVC (Non-Phthalate)	Indirect blood and skin contact	Yes	No	No	No	No	No	No
Pinch Clamp	Polypropylene with ink printing	Skin contact	No	No	No	No	No	No	No
Adaptor, Female Luer	PVC (Non-Phthalate)	Indirect blood and skin contact	Yes	No	No	No	No	No	No
Cap, Male Luer Lock	ABS	Indirect blood and skin contact	No	No	No	No	No	No	No
UV Adhesive	Loctite 3921 acrylic adhesive	Indirect blood contact	No	No	No	No	No	No	No
Lubricant	Silicone	Indirect blood, and tissue/skin contact	No	No	No	No	No	No	No
Needle, Huber, Straight w/ Tip Protector	Stainless Steel, Polyethylene	Indirect blood and tissue/skin contact	No	No	No	No	No	No	No
Y-Site Adapter	PVC (Non-Phthalate)	Indirect blood and skin contact	Yes	No	No	No	No	No	No
Housing	K-Resin (Styrene Butadiene Copolymer)	Skin contact	No	No	No	No	No	No	No
Trapdoor	K-Resin (Styrene Butadiene Copolymer)	N/A	No	No	No	No	No	No	No
Handle (Left, Right)	K-Resin (Styrene Butadiene Copolymer)	Skin contact	No	No	No	No	No	No	No
Shutter	Stainless Steel	N/A	No	No	No	No	No	No	No
Sleeve	Stainless Steel	N/A	No	No	No	No	No	No	No
Foam Backing	Closed-Cell Polyethylene Foam	Skin contact	No	No	No	No	No	No	No
Insert, Base	K-Resin (Styrene Butadiene Copolymer)	N/A	No	No	No	No	No	No	No

Tyvek Pouch	Uncoated Tyvek 1059B W/ 48 GA PET	Indirect contact; primary packaging material.	No	No	No	No	No	No	No

2.1. REACH information

REACH substance not present

2.2. Materials of Animal or Human Origin / Medicinal Substances / Phthalates

The PowerLoc Max Power Injectable Infusion Set product and packaging do not contain natural rubber latex. The PowerLoc Max Power Injectable Infusion Set has no material of animal origin and no material that is a medicinal substance. The PowerLoc Max Power Injectable Infusion Set does not contain DEHP.

2.3. RoHS Information

Not Applicable as these devices are not electronic or electrical equipment

2.4. Conflict Materials

Conflict Materials not present

2.5. Applied Standards

Standard	***Rev.***	***Title***
BS EN ISO 13485	2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
BS EN 1041	2008	Information Supplied by the Manufacturer of Medical Devices
BS EN ISO 15223-1	2016	Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
ISO 11135	2014	Sterilization of Health Care Products - Ethylene Oxide - Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
BS EN ISO 10993-7	AC: 2009	Biological Evaluation of Medical Devices: Ethylene Oxide Sterilization Residuals
EN ISO 11607-1	2009+A1:2014	Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
EN ISO 11607-2	2006+A1:2014	Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
ISO 8536-4	2010	Infusion Equipment for Medical Use – Part 4: Infusion set for single-use, gravity feed
ISO 8536-10	2004	Infusion Equipment for Medical Use – Part 10: Accessories for fluid lines for use with pressure infusion equipment
BS EN ISO 10993-1	2009	Biological Evaluation of Medical Devices – Part 1
BS EN ISO 14971	2012	Medical Devices – Application of Risk Management to Medical Devices

ISO 594-1	1986	Conical Fittings with a 6% (Luer) taper for syringes, needles and other certain medical equipment- Part 1: General Requirements
ISO 594-2	1998	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings
BS EN 62366	2008	Medical devices — Application of usability engineering to medical devices
ISO 7864	2016	Sterile hypodermic needles for single use
ISO 9626	2016	Stainless steel needle tubing for the manufacture of medical devices
ISO 23908	2013	Sharps injury protection - Requirements and test methods. Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

2.6. Legal Manufacturer Information

Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116
Phone: 801-522-5000

2.7. Manufacturing Site Information

Forefront Medical Technology (Jiangsu) Co., Ltd.
No.8, Changyang Road
Wujin Economic Development Zone
213145 Changzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

3. Regulatory Information

3.1. US Regulatory Information

The PowerLoc Max Power Injectable Infusion Set* is cleared under the following US 510(k):

510(k) #	Device Name	Decision Date	510(k) Class
K171735	PowerLoc MAX Power-Injectable Infusion Set and SafeStep Huber Needle Set	08/08/2017	II

*Please refer to EU Declaration of Conformity DC-EU-PORT-03 Revision 13 for a list of applicable product codes

3.2. EU Regulatory Information

The PowerLoc Max Power Injectable Infusion Set* are CE marked under the following criteria:

Comply with:
European Community Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) as amended by Directive 2007/47/EC.

Supplementary Information:

Conformity assessment procedure: Annex II
Device classification: Class IIa in accordance with Annex IX, Rule 7
Notified body: British Standards Institution
Notified body number: 2797
Full Quality Assurance Certificate: CE 551333
Design Examination Certificate: Not applicable
GMDN Code: 17701
GMDN Term: Vascular port administration set
*Please refer to EU Declaration of Conformity DC-EU-PORT-03 Revision 13 for a list of applicable product codes

3.3. Regulatory Information – Other Geographies

The PowerLoc Max Power Injectable Infusion Sets* are commercialized in the following countries (not comprehensive):

Country	License No	Class
Canada	7189	2
Australia	136878	2a
Brazil	80689090178	2
Singapore	DE0016737	B
Thailand	USA6207706	N/A
Israel	120630	2a
Argentina	PM-634-234	2
Saudi Arabia	GHTF-2015-0689	2a

*Commercialization information is current according to the time of release of this document – Nov 2020

3.4. Instructions & Labeling Languages

See IFU in Product or on Manufacturer Website