Table of Contents:

1 Scope

The Product specification applies to the following products:

RMF: RMF-120-003 (Vasofix®) RMF-120-030 (Vasofix® Safety)			
Basic UDI-DI: 40392390000007622Q (Vasofix® Braunüle®/ Vasofix® Certo) 40392390000007642U (Vasofix® Safety)			
Item No	**Product name**	**Designation**	**Shelf-Life**
---	**Vasofix® Braunüle®**		**---**
4050051	Vasofix® Braunüle®	VASOFIX G22 (KKM)	5 years
4050052	Vasofix® Braunüle®	VASOFIX G20 (KKM)	5 years
4050054	Vasofix® Braunüle®	VASOFIX G18 X 45MM (KKM)	5 years
4050055	Vasofix® Braunüle®	VASOFIX G16 (KKM)	5 years
4268091B	Vasofix® Braunüle®	VASOFIX IV G22X25MM BLUE	5 years
4268113B	Vasofix® Braunüle®	VASOFIX IV G20X33MM PINK	5 years
4268130B	Vasofix® Braunüle®	VASOFIX IV G18X45MM GREEN	5 years
4268334B	Vasofix® Braunüle®	VASOFIX IV G18X33MM GREEN	5 years
4268156B	Vasofix® Braunüle®	VASOFIX 1,5 X 45 MM, 17 G	5 years
4268172B	Vasofix® Braunüle®	VASOFIX IV G16X50MM GREY	5 years
4268210B	Vasofix® Braunüle®	VASOFIX IV G14X50MM ORANGE	5 years
---	**Vasofix® Certo**		**---**
4269071	Vasofix® Certo	VASOFIX CERTO G24X19MM YELLOW	5 years
4269098	Vasofix® Certo	VASOFIX CERTO G22X25MM 50/BOX	5 years
4269110	Vasofix® Certo	VASOFIX CERTO G20X33MM 50/BOX	5 years
4269217	Vasofix® Certo	VASOFIX CERTO G20X25MM 50/BOX	5 years
4269136	Vasofix® Certo	VASOFIX CERTO G18X45MM	5 years
4269330	Vasofix® Certo	VASOFIX CERTO, 18G, 1.3X33MM	5 years
4269152	Vasofix® Certo	VASOFIX CERTO, 17G, 1.5X45MM	5 years
4269179	Vasofix® Certo	VASOFIX CERTO G16X50MM	5 years
4269225	Vasofix® Certo	VASOFIX CERTO G14X50MM	5 years
---	**Vasofix® Safety FEP**		**---**
4268091S	Vasofix® Safety	VASOFIX SAFETY FEP 22G,1 IN.,0.9X25MM	5 years
4268113S	Vasofix® Safety	VASOFIX SAFETY FEP 20G,1.25 IN.,1.1X33MM	5 years
4268130S	Vasofix® Safety	VASOFIX SAFETY FEP 18G,1.75 IN.,1.3X45MM	5 years
4268334S	Vasofix® Safety	VASOFIX SAFETY FEP 18G,1.25 IN.,1.3X33MM	5 years
4268156S	Vasofix® Safety	VASOFIX SAFETY FEP 17G,1.75 IN.,1.5X45MM	5 years
4268172S	Vasofix® Safety	VASOFIX SAFETY FEP 16G,2 IN., 1.7X50MM	5 years
4268210S	Vasofix® Safety	VASOFIX SAFETY FEP 14G,2 IN., 2.2X50MM	5 years
---	**Vasofix® Safety PUR**		**---**
4269071S	Vasofix® Safety	VASOFIX SAFETY PUR 24G,0.75 IN.,0.7X19MM	5 years
4269098S	Vasofix® Safety	VASOFIX SAFETY PUR 22G,1 IN.,0.9X25MM	5 years
4269110S	Vasofix® Safety	VASOFIX SAFETY PUR 20G,1.25 IN,1.1X33MM	5 years
4269217S	Vasofix® Safety	VASOFIX SAFETY PUR 20G,1 IN.,1.1X25MM	5 years
4269136S	Vasofix® Safety	VASOFIX SAFETY PUR 18G,1.75 IN.,1.3X45MM	5 years
4269330S	Vasofix® Safety	VASOFIX SAFETY PUR 18G,1.25 IN.,1.3X33MM	5 years
4269152S	Vasofix® Safety	VASOFIX SAFETY PUR 17G,1.75 IN.,1.5X45MM	5 years
4269179S	Vasofix® Safety	VASOFIX SAFETY PUR 16G,2 IN., 1.7X50MM	5 years
4269225S	Vasofix® Safety	VASOFIX SAFETY PUR 14G,2 IN.,2.2X50MM	5 years
---	**Vasofix® Safety FEP (European Labelling - 01)**		**---**
4268091S-01	Vasofix® Safety	VASOFIX SAFETY FEP 22G,1 IN.,0.9X25MM-EU	5 years

Effective

4268113S-01	Vasofix® Safety	VASOF.SAFTY FEP 20G,1.25 IN.,1.1X33MM-EU	5 years
4268130S-01	Vasofix® Safety	VASOF.SAFTY FEP 18G,1.75 IN.,1.3X45MM EU	5 years
4268334S-01	Vasofix® Safety	VASOF.SAFTY FEP 18G,1.25 IN.,1.3X33MM-EU	5 years
4268156S-01	Vasofix® Safety	VASOF.SAFTY FEP 17G,1.75 IN.,1.5X45MM-EU	5 years
4268172S-01	Vasofix® Safety	VASOF. SAFETY FEP 16G,2 IN., 1.7X50MM-EU	5 years
4268210S-01	Vasofix® Safety	VASOF. SAFETY FEP 14G,2 IN., 2.2X50MM-EU	5 years
---	**Vasofix® Safety PUR (European Labelling - 01)**		---
4269071S-01	Vasofix® Safety	VASOF.SFTY PUR 24G,0.75 IN.,0.7X19MM-EU	5 years
4269098S-01	Vasofix® Safety	VASOFIX SAFETY PUR 22G,1 IN.,0.9X25MM-EU	5 years
4269110S-01	Vasofix® Safety	VASOF.SAFTY PUR 20G,1.25 IN,1.1X33MM EU	5 years
4269217S-01	Vasofix® Safety	VASOFIX SAFETY PUR 20G,1 IN.,1.1X25MM-EU	5 years
4269136S-01	Vasofix® Safety	VASOF.SAFTY PUR 18G,1.75 IN.,1.3X45MM-EU	5 years
4269330S-01	Vasofix® Safety	VASOF.SAFETY PUR 18G,1.25 IN.,1.3X33MM-EU	5 years
4269152S-01	Vasofix® Safety	VASOF.SAFTY PUR 17G,1.75 IN.,1.5X45MM-EU	5 years
4269179S-01	Vasofix® Safety	VASOF.SAFTY PUR 16G,2 IN., 1.7X50MM-EU	5 years
4269225S-01	Vasofix® Safety	VASOFIX SAFETY PUR 14G,2 IN.,2.2X50MM-EU	5 years
---	**Vasofix® Safety FEP (Asia Pacific Labelling - 03)**		---
4268091S-03	Vasofix® Safety	VASOFIX SAFETY FEP 22G,1 IN.,0.9X25MM-AP	5 years
4268113S-03	Vasofix® Safety	VASOF.SAFTY FEP 20G,1.25 IN.,1.1X33MM-AP	5 years
4268130S-03	Vasofix® Safety	VASOF.SAFTY FEP 18G,1.75 IN.,1.3X45MM-AP	5 years
4268334S-03	Vasofix® Safety	VASOF.SAFTY FEP 18G,1.25 IN.,1.3X33MM-AP	5 years
4268156S-03	Vasofix® Safety	VASOF.SAFTY FEP 17G,1.75 IN.,1.5X45MM-AP	5 years
4268172S-03	Vasofix® Safety	VASOF. SAFETY FEP 16G,2 IN., 1.7X50MM-AP	5 years
4268210S-03	Vasofix® Safety	VASOF. SAFETY FEP 14G,2 IN., 2.2X50MM-AP	5 years
---	**Vasofix® Safety PUR (Asia Pacific Labelling - 03)**		---
4269071S-03	Vasofix® Safety	VASOF.SAFTY PUR 24G,0.75 IN.,0.7X19MM-AP	5 years
4269098S-03	Vasofix® Safety	VASOFIX SAFETY PUR 22G,1 IN.,0.9X25MM-AP	5 years
4269110S-03	Vasofix® Safety	VASOF.SAFTY PUR 20G,1.25 IN,1.1X33MM-AP	5 years
4269217S-03	Vasofix® Safety	VASOFIX SAFETY PUR 20G,1 IN.,1.1X25MM-AP	5 years
4269136S-03	Vasofix® Safety	VASOF.SAFTY PUR 18G,1.75 IN.,1.3X45MM-AP	5 years
4269330S-03	Vasofix® Safety	VASOF.SAFETY PUR 18G,1.25 IN.,1.3X33MM-AP	5 years
4269152S-03	Vasofix® Safety	VASOF.SAFTY PUR 17G,1.75 IN.,1.5X45MM-AP	5 years
4269179S-03	Vasofix® Safety	VASOF.SAFTY PUR 16G,2 IN., 1.7X50MM-AP	5 years
4269225S-03	Vasofix® Safety	VASOFIX SAFETY PUR 14G,2 IN.,2.2X50MM-AP	5 years
---	**Vasofix® Safety PUR (CIS Labelling - 20)**		---
4269071S-20	Vasofix® Safety	VASOF.SAFTY PUR 24G,0.75 IN.,0.7X19MM-CIS	5 years
4269098S-20	Vasofix® Safety	VASOFIX SAFETY PUR 22G,1 IN.,0.9X25MM-CIS	5 years
4269110S-20	Vasofix® Safety	VASOF.SAFTY PUR 20G,1.25 IN,1.1X33MM-CIS	5 years
4269217S-20	Vasofix® Safety	VASOFIX SAFETY PUR 20G,1 IN.,1.1X25MM-CIS	5 years
4269136S-20	Vasofix® Safety	VASOF.SAFTY PUR 18G,1.75 IN.,1.3X45MM-CIS	5 years
4269330S-20	Vasofix® Safety	VASOF.SAFETY PUR 18G,1.25 IN.,1.3X33MM-CIS	5 years
4269152S-20	Vasofix® Safety	VASOF.SAFTY PUR 17G,1.75 IN.,1.5X45MM-CIS	5 years
4269179S-20	Vasofix® Safety	VASOF.SAFTY PUR 16G,2 IN., 1.7X50MM-CIS	5 years
4269225S-20	Vasofix® Safety	VASOFIX SAFETY PUR 14G,2 IN.,2.2X50MM-CIS	5 years
---	**Vasofix® Safety PUR (India Labelling - IN)**		---
4269179SIN	Vasofix® Safety	VX SAFETY PUR 16G, 2 IN., 1.7 x 50MM-IN	5 years
4269136SIN	Vasofix® Safety	VX SAFETY PUR 18G, 1.75 IN., 1.3 x 45MM-IN	5 years
4269110SIN	Vasofix® Safety	VX SAFETY PUR 20G, 1.25 IN., 1.1 x 25MM-IN	5 years
4269098SIN	Vasofix® Safety	VX SAFETY PUR 22G, 1 IN., 0.9 x 50MM-IN	5 years
4269071SIN	Vasofix® Safety	VX SAFETY PUR 24G, 0.75 IN., 0.7 x 19MM-IN	5 years

2 Intended use and Classification

2.1. Intended Use

Vasofix® Safety, Vasofix® Branüle®, Vasofix® Certo are sterile, PVC-free; DEHP-free, and not made with natural rubber latex, single use devices to generate intravascular and tissue access to sample blood, or administer fluids and blood intravascularly.

Vasofix® Safety has an anti-needle-stick feature to reduce the risk of accidental needle-stick injuries.

Indications

Vasofix® Safety, Vasofix® Branüle®, Vasofix® Certo are peripheral indwelling catheters of the catheter-over-the needle type which are routinely used for venipuncture. The products operate by puncturing the skin and vessel wall with a sharp cannula which is removed after confirmation of vessel entry and advancement of the catheter.

The product is a path for fluids in and out of the body via the catheter, which remains in the tissue during use.

Bolus injections can be operated via the port on the catheter hub.

The product may also facilitate the placement of Vascular Access devices such as guidewires, CVC, PICC and Midline catheters into the vascular system.

Contraindications

The products should not be used in patients with known hypersensitivity to any of the materials employed. Products of the Vasofix® family shall not be used for arterial access, subcutaneous access and high pressure power injection applications.

2.2. Short Description of the Intended Use

The peripheral IV Catheters are sterile and single use devices to generate intravascular and tissue access to sample blood or administer fluids, medication and blood intravascularly.

Product group	Basic UDI-ID	Intended Use (description on label)
Vasofix®	40392390000007622Q	IV indwelling cannula with injection port
Vasofix® Safety	40392390000007642U	Safety IV catheter with injection port

2.3 Product Classification

Classification according to the *Regulation (EU) 2017/745* of the European Parliament and of the Council on medical devices in accordance with Annex VIII

Product Name	Conformity Assessment Procedure	Classification	Rule	Paragraph
Vasofix® Braunüle® Vasofix® Certo Vasofix® Safety	IX	IIa	7	--

Classification according to the *Council Directive 93/42/EEC* concerning medical devices Annex IX

Product Name	Conformity Assessment Procedure	Classification	Rule	Paragraph
Vasofix® Braunüle® Vasofix® Certo Vasofix® Safety	II (excluding section 4)	IIa	7	--

Classification according to the GMDN Code (GMDN = Global Medical Device Nomenclature)

Product Name	GMDN Code	GMDN Designation
Vasofix® Braunüle® Vasofix® Certo Vasofix® Safety	32151	Peripheral vascular infusion catheter

Classification according to the UMDNS Code
(UMDNS = Universal Medical Device Nomenclature System)

Product Name	UMDNS Code	UMDNS Designation
Vasofix® Braunüle® Vasofix® Certo Vasofix® Safety	10-582	Cannula, Venous

3 Product description

The Vasofix® Braunüle® / Vasofix® Certo / Vasofix® Safety is an over-the-needle type catheter.

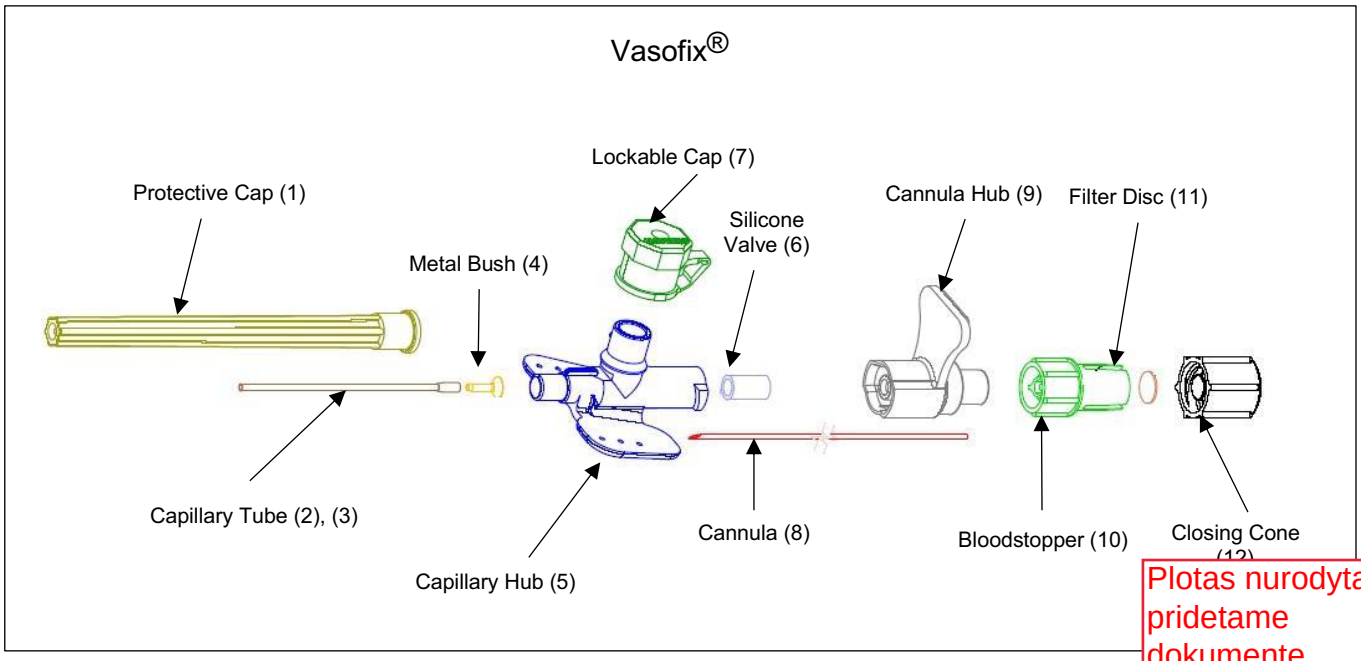
Over-the-needle type catheter devices are well known and routinely used for peripheral venipuncture for establishing access to the blood system of a patient to deliver infusion solutions, blood or pharmaceuticals in carrier solutions or for monitoring systemic pressure.

Usually after removing the protective sheath the point of the metal cannula is inserted transcutaneously into a selected blood vessel and the plastic cannula is pushed forward while the metal cannula is held in place. After successful insertion of the plastic cannula the metal cannula is withdrawn.

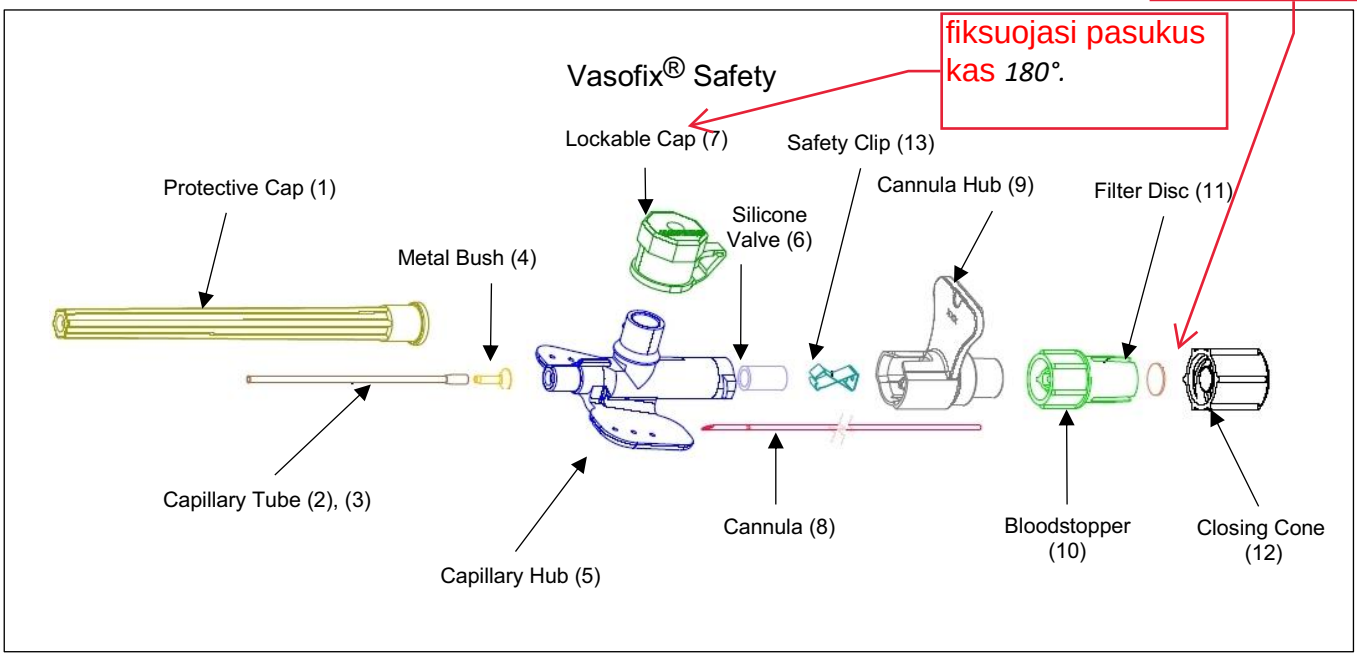
Using the female 6% conical taper (Luer) incorporated in the hub, a fluid administration set or other equipment to form part of a fluid line with a corresponding male taper is connected to the I.V. cannula. The device is conveniently fixed to the skin of a patient by adhesive tape or a surgical suture. Medication can be added with a syringe via the lid covered injection port with resealing valve.

Vasofix® Safety in addition provides the feature avoiding accidental needle stick injuries (NSI) of healthcare workers and helps drastically reducing the risk of exposure to blood-born pathogens via needle stick injuries. The most important fact for each person concerned is the additional safety throughout their daily work being protected against hepatitis (B + C), HIV or other infection diseases.

3.1 Exploded assembly drawing



Plotas nurodytas pridetame dokumente



Effective

3.2 Components and materials

3.2.1 List of materials Vasofix® Group

No.	Component	Material/Polymer type	Material Abbreviation
1.	Protective Cap	Polyethylene, high density	PE-HD
2.	Capillary Tube for Vasofix® Braunüle®	Perfluoro (ethylene propylene) plastic; preferred term for PFEP + radio-opaque stripes	FEP+ radio-opaque
3.	Capillary Tube for Vasofix® Certo	Polyurethane + radio-opaque material stripes	PUR+ radio-opaque
4.	Metal Bush	Stainless steel 305	SUS
5.	Capillary Hub	Polypropylene	PP
6.	Silicone Valve	Silicone plastic	SI
7.	Lockable Cap	Polyethylene, low density	PE-LD
8.	Cannula	Stainless steel 304	SUS
9.	Cannula Hub	Methyl methacrylate-acrylonitrile-butadiene-styrene plastic	MABS
10.	Housing for Bloodstopper	Methyl methacrylate-acrylonitrile-butadiene-styrene plastic	MABS
11.	Filter Disc	hydrophobic acrylic copolymer on non woven nylon support	AC on PA 6
12.	Closing Cone	Polystyrene	PS
13.	Adhesive	UV curing adhesive	-
14.	Lubricant	Silicone oil	-
15.	Single Peel Pack	Coated paper Transparent, unpowdered	Medical Grade paper PE mono foil
16.	Container box	Cardboard box with label	Duplex
17.	Transport / multipackage box	Double wall corrugated paper with label	-

3.2.2 List of materials Vasofix® Safety Group

No.	Component	Material/Polymer type	Material Abbreviation
1.	Protective Cap	Polyethylene, high density	PE-HD
2.	Capillary Tube for Vasofix® Safety (FEP)	Perfluoro (ethylene propylene) plastic; preferred term for PFEP + radio-opaque stripes	FEP+ radio-opaque
3.	Capillary Tube for Vasofix® Safety (PUR)	Polyurethane + radio-opaque material stripes	PUR+ radio-opaque
4.	Metal Bush	Stainless steel 305	SUS
5.	Capillary Hub	Polypropylene	PP
6.	Silicone Valve	Silicone plastic	SI
7.	Lockable Cap	Polyethylene, low density	PE-LD
8.	Cannula	Stainless steel 304	SUS
9.	Cannula Hub	Methyl methacrylate-acrylonitrile-butadiene-styrene plastic	MABS
10.	Housing for Bloodstopper	Methyl methacrylate-acrylonitrile-butadiene-styrene plastic	MABS
11.	Filter Disc	hydrophobic acrylic copolymer on non woven nylon support	AC on PA 6
12.	Closing Cone	Polystyrene	PS
13.	Spring Clip	Stainless steel 302	SUS
14.	Adhesive	UV curing adhesive	-
15.	Lubricant	Silicone oil	-
16.	Single Peel Pack	Coated paper Transparent, unpowdered	Medical Grade paper PE mono foil
17.	Container box	Cardboard box with label	Duplex
18.	Transport / multipackage box	Double wall corrugated paper with label	-

3.3 Basic product characteristics and features

Feature	Remarks
Safety feature	Vasofix® passive Safety Clip (self-activating)
Injection port	female Luer
Fixation wings	-
Closing cone	for closing catheter hub
Detachable bloodstopper	-
Capillary materials	FEP / PUR
Cannula Bevel geometry	back cut bevel
Catheter hub connection type	Luer Lock
Catheter hub	translucent / colour coded
Cannula hub connection type	Luer
Gauge Sizes	G14, G16, G17, G18, G20, G22, G24
Sterile	Ethylenoxide (ETO)
Hypoallergenic	latex-free
	PVC-free
Shelf Life	5 years

3.4 Packaging

The packaging has to protect the product from contamination and mechanical damages.

Primary Packaging:	Individual single peel pack designated as a microbiological barrier to assure the sterility of the product.
Duplex Box (dispenser):	Container box containing a certain number of primary packaging. 50pcs per box
Carton:	Transport box for dispatching and additional protection against mechanical damages during transportation. 200pcs per carton

3.5 All components / complete set

3.5.1 Protective Cap

The protective cap covers the plastic cannula over its total length against mechanical impacts and the inside of the device against microbial contamination when unpacked immediately prior to use.

3.5.2 Closing Cone

The closing cone with male luer lock connector is located on the proximal end of the blood stopper can be used for temporary closure of the catheter housing assuming the catheter lumen is blocked with a heparin or saline block.

3.5.3 Capillary Tube

A thin-wall plastic capillary made of polymer with four longitudinally oriented radio-opaque stripes fully incorporated in the tubing wall polymer matrix. The tip of the capillary is smoothly rounded and tapered and fitted close to the heel of the metal cannula bevel. Four radio-opaque stripes are embedded in the catheter wall to leave clear sections (windows) separating the stripes for visual control of secondary blood flash back.

3.5.4 Capillary Hub

Capillary hub body:

- with integrated injection port, fixation wing for ease of fixation to the patient's body surface, and with a female 6 % luer lock connection.

Injection port:

- with one way valve for injection of additive medication with a luer or luer lock syringe without needle. The valve opens under the pressure of injected fluid, and recloses automatically upon pressure relief. To protect against bacterial contamination the port features a hinged lid which can be opened and closed as desired. The lid body is colour coded to indicate the nominal size of the cannula.

3.5.5 Cannula Hub

The transparent cannula hub material incorporates a flashback chamber which allows visual control of first blood flashback and confirms a successful venipuncture of the cannula.

3.5.6 Cannula

A metal cannula with back cut bevel configuration is used to puncture the appropriate blood vessel intravenous. The bevel geometry allows to facilitate easy and low pain penetration of the skin with a minimum of puncture force and less traumatic reactions.
The bevel geometry allows a wide range of puncture angle depending on preference of user.

3.5.7 Safety Clip

The Vasofix® Safety intravenous catheter features a safety metal clip which is automatically engaged over the sharp needle tip when the needle bevel exits the catheter hub. This feature protects the user from infections caused by needle stick injuries.
Vasofix® Safety intravenous catheter do not require any changes in the puncture technique compared with non-safety devices.

3.5.8 Bloodstopper

The blood stopper incorporates a hydrophobic filter membrane which allows air to pass to escape and blood to flow once the needle tip entered the blood vessel. Its porosity and hydrophobic finish is selected to allow for easy air escape while the entering blood is retained inside the cannula hub.

4 General Requirements

Physical-technical requirements

Standard	Designation
ISO 10555-1	Intravascular catheters – Sterile and single-use catheters, Part 1: General requirements
EN ISO 10555-1:2009	Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004)
ISO 10555-5	Intravascular catheters – Sterile and single-use catheters, Part 5 : Over-needle peripheral catheters
ISO 594-1	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements
EN 20594-1:1993 EN 20594-1:1993/A1:1997 EN 20594-1:1993/AC:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements (ISO 594-1:1986)
ISO 594-2	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings
ISO 9626	Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods

Biological requirements

Standard	Designation
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
ISO 10993-4 + Amd 1	Biological evaluation of medical devices Part 4: Selection of tests of interactions with blood
EN ISO 10993-4:2009	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)
ISO 10993-7	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
ISO 8536-4	Infusion equipment for medical use Part 4: Infusion sets for single use, gravity feed (for Pyrogen free)

Miscellaneous requirements

Standard	Designation
ISO 14971	Medical devices – Application of risk management to medical devices
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices (ISO 14791:2007, Corrected version 2007-10-01)
ISO 13485 + Cor.1	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 13485:2012 EN ISO 13485:2012/AC:2012	Medical devices – Quality management systems – Requirements for regulatory purpose (ISO 13485:2003)
MEDDEV 2.7.1 Rev.4	Guidelines on medical devise – Clinical evaluation: a guide for manufacturers and notified bodies
ISO 23908	Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling *Only applicable for safety version

Sterilization

Standard	Designation
EN ISO 11737-2	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11737-1	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
ISO 11737-1	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
ISO 11737-2	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 10993-7	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-7	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
EN 556-1 EN 556-1:2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices
ISO 11135:2014	Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11135	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)

Packaging

Standard	Designation
ISO 11607-1 +Amd1: 2014	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)
EN ISO 11607-2 +Amd1: 2014	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)
ISO 15223-1	Medical devices – Symbols to be used with medical devices labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices

Storage conditions
No special storage conditions.
Storage as commonly used for medical products. Clean, dry and cool.

Transport conditions
No special transportation conditions
Transportation as commonly used for medical products

5 Sterilization method

The product is Ethylene Oxide (EO) sterilized.
The EO Residuals are acc. to ISO 10993-7.

– End of document –

6 Document History

1.0	Creation of document
2.0	GChC-M-11-026 Addition of new article numbers for CIS region under pt.1
3.0	GChC-M-11-026 version 2: Change of article number list under pt.1 (CIS region code only for Vasofix Safety PUR products – exclusion of FEP articles)
4.0	Pt. 1: RMF-number included
5.0	HC-CHC-M-DIV-655 Creation of Appendix 1: Technical Data Sheet Vasofix / Vasofix Safety RMF-120-000-A03
6.0	Pt. 4: - GMDN code change from 34905 in 40601 - GMDN designation added
7.0	Pt. 1: - Update of article no. list HC-CHC-M-DIV-748 - Pt.7: Added characteristic: Lubricant (max. 0.25mg/cm^2)
8.0	HC-CHC-M-DIV-1010 Harmonization of Global Test Specification for IVC Products (In, InS, Vx, VxS & InS3): - Pt. 7: Content updated related to creation of Global Test Spec RMF-120-000-TS-01
9.0	HC-CHC-M-DIV-2052 Update of Vasofix Product Specification, Vasofix Test Specification and VasoVet Test Specification: - Update according to new revision of Product Specification Template. - To update and align section 4 General Requirements as per the Applied Standard for IVC (RD/2017/199/AA/PROFIX) - Change GMDN code and designation: To replace 40601 Peripheral vascular catheter with 32151 Peripheral vascular infusion catheter. - Added Basic UDI-DI in section 1 - Added classification according MDD and amended the classification according to MDR. - Correction of standard 'Defined flow rate through Catheter (capillary)' from ISO 10555-5 to ISO 10555-1.
10.0	HC-CHC-M-DIV-1585: Change of Auxiliary Material - Pall Versapor 1200R - Standardization of material description of Filter Disc in 3.2.1 & 3.2.2 - Update according to new revision of Product Specification Template. - Chapter 6 "Properties" deleted. Content is covered with test specification.
11.0	HC-CHC-M-DIV-1926 - Creation of Vasofix Safety Article Codes (incl. label) for INDIAN Market - Add 5 new articles for Vasofix® Safety PUR (India Labelling - IN) in section 1.

Title: Vasofix, Vasofix Safety Initiator: Jumaria . Masri

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Tan, Lee Ling (tanleemy)
Title: BMI-RD-Manager
Date: Monday, 03 April 2023, 05:20 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Vivekanandan, Jaya Sarmman (vivejamy)
Title: BMI Quality Management-Director
Date: Monday, 03 April 2023, 07:27 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Fu, YongJi (fuyongmy)
Title: BMI - R&D - Vice President
Date: Monday, 03 April 2023, 12:36 W. Europe Daylight Time
Meaning: Approve Document
==========

Effective