

PLAN1HEALTH, A POLYMEDICURE COMPANY GROUP

HEALTHPORT®

LP



ISSUED BY (RT)	VERIFIED BY (PMIN, PSI)	APPROVED BY (RGQ)	
			Date
			Signature

GENERAL INFORMATIONS

Intended use

The HEALTHPORT LP is indicated for implantation in the central venous system in the long and medium term to allow the repeated infusion of therapeutic solutions, such as chemotherapy, antibiotics, nutrients, blood products / blood components, but also the collection of blood samples. Therefore the HEALTHPORT LP is indicated for patients on long-term therapy who require repeated access for continuous infusions or bolus injections.

Device Description

The HEALTHPORT LP (Low Profile) is a subcutaneous implantable venous access device, consisting of a single titanium chamber, which guarantees a longer duration of use without showing lesions of the same after multiple punctures. Titanium guarantees maximum mechanical reliability and stability over time.

HEALTHPORT LP features full MRI scan compatibility supported by specific tests conducted up to 3 Tesla.

The HEALTHPORT LP has a height of only 10.2 mm to facilitate insertion into the subcutaneous pocket. Its soft design has been studied to minimize possible complications after positioning such as skin decubitus.

The HEALTHPORT LP has a useful septum of large dimensions, in fact, the silicone septum measures a good 12.8 mm in diameter, guaranteeing the reduction of close punctures.

The connection to the catheter takes place through a Ti6Al4V titanium connector which has excellent mechanical properties and excellent resistance to corrosion, combined with a low specific weight and biocompatibility qualities. The connected catheters are graduated in their length [cm].

The silicone catheter has a blunt tip for better a-traumaticity.

Catheter description:

Polyurethane 5 FR:

INTERNAL DIAMETER	OUTER DIAMETER	LENGTH	CENTIMETER
1.1 mm	1.7 mm	780 mm	Yes

Silicone 6.5 FR:

INTERNAL DIAMETER	OUTER DIAMETER	LENGTH	CENTIMETER
1.0 mm	2.1 mm	780 mm	Yes

Silicone 8 FR:

INTERNAL DIAMETER	OUTER DIAMETER	LENGTH	CENTIMETER
1.5 mm	2.7 mm	780 mm	Yes

Package configuration HEALTPORT LP All-in-One KIT consists of:

- Titanium chamber
- Catheter
- Connector
- Huber needle 22GA x 25.4 mm
- Luer connector
- Introducer - peel-away dilator
- 18 GA introducer needle
- 0.89 mm "J" guide
- Tunneler in stainless steel

Package configuration HEALTPORT LP KIT consists of:

- Titanium chamber
- Catheter
- Connector
- Huber needle 22GA x 25.4 mm
- Luer connector

The adhesive labels provided, bearing the code and lot number, used:

- tyvek, pouch
- box
- patient record,

allow perfect traceability.

Legal Manufacturer

Plan 1 Health Srl,
via Solari 5, 33020 Amaro (UD) ITALY

Production Site

Plan 1 Health Srl,
via Solari 5, 33020 Amaro (UD) ITALY

Certifications:**CE certified**

CE marked in accordance with Legislative Decree no. 46 of 24.2.1997 (in implementation of the European MDD directive no. 93/42 / EEC) and subsequent amendments and additions

ISO 13485: 2016 Certificate No .:2182609

Notified Body: DEKRA

Notified Body Number: 0344

GMDN classification: 61494

Device Class

Class III device

BD / RDM registration identifier:

- 506678 (201.15.xx.xx)

CND code: C01020401

SPECIFICATION INFORMATIONApproved Materials of Constructions

Part	Base material
catheter	Polyurethane / silicone
Chamber	Titanium
Connector	Polyurethane / silicone
Huber needle	Stainless steel
"J" guidewire	Steel AISI 340
Vein Lift	terlux
Needle with a truncated point	Stainless steel
Tunneler	Stainless steel
Guide Metal	Nitinol
Dispenser Metal Guide	HDPE polyethylene
Septum	Silicone
Luer connector	polypropylene
Peel away introducer	polypropylene
Syringe	Transparent polypropylene

Sterilization Method/Shelf Life:**Sterilization Method:** Ethylene Oxide Sterilization.**Shelf Life:** Five years from the date of manufacturing.

Standards Compliance:

Document Code	Document Description
ISO 10555-1: 2013	Intravascular catheters - Sterile and single - use catheters - Part 1: General requirements
ISO 10555-6: 2015	Intravascular catheters - Sterile and single - use catheters - Part 6: Subcutaneous implanted ports
EN ISO 14971: 2012	Application of Risk Management for Medical Devices
EN ISO 11135-1: 2007	Validation and routine control of EO Sterilization
EN ISO 15223-1: 2016	Medical Devices - Symbols to be used with medical devices labels, labeling and information to be supplied Part 1: General requirements
EN ISO 11607-1: 2009	Packaging for terminally sterilized medical devices - requirements for materials, sterile barrier & packaging systems.
EN 62366-1: 2008	Medical Devices - Application of usability engineering to medical devices
EN ISO 10993 -1: 2009 / AC: 2010	Biological evaluation of medical devices - Evaluation and testing within a risk management process.
EN ISO 10993-7: 2008 / AC: 2009	Biological evaluation of medical devices - Ethylene oxide sterilization residuals
ISO 14644-1: 2015	Cleanroom and associated controlled environments - Classification of air cleanliness
EN 556-1: 2002	Sterilization of medical devices - Requirements for medical devices marked "STERILE" - Requirements for terminally sterilized medical devices
EN 1041: 2013	Information provided by the medical device manufacturer
EN ISO 10555-1: 2018	Intravascular Catheters - Sterile Disposable Intravascular Catheters - Part 1: General Requirements
ISO 14630: 2012	Inactive medical devices
NF S94-370 (04/1999)	Implantable catheter chambers
ASTM F 67 and ASTM F 136	materials

Packaging Characteristics

Single sterile package with label conforming to the essential requirements of Directive 93/42 EEC and subsequent integration 2007/47 EEC. Supplied with external barrier consisting of a Tyvek envelope on PE, and internal barrier supplied by PETG blister packs sealed on Tyvek sheet.

Unit

Quantity	1 No.
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Carton

Quantity	1 No.
Dimensions - L x H x W (mm)	225x25x320

Shipping Packaging

Quantity	1 No.
Dimensions - L x H x W (mm)	225x25x320

Conservation conditions:

To preserve between 5°C and 35°C

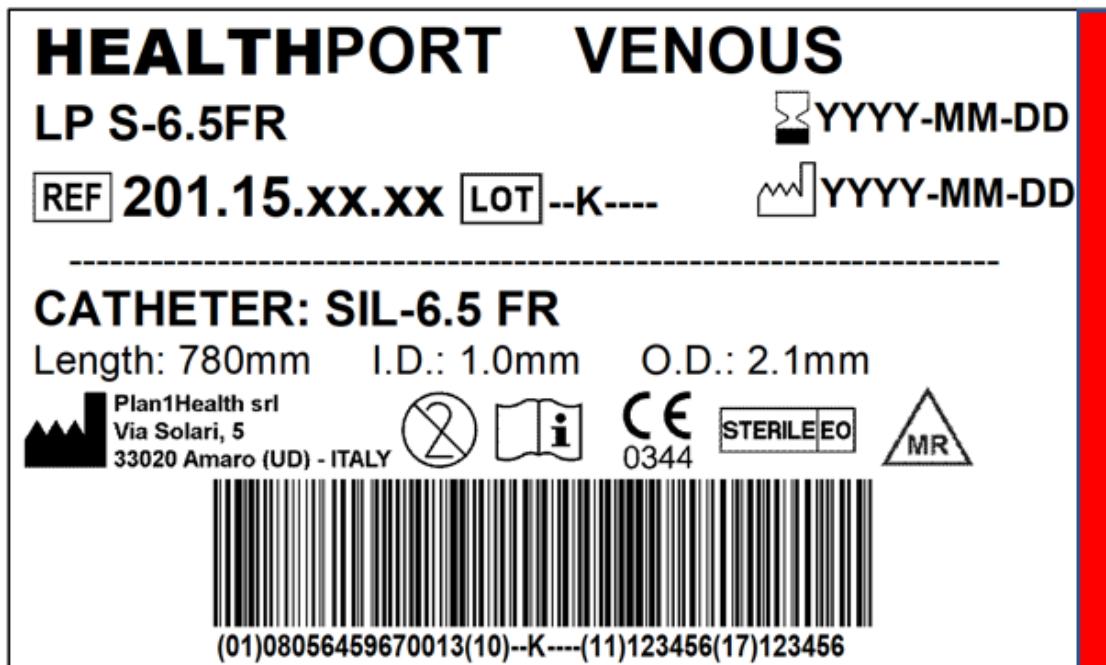
Materials of Concern

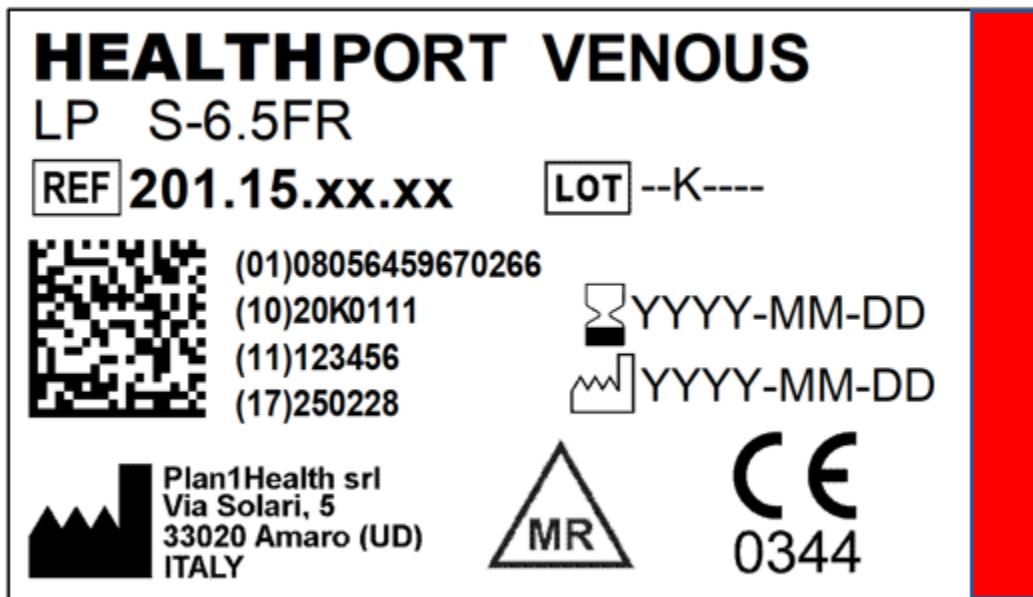
DEHP free	YES
Latex free	YES
BSE / TSE substances of animal origin	No

Codes and descriptions

Product Code	Product Description	Maximum punctures with 22GA huber needle num.	Base diameter	Weight	Height	Internal Vol
201.15.12.21	LP 6.5FR silicone catheter All-in-One	2000	26mm	8.5gr	10.2mm	0.53ml
201.15.12.31	LP 8FR silicone catheter All-in-One	2000	26mm	8.5gr	10.2mm	0.53ml
201.15.12.41	LP 5FR polyurethane catheter All-in-One	2000	26mm	8.5gr	10.2mm	0.53ml
201.15.10.21	LP 6.5FR silicone catheter	2000	26mm	8.5gr	10.2mm	0.53 ml
201.15.10.31	LP 8FR silicone catheter	2000	26mm	8.5gr	10.2mm	0.53ml
201.15.10.41	LP 5FR polyurethane catheter	2000	26mm	8.5gr	10.2mm	0.53ml

ANNEX A: product labels

Single unit label (Example):

Patient Label (Example):

ATTACHMENT B: Photo of the finished product