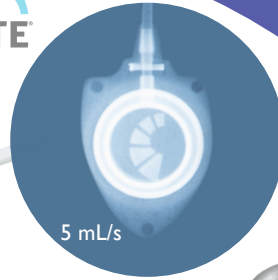




INTRAVASCULAR THERAPIES
Vascular access range



polysite™



heliosite™



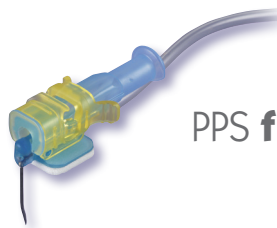
maxflo™ expert



CT PICC easy™



lifecath™

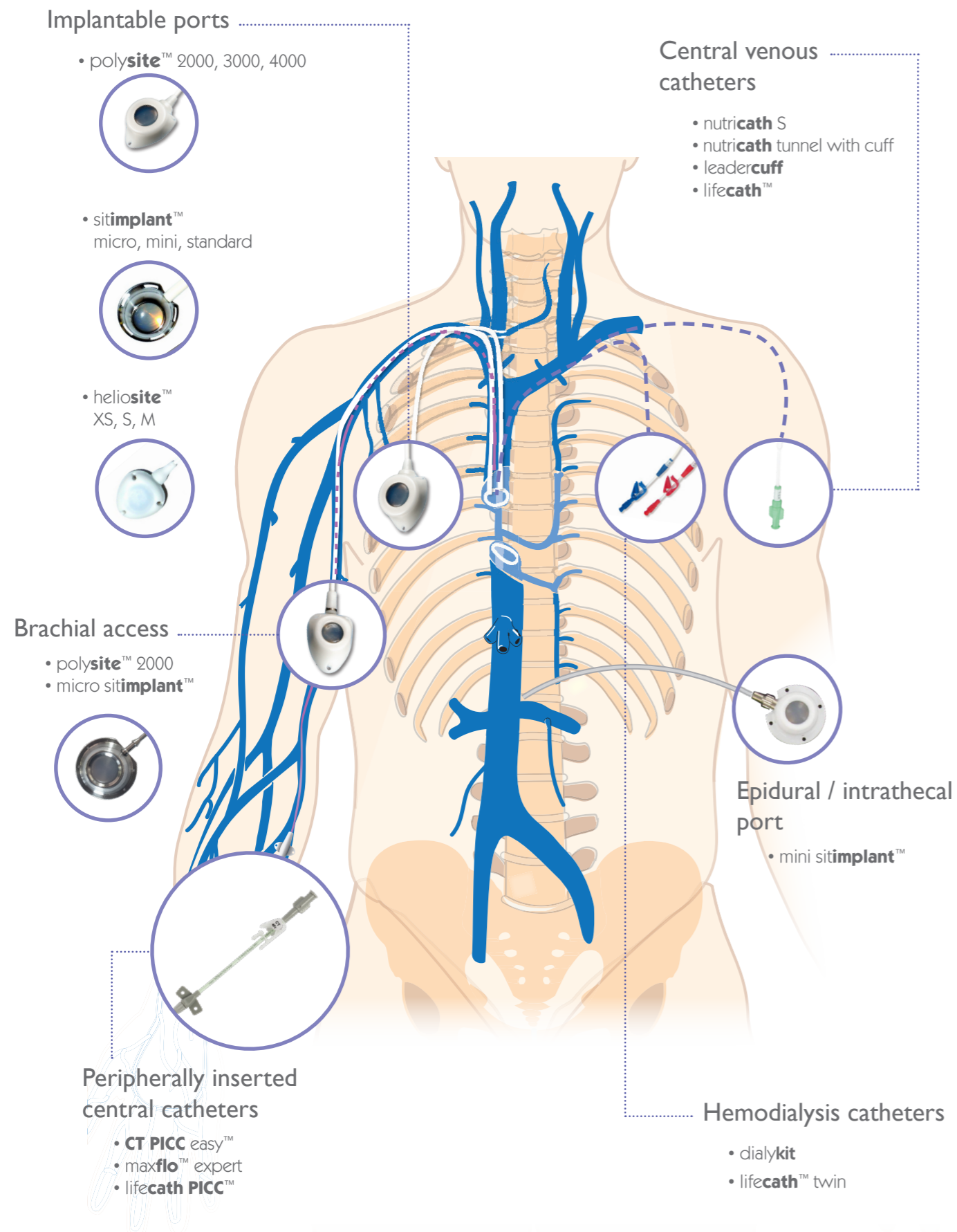


PPS flow +™



Value Life

Vascular access range



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STANDARD

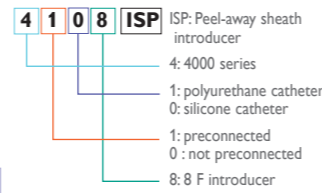


Venous standard port polysite™ 4000 series - Hybrid: Titanium and POM⁽¹⁾

Compatible
injection of contrast
media during CT
scan and MRI
procedures
(cf. Page 8)



- Profile-shaped design
- Easy to connect
- Titanium-POM⁽¹⁾ combination: low weight
- Titanium reservoir: compatibility with anti-neoplastic agents
- Radiopaque connecting ring



Port features

Port type	Adult	Septum diameter	12.1 mm
Materials	POM ⁽¹⁾ + Titanium	Weight	7.6 g
Base diameter	30.8x22.6 mm	Port height	12.2 mm

Silicone catheters

Catheter				Port internal volume (mL)	Introducer Sheath (Fr)	Preconnected catheter	Product codes	Implantation technique	Kit (see page 14)
OD (mm)	ID (mm)	Length (cm)	Internal volume (mL/10cm)						
2.40	1.20	60	0.13	0.6			4008	Surgical	2
2.40	1.20	60	0.13	0.6	8		4008 ISP	Modified Seldinger	4
2.40	1.20	60	0.13	0.6		x	4108	Surgical	2
2.40	1.20	60	0.13	0.6	8	x	4108 ISP	Modified Seldinger	4
3.18	1.57	60	0.22	0.6			40010	Surgical	2
3.18	1.57	60	0.22	0.6	10		40010 ISP	Modified Seldinger	4
3.18	1.57	60	0.22	0.6		x	41010	Surgical	2
3.18	1.57	60	0.22	0.6	10	x	41010 ISP	Modified Seldinger	4

Polyurethane catheters

Catheter				Port internal volume (mL)	Introducer Sheath (Fr)	Preconnected catheter	Product codes	Implantation technique	Kit (see page 14)
OD (mm)	ID (mm)	Length (cm)	Internal volume (mL/10cm)						
2.30	1.45	60	0.18	0.58			4017	Surgical	2
2.30	1.45	60	0.18	0.58	7		4017 ISP	Modified Seldinger	4
2.30	1.45	60	0.18	0.58		x	4117	Surgical	2
2.30	1.45	60	0.18	0.58	7	x	4117 ISP	Modified Seldinger	4
2.65	1.70	60	0.24	0.59			4018	Surgical	2
2.65	1.70	60	0.24	0.59	8		4018 ISP	Modified Seldinger	4
2.65	1.70	60	0.24	0.59		x	4118	Surgical	2
2.65	1.70	60	0.24	0.59	8	x	4118 ISP	Modified Seldinger	4
3.00	1.90	60	0.30	0.5			4019	Surgical	2
3.00	1.90	60	0.30	0.5	9		4019 ISP	Modified Seldinger	4
3.00	1.90	60	0.30	0.5		x	4119	Surgical	2
3.00	1.90	60	0.30	0.5	9	x	4119 ISP	Modified Seldinger	4

(1) Polyoxymethylene. (2) See I.F.U.
The polysite™ range is sterilized by ethylene oxide. polysite™ is a registered trademark of PEROUSE MEDICAL.

MINI



Compatible
injection of contrast
media during CT
scan and MRI
procedures
(cf. Page 8)

Vascular access
range

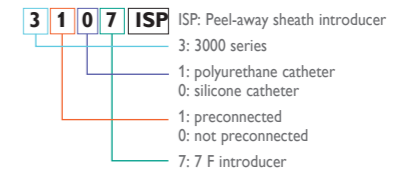
Venous mini port polysite™ 3000 series - Hybrid: Titanium and POM⁽¹⁾



- Profile-shaped design
- Easy to connect
- Titanium-POM⁽¹⁾ combination: low weight
- Titanium reservoir: compatibility with antineoplastic agents
- Radiopaque connecting ring

Port features

Port type	Adult	Septum diameter	10.5 mm
Materials	POM ⁽¹⁾ + Titanium	Weight	5.0 g
Base diameter	25.8x20.9 mm	Port height	10.1 mm



Silicone catheters

Catheter				Port internal volume (mL)	Introducer Sheath (Fr)	Preconnected catheter	Product codes	Implantation technique	Kit (see page 14)
OD (mm)	ID (mm)	Length (cm)	Internal volume (mL/10cm)						
2.16	1.02	60	0.09	0.35			3007	Surgical	2
2.16	1.02	60	0.09	0.35	7		3007 ISP	Modified Seldinger	4
2.16	1.02	60	0.09	0.35		x	3107	Surgical	2
2.16	1.02	60	0.09	0.35	7	x	3107 ISP	Modified Seldinger	4
2.40	1.20	60	0.13	0.35			3008	Surgical	2
2.40	1.20	60	0.13	0.35	8		3008 ISP	Modified Seldinger	4
2.40	1.20	60	0.13	0.35		x	3108	Surgical	2
2.40	1.20	60	0.13	0.35	8	x	3108 ISP	Modified Seldinger	4

Polyurethane catheters

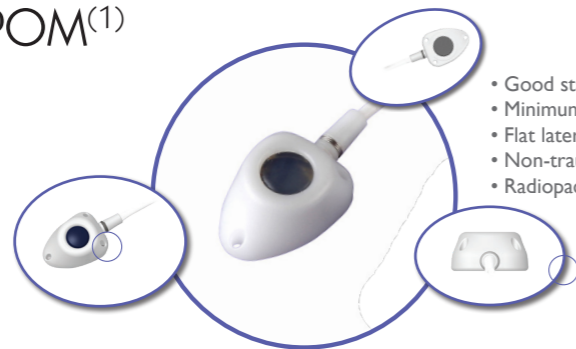
Catheter				Port internal volume (mL)	Introducer Sheath (Fr)	Preconnected catheter	Product codes	Implantation technique	Kit (see page 14)
OD (mm)	ID (mm)	Length (cm)	Internal volume (mL/10cm)						
2.30	1.45	60	0.18	0.37			3017	Surgical	2
2.30	1.45	60	0.18	0.37	7		3017 ISP	Modified Seldinger	4
2.30	1.45	60	0.18	0.37		x	3117	Surgical	2
2.30	1.45	60	0.18	0.37	7	x	3117 ISP	Modified Seldinger	4

(1) Polyoxymethylene. (2) See I.F.U.
The polysite™ range is sterilized by ethylene oxide. polysite™ is a registered trademark of PEROUSE MEDICAL.



Venous micro port polysite™ 2000 series - Hybrid: Titanium and POM⁽¹⁾

Compatible
injection of contrast
media during CT
scan and MRI
procedures
(cf. Page 8)



- Good stability
- Minimum weight
- Flat lateral edges for good adherence
- Non-traumatic angle
- Radiopaque connecting rings



Port features

Port type	Paediatric or Adult
Materials	POM ⁽¹⁾ + Titanium
Base diameter	22.0x17.0 mm

Septum diameter	7.8 mm
Weight	2.9 g
Port height	8.7 mm

2 1 0 5 ISP ISP: Peel-away sheath introducer
2: 2000 series
1: polyurethane catheter
0: silicone catheter
1: preconnected
0: not preconnected
5: 5 F introducer

Silicone catheters

	Catheter				Port internal volume (mL)	Introducer Sheath (Fr)	Preconnected catheter	Product codes	Implantation technique	Kit (see page 14)
	OD mm	ID mm	Length (cm)	Internal volume (mL/10cm)						
PAEDIATRIC	1.65	0.65	60	0.04	0.2			2005	Surgical	2
	1.65	0.65	60	0.04	0.2	5		2005 ISP	Modified Seldinger	3
	1.65	0.65	60	0.04	0.2		x	2105	Surgical	2
	1.65	0.65	60	0.04	0.2	5	x	2105 ISP	Modified Seldinger	3
ADULT	2.16	1.02	80	0.09	0.2			2007	Surgical	2
	2.16	1.02	80	0.09	0.2	7		2007 ISP	Modified Seldinger	4
	2.16	1.02	80	0.09	0.2		x	2107	Surgical	2
	2.16	1.02	80	0.09	0.2	7	x	2107 ISP	Modified Seldinger	4

Polyurethane catheters

	Catheter				Port internal volume (mL)	Introducer Sheath (Fr)	Preconnected catheter	Product codes	Implantation technique	Kit (see page 14)
	OD (mm)	ID (mm)	Length (cm)	Internal volume (mL/10cm)						
PAEDIATRIC	1.65	1.05	60	0.10	0.1			2015	Surgical	2
	1.65	1.05	60	0.10	0.1	5		2015 ISP	Modified Seldinger	3
	1.65	1.05	60	0.10	0.1		x	2115	Surgical	2
	1.65	1.05	60	0.10	0.1	5	x	2115 ISP	Modified Seldinger	3
ADULT	2.00	1.30	80	0.15	0.14			2016	Surgical	2
	2.00	1.30	80	0.15	0.14	6		2016 ISP	Modified Seldinger	4
	2.00	1.30	80	0.15	0.14		x	2116	Surgical	2
	2.00	1.30	80	0.15	0.14	6	x	2116 ISP	Modified Seldinger	4

(1) Polyoxymethylene. (2) See I.F.U.
The polysite™ range is sterilized by ethylene oxide. polysite™ is a registered trademark of PEROUSE MEDICAL.



Hand carried ultrasound system echosite™ WED 3100

Vascular access
range



Good-quality image

- Increased procedural accuracy
- Advanced imaging features for exceptional image quality with minimal key strokes

Intuitive design, simplified settings

- Ideal for real time central venous catheter placement

Really suitable for central venous catheter placement

- Linear probe settings: 5.5 MHz, 7.5 MHz and 8.5 MHz
- Depth detect up to 8cm

Rapid boot-up time

- Under 3 seconds from cold start to scanning

Light and compact

- Only 700g



Product codes	Description
ES001	Ultrasound scanner ECHO-Site™ WED 3100: • Monitor and its base • Linear probe with adjustable frequency: 5.5, 7.5 and 8.5 MHz • Battery (3 hours of battery life) • Carrying bag
ES001B	Battery (3 hours of battery life)
ES001P	Linear probe with adjustable frequency: 5.5, 7.5 and 8.5 MHz

Manufacturer:
Shenshen Well. D Medical Electronics Co., Ltd
13/F & 12/F North, New Energy Bldg.,
Nanhai Ave., Nansham District,
Shenzhen 518054, China

Authorized EU representative:
Wellkang Ltd. t/a Wellkang Tech. Consulting,
Suite b, 29 Harley Street
London W1G 9QR, UK

Distributor:
PEROUSE
A Vygon company

Vascular Access Division - Route du Manoir - 60173 Ivry le Temple - France
Tel: +33 (0) 3 44 08 17 00 - Fax: +33 (0) 3 44 08 17 01



Use recommendations

polysite™ and seesite™ Injection of contrast media during CT scan or MRI procedures



- Use an angled Huber needle (without tubing) or a Huber needle with tubing validated for high pressure injection.
- Select the appropriate Huber needle gauge to the viscosity of the contrast medium used and to the implantable port reference following the recommendations in table (hereafter).
- Set the maximum injector pressure to 22.4 bars or 325 psi in order to guarantee the reliability of the system.
- Only use 19G or 20G needles for polysite™ and seesite™ Standard (series 4000) and Mini (series 3000) and 20G or 22G for polysite™ and seesite™ micro (series 2000), in accordance with table hereafter.
- Do not inject more than 3 mL/s when using a 22G Huber needle.
- Always ensure that the injection circuit is fully operational (Huber needle and implantable port) by obtaining reflux of blood and injecting 10-20 ml of normal saline without difficulty.
- Warm the contrast medium to 37 °C (100 °F) before use ⁽¹⁾.
- Always ensure that the catheter is equal or less than 25 cm long (do not administer this type of injection with a femoral catheter) ⁽¹⁾.
- Never exceed the maximum recommended flow rate for a given port.
- Never inject contrast media with a viscosity greater than that shown in table hereafter.
- Rinse the implantable port with 10 to 20 ml of 0.9% NaCl before and after use followed by usual rinsing procedures.

Not following these recommendations may lead to failure of the system through excess pressure or obstruction.

(1) See IFU

Source: test report - CE file, march 2010 (Implantable ports technical file on polysite™ 2000, 3000 & 4000 (DT002), part VI / Evaluation of the conception of polysite™ 2000, 3000 & 4000 series, §14 / Qualification of our implantable ports polysite™ for injection of contrast media (page 18).
Version September 2010, RRD-0049-01 rev 0:
Simulation of contrast media injection on polysite™ ports report – p. 10-11 (§XI. Test summary).

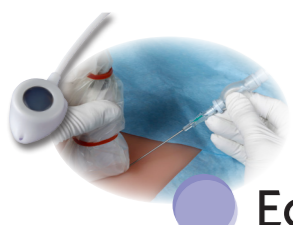
Maximum flow rates recommended for injecting contrast medium

The following conditions must be observed.

	polysite™ Product codes	Maximum recommended flow rate (mL/s) with 25 cm catheter	Maximum recommended pressure (CT scan function)	Viscosity (cP) / maximum recommended iodine concentration (mgI/mL) in contrast media	Recommended diameter of angled needle (Gauge)
M I C R O	2005, 2005 ISP, 2005 ECHO	1	325 psi or 22.4 bar	6cP i.e. 300 mgI/mL (e.g.: Xenetix™ 300, pre-warmed to 37°C)*	20G or 22G
	2105, 2105 ISP, 2105 ECHO				
	2015, 2015 ISP, 2015 ECHO	2			
	2115, 2115 ISP, 2115 ECHO				
	2016, 2016 ISP, 2016 ECHO				
	2116, 2116 ISP, 2116 ECHO	3			
	2007, 2007 ISP, 2007 ECHO				
2107, 2107 ISP, 2107 ECHO					
M I N I	3007, 3007 ISP, 3007 ECHO	3	325 psi or 22.4 bar	10cP i.e. 350 mgI/mL (e.g.: Xenetix™ 350, pre-warmed to 37°C)*	19G or 20G
	3107, 3107 ISP, 3107 ECHO				
	3017, 3017 ISP, 3017 ECHO				
	3117, 3117 ISP, 3117 ECHO				
	3008, 3008 ISP, 3008 ECHO				
3108, 3108 ISP, 3108 ECHO	5				
4017, 4017 ISP, 4017 ECHO					
4117, 4117 ISP, 4117 ECHO					
4008, 4008 ISP, 4008 ECHO					
4108, 4108 ISP, 4108 ECHO					
4018, 4018 ISP, 4018 ECHO					
4118, 4118 ISP, 4118 ECHO					
4019, 4019 ISP, 4019 ECHO					
4119, 4119 ISP, 4119 ECHO					
40010, 40010 ISP, 40010 ECHO					
41010, 41010 ISP, 41010 ECHO					

* Xenetix™ is a registered trade mark of Guerbet Laboratories.

All references are CE certified for high pressure injections of contrast media during CT scan and MRI procedures (see IFU).



Echo-guided kit polysite™ echo - Hybrid: Titanium and POM⁽¹⁾

Compatible
injection of contrast media during CT scan and MRI procedures (cf. Page 8)

NEW

Set of implantable port designed for ultrasound guided venipuncture
Increased success rate - Faster and more accurate venipuncture

In accordance with HAS check list 2010^(a), SF2H 2012^(b) and NICE 2004^(c) recommendations



Bulb introducer:

- Lightweight design: operator comfort
- Clear bulb: blood flashback verification
- Valve included: prevention of blood loss and air embolus during guidewire insertion
- No more connection and disconnection of a syringe onto the needle
- Shorter overall length as compared to a needle/syringe assembly: closer proximity to the puncture site

Echogenic puncture needle:

- Good needle tip visualization, thanks to an echogenic improvement technique



Also included in the kit:

- Sterile drape
- LATEX FREE protective sheath for ultrasound system probe
- 2 sterile elastics
- Sterile gel

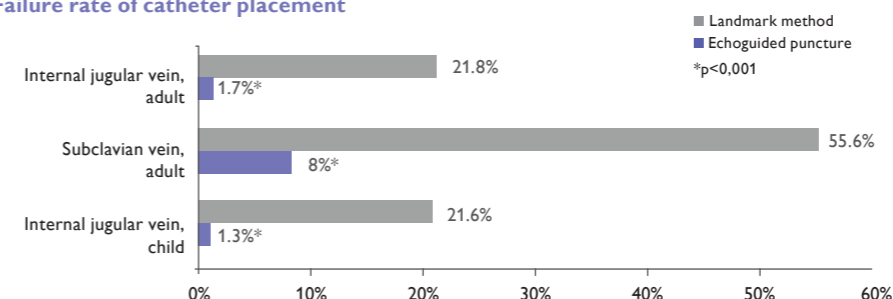
		Port features			Catheter features				Introducer Sheath (Fr)	Preconnected catheter	Product codes	Kit (see page 14)				
		Dimensions (LxWxH) (mm)	Weight (g)	Internal volume (mL)	Material Silicone (Si) or Polyurethane (PU)	OD (mm)	ID (mm)	Length (cm)					Internal volume (mL/10cm)			
PEDIATRIC	Micro series	22.0 x17.0 x8.7	2.9	0.2	Si	1.65	0.65	60	0.04	5		2005 ECHO	5			
												x		2105 ECHO		
				0.1	PU	1.65	1.05	60	0.10	5		x		2015 ECHO		
														2115 ECHO		
	ADULT	Mini series	25.8 x20.8 x10.1	5	0.14	PU	2.00	1.30	60	0.15	6		2016 ECHO	6		
													x		2116 ECHO	
					0.2	Si	2.16	1.02	60	0.09	7		x		2007 ECHO	
															2107 ECHO	
		Standard series	31.0 x22.2 x12.2	7.6		0.35	Si	2.16	1.02	60	0.09	7		3007 ECHO	6	
														x		3107 ECHO
						0.37	PU	2.30	1.45	60	0.18	7		x		3017 ECHO
																3117 ECHO
0.35	Si					2.40	1.20	60	0.13	8		x	3008 ECHO			
													3108 ECHO			
0.58	PU					2.30	1.45	60	0.18	7		x	4017 ECHO			
													4117 ECHO			
									x	4018 ECHO						
										4118 ECHO						
										x	4008 ECHO					
											4108 ECHO					
											4019 ECHO					
											4119 ECHO					
											40010 ECHO					
											41010 ECHO					

(1) Polyoxymethylene.
The polysite™ range is sterilized by ethylene oxide. polysite™ is a registered trademark of PEROUSE MEDICAL.
(a) HAS 2010 French health authority - Check list relative to «central venous catheters or vascular device implantation».
(b) SF2H 2012: French Society for hospital hygiene. «Prevention of venous implantable port catheter infections».
(c) NICE 2004: National Institute for Clinical Excellence, UK: Echoguidance is recommended on internal jugular access on adult and child.

Echoguided venipuncture benefits

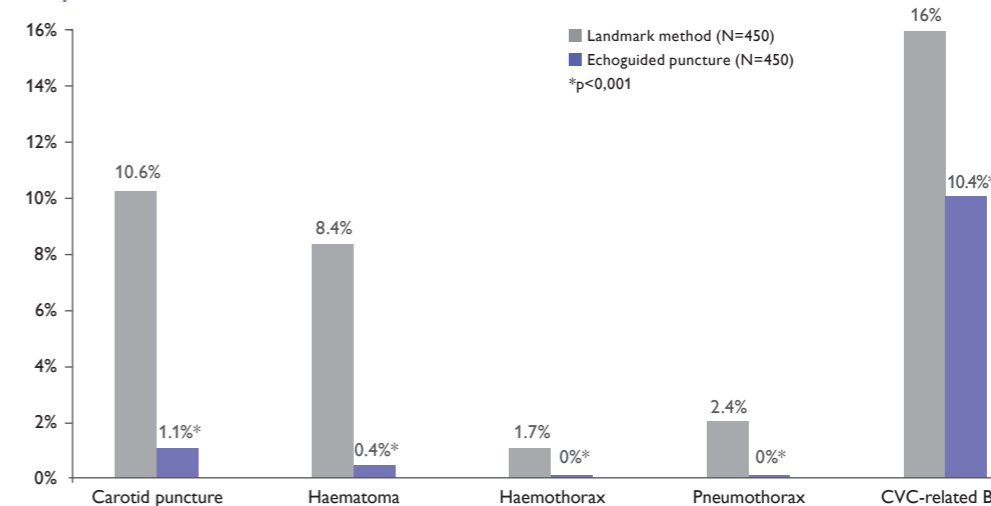
Increased success rate⁽³⁾

Failure rate of catheter placement



Reduction of the number of attempts^{(3) (4)}
Decreased complications rate⁽⁴⁾

Complication rate



(3) D. Hind, Ultrasonic locating devices for central venous cannulation: meta-analysis, BMJ, Vol. 327, 16 August 2003.
(4) D. Karakitsos Real-time ultrasound-guided catheterisation of the internal jugular vein: a prospective comparison with the landmark technique in critical care patients Critical Care, 17 November 2006, Vol.10, n°6.



Pressure injectable implantable port kit seesite™ - Hybrid: Titanium and POM⁽¹⁾

Compatible
injection of contrast
media during CT
scan and MRI
procedures
(cf. Page 8)

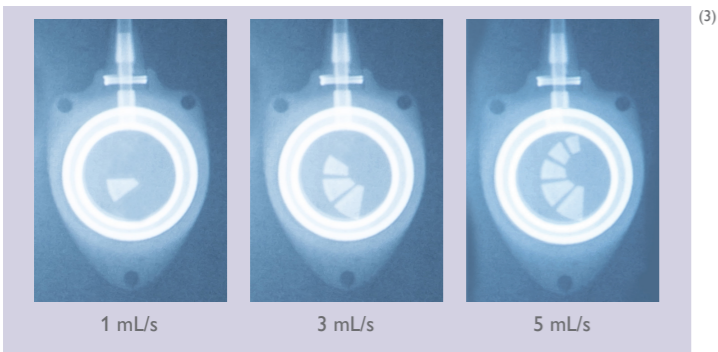


- Radiopaque marking detectable by X-ray
- Silicone filled suture holes
- Each graduation = 1 mL/s
- Radiopaque connecting ring

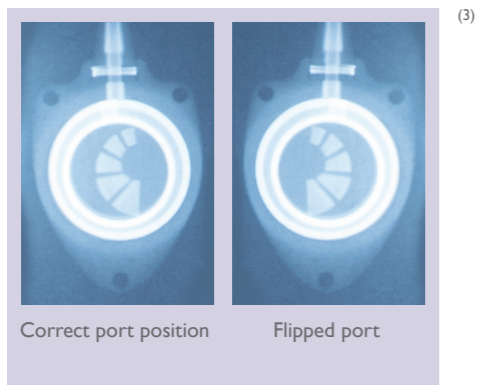
Patient safety

Maximum flow rate injection detectable by x-ray

- From 1 to 5 mL/s



Easy to check the good position of the port



Practitioner comfort

Included ready-to-use kit

- Dedicated to ultrasound guided venipuncture technique⁽⁴⁾

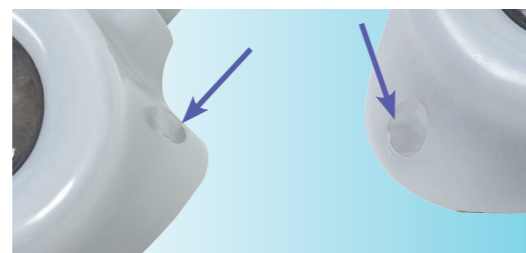


Wide choice of silicone and polyurethane catheters

- From 5F to 10F

Silicone filled suture holes

- For easy port removal



Complete port placement kit

Vascular access
range

seesite™ kit also contains:

- PPS™ CT Safety Huber needle, compatible with contrast medium injections⁽⁵⁾



Patient safety

Prevention of catheter obstruction

- Single-handed safety Huber needle allowing positive pressure during removal^{(5) (6) (7)}

Practitioner comfort

Compatible with pressure injection of contrast media

- Secure check of blood reflux after port placement⁽⁶⁾

		Port features				Catheter features						Product codes	Recommended maximum flow rate (mL/s) with 25 cm catheter	Viscosity (cP) / recommended maximum iodine concentration for contrast medium ⁽²⁾	Kit (see page 14)
		Dimensions (LxWxH) (mm)	Weight (g)	Internal volume (mL)	Material Silicone (Si) or Polyurethane (PU)	OD (mm)	ID (mm)	Length (cm)	Catheter internal volume (mL/10cm)	Introducer diameter (Fr)	Preconnected catheter				
PAEDIATRIC	Micro series	22.0 x 17.0 x 8.7	2.9	0.2	Si	1.65	0.65	60	0.04	5		2005 SEE	1	6cP or 300mg/mL	7
											x				
ADULT	Mini Series	25.8 x 20.8 x 10.1	5.0	0.35	Si	2.16	1.02	60	0.09	7		3007 SEE	3	10cP or 350mg/mL	8
				0.37	PU	2.30	1.45	60	0.18	7	x	3017 SEE			
				0.35	Si	2.40	1.20	60	0.13	8	x	3117 SEE			
	Standard Series	31.0 x 22.2 x 12.2	7.6	0.59	PU	2.65	1.70	60	0.24	8		3008 SEE	5	10cP or 350mg/mL	8
				0.6	Si	2.40	1.20	60	0.13	8	x	3108 SEE			
				0.39	PU	3.00	1.90	60	0.30	9	x	4018 SEE			
											x	4118 SEE	5		
											x	4008 SEE	5		
											x	4108 SEE	5		
											x	4019 SEE	5		
											x	4119 SEE	5		
											x	40010 SEE	5		
											x	41010 SEE	5		

(1) Polyoxymethylene. (2) See seesite™ IFU. (3) Non contractual pictures. (4) In accordance with HAS 2010 which is French health authority - Check list relative to «central venous catheters or vascular device implantation» and NICE 2004: National Institute for Clinical Excellence, UK: Echoguidance is recommended for internal jugular access on adult and child. The seesite™ range is sterilized by ethylene oxide. seesite™ is a registered trademark of PEROUSE MEDICAL.

(5) See PPS™ CT IFU. (6) SF2H 2012: French Society for hospital hygiene. «Prevention of venous implantable port catheter infections». (7) Lapalu J & al., Totally Implantable Port Management: Impact of positive pressure during needle withdrawal on catheter tip occlusion (An experimental study), Journal of Vascular Access, 2010.

Kit composition

Venous accessories

For modified Seldinger and US-guided venipuncture technique:
seesite™



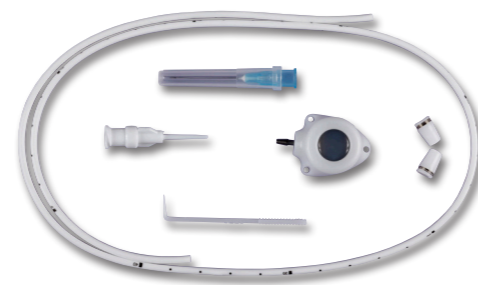
For modified Seldinger technique:
polysite™ ISP



polysite™ echo



For surgical technique:
polysite™



All kits contain in addition to the accessories: one implantable port, one catheter and 2 connection rings (only one for preconnected reference.)

Technique	Surgical	Modified Seldinger (ISP)		Modified Seldinger + US-guided venipuncture			
		3	4	ECHO		SEESITE™	
Kit	2	3	4	5	6	7	8
Straight Huber needle	22G	22G	22G	22G	22G	22G	22G
Vein pick	x	x	x	x	x	x	x
Flushing device preconnected to the catheter* (only for non preconnected references)	x	x	x	x	x	x	x
Peelable introducer	-	12 cm	17 cm	12 cm	17 cm	12 cm	17 cm
J guidewire marked every 10 cm	-	0.018"/40 cm	0.035"/60cm	-	-	-	-
J guidewire marked every 10 cm with thumbfeed advancer	-	-	-	0.018"/40 cm	0.035"/60cm	0.018"/40 cm	0.035"/60 cm
Puncture needle	-	20G/4.5 cm	18G/7 cm	-	-	-	-
Puncture needle with echogenic improvement of the distal tip	-	-	-	20G/4.5 cm	18G/7 cm	20G/4.5 cm	18G/7 cm
Tunneling device	-	Ø2mm / 18 cm	Ø2.5mm / 23 cm	Ø2mm / 18 cm	Ø2.5mm / 23 cm	Ø2mm / 18 cm	Ø2.5mm / 23 cm
Syringe	-	x	x	x	x	x	x
Raulerson device	-	-	-	x	x	x	x
Civ-Flex™ (Probe sheath, elastic bands, gel)	-	-	-	x	x	x	x
Safety Huber needle compatible with pressure injection PPS™ CT	-	-	-	-	-	22G/20 mm	20G/20 mm

* not preconnected for references 4019, 4019 ISP, 4019 ECHO and 4019 SEE



Implantable port

sitimplant™ - Full Titanium port

Compatible injection of contrast media during CT scan and MRI procedures (cf. Page 18)

Vascular access range



- Easy septum location by palpation
- Round base for stability
- Low profile for best patient comfort and aesthetics
- Robust and light

3 sizes: adapted to any patient morphology



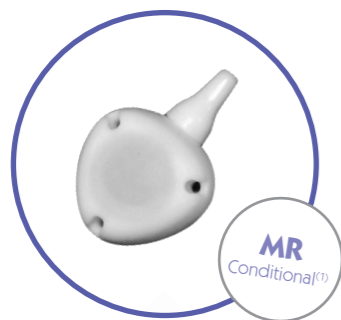
	Dimensions (base ØxH) (mm)	Septum diameter (mm)	Weight (g)	Internal volume (mL)	OD		Internal volume (mL/10cm)	Introducer size	Pre-connected catheter	Product codes			Kit description (see p.17)	
					Fr	mm				ID (mm)	Surgical Kit	Modified Seldinger Kit		IV cannula (12G)
Micro	19x8	8	3.5	0.17	4	1.3	0.8	0.05			2211.71			1
					4	1.3	0.8	0.05	4F	x	2211.77			2
					4	1.3	0.8	0.05	4F		2211.78			2
					5.1	1.7	1.0	0.08			2211.91			1
					6.6	2.2	1.1	0.10			2211.61			1
					6.6	2.2	1.1	0.10	7F		2211.67			3
Mini	24x10	10	8	0.27	6.6	2.2	1.1	0.10	7F	x	2211.68			3
					4	1.3	0.8	0.05			2215.014			1
					4	1.3	0.8	0.05		x	2215.024			1
					5.1	1.7	1.0	0.08	6F	x	2215.125			4
					6	2.0	1.2	0.11				2215.216		5
					6.6	2.2	1.1	0.10			2215.016			1
					6.6	2.2	1.1	0.10	7F		2215.116			3
					6.6	2.2	1.1	0.10	7F			82215.116		6
					6.6	2.2	1.1	0.10		x	2215.026			1
					6.6	2.2	1.1	0.10	7F	x	2215.126			3
					8.4	2.8	1.1	0.10			2215.017			1
					8.4	2.8	1.1	0.10	9F		2215.117			3
					9.6	3.2	1.6	0.20			2215.019			1
					9.6	3.2	1.6	0.20	10F		2215.119			3
Standard	28x11	13	10.5	0.47	9.6	3.2	1.6	0.20	10F	x	2215.129			3
					6	2.0	1.2	0.11				2216.216		5
					6.6	2.2	1.1	0.10			2216.016			1
					6.6	2.2	1.1	0.10	7F		2216.116			3
					6.6	2.2	1.1	0.10	7F			82216.116		6
					6.6	2.2	1.1	0.10		x	2216.026			1
					6.6	2.2	1.1	0.10	7F	x	2216.126			3
					8.4	2.8	1.1	0.10			2216.017			1
					8.4	2.8	1.1	0.10	9F		2216.117			3
					9.6	3.2	1.6	0.20			2216.019			1

(1) See sitimplant IFU



Implantable port heliosite™ - Hybrid: Titanium and compact silicone

Compatible
injection of contrast
media during CT
scan and MRI
procedures
(cf. Page 18)



- Smooth design for minimal fibrotic adherence
- Low profile for best patient comfort and aesthetics
- Compact silicone casing
- Click & lock connection system

3 sizes : adapted to any patient morphology



• XS



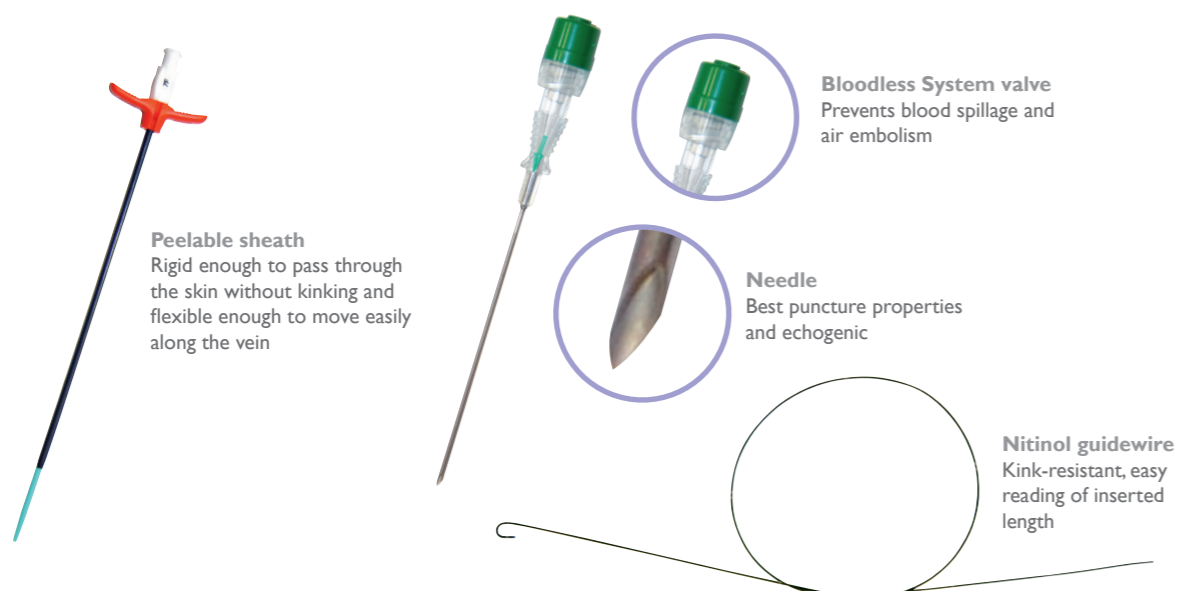
• S



• M

Port sizes	Dimensions (base ØxH) (mm)	Septum diameter (mm)	Weight (g)	Internal volume (mL)	OD		"ID (mm)"	Internal volume (mL/10cm)	Exit tube internal diameter	Introducer diameter	Pre-connected catheter	Product codes: Modified Seldinger kit	Kit description (see page 17)
					Fr	mm							
XS	23 x 9	8	5	0.19	6.6	2.2	1.1	0.10	1.1 mm	7F		2217.116	4
												x	2217.126
S	25 x 10	10	6.3	0.31	6.6	2.2	1.1	0.10	1.1 mm	7F		2218.116	4
												x	2218.126
M	27 x 11	12	8	0.45	6.6	2.2	1.1	0.10	1.1 mm	7F		2219.116	4
												x	2219.126

Benefits of the accessories included into the modified Seldinger kit:



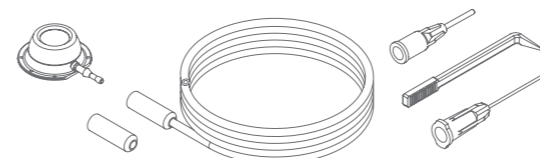
(1) See heliosite IFU



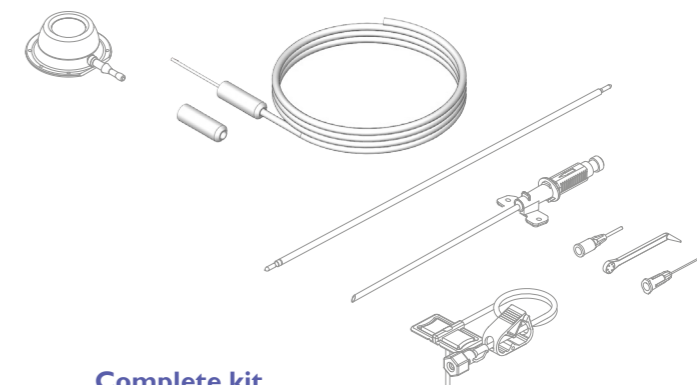
Vascular access
range

sitimplant™ and heliosite™ kit composition

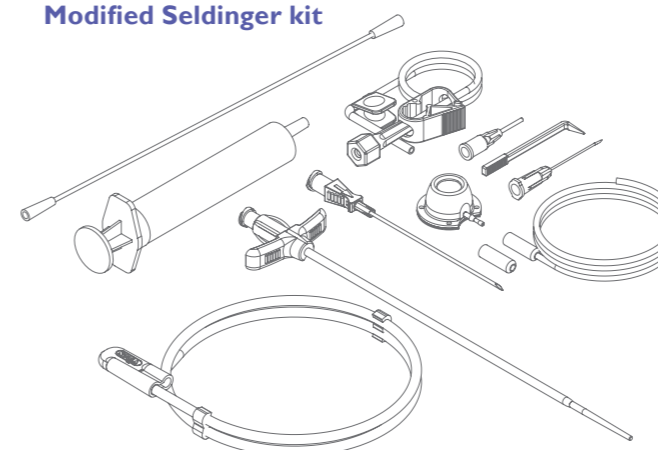
Surgical kit



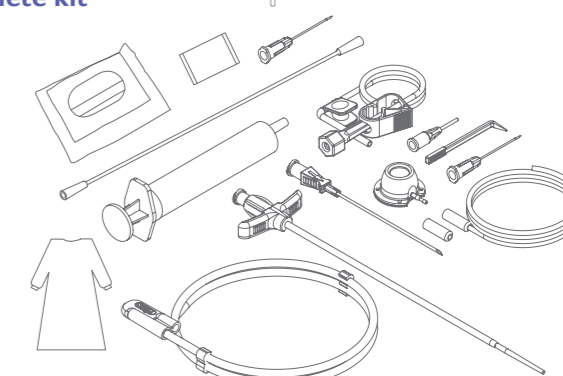
IV cannula kit



Modified Seldinger kit



Complete kit



All kits contain in addition to the accessories: an implantable port, a radiopaque catheter and 2 connection rings (only one for preconnected references).

Kit	Surgical kit	Modified Seldinger kit			IV cannula kit	Complete set
	1	2	3	4	5	6
Straight Huber needle	22G / 25mm	22G / 25mm	22G / 25mm	22G / 25mm	22G / 25mm	22G / 25mm
Flushing device	x	x	x	x	x	x
Vein pick	x	x	x	x	x	x
Peelable introducer	-	7 cm	14 cm	14 cm	-	14 cm
Nitinol J guidewire, marked every 10 cm with thumbfeed advancer	-	0,021" - 30 cm	0,035" - 53 cm	0,035" - 53 cm	-	0,035" - 53 cm
Puncture needle with BLS valve	-	20G - 38 mm	18G - 68 mm	18G - 68 mm	-	18G - 68 mm
Tunneling device	-	2.5 mm x 23 cm	3,0 mm x 23 cm	2.5 mm x 23 cm	3,0 mm x 23 cm	2.5 mm x 23 cm
Syringe	-	10mL	10mL	10mL	-	10mL
Huber needle with connecting line: hubsite™	-	22G-20mm	20G-20mm	20G-20mm	-	20G-20mm
IV cannula	-	-	-	-	12 G	-
Stylet within the catheter	-	-	-	-	x	-
Hypodermic needles	-	-	-	-	-	18G & 21G
2 surgical gowns	-	-	-	-	-	L & XL
Large fenestrated drape with adhesive aperture	-	-	-	-	-	180 x 300 cm (aperture 15x15 cm)



sitimplant™ and heliosite™ Injection of contrast media during CT scan or MRI procedures



CT SCAN COMPATIBLE and MR CONDITIONAL
See IFU

Warm the contrast media to body temperature prior to CT-rated injection. Failing to warm the contrast media would result in 50% reduction of the flow rate and could damage the port. Ensure that the needle is correctly placed in the port, securely taped to the skin and covered with an adhesive dressing before commencing CT-rated injection. Do not exceed the maximum pressure of 24 bar (350 psi) during CT-rated injection. After the procedure flush the port system with 20ml normal saline with push-pause technique, followed by standard rinsing procedures. Verify that the port and the Huber needles which you will use for CT-rated injection are listed in the table below. Check the patient medical record for the port and needle codes.

Do not exceed the maximum flow rate and maximum pressure listed in the table below. Do not use a sitimplant™ or heliosite™ for CT-rated injections if it shows signs of obstruction, even when intermittent, such as pinch-off syndrome. Computed Tomography machine pressure limiting features may not prevent overpressurisation of an occluded port system, resulting in catheter failure including but not limited to: catheter rupture, embolization or drug extravasation. Use only needles and extension lines which are designed to withstand CT-rated injection.

Disregarding the recommended procedure and precautions for CT-rated injection may cause catheter failure and put the patient at risk.

CT-rated Ports				perfusafe2 Ref. 5249 - 5250			hubsite2 Ref. 1239 - 1251 - 1256			injectsite Ref. 1058		
Ref.	Size	Material	Ø	19G	20G	22G	19G	20G	22G	19G	20G	22G
2216.xx9	M	Si	9.6 Fr	7 ml/s	7 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s
2216.xx7	M	Si	8.4 Fr	6 ml/s	6 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s
2216.xx6	M	Si	6.6 Fr	6 ml/s	6 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s
2215.xx9	S	Si	9.6 Fr	6 ml/s	6 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s
2215.xx7	S	Si	8.4 Fr	6 ml/s	6 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s
2215.xx6	S	Si	6.6 Fr	6 ml/s	6 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s
2219.xx6	M	Si	6.6 Fr	5 ml/s	5 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s
2218.xx6	S	Si	6.6 Fr	4 ml/s	4 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s
2217.xx6	XS	Si	6.6 Fr	4 ml/s	4 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s	5 ml/s	5 ml/s	2 ml/s



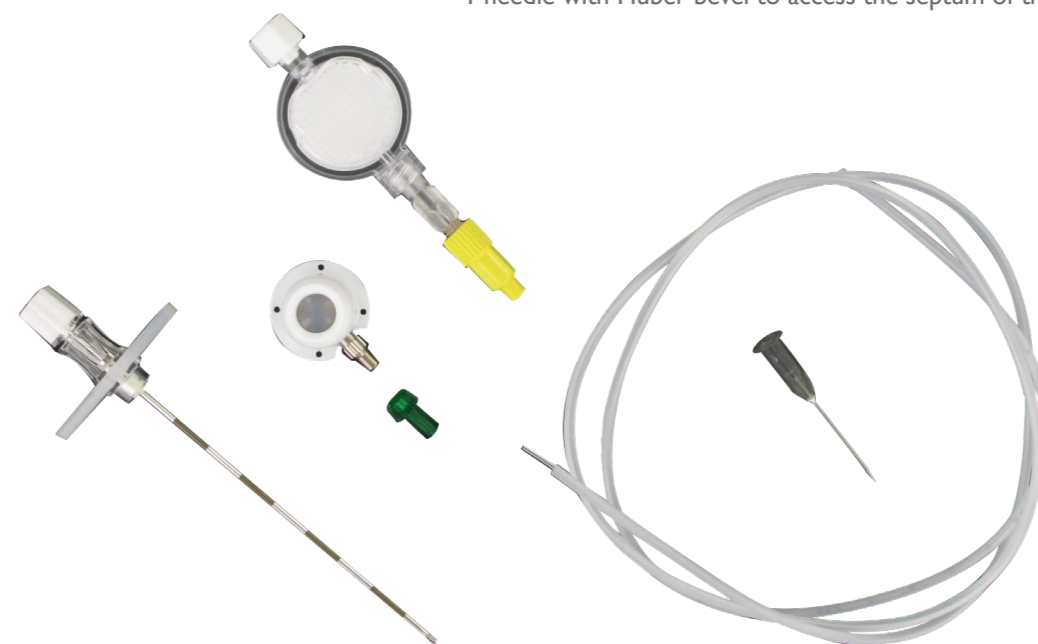
Port for pain relief mini sitimplant™



The mini sitimplant™, for pain relief is a completely implantable device featuring a Titanium reservoir enclosed in a Silicone casing. The distal tip of the catheter, which is placed in the epidural or intrathecal space has a closed tip with 3 lateral eyes.

Contents of the tray:

- 1 implantable port,
- 1 Polyurethane catheter (90cm long, int. Ø 0.5mm, ext. Ø 1.0mm; 20G), radiopaque, centimeter distance markings from 5 to 20cm. The catheter is attached to the connector on the port by a threaded Titanium collar.
- 1 Tuohy needle (90mm long, int. Ø 1.2mm, ext. Ø 1.5mm, 17G) with centimeter distance markings and a winged, transparent hub,
- 1 flat epidural bacterial filter 0.2µm fitted with a removable compression hub,
- 1 needle with Huber bevel to access the septum of the port.



Code	Implantable port					Catheter		
	Weight (g)	Priming volume (mL)	Height (mm)	Diameter (mm)	Puncture area (cm²)	Int. Ø (mm)	Ext. Ø (mm)	Length (cm)
2201.51	4.3	0.29	10.5	23	0.63	0.5	1.0	90

Conventional and high pressure Polyurethane PICC-Line lifecath PICC™ & maxflo™ expert

lifecath PICC™

lifecath PICC™ catheters are designed for ambulatory patients who require short to long term central venous access.



Maximum longevity

YIGON PICCs are manufactured from long-term biostable polyurethane: offering extended dwell times to suit all therapy requirements. Long-term biostable Polyurethane provides good mechanical and biochemical stability throughout treatment.

maxflo™ & high flow applications

maxflo™ CT RATED can be used whenever a PICC is indicated, including high-pressure administration. To allow radiologists to get the best CT scan image quality, maxflo is designed to withstand injection of high-viscosity contrast medium up to 7 mL/s, with a CT injector pressure of up to 325psi (22.4bar).



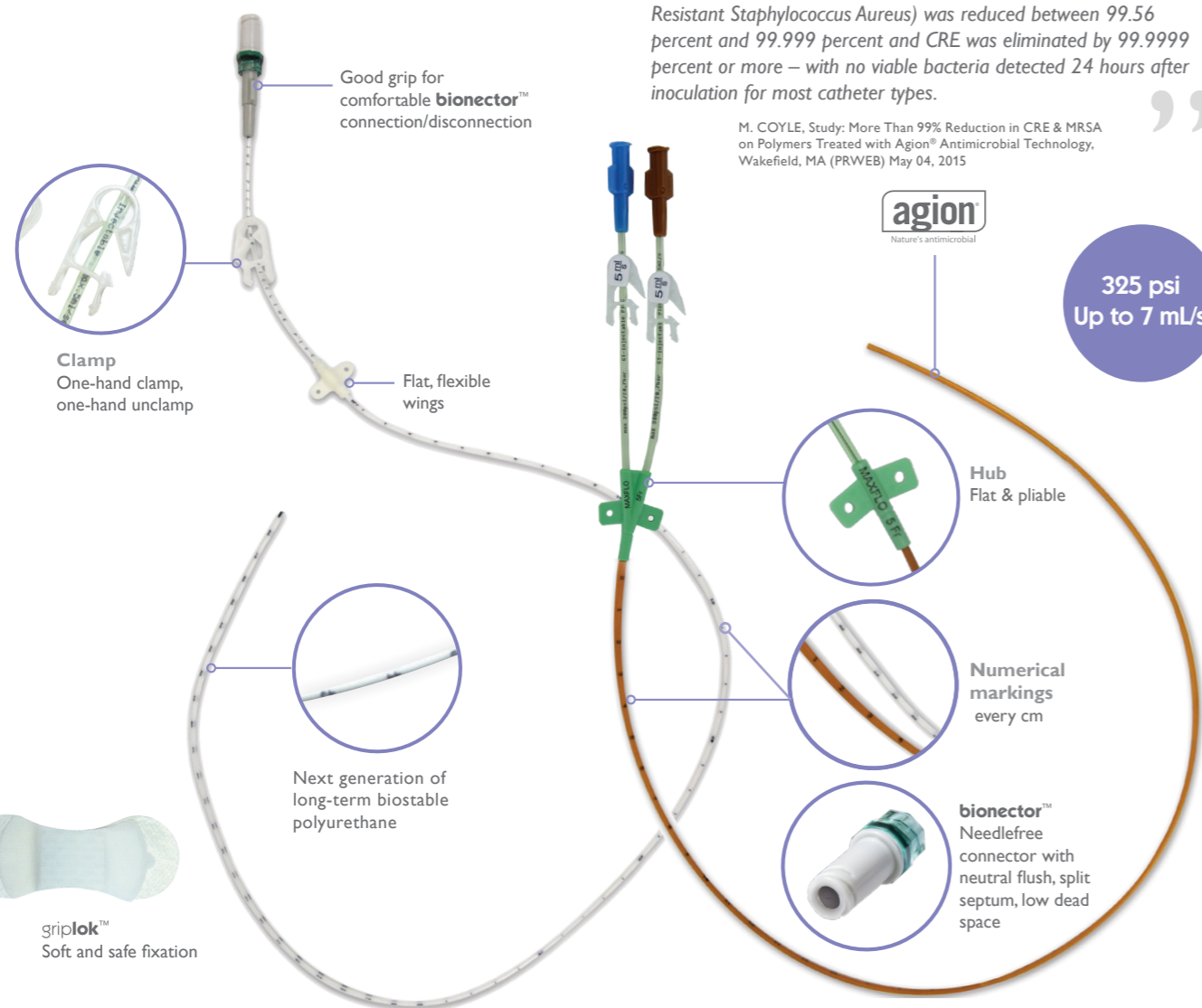
Agion™ antimicrobial technology efficiency

“ Testing a range of medical-grade polymers, Sciessent found that those treated with Agion™ antimicrobial technology killed more than 99 percent of antibiotic-resistant pathogens. In the case of multiple types of central-venous catheters, MRSA (Methicillin-Resistant Staphylococcus Aureus) was reduced between 99.56 percent and 99.999 percent and CRE was eliminated by 99.9999 percent or more – with no viable bacteria detected 24 hours after inoculation for most catheter types.

M. COYLE, Study: More Than 99% Reduction in CRE & MRSA on Polymers Treated with Agion® Antimicrobial Technology, Wakefield, MA (PRWEB) May 04, 2015

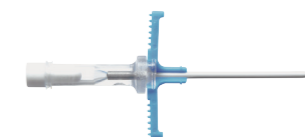


325 psi
Up to 7 mL/s



PICC placement kits

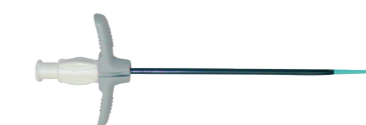
• Either a peelable cannula, with easy check of blood return



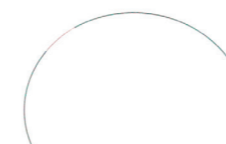
• Or with a Micro-Seldinger introducer set which allows placement with ultrasound in the middle third of the upper arm



Safety puncture needle
Echogenic safety needle



Peelable sheath
Rigid enough - to help go through the skin but flexible - to help slide along the vein



Nitinol guidewire
Kink-resistant, intuitive reading of inserted length every 5 cm and every cm in the distal portion.
Includes choice of radiology guidewire.

lifecath PICC™

Lumen	Fr	Ext. Ø (mm)	Overall length (cm)	Catheter length (cm)	Gravity flow rate (ml/min)	Priming volume (ml)	Product codes			
							With peelable cannula	With Micro Seldinger kit 50 cm guidewire	With Micro Seldinger kit 67cm guidewire for fluoroscopy	Over-the-wire Seldinger 135cm guidewire for fluoroscopy
1	3	1.0	75	60	1.6	0.46	1294.13	1294.113	-	-
1	4	1.35	75	60	9.4	0.66	1294.14	1294.114	1294.414	1294.514
1	5	1.67	75	60	36	1.0	1294.15	1294.115	1294.415	1294.515
2	4.5	1.5	71.5	60	8.2(x2)	0.51/0.51	1294.245	1294.345	1294.445	1294.545

maxflo™ expert

Lumen	Fr	Ext Ø (mm)	Length (cm)	Gravity flow rate (mL/min)	Priming volume (mL)	Maximum flow rate	Maximum pressure	Product codes		
								MST kit with 50 cm guidewire	MST kit with 67 cm guidewire	MST kit with 135 cm guidewire
1	4	1.35	55	19	0.8	5 mL/s	325psi (22.4bar)	8394.14*	8394.414*	8394.514*
1	5	1.70	55	28	0.8	6 mL/s	325psi (22.4bar)	8394.15	8394.415	8394.515
1	5	1.75	55	46	1	7 mL/s	325psi (22.4bar)	8394.105*	8394.405*	8394.505*
2	5	1.75	55	9 (x2)	0.75 (x2)	5 mL/s	325psi (22.4bar)	8394.25*	8394.425*	8394.525*
2	6	2.0	55	14 (x2)	0.8 (x2)	5 mL/s	325psi (22.4bar)	8394.26	8394.426	8394.526
2	6	2.0	55	14 (x2)	0.8 (x2)	6 mL/s	325psi (22.4bar)	8394.206*	8394.406*	8394.506*
3	6	2.0	55	4 (x2) 10	0.45 (x2) 0.85	5 mL/s	325psi (22.4bar)	8394.36*	8394.436*	8394.536*

* with reverse tapering (bump tube)

Tray description

- PICC-Line with pre-mounted stylet in temporary T-piece flush port
- Introducer:
 - Peelable cannula* or
 - MST kit with 21G safety echogenic puncture needle, Nitinol guidewire with thumb-feed advancer: Ø 0.018" x L. 50cm/67cm/135cm and 7cm peelable sheath

- Scalpel (not included in peelable cannula kit)
- bionector™
- griplok™
- Measuring tape

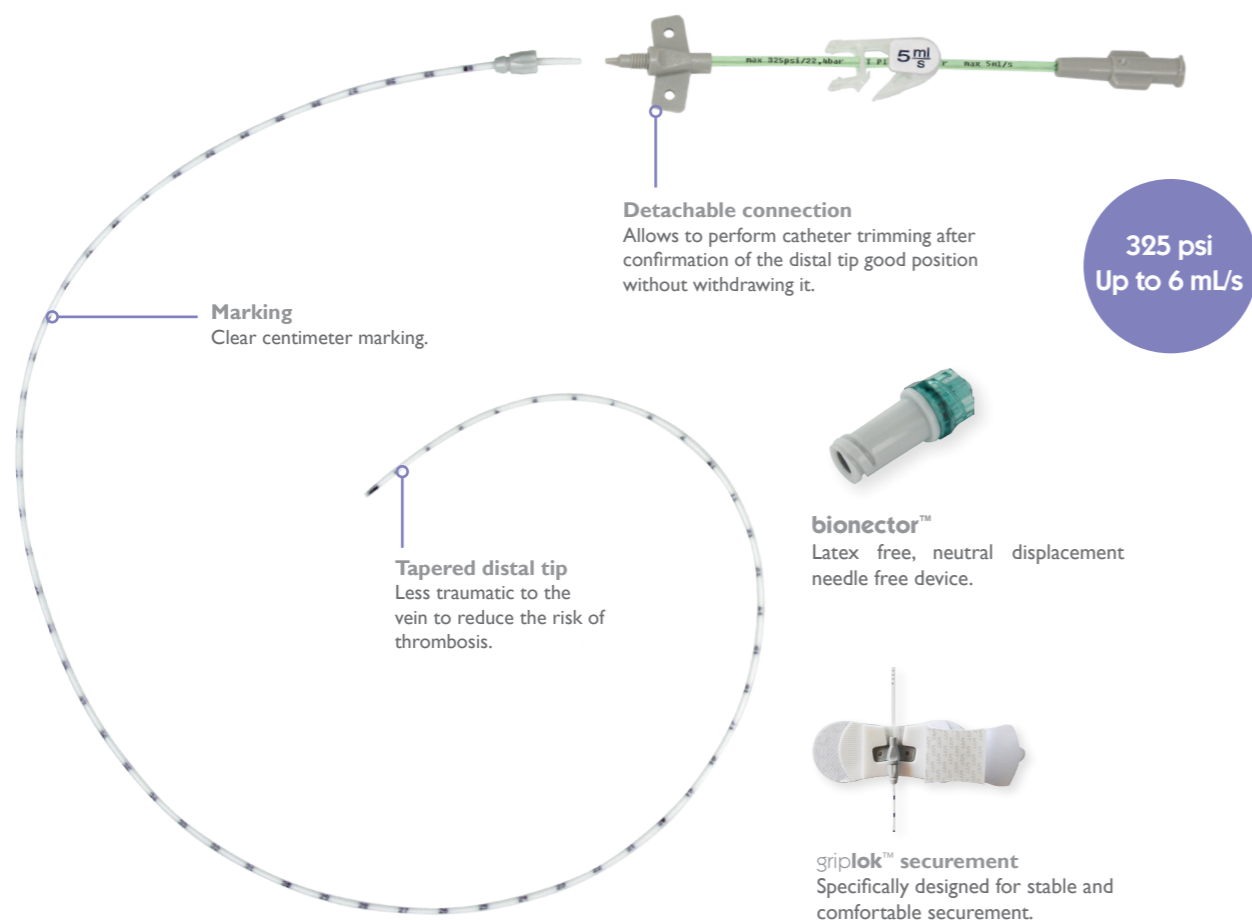
*maxflo is only supplied with MST kit (no maxflo with peelable cannula introducer)

PICC-Line with proximal trimming CT PICC easy

Compatible
injection of contrast media during CT scan and MRI procedures (1)

Catheter with proximal trimming:

- Makes insertion easier and more accurate when using the ECG technique (no need to cut the catheter before insertion)
- Preserves the integrity of the tapered distal tip which is less traumatic for the vein and minimises the risk of thrombosis
- Compatible with pressure injection up to 6 mL/s and 325 psi (22.4bar)



Catheter							
Ø	Ext. Ø (mm)	Int. Ø (mm)	Gravity flow rate (mL/min)	Priming volume	Maximum indicated power injection flow rate	Maximum pressure	Product codes
3Fr	1.00	0.60	3.0	0.6	1 mL/s	325 psi	V021292213
4Fr	1.35	0.90	14.0	0.9	5 mL/s	325 psi	V021292214
5Fr	1.67	1.1	28.0	1.00	6 mL/s	325 psi	V021292215

Tray description

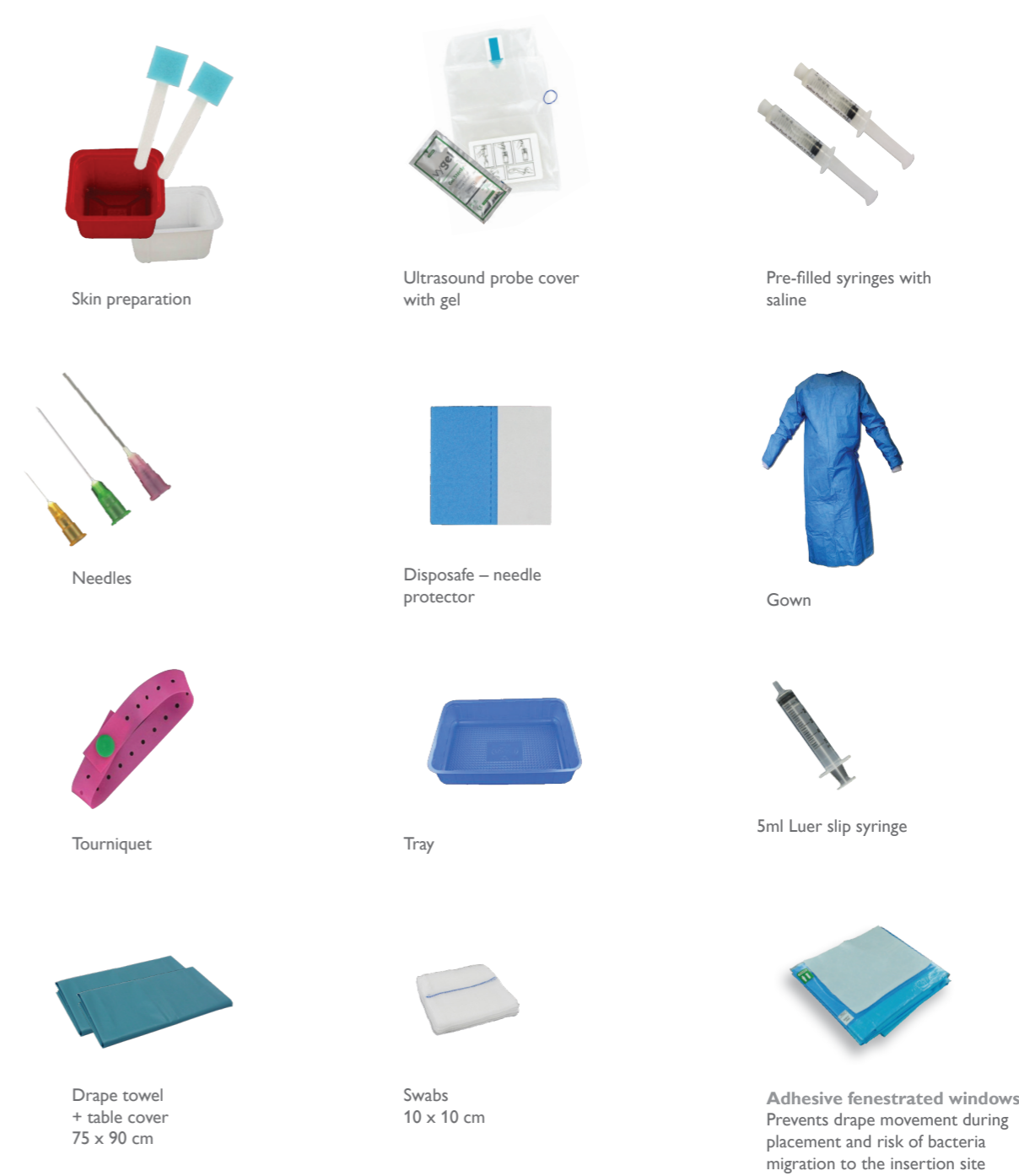
Micro-Seldinger kit:

- 1 totally radiopaque catheter (60 cm long) in biostable polyurethane with temporary wings
- 1 metallic stylet to make the catheter more rigid and thus make insertion easier
- 1 «T» proximal connector. The lateral port of the T connector can be used to inject saline solution
- 1 detachable extension line with a Robert clamp
- 1 safety introducer needle 21G x 7cm
- 1 straight Nitinol guidewire 50 cm - 0.018"
- 1 peelable sheath + dilator
- 1 Luer slip syringe 10 ml
- 1 slide clamp
- 1 measuring tape
- 1 griplok™, securement device
- 1 bionector™
- 1 safety scalpel

Insertion pack

VYGON has the possibility to offer complete insertion sets for PICC-Line, port and CVC placement. These sets can be standard or customized.

Example of components:



(1) See CT PICC Easy IFU

Long term central venous catheter

Single lumen catheter with detachable hub

nutricath S, nutricath tunnel with cuff and leadercuff catheters are specially designed for long term intensive vascular access treatment as haematology and parenteral nutrition.

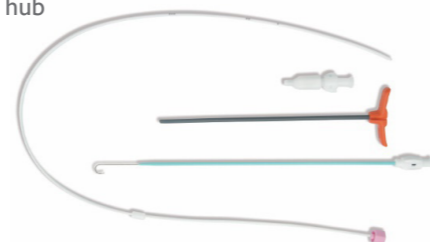
nutricath S

Single lumen silicone catheter with detachable hub



nutricath tunnel with cuff

Single lumen silicone catheter with subcutaneous cuff and detachable hub



nutricath S & nutricath tunnel with cuff

Catheter				Product codes			
OD (Fr)	OD (mm)	ID (mm)	Length (cm)	nutricath S (without cuff)		nutricath tunnel with cuff	
				Surgical kit	IV cannula kit	Modified Seldinger kit	Modified Seldinger kit
4	1.3	0.8	35		2180.13	2171.13	
			60/58		2181.13		2101.13
5	1.7	1	35		2180.17	2171.17	
			60/58		2181.17		2101.17
6	2.0	1.2	35		2180.20	2171.20	
			60/58		2181.20	2182.20	2101.20
9.6	3.2	2	35	2180.30			
			60/58	2181.30			2101.30

Surgical kit

- 1 radiopaque silicone catheter with stylet marked at 10, 15 and 20 cm from the distal tip
- 1 detachable compression hub

IV cannula kit

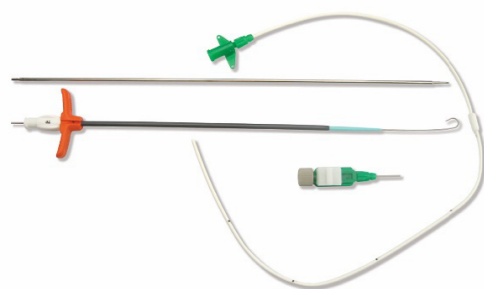
- 1 radiopaque silicone catheter with stylet marked at 10, 15 and 20 cm
- 1 introducer: short I.V. cannula type
- 1 detachable compression hub

Modified Seldinger kit

- 1 radiopaque silicone catheter with stylet marked at 10, 15 and 20 cm from the distal tip
- Straight guidewire for nutricath S except for 2182.20 code: J guidewire
- J guidewire for nutricath tunnel codes
- Puncture needle (20G for 4F catheter, 18G for others).
- 1 non peelable introducer for nutricath S codes
- 1 peelable introducer for nutricath tunnel codes
- 1 detachable compression hub
- Tunneling device only for nutricath tunnel codes and code 2182.20

leadercuff

Single lumen polyurethane catheter with subcutaneous cuff and detachable hub (vyflow™ hub: on/off positions)



Catheter				Product codes
OD (Fr)	OD (mm)	ID (mm)	Length (cm)	Modified Seldinger Set
5	1.8	1.2	60	1227.17
6	2.0	1.4	60	1227.20

Modified Seldinger kit

- 1 XRO polyurethane catheter
- J guidewire (0.038" - 53 cm)
- Puncture needle (18G - 6.8 cm)
- 1 peelable introducer
- 1 detachable compression hub: vyflow™
- Tunneling device

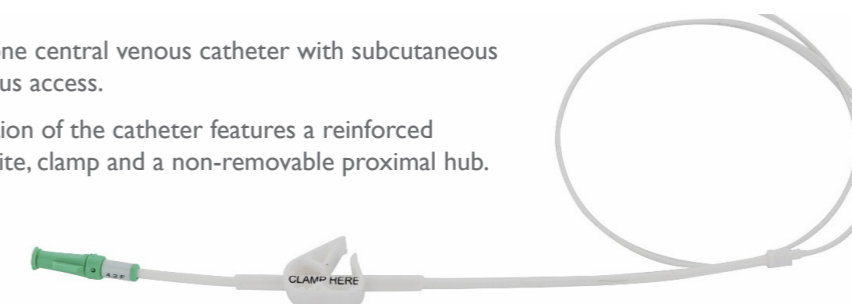


Long term central venous catheter

lifecath™ - Silicone catheter

lifecath™ is a silicone central venous catheter with subcutaneous cuff for long-term venous access.

The extra-vascular section of the catheter features a reinforced section with clamping site, clamp and a non-removable proximal hub.



Lumen	Catheter				Product codes	
	OD (Fr)	OD (mm)	ID (mm)	Length (mm)	Surgical set with tunneler	Modified Seldinger set
1	2.7	1.0	0.5	75	2191.27	2191.273
	4.2	1.4	0.7	75	2191.42	2191.425
	5	1.7	0.95	75	2191.50	2191.506
	6.6	2.2	1.1	90	2191.66	2191.667
	9.6	3.2	1.6	90	2193.96	2193.960
2	7	2.4	0.6/1.0	90	2293.070	2293.70
	9	3.0	0.7/1.3	90	2293.090	2293.90
	9	3.0	1.3/1.3	90	2293.095	2293.95
	11	3.7	1.0/1.6	90	2293.110	2293.11
3	14	4.7	1.6/1.6	90	2293.140	2293.14
	12.5	4.1	1.0/1.0/1.5	90	2294.025	2294.125

lifecath™ apheresis is a double-lumen silicone catheter with subcutaneous cuff for long-term venous access: apheresis. Inserted by percutaneous puncture with a peelable introducer sheet. The venous distal opening is separated from the arterial opening by a distance of 2 cm.



Lumen	Catheter				Product codes	
	OD (Fr)	OD (mm)	ID (mm)	Length* (cm)	Surgical set	Modified Seldinger set
2	9	3.0	0.7/0.7	27		2296.951
		3.0	0.8/0.8	34		2296.952
	11	3.75	0.8/1.0	27		2296.111
		3.75	0.8/1.2	34		2296.112
	14	4.5	1.0/1.0	27		2296.190
		4.5	1.2/1.2	34		2296.260
3	12.5	4.1	1.0/1.0/1.5	90	2224.100	2224.000

*27 cm catheters have a subcutaneous cuff placed at 19 cm from the distal tip.
34 cm catheters have a subcutaneous cuff placed at 26 cm from the distal tip.

Surgical set

- 1 radiopaque silicone catheter with Dacron cuff
- 1 tunnelling device (catheter with $\geq 7F$ is supplied with 2 tunnelling devices - plastic and metallic)
- 1 fixation wing (only available with catheter $4.2 \leq \text{OD} \leq 9F$)
- 1 scalpel (only available in 2193.96 code)
- Injection cap(s)

Modified Seldinger kit for lifecath™

- 1 radiopaque silicone catheter with Dacron cuff
- 1 peelable introducer sheet
- 1 scalpel
- 1 tunnelling device (catheter with $\geq 7F$ is supplied with 2 tunnelling devices - plastic and metallic)
- 1 supplementary fixation wing (only available with catheter $\text{OD} \leq 9F$)
- injection cap(s)

Modified Seldinger kit for lifecath™ apheresis

- 1 double-lumen radiopaque silicone catheter with Dacron cuff
- 1 peelable introducer sheet
- 1 dilator
- 1 tunnelling needle
- 1 10 ml syringe
- 2 injections caps
- 1 scalpel



Hemodialysis catheter

lifecath™ twin is composed of 2 separate catheters made of biostable polyurethane, totally radiopaque, with distance markings from 4 to 21 cm. Both catheters have a subcutaneous cuff. The distal end of the catheter features 6 lateral eyes for improved catheter performance.

Catheter diameter	Usable length (arterial / venous) (cm)	Product codes
10Fr (2.1 x 3.3 mm)	18/21	1276.200
	22/25	1276.201
	27/30	1276.202

Tray presentation containing:

- 2 biostable PUR catheters 10 Fr Length 52 cm
- 2 puncture needles ø 1.06 x 1.26 mm 18G Length 70 mm
- 2 peelaway introducers 11 Fr
- 1 peelaway introducer 6 Fr
- 2 tunneling devices
- 2 tunnel rod extensions, red and blue
- 2 catheter protection sleeves, red and blue
- 2 Nitinol "J" guidewires with thumbfeed advancer
- 2 injection caps
- 1 scalpel
- 2 clamps
- 2 Lifecath Lock

- The 10 Fr catheters offer a flow rate superior to 400 mL/min
- 2 separate catheters reduce the risk of catheter occlusion
- Priming volume printed on the extra-cutaneous section of the catheter
- The 6 Fr peel-away Desilet offers the physician the possibility to insert lifecath twin with only one puncture

dialykit is composed of 2 separate 9.6Fr silicone catheters totally radiopaque and feature markings at 10, 20 and 30cm from the distal tip.

At the distal end, the catheters have 5 lateral eyes (over 25mm) for improved flow rate. The catheters are inserted through 2 standard Desilet introducers.

Product code: 2206.30

Kit composition:

- 2 radiopaque silicone catheters (Ø 2.0 x 3.2mm, 40cm long)
- 2 proximal adaptors with silicone tubing (clamping area) with blue (venous) and red (arterial) hubs
- 2 puncture needles (Ø 1.06 x 1.26mm • 18G - 70mm long)
- 2 Desilet introducers with J guidewires (53cm long)
- 1 Alene needle for catheter tunnelling
- 2 Dermafilm (transparent adhesive film) code 38.15.20
- 2 injection caps
- 2 syringes (10ml)
- 4 hypodermic needles (21G and 18G • 38mm long)
- 2 scalpels

The removable proximal end of the dialykit allows:

- A retrograde tunnelling of the catheters
- An easy adjustment of the length by the physician



Huber needles range with and without connecting line

Huber needles

- Complete range of sizes and gauges
- For the puncture of implantable ports

Description	Gauge	Needle Ø (mm)	Usable length (mm)	Product codes
Curved	23	0.6	20	522506
			25	522507
			35	523807
	22	0.7	20	522509
			35	523809
			19	522511
Straight	23	0.6	20	522511
			35	523811
			22	0.7
	20	0.9	30	512507
			38	513807
			19	1.1
			28	512511
			28	513811



polyperf™ without Y Site - Huber needle

- Curved Huber needle with connecting line (25 cm)
- No interaction with anti-mitotic drugs

Gauge	Needle Ø (mm)	Usable length (mm)	Product codes
22	0.7	15	581507
		17	581707
		20	582007
		25	582507
		30	583007
		35	583507
20	0.9	15	581509
		17	581709
		20	582009
		25	582509
		30	583009
		35	583509
19	1.1	15	581511
		17	581711
		20	582011
		25	582511
		20	583011
		35	583511

Bold references are the most commonly used. Other references are only available upon request with a minimum lead time of 12 weeks.

Winglets:

- good grip
- good stability



Winglets colour coded:

- easy identification of the gauge

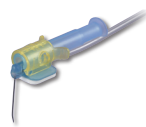
polyperf™ with Y site - Huber needle

Gauge	Needle Ø (mm)	Usable length (mm)	Product codes
22	0.7	20	592007
		25	592507
20	0.9	20	592009
		25	592509
19	1.1	20	592011
		25	592511

Packed in box of 10 units
 Bold references are the most commonly used. Other references are only available upon request with a minimum lead time of 12 weeks.
 This device is not made with dry or natural rubber latex.



Huber needles and polyperf™ are sterilized by ethylene oxide. polyperf™ is a registered trademark of PEROUSE MEDICAL.



Safety Huber needles polyperf™ safe



**POSITIVE
PRESSURE
DURING
REMOVAL**

polyperf™ safe

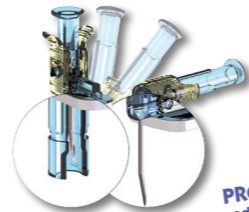
Single hand activation:
decreased blood exposure risk versus double and activated device⁽³⁾

Possible positive pressure

- According to implantable port using recommendations⁽¹⁾
- Withdrawal of the needle with only one hand

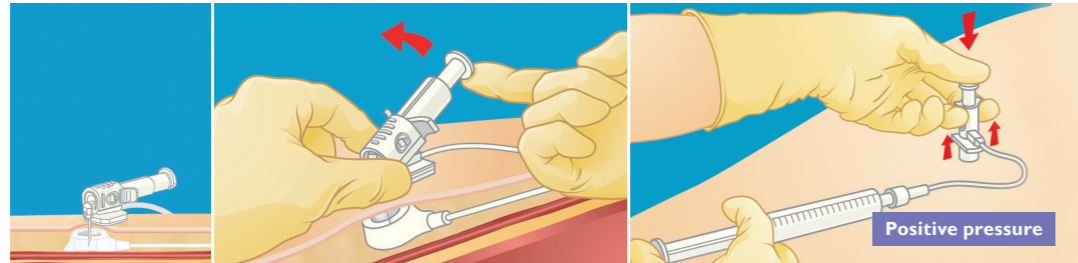
Prevention of needlestick injury

- Eliminates the risk of needlestick injury
- No rebound effect when withdrawing the needle
- No risk of contact with the body of the needle⁽²⁾
- Total protection until discarded in sharps container



PROTECTION
needle tip and body

Withdrawal of the needle



Normal position for use (horizontal piston) before withdrawal.

Preparation: lift the piston from the horizontal position to the vertical position.

Using your thumb, lower the piston to put it in contact with the skin and simultaneously lift the extractor (with an upwards movement) until there is a CLIC corresponding to the total locking of the needle. This final operation eliminates any risk of accidental needlestick injury.

Gauge	Needle Ø (mm)	Needle length (mm)	Product codes without lateral Y site	Product codes with lateral Y site
22G	0.7	15	601507*	611507*
22G	0.7	17	601707	611707
22G	0.7	20	602007	612007
22G	0.7	25	602507	612507
22G	0.7	30	603007	613007
22G	0.7	35	603507	613507
20G	0.9	15	601509*	611509*
20G	0.9	17	601709	611709
20G	0.9	20	602009	612009
20G	0.9	25	602509	612509
20G	0.9	30	603009	613009
20G	0.9	35	603509	613509
19G	1.1	15	601511*	611511*
19G	1.1	17	601711	611711
19G	1.1	20	602011	612011
19G	1.1	25	602511	612511
19G	1.1	30	603011	613011
19G	1.1	35	603511	613511

Bold references are the most commonly used. Other references are only available upon request with a minimum lead time of 12 weeks.

* For paediatric use only.

(1) According to HAS 2000 (French Health Authority) and SF2H 2012 (French Society for Hospital Hygiene) guidelines.

(2) Biomatech study n°148381 - 28 June 2012 - p.64-66.

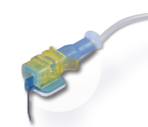
(3) Survey of the occurrence circumstances of Accidental Blood Exposure due to punctures with safety materials, GERES – AFSSAPS Collaboration, G. Pellissier, 18th Annual GERES conference, 2008.

polyperf™ safe and PPS™ Quick Huber needle are packaged in cartons of 12 units. Sterilized using ethylene oxide.

NO DEHP

This device is not made with dry or natural rubber latex.

polyperf™ safe and PPS™ quick are registered trademarks of PEROUSE MEDICAL.



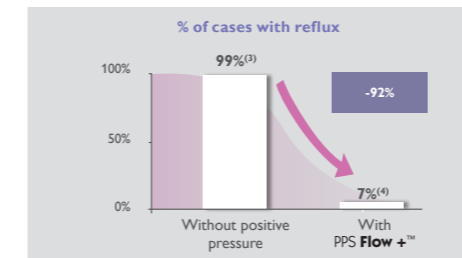
Safety Huber needles PPS flow +™

**AUTOMATIC
POSITIVE
PRESSURE
during removal**

Vascular access
range

Automatic positive pressure⁽¹⁾ upon removal

- Prevention of catheter obstruction: catheter obstruction rate on implantable port: 28%⁽²⁾
- Significant reduction of blood reflux at the distal tip of the catheter



Manual positive pressure:
Reflux in 20% of cases⁽¹⁾
(operator-dependent)

Benefit of an automatic positive pressure⁽³⁾

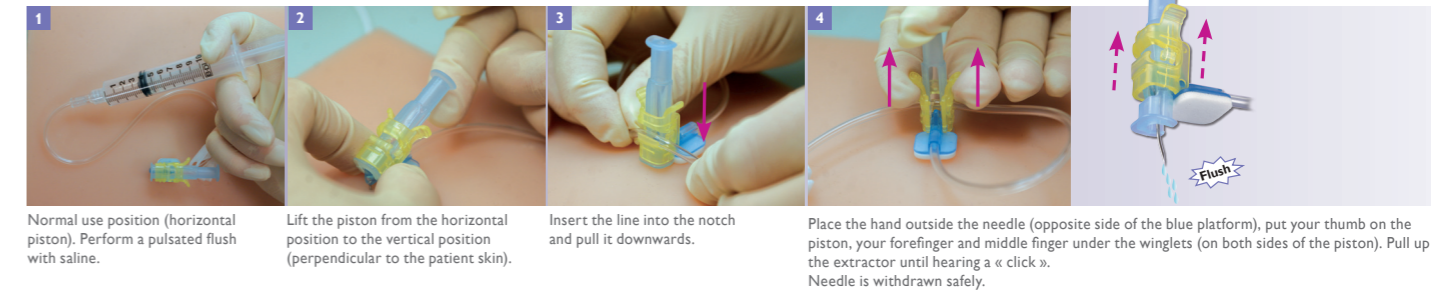


Cost reduction

- Reduction of the use of fibrinolytic agents⁽³⁾
- Cost reduction due to catheter obstruction complications⁽⁵⁾ (X-rays, nursing time, explantation, etc.)

Single hand activation: decreased blood exposure risk versus double and activated device⁽⁶⁾

Removal steps



1 Normal use position (horizontal piston). Perform a pulsated flush with saline.

2 Lift the piston from the horizontal position to the vertical position (perpendicular to the patient skin).

3 Insert the line into the notch and pull it downwards.

4 Place the hand outside the needle (opposite side of the blue platform), put your thumb on the piston, your forefinger and middle finger under the winglets (on both sides of the piston). Pull up the extractor until hearing a « click ». Needle is withdrawn safely.

Gauge	Needle Ø (mm)	Needle length (mm)	Product codes without needleless connector	
			without Y site	with Y site
22G	0.7	15	701507*	711507*
22G	0.7	17	701707	711707
22G	0.7	20	702007	712007
22G	0.7	25	702507	712507
22G	0.7	30	703007	713007
22G	0.7	35	703507	713507
20G	0.9	15	701509*	711509*
20G	0.9	17	701709	711709
20G	0.9	20	702009	712009
20G	0.9	25	702509	712509
20G	0.9	30	703009	713009
20G	0.9	35	703509	713509
19G	1.1	15	701511*	711511*
19G	1.1	17	701711	711711
19G	1.1	20	702011	712011
19G	1.1	25	702511	712511
19G	1.1	30	703011	713011
19G	1.1	35	703511	713511

References in bold are the most commonly used. Other references are only available upon request with a minimum lead time of 12 weeks.

* For paediatric use only.

(1) According to HAS 2000 (French Health Authority) and SF2H 2012 (French Society for Hospital Hygiene) guidelines.

(2) Carlo JT et al., The American Journal of Surgery 188:722-727, 2004.

(3) Lapalu J & al., Totally Implantable Port Management: Impact of positive pressure during needle withdrawal on catheter tip occlusion (An experimental study). Journal of Vascular Access, 2010.

(4) H.Leveret, O.Albert, E. Barret, S.Villiers, MC.Douard, Poster for WoCoVa, A randomized experimental comparison of two safety Huber needles (HN) allowing manual or automatic positive pressure during needle removal: effect on the distal catheter reflux, 2014.

(5) Biffi R & al., Totally implantable central venous access ports for long-term chemotherapy, Annals of Oncology 9:767-773, 1998.

(6) Survey of the occurrence circumstances of Accidental Blood Exposure due to punctures with safety materials, GERES – AFSSAPS Collaboration, G. Pellissier, 18th Annual GERES conference, 2008.

PPS flow +™ safety Huber needles are packaged in cartons of 12 units. Sterilized using ethylene oxide.

NO DEHP

This device is not made with dry or natural rubber latex.

PPS flow +™ is a registered trademark of PEROUSE MEDICAL.



Safety Huber needle PPS™ CT

Max. flow rate:
22G = 2 mL/sec 19G & 20G = 5mL/sec
Max. pressure setting: 300 psi

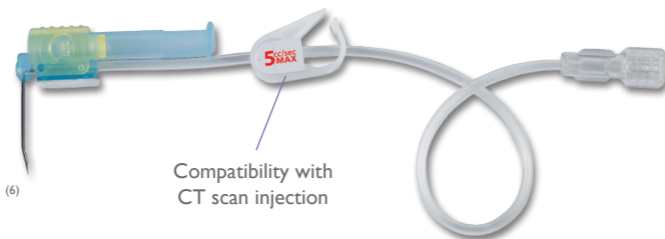
Possible positive pressure

- According to implantable port using recommendations ⁽²⁾
- Withdrawal of the needle with only one hand

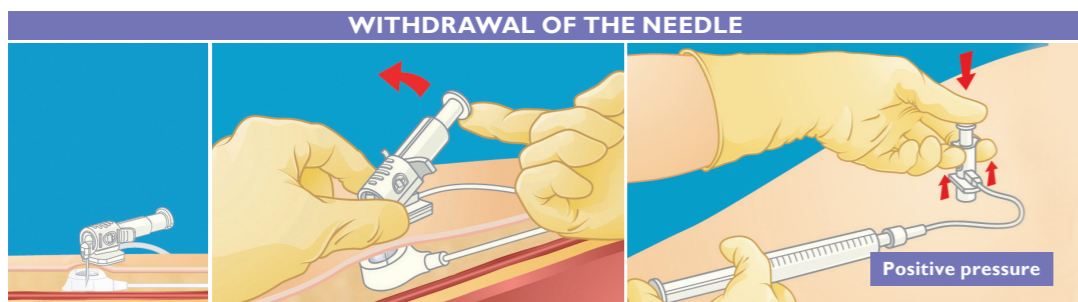
Prevention of needlestick injury

- Decreases blood exposure risk versus double and activated device ⁽⁶⁾
- No rebound effect when withdrawing the needle
- No risk of contact with the needle body
- Total protection until discarded in sharps container ⁽³⁾

**POWER
INJECTION
COMPATIBLE**
(1)



Compatibility with
CT scan injection

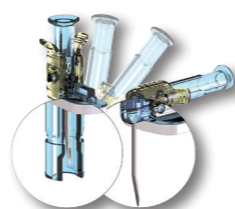


WITHDRAWAL OF THE NEEDLE

Normal position for use
(horizontal piston)
before withdrawal.

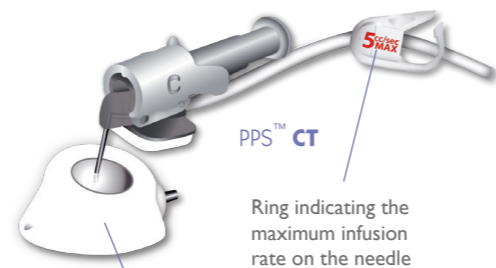
Preparation: lift the piston from the horizontal
position to the vertical position.

Using your thumb, lower the piston to put it in contact
with the skin and simultaneously lift the extractor (with
an upwards movement) until there is a CLIC corresponding
to the total locking of the needle. This final operation
eliminates any risk of accidental needlestick injury.



PROTECTION
needle tip and body

Gauge	Needle Ø (mm)	Needle length (mm)	Max. Flow rate	Product codes	
				without Y site	with Y site
22G	0.7	15	2 mL/sec 300 psi	801507*	811507*
	0.7	17		801707	811707
	0.7	20		802007	812007
	0.7	25		802507	812507
	0.7	30		803007	813007
20G	0.9	15	5 mL/sec 300 psi	801509*	811509*
	0.9	17		801709	811709
	0.9	20		802009	812009
	0.9	25		802509	812509
	0.9	30		803009	813009
19G	1.1	15	5 mL/sec 300 psi	801511*	811511*
	1.1	17		801711	811711
	1.1	20		802011	812011
	1.1	25		802511	812511
	1.1	30		803011	813011
19G	1.1	35		803511	813511



PPS™ CT

Ring indicating the
maximum infusion
rate on the needle

Implantable port
compatible
with power
injection

Bold references are the most commonly used. Other references are only available upon request with a minimum lead time of 12 weeks.
* For paediatric use only.

NO DEHP

This device is not made with dry or natural rubber latex.

(1) See Instructions for use.

(2) According to HAS 2000 (French Health Authority) and SF2H 2012 (French Society for Hospital Hygiene) guidelines.

(3) Biomatech study n°148381 – 28 June 2012 – p.64-66.

PPS™ CT is packed in a carton of 12 units .

Sterilization by ethylene oxide.

PPS™ CT is a registered trade mark of PEROUSE MEDICAL.



Clear Transparent Film Dressing specifically designed to maintain Huber needles, CVC and picc lines in place

polyfilm™

Vascular access
range

EASY REMOVAL
Non adhesive central window

Non-adhesive central window: 3 x 7.5 cm / 1 1/4 in x 3 in

- Non-adhesive guaranteeing stability of the needle upon removal of the dressing:
 - Reduces the risk of pain
 - Prevents accidental needle-stick injury during dressing removal
- Strengthened: to avoid any risk of tearing leading to breach of asepsis
- Transparent: optimal monitoring site and detection of possible complications

Two-part applicator frame
• Easy to apply

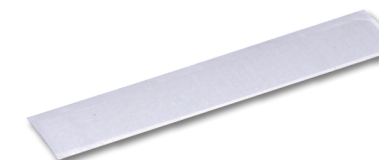


Polyurethane flexible film

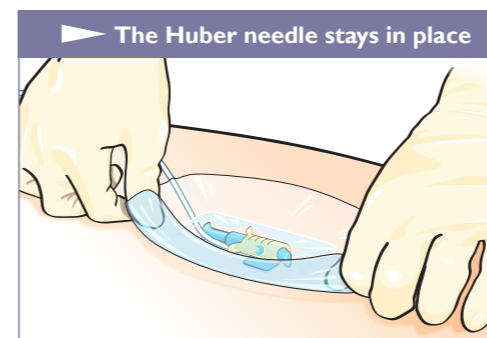
- Hypoallergenic for optimum skin tolerance
- Breathable to prevent humidity accumulation under the dressing and therefore early displacement
- Barrier against bacteria and viruses, offering protection regarding the risks of contamination
- Liquid-impermeable to avoid displacement in the event of accidental immersion

Holding strips (included in the pouch)

- Huber needle maintenance under the dressing
- Date of application can be written on the strip



Product code	Description	Dimensions	Unit per box
PF121401	POLYFILM™, dressing holding strips	12 x 14 cm 4 3/4 in x 5 1/2 in	50 units



The Huber needle stays in place

Easy removal thanks
to the non-adhesive window

polyfilm™ is sterilized by ethylene oxide. polyfilm™ is a registered trademark of PEROUSE MEDICAL.

For further information, please contact: questions@vygon.com

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