
















Instructions for Use
SteerEase™ Introducer







Lifetech Scientific (Shenzhen) Co., Ltd

IFU of SteerEase Introducer



SteerEase™

	Catalogue number
	Use by
	Date of manufacture
	Serial number
	Lot Number
	Consult Instructions for Use
	Sterilized using ethylene oxide
	Non-pyrogenic
	Do not reuse
	Do not use if package is damaged
	Do not resterilize
	Store at room temperature
	Keep dry
	Keep away from sunlight
	Manufacturer

	<p>Authorised representative in the European Community</p>
	<p>Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union Acts.</p>
	<p>Contents inside the box</p>
	<p>Outer Diameter</p>
	<p>Inner Diameter</p>
	<p>Length</p>

1 Device Description

1.1 Device Structure

The SteerEase Introducer consists of a sheath (Figures 1 and 2), a dilator (Figures 3 and 4), a loader (Figure 5), a haemostatic valve (Figure 6) and a delivery cable (Figure 7). There are two types of sheath with distal curve of 45° (Figure 2, SFA) and 180° (Figure 1, SFP). The SteerEase Introducer is intended to reach the cardiovascular system or the peripheral vasculature and would provide a pathway to perform the delivery of the devices.

1.1.1 Sheath

Sheath is used to deliver the device. Extension soft tube and stopcock are used to minimize bleeding and to flush the system.

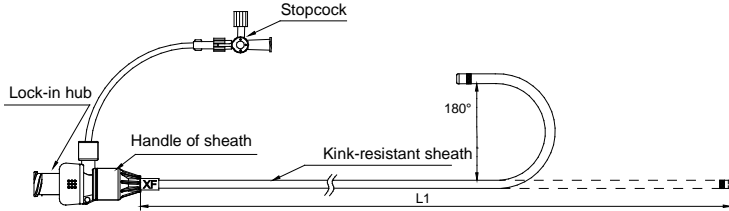


Figure 1. Sheath (SFP)

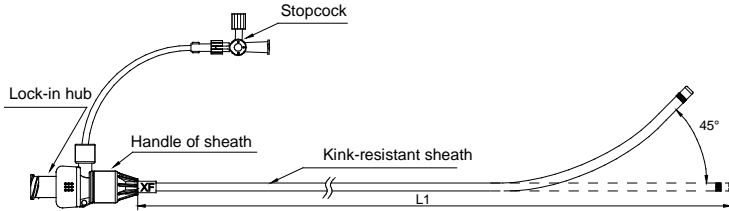


Figure 2. Sheath (SFA)

1.1.2 Dilator

Dilator is used to ease the penetration of tissue.

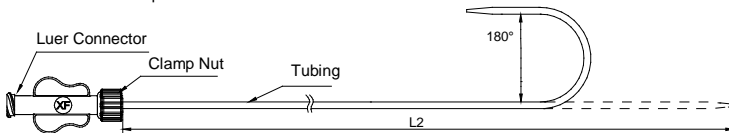


Figure 3. Dilator (SFP)

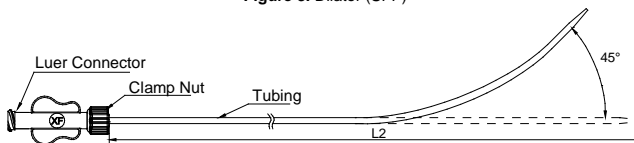


Figure 4. Dilator (SFA)

1.1.3 Loader (optional)

Loader is used to introduce a device into a sheath.

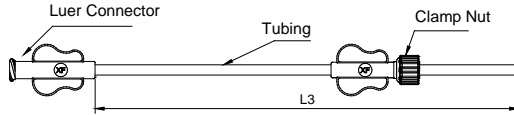


Figure 5. Loader

1.1.4 Haemostatic Valve (optional)

Haemostatic valve is used to minimize bleeding and to flush delivery system.

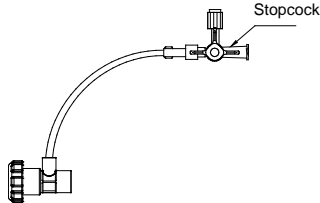


Figure 6. Haemostatic Valve

1.1.5 Delivery Cable (optional)

Delivery cable is attached to a device for controlling its movement through the sheath, deploying and retrieving the device. Plastic vise is used to control cable and served as a "handle" for disconnecting (unscrewing) the device.

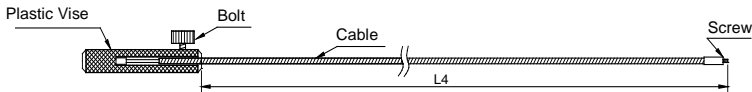


Figure 7. Delivery Cable

1.2 Device Models and Size Parameters

Table 1. Model Chart of the SteerEase Introducer

Curve Type	SteerEase Introducer Model				
	5F	6F	7F	8F	9F
A	SFA5F	SFA6F	SFA7F	SFA8F	SFA9F
	SFA5F-f	SFA6F-f	SFA7F-f	SFA8F-f	SFA9F-f
P	SFP5F	SFP6F	SFP7F	SFP8F	SFP9F
	SFP5F-f	SFP6F-f	SFP7F-f	SFP8F-f	SFP9F-f
Curve Type	SteerEase Introducer Model				
	10F	11F	12F	13F	14F
A	SFA10F	SFA11F	SFA12F	SFA13F	SFA14F
	SFA10F-f	SFA11F-f	SFA12F-f	SFA13F-f	SFA14F-f
P	SFP10F	SFP11F	SFP12F	SFP13F	SFP14F
	SFP10F-f	SFP11F-f	SFP12F-f	SFP13F-f	SFP14F-f

Table 2. Composition of the SteerEase Introducer

Components Types	Sheath	Dilator	Loader	Haemostatic Valve	Delivery Cable
SFAxF/SFPxF	✓	✓	✓	✓	✓
SFAxF-f/SFPxF-f	✓	✓	✗	✗	✗

Note: ✓ : Included; ✗: Not included.

Table 3. Size Parameters of the SteerEase Introducer

Components Parameters Specification	Sheath /mm			Dilator /mm		Loader /mm			Delivery Cable /mm	
	L ₁	ID	OD	L ₂	OD	L ₃	ID	OD	L ₄	OD
5F	800	1.8	2.2	850	1.8	85	1.8	2.6	1150	1.6
6F		2.1	2.6		2.1		2.9			
7F		2.5	2.9		2.5		3.2			
8F		2.8	3.2	2.8	90	2.8	3.6			
9F		3.1	3.6	3.1	95	3.1	3.9			
10F		3.5	3.9	3.5	105	3.5	4.3			
11F		3.8	4.3	3.8		4.6				
12F		4.1	4.6	4.1	135	4.1	4.9			
13F		4.5	4.9	4.5		5.3				
14F		4.8	5.3	4.8		5.5				

Note: 0.038 inch Guide Wire recommended

2 Indications and Usage

The SteerEase Introducer is intended to reach the cardiovascular system or the peripheral vasculature and would provide a pathway to perform the delivery of the devices.

3 Contraindications

None known.

4 Directions for Use

- 4.1 Follow precautions according to the device's Instructions for use.
- 4.2 Select an appropriate introducer to ensure that the ID of the sheath is appropriate for the maximum diameter of the device to be used.
- 4.3 Inspect the sterile pouch to verify that it is unopened and undamaged.
- 4.4 Gently open the sterile pouch and inspect the introducer to ensure that it is undamaged.
- 4.5 Flush all components with saline solution, and then tighten the clamp nut after the dilator is inserted into the sheath to ensure the dilator connected with sheath securely (Figure 8).

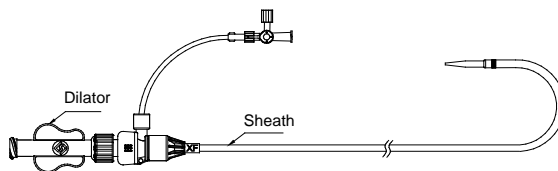


Figure 8. A sheath inserted with a dilator

- 4.6 Place a guide wire using standard Seldinger technique according to the device's instructions for use.
- 4.7 Advance the sheath and the dilator together over the guide wire until the sheath is positioned properly according to the device's instructions for use.
- 4.8 Remove the dilator and guide wire. Allow back bleeding to exhaust all air residual in the system.

- 4.9 Attach a haemostatic valve to the loader and flush with saline solution (Figure 9).

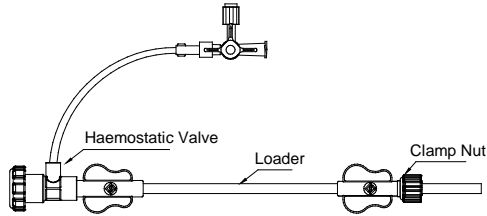


Figure 9. A loader connected with a haemostatic valve

- 4.10 Capture, deploy and retrieve the device according to the device's instructions for use.

5 Expiry Date

The SteerEase Introducer is sterilized by ethylene oxide. Please use the device before the "Use by" date specified on the label.

6 Warnings

- 6.1 The SteerEase Introducer must be used before expiration date noted on the package. Read the Instructions for Use carefully, check package and products in it before use. If any damages such as package broken, sheath bent, screw loose happened, please contact your Lifetech representatives or the manufacture directly.
- 6.2 The SteerEase Introducer should only be used by physicians who are professionally trained. Type of introducer should be strictly determined based on patient's condition.
- 6.3 Patients should be heparinized during the whole operation process. All components of the SteerEase Introducer must be flushed with sterile heparinized saline.
- 6.4 Fully immerse the device in the sterile saline solution and then pull it into the loader by a delivery cable and exhaust the air. Thrombus caused by air is not allowed in an operation.
- 6.5 Immediately change a new introducer when the sheath is bent during an operation.
- 6.6 Contents supplied sterile using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damaged, contact your Lifetech representatives directly.
- 6.7 For single patient use only. Do not reuse, reprocess or re-sterilization. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness even death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness even death of the patients.
- 6.8 After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

7 Storage and Transportation

- 7.1 The SteerEase Introducer should be stored in ventilated and clean location at room temperature. Relative humidity in storage is less than 80%.
- 7.2 Be careful in handling. Do not squeeze, wet, bend or expose in direct sunlight during freight.
- 7.3 Any other questions please contact agents or the manufacturer directly.

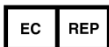
8 Package and Label

- 8.1 All components of the SteerEase introducer are sterilized using ethylene oxide.
- 8.2 All components in the package are fixed in a lining card, sealed into inner and outer Tyvek/film pouches.
- 8.3 The Instructions for Use, a customer feedback form and a certificate of compliance are inside the carton box.
- 8.4 A label is affixed to seal one end of the box and another label to seal the other end.



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