INSTRUCTIONS FOR USE

Sheath Introducer

Sheath introducer should be used to allow flushing, infusion and pressure monitoring. When clinically indicated, the sheath and obturator may be removed (see above).

POTENTIAL COMPLICATIONS:
Potential complications include, but are not limited to: air embolism, infection, disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Resterilization may also create a risk of contamination of the device and/or cause patient resterilization may compromise the structural integrity of the device and/or lead to device failure.

Sheath French size should be used introducer when it is left in place. An obturator that is one French size smaller or equal to the sheath French size should be placed into the sheath. After the sheath is flushed, place the obturator through the sheath and snap into place. A suitable solution should be flushed through the side arm after obturator is placed.

CAUTIONS:
Do not use device with a power injector.
Do not advance the introducer and/or guide wire if resistance is met.

WARNINGS:
This device is intended for single use only. Do not reuse or resterilize.
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient injury, illness or death of the patient. Resterilization may compromise the structural integrity of the device and/or lead to device failure.

Read instructions prior to use.

Note:
• Aspirate from the side port extension to remove any potential air. After aspiration, flush the side port with a suitable solution. Stopcock should be turned off to maintain flush in side port.

Note:
• Note: Collected fibrin at the tip of the sheath may be aspirated via the side arm tubing prior to removal of the puncture site, should be started as the sheath is slowly removed.

Note:
• Note: Fibrin at the tip of the sheath may be aspirated via the side arm tubing prior to removal of the sheath introducer assembly, leaving the sheath introducer in the vessel.

Note:
• Hold guide wire in place and remove access needle. Hold pressure at the site until the introducer/dilator assembly is placed.

Note:
• Determine the cause of resistance before proceeding.

Note:
• Warning: Do not advance the guide wire if resistance is met.

INSTRUMENTS
One (1) Sheath Introducer
One (1) Vessel Dilator
One (1) Mini Guide Wire

Components The Prelude Sheath Introducer consists of the following components. These devices are intended to be used together. The components are:

• Sheath Introducer
• Vessel Dilator
• Mini Guide Wire

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