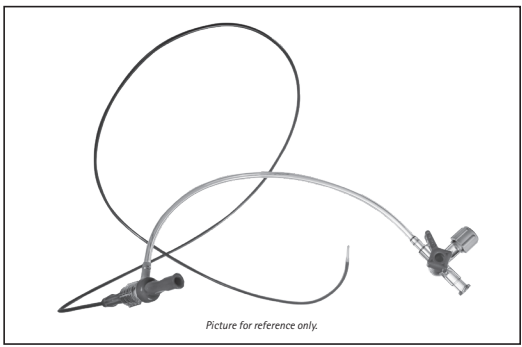
COMPASS™

Guiding Introducer Sheath

INSTRUCTIONS FOR USE



Picture for reference only.

IFU-26090-001_rev00(01.09.2021)

Do not reuse

Do not resterilize

Do not use if package is damaged

Store at room temperature

Rx only

STERILE EO
Sterilized using ethylene oxide

Consult instructions for use

Keep dry

LATEX
Not made with natural rubber latex

PHT
DEHP
Not made with DEHP

Keep away from sunlight

Interventional Systems
B BRAUN

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COMPASS™ Guiding Introducer Sheath

Read all instructions carefully prior to use. Observe all warnings and precautions noted throughout instructions. Failure to do so may result in serious complications.

INTENDED USE

The COMPASS™ Guiding Introducer Sheath is indicated to be used for introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature. The device is also intended to be used within a pediatric population.

DEVICE DESCRIPTION

The COMPASS™ Guiding Introducer Sheath consists of the following parts:

- One (1) introducer sheath with hemostasis valve and
- One (1) dilator - 45cm, 60cm and 90cm product models or
- Two (2) dilators - 15cm product models

The COMPASS™ Guiding Introducer Sheath consists of an introducer sheath with hemostasis valve and side port, as well as locking dilator with a tapered tip at the distal end. The locking dilator with snap-fit secures the dilator for safe insertion and prevents backout. The main introducer sheath tubing is connected at the proximal end to a hemostasis valve with side port tubing that is connected to a plastic 3-way stopcock valve. The side port is used for flushing the introducer sheath. The introducer sheath is introduced into the vascular system with the aid of the locking dilator. The hemostasis valve at the proximal end of the introducer sheath conforms and seals around guide wires and catheters to reduce blood leakage from the introducer sheath. A radiopaque marker helps identify the distal end of the introducer sheath. The introducer sheath has a hydrophobic silicone coating on the outer surface of the distal portion.

DIRECTIONS FOR USE

SHEATH PREPARATION:

1. Prepare the insertion using aseptic technique and local anaesthesia as necessary.
2. Remove the COMPASS™ Guiding Introducer Sheath and dilator from the packaging using aseptic technique and examine for possible damage and defects. Do not use in case of visible damage.
3. Ensure that the detachable hemostasis valve is securely tightened to the hub of the sheath.
4. Flush dilator, introducer sheath and side port with saline, suitable isotonic solution or heparinized intravenous fluid. After flushing side port, turn stopcock to OFF position to keep flushing solution in side port and prevent bleeding after insertion into the vessel.

SHEATH INSERTION:

1. Insert dilator tip trough the hemostatis valve of the COMPASS™ Guiding Introducer Sheath completely into the introducer sheath until the dilator hub comes in contact with the hemostasis valve to ensure that the tapered portion of the dilator is beyond the end of the introducer sheath. When advancing the introducer sheath, ensure that the dilator remains fully inserted into the introducer sheath to avoid damage to the vessel.

2. Follow standard recommended practice for vessel puncture or incision. While holding the access needle, place flexible or J-end of the guide wire through access needle into the vessel.

Remark: Refer to product labelling for the guide wire size compatible with system components.

Caution: Do not advance the guide wire if resistance is met. Determine cause of resistance before proceeding.

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

4. Insert the introducer sheath / dilator assembly over the guide wire into the vessel. Under fluoroscopic guidance, carefully advance the introducer sheath / dilator assembly over the guide wire until it is at the desired location. Do not allow dilator to back out of the introducer sheath while advancing. Stop advancement if resistance is met and investigate cause before proceeding.

5. After the introducer sheath / dilator assembly has been positioned to the desired location, hold the introducer sheath steady and maintain guide wire position while withdrawing the dilator from the introducer sheath over the guide wire until it is completely removed.

6. Aspiration 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 fluid in side port.

7. While maintaining the position of the guide wire, advance catheter or other interventional device over the guide wire into the introducer sheath.

Remark: Hold the introducer sheath in place when inserting, positioning, or removing the devices.

Remark: When the introducer sheath will remain in a vessel for an extended time period, consider using a continuous drip of heparinized intravenous fluid under pressure administered through the side port connection.

SHEATH REMOVAL:

1. Insert the dilator over the guide wire and fully into the introducer sheath.
2. The introducer sheath may be removed when clinically indicated. Compression on the vessel above the puncture site should be started as the introducer sheath is slowly removed.

Remark: Collected fibrin at the tip of the introducer sheath may be aspirated via the side arm tubing prior to removal of the introducer sheath.

3. Discard the introducer sheath appropriately.
4. Upon removal of the introducer sheath, precautions should be taken to prevent bleeding, vessel damage, or other serious injury.

CONTRAINDICATIONS

The COMPASS™ Guiding Introducer Sheath is not designed, sold or intended for any use other than indicated.
It is the responsibility of the physician to determine whether any physical impairment of the patient would contraindicate the use of this device.
Do not attempt introducer sheath insertion or use if the following conditions apply:

- Anatomical irregularities in the patients extremities that could interfere with proper placement of the catheter
- An adjacent vascular access device that could compromise catheter care and cleanliness
- Prior trauma to vessels that could interfere with insertion of the catheter
- Infection or lesion near the insertion site
- Radial access is contraindicated if there is an abnormal Allen's Test, radial pulse, or insufficient dual arterial supply

WARNINGS

- Read the instructions prior to use.
- This device should only be used by or under the direction of physicians thoroughly trained in the technique of catheter delivery systems.
- This device is intended for single use only. Do not reuse, resterilize or autoclave. Reuse of single use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure. The manufacturer will not be responsible for any direct, incidental or consequential damages resulting from resterilization or reuse.

- Do not alter this device. Alterations may impair function.
- Do not attempt to advance or withdraw the introducer, guide wire, catheter, or other interventional device if resistance is felt. Use fluoroscopy to determine the cause. If the cause cannot be determined and corrected, discontinue the procedure and withdraw the introducer sheath. Continued advancement or retraction against resistance may result in serious injury, and / or breakage of the guide wire, introducer sheath, catheter or interventional medical device.
- Do not use the device if the package or contents appear damaged in any way.
- Protection tube from sheath and dilator must be removed prior to use.
- Do not use the device with a power injector.
- Verify compatibility of the introducer sheath, device, catheter and accessories prior to use.
- Do not attempt to use a guide wire with a maximum diameter greater than specified on package label. Device damage or breakage may occur.
- Do not attempt to insert a catheter or other interventional device with a diameter larger than the introducer sheath size indicated. Device damage or breakage may occur.
- Observe sterile technique at all times when handling and inserting or removing the catheter.
- Adequate heparinization must be maintained during the procedure.
- Device contains metal parts: do not expose to MRI.
- The medical techniques and procedures described in these instructions are presented as an example only, and do not represent ALL medically acceptable protocols. They are not intended as a substitute for the physicians experience and judgment in treating any specific patient.

In case of radial access:

- Prior to beginning radial artery access, an assessment such as the Allen's test should be performed to access the presence/adequacy of dual arterial circulation to the hand.
- Do not leave the introducer in place for extended periods of time without a catheter or obturator to support the cannula wall.

PRECAUTIONS

- Examine packaging and device before use. Do not use if either the packaging or device is damaged or if sterile barrier has been compromised.
- The device is supplied sterile. The package will serve as an effective barrier until the "use by" (expiration) date printed on the box.
- Do not expose to organic solvents.
- Store at room temperature, keep dry.
- Before use, make sure the sheath (Fr.) and dilator size are appropriate for the access vessel and the system to be used.
- Individual patient anatomy and physician technique may require procedural variations.
- Do not attempt introducer sheath advancement or withdrawal without guide wire and dilator secured in place. Severe vascular damage and / or injury may occur.
- Insertion into and removal from artery may cause excessive bleeding and / or other complications.

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to:

- Air embolism
- Bleeding
- Hematoma
- Infection / Sepsis
- Intimal tear
- Thromboembolism
- Thrombophlebitis
- Thrombosis
- Vessel spasm
- Perforation or laceration of the vessel wall
- Risks normally associated with percutaneous diagnostic and / or interventional procedures

Some of the complications listed above could result in death or serious injury to the patient.