stryker®
Neurovascular

Dash™

Hydrophilic Sheath Introducer

Dash™

English

Hydrophilic Sheath Introducer

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING
Contents supplied STERILE using an ethylene oxide (EO) process. Non-pyrogenic. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization 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, or death of the patient.

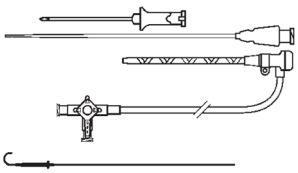
After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Used product and any associated used materials should be handled and processed as biohazardous material.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. TO AVOID COMPLICATIONS, OBSERVE ALL WARNINGS AND PRECAUTIONS DETAILED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

DEVICE DESCRIPTION
The 9F Dash Reinforced Thinwall Hydrophilic Introducer is a flexible Sheath Introducer. The Sheath has a radiopaque tip on the distal end and a hemostasis valve at proximal end. The 9F Dash Sheath shaft has a lubricious coating to reduce friction during use. The inner lumen of the 9F Dash Sheath shaft is compatible with 9F or smaller intermediate catheters. The included dilator has an inner lumen suitable for use with the provided .038″ guidewire. The dilator has a tapered tip at the distal end and a female luer fitting at the proximal end.

Contents

- One (1) Sheath Introducer
- One (1) Vessel Dilator
- One (1) Mini Guide Wire
- One (1) Access Needle



Intended User
This device should be used by clinicians with adequate training in the use of the device. (These products are typically used by interventional radiologists, interventional cardiologists, diagnostic only cardiologists and vascular surgeons).

Intended Patient Population
The Dash Hydrophilic Sheath Introducer and accessories are used in patients who require vascular access for a diagnostic or therapeutic procedure.

Clinical Benefits
The Dash Hydrophilic Sheath Introducer product line devices will provide access and allow percutaneous introduction of various devices into the vasculature, while maintaining hemostasis and minimizing blood loss during the procedure.

INTENDED USE/INDICATIONS FOR USE
The Dash™ Hydrophilic Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

CONTRAINDICATIONS
None known.

WARNINGS
- Do not advance the introducer and/or guide wire if resistance is met.
- Do not use device with a power injector.
- Appropriate flushing protocols should be utilized to prevent thrombus formation during procedural use.

PRECAUTIONS
- Read instructions prior to use.
- This device is intended for single use only. Do not reuse or resterilize.
- This device is sterile if package is unopened or undamaged.
- This device is non-pyrogenic.
- This device should be used by clinicians with adequate training in the use of the device.
- Utilize appropriate anticoagulant therapy for patient during procedure.
- Prior to use, ensure that the sheath and dilator are the appropriate size for the access vessel and devices to be use.

ADVERSE EVENTS
Potential complications include, but are not limited to:
- air embolism
- infection
- hematoma
- bleeding
- perforation or laceration of the vessel wall
- thrombus formation
- pseudo aneurysm formation
- guide wire embolization
- vessel spasm
- risks normally associated with percutaneous diagnostic and/or interventional procedures.

ADVERSE EVENT REPORTING
Any serious product-related incidents should be reported to both Stryker Neurovascular and the competent authority of the European Member State, or equivalent regulatory authority, where the user and/or patient is established. Please make every attempt to retain any suspect device, its associated components and their packaging for return to Stryker Neurovascular.

HOW SUPPLIED
Packaging is designed to maintain sterility according to the expiration date on the label unless the primary product pouch has been labeled otherwise, opened or damaged.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

Handling and Storage
- Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS
The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the device. The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the clinician's experience and judgment in treating any specific patient.

1. Identify the insertion site and prepare the site using proper aseptic technique and local anesthesia as required.

2. Remove the Dash™ Hydrophilic Sheath Introducer components from package using proper aseptic technique.

3. Flush all components with heparinized saline or suitable isotonic solution. Be sure to wet the outer surface of the sheath introducer to activate the hydrophilic coating. The sheath should not be used in a dry state.

Warning: After flushing side port, turn stopcock to off position to maintain flush inside port and prevent bleed back upon insertion into the vessel.

Warning: Do not wipe outer surface of the sheath introducer with dry gauze.

4. Insert vessel dilator into Dash Hydrophilic Sheath Introducer through hemostasis valve and snap into place.

Warning: Dilator must be securely snapped into place to avoid damage to the vessel.

5. Insert access needle into vessel.
a. While holding the access needle, place the flexible end or J end of the guide wire through access needle into vessel.

Note: Refer to product labeling for appropriate guide wire compatibility with the system components.

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

6. Hold guide wire in place while removing access needle. Apply manual pressure above puncture site during needle removal and until the introducer/dilator assembly is placed.

Warning: Do not withdraw the guide wire from the access needle after it has been inserted because it may damage the guide wire.

7. Insert the introducer/dilator assembly over the guide wire into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel.

Warning: Ensure that the surface of the sheath is wet prior to insertion; the sheath should not be used in a dry state.

Warning: During insertion, hold assembly near distal tip while passing over the guide wire and into the vessel to avoid buckling.

8. After introducer/dilator assembly has been placed into vessel, detach the dilator from the introducer by bending the dilator hub down slightly (this will unsnap the dilator hub from the introducer cap). While holding the sheath, carefully remove the dilator and guide wire together, leaving the sheath introducer in the vessel.

9. Aspirate from the side port extension to remove any potential air or debris. After aspiration, flush the side port with a suitable solution.

Warning: Stopcock handle must be turned to the off position (toward the sheath hub) to prevent inadvertent blood loss.

10. Use caution when inserting and removing selected device(s) (wires, catheters, etc.) into Dash Hydrophilic Sheath Introducer.

Note: Hold the sheath in place when inserting, positioning, or removing the devices. Always exchange or remove devices slowly through the sheath.

11. To temporarily suture the sheath in place, use the rotating suture ring.

12. REMOVAL: The sheath should be removed within 24 hours. Compression on the vessel, above the puncture site, should be started as the sheath is slowly removed. Non-occlusive compression should be used to achieve hemostasis once the sheath is removed.

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

DISPOSAL: After use, dispose of product and packaging in accordance with hospital protocol.

WARRANTY

Stryker Neurovascular warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Stryker Neurovascular's control directly affects the instrument and the results obtained from its use. Stryker Neurovascular's obligation under this warranty is limited to the repair or replacement of this instrument and Stryker Neurovascular shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Stryker Neurovascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Stryker Neurovascular assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

UPN Product Number	REF Catalog Number
Do not use if package is damaged.	Recyclable Package
Consult instructions for use.	Use By
Contents	For single use only. Do not reuse.
Legal Manufacturer	Do Not Resterilze
Date of Manufacture	STERILE EO Sterilized using ethylene oxide.
LOT Lot	MD Medical Device
GW Maximum Guidewire OD	UDI Unique Device Identifier
SI Includes Sheath Introducer	STERILE EO Sterile Barrier Packaging
VD Includes Vessel Dilator	GTIN Global Trade Item Number
MG Includes Mini Guidewire	AN Includes Access Needle

Legal Manufacturer

Merit Medical Systems, Inc.,
1600 West Parkway
South Jordan, UT 84095

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Stryker Neurovascular
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USA Customer Service
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Do not use if package is damaged.

Recyclable Package

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