

Dash Hydrophilic Sheath Introducer

RX 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.

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

Dimensions of the Echo Intracranial Base Catheter are included on the individual device label. The Echo Intracranial Base Catheters are available in 2 different lengths, the device configurations are presented in Table 1 below. Compatibility information for the Echo Intracranial Base Catheter is presented in Table 2.

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 use/Indications for use

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

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 adverse events associated with the use of catheters or with the endovascular procedures 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.