

Merit Advance®

ANGIOGRAPHIC NEEDLES

DEVICE DESCRIPTION

The Merit Advance® Angiographic Needles are used to gain access to blood vessels and incorporate a translucent standard female luer locking connector for immediate bleed back visualization and is color coded for needle gauge identification.

HOW SUPPLIED

The Merit Advance® Angiographic Needles are single use devices supplied sterile and non-pyrogenic.

INTENDED USE

The Merit Advance® Angiographic Needle is intended for percutaneous vascular access.

CONTRAINDICATIONS

There are no contraindications associated with the Merit Advance® Angiographic Needle.

CLINICAL BENEFITS

The Merit Advance® Angiographic Needles are used to gain access to blood vessels for the introduction of other associated devices to be used on patients in diagnostic and interventional procedures.

WARNINGS

Withdrawal, pull back, or manipulation of the guide wire distal tip through the needle tip may result in breakage or embolization.

Do not advance the guide wire if resistance is met.

PRECAUTIONS

- Product is sterile if package is unopened and undamaged. Prior to use, carefully examine the needle to verify that the sterile package or product has not been damaged in shipment. Do not use a damaged needle.
- Read instructions prior to use.
- Store in a cool, dry place.
- This device is intended for single use only.
- Do not reuse or resterilize.

POTENTIAL COMPLICATIONS AND RESIDUAL RISKS

Potential complications include risks normally associated with percutaneous diagnostic and/or interventional procedures.

Other complications include, but are not limited to: Air embolism, Thrombus formation, Infection, Pseudo aneurysm formation, Hematoma, Guide wire embolization, Bleeding, Perforation or laceration of the vessel wall, and Foreign Body.

EQUIPMENT REQUIRED

1. Surgical gloves and drapes
2. Merit Advance® Angiographic Needle
3. Other equipment as necessary

INSTRUCTIONS FOR USE

1. Remove needle from packing using standard aseptic technique.
2. Identify the insertion site and prepare the site using proper aseptic technique and local anesthesia as required.
3. Insert a Merit Advance® Angiographic Needle using standard technique.
4. DISPOSAL: After use, dispose of product and packaging in accordance with hospital protocol.

STORAGE CONDITIONS

















Do not store in areas of excessive heat or humidity.

TRANSPORTATION CONDITION

Do not expose to excessive heat or humidity during transit.

SHELF LIFE

3 years

| SYMBOL | DESIGNATION |
|---|---|
|  | Use by date: YYYY-MM-DD |
|  | Batch code |
|  | Catalog number |
|  | Sterilized using ethylene oxide |
|  | Do Not Use If Package is Damaged and Consult Instruction for Use |
|  | Single use |
|  | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. |
|  | Do not resterilize |
|  | Caution |
|  | Date of Manufacture: YYYY-MM-DD |
|  | Medical Device |
|  | Single Sterile Barrier System |
|  | Authorized Representative in European Community |
|  | Manufacturer |
|  | Consult Instructions for Use. For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, available within seven days, call U.S.A or E.U. Customer Service |
|  | Unique Device Identifier |

Basic UDI-DI: **TBD**



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Authorized Representative:
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