Merit Advance®
NEEDLES

DEVICE DESCRIPTION
The Merit Advance® 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 identication.

INTENDED USE
The Merit Advance Needle is intended for providing a puncture site for the introduction of vascular and non-vascular devices.

CLINICAL BENEFITS
The Merit Advance Needles provide an indirect clinical benefit to the patients, as they are used to gain access to blood vessels and non-vascular cavities for the introduction of other associated devices for diagnostic and interventional procedures.
Merit does not claim direct clinical benefits to the patients for the Advance Needles.

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.

INSPECTION PRIOR TO USE
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.

CAUTIONS
- Read instructions prior to use.
- Store in a cool, dry place.
- This device is intended for single use only.
- Do not reuse or resterilize.

CONTRAINDICATIONS
There are no contraindications associated with the Merit Advance Needle.

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
- Foreign Body

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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 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
	Caution
	Do Not Use If Package is Damaged and Consult Instruction for Use
REF	Catalog number
LOT	Lot Number
MD	Medical Device
UDI	Unique Device Identifier
	Single use
	Do not resterilize
	Consult Instructions for Use. For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
STERILE EO	Sterilized using ethylene oxide
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single Sterile Barrier System
	Use by: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
	Manufacturer
	Non-pyrogenic
EC REP	Authorized Representative in European Community
	Contains Cobalt

Basic UDI-DI: 0884450BUDI441PR

MERITMEDICAL®

CE 2797

www.merit.com

Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah 84095 U.S.A.
1-801-253-1600 U.S.A Customer Service 1-800-356-3748

EC REP Authorized Representative:
Merit Medical Ireland Ltd,
Parkmore Business Park West,
Galway, Ireland
EU Customer Service +31 43 358 82 22

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