



Angiographic Catheters -Including Performa Ultimate (all models)

INSTRUCTIONS FOR USE

DESCRIPTION:

Angiographic catheters are single-use, sterile, non-pyrogenic, disposable intravascular catheters.

INDICATIONS:

Angiographic catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.

CONTRAINDICATIONS:

None known.

WARNING:

- The Impress® angiographic catheter with hydrophilic coating should not be used in the coronary arteries.
- Angiographic catheters are single use.
- Recommended guide wire size: See the individual catheter label.
- Guide wire use has been associated with greater incidence of thrombus formation.

PRECAUTIONS:

- Do not use if package is opened or damaged.
- Do not use after expiration date.
- Do not autoclave.
- Carefully remove the catheters from the package by grasping the hub and slowly withdrawing it from the package.
- If resistance is felt when removing the guidewire from the catheter, remove the guide wire and catheter as a unit to prevent potential damage to the vessel wall.
- Flush all devices entering a blood vessel with sterile heparinized saline or similar isotonic solution before use.
- For catheters containing hydrophilic polymer coating on the distal surface of the catheter, the surface of the distal portion of the catheter must be completely wet to remain lubricated. Proper caution must be taken to wet the catheter prior to and during use.

ADVERSE EVENTS:

Merit Medical angiographic catheters should be used by physicians familiar with percutaneous catheter introduction. Complications which may be associated with the use of angiographic catheters include, but are not limited to, the following.

- Thrombus formation/emboli
- Hematoma at puncture site
- Plaque dislodgement
- Cardiac arrhythmias
- Perforation of the vessel wall
- Vascular occlusion
- Stroke and death
- Air emboli
- Arterial wall damage
- Myocardial infarction
- Infection
- Allergic reaction to contrast media
- Vascular spasm

REUSE PRECAUTION STATEMENT

For single patient 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, transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

DIRECTIONS FOR USE:

1. A coated guide wire is recommended for use with Merit angiographic catheters.
2. Introduce the catheter into the blood vessel using vascular entry technique of choice.
3. PIGTAIL catheters. Pigtail catheters are fitted with a straightener. It is split for easy removal after the catheter tip is on the guide wire.
 - Slide straightener forward until pigtail is straight.
 - Place catheter tip on guide wire and remove straightener by pulling on the straightener tab.
4. Marker Band: Anatomical measurement accuracy is $\pm 4\%$.

Storage: Sterile and non-pyrogenic in unopened and undamaged inner package. Store in a cool dry place.

Shelf Life: The shelf life is established at 3 years from date of sterilization.

Transportation: Do not expose to high temperature or humidity.



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