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ENGLISH

Coronary Guidewire Introducer Needles

Models: 12-002069; 12-004924; 12-004925; 12-004943, 10-009161 and 10-009130

Intended Use/Purpose:
The intended use of Coronary Guidewire Introducer Needles is to gain peripheral vascular access for the placement of a guidewire into coronary arteries during coronary angiography or cardiac catheterization.

Devices Description:
The ArcRoyal Coronary Guidewire Introducer Needles are supplied as single use devices. These devices are used to create a puncture site to gain peripheral access to the circulatory system in order to advance the guidewire during surgical procedures, by trained physicians.
The Coronary Guidewire Introducer Needles are composed of two main parts: a cannula and stylet. The needle consists of a stainless steel one-wall cannula and a luer lock hub for immediate bleed-back visualization. They are available with a clear window wall hub. The construction of the needle hub from clear material means that blood flow is visually detected at the earliest point in the procedure. The hub of an introducer needle is designed with an ergonomic feel for ease of handling and is offered with a standard hub or a Seldinger shield.

Indication for Use/Operating principle:
The Coronary Guidewire Introducer Needles are intended to be used to create a puncture site to gain peripheral access to the circulatory system in order to advance the guidewire.
The Coronary Guidewire Introducer Needles feature a non-coring 'B' arterial bevel which is designed for anterior, single wall, arterial percutaneous puncture. The tapered luer hub allows for easy coronary guidewire insertion.

Warnings:
- Contents are supplied sterile and are intended for single use only. Do not re-sterilize, reuse or reprocessing has not been evaluated and may lead to its failure and subsequent patient illness, infection or other injury.
- Inspect the package integrity before use.
- Do not use if package is open or damaged and if the expiry date has been exceeded.
- Do not continue to use if any of the component are damaged during the procedure.

Precautions:
- This device is intended for use by trained physicians or members of surgical teams.

Pre-Procedural Preparations: Flush needles with sterile saline.

Direction for Use:
- Prepare and drape the skin at the intended puncture site; achieve local anesthesia as necessary.
- Using imaging guidance carefully insert the needle through the skin, without applying excessive force
- Using imaging guidance, advance the needle to the intended vessel or target site.
- Advance the appropriate guidewire of choice through the needle.
- Confirm access to desired location with wire
- Remove needle and continue with procedure.

Possible complications:
- Minor Pain at insertion site
- Minor Bleeding
- Hematoma at insertion site
- Infection
- Vessel puncture
- Air Embolism
- Arterial dissection

Storage: Store in a dry cool place at controlled room temperature.

Disposal: After use, this product may be a potential biohazard. Handle in a manner which will prevent accidental puncture. Dispose in accordance with applicable laws and regulations.

Symbol Glossary:

ISO 15223 Symbol	Title	Description
MD	Medical Device	Indicates the item is a medical device
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
STERILE EO	Sterile EO	Indicates a medical device that has been subjected to an Ethylene Oxide sterilization process
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside
	Single sterile barrier system	Indicates a single sterile barrier system
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized
	Keep Away from Sunlight	Indicates a medical device that needs protection from light sources
	Keep Dry	Indicates a medical device that needs to be protected from moisture
	Fragile, Handle with Care	Indicates a medical device that can be broken or damaged if not handled carefully
	Do Not Use if Package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
UDI	Unique Device Identifier	Indicates a carrier that contains unique device identifier information
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Use-by Date	Indicates the date after which the *medical device* is not to be used