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AngioFLEX® and AngioFLEX® 2 Diagnostic Guidewires – Instructions for Use

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Swedish

CAUTION

- **Carefully read all instructions prior to use. Observe all warnings and cautions. Failure to do so may result in complications.**

INTENDED USE

AngioFLEX® and AngioFLEX® 2 Diagnostic Guidewires are sterile single use devices designed for percutaneous vessel entry using the Seldinger technique to facilitate the placement of an intravascular device during diagnostic procedures. The device is intended for transient use in adult patients.

DEVICE DESCRIPTION

AngioFLEX® and AngioFLEX® 2 Diagnostic Guidewires are manufactured from stainless steel, utilizing a proprietary construction process and are available with PTFE*-coating, a hydrophilic coating or without a coating. AngioFLEX® and AngioFLEX® 2 Diagnostic Guidewires provide a highly lubricous surface to reduce damage to vessel walls during insertion and removal.

AngioFLEX® and AngioFLEX® 2 Diagnostic guidewires are made of materials which provides coil to wire strength of union and kink resistance, to ensure integrity throughout the procedure. These materials are also corrosion resistant which prevents premature device failure. Furthermore, guidewire materials are selected for their ability to support devices being inserted into the vasculature.

AngioFLEX® and AngioFLEX® 2 Diagnostic Guidewires offer a selection of wires with different shapes and stiffness levels and thus trackability.

AngioFLEX® and AngioFLEX® 2 Diagnostic guidewires are packaged in a guidewire dispenser which typically is fitted with a luer hub. The luer hub facilitates flushing of the guidewire with heparinized saline solution prior to use.

“J”-tip configuration are typically packaged with a “J”-straightener. The “J”-straightener helps straighten the J tip, which aids the clinical staff to easily insert the guidewire into the introducer/puncture needle.

The PTFE and hydrophilic coated guidewires offer increased lubricity.

Package contents

Each AngioFLEX® and AngioFLEX® 2 guidewire is supplied in individual pouches, each including;

- 1 x guidewire
- 1 x guidewire dispenser with luer hub
- 1 x J straightener (only with J tips wires)

Dimensions of the product are indicated on the box and pouch label. Each box contains an Instructions for Use leaflet (IFU).

How supplied

All contents are supplied STERILE and non-pyrogenic in unopened and undamaged packaging. The devices are sterilised by ethylene oxide. Do not use any unit if sterile package has been damaged or opened. DO NOT RE-USE OR RE-STERILISE the device.

Do not re-sterilize, reprocess, or reuse. Reuse, reprocessing or re-sterilization 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 re-sterilization 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.

Storage

Protect from direct sunlight, any source of heat, and moisture. Store at room temperature and do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that catheters are used prior to expiration date on package label.

CONTRAINDICATIONS

Guidewires should not be used, when the target vessel presents the following underlying pathology:

- Thrombosed vessel, damaged or collapsed vessels
- History of cardiac tamponade
- Severe arterial atherosclerosis
- Insufficient collateral perfusion

Guidewires should not be used, when the cannulation site is not suitable due to:

- Synthetic arterial or vascular grafts
- Infection at the site of cannulation

WARNING

- **Do not use in patients with known allergies to Stainless Steel, Sodium Hyaluronate Nickel, Titanium or Polytetrafluoroethylene (PTFE).**
- **This product is STERILE and for SINGLE USE only. Do not re-use, reprocess or re-sterilise. Do not use the guidewire or accessories if any sign of damage is visible.**

INSTRUCTIONS FOR USE

CAUTION

- **This device should be used only by cardiologists and specialist physicians thoroughly trained and experienced in the technique of percutaneous vessel entry utilizing the Seldinger technique.**
- **Any time that a guidewire is used there is a possibility of thrombus formation/ emboli, vessel wall damage, and plaque dislodgement, which could result in myocardial infarction, cardiac arrhythmia, stroke or death. The physician should be familiar with the use of angiography products and the literature concerning the complications of using a guidewire and follow the relevant health and hospital guidance.**
- **Prior to use, inspect for damage such as kinks or material separation. If damaged, DO NOT USE.**
- **Employ aseptic techniques during removal from the package and during use.**

Flushing

In order to reduce the potential of clot formation, it is recommended that the guidewire be flushed with saline or heparinized saline prior to use by following the below instructions:

1) Attach the syringe filled with saline or heparinised saline fluid to the luer connection
2) Inject solution into the guidewire dispenser surrounding guidewire
3) Flush several times or as per the hospital protocol.
4) Detach syringe

5) Dispense guidewire

Activation of hydrophilic guidewires

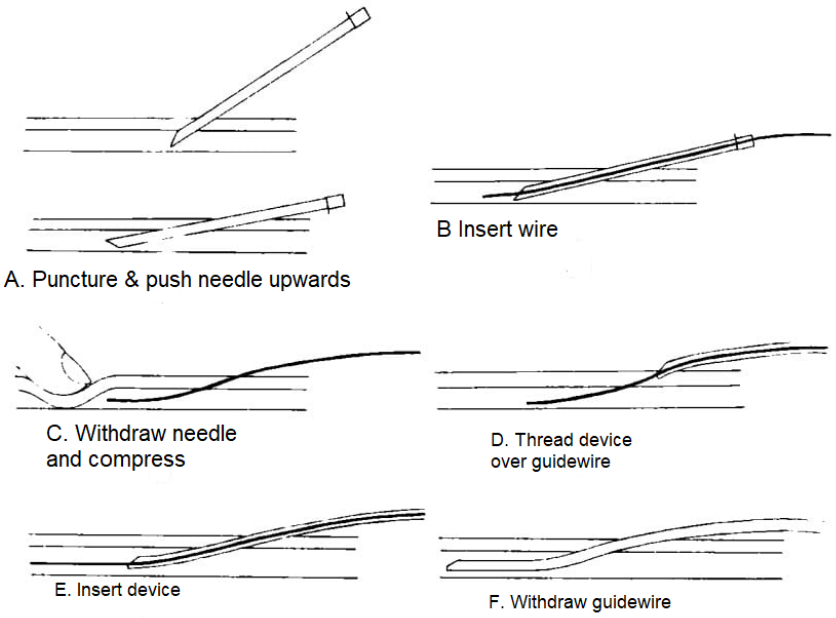
The above procedure is especially important to activate the hydrophilic coated guidewires. To activate the hydrophilic coating follow steps 1-5 above. If manipulation of the guidewire becomes diminished, remove the guidewire and reactivate the hydrophilic coating by repeating the flushing procedure.

WARNING

- **Use of alcohol, antiseptic solutions or other solvents on coated guidewires must be avoided because they may adversely affect the coating surface.**

Guidewire Insertion

Insert the flexible tip of the guidewire percutaneously, utilising the Seldinger technique, as shown in the diagram below:



WARNING

- **Excess blood can be removed from the guidewire by wiping the surface with a guidewire sponge moistened with heparinised saline solution. Never use a dry sponge as this may damage the wire surface resulting in increased resistance upon reinsertion.**

J-Tip guidewires

AngioFLEX® and AngioFLEX® 2 Diagnostic “J” guidewires are provided with a “J” straightener to aid in the insertion of the wire into the introducer needle. Advance the wire until 2-3 mm of the tip extends from the “J” straightener. Insert wire into needle hub and advance through needle. Remove “J” straightener proximally and discard.’

Guidewire advancement

Advance the guidewire slowly and do not use excessive force to advance the guidewire is in a vessel. Care should be taken when manipulating a guidewire during placement.

During advancement of the catheter and guidewire within the aorta, it is recommended that the guidewire be removed at the appropriate level of the aorta.

If the guidewire is over advanced, it could cause vessel damage and/or reach undesired location. This can be prevented by visualising the guidewire during the procedure.

If a guidewire is over advanced into an undesired location, please gently retract it to the correct location before proceeding. If vessel damage is caused by over advancement, follow the appropriate clinical protocol.

WARNING

- **Do not use excessive force. Advancement with excessive force may cause vessel damage.**
- **Over advancement of the guidewire can result in serious injuries or arrhythmias.**

Removal of guidewire

Avoid withdrawing guidewires through a metal needle or cannula. The sharp edge of the needle may scrape the coating or damage the guidewire. It is suggested that a catheter or introducer sheath replace the needle as soon as the guidewire has reached the appropriate position.

If resistance is felt when removing from a catheter, the guidewire and catheter should be removed as a unit, to prevent potential damage to the vessel wall.

WARNING

- **Do not withdraw the guidewire through a metal needle or cannula.**

GUIDEWIRE RANGE

AngioFLEX® Uncoated stainless steel range		**AngioFLEX® 2 Hydrophilic coated range**	
J-Tip Double ended wires		**Angled guidewires**	
KJ3SFUXXXYYY	45-150 cm, 0.025”-0.038”	KAFGXXXXA/2	150-260 cm, 0.018”-0.038”
Straight guidewires		**Straight guidewires**	
KSFUXXXYYY	40-150 cm, 0.018”-0.038”	KAFGXXYYS/2	150-260 cm, 0.018”-0.038”
J-Tip single ended		**Angled stiff guidewires**	
KJ3FUXXXYYY	40-150 cm, 0.025”-0.038”	KAFGXXXXAS/2	80-260 cm, 0.035”-0.038”

AngioFLEX® PTFE coated range					
J-Tip Single ended wires		**J-Tip single ended super stiff wire**		**Straight guidewires**	
KJ1.5FCXXXYYY, KJ3FCXXXYYY	80-400 cm, 0.018”-0.038”	KJ3FCSSXXXYYY	260 cm, 0.035”	KSFCXXXYYY	40-260 cm, 0.018”-0.038”
J-Tip moveable core		**Bentson**		**Straight tip super stiff wire**	
KJ3MCXXXYYY	150 cm, 0.035”-0.038”	KSFCBXXXYYY	150-180 cm, 0.035”	KSFCSSXXXYYY	150-260 cm, 0.035
J-Tip double ended wires		**Rosen**		**Straight tip movable core**	
KJ1.5FCXXXYYY, KJ3SFCXXXYYY	40-260 cm, 0.021”-0.038”	KR1.5FCXXXYYY	180 cm, 0.035”	KSMCXXXYYY	150-260 cm, 0.035”-0.038”

SUMMARY SAFETY AND CLINICAL PERFORMANCE (SSCP)

The Summary of Safety and Clinical Performance (SSCP) can be referenced on the Eudamed public website (https://ec.europa.eu/tools/eudamed) or can be requested directly from Kimal (regulatory_department@kimal.co.uk)

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