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IMPORTANT SAFETY INFORMATION
EU Commercial Products

MIVI Q™ Aspiration Catheters

- **Q3-36163-E, Q4-43150-E, Q5-57145-E, Q6-69145-E**
- **See IFU packaged with product for complete instructions on device usage** (ref. IFU 101546.E)

Intended Use/Indications for Use

The Q Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi in the peripheral and neurovascular systems. It may also be used as a diagnostic angiographic catheter.

Contraindications

· Vessels smaller than the catheter's distal outer diameter.

Warnings

· The Q Aspiration Catheter is intended to be used by physicians skilled in the eld(s) of Interventional Radiology, Interventional Neuroradiology, Neurosurgery and/or Neurology who are skilled in endovascular interventional procedures for acute ischemic stroke or acute limb ischemia.

· Do not use the Q Aspiration Catheter with a guide catheter/sheath < 90 cm in length. This may result in the catheter body extending past the guide/sheath.

· Do not use the device in patients who are allergic to polyether block amides (PEBAX), polytetrafluoroethylene (PTFE) or polyether based thermoplastic polyurethanes (TPU).

· Never advance or retract the catheter against resistance without careful assessment of cause using fluoroscopy. If cause cannot be determined, withdraw the catheter.

· Do not torque the control wire of the Q Aspiration Catheter. Torqueing, movement against resistance or forced insertion of the catheter may result in device damage, vessel damage and/or tip breakage which may result in injury to the patient.

· If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove or replace catheter.

· Use caution when injecting contrast agents into the distal cerebral neurovasculature through the guide catheter/ sheath with a Q Aspiration Catheter in place. The potential for an increase in flow through the Q Aspiration Catheter may result in injury to the patient.

Precautions

· Store in a dark, dry place.

· Use prior to the "Use By" date.

· Do not expose device to solvents.

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· The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in impaired structural integrity and/or function.

· Do not use open or damaged packages.

· Upon removal from package, inspect device to ensure it is not damaged. Do not use kinked or damaged devices.

· Confirm the compatibility of the Q Aspiration Catheter with any interventional devices to be used in conjunction with the catheter (e.g. guide catheter, microcatheter, guidewire).

· Exercise care when handling the catheter before and during a procedure to reduce the possibility of damage.

· Upon insertion and removal of the catheter, ensure the hemostasis valve is large enough to accommodate smooth movement.

· Manipulate the catheter under fluoroscopic visualization. Do not attempt to move the catheter without observing the resultant tip response.

· Avoid angular strain on the control wire during preparation and insertion.

· Ensure that the proximal radiopaque marker does not extend past the distal marker band of the guide catheter.

· When performing aspiration, ensure that the stopcock on the rotating hemostasis Y valve is open for only the minimum time needed to remove thrombus. Excess aspiration or failure to close the stopcock when aspiration is complete is not recommended.

· Excessive force on the Q Aspiration Catheter is not recommended. If repositioning of the catheter is necessary, repositioning should be performed using appropriate techniques.

· Do not exceed 300 kPa during contrast injection.

· Do not use automated high-pressure contrast injection equipment with the Q Aspiration Catheter because it may damage the device.

· If an intraluminal device becomes lodged in catheter, or if the catheter becomes severely kinked, withdraw the entire system (intraluminal device, catheter and guiding catheter).

Adverse Events

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with possible complications. Potential complications include, but are not limited to, the following:

· access site complications (hemorrhage, hematoma, fistula, etc.)

· air embolism

· allergic reaction (contrast, materials, device)

· death

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· device malfunction

· emboli/distal embolization

· inability to remove all thrombus

· infection

· intracranial hemorrhage

· ischemia

· kidney damage

· neurological deficits or new stroke

· vasospasm

· vessel trauma (dissection or perforation)

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MIVI Super 90™ 8F Guide Catheters

- MIA-9080S-E, MIA-9095S-E
- See IFU packaged with product for complete instructions on device usage (ref. IFU 101214.E).

Intended Use/Indications for Use

The Super 90 8F Guide Catheter is indicated for use in facilitating the insertion and guidance of catheters into a selected blood vessel in the peripheral and neuro vascular system. It may also be used as a diagnostic angiographic catheter.

Contraindications

None known

Warnings

· The Super 90 8F Guide Catheter should only be used by physicians who are skilled in interventional procedures in the peripheral and neuro vascular systems.

· Do not use the device in patients who are allergic to polyether block amides (PEBAX/ VESTAMID), polytetrafluoroethylene (PTFE), polycarbonate or polyolefins.

· Never advance or retract the catheter against resistance without careful assessment of the cause using fluoroscopy. If a cause cannot be determined, withdraw catheter. Excessive torqueing, movement against resistance or forced insertion may result in catheter damage, vessel damage and/or tip breakage which may result in injury to the patient.

· If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove or replace catheter.

Precautions

· Store in a dark, dry place.

· Use prior to the “Use By” date.

· Do not expose device to solvents.

· The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in impaired structural integrity and/or function.

· Confirm the compatibility of the Super 90 8F Guide Catheter with any interventional devices to be used in conjunction with the catheter.

· Do not use open or damaged packages.

· Upon removal from package, inspect device to ensure it is not damaged. Do not use kinked or damaged devices.

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· Exercise care when handling the catheter before and during a procedure to reduce the possibility of damage.

· Once hydrated, do not allow the device to dry out.

· Manipulate the catheter under fluoroscopic visualization. Do not attempt to move the catheter without observing the resultant tip response.

· Do not use automated high-pressure contrast injection equipment with the catheter, it may damage the device.

· Excessive force on the Super 90 8F Guide Catheter is not recommended. If repositioning of the catheter is necessary, repositioning should be performed using appropriate techniques.

· If intraluminal device becomes lodged in catheter, or if the catheter becomes severely kinked, withdraw the entire system (intraluminal device, catheter and guiding catheter).

Potential Complications

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with possible complications. Potential complications include, but are not limited to, the following:

· Access site complications (hemorrhage, hematoma, AV fistula, etc.)

· Allergic reaction (to contrast, materials or device)

· Death

· Embolism (air, thrombus or device)

· Infection

· Intracranial hemorrhage

· Ischemia

· Kidney damage

· Neurological deficits including stroke

· Vasospasm

· Vessel trauma (dissection or perforation)

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MIVI High Flow Tubing

- **HFT 110-E**
- See IFU packaged with product for complete instructions on device usage (ref. IFU 100813.F)

Intended Use/Indications for Use

MIVI's High Flow Tubing is intended to be used in conjunction with commercially available aspiration pumps and aspiration catheters to aspirate, remove, or sample body fluids.

Contraindications

None known

Warnings

None

Precautions

• Use prior to the "Use By" date.

• The device is intended for single use only. Do not resterilize or reuse.