CAUTIONS / PRECAUTIONS

Do not exceed 2,070 kPa (300 psi) infusion pressure. Excessive tightening of a hemostatic valve onto the microcatheter might result in damage to the microcatheter and guidewire. In severe cases, tip separation of the microcatheter and guidewire may result in damage to the microcatheter shaft.

Excelsior® XT-27™ and XT-27™ Flex Pre-Shaped Microcatheter

See package insert for complete indications, contraindications, warnings and instructions for use.

INTENDED USE / INDICATIONS FOR USE

Styker Neurovascular Excelsior XT-27 Microcatheter is intended to assist in the delivery of diagnostic agents (such as contrast media), therapeutic agents, and non-liquid interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.

CONTRAINDICATIONS

None known.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with the use of microcatheters or with the endovascular procedures include, but are not limited to: access site complications, allergic reaction, aneurysm perforation, aneurysm rupture, death, embolism (air, foreign body, plaque, thrombus), hematoma, hemorrhage, infection, ischemia, neurological deficits, pseudoaneurysm, stroke, transient ischemic attack, vasospasm, vessel dissection, vessel occlusion, vessel perforation, vessel rupture, vessel thrombosis.

WARNINGS

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.

For single 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, 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

These devices should only be used by physicians who have received appropriate training in interventional neuroradiology.

Limited testing has been performed with solutions such as contrast media, interventional devices such as stents, and therapeutic agents such as PVA particles. The use of these catheters for delivery of products other than the types that have been tested for compatibility is not recommended.

Do not use a microcatheter that has been damaged. Damaged microcatheters may rupture, causing vessel trauma or tip detachment during steering maneuvers.

Do not exceed 2,070 kPa (300 psi) infusion pressure. Excessive pressure could dislodge a clot, perforate a vessel wall, or damage microcatheter and guidewire. In severe cases, tip separation of the microcatheter or guidewire may occur.

Inspect product before use for any bends, kinks or damage. Do not use a microcatheter that has been damaged. Damaged microcatheters may rupture, causing vessel trauma or tip detachment during steering maneuvers.

Do not exceed 2,070 kPa (300 psi) infusion pressure. Excessive pressure could dislodge a clot, causing thrombembolism, or could result in a ruptured microcatheter or severed tip, causing vessel injury.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

These devices should only be used by physicians who have received appropriate training in interventional neuroradiology.

Limited testing has been performed with solutions such as contrast media, interventional devices such as stents, and therapeutic agents such as PVA particles. The use of these catheters for delivery of products other than the types that have been tested for compatibility is not recommended.

Do not use catheter with glue, glue mixture or non-adhesive liquid embolic agent.

The microcatheters are not intended for use inside the human body.

Carefully inspect all devices prior to use. Verify shape, size and condition are suitable for the specific procedure.

Exercise care in handling of the microcatheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.

Shaping mandrel is not intended for use inside the human body.

Discontinue use of microcatheter for infusion if increased resistance is noted. Resistance indicates possible blockage. Do not attempt to clear blockage by over-pressureization. Do so may cause the microcatheter to rupture, resulting in vascular damage or patient injury.

Do not exceed 2,070 kPa (300 psi) infusion pressure. Excessive pressure could dislodge a clot, causing thrombembolism, or could result in a ruptured microcatheter or severed tip, causing vessel injury.