

## Dominant Flex Surgical Suction Pump

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

### INDICATIONS FOR USE

The intended use of the Dominant Flex suction pump is the creation of a constant vacuum for use in hospitals and clinics. This vacuum can be used for general suction, to aspirate and remove: surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials and during specific procedures which may include, vacuum extraction, aesthetic body contouring, aspiration during flexible endoscopy, use with cardiac tissue stabilizers during off-pump coronary artery bypass, and epicardial ablation probes.

### WARNINGS

- For use only by medically trained persons who have been adequately trained in suction procedures and in the use of aspirators.
- To avoid risk of electric shock, this equipment must only be connected to a fixed mains socket with protective earth.
- The device must not be used for suctioning explosive, easily flammable or corrosive liquids.
- The connecting tubing supplied with the device must never come into direct contact with the suction area. A sterile suction catheter must always be used (risk of infection).
- Before cleaning the device, pull the plug out of the fixed mains socket.
- No modification of this equipment is allowed.
- Consult the indications for use and consider risk factors and contraindications before using the Dominant Flex. Failure to read and follow all instructions in this manual prior to use may result in serious or fatal injury of the patient.
- Do not connect this device to a passive drainage tube.
- Not suitable for setting at a low vacuum, as needed for example for thoracic drainage without specialized accessories. Not approved for outdoor use or transport applications.

### PRECAUTIONS

- Incorrect use can cause pain and injury to the patient.
- Do not use sterile accessories when the sterile packaging is damaged.
- The use of mobile telephones, LAN / WLAN, walkie-talkies (two-way radios) and cordless telephones sets can affect the Dominant Flex pump. A safety distance of min. 3.3 ft (1 m) to the Dominant Flex pump is recommended.
- Portable and mobile RF communications equipment can affect medical devices.
- The rack version requires a minimum distance of 5 cm to the enclosure to prevent overheating of the device.
- The patient should be monitored regularly according to the physicians' instructions and facility guidelines. Objective indications or signs of a possible infection or complication must be met immediately (e.g. fever, pain, redness, increased warmth, swelling or purulent discharge).
- Non-observance can lead to considerable danger of the patient. Monitor the Dominant Flex frequently for operating status.
- To prevent the device from overheating, the exhaust at the bottom of the unit must be unobstructed when the unit is operational.

## AXS Universal™ Liner Set and Aspiration Tubing

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

### INDICATIONS FOR USE

AXS Universal Liner Set and Aspiration Tubing is suitable for the safe collection and disposal of suctioned fluids. It is allowed for use only by medically trained staff who are aware of the in-house hygienic regulations. Medela can only guarantee the safe function if used in combination with Medela components.

### AXS Catalyst® Distal Access Catheter

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

### INTENDED USE/INDICATIONS FOR USE

1. The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.
2. The AXS Catalyst Distal Access Catheter is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA are candidates for treatment.

### CONTRAINDICATIONS

None known.

### ADVERSE EVENTS

Potential adverse events associated with the use of catheters 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

### WARNING

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.

- Limited testing has been performed with solutions such as contrast media, and saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.
- Not intended for use with power injectors.
- 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 and replace catheter.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the device against resistance could dislodge a clot, perforate a vessel wall, or damage the device.
- Excessive aspiration may cause patient complications.

### PRECAUTIONS

- Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. Ensure the catheter's labeled outer diameter is smaller than the treatment vessel diameter. Do not use a device that has been damaged in any way. Damaged device may cause complications.
- To control the proper introduction, movement, positioning and removal of the catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- Use the product prior to the "Use By" date printed on the label.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.
- Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.