

Dominant Flex Surgical Suction Pump

RX ONLY

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

RX ONLY

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.