Instructions for Use (IFU) Brief Summaries

Hēlo® Thrombectomy System (HEL1595):

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Device Description:

The Hēlo® 15F Thrombectomy System is a minimally invasive aspiration system designed for the removal of thromboembolic material from the pulmonary arteries. Acute, sub-acute, and acute-on-chronic thrombus was identified on histopathologic examination of aspirated thrombus taken from subjects (n=11) enrolled in the ENGULF ITT cohort.

Indications for Use:

The Hēlo® Thrombectomy System is indicated for:

- The non-surgical removal of emboli and thrombi from pulmonary arteries and venous vasculature.
- The system allows for injection, infusion, and/or aspiration of contrast media and other fluids into or from blood vessels.

The Hēlo® Thrombectomy System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

Contraindications:

- Not intended for use in the cerebral, carotid, or coronary arteries.
- Not intended for use in endarterectomy procedures or vessel dilation.
- Not intended for use in vessels < 8 mm diameter.
- Not intended for the removal of fibrous, adherent, or calcified material (e.g., chronic clot)

Warnings:

- Intended for single use only. Do not resterilize or reuse this device.
- Should be used with fluoroscopic guidance and proper anticoagulation agents.
- Use by the “Use By” date specified on the product packaging.
- Avoid using excessive force to advance or retract the Hēlo Thrombectomy System against resistance. If excessive resistance occurs, retract and remove the device. Excessive force against resistance may result in damage to the device or vessel perforation.
- Placing a guidewire too deep into the pulmonary vasculature increases the possibility of vessel perforation.
- Placing the funnel shaped tip of the Aspiration Catheter too distal in the pulmonary vasculature or excessive manipulation of the funnel shaped tip in smaller, peripheral, and segmental pulmonary artery branches can result in vessel injury, which may cause hemoptysis.
- In the event of patient deterioration, remove the Hēlo Thrombectomy System.
- Do not use in blood vessels that have a history of therapeutic irradiation. Vessel perforation may occur.
- No modifications of this equipment are allowed.

Precautions:

- Contents are sterile and non-pyrogenic if package and sterile pouch is undamaged or unopened. Do not use if package is opened and/or damaged.
- Intended for use by physicians trained and experienced in percutaneous interventional endovascular techniques requiring fluoroscopic visualization.
- Ultrasound guidance should be used to ensure desired vessel target area is accessed during introducer sheath placement.
- Flush each device with sterile saline to purge air prior to use.
- Do not place the suction canister at a position elevated more than 12 inches above the patient to avoid backflow.

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Potential Complications/Adverse Events

- Access site hematoma
- Adverse reaction to device materials
- Aneurysm
- Angina
- Air embolism
- Arrhythmias
- Arteriovenous fistula
- Bradycardia
- Cardiac tamponade
- Cardiac perforation
- Cardiogenic shock
- Death
- Distal embolism
- Drug reaction to contrast, thrombolytic or anticoagulation
- Embolism
- Fever
- Foreign body embolism
- Fistulation
- General discomfort, tenderness, or pain
- Hemoglobinuria
- Hemolysis
- Hemoptysis
- Hypo/Hypertension
- Hypoxemia
- Infection
- Inflammatory response
- Myocardial infarction
- Nausea/vomiting
- Neurological deficit
- Organ impairment
- Pericardial effusion
- Perforation of pulmonary arteries
- Peripheral nerve damage
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary infarction
- Renal failure
- Respiratory failure
- Retroperitoneal hemorrhage
- Right bundle branch block
- Stroke/transient ischemic attack
- Tachycardia
- Valvular disruption/injury
- Vascular spasm
- Vasovagal reaction
- Ventricular rupture
- Vessel dissection/perforation
- Vessel stenosis

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Hēlo® Return Blood Return System (HELRET1):

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Device Description:

The Hēlo® Return Blood Return System (Hēlo® Return) is used to filter aspirated contents from the Hēlo® Thrombectomy Catheter for autologous blood return. Hēlo® Return is placed in the sterile field, creating a connection between the suction port of the Hēlo® Thrombectomy Catheter and the vacuum pump. When Hēlo® Return is toggled to ON, aspiration with the Hēlo® Thrombectomy Catheter can be performed to remove clot and accumulate blood, while providing audible feedback to the operator when there is rapid flow of blood through the device.

Indications for Use:

The Hēlo® Return Blood Return System is used with the Hēlo® Thrombectomy System to filter and return blood aspirated during the thrombectomy procedure, back to the patient.

Contraindications:

- Not intended for use without anticoagulation.

Warnings:

- Intended for single use only. Do not re-sterilize or reuse this device.
- Examine each device before use to verify it is not damaged.
- Use by the "Use By" date specified on the product packaging.
- No modifications of this equipment are allowed.
- Avoid using excessive force to inject/aspirate contents to/from the device. Excessive force against resistance may result in damage to the device.
- Do not reinject blood through the Hēlo® Thrombectomy Catheter.
- Injecting filtered blood into a catheter or sheath containing thrombus introduces risk of embolus.

Precautions:

- Hēlo® Return is for use only with the Hēlo® Thrombectomy Catheter.
- Do not use if package is opened and/or damaged. Examine each package for the integrity of the sterile barrier prior to use. If packaging appears damaged, discard the device.
- Do not remove the suction hose from the Hēlo® Thrombectomy Catheter while vacuum is active.
- Aspirated blood should not sit in the Hēlo® Return canister or aspiration tubing for more than 15 minutes. Blood should be filtered for re-injection within 15 minutes following the first aspiration into the canister.
- Maintain a patient ACT level >300 seconds throughout the thrombectomy procedure when using Hēlo® Return.

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