SQUID Safety and Warnings

Contraindications

The use of the SQUID Liquid Embolic Agent is contraindicated under the following circumstances:

- When optimal catheter placement is not possible
- When vasospasm stops blood flow

Potential Complications

Potential complications of the device or procedure include or are synonymous with, but are not limited to:

- Access site complications such as radial artery spasm, radial artery perforation, infection, necrosis, pain and tenderness, compartment syndrome, limb amputation, radial artery occlusion, hematoma or hemorrhage, sterile inflammation, granulomas, hand dysfunction, and pathological hand cold intolerance
- Allergic reaction
- Artery Occlusion / Stenosis
- Cardiac Disorder (such as arrythmia, myocardial infarction)
- Catheter entrapment
- Cerebral infarction
- Death
- Fluoroscopy-related risks to physicians and patients associated with x-ray exposure may include, but are not limited to, alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, delayed neoplasia
- Headache
- Hemorrhage / Rupture
- Hydrocephalus
- Infection
- Inflammatory Response
- Neurological Deficit
- Non-target embolization (passage of embolic material into unintended vessels adjacent to the target) which may cause but is not limited to: blindness, dysesthesias of the face (increased or decreased sensitivity), facial weakness, or deafness
- Organ Disorders
- Puncture Site Injury
- Renal Failure
- Respiratory Failure
- Seizure
- Thromboembolic Events and Ischemic Events (TIA/stroke)
- Vascular complications including but not limited to dissection, perforation, rupture, occlusion, vasospasm, hypotension
- Vasospasm

Precautions for Use

Rx Only: Federal law (USA) restricts this device to sale by or on the order of a physician.

- Use before the expiration date.
- Inspect product packaging carefully prior to use. Do not use if the sterile barrier is opened or damaged. The product is sterile as long as the packaging has not been damaged.
- Do not reuse or re-sterilize the device. Re-use of the device will lead to an increased risk of microbiological contamination for the patient.
- Always consider the potential for SQUID to interact with other embolic agents, e.g., cyanoacrylates, coated coils, particles and/or embolic spheres. Balt has not evaluated the compatibility of the SQUID LEA with PVA based embolic agents due to the solubility of PVA in DMSO and DMSO-water mixtures.
- Operators should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.
- Read the catheter instructions for use carefully prior to using SQUID.
- Verify that the catheters and accessories used in direct contact with the SQUID are clean and compatible with the material and do not trigger precipitation or degrade with contact. Refer to the respective Warnings and Directions for Use sections.
- If using radial artery access, perform a screening examination of the radial artery per institutional practices to ensure that radial access is appropriate for the patient.
- If using a guide sheath or introducer sheath, ensure the radial artery lumen diameter is larger than the outer diameter of the guide sheath or introducer sheath.
- Use only the SQUID syringes to inject DMSO and SQUID. Other syringes may not be compatible with DMSO.
- When injecting SQUID, fluoroscopic visualization should reveal SQUID progressing through the catheter lumen. It is recommended to get fluoroscopic images prior to reaching the minimal dead space of the catheter in order to visualize the embolic material before it exits the tip of the catheter.

- Using the syringe-catheter interface adapter will reduce catheter dead space (see the microcatheter label). Failure to comply with the appropriate volumes may result in unintended embolization. Only use thumb pressure to inject SQUID. Using the palm of your hand to advance plunger may result in catheter rupture due to over pressurization in the event of catheter occlusion.
- If SQUID escapes outside the vascular space, as might occur if the vessel wall is compromised, a subacute inflammatory response to the material may occur.
- Wait a few seconds following completion of SQUID injection before attempting micro-catheter retrieval in order not to cause fragmentation of SQUID into non-target vessels.
- Difficult catheter removal or catheter entrapment may be caused by one or more of the following factors:
    - Patient Anatomy: very distal vessel location, fed by afferent lengthened, small or tortuous vessels
    - Prolonged catheterization time
    - Vasospasm
    - Reflux
    - Injection time

- To reduce the risk of catheter entrapment, carefully select catheter placement and manage reflux to minimize the factors listed above.
    - Should catheter removal become difficult, the following technique allows for easier retrieval of the catheter:
        - Carefully pull the catheter to assess any resistance to removal.
        - If resistance is felt, remove any "slack" in the catheter.
        - Gently apply traction to the catheter to minimize the risk of catheter separation. Refer to catheter IFU for appropriate use.
        - Hold this traction for a few seconds and release. Assess traction on vasculature to minimize risk of hemorrhage.
        - This process can be repeated intermittently until the catheter is retrieved.
    - For entrapped catheters:
        - Under some difficult clinical situations, it may be safer to leave a flow-directed catheter in the vascular system, rather than risk rupturing the vessel and, consequently a hemorrhage, by exercising too much traction on an entrapped catheter.
        - This is accomplished by stretching the catheter and cutting the shaft near the entry point of vascular access allowing the catheter to remain in the artery.
        - If the catheter breaks during removal, distal migration or coiling of the catheter may occur. Same day surgical resection should be considered to minimize the risk of thrombosis.

Warnings[1]

- Performing embolization to occlude blood vessels is a high-risk procedure. The procedure should be carried out by a specialist with the appropriate neuroendovascular training, and a thorough knowledge of the medical condition to be treated, angiographic techniques, and super-selective embolization.
- The safety and effectiveness of SQUID has not been evaluated in:
    - patients with chronic subdural hematoma(s) who were surgically treated by craniotomy.
    - pediatric populations.
    - pregnant women.
    - patients with significant liver or kidney function impairment.
- The safety and effectiveness of SQUID as a long-term implant has not been established.
- The safety and effectiveness of SQUID for radial neurovasculature access in direct comparison to a transfemoral approach has not been demonstrated. The risks and benefits for radial access against a transfemoral approach should be carefully weighed and considered for each patient.
- The safety and effectiveness of SQUID in areas other than those identified in the Indications for Use has not been established.
- The patient's anatomy must be amenable to micro-catheter tip placement at a location within the middle meningeal artery in close proximity to the target treatment site or else cSDH may not be amenable to treatment.
- Avoid use of monopolar electrocautery devices due to possibility of electrical arcing with tantalum metal for surgical resection; bipolar devices should be used with caution.
- Do not prematurely expose SQUID to any amount of saline solution, blood or contrast agents, as solidification of SQUID may occur.

[1] Procedural warnings are listed within the Directions for Use section of the IFU