

Squid Safety & Warnings

Contraindications

SQUID is not indicated for use in pregnant women, in children under 5 kg or in patients with significant liver function impairment.

Potential Complications

Potential complications include, but are not limited to:

- Catheter entrapment
- Catheter rupture
- Device migration and cast movement
- Haematoma
- Arterial thrombosis
- Ischemic events due to embolic migration, vasospasm, Thrombosis
- Hemorrhagic events: vascular rupture, perforation.

Hemorrhagic complications related to attempts to remove entrapped catheter

- Some haemodynamic changes induced by the embolisation may result in bleeding complications.
- These ischemic or haemorrhagic complications may result in various functional neurological deficits and possibly death.

Precautions for Use

- Performing embolisation to occlude blood vessels is a high-risk procedure. The procedure should be carried out by a specialist with the appropriate interventional neuroradiology training, and a thorough knowledge of the medical condition to be treated, angiographic techniques, and super-selective embolisation.

- Use before the expiry 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 resterilize the device. Re-use of the device will lead to an increased risk of microbiological contamination for the patient.
- 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.
- Wait a few seconds following completion of Squid injection before attempting micro-catheter retrieval in order not to cause fragmentation of SQUID into nontarget vessels.
- Difficult catheter removal or catheter entrapment may be caused by one or more of the following factors:
 - Angioarchitecture: very distal arteriovenous malformation, fed by afferent lengthened, small or tortuous pedicles
 - Prolonged catheterisation 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.

SQUID REFLUX along the distal tip of the micro catheter: Apart from the risk of ischemic complications due to unintended embolisation, significant reflux may result in entrapment of the micro-catheter causing difficult removal. The reflux allowed must always be compared to the angio-architecture of the malformation to minimize the risk of unintentional embolization or difficult catheter removal. In general, do not allow more than 1 cm of Squid to reflux back over the distal tip of the micro-catheter.

- 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 (approximately 3-4 cm of stretch to the catheter).
 - Hold this traction for a few seconds and release. Assess traction on vasculature to minimize risk of haemorrhage.
 - This process can be repeated intermittently until catheter is retrieved.
 - Do not apply more than 10 cm of traction to catheter, to minimize the risk of catheter rupture.
- 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 malformation and, consequently a haemorrhage, 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 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

It is recommended to get fluoroscopic images prior to reaching the minimal dead space of the catheter in order to visualise 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 embolisation. The syringe-catheter interface adapter is compatible including with SONIC® (Balt extrusion, France) catheters.
- Only use thumb pressure to inject SQUID. Using the palm of your hand to advance plunger may result in catheter rupture due to overpressurisation in the event of catheter occlusion.
- Inject SQUID and DMSO at a slow, steady rate, not to exceed 0.3 ml/minute. Animal studies have shown that a rapid injection of DMSO into the vasculature may lead to vasospasm and/or angioneurosis.

- DO NOT interrupt SQUID injection for longer than two minutes prior to re-injection. Solidification of SQUID may occur at the catheter tip resulting in catheter occlusion, and use of excessive pressure to clear the catheter may result in catheter rupture.
- Adequate fluoroscopic visualisation must be maintained during SQUID delivery or non-target vessel embolization may result. If visualisation is lost at any time during the embolisation procedure, HALT SQUID delivery until adequate visualisation is re-established. Overpressurisation and rupture can occur if 0.05 ml of SQUID is injected and is not visualised exiting the catheter tip.
- STOP INJECTION if increased resistance to SQUID injection is observed -. Do not attempt to clear or overcome resistance by applying increased injection mpressure. If this occurs, determine the cause of resistance (for example, SQUID occlusion in the catheter lumen), and replace the catheter. Use of excessive pressure may result in catheter rupture and embolization of unintended areas.
- After using a micro-catheter with SQUID, do not attempt to clear the micro-catheter or to inject any material through it. Attempts to clear catheter may lead to embolus or embolization of unintended area.
- 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.