Squid Peri Safety & Warnings

Contraindications

SQUIDPERI is not indicated for use in pregnant women, in children under 5 kg or 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

• Hematoma

• Arterial thrombosis

• Ischemic events due to embolic migration, vasospasm, thrombosis

• Hemorrhagic events: vascular rupture, perforation. Hemorrhagic complications related to attempts to remove entrapped catheter

• Hemodynamic changes induced by the embolization may result in hemorrhagic complications.

• These ischemic or hemorrhagic 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 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 microbiologic contamination for the patient.

• Read the catheter instructions for use carefully prior to using SQUIDPERI.

• Verify that the catheters and accessories used in direct contact with the SQUIDPERI 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 the SQUIDPERI injection to retrieve the micro-catheter in order not to cause fragmentation of SQUIDPERI into non-target 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

- Long 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.

SQUIDPERI 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 angioarchitecture of the malformation, in order to minimize the risk of unintentional embolisation or difficult catheter removal. In general, do not allow more than 1 cm of SQUIDPERI 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 the risk

of hemorrhage.

- 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

• Use only the EMBOFLU SQUIDPERI syringes to inject DMSO and SQUIDPERI. Other syringes may not be compatible with DMSO.

• Use only SQUIDPERI-compatible micro-catheters (as, for example Sonic© Balt Extrusion, France). **Always**

check with the manufacturer of the micro-catheter its compatibility with SQUIDPERI. Other micro catheters may not be compatible with SQUIDPERI and their use can result in thromboembolic events due to catheter degradation.

• Adjunctive coil use should be considered if angiography shows that venous drainage of the AVM appears almost simultaneously with arterial opacification

• Premature solidification of SQUIDPERI may occur if micro catheter Luer contacts any amount of saline solution, blood or contrast agents

• Failure to continuously mix SQUIDPERI for the required time may result in inadequate suspension of the tantalum, resulting in inadequate fluoroscopic visualisation during delivery. Inject SQUIDPERI immediately after mixing. If SQUIDPERI injection is delayed, tantalum settling can occur within the syringe resulting in poor visualization of SQUIDPERI during injection.

• When injecting SQUIDPERI, fluoroscopic visualization should reveal SQUIDPERI progressing through the catheter lumen. It is recommended to obtain fluoroscopic imaging 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 micro-catheter 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 SQUIDPERI. Using the palm of your hand to advance the plunger, may result in catheter rupture due to over pressurization in mthe event of catheter occlusion.

• Inject SQUIDPERI 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 angionecrosis.

• **DO NOT** interrupt SQUIDPERI injection for longer than two minutes prior to re-injection. Solidification of SQUIDPERI 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 SQUIDPERI delivery or non-target vessel embolisation may result. If visualisation is lost at any time during the embolisation procedure, HALT SQUIDPERI delivery until adequate visualisation is re-established.

Over-pressurization and rupture can occur if 0.05 ml of SQUIDPERI is injected and is not visualized exiting the catheter tip.

• STOP INJECTION if increased resistance to SQUIDPERI injection is observed. Do not attempt to clear or overcome resistance by applying increased injection pressure. If this occurs, determine the cause of resistance (for example, SQUIDPERI occlusion in catheter lumen), and replace catheter. Use of excessive pressure may result in catheter rupture and embolization of unintended areas.

• After using a micro catheter with SQUIDPERI, do not attempt to clear the micro catheter or to inject any material through it. Attempts to clear catheter may lead to embolus or embolisation of unintended area.

• If SQUIDPERI escapes outside the vascular space, as might occur if the vessel wall is compromised, a subacute inflammatory response to the material may occur.