SQUID™ Liquid Embolic Agent
Instructions for Use

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

INSTRUCTIONS FOR USE: It is recommended to read the instructions for use carefully, in particular the precautions for use, notes and warnings prior to using this product. Failure to do so may result in complications.

SQUID and DMSO are sterile (dry heat) and non-pyrogenic.

Syringes and the syringe-catheter interface adapter are sterile (ethylene oxide) and non-pyrogenic.

This device is intended for SINGLE USE ONLY. DO NOT RESTERILIZE AND/OR REUSE.

1. DEVICE DESCRIPTION

SQUID is a non-adhesive, Liquid Embolic Agent (LEA) consisting of an Ethylene Vinyl Alcohol (EVOH) copolymer dissolved in Dimethyl Sulfoxide (DMSO) and suspended micronized tantalum powder to provide contrast for visualization under fluoroscopy. The SQUID LEA consists of:

- 1 vial of SQUID
- 1 vial of DMSO
- SQUID delivery syringe(s)
- 1 DMSO delivery syringe
- Syringe adapter(s)
- Stickers to identify the vials of SQUID

A DMSO-compatible delivery micro-catheter is used to access the embolization site and deliver SQUID. The adapter is an interface between the SQUID delivery syringe and the delivery catheter. SQUID is available in six product formulations:

- SQUID 12/12LD (4% EVOH)
- SQUID 18/18LD (5.3% EVOH)
- SQUID 34/34LD (7% EVOH)

SQUID 12 will travel more distally and penetrate deeper into the vascular bed due to its lower viscosity compared to SQUID 18 or 34, while the LD (Low Density) version will have a lower amount of tantalum powder.

2. PRINCIPLE OF OPERATION

SQUID Liquid Embolic Agent is delivered through a DMSO-compatible micro-catheter into the vasculature under fluoroscopic control. The DMSO solvent dissipates into the blood and interstitial fluids, causing the EVOH copolymer and suspended tantalum to solidify in situ into a spongy, coherent embolus. SQUID immediately solidifies from the outside to the inside, while progressing more distally in the vessel.

3. INDICATIONS FOR USE

The SQUID Liquid Embolic Agent is indicated for the embolization of the middle meningeal artery (MMA) as an adjunct to usual care treatment in patients with symptomatic chronic subdural hematoma(s) (SDH) measuring 10 mm or greater in thickness in whom an intervention is deemed necessary as determined by a neurosurgeon.

4. 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

5. 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

6. WARNINGS (Procedural warnings are listed within the Directions for Use section)

- 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.

7. PRECAUTIONS FOR USE

- 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.

8. HANDLING and STORAGE

Store in a dry place at room temperature and away from light. Prior to use, maintain product temperature above 19°C/66°F. If DMSO in the product freezes due to exposure to temperatures below 19°C/66°F, allow both vials to thaw at room temperature then prepare device per instructions for use.

9. MRI COMPATABILITY

MRI Safety Information

MR Conditional

A patient with SQUID may be safely used under the following conditions. Failure to follow these conditions might result in injury to the patient.

Parameter	*Condition of Use/Information*
Static Magnetic Field Strength (Bo)	≤3.0T
Static Magnetic Field (Bo) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Polarization	Circularly Polarized (CP) (i.e., quadrature drive)
RF Transmit Coil Type	Any Transmit RF coil may be used
RF Receive Coil Type	Any Receive RF coil may be used
RF Operating Mode	Normal Operating Mode
Scan Duration	Scan for 60 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 5 minutes before resuming scanning.
MR Image Artifact	The image artifact can extend approximately 5 mm from the Balt Medical SQUID/SQUID PERI Family. Imaging protocol modifications may be necessary to compensate for the MR image artifact.

10. DIRECTIONS FOR USE

1) Shake SQUID at least 20 minutes in a mixer (Scientific Industries Genie 2, Model No(s). 120V SI-0236, 240V SI-0246, Vial Attachment No. SI-0570) at a setting of 8. Continue mixing until ready to inject SQUID according to the instructions of the corresponding step below. Caution: Failure to continuously mix SQUID for the required time (20 minutes) may result in inadequate fluoroscopic visualization during delivery and/or micro-catheter occlusion.
2) Confirm microcatheter placement with injection of contrast agent.

WARNING
SQUID should only be administered through DMSO compatible microcatheters. . SQUID has been tested for compatibility with Balt USA ECLIPSE 2L and Medtronic Marathon Microcatheters. Testing was performed with SQUID34 to represent worst-case viscosity and at the recommended steady infusion rate of 0.16 ml/minute. The maximum pressure recorded was 95 psi at these settings, which were below the labeled burst pressure of the tested microcatheters. Use with incompatible microcatheters can result in thromboembolic events. Check with the microcatheter manufacturer's instructions for use for DMSO compatibility prior to utilizing with SQUID.

3) Flush the contrast agent from the micro catheter hub with at least **10 ml** of saline solution to ensure that no contrast agent is left inside. Leave the syringe connected.
4) Filling catheter dead space: aspirate approximately 0.8 ml of sterile DMSO into a DMSO syringe. Inject the DMSO into the delivery micro-catheter in sufficient volume to fill the catheter dead space. Refer to catheter label to determine the dead space volume.
5) Fill one of the provided syringes with SQUID. When filling the syringe with SQUID, aspirate approximately 1.1 ml of SQUID so that the plunger head is beyond the 1 ml graduation mark on the syringe barrel. This excess volume of SQUID will be used to fill (prime) the interface adapter.
6) Connect the interface adapter to the syringe.
7) Inject SQUID through the interface adapter until the distal end of the plunger head is even with the 1 ml graduation mark on the syringe barrel.
8) Any excess SQUID on the tip of the syringe may be wiped off with a clean, dry and particle free cloth.
9) Remove the DMSO syringe from the catheter. Overfill and wash the luer hub with the remaining solution of DMSO.
10) Immediately connect the SQUID syringe firmly to the micro-catheter hub, making sure there is no air in the hub during the connection.
11) Inject SQUID. It is recommended that SQUID be injected at a steady rate of 0.16 ml/minute (0.25ml/90 seconds) to ensure the pressure does not exceed the labeled burst pressure ratings of the compatible microcatheters. Do not exceed 0.3 ml/minute.

WARNINGS:

- Inject SQUID immediately after mixing. If SQUID injection is delayed, Tantalum settling can occur within the syringe resulting in poor visualization of SQUID during injection and/or micro-catheter occlusion.

WARNING
Use only thumb pressure to inject SQUID and continuously verify its exit from the catheter tip. Stop injection immediately if resistance is felt or SQUID is not visualized exiting the catheter, as these may indicate catheter occlusion. Over-pressurization or prolonged interruption of injection can lead to catheter rupture.

- Stop injection if abnormal dilation of the micro-catheter diameter is observed. An increase in the micro-catheter diameter can be a sign that the catheter is blocked. The increase in the micro-catheter diameter can be best determined by dual fluoroscopy at low magnification or with 'road mapping' technique, making it possible to examine the largest possible section of the micro-catheter.
- Do not allow more than 1 cm of SQUID to reflux back over the distal tip of the micro-catheter. Apart from the risk of ischemic complications due to un-intended embolization, significant reflux may result in entrapment of the micro-catheter causing difficult removal. The reflux allowed must always be compared to the anatomy of the cerebral vasculature to minimize the risk of unintentional embolization or difficult catheter removal.
- If loss of adequate fluoroscopic visualization occurs at any time during the SQUID delivery, HALT SQUID delivery until adequate visualization is re-established, otherwise non-target vessel embolization may result.
- Do not attempt to clear the micro-catheter or to inject any material through it after use with SQUID. Attempts to clear catheter may lead to embolus or embolization of unintended area.
- Do not use more than 0.87g/kg of DMSO per subject being treated with cSDH.

12) If a second SQUID syringe is required, when the new SQUID syringe is ready, simply remove the empty syringe and connect the new syringe.
13) Upon completion of SQUID injection, wait a few seconds, slightly aspirate syringe, and then gently pull the catheter to separate it from the SQUID cast.

NOTE: Stickers have been designed to be applied on the SQUID vials before placing them in the mixer. By numbering the vials in advance of placing them in the mixer, it is easier to identify the proper order for use after being sufficiently mixed.

11. DISPOSAL

After use, the product and its packaging should be disposed of in accordance with institutional guidelines for biohazard disposition.

12. SUMMARY OF CLINICAL STUDY RESULTS

Purpose

The purpose of the Squid Trial for the Embolization of the Middle Meningeal Artery (STEM) was to provide an assessment of the safety and effectiveness of adjunctive Middle Meningeal Artery Embolization (MMAE) with SQUID for the management of Chronic Subdural Hematoma (cSDH).

Design

The STEM study **(Figure 1)** was a pivotal, international, multi-center, prospective, randomized (1:1) controlled trial, designed to test the hypothesis that embolization of the middle meningeal artery with SQUID as an adjunct to standard management (either non- surgical or surgical management) is safe and effective in reducing the incidence of residual or recurrent cSDH at 6 months, the need for surgical rescue or re-operation, and neurological death, stroke or MI. The study was conducted at 25 sites in the United States and 7 sites in the European Union countries (France, Germany and Spain).

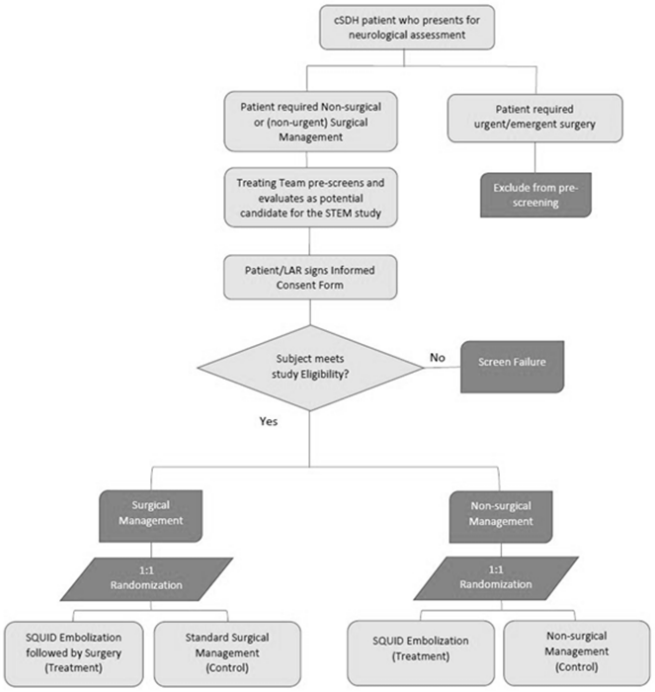
Note: SQUID has not been studied for use in patients with chronic subdural hematoma(s) who will be surgically treated by craniotomy.

After obtaining informed consent, eligible study subjects were divided into two cohorts (surgical management and non-surgical medical management (NSMM)) based on the clinical judgement of the treating team. The study stratified enrollment by patients that were treated with surgery, with and without adjunctive embolization (surgical cohort), and those that were treated with non-surgical medical management (NSMM), with and without adjunctive embolization (non-surgical cohort). Subjects requiring emergency surgery were excluded from the study.

Once assigned to a cohort, each subject was randomized 1:1 to the test or control arm. The control group received standard of care (SOC) treatment consisting of either surgical management alone (burr hole evacuation, Subdural Evacuating Port System (SEPS)) for the surgical cohort, or NSMM alone (medication management, observation, lifestyle modifications) for the non-surgical cohort. The test group received SOC treatment (surgery or NSMM) in addition to MMAE with SQUID. Subjects who were placed in the surgical cohort received SOC surgery within 48 hours of randomization. Subjects who were randomized to the test arm underwent MMAE within 24 hours of randomization (followed by SOC surgery within 48 hours of randomization, if applicable). Crossover was not permitted between the randomized arms.

A summary of patient enrollment and completion of clinical follow-up for each treatment arm is provided in **Figure 2**.

Figure 1: STEM Study Design



The primary effectiveness endpoint was treatment failure, defined by any of the following events:

1. Residual or re-accumulation of the SDH (≥10 mm) on 180-day scan from intervention; or
2. Re-operation (after index procedure) or surgical rescue within 180-days of intervention. (Re-operation or surgical rescue included cSDH drainage via any surgical procedure OR embolization of the MMA with any commercially available product); or
3. Any new, major disabling stroke, myocardial infarction (MI) or death from any neurological cause within 180-days of intervention.

Major disabling stroke is defined as an increase in the National Institutes of Health Stroke Scale (NIHSS) of 4 points or more from baseline that persists for 24 or more hours from the time of the event (Major stroke), AND results in the modified Rankin Scale (mRS) of 3 or greater at 90 days from the event (Disabling stroke). In this endpoint, re-operation or surgical rescue includes cSDH evacuation via any surgical procedure OR MMAE with any commercially available product on the index side (left, right, or bilateral) as designated at the time of screening. Success on both sides was required for bilateral cSDH.

The primary effectiveness endpoint assessed at the 180-day visit was the percentage of subjects who are considered treatment failures by meeting any of the listed components. The number and percentage of participants who are considered treatment failures are provided separately by all combinations of embolization (treatment arm) vs. non-embolization (control arm) and by stratum. The treatment arm and the control arm were compared using a Cochran-Mantel-Haenszel (CMH) test, where Non-surgical Management vs Surgical Management served as the stratification factor.

The Primary Safety endpoint was major disabling stroke or any death within 30-days from intervention. The primary safety endpoints were adjudicated by a clinical events committee and analyzed descriptively.

The primary safety analysis of the incidence of major disabling stroke or any death within 30 days from intervention is presented by treatment arm (aggregated across and within each of the surgical management and non-surgical management strata). 95% confidence intervals are presented for the incidence in each arm and for the difference between treatment arms (aggregated across and within strata).

An independent imaging core laboratory provided a standardized assessment of imaging collected during this study and all subjects were followed for one year post randomization.

The clinical secondary effectiveness endpoint evaluated the mRS (analyzed as shift) at 180-days from intervention. The 'shift' analysis evaluated the entire range of the mRS at a visit (all 7 levels: 0 = no symptoms at all, 1 = no significant disability, 2 = slight disability, 3 = moderate disability, 4 = moderately severe disability, 5 = severe disability, and 6 = death) unlike the binary mRS analysis which classifies the 7 levels into two groups (<2 and 2). Treatments were compared using a van Elteren test.

Subject Disposition

At the time of database lock, of 319 patients enrolled in the STEM study, including 149 test patients, 161 control patients, and 9 screen failures. Study disposition for the study population provides a summary of subject disposition and analysis populations by treatment arm in **Figure 2.** The intent to treat population (ITT) includes all subjects who signed informed consent and were randomized and this population analyzed subjects per their assigned treatment. Primary and secondary effectiveness analyses used the (modified intent-to-treat) mITT analysis population which is a subset of the ITT population, only including those ITT subjects that had their assigned intervention started. Intervention start was defined as time of wrist/groin puncture for subjects randomized to SQUID or SQUID plus surgery groups, for surgical only subjects, intervention start was, knife to skin time; and for non-surgical management, intervention start was considered time of randomization. Safety analyses used the safety population which includes all subjects who signed the informed consent and were randomized and analyzed subjects per the treatment received.

The safety population and ITT population both include a total of 310 subjects and the mITT population includes 303 subjects.

Inclusion Criteria

Male and female subjects who met the following criteria were given consideration for inclusion in the study, provided that no exclusion criterion was met:

- Subject age ≥ 30 at the time of consent.
- Pre-morbid mRS 0-1 within the previous 12 months
- cSDH measures ≥ 10 mm in greatest thickness
- cSDH exerts mass effect upon the subjacent brain as indicated by local cortical flattening or midline shift
- Imaging characteristics indicative of chronicity (≥ 50% of the volume of the collection should be isodense or hypodense to normal cortical gray matter on Computed Tomography (CT))
- Subject presents with one or more of the following neurological symptoms:
    - Headache
    - Cognitive decline
    - Speech difficulty or aphasia
    - Gait impairment or imbalance
    - Focal neurological deficit (weakness, paresthesia or sensory deficit involving of one or more extremities or facial droop) and/or Seizure
- Subject, or his/her legally authorized representative, understands the nature of the procedure, consents to participation in the study and provides a signed Informed Consent Form
- Female Subjects of child-bearing potential must be able to provide a current negative urine pregnancy test and agree to an appropriate method of contraception throughout the trial
- Subject is able and willing to return to the investigational site for all follow-up visits (e.g., 30-day, 90-day, 180-day and 1-year), as required per protocol.

Exclusion Criteria

Subjects who met any of the following criteria were to be excluded from the study:

- Subject with prior ipsilateral craniotomy or burr hole evacuation of cSDH
- Subject with prior Embolization of either MMA
- Subject requires (in the opinion of the treating surgeon) a full or mini craniotomy.
- Subject with urgent or emergent (within 1 hour of assessment) subdural hematoma evacuation needed
- Subject with a cSDH with a focal location (confined to the frontal or temporal base or the inter-hemispheric space without cerebral convexity involvement)
- cSDH developed due to underlying condition such as a vascular lesion, brain tumor, arachnoid cyst, spontaneous intracranial hypotension or secondary to a previous craniotomy
- Life expectancy of <1 year
- Subject who presents with an intracranial mass other than subdural hematoma
- Subject who presents with a meningioma with mass effect and/or ≥ 1 cm or currently undergoing radiation therapy for carcinoma or sarcoma of the head or neck region
- Subject with serum creatinine level > 3.0 mg/dL at time of enrollment (this will restrict the use of contrast) and not on dialysis
- Subject with significant liver function impairment at time of enrollment
- Subject with a life-threatening allergy to radiographic contrast (unless treatment for allergy is tolerated or can be managed medically)
- Subject who is currently enrolled in another investigational study protocol that could potentially confound the current study endpoints

Figure 2: Subject Disposition Summary by Treatment Arm

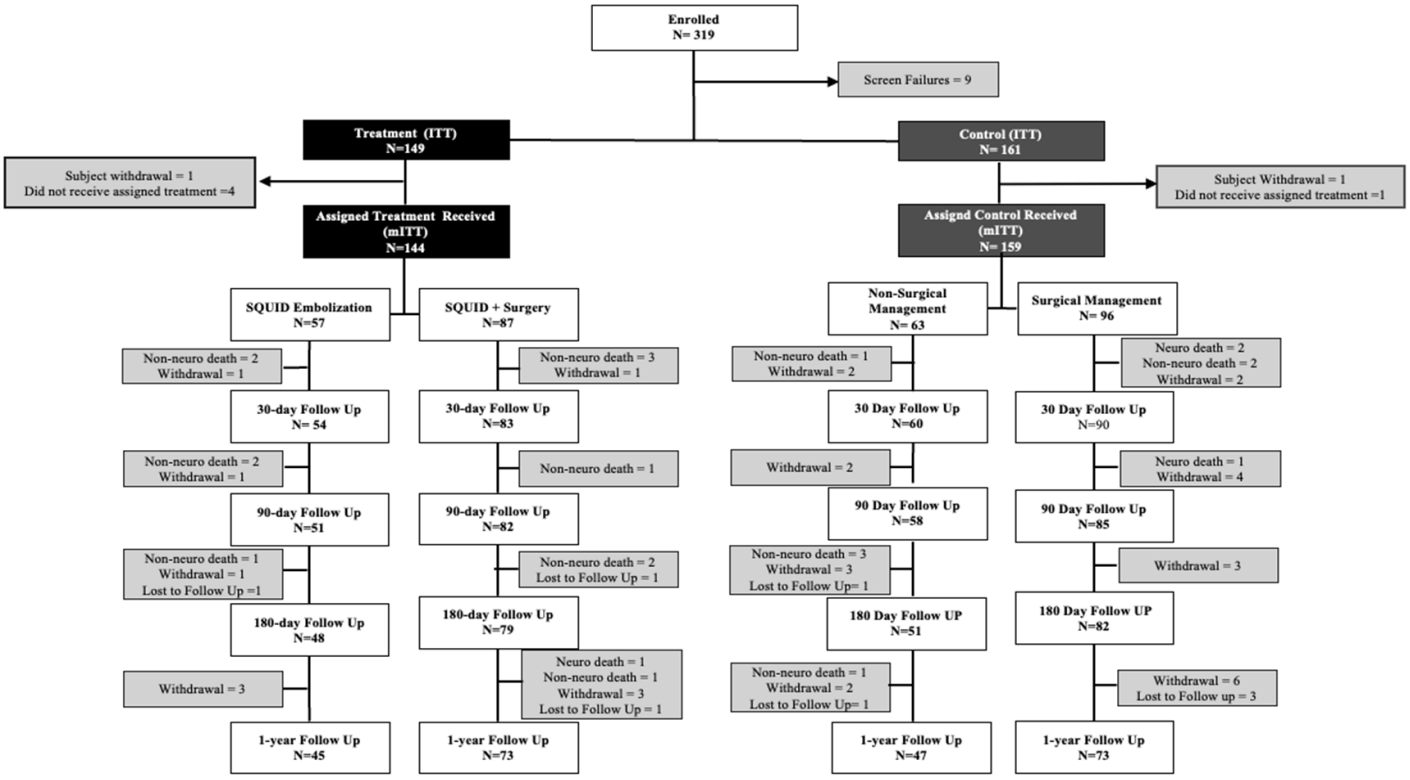


Table 1: Table: Study Compliance at the 180-Day Primary Endpoint Visit (mITT Population)

	Treatment		Control	
	SQUID + NSMM	**SQUID + Surgery**	**NSMM alone**	**Surgery alone**
Total ITT Subjects	**149**		**161**	
Total mITT Subjects[1]	**57**	**87**	**63**	**96**
Non-Eligible or Non-Evaluable for 180-Day Follow-up	12	16	17	26
Death prior to 180-Day Follow-up	5	6	4	5
Lost to Follow-up	1	1	1	0
Withdrawal prior to 180-Day Follow-up	3	1	7	9
Eligible but not Evaluable	3	8	5	12
Reason for non-evaluable: Missed Visit	2	5	3	10
Reason for non-evaluable: No Imaging	1	3	2	2
Eligible for 180-Day Follow-up	48	79	51	82
180-day Follow-up Visit Completed	46	74	47	69
Missed Visit	2	5	4	13
Eligible with Evaluable observed data at 180-day Visit*	45[2]	71	46	70
Had event prior to visit (Evaluable)*	1[2]	0	4[3]	3[4]
Subjects evaluable for primary endpoint*	**46**	**71**	**50**	**73**
Subjects imputed for the primary endpoint	11	16	13	23
Total subjects used in primary endpoint analysis (including imputed data)	**57**	**87**	**63**	**96**

[1]Total mITT patients excludes 1 test subject and 1 control subject who withdrew from the study prior to intervention starting, and 4 test subjects and 1 control subject who did not receive the assigned treatment based on clinical judgment of patient conditions at the time of index procedure as depicted in **Figure 2**.

[2]One test subject in the NSMM cohort exited early due to a misunderstanding of the required timeframe for follow up after meeting a primary endpoint criterion. This patient is considered evaluable since they had a primary endpoint failure despite not completing the 180-day visit.

[3]Two control (NSMM cohort) subjects died and two subjects were withdrawn after meeting primary endpoint criterion, all prior to the visit window. These patients are considered evaluable since they had a primary endpoint failure despite not completing the 180-day visit.

[4]Three control (surgery cohort) subjects died, one of which occurred after meeting primary endpoint criterion 2, all prior to the visit window. These patients are considered evaluable since they had a primary endpoint failure despite not completing the 180-day visit.

*Total evaluable for the primary endpoint is the sum of the "Eligible with Evaluable observed data at 180-day Visit" and "Had event prior to visit (Evaluable)" rows.

Subject baseline demographics and characteristics are summarized below **(Tables 2 – 4).** The study population was predominantly male (69.7%), enrolled in the United States (84.2%) and with a mean age of 73 years. The US population was predominantly white (68.7%) and non-Hispanic or Latino (76.8%). Mean BMI was >25 kg/m2 indicating an overweight population in both treatment and control groups.

Table 2: Patient Demographics and Baseline Characteristics (ITT Population)

	Treatment			Control			
Parameter	**SQUID + NSMM (N=58)**	**SQUID + Surgery (N=91)**	**Treatment Total (N=149)**	**NSMM alone (N=63)**	**Surgery alone (N=98)**	**Control Total (N=161)**	**Total (N=310)**
Country							
United States	51 (87.9%)	77 (84.6%)	128 (85.9%)	55 (87.3%)	78 (79.6%)	133 (82.6%)	261 (84.2%)
France	4 (6.9%)	8 (8.8%)	12 (8.1%)	6 (9.5%)	11 (11.2%)	17 (10.6%)	29 (9.4%)
Germany	3 (5.2%)	4 (4.4%)	7 (4.7%)	2 (3.2%)	6 (6.1%)	8 (5.0%)	15 (4.8%)
Spain	0 (0.0%)	2 (2.2%)	2 (1.3%)	0 (0.0%)	3 (3.1%)	3 (1.9%)	5 (1.6%)
Age (years)	74.2 ± 9.84 (58)	72.0 ± 10.63 (91)	72.8 ± 10.35 (149)	72.2 ± 12.66 (63)	74.2 ± 10.35 (98)	73.4 ± 11.31 (161)	73.1 ± 10.85 (310)
Gender							
Male	39 (67.2%)	58 (63.7%)	97 (65.1%)	46 (73.0%)	73 (74.5%)	119 (73.9%)	216 (69.7%)
Female	19 (32.8%)	33 (36.3%)	52 (34.9%)	17 (27.0%)	25 (25.5%)	42 (26.1%)	94 (30.3%)
Race[1]							
Native American or Alaskan Native	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Asian	2 (3.4%)	7 (7.7%)	9 (6.0%)	2 (3.2%)	5 (5.1%)	7 (4.3%)	16 (5.2%)
Black or African American	4 (6.9%)	4 (4.4%)	8 (5.4%)	5 (7.9%)	10 (10.2%)	15 (9.3%)	23 (7.4%)
Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
White	43 (74.1%)	62 (68.1%)	105 (70.5%)	46 (73.0%)	62 (63.3%)	108 (67.1%)	213 (68.7%)
Unknown	2 (3.4%)	3 (3.3%)	5 (3.4%)	1 (1.6%)	2 (2.0%)	3 (1.9%)	8 (2.6%)
N/A, EU Subject	7 (12.1%)	14 (15.4%)	21 (14.1%)	8 (12.7%)	20 (20.4%)	28 (17.4%)	49 (15.8%)
Other	0 (0.0%)	2 (2.2%)	2 (1.3%)	1 (1.6%)	0 (0.0%)	1 (0.6%)	3 (1.0%)
Ethnicity							
Hispanic or Latino	6 (10.3%)	5 (5.5%)	11 (7.4%)	7 (11.1%)	1 (1.0%)	8 (5.0%)	19 (6.1%)
Not Hispanic or Latino	43 (74.1%)	71 (78.0%)	114 (76.5%)	48 (76.2%)	76 (77.6%)	124 (77.0%)	238 (76.8%)
N/A, EU Subject	7 (12.1%)	14 (15.4%)	21 (14.1%)	8 (12.7%)	20 (20.4%)	28 (17.4%)	49 (15.8%)
Unknown	2 (3.4%)	1 (1.1%)	3 (2.0%)	0 (0.0%)	1 (1.0%)	1 (0.6%)	4 (1.3%)
Weight (kg)	78.1 ± 19.12 (58)	76.5 ± 15.81 (91)	77.1 ± 17.13 (149)	80.6 ± 19.19 (63)	79.0 ± 16.05 (98)	79.6 ± 17.31 (161)	78.4 ± 17.24 (310)
Height (cm)	171.9 ± 8.89 (58)	171.6 ± 8.73 (91)	171.7 ± 8.76 (149)	173.5 ± 11.19 (63)	172.1 ± 10.30 (98)	172.7 ± 10.64 (161)	172.2 ± 9.78 (310)
BMI	26.3 ± 5.25 (58)	25.9 ± 4.55 (91)	26.0 ± 4.82 (149)	26.7 ± 5.03 (63)	26.5 ± 4.55 (98)	26.6 ± 4.73 (161)	26.3 ± 4.78 (310)
Smoking History							
Current Smoker	8 (13.8%)	7 (7.7%)	15 (10.1%)	9 (14.3%)	5 (5.1%)	14 (8.7%)	29 (9.4%)
Previous Smoker	19 (32.8%)	37 (40.7%)	56 (37.6%)	18 (28.6%)	28 (28.6%)	46 (28.6%)	102 (32.9%)
Never Smoked	31 (53.4%)	47 (51.6%)	78 (52.3%)	36 (57.1%)	65 (66.3%)	101 (62.7%)	179 (57.7%)
Addiction - Alcohol	5 (8.6%)	12 (13.2%)	17 (11.4%)	4 (6.3%)	11 (11.2%)	15 (9.3%)	32 (10.3%)
Ongoing use	0 (0.0%)	8 (8.8%)	8 (5.4%)	4 (6.3%)	5 (5.1%)	9 (5.6%)	17 (5.5%)

	Treatment			Control			
Parameter	**SQUID + NSMM (N=58)**	**SQUID + Surgery (N=91)**	**Treatment Total (N=149)**	**NSMM alone (N=63)**	**Surgery alone (N=98)**	**Control Total (N=161)**	**Total (N=310)**
Addiction - Drugs/Other Substance Abuse (includes use of marijuana)	4 (6.9%)	6 (6.6%)	10 (6.7%)	2 (3.2%)	4 (4.1%)	6 (3.7%)	16 (5.2%)
Ongoing use	2 (3.4%)	6 (6.6%)	8 (5.4%)	1 (1.6%)	3 (3.1%)	4 (2.5%)	12 (3.9%)
Prior Stroke	1 (1.7%)	1 (1.1%)	2 (1.3%)	2 (3.2%)	0 (0.0%)	2 (1.2%)	4 (1.3%)
Anti-coagulant, Anti-platelet, and Steroid Use							
Aspirin	13 (22.4%)	16 (17.6%)	29 (19.5%)	11 (17.5%)	17 (17.3%)	28 (17.4%)	57 (18.4%)
Heparin	0 (0.0%)	2 (2.2%)	2 (1.3%)	2 (3.2%)	6 (6.1%)	8 (5.0%)	10 (3.2%)
Thienopyridines	3 (5.2%)	4 (4.4%)	7 (4.7%)	5 (7.9%)	3 (3.1%)	8 (5.0%)	15 (4.8%)
Warfarin/Other Vitamin K Antagonist	4 (6.9%)	6 (6.6%)	10 (6.7%)	5 (7.9%)	6 (6.1%)	11 (6.8%)	21 (6.8%)
Other – ASA-dipyridamole	0 (0.0%)	2 (2.2%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.6%)
Other – NOAC/DOAC	1 (1.7%)	5 (5.5%)	6 (4.0%)	7 (11.1%)	5 (5.1%)	12 (7.5%)	18 (5.8%)
Total (on one or more anti-coagulant/antiplatelet medications)	21 (36.2%)	35 (38.5%)	56 (37.6%)	30 (47.6%)	37 (37.8%)	67 (41.6%)	123 (39.7%)
Total (on one or more) steroid medications	7 (12.1%)	6 (6.6%)	13 (8.7%)	12 (19.0%)	6 (6.1%)	18 (11.2%)	31 (10.0%)

Note: continuous data displayed as mean ± SD (n); categorical data displayed as n/N (%), the number and percentage of participants with that particular response. The Total row is reporting the number and percentage of participants on one or more anticoagulant/antiplatelet.

[1]Subjects may indicate more than one race.

[2] Race and ethnicity data was captured only for the US population as privacy laws do not allow collection of this information in the EU population.

Table 3: Baseline cSDH Clinical Characteristics – Site Reported (ITT population)

	Treatment (N=149)	**Control (N=161)**
Anatomic Side of cSDH		
Bilateral	26/149 (17.4%)	37/161 (23.0%)
Unilateral - Left Side	57/149 (38.3%)	52/161 (32.3%)
Unilateral - Right Side	66/149 (44.3%)	72/161 (44.7%)
Unilateral - Total	123/149 (82.6%)	124/161 (77.0%)
cSDH Thickness, mm[1]		
Left	18.0 ± 5.83 (82)	18.3 ± 6.33 (89)
Right	18.3 ± 6.22 (91)	17.7 ± 6.33 (109)
Density of cSDH[1,2]		
Left		
≥50% Isodense or Hypodense	82/82 (100.0%)	89/89 (100.0%)
Right		
≥50% Isodense or Hypodense	90/90 (100.0%)	108/108 (100.0%)

	Treatment (N=149)	Control (N=161)
cSDH Clinical Presentation[3]		
Headache	98/149 (65.8%)	95/161 (59.0%)
Cognitive decline	43/149 (28.9%)	48/161 (29.8%)
Speech difficulty or Aphasia	26/149 (17.4%)	41/161 (25.5%)
Gait impairment or imbalance	72/149 (48.3%)	77/161 (47.8%)
Focal neurological deficit (weakness, paresthesia, sensory deficit involving of one or more extremities or facial droop)	60/149 (40.3%)	63/161 (39.1%)
Seizure	7/149 (4.7%)	9/161 (5.6%)
Other	43/149 (28.9%)	42/161 (26.1%)
NIHSS	1.49 ± 2.619 (142)	1.68 ± 2.340 (154)
mRS	1.57 ± 1.284 (148)	1.58 ± 1.297 (161)

Note: continuous data displayed as mean ± SD (n); categorical data displayed as n/N (%), the number and percentage of participants with that particular response.
[1]Thickness and density measurements include measurements for both sides for bilateral subjects.
[2]Percentage calculated out of number of subjects with that target side.
[3]Subjects may have more than one symptom.

Table 4: Treatment and Procedure Characteristics – Treatment Subjects (Safety Population)

	Treatment	
Characteristic	**SQUID + NSMM (N=57)**	**SQUID + Surgery (N=87)**
Anatomic Side (target)		
Bilateral	10/57 (17.5%)	16/87 (18.4%)
Unilateral	47/57 (82.5%)	71/87 (81.6%)
Anatomic Side (target with embolization)		
Bilateral	25/57 (43.9%)	21/86 (24.4%)
Unilateral	32/57 (56.1%)	65/86 (75.6%)
Surgical Procedure Type		
Burr-hole Evacuation		76/87 (87.4%)
SEPS		10/87 (11.5%)
Other		1/87 (1.1%)
Total Embolization time[1] (minutes)	82.3 ± 40.21 (57)	79.3 ± 43.32 (87)
Total Surgical time (minutes)		51.8 ± 35.58 (86)
Anesthesia (Embolization)		
Conscious Sedation/Local Anesthesia	2/57 (3.5%)	7/87 (8.0%)

Characteristic	Treatment	
	SQUID + NSMM (N=57)	SQUID + Surgery (N=87)
General Anesthesia	55/57 (96.5%)	80/87 (92.0%)
Anesthesia (Surgery)		
Conscious Sedation/Local Anesthesia		3/87 (3.4%)
General Anesthesia		84/87 (96.6%)
Target Vessel Location[2]		
Posterior Middle Meningeal Artery Branch 1	37/57 (64.9%)	50/87 (57.5%)
Posterior Middle Meningeal Artery Branch 2	13/57 (22.8%)	15/87 (17.2%)
Anterior Middle Meningeal Artery Branch 1	47/57 (82.5%)	60/87 (69.0%)
Anterior Middle Meningeal Artery Branch 2	20/57 (35.1%)	12/87 (13.8%)
Duration of SQUID Injection[3]		
<1 minute	41/123 (33.3%)	46/162 (28.4%)
1-5 minutes	68/123 (55.3%)	80/162 (49.4%)
>5 minutes	14/123 (11.4%)	36/162 (22.2%)
SQUID Product Formulation[2]		
SQUID 12	35/57 (61.4%)	56/87 (64.4%)
SQUID 12LD	0/57 (0.0%)	2/87 (2.3%)
SQUID 18	36/57 (63.2%)	39/87 (44.8%)
SQUID 18LD	0/57 (0.0%)	1/87 (1.1%)
SQUID 34	0/57 (0.0%)	0/87 (0.0%)
SQUID 34LD	1/57 (1.8%)	0/87 (0.0%)
cSDH evacuation adequate (yes)		84/86 (97.7%)
Access Site[2]		
Radial Artery	21/57 (36.8%)	35/87 (40.2%)
Femoral Artery	37/57 (64.9%)	53/87 (60.9%)

Note: continuous data displayed as mean ± SD (n); categorical data displayed as n/N (%), the number and percentage of participants with that particular response.
[1]Some subjects had non-target side treated with SQUID and that is included in the total embolization time.
[2]Subjects could be counted in more than one category.
[3]Based on total number of injections.

Technical Results

In the embolization group, middle meningeal artery embolization was attempted in 144 of 149 patients (97%), and the procedure was technically successful in 142 of 144 patients (99%). The mean duration of the embolization procedure was approximately 80 minutes in both the surgical stratum and the nonsurgical stratum. Among the 189 patients who were to receive surgical standard treatment, 187 (99%) underwent surgical drainage. Most patients in the surgical stratum underwent burr-hole evacuation (166 of 187 patients [89%]) or SEPS drainage (14 of 187 patients [7%]); the mean duration of the surgical procedure was approximately 50 minutes.

Primary Effectiveness Endpoint Results

The study met its pre-specified primary effectiveness endpoint. Adjunctive middle meningeal artery (MMA) embolization with SQUID (treatment arm) reduced the failure rate of standard management alone (control arm) in subjects with symptomatic chronic SDH. In the mITT population, the failure rate in the control arm was 38.2% (47 failures in 123 evaluable patients) versus 16.2% (19 failures in 117 evaluable

patients) in the treatment arm resulting in an odds ratio of 0.36 (p = 0.0010) (**Table 5**).

A pre-specified exploratory analysis of the composite primary endpoint within each strata (surgical and non-surgical management), was performed. In the non-surgical management stratum, the failure rate in the control group was 58.0% (29 failures in 50 evaluable patients) versus 19.6% (9 failures in 46 patients) in the SQUID group. In the surgical management stratum, the failure rate in the control group was 24.7% (18 failures in 73 evaluable patients) versus 14.1% (10 of 71 evaluable patients) in the adjunctive SQUID group (**Table 5**)**.** As shown in Table 5, this exploratory analysis resulted in an odds ratio of 0.21 (95% CI: 0.09, 0.50) in the NSMM cohort and an odds ratio of 0.56 (95% CI: 0.25, 1.28) in the surgical cohort, where the NSMM cohort demonstrated a more favorable trend compared to the control than that of the surgical cohort when considering the primary effectiveness endpoint.

Components of primary effectiveness endpoints are shown in **Table 6**.

Table 5: Primary Endpoint Failures (mITT population)

	Observed Data		Treatment Effect	
	Treatment (N=144)	**Control (N=159)**	**Odds Ratio [95% CI]**	**P-value**
Primary effectiveness outcome	19/117 (16.2%)	47/123 (38.2%)	0.36 [0.20, 0.65]	0.0010
Non-surgical Management Strata	9/46 (19.6%)	29/50 (58.0%)	0.21 [0.09, 0.50]	
Surgical Management Strata	10/71 (14.1%)	18/73 (24.7%)	0.56 [0.25, 1.28]	

CI=Confidence interval.
Based on multiple imputation methods.

Table 6: Components of Effectiveness Endpoint (mITT population)

	Treatment		Control	
	SQUID + NSMM (N=57)	**SQUID + Surgery (N=87)**	**NSMM alone (N=63)**	**Surgery alone (N=96)**
Primary Effectiveness endpoint at 180-day visit	9/46 (19.6%)	10/71 (14.1%)	29/50 (58.0%)	18/73 (24.7%)
Missing data, n	11	16	13	23
Primary Endpoint Component				
Residual or re-accumulation of the SDH (≥10 mm) on scan at the 180-day visit	2/46 (4.3%)	2/71 (2.8%)	1/50 (2.0%)	3/73 (4.1%)
Re-operation (after index procedure) or surgical rescue within 180-days of intervention*	7/46 (15.2%)	5/71 (7.0%)	27/50 (54.0%)	12/73 (16.4%)
Any new major disabling stroke, myocardial infarction (MI) or death from any neurological cause within 180 days of intervention*	0/46 (0.0%)	3/71 (4.2%)	1/50 (2.0%)	3/73 (4.1%)

Note: Rate for individual components only includes subjects whose first failure was for that component (i.e. if they failed multiple components they are only included as a failure in the first component they failed).
*Based on treatments or events through the 180-day visit window close (222 days).

In the overall cohort and within each primary management stratum (surgery and non-surgery), the rates of primary endpoint failure in treatment group (SQUID adjunctive to standard management) were lower than in the respective control group (standard management alone). In all groups, the vast majority of re-interventions occurred within 30 days, and re-intervention after 90 days was very rare. Figures 3 and 4 show Kaplan-Meier analyses of time to re-intervention (i.e., corresponding to primary endpoint failure component "*Re-operation (after index procedure) or surgical rescue within 180-days of intervention*").

Figure 3: Kaplan-Meier Analysis of Time to Re-Intervention Post-Randomization by Randomized Treatment

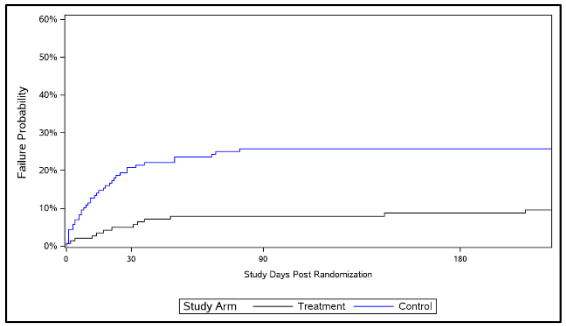
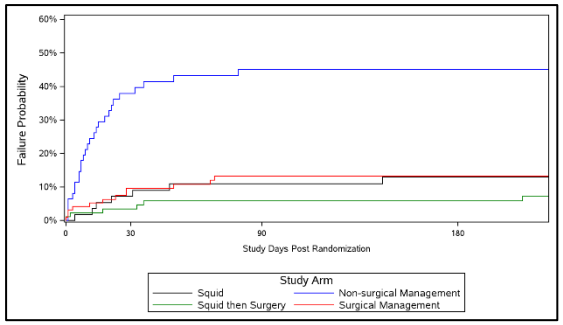


Figure 4: Kaplan-Meier Analysis of Time to Re-Intervention Post-Randomization by Randomized Treatment and Surgical Strata



A prespecified hypothesis driven secondary effectiveness endpoint was conducted for mRS shift. When compared across the entire spectrum of mRS scores, there was no evidence of a difference in the distribution of mRS scores between treatment arms (p=0.6524).

Table 7: Secondary Effectiveness Endpoint mRS Shift Analysis at 180-day Visit (mITT Population)

mRS Value	Treatment (N=144)	Control (N=159)	Total (N=303)
0	57/117 (48.7%)	53/116 (45.7%)	110/233 (47.2%)
1	31/117 (26.5%)	39/116 (33.6%)	70/233 (30.0%)
2	10/117 (8.5%)	4/116 (3.4%)	14/233 (6.0%)
3	5/117 (4.3%)	9/116 (7.8%)	14/233 (6.0%)
4	2/117 (1.7%)	2/116 (1.7%)	4/233 (1.7%)
6	12/117 (10.3%)	9/116 (7.8%)	21/233 (9.0%)
Van-Elteren Test P-value (stratified) = 0.6524			
Wilcoxon rank-sum P-value (non-stratified) = 0.6583			
P-values based on multiple imputation methods. n/N (X.x%): denominator is subjects in that arm with an available mRS at 180 days. If subject died prior to the visit and mRS missing then set as a 6 in this analysis.			

Primary Safety Endpoint Events

The primary safety endpoint events (major disabling stroke or any death within 30-days) are presented by treatment and control arm in **Table 8** and by strata in **Table 9**. There were no significant differences between groups in the rate of primary safety events, with the confidence for the between-group difference in rates including zero in all cases **(Table 8 and Table 9).**

Table 8: Primary Safety Endpoint Events (CEC Adjudicated) [Safety Population]

	Treatment (N=144)		Control (N=166)		
	n (%)	95% Exact CI	n (%)	95% Exact CI	Difference [95% Exact CI]
Major disabling stroke or any death within 30-days, from intervention	4 (2.8%)	0.8%, 7.0%	5 (3.0%)	1.0%, 6.9%	-0.2% [-4.5%, 4.4%]
Major disabling stroke within 30-days	0 (0.0%)	0.0%, 2.5%	1 (0.6%)	0.0%, 3.3%	-0.6% [-3.4%, 2.0%]
Any death within 30-days	4 (2.8%)	0.8%, 7.0%	5 (3.0%)	1.0%, 6.9%	-0.2% [-4.5%, 4.4%]
Overall rate based on first failure only. Note: Data displayed as n (%), the number and percentage of participants with a primary safety event.					

Table 9: Primary Safety Endpoint Events by Treatment arm and strata (CEC Adjudicated) [Safety Population]

	Treatment (N=144)				Control (N=166)					
	SQUID + NSMM (N=57)		SQUID + Surgery (N=87)		NSMM alone (N=66)		Surgery alone (N=100)		Difference [95% Exact CI]	
	n (%)	95% Exact CI	n (%)	95% Exact CI	n (%)	95% Exact CI	n (%)	95% Exact CI	[SQUID + NSMM] - [NSMM alone]	[SQUID + Surgery] - [Surgery alone]
Major disabling stroke or any death within 30-days, from intervention	2 (3.5%)	0.4%, 12.1%	2 (2.3%)	0.3%, 8.1%	1 (1.5%)	0.0%, 8.2%	4 (4.0%)	1.1%, 9.9%	2.0% [-5.1%, 10.9%]	-1.7% [-8.0%, 4.6%]
Major disabling stroke within 30-days	0 (0.0%)	0.0%, 6.3%	0 (0.0%)	0.0%, 4.2%	0 (0.0%)	0.0%, 5.4%	1 (1.0%)	0.0%, 5.5%	NA	-1.0% [-5.5%, 3.3%]
Any death within 30-days	2 (3.5%)	0.4%, 12.1%	2 (2.3%)	0.3%, 8.1%	1 (1.5%)	0.0%, 8.2%	4 (4.0%)	1.1%, 9.9%	2.0% [-5.1%, 10.9%]	-1.7% [-8.0%, 4.6%]
The Safety Population consists of all randomized subjects analyzed by treatment actually received. Overall rate based on first failure only. Note: Data displayed as n (%), the number and percentage of participants with a primary safety event.										

Primary Safety Events through 180-Days

Table 10 summarizes the CEC-adjudicated primary safety endpoint events by treatment and control groups through the 180-day follow-up window and **Table 11** by treatment group and strata. Confidence intervals for the differences in event rates all included zero. Twelve (12) additional deaths occurred in the subject population between 30 days through the 180-day window, equating to 21 deaths in total. None of the additional deaths were adjudicated as neurological by the CEC. Three (3) additional major disabling strokes occurred between 30 and 180-days, 2 in the treatment arm (both in SQUID plus surgery subjects) and 1 additional in the control arm (non-surgical subject).

Table 10: Primary Safety Endpoint Events at 180-Days*: CEC Adjudicated (Safety Population)

	Treatment (N=144)		Control (N=166)		
	n (%)	95% Exact CI	n (%)	95% Exact CI	Difference [95% Exact CI]
Major disabling stroke or any death within 180-days, from intervention	13 (9.0%)	4.9%, 14.9%	10 (6.0%)	2.9%, 10.8%	3.0% [-3.1%, 9.6%]

	Treatment (N=144)		Control (N=166)		
	n (%)	95% Exact CI	n (%)	95% Exact CI	Difference [95% Exact CI]
Major disabling stroke within 180-days	2 (1.4%)	0.2%, 4.9%	2 (1.2%)	0.2%, 4.3%	0.2% [-3.2%, 3.9%]
Any death within 180-days	12 (8.3%)	4.4%, 14.1%	9 (5.4%)	2.5%, 10.0%	2.9% [-2.9%, 9.3%]

*All events through the close of the 180-day visit window are included, i.e., 222 days.
Overall rate based on first failure only.
Note: Data displayed as n (%), the number and percentage of participants with a primary safety event.

Table 11: Primary Safety Endpoint Events through 180-Day Follow-up* by Treatment arm and Strata (CEC adjudicated) [Safety Population]

	Treatment (N=144)				Control (N=166)				
	SQUID + NSMM (N=57)		SQUID + Surgery (N=87)		NSMM alone (N=66)		Surgery alone (N=100)		Difference [95% Exact CI]
	n (%)	95% Exact CI	n (%)	95% Exact CI	n (%)	95% Exact CI	n (%)	95% Exact CI	[SQUID + NSMM] - [NSMM alone] / [SQUID + Surgery] - [Surgery alone]
Major disabling stroke or any death within 180-days, from intervention	5 (8.8%)	2.9%, 19.3%	8 (9.2%)	4.1%, 17.3%	5 (7.6%)	2.5%, 16.8%	5 (5.0%)	1.6%, 11.3%	1.2% [-9.3%, 12.5%] / 4.2% [-3.4%, 12.9%]
Major disabling stroke within 180-days	0 (0.0%)	0.0%, 6.3%	2 (2.3%)	0.3%, 8.1%	1 (1.5%)	0.0%, 8.2%	1 (1.0%)	0.0%, 5.5%	-1.5% [-8.2%, 5.0%] / 1.3% [-3.5%, 7.4%]
Any death within 180-days	5 (8.8%)	2.9%, 19.3%	7 (8.0%)	3.3%, 15.9%	4 (6.1%)	1.7%, 14.8%	5 (5.0%)	1.6%, 11.3%	2.7% [-7.7%, 14.2%] / 3.0% [-4.4%, 11.6%]

*All events through the close of the 180-day visit window are included, i.e., 222 days.
The Safety Population consists of all randomized subjects analyzed by treatment actually received.
Overall rate based on first failure only.
Note: Data displayed as n (%), the number and percentage of participants with a primary safety event.

Adverse Events through 180 days

Device- and embolization procedure-related adverse events (AEs) and serious AEs (SAEs) through 180 days are shown in **Table 12**. Neurologic deaths and neurologic events of interest through 180 days are shown in **Table 13**.

The 180-day rate of SAEs related to the embolization procedure alone was 5.6% (8/144), and the 180-day rate of SAEs related to SQUID was 1.4% (2/144). The overall rates of AEs and SAEs through 180 days in the treatment arm (SQUID + SOC) were 75% (108/144) and 63.2% (91/144), respectively. Worsening of subdural hematoma was the most reported AE in the treatment arm and occurred in 18/144 (12.5%) subjects.

The overall rates of AEs and SAEs through 180 days for the control arm (SOC alone) were 66.9% (111/166) and 44.0% (73/166), respectively. The most frequently reported SAE in the control arm was worsening subdural hematoma occurring in 40/166 (24.1%) subjects.

Neurologic death occurred in 0.7% (1/144) of treatment arm subjects and 1.8% (3/166) of control arm subjects.

Table 12: Overall Incidence of AEs by Seriousness and Relation Through 180 Days (Safety Population)

Relatedness*	Treatment Arm n/N (%)	Control Arm n/N (%)
All AEs (including SAEs, non-SAEs) through 180 days	108/144 (75.0%)	111/166 (66.9%)
Non-SAEs	54/144 (37.5%)	65/166 (39.2%)
SAEs	91/144 (63.2%)	73/166 (44.0%)
SAEs Related to Embolization Procedures through 180 days	8/144 (5.6%)	Not Applicable
SAEs Related to SQUID through 180 days	2/144 (1.4%)	Not Applicable
Non-SAEs Related to SQUID through 180 days	4/144 (2.8%)	Not Applicable
Unintended Vessel Occlusion	0/144 (0.0%)	Not Applicable
Catheter Entrapment	1/144 (0.7%)	Not Applicable
Access Site Complications	2/144 (1.4%)	Not Applicable
Unintended SQUID Migration	0/144 (0.0%)	Not Applicable
Worsening SDH	18/144 (12.5%)	40/166 (24.1%)

Note: Data presented as the number and percentage of subjects in which the event occurred. More than one event may have occurred in a given subject
*Device and procedure relatedness was adjudicated by CEC if available, otherwise by investigational sites.
An event was considered related to the device or procedure if it was adjudicated as "possibly," "probably," or "causally" related.

Table 13: Neurologic Death and Neurologic Events of Interest through 180 Days (Safety Population)

	Treatment Arm	Control Arm
	SQUID + SOC	SOC Alone
Death Classification and Relatedness1	n/N (%)*	n/N (%)*
All Neurologic Deaths[1]	1/144 (0.7%)	3/166 (1.8%)
Related to Study Device[1]	0/144 (0.0%)	0/166 (0.0%)
Related to Embolization Procedure[1]	0/144 (0.0%)	N/A
Related to Surgery Procedure[1,2]	0/144 (0.0%)	N/A
Other[3]	1/144 (0.7%)	3/166 (1.8%)
Neurologic Events of Interest[1]	n/N (%) [# events]*	n/N (%) [# events]*
Stroke[1]	9/144 (6.3%) [9]	7/166 (4.2%) [7]
Cerebral Infarction	0/144 (0.0%) [0]	1/166 (0.6%) [1]
Serious Intracranial Hemorrhage	1/144 (0.7%) [1]	1/166 (0.6%) [1]
New onset of seizures	13/144 (9.0%) [13]	6/166 (3.6%) [6]
TIA	2/144 (1.4%) [3]	1/166 (0.6%) [1]

*Data presented as the number and percentage of subjects in which the event occurred [with total number of events for neurologic events of interest].
[1] Neurological deaths and relatedness, and stroke and relatedness, were adjudicated by the Clinical Events Committee (CEC), and all other events were site reported.
[2]Denominator is based on the number of patients receiving surgery.
[3]Other relatedness is defined as relatedness not pertaining to study device, embolization procedure, or surgery procedure.

Adverse Events through 1 year

Site reported adverse events (AEs) and serious adverse events (SAEs) experienced by the embolized (treatment) group through 1 year are presented by MedDRA System Organ Class (SOC) and Preferred Term (PT) in **Table 14** and the control group in **Table 15.**

A total of 113 SAEs were experienced in 61 subjects in the treatment arm (25 SAEs in SQUID subjects and 88 events in SQUID plus surgery subjects) (**Table 14**). A total of 127 SAEs were experienced in 72 subjects in the control group (**Table 15**). The most frequently reported SAE in the treatment group was worsening of subdural hematoma with 18 total events (7 events in SQUID, 11 in SQUID plus surgery). Worsening of subdural hematoma was also the most reported AE in the treatment group (22 total events in 18 subjects), with 8 events occurring in the SQUID strata and 14 events in the SQUID plus surgery strata (**Table 16**). Similarly, in the control group, subdural hematoma SAEs and AEs were the most commonly reported events with 39 subdural hematoma SAEs in 36 subjects (26 SAEs in non-surgical group and 13 SAEs in surgical group). Forty (24.1%) subjects in the control group experienced an AE of subdural hematoma (32 events in the non-surgical group, 17 AEs in the surgical group, **Table 17**). The rate of events in the SOC of Infections and infestations were higher in the treatment arm (9.0%) (**Table 14**) compared to control (4.8%) (**Table 15)** however, none of these events were considered device-related.

Table 14: Site Reported AEs and SAEs by Term through 1 year - Treatment Group (Safety Population)

	Treatment											
	SQUID + NSMM (N=57)				SQUID + Surgery (N=87)				Treatment Total (N=144)			
	Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event	
MedDRA SOC PT	Total Events	Sub-jects1 (%)	Total Events	Sub-jects1 (%)	Total Events	Sub-jects1 (%)	Total Events	Sub-jects1 (%)	Total Events	Sub-jects1 (%)	Total Events	Sub-jects1 (%)
Overall-Adverse	112	43 (75.4%)	25	21 (36.8%)	240	69 (79.3%)	88	40 (46.0%)	352	112 (77.8%)	113	61 (42.4%)
Blood and lymphatic system disorders	4	4 (7.0%)	0	0 (0.0%)	7	5 (5.7%)	0	0 (0.0%)	11	9 (6.3%)	0	0 (0.0%)
Cardiac disorders	1	1 (1.8%)	1	1 (1.8%)	10	10 (11.5%)	6	6 (6.9%)	11	11 (7.6%)	7	7 (4.9%)
Ear and labyrinth disorders	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (0.7%)	0	0 (0.0%)
Eye disorders	0	0 (0.0%)	0	0 (0.0%)	5	5 (5.7%)	1	1 (1.1%)	5	5 (3.5%)	1	1 (0.7%)
Gastrointestinal disorders	10	9 (15.8%)	3	3 (5.3%)	20	12 (13.8%)	11	8 (9.2%)	30	21 (14.6%)	14	11 (7.6%)
General disorders and administration site conditions	6	5 (8.8%)	0	0 (0.0%)	7	7 (8.0%)	0	0 (0.0%)	13	12 (8.3%)	0	0 (0.0%)
Hepatobiliary disorders	0	0 (0.0%)	0	0 (0.0%)	3	2 (2.3%)	1	1 (1.1%)	3	2 (1.4%)	1	1 (0.7%)
Infections and infestations	14	11 (19.3%)	3	3 (5.3%)	28	23 (26.4%)	13	10 (11.5%)	42	34 (23.6%)	16	13 (9.0%)
Injury, poisoning and procedural complications	16	12 (21.1%)	9	8 (14.0%)	40	30 (34.5%)	17	14 (16.1%)	56	42 (29.2%)	26	22 (15.3%)
Investigations	4	2 (3.5%)	0	0 (0.0%)	4	4 (4.6%)	0	0 (0.0%)	8	6 (4.2%)	0	0 (0.0%)
Metabolism and nutrition disorders	2	1 (1.8%)	0	0 (0.0%)	11	10 (11.5%)	2	2 (2.3%)	13	11 (7.6%)	2	2 (1.4%)
Musculoskeletal and connective tissue disorders	4	4 (7.0%)	0	0 (0.0%)	10	4 (4.6%)	4	2 (2.3%)	14	8 (5.6%)	4	2 (1.4%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	1 (1.8%)	1	1 (1.8%)	2	2 (2.3%)	1	1 (1.1%)	3	3 (2.1%)	2	2 (1.4%)
Nervous system disorders	30	22 (38.6%)	6	6 (10.5%)	54	36 (41.4%)	19	16 (18.4%)	84	58 (40.3%)	25	22 (15.3%)
Psychiatric disorders	5	4 (7.0%)	1	1 (1.8%)	14	13 (14.9%)	3	3 (3.4%)	19	17 (11.8%)	4	4 (2.8%)
Renal and urinary disorders	3	3 (5.3%)	0	0 (0.0%)	6	6 (6.9%)	0	0 (0.0%)	9	9 (6.3%)	0	0 (0.0%)
Respiratory, thoracic and mediastinal disorders	2	2 (3.5%)	0	0 (0.0%)	12	9 (10.3%)	8	6 (6.9%)	14	11 (7.6%)	8	6 (4.2%)
Skin and subcutaneous tissue disorders	2	2 (3.5%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	2	2 (1.4%)	0	0 (0.0%)
Vascular disorders	7	6 (10.5%)	1	1 (1.8%)	7	7 (8.0%)	2	2 (2.3%)	14	13 (9.0%)	3	3 (2.1%)

SOC=System organ class; PT=Preferred term.

[1] Data presented as y (%) where y is number of participants with at least one event of that type and percentage is calculated out of the total participants in the population.

Table 15: Site Reported AE and SAEs by Term through 1 year - Control Group (Safety Population)

	Control											
	NSMM alone (N=66)				Surgery alone (N=100)				Control Total (N=166)			
	Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event	
MedDRA SOC PT	Total Events	Sub-jects1 (%)	Total Events	Sub-jects1 (%)	Total Events	Sub-jects1 (%)	Total Events	Sub-jects1 (%)	Total Events	Sub-jects1 (%)	Total Events	Sub-jects1 (%)
Overall-Adverse Events	112	45 (68.2%)	59	33 (50.0%)	197	71 (71.0%)	68	39 (39.0%)	309	116 (69.9%)	127	72 (43.4%)
Cardiac disorders	4	4 (6.1%)	3	3 (4.5%)	9	6 (6.0%)	2	2 (2.0%)	13	10 (6.0%)	5	5 (3.0%)
Ear and labyrinth disorders	0	0 (0.0%)	0	0 (0.0%)	2	1 (1.0%)	0	0 (0.0%)	2	1 (0.6%)	0	0 (0.0%)
Eye disorders	2	2 (3.0%)	0	0 (0.0%)	3	3 (3.0%)	0	0 (0.0%)	5	5 (3.0%)	0	0 (0.0%)
Gastrointestinal disorders	5	4 (6.1%)	1	1 (1.5%)	6	5 (5.0%)	2	2 (2.0%)	11	9 (5.4%)	3	3 (1.8%)
General disorders and administration site conditions	6	6 (9.1%)	2	2 (3.0%)	9	8 (8.0%)	1	1 (1.0%)	15	14 (8.4%)	3	3 (1.8%)
Hepatobiliary disorders	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	0	0 (0.0%)	1	1 (0.6%)	0	0 (0.0%)
Infections and infestations	7	4 (6.1%)	5	3 (4.5%)	17	14 (14.0%)	7	5 (5.0%)	24	18 (10.8%)	12	8 (4.8%)
Injury, poisoning and procedural complications	39	29 (43.9%)	28	25 (37.9%)	52	39 (39.0%)	27	23 (23.0%)	91	68 (41.0%)	55	48 (28.9%)
Investigations	1	1 (1.5%)	0	0 (0.0%)	6	6 (6.0%)	1	1 (1.0%)	7	7 (4.2%)	1	1 (0.6%)
Metabolism and nutrition disorders	5	3 (4.5%)	4	2 (3.0%)	7	5 (5.0%)	3	2 (2.0%)	12	8 (4.8%)	7	4 (2.4%)
Musculoskeletal and connective tissue disorders	2	2 (3.0%)	0	0 (0.0%)	4	4 (4.0%)	1	1 (1.0%)	6	6 (3.6%)	1	1 (0.6%)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	2	2 (3.0%)	2	2 (3.0%)	3	3 (3.0%)	1	1 (1.0%)	5	5 (3.0%)	3	3 (1.8%)
Nervous system disorders	26	18 (27.3%)	7	7 (10.6%)	50	31 (31.0%)	14	12 (12.0%)	76	49 (29.5%)	21	19 (11.4%)
Psychiatric disorders	5	4 (6.1%)	3	2 (3.0%)	9	7 (7.0%)	1	1 (1.0%)	14	11 (6.6%)	4	3 (1.8%)
Renal and urinary disorders	0	0 (0.0%)	0	0 (0.0%)	4	4 (4.0%)	1	1 (1.0%)	4	4 (2.4%)	1	1 (0.6%)
Reproductive system and breast disorders	1	1 (1.5%)	0	0 (0.0%)	1	1 (1.0%)	0	0 (0.0%)	2	2 (1.2%)	0	0 (0.0%)
Respiratory, thoracic and mediastinal disorders	4	3 (4.5%)	3	2 (3.0%)	10	10 (10.0%)	5	5 (5.0%)	14	13 (7.8%)	8	7 (4.2%)
Social circumstances	1	1 (1.5%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (0.6%)	0	0 (0.0%)
Vascular disorders	2	1 (1.5%)	1	1 (1.5%)	4	4 (4.0%)	2	2 (2.0%)	6	5 (3.0%)	3	3 (1.8%)

SOC=System organ class; PT=Preferred term.

[1]Data presented as y (%) where y is number of participants with at least one event of that type and percentage is calculated out of the total participants in the population.

Site Reported Related Adverse Events through 1 year

Related adverse events are those that were classified by the sites as being; possibly, probably, or having a causal relationship to the device, embolization procedure, and/or surgical procedure. **Table 18** below summarizes related events by MedDRA coded SOC and PT terms for the SQUID, SQUID plus surgery, and surgical management alone group that occurred at any time during the study (i.e., through 1 year). The non-surgical management alone group is excluded from this table as no surgical procedure or device was used in this group.

- Related Serious Adverse Events (SAE) occurred in ≤10% of subjects overall.
  - Eight (8) related SAEs were reported in the SQUID embolization arm.
  - Twenty (20) related SAEs were reported in the SQUID embolization plus surgery arm.
  - Nineteen (19) related SAEs were reported in surgical management arm.

Table 16: Site Reported AEs and SAEs through 1 year for Subdural Hematoma – Treatment Group (Safety Population)

	Treatment											
	SQUID + NSMM (N=57)				SQUID + Surgery (N=87)				Treatment Total (N=144)			
	Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event	
MedDRA SOC PT	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)
Overall-Adverse Events	112	43 (75.4%)	25	21 (36.8%)	240	69 (79.3%)	88	40 (46.0%)	352	112 (77.8%)	113	61 (42.4%)
Injury, poisoning and procedural complications	16	12 (21.1%)	9	8 (14.0%)	40	30 (34.5%)	17	14 (16.1%)	56	42 (29.2%)	26	22 (15.3%)
Subdural hematoma	8	8 (14.0%)	7	7 (12.3%)	14	10 (11.5%)	11	9 (10.3%)	22	18 (12.5%)	18	16 (11.1%)

SOC=System organ class; PT=Preferred term.
[1] Data presented as y (%) where y is number of participants with at least one event of that type and percentage is calculated out of the total participants in the population.

Table 17: Site Reported AEs and SAEs through 1 year for Subdural Hematoma – Control Group (Safety Population)

	Control											
	NSSM alone (N=66)				Surgery alone (N=100)				Control Total (N=166)			
	Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event	
MedDRA SOC PT	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)
Overall-Adverse Events	112	45 (68.2%)	59	33 (50.0%)	197	71 (71.0%)	68	39 (39.0%)	309	116 (69.9%)	127	72 (43.4%)
Injury, poisoning and procedural complications	39	29 (43.9%)	28	25 (37.9%)	52	39 (39.0%)	27	23 (23.0%)	91	68 (41.0%)	55	48 (28.9%)
Subdural hematoma	32	24 (36.4%)	26	23 (34.8%)	17	16 (16.0%)	13	13 (13.0%)	49	40 (24.1%)	39	36 (21.7%)

SOC=System organ class; PT=Preferred term.
[1] Data presented as y (%) where y is number of participants with at least one event of that type and percentage is calculated out of the total participants in the population.

Table 18: Site Reported Related Adverse Events through 1 year - Treatment and Surgical Subjects (Safety Population)

	SQUID + NSMM (N=57)				SQUID + Surgery (N=87)				Surgery alone (N=100)			
	Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event	
MedDRA SOC PT	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)
Overall-Adverse Events	18	16 (28.1%)	8	8 (14.0%)	47	30 (34.5%)	20	13 (14.9%)	43	29 (29.0%)	19	13 (13.0%)

	SQUID + NSMM (N=57)				SQUID + Surgery (N=87)				Surgery alone (N=100)			
	Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event	
MedDRA SOC PT	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)
Blood and lymphatic system disorders	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Anemia	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Cardiac disorders	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Sinus tachycardia	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Ear and labyrinth disorders	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	0	0 (0.0%)
Vertigo	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	0	0 (0.0%)
Eye disorders	0	0 (0.0%)	0	0 (0.0%)	3	3 (3.4%)	1	1 (1.1%)	1	1 (1.0%)	0	0 (0.0%)
Eyelid ptosis	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	0	0 (0.0%)
Retinal detachment	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)
Vision blurred	0	0 (0.0%)	0	0 (0.0%)	2	2 (2.3%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Gastrointestinal disorders	1	1 (1.8%)	0	0 (0.0%)	2	2 (2.3%)	2	2 (2.3%)	1	1 (1.0%)	0	0 (0.0%)
Ileus paralytic	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)
Nausea	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	0	0 (0.0%)
Vomiting	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)
General disorders and administration site conditions	1	1 (1.8%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Fatigue	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Gait disturbance	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Infections and infestations	1	1 (1.8%)	1	1 (1.8%)	3	3 (3.4%)	1	1 (1.1%)	2	1 (1.0%)	2	1 (1.0%)
Periorbital cellulitis	1	1 (1.8%)	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Pneumonia	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	1	1 (1.0%)	1	1 (1.0%)
Postoperative wound infection	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Urinary tract infection	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	1	1 (1.0%)	1	1 (1.0%)
Injury, poisoning and procedural complications	3	3 (5.3%)	2	2 (3.5%)	12	10 (11.5%)	7	6 (6.9%)	17	15 (15.0%)	9	8 (8.0%)
Brain herniation	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	1	1 (1.0%)
Fall	1	1 (1.8%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	1	1 (1.0%)	0	0 (0.0%)
Incision site pain	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	2	2 (2.0%)	0	0 (0.0%)
Incision site swelling	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	0	0 (0.0%)
Pneumocephalus	0	0 (0.0%)	0	0 (0.0%)	2	2 (2.3%)	1	1 (1.1%)	3	3 (3.0%)	0	0 (0.0%)
Procedural complication	0	0 (0.0%)	0	0 (0.0%)	2	2 (2.3%)	0	0 (0.0%)	4	4 (4.0%)	3	3 (3.0%)
Subdural hematoma	2	2 (3.5%)	2	2 (3.5%)	5	4 (4.6%)	5	4 (4.6%)	3	3 (3.0%)	3	3 (3.0%)
Subdural hemorrhage	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	1	1 (1.0%)	1	1 (1.0%)
Surgical procedure repeated	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	1	1 (1.0%)
Metabolism and nutrition disorders	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	1	1 (1.0%)	1	1 (1.0%)
Hypernatremia	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	1	1 (1.0%)
Hypokalemia	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Musculoskeletal and connective tissue disorders	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	1	1 (1.0%)	0	0 (0.0%)
Facial asymmetry	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	0	0 (0.0%)
Muscular weakness	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)
Nervous system disorders	10	10 (17.5%)	4	4 (7.0%)	17	14 (16.1%)	6	5 (5.7%)	16	13 (13.0%)	6	5 (5.0%)
Amnesia	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Aphasia	1	1 (1.8%)	1	1 (1.8%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Carotid artery occlusion	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)

	SQUID + NSMM (N=57)				SQUID + Surgery (N=87)				Surgery alone (N=100)			
	Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event		Adverse Event		Serious Adverse Event	
MedDRA SOC PT	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)	Total Events	Sub-jects[1] (%)
Cerebral artery occlusion	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)
Cerebral atrophy	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	0	0 (0.0%)
Cerebrovascular accident	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)
Dysesthesia	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	1	1 (1.0%)	0	0 (0.0%)
Dysarthria	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Encephalopathy	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	1	1 (1.0%)	1	1 (1.0%)
Facial paralysis	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Headache	2	2 (3.5%)	0	0 (0.0%)	3	3 (3.4%)	0	0 (0.0%)	6	6 (6.0%)	2	2 (2.0%)
Hydrocephalus	1	1 (1.8%)	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Ischemic stroke	1	1 (1.8%)	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	1	1 (1.0%)
Nystagmus	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Partial seizures	1	1 (1.8%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	2	2 (2.0%)	1	1 (1.0%)
Seizure	1	1 (1.8%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)
Simple partial seizures	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	1	1 (1.0%)
Status epilepticus	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)
Syncope	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Transient ischemic attack	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)
Upper motor neuron lesion	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	3	3 (3.0%)	0	0 (0.0%)
VIth nerve paralysis	1	1 (1.8%)	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Psychiatric disorders	0	0 (0.0%)	0	0 (0.0%)	4	4 (4.6%)	2	2 (2.3%)	3	2 (2.0%)	1	1 (1.0%)
Confusional state	0	0 (0.0%)	0	0 (0.0%)	2	2 (2.3%)	1	1 (1.1%)	2	2 (2.0%)	0	0 (0.0%)
Depression	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.0%)	1	1 (1.0%)
Hallucination	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Mental status changes	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)
Vascular disorders	1	1 (1.8%)	1	1 (1.8%)	2	2 (2.3%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Deep vein thrombosis	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Peripheral artery thrombosis	1	1 (1.8%)	1	1 (1.8%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)
Vessel perforation	0	0 (0.0%)	0	0 (0.0%)	1	1 (1.1%)	0	0 (0.0%)	0	0 (0.0%)	0	0 (0.0%)

Device Effect = Unlikely, Possibly, Probably, or Causal relationship to Device and/or Procedure.
SOC=System organ class; PT=Preferred term.
[1]Data presented as y (%) where y is number of participants with at least one event of that type and percentage is calculated out of the total participants in the population.
[2]Non-surgical management subjects are excluded from this table as no surgical procedure or device was used in those subjects.

Through 180 days: there were a total of 21 deaths: 17 non-neurological and 4 neurological. Through 1 year: there were a total of 25 deaths: 21 up to 180 days described above and additional 4 non-neurological deaths that occurred between 180 days and 1 year.

Final Conclusions

Among patients with symptomatic chronic subdural hematoma, adjunctive middle meningeal artery embolization resulted in a lower risk of treatment failure than standard treatment alone, without resulting in an increased incidence of disabling stroke or death in the short term. The benefits of the device outweigh probable risks when considering the clinically significant results of the pivotal data conducted in the intended population under its proposed condition of use.

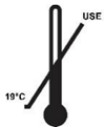
WARRANTY

Balt warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning, and sterilization of the device, as well as factors relating to the patient, diagnosis, treatment, surgical procedure, and other matters beyond Balt's control directly affect the device and the results obtained from its use. Balt's obligation under this warranty is limited to the repair or replacement of this device and Balt shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Balt neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Balt assumes no liability with respect to devices reused, reprocessed, or re-sterilized, and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device. Prices, specifications, and model availability are subject to change without notice.

Notice to user and/or patient: Any serious incident that occurs in relation to SQUID should be reported to the manufacturer and to the FDA through Medical Device Reporting (MAUDE Database).

13. Symbol Glossary

Symbols Glossary			
	**Use-by date** ISO 15223-1 §5.1.4 Indicates the date after which the medical device is not to be used.		**Keep away from sunlight** ISO 15223-1 §5.3.2 Indicates a medical device that needs protection from light sources.
	**Manufacturer** ISO 15223-1 §5.1.1 Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.		**Keep dry** ISO 15223-1 §5.3.4 Indicates a medical device that needs to be protected from moisture.
	**Date of manufacture** ISO 15223-1 §5.1.3 Indicates the date when the medical device was manufactured.		**Do not use if package is damaged and consult instructions for use** ISO 15223-1 §5.2.8 Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	**Sterilized using ethylene oxide** ISO 15223-1 §5.2.3 Indicates a medical device that has been sterilized using ethylene oxide.		**Caution** ISO 15223-1 §5.4.4 Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	**Sterilized using steam or dry heat** ISO 15223-1 §5.2.3 Indicates a medical device that has been sterilized using steam or dry heat.		**Do not resterilize** ISO 15223-1 §5.2.6 Indicates a medical device that is not to be resterilized.

Symbols Glossary			
	**Non-pyrogenic** ISO 15223-1 §5.6.3 Indicates a medical device that is non-Pyrogenic.		**Lower limit of temperature** ISO 15223-1 Indicates the lower limit of temperature to which the medical device can be safely exposed.
	**Do not re-use** ISO 15223-1 §5.4.2 Indicates a medical device that is intended for one single use only.		**MR Conditional** ASTM F2503-20 Medical Devices - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
	**Catalogue number** ISO 15223-1 §5.1.6 Indicates the manufacturer's catalogue number so that the medical device can be identified.		**Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.** 21 Code of Federal Regulations (CFR) sec. 801.109(b)(1) Indicates a medical device that is a prescription device.
	**Batch code** ISO 15223-1 §5.1.5 Indicates the manufacturer's batch code so that the batch or lot can be identified.		**Contents**
	**Consult instructions for use or consult electronic instructions for use** ISO 15223-1 §5.4.3 Indicates the need for the user to consult the instructions for use.		

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