Embrace™ Hydrogel Embolic System

INSTRUCTIONS FOR USE

Rx Only

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

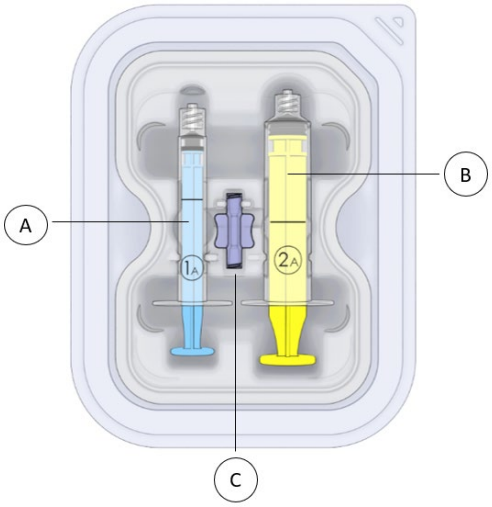
This device should be used only by physicians with a thorough understanding of angiography and percutaneous interventional procedures.

Device Description

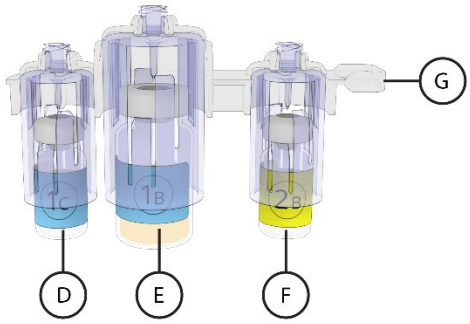
The Embrace™ Hydrogel Embolic System (HES) is a biocompatible, hydrophilic, persistent, hydrogel produced from polyethylene glycol. The HES is available as a two-part system that forms *in situ* at the target location. Embrace is designed to offer controlled, targeted embolization utilizing the Instylla™ Microcatheter and Instylla™ Delivery Kit. The HES hydrogel is formulated to be absorbed in approximately 11 months.

Contents

	Item	*Description*	*Quantity*
Accessory Kit	A	Syringe 1A – 3mL (Light Blue)	1
	B	Syringe 2A – 10mL (Yellow)	1
	C	Female-to-female Luer Connector	1
Precursor Kit	D	Vial 1C with attached vial spike	1
	E	Vial 1B with attached vial spike	1
	F	Vial 2B with attached vial spike	1
	G	Vial Holder	1



Accessory Kit



Precursor Kit

Devices and Accessories Needed to Perform the Procedure

- Instylla Microcatheter (1.7F or 1.2F)
- Instylla Delivery Kit
- Commercially available microcatheter (inner diameter ≥0.027 inch for use with 1.7F Instylla Microcatheter or ≥0.021 inch for use with 1.2F Instylla Microcatheter) with guidewire
- Aqueous, non-ionic iodinated contrast medium (triiodobenzene-based) having ≥ 300mg Iodine per mL with viscosity less than 26 cP at 20°C
- ≤ 0.014" guidewire (for use with 1.7F Instylla Microcatheter) or ≤ 0.010" guidewire (for use with 1.2F Instylla Microcatheter)

Note: Consult the applicable product labeling for any external devices used with Embrace HES.

Intended Use/Indications for Use

The Embrace HES is indicated for embolization of hypervascular tumors in peripheral arteries ≤ 5mm.

Magnetic Resonance Imaging

The Embrace HES is MR Safe.

Contraindications

Embolization procedures should not be performed if:

- Patient is intolerant to occlusion procedures
- Vascular anatomy or blood flow precludes correct catheter placement or embolic injection
- Presence or likely onset of unresolvable vasospasm
- Known or suspected conditions that would prevent successful catheterization of targeted vasculature
- Presence of bilioenteric anastomoses or prior biliary interventions with stenting
- Presence of collateral vessel pathways which could potentially endanger non-target tissue
- Vascular resistance proximal to the feeding arteries precluding passage of Embrace HES into the lesion
- In large-diameter arteriovenous shunts (i.e. where the blood does not pass through an arterial/capillary/venous transition but directly from an artery to a vein) in the pulmonary vasculature
- Any neurovasculature or coronary location
- Known allergies to polyethylene glycol (PEG), ferrous compounds, tert Butyl Hydroperoxide that are not amenable to premedication

The safety and effectiveness of Embrace HES in pediatric patients and pregnant women has not been established.

Warnings

- Embolization with Embrace HES should be carried out under the direction of personnel with interventional training and thorough knowledge of angiographic techniques.
- Pay careful attention for signs of mistargeted embolization. During injection carefully monitor patient vital signs. Consider terminating the procedure if any signs of mistargeting occur or patient symptoms develop.

- Embrace HES may not polymerize in clinical conditions with high flow, shunting, and/or reflux leading to increased exposure to Embrace HES precursor solutions.
- Tert-butyl hydroperoxide (TBHP), a component of the precursor solution, elicits genotoxicity and sensitization in animals. Biocompatibility of the unpolymerized precursor solutions has not been established.
- Embolization should not be performed if Embrace HES cannot be safely delivered in conditions of high flow, shunting, and/or reflux.
- Serious radiation induced skin injury may occur to the patient due to long periods of fluoroscopic exposure, large patient diameter, angled x-ray projections, and multiple image recording runs or radiographs. Refer to your facility's clinical protocol to ensure the proper radiation dose is applied for each specific type of procedure performed. Physicians should monitor patients who may be at risk.
- Safety of Embrace HES at injected volumes greater than 7.5 mL into the patient has not been evaluated. Total volume of Embrace HES injected should not exceed 7.5 mL.

Precautions

- Patients with known allergy to contrast media may need to be premedicated prior to embolization.
- Additional evaluations or precautions may be necessary in managing periprocedural care for patients with the following conditions:
    - Bleeding diathesis or hypercoagulative state
    - Immunocompromised
- Do not use if any of the contents of the Embrace HES or package appear broken or damaged. Prior to use, carefully examine the unit to verify that the sterile package has not been damaged. If the sterile packaging has been damaged, or unintentionally opened prior to use, discard the unit.
- For single-use only, do not resterilize. Attempts to reuse or resterilize this device may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness, or death. Reusing, reprocessing, or resterilizing may also create a risk of contamination of the device and/or cause patient infection or cross infection including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death.
- Dispose of the used device or any unused material safely, following your institution's local procedure for the disposal of medical waste.
- All procedures must be performed according to accepted aseptic technique.
- Exercise care in handling the microcatheter during a procedure to reduce the possibility of accidental breakage, bending, or kinking.
- Excessive tightening of a hemostatic valve (such as the Tuohy-Borst) onto the Instylla Microcatheter shaft may result in damage to the microcatheter.
- Precursor injection into high blood flow or directly near vessel branching may prevent embolic formation. If no evidence of embolic formation is present following the injection of 2mL liquid precursors (1mL of each precursor), reposition catheter tip and confirm appropriate position prior to additional injection.

- Excess injection of Embrace HES may result in retrograde flow in the vessel leading to the embolization of other non-target tissues or organs.

Potential Complications

Vascular embolization is a high-risk procedure. Complications may occur at any time during or after the procedure, and may include, but are not limited to, the following:

- Paralysis resulting from non-targeted embolization or ischemic injury from adjacent tissue edema
- Inadvertent embolization of a non-target vessel or territory
- Pulmonary embolism due to arterial venous shunting
- Thrombosis
- Ischemia, infarction, or tissue necrosis at an undesirable location
- Vessel or lesion rupture and hemorrhage
- Vasospasm
- Air embolism
- General edema
- Hypotensive crisis
- Embolization failure or recanalization requiring secondary intervention
- Foreign body reactions or infection necessitating medical intervention
- Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgment, nerve and/or circulatory injuries, or vessel trauma [e.g. dissection, perforation, rupture])
- Pain and/or rash, possibly delayed from the time of embolization
- Post-embolization syndrome
- Toxic or allergic reactions to embolic material
- Death

How Supplied

Supplied sterile.
Store in a cool, dry place.
Use by the date indicated on the product label.
Do not freeze.
Do not re-sterilize.
Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.

Clinical Study Results

Study Purpose and Objectives

The objective of this study was to evaluate the Embrace HES for the embolization of hypervascular tumors as compared to Standard of Care (SOC) transarterial embolization (TAE)/

conventional transarterial chemoembolization (cTACE). The primary effectiveness endpoint for this study was Technical Success. The primary safety endpoint was freedom from specific major adverse events (MAE) through 30 days post-index procedure (as adjudicated by the Clinical Events Committee (CEC)) compared with a literature-derived performance goal (PG) set to 75%. Other evaluations included (but were not limited to) Procedural Characteristics (including procedure times and catheter repositioning due to non-embolization), Objective Target (Treated) Tumor Response and Quality of Life evaluated using the European Organization for Research and Treatment of Cancer EORTC Core Quality of Life Questionnaire (QLQ-C30) and EORTC QLQ Hepatocellular Carcinoma HCC 18 as appropriate.

Study Design

Prospective, randomized (2:1), double-blinded multicenter clinical study to evaluate the Embrace HES for the embolization of hypervascular tumors as compared to Standard of Care TAE/cTACE.

Inclusion Criteria:

Subjects who met all of the following criteria were eligible for participation in the study:

1. Male or female subjects aged ≥ 22 years old
2. Subjects with confirmed finding of hypervascular tumor on CT and/or MRI for whom TAE or cTACE is medically indicated, including but not limited to: a. Subjects with unresectable primary or metastatic hepatic cancer b. Subjects with primary, metastatic, or benign renal tumors c. Subjects with bone metastases d. Subjects with adrenal tumors e. Subjects with other hypervascular tumors
3. Subjects with at least one target lesion that is well-delineated such that, in the Investigator's opinion, the lesion can be measured in at least one dimension as 1 cm or more, suitable for remeasurement, and demonstrating definitive arterial enhancement. (Note: Pre-operative tumors do not need to meet this criterion.)
4. Subjects with at least one target vessel ≤ 5mm and Instylla HES can be delivered to the target vessel(s).
5. Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0-2 (PS 0-1 for metastatic disease)
6. Subject or authorized representative have been informed of the nature of the study and has provided written informed consent approved by the appropriate local Ethics Committee/Institutional Review Board and agrees to comply with all protocol-specified follow-up appointments.
7. Expected life expectancy ≥ 6 months after Index embolization

Exclusion Criteria:

Subjects who met any of the following criteria were excluded from participation in the study:

1. Embolization for lesions other than hypervascular tumors, such as arteriovenous malformations.
2. It is anticipated that not all target vessels requiring embolization during the index procedure can be embolized with either HES alone or the SOC embolization agent as assigned.

3. Undergoing radioembolization or DEB-TACE for index procedure
4. Undergoing a planned secondary procedure the same day as the index procedure
5. Requires TAE/cTACE for liver tumors via extrahepatic collateral artery(ies)
6. Prior radioembolization of the target tumor lesion/vascular bed within 30 days of the index procedure.
7. For subjects with HCC or undergoing embolization to the liver: Child-Pugh Class C or presence of complete portal vein thrombosis.
8. Tumor lesions > 8 cm in diameter (in one direction) or >50% tumor volume burden of the target organ
9. If subject was treated with Avastin, last dose is within 4 weeks of the planned procedure.
10. Known severe atheromatosis or vascular anatomy that precludes catheterization
11. Presence of bilioenteric anastomoses and/or prior biliary stenting/drainage or any violation of the biliary sphincter, including sphincterotomy for embolization of liver tumors.
12. Target lesion supplied by the pulmonary artery, coronary artery, or cerebral or cerebellar artery (requiring embolization of these arteries) or the artery to be embolized has connections to these arteries via a collateral pathway
13. Known allergies (based on history) to PEG, ferrous compounds, tert Butyl Hydroperoxide, contrast media, or procedural sedatives/anesthetics that are not amenable to pre-medication
14. Uncorrectable impaired clotting: Platelet count 1.5
15. Serum creatinine > 2 mg/dL
16. Serum bilirubin level > 3 mg/dL
17. Serum albumin < 2.5 g/dL
18. Any contraindication to angiography or embolization protocol utilized at treating institution.
19. Pregnant or breastfeeding or females planning on becoming pregnant within the next 3 months (women of child-bearing potential must undergo a pregnancy test performed in accordance with local institutional requirements).
20. Other concurrent conditions, including an ongoing adverse effect or complication of prior therapy or adverse drug reactions, that in the opinion of the Investigator or Clinical Events Committee, would be unlikely to receive clinical benefit from the study procedure or participation in the study may compromise subject safety or study objectives (including but not limited to ongoing acute infection, renal dysfunction, morbid obesity, severe cardiac disease).
21. Enrollment in a concurrent study in which the study treatment may confound the evaluation of the study device.

<u>Follow Up Schedule:</u>

The Schedule of Events and Assessments conducted during this trial is summarized in Table 1.

Table 1: Schedule of Events and Assessments

Procedure	**Screening/Baseline Assessment** ***(within 45 days prior to planned vascular embolization)***	**Index Procedure** ***(Vascular Embolization)***	**Discharge**	**Follow-up: Day 30 ± 7 days and Day 90 ± 14 days**	**Follow-up: Day 180 ± 30 days (Remote visit unless in-person visit warranted)**
Demographic Information	✓				
Indication for Embolization	✓				
Disease Features[a]	✓				
Med./Surgical History/Current Status including Prior Therapies	✓				
CT Scan (Multiphasic CT for hepatic tumors) / MR at baseline and follow-up for assessment of radiologic response	✓*			✓*	
Targeted Physical Exam or Assessment[b]	✓		✓ (vitals only)	✓ (vitals only)	
EORTC QLQ-C30 and EORTC QLQ-HCC 18 (QLQ-HCC for hepatic subjects only)	✓			✓	✓
ECOG Performance Score/Child-Pugh Classification	✓			✓	
Laboratory Testing[c]	✓			✓	
Pregnancy test for women of childbearing age	✓	✓			
RANDOMIZE		✓			
Angiography		Pre- and Post-Embolization Procedure	If clinically indicated		
Embolization Procedural Details		✓			
Concomitant Medications		✓	✓	✓	✓
Adverse Events (per NCI CTCAE Version 5.0) and severity rated in accordance with SIR guidelines; pain Numeric Rated Scale[d]		✓	✓	✓	✓

*The same imaging modality/protocol is to be used pre- and post-vascular embolization. Also, it is preferred that the same CT or MR system be used for the same subject for the duration of the study. If tumor is benign, baseline imaging can be taken within 60 days of Index procedure. Images for tumors collected as standard of care prior to the informed consent process but within 45 days (or 60 days for benign tumors) of Index procedure may be utilized as the baseline imaging.

[a]Tumor etiology, tumor location, tumor staging, number and dimension of tumor lesions (cm)

[b]At baseline, targeted physical examination including vitals (sitting blood pressure, pulse, respiratory rate, temperature, weight). At follow-up: Physical Assessment: including vitals (sitting blood pressure, pulse, respiratory rate, temperature, weight) to evaluate for

Procedure	Screening/Baseline Assessment *(within 45 days prior to planned vascular embolization)*	Index Procedure *(Vascular Embolization)*	Discharge	Follow-up: Day 30 ± 7 days and Day 90 ± 14 days	Follow-up: Day 180 ± 30 days (Remote visit unless in-person visit warranted)
changes from baseline. An in-person visit is preferred, but a remote (e.g., over the phone or via telehealth) visit can be substituted for select follow-up components if necessary. [c]At baseline, complete blood count plus platelets, albumin, glucose, creatinine, AST/ALT, bilirubin, INR, and Alpha-fetoprotein levels in subjects with hepatic malignant tumors and Alkaline phosphatase for liver tumors. At follow-up, all baseline labs, excluding INR [d] Note: if subject was experiencing pain, the pain severity was to be scored using a Numeric Rated Scale where 0 represents no pain, and 10 represents the worst-possible pain					

Primary Safety Endpoint

The primary safety endpoint was freedom from major adverse events (MAE) through 30 days post index procedure (as adjudicated by the CEC) compared with a literature-derived performance goal (PG) of 75%.

The following events were considered MAE, if deemed by the CEC to be definitely or probably device and/or procedure-related and satisfied the criteria for a Grade ≥ 3 event in accordance with the SIR recommendations.

- Death
- Non-target embolization (NTE) of the index procedure, e.g., severe, intractable abdominal pain, gastroduodenal ulceration, intestinal ischemia, pancreatitis, cholecystitis AND angiographic/CT evidence of NTE
- Unintended target tissue ischemia (defined as symptomatic healthy/non-diseased tissue ischemia in the target organ)
- Pulmonary embolism
- Vascular injury requiring surgical/endovascular intervention
- Renal failure defined as increase in serum creatinine of ≥2mg/dL above baseline that persists to the Day 30 visit
- Hepatic failure (Grade 3+ asterixis, encephalopathy) that persists to the Day 30 visit
- Abscess in target organ/tissue: defined as clinical symptoms of infection (fever, leukocytosis, bacteremia), imaging consistent with the diagnosis of abscess, and a positive drainage culture
- Toxic and/or allergic reactions to the HES hydrogel manifested as immediate anaphylaxis or acute kidney injury (AKI - severe azotemia, oliguria, and/or anuria) with no other apparent etiology, e.g., contrast sensitivity.

Primary Effectiveness Endpoint

The primary effectiveness endpoint of this study was technical success, defined as the successful delivery of the embolic agent to the index tumor feeding vessel, achieving stasis of flow, as characterized by the absence of contrast flow within the targeted vessel. This determination was made by independent radiologists (Core Laboratory) through comparison of pre- and final post-procedure angiograms. Stasis of flow, as defined, is an established metric for evaluating

embolic devices per Society of Interventional Radiology (SIR) guidelines and aligns with the proposed indication for use of the device.

Subjects could contribute more than one effectiveness endpoint evaluation based on the number of target vessel embolizations . Target vessels were defined as a single discrete vascular bed. Sites captured and provided images to the Imaging Core Lab for independent assessment a digitally subtracted angiogram (DSA), with a minimum frame rate of 2 frames per second, from contrast injection through clearance (about 5- 10 seconds) before and after embolization. Per protocol, the DSA included arterial opacification and complete venous drainage of the intended target vessel.

If technical success of a target vessel could not be achieved with the assigned therapy, an ancillary (secondary) embolic agent could be used to complete the embolization procedure. If an ancillary (secondary) embolic was required to achieve successful embolization of the target vessel, this was considered a target vessel technical failure for HES only, regardless of determination by an independent radiologist. Multiple embolics could be used for the standard of care treatment.

The primary analysis population for the primary effectiveness and primary safety endpoints was the Per Protocol (PP) population, which consisted of the modified Intent-to-Treat (mITT) population (those with a target vessel treated (i.e., embolic agent/chemoembolic agent delivered to target tumor)) who did not have any major protocol deviations that would impact the corresponding endpoint. Given the different timing of the primary effectiveness and primary safety endpoints (during procedure for effectiveness and through 30 days for safety), these endpoints were further evaluated in subgroups of the Per Protocol population, the Effectiveness Evaluable (EE) population and the Safety Evaluable (SE) population. The As Treated (AT) population includes mITT subjects, but analyzed according to treatment received rather than treatment assignment. The mITT and AT populations were utilized as a secondary analysis population for primary effectiveness.

Subject Disposition

Between March 5, 2021 and May 1, 2024, a total of 182 subjects were consented in the study. Of these, 150 subjects were randomized, with 102 assigned to the HES treatment arm and 48 subjects to the control arm. Subject disposition for those who consented is shown in Table 2. Among the randomized subjects, 136 (91%) completed the 90-day Clinical Investigation Phase and 129 (86%) completed the Day 180 visit. Approximately 4% of subjects were lost to follow-up.

Table 2: Subject Disposition

	Hydrogel Embolic System (HES) N=102	**Standard of Care TAE/cTACE N=48**
Index Procedure	100.0% (102/102)	100.0% (48/48)
Completed 90-day visit	90.2% (92/102)	91.7% (44/48)
Completed Study [1]	86.3% (88/102)	85.4% (41/48)

	Hydrogel Embolic System (HES) N=102	Standard of Care TAE/cTACE N=48
Early Termination/Withdrawal	13.7% (14/102)	14.6% (7/48)
Subject non-compliant with protocol	0.0% (0/102)	2.1% (1/48)
Lost to follow-up	3.9% (4/102)	4.2% (2/48)
Investigator elected to withdraw subject [2]	2.9% (3/102)	0.0% (0/48)
Death	4.9% (5/102)	6.3% (3/48)
Other [3]	2.0% (2/102)	2.1% (1/48)

[1] A subject is considered to have completed the study if he/she completed all visits through Day 180 Follow-up visit.
[2] Investigator could elect to withdraw patients for the following reasons: (1) subject received liver transplant and was no longer necessary to follow the subject per standard of care, (1) subject was unhomed and non-compliant with study follow up, and (1) subject was medically complicated and mental status declined prior to study exit making them incapable of signing a revised consent
[3] Other includes: HES (1) Subject transferred to hospice care and withdrew from study, (1) site closed prior to subject's 180 day visit and SOC (1) subject experienced disease progression and was referred to RAD/ONC for follow up

Demographics

The study population's demographic characteristics were well-balanced across treatment arms. The average age of participants was 65.4 years, with a slightly higher proportion of males (56%). The population was predominantly white (79%), while 10% identified as Black/African American, and approximately 5% as Asian. Additionally, the treatment arms demonstrated comparable measures for height, weight, and body mass index, further supporting the demographic consistency between treatment arms.

Table 3: Demographic and Baseline Characteristics

	Hydrogel Embolic System (HES) N=102	Standard of Care TAE/cTACE N=48
Age (years)		
Mean ± SD (N)	65.6 ± 12.37 (102)	65.1 ± 14.09 (48)
Median (Min, Max)	68.0 (31.0, 87.0)	68.5 (23.0, 81.0)
Gender		
Male	50.0% (51/102)	68.8% (33/48)
Female	50.0% (51/102)	31.3% (15/48)
Race		
American Indian or Alaska Native	1.0% (1/102)	0.0% (0/48)
Asian	4.9% (5/102)	4.2% (2/48)

	Hydrogel Embolic System (HES) N=102	Standard of Care TAE/cTACE N=48
Asian Indian	0.0% (0/102)	4.2% (2/48)
Other Asian	0.0% (0/102)	2.1% (1/48)
Black or African American	11.8% (12/102)	6.3% (3/48)
Chinese	2.0% (2/102)	0.0% (0/48)
White	75.5% (77/102)	85.4% (41/48)
Pacific Islander	1.0% (1/102)	0.0% (0/48)
Other	3.9% (4/102)	2.1% (1/48)
Ethnicity		
Hispanic or Latino	14.7% (15/102)	12.5% (6/48)
Not Hispanic or Latino	85.3% (87/102)	87.5% (42/48)
BMI (kg/m^2)		
Mean ± SD (N)	29.2 ± 6.42 (102)	28.8 ± 6.29 (47)
Median (Min, Max)	28.1 (16.3, 45.5)	27.5 (16.1, 43.2)

Table 4 summarizes the baseline conditions for the mITT Population, which were well-balanced across treatment arms, including the primary indications for vascular embolization and prevalence of metastatic disease. Most subjects underwent vascular embolization for either definitive therapy for local tumor control (36%) or for addressing surgically unresectable or inoperable disease (23%). Preoperative embolization was the third most common indication, accounting for 13% of the population. Approximately 27% of subjects were treated for metastatic disease.

This was predominantly a non-smoking population. Consistent with protocol eligibility criteria, baseline ECOG performance scores were below 2, with ~95% of subjects having a score of 0 or 1. Additionally, there were very few cases of significant cardiovascular disease (NYHA Classification III or greater) or severe liver dysfunction (Child-Pugh Class C or higher).

Table 4: Baseline Conditions

	Hydrogel Embolic System (HES) N=102	Standard of Care TAE/cTACE N=48
Smoking History		
Current Smoker	11.8% (12/102)	14.6% (7/48)
Past Smoker	32.4% (33/102)	35.4% (17/48)
Never Smoker	55.9% (57/102)	50.0% (24/48)
Primary Indication for Vascular Embolization		

	Hydrogel Embolic System (HES) N=102	Standard of Care TAE/cTACE N=48
Palliation	9.8% (10/102)	6.3% (3/48)
Definitive Therapy for Local Tumor Control (No additional therapy planned)	35.3% (36/102)	37.5% (18/48)
Surgically unresectable or inoperable disease	23.5% (24/102)	20.8% (10/48)
Preoperative Embolization for Curative Resection or Tumor Ablation	12.7% (13/102)	14.6% (7/48)
Bridge for Liver Transplantation	1.0% (1/102)	2.1% (1/48)
Downstage for Liver Transplantation	1.0% (1/102)	0.0% (0/48)
Control of tumor bleeding (non-traumatic organ infarct only)	2.9% (3/102)	0.0% (0/48)
Reduce risk of rupture	7.8% (8/102)	8.3% (4/48)
Other [1]	5.9% (6/102)	10.4% (5/48)
Being treated for metastatic disease		
Yes	27.5% (28/102)	25.0% (12/48)
No	72.5% (74/102)	75.0% (36/48)
Baseline ECOG Performance Score		
0	63.7% (65/102)	62.5% (30/48)
1	28.4% (29/102)	37.5% (18/48)
2	7.8% (8/102)	0.0% (0/48)
3	0.0% (0/102)	0.0% (0/48)
4	0.0% (0/102)	0.0% (0/48)
5	0.0% (0/102)	0.0% (0/48)
Not Done	0.0% (0/102)	0.0% (0/48)
Baseline NYHA Classification		
Class I	15.7% (16/102)	8.3% (4/48)
Class II	2.9% (3/102)	2.1% (1/48)
Class III	2.9% (3/102)	2.1% (1/48)
Class IV	1.0% (1/102)	0.0% (0/48)
N/A	77.5% (79/102)	87.5% (42/48)
Baseline Child-Pugh Classification		
A	54.9% (56/102)	60.4% (29/48)
B	7.8% (8/102)	2.1% (1/48)

	Hydrogel Embolic System (HES) N=102	Standard of Care TAE/cTACE N=48
C	1.0% (1/102)	0.0% (0/48)
N/A	36.3% (37/102)	37.5% (18/48)
[1] Other reasons include: HES (1) embolization for transplant consult, (1) preoperative, (1) reduce growth/pain syndrome, (1) locoregional therapy for tumor control, (1) repeat embolization, (1) definitive therapy, subject did not consider transplant and SOC (1) preoperative to reduce bleeding, (3) locoregional therapy for tumor control, (1) right proximal humerus lesion		

Safety and Effectiveness Results

Safety Results:

The primary safety endpoint was freedom from major adverse events (MAE) through 30 days post index procedure (as adjudicated by the CEC) compared with a literature-derived performance goal (PG) of 75%. There were no unanticipated adverse device effects or adverse events designated as device-related only by the CEC. The primary safety endpoint met the goal with a rate of 99% (lower one-sided 95% CI= 95.15%). The performance goal was met ($p<0.001$).Two MAE events occurred in the same subject, who developed an allergic reaction after HES embolization (increased heart rate, diaphoresis, and pallor requiring epinephrine, albuterol, solumedrol, Narcan, and Romazicon), with subsequent development of a cool foot and access site arterial thrombosis the following day. Of note, the allergic reaction event was not classified as an MAE by the CEC as it resolved with pharmacological treatment. Catheter repositioning due to non-embolization was evaluated to assess patient exposure to unpolymerized precursors. The rate of catheter repositioning due to non-embolization in HES was 3.0%.

The Primary Safety Endpoint analysis is presented in Table 5.

Table 5. Primary Safety Endpoint

	Hydrogel Embolic System (HES) N = 96	
	Number of Events N	Number of Subjects with Events % (n/N)
Primary Safety Endpoint Events [1]	2	1.0% (1/96)
Toxic and/or allergic reaction to HES hydrogel [5]	1	1.0% (1/96)
Non-target embolization of the index procedure	0	0.0% (0/96)
Unintended target tissue ischemia	0	0.0% (0/96)
Pulmonary embolism	0	0.0% (0/96)
Vascular injury requiring surgical/endovascular intervention [5]	1	1.0% (1/96)

	Hydrogel Embolic System (HES) N = 96	
	Number of Events N	**Number of Subjects with Events % (n/N)**
Renal failure that persists to 30 day visit	0	0.0% (0/96)
Hepatic failure that persists to 30 day visit	0	0.0% (0/96)
Abscess in target organ/tissue	0	0.0% (0/96)
Death	0	0.0% (0/96)
Freedom from Major Adverse Events for 30 Days Post-Index Procedure		
Lower Limit of One-sided 95% CI [3]		95.15%
p-value [4]		<0.001

[1] The primary safety endpoint includes MAEs deemed by the CEC to be definitely device and/or procedure-related or probably device and/or procedure-related and satisfies the criteria for a Grade ≥3 event, classified in accordance with the 2017 Society for Interventional Radiology (SIR) Guidelines..
[2] SE population includes mITT subjects who do not have major protocol deviations that impacts the primary safety endpoint identified for HES-treated subjects.
[3] One-sided 95% Clopper-Pearson exact confidence interval. The study device is considered to achieve the safety objective if the lower limit of the one-sided 95% CI is greater than the pre-specified performance goal of 75%.
[4] P-value is based on an exact binomial test comparing the proportion of subjects who are free from MAE to the performance goal of 75%. The hypothesis is evaluated at a one-sided 0.05 significance level.
[5] Both the MAEs occurred in the same subject. The subject developed an allergic reaction after HES embolization, characterized by increased heart rate, diaphoresis, and pallor, requiring administration of epinephrine, albuterol, solumedrol, Narcan, and Romazicon. The allergic reaction event was not classified as an MAE by the CEC as it resolved with pharmacological treatment. The subject developed a cool foot and access site arterial thrombosis the following day.

At least one adverse event was reported for 81.2% (82/101) of subjects treated with HES and 71.4% (35/49) of subjects treated with Standard of Care. Serious adverse events (SAEs) were reported in 30.7% (31/101) treated with HES and 18.4% (9/49) with Standard of Care. The majority of SAEs were unrelated to the device and/or procedure. Specifically, 47 of 52 SAEs (90.2%) in the HES arm and 15 of 16 SAEs (93.8%) in the Standard of Care arm were determined to be unrelated.

The severity of adverse events (AE)'s delineated by CTCAE grade was similar between the treatment arms. Grade 3 or greater AEs were reported for 36.7% of subjects in the HES arm and 30.6% in the Standard of Care arm. The most frequently reported AEs occurring through the Day 90 visit were abdominal pain (27% HES vs. 18% Standard of Care; p=0. 312), nausea (12% HES vs. 6% Standard of Care; p=0.387), fatigue (7% HES vs. 6% Standard of Care; p=>0.999) and post-embolization syndrome (11% HES vs. 8% Standard of Care; p=0.774). These symptoms/events were predominantly transient and typically occurred within the first few days following the study procedure which is consistent for patients undergoing TAE/cTACE.

The data do not show significant differences in the percent of subjects for whom Device and Procedure Related AEs were reported (28.7% for the HES arm and 22.4% for the Standard of Care arm, p=0.440) or Procedure Related AEs (25.7% for the HES arm and 16.3% for the Standard of Care arm, p=0.219). No subject in either treatment arm experienced a clinically

relevant non-target embolization (NTE). Two (2) subjects treated with HES were reported to have experienced NTE with the events identified on the completion angiograms. These events were asymptomatic, did not require treatment and did not result in sequalae. The incidence of Serious Device and Procedure Related events was low for both treatment arms, 3.0% for HES, and 0% for Standard of Care, respectively. The incidence of Procedure only SAEs was identical for both treatment arms at 2.0%. Of note, there were no device and/or procedure-related significant hepatic or renal complications leading to liver or kidney dysfunction, nor were there any reports of tumor abscess infarct or procedural-related mortality. Deaths were reported in 5 subjects (5%) in the HES arm and 3 subjects (6%) in the Standard of Care arm. All deaths occurred more than 30 days post-index procedure and were classified by the CEC as unrelated to the device or procedure, as the events were primarily associated with disease progression and/or comorbidities.

Overall, the AEs observed in this trial are consistent with a patient population undergoing HVT embolization.

Serious Adverse Events (SAE):

SAEs categorized as either Device and Procedure Related or Procedure Related only are summarized in Table 6. There were no device-related only SAEs. Device and Procedure Related SAEs were reported for 3% of subjects in the HES arm and none in the Standard of Care Arm. SAEs classified as Procedure-related only were reported in 2.0% of subjects in both treatment arms.

Table 6: Summary of Serious Device and Procedure Related Events

	Hydrogel Embolic System (HES) N = 101		**Standard of Care TAE/cTACE N = 49**	
	Number of Events N	**Number of Subjects with Events % (n/N)**	**Number of Events N**	**Number of Subjects with Events % (n/N)**
Total Number of Device and Procedure Related Serious Adverse Events	3	3.0% (3/101)	0	0.0% (0/49)
Immune System Disorders	1	1.0% (1/101)	0	0.0% (0/49)
Anaphylactic Reaction	1	1.0% (1/101)	0	0.0% (0/49)
Injury, Poisoning And Procedural Complications	2	2.0% (2/101)	0	0.0% (0/49)
Post Embolisation Syndrome	2	2.0% (2/101)	0	0.0% (0/49)
Total Number of Device Related Serious Adverse Events	0	0.0% (0/101)	0	0.0% (0/49)

	Hydrogel Embolic System (HES) N = 101		Standard of Care TAE/cTACE N = 49	
	Number of Events N	**Number of Subjects with Events % (n/N)**	**Number of Events N**	**Number of Subjects with Events % (n/N)**
Total Number of Procedure Related Serious Adverse Events	2	2.0% (2/101)	1	2.0% (1/49)
General Disorders And Administration Site Conditions	1	1.0% (1/101)	0	0.0% (0/49)
Generalised Oedema	1	1.0% (1/101)	0	0.0% (0/49)
Injury, Poisoning And Procedural Complications	1	1.0% (1/101)	0	0.0% (0/49)
Vascular Procedure Complication	1	1.0% (1/101)	0	0.0% (0/49)
Vascular Disorders	0	0.0% (0/101)	1	2.0% (1/49)
Hypotensive Crisis	0	0.0% (0/101)	1	2.0% (1/49)

Effectiveness Results:

The primary effectiveness endpoint of this study was technical success, defined as the successful delivery of the embolic agent to the index tumor feeding vessel, achieving stasis of flow, as characterized by the absence of contrast flow within the targeted vessel. Non-inferiority of HES compared to Standard of Care was demonstrated using the pre-specified non-inferiority margin of 10%. The analysis for Technical Success was based on 132 vessels in 97 subjects treated with HES and 66 vessels in 48 subjects treated with Standard of Care. Technical Success, as assessed by blinded interventional radiologists (Core Laboratory), was achieved in 88.6% of the HES-treated vessels, and 77.3% of the Standard of Care-treated vessels (Table 7). Technical success (as determined by the independent radiologist) was not achieved due to incomplete stasis or the use of a secondary embolic. This represents a difference of 10.9% in favor of HES, with a two-sided 95% CI lower bound of -2.42% (p=0.001). Sensitivity analyses, including an analysis of all evaluable vessels and a tipping point analysis that considered unevaluable vessels as technical failures, confirmed non-inferiority of HES relative to Standard of Care. Subgroup analyses by gender and tumor location (hepatic vs non-hepatic) revealed no statistically significant differences in the primary effectiveness outcome across the evaluated subgroups.

Table 7: Primary Effectiveness Endpoint in EE Population

	Hydrogel Embolic System (HES)	**Standard of Care TAE/cTACE**	**Difference [3] 95% CI**	**P-value**
Target vessels in which Technical Success achieved [1] – EE Population [2]	88.6% (117/132) (N=97)	77.3% (51/66) (N=48)	10.9% (-2.42%, 24.28%)	0.001

[1] Subjects may contribute more than one target vessel, but only those vessels targeted for embolization prior to randomization are included in the primary effectiveness analysis.
[2] EE population includes all mITT subjects who do not have major protocol deviations that would impact the primary effectiveness endpoint. mITT population includes all enrolled subjects who were randomized and have a target vessel treated. Data analyzed according to randomized treatment assignment. Per-Protocol population includes mITT subjects who do not have a major protocol deviation.
AT population includes mITT subjects, analyzed according to treatment received.
[3] Non-inferiority was assessed using a generalized estimating equation (GEE) model to obtain an estimate of the risk difference between treatments and its two-sided 95% confidence interval

Subgroup Analysis:

In the EE Population, a greater number of hepatic tumor feeding vessels (136 vessels) were embolized compared with non-hepatic tumor vessels (62 vessels). However, the number of vessels embolized in males and females were roughly equivalent, 105 vs. 93 vessels respectively. The statistical tests revealed that the p-values for the test of homogeneity across subgroups exceeded the predetermined significance threshold of 0.15. These findings indicate that there is no statistically significant evidence to suggest differences in the primary effectiveness outcomes across the evaluated subgroups for tumor location or gender. Results of these subgroup analyses are summarized in Table 8.

Table 8: Primary Effectiveness Endpoint Subgroup Analyses and Test for Homogeneity Proportion of Target Vessels with Technical Success

By Strata	Hepatic		Non-Hepatic		Test of Homogeneity P-value [4]
	Hydrogel Embolic System (HES) N=67	Standard of Care TAE/cTACE N=33	Hydrogel Embolic System (HES) N=30	Standard of Care TAE/cTACE N=15	
Target vessels in which Technical Success achieved [3]	87.1% (81/93)	76.7% (33/43)	92.3% (36/39)	78.3% (18/23)	0.656
By Sex	**Male**		**Female**		
	Hydrogel Embolic System (HES) N=48	Standard of Care TAE/cTACE N=33	Hydrogel Embolic System (HES) N=49	Standard of Care TAE/cTACE N=15	
Target vessels in which Technical Success achieved [3]	92.2% (59/64)	73.2% (30/41)	85.3% (58/68)	84.0% (21/25)	0.169

[1] Technical Success determined by a central independent radiologist via comparison of the pre- and final post-procedure angiograms.
[2] EE population includes all mITT subjects who do not have major protocol deviations that would impact the primary effectiveness endpoint.
[3] Subjects may contribute more than one target vessel, but only those vessels targeted for embolization prior to randomization are included in th e primary effectiveness analysis.
[4] A test for homogeneity across strata or sex was performed with a GEE regression model utilizing a normal distribution with an identity link and strata or sex, treatment group and a strata, or sex-by-treatment group interaction term. The p-value shown is for the interaction term and is assessed at a 0.15 significance level.

Tumor Response:

The study demonstrated high tumor response rates across various lesion types, with comparable outcomes between treatment arms. In the EE population, following the index and any subsequent embolization procedures, both HES and Standard of Care achieved a 100% Disease Control Rate (DCR = complete response + partial response + stable disease) at Day 30 for non-hepatic embolized lesions (e.g., renal cell carcinoma, renal angiomyolipoma, bone tumors). By Day 90, the DCRs were 95.8% with HES and 80.0% with Standard of Care. For non-HCC hepatic embolized lesions (e.g., benign liver lesions, metastatic liver tumors), Day 30 DCRs were 88.9% with HES and 100.0% with Standard of Care, while Day 90 DCRs were 91.3% and 93.3%, respectively. In HCC embolized lesions, both treatment arms demonstrated favorable Objective Response Rates (ORR = complete response + partial response) and DCRs at Days 30 and 90. The Day 30 ORRs were 47.7% with HES and 50.0% with Standard of Care, and 45.5% and 56.5%, respectively, by Day 90. The Day 30 DCRs were 95.5% with HES and with Standard if Care it was 100%. DCRs at Day 90 were 90.9% with HES and 95.7% with Standard of Care.

Clinical Study Conclusions

Both the pre-specified hypothesis for effectiveness and safety were established, therefore, the study is considered successful. Results of this study support the use of Embrace HES as a safe and effective alternative to currently available embolization methods for treatment of a variety

of hypervascular tumors. The positive outcomes, taken with the low rate of serious device and/or procedure related adverse events, support a favorable risk-benefit assessment for Embrace HES when used to embolize hypervascular tumors in peripheral arteries ≤ 5 mm.

Instructions for Use

Procedural Preparation

1. Inspect packaging of the Embrace HES prior to use to ensure seal integrity for maintenance of sterility.
2. Carefully evaluate the vascular network associated with the lesion using high resolution imaging prior to beginning the embolization procedure. Estimate proper catheter tip location for embolization and evaluate vessel diameter at that location.
3. Because of the potential for misembolization, the physician should be sure to carefully evaluate the amount of Hydrogel Embolic System material that is anticipated to be delivered according to the size of the target vessels at the desired level of occlusion in the vasculature.
4. The Embrace hydrogel is not radiopaque. The embolization should be monitored using fluoroscopic visualization by adding contrast medium to the physiologic suspension fluid as specified in the instructions below.

Embolic Preparation

Precursor 1

5. Using syringe 1A, draw up contrast to the black 1.5mL fill line.
6. Remove vial 1B from the vial holder, engage the vial spike by pressing it down, and transfer the contrast from the syringe 1A syringe into vial 1B.
7. Remove vial 1C from the vial holder and engage the vial spike.
8. Using the same syringe 1A, draw up the entire volume (approximately 2mL) of the solution from vial 1C and transfer to vial 1B.
9. Swirl and lightly agitate the vial 1B 10-20 times to combine the liquids.
10. This is the Precursor 1 reservoir for future transfer to the Delivery Kit syringe.

Precursor 2

11. Using syringe 2A, draw up contrast to the black 8mL fill line.
12. Remove vial 2B from the vial holder and engage the vial spike.
13. Using the same syringe 2A, draw up the entire volume (approximately 2mL) of the solution from vial 2B.
14. Attach the female-to-female luer connector and invert the syringe 10-20 times to mix.
15. This is the Precursor 2 reservoir for future transfer to the Delivery Kit syringe.

The total volume of the assembled precursors is 7.5 mL. The precursors should be used within 3 hours of preparation.

To Deliver Hydrogel Embolic System

Instylla Microcatheter Insertion

16. Select a suitable outer microcatheter (inside diameter ≥0.027 inch (0.69mm) or ≥0.021 inch (0.53mm)) based on the diameter and length required to access the anticipated target vessel.
17. Prepare and introduce outer microcatheter per manufacturer's IFU and standard interventional technique to the target area.

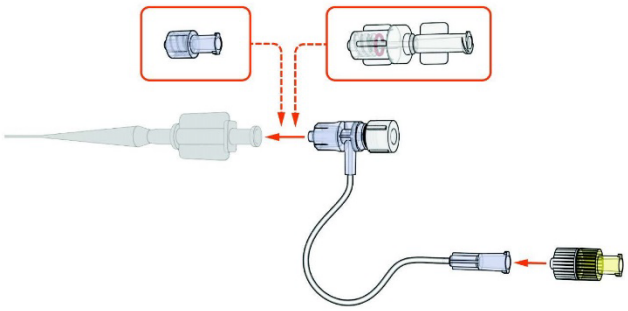
18. Perform contrast injections to assess hemodynamics prior to embolization.
    Note: Therapeutic embolization should not be performed when high blood flow may prevent formation of hydrogel, as in vessels larger than 5mm, or if the catheter tip is positioned at a bifurcation/branch point. Since the delivery of the embolic is dependent on blood flow through the vasculature distal to the catheter tip, it is important that the catheter does not occlude the vessel in which it is placed or impinge on a vessel wall.
19. Prepare the appropriate Instylla Microcatheter per its instructions and Table 9 below.
    Note: An outer microcatheter with inside diameter ≥0.027 inch (0.69mm) is required for use with the Instylla 1.7F Microcatheter, and a microcatheter with inside diameter ≥0.021 inch (0.53mm) is required for use with the Instylla 1.2F Microcatheter. The short or long adapters enable catheter length compatibility for a range of off-the-shelf outer microcatheters. Commonly used compatible systems are listed in Table 9 below.

Table 9: Common Catheter System Details

Outer Microcatheter	Instylla Microcatheter (Size and Length)	Extension Adapter Required	Instylla Microcatheter Priming Volume (mL)	Tuohy Borst with Side-port Priming Volume (mL)
2.8F BSC Renegade Hi-Flo 115cm	1.7F, 122cm	None	0.20	0.60
2.9F Merit Maestro 110cm		Short		0.75
2.8F Terumo Progreat 110cm		Long		0.85
2.8F BSC Renegade Hi-Flo 135cm	1.7F, 142cm	None	0.25	0.65
2.8F BSC Direxion 130cm (Straight and Bern)		Short		0.75
2.9F Merit Maestro 130cm		Short		0.80
2.8F Terumo Progreat 130cm		Long		0.90
2.8F Guerbet DraKon 130cm		Short		0.75
2.8F BSC Renegade Hi-Flo 150cm	1.7F, 162cm	Long	0.30	0.90
2.9F Merit Maestro 150cm		Short		0.85
2.8F Terumo Progreat 150cm		Long		0.95
2.8F Guerbet DraKon 150cm		Short		0.75
2.5F Cook Cantata 110cm	1.2F, 122cm	Long	0.10	0.80
2.4F Terumo Progreat 110cm		Long		0.80
2.5F Cook Cantata 135cm	1.2F, 142cm	None	0.15	0.60
2.4F BSC Renegade STC 130cm		Short		0.70
2.5F BSC Renegade Fiber Braided 130cm		Long		0.85
2.4F BSC Direxion 130cm (Straight and Bern)		Short		0.70
2.0F BSC TruSelect 130cm (Straight and Bern)		Short		0.65
2.4F Terumo Progreat 130cm		Long		0.85
2.4F Guerbet DraKon 130cm		Short		0.70
2.5F Cook Cantata 150cm	1.2F, 162cm	Long	0.20	0.85
2.4F BSC Renegade STC 150cm		Short		0.70
2.5F BSC Renegade Fiber Braided 150cm		Long		0.85
2.4F Terumo Progreat 150cm		Long		0.85
2.4F Guerbet DraKon 150cm		Short		0.75

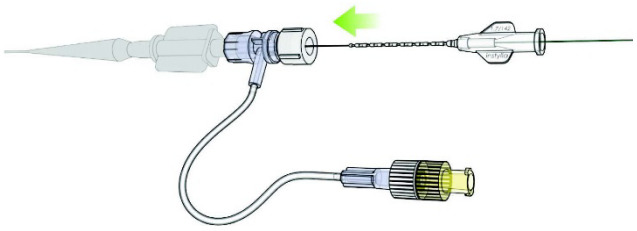
20. Connect a check valve connector to the extension arm and the required extension adapter (if applicable) to the Tuohy Borst and flush the assembly. Connect to the hub of the outer microcatheter per **Figure 1**.

Figure 1



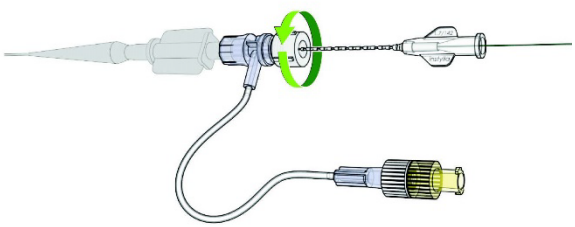
21. With an ≤ 0.014 inch or ≤ 0.010 inch guidewire loaded into the Instylla Microcatheter, 1.7F or 1.2F, respectively, insert the Instylla Microcatheter into the Tuohy-Borst. (per **Figure 2**)

Figure 2



22. With fluoroscopic imaging, advance the Instylla Microcatheter until the proximal edge of the radiopaque tip marker is at, or just beyond the distal edge of the outer microcatheter radiopaque tip marker. Tighten the Tuohy-Borst to anchor the Instylla Microcatheter (per **Figure 3**). Adjust as required to maintain the tip position relationship noted.
    If the catheter tip offset cannot be achieved, remove the guidewire from the Instylla Microcatheter and flush saline through the side port of the Tuohy Borst.

Figure 3



    a. To confirm desired target location, contrast media may be injected through the Instylla Microcatheter.

b. If contrast is injected, flush with saline prior to continuing.

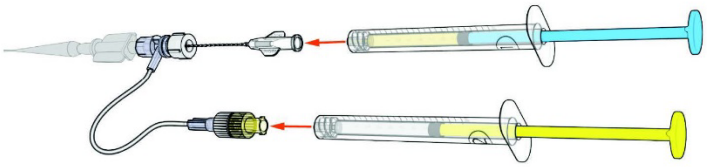
23. Remove the guidewire.

The resultant assembly is the microcatheter assembly used for embolic delivery.

Embolic Delivery with the Instylla Delivery Kit

Note: The blue 1 mL syringe from the Instylla Delivery Kit is the delivery syringe for Precursor 1 and is connected to the luer hub of the Instylla Microcatheter that is inserted into the Tuohy-Borst (per **Figure 4**). The yellow 1 mL syringe from the Instylla Delivery Kit is the delivery syringe for Precursor 2 and is connected to the extension arm of the Tuohy-Borst (per **Figure 4**).

Figure 4



24. Prime the Instylla Microcatheter lumen with Precursor 1 (blue syringe) per volumes listed in Table 9 by withdrawing Precursor 1 from vial “1B”.
25. Prime the outer microcatheter via the side-port of the Tuohy-Borst with Precursor 2 (yellow syringe) per volumes listed in Table 9 by withdrawing from the “2A” syringe.
26. Reload the syringes to 1 mL of the respective Precursors and reconnect to the appropriate hubs.
27. Engage the syringes into the syringe holder and connect the plunger clip (per **Figure 5**).

Figure 5

28. Deliver the embolic with a starting injection rate of approximately 0.02-0.1 mL/second per syringe with pulsatile (“puff”) delivery, holding the plunger against any back pressure. Continue embolic infusion under fluoroscopic imaging, adjusting delivery as required until desired embolization endpoint is achieved.
29. When embolization is observed, retract the catheter assembly tip within the delivery vessel and wait for a minimum of 60 seconds.
30. Deliver a small amount of contrast from the guide catheter to confirm embolization. Repeat embolic delivery as required to achieve desired level of embolization.
31. If the embolization procedure requires additional volume than is contained within the Instylla Delivery Kit Syringes; reload the system following the prior procedures detailed for transfer of material from the reservoirs to the respective delivery syringe. Continue delivery of the embolic materials until the desired level of vascular occlusion is achieved.
32. To confirm desired level of occlusion, an angiogram may be taken. Flush the Instylla Microcatheter with saline and remove with the Tuohy-Borst and adapters. Perform angiogram per hospital protocol.
33. If additional embolization is required, reprime both inner and outer microcatheters per steps 24 and 25. Once desired level of occlusion is achieved, retract catheter system.

Discard any open, unused Embrace HES materials and components.

Adverse Event Reporting

If a serious device-related injury occurs as a result of using this product, please report the incident to the regulatory authorities and contact the manufacturer:

Instylla, Inc.
201 Burlington Road
Bedford, MA 01730
Phone: 781- 790-4860

Instylla, Inc.
201 Burlington Road
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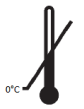
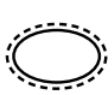
Symbols Glossary in accordance with ISO 15223-1 and ASTM F2503

Symbol	Title of Symbols	Description of Symbol	Reference Number
	Manufacturer	Indicates the medical device manufacturer.	5.1.1.
	Use-by date	Indicates the date after which the medical device is not to be used	5.1.4.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5.
	Catalog number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6.
	Sterilized using steam or dry heat	Indicates a medical device that has been sterilized using steam or dry heat.	5.2.5
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3.
	Do not resterilize	Indicates a medical device that is not to be resterilized.	5.2.6.
	Do not use if package is damaged and consult instructions for use	Indicates 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.	5.2.8.
	Keep dry	Indicates a medical device that needs to be protected from moisture	5.3.4
	Do not reuse	Indicates a medical device that is intended for single use only.	5.4.2.
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.	5.6.3.
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.	5.4.3.
	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.	5.3.5
	Single sterile barrier system	Indicates a single sterile barrier system	5.2.11
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside.	5.2.14
	Medical device	Indicates that the item is a medical device.	5.7.7

	Unique device identifier	Indicates a carrier that contains unique device identifier information	5.7.10
	MR Safe .	Indicates that the item poses no known hazards resulting from exposure to any MR environment	6.3.1