INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Imperative Care Zoom System consists of the following devices:

- Zoom Catheters
  - Zoom™ (71, 55, 45, 35) Catheters
- Large Distal Platform Catheters (LDP Catheters)
  - Zoom™ 88 Large Distal Platform™ (Zoom 88 LDP)
  - Zoom™ 88 Large Distal Platform™ Support (Zoom 88 LDP Support)
  - TracStar™ LDP Large Distal Platform™ (TracStar LDP)
- Zoom Aspiration Tubing and Zoom POD Aspiration Tubing
- Zoom Aspiration Pump

The Zoom Catheters and the LDP Catheters are intended to be used as a system in conjunction with the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing and the Zoom Aspiration Pump (or equivalent vacuum pump) to aspirate thrombus in patients with acute ischemic stroke. The Zoom Catheters and LDP Catheters are single lumen, braid and coil reinforced, variable stiffness catheters with a radiopaque marker and a lubricious hydrophilic coating on the distal portion of the catheter (Table 1). The catheters have a luer hub on the proximal end.

Dimensions for each catheter are included on the individual device label. The Zoom Catheters are compatible with 0.014" – 0.018" guidewires. The LDP Catheters are compatible with 0.038" or smaller guidewires. An additional support catheter may be used to assist in accessing the target vasculature. Information on catheter compatibility with guide sheaths/introducer sheaths is provided in Table 3.

All catheters are packaged with an accessory rotating hemostasis valve (RHV). The RHV is intended to be attached to the proximal hub of the catheter and used to control hemostasis during use with other devices.

The Zoom System catheters are offered with various working lengths, nominal inner diameters (ID), and outer diameters (OD). The following device sizes are available:

TABLE 1 – CATHETER SIZES

Model Number	Product Name	Distal Diameter		Proximal Diameter		Nominal Working Length	Hydrophilic Coating Length
		Inner	Outer	Inner	Outer		
ICTC088110	Zoom™ 88 LDP, 110 cm	0.088"	0.107"	0.088"	0.110"	110 cm	18 cm
ICTC088100S	Zoom™ 88 LDP Support, 100 cm	0.088"	0.107"	0.088"	0.110"	100 cm	14 cm
ICAC088105	TracStar LDP, 105 cm	0.088"	0.107"	0.088"	0.110"	105 cm	14 cm
ICAC088095	TracStar LDP, 95 cm	0.088"	0.107"	0.088"	0.110"	95 cm	14 cm
ICAC088090	TracStar LDP, 90 cm	0.088"	0.107"	0.088"	0.110"	90 cm	14 cm
ICAC088080	TracStar LDP, 80 cm	0.088"	0.107"	0.088"	0.110"	80 cm	14 cm
ICRC071137	Zoom 71, 137 cm	0.071"	0.083"	0.071"	0.083"	137 cm	35 cm
ICRC055137	Zoom 55, 137 cm	0.055"	0.069"	0.067"	0.080"	137 cm	35 cm
ICRC045144	Zoom 45, 144 cm	0.045"	0.060"	0.064"	0.080"	144 cm	65 cm
ICRC035158	Zoom 35, 160 cm	0.035"	0.051"	0.047"	0.061"	160 cm	90 cm

TABLE 2 – CATHETER VESSEL SIZING GUIDELINES

Device Distal Inner Diameter	Device Distal Outer Diameter (mm)	Recommended Vessel Diameter[1] (mm)
0.088”	2.7	> 3.5
0.071”	2.1	> 3.5
0.055”	1.8	3.0 – 3.5
0.045”	1.5	2.5 – 3.0
0.035”	1.3	2.0 – 2.5

[1]Select a catheter based on the sizing in Table 1, the recommendations in Table 2, and the smallest vessel diameter at the thrombus site.

TABLE 3 – CATHETER COMPATIBILITY

Product Name	Guide Sheath or Introducer Sheath / Minimum Inner Diameter	Microcatheter or Intermediate Catheter / Maximum Outer Diameter
Zoom 88 LDP	8F / 0.115”	6F / 0.083”
Zoom 88 LDP Support	8F / 0.115”	6F / 0.083”
TracStar LDP	8F / 0.115”	6F / 0.083”
Zoom 71	6F / 0.088”	5F / 0.065”
Zoom 55	6F / 0.088”	2.4F / 0.031”
Zoom 45	6F / 0.088”	2.4F / 0.031”
Zoom 35	5F / 0.068”	1.4F / 0.018”

The Zoom Aspiration Tubing, Zoom POD Aspiration Tubing, and Zoom Aspiration Pump are packaged and sold separately from the catheters. Refer to the individual *Instructions for Use* for more information.

INDICATIONS FOR USE

The Zoom System, when used with the Zoom Aspiration Pump (or equivalent vacuum pump), is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of last known well.

Patients who are ineligible for intravenous thrombolytic drug therapy or who have not responded to thrombolytic drug therapy are candidates for treatment.

CONTRAINDICATIONS

There are no known contraindications.

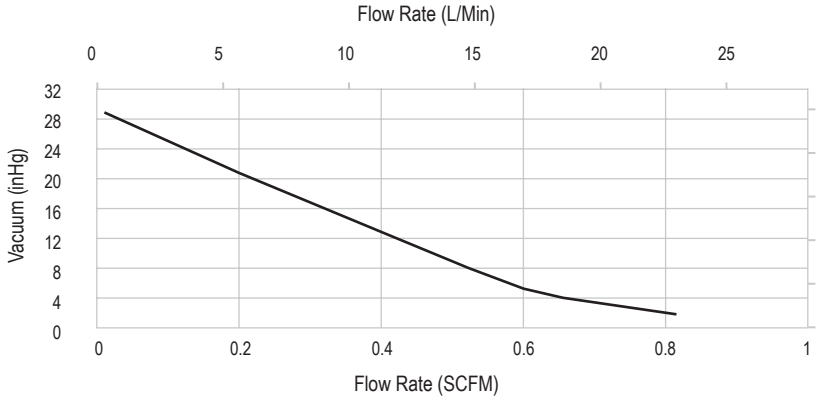
WARNINGS

- **Verify aspiration pump is appropriate before use.**

  The Zoom System catheter(s) have been verified for use with the Zoom Aspiration Tubing, Zoom POD Aspiration Tubing, and Zoom Aspiration Pump. The Zoom Aspiration Pump is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is

characterized by the pressure-flow performance curve presented in Figure 1. If using a vacuum pump other than the Zoom Aspiration Pump, carefully review the vacuum pump performance parameters to ensure it can achieve the same operating vacuum pressures between -20 inHg and -29.9 inHg and corresponds to the same flow rate ranges (Figure 1).

FIGURE 1 – PUMP PRESSURE-FLOW PERFORMANCE CURVE FOR THE ZOOM ASPIRATION PUMP



- The Zoom System should only be used by physicians who have received appropriate training in interventional techniques and treatment of acute ischemic stroke.
- This device is intended for single use only. Do not resterilize or reuse. After use, dispose in accordance with hospital and/or local government policy.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Extreme caution should be used if it is required that the catheters be advanced near or through any aneurysms or other vascular malformations.
- Exercise care when manipulating the device through tortuous anatomy. Do not advance or withdraw the catheters or accessory/adjunctive devices against resistance without careful assessment of the cause under fluoroscopy. If the cause cannot be determined, withdraw all devices as a single unit. Excessive manipulation or torquing the device against resistance may result in damage to the vasculature or the device.
- The distal portion of the catheters has a lubricious hydrophilic coating and should be hydrated per preparation Step 6 with heparinized saline before inserting the catheter into the patient. Failure to abide by this warning may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated in a bath of heparinized saline.
- Do not use automated high-pressure contrast injection equipment with the Zoom System as it may damage the device.
- When performing aspiration, ensure that the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing clamp is open for only the minimum time needed to remove the thrombus. Do not aspirate for more than 60 continuous seconds when no clot is engaged with the catheter. Excessive aspiration or failure to close the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing clamp when aspiration is complete can result in serious patient injury.
- Do not perform more than 3 clot retrieval attempts with the Zoom System.
- Do not stop aspiration if the thrombus is engaged with the Zoom System. Stopping aspiration while thrombus is engaged can result in distal embolization and serious patient injury.
- The safety and effectiveness of mechanical neurothrombectomy devices has only been evaluated via transfemoral access.
- The Zoom System catheters are not recommended for use in combination with stent-retrievers.
- Direct aspiration using the LDP Catheters (Zoom 88 LDP, Zoom 88 LDP Support, TracStar LDP) alone is not supported by the Imperative Trial due to insufficient data. Aspiration through the LDP Catheter (Zoom 88 LDP, Zoom 88 LDP Support, or TracStar LDP) must be performed in conjunction with a Zoom (71, 55, 45, or 35) Catheter.

PRECAUTIONS

- Use prior to the “Use By” date specified on the product package.

- Prior to use, ensure that the dimensions (e.g., diameter and length) of the catheters and accessory/adjunctive devices to be used in the procedure are compatible with each other and appropriate for the target vasculature.
- Use the Zoom System in conjunction with fluoroscopic visualization.

  Note: Sufficient shielding, reduced fluoroscopy times, and modified X-ray technical factors should be used when possible to limit patient and physician exposure to X-ray radiation doses.
- The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice.
- Maintain a constant infusion of an appropriate flush solution. If using a heparinized flush solution, care should be taken to account for the additional heparin being administered via the flush solution. Failure to do so can result in coagulopathy and excessive bleeding at the access site.
- Hemostasis valves should be appropriately used throughout the procedure to minimize blood loss. Monitoring of intra-procedural blood loss throughout the procedure should also be performed to ensure that appropriate management may be instituted as necessary.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
- Use caution when manipulating, advancing, and/or withdrawing the catheter through needles, metal cannulas, stents, or other devices with sharp edges, or through tortuous or calcified blood vessels. Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature, or device damage. This may result in adverse events requiring additional intervention.
- Do not use if the labeling is incomplete or illegible.
- Use of an access site introducer sheath is necessary to introduce the LDP Catheter into the patient's vasculature. A support catheter + guidewire are required when advancing the LDP Catheter into the hemostasis valve on the access site introducer sheath. Attempting to introduce the LDP Catheter without these accessories can result in kinking or other damage to the device.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following:

- Acute occlusion, ischemia
- Unstable angina
- Arrhythmia, including ventricular fibrillation
- Death
- Distal embolization including to a previously uninvolved territory
- Emboli
- False aneurysm formation
- Fever
- Access site complications (hematoma or hemorrhage, sterile inflammation, granulomas)
- Infection, sepsis
- Intracranial hemorrhage
- Hypotension/hypertension
- Acute myocardial infarction
- Infarction/necrosis
- Neurological defects including stroke
- Vessel spasm, thrombosis, dissection, perforation, rupture
- Drug reactions (e.g., coagulopathy, renal insufficiency/failure, allergic reaction)

This device is required to be used with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

DEVICE PREPARATION AND USE

1. Select the appropriate size catheter(s) based on the vessel diameter and the distance from the access site to the target anatomy (see Table 1 and Table 2).
   - Select an appropriate introducer sheath or guide sheath per Table 3 to access the appropriate cerebral artery proximal to the thrombus occlusion site.

     Note: Follow the appropriate introducer sheath or guide sheath Instructions for Use when performing this step.
2. Open the product pouch and place the pouch card into the sterile field. Exercise care when removing the pouch card from the product pouch to prevent damage to the device and accessories.

3. Remove the rotating hemostasis valve (RHV) from the pouch card by removing it from the card tabs before gently lifting the catheter luer from the pouch card tab and removing the catheter shaft from the protective tubing.
4. Inspect the catheter(s) and accessories for kinks or other damage. If damage is noted, do not use the device. Replace with an undamaged device.
5. Attach the provided RHV to the luer of the catheter(s).
6. Hydrate the outer surface of the catheter(s) and flush the lumen of the catheter(s) and RHV with heparinized saline.

   Note: To avoid the introduction of embolic fibers, do not use fabric/cloth/gauze to hydrate or wipe down the catheters. Catheters should be hydrated in a bath of heparinized saline.
7. Open the RHV and advance a guidewire or support catheter + guidewire into the Zoom Catheter or the LDP Catheter if it will be used for aspiration with the Zoom Catheter until the distal tip of the support catheter is past the distal tip of the other catheters and then tighten the RHV to secure the support catheter in place. Do not overtighten the RHV as it could deform the support catheter lumen and prevent passage of a guidewire.

   Note: For Zoom Catheters, a 0.014" - 0.018" guidewire may be used. For LDP Catheters, a 0.038" or smaller guidewire may be used.
8. Gently insert the Zoom Catheter or the combined LDP Catheter and Zoom Catheter with the support catheter and guidewire assembly (device assembly) into the access site introducer sheath or guide catheter using conventional techniques and in accordance with the sheath or guide catheter manufacturer's Instructions for Use.
9. Under fluoroscopy, advance the device assembly into the patient's vasculature using conventional catheterization techniques.

   Note: If injection through the Zoom Catheter and/or LDP Catheter is necessary, remove the support catheter and guidewire and aspirate the catheter lumen prior to injection.

THROMBECTOMY USING THE ZOOM SYSTEM

10. Position the Zoom System catheter(s) proximal to the thrombus. Remove the support catheter and the guidewire, as necessary.
11. Ensure the clamp on the Zoom or Zoom POD Aspiration Tubing is in the closed position and attach the Zoom or Zoom POD Aspiration Tubing to the Zoom Aspiration Pump (or equivalent vacuum pump). Turn on the Zoom Aspiration Pump (or equivalent vacuum pump) per the pump Instructions for Use. Allow the Zoom Aspiration Pump (or equivalent vacuum pump) to run until the aspiration gauge reads at least -20 inHg.
12. Connect each catheter, either directly or to the side port of the RHV, independently to a Zoom or Zoom POD Aspiration Tubing and a Zoom Aspiration Pump (or equivalent vacuum pump).

    Note: When using the LDP Catheter (Zoom 88 LDP, Zoom 88 LDP Support, or TracStar LDP), the LDP Catheter must be used in conjunction with a Zoom (71, 55, 45, or 35) Catheter.
13. To begin aspiration, open the clamp on the Zoom or Zoom POD Aspiration Tubing. To stop aspiration, close the clamp on the Zoom or Zoom POD Aspiration Tubing and turn off the Zoom Aspiration Pump (or equivalent vacuum pump).
14. Using a 5 cc or 10 cc syringe, aspirate approximately 5 cc of blood from the Zoom/LDP Catheter(s) to remove any thrombus that may remain in the catheter.
15. Obtain a post-treatment angiogram to verify that the thrombus has been removed.
16. After the procedure has been completed, remove the Zoom/LDP Catheter(s) per standard procedure.

    Note: While removing the devices, aspirate through the Zoom/LDP Catheter(s) to collect any fibrin that may have been deposited within or at the tip of the catheters.
17. Discard the Zoom Catheters, LDP Catheters, Zoom Aspiration Tubing, and/or Zoom POD Aspiration Tubing appropriately per facility procedure.

CLINICAL DATA SUMMARY

The Imperative Care Zoom Catheters and the LDP Catheters were studied in the Imperative Trial, a prospective, multi-center, open-label, single-arm pivotal clinical investigation designed to assess the safety and effectiveness of the Zoom System in subjects diagnosed with acute ischemic stroke secondary to large vessel occlusions and undergoing a stroke mechanical neurothrombectomy procedure within 8 hours of last known well. A total of 260 evaluable subjects were enrolled across 26 clinical sites in the United States. Further details on this study can be accessed at ClinicalTrials.gov using the identifier NCT04129125.

RECONCILIATION OF EVALUABLE SUBJECTS

	Intervention/ Treatment (Day 0)	24-Hour Assessment (Day 1)	Discharge/Day 7 Assessment (Day 3-7)	90-Day Follow Up Assessment (Day 90)	Total Withdrawal, LTF, and Deaths
Evaluable Subjects	260	260	259	253	
Withdrawal	0	0	1	4	5
Lost to Follow-up (LTF)	N/A	0	0	5	5
Death	0	1*	5	27	33
Subjects Completing Each Visit	260	259	253	217	

* One subject death occurred 2 days post-procedure, but declining status prevented the 24-hour visit from being completed.

IMPERATIVE TRIAL MECHANICAL NEUROTHROMBECTOMY PROCEDURE

Mechanical neurothrombectomy was performed using the Zoom System under general anesthesia or conscious sedation, at the discretion of the investigator. The Zoom Catheters and the LDP Catheters were the primary device. An LDP Catheter was employed to access the vasculature in all cases, while its use to aspirate was according to the treating physicians' preference. Aspiration was applied through an LDP Catheter alone or in conjunction with a Zoom (71, 55, 45, or 35) Catheter either proximal to the clot or at the clot in 92% (238/260) of subjects and in 52% (124/238) of these subjects, aspiration was applied through an LDP Catheter alone or in conjunction with a Zoom (71, 55, 45, or 35) Catheter at the clot. If multiple revascularization attempts were required, the Zoom System was recommended to be used for at least the first three attempts before considering switching to any non-Zoom System device. If the modified thrombolysis in cerebral infarction (mTICI) score ≥ 2b revascularization was not achieved after three attempts with the study device, the procedure was considered a treatment failure for the primary effectiveness endpoint analysis. The subject received standard hospital/medical care after mechanical neurothrombectomy.

From the 260 subjects, the analyzed cohort includes 211 subjects of which 210 underwent concomitant aspiration mechanical neurothrombectomy with combined use of an LDP Catheter (Zoom 88 LDP, Zoom 88 LDP Support, or TracStar LDP) and a Zoom (71, 55, 45, or 35) Catheter and one underwent concomitant aspiration mechanical neurothrombectomy with two Zoom (55 + 35) Catheters. Subjects with single catheter aspiration mechanical neurothrombectomy were excluded from the analysis (n=49), including 28 subjects with direct clot aspiration applied only through the LDP Catheter (Zoom 88 LDP, Zoom 88 LDP Support, or TracStar LDP) for at least one pass and 21 subjects with direct clot aspiration applied only through the Zoom (71, 55, 45, or 35) Catheters for at least one pass. The limited sample size of 28 subjects with direct clot aspiration applied only through the LDP Catheter for at least one pass was not sufficient to establish the safety and effectiveness of the LDP Catheters for use in direct aspiration alone.

KEY INCLUSION CRITERIA

1. Age 18 and older.
2. National Institutes of Health Stroke Scale (NIHSS) score ≥ 6.
3. The operator feels that the stroke can be treated with endovascular thrombectomy approaches and the interventionalist estimates that groin puncture can be achieved within 8 hours from time last seen well.
4. Pre-event modified Rankin Scale (mRS) score 0-1.
5. Large vessel occlusion of the intracranial internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 and M2 segments, basilar, and vertebral arteries as evidenced by magnetic resonance angiography (MRA) or computed tomography angiography (CTA).
6. For strokes in anterior circulation, Alberta Stroke Program Early CT Score (ASPECTS) ≥ 6; for strokes in posterior circulation, pc-ASPECTS ≥ 8.
7. Non-contrast CT/CTA or MRI/MRA for trial eligibility performed or repeated at treating stroke center or outside medical facility within two hours of treatment initiation.
8. If indicated per American Heart Association (AHA) clinical guidelines, thrombolytic therapy should be administered as soon as possible.
9. Consenting requirements met according to local institutional review board (IRB) or ethics committee.

KEY EXCLUSION CRITERIA

1. Female known to be pregnant at time of admission.
2. Patient has suffered a stroke in the past 3 months.
3. Presence of an existing or pre-existing large territory infarction.
4. Pre-existing neurological or psychiatric disease that would confound the neurological or functional evaluation, e.g., dementia with prescribed anti-cholinesterase inhibitor.
5. Known history of severe contrast allergy or absolute contraindication to iodinated contrast.
6. Clinical history, past imaging, or clinical judgement suggest that the intracranial occlusion is chronic.
7. Life expectancy of less than 6 months prior to stroke onset.
8. Clinical symptoms suggestive of bilateral stroke or stroke in multiple territories.
9. Subject participating in another clinical trial involving an investigational device or drug.
10. Known cancer with metastases.
11. Evidence of active systemic infection.
12. Any known hemorrhagic or coagulation deficiency.

KEY BASELINE DEMOGRAPHICS

Characteristics	Summary
Female, % (n/N)	49% (103/211)
Age, Median (IQR)	69 years (59-79 years)
Admission NIHSS, Median (IQR)	14 (10-20)
mRS before Stroke[§] 0 1	 172/210 (82%) 38/210 (18%)
Baseline ASPECTS per Core Lab, Mean ± SD	8.8 ± 1.7
Baseline pc-ASPECTS per Core Lab, Mean ± SD	9.7 ± 0.5
Baseline Core Infarct Volume per Core Lab, Mean ± SD	13 ± 25 mL

Characteristics	Summary
Initial Occlusion Location On CTA[‡] ICA MCA – M1 MCA –M2 Vertebral Basilar Multiple Territories[‡]	 10% (20/201) 60% (120/201) 25% (50/201) 0.0% (0/201) 3.3% (7/201) 2.0% (4/201)

[§] The baseline mRS for one subject was not reported.

† The baseline CTA form was not completed or did not indicate the initial occlusion location for 10 subjects resulting in a sample size of N=201 for this characteristic. The treated occlusion locations for these 10 subjects were: ICA (N=1), MCA-M1 (N=6), and MCA-M2 (N=3).

[‡] In the cases with occlusions in multiple territories the following locations were treated:

- Unilateral, right MCA-M1 and right ACA

- Unilateral, right MCA-M1 and right ACA
- Bilateral, right MCA-M1 and left ICA
- Unilateral, right MCA-M1 and right ACA

CATHETERS USED FOR CONCOMITANT ASPIRATION

In all but one subject, which used a combination of the Zoom 55 and Zoom 35 Catheters, concomitant aspiration within the Imperative Trial was performed using a combination of an LDP Catheter (Zoom 88 LDP, Zoom 88 LDP Support, TracStar LDP) and a smaller diameter Zoom (71, 55, 45, or 35) Catheter. The Zoom Catheters most commonly used with the LDP Catheters on the first procedural pass were: Zoom 71 (81%, 170/211), Zoom 55 (15%, 31/211), Zoom 45 (2.4%, 5/211), and Zoom 35 (1.9%, 4/211).

RESULTS

The primary effectiveness endpoint was independent core lab adjudicated reperfusion success, defined as achieving a mTICI score of ≥ 2b in three or fewer passes with the Zoom System (primary modality), without using additional mechanical neurothrombectomy devices or rescue therapy (e.g., intra-arterial lytics).

Core lab adjudicated reperfusion success within three or fewer passes was achieved in 84% (177/211; 95% confidence interval (CI) of 78% to 89%) of subjects, with a p-value < 0.001 compared to the performance goal (PG). The performance goal of a lower bound of the two-sided 95% CI > 69% was met.

PRIMARY EFFECTIVENESS ANALYSIS RESULTS

Endpoint	Rate, % (n/N)	95% Confidence Interval	PG, %	P-Value
Primary Analysis mTICI ≥ 2b in three or fewer passes of Zoom System without using other devices	84% (177/211)	[78% - 89%]	> 69% for lower bound two-sided 95% CI	< 0.001
Additional Analysis mTICI ≥ 2b in three or fewer passes of Zoom System, use of any non-study devices after achieving mTICI ≥ 2b with Zoom System imputed as a failure	82% (173/211)	[76% - 87%]	> 69% for lower bound two-sided 95% CI	< 0.001

REPERFUSION SUCCESS AFTER ALL PASSES WITH ZOOM SYSTEM AND END OF PROCEDURE

Endpoint	Rate, % (n/N)	95% Confidence Interval
mTICI ≥ 2b after all passes with Zoom System	87% (183/211)	[81% – 91%]
mTICI ≥ 2b at end of procedure	91% (192/211)	[86% – 94%]

The primary safety endpoint was the rate of ECASS III defined symptomatic intracranial hemorrhage (sICH), confirmed by imaging 24 hours post-procedure and adjudicated by an independent core lab and Independent Safety Board (ISB). sICH was observed in 0.9% (2/211; 95% CI of 0.1% to 3.4%) of subjects, which meets the pre-specified performance goal of ≤ 6.0% for the observed rate.

The secondary safety endpoints included an all-cause mortality rate of 12.3% (26/211; 95% CI of 8.1% to 17.2%), a rate of all intracranial hemorrhage (ICH) within 24 hours post-procedure as adjudicated by the independent core lab of 20.0% (42/210; 95% CI of 14.8% to 26.1%), a rate of device-related serious adverse events (SAE) as adjudicated by the ISB of 1.4% (3/211; 95% CI of 0.3% to 4.1%) at 90-day follow-up, a rate of procedure-related serious vessel injury (dissections and perforations) of 0.5% (1/211; 95% CI of < 0.1% to 2.6%) and a rate of embolization in new territory (ENT) of 1.0% (2/200; 95% CI of 0.1% to 3.6%).

The median time from puncture to achieve mTICI ≥ 2b flow was 19 minutes.

PRIMARY SAFETY ANALYSIS RESULTS

Endpoint	Rate, % (n/N)	95% Confidence Interval	95% Confidence Interval
ECASS III sICH	0.9% (2/211)	[0.1% – 3.4%]	Observed rate ≤ 6.0%

SECONDARY SAFETY ENDPOINT RESULTS

Endpoint	Rate, % (n/N)	95% Confidence Interval
90 Day All-Cause Mortality	12.3% (26/211)	[8.1% – 17.2%]
Core Lab Adjudicated ICH	20.0% (42/210‡)	[14.8% – 26.1%]
Embolism in New Territory (ENT)	1.0% (2/200§)	[0.1% – 3.6%]

‡Imaging for one case was inadequate for the core lab to determine if there was a hemorrhage. The site reported no hemorrhage and no neurological deterioration for this subject.

§ENT assessment forms were not completed for 11 subjects.

In total, 147/211 (69.7%) subjects had at least one adverse event, with 74/211 (35.1%) subjects having at least one serious adverse event.

ADVERSE EVENT DATA

	Rate, % (n/N)	95% Confidence Interval
Non-Serious Adverse Event (AE)	62% (131/211)	[55% – 69%]
Serious Adverse Event (SAE)	35% (74/211)	[29% – 42%]
Device Related SAE, Adjudicated by ISB	1.4% (3/211)	[0.3% – 4.1%]
Procedure Related Serious Vessel Injury (Dissections and Perforations)	0.5% (1/211)	[< 0.1% – 2.6%]

COMMON SERIOUS ADVERSE EVENTS

System Organ Class	Preferred Term	Rate, % (n/N)
Cardiac disorders	Cardiac arrest	1.9% (4/211)
	Cardiac failure	1.4% (3/211)
Gastrointestinal disorders	Dysphagia	1.9% (4/211)
	Gastrointestinal haemorrhage	1.9% (4/211)
Infections and infestations	Pneumonia	2.4% (5/211)
	Urinary tract infection	1.9% (4/211)

System Organ Class	Preferred Term	Rate, % (n/N)
Injury, poisoning and procedural complications	Vascular pseudoaneurysm[§§]	1.4% (3/211)
	Vessel perforation	0.5% (1/211)
Nervous system disorders	Brain oedema	1.9% (4/211)
	Cerebral artery occlusion	1.4% (3/211)
	Cerebral artery restenosis	1.9% (4/211)
	Cerebral haemorrhage	0.9% (2/211)
	Cerebrovascular accident	1.9% (4/211)
	Haemorrhagic transformation stroke	1.9% (4/211)
	Seizure	1.9% (4/211)
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	2.8% (6/211)
	Pneumonia aspiration	3.3% (7/211)
	Respiratory failure	3.3% (7/211)

[§§]All groin pseudoaneurysms

IMPERATIVE TRIAL CONCLUSIONS

Stroke mechanical neurothrombectomy with the Zoom System is safe and effective in subjects with large vessel occlusions within eight hours of last known well. All pre-specified performance goals were met.

PACKAGING

The Zoom Catheters and LDP Catheters are placed inside a protective high-density polyethylene (HDPE) tube and then secured to a HDPE packaging card. A rotating hemostasis valve (RHV) is included in the packaging. The packaging card is placed into a nylon/Tyvek pouch which is thermally sealed to maintain sterility post sterilization.

The catheters are sterilized using ethylene oxide (EtO).

The catheters will remain sterile unless the pouch is opened, damaged, or the “Use By” date has passed.

MATERIALS

The Zoom Catheters and LDP Catheters are not made with natural rubber latex.

STORAGE AND HANDLING

Keep dry. Keep away from sunlight. Store at room temperature.

SYMBOLS GLOSSARY

Except where indicated with an asterisk (*), Standard Reference: ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements, §5 Symbols.

Symbol	Definition
	Manufacturer
	Lot number
	Use by
	Attention - See instructions for use for safety information and symbols glossary
	Catalogue number
	Single sterile barrier system with protective packaging outside. Sterilized by ethylene oxide.
	Nonpyrogenic
	*Prescription only - U.S. Federal Law restricts this device to use by or on the order of a physician
	Do not use if packaging is damaged
	Do not resterilize
	Do not reuse
	*Contents (numeral indicates quantity of systems in package)
	Keep away from sunlight
	Keep dry
	Medical device

WARRANTY

Imperative Care, Inc. (“Imperative Care”) 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 for a particular use. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Imperative Care’s control directly affect the device and the results obtained from its use. Imperative Care’s obligation under this warranty is limited to the replacement of this device and Imperative Care shall not be liable for any incidental, consequential, or special loss, damage, or expense directly or indirectly arising from the use of this device. Imperative Care neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty is valid only if the device is used in accordance with the manufacturer’s instructions, and the warranty is limited to the original user. Any sale or other transfer or use of the device covered by this warranty to or by a user other than the original user shall cause this warranty to terminate immediately. Imperative Care assumes no liability with respect to devices reused, reprocessed, or resterilized, or serviced, repaired or modified by any party other than the original manufacturer, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such devices.

ELEVATING STROKE CARE™

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1359 Dell Avenue
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+1.408.502.7548

℞ Only

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