2	7	5	4	8
Study #				

Site #				

Subject #		

Contents

REGISTRATION FORM: Baseline (Pre-Procedure) 3
Demographics: Baseline (Pre-Procedure) 4
Index Diagnosis: Baseline (Pre-Procedure) 5
Medical History: Baseline (Pre-Procedure) 12
Leg Pain Severity Score - Baseline (Pre-Procedure) – DVT ONLY 20
Villalta Score – Baseline (Pre Procedure) – DVT ONLY 21
Revised Venous Clinical Severity Score – (Baseline Pre-Procedure) – DVT ONLY 23
CEAP-C – (Baseline Pre-Procedure) – DVT ONLY 25
EQ-5D-5L (Baseline Pre-Procedure) – DVT ONLY 26
VEINES – Baseline (Pre-Procedure) – DVT ONLY 28
Rutherford Classification – Baseline (Pre-Procedure) – ALI ONLY 32
Procedural information – ALI – Day 0 33
Procedural information – DVT – Day 0 47
Procedural information – SMA – Day 0 53
Devices Used 59
Leg Pain Severity Score – Day 7/Discharge – DVT ONLY 61
Rutherford Classification – Day 7/Discharge – ALI ONLY 62
Discharge Details – Day 7/Discharge 63
Rutherford Classification – 30 Day Follow Up – ALI ONLY 64
Leg Pain Severity Score – Day 30 Follow-Up – DVT ONLY 65
Villalta Score – Day 30 Follow-Up – DVT ONLY 66
Revised Venous Clinical Severity Score – Day 30 Follow-Up – DVT ONLY 68
CEAP-C – Day 30 Follow-Up – DVT ONLY 70
EQ-5D-5L - Day 30 Follow-Up – DVT ONLY 71
VEINES – Day 30 Follow-Up – DVT ONLY 73
Follow Up Information - 30 Day Follow Up 77
Rutherford Classification – 180 Day Follow Up – ALI ONLY 95
Leg Pain Severity Score – Day 180 Follow-Up – DVT ONLY 96
Villalta Score – Day 180 Follow-Up – DVT ONLY 97
Revised Venous Clinical Severity Score – Day 180 Follow-Up – DVT ONLY 99

CEAP-C – Day 180 Follow-Up – DVT ONLY 101
EQ-5D-5L - Day 180 Follow-Up – DVT ONLY 102
VEINES – Day 180 Follow-Up – DVT ONLY 104
Follow Up Information – 180 Day Follow Up 108
Unscheduled Imaging 126
Adverse Event 141
Study Exit 144

2	7	5	4	8

Study #

Site #

Subject #

REGISTRATION FORM: Baseline (Pre-Procedure)

Date of patient enrollment: __ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY

A patient is considered enrolled upon insertion of an Indigo catheter into the patient's body.

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Demographics: Baseline (Pre-Procedure)

Age: ____ (years)

Sex:

- ○ Male
- ○ Female

Weight: _____ (000.0)

Weight unit:

- ○ kg
- ○ lbs

Height: _____ (000.0)

Height unit:

- ○ cm
- ○ in

Race:

- ○ Japanese
- ○ Not Japanese

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Index Diagnosis: Baseline (Pre-Procedure)

Index diagnosis:

- ○ ALI
- ○ DVT
- ○ SMA Occlusion

Proper Use Guidelines for Disease State

ALI Diagnosis

Anatomical Conditions:
Does patient have thrombosis or embolism in the arteries of the lower extremities?
Patients who have difficulty with skin incision or anaesthesia, or in situations where it is preferable to perform the procedure in an angiographic room, or with thrombus extending into small-calibre arteries such as the femoral artery.

- ○ Yes
- ○ No

High-risk conditions:
Does patient have acute ischemia requiring prompt treatment?

- ○ Yes
- ○ No

Is surgical thrombectomy not feasible (Surgeon who can perform surgical thrombectomy and/or operating room not available) or is expected to be difficult even if performed or for which residual thrombus still needs to be removed after surgical thrombectomy?

- ○ Yes
- ○ No

Other reason why patient met proper use guidelines for ALI, specify:_____

_____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Index Diagnosis: Baseline (Pre-Procedure)

DVT Diagnosis

Does the patient have acute and subacute deep vein thrombosis including iliac vein occlusion (within 3 months of onset)?

- ○ Yes
- ○ No

Does the patient have critical deep vein thrombosis with arterial ischemia (painful blue groin tumor/Phlegmasia cerulea dolens, painful leucoma, venous gangrene)?

- ○ Yes
- ○ No

Does the patient have deep vein thrombosis that significantly interferes with daily life due to constant pain despite anticoagulation therapy and appropriate conservative therapy such as leg elevation or compression therapy. (VCSS pain score 3)?

- ○ Yes
- ○ No

Deep vein thrombosis that significantly interferes with daily life due to constant pain despite anticoagulation therapy and appropriate conservative therapy such as leg elevation or compression therapy. (VCSS pain score 2 also Villalta Score 15+)?

- ○ Yes
- ○ No

Within 1 week of onset, did the patient have no more than 1 cm extension into the IVC, and patency of the inflow vein, popliteal and lower vein?

- ○ Yes
- ○ No

SMA Occlusion Diagnosis

Did the patient have acute arterial occlusion (thrombosis or embolism) in abdominal visceral arteries, mainly the superior mesenteric artery?

- ○ Yes
- ○ No

2	7	5	4	8

Study #

Site #

Subject #

Index Diagnosis: Baseline (Pre-Procedure)

Did the patient present with acute abdomen?

- ○ Yes
- ○ No

Can bowel preservation be expected by thrombus aspiration: no extensive bowel necrosis or generalized peritonitis? *(If there is strong suspicion of intestinal necrosis, consider immediate bowel resection by a surgeon. If the findings of the laparotomy and intraoperative examination (ICG fluorescence) indicate that thrombus aspiration is expected to prolong the remaining bowel and preserve organs, the device may be used under a DSA device.)*

- ○ Yes
- ○ No

Date of symptom onset: __ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY

If ALI, specify index limb and thrombus location (target vessel):

RIGHT LEG:

Right External Iliac: ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent	Right Common Iliac: ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent
Right Common femoral: ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent	Right Superficial femoral: ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent
Right Profunda (Deep femoral): ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent	Right Popliteal - P1 (Proximal): ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Index Diagnosis: Baseline (Pre-Procedure)

RIGHT LEG:

Right Popliteal – P2 (Mid): ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent	Right Popliteal - P3 (Distal): ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent
Right Anterior Tibial: ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent	Right Tibioperoneal Trunk: ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent
Right Posterior Tibial: ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent	Right Peroneal: ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent
Right Dorsalis pedis: ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent	Right Leg Other Location, Specify: _____ ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent

2	7	5	4	8

Study #

Site #

Subject #

Index Diagnosis: Baseline (Pre-Procedure)

If ALI, specify index limb and thrombus location (target vessel):

LEFT LEG:

Left External Iliac: o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent	Left Common Iliac: o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent
Left Common femoral: o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent	Left Superficial femoral: o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent
Left Profunda (Deep femoral): o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent	Left Popliteal - P1 (Proximal): o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent
Left Popliteal – P2 (Mid): o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent	Left Popliteal - P3 (Distal): o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent
Left Anterior Tibial: o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent	Left Tibioperoneal Trunk: o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent
Left Posterior Tibial: o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent	Left Peroneal: o Native vessel o Vein Bypass Graft o Synthetic Bypass Graft o Stent Graft o Stent

2	7	5	4	8
Study #				

Site #				

Subject #		

Index Diagnosis: Baseline (Pre-Procedure)

If ALI, specify index limb and thrombus location (target vessel):

LEFT LEG:

Left Dorsalis pedis: ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent	Left Leg Other Location, Specify: _____ ○ Native vessel ○ Vein Bypass Graft ○ Synthetic Bypass Graft ○ Stent Graft ○ Stent

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Index Diagnosis: Baseline (Pre-Procedure)

If SMA, specify segment:

☐ Main Trunk *(Check applicable regions below)*	
☐ *Region 1 (From origin of SMA to MCA, including origin of MCA)*	○ Native vessel ○ Stent
☐ *Region 2 (Beyond origin of MCA, excluding origin of MCA, to ICA including origin of ICA)*	○ Native vessel ○ Stent
☐ Middle Colic Artery (MCA) - Region 3	○ Native vessel ○ Stent
☐ Ileocolic Artery (ICA) - Region 3	○ Native vessel ○ Stent
☐ Peripheral Branches - Region 3 – Beyond origin of ICA (excluding origin of ICA), including branches	○ Native vessel ○ Stent
☐ Other target vessel segment, specify: _____	○ Native vessel ○ Stent

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Medical History: Baseline (Pre-Procedure)

Medical History General:

Hypertension: ○ Yes ○ No ○ Unknown	Dyslipidemia: ○ Yes ○ No ○ Unknown
Carotid artery disease: ○ Yes ○ No ○ Unknown	Congestive heart failure: ○ Yes ○ No ○ Unknown
Ischemic heart disease: ○ Yes ○ No ○ Unknown	Cerebrovascular disease: ○ Yes ○ No ○ Unknown

History of Stroke: *(Check all applicable)*

☐ Ischemic stroke

☐ Hemorrhagic stroke

☐ Subarachnoid hemorrhage

PAD

○ Yes
○ No
○ Unknown

PAD category: *(Check all applicable)*

☐ Right Leg

☐ Left Leg

2	7	5	4	8

Study #

Site #

Subject #

Medical History: Baseline (Pre-Procedure)

History of chronic limb ischemia

- ○ Yes
- ○ No
- ○ Unknown

History of ALI (outside of index event)

- ○ Yes
- ○ No
- ○ Unknown

If Yes, ALI - Affected limb

- ○ Right
- ○ Left
- ○ Bilateral

Popliteal Aneurysm

- ○ Yes
- ○ No
- ○ Unknown

If Yes, Popliteal Aneurysm – which leg(s)

- ☐ Right
- ☐ Left

If Yes, Treatment(s) done:	
Right Leg	**Left Leg**
☐ Stent Graft ☐ Bypass Graft ☐ None of the above	☐ Stent Graft ☐ Bypass Graft ☐ None of the above

Coronary artery disease

- ○ Yes
- ○ No
- ○ Unknown

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Medical History: Baseline (Pre-Procedure)

Angina

- ○ Yes
- ○ No
- ○ Unknown

If Yes: Type of angina

- ○ Stable angina
- ○ Unstable angina

Atrial fibrillation

- ○ Yes
- ○ No
- ○ Unknown

History of MI

- ○ Yes
- ○ No
- ○ Unknown

Deep venous thrombosis (DVT)

- ○ Yes
- ○ No
- ○ Unknown

If Yes: DVT - Affected limb

- ○ Right
- ○ Left
- ○ Bilateral

Previous diagnosis of May-Thurner syndrome

- ○ Yes
- ○ No
- ○ Unknown

2	7	5	4	8

Study #

Site #

Subject #

Medical History: Baseline (Pre-Procedure)

Previous intervention on the index limb
- ○ Yes
- ○ No
- ○ Unknown

If Yes previous intervention on index limb: check all that apply

☐ Endovascular thrombectomy	☐ Surgical revascularization
☐ Stent	☐ Stent Graft
☐ Drug Coated Balloon	☐ Thrombolytics
☐ Bypass graft If Yes, Bypass Graft Type: ○ Native ○ Synthetic	

History of pulmonary embolism (PE)
- ○ Yes
- ○ No
- ○ Unknown

PE Status
- ○ Current (with index DVT)
- ○ Previous

IVC filter in place
- ○ Yes
- ○ No

Intra-cardiac thrombus
- ○ Yes
- ○ No
- ○ Unknown

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Medical History: Baseline (Pre-Procedure)

Varicose veins
- ○ Yes
- ○ No

Renal insufficiency
- ○ Yes
- ○ No
- ○ Unknown

If Yes, Renal Insufficiency - dialysis status
- ○ Currently on maintenance dialysis
- ○ On dialysis in the past
- ○ Never dialyzed

Kidney transplantation
- ○ Yes
- ○ No
- ○ Unknown

Any history of hypercoagulable state
- ○ Yes
- ○ No
- ○ Unknown

Active bleed
- ○ Yes
- ○ No
- ○ Unknown

History of anemia
- ○ Yes
- ○ No
- ○ Unknown

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Medical History: Baseline (Pre-Procedure)

Contraindication to thrombolytics

- ○ Yes
- ○ No
- ○ Unknown

Diabetes

- ○ Yes - Insulin dependent
- ○ Yes - Non-insulin dependent
- ○ No
- ○ Unknown

Cancer or malignant neoplasm

- ○ Yes
- ○ No
- ○ Unknown

If Yes for Cancer, Is the subject on active therapy?

- ☐ No
- ☐ Yes, chemo
- ☐ Yes, radiation

History of mesenteric ischemia

- ○ Yes
- ○ No
- ○ Unknown

If Yes for History of mesenteric ischemia, Treatment:

- ○ None
- ○ Abdominal surgery
- ○ Other treatment

Inflammatory bowel disease

- ○ Yes
- ○ No
- ○ Unknown

Medical History: Baseline (Pre-Procedure)

Immobile (non-ambulatory)

- ○ Yes
- ○ No

Amputation of lower limb

- ○ Yes
- ○ No

If Yes, Amputation of lower limb:

Amputation - Affected limb ○ Right ○ Left ○ Bilateral	
Amputation level – Right ○ Minor: distal to the ankle ○ Major: at or proximal to the ankle	Amputation level – Left ○ Minor: distal to the ankle ○ Major: at or proximal to the ankle

Social History

Alcohol abuse within last 6 months

- ○ Yes
- ○ No
- ○ Unknown

Status of tobacco use

- ○ None
- ○ Former
- ○ Current

If current or former smoker, Brinkman index: _____ (whole number)

Brinkman Index is the number of cigarettes smoked per day multiplied by the number of years of smoking.

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Medical History: Baseline (Pre-Procedure)

Concomitant Medication

Check which of the following medications the patient is currently taking:

☐ Aspirin	☐ Clopidogrel	☐ Ticlopidine
☐ Prasugrel	☐ Cilostazol	☐ None of the Above

2	7	5	4	8

Study #

Site #

Subject #

Leg Pain Severity Score - Baseline (Pre-Procedure) – DVT ONLY

Was Leg Pain Severity Score assessed?

- ○ Yes
- ○ No

If Yes, Assessment date: __ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy

0 = No pain at all
10 = Worst pain ever possible

Leg Pain Severity Score - Right Leg	Leg Pain Severity Score - Left Leg
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Villalta Score – Baseline (Pre Procedure) – DVT ONLY

Was Villalta Score assessed**?**

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Right Leg	Left Leg
Pain - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pain - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Cramps - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Cramps - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Heaviness - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Heaviness - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Paresthesia - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Paresthesia - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Pruritis - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pruritis - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Pretibial edema - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pretibial edema - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Villalta Score – Baseline (Pre Procedure) – DVT ONLY

Right Leg	Left Leg
Skin induration - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Skin induration - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Hyperpigmentation - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Hyperpigmentation - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Redness - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Redness - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Venous ectasia - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Venous ectasia – Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Pain on calf compression - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pain on calf compression - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Venous ulcer - Right Leg ○ Present ○ Absent	Venous ulcer - Left Leg ○ Present ○ Absent

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Revised Venous Clinical Severity Score – (Baseline Pre-Procedure) – DVT ONLY

Was Revised Venous Clinical Severity Score assessed?

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Right Leg	Left Leg
Pain - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pain - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Varicose veins - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Varicose veins - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Venous edema - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Venous edema - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Skin pigmentation - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Skin pigmentation - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Inflammation - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Inflammation – Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Induration - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Induration - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Revised Venous Clinical Severity Score – (Baseline Pre-Procedure) – DVT ONLY

Right Leg	Left Leg
Active ulcer number - Right Leg ○ 0 ○ 1 ○ 2 ○ >= 3	Active ulcer number - Left Leg ○ 0 ○ 1 ○ 2 ○ >= 3
Active ulcer duration - Right Leg ○ 0 - N/A ○ 1 - < 3 months ○ 2 - >= 3 months and < 1 year ○ 3 - Not healed for >= 1 year	Active ulcer duration - Left Leg 1. 0 - N/A 2. 1 - < 3 months 3. 2 - >= 3 months and < 1 year 4. 3 - Not healed for >= 1 year
Active ulcer size - Right Leg ○ 0 - N/A ○ 1 - Diameter < 2 cm ○ 2 - Diameter >= 2 cm and < 6 cm ○ 3 - Diameter >= 6 cm	Active ulcer size - Left Leg ○ 0 - N/A ○ 1 - Diameter < 2 cm ○ 2 - Diameter >= 2 cm and < 6 cm ○ 3 - Diameter >= 6 cm
Use of compression therapy - Right Leg ○ 0 - Not used ○ 1 - Intermittent use of stockings ○ 2 - Wears stockings most of the day ○ 3 - Full compliance stockings	Use of compression therapy - Left Leg ○ 0 - Not used ○ 1 - Intermittent use of stockings ○ 2 - Wears stockings most of the day ○ 3 - Full compliance stockings

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

CEAP-C – (Baseline Pre-Procedure) – DVT ONLY

Was CEAP-C assessed??

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Check all that apply:

CEAP-C Right Leg	CEAP-C Left Leg
☐ C0 No visible or palpable signs of venous disease	☐ C0 No visible or palpable signs of venous disease
☐ C1 Telangiectasies or reticular veins	☐ C1 Telangiectasies or reticular veins
☐ C2 Varicose veins; distinguished from reticular veins by a diameter of 3 mm or more	☐ C2 Varicose veins; distinguished from reticular veins by a diameter of 3 mm or more
☐ C3 Edema	☐ C3 Edema
☐ C4A Changes in skin and subcutaneous tissue secondary to CVD - Pigmentation or eczema	☐ C4A Changes in skin and subcutaneous tissue secondary to CVD - Pigmentation or eczema
☐ C4B Changes in skin and subcutaneous tissue secondary to - Lipodermatosclerosis or atrophie blanche	☐ C4B Changes in skin and subcutaneous tissue secondary to - Lipodermatosclerosis or atrophie blanche
☐ C5 Healed venous ulcer	☐ C5 Healed venous ulcer
☐ C6 Active venous ulcer	☐ C6 Active venous ulcer
CEAP-C Symptomatic Modifier - Right Leg ○ S, Symptomatic ○ A, Asymptomatic	**CEAP-C Symptomatic Modifier - Left Leg** ○ S, Symptomatic ○ A, Asymptomatic

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

EQ-5D-5L (Baseline Pre-Procedure) – DVT ONLY

Was the EQ-5D-5L QOL administered?

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

MOBILITY:

- ○ I have no problems in walking about
- ○ I have slight problems walking about
- ○ I have moderate problems in walking about
- ○ I have severe problems in walking about
- ○ I am unable to walk about

SELF-CARE

- ○ I have no problems washing or dressing myself
- ○ I have slight problems washing or dressing myself
- ○ I have moderate problems washing or dressing myself
- ○ I have severe problems washing or dressing myself
- ○ I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- ○ I have no problems doing my usual activities
- ○ I have slight problems doing my usual activities
- ○ I have moderate problems doing my usual activities
- ○ I have severe problems doing my usual activities
- ○ I am unable to do my usual activities

PAIN/DISCOMFORT

- ○ I have no pain or discomfort
- ○ I have slight pain or discomfort
- ○ I have moderate pain or discomfort
- ○ I have severe pain or discomfort
- ○ I have extreme pain or discomfort

2	7	5	4	8

Study #

Site #

Subject #

EQ-5D-5L (Baseline Pre-Procedure) – DVT ONLY

ANXIETY/DEPRESSION

- ○ I am not anxious or depressed
- ○ I am slightly anxious or depressed
- ○ I am moderately anxious or depressed
- ○ I am severely anxious or depressed
- ○ I am extremely anxious or depressed

0 = Worst heath condition imaginable
100 = The best health imaginable

Patient reported visual analog scale (0-100):_____(whole number)

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Baseline (Pre-Procedure) – DVT ONLY

Was the VEINES QOL/Sym administered?

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

These questions are about your leg problem(s):

1. During the past 4 weeks, how often have you had any of the following leg problems?

Heavy legs ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Aching legs ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Swelling ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Night cramps ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Heat or burning sensation ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Restless legs ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Throbbing ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Itching ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Tingling sensation (e.g. pins and needles) ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Baseline (Pre-Procedure) – DVT ONLY

2. At what time of day is your leg problem most intense?
   - ○ On waking
   - ○ At mid-day
   - ○ At the end of the day
   - ○ During the night
   - ○ At any time of the day
   - ○ Never

3. Compared to one year ago, how would you rate your leg problem in general now?
   - ○ Much better now than one year ago
   - ○ Somewhat better now than one year ago
   - ○ About the same now as one year ago
   - ○ Somewhat worse now than one year ago
   - ○ Much worse now than one year ago
   - ○ I did not have any leg problem last year

4.The following items are about activities that you might do in a typical day.

Does your leg problem now limit you in these activities? If so, how much?

Daily activities at work	○ I do not work ○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All
Daily activities at home (e.g. housework, ironing, doing odd jobs/repairs around the house, gardening, etc…)	○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All
Social or leisure activities in which you are standing for long periods (e.g. parties, weddings, taking public transportation, shopping, etc…)	○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All
Social or leisure activities in which you are sitting for long periods (e.g. going to the cinema or the theater, traveling, etc…)	○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Baseline (Pre-Procedure) – DVT ONLY

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your leg problem?

Cut down the amount of time you spent on work or other activities	○ Yes ○ No
Accomplished less than you would like	○ Yes ○ No
Were limited in the kind of work or other activities	○ Yes ○ No
Had difficulty performing the work or other activities (for example, it took extra effort)	○ Yes ○ No

6. During the past 4 weeks, to what extent has your leg problem interfered with your normal social activities with family, friends, neighbors or groups?

- ○ Not at all
- ○ Slightly
- ○ Moderately
- ○ Quite a bit
- ○ Extremely

7. How much leg pain have you had during the past 4 weeks?

- ○ None
- ○ Very mild
- ○ Mild
- ○ Moderate
- ○ Severe
- ○ Very severe

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Baseline (Pre-Procedure) – DVT ONLY

8. These questions are about how you feel and how things have been with you during the past 4 weeks as a result of your leg problem. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks –

Have you felt concerned about the appearance of your leg(s)?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Have you felt irritable?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Have you felt a burden to your family or friends?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Have you been worried about bumping into things?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Has the appearance of your leg(s) influenced your choice of clothing?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Rutherford Classification – Baseline (Pre-Procedure) – ALI ONLY

Was Rutherford Classification assessed?

- ○ Yes
- ○ No

If Yes, Date of Evaluation __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Rutherford Classification Category - Right Leg

- ○ I. Viable
- ○ IIA. Threatened Marginally (Often)
- ○ IIB. Threatened Immediately (Usually)
- ○ III. Irreversible

Rutherford Classification Category - Left Leg

- ○ I. Viable
- ○ IIA. Threatened Marginally (Often)
- ○ IIB. Threatened Immediately (Usually)
- ○ III. Irreversible

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – ALI – Day 0

Procedure Information

Date and time of arterial puncture:

__ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY __ __: __ __ HH:MM (24hr clock)

Name of the primary physician performing the procedure:

_____

Etiology of thrombus:

- ○ Embolic
- ○ Thrombotic

Access site for Indigo Aspiration System:
If multiple access attempts were made, select options for all successful access sites (check all the apply):

- ☐ Right femoral
- ☐ Right popliteal
- ☐ Left femoral
- ☐ Left popliteal
- ☐ Other, specify:_____

Were pre-procedure thrombolytics administered?

- ○ Yes
- ○ No

Total procedure time: __ __ __ (mins)

Total aspiration time: __ __ __ (mins) Total aspiration time ***OR*** Unknown ☐

2	7	5	4	8
Study #				

Site #				

Subject #		

Procedural information – ALI – Day 0

Estimated blood loss (canister volume minus flush volume)

__ __ __ __ cc (whole number, up to 4 digits) ***OR*** Estimated blood loss Unknown ☐

Procedure Information - Additional Treatment

Were any additional treatments performed during the index procedure?

- ○ Yes
- ○ No

If yes, Record any additional treatments performed during the index procedure

- ☐ Balloon
- ☐ Bypass graft
- ☐ Fogarty
- ☐ Stent
- ☐ Thrombolytics
- ☐ Other treatment, specify _____

If Yes, Please complete the Procedure Information Additional Treatment Log for every additional procedure performed: *Please see log below:*

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – ALI – Day 0

Procedure Information - Additional Treatment Log:

Please check box of all additional treatments patient received:

☐ Balloon	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel
☐ Bypass graft	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – ALI – Day 0

Procedure Information - Additional Treatment Log:

Please check box of all additional treatments patient received:

☐ Fogarty	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel
☐ Stent	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel

2	7	5	4	8
Study #				

Site #				

Subject #		

Procedural information – ALI – Day 0

Procedure Information - Additional Treatment Log:

Please check box of all additional treatments patient received:

☐ Thrombolytics	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel
☐ Other Treatment, Specify:_____ _____	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – ALI – Day 0

Technical Success

Primary technical success should be defined per vessel treated on an intent-to-treat basis and applies only to segment treated with Indigo. Defined as successful use of the device to re-establish any antegrade flow and complete or near complete (95% by volume) removal of thrombus as assessed by visual analysis of angiographic images or by other objective imaging such as DUS, CTA, or MRA.

Was blood flow restored to the affected limb?

- ○ Yes
- ○ No

If No, Explain:_____

_____

_____

At the end of the procedure, what was the residual stenosis?

__ __ __ % (whole number, up to 3 digits)

2	7	5	4	8
Study #				

Site #				

Subject #		

Procedural information – ALI – Day 0

Select all vessels treated during procedure (check all that apply):

☐ **Right Leg**

☐ **Right External Iliac**	
Was Technical Success achieved in the Right External Iliac?	○ Yes ○ No
If yes, specify degree of flow restored to the Right External Iliac	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right External Iliac?	○ Yes ○ No

☐ **Right Common Iliac**	
Was Technical Success achieved in the Right Common Iliac?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Common Iliac	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right Common Iliac?	○ Yes ○ No

☐ **Right Common Femoral**	
Was Technical Success achieved in the Right Common Femoral?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Common Femoral	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right Common Femoral?	○ Yes ○ No

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – ALI – Day 0

☐ **Right Superficial Femoral**	
Was Technical Success achieved in the Right Superficial Femoral?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Superficial femoral	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right Superficial femoral?	○ Yes ○ No

☐ **Right Profunda (Deep Femoral)**	
Was Technical Success achieved from the Right Profunda (Deep Femoral)?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Profunda (Deep femoral)	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right Profunda (Deep femoral)?	○ Yes ○ No

☐ **Right Popliteal - P1 (Proximal)**	
Was Technical Success achieved in the Right Popliteal - P1 (Proximal)?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Popliteal - P1 (Proximal)	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right Popliteal - P1 (Proximal)?	○ Yes ○ No

☐ **Right Popliteal - P2 (Mid)**	
Was Technical Success achieved in the Right Popliteal - P2 (Mid)?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Popliteal - P2 (Mid)	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from Right Popliteal - P2 (Mid)?	○ Yes ○ No

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – ALI – Day 0

☐ **Right Popliteal - P3 (Distal)**	
Was Technical Success achieved in the Right Popliteal - P3 (Distal)?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Popliteal - P3 (Distal)	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right Popliteal - P3 (Distal)?	○ Yes ○ No

☐ **Right Anterior Tibial**	
Was Technical Success achieved in the Right Anterior Tibial?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Anterior Tibial	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right Anterior Tibial?	○ Yes ○ No

☐ **Right Tibioperoneal Trunk**	
Was Technical Success achieved in the Right Tibioperoneal Trunk?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Tibioperoneal Trunk	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from Right Tibioperoneal Trunk?	○ Yes ○ No

☐ **Right Posterior Tibial**	
Was Technical Success achieved in the Right Posterior Tibial?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Posterior Tibial	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from Right Posterior Tibial?	○ Yes ○ No

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – ALI – Day 0

☐ **Right Peroneal**	
Was Technical Success achieved in the Right Peroneal?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Peroneal	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right Peroneal?	☐ Yes ☐ No

☐ **Right Dorsalis pedis**	
Was Technical Success achieved in the Right Dorsalis pedis?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Dorsalis pedis	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right Dorsalis pedis?	○ Yes ○ No

☐ **Right leg, Other vessel Specify:**_____	
Was Technical Success achieved in the Right Other vessel?	○ Yes ○ No
If yes, specify degree of flow restored to the Right Other vessel	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Right Other vessel?	○ Yes ○ No

2	7	5	4	8
Study #				

Site #				

Subject #		

Procedural information – ALI – Day 0

Select all vessels treated during procedure (check all that apply):

☐ **Left Leg**

☐ **Left External Iliac**	
Was Technical Success achieved in the Left External Iliac?	○ Yes ○ No
If yes, specify degree of flow restored to the Left External Iliac	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left External Iliac?	○ Yes ○ No

☐ **Left Common Iliac**	
Was Technical Success achieved in the Left Common Iliac?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Common Iliac	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left Common Iliac?	○ Yes ○ No

☐ **Left Common Femoral**	
Was Technical Success achieved in the Left Common Femoral?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Common femoral	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left Common femoral?	○ Yes ○ No

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – ALI – Day 0

☐ **Left Superficial Femoral**	
Was Technical Success achieved in the Left Superficial Femoral?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Superficial femoral	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left Superficial femoral?	○ Yes ○ No

☐ **Left Profunda (Deep Femoral)**	
Was Technical Success achieved from the Left Profunda (Deep Femoral)?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Profunda (Deep femoral)	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left Profunda (Deep femoral)?	○ Yes ○ No

☐ **Left Popliteal - P1 (Proximal)**	
Was Technical Success achieved in the Left Popliteal - P1 (Proximal)?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Popliteal - P1 (Proximal)	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left Popliteal - P1 (Proximal)?	○ Yes ○ No

☐ **Left Popliteal - P2 (Mid)**	
Was Technical Success achieved in the Left Popliteal - P2 (Mid)?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Popliteal - P2 (Mid)	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from Left Popliteal - P2 (Mid)?	○ Yes ○ No

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – ALI – Day 0

☐ **Left Popliteal - P3 (Distal)**	
Was Technical Success achieved in the Left Popliteal - P3 (Distal)?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Popliteal - P3 (Distal)	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left Popliteal - P3 (Distal)?	○ Yes ○ No

☐ **Left Anterior Tibial**	
Was Technical Success achieved in the Left Anterior Tibial?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Anterior Tibial	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left Anterior Tibial?	○ Yes ○ No

☐ **Left Tibioperoneal Trunk**	
Was Technical Success achieved in the Left Tibioperoneal Trunk?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Tibioperoneal Trunk	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from Left Tibioperoneal Trunk?	○ Yes ○ No

☐ **Left Posterior Tibial**	
Was Technical Success achieved in the Left Posterior Tibial?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Posterior Tibial	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from Left Posterior Tibial?	○ Yes ○ No

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – ALI – Day 0

☐ **Left Peroneal**	
Was Technical Success achieved in the Left Peroneal?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Peroneal	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left Peroneal?	○ Yes ○ No

☐ **Left Dorsalis pedis**	
Was Technical Success achieved in the Left Dorsalis pedis?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Dorsalis pedis	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left Dorsalis pedis?	○ Yes ○ No

☐ **Left Leg Other vessel, Specify:**_____	
Was Technical Success achieved in the Left Other vessel?	○ Yes ○ No
If yes, specify degree of flow restored to the Left Other vessel	○ Complete antegrade flow ○ Partial/delayed flow
If no, was any thrombus removed from the Left Other vessel?	○ Yes ○ No

Concomitant Medications

Check which of the following medications the patient is currently taking:

☐ Aspirin	☐ Clopidogrel	☐ Ticlopidine
☐ Prasugrel	☐ Cilostazol	☐ None of the Above

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – DVT – Day 0

Procedure Information

Date and time of venous puncture for index procedure:

__ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY __ __: __ __ HH:MM (24hr clock)

Name of the primary physician performing the procedure:

_____

Index Diagnosis

- ○ Provoked DVT
- ○ Unprovoked DVT, explain: _____
- ○ Unknown

Was May-Thurner Syndrome diagnosed during index procedure?

- ○ Yes
- ○ No

Access site for Indigo Aspiration System

If multiple access attempts were made, select options for all successful access sites:

☐ Right popliteal	☐ Left popliteal
☐ Right femoral	☐ Left femoral
☐ Right internal jugular	☐ Left internal jugular
☐ Right external jugular	☐ Left external jugular
☐ Right tibial	☐ Left tibial
☐ Right short saphenous	☐ Left short saphenous
☐ Other access site, specify: _____	

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – DVT – Day 0

Total procedure time:

__ __ __ (mins)

Total aspiration time:

__ __ __ (mins) ***OR*** Total aspiration time Unknown ☐

Estimated blood loss (canister volume minus flush volume)

__ __ __ __ cc (whole number, up to 4 digits) ***OR*** Estimated blood loss Unknown ☐

Procedure Information - Additional Treatment

Were any additional treatments performed during the index procedure?

- ○ Yes
- ○ No

If yes, Record any additional treatments performed during the index procedure

- ☐ Angioplasty
- ☐ IVC filter placement
- ☐ IVC filter removal
- ☐ Fogarty
- ☐ Stenting
- ☐ Other treatment, specify: _____

If Yes, Please complete the Procedure Information Additional Treatment Log for every additional procedure performed: *Please see log below:*

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – DVT – Day 0

Procedure Information - Additional Treatment Log:

Please check box of all additional treatments patient received:

☐ Angioplasty	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel
☐ IVC filter placement	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel

2	7	5	4	8
Study #				

Site #				

Subject #		

Procedural information – DVT – Day 0

Procedure Information - Additional Treatment Log:

Please check box of all additional treatments patient received:

☐ IVC filter removal	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel
☐ Fogarty	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel

2	7	5	4	8
Study #				

Site #				

Subject #		

Procedural information – DVT – Day 0

Procedure Information - Additional Treatment Log:

Please check box of all additional treatments patient received:

☐ Stenting	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel
☐ Other treatment, Specify:_____ _____	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel

2	7	5	4	8
Study #				

Site #				

Subject #		

Procedural information – DVT – Day 0

Venography

Estimate of thrombus reduction in target venous segment as assessed by physician visual estimate of intraprocedural venography

__ __ __ % (whole number, up to 3 digits)

Technical Success

Was technical success, defined as complete or near complete (≥75%) reduction in venous thrombus from the target venous segment, as assessed by physician visual estimate of intraprocedural venography, achieved?

- ○ Yes
- ○ No

If No, was any other revascularization strategy used in the target vessel?

- ○ Yes, please describe above in Additional Treatments section
- ○ No

Concomitant Medications

Check which of the following medications the patient is currently taking:

☐ Aspirin	☐ Clopidogrel	☐ Ticlopidine
☐ Prasugrel	☐ Cilostazol	☐ None of the Above

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – SMA – Day 0

Date and time of arterial puncture:

__ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY __ __: __ __ HH:MM (24hr clock)

Name of the primary physician performing the procedure:

_____

Location of arterial puncture

- ○ Right femoral
- ○ Left femoral
- ○ Other location, specify: _____

Total procedure time: __ __ __ (mins)

Total aspiration time:

__ __ __ (mins) ***OR*** Total aspiration time Unknown ☐

Estimated blood loss (canister volume minus flush volume)

__ __ __ __ cc (whole number, up to 4 digits) ***OR*** Estimated blood loss Unknown ☐

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – SMA – Day 0

Procedure Information - Additional Treatment

Were any additional treatments performed during the index procedure?

- ○ Yes
- ○ No

If yes, Record any additional treatments performed during the index procedure

- ☐ Balloon
- ☐ Bypass graft
- ☐ Fogarty
- ☐ Stent
- ☐ Thrombolytics
- ☐ Other, specify _____

If Yes, Please complete the Procedure Information Additional Treatment Log for every additional procedure performed: ***Please see log below:***

2	7	5	4	8
Study #				

Site #				

Subject #		

Procedural information – SMA – Day 0

Procedure Information - Additional Treatment Log:

Please check box of all additional treatments patient received:

☐ Balloon	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel
☐ Bypass graft	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel

2	7	5	4	8
Study #				

Site #				

Subject #		

Procedural information – SMA – Day 0

Procedure Information - Additional Treatment Log:

Please check box of all additional treatments patient received:

☐ Fogarty	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel
☐ Stent	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel

2	7	5	4	8
Study #				

Site #				

Subject #		

Procedural information – SMA – Day 0

Procedure Information - Additional Treatment Log:

Please check box of all additional treatments patient received:

☐ Thrombolytics	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel
☐ Other Treatment, Specify:_____ _____	Timing of additional treatment: ○ During index procedure, before use of Indigo ○ During index procedure, between Indigo passes ○ During index procedure, after use of Indigo ○ Planned staged procedure ○ Other timing, specify: _____ If planned staged procedure, describe:_____ Describe location of additional treatment: ○ Target vessel ○ Non-target vessel

2	7	5	4	8

Study #

Site #

Subject #

Procedural information – SMA – Day 0

Technical Success

Was there restoration of antegrade blood flow without the need for other revascularization strategies, such as vascular surgery or bypass, etc. in the target vessel?

- ○ Yes
- ○ No

If No, was any other revascularization strategy used in the target vessel?

- ○ Yes, please describe above in Additional Treatments section
- ○ No

Was there device-related distal embolization? *Device-related distal embolization is defined as a distal filling defect with an abrupt cut-off, determined to be new since the pre-procedure angiogram, present at the end of the procedure, and clinically significant requiring intervention other than Indigo use. If the area in question was not clearly visualized, filling defects distal to the target lesion cannot be categorized as emboli.*

- ○ Yes
- ○ No

Concomitant Medications

Check which of the following medications the patient is currently taking:

☐ Aspirin	☐ Clopidogrel	☐ Ticlopidine
☐ Prasugrel	☐ Cilostazol	☐ None of the Above

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Devices Used

Enter all catheters and separators used for index procedure. Pumps, canisters and tubing do not need to be entered unless there was a device deficiency to report.

Select device used during the procedure	○ CAT3 ○ CAT5 ○ CAT6 ○ CAT8 ○ CATD ○ Separator ○ Indigo Aspiration Tubing ○ Engine Pump/Canister
Was a device deficiency noted with this component?	○ Yes ○ No
Lot # _____	

Type of deficiency

☐ Aspiration tubing leak or tear	☐ Catheter broken / fractured out of the box
☐ Catheter broken / in patient, retrieved	☐ Catheter broken / in patient, unable to retrieve
☐ Catheter cracked / leaking	☐ Catheter - difficulty advancing
☐ Catheter - kinked / bent	☐ Catheter lumen puncture / tear
☐ Pump damaged / cracked	☐ Pump - low or inadequate aspiration power
☐ Pump not powering on	☐ Pump power inlet / cord damaged
☐ Separator bulb broken off	☐ Separator wire kinked
☐ Other type of deficiency, specify: _____	

2	7	5	4	8

Study #

Site #

Subject #

Devices Used

Is this device deficiency associated with an Adverse Event?

- ○ Yes
- ○ No

If Yes, AE Number: _____ (whole number)

Action taken

Provide information on whether additional intervention was required due to device deficiency, or a new device was used

- ○ Opened an additional device, no additional intervention required
- ○ No action needed, no additional intervention required
- ○ Other outcome and action taken, specify: _____

_____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Leg Pain Severity Score – Day 7/Discharge – DVT ONLY

Was Leg Pain Severity Score assessed?

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

0 = No pain at all
10 = Worst pain ever possible

Leg Pain Severity Score - Right Leg	Leg Pain Severity Score - Left Leg
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Rutherford Classification – Day 7/Discharge – ALI ONLY

Was Rutherford Classification assessed?

- ○ Yes
- ○ No

If Yes, Date of Evaluation __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Rutherford Classification Category - Right Leg

- ○ I. Viable
- ○ IIA. Threatened Marginally (Often)
- ○ IIB. Threatened Immediately (Usually)
- ○ III. Irreversible

Rutherford Classification Category - Left Leg

- ○ I. Viable
- ○ IIA. Threatened Marginally (Often)
- ○ IIB. Threatened Immediately (Usually)
- ○ III. Irreversible

2	7	5	4	8

Study #

Site #

Subject #

Discharge Details – Day 7/Discharge

Was the subject discharged?

- ○ Yes
- ○ No

If Yes, Discharge Date: _ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY

Discharge location

- ○ Home, (with or without outpatient therapy/care)
- ○ Skilled Nursing Facility (e.g., acute rehabilitation or sub-acute facility)
- ○ Nursing home
- ○ Long stay hospital
- ○ Hospice
- ○ Other discharge location, specify: _____

Total number of days in ICU: ___ ___

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Rutherford Classification – 30 Day Follow Up – ALI ONLY

Was Rutherford Classification assessed?

- ○ Yes
- ○ No

If Yes, Date of Evaluation __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Rutherford Classification Category - Right Leg

- ○ I. Viable
- ○ IIA. Threatened Marginally (Often)
- ○ IIB. Threatened Immediately (Usually)
- ○ III. Irreversible

Rutherford Classification Category - Left Leg

- ○ I. Viable
- ○ IIA. Threatened Marginally (Often)
- ○ IIB. Threatened Immediately (Usually)
- ○ III. Irreversible

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Leg Pain Severity Score – Day 30 Follow-Up – DVT ONLY

Was Leg Pain Severity Score assessed?

- ○ Yes
- ○ No

If Yes, Assessment date: __ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy

0 = No pain at all
10 = Worst pain ever possible

Leg Pain Severity Score - Right Leg	Leg Pain Severity Score - Left Leg
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Villalta Score – Day 30 Follow-Up – DVT ONLY

Was Villalta Score assessed**?**

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Right Leg	Left Leg
Pain - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pain - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Cramps - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Cramps - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Heaviness - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Heaviness - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Paresthesia - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Paresthesia - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Pruritis - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pruritis - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Pretibial edema - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pretibial edema - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Villalta Score – Day 30 Follow-Up – DVT ONLY

Right Leg	Left Leg
Skin induration - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Skin induration - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Hyperpigmentation - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Hyperpigmentation - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Redness - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Redness - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Venous ectasia - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Venous ectasia – Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Pain on calf compression - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pain on calf compression - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Venous ulcer - Right Leg ○ Present ○ Absent	Venous ulcer - Left Leg ○ Present ○ Absent

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Revised Venous Clinical Severity Score – Day 30 Follow-Up – DVT ONLY

Was Revised Venous Clinical Severity Score assessed?

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Right Leg	Left Leg
Pain - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pain - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Varicose veins - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Varicose veins - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Venous edema - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Venous edema - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Skin pigmentation - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Skin pigmentation - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Inflammation - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Inflammation – Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Induration - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Induration - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Revised Venous Clinical Severity Score – Day 30 Follow-Up – DVT ONLY

Right Leg	Left Leg
Active ulcer number - Right Leg o 0 o 1 o 2 o >= 3	Active ulcer number - Left Leg o 0 o 1 o 2 o >= 3
Active ulcer duration - Right Leg o 0 - N/A o 1 - < 3 months o 2 - >= 3 months and < 1 year o 3 - Not healed for >= 1 year	Active ulcer duration - Left Leg 5. 0 - N/A 6. 1 - < 3 months 7. 2 - >= 3 months and < 1 year 8. 3 - Not healed for >= 1 year
Active ulcer size - Right Leg o 0 - N/A o 1 - Diameter < 2 cm o 2 - Diameter >= 2 cm and < 6 cm o 3 - Diameter >= 6 cm	Active ulcer size - Left Leg o 0 - N/A o 1 - Diameter < 2 cm o 2 - Diameter >= 2 cm and < 6 cm o 3 - Diameter >= 6 cm
Use of compression therapy - Right Leg o 0 - Not used o 1 - Intermittent use of stockings o 2 - Wears stockings most of the day o 3 - Full compliance stockings	Use of compression therapy - Left Leg o 0 - Not used o 1 - Intermittent use of stockings o 2 - Wears stockings most of the day o 3 - Full compliance stockings

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

CEAP-C – Day 30 Follow-Up – DVT ONLY

Was CEAP-C assessed??

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Check all that apply:

CEAP-C Right Leg	CEAP-C Left Leg
☐ C0 No visible or palpable signs of venous disease	☐ C0 No visible or palpable signs of venous disease
☐ C1 Telangiectasies or reticular veins	☐ C1 Telangiectasies or reticular veins
☐ C2 Varicose veins; distinguished from reticular veins by a diameter of 3 mm or more	☐ C2 Varicose veins; distinguished from reticular veins by a diameter of 3 mm or more
☐ C3 Edema	☐ C3 Edema
☐ C4A Changes in skin and subcutaneous tissue secondary to CVD - Pigmentation or eczema	☐ C4A Changes in skin and subcutaneous tissue secondary to CVD - Pigmentation or eczema
☐ C4B Changes in skin and subcutaneous tissue secondary to - Lipodermatosclerosis or atrophie blanche	☐ C4B Changes in skin and subcutaneous tissue secondary to - Lipodermatosclerosis or atrophie blanche
☐ C5 Healed venous ulcer	☐ C5 Healed venous ulcer
☐ C6 Active venous ulcer	☐ C6 Active venous ulcer
CEAP-C Symptomatic Modifier - Right Leg ○ S, Symptomatic ○ A, Asymptomatic	**CEAP-C Symptomatic Modifier - Left Leg** ○ S, Symptomatic ○ A, Asymptomatic

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

EQ-5D-5L - Day 30 Follow-Up – DVT ONLY

Was the EQ-5D-5L QOL administered?

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

MOBILITY:

- ○ I have no problems in walking about
- ○ I have slight problems walking about
- ○ I have moderate problems in walking about
- ○ I have severe problems in walking about
- ○ I am unable to walk about

SELF-CARE

- ○ I have no problems washing or dressing myself
- ○ I have slight problems washing or dressing myself
- ○ I have moderate problems washing or dressing myself
- ○ I have severe problems washing or dressing myself
- ○ I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- ○ I have no problems doing my usual activities
- ○ I have slight problems doing my usual activities
- ○ I have moderate problems doing my usual activities
- ○ I have severe problems doing my usual activities
- ○ I am unable to do my usual activities

PAIN/DISCOMFORT

- ○ I have no pain or discomfort
- ○ I have slight pain or discomfort
- ○ I have moderate pain or discomfort
- ○ I have severe pain or discomfort
- ○ I have extreme pain or discomfort

2	7	5	4	8

Study #

Site #

Subject #

EQ-5D-5L - Day 30 Follow-Up – DVT ONLY

ANXIETY/DEPRESSION

- ○ I am not anxious or depressed
- ○ I am slightly anxious or depressed
- ○ I am moderately anxious or depressed
- ○ I am severely anxious or depressed
- ○ I am extremely anxious or depressed

0 = Worst heath condition imaginable
100 = The best health imaginable

Patient reported visual analog scale (0-100):_____(whole number)

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Day 30 Follow-Up – DVT ONLY

Was the VEINES QOL/Sym administered?

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

These questions are about your leg problem(s):

4. During the past 4 weeks, how often have you had any of the following leg problems?

Heavy legs ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Aching legs ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Swelling ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Night cramps ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Heat or burning sensation ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Restless legs ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Throbbing ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Itching ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Tingling sensation (e.g. pins and needles) ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Day 30 Follow-Up – DVT ONLY

5. At what time of day is your leg problem most intense?
   - ○ On waking
   - ○ At mid-day
   - ○ At the end of the day
   - ○ During the night
   - ○ At any time of the day
   - ○ Never

6. Compared to one year ago, how would you rate your leg problem in general now?
   - ○ Much better now than one year ago
   - ○ Somewhat better now than one year ago
   - ○ About the same now as one year ago
   - ○ Somewhat worse now than one year ago
   - ○ Much worse now than one year ago
   - ○ I did not have any leg problem last year

4.The following items are about activities that you might do in a typical day.

Does your leg problem now limit you in these activities? If so, how much?

Daily activities at work	○ I do not work ○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All
Daily activities at home (e.g. housework, ironing, doing odd jobs/repairs around the house, gardening, etc…)	○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All
Social or leisure activities in which you are standing for long periods (e.g. parties, weddings, taking public transportation, shopping, etc…)	○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All
Social or leisure activities in which you are sitting for long periods (e.g. going to the cinema or the theater, traveling, etc…)	○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Day 30 Follow-Up – DVT ONLY

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your leg problem?

Cut down the amount of time you spent on work or other activities	○ Yes ○ No
Accomplished less than you would like	○ Yes ○ No
Were limited in the kind of work or other activities	○ Yes ○ No
Had difficulty performing the work or other activities (for example, it took extra effort)	○ Yes ○ No

6. During the past 4 weeks, to what extent has your leg problem interfered with your normal social activities with family, friends, neighbors or groups?

- ○ Not at all
- ○ Slightly
- ○ Moderately
- ○ Quite a bit
- ○ Extremely

7. How much leg pain have you had during the past 4 weeks?

- ○ None
- ○ Very mild
- ○ Mild
- ○ Moderate
- ○ Severe
- ○ Very severe

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Day 30 Follow-Up – DVT ONLY

8. These questions are about how you feel and how things have been with you during the past 4 weeks as a result of your leg problem. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks –

Have you felt concerned about the appearance of your leg(s)?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Have you felt irritable?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Have you felt a burden to your family or friends?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Have you been worried about bumping into things?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Has the appearance of your leg(s) influenced your choice of clothing?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time

2	7	5	4	8
Study #				

Site #				

Subject #		

Follow Up Information - 30 Day Follow Up

Visit Status

- ○ Visit completed
- ○ Missed visit
- ○ Subject exited the study before visit

If visit completed, visit date: _ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY

Primary imaging modality used to assess patency

- ○ DUS
- ○ CTA
- ○ MRA
- ○ Angiography
- ○ No Imaging Performed

If Imaging Done, Date of Imaging: _ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY

Was patency maintained in all vessels treated with Indigo since the last visit? *Patency is defined as Demonstrably patent by an accepted imaging technique of the specific arterial site treated, such as with DUS (preferred), CTA, MRA, or arteriography that clearly shows flow through the lesion. Stenosis developing within the treated segment without reocclusion is not considered a loss of patency but will contribute to recurrent ischemia.*

- ○ Yes
- ○ No

If no, specify vessel(s) that was not patent ***(Left Leg Indications listed after Right Leg)***

☐ **Right Leg ALI Procedure**

☐ Right External Iliac	Reason patency not maintained in Right External Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Right Leg ALI Procedure**

☐ Right Common Iliac	Reason patency not maintained in Right Common Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Common femoral	Reason patency not maintained in Right Common femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8
Study #				

Site #				

Subject #		

Follow Up Information - 30 Day Follow Up

☐ **Right Leg ALI Procedure**

☐ Right Superficial femoral	Reason patency not maintained in Right Superficial femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Profunda (Deep femoral)	Reason patency not maintained in Right Profunda (Deep femoral) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Right Leg ALI Procedure**

☐ Right Popliteal - P1 (Proximal)	Reason patency not maintained in Right Popliteal - P1 (Proximal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Popliteal – P2 (Mid)	Reason patency not maintained in Right Popliteal – P2 (Mid) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8
Study #				

Site #				

Subject #		

Follow Up Information - 30 Day Follow Up

☐ **Right Leg ALI Procedure**

☐ Right Popliteal - P3 (Distal)	Reason patency not maintained in Right Popliteal - P3 (Distal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Anterior Tibial	Reason patency not maintained in Right Anterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Right Leg ALI Procedure**

☐ Right Tibioperoneal Trunk	Reason patency not maintained in Right Tibioperoneal Trunk ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Posterior Tibial	Reason patency not maintained in Right Posterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Right Leg ALI Procedure**

☐ Right Peroneal	Reason patency not maintained in Right Peroneal ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Dorsalis pedis	Reason patency not maintained in Right Dorsalis pedis ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Right ALI Procedure**

☐ Right Other Right leg other location, specify:	Reason patency not maintained in Right Other Vessel ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Left Leg ALI Procedure**

☐ Left External Iliac	Reason patency not maintained in Left External Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Common Iliac	Reason patency not maintained in Left Common Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Left Leg ALI Procedure**

☐ Left Common femoral	Reason patency not maintained in Left Common femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Superficial femoral	Reason patency not maintained in Left Superficial femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Left Leg ALI Procedure**

☐ Left Profunda (Deep femoral)	Reason patency not maintained in Left Profunda (Deep femoral) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Popliteal - P1 (Proximal)	Reason patency not maintained in Left Popliteal - P1 (Proximal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Left Leg ALI Procedure**

☐ Left Popliteal – P2 (Mid)	Reason patency not maintained in Left Popliteal – P2 (Mid) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Popliteal - P3 (Distal)	Reason patency not maintained in Left Popliteal - P3 (Distal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Left Leg ALI Procedure**

☐ Left Anterior Tibial	Reason patency not maintained in Left Anterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Tibioperoneal Trunk	Reason patency not maintained in Left Tibioperoneal Trunk ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Left Leg ALI Procedure**

☐ Left Posterior Tibial	Reason patency not maintained in Left Posterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Peroneal	Reason patency not maintained in Left Peroneal ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Left Leg ALI Procedure**

☐ Left Dorsalis pedis	Reason patency not maintained in Left Dorsalis pedis ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Other Left leg other location, specify:	Reason patency not maintained in Left Other Vessel ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Main Trunk SMA Procedure**

Patency is defined as Demonstrably patent by an accepted imaging technique of the specific arterial site treated, such as with DUS (preferred), CTA, MRA, or arteriography that clearly shows flow through the lesion. Stenosis developing within the treated segment without reocclusion is not considered a loss of patency but will contribute to recurrent ischemia.

Reason patency not maintained in Main Trunk:

- ○ Patient non-compliant with anticoagulation
- ○ Hypercoagulable state
- ○ Failed revascularization
- ○ Vessel dissection
- ○ Stent thrombosis
- ○ Percutaneous Transluminal Angioplasty complication
- ○ Other reason, Specify: _____

☐ **Ileocolic Artery (ICA) SMA Procedure**

Reason patency not maintained in Ileocolic Artery (ICA)

- ○ Patient non-compliant with anticoagulation
- ○ Hypercoagulable state
- ○ Failed revascularization
- ○ Vessel dissection
- ○ Stent thrombosis
- ○ Percutaneous Transluminal Angioplasty complication
- ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

☐ **Peripheral Branches SMA Procedure**

Reason patency not maintained in Peripheral Branches

- ○ Patient non-compliant with anticoagulation
- ○ Hypercoagulable state
- ○ Failed revascularization
- ○ Vessel dissection
- ○ Stent thrombosis
- ○ Percutaneous Transluminal Angioplasty complication
- ○ Other reason, Specify: _____

☐ **Other SMA Target Vessel Procedure**

Other target vessel segment, specify_____

Reason patency not maintained in Other SMA Target Vessel Segment

- ○ Patient non-compliant with anticoagulation
- ○ Hypercoagulable state
- ○ Failed revascularization
- ○ Vessel dissection
- ○ Stent thrombosis
- ○ Percutaneous Transluminal Angioplasty complication
- ○ Other reason, Specify: _____

If visit completed, were any reinterventions performed on the target vessel since last visit?

- ○ Yes
- ○ No

If Yes, log as an Adverse Event and reference AE #(s): _____

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 30 Day Follow Up

Concomitant Medication

Check which of the following medications the patient is currently taking:

☐ Aspirin	☐ Clopidogrel	☐ Ticlopidine
☐ Prasugrel	☐ Cilostazol	☐ None of the Above

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Rutherford Classification – 180 Day Follow Up – ALI ONLY

Was Rutherford Classification assessed?

- ○ Yes
- ○ No

If Yes, Date of Evaluation __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Rutherford Classification Category - Right Leg

- ○ I. Viable
- ○ IIA. Threatened Marginally (Often)
- ○ IIB. Threatened Immediately (Usually)
- ○ III. Irreversible

Rutherford Classification Category - Left Leg

- ○ I. Viable
- ○ IIA. Threatened Marginally (Often)
- ○ IIB. Threatened Immediately (Usually)
- ○ III. Irreversible

2	7	5	4	8
Study #				

Site #				

Subject #		

Leg Pain Severity Score – Day 180 Follow-Up – DVT ONLY

Was Leg Pain Severity Score assessed?

- ○ Yes
- ○ No

If Yes, Assessment date: __ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy

0 = No pain at all
10 = Worst pain ever possible

Leg Pain Severity Score - Right Leg	Leg Pain Severity Score - Left Leg
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Villalta Score – Day 180 Follow-Up – DVT ONLY

Was Villalta Score assessed**?**

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Right Leg	Left Leg
Pain - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pain - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Cramps - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Cramps - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Heaviness - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Heaviness - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Paresthesia - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Paresthesia - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Pruritis - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pruritis - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Pretibial edema - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pretibial edema - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Villalta Score – Day 180 Follow-Up – DVT ONLY

Right Leg	Left Leg
Skin induration - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Skin induration - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Hyperpigmentation - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Hyperpigmentation - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Redness - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Redness - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Venous ectasia - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Venous ectasia – Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Pain on calf compression - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pain on calf compression - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Venous ulcer - Right Leg ○ Present ○ Absent	Venous ulcer - Left Leg ○ Present ○ Absent

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Revised Venous Clinical Severity Score – Day 180 Follow-Up – DVT ONLY

Was Revised Venous Clinical Severity Score assessed?

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Right Leg	Left Leg
Pain - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Pain - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Varicose veins - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Varicose veins - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Venous edema - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Venous edema - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Skin pigmentation - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Skin pigmentation - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Inflammation - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Inflammation – Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe
Induration - Right Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe	Induration - Left Leg ○ 0 - None ○ 1 - Mild ○ 2 - Moderate ○ 3 - Severe

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Revised Venous Clinical Severity Score – Day 180 Follow-Up – DVT ONLY

Right Leg	Left Leg
Active ulcer number - Right Leg ○ 0 ○ 1 ○ 2 ○ >= 3	Active ulcer number - Left Leg ○ 0 ○ 1 ○ 2 ○ >= 3
Active ulcer duration - Right Leg ○ 0 - N/A ○ 1 - < 3 months ○ 2 - >= 3 months and < 1 year ○ 3 - Not healed for >= 1 year	Active ulcer duration - Left Leg 9. 0 - N/A 10. 1 - < 3 months 11. 2 - >= 3 months and < 1 year 12. 3 - Not healed for >= 1 year
Active ulcer size - Right Leg ○ 0 - N/A ○ 1 - Diameter < 2 cm ○ 2 - Diameter >= 2 cm and < 6 cm ○ 3 - Diameter >= 6 cm	Active ulcer size - Left Leg ○ 0 - N/A ○ 1 - Diameter < 2 cm ○ 2 - Diameter >= 2 cm and < 6 cm ○ 3 - Diameter >= 6 cm
Use of compression therapy - Right Leg ○ 0 - Not used ○ 1 - Intermittent use of stockings ○ 2 - Wears stockings most of the day ○ 3 - Full compliance stockings	Use of compression therapy - Left Leg ○ 0 - Not used ○ 1 - Intermittent use of stockings ○ 2 - Wears stockings most of the day ○ 3 - Full compliance stockings

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

CEAP-C – Day 180 Follow-Up – DVT ONLY

Was CEAP-C assessed??

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

Check all that apply:

CEAP-C Right Leg	CEAP-C Left Leg
☐ C0 No visible or palpable signs of venous disease	☐ C0 No visible or palpable signs of venous disease
☐ C1 Telangiectasies or reticular veins	☐ C1 Telangiectasies or reticular veins
☐ C2 Varicose veins; distinguished from reticular veins by a diameter of 3 mm or more	☐ C2 Varicose veins; distinguished from reticular veins by a diameter of 3 mm or more
☐ C3 Edema	☐ C3 Edema
☐ C4A Changes in skin and subcutaneous tissue secondary to CVD - Pigmentation or eczema	☐ C4A Changes in skin and subcutaneous tissue secondary to CVD - Pigmentation or eczema
☐ C4B Changes in skin and subcutaneous tissue secondary to - Lipodermatosclerosis or atrophie blanche	☐ C4B Changes in skin and subcutaneous tissue secondary to - Lipodermatosclerosis or atrophie blanche
☐ C5 Healed venous ulcer	☐ C5 Healed venous ulcer
☐ C6 Active venous ulcer	☐ C6 Active venous ulcer
CEAP-C Symptomatic Modifier - Right Leg ○ S, Symptomatic ○ A, Asymptomatic	**CEAP-C Symptomatic Modifier - Left Leg** ○ S, Symptomatic ○ A, Asymptomatic

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

EQ-5D-5L - Day 180 Follow-Up – DVT ONLY

Was the EQ-5D-5L QOL administered?

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

MOBILITY:

- ○ I have no problems in walking about
- ○ I have slight problems walking about
- ○ I have moderate problems in walking about
- ○ I have severe problems in walking about
- ○ I am unable to walk about

SELF-CARE

- ○ I have no problems washing or dressing myself
- ○ I have slight problems washing or dressing myself
- ○ I have moderate problems washing or dressing myself
- ○ I have severe problems washing or dressing myself
- ○ I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- ○ I have no problems doing my usual activities
- ○ I have slight problems doing my usual activities
- ○ I have moderate problems doing my usual activities
- ○ I have severe problems doing my usual activities
- ○ I am unable to do my usual activities

PAIN/DISCOMFORT

- ○ I have no pain or discomfort
- ○ I have slight pain or discomfort
- ○ I have moderate pain or discomfort
- ○ I have severe pain or discomfort
- ○ I have extreme pain or discomfort

2	7	5	4	8

Study #

Site #

Subject #

EQ-5D-5L - Day 180 Follow-Up – DVT ONLY

ANXIETY/DEPRESSION

- ○ I am not anxious or depressed
- ○ I am slightly anxious or depressed
- ○ I am moderately anxious or depressed
- ○ I am severely anxious or depressed
- ○ I am extremely anxious or depressed

0 = Worst heath condition imaginable
100 = The best health imaginable

Patient reported visual analog scale (0-100):_____(whole number)

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Day 180 Follow-Up – DVT ONLY

Was the VEINES QOL/Sym administered?

- ○ Yes
- ○ No

If Yes, Assessment date: __ _ - __ __ __ - __ __ __ __ dd-mmm-yyyy

These questions are about your leg problem(s):

7. During the past 4 weeks, how often have you had any of the following leg problems?

Heavy legs ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Aching legs ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Swelling ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Night cramps ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Heat or burning sensation ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Restless legs ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Throbbing ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	Itching ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never
Tingling sensation (e.g. pins and needles) ○ Every Day ○ Several times a week ○ About once a week ○ Less than once a week ○ Never	

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Day 180 Follow-Up – DVT ONLY

8. At what time of day is your leg problem most intense?
   - ○ On waking
   - ○ At mid-day
   - ○ At the end of the day
   - ○ During the night
   - ○ At any time of the day
   - ○ Never

9. Compared to one year ago, how would you rate your leg problem in general now?
   - ○ Much better now than one year ago
   - ○ Somewhat better now than one year ago
   - ○ About the same now as one year ago
   - ○ Somewhat worse now than one year ago
   - ○ Much worse now than one year ago
   - ○ I did not have any leg problem last year

4.The following items are about activities that you might do in a typical day.

Does your leg problem now limit you in these activities? If so, how much?

Daily activities at work	○ I do not work ○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All
Daily activities at home (e.g. housework, ironing, doing odd jobs/repairs around the house, gardening, etc…)	○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All
Social or leisure activities in which you are standing for long periods (e.g. parties, weddings, taking public transportation, shopping, etc…)	○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All
Social or leisure activities in which you are sitting for long periods (e.g. going to the cinema or the theater, traveling, etc…)	○ YES, Limited A Lot ○ YES, Limited A Little ○ NO, Not Limited At All

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Day 180 Follow-Up – DVT ONLY

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your leg problem?

Cut down the amount of time you spent on work or other activities	○ Yes ○ No
Accomplished less than you would like	○ Yes ○ No
Were limited in the kind of work or other activities	○ Yes ○ No
Had difficulty performing the work or other activities (for example, it took extra effort)	○ Yes ○ No

6. During the past 4 weeks, to what extent has your leg problem interfered with your normal social activities with family, friends, neighbors or groups?

- ○ Not at all
- ○ Slightly
- ○ Moderately
- ○ Quite a bit
- ○ Extremely

7. How much leg pain have you had during the past 4 weeks?

- ○ None
- ○ Very mild
- ○ Mild
- ○ Moderate
- ○ Severe
- ○ Very severe

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

VEINES – Day 180 Follow-Up – DVT ONLY

8. These questions are about how you feel and how things have been with you during the past 4 weeks as a result of your leg problem. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks –

Have you felt concerned about the appearance of your leg(s)?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Have you felt irritable?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Have you felt a burden to your family or friends?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Have you been worried about bumping into things?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time
Has the appearance of your leg(s) influenced your choice of clothing?	○ All of the Time ○ Most of the Time ○ A Good Bit of the Time ○ Some of the Time ○ A Little of the Time ○ None of the Time

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information – 180 Day Follow Up

Visit Status

- ○ Visit completed
- ○ Missed visit
- ○ Subject exited the study before visit

If visit completed, visit date: _ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY

Primary imaging modality used to assess patency

- ○ DUS
- ○ CTA
- ○ MRA
- ○ Angiography
- ○ No Imaging Performed

If Imaging Done, Date of Imaging: _ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY

Was patency maintained in all vessels treated with Indigo since the last visit? *Patency is defined as Demonstrably patent by an accepted imaging technique of the specific arterial site treated, such as with DUS (preferred), CTA, MRA, or arteriography that clearly shows flow through the lesion. Stenosis developing within the treated segment without reocclusion is not considered a loss of patency but will contribute to recurrent ischemia.*

- ○ Yes
- ○ No

If no, specify vessel(s) that was not patent ***(Left Leg Indications listed after Right Leg):***

2	7	5	4	8
Study #				

Site #				

Subject #		

Follow Up Information - 180 Day Follow-Up

☐ **Right Leg ALI Procedure**

☐ Right External Iliac	Reason patency not maintained in Right External Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Common Iliac	Reason patency not maintained in Right Common Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Right Leg ALI Procedure**

☐ Right Common femoral	Reason patency not maintained in Right Common femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Superficial femoral	Reason patency not maintained in Right Superficial femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Right Leg ALI Procedure**

☐ Right Profunda (Deep femoral)	Reason patency not maintained in Right Profunda (Deep femoral) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Popliteal - P1 (Proximal)	Reason patency not maintained in Right Popliteal - P1 (Proximal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Right Leg ALI Procedure**

☐ Right Popliteal – P2 (Mid)	Reason patency not maintained in Right Popliteal – P2 (Mid) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Popliteal - P3 (Distal)	Reason patency not maintained in Right Popliteal - P3 (Distal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Right Leg ALI Procedure**

☐ Right Anterior Tibial	Reason patency not maintained in Right Anterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Tibioperoneal Trunk	Reason patency not maintained in Right Tibioperoneal Trunk ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Right Leg ALI Procedure**

☐ Right Posterior Tibial	Reason patency not maintained in Right Posterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Peroneal	Reason patency not maintained in Right Peroneal ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8
Study #				

Site #				

Subject #		

Follow Up Information - 180 Day Follow-Up

☐ **Right Leg ALI Procedure**

☐ Right Dorsalis pedis	Reason patency not maintained in Right Dorsalis pedis ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg ALI Procedure**

☐ Right Other Right leg other location, specify:	Reason patency not maintained in Right Other Vessel ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8
Study #				

Site #				

Subject #		

Follow Up Information - 180 Day Follow-Up

☐ **Left Leg ALI Procedure**

☐ Left External Iliac	Reason patency not maintained in Left External Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Common Iliac	Reason patency not maintained in Left Common Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Left Leg ALI Procedure**

☐ Left Common femoral	Reason patency not maintained in Left Common femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Superficial femoral	Reason patency not maintained in Left Superficial femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Left Leg ALI Procedure**

☐ Left Profunda (Deep femoral)	Reason patency not maintained in Left Profunda (Deep femoral) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Popliteal - P1 (Proximal)	Reason patency not maintained in Left Popliteal - P1 (Proximal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Left Leg ALI Procedure**

☐ Left Popliteal – P2 (Mid)	Reason patency not maintained in Left Popliteal – P2 (Mid) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Popliteal - P3 (Distal)	Reason patency not maintained in Left Popliteal - P3 (Distal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Left Leg ALI Procedure**

☐ Left Anterior Tibial	Reason patency not maintained in Left Anterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Tibioperoneal Trunk	Reason patency not maintained in Left Tibioperoneal Trunk ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Left Leg ALI Procedure**

☐ Left Posterior Tibial	Reason patency not maintained in Left Posterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Peroneal	Reason patency not maintained in Left Peroneal ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Left Leg ALI Procedure**

☐ Left Dorsalis pedis	Reason patency not maintained in Left Dorsalis pedis ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Other Left leg other location, specify:	Reason patency not maintained in Left Other Vessel ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Main Trunk SMA Procedure**

Patency is defined as Demonstrably patent by an accepted imaging technique of the specific arterial site treated, such as with DUS (preferred), CTA, MRA, or arteriography that clearly shows flow through the lesion. Stenosis developing within the treated segment without reocclusion is not considered a loss of patency but will contribute to recurrent ischemia.

Reason patency not maintained in Main Trunk:

- ○ Patient non-compliant with anticoagulation
- ○ Hypercoagulable state
- ○ Failed revascularization
- ○ Vessel dissection
- ○ Stent thrombosis
- ○ Percutaneous Transluminal Angioplasty complication
- ○ Other reason, Specify: _____

☐ **Ileocolic Artery (ICA) SMA Procedure**

Reason patency not maintained in Ileocolic Artery (ICA)

- ○ Patient non-compliant with anticoagulation
- ○ Hypercoagulable state
- ○ Failed revascularization
- ○ Vessel dissection
- ○ Stent thrombosis
- ○ Percutaneous Transluminal Angioplasty complication
- ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

☐ **Peripheral Branches SMA Procedure**

Reason patency not maintained in Peripheral Branches

- ○ Patient non-compliant with anticoagulation
- ○ Hypercoagulable state
- ○ Failed revascularization
- ○ Vessel dissection
- ○ Stent thrombosis
- ○ Percutaneous Transluminal Angioplasty complication
- ○ Other reason, Specify: _____

☐ **Other SMA Procedure**

Other target vessel segment, specify_____

Reason patency not maintained in Other Target Vessel Segment

- ○ Patient non-compliant with anticoagulation
- ○ Hypercoagulable state
- ○ Failed revascularization
- ○ Vessel dissection
- ○ Stent thrombosis
- ○ Percutaneous Transluminal Angioplasty complication
- ○ Other reason, Specify: _____

If visit completed, were any reinterventions performed on the target vessel since last visit?

- ○ Yes
- ○ No

If Yes, log as an Adverse Event and reference AE #(s): _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Follow Up Information - 180 Day Follow-Up

Concomitant Medication

Check which of the following medications the patient is currently taking:

☐ Aspirin	☐ Clopidogrel	☐ Ticlopidine
☐ Prasugrel	☐ Cilostazol	☐ None of the Above

2	7	5	4	8
Study #				

Site #				

Subject #		

Unscheduled Imaging

Primary imaging modality used to assess patency

- ○ DUS
- ○ CTA
- ○ MRA
- ○ Angiography

If Imaging Done, Date of Imaging: _ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY

Was patency maintained in all vessels treated with Indigo since the last visit? *Patency is defined as Demonstrably patent by an accepted imaging technique of the specific arterial site treated, such as with DUS (preferred), CTA, MRA, or arteriography that clearly shows flow through the lesion. Stenosis developing within the treated segment without reocclusion is not considered a loss of patency but will contribute to recurrent ischemia.*

- ○ Yes
- ○ No

If no, specify vessel(s) that was not patent ***(Left Leg Indications listed after Right Leg):***

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Right Leg**

☐ Right External Iliac	Reason patency not maintained in Right External Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg**

☐ Right Common Iliac	Reason patency not maintained in Right Common Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Right Leg**

☐ Right Common femoral	Reason patency not maintained in Right Common femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg**

☐ Right Superficial femoral	Reason patency not maintained in Right Superficial femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Right Leg**

☐ Right Profunda (Deep femoral)	Reason patency not maintained in Right Profunda (Deep femoral) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg**

☐ Right Popliteal - P1 (Proximal)	Reason patency not maintained in Right Popliteal - P1 (Proximal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Right Leg**

☐ Right Popliteal – P2 (Mid)	Reason patency not maintained in Right Popliteal – P2 (Mid) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg**

☐ Right Popliteal - P3 (Distal)	Reason patency not maintained in Right Popliteal - P3 (Distal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Right Leg**

☐ Right Anterior Tibial	Reason patency not maintained in Right Anterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg**

☐ Right Tibioperoneal Trunk	Reason patency not maintained in Right Tibioperoneal Trunk ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Right Leg**

☐ Right Posterior Tibial	Reason patency not maintained in Right Posterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right**

☐ Right Peroneal	Reason patency not maintained in Right Peroneal ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Right**

☐ Right Dorsalis pedis	Reason patency not maintained in Right Dorsalis pedis ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Right Leg**

☐ Right Other Right leg other location, specify:	Reason patency not maintained in Right Other Vessel ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Left Leg**

☐ Left External Iliac	Reason patency not maintained in Left External Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg**

☐ Left Common Iliac	Reason patency not maintained in Left Common Iliac ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Unscheduled Imaging

☐ **Left Leg**

☐ Left Common femoral	Reason patency not maintained in Left Common femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg**

☐ Left Superficial femoral	Reason patency not maintained in Left Superficial femoral ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Left Leg**

☐ Left Profunda (Deep femoral)	Reason patency not maintained in Left Profunda (Deep femoral) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg**

☐ Left Popliteal - P1 (Proximal)	Reason patency not maintained in Left Popliteal - P1 (Proximal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Left Leg**

☐ Left Popliteal – P2 (Mid)	Reason patency not maintained in Left Popliteal – P2 (Mid) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg**

☐ Left Popliteal - P3 (Distal)	Reason patency not maintained in Left Popliteal - P3 (Distal) ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Left Leg**

☐ Left Anterior Tibial	Reason patency not maintained in Left Anterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg ALI Procedure**

☐ Left Tibioperoneal Trunk	Reason patency not maintained in Left Tibioperoneal Trunk ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

2	7	5	4	8

Study #

Site #

Subject #

Unscheduled Imaging

☐ **Left Leg**

☐ Left Posterior Tibial	Reason patency not maintained in Left Posterior Tibial ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left**

☐ Left Peroneal	Reason patency not maintained in Left Peroneal ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Unscheduled Imaging

☐ **Left**

☐ Left Dorsalis pedis	Reason patency not maintained in Left Dorsalis pedis ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

☐ **Left Leg**

☐ Left Other Left leg other location, specify:	Reason patency not maintained in Left Other Vessel ○ Patient non-compliant with anticoagulation ○ Hypercoagulable state ○ Failed revascularization ○ Vessel dissection ○ Stent thrombosis ○ Percutaneous Transluminal Angioplasty complication ○ Other reason, Specify: _____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Adverse Event

Adverse Event Term:_____

Does the event qualify as any of the following events of interest?

- ○ Yes
- ○ No

If Yes, specify endpoint event type:

☐ Device-related serious adverse event

☐ Major amputation: *Complete or partial removal that occurs at or proximal to the ankle*

Date of Major Amputation _ __ - __ __ __ -__ __ __ __ DD-MMM-YYYY

☐ Event requiring arterial reintervention through 6 months excluding planned staged procedure

☐ Device-related bleeding:

If device-related bleeding, what was the amount of the decrease in Hemoglobin level? _____g/dL (decimal)

If device-related bleeding, number of units transfused: ___ ___ units

☐ Clinically significant re-thrombosis of the target venous segment requiring re-intervention, within 30 days

☐ New symptomatic pulmonary embolism within 30 days

☐ Device-related distal embolization. *Device-related distal embolization is defined as a distal filling defect with an abrupt cut-off, determined to be new since the pre-procedure angiogram, present at the end of the procedure, and clinically significant requiring intervention other than Indigo use. If the area in question was not clearly visualized, filling defects distal to the target lesion cannot be categorized as emboli.*

Provide event details and circumstances surrounding the event:_____

_____

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Adverse Event

Start Date: _ __ - __ __ __ -__ __ __ __DD-MMM-YYYY

Outcome:

- ○ Resolved
- ○ Resolved with clinical sequelae
- ○ Event Ongoing
- ○ Unresolved (at time of study exit/death due to other event)
- ○ Death due to this event

Date Resolved: _ __ - __ __ __ -__ __ __ __DD-MMM-YYYY

Action Taken (check all that apply)

- ☐ None
- ☐ Medication Given
- ☐ Transfusion
- ☐ Medical procedure - non-target vessel, specify: _____
- ☐ Target vessel reintervention procedure

Target vessel reintervention, specify intervention type:_____

Target vessel reintervention, specify reason for reintervention_____

Relationship to index disease state:

- ○ Unrelated
- ○ Possible
- ○ Probable
- ○ Definite

Relationship to Index Procedure

- ○ Unrelated
- ○ Possible
- ○ Probable
- ○ Definite

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Adverse Event

Relationship to Indigo System:

- ○ Unrelated
- ○ Possible
- ○ Probable
- ○ Definite

Specify device:_____

Device lot number:_____

Relationship to Thrombolytics

- ○ Unrelated
- ○ Possible
- ○ Probable
- ○ Definite
- ○ N/A

Was this a Serious Adverse Event (SAE)?

- ○ Yes
- ○ No

If Yes (check all that apply):

- ☐ Death
- ☐ Serious deterioration in the health of the participant that resulted in any of the following:

  Check all that apply:

  - ☐ Life threatening illness or injury
  - ☐ Permanent impairment of a body structure or a body function
  - ☐ Hospitalization or prolongation of patient hospitalization
  - ☐ Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
  - ☐ Chronic disease

- ☐ Fetal distress, fetal death or a congenital physical or mental impairment or birth defect

Penumbra

2	7	5	4	8

Study #

Site #

Subject #

Study Exit

Date of study exit: _ __ - __ __ __ -__ __ __ __DD-MMM-YYYY
(Exit date, Date of death, or Date of last contact)

Did the subject complete the study?

- ○ Yes
- ○ No

If the subject did not complete the study, indicate the primary reason

- ○ Subject withdrew consent
- ○ Investigator decision, explain: _____
- ○ Lost to follow-up
- ○ Subject deceased
- ○ Other reason, specify: _____

Is Data Entry for this patient complete?

- ○ Yes
- ○ No

If "Yes", all un-saved records within the Patient Record Page Visits Table will become inaccessible/disabled, effectively completing data entry for this patient. Please ensure that all data has been entered, or indicate "No" here until this is the case. This record will be considered incomplete until all fields on this record are complete, and this question is answered "Yes".