Imperial College London

Participant No.: ☐☐☐

CASE REPORT FORMS

(SET Centres)

Patient Initials: ☐☐☐

Participant ID: ☐☐☐

Site Number: ☐☐

Imperial College London

Participant No.: ☐ ☐ ☐

Inclusion / Exclusion Checklist

Inclusion Criteria

The following criteria MUST be answered YES for participant to be included in the trial (except where NA is appropriate):		**Yes**	**No**
1.	**Capacity to provide informed consent**	☐	☐
2.	**Patient age ≥ 18 years**	☐	☐
3.	**Ankle Brachial Pressure Index (ABPI) < 0.9 OR positive stress test (fall in ankle pressure >30mmHg, 40 secs post 1 min treadmill at 10% gradient, 4km/hr)**	☐	☐
4.	**Positive Edinburgh Claudication Questionnaire**	☐	☐
If any of the above criteria is answered NO, the participant is NOT eligible for the trial and must not be included in the study.			

Exclusion Criteria

The following criteria MUST be answered NO for the participant to be included in the trial:		**Yes**	**No**
1.	Severe Intermittent Claudication requiring invasive intervention as determined by the treating clinician	☐	☐
2.	Critical Limb Ischaemia (as defined by the European Consensus Document)	☐	☐
3.	Co-morbid disease prohibiting walking on a treadmill or taking part in supervised exercise therapy	☐	☐
4.	Popliteal entrapment syndrome	☐	☐
5.	Pregnancy ☐ N/A - Male	☐	☐
6.	Any implanted electronic, cardiac or defibrillator device	☐	☐
7.	Commenced vascular symptom specific medication in previous 6 months e.g. naftidrofuryl oxalate, Cilostazol	☐	☐
8.	Acute deep vein thrombosis	☐	☐
9.	Broken or bleeding skin including leg ulceration	☐	☐
10	Peripheral neuropathy	☐	☐
11.	Recent lower limb injury or lower back pain.	☐	☐
If any of the above criteria is answered YES, the participant is NOT eligible for the trial and must not be included in the study.			

Signed_____ Dated _____

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Informed Consent	
Date participant signed written consent form:	__ __ / __ __ __ / __ __ __ __ (DD / MMM / YYYY)
Name of person taking informed consent: _____	

SCREENING	
Date of Assessment:	D D M M M Y Y Y Y
Pregnancy	
☐ Male = Not Applicable ☐ Female or 'other gender' N/A - Not of child bearing potential	
☐ Female or 'other gender' of child bearing potential- Date of Test	__ __ / __ __ __ / __ __ __ __ **(DD / MMM / YYYY)**
Result:	☐ **Negative** ☐ **Positive = DO NOT RANDOMISE**

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Participant No.: ☐☐☐

Medication List: Only commonly used medications have been listed as a guide. If the patient is on a medication that is not listed, please add. Please tick as many as apply and add all medications the participant is currently taking to the comeds form.		
Is the subject taking any medication? ☐ Yes, complete below and a conmed form		☐ No
Medication:		
Currently taking antiplatelets:	☐ Yes	☐ No
Currently taking glycoprotein IIb/IIIa antagonists:	☐ Yes	☐ No
Currently taking lipid modification therapy:	☐ Yes	☐ No
Currently taking Anticoagulant:	☐ Yes	☐ No
Currently taking Antihypertensives:	☐ Yes	☐ No
Currently taking other medications:	☐ Yes	☐ No

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Participant No.: ☐☐☐

Ankle Brachial Pressure Index:

Was an ABPI test carried out?	☐ Yes, complete table ☐ No, please complete stress test

Systolic pressure	**Right Arm**	**Left Arm**
Brachial	☐☐☐ mmHg	☐☐☐ mmHg
Systolic pressure	Right Ankle	Left Ankle
Dorsalis Pedalis	☐☐☐ mmHg	☐☐☐ mmHg
Posterior Tibial	☐☐☐ mmHg	☐☐☐ mmHg
ABPI	☐.☐	☐.☐

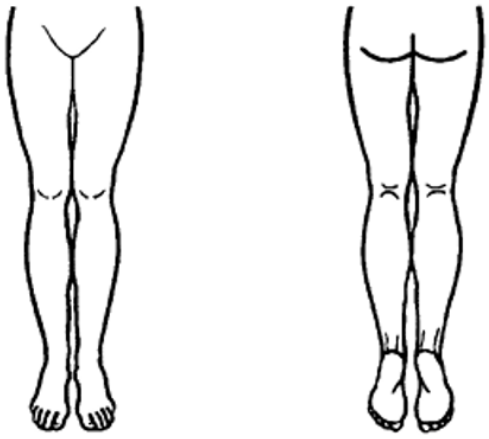
Stress Test:

Stress test performed: ☐ Yes ☐ No, please provide a reason_____

Result	☐☐☐ mmHg
Positive (a positive result is defined as a fall in ankle pressure >30mmHg, 40 secs post 1 min treadmill at 10% gradient, 4 km/h)	☐ Yes ☐ No

Edinburgh Claudication Questionnaire:	
Do you get a pain or discomfort in your leg(s) when you walk?	☐ Yes
	☐ No
	☐ I am unable to walk
If you answered 'Yes' to question 1- please answer the following questions. Otherwise you need not continue.	
2. Does this pain ever begin when you are standing still?	☐ Yes
	☐ No
3. Do you get it if you walk uphill or hurry?	☐ Yes
	☐ No
4. Do you get it when you walk at an ordinary pace on the level?	☐ Yes
	☐ No
5. What happens to it if you stand still?	☐ Usually continues for more than 10 minutes
	☐ Usually disappears in 10 minutes or less

6. Where do you get this pain or discomfort? Mark the place(s) with 'x' on the diagram below



Note for researcher: Definition of positive classification required all of the following responses:

'Yes' to Q1

'No' to Q2

'Yes' to Q3 and

'Usually disappears in 10 minutes or less' to Q5

Grade 1 = 'No' to Q4

Grade 2 = 'Yes' to Q4

If these criteria are fulfilled, a definite claudicant is one who indicates pain in the calf, regardless of whether pain is also marked in other sites; a diagnosis of atypical claudication is made if pain is indicated in the thigh or buttock, in the absence of any calf pain. Subjects should not be considered to have claudication if pain is indicated in the hamstrings, feet, shins, joints or appears to radiate, in the absence of any pain in the calf.

Score:

☐ Definite claudicant

☐ Atypial claudicant

☐ Subject does not have claudication. (subject is not eligible for the trial, do not randomise)

Past Medical History

Has the subject experienced any of the following past and/or concomitant diseases or past surgeries?

☐ Yes, please tick all that apply. ☐ No

Condition	Yes	No	
Hypertension	☐	☐	
Stroke	☐	☐	
Heart Attack	☐	☐	
High Cholesterol	☐	☐	
Angina	☐	☐	
Diabetes	☐	☐	
Previous lower limb interventions:			
Bypass revascularisation	☐	☐	
Angio revascularisation	☐	☐	
Other	☐	☐	_____

Is the patient eligible to take part in the study? ☐ Yes ☐ No

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Participant No.: ☐ ☐ ☐

Patient Contact Form:

Title	☐ Mr ☐ Mrs ☐ Miss ☐ Ms Other ☐
First Name	
Last Name	
Address	
Email	@
Telephone No.	
Mobile No.	
Preferred Method of contact	

Best Contact Details:

Title	☐ Mr ☐ Mrs ☐ Miss ☐ Ms Other ☐
First Name	
Last Name	
Address	
Telephone No.	

GP details:

Initials		Surname	
Address			

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Participant No.: ☐ ☐ ☐

RANDOMISATION

Allocated Treatment (SET Centre)	
☐	Best medical therapy including exercise advice and supervised exercise therapy (control)
☐	Best medical therapy including exercise advice, supervised exercise therapy and neuromuscular electrical stimulation (treatment)

Ask the patient to complete the following questionnaires before you inform them of their treatment allocation

- **EQ-5D-5L Baseline**
- **SF-36 Baseline**
- **Intermittent Claudication Questionnaire (ICQ)**

Study device details: Only complete if the patient was allocated to the device arm

Date the patient received the device (if allocated to the device group)

__ __ / __ __ __ / __ __ __ __

(DD / MMM / YYYY)

Device ID: _____

Did the patient receive a data logger?

☐ No

☐ Yes, data logger ID _____

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Participant No.: ☐ ☐ ☐

VISIT 1 BASELINE

Date of Assessment:	D D M M M Y Y Y Y	

Baseline Demographic Data:

Date of Birth: D D M M M Y Y Y Y

Gender: ☐ Male ☐ Female ☐ Other

Ethnicity:

White:

English/Welsh/Scottish/ Northern Irish/British ☐ | Irish ☐ | Gypsy or Irish Traveller ☐ | White Other, ☐ (please specify) _____

Mixed race/ Multiple ethnic background:

White & Black Caribbean ☐ | White & Black African ☐ | White & Asian ☐ | Other mixed/ multiple ethnic background, ☐ (please specify) _____

Asian or Asian British:

Indian ☐ | Pakistani ☐ | Bangladeshi ☐ | Other Asian background, ☐ (please specify) _____

Chinese ☐

Black or Black British:

Caribbean ☐ | African ☐ | Other Black background, ☐ (please specify) _____

Any other ethnic group:

Arab ☐ | Other, ☐ **(**please specify**)** _____

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Participant No.: ☐☐☐

Work:			
Is the patient retired?	☐ Yes ☐ No If no, :		
☐ Higher managerial and professional occupations	☐ Lower managerial and professional occupations	☐ Intermediate occupations (e.g. clerical, sales, service)	☐ Small employers and own account workers
☐ Lower supervisory and technical occupations	☐ semi-routine occupations	☐ Routine occupations	☐ Student
☐ Never worked or long-term unemployed			
If working, please specify occupation			
Is this work full time or part time?	☐ full time	☐ part time	☐ n/a, not working
Is your performance at work, or (carrying out your daily activities) limited by your Intermittent Claudication?	☐ A lot	☐ A little	☐ Not at all
Have you taken any days off work due to your Intermittent Claudication in the past year?	☐ No ☐ N/A (patient is retired or not working)		
	☐ Yes, Specify number of days	☐☐☐	

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Baseline Vital signs:

Weight ☐☐☐.☐ Kg BMI calculated automatically on the database

Height ☐☐☐ cm

Pulse rate ☐☐☐ Bpm

Blood pressure (supine and resting) ☐☐☐/☐☐☐ mmHg

Systolic Diastolic

Baseline Lifestyle Information:

Subject's smoking status: ☐ Never smoked

☐ Current Smoker

Participant's average daily use:
Number of cigarettes/pipes per day: ☐☐☐

Date when smoking started ☐☐☐☐☐☐☐☐ (D D M M M Y Y Y Y)

☐ Former Smoker

Date when smoking ceased ☐☐☐☐☐☐☐☐ (D D M M M Y Y Y Y)

When smoking, participant's average daily use: Number of cigarettes/pipes per day: ☐☐☐

Does the participant use electronic cigarettes? ☐ Yes ☐ No

If yes,

☐ High user ☐ Moderate user ☐ Low user

Does the participant consume alcohol? ☐ Never ☐ current drinker: _____ units per week

Small glass of red/white/rose wine (125ml)= 1.5 units; standard glass of red/white/rose wine (175ml)=2.1 units; Large glass of red/white/rose wine (250ml)=3 units; Pint of lower strength larger/beer/cider (3.6%)= 2 units; Pint of higher strength larger/beer/cider (5.2%)= 3 units; Bottle of higher strength larger/beer/cider (330ml)=1.7 units; Can of higher strength larger/beer/cider (440ml)= 2 units; Alcopop (275ml)=1.5 units; Single small shot of spirits (25ml)=1 unit (Source: NHS Choices)

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Participant No.: ☐☐☐

Haemodynamic Assessment:

Baseline Duplex ultrasonography Haemodynamics-Duplex Ultrasonography – Using the appropriate arterial ultrasonography probe and pre-set volume flow algorithms on a Duplex Ultrasound machine, flow within the Common femoral artery (CFA), preferably of the most affected limb, will be measured, approximately 5 cm below the mid-inguinal point at the groin. Measures include volume flow (VF, cc/min) and time-averaged mean velocity (TAMV, cm/s). In the control group, only resting values will be undertaken over a 3-minute period. The intervention group will have these parameters measured at rest, at 15 and 30-minutes into device use and then at 1 and 5 minutes after device cessation.

Leg measured
(select the worst leg if both are affected) ☐ **Left** ☐ **Right**

Common femoral artery diameter ☐☐.☐ **mm**

Allocated Group	Time point	Volume Flow (cc/min)	Time averaged Mean Velocity (cm/s)
Control group	Baseline (Rest)		
NMES group – Before device use	Baseline (Rest)		
NMES group – During device use	15 minutes		
NMES group – During device use	30 minutes		
NMES group – After device cessation	1 minute		
NMES group – After device cessation	5 minutes		

Send a copy of the anonymised duplex report to the Coordinating Centre using the Imperial College file transfer nesictrial@imperial.ac.uk

Anonymised duplex report sent to the Coordinating Centre?	☐ Yes ☐ No, provide a reason_____

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Participant No.: ☐☐☐

Baseline Laser Doppler Flowmetry- Position the single fibre laser optical probe of the LDF machine on the dorsal aspect of the leg using single use adhesive pads. Once the probe is placed, measurement is continuously collected via the LDF software. **In the control group:** this will be at rest for a 3-minute duration **The intervention group:** data will be collected at rest until 5-minutes after device cessation.

Send a copy of the anonymised report to the Coordinating Centre using the Imperial College file transfer nesictrial@imperial.ac.uk

Control group ☐		**Device group** ☐	
Leg measured: ☐ Left ☐ Right (select the worst leg if both are affected)		Leg measured: ☐ Left ☐ Right (select the worst leg if both are affected) Device intensity:_____	
Flux: (mean value at rest)	☐☐☐.☐	**Flux (mean value at rest)**	☐☐☐.☐
		Flux (mean value during device use)	☐☐☐.☐
		Flux (mean value after device cessation)	☐☐☐.☐
Temperature of foot	☐☐.☐ °C	**Temperature of foot**	☐☐.☐ °C
Anonymised report sent to the Coordinating Centre?	☐ Yes ☐ No, provide a reason_____		

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Participant No.: ☐☐☐

Baseline Peripheral Pulse Examination:

Right Leg				Left Leg			
Common Femoral		Popliteal		Common Femoral		Popliteal	
Dorsal pedalis		Posterior Tibial		Dorsal pedalis		Posterior Tibial	
3= aneurysmal 2= Normal 1= Reduced 0= Absent							

Depending on the allocated treatment:

- Provide training on device use and/or data logger
- Schedule an appointment for supervised exercise therapy
- Ensure best medical therapy is provided
- Provide a copy of the device compliance diary and/or resource use diary

Baseline Treadmill Test:

Did the patient complete the treadmill test?	☐ Yes ☐ No, provide a reason_____
Patient's subjective initial walking distance estimate:	☐☐☐.☐☐ Meters
Patient's subjective absolute walking distance estimate:	☐☐☐.☐☐ Meters

Treadmill test (Gardner-Skinner Protocol): Start the treadmill with a constant speed of 3.2 km/hour on a 0% incline and increase the gradient by 2% every 2 minutes.

Patients will indicate the start of their claudication pain, which will be recorded as the Initial Claudication Distance (ICD) and finally stop the test at the point the patient does not want to continue due to lower limb pain; this is the Absolute Walking Distance (AWD)

Speed:	☐☐•☐☐ Km/hour
Incline: (record the incline at which the patient requests to stop)	☐☐•☐☐ %
Initial Claudication Distance (ICD):	☐☐☐•☐☐ Meters
Absolute Walking Distance (AWD):	☐☐☐•☐☐ Meters

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Participant No.: ☐☐☐

3 MONTH VISIT

Date of Assessment: D D M M M Y Y Y Y

- Ask the patient to complete a copy of the EQ-5D-5L, SF36, Intermittent Claudication Questionnaire (ICQ) and the Device experience questionnaire
- Record any related Adverse Events or Serious Adverse Events on the appropriate forms
- Remember to collect the Resource Use Diary and/or Device Compliance Diary
- If the patient received a data logger check it has been returned

Has the patient experienced any adverse events or serious adverse events since the last visit?

☐ Yes, please complete an adverse event and/or serious adverse event form

☐ No

Have there been any changes to concomitant medications since the last visit?

☐ Yes, please complete/update the concomitant medications form

☐ No

Physical Examination

3 Month Ankle Brachial Pressure Index:

Systolic pressure	Right Arm	Left Arm
Brachial	☐☐☐ mmHg	☐☐☐ mmHg
Systolic pressure	**Right Ankle**	**Left Ankle**
Dorsalis Pedalis	☐☐☐ mmHg	☐☐☐ mmHg
Posterior Tibial	☐☐☐ mmHg	☐☐☐ mmHg
ABPI	☐.☐ mmHg	☐.☐ mmHg

☐ Could not complete test, please provide a reason:

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Participant No.: ☐☐☐

3 Month Peripheral Pulse Examination:

Right Leg				Left Leg			
Common Femoral		Popliteal		Common Femoral		Popliteal	
Dorsal pedalis		Posterior Tibial		Dorsal pedalis		Posterior Tibial	
3= aneurysmal 2= Normal 1= Reduced 0= Absent							
☐ Could not complete test, please provide a reason:							

3 Month Haemodynamic Assessment:

Duplex ultrasonography Haemodynamics-Duplex Ultrasonography – Using the appropriate arterial ultrasonography probe and pre-set volume flow algorithms on a Duplex Ultrasound machine, flow within the Common femoral artery (CFA), preferably of the most affected limb, will be measured, approximately 5 cm below the mid-inguinal point at the groin. Measures include volume flow (VF, cc/min) and time-averaged mean velocity (TAMV, cm/s). In the control group, only resting values will be undertaken over a 3-minute period. The intervention group will have these parameters measured at rest, at 15 and 30-minutes into device use and then at 1 and 5 minutes after device cessation.

Leg measured
(select the worst leg if both are affected – **complete a protocol deviation form if <u>not</u> the same leg as baseline**)

☐ **Left** ☐ **Right**

Common femoral artery diameter ☐☐.☐ **mm**

Allocated Group		Time point	Volume Flow (cc/min)	Time averaged Mean Velocity (cm/s)
Control group		Baseline (Rest)		
NMES group	Before device use	Baseline (Rest)		
	During device use	15 minutes		
		30 minutes		
	After device cessation	1 minute		
		5 minutes		

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Participant No.: ☐☐☐

Send a copy of the anonymised duplex report to the Coordinating Centre using the Imperial College file transfer nesictrial@imperial.ac.uk	
Anonymised duplex report sent to the Coordinating Centre?	☐ Yes ☐ No, provide a reason_____

3 Month Laser Dopper Flowmetry:	
Date of Assessment:	D D M M M Y Y Y Y
Position the single fibre laser optical probe of the LDF machine on the dorsal aspect of the leg using single use adhesive pads. Once the probe is placed, measurement is continuously collected via the LDF software. **In the control group:** this will be at rest for a 3-minute duration. **The intervention group:** data will be collected at rest until 5-minutes after device cessation. **Send a copy of the anonymised report to the Coordinating Centre using the Imperial College file transfer** nesictrial@imperial.ac.uk	
Anonymised report sent to the Coordinating Centre?	☐ Yes ☐ No, provide a reason_____

Control group ☐		**Device group** ☐	
Leg measured: ☐ Left ☐ Right (if both are affected please select the worst leg – **complete a protocol deviation form if not the same leg as baseline**)		Leg measured**:** ☐ Left ☐ Right (if both are affected please select the worst leg) Device intensity:_____	
Flux: **(mean value at rest)**	☐☐☐.☐	**Flux** **(mean value at rest)**	☐☐☐.☐
		Flux **(mean value during device use)**	☐☐☐.☐
		Flux **(mean value after device cessation)**	☐☐☐.☐
Temperature of foot	☐☐.☐ °C	**Temperature of foot**	☐☐.☐ °C
Anonymised report sent to the Coordinating Centre?	☐ Yes ☐ No, provide a reason_____		

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Participant No.: ☐☐☐

3 Month Treadmill Test:

Do you think you can walk further since the last treadmill test? ☐ Yes ☐ No

Patient's subjective initial walking distance estimate:	☐☐☐.☐☐ Meters
Patient's subjective absolute walking distance estimate:	☐☐☐.☐☐ Meters

Gardner-Skinner Protocol: Start the treadmill with a constant speed of 3.2 km/hour on a 0% incline and increase the gradient by 2% every 2 minutes.

Patients will indicate the start of their claudication pain, which will be recorded as the Initial Claudication Distance (ICD) and finally stop the test at the point the patient does not want to continue due to lower limb pain; this is the Absolute Walking Distance

Speed:	☐☐.☐☐ Km/hour
Incline: (record the inclince at which the patient requests to stop)	☐☐.☐☐ %
Initial Claudication Distance (ICD):	☐☐☐.☐☐ Meters
Absolute Walking Distance (AWD):	☐☐☐.☐☐ Meters
☐ Could not complete the test, please provide a reason. NB, if the patient could not complete the test invite them to return to complete the test before the next follow up	

6 MONTH FOLLOW UP

Date of Assessment: D D M M M Y Y Y Y

- Ask the patient to complete a copy of the EQ-5D-5L, SF36 and ICQ
- Record any Adverse Events or Serious Adverse Events on the appropriate forms

Has the patient experienced any adverse events or serious adverse events since the last visit?

☐ Yes, please complete an adverse event and/or serious adverse event form

☐ No

Have there been any changes to concomitant medications since the last visit?

☐ Yes, please complete/update the concomitant medications form

☐ No

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Participant No.: ☐☐☐

6 Month Ankle Brachial Pressure Index:

Systolic	Right Arm	Left Arm
Brachial	☐☐☐ mmHg	☐☐☐ mmHg
	Right Ankle	Left Ankle
Dorsalis Pedalis	☐☐☐ mmHg	☐☐☐ mmHg
Posterior Tibial	☐☐☐ mmHg	☐☐☐ mmHg
ABPI	☐☐☐ mmHg	☐☐☐ mmHg
☐ Could not complete test, please provide a reason:		

6 Month Peripheral Pulse Examination:

Right Leg				Left Leg			
Common Femoral		Popliteal		Common Femoral		Popliteal	
Dorsal pedalis		Posterior Tibial		Dorsal pedalis		Posterior Tibial	
3= Aneurysmal 2= Normal 1= Reduced 0= Absent							
☐ Could not complete test, please provide a reason:							

Imperial College London

Participant No.: ☐☐☐

6 Month Laser Dopper Flowmetry:

Date of Assessment: D D M M M Y Y Y Y

Position the single fibre laser optical probe of the LDF machine on the dorsal aspect of the leg using single use adhesive pads. Once the probe is placed, measurement is continuously collected via the LDF software. **In both groups** this will be at rest for a 3-minute duration.

Send a copy of the anonymised report to the Coordinating Centre using the Imperial College file transfer nesictrial@imperial.ac.uk

Leg measured: ☐ Left ☐ Right
(if both are affected please select the worst leg – **complete a protocol deviation form if not the same leg as baseline**)

Flux: **(mean value at rest)**	☐☐☐.☐	**Temperature of foot**	☐☐.☐ °C
Anonymised report sent to the Coordinating Centre?	☐ Yes ☐ No, provide a reason_____		

6 Month Treadmill Test:

Do you think you can walk further since the last treadmill test? ☐ Yes ☐ No

Patient's subjective initial walking distance estimate:	☐☐☐.☐☐ Meters
Patient's subjective absolute walking distance estimate	☐☐☐.☐☐ Meters

Gardner-Skinner Protocol: Start the treadmill with a constant speed of 3.2 km/hour on a 0% incline and increase the gradient by 2% every 2 minutes.

Patients will indicate the start of their claudication pain, which will be recorded as the Initial Claudication Distance (ICD) and finally stop the test at the point the patient does not want to continue due to lower limb pain; this is the Absolute Walking Distance

Speed:	☐☐.☐☐ Km/hour
Incline: (record the incline at which the patient requests to stop)	☐☐.☐☐ %
Initial Claudication Distance (ICD):	☐☐☐.☐☐ Meters
Absolute Walking Distance (AWD):	☐☐☐.☐☐ Meters
☐ Could not complete the test, please provide a reason. NB, if the patient could not complete the test invite them to return to complete the test before the next follow up	

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Participant No.: ☐☐☐

12 MONTH FOLLOW UP

Date of Assessment: D D M M M Y Y Y Y

- Ask the patient to complete a copy of the EQ-5D-5L, SF36 and ICQ
- Record any Adverse Events or Serious Adverse Events on the appropriate forms

Has the patient experienced any adverse events or serious adverse events since the last visit?

☐ Yes, please complete an adverse event and/or serious adverse event form

☐ No

Have there been any changes to concomitant medications since the last visit?

☐ Yes, please complete/update the concomitant medications form

☐ No

12 Month Lifestyle

If the patient was a smoker at baseline are they still smoking?

☐ Yes

☐ No

☐ N/A, patient was not a current smoker at baseline

If yes, participant's average daily use:
Number of cigarettes/pipes per day: ☐☐☐

Was the patient randomised to the device? ☐ Yes ☐ No

If yes, did they use the device beyond the 3 month treatment period?

☐ Yes, please specify average use per week ☐ No

☐☐☐ Minutes

For how many weeks?

☐☐☐ Weeks

Imperial College London

Participant No.: ☐☐☐

12 Month Ankle Brachial Pressure Index:

Systolic	Right Arm	Left Arm
Brachial	☐☐☐ mmHg	☐☐☐ mmHg
	Right Ankle	Left Ankle
Dorsalis Pedalis	☐☐☐ mmHg	☐☐☐ mmHg
Posterior Tibial	☐☐☐ mmHg	☐☐☐ mmHg
ABPI	☐.☐ mmHg	☐.☐ mmHg
☐ Could not complete test, please provide a reason:		

12 Month Peripheral Pulse Examination:

Right Leg				Left Leg			
Common Femoral		Popliteal		Common Femoral		Popliteal	
Dorsal pedalis		Posterior Tibial		Dorsal pedalis		Posterior Tibial	
3= Aneurysmal 2= Normal 1= Reduced 0= Absent							
☐ Could not complete test, please provide a reason:							

Imperial College London

Participant No.: ☐☐☐

12 Month Laser Dopper Flowmetry:

Date of Assessment: D D M M M Y Y Y Y

Position the single fibre laser optical probe of the LDF machine on the dorsal aspect of the leg using single use adhesive pads. Once the probe is placed, measurement is continuously collected via the LDF software. **In both groups** this will be at rest for a 3-minute duration.

Send a copy of the anonymised report to the Coordinating Centre using the Imperial College file transfer nesictrial@imperial.ac.uk

Leg measured: ☐ Left ☐ Right
(if both are affected please select the worst leg – **complete a protocol deviation form if not the same leg as baseline**)

Flux: **(mean value at rest)**	☐☐☐.☐	**Temperature of foot**	☐☐.☐ °C
Anonymised report sent to the Coordinating Centre?	☐ Yes ☐ No, provide a reason_____		

12 Month Treadmill Test:

Do you think you can walk further since the last treadmill test? ☐ Yes ☐ No

Patient's subjective initial walking distance estimate: ☐☐☐.☐☐ Meters

Patient's subjective absolute walking distance estimate: ☐☐☐.☐☐ Meters

Gardner-Skinner Protocol: Start the treadmill with a constant speed of 3.2 km/hour on a 0% incline and increase the gradient by 2% every 2 minutes.

Patients will indicate the start of their claudication pain, which will be recorded as the Initial Claudication Distance (ICD) and finally stop the test at the point the patient does not want to continue due to lower limb pain; this is the Absolute Walking Distance

Speed:	☐☐•☐☐ Km/hour
Incline: (record the incline at which the patient requests to stop)	☐☐•☐☐ %
Initial Claudication Distance (ICD):	☐☐☐•☐☐ Meters
Absolute Walking Distance (AWD):	☐☐☐•☐☐ Meters
☐ Could not complete the test, please provide a reason.	

Participant No.: ☐ ☐ ☐

ADVERSE EVENT/ DEVICE EFFECTS FORM

All adverse events *related* to the device or not should be recorded on this page. For definitions of seriousness, intensity and relationship to the device please refer to the study protocol.

AE No	**Event Description** (Please give Diagnosis if known)	**Onset date** (DD/MMM/YYYY)	**Stop date** (DD/MMM/YYYY)	**Ongoing?**	**Frequency** 1- Single episode 2- Intermittent 3- Frequent 4- Continuous 5- Unknown	**Severity** 1- Mild 2- Moderate 3- Severe 4- Life threatening / disabling 5- Fatal	**Relationship to device:** 0- Definitely 1- Probably 2- Possibly 3 – Unlikely 4 – Not related 5 – Not assessable	**If related to the device. Is the event as a result of a device deficiency e.g.** Misuse, use error, device malfunction, device durability, device reliability, inadequate labelling, device identity, device quality.	**Serious?** If serious please complete an SAE form	**Treatment**	**Outcome** 1- Recovered 2- Not yet recovered 3- Death (complete an SAE form) 4- Unknown
		___/_____/____	___/_____/____	☐ **No** ☐ **Yes**				☐ **No** ☐ **N/A, not related to device** ☐ **Yes, specify** _____	☐ **No** ☐ **Yes**		
		___/_____/____	___/_____/____	☐ **No** ☐ **Yes**				☐ **No** ☐ **N/A, not related to device** ☐ **Yes, specify** _____	☐ **No** ☐ **Yes**		

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Participant No.: ☐ ☐ ☐

AE No	Event Description (Please give Diagnosis if known)	Onset date (DD/MMM/YYYY)	Stop date (DD/MMM/YYYY)	Ongoing?	Frequency 1- Single episode 2- Intermittent 3- Frequent 4- Continuous 5- Unknown	Severity 1- Mild 2- Moderate 3- Severe 4- Life threatening / disabling 5- Fatal	Relationship to device: 0- Definitely 1- Probably 2- Possibly 3 – Unlikely 4 – Not related 5 – Not assessable	If related to the device. Is the event as a result of a device deficiency e.g. Misuse, use error, device malfunction, device durability, device reliability, inadequate labelling, device identity, device quality.	Serious? If serious please complete an SAE form	Treatment	Outcome 1- Recovered 2- Not yet recovered 3- Death (complete an SAE form) 4- Unknown
		___/_____/____	___/_____/____	☐ No ☐ Yes				☐ No ☐ N/A, not related to device ☐ Yes, specify _____	☐ No ☐ Yes		
		___/_____/____	___/_____/____	☐ No ☐ Yes				☐ No ☐ N/A, not related to device ☐ Yes, specify _____	☐ No ☐ Yes		
		___/_____/____	___/_____/____	☐ No ☐ Yes				☐ No ☐ N/A, not related to device ☐ Yes, specify _____	☐ No ☐ Yes		

Participant No.: ☐ ☐ ☐

AE No	Event Description (Please give Diagnosis if known)	Onset date (DD/MMM/YYYY)	Stop date (DD/MMM/YYYY)	Ongoing?	Frequency 1- Single episode 2- Intermittent 3- Frequent 4- Continuous 5- Unknown	Severity 1- Mild 2- Moderate 3- Severe 4- Life threatening / disabling 5- Fatal	Relationship to device: 0- Definitely 1- Probably 2- Possibly 3 – Unlikely 4 – Not related 5 – Not assessable	If related to the device. Is the event as a result of a device deficiency e.g. Misuse, use error, device malfunction, device durability, device reliability, inadequate labelling, device identity, device quality.	Serious? If serious please complete an SAE form	Treatment	Outcome 1- Recovered 2- Not yet recovered 3- Death (complete an SAE form) 4- Unknown
		___/_____/____	___/_____/____	☐ No ☐ Yes				☐ No ☐ N/A, not related to device ☐ Yes, specify _____	☐ No ☐ Yes		
		___/_____/____	___/_____/____	☐ No ☐ Yes				☐ No ☐ N/A, not related to device ☐ Yes, specify _____	☐ No ☐ Yes		

I have reviewed the AEs/ADEs on this page and have assessed them for seriousness, causality, severity and outcome and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant

PI signature_____ **Date:**_____ ☐ **Please check box if this is the last page used**

Participant No.: ☐ ☐ ☐

CONCOMITANT MEDICATION FORM

Only record vascular specific medication or changes to baseline medication throughout the study

CM No.	Medication name (Record Generic name)	Start date (DD/MMM/YYYY)	Stop date (DD/MMM/YYYY)	Or tick if ongoing at end of study?	Reason for use (Enter related AE diagnosis, or other reasons for use, e.g. Prophylaxis)	Dose (Units)	Route	Frequency
__.		____/_____/_____	____/_____/_____	☐				
__.		____/_____/_____	____/_____/_____	☐				
__.		____/_____/_____	____/_____/_____	☐				
__.		____/_____/_____	____/_____/_____	☐				
__.		____/_____/_____	____/_____/_____	☐				
__.		____/_____/_____	____/_____/_____	☐				
__.		____/_____/_____	____/_____/_____	☐				
__.		____/_____/_____	____/_____/_____	☐				

☐ **Please check box if this is the last page used**

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Participant No.: ☐ ☐ ☐

SERIOUS ADVERSE EVENTS/EFFECTS FORM	
Serious Adverse Event/Effect Description	**Please state**_____
Related to AE No	
Serious reason	☐Death ☐Life threatening ☐ Persistently disabling ☐Hospitalisation required ☐Congenital abnormality ☐Other medical important event: detail_____
Onset Date	__ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)
Treatment for SAE	
Frequency	☐Single Episode ☐Intermittent ☐Frequent ☐Continuous ☐Unknown
Severity	☐ Mild (aware of it easily tolerated) ☐ Moderate (discomfort/interference with usual activity) ☐ Severe (inability to carry out normal activity) ☐ Life threatening or disabling ☐ Fatal
Relationship to the Device (LOCAL PI MUST ASSESS RELATIONSHIP)	☐**Not related** (no evidence of a causal relationship between device and event). ☐**Unlikely** (there is little evidence (e.g. event did not occur within a reasonable time). There is another reasonable explanation for the event (e.g. clinical condition, concomitant treatment). ☐**Possible** (there is some evidence (e.g. event occurs within a reasonable time). However, there may be other factors (e.g. clinical condition, other concomitant treatments) ☐**Probable** (there is evidence to suggest a causal relationship. Other factors are unlikely. ☐**Definite** (there is clear evidence to suggest a causal relationship. Other factors can be ruled out) ☐ Not assessable
If Related, assess if the event was anticipated i.e. listed in the IFU or protocol.	☐Anticipated ☐Unanticipated **(PI MUST ASSESS IF THE EVENT WAS ANTICPATED)**

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Participant No.: ☐ ☐ ☐

Action taken. Details of any intervention required / any further information	☐ **None** ☐ **Temporarily withdrawn** ☐ **Permanently withdrawn** ☐ **N/A - post treatment** Please state any additional details: _____
Ongoing	☐Yes ☐No: end date __ __ / __ __ __ / 2 0 __ __ (DD / MMM / YYYY)
Outcome	☐Recovered ☐ Recovering/Improving ☐ Not recovered ☐Fatal ☐Not assessable
Principal Investigator Signature (to confirm review and assessment of SAE)	_PI SIGN_____DATE_____

CI use only (assessed via the database)

Does CI agree with the local PI assessment?	☐Yes ☐No (if not please complete below)

If no, CI relatedness	☐**Not related** (no evidence of a causal relationship between and event). ☐**Unlikely** (there is little evidence (e.g. event did not occur within a reasonable time). There is another reasonable explanation for the event (e.g. clinical condition, concomitant treatment). ☐**Possible** (there is some evidence (e.g. event occurs within a reasonable time). However, there may be other factors (e.g. clinical condition, other concomitant treatments) ☐**Probable** (there is evidence to suggest a causal relationship. Other factors are unlikely. ☐**Definite** (there is clear evidence to suggest a causal relationship. Other factors can be ruled out) ☐ Not assessable

If Related, assess expectedness in relation to device	☐ Anticipated ☐ Unanticipated

Participant No.: ☐☐☐

Protocol Deviation Form (please use more than one page for multiple deviations) **PI to electronically sign off all protocol deviations and violations on the eCRF.**	
Protocol Deviation number:	☐☐☐
Date deviation reported:	D D / M M M / Y Y Y Y
Type of protocol deviation	☐ Inclusion/Exclusion criteria ☐ Compliance ☐ Missed study visit ☐ Consent issue ☐ Visit outside window ☐ Blinding/unblinding ☐ Repeated protocol deviations (of same type) ☐ AE/SAE reporting ☐ Study measurements/assessments ☐ Primary outcome measure ☐ Secondary outcome measure ☐ Safety outcome ☐ Other Please give details
Type of protocol deviation	☐ Deviation ☐ Violation
Details of deviation:	
Steps taken to rectify:	

Participant No.: ☐ ☐ ☐

Study Completion/Termination Form

Q1. Completion status

☐ **Completed**

☐ **Incomplete**

If incomplete, termination date:

D	D	M	M	M	Y	Y	Y	Y

If incomplete, termination reason:

☐ **Serious Adverse Effect**

☐ **Termination of study by Sponsor**

☐ **Investigator decision**

☐ **Inability or subject failure to comply with protocol**

☐ **Subject withdrew**

☐ **Death**

☐ **Other** _____

Q2. If subject withdrew, which of the following is the participant withdrawing from? (tick as many boxes as required)

☐ **Using the stockings**

☐ **Attending follow up appointments**

☐ **Completing further questionnaires**

☐ **Contact from study office (telephone / email) excludes the posting of questionnaires** ***delete as appropriate**

Participant No.: ☐☐☐

Study Sign Off Form

Investigator's Statement: I have reviewed the data recorded in this CRF and confirm that the data are complete and accurate

Investigator (Full name): _____

Investigator Signed? ☐ **PI must sign-off all casebooks on the eCRF**

Signature Date: D D M M M Y Y Y Y