# ProspectIve, MuLti-Center Study to EvaLUate TreatMent of subjects with OcclusivE Disease with a Novel PAcliTaxel-CoatEd Angioplasty Balloon in Below-The- Knee (BTK) arteries: a Post Market clinical Study

Published: 23-10-2018
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The objective of this study is to obtain further data on the safety and performance of the Stellarex Balloon in the treatment of lesions in *below the knee* popliteal (P3 segment) and infra-popliteal arteries according to the Instructions for Use in...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Vascular therapeutic procedures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON55654

**Source**
ToetsingOnline

**Brief title**
ILLUMENATE BTK Post Market Study

### Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
narrowing of blood vessel under the knee, vessel stenosis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Philips Image Guided Therapy Corporation
**Source(s) of monetary or material Support:** the industry/company as described in question B6/B7

## Intervention

**Keyword:** angioplasty balloon, 'below the knee' artery, paclitaxel

## Outcome measures

**Primary outcome**

Primary safety endpoint

Composite MALE + POD; freedom from the following through 30 days:

1. Major Adverse Limb Events (MALE) 2. Perioperative Death (POD)

Major Adverse Limb Event (MALE) is defined as the composite of either major

amputation or major re-intervention through 30 days of the index procedure.

Major re-intervention is defined as creation of a new surgical bypass graft,

the use of thrombectomy or thrombolysis or a major surgical graft revision such

as a jump graft or an interposition graft.

Primary performance endpoint

Composite patency + limb salvage through 6 months:

1. Patency defined as freedom from occluded target lesions (flow/no flow)

verified by duplex ultrasound (DUS) and clinically-driven target lesion

revascularization (CD-TLR)

2. Freedom from major amputation in the Target Limb

RCC 3: Clinically-driven target lesion revascularization is defined as a restenosis of >=70% in the target lesion by angiography or no flow by DUS and change in RCC > 1 class or drop in ABI by >= 0.15

RCC 4 or 5: Clinically-driven target lesion revascularization is defined as a restenosis of >=70% in the target lesion with wound persistence, new wounds or reoccurrence of ischemic rest pain.

Major Amputation is defined as an unplanned index limb loss at or proximal to the transtibial level.

**Secondary outcome**

1. Major adverse event (MAE) rate at 6, 12 and 24 months post- index procedure, defined as a composite rate of all-cause death, target limb major amputation and CD-TLR.

Secondary Outcomes

2. Rate of CD-TLR at 6, 12 and 24 months.

3. Patency rate at 6, 12 and 24 months, defined as the presence of target lesion flow (absence of occlusion or no flow) as determined by DUS and freedom from CD- TLR.

4. Rate of procedural complications defined as occurrence of all- cause death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in target limb, or thrombosis of target vessel through the end of the procedure.

5. Rate of device or procedure related death at 30 days.

6. Rate of major target limb amputation at 6, 12, 24 months post-procedure.

7. Rate of clinically driven target vessel revascularization (CD- TVR) through 6, 12 and 24 months.

8. Lesion success: achievement of a final in-lesion residual diameter stenosis of <50% (as determined by the angiographic core laboratory), using allowed pretreatment devices after guidewire passage through the lesion.

9. Technical success: achievement of a final in-lesion residual diameter stenosis of <50% (as determined by the angiographic core laboratory), using the Stellarex 0.014* Drug-Coated Balloon without a device malfunction after guidewire passage through the lesion.

10. Change in ankle-brachial index (ABI), toe pressures (TP) or waveforms/TcPO2 from pre-procedure to 30 days, 6, 12, and 24 months.

11. Change in RCC from pre-procedure to 30 days, 6, 12, and 24 months.

12. Change in EQ-5D from pre-procedure to 30 days, 6, 12, and 24 months.

13. In RCC 5 subjects, percentage of wounds healed from baseline to 30 days, 6 and 12 months post-procedure as reported by the Investigator at the Investigative site.

Wound healing is defined as complete epithelialization of the arterial target limb wounds.

# Study description

**Background summary**

Blood vessels can sometimes narrow or close-off, stopping a normal amount of blood from flowing through the blood vessels. When this occurs and if the narrowing is severe enough, one can experience pain in the legs at rest. In some cases, a balloon catheter can be used to open up or widen the narrowed

blood vessels. A balloon catheter is made up of a small balloon attached to the end of a thin tube. The physician can insert this balloon catheter into the blood vessel where the narrowing or closure is located. The balloon can then be opened (inflated) in order to decrease the narrowing which in turn increases the blood flow. This is called balloon angioplasty.
Spectranetics has developed the stellarex balloon catheter that is the same shape and size to other balloon catheters except that the balloon is coated with a drug called paclitaxel.
Paclitaxel is a well-known drug that is currently used to treat different conditions, such as some types of cancer. Paclitaxel is also used as a coating on stents, or wire mesh devices that hold open narrowed blood vessels. These paclitaxel coated stents are used in blood vessels in the heart and abdomen.
The Stellarex balloon is CE marked on 2016 and to be used in this study as per its intended use.

**Study objective**

The objective of this study is to obtain further data on the safety and performance of the Stellarex Balloon in the treatment of lesions in *below the knee* popliteal (P3 segment) and infra-popliteal arteries according to the Instructions for Use in Rutherford-Becker Classification (RCC) 3, 4 and 5 patient populations.

**Study design**

Prospective, multi-center, single arm study that will be conducted in Europe

**Intervention**

Procedure:
Balloon angioplasty is a common treatment option used to open blockages in narrowed blood vessels. This procedure will be exactly the same as any current type of balloon angioplasty.
If the patient decides to be in the study he/she will need to agree to be available for the required follow-up visits and various tests at different time points before and after the procedure. The patient will undergo follow-up visits at the investigator*s office at 1 and 6 months after the procedure as well as at 1 and 2 years after the procedure. Additional details of the follow-up requirements are provided below.

After the Procedure and Before Going Home
Before leaving the hospital:
• The patient will have an examination by the investigator or his/her designee.
• The patient will be asked how they are feeling and what medications they are taking.
• The patient may also have an ultrasound exam of your leg which is different

from the ABI, TBI you had done previously. This ultrasound exam uses high frequency sound waves to see how the blood is flowing in the vessel that was treated (like taking pictures of an unborn baby). It uses no x-rays and is done by placing a wand on the skin. It should not cause pain or discomfort. A recording of the ultrasound will be sent to an independent laboratory (known as a core lab) for review and analysis.

1 Month After the Procedure
The patient will have an office visit with the investigator to see how you are doing after the procedure. During this visit, the patient will have the following things done:
• The patient will have an examination done by the investigator or his/her designee.
• The patient will be asked how he/she is feeling and what medications they are taking.
• The patient will have an Ankle-Brachial Index (ABI) or Toe-Brachial Index (TBI) done.
• If The patient did not have an ultrasound exam of your leg done after the procedure and before you went home, he/she will have this test done to measure the blood flow through the vessel that was treated.
• If the patient does have a wound on the foot or toes and these wounds were present before the procedure, the doctor will evaluate the healing status of the wounds.

6 Months, 1 and 2 years After the Procedure
The patient will have an office visit with the investigator to see how he/she are doing. During this visit, the patient will have the following exams and tests done:
• The patient will have an examination done by the investigator or his/her designee.
• The patient will be asked how he/she is feeling and what medications they are taking.
• The patient will be asked to complete a questionnaire about his/hers activities of daily living and overall health.
• The patient will have an Ankle-Brachial Index (ABI) or Toe-Brachial Index (TBI) done.
• The patient will have an ultrasound exam of his/her leg to measure the blood flow through the vessel that was treated.
• If the patient does have a wound on his/her foot or toes and these wounds were present before the procedure, the doctor will evaluate the healing status of the wounds.

At any time the investigator may ask that the patient comes back more often if he/she thinks that it is needed for your health and safety. The investigator will treat the patient according to their standard practice. If the patient has any symptoms, is seen by any other doctor or are hospitalized, it is important

that the patient calls the study investigator as soon as possible to let them know.

At the end of study participation, the patient*s health status will be followed by the treating physician according to the hospital standard of care.

**Study burden and risks**

Since this is a post market study research of a CE marked device that will be used as its intended use, the potential risks do not differ from patients, that will be treated by a drug coated balloon, not participating the research.

As with any device requiring mechanical deployment and retraction, such as the Stellarex balloon, there exists a risk of mechanical failure of the device resulting in potential surgical intervention to remove the device.
It is expected that the fluoroscopy time of the index procedure will be similar to that required for similar procedures conducted outside of a clinical study and will not pose additional risks to the subject or laboratory personnel.
All risks listed in the IFU could cause prolonged illness, permanent impairment of daily function, or, in rare cases, death. Possible treatments could include, but are not limited to cardiac surgery and vascular surgery.
The effects of the study device (especially of the paclitaxel component) on an unborn baby are not known. Women planning to become pregnant or men planning to father a child cannot be in the study. Women should not breastfeed while in this study. Individuals of child-bearing potential must take precautions to avoid becoming pregnant or impregnating their partner for the duration of the study.

Extensive reliability engineering testing has been performed on the Stellarex balloon to mitigate risks to the subject as well as the physician operator and staff due to product failure (Please refer to IFU for complete list of risks and mitigations). Additionally, other testing using the study device has been conducted to ensure that the system performs as intended without introducing more risks during the index procedure or during follow-up. Risks may be further limited by providing medications such as aspirin or clopidogrel and continuing to monitor subjects following the index procedure.
While some of the potential risks identified have occurred in prior DCB PTA studies, and the Sponsor believes the Stellarex balloon has a favorable risk-benefit profile, information from this study will be used to confirm the acceptability of identified risks and detection of emerging risks.

# Contacts

**Public**

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**Scientific**

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**

Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1. Subjects intended to be treated with the Stellarex 0.014* Drug-Coated Balloon for de-novo or restenotic lesions in native *below the knee* popliteal (P3 segment) and infra-popliteal arteries ending at the tibiotalar joint (ankle), as per the Instruction for Use (IFU).
2. Rutherford-Becker clinical category classification (RCC) 3 patients with claudication or RCC 4 or 5 subjects with documented Critical Limb Ischemia (CLI) defined as
2.1 RCC 3 subjects: subjects with severe claudication
2.2 RCC 4 subjects: subjects with persistent, recurring ischemic rest pain requiring analgesia for at least two weeks; or
2.3 RCC 5 subjects: subjects with minor tissue loss of the foot or toes; or
3. Age >=18 years old.
4. Reconstitution of the target vessel at the ankle and run-off into a patent dorsalis pedis or plantar arteries defined as <50% stenosis by visual estimate.
5. Is able and willing to provide written informed consent and comply with all required follow-up evaluations within the defined follow- up visit windows

prior to enrollment in the study.
6. Life expectancy > 1 year.

### Exclusion criteria

1. Subjects with any medical condition that would make him/her inappropriate for treatment with the Stellarex balloon as per the Instructions for Use (IFU) or in the opinion of the investigator.
2. Has impaired renal function defined as serum creatinine >2.5 mg/dl that cannot be adequately pre-treated or subjects on dialysis.
3. Subjects already enrolled in other investigational (interventional) studies that would interfere with study endpoints.
4. Subjects that in the judgment of the investigator would require treatment of the contralateral limb within 3 days prior to the index procedure or 30 days after. Note: Unless contralateral treatment is required to facilitate adequate access to the target lesion (e.g. contralateral iliac).
5. Previous or planned surgical or catheter-based procedure within 3 days before or 30 days after the index procedure. Note: This excludes successful inflow artery treatment within the same hospitalization or a documented preplanned minor amputation. Successful inflow artery treatment is defined as attainment of residual diameter stenosis <= 30% without major vascular complication (e.g. absence of flow-limiting dissection, embolic event). These inflow arteries must be treated without the need for laser, atherectomy, thrombectomy, cryoplasty, brachytherapy and cutting/scoring balloons. Treatment with a Stellarex DCB of the inflow lesion, if according to its intended use, is allowed.
6. Prior endovascular treatment of the target lesion within three (3) months of the index procedure.
7. Prior stent placement in the target lesion(s).
8. Single focal lesion < 4cm in length in the absence of additional treatable popliteal or infra-popliteal lesions.
9. Subjects confined to bed that are completely non-ambulatory.
10. For RCC 5 subjects: Non-arterial ulcers such as venous ulcers, neurotrophic ulcers, heel pressure ulcers, ulcers potentially involving calcaneus region or ulcers in the proximal one-half of the foot or higher (from mid-foot and higher going up the leg).
11. Subjects scheduled to undergo a planned major amputation.
12. Presence of concentric calcification that precludes adequate vessel preparation per IFU.

## Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-04-2018 |
| Enrollment: | 15 |
| Type: | Actual |

## Medical products/devices used

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| Generic name: | StellarexTM 0.014 OTW Drug-coated Angioplasty Balloon (Stellarex Balloon) |
| Registration: | Yes - CE intended use |

# Ethics review

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| Approved WMO Date: | 23-10-2018 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

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| Approved WMO Date: | 20-08-2019 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

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| Approved WMO Date: | 14-02-2020 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

Approved WMO

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|---|---|
| Date: | 11-01-2022 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| ClinicalTrials.gov | NCT03395236 |
| CCMO | NL64675.100.18 |