SYNOPSIS

Title	Physician-initiated trial investigating the efficacy of the self-expanding iVolution nitinol stent for treatment of femoropopliteal lesions
Objective	The objective of this clinical investigation is to evaluate the short-term (up to 12 months) outcome of treatment by means of the self-expanding iVolution nitinol stent in symptomatic (Rutherford 2-4) femoropopliteal arterial stenotic or occlusive lesions.
Primary Endpoint	1. Primary patency at 12 months, defined as freedom from >50% restenosis at 12 months as indicated by an independently verified duplex ultrasound peak systolic velocity ratio (PSVR) <2.5 in the target vessel with no reintervention
Secondary Endpoints	1. Primary patency rate at 1- & 6-month follow-up, defined as freedom from >50% restenosis at 1 and 6 months as indicated by duplex ultrasound peak systolic velocity ratio (PSVR) <2.5 in the target vessel with no reintervention 2. Technical success, defined as the ability to cross and stent the lesion to achieve residual angiographic stenosis no greater than 30% and residual stenosis less than 50% by duplex imaging. 3. Freedom from Target Lesion Revascularization (TLR) at 1-, 6- & 12-month follow-up, defined as a repeat intervention to maintain or re-establish patency within the region of the treated arterial vessel plus 5mm proximal and distal to the treated lesion edge 4. Clinical success at follow-up is defined as an improvement of Rutherford classification at 1-, 6- & 12-month follow-up of one class or more as compared to the pre-procedure Rutherford classification. 5. Serious adverse events as defined per ISO 14155:2011
Methodology	Prospective, multi-center, physician-sponsored clinical study
Enrollment	120 subjects
Inclusion Criteria	1. De novo lesion located in the femoropopliteal arteries suitable for endovascular treatment 2. Patient presenting with a score from 2 to 4 according to the Rutherford classification 3. Patient is willing and able to comply with specified follow-up evaluations at the predefined time intervals 4. Patient is >18 years old 5. Patient understands the nature of the procedure and provides written informed consent, prior to enrollment in the study 6. Prior to enrollment, the target lesion was crossed with standard guidewire manipulation
Angiographic Inclusion Criteria	1. One target lesion is located within the native SFA: distal point 3 cm above knee joint 2. The target lesion has angiographic evidence of stenosis or occlusion 3. Length of the target lesion is ≤ 15 cm by visual estimation 4. Target vessel diameter visually estimated is ≥4 mm and ≤7 mm 5. There is angiographic evidence of at least one vessel-runoff to the foot
Exclusion Criteria	1. Presence of a stent in the target vessel that was placed during a previous procedure 2. Presence of an aortic thrombosis or significant common femoral ipsilateral stenosis 3. Previous bypass surgery in the same limb 4. Patients contraindicated for antiplatelet therapy, anticoagulants or thrombolytics

5. Patients who exhibit persistent acute intraluminal thrombus at the target lesion site
6. Perforation at the angioplasty site evidenced by extravasation of contrast medium
7. Patients with known hypersensitivity to nickel-titanium or other study device components
8. Patients with uncorrected bleeding disorders
9. Female patient with child bearing potential not taking adequate contraceptives or currently breastfeeding
10. Life expectancy of less than 12 months
11. Ipsilateral iliac artery treatment before target lesion treatment with a residual stenosis > 30%
12. Use of thrombectomy, atherectomy or laser devices during procedure
13. Any patient considered to be hemodynamically unstable at onset of procedure
14. Patient is currently participating in another investigational drug or device study that has not reached the primary endpoint

Monitor: Monitoring will be provided in accordance with ISO 14155:2011

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Participating sites:
- Dr. Bosiers, Dr. Deloose – A.Z. Sint-Blasius, Dendermonde, Belgium
- Dr. Peeters – Imelda Hospital, Bonheiden, Belgium
- Dr. Keirse – R.Z. Heilig-Hart, Tienen, Belgium
- Dr. Maene – OLV Hospital, Aalst, Belgium

Study conduct: The study will be conducted in accordance with the Declaration of Helsinki and ISO 14155:2011, and comply with requirements regarding Ethics Committees and any other applicable regulations.

Study investigations

Time		Tests and Procedures
Pre-Procedure (up to 24 hours before procedure, unless otherwise noted.)	1. 2. 3. 4.	Medical History Medication Registration Physical Exam (Rutherford, ABI) Consenting patient
Procedure	1. 2. 3. 4. 5.	Angiography pre-procedure Study inclusion Intervention details Angiography post-procedure Adverse Event recording/reporting
1 day post-procedure	1. 2. 3.	Medication Registration Physical Examination (Rutherford, ABI) Adverse Event recording/reporting
1 month follow-up (± 7 days)	1. 2. 3. 4.	Medication Registration Physical Examination (Rutherford, ABI) Core-Lab Color Flow Doppler Ultrasound Adverse Event recording/reporting
6 month follow-up (± 30 days)	1. 2. 3. 4.	Medication Registration Physical Examination (Rutherford, ABI) Color Flow Doppler Ultrasound Adverse Event recording/reporting
12 month follow-up (± 30 days)	1. 2. 3. 4.	Medication Registration Physical Examination (Rutherford, ABI) Core-lab Color Flow Doppler Ultrasound Adverse Event recording/reporting