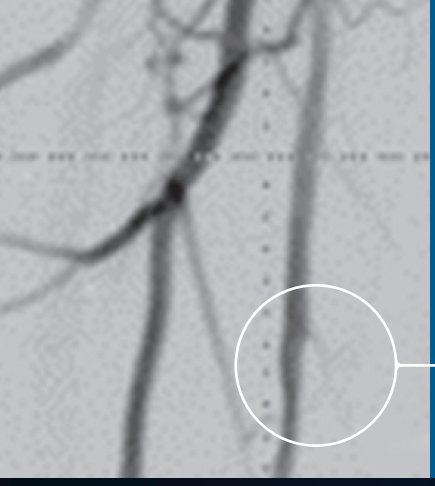
PHILIPS

Peripheral vascular

See clearly.
Treat optimally.



Angiography alone is not enough

Angiography provides information on luminal characteristics of peripheral arteries, but severely underestimates the extent of atherosclerosis in patients with PAD, even in “normal appearing” vessels.[1]

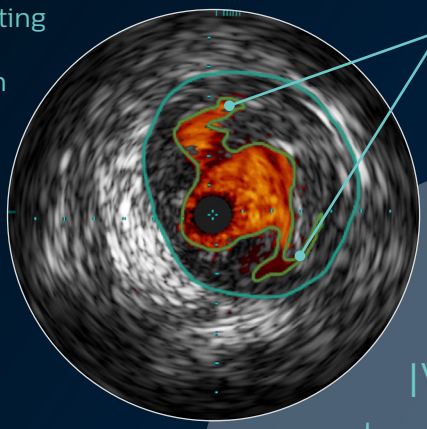
Is this a dissection, calcium, thrombus or stenosis?

Visualize the **best path forward with IVUS eyes**

Philips IVUS provides the visualization needed to gain deeper insights into the lesion and choose the best procedural path forward.

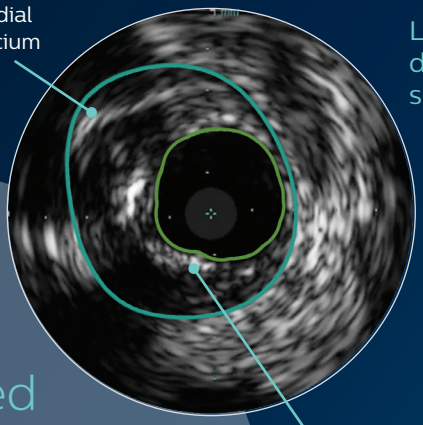
Dissection

Flow-limiting vs. minor dissection



Calcium

Location and degree of severity

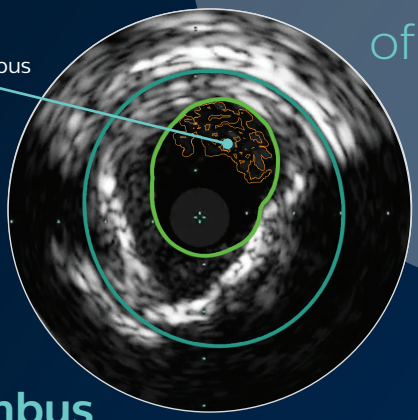


IVUS changed treatment plans in

79%

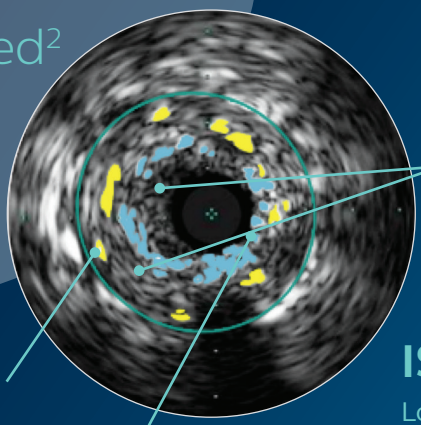
of cases studied[2]

N=47; not indicative of future performance



Thrombus

Pinpoint location



ISR

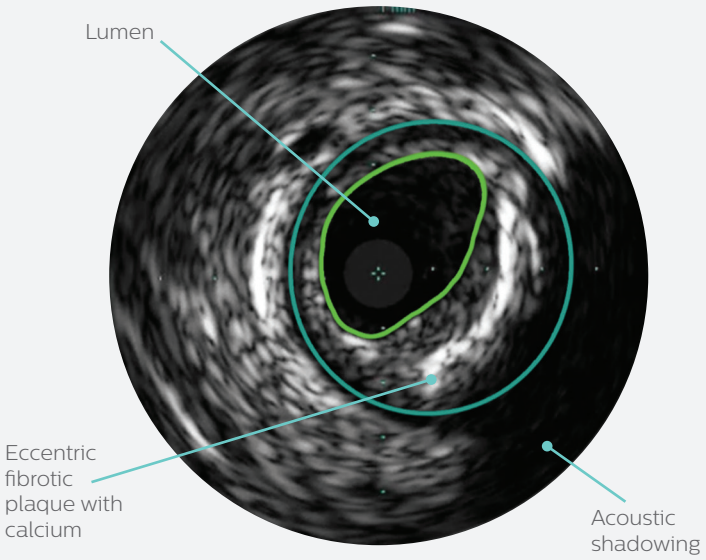
Location of plaque inside, between or outside the stent

IVUS borders and coloration are for demonstration purposes only.

Full view treatment planning

The integration of visualization and interventional technologies allows physicians to see the complete picture and create a more informed and individualized procedural approach.

Treatment plan example 1



See clearly.

Vessel size: 5.5 mm diameter

Plaque morphology: Fibrotic plaque with intimal and medial calcium

Plaque geometry: Eccentric lesion

Guidewire position: True lumen

Treat optimally.

Quick-Cross catheter:
Confidently cross challenging morphologies

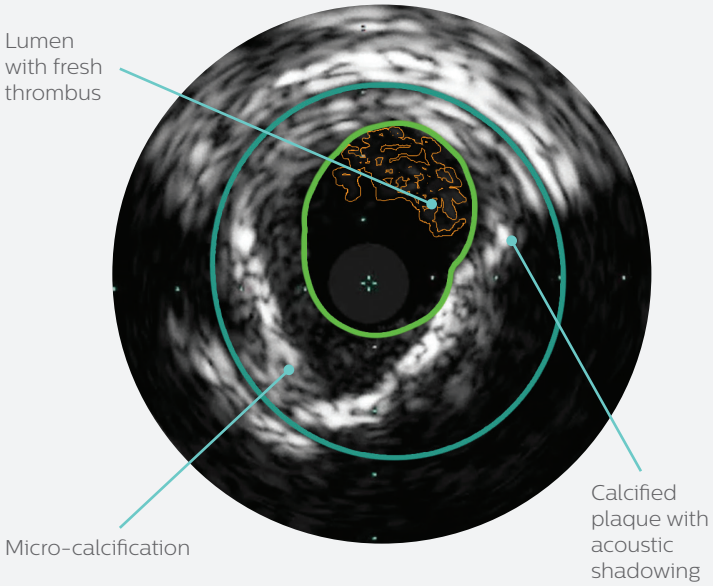
Phoenix deflecting atherectomy:
Front facing to cut, capture and clear mixed morphologies, including calcium

Deflecting capabilities for larger luminal gain

AngioSculpt scoring balloon:
Score calcium to reduce dissection[4]

Stellarex DCB:
Designed for performance in calcium

Treatment plan example 2



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See clearly.

Vessel size: 6 mm diameter

Plaque morphology: Mixed, thrombic plaque with medial calcium

Plaque geometry: Eccentric lesion

Guidewire position: True lumen

Treat optimally.

Quick-Cross catheter:
Confidently cross challenging morphologies

Turbo-Power laser atherectomy:
Forward facing directional debulking to clear thrombus

Rotation for improved deliverability in calcified lesions

AngioSculpt scoring balloon:
Safely dilate residual stenosis[4]

Stellarex DCB:
Designed for performance in calcium

Confirm optimal treatment with IVUS:

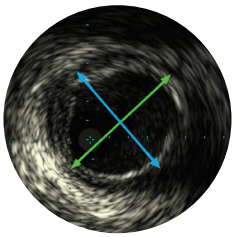
No dissections · Reduce residual stenosis · Stent fully deployed · Treated entire lesion

See clearly critical lesion characteristics

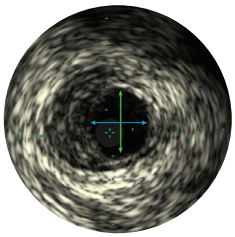
Choosing the best path forward starts by seeing clearly. IVUS provides the visualization guidance essential for assessing clinical challenges quickly and precisely to guide treatment decisions. Only Philips provides 0.014″, 0.018″ and 0.035″ IVUS platforms.

Vessel size

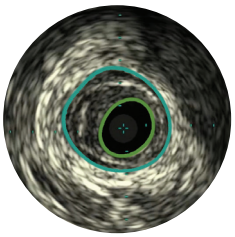
Guides device sizing to ensure precise wall apposition, drug delivery, and placement



Vessel diameter



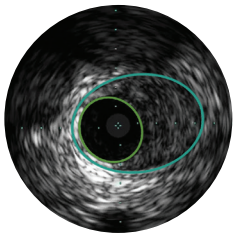
Lumen diameter



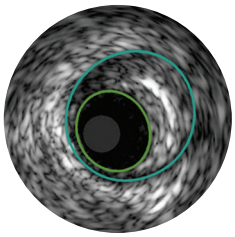
Plaque burden

Plaque morphology

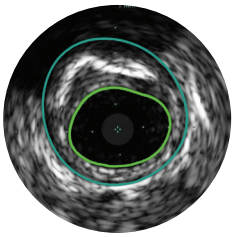
Understand plaque type and severity to help guide proper device selection



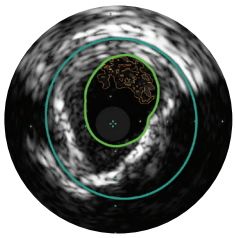
Soft



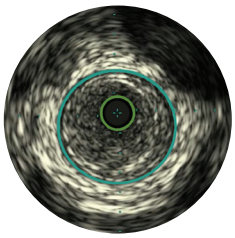
Fibrous



Calcific



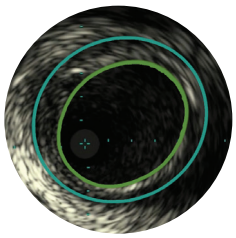
Thrombus



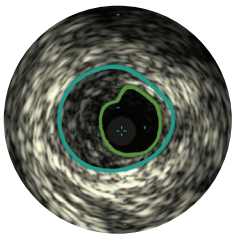
CTO

Plaque geometry

Visualize plaque burden location for precise treatment



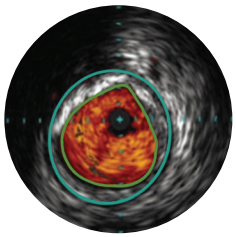
Concentric



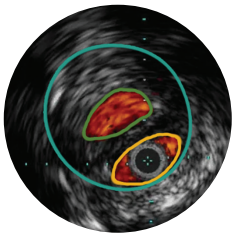
Eccentric

Guidewire position

Confirm true lumen or sub-intimal guidewire location



True lumen



Sub-intimal

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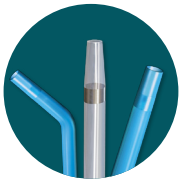
Treat optimally with versatility

The Philips portfolio of therapeutic devices offers the versatility needed to treat the majority of PAD cases, including complex lesions.

Crossing

Cross your toughest lesions



Quick-Cross catheter

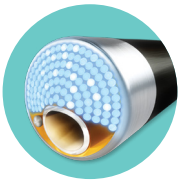
#1 selling support catheter

Pioneer Plus catheter

Only IVUS-guided re-entry catheter

Vessel prep

Prepare multiple lesion morphologies, locations and characteristics, including CTOs, ISR, thrombus, calcium, neo-intimal hyperplasia, mixed morphologies and ostial lesions

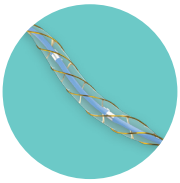


Turbo-Elite and Turbo-Power laser atherectomy

Clinically proven ablation in all lesion types above and below the knee and indicated for ISR*[6]

Phoenix atherectomy

Front-cutting mechanical atherectomy for treating mixed morphologies with low risk of embolization[5]

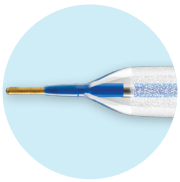


AngioSculpt scoring balloon

Reduces risk of flow-limiting dissections, including calcified lesions[4]

Definitive treatment

Treat lesions without leaving metal behind



Stellarex drug-coated balloon

Durable treatment effect with a low-drug dose in common to complex patients; only DCB reporting durable 2yr patency in severely calcified lesions[3]

*Bare metal stent

Only Philips offers advanced visualization and specialized therapies that enable clinicians to tailor treatments in even the most complex patients.

See clearly.

Treat optimally.

Important safety information

The Stellarex 0.035" OTW drug-coated angioplasty balloon is indicated for percutaneous transluminal angioplasty (PTA), after appropriate vessel preparation of de novo or restenotic lesions up to 180mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-6mm.

The Stellarex 0.035" OTW drug-coated angioplasty balloon is contraindicated for use in:

- Patients with known hypersensitivity to paclitaxel or structurally related compounds
- Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy
- Women who are breastfeeding, pregnant or are intending to become pregnant, or men intending to father children
- Coronary arteries, renal arteries and supra-aortic/cerebrovascular arteries
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system

Possible adverse effects associated with the balloon dilation procedure include, but are not limited to: Abrupt vessel closure; Allergic reaction to contrast medium, antiplatelet therapy or catheter system components (drug, excipients and materials); Amputation/Loss of limb; Arrhythmias; Arterial aneurysm; Thrombosis; Arterio-venous fistula (AVF); Bleeding; Death; Embolism/Device embolism; Fever; Hematoma; Hemorrhage; Hypertension/Hypotension; Infection or pain at insertion site; Inflammation; Ischemia or infarction of tissue/organ; Occlusion; Pain or tenderness; Peripheral edema; Pseudoaneurysm; Renal insufficiency or failure; Restenosis; Sepsis or systemic infection; Shock; Stroke/Cerebrovascular accident; Vessel dissection, perforation, rupture, spasm or recoil; Vessel trauma that requires surgical repair; Balloon rupture; Detachment of a component of the balloon and/or catheter system; Failure of the balloon to perform as intended; Failure to cross the lesion.

Additional complications that may be associated with the addition of paclitaxel to the balloon include, but may not be limited to the following: Allergic/Immunologic reaction to paclitaxel; Alopecia; Anemia; Gastrointestinal symptoms (diarrhea, nausea, pain, vomiting); Hematologic dyscrasia (including neutropenia, leukopenia, thrombocytopenia); Hepatic enzyme changes; Histologic changes in vessel wall including inflammation, cellular damage or necrosis; Myalgia/Arthralgia; Myelosuppression; Peripheral neuropathy.

Caution:

Federal law restricts this device to sale by or on the order of a physician.

1. Kashyap VS, Pavkov ML, Bishop PD, et al. Angiography underestimates peripheral atherosclerosis: lumenography revisited. *J Endovasc Ther.* 2008;15(1):117-125.
2. Spark I, Allan R. The role of IVUS in peripheral interventions. *Charing Cross.* 2018. London, UK.
3. Mathews S. NCVH. 2018. ILLUMENATE pivotal Stellarex DCB IDE study 2-year outcomes. May 30, 2018. New Orleans, LA.
4. Kiesz RS, Scheinert D, Peeters PJ, et al. Results from the international registry of the AngioSculpt Scoring Balloon Catheter. *J Am Coll Cardiol.* 2008;51:10(suppl B);75.
5. Davis, Thomas et al., Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study. Vascular. September 27, 2017, DOI: 10.1177/1708538117712383.
6. Dippel et al. Randomized controlled study of excimer laser atherectomy for treatment of femoropopliteal in-stent restenosis: initial results from the EXCITE ISR trial (EXCImer Laser Randomized Controlled Study for Treatment of FemoropopliTEal In-Stent Restenosis). JACC Cardiovasc Interv. 2015 Jan;8(1 Pt A):92-101.

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