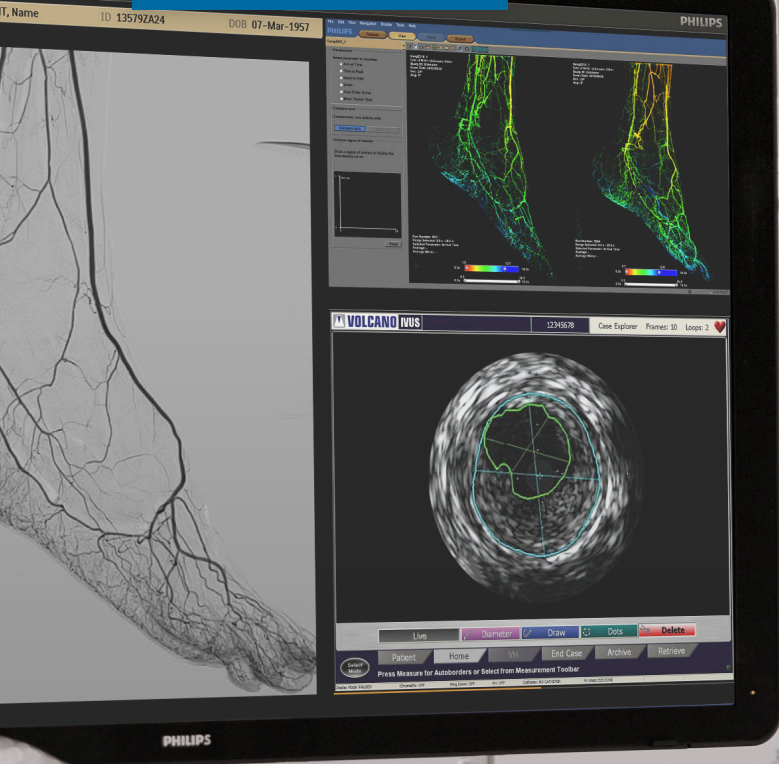


PHILIPS

Image Guided Therapy

Peripheral devices



Philips IGT Devices peripheral portfolio

Image Guided Therapy Devices

Comprehensive product portfolio³

Decide

- **Imaging**
- **Visions PV**
Digital IVUS catheters

Guide

- **Imaging**
- **Visions PV**
Digital IVUS catheters

Treat

Crossing solutions

- **Quick-Cross**
Support catheters
- **Pioneer Plus**
IVUS-guided re-entry catheter

Vessel prep

- **Phoenix**
Mechanical atherectomy
- **Turbo-Elite & Turbo-Power**
Laser atherectomy
- **AngioSculpt**
Scoring balloon

Drug-coated solutions

- **Stellarex**
Drug-coated angioplasty balloon
For above and below the knee

Confirm

- **Imaging**
- **Visions PV**
Digital IVUS catheters



Core M2

Introducing a small footprint, touchscreen-operated digital IVUS imaging system, designed for peripheral vascular procedures and operable directly from the sterile field.

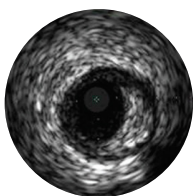
Benefits

89% of users experienced substantial **image quality improvements**.¹

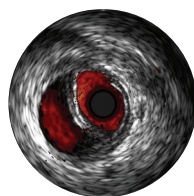
All users experienced that the system is **significantly faster and easier** to use than the previous system they used.^{1,2}

Core integrated and mobile systems

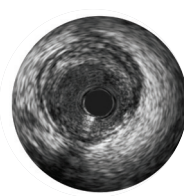
One system, **many choices**



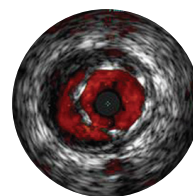
Digital IVUS imaging



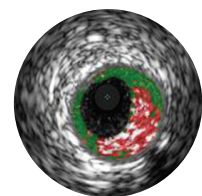
Peripheral imaging



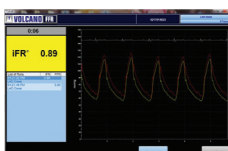
Rotational IVUS imaging



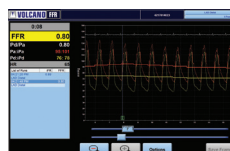
ChromaFlo imaging*



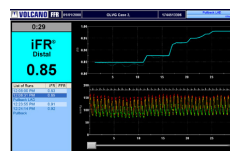
VH IVUS imaging*



FFR modality**



iFR modality**

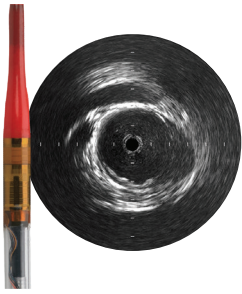


iFR Scout modality**

Streamlined workflow by importing and exporting patient data using DICOM Worklist. Document your results via DICOM Store, DVD or printout.

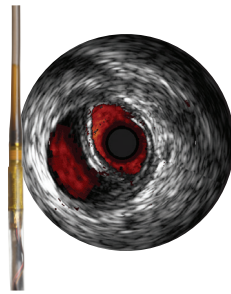
Peripheral family of **IVUS** catheters

A full line of IVUS catheters – to help guide your treatment strategies



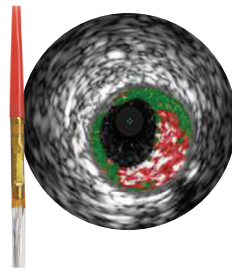
Visions PV .035 catheter

- with centimeter markers
- 0.035" guide wire compatible
- 60 mm max imaging diameter



Visions PV .018 catheter

- 0.018" guide wire compatible
- 24 mm max imaging diameter



Visions PV .014P catheter

- 0.014" guide wire compatible
- 20 mm max imaging diameter

IVUS allows assessment of:

- % Stenosis
- Calcium and thrombus
- Real time vessel diameters
- Length of stenosis
- Dissection
- Position of wire in true or false lumen
- Location of side branches (without using contrast)
- Completeness of treatment

Pioneer Plus IVUS-guided re-entry catheter

Delivering quick, confident and controlled true lumen re-entry*



6F sheath compatibility.

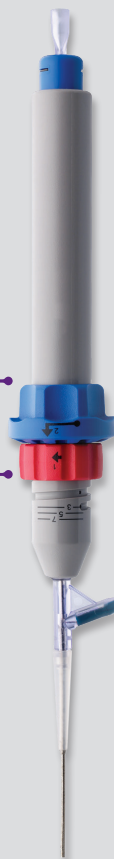
Radiopaque IVUS transducer offers enhanced imaging for diagnosis and targeting.[†]

Radiopaque curved-needle housing to enable targeting. Adjustable needle depth (3mm, 5mm and 7mm).

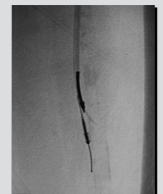
Triple-braided shaft for enhanced trackability, torque control and needle movement.

Thumb-activated safety lock for ease of use.

Intuitive, easy-to-use handle allows for single-handed deployment of needle.



The **only** re-entry device with IVUS and ChromaFlo



Procedural time for effective re-entry ranging from

6-10 minutes¹



Subintimal angioplasty procedural success rate from **95 to 100%²**

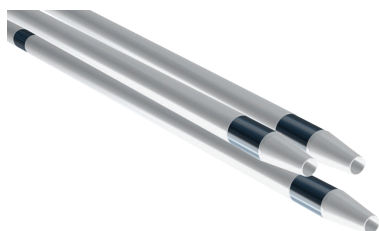
IVUS guidance and direction **minimizes** potential procedural complications³



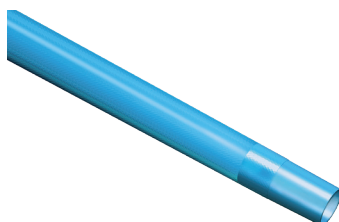


Quick-Cross support catheters

The support you need to handle any lesion



Quick-Cross support catheter
Wire support for crossing occlusions



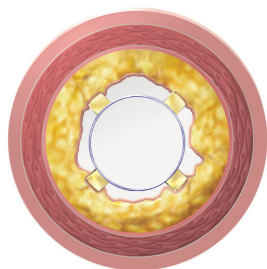
Quick-Cross Extreme support catheter
Designed for tougher lesions



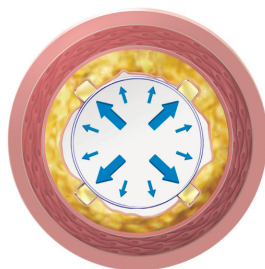
Quick-Cross Select support catheter
Designed for branched anatomies

AngioSculpt PTA scoring balloon catheter

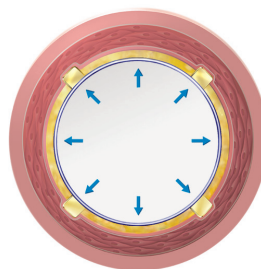
Plaque scoring for enhanced luminal gain^{1,2}



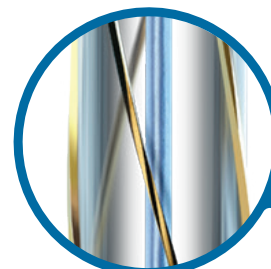
Precision
Edges lock in



Power
~15 – 25x scoring force



Safety
~1x force post-scoring



Scoring Element
Smooth electropolished nitinol struts leading to a uniform scoring resulting in low dissection rates and no significant device slippage.^{1,2}

Atherectomy systems

Phoenix mechanical atherectomy system

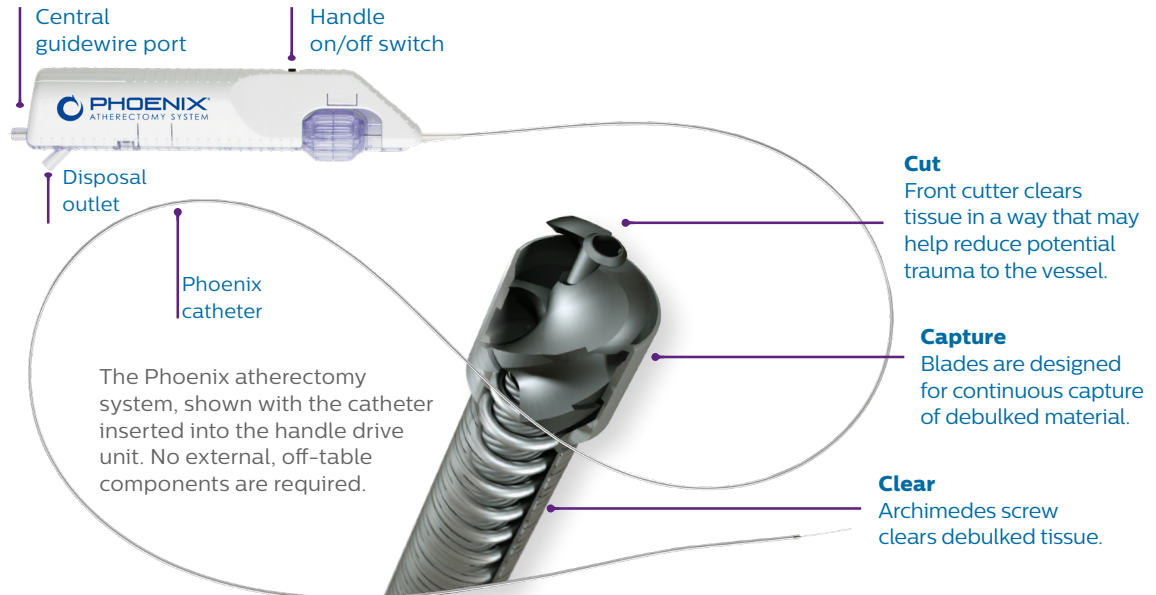
A simple and easy to use system for ATK & BTK lesions

Offering of 3 catheter diameters* has been shown to effectively treat most peripheral vasculature.¹

- 1.8 and 2.2mm tracking catheters are suited for treating small vessels or highly stenosed lesions.

- 2.2mm deflected catheter suited for more lumen gain in above and below the knee lesions.**

- 2.4mm deflecting catheter is suited for larger vessels or eccentric lesions.



Phoenix guidewire



Designed to **work together** with Phoenix rotational atherectomy system

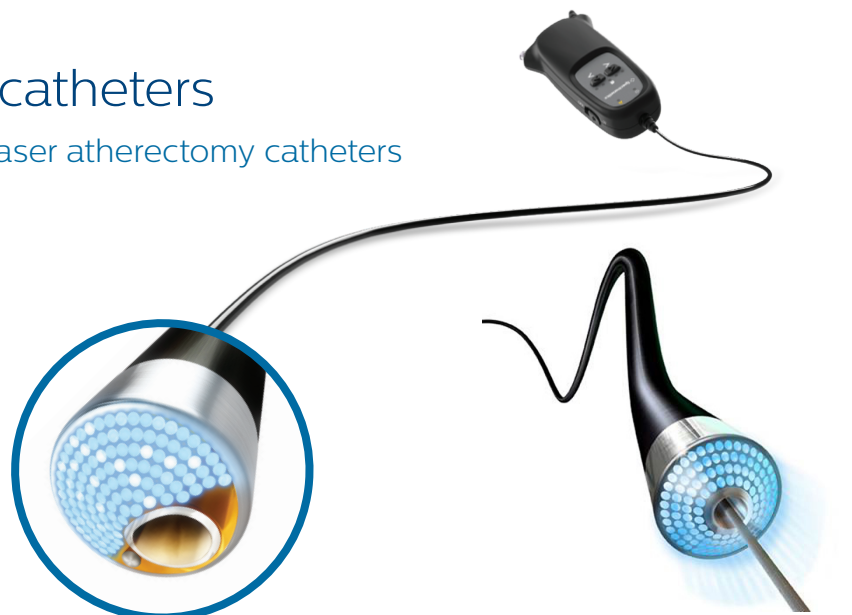
Laser atherectomy catheters

Turbo-Elite and Turbo-Power laser atherectomy catheters

The Turbo-Elite and Turbo-Power laser atherectomy catheters capture the power of ultraviolet light to provide a versatile and reliable tool for treating multiple lesion morphologies.

Laser safely and effectively vaporizes complex morphologies

- Plaque vaporization at the tip
- Recanalization device
- No moving blades



Turbo-Power laser atherectomy catheter ease of use for maximal lumen gain*** through precise directional control or automatic rotation

Turbo-Elite laser atherectomy catheter to treat complex morphologies

Stellarex

low-dose 0.035" and 0.014" drug-coated balloon family

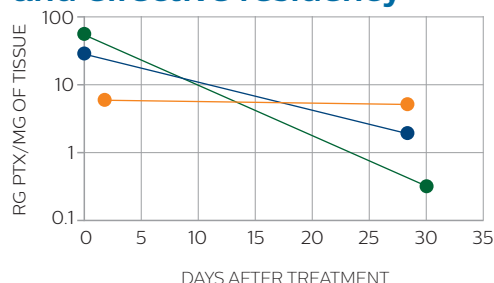
Differentiated technology—next-generation EnduraCoat

Stellarex EnduraCoat was designed for performance in complex and severely calcified lesions and patients with multiple comorbidities.

- Hybrid paclitaxel offers prompt drug transfer and sustained tissue residency through 28 day restenotic window¹
- Excipient polyethylene glycol (PEG) offers excellent adhesion and durability to protect low dose paclitaxel^{2,3}
- Reduces drug loss during transit, relieving clinicians of transit time requirements^{4,5}



High transfer efficiency and effective residency⁶



Based on animal testing

- PEG forms strong ionic bonds with hydroxyl apatite (HAp), the primary component of calcified atherosclerotic lesions.⁷
- PEG's affinity for HAp may result in limited PTX washout in the presence of calcium.
- PEG may protect PTX, giving it time to be absorbed into vessel when calcium is present.

Hybrid
paclitaxel

+

PEG
excipient

=

**Top-tier clinical
outcomes**

Why an effective low drug dose matters

Dose excess and particulate downstream possibly results in a delay of wound healing, loss of microcirculation and creation of aneurysms⁹⁻¹². Stellarex is a low dose DCB with a long-term treatment effect¹³ in femoropopliteal lesions at three years.

2 $\mu\text{g}/\text{mm}^2$

**Only low DCB drug dose
still effective in SFA
at 3 years¹³**

- In.Pact has a 75% higher drug dose than Stellarex^{4,8}
- Compared to Stellarex, In.Pact loses 2.7 times more drug (μg) during tracking to the deployment site⁵
- In.Pact coating visually flakes off during device prep⁵
- Lutonix low dose is mostly amorphous paclitaxel, which may lead to short-term tissue residency²

Track

PEG offers exceptional durability during handling, tracking and inflation, helping prevent premature drug loss^{2,5}

Deliver

EnduraCoat achieves uniform and efficient drug transfer¹

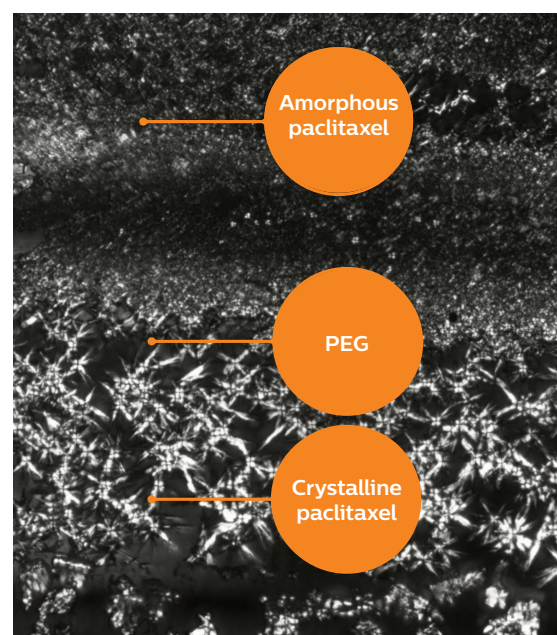


Image on file at Philips.

Sustain

Hybrid paclitaxel provides prompt drug availability with amorphous and sustained tissue Residency with crystalline formulation¹

References and legal notes

Important safety information

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

P2

1. Based on initial feedback during limited market release (16 of 18 responses, data on file)
2. Previous system was Volcano S5
3. For product references/codes, please refer to the 'Ordering information' insert.

* With selected catheters only

** Coronary physiology applications

P3

1. Saket R., Razavi, M., Padidar A., et al. Novel Intravascular Ultrasound-Guided Methods to Create Transintimal Arterial Communications: Initial Experience in Peripheral Occlusive Disease and Aortic Dissection. *J Endovasc Ther.* 2004; 11: 274-280.
2. Al-Ameri, H et al. Peripheral Chronic Total Occlusions Treated with Subintimal Angioplasty and a True Lumen Re-Entry Device. *Journal of Invasive Cardiology.* 2009; 21(9): 468-472.
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* Saket et al., Novel Intravascular Ultrasound-Guided Method to Create Transintimal Arterial Communications, *J Endovascular Therapy*, 11:274-280, 2004.

Krishnamurthy et al., Intravascular ultrasound-guided true lumen reentry device for recanalization of unilateral chronic total occlusion of iliac arteries: technique and follow-up. *Ann Vasc Surg.* 24:487-97, 2010.

† The Pioneer Plus catheter can only be used with Philips s5, s5i, or CORE Imaging System. The catheter will not operate if connected to other imaging systems. Philips s5, s5i, and CORE Intravascular Ultrasound Systems are manufactured by Philips.

P4

1. E Blessing et al. Treatment of femoropopliteal lesions with the Angiosculpt scoring balloon – results from the Heidelberg PANTHER registry, *Vasa* (2018), 1-7
2. Blessing E. The PANTHER Study. *Endovascular Today Europe Suppl.* Volume 3, No.4, 2015

P5

1. Davis T, Ramaiah V, Niazi K, Martin Gissler H, Crabtree T. Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study. *Vascular.* 2017 Dec;25(6):563-575
- * The Phoenix atherectomy 1.8 mm tracking catheter is indicated for vessels of 2.5 mm in diameter or above. The Phoenix atherectomy 2.2 mm tracking, deflected and 2.4 mm deflecting catheters are indicated for vessels 3.0 mm in diameter or above. While the 1.8 mm and 2.2 mm tracking & deflected catheters are indicated for femoral, popliteal, or distal arteries located below the knee, the Phoenix 2.4 mm deflecting catheter is indicated for femoral and popliteal only. See IFU.

** vs. 2.2 tracking catheter, based on bench tests. Bench test results not indicative of clinical performance. 2.2mm deflected catheter was not included in the EASE trial.

*** When comparing 7F Turbo-Power to 2.0 Turbo-Elite. >10% luminal gain when comparing 6F Turbo-Power to 2.0 Turbo-Elite.(Data on file at SPNC, a Philips company)

P6

1. Granada JF. Future directions, clinical applications and local drug delivery technologies. Presented at the Transcatheter Cardiovascular Therapeutics (TCT) 25th Annual Scientific Symposium; October 27-November 1, 2013; San Francisco, California. Slide 7, 15.
2. Mark J, et al. Physical properties of polymers. Cambridge University Press. 3rd ed. 2004.
3. Adamson AW. Physical Chemistry of Surfaces fourth ed. New York: John Wiley and Sons, 1982.
4. Stellarex IFU. P011966-D.
5. Data on file. D044595-00.
6. Superimposed PK curves from different datasets: Melder R, EuroPCR 2012, Yazdani, et al. Catheterization and Cardiovascular Interventions 014;83:132-140. Stellarex: Data on file. Spectranetics Document. 2014. Spectranetics Pre-clinical Animal Study ADO097.
7. Venkatasubbu GD, et al. Surface modification and paclitaxel drug delivery of folic acid modified polyethylene glycol functionalized hydroxyapatite nanoparticles. *Powder Technology.* 2013;235:437-442.
8. Laird, et al. *J Am Coll Cardio.* 2015;66:2329-2338. In.Pact Summary of Safety and Effectiveness Data (SSED). Medtronic In.Pact Instructions for Use, M052624T001 Rev 1F.
9. Diamantopoulos A, Gupta Y, Zayed H, Katsanos K. Paclitaxel-coated balloons and aneurysm formation in peripheral vessels. *J VascSurg.* 2015 Nov;62(5):1320-2
10. Schmidt A et al. First experience with drug-eluting balloons in infrapopliteal arteries: restenosis rate and clinical outcome. *J Am Coll Cardiol.* 2011 Sep 6;58(11):1105-9
11. Liistro F et al. Drug-eluting balloon in peripheral intervention for below the knee angioplasty evaluation (DEBATE-BTK): a randomized trial in diabetic patients with critical limb ischemia. *Circulation.* 2013 Aug 6;128(6):615-21
12. Zeller T, et al. IN.PACT DEEP Trial Investigators. Drug-eluting balloon versus standard balloon angioplasty for infrapopliteal arterial revascularization in critical limb ischemia: 12-month results from the IN.PACT DEEP randomized trial. *J Am Coll Cardiol.* 2014 Oct 14;64(15):1568-76
13. Mathews SJ, Stellarex in the Treatment of the SFA and Popliteal: Late-Breaking 3-Year Data, oral presentation, NCVH June 2019

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