Stealth 360™

Peripheral Orbital Atherectomy System

BROAD RANGE OF CALCIUM. ONE SOLUTION.

DUAL-ACTION + VERSATILE + PROVEN

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Check the regulatory status of the device in areas where CE marking is not the regulation in force.

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POWERFUL TECHNOLOGY FOR MORE PATIENTS

The Stealth 360™ Orbital Atherectomy System (OAS) is specifically designed to treat mild to severe calcific plaque in peripheral arteries with a diamond-coated crown.[1] The crown orbits 360 degrees against the vessel wall to get from calcified to compliant, safely and efficiently.[2,3]

Sleek, electric-powered handle allows two-minute set-up and provides efficient torque transfer to the shaft and crown[4]

Easy, one-touch start button makes device power-up effortless

Three convenient one-touch speed controls allows for quick adjustments within the sterile field

GlideAssist™ for the 1.25 Micro Crown* (4 Fr) enables the crown to spin at a slow speed (5k RPM), reducing friction in the system to:

- Facilitate tracking of the devices
- Provide easier removal of the device
- Allow smoother repositioning of the ViperWire Advance™ Guide Wire during procedures as compared to Stealth 360™ OAS without GlideAssist™ Mode

Prime button allows quick flushing

† Set up times may vary.

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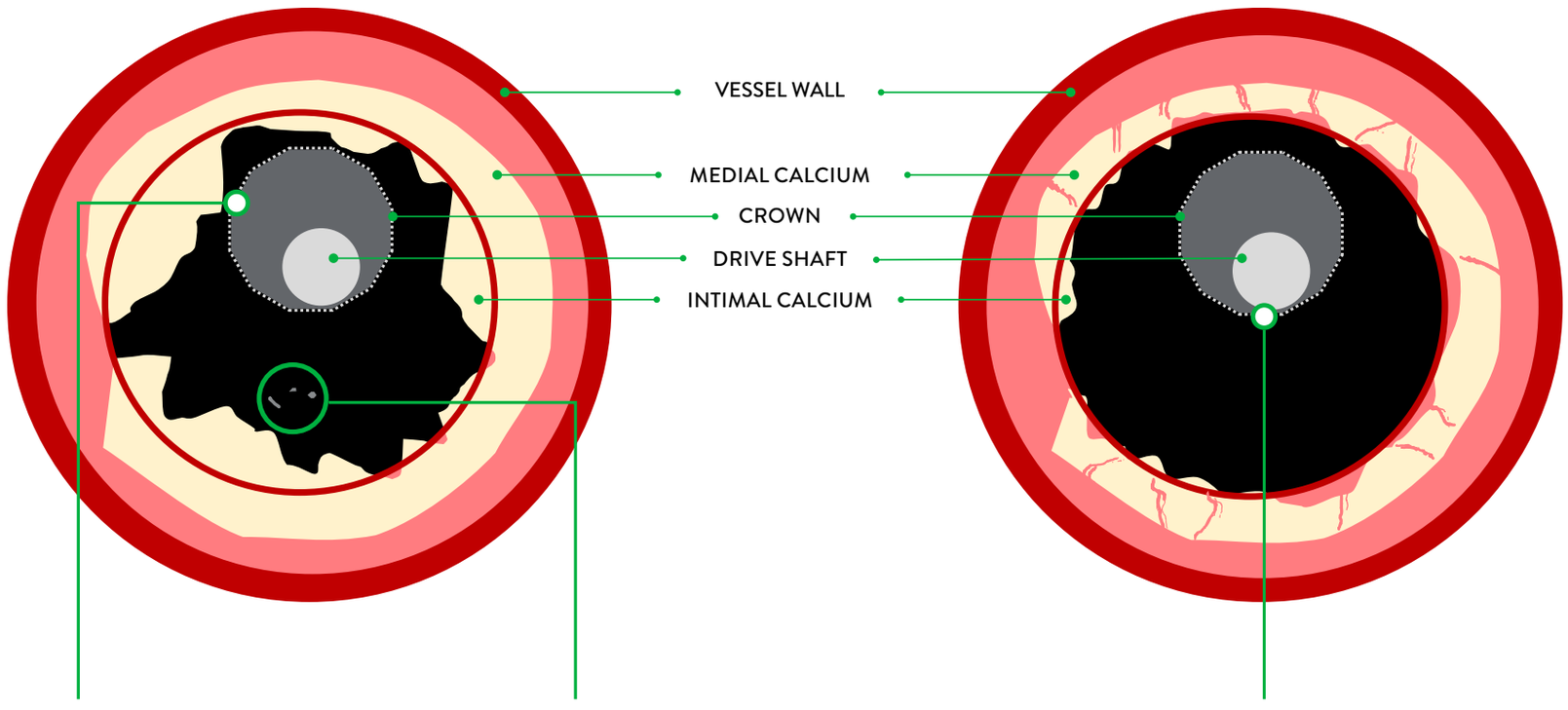
DUAL-ACTION

Uniquely designed to enable simultaneous modification of both intimal and medial calcium.

Differential Sanding Modifies Intimal Calcium[5]

Fractures Medial Calcium[6]



Crown's diamond surface sands intimal calcium while potentially minimizing damage to medial layer[5,7]

Generated particulates average ~2 microns, smaller than red blood cells[5]

Rotation of crown over the wire generates high frequencies (1000 – 1900 Hz) producing pulsatile mechanical forces[8]

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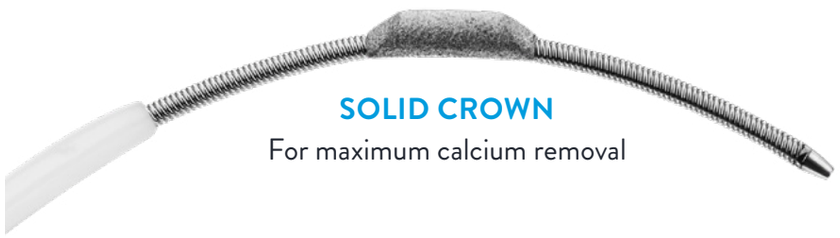
VERSATILE – A SPECIALIZED APPROACH TO PAD

The low-profile design of the Stealth 360™ OAS can help minimize access site complications[9] and improve procedural range.[10]

Improved Clinical Experience

- Low profile systems can reduce access site complications[9] and allow for non-femoral access options, like transpedal.
- The Stealth 360™ OAS low profile design allows for the treatment of small and large vessels without the need to upsize your catheter and sheath size.



SOLID CROWN
For maximum calcium removal

CLASSIC CROWN
For vessel bends, ostial lesions and distal BTK procedures

MICRO CROWN (1.25) WITH GLIDEASSIST™
For tortuous vessels and tight bends BTK

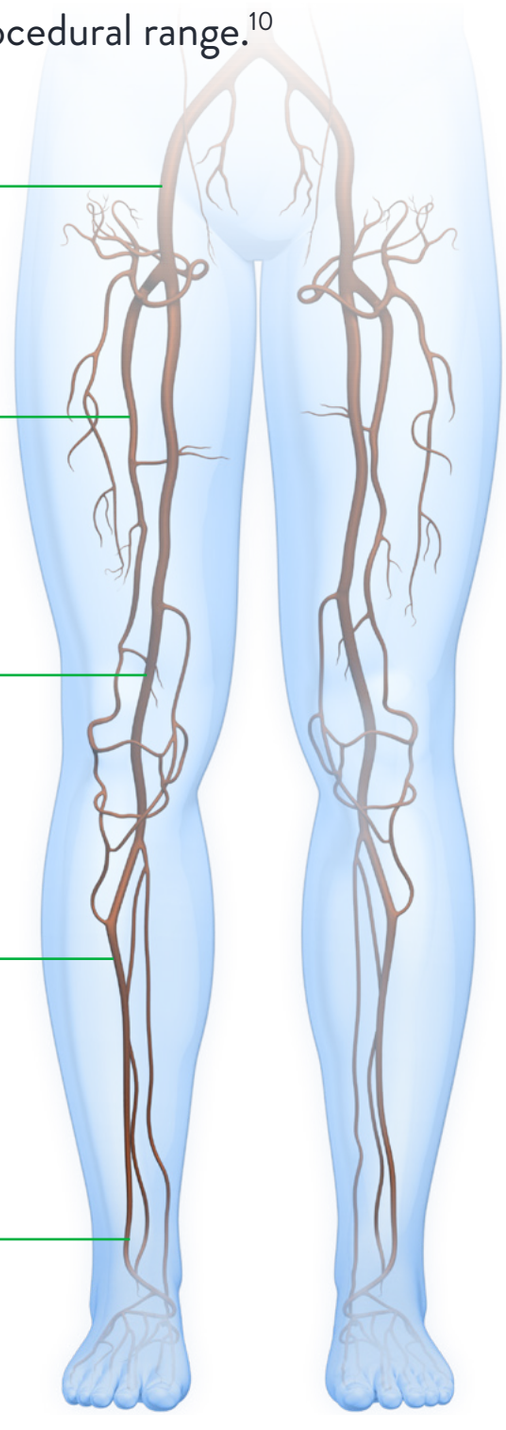
Iliac and Common Femoral Arteries
Vessel Diameter Range: 5.0-10.0 mm
- 2.00 mm Solid Crown

Superficial Femoral Artery
Vessel Diameter Range: 4.0-7.0 mm
- 2.00 mm Solid Crown
- 1.50 mm Solid Crown
- 2.00 mm Classic Crown

Popliteal Artery
Vessel Diameter Range: 4.0-6.0 mm
- 1.25 mm Micro Crown
- 1.50 mm Solid Crown
- 1.25 mm Solid Crown
- 2.00 mm Classic Crown

Tibial and Peroneal Arteries
Vessel Diameter Range: 2.0-4.0 mm
- 1.25 mm Micro Crown
- 1.25 mm Solid Crown
- 1.50 mm Classic Crown

Distal Tibial Artery
Vessel Diameter Range: 2.0-2.5 mm
- 1.25 mm Micro Crown



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PROVEN

Orbital atherectomy is proven to be effective with a full range of calcified lesions above- and below-the-knee, and across a wide range of Rutherford Classes (RC 2-6).[10]

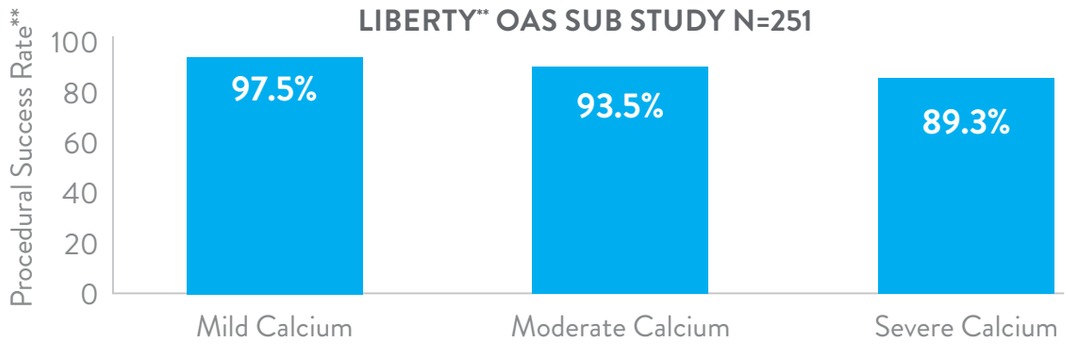
More than 4,800 real-world patients with over 7,000 lesions treated in peripheral clinical trials.*[11]

Long-Term Results revealed by Liberty 360 Study

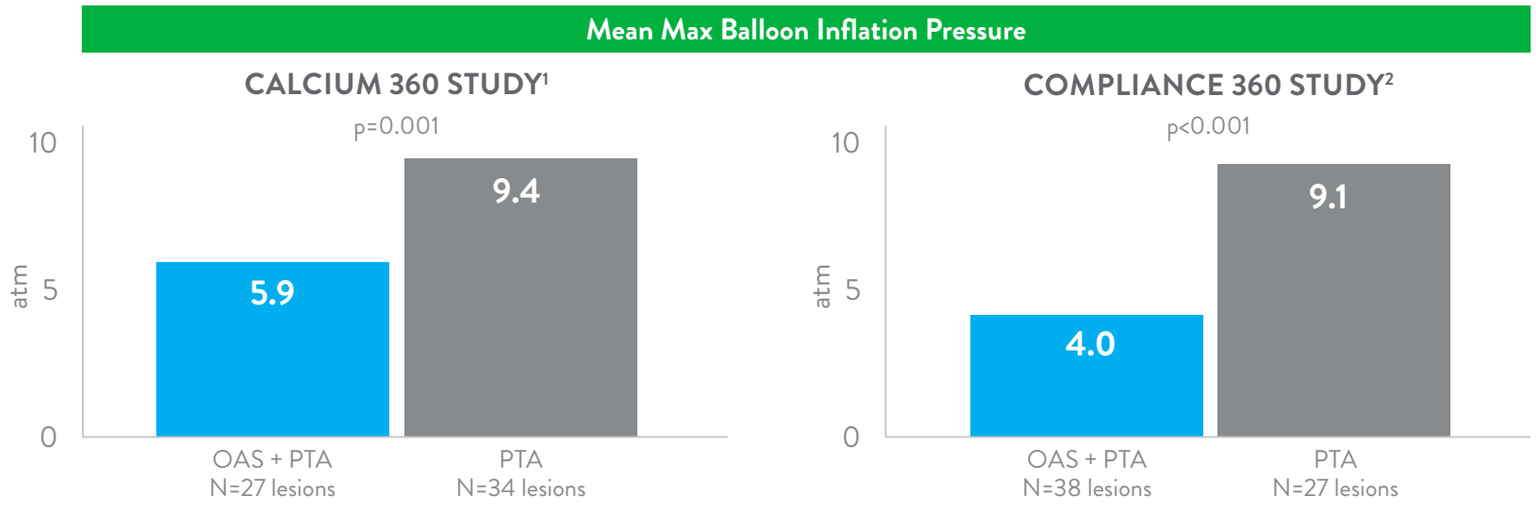
95%
Freedom from major amputation at 3 years, RC 4-5[10]

89%
Freedom from amputation at 3 years, RC 6[10]

High Rate of Procedural Success Across a Wide Range of Calcified Lesions (RC 2–6)[12]



Lower Max Balloon Inflation Pressure Compared to PTA[1,2]



*Counts updated 06Jan2020—subject to change (include PAD I, PAD II, OASIS, CONFIRM, CALCIUM, COMPLIANCE, TRUTH, CLARITY, LIBERTY, OPTIMIZE, REACH PVI)
**Calcium Grades based on PACSS. Procedural success <50% residual stenosis for target lesion (core lab)

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PRODUCT ORDERING INFORMATION

Stealth 360™ Peripheral Orbital Atherectomy System

Micro Crown Model Number	Crown Size	Length	Quantity	Sheath Size Compatibility
P-2ST-MI125-145*	1.25 mm	145 cm	1 each	4F

*GlideAssist is only available on the 1.25 Micro Crown

Solid Crown Model Number	Crown Size	Length	Quantity	Sheath Size Compatibility
P-2ST-SO125-145	1.25 mm	145 cm	1 each	6F
P-2ST-SO150-145	1.50 mm	145 cm	1 each	6F
P-2ST-SO200-145	2.00 mm	145 cm	1 each	6F
Classic Crown Model Number	**Crown Size**	**Length**	**Quantity**	**Sheath Size Compatibility**
P-2ST-CL150-145	1.50 mm	145 cm	1 each	6F
P-2ST-CL200-145	2.00 mm	145 cm	1 each	6F

ViperWire Advance™ Peripheral Guide Wire

Model Number	Description	Length	Quantity
VPR-GW-14	0.014" Shaft/0.014" Tip	335 cm	Box of 5
VPR-GW-17	0.014" Shaft/0.017" Tip	335 cm	Box of 5

ViperWire Advance™ Peripheral Guide Wire with Flex Tip

Model Number	Description	Length	Quantity
VPR-GW-FLEX14	0.014" Shaft/0.014" Tip	335 cm	Box of 5
VPR-GW-FLEX18	0.014" Shaft/0.018" Tip	335 cm	Box of 5

ViperSlide™ Lubricant

Model Number	Description	Quantity
VPR-SLD2	100 mL Bag	Box of 10

OAS Pump

Model Number	Description	Quantity
SIP-3000	Saline Pump	1 each

The Complete Stealth 360™ OAS System utilizes:

- OAS Pump
- ViperWire Advance™ Peripheral Guide Wire
- ViperSlide™ Lubricant
- Saline Line
  (comes packaged with the Stealth 360™ device)

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1. Shammas NW, Lam R, Mustapha J, Ellichman J, et al. Comparison of orbital atherectomy plus balloon angioplasty vs. balloon angioplasty alone in patients with critical limb ischemia: results of the CALCIUM 360 randomized pilot trial. *J Endovasc Ther.* 2012 Aug;19(4):480-8.
2. Dattilo R, Himmelstein SI, Cuff RF. The COMPLIANCE 360° Trial: a randomized, prospective, multicenter, pilot study comparing acute and long-term results of orbital atherectomy to balloon angioplasty for calcified femoropopliteal disease. *J Invasive Cardiol.* 2014;26(8):355-60.
3. Das T, Mustapha J, Indes J, et al. Technique optimization of orbital atherectomy in calcified peripheral lesions of the lower extremities: the CONFIRM series, a prospective multicenter registry. *Catheter Cardiovasc Interv.* 2014 Jan 1;83(1):115-122.
4. Moses J. Vessel Preparation With Orbital Atherectomy for Treating Severe Coronary Calcium for Stent Delivery. *Cardiac Interventions Today.* 2015;May/June:75.
5. Adams GL, Khanna PK, Staniloae CS, et al. Optimal techniques with the Diamondback 360° System achieve effective results for the treatment of peripheral arterial disease. *J Cardiovasc Transl Res.* 2011 Apr;4(2):220-9.
6. Mustapha J, et al. Orbital Atherectomy Treatment of Peripheral Artery Disease and Critical Limb Ischemia. *J Crit Limb Ischem.* 2021;1(3):E118-E125.
7. Krishnan P, Martinsen BJ, Tarricone A, et al. Minimal Medial Injury After Orbital Atherectomy. *J Endovasc Ther.* 2017 Feb;24(1):167-168.
8. Zheng Y, Belmont B, Shih AJ. Experimental investigation of the abrasive crown dynamics in orbital atherectomy. *Med Eng Phys.* 2016 Jul;38(7):639-647.
9. Bosiers M, Deloose K, Callaert J, et al. 4-French-compatible endovascular material is safe and effective in the treatment of femoropopliteal occlusive disease: results of the 4-EVER trial. *J Endovasc Ther.* 2013 Dec;20(6):746-56.
10. Giannopoulos S, Secemsky EA, Mustapha JA, et al. Three-Year Outcomes of Orbital Atherectomy for the Endovascular Treatment of Infrainguinal Claudication or Chronic Limb-Threatening Ischemia. *J Endovasc Ther.* 2020 Oct;27(5):714-725.
11. Data on file at Abbott - Clindex Report. 2020 Mar.
12. Data on file at Abbott - Suppl. Table C03 from LIBERTY OAS Sub-analysis by PACSS Grade.

These instructions do not replace the Stealth 360™ Peripheral Orbital Atherectomy System Instructions for Use (IFU).
Refer to the Stealth 360™ Peripheral Orbital Atherectomy System IFU for the use and operation of the Stealth 360™ Peripheral Orbital Atherectomy System.

Stealth 360™ Peripheral Orbital Atherectomy System is manufactured and distributed by Cardiovascular Systems, Inc. (CSI).
CSI is a subsidiary of the Abbott Group of Companies.

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