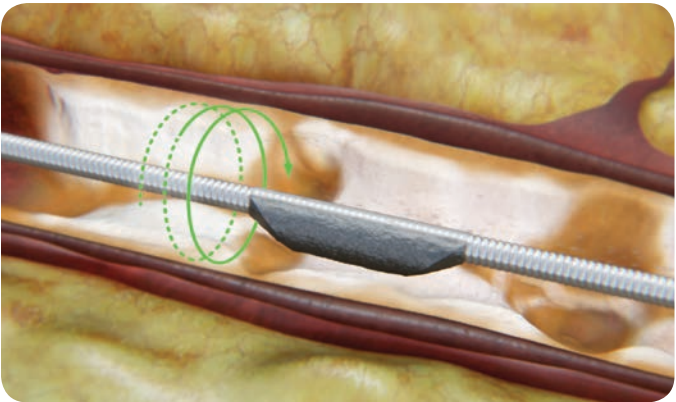


# UNPARALLELED TECHNOLOGY. POWERFUL RESULTS.

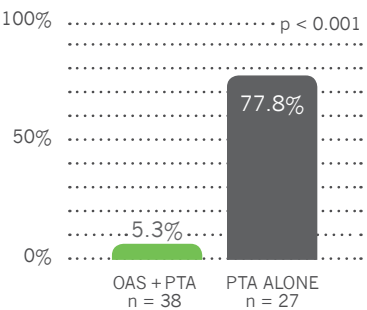
## UNIQUE MECHANISM OF ACTION

The *Stealth 360* Peripheral Atherectomy System is designed with proprietary orbital technology to facilitate crown contact with 360 degrees of the vessel wall. The diamond-coated crown differentially sands away arterial calcium from atherosclerotic tissue, leveraging centrifugal force to facilitate compliance change<sup>1,2</sup> while the orbital action allows continuous blood flow during treatment<sup>1</sup>.



## FEWER COMPLICATIONS<sup>2</sup>

Our studies demonstrated orbital atherectomy + low pressure PTA resulted in lower complications<sup>3</sup> and less bailout stenting than PTA alone.<sup>2</sup>



### PERCENT OF LESIONS REQUIRING BAILOUT STENTS<sup>2</sup>

COMPLIANCE 360<sup>®</sup> Study: prospective, randomized, multi-center study comparing orbital atherectomy + PTA to PTA alone in calcified lesions above-the-knee (ATK).  
Bailout stent: stent placed due to residual stenosis >30%.

<sup>1</sup>. Adams GL, et al. Optimal techniques with the Diamondback 360 System achieve effective results for the treatment of peripheral artery disease. J Cardiovasc Transl Res. 2011 Apr; 4(2):220-9.  
<sup>2</sup>. Dattilo R, et al. 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.  
<sup>3</sup>. Shammas NW, 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; 19(4):480-88.

## CHOOSE THE RIGHT CROWN FOR THE LESION.

Devices are available in 3 unique crown designs in multiple sizes.

### SOLID CROWNS

MODEL NUMBER	CROWN SIZE	SHAFT LENGTH	INTRODUCER SHEATH	QTY
P-2ST-S0125-145	1.25 mm	145 cm	6 Fr	1
P-2ST-S0150-145	1.50 mm	145 cm	6 Fr	1
P-2ST-S0200-145	2.00 mm	145 cm	6 Fr	1

### CLASSIC CROWNS

MODEL NUMBER	CROWN SIZE	SHAFT LENGTH	INTRODUCER SHEATH	QTY
P-2ST-CL150-145	1.50 mm	145 cm	6 Fr	1
P-2ST-CL200-145	2.00 mm	145 cm	6 Fr	1

### \*MICRO CROWN with GLIDEASSIST

MODEL NUMBER	CROWN SIZE	SHAFT LENGTH	INTRODUCER SHEATH	QTY
P-2ST-MI125-145	1.25 mm	145 cm	4 Fr	1

The *Stealth 360* Peripheral Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. Contraindications for the system include use in coronary arteries, bypass grafts, stents, or where thrombus or dissections are present. Although the incidence of adverse events is rare, potential events that can occur with atherectomy include: pain, hypotension, CVA/TIA, death, dissection, perforation, distal embolization, thrombus formation, hematuria, abrupt or acute vessel closure, or arterial spasm.

**Caution:** Federal law (USA) restricts this device to sale by, or on the order of, a physician.

DISTRIBUTED BY:



For more information, please visit our website at [www.OrbusNeich.com](http://www.OrbusNeich.com) or contact us:

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\*Only for Belgium, Denmark, Germany, Ireland, Netherlands, Norway, Sweden and UK

MANUFACTURED BY:



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\*Micro Crown with *GLIDEASSIST* – CE mark pending  
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# STEALTH 360

PERIPHERAL ORBITAL ATHERECTOMY SYSTEM



## ADVANCING PAD TREATMENTS IN CALCIFIED LESIONS.

Distributed by:



Manufactured by:



# POWERFUL TECHNOLOGY FOR MORE PATIENTS

Having a greater impact on PAD starts with optimally treating patients. The *Stealth 360* gives you the power to treat calcific plaque in peripheral arteries with our differential sanding technology.<sup>1</sup> This can change lesion compliance, allowing for low pressure balloon inflation to minimize vessel damage.<sup>2</sup>

**SOLID CROWN**  
For maximum calcium removal

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

**MICRO CROWN WITH GLIDEASSIST\***  
For tortuous vessels and tight bends BTK

Convenient three-speed controls\* allow quick adjustments within the sterile field

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

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

Prime button allows quick flushing

*GlideAssist* for the 1.25 Micro Crown\* (4 Fr) enables the crown to spin at a slow speed (5k RPM) for easier tracking and removal of the device

## THE COMPLETE STEALTH 360 SYSTEM UTILIZES:

- OAS Pump
- *ViperWire Advance*
- *ViperSlide*
- Saline Line (comes packaged with the *Stealth 360* device)

<sup>1</sup> Babaev et al. Orbital atherectomy plaque modification assessment of the femoropopliteal artery via intravascular ultrasound (TRUTH study). *Vasc Endovascular Surg*. 2015 Oct;49(7):118-94.

<sup>2</sup> Dattilo R, et al. 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.

\* *GlideAssist* mode is only available on the 1.25 Micro Crown.