

Stealth 360^o™ Orbital PAD System

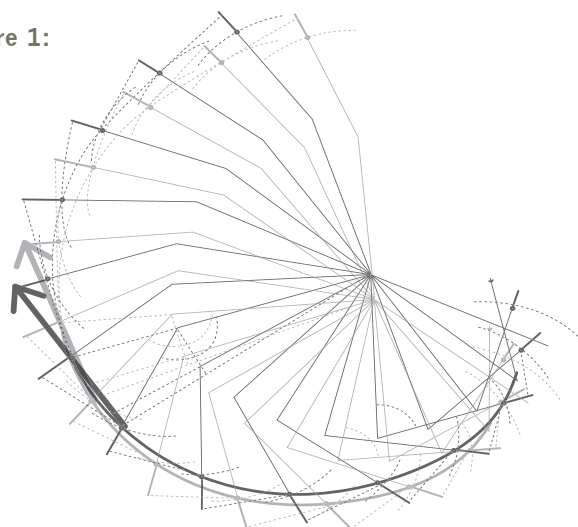
A Technology Overview

The Stealth 360^o Orbital PAD System is an atherectomy system designed to treat occlusive peripheral arterial disease (PAD).

How it Works

The unique orbital atherectomy system utilizes an eccentrically mounted diamond-coated “crown” to sand away the plaque. The system operates on the principles of centrifugal force. As the crown rotates and orbit increases, centrifugal force presses the crown against the lesion or plaque, removing a small amount of plaque with each orbit. (Figure 1)

Figure 1:



$$\text{CENTRIFUGAL FORCE}$$

$$CF = \text{mass} * \text{rotational speed}^2$$

$$\text{radius of the orbit}$$

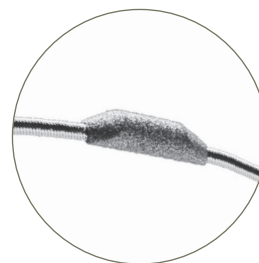
The Stealth 360^o has two different crown offerings:

- **Classic Crown.** The flexible Classic Crown is recommended for compromised flow, vessel bends, ostial lesions, and distal below-the-knee lesions. (Figure 2)
- **Solid Crown.** The Solid Crown has more diamond-coated surface area and is recommended for maximal plaque removal in the shortest amount of time, adequate flow to the foot and chronic total occlusions. (Figure 2)

Figure 2:



CLASSIC CROWN

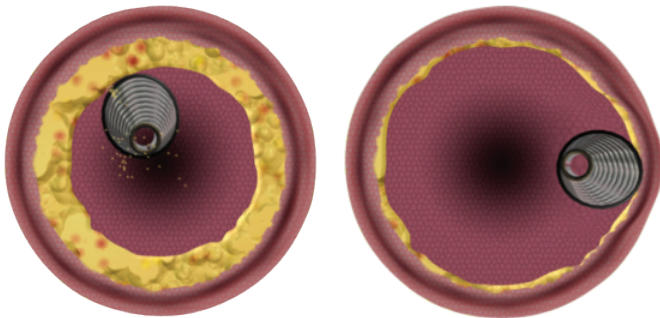


PREDATOR
SOLID CROWN

Differential Sanding

The system's unique mechanism of action sands the hardened plaque while the healthy vessel wall flexes away from the crown, reducing the potential for vessel injury — a concept known as differential sanding. (Figure 3)

Figure 3:



The plaque is sanded into small particles which minimizes the risk of vascular bed overload which may cause slow blood flow to the foot.

The capillaries provide the connection between the arterial and venous system, and continuous blood flow.

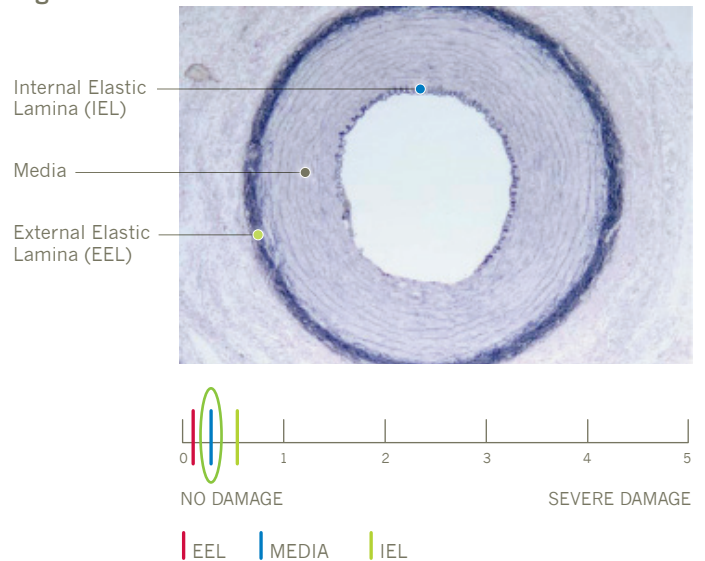
Of 33 experiments performed:

93.14 percent of particulate were smaller than a red blood cell with a 99 percent confidence interval²

99.3 percent of particles were smaller than a capillary lumen with a 99 percent confidence interval²

Damage to the vessel wall increases the possibility of a re-blockage at the same treatment site. The Stealth 360° mechanism of action is intended to minimize vessel wall damage, thereby decreasing the potential for a re-blockage at the same treatment site.¹

Figure 4:



Analysis of 434 porcine histological cross sections after treatment with orbital atherectomy indicates that differential sanding causes minimal to no damage to the vessel wall.² (Figure 4)

Stealth 360° Treatment

The Stealth 360° Orbital PAD System quickly and effectively treats peripheral atherosclerotic disease.

The advantages of removing plaque include:

- Facilitating lower pressure balloon inflations (≤ 4 atms)
- Restoring blood flow without having to place a stent
- Addressing the unique challenges of “no stent zones”
- If a stent is needed, assisting with optimal stent expansion and apposition

The electric-powered device has simple and convenient speed adjustments on the handle allowing for precise control during the procedure. The small crossing profile of the Classic and Solid Crowns creates an opening in

the vessel up to two times the size of the crown. This eliminates the need for multiple devices to be used during the procedure, reduces the procedure time and minimizes the skin entry site opening.

The orbital motion is designed to create a smooth concentric vessel opening or lumen, which may improve blood flow.

The process of sanding the plaque eliminates the need to remove or empty the material, reducing procedure time and minimizing vessel trauma. Decades worth of plaque buildup can be removed in as little as two minutes.

Commitment to Clinical Rigor

CSI is committed to obtaining evidence-based clinical and scientific data that continues to demonstrate the safety and efficacy of orbital treatment in real-world situations. Over 2,400 patients have been studied to date, revealing consistent, predictable and repeatable results. The safety of orbital treatment is supported by extremely low rates of perforations, bailout stenting and mortality across all studies.^{3,4}

References:

1. Costa. *Molecular Basis of Restenosis and Drug-Eluting Stents*. *Circ*. 2005; 111:2257-2273.
2. CSI data on file.
3. Compilation of CSI data: OASIS, CALCIUM 360, CONFIRM I Diamondback, CONFIRM II Predator.
4. Safian R. OASIS. *Catheterization and Cardiovascular Interventions*. 2009. 73:406-412.