Combining Balloon Angioplasty and Embolic Particle Removal

Use PROTEUS to Perform

Embolic Removal

Balloon Angioplasty
Designed To **Remove Embolic Particles** in a **Simple, Quick, and Cost-Effective Manner**

**Distal Embolization**
Distal Embolization was shown to lead to prolonged procedure time, additional contrast use and radiation time.¹

**Capture & Removal**
The PROTUES suction mechanism is activated by pulling back on the catheter handle. The process is simple and takes seconds.²

**Clinical Outcomes**
Histological analysis of captured embolic particles confirmed atheromatous material, acute thrombus, chronic thrombus, and neointima.²

---

**How it Works?**

- **Device Deployment**
- **Folding Inwards**
- **Embolic Capture**
- **Debris Removal**
Treating Lower Limbs – Preserving Distal Flow

Following initial roadmapping, the physician may diagnose a potential threat to distal embolization in the vessel. PROTEUS can be a very useful tool as a primary PTA of the lesion, while capturing and removing the embolic material through its proprietary suction mechanism.

Acute, totally occluded long ISR lesion in the left SFA. A femoral crossover approach using a 7Fr introducer sheath was taken. During roadmapping, the proximal segment showed evidence of irregular flow. A 6x100mm PROTEUS device was used for angioplasty and debris removal (2min @ 8 atm) through its suction mechanism. The distal SFA was treated with a standard PTA balloon. Post angiography revealed a patent vessel with no distal embolic events. Analysis of the removed particles showed evidence of chronic thrombus.

Following primary atherectomy, the lesion may show evidence of irregular vessel wall with or without compromised flow phenomena. PROTEUS can be used for vessel dilatation and the removal of residual embolic debris from the lesion site.

A right, long, heavily calcified, SFA chronic total occlusion was treated with a Turbohawk atherectomy device. Post angiography revealed irregular vessel wall with slow flow patterns in its mid section. A 6x100mm PROTEUS device was prepped and deployed (2min @ 8atm) followed by embolic capture and removal through its suction mechanism. Lesion outflow and distal perfusion were significantly improved with no vessel dissection or distal embolic events recorded. A large thrombotic mass (>10mm) and multiple smaller particles were recorded during examination of the removed device.

Endovascular interventions may cause particles dislodgement that can lead to distal embolization. PROTEUS can be an effective tool to contain and remove released particles.

The patient was identified with a long 90% stenotic ISR SFA lesion and moderately diffused posterior and anterior tibial (ATA) arteries. Laser atherectomy was used to ablate the SFA. Post angiography revealed a patent SFA with an abrupt ‘cutoff’ in the proximal segment of the ATA. A 4x100mm PROTEUS device was prepped, crossed and inflated to 10 atm. PROTEUS was then deflated to 2 atm, folded and deflated creating a suction effect for embolic removal. A 3mm atheromatous plaque was noted within the confines of the device upon extraction. Completion angiography showed a patent popliteal and two vessel run-offs with improved perfusion to the foot.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.
**PROTEUS** integrates in every step of the procedure:

PROTEUS is an ideal solution for lower limbs angioplasty interventions, from vessel preparation (first in the lesion) to PTA rescues procedures following primary intervention. PROTEUS is a useful tool in many clinical settings in the infrainguinal (SFA and infrapopliteal) arteries:

- Occlusive and sub-occlusive lesions
- Flow limiting & thrombus containing lesions
- Post atherectomy and post thrombectomy dilatation

PROTEUS is designed to effectively treat lower limb plaque by combining dilatation of stenotic lesions and embolic capture through suction mechanism for debris capture and removal.

---

**Indications for Use**

“The Angioslide PROTEUS™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and containment of embolic material during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

The Angioslide PROTEUS™ PTA Balloon Catheter with Embolic Capture Feature is not intended for use in the renal, cerebral, coronary or carotid vasculature.”

**PROTEUS Mechanism of Action**

“The embolic capture feature involves a single-use suction mechanism that works through inward folding of the balloon, which creates negative pressure within the capture cavity for debris capture and removal. The reduced pressure in the capture cavity causes some of the particles that are released during the procedure to flow into the cavity for containment and removal.”

---

**References:**

4. PROTEUS IFU.