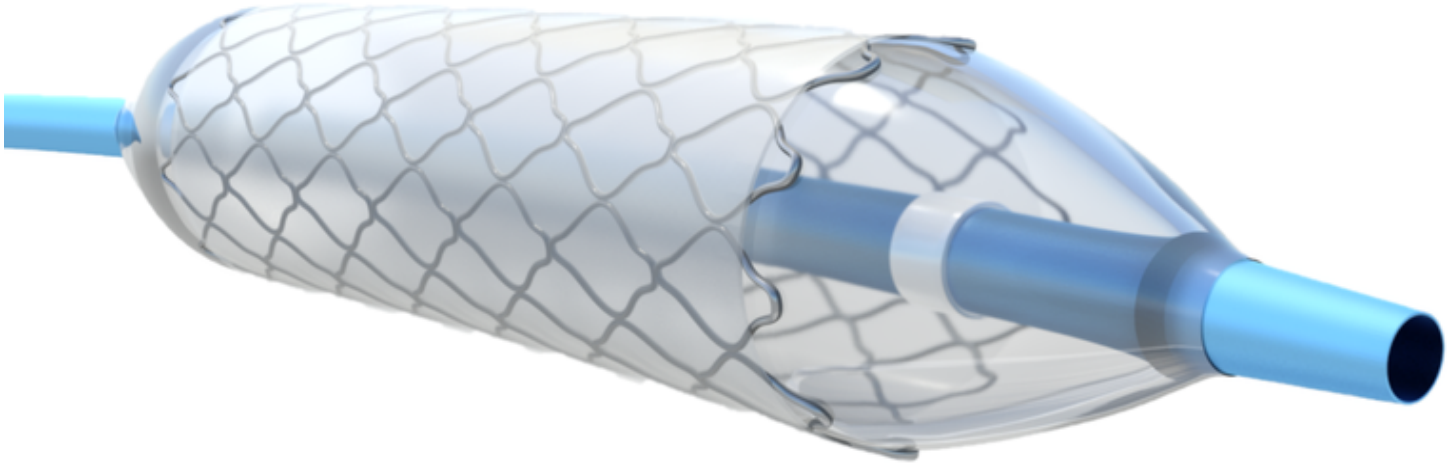
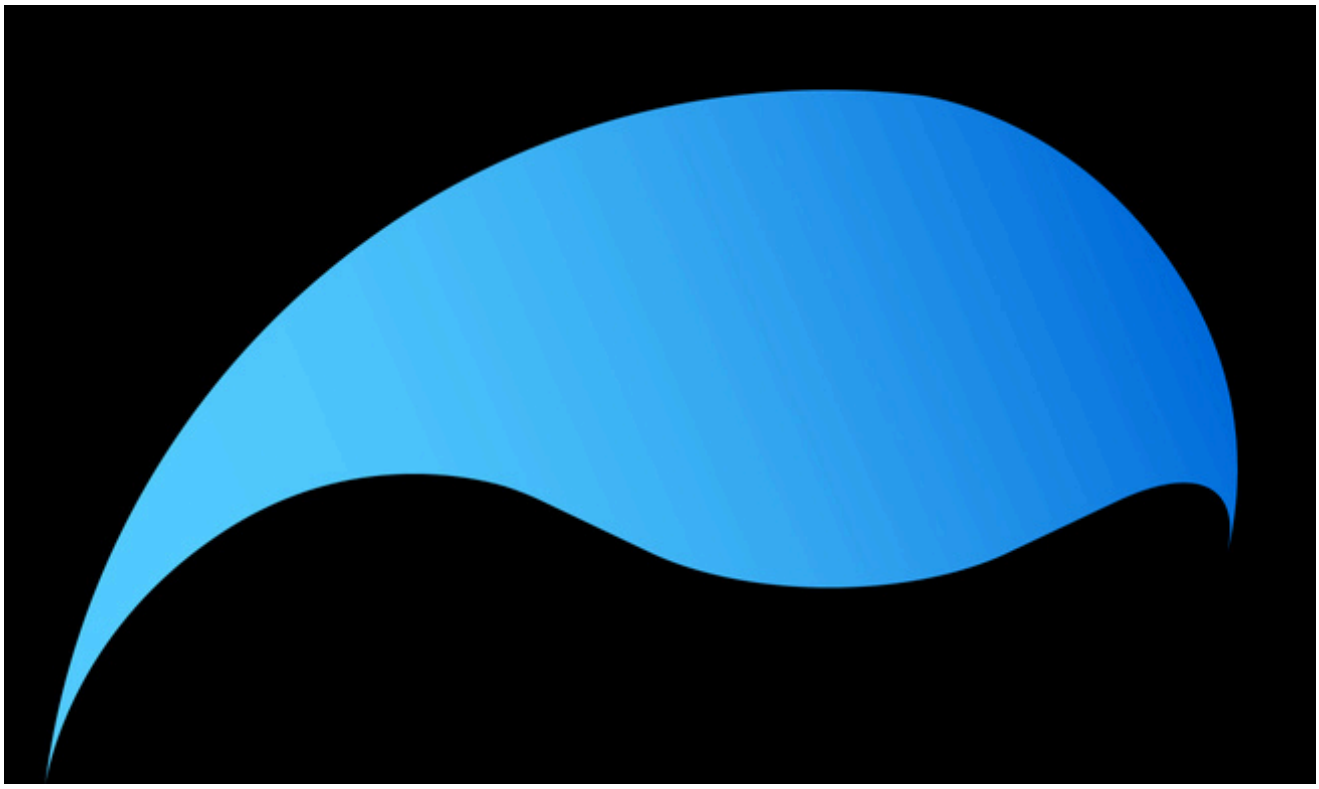
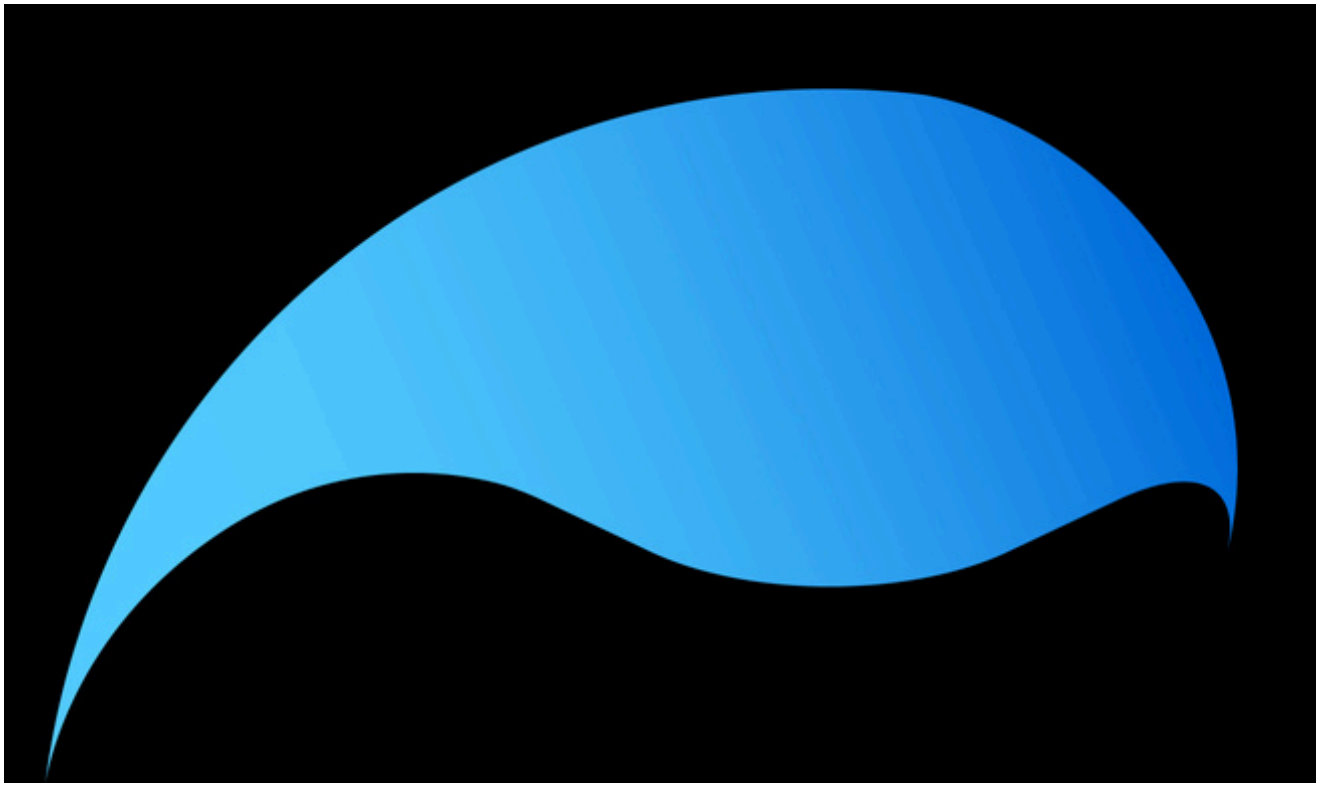


InSitu Technologies® Inc.

Extending Life and Improving Health™

Silene Peripheral Covered Stent



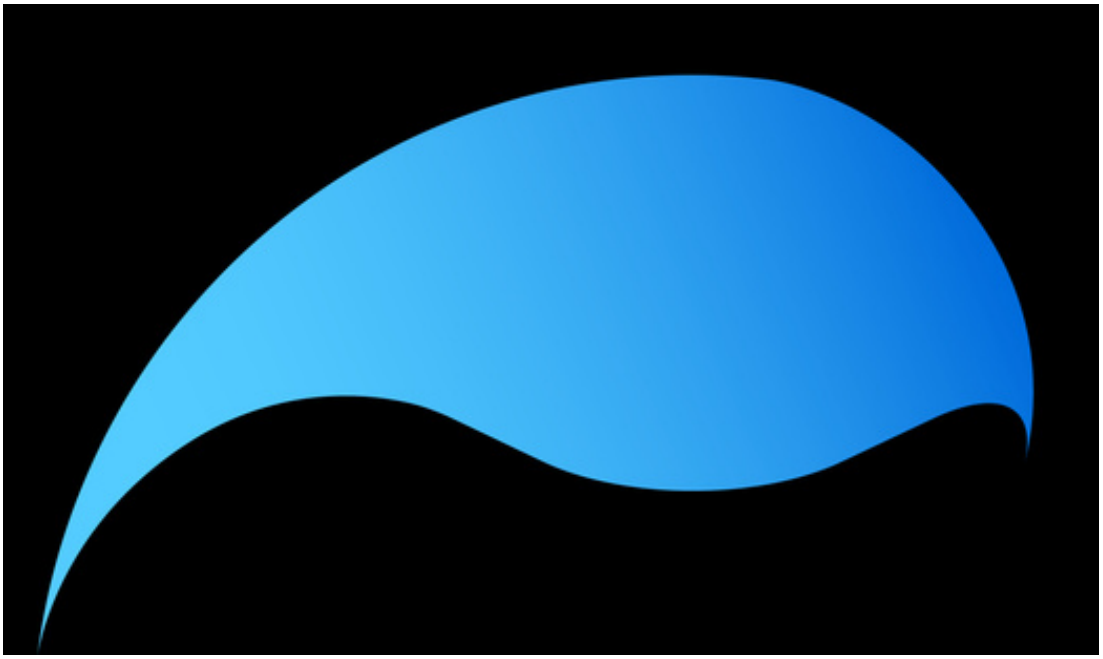


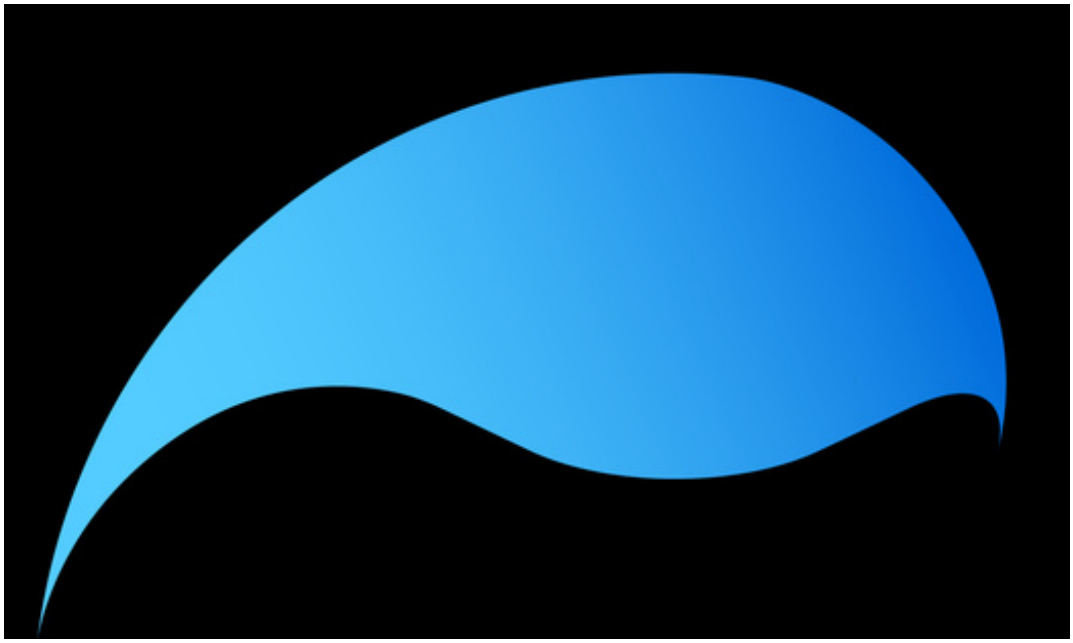
Indications For Use:

The Silene Peripheral Covered Stent is indicated for restoring and improving the patency of the iliac arteries.

Clinical Application:

The device will be used in the peripheral vasculature to improve luminal patency in diseased vessels.





US patented and proven Direct-Stent Platform

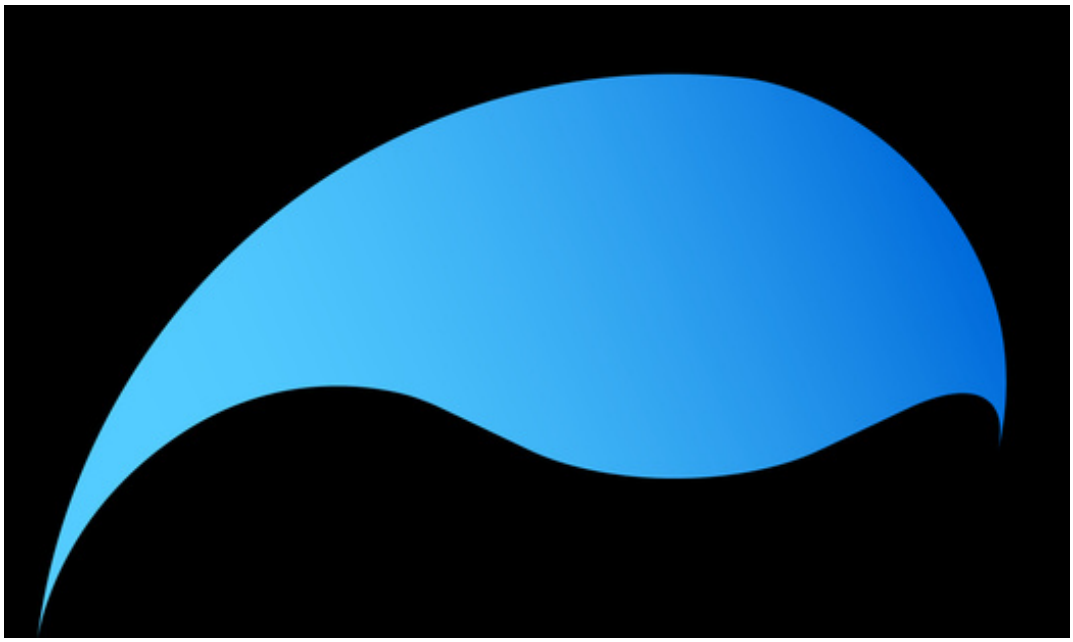
- Hybrid stent cell design for optimum radial strength
- Variable width struts for superior flexibility

Patented Micro-porous ePTFE Polymer

- Enhances hemocompatibility
- Promotes endothelialization

Proprietary Manufacturing Technology

- Ensuring high crimp retention
- Excellent navigability due to a unique balloon pillowing technology and the stent design
- Optimum trackability and deliverability in tortuous anatomy



Simultaneous Endovascular Treatment of Synchronous Symptomatic Acute Type B Aortic Dissection and Large Infrarenal Aortic Aneurysm

Ettore Dinoto, Felice Pecoraro, Arduino Farina,

Alessia Viscardi, Guido Bajardi. Aug 2020.

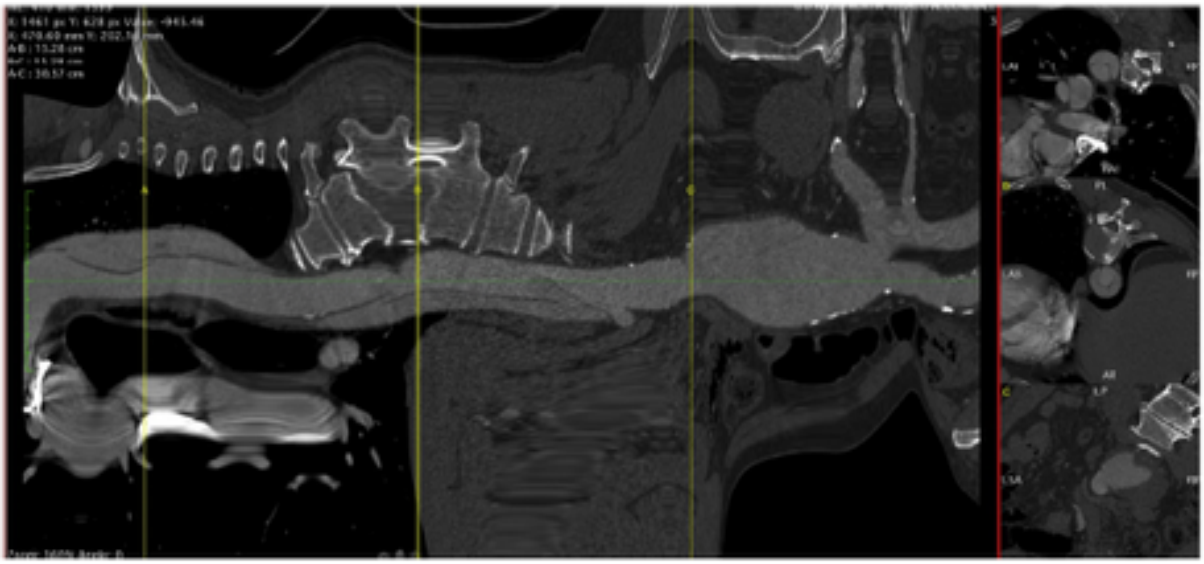
International Journal of Surgery Case Reports,

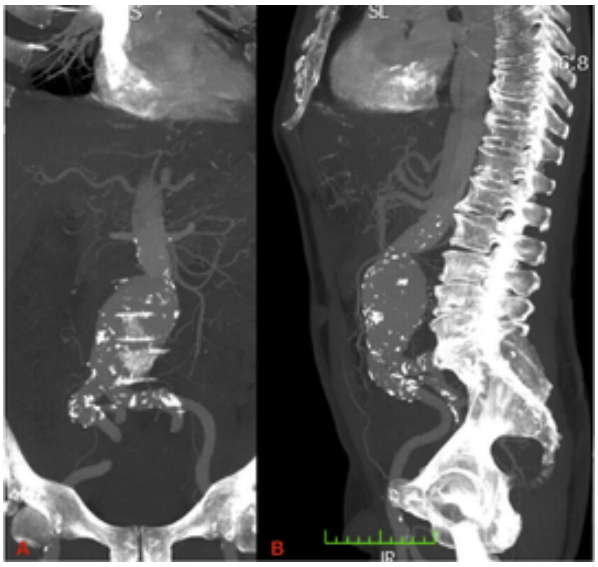
Case Summary:

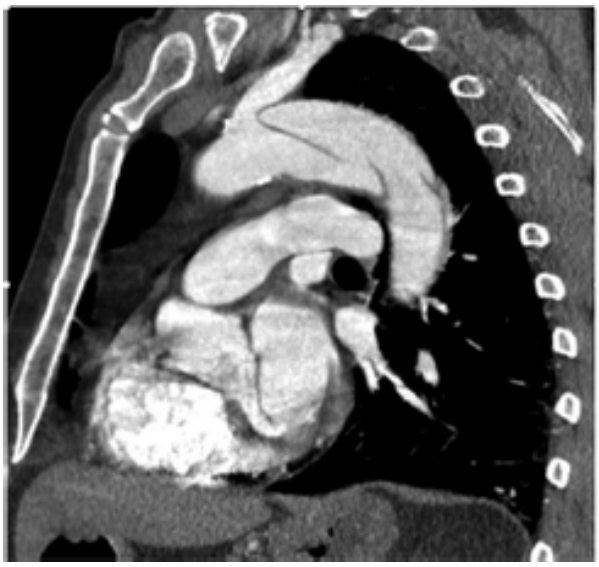
Patient presented with an acute type B aortic dissection (ATBAD) and an infrarenal abdominal aortic aneurysm (AAA). A totally endovascular solution, involving a Silene covered stent and 3 various other stents, was used to treat both simultaneously. This solution was successful and proved to be quick and less invasive allowing for shorter hospital stay.

Case Details:

A 65-year-old male with hypertension and diabetes melli-tus complained of sudden thoraco-abdominal pain. At history he referred to be in treatment with antiplatelet and anti-hypertensive drugs. Patient denied any previous family history of similar pathology. CT-scan showed an ATBAD, from left subclavian artery (LSA) to the superior mesenteric artery (SMA), and a 72 mm large infrarenal AAA. CT-angiography showed a significant true lumen compression from an expanding false lumen (Figs. 1–3). No malperfusions symptoms or signs were evident. Uncontrollable systemic hyper-tension and pain (thoracic and abdominal) were the indications to treatment. To reduce the invasiveness of the procedures reduce the invasiveness of the procedures and address simultaneously both ATBAD and AAA a totally endovascular approach was chosen.







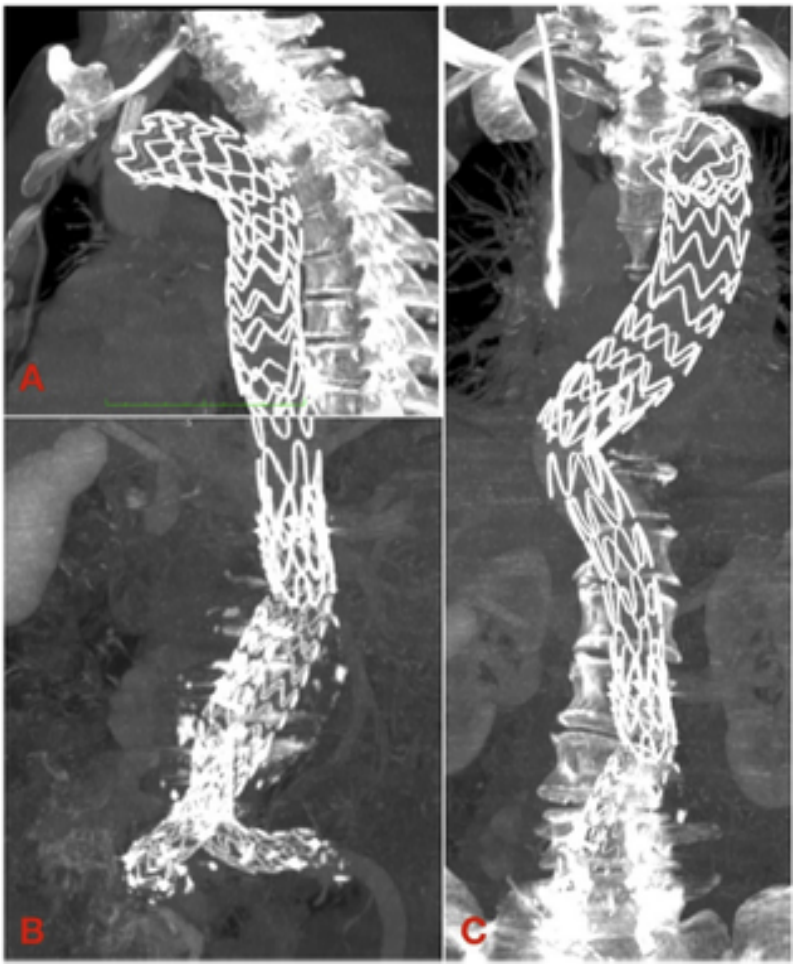
Figures 1-3. CT images showing the dissection and abdominal aneurysm.

Intervention was conducted without the placement of a spinal drain.

In our vascular operating room, under general anesthesia and systemic heparinization (ACT > 250 s), a bilateral surgical common femoral artery (CFA) and a bilateral percutaneous brachial artery (BA) accesses were gained. A through and through wire from the right CFA to the right BA (bodyfloss technique) was constructed in consideration of the arch anatomy and to create a stable platform for the thoracic stent-graft advancement and deployment by applying adequate tension to the bodyfloss wire.

An adequate proximal landing zone was identified in zone 2Hishimaru aortic arch. To maintain LSA perfusion a chimney wasplanned. From the left BA access a 10 × 31 mm Silene covered stent (InSitu Technologies Inc, St. Paul, MN, USA) was advancedand parked at the origin of the LSA so that half of the length was positioned inside the aortic arch and the remaining into the LSA.A 40 × 223 mm Valiant Navion (Medtronic, Inc., Minneapolis, MN,USA) was placed and deployed in zone 2 aortic arch through the bodyfloss wire. At this stage, the Silene covered stent (InSitu Tech-nologies Inc) was deployed. A kissing ballooning of both the Valiant Navion (Medtronic, Inc.) thoracic stent-graft and the LSA chimney was performed. Sizing of the thoracic and LSA devices were per-formed according to the current understandings. The control angiography

confirmed the adequate proximal sealing, the absence of leakages and the maintained LAS patency.



The second step consisted of endovascular aneurysm repair (EVAR) carried with a 32 mm bifurcated ENDURANT II (Medtronic, Inc.) stent-graft from the infrarenal aorta to both common iliacs carried with the use of the speed cannulation gate technique. The control angiography confirmed the adequate proximal and distal sealing, the absence of leakages and the maintained internal iliacs patency.

Figure 4. Postoperative CT MPR showing Thoracic graft (A), abdominal graft (B) and final structure of prosthetic implant (C).

The third step was performed with the placement of a 36 × 180mm Zenith endovascular dissection stent (Cook Medical, Blooming-ton, IN, USA) between the thoracic and the abdominal stent-graft. This bare metal stent is intended to supports the collapsed true lumen without covering the reno-visceral branches as reported in the PETTICOAT (provisional extension to induce complete attachment) technique (Fig. 4). The final angiographic control confirmed the above mentioned partial findings and the maintained patency of reno-visceral arteries and a reduced refueling of the false lumen.

After procedure the patient was transferred in the intensive care unit (ICU) for monitoring of vital functions where the extubation was carried after 12 h with no complications or signs of spinal cord ischemia (SCI). On the second postoperative day the patient was transferred from ICU and discharged at home after seven days.

The one year CT angiography showed good placement of thoracic and abdominal graft with good remodeling of false lumen in absence of symptoms and complete exclusion of

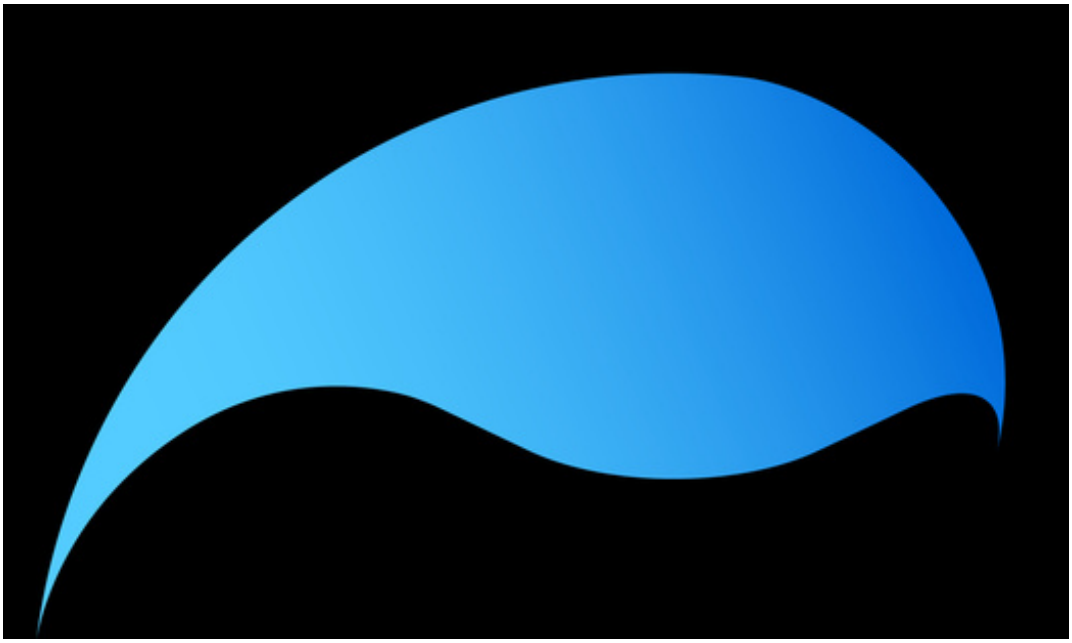
AAA.

Discussion:

A simultaneous AAA in cases presenting ATBAD is reported in the Literature with a prevalence of 1–7% in patient treated for aortic disease. In this circumstance, the AAA etiology is still a not fully understood: it can be associated to a pre-existing asymptomatic degenerative atherosclerotic lesion, or it can be the result of the rapid expansion determined by the dissecting flap. This close correlation further is demonstrated, also by evidences in some cases of dissection in patient previously treated for AAA. AAA rupture has been detected at admission in three-fourths of patients with ATBAD that extended to or involved a coexisting unoperated atherosclerotic aneurysms. This association, increasing the risk of thoracic or aortic rupture, indicates such combination of aortic lesions as “complicated” dissection. Thus, a coexisting aortic lesion must be considered for treatment as quickly as possible. The reported simultaneous approach can be performed endovascularly also when supra-aortic branches are involved with the combination of proper devices. Molinari et al. suggested an extensive endovascular treatment with TEVAR to close the primary entry tear and exclusion of all distal reentries by an abdominal bifurcated endograft to avoid the risk of rupture or collapse of true lumen in patient with dissection type B involving carrefour and iliac artery. Patel et al. described a case of complex TBAD associated to a pressurized infrarenal AAA treated with a TEVAR and EVAR ina single stage. Moreover EVAR has been associated to accept-able outcomes even when employed outside the instruction for use. Despite a known increased risk after emergent AAA surgical repair and the indication to full heparinization during TEVAR and chimneys, in a reported literature review simultaneous interventions with TEVAR showed also good outcomes.

Conclusion:

In literature studies reporting simultaneous treatment of ATBAD and AAA are lacking. This experience using a totally endovascular solution to address both diseases even with the involvement of supra-aortic branches and the reno-visceral aortic segment was feasible. This solution represents a rapid and less invasive approach to address high complex disease and allowed fast discharge and limited ICU stay.



A Versatile Stent to Treat a Wide Range of Vascular Pathologies

Caterina Del Principe

ORE 12 Italia

“Even in the most difficult anatomical conditions we could appreciate the properties of the Silene stent. In particular, the low profile which allowed us easy access from the humeral site, the excellent navigability and precision of release, the possibility of overdilation and high radial force.”

Dr. Roberto Chiappa

Review in Italian:

InSitu Technologies® è una azienda private statunitense specializzata da più di 20 anni in soluzioni vascolari innovativo, come stent ricoperti e palloni. Gli stent reicoperti sono

in grado di esculdere la placca e l'endotelio mitigando la perdita tardiva del lume e la dormazione di neointima. Ciò può compotare una riduzione della restenosi, causata dalla proliferazione e migrazione delle cellule muscolari lisce nella tonaca intima.

Insitu Technologies® ha brevettato un design innovativo delle celle, denominato "open-closed cells" [Fig 1], che permette di mantenere una buona flessibilità, e quindi adattabilità alla conformazione delle pareti del vaso, associata ad una elevataforza radiale, Quest'ultima caratteristica, in particolare, è garantita dalla lega in cromo-cobalto, di cui è constituita la maglia, Esternamente lo stent SILEN è ricoperto da un singolo strato die PTFE, polimero brevattato biocompatibile ed inerte, che permette di minimizzare il contatto metallic con le pareti vascolari, favorendo al contempo la neoendotelizzazione grazie alla sua struttura microporosa. L'ottimale precision in fase di rilascio è garantita dal sistema di aperture "balloon expandable". Il meccanismo di base di questo tipo di stent è la simultanea espansione radiale e la deformabilità della maglia: lo stent, crimpato su un palloncino in nylon a bassa complianza, conserva la forma e le dimensioni del Pallone gonfio ed è tenuto in situ dall'elasticità residua delle pareti. Il rivestimento in ePTFE è fissato allo stent in modo tale da mantenere entrambe le estremità libere. Ciò garantisce un perfetto e sicuro ancoraggio alle pareti e quindi elimina il rischio di migrazione dello stent all'interno del vaso.

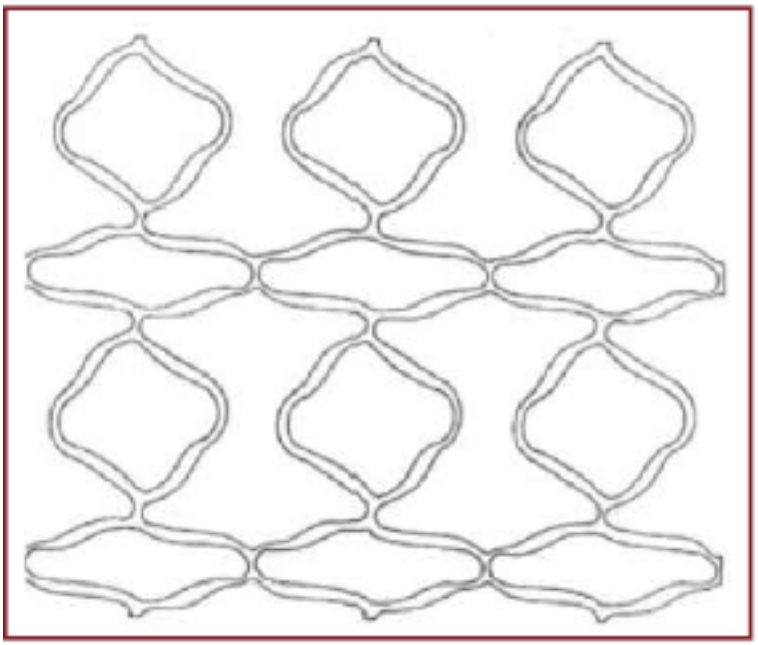


Fig 1.

Il design ibrido delle celle ed il perfetto accoppiamento con il rivestimento in ePTFE favoriscono una sensibile riduzione del profile ed una eccellente navigabilità all'interno dell'albero vascolare permettono la sovradilatazione sicura dello stent oltre il valore nominale, senza alcun rischio di frattura della maglia metallica o di lacerazione del rivestimento.

"Le caratteristiche biomeccaniche, l'eccellenta maneggevolezza e l'ampia di diametri elunghezze, redono lo stent graft SILEN estremamente versatile, con possibili applicazioni nella maggior parte delle procedure endovascolari" spiega il Dott. Roberto Chiappa, responsabile della Unità Operativa di Chirurgia Vascolare dell'ospedale Sandro Pertini di Roma, "In particolare abbiamo apprezzato gli ottimi risultati ottenuti

utilizzando lo stent graft SILEN nelle revascolarizzazioni aorto iliache e nel trattamento della patologia dilatativa aortic complessa con endo protesi fenestrate o preservazione del circolo visceral con tecnica chimney", prosegue il Dott. Chiappa.

La prevalenza della malattia arteriosa ostruttiva periferica supera il 14% nei pazienti con età superiore a 70 anni : la localizzazione della malttia al tratto aorto iliaco non èinfrequente e le manifestazioni cliniche possono variare, a seconda della gravità e dell'estensione delle lesion, dalla claudicatio intermittens all'ischemia critica. La nascita e lo sviluppo delle technice endovascolari ha introdotto una nuova forma di trattamento per una patologia che un tempo era affrontabile esclusivamente con interventi chirurgici complessi. "La disponibilità di una protessi ricoperta come lo stent graft SILEN, caratterizzata da basso profilo, elevata capacità di navigazione, proprietà biomeccaniche di conformabilità ed elevata forza radiale, unitamente ad elevata biocompatibilità ed ampia gamma di diametric, ha certamente favorite le possibilità di trattamento endovascolare anche nei casi di esteso coinvolgimento ostruttivo della biforcazione aorto-ilica [Fig, 2a] e del tratto aortic sottorenale (covered endovascular reconstruction of aortic bifurcation- CERAB)" prosegue il Dott. Chiappa.

Anche il trattamento della patologia dilatativa aortic ha subito un radical cambiamento con l'avvento delle endoprotesi aortiche. In anatomie favorevoli il trattamento endovascolare permette la prevenzione della rottura dell'aneurisma con una sensible riduzione della morbilità e mortalità perioperatoria. Tuttavia, oltre il 30% dei pacienti con aneurisma dell'aorta addominale presente una conformazione anatomica, in perticolare del coletto corto o assente, angolato o conico. In questi casi l'endoprotesi aortic va rilasciata in posizione più prossimale, in un segmento aortico sano che passo garantire il "fissaggio" e la "tenuta emostatica". Ciò comporterebbe, però, la copertura di rami viscerali renali e mesenterici, la cui perfusione è, invece, assicurata dal contemporaneo utilizzo di stent graft, Questi ultimo vengono inseriti in apposite "fenestrature" o "branche laterali" dell'endoprotesi [Fig. 3] o decorrono esternamente e parallelamente ad essa (parallel graft – chimnet/snorkeling) [Fig. 2b].

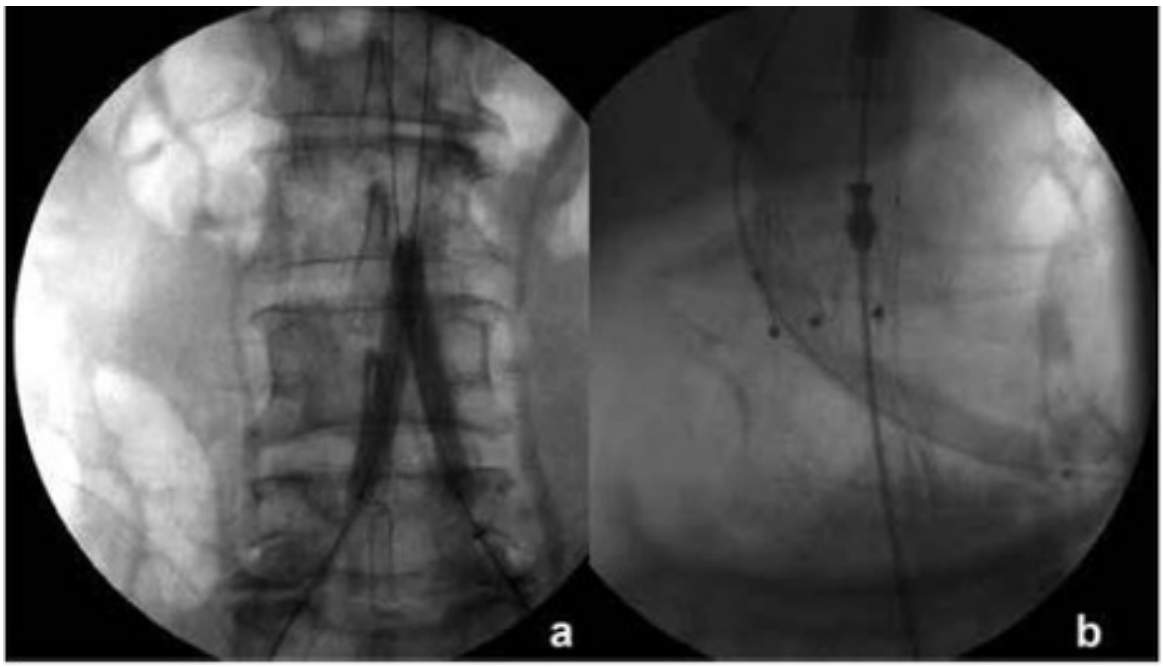


Fig. 2: a) kissing stent graft aorto iliaco con SILENE™;
b) trattamento endoprotesico di aneurisma pararenale sinistro con tecnica chimney: rilascio di stent graft SILENE™ .

“Anche nelle più difficili condizioni anatomiche abbiamo potuto apprezzare le proprietà dello stent SILEN. In particolare il basso profile, che ci ha permesso un facile accesso dal sito omerale, le eccelenti doti di navigabilità e precisione di rilascio, la possibilià di sovradilatazione e l’elevata forza radiale, Tutte queste important caratteristiche, unitamente alla conformabilità ci hanno garantito una sicura e duratura perfusione dei rami viscerali” conclude il Dott. Chiappa, il quale riconosce “nella versatilità e nella maneggevolezza I punti di forza dello stent SILEN, presidio indispensabile nell’armamentario di ogni chirurgo vascolare oer il trattamento endoluminale della patologia aorto ilica steno-ostruttiva e dilatativa complessa”.

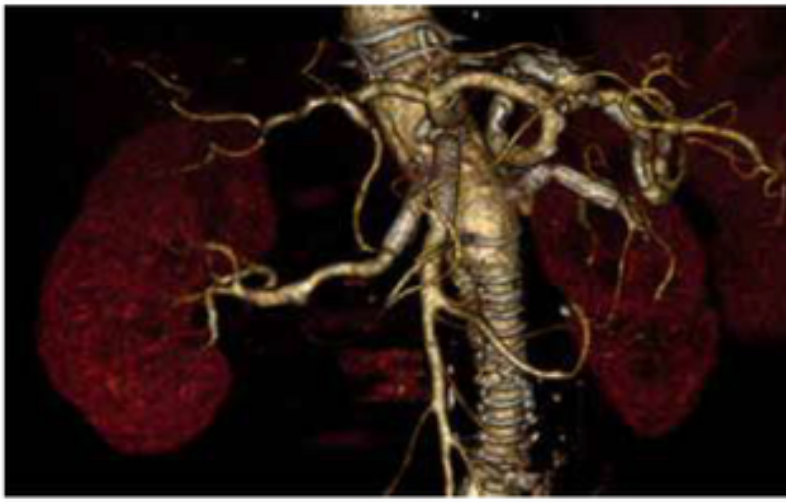


Fig. 4: Volume Rendering del controllo postoperatorio.

Review in English:

InSitu Technologies® is a US private company that has specialized for more than 20 years in innovative vascular solutions, such as covered stents and balloons. The covered stents are able to excrete the plaque and the endothelium, mitigating the late loss of the lumen and the dormancy of neointima. This may result in a reduction in restenosis, caused by the proliferation and migration of smooth muscle cells in the inner tunic.

Insitu Technologies® has patented an innovative design of the cells, called "open-closed cells" [Fig 1], which maintains a good flexibility, and therefore adaptability to the conformation of the vessel walls, associated with a high radial force. In particular, the characteristic is guaranteed by the chromium-cobalt alloy, of which the mesh is made. Externally the SILEN stent is covered with a single layer of PTFE, a patented biocompatible and inert polymer, which allows to minimize the metallic contact with the vascular walls, while favoring neo-endothelialization thanks to its microporous structure. Optimal precision in the release phase is guaranteed by the "balloon expandable" opening system. The basic mechanism of this type of stent is the simultaneous radial expansion and deformability of the mesh: the stent, crimped on a low compliant nylon balloon, retains the shape and size of the inflated balloon and is held in place by elasticity residual of the walls. The ePTFE liner is attached to the stent in such a way that both ends are kept free. This ensures perfect and safe anchoring to the walls and therefore eliminates the risk of migration of the stent inside the vessel.

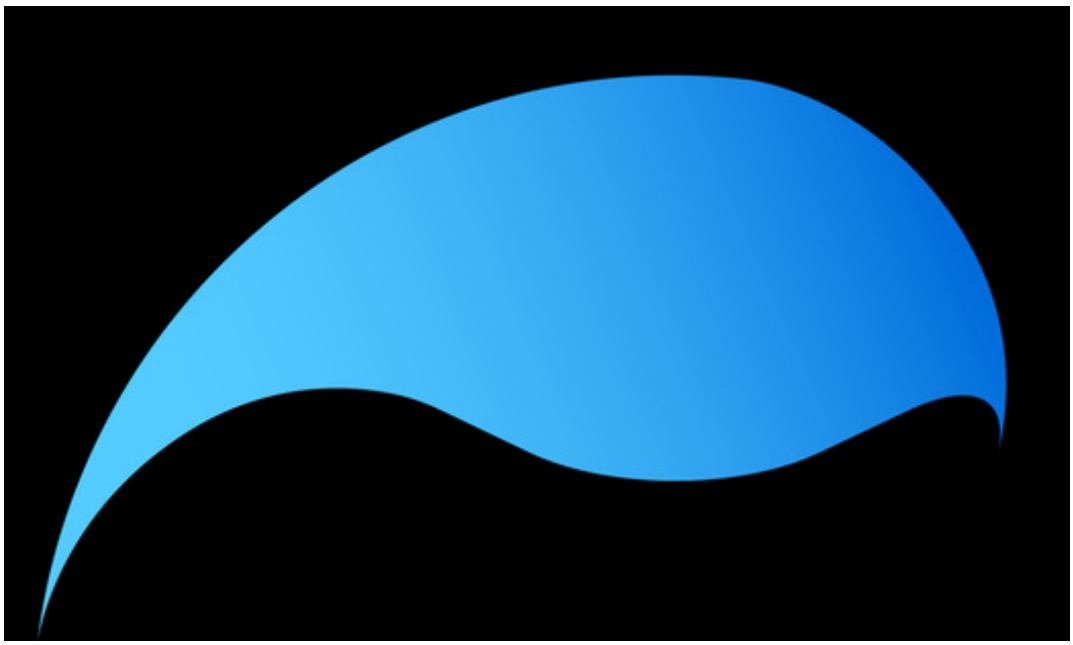
The hybrid design of the cells and the perfect coupling with the ePTFE coating favor a significant reduction of the profile and an excellent navigability inside the vascular tree allow the safe overdilation of the stent beyond the nominal value, without any risk of fracture of the metal mesh or tearing of the coating.

"The biomechanical characteristics, the excellent handling and the wide diameters and lengths make the SILEN stent graft extremely versatile, with possible applications in most endovascular procedures" explains Dr. Roberto Chiappa, head of the Vascular Surgery Unit of the Sandro Pertini hospital in Rome, "In particular we appreciated the excellent results obtained using the SILENstent graft in aorto-iliac revascularization and in the treatment of complex aortic dilated pathology with fenestrated endo prosthesis or preservation of the visceral circulation with chimney technique", continues Dr. Chiappa.

The prevalence of peripheral obstructive arterial disease exceeds 14% in patients over 70 years of age: the localization of malttia in the aorto-iliac tract is not uncommon and clinical manifestations may vary, depending on the severity and extent of the lesions, from claudication intermittent to critical ischemia. The birth and development of endovascular techniques has introduced a new form of treatment for a pathology that was once only accessible with complex surgical interventions. "The availability of a covered protector such as the SILEN stent graft, characterized by low profile, high navigation capacity, biomechanical properties of conformability and high radial force, together with high biocompatibility and a wide range of diameters, has certainly favored the possibilities of endovascular treatment also in cases of extensive obstructive involvement of the aorto-ilic bifurcation [Fig, 2a] and of the subrenal aortic tract (covered endovascular reconstruction of aortic bifurcation - CERAB) ”continues Dr. Chiappa.

The treatment of dilated aortic pathology has also undergone a radical change with the advent of aortic endoprostheses. In favorable anatomies, endovascular treatment allows the prevention of rupture of the aneurysm with a significant reduction in perioperative morbidity and mortality. However, over 30% of patients with an aneurysm of the abdominal aorta present an anatomical conformation, in particular of the coletto short or absent, angled or conical. In these cases, the aortic endoprosthesis should be released in a more proximal position, in a healthy aortic segment that can ensure "fixation" and "hemostatic sealing". This would, however, involve the covering of visceral renal and mesenteric branches, whose perfusion is, instead, ensured by the simultaneous use of stent graft. The latter are inserted into special "fenestrations" or "lateral branches" of the endoprosthesis [Fig. 3] or run externally and parallel to it (parallel graft - chimnet / snorkeling) [Fig. 2b].

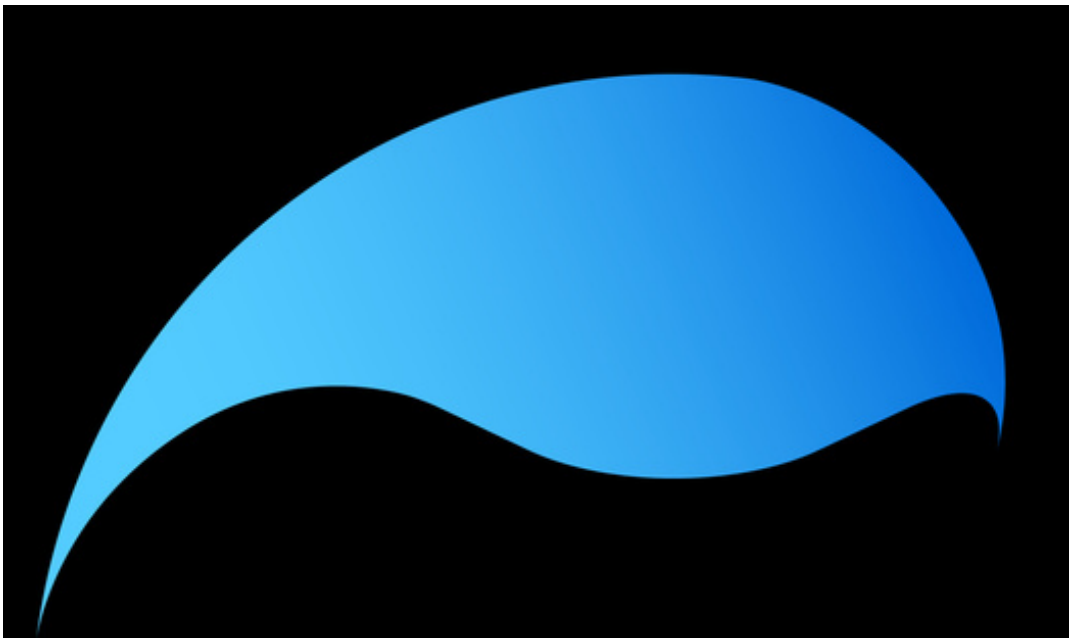
“Even in the most difficult anatomical conditions we have been able to appreciate the properties of the SILEN stent. In particular the low profile, which allowed us easy access from the humeral site, the excellent qualities of navigability and release precision, the possibility of over-stretching and the high radial force. All these important characteristics, together with the conformability, have guaranteed us a safe and lasting perfusion of the visceral branches "concludes Dr. Chiappa, who recognizes "in the versatility and manageability the strengths of the SILEN stent, an indispensable aid in the armamentarium of every vascular surgeon for the endoluminal treatment of aorto-ilic pathology steno-obstructive and complex dilation ".



Silene Peripheral Covered Stent

Stent Design:	Direct-Stent U.S. Patented Hybrid Cell Design
Stent Material:	Cobalt Chromium
Stent Covering Polymer:	ePTFE
Wall Thickness:	0.076 mm / 0.003”
Variable Strut Width:	0.046 mm-0.127 mm / 0.0018-0.005”
Delivery System:	Over the Wire (OTW)
Balloon Material:	Semi-Compliant, Nylon Blend
Optimal Deployment Pressure:	6-7 ATM
Rated Burst Pressure:	10-14 ATM
Shaft Size (Proximal-Distal):	5-7 F
Crimped Profiles:	1.7 – 3.0 mm
Tip Entry Profile:	0.0039”
Recommended Guidewire:	0.035”
Minimum Sheath Introducer:	6-9 F
Working Length:	~130 cm

Stent Expansion Range:	6.0 – 12.0 mm
Stent Lengths:	14 – 70 mm



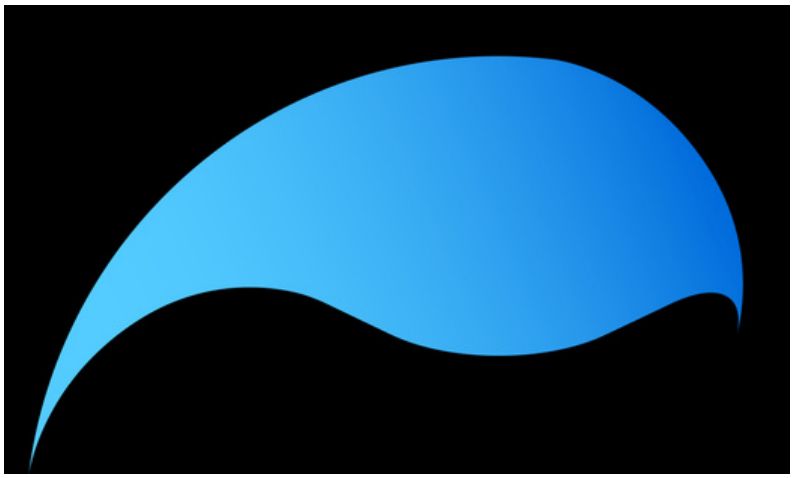
General Comparison

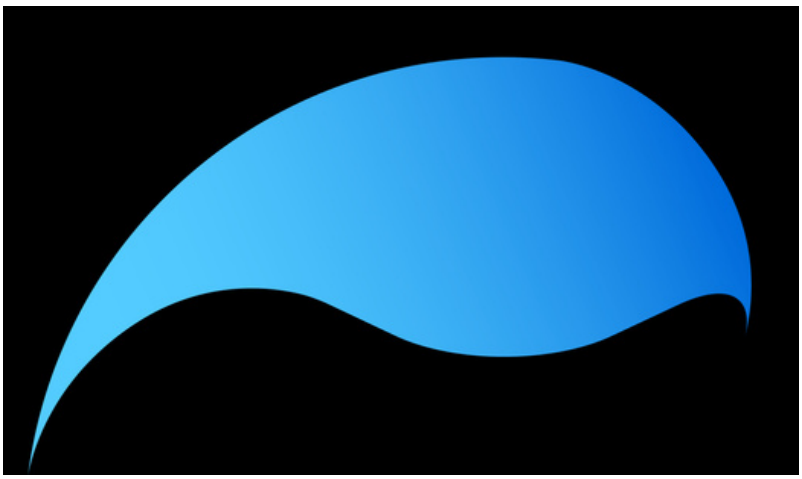
Characteristics	InSitu	Atrium	Bently
Design	Single layer design	Encapsulated design	Single stent-Single layer design
Covering	Thin ePTFE Aids in tracking	Relatively bulky	Relatively thick tubing
Stent Platform	Patented Direct-Stent® Hybrid open/closed cell	Flexible, open cell design	Open/Closed cell design
Flexibility	Optimal flexibility	stiffer	stiffest
Deployment Pressure	Easy to deploy	Requires highest pressure	Requires higher pressure
Porosity	Optimal porosity	Less porous	N/A
Stent Material	Cobalt Chromium L605	316L Stainless Steel	Cobalt Chromium L605

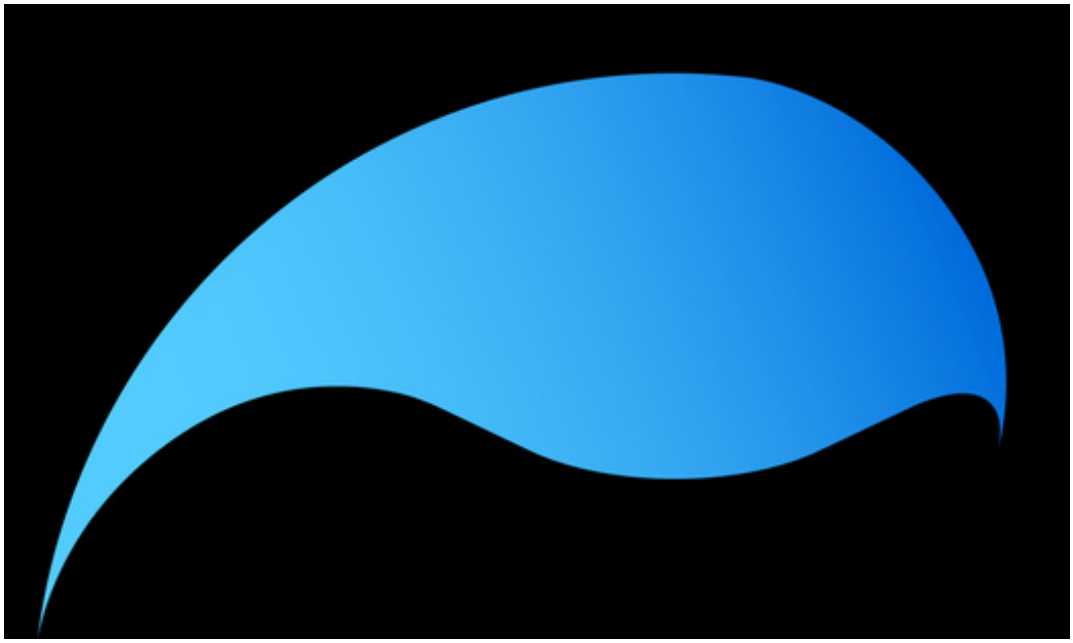
Technical Comparison

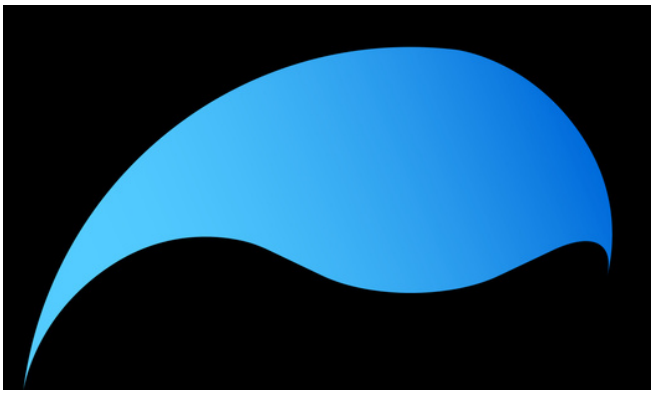
Characteristics	InSitu	Atrium
Size Range (Ø, Length)	6 - 12 mm, 15 - 70 mm	5 – 10 mm, 16 – 59 mm
Deployment Pressure	6-7 ATM	8-12 atm
Rated Burst Pressure	15 atm (8 mm), 14 atm (9 mm), 13 atm (10 mm)	12 atm
Covering	ePTFE	PTFE
Thickness (covering)	190 µm	N/A
Sheath Compatibility	6-9 F	6-9 F
Premounted Profile	1.6-2.9 mm	1.6-3.5 mm

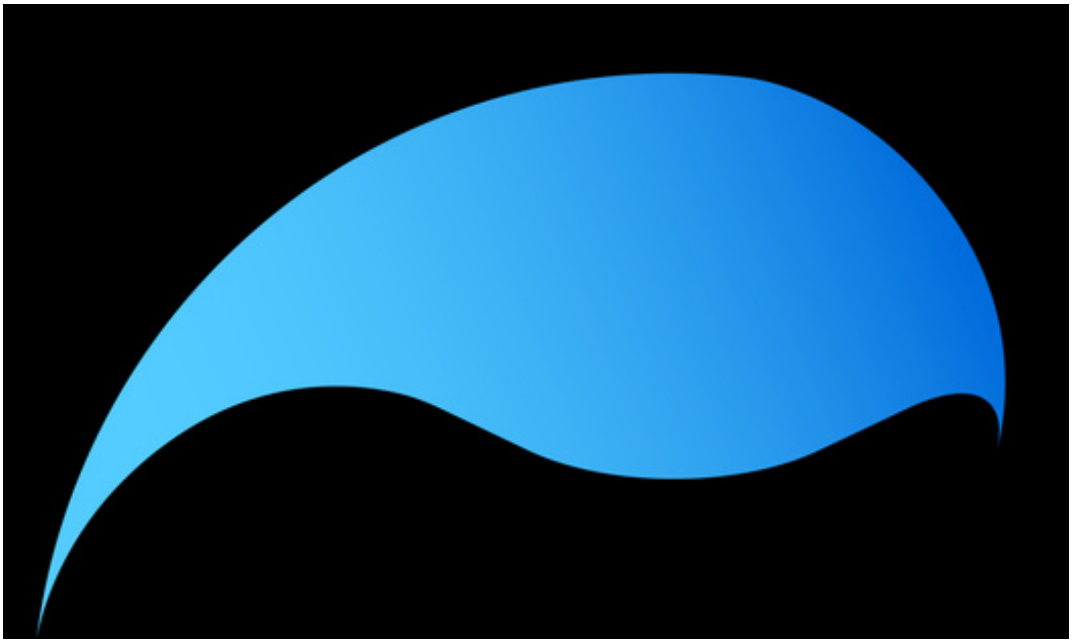
Characteristics	InSitu	Bently
Size Range (Ø, Length)	6 - 12 mm, 15 - 70 mm	5 – 10 mm, 16– 57 mm
Deployment Pressure	6-7 ATM	8-9 ATM
Rated Burst Pressure	15 atm (8 mm), 14 atm (9 mm), 13 atm (10 mm)	13 atm (5.0-7.0 mm) 12 atm (8-10 mm)
Covering	ePTFE	ePTFE
Thickness (covering)	190 µm	203 µm
Sheath Compatibility	6-9 F	6-8 F
Premounted Profile	1.6-2.9 mm	N/A











To speak with an InSitu team member about the Silene Peripheral Covered Stent or other devices from our portfolio of coronary and peripheral devices…

Contact sales@insitu-tech.com

or visit us at www.insitu-tech.com

Corporate Headquarters

For International Distribution

Caution: Federal USA law restricts these devices to sale distribution and use by or on the order of a physician

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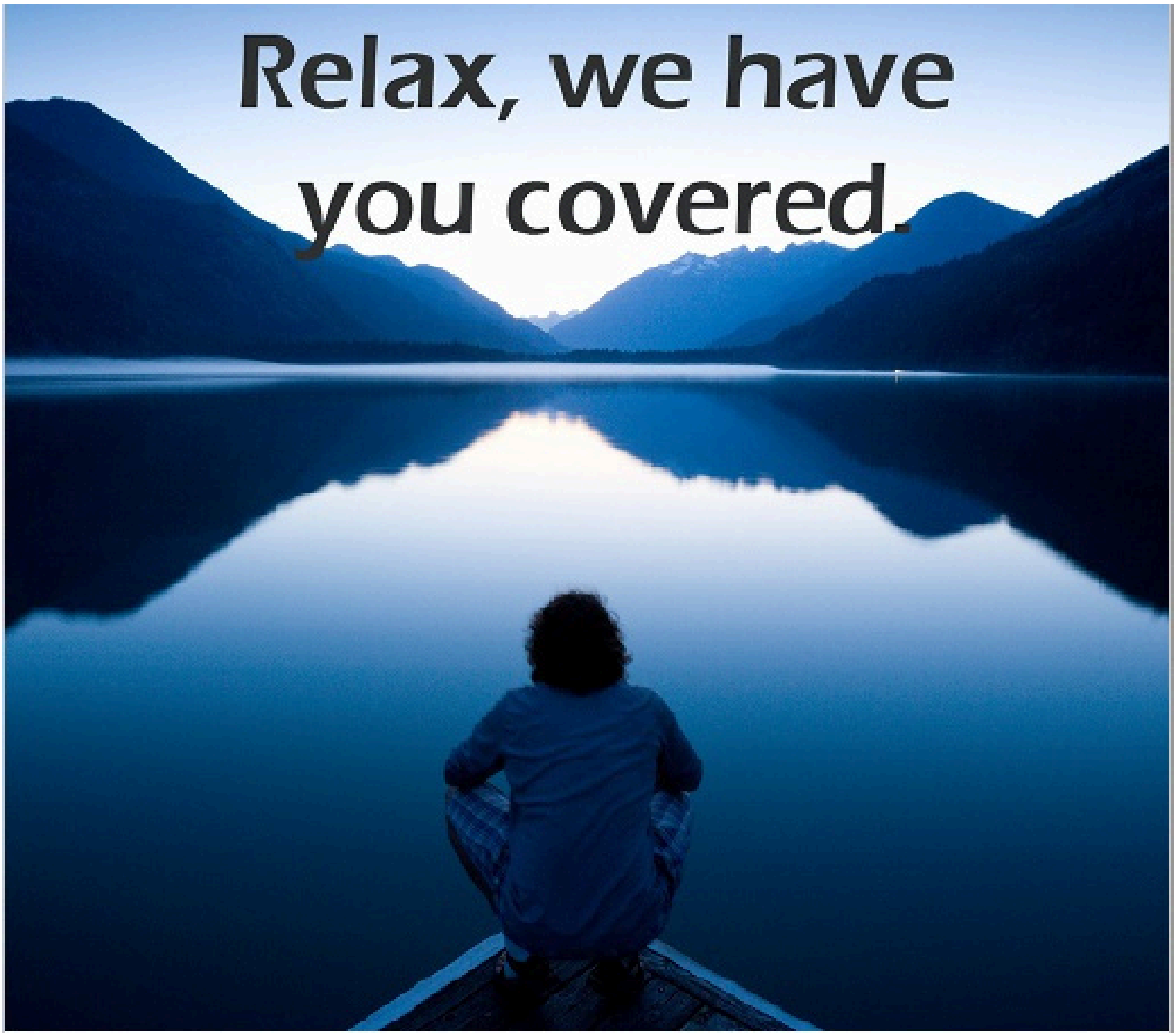
Relax, we have
you covered.

Not only do we offer a one-of-a-kind covered stent, we also have a full portfolio of coronary & peripheral devices.

www.insitu-tech.com call: 651-389-1017 email: sales@insitu-tech.com