

SeQuent[®] Please OTW

Drug Coating Balloon Technology for peripheral Angioplasty



Vascular Systems

SeQuent® Please OTW Paclitaxel - Releasing Balloon Catheter

The interventional approach to treat peripheral artery occlusive disease (PAOD) as a treatment of choice is gaining continuous acceptance. SeQuent® Please OTW offers a targeted, polymer-free and homogenous drug delivery which was enhanced for larger balloons sizes. This innovative product is the result of our sustained research and development for significant improvements in peripheral and coronary balloon angioplasty.



SeQuent® Please OTW

The next level in treating stenosis

B. Braun Matrix Coating Technology

Effective local drug delivery

The next level in treating peripheral stenoses

- ▶ More than 10 years experience and leadership in drug coated balloon angioplasty
- ▶ Outstanding coating technology for peripheral arteries
- ▶ Continued research and product development in interventional drug delivery approaches
- ▶ Clinical evidence showing positive vascular remodeling

Product features and benefits

- ▶ Single shot, short-term Paclitaxel delivery for long-term vessel therapy
- ▶ Targeted drug delivery into the vascular wall
- ▶ Homogeneous and complete polymer-free drug distribution
- ▶ No need for stent-in-stent procedures
- ▶ Unlimited treatment options when re-interventions are necessary

SeQuent[®] Please OTW Paclitaxel - Releasing Balloon Catheter

Mode of action



Pure Paclitaxel coating

A short single dose drug application is only possible if Paclitaxel is bioavailable on the balloon surface. Paclitaxel, if applied directly to the balloon surface, needs a matrix, which allows a reliable release and enables an immediate uptake into the vascular wall. If Paclitaxel is applied as a firm compound the required bioavailability is not given.



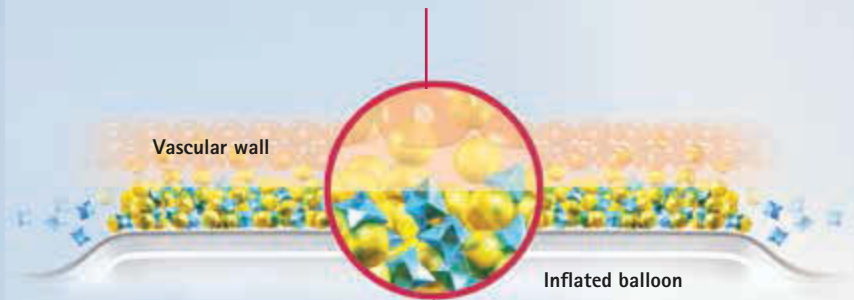
SeQuent[®] Please OTW with B. Braun Matrix Technology*

The SeQuent[®] Please OTW is a matrix coated peripheral over-the-wire balloon catheter with Paclitaxel as active agent. Based on the evidence of and leadership in B. Braun's coronary polymer-free coating technology a new B. Braun Matrix coating* was developed to treat PAOD.



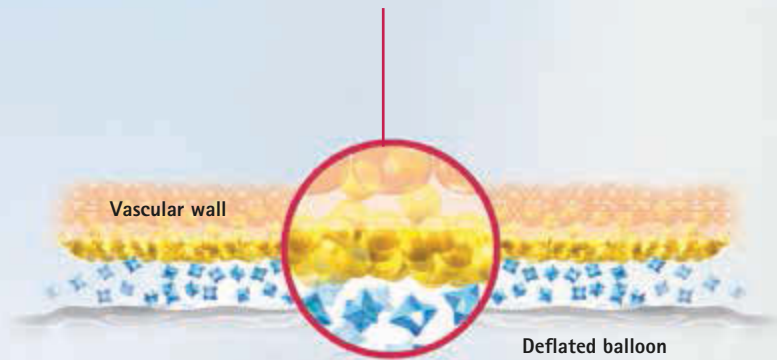
SeQuent[®] Please OTW

Combines targeted drug delivery with PTA balloon like flexibility and handling.



Balloon surface in contact with the vascular wall

At the minimum 30 second balloon inflation for effective drug delivery into the vascular wall.



Paclitaxel migrates into the vascular wall

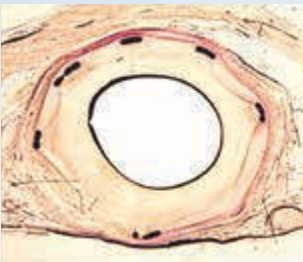
The matrix dissolves. Paclitaxel migrates into the SMC to prevent proliferation without any residues.

* Dispersion of Paclitaxel and Resveratrol

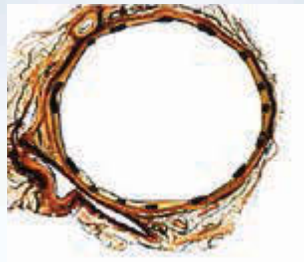
The B. Braun Matrix Coating Technology

Safe and effective local drug delivery

Histological evaluation of the explanted arteries 30 days after treatment



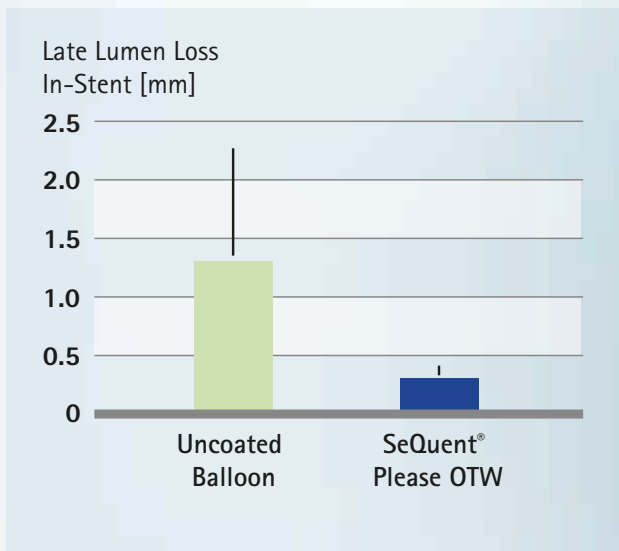
Uncoated balloon



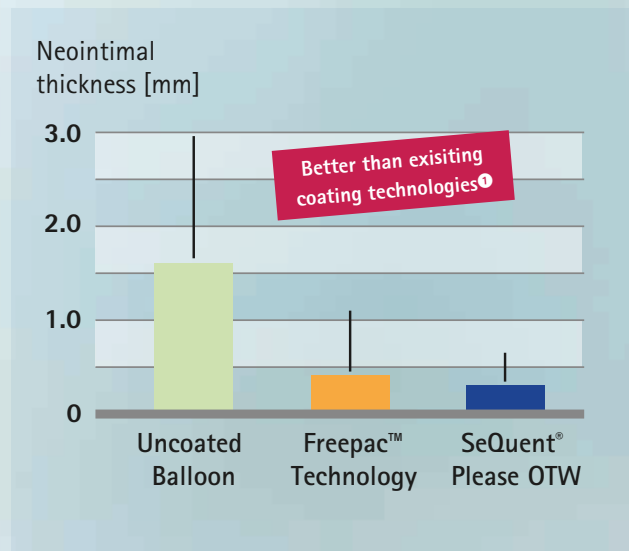
SeQuent® Please OTW

- ▶ Efficacious inhibition of neointimal proliferation (lumen narrowing)
- ▶ Complete vessel healing
- ▶ Complete endothelialization

Late Lumen Loss in-stent Porcine coronary arteries



Neointimal Thickness Porcine iliofemoral arteries

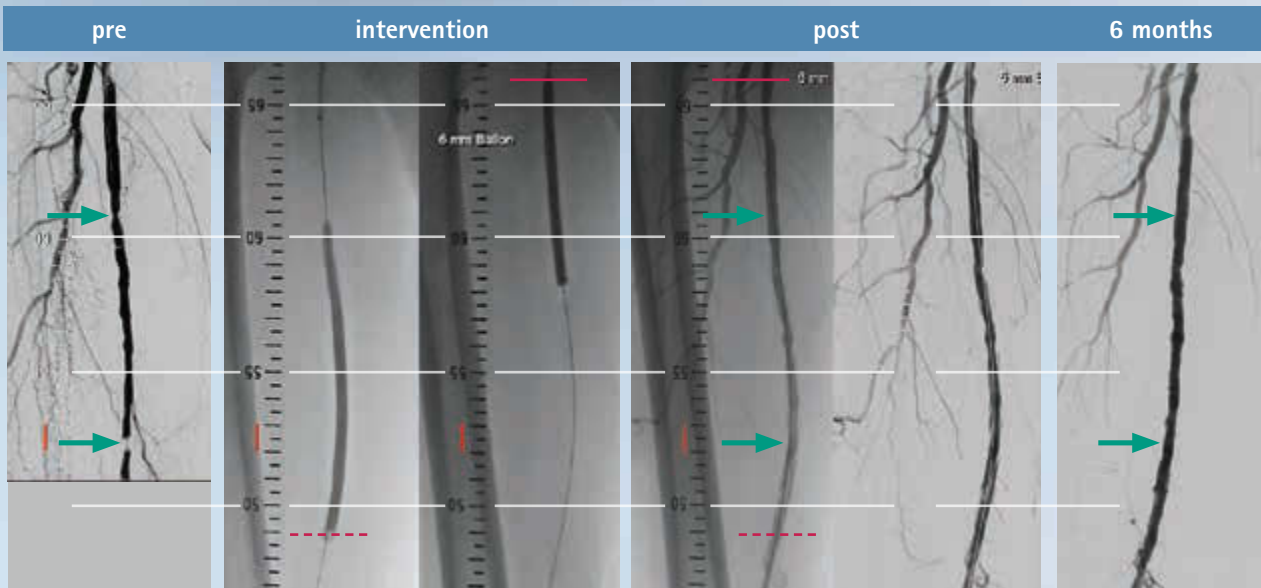


Excellent efficacy in inhibition of neointimal proliferation




SeQuent® Please OTW

Paclitaxel transfer to vessel wall

Intervention with two SeQuent Please OTW



Stenosis of the superficial femoral artery (SFA) treated with two SeQuent® Please OTW. Angiography before, directly and six months after intervention.

 Stenosis
 distal part of the balloon
 proximal part of the balloon

- ▶ Novel paclitaxel B. Braun Matrix coating
- ▶ Low profile tip and balloon design for reduced friction and advanced crossing performance
- ▶ Excellent pushability
- ▶ Homogeneous drug delivery
- ▶ Effectively inhibiting neointimal proliferation
- ▶ Several randomised trials (Thunder, Fempac, Pacifier) have demonstrated safety and efficacy of Paclitaxel coated balloons in peripheral arteries.^{2 3 4 5}



² Thunder: Tepe et al. N Engl J Med; 358; 689 - 99

³ Thunder, 5 year follow up: Tepe et al. J AM Coll Cardiol Intv. 2015; 8: 102 - 108

⁴ FEMPAC: Werk et al. Circulation 2008; 118: 1358 -1365

⁵ PACIFIER: Werk et al. Circ Cardiovasc Intv 2012; 5: 831 - 840

SeQuent[®] Please OTW Order Information

SeQuent[®] Please OTW 035

		Balloon Diameter (mm)	Balloon Length (mm)	Order Number
Shaft length	75 cm	4.0	40	35040040
Shaft lumen	0.035"	5.0	40	35150040
Sheath compatibility	5 F Balloon diam. 4.0 mm	6.0	40	35160040
		7.0	40	35170040
		8.0	40	35180040
		4.0	60	35140060
	6 F Balloon diam. 5.0 - 8.0 mm	5.0	60	35150060
		6.0	60	35160060
		7.0	60	35170060
		8.0	60	35180060
		4.0	80	35140080
		5.0	80	35150080
		6.0	80	35160080
		4.0	120	35140120
5.0	120	35150120		
6.0	120	35160120		
4.0	150	35140150		
5.0	150	35150150		
6.0	150	35160150		

SeQuent® Please OTW 035

		Balloon Diameter	Balloon Length	Order Number
Shaft length	130 cm	4.0	40	35340040
Shaft lumen	0.035"	5.0	40	35350040
Sheath compatibility	5 F Balloon diam. 4.0 mm	6.0	40	35360040*
	6 F Balloon diam. 5.0 - 6.0 mm	4.0	60	35340060
		5.0	60	35350060
		6.0	60	35360060*
		4.0	80	35340080
		5.0	80	35350080
		6.0	80	35360080*
		4.0	120	35340120
		5.0	120	35350120
		6.0	120	35360120*
		4.0	150	35340150
		5.0	150	35350150
		6.0	150	35360150*

* registration pending

SeQuent® Please OTW 014

		Balloon Diameter	Balloon Length	Order Number
Shaft length	130 cm	1.5	40	14215040
Shaft lumen	0.014"	2.0	40	14220040
Sheath compatibility	4 F Balloon diam. 1.5 - 3.0 mm	2.5	40	14225040
		3.0	40	14230040
		1.5	80	14215080
		2.0	80	14220080
		2.5	80	14225080
		3.0	80	14230080
		1.5	120	14215120
		2.0	120	14220120
		2.5	120	14225120
		3.0	120	14230120
		2.0	150	14220150
		2.5	150	14225150
		3.0	150	14230150

B. Braun Vascular Systems Interventional Radiology



SeQuent® Please OTW



VascuFlex Peripheral Stents



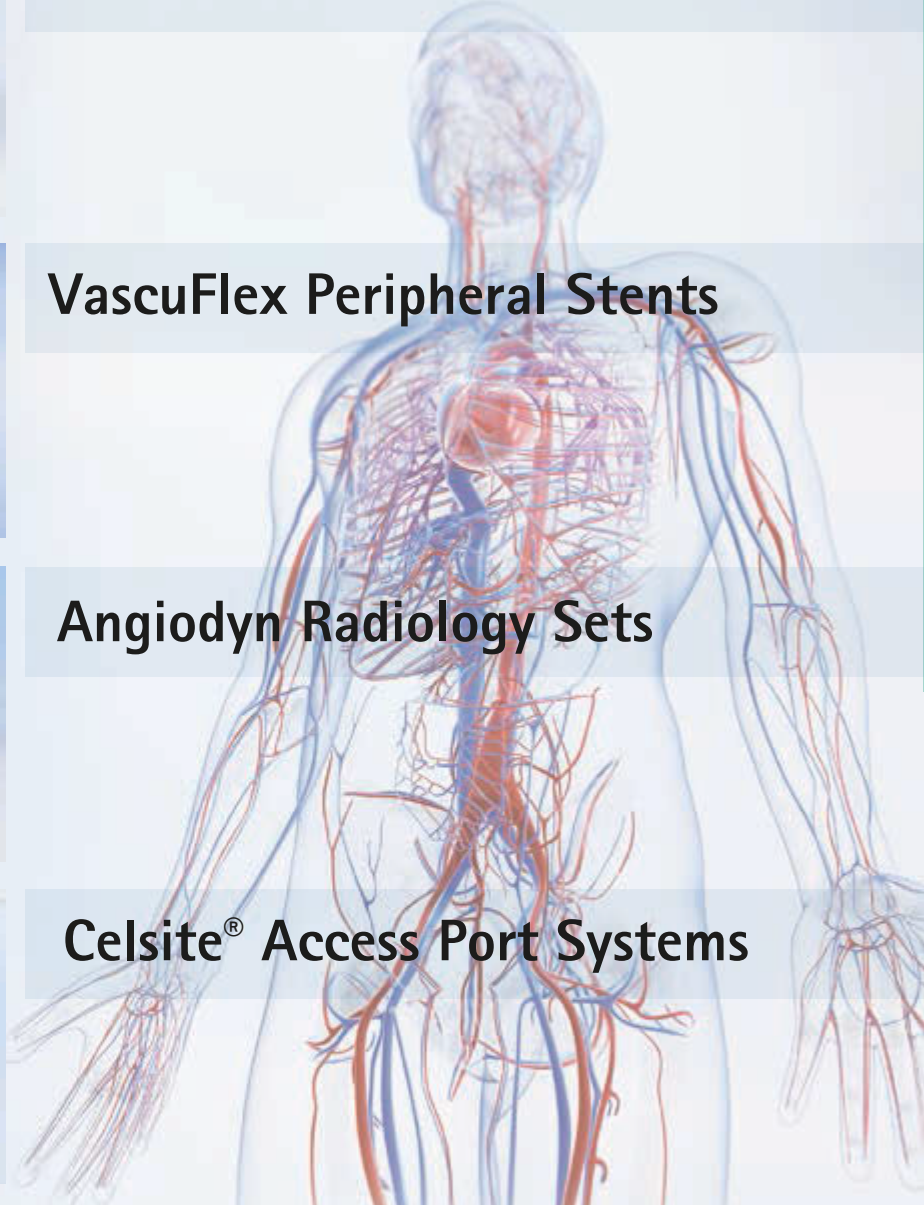
Angiodyn Radiology Sets



Celsite® Access Port Systems



VenaTech™ Vena Cava Filter



Distributor

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