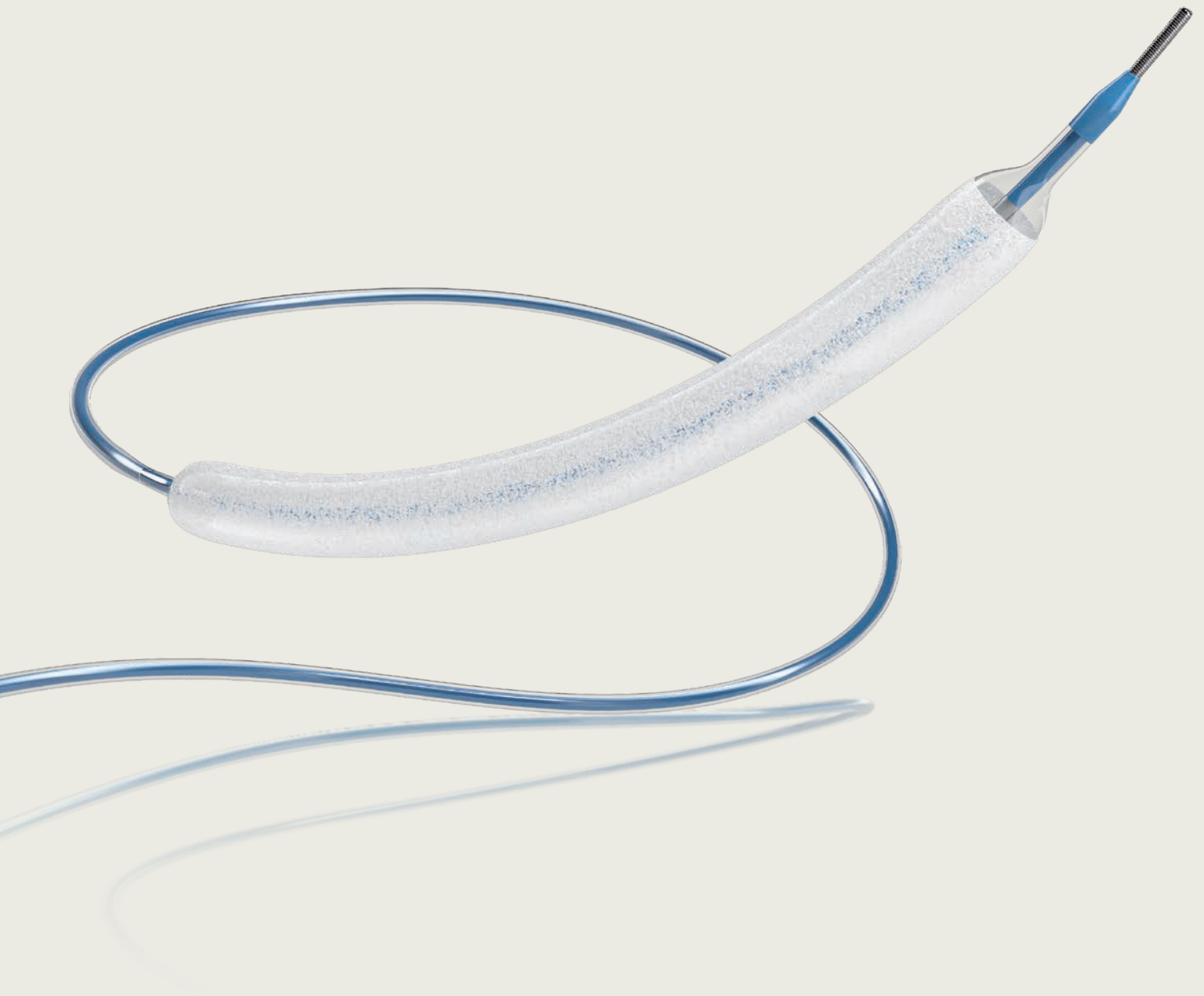


SeQuent® Please OTW 014 | 018 | 035

Peripheral Drug-Coated
Balloon Catheter



SeQuent® Please OTW

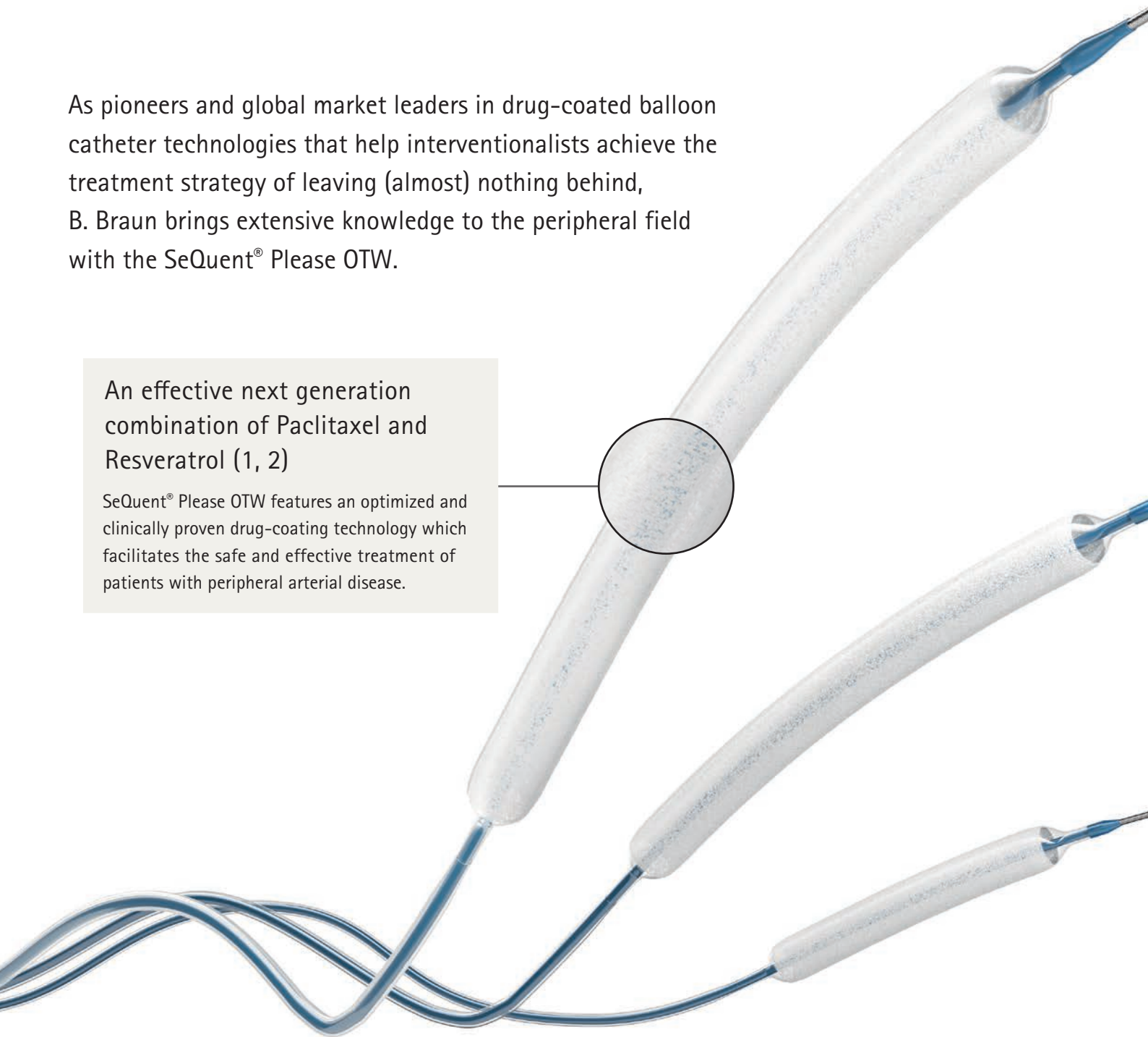
Peripheral Drug-Coated Balloon Catheter

Leave Nothing Behind

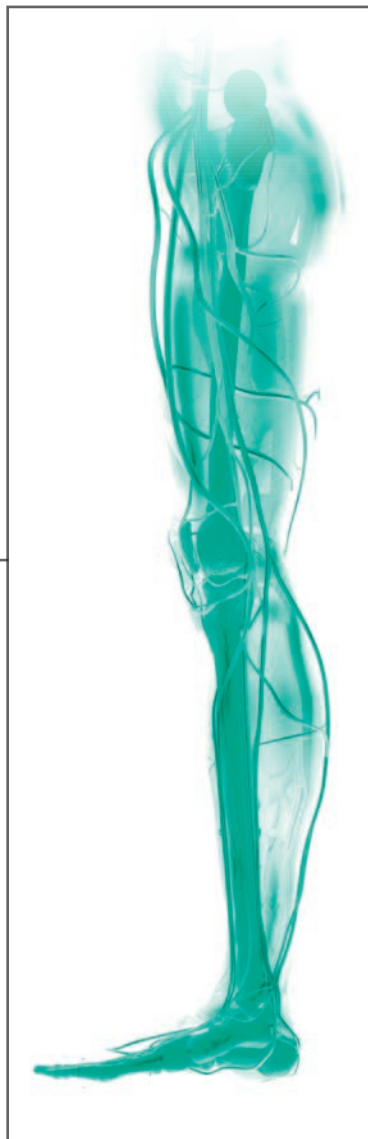
As pioneers and global market leaders in drug-coated balloon catheter technologies that help interventionalists achieve the treatment strategy of leaving (almost) nothing behind, B. Braun brings extensive knowledge to the peripheral field with the SeQuent® Please OTW.

An effective next generation combination of Paclitaxel and Resveratrol (1, 2)

SeQuent® Please OTW features an optimized and clinically proven drug-coating technology which facilitates the safe and effective treatment of patients with peripheral arterial disease.



For Above and Below the Knee



Long-term efficacy with short-term drug release (1, 2)

- Paclitaxel with an effective drug dose of $3\mu\text{g}/\text{mm}^2$ (3, 4)
- Significant reduction of TLR and in late lumen loss (LLL) compared to uncoated balloons (1, 2, 5)

Resveratrol: A naturally occurring matrix builder

- Naturally occurring, plant-based substance found for example in the skin of red grapes & raspberries (5)
- Acts as matrix builder and makes the Paclitaxel bioavailable (5)
- Enables fast and effective drug transfer into vessel wall (5)

Mechanically resistant coating (5)

- Homogeneous coating even in the balloon folds exceeding distal and proximal markers (5)
- Low drug loss in simulated use (5)
- Efficient available drug dose at inflation (1, 2, 5)

(1) Albrecht T et al. Cardiovasc Intervent Radiol. 2018 Jul;41(7):1008-14.

(2) Langhoff R et al. Angiology. 2021 Mar 29;3319721997314.

(3) Tepe G et al. N Engl J Med. 2008 Feb 14;358(7):689-99.

(4) Tepe G et al. Cardiovasc Intervent Radiol. 2017 Oct;40(10):1535-44.

(5) Data on file at B. Braun.

CONSEQUENT RCT and Registry

Clinical Evidence

CONSEQUENT Demonstrates Safety and Efficacy

Safety and efficacy of SeQuent® Please OTW was demonstrated in an unselected, all-comers cohort (2) whereas two-year efficacy and safety was shown in the CONSEQUENT RCT (1, 4).

CONSEQUENT All Comers Registry (2)

- 879 lesions in 784 consecutive patients
- De novo, ISR, ATK and BTK lesions
- Average lesion length: 12.0 ± 9.3 cm
- 53.3% claudicants, 46.7% CLI patients

	CLI (%)	Claudicants (%)
Primary endpoint		
TLR	6.3	9.6
Secondary endpoints		
Primary patency	89.9	87.1
TVR	10.6	11.0
Non-TVR	4.3	6.2
All-cause mortality*	7.0	2.0



CONSEQUENT RCT (4)

153 patients:

78 DCB vs. 75 POBA

Average lesion length:

13.2 cm \pm 10.4 cm

TASC C&D lesions:

23.5 %

Pre-procedure diameter stenosis:

76.6 % \pm 18.1 %

Pre-dilatation:

in only 55.6 %

Positive remodeling (LLL < 0 mm):

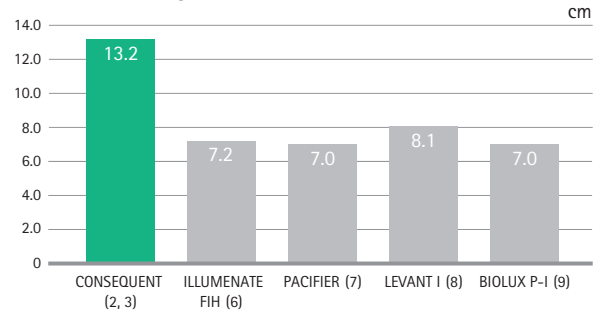
35.2 % in DCB group

Bailout stenting:

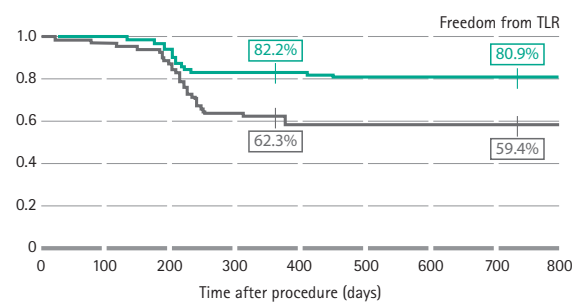
16.3 %

(comparable in both groups)

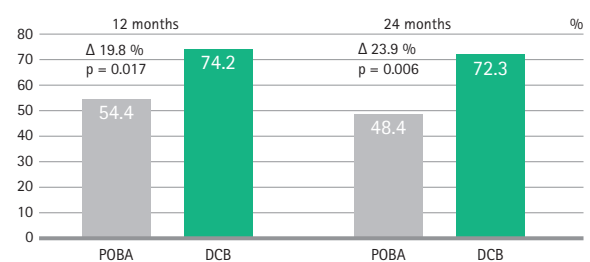
Mean lesion length



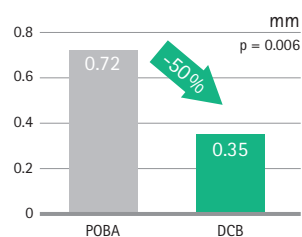
24-month Kaplan-Meier Curve (3)



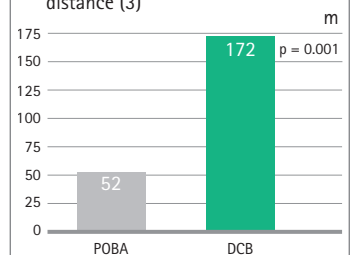
Primary Patency (2, 3)



6-month late lumen loss (LLL) (2)



24-month increase in walking distance (3)



(6) Schroeder H et al. Catheter Cardiovasc Interv. 2015 Aug;86(2):278-86.

(7) Werk M et al. Circ Cardiovasc Interv. 2012;5(6):831-840.

(8) Scheinert D et al. JACC Cardiovasc Interv. 2014;7(1):10-19.

(9) Zeller T et al. JACC Cardiovasc Interv. 2015;8(12):1614-1622.

SeQuent® Please OTW

Peripheral Drug-Coated Balloon Catheter

New

SeQuent® Please OTW 014

Shaft length 130 cm	Shaft length 150 cm	Balloon diameter (mm)	Balloon length (mm)	Introducer sheath (F)	Nominal pressure (atm)	Rated burst pressure (atm)
14215040*	–	1.5	40	4	6	16
14215080*	–	1.5	80	4	6	16
14215120*	–	1.5	120	4	6	16
14220040	14320040	2.0	40	4	6	16
14220080	14320080	2.0	80	4	6	15
14220120	14320120	2.0	120	4	6	15
14220150	14320150	2.0	150	4	6	15
14225040	14325040	2.5	40	4	6	16
14225080	14325080	2.5	80	4	6	15
14225120	14325120	2.5	120	4	6	15
14225150	14325150	2.5	150	4	6	15
14230040	–	3.0	40	4	6	15
14230080	–	3.0	80	4	6	15
14230120	–	3.0	120	4	6	15
14230150	–	3.0	150	4	6	15

SeQuent® Please OTW 035

Shaft length 75 cm	Shaft length 130 cm	Balloon diameter (mm)	Balloon length (mm)	Introducer sheath (F)	Nominal pressure (atm)	Rated burst pressure (atm)
35040040	35340040	4.0	40	5	6	16
35140060	35340060	4.0	60	5	6	16
35140080	35340080	4.0	80	5	6	15
35140120	35340120	4.0	120	5	6	15
35140150	35340150	4.0	150	5	6	15
35150040	35350040	5.0	40	6	6	14
35150060	35350060	5.0	60	6	6	14
35150080	35350080	5.0	80	6	6	13
35150120	35350120	5.0	120	6	6	13
35150150	35350150	5.0	150	6	6	13
35160040	35360040	6.0	40	6	6	13
35160060	35360060	6.0	60	6	6	13
35160080	35360080	6.0	80	6	6	12
35160120	35360120	6.0	120	6	6	12
35160150	35360150	6.0	150	6	6	12
35170040	–	7.0	40	6	6	12
35170060	–	7.0	60	6	6	12
35180040	–	8.0	40	6	6	12
35180060	–	8.0	60	6	6	12

* Upon request

New

SeQuent® Please OTW 018

Shaft length 75 cm	Shaft length 130 cm	Balloon diameter (mm)	Balloon length (mm)	Introducer sheath (F)	Nominal pressure (atm)	Rated burst pressure (atm)
–	18220040	2.0	40	4	6	16
–	18220080	2.0	80	4	6	15
–	18220120	2.0	120	4	6	15
–	18220150	2.0	150	4	6	15
–	18225040	2.5	40	4	6	16
–	18225080	2.5	80	4	6	15
–	18225120	2.5	120	4	6	15
–	18225150	2.5	150	4	6	15
–	18230040	3.0	40	4	6	16
–	18230080	3.0	80	4	6	15
–	18230120	3.0	120	4	6	15
–	18230150	3.0	150	4	6	15
18135040	18235040	3.5	40	4	6	16
18135080	18235080	3.5	80	4	6	15
18135120	18235120	3.5	120	4	6	15
18135150*	18235150*	3.5	150	4	6	15
18140040	18240040	4.0	40	4	6	16
18140060	18240060	4.0	60	4	6	16
18140080	18240080	4.0	80	4	6	15
18140120	18240120	4.0	120	4	6	15
18140150	18240150	4.0	150	4	6	15
18150040	18250040	5.0	40	5	6	14
18150060	18250060	5.0	60	5	6	14
18150080	18250080	5.0	80	5	6	13
18150120	18250120	5.0	120	5	6	13
18150150	18250150	5.0	150	5	6	13
18160040	18260040	6.0	40	5	6	14
18160060	18260060	6.0	60	5	6	14
18160080	18260080	6.0	80	5	6	12
18160120	18260120	6.0	120	5	6	12
18160150	18260150	6.0	150	5	6	12
18170040	–	7.0	40	5	6	12
18170060	–	7.0	60	5	6	12
18180040	–	8.0	40	5	6	12
18180060	–	8.0	60	5	6	12

Technical specifications

Shaft profile	SP OTW 035: 4.9F – 5.4F SP OTW 018: 3.6F – 4.2F SP OTW 014: 3.2F – 3.6F	Coating (drug)	Paclitaxel (concentration 3 µg/mm ²)
		Coating (excipient)	Resveratrol (naturally occurring substance)
Lesion entry profile	SP OTW 035: 0.041" – 0.051" SP OTW 018: 0.021" – 0.032" SP OTW 014: 0.018"	Radiopaque markers	2 markers (Platinum/Iridium), proximal and distal

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