



SeQuent® Please Neo

Clinically Proven Drug Coated
Balloon Catheter

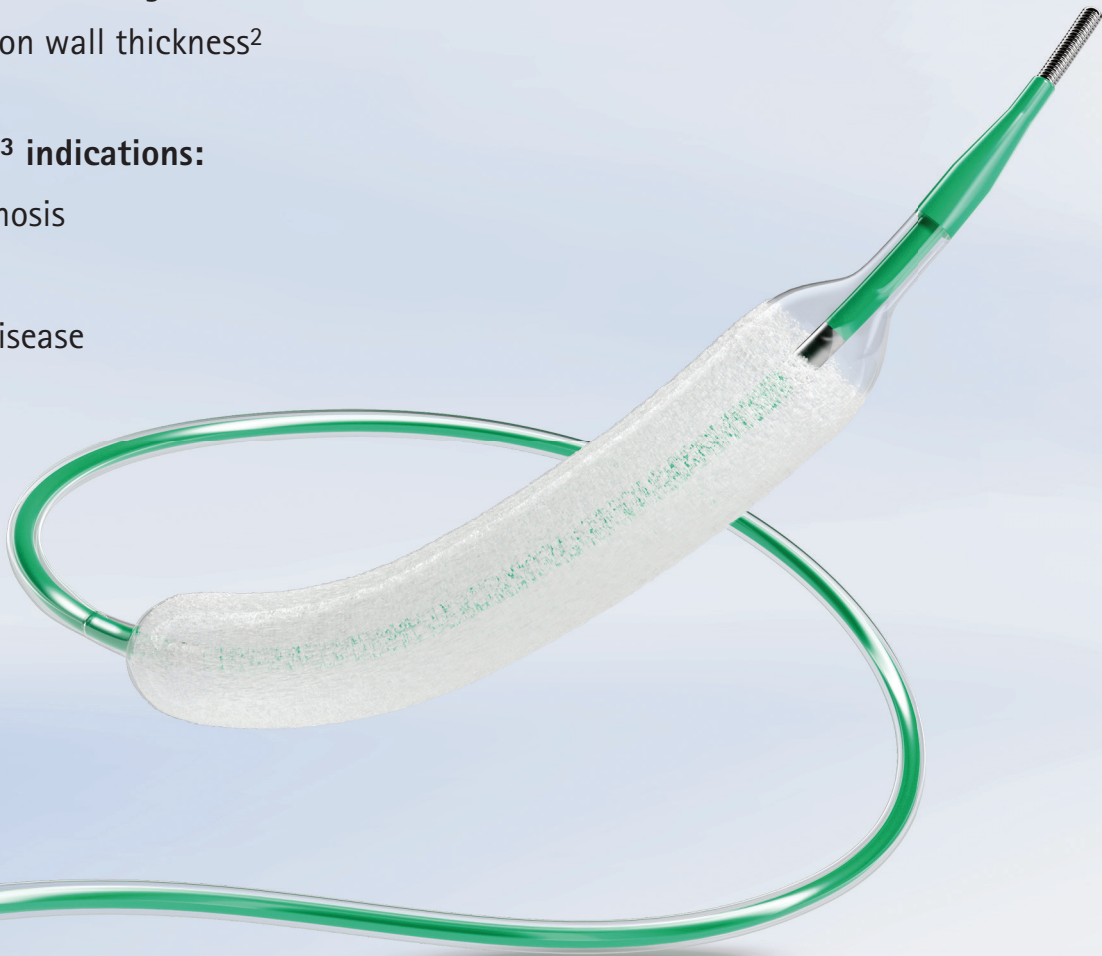
THE SECOND GENERATION DCB

Outstanding performance¹:

- Advanced crossing properties
- Improved pushability
- Hydrophilic shaft coating
- Reduced balloon wall thickness²

Clinically proven³ indications:

- In-stent restenosis
- De novo
- Small vessel disease
- Bifurcations



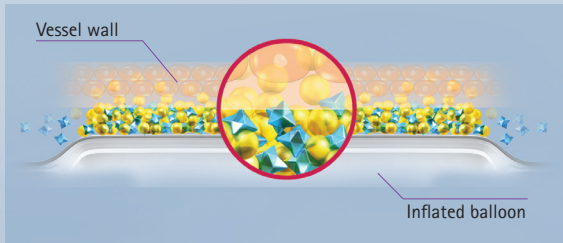
OVER 28 CLINICAL TRIALS WITH OVER 5,900 ENROLLED PATIENTS

IMPLANT-FREE WITH SeQuent® Please NEO

No stent-related complications and only **1-month DAPT** for the treatment with DCB-only

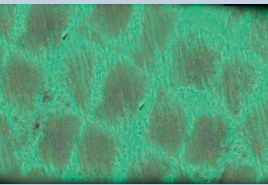
Clinically proven Paclitaxel & Iopromide coating¹⁻⁴

The matrix coating of Paclitaxel and Iopromide ensures the effective drug release into the vessel wall.



Homogenous drug delivery¹⁻⁴

Only a "single shot" drug delivery with SeQuent® Please NEO is needed to ensure a sustained anti-proliferative effect. A short inflation time of only 30 seconds proved to be sufficient to inhibit cell proliferation.²



Stent struts of a DES lead to an inhomogenous drug distribution pattern. About 85 % of the vascular wall is not covered by the struts resulting in low drug tissue level.¹

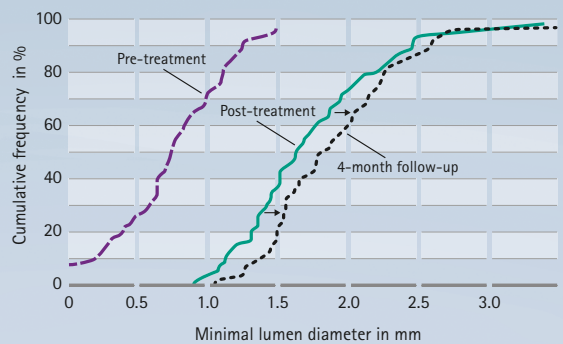


Homogenous drug distribution with SeQuent® Please NEO.³

PROVEN LATE LUMEN ENLARGEMENT

SeQuent® Please NEO supports the inherent mechanism of natural vessel restoration and leads to late lumen enlargement

Clinical trial to study late lumen enlargement of de novo lesions after DCB-only⁵



Angiographic Measure	Minimal Lumen Diameter in mm
Pre-treatment	0.81 ± 0.47
Post-treatment	1.75 ± 0.58
4-month follow-up	1.91 ± 0.55
p-value pre vs. post	< 0.001
p-value post vs. 4-month follow-up	< 0.001

Late lumen enlargement after 4 months
+ 0.16 mm

¹ Data on file J. Wamser, AE-RA-DE03 & T. Saeger, AE-TE-DE03
² Data on file. Compared to SeQuent® Please
³ See instructions for use

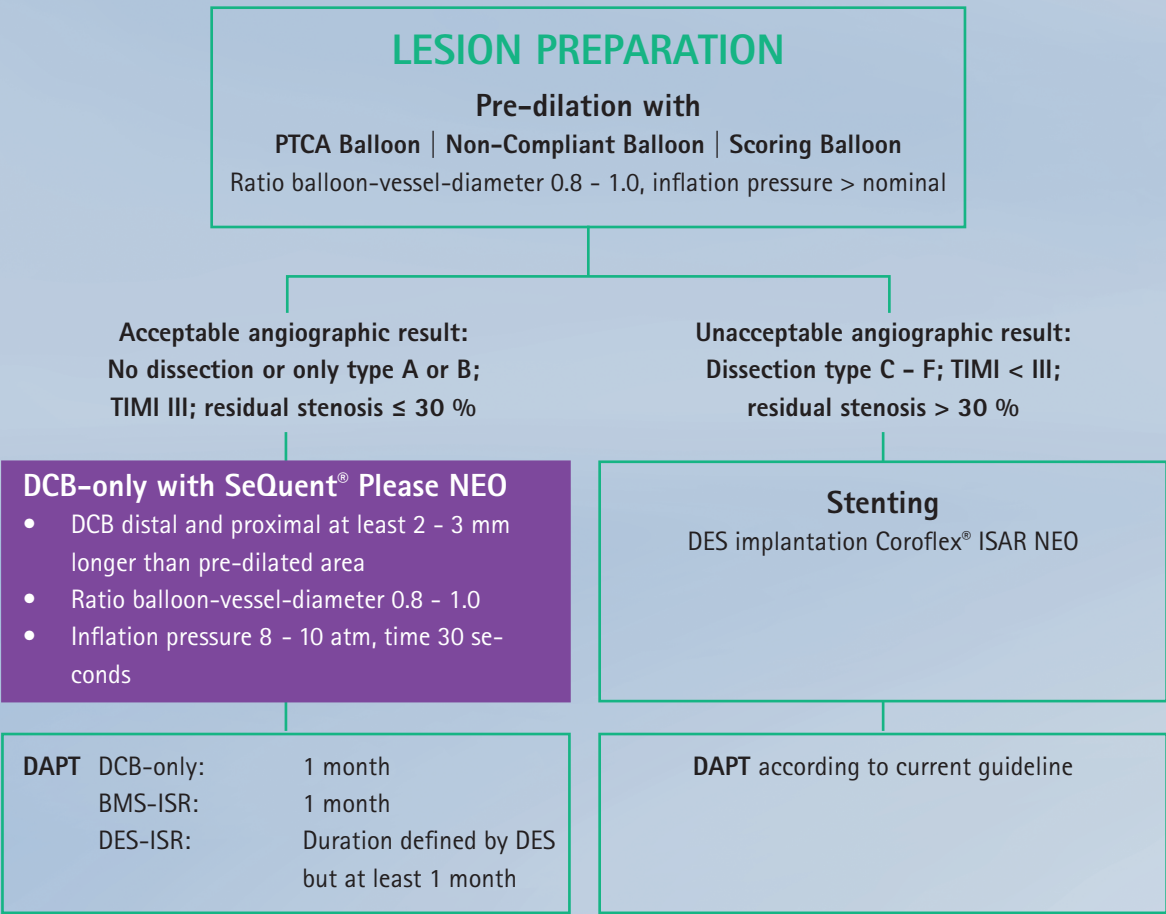
¹ Axel, Dorothea I., et al. "Paclitaxel inhibits arterial smooth muscle cell proliferation and migration in vitro and in vivo using local drug delivery." Circulation 96.2 (1997): 636-645.
² Scheller B, Speck U, Abramjuk C, Bernhardt U, Böhm M, Nickenig G. Paclitaxel balloon coating, a novel method for prevention and therapy of restenosis. Circulation. 2004;110(7):810-814
³ Scheller, Bruno, et al. "Paclitaxel balloon coating, a novel method for prevention and therapy of restenosis." Circulation 110.7 (2004): 810-814.
⁴ Scheller, Bruno, Ulrich Speck, and Michael Böhm. "Prevention of restenosis: is angioplasty the answer?." Heart 93.5 (2007): 539.
⁵ Kleber FX, Schulz A, Waliszewski M, et al. Local paclitaxel induces late lumen enlargement in coronary arteries after balloon angioplasty. Clin Res Cardiol. 2015;104(3):217-225.

ADVANTAGES OF DCB-ONLY

- Efficacy of DCB⁶
- Enable positive remodeling
 - Keep natural vessel vasomotion
 - Only 1-month DAPT: Cost efficacy studies ongoing

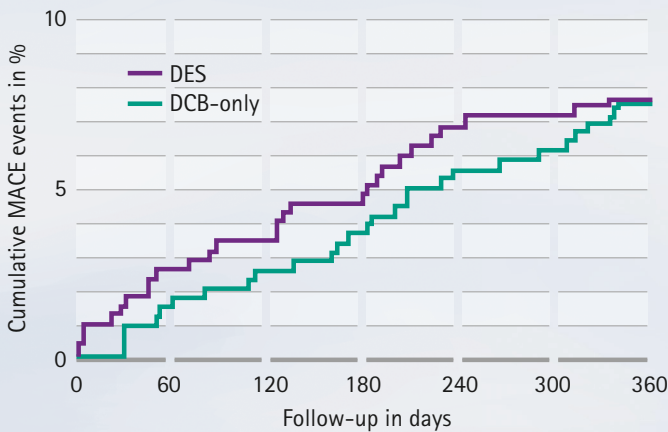
DCB-only provides the standard of care for all patients with high bleeding risks and atrial fibrillation⁶

METHODOLOGY⁷



GO IMPLANT-FREE

BASKET-SMALL 2: Randomized clinical trial for DCB-only vs. DES in de novo lesions (small vessel disease)⁸

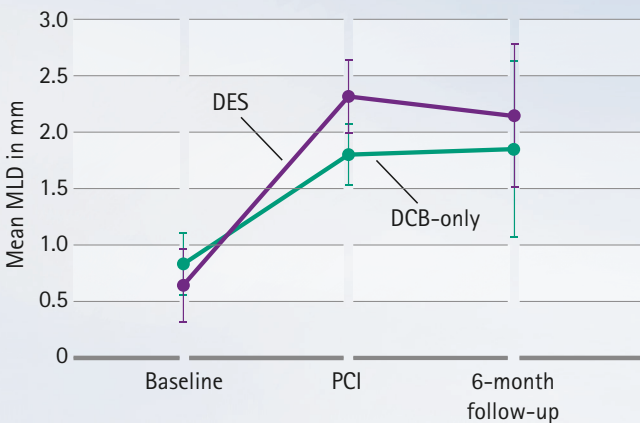


Primary endpoint: MACE at 12-month follow-up in %

DES (Xience/ Taxus® Element™)	7.54
DCB-only (SeQuent® Please NEO)	7.57
p-value	0.92

DCB-only is non-inferior to DES in de novo lesions up to 3 mm

OCTOPUS II: Clinical trial using OCT to evaluate the use of DCB without stenting in de novo lesions⁹



Primary endpoint: Late Lumen Loss at 6-month follow-up in mm

DES (Xience) ¹⁰	0.16 ± 0.15
DCB-only (SeQuent® Please)	-0.13 ± 0.44
p-value	< 0.05

DCB-only achieves long-term late lumen gain contrary to DES

⁶ Valgimigli, Marco et al. "2017 ESC focused update on dual antiplatelet therapy in coronary artery disease developed in collaboration with EACTS: The Task Force for dual antiplatelet therapy in coronary artery disease of the European Society of Cardiology (ESC) and of the European Association for Cardio-Thoracic Surgery (EACTS)." European heart journal vol. 39,3 (2018): 213-260

⁷ Kleber FX, Rittger H, Bonaventura K, et al. Drug-coated balloons for treatment of coronary artery disease: updated recommendations from a consensus group. Clin Res Cardiol. 2013;102(11):785-797

⁸ Jeger, Raban V., et al. "Drug-coated balloons for small coronary artery disease (BASKET-SMALL 2): an open-label randomised non-inferiority trial." The Lancet 392.10150 (2018): 849-856.

⁹ Poerner, Tudor C., et al. "Fractional flow reserve-guided coronary angioplasty using paclitaxel-coated balloons without stent implantation: feasibility, safety and 6-month results by angiography and optical coherence tomography." Clinical Research in Cardiology 106 (2017): 18-27.

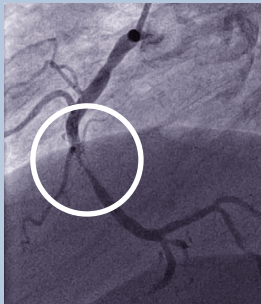
¹⁰ Poerner TC, Otto S, Gassdorf J, et al. Stent coverage and neointimal proliferation in bare metal stents postdilated with a Paclitaxel-eluting balloon versus everolimus-eluting stents: prospective randomized study using optical coherence tomography at 6-month follow-up. Circ Cardiovasc Interv. 2014;7(6):760-767

SeQuent® Please NEO

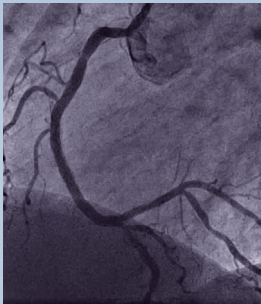
CLINICALLY PROVEN INDICATIONS

IN-STENT RESTENOSIS

Patient: Male, 55 years
Indication: ISR of BMS (3.5 x 15 mm) implanted 2 years ago
Procedure: Pre-dilation 3.5 x 15 mm PTCA balloon
DCB-only SeQuent® Please (3.5 x 20 mm) proximal lesion
DCB-only SeQuent® Please (3.5 x 15 mm) distal lesion



Pre-treatment



Post-treatment



4-month follow-up

Drug coated balloons are recommended for the treatment of in-stent restenosis (BMS or DES) by the ESC Guidelines⁵

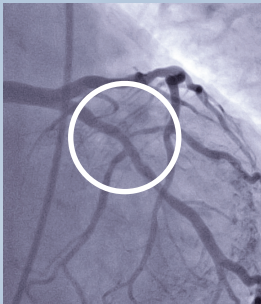
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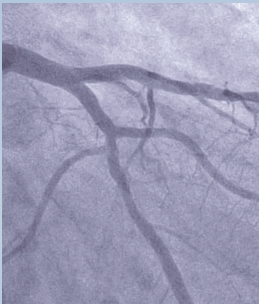
Patient: Female, 67 years
Indication: De novo stenosis of obtuse marginal branch
Procedure: Pre-dilation 2.5 x 15 mm PTCA balloon
DCB-only SeQuent® Please (2.5 x 20 mm)



Pre-treatment



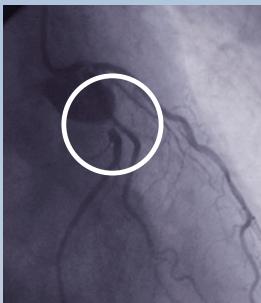
Post-treatment



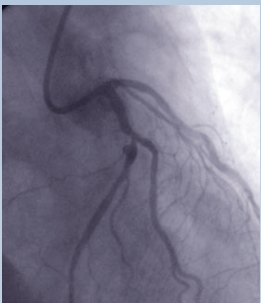
4-month follow-up

BIFURCATION

Patient: Male, 54 years
Indication: Stenoses of mid circumflex artery (CX) and its posterolateral branch (PL-CX)
Procedure: Pre-dilation 2.5 x 20 mm PTCA balloon of CX
DCB-only SeQuent® Please (3.0 x 15 mm) of PL-CX
DCB-only SeQuent® Please (3.0 x 20 mm) of CX



Pre-treatment



Post-treatment

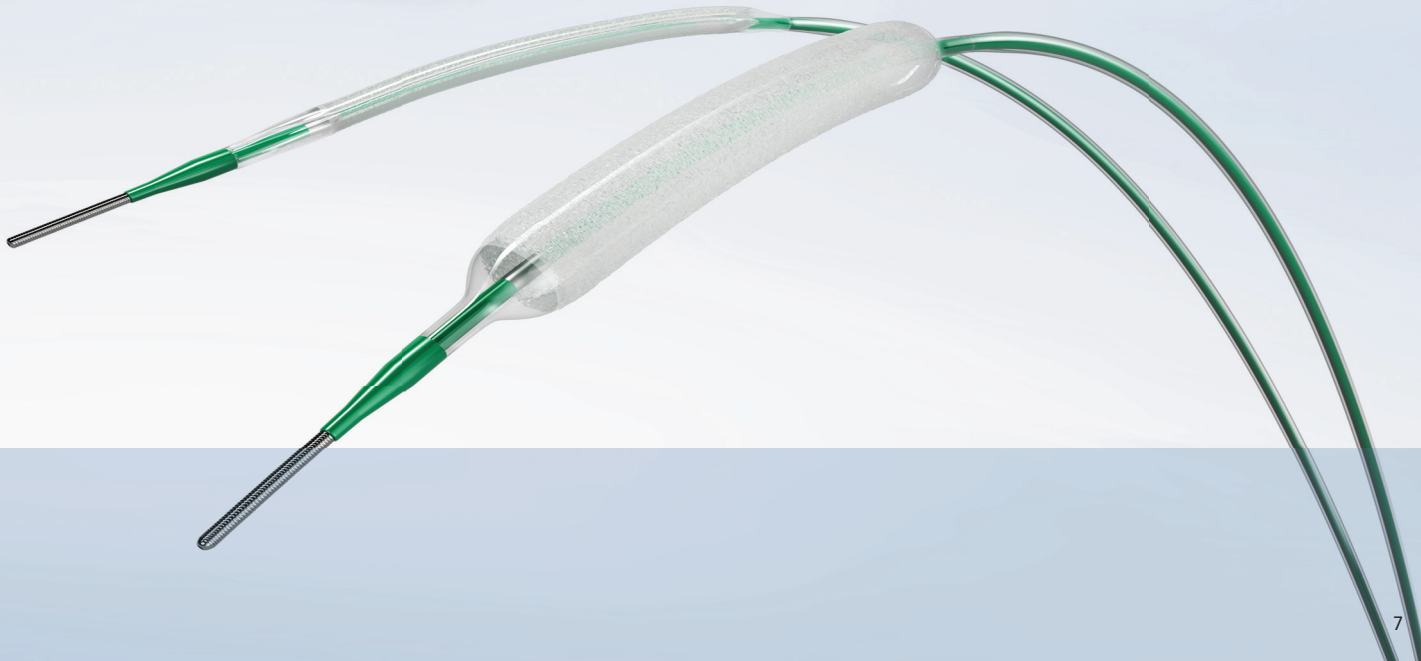


4-month follow-up

Windecker S, Kolh P, et al. 2014 ESC/EACTS Guidelines on myocardial revascularization: The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J. 2014;35(37):2541-2619

Balloon Diameter	Balloon Length						Nominal Pressure	Rated Burst Pressure
	15 mm	20 mm	25 mm	30 mm	35 mm	40 mm		
2.0 mm	5023210	5023220	5023230	5023240	5023250	5023260	6 atm	14 atm
2.5 mm	5023212	5023222	5023232	5023242	5023252	5023262	6 atm	14 atm
3.0 mm	5023214	5023224	5023234	5023244	5023254	5023264	6 atm	14 atm
3.5 mm	5023216	5023226	5023236	5023246	5023256	5023266	6 atm	14 atm
4.0 mm	5023217	5023227	5023237	5023247	5023257	5023267	6 atm	14 atm

Technical Data	
Proximal shaft	1.9 F
Distal shaft	2.5 F
Usable length	145 cm
Balloon crossing profile	0.033" - 0.037"
Lesion entry profile	0.016"
Guiding catheter compatibility	5 F standard guiding catheter
Guidewire compatibility	0.014"
Rated burst pressure [RBP]	14 atm
Nominal pressure [NP]	6 atm



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