SeQuent® Please NEO

Clinically Proven Drug Coated Balloon Catheter

B|BRAUN
SHARING EXPERTISE

SeQuent® Please NEO

CUTTING-EDGE DRUG COATED BALLOON CATHETER

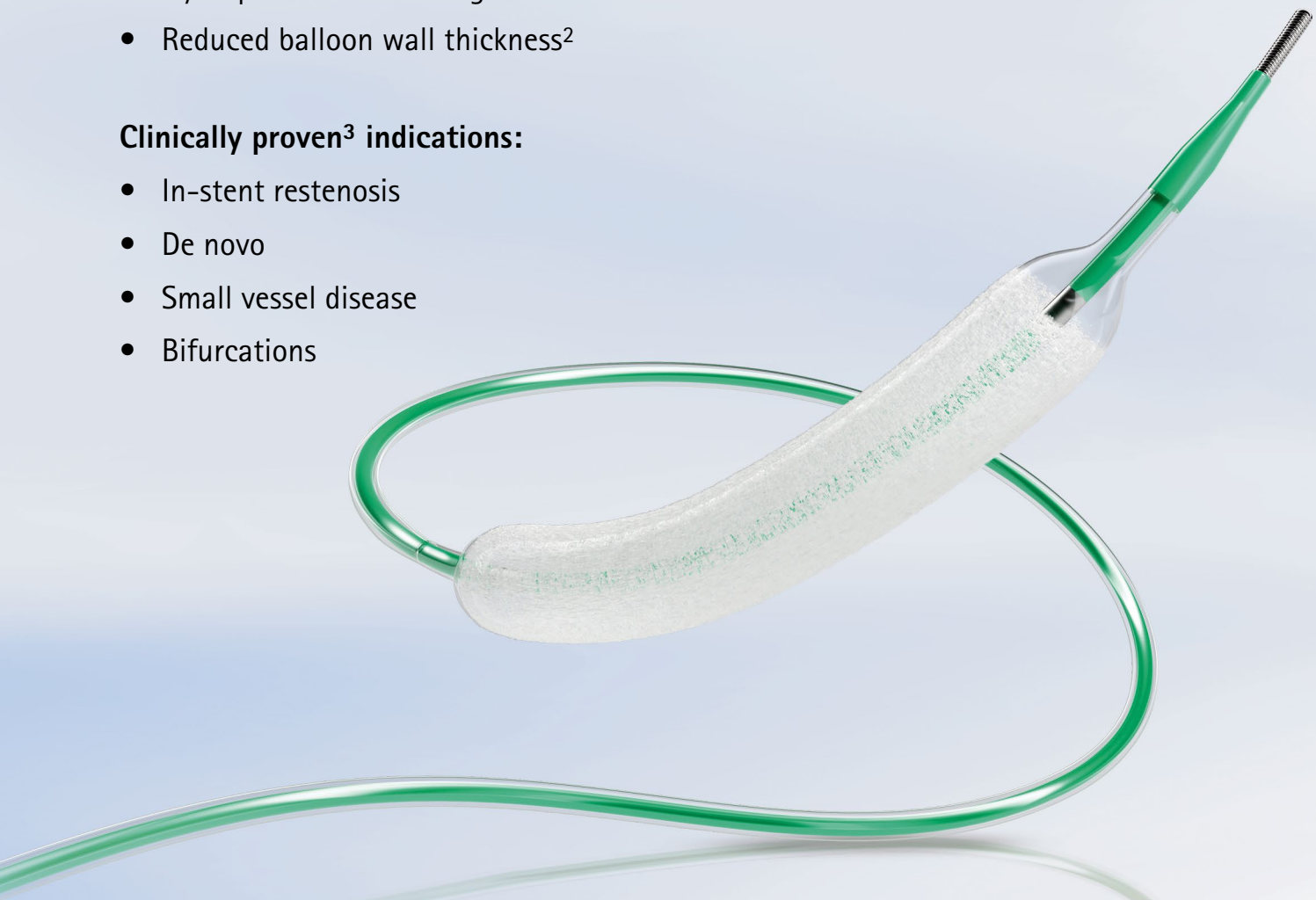
THE SECOND GENERATION DCB

Outstanding performance[1]:

- Advanced crossing properties
- Improved pushability
- Hydrophilic shaft coating
- Reduced balloon wall thickness[2]

Clinically proven[3] indications:

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



OVER 28 CLINICAL TRIALS WITH OVER 5,900 ENROLLED PATIENTS

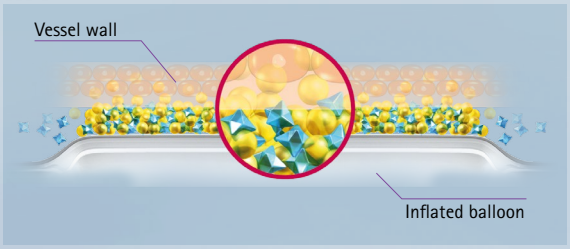
[1] Data on file J. Wamser, AE-RA-DE03 & T. Saeger, AE-TE-DE03
[2] Data on file. Compared to SeQuent® Please
[3] See instructions for use

IMPLANT-FREE WITH SeQuent® Please NEO

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

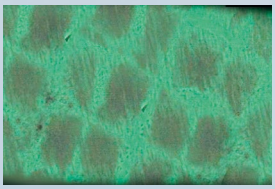
Clinically proven Paclitaxel & Iopromide coating[1-4]

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



Homogenous drug delivery[1-4]

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]



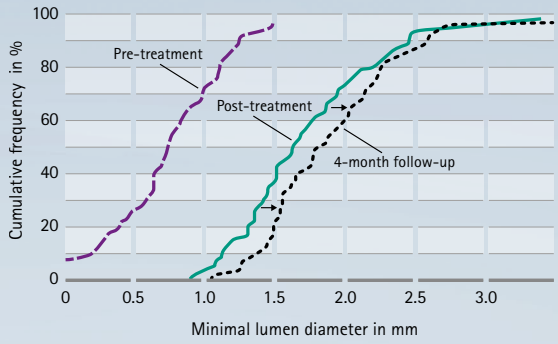
Stent struts of a DES lead to an inhomogenous drug distribution pattern. About 85 % of the vascular wall is not covered by the struts resulting in low drug tissue level.[1]

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-only[5]



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] 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.

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DCB-ONLY TREATMENT

ADVANTAGES OF DCB-ONLY

Efficacy of DCB[6]

- **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 fibrillation[6]

METHODOLOGY[7]

LESION PREPARATION

Pre-dilation with

PTCA Balloon | Non-Compliant Balloon | Scoring Balloon

Ratio balloon-vessel-diameter 0.8 - 1.0, inflation pressure > nominal

Acceptable angiographic result:
No dissection or only type A or B;
TIMI III; residual stenosis ≤ 30 %

DCB-only with SeQuent® Please NEO

- DCB distal and proximal at least 2 - 3 mm longer than pre-dilated area
- Ratio balloon-vessel-diameter 0.8 - 1.0
- Inflation pressure 8 - 10 atm, time 30 seconds

DAPT DCB-only: 1 month
BMS-ISR: 1 month
DES-ISR: Duration defined by DES but at least 1 month

Unacceptable angiographic result:
Dissection type C – F; TIMI < III;
residual stenosis > 30 %

Stenting

DES implantation Coroflex® ISAR NEO

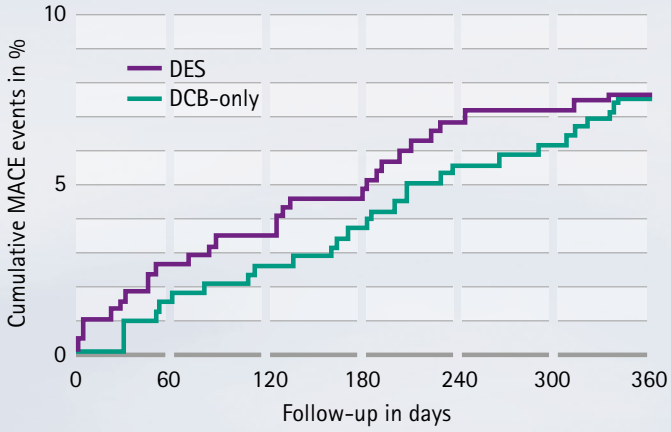
DAPT according to current guideline

[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

GO IMPLANT-FREE

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

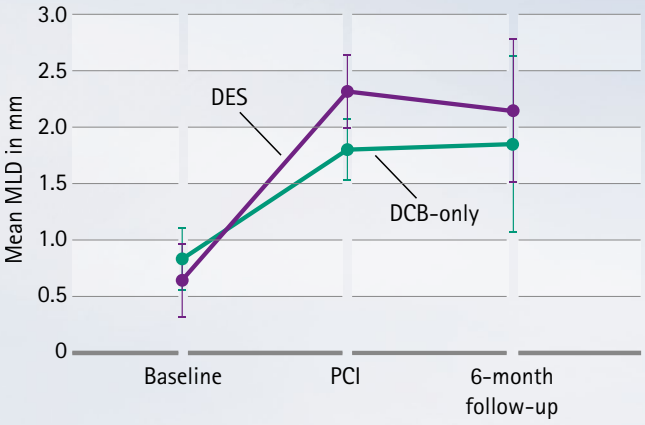


Primary endpoint: MACE at 12-month follow-up in %

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 lesions[9]



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

[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

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CLINICALLY PROVEN INDICATIONS

IN-STENT RESTENOSIS

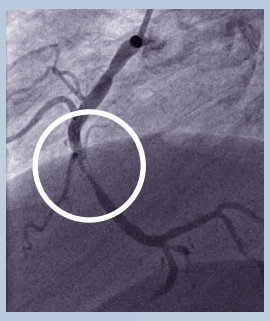
Patient: Male, 55 years

Indication: ISR of BMS (3.5 x 15 mm) implanted 2 years ago

Procedure: Pre-dilation 3.5 x 15 mm PTCA balloon

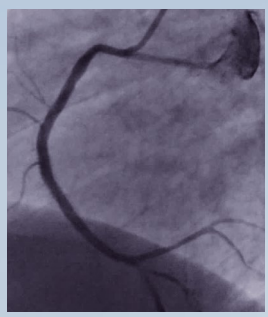
DCB-only SeQuent® Please (3.5 x 20 mm) proximal lesion

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 Guidelines[5]	I	A	507-511,524

DE NOVO LESION

Patient: Female, 67 years

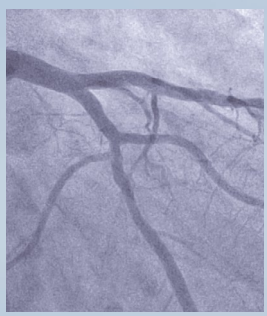
Indication: De novo stenosis of obtuse marginal branch

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

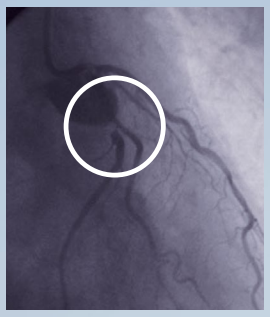
Patient: Male, 54 years

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

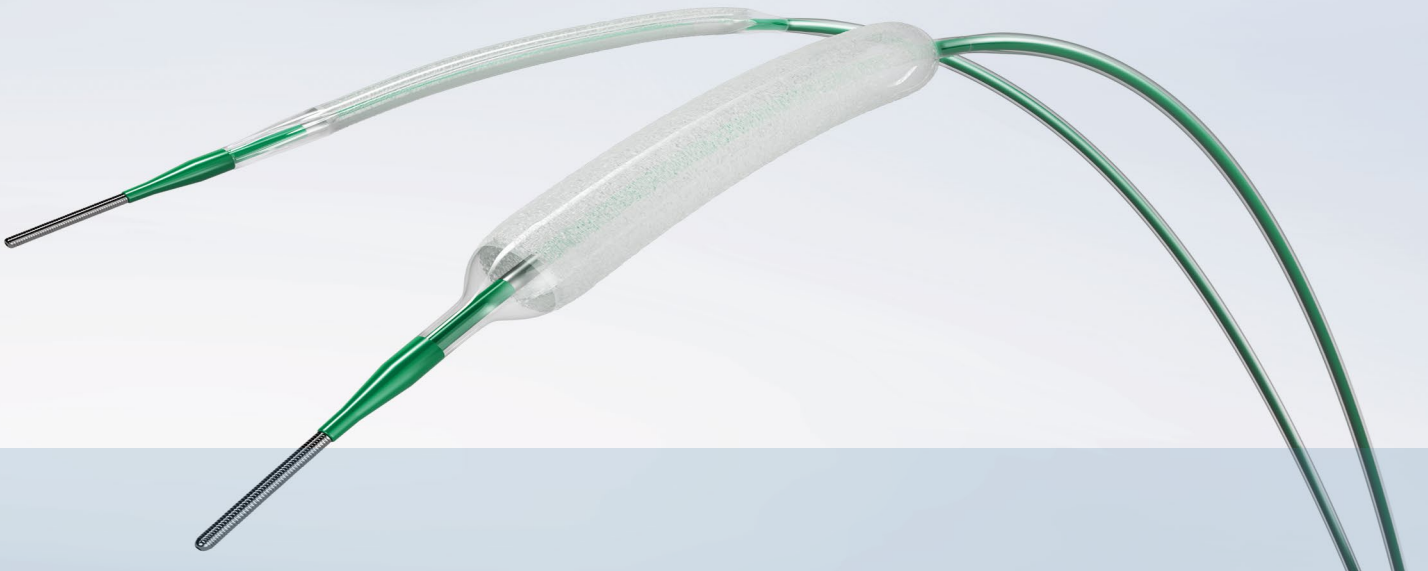
Post-treatment

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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