B BRAUN
SHARING EXPERTISE

INTERVENTIONAL
VASCULAR
DIAGNOSTICS
AND THERAPY

SeQuent® Please NEO

CLINICALLY PROVEN DRUG COATED BALLOON CATHETER

SeQuent® Please NEO

CUTTING-EDGE DRUG COATED BALLOON CATHETER

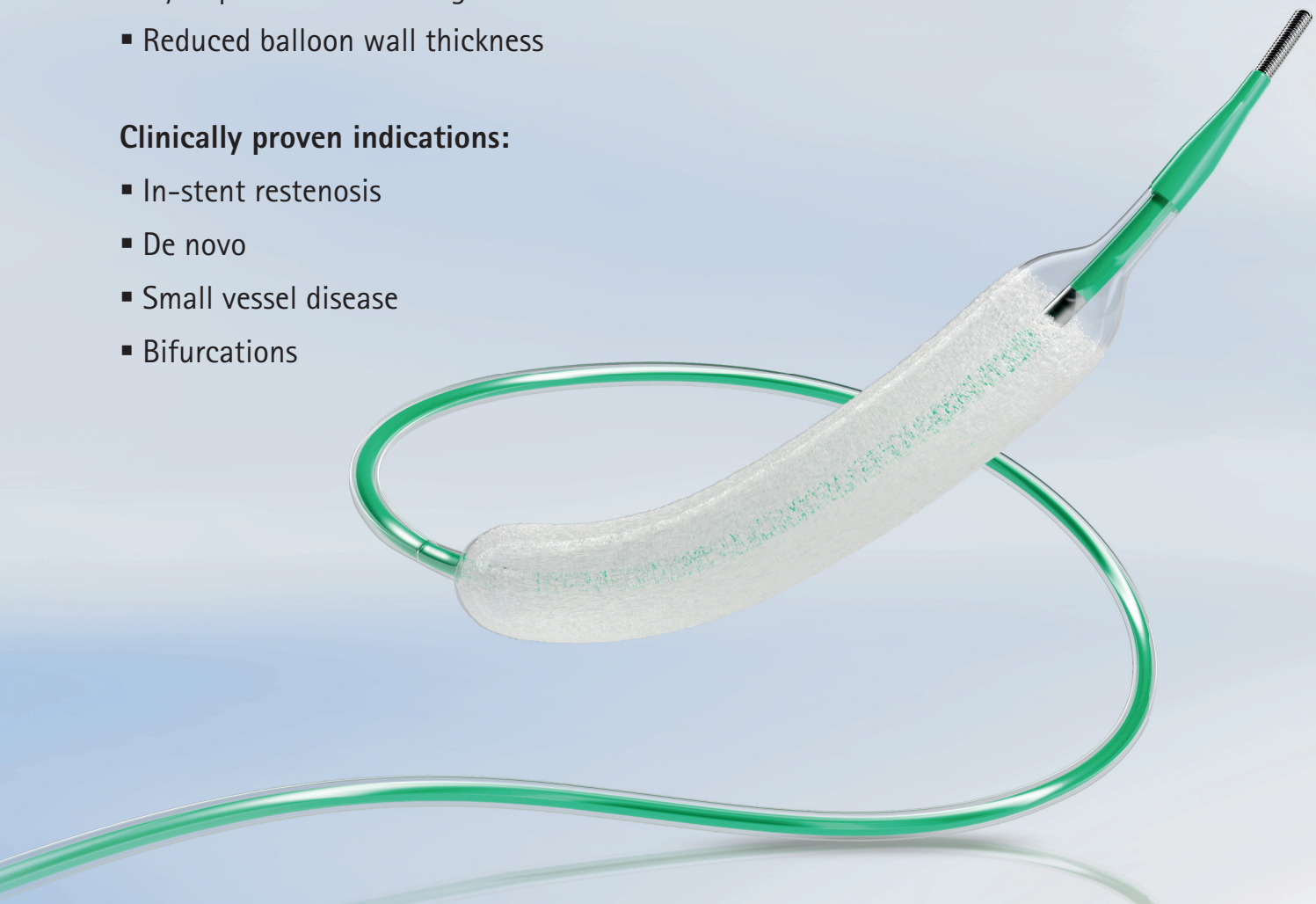
THE SECOND GENERATION DCB

Outstanding performance:

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

Clinically proven indications:

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



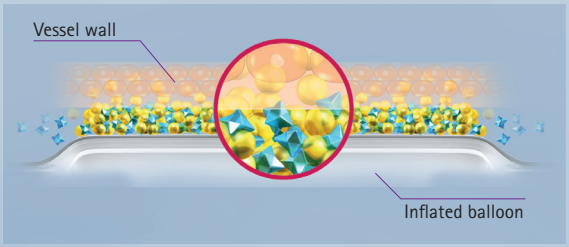
OVER 28 CLINICAL TRIALS WITH OVER 5,900 ENROLLED PATIENTS

IMPLANT-FREE WITH SeQuent® Please NEO

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

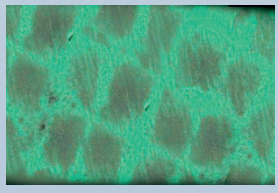
Clinically proven Paclitaxel and Iopromide coating

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]



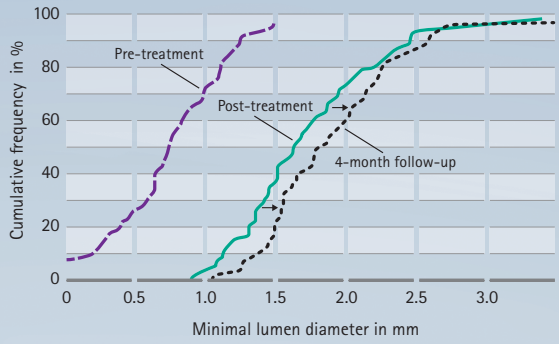
Stent struts of a DES lead to an inhomogenous drug distribution pattern. About 85 % of the vascular wall is not covered by the struts resulting in low drug tissue level.[1]

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

[1-4] Axel DI et al. Circulation 1997; 96: 636-45. | Hwang CW et al. Circulation 2004; 104: 600-5. | Scheller B et al. Circulation 2004; 110: 810-4. | Scheller B et al. Heart 2007; 93: 539-41.
[5] Kleber F et al. Clin Res Cardiol 2015; 104: 217-25.

SeQuent® Please NEO

DCB-ONLY TREATMENT

ADVANTAGES OF DCB-ONLY

No unnecessary stent implantation

- **No inflammation** due to a foreign body implant
- **No risk** of stent thrombosis
- **No stent-related limitations** for further treatment
- **No stent edge effect**

Efficacy of DCB

- **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

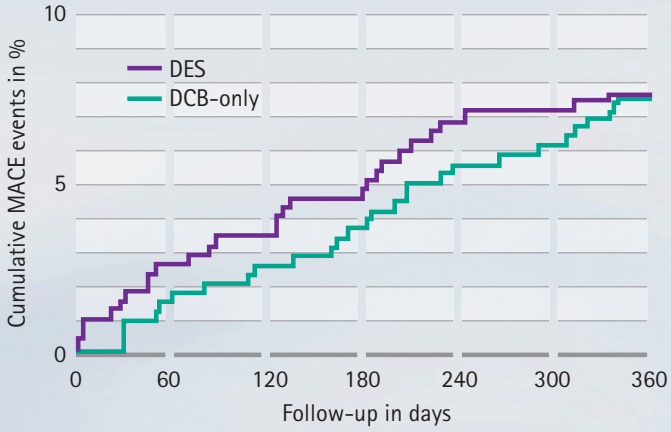
DES implantation Coroflex® ISAR NEO

DAPT according to current guideline

[6] Valgimigli M et al. European Heart Journal 2018; 39(3): 213-60.
[7] Kleber F et al. Clin Res Cardiol 2013; 102: 785-97.

GO IMPLANT-FREE

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

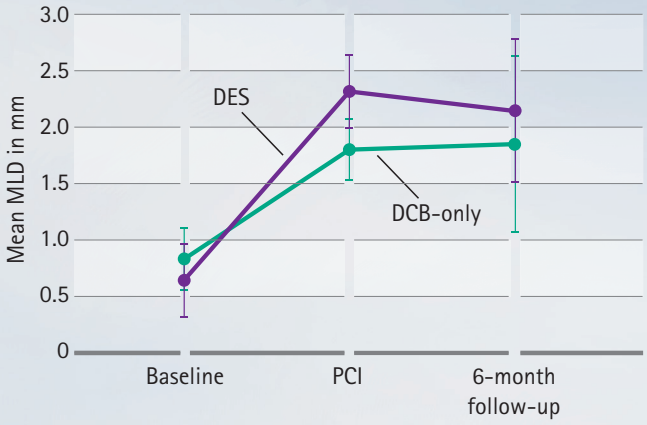


Primary endpoint: MACE at 12-month follow-up in %

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 R et al. The Lancet 2018; 392(10150): 849-56.
[9] Poerner T et al. Clin Res Cardiol 2017; 106: 18–27.
[10] Poerner T et al. CCI 2014; 7(6): 760-7.

SeQuent® Please NEO

CLINICALLY PROVEN INDICATIONS

IN-STENT RESTENOSIS

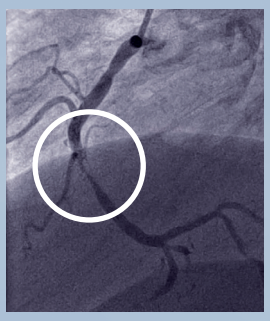
Patient: Male, 55 years

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

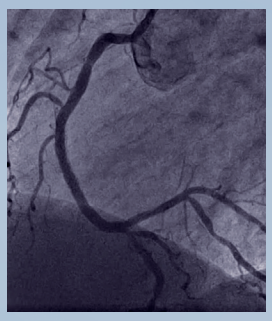
Procedure: Pre-dilation 3.5 x 15 mm PTCA balloon

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

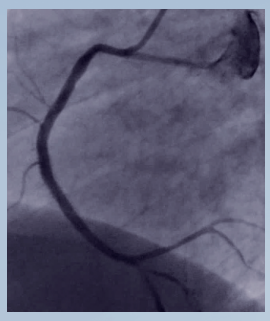
DCB-only SeQuent® Please (3.5 x 15 mm) distal lesion



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 Guidelines[11]	I	A	507-511,524

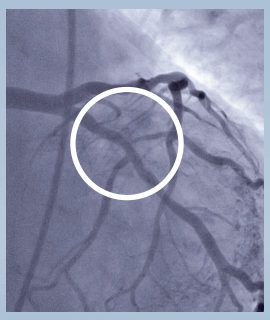
DE NOVO LESION

Patient: Female, 67 years

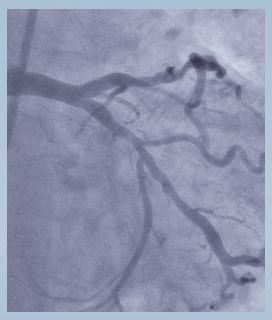
Indication: De novo stenosis of obtuse marginal branch

Procedure: Pre-dilation 2.5 x 15 mm PTCA balloon

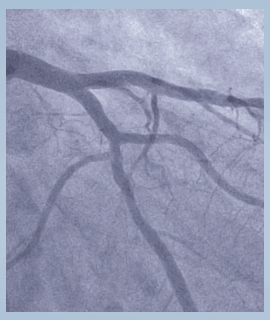
DCB-only SeQuent® Please (2.5 x 20 mm)



Pre-treatment



Post-treatment



4-month follow-up

BIFURCATION

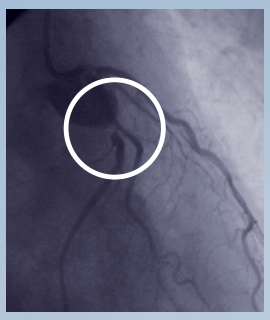
Patient: Male, 54 years

Indication: Stenoses of mid circumflex artery (CX) and its posterolateral branch (PL-CX)

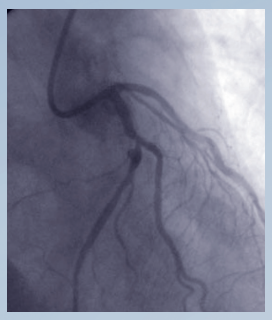
Procedure: Pre-dilation 2.5 x 20 mm PTCA balloon of CX

DCB-only SeQuent® Please (3.0 x 15 mm) of PL-CX

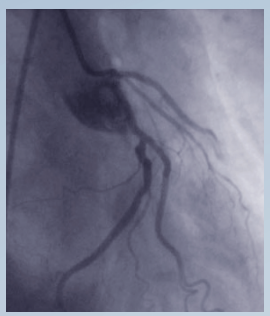
DCB-only SeQuent® Please (3.0 x 20 mm) of CX



Pre-treatment



Post-treatment

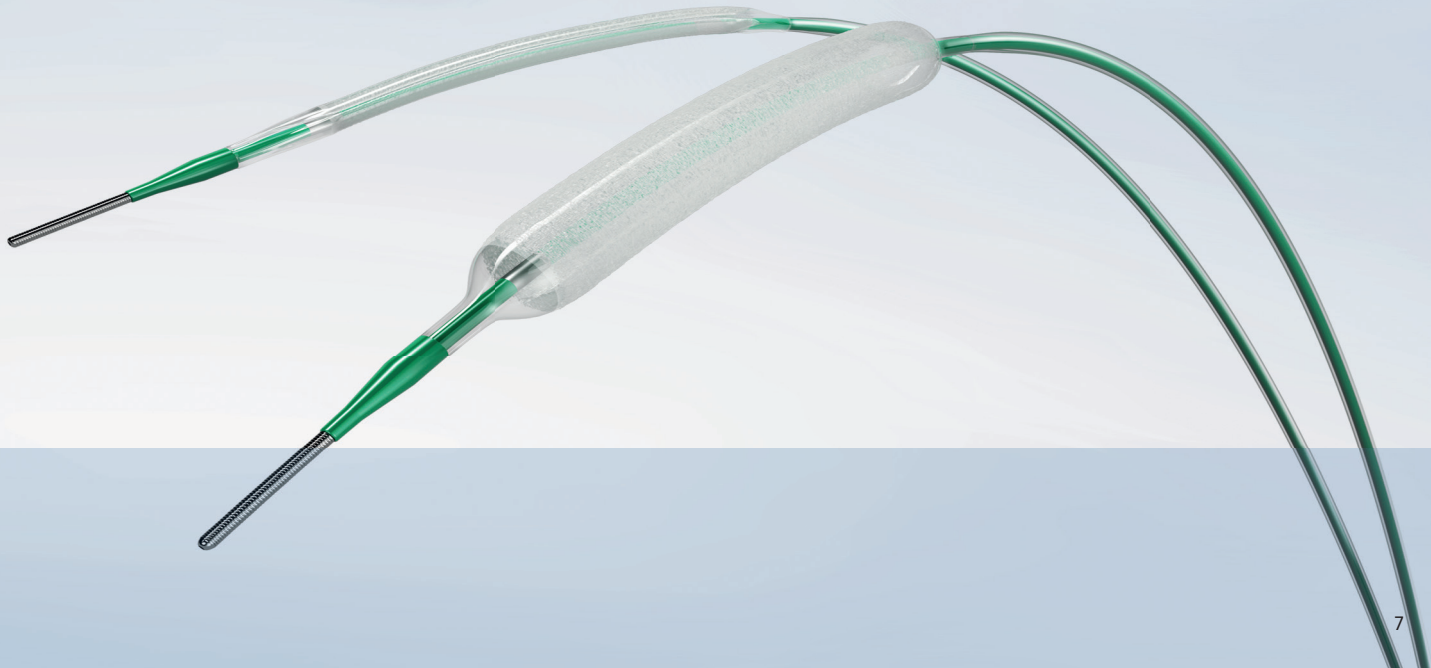


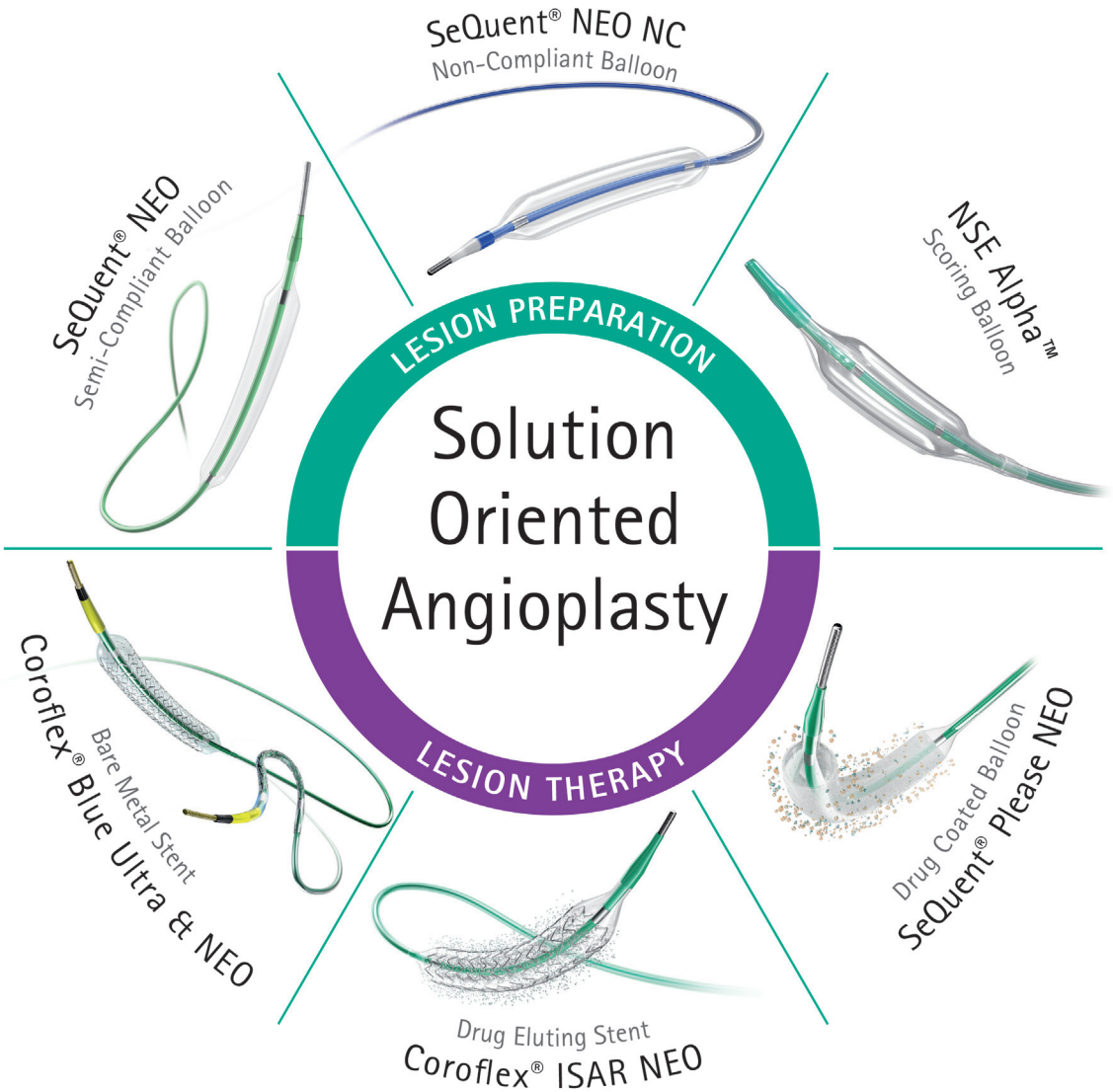
4-month follow-up

[11] Windecker S et al. European Heart Journal 2014; 35: 2541-619.

Balloon Diameter	Balloon Length							Nominal Pressure	Rated Burst Pressure
	10 mm	15 mm	20 mm	25 mm	30 mm	35 mm	40 mm		
2.0 mm	5023200	5023210	5023220	5023230	5023240	5023250	5023260	6 atm	14 atm
2.25 mm	5023201	5023211	5023221	5023231	5023241	5023251	5023261	6 atm	14 atm
2.5 mm	5023202	5023212	5023222	5023232	5023242	5023252	5023262	6 atm	14 atm
2.75 mm	5023203	5023213	5023223	5023233	5023243	5023253	5023263	6 atm	14 atm
3.0 mm	5023204	5023214	5023224	5023234	5023244	5023254	5023264	6 atm	14 atm
3.5 mm	5023206	5023216	5023226	5023236	5023246	5023256	5023266	6 atm	14 atm
4.0 mm	5023207	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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