

# SeQuent® Please NEO

Clinically proven Polymer-free Drug Coated Balloon Catheter



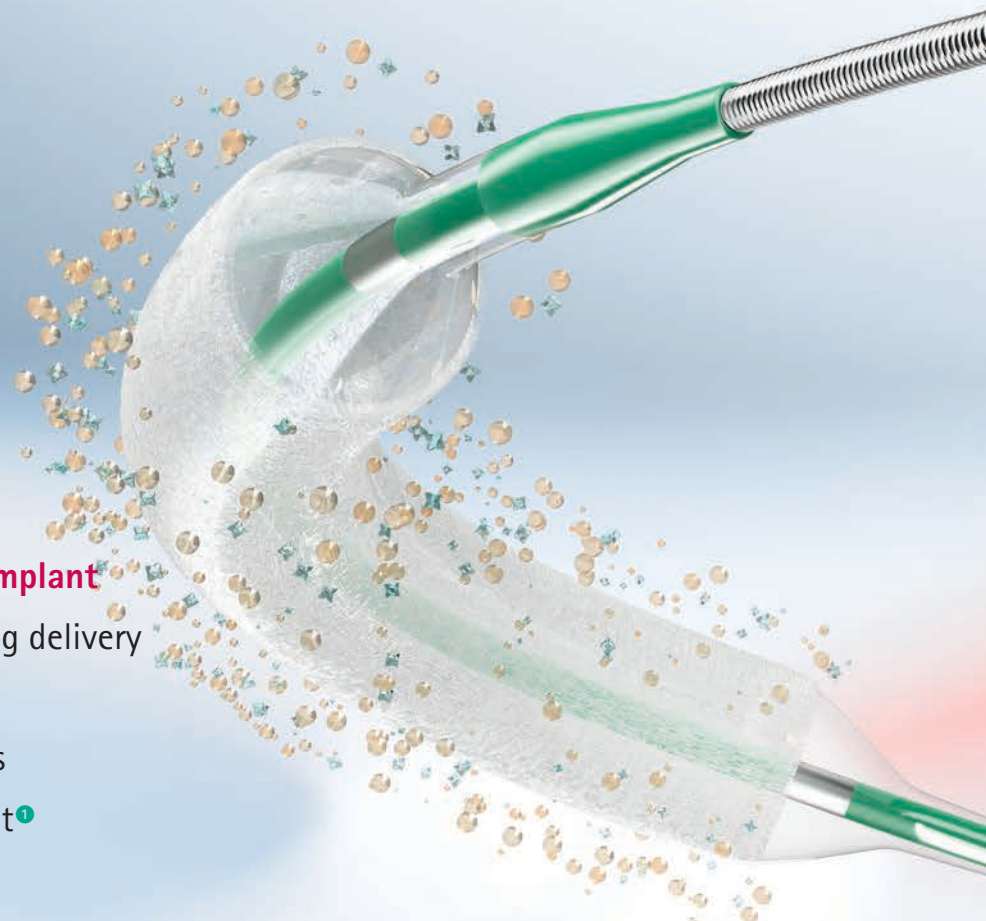
Vascular Systems

# SeQuent<sup>®</sup> Please NEO

## The Drug Coated Balloon with Clinical Evidence

# NATURAL LUMEN

## Polymer-Free Drug Delivery



### Moving forward without any implant

- Effective and homogenous drug delivery
- Short DAPT of only one month
- No stent related complications
- Proven late lumen enlargement<sup>1</sup>

### Moving forward with outstanding performance

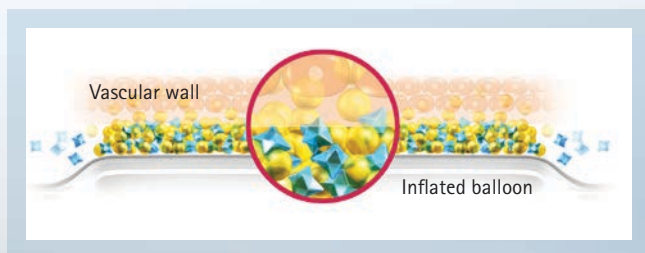
- Advanced crossing performance
- Superior pushability
- Hydrophilic coating
- Reduced balloon wall thickness

<sup>1</sup> Kleber FX et al. Clin Res Cardiol 2013; 102:785-797

# ENLARGEMENT

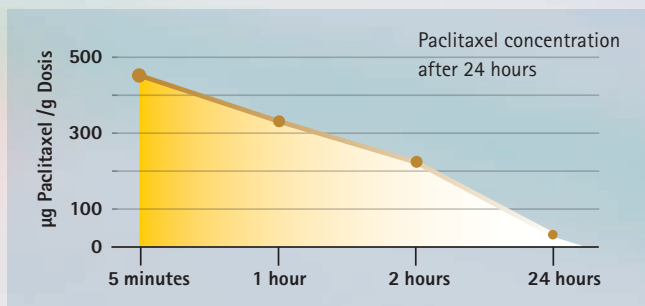
## Unique coating with Paclitaxel and Iopromide

The clinically proven matrix coating of Paclitaxel and Iopromide ensures the homogenous drug release into the vessel wall.



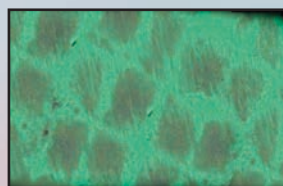
## Long-term efficacy with short-term release

Only a "single shot" drug delivery with SeQuent® Please NEO is needed to ensure a sustained antiproliferative effect. After 24 hours the Paclitaxel concentration in the vascular cells reaches the bottom level.

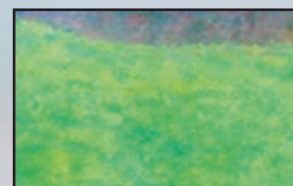


## Effective and homogenous drug delivery<sup>2-5</sup>

A short inflation time of only 30 seconds proved to be sufficient to inhibit cell proliferation.<sup>3</sup>



Stent struts of a DES lead to an inhomogeneous patterned drug distribution. About 85 % of the vascular wall is not covered by the struts resulting in low drug tissue level.<sup>2</sup>



Homogenous drug distribution SeQuent® Please NEO with PACCOCATH™ technology.<sup>5</sup>

# SeQuent® Please NEO: Natural Vessel Restoration

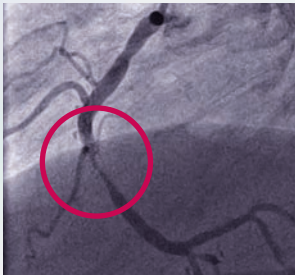
## POSITIVE VESSE

### In-stent restenosis

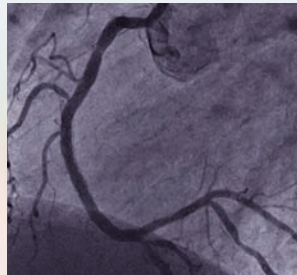
**Patient:** Male, 55 years

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

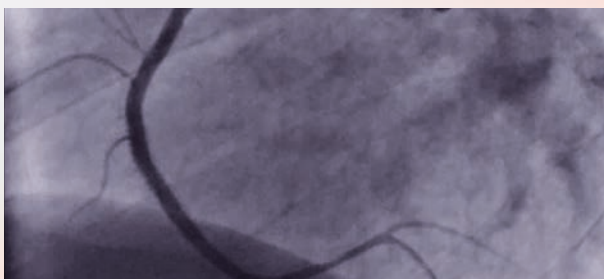
**Procedure:** Predilatation 3.5 x 15 mm PTCA-Balloon  
DCB-only SeQuent® Please NEO (3.5 x 20 mm) proximal lesion  
DCB-only SeQuent® Please NEO (3.5 x 15 mm) distal lesion



Pre intervention



Post intervention

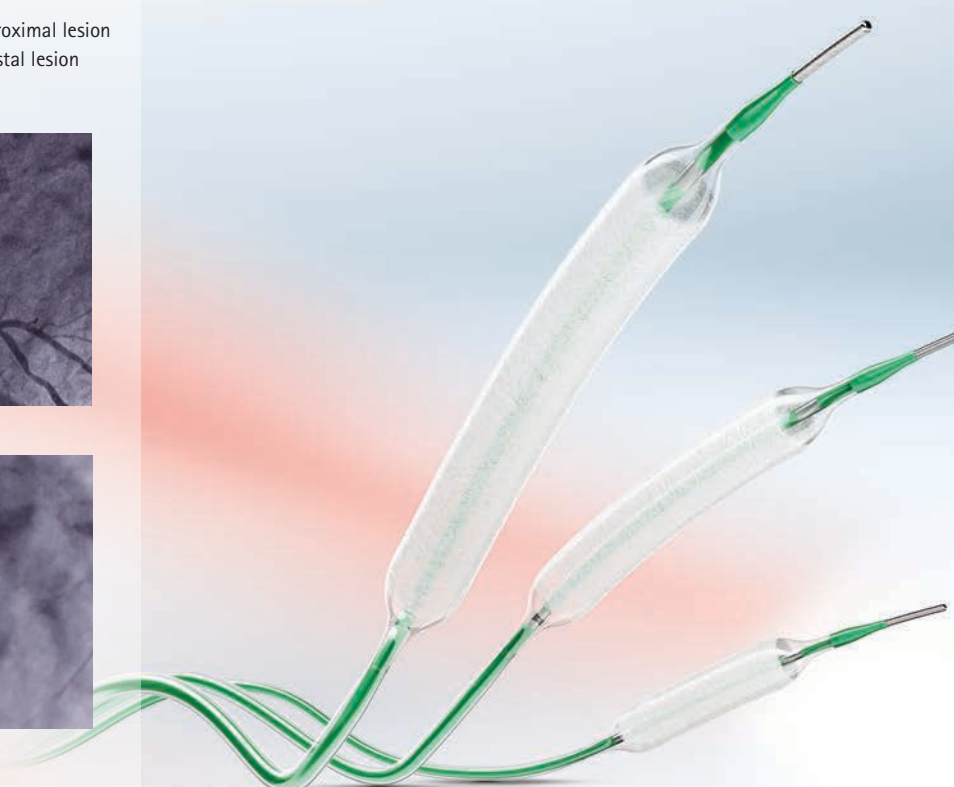


Follow-up 4 months

**Drug-coated balloons are recommended for the treatment of in-stent restenosis (within BMS or DES)**

**I A 507-511,524**

**SeQuent® Please NEO with only one month DAPT is a feasible therapeutic alternative to DES/BVS with a DAPT up to 12 month.**





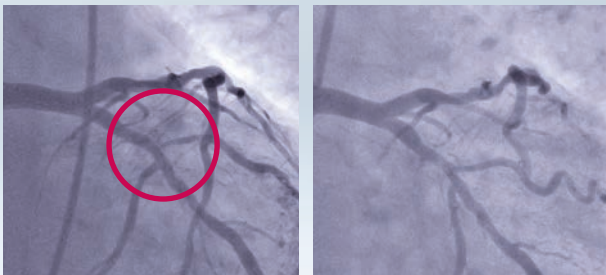
# L REMODELING

## De-novo stenosis

**Patient:** Female, 67 years

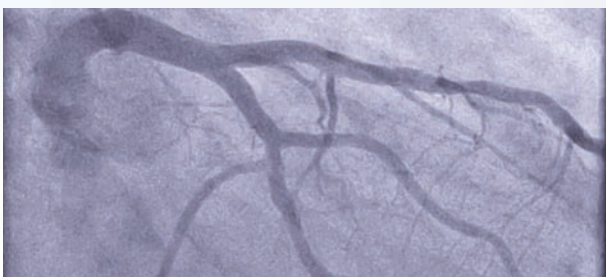
**Indication:** De-novo stenosis of obtuse marginal branch

**Procedure:** Predilatation 2.5 x 15 mm PTCA-Balloon  
DCB-only SeQuent® Please NEO (2.5 x 20 mm)



Pre intervention

Post intervention



Follow-up 4 months

## Bifurcation

**Patient:** Male, 54 Years

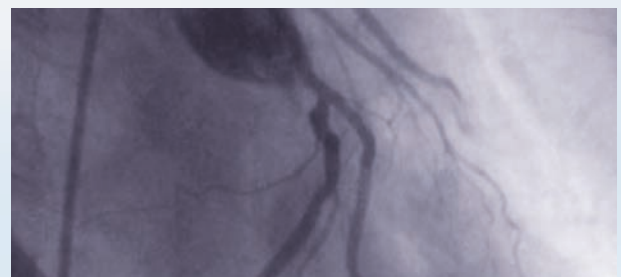
**Indication:** Stenoses of mid circumflex artery (CX) and its posterolateral branch (PL-CX)

**Procedure:** Predilatation 2.5 x 20 mm PTCA balloon of CX  
DCB-only SeQuent® Please NEO 3.0 x 15 mm of PL-CX  
DCB-only SeQuent® Please NEO 3.0 x 20 mm of CX



Pre intervention

Post intervention



Follow-up 4 months

## Further indications for SeQuent® Please NEO:

Patients with high risk of bleeding due to oral anticoagulants (e.g. mechanical prosthetic heart valve, atrial fibrillation, pulmonary embolism).

# SeQuent® Please NEO: Clinical Evidence

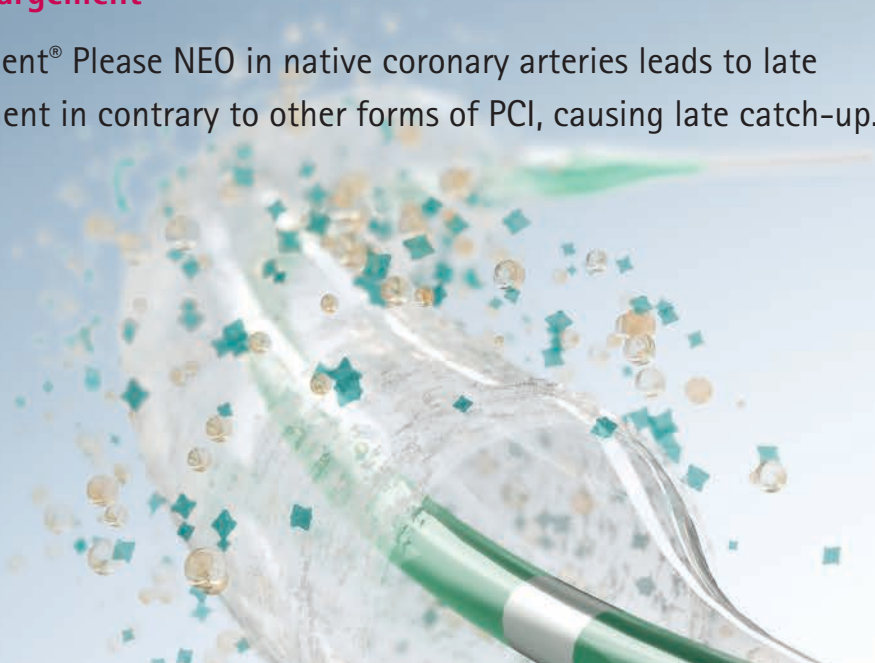
## THE DRUG COAT WITH CLINICAL

### The proven SeQuent® Please NEO concept

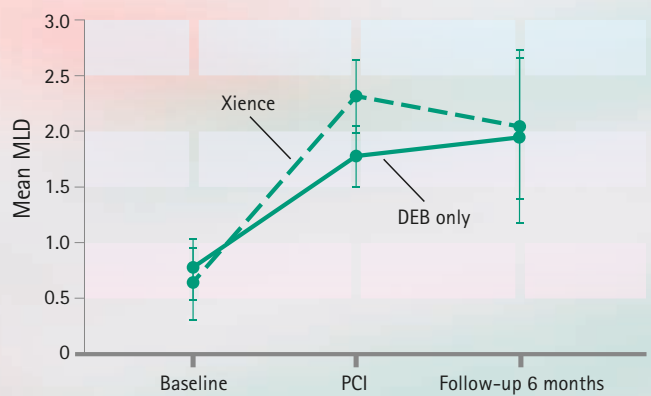
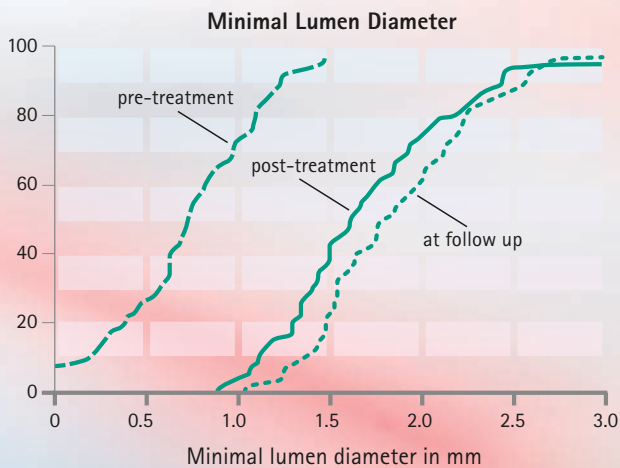
- More than 20 studies/registries have shown the outstanding effect of SeQuent® Please NEO.
- SeQuent® Please NEO is the only DCB with a class IA recommendation for ISR in the ESC guidelines.
- SeQuent® Please NEO is clinically proven for the treatment of de-novo lesions.

### Late lumen enlargement

The use of SeQuent® Please NEO in native coronary arteries leads to late lumen enlargement in contrary to other forms of PCI, causing late catch-up.



# STENTED BALLOON THERAPY EVIDENCE



## Kleber et al.: DCB for treatment of de-novo lesions<sup>6</sup>

Angiographic measure	Minimal lumen diameter
Pre-intervention	0.81 ± 0.47
Post-intervention	1.75 ± 0.58
Follow-up	1.91 ± 0.55
p value pre vs. post	<0.001
p-value post vs. follow-up	<0.001

### Late lumen enlargement after 4 month

**0.16 mm**

## OCTOPUS II: OCT to evaluate the use of DCB without stenting<sup>7</sup>

LLL DES (Xience)	0.29 ± 0.56
LLL DCB only (SeQuant® Please)	-0.19 ± 0.50
p-value	<0.05

### Late lumen enlargement after 6 month

**0.19 mm**

**SeQuant® Please NEO supports the inherent mechanism of natural vessel restoration and leads to a late lumen enlargement.**

<sup>6</sup> Kleber F et al. Clin Res Cardiol 2014 <sup>7</sup> Poerner T et al. Presentation 2013, Klinik für Innere Medizin, Universitätsmedizin Jena, Germany

# SeQuent® Please NEO

## DCB-only Treatment Recommendations

# POLYMER-FREE

### 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 Typ A or B;  
TIMI III; residual stenosis ≤ 30 %

Dissection Type C-F; TIMI < III;  
residual stenosis > 30%

#### DCB-only with SeQuent® Please NEO

- DCB distal and proximal at least 2-3 mm longer as predilatated area
- ratio balloon-to-vessel diameter 0.8-1.0
- 8-10 atm, 30 sec. inflation time

<b>DAPT</b>	DEB only:	4 weeks
	BMS-ISR:	4 weeks
	DES-ISR:	time defined by DES but at least 4 weeks
	Spot-BMS + DEB:	3 months

#### Stenting

DES implantation Coroflex® ISAR

DAPT according to current guideline

### Full therapeutic concept for indication related treatment

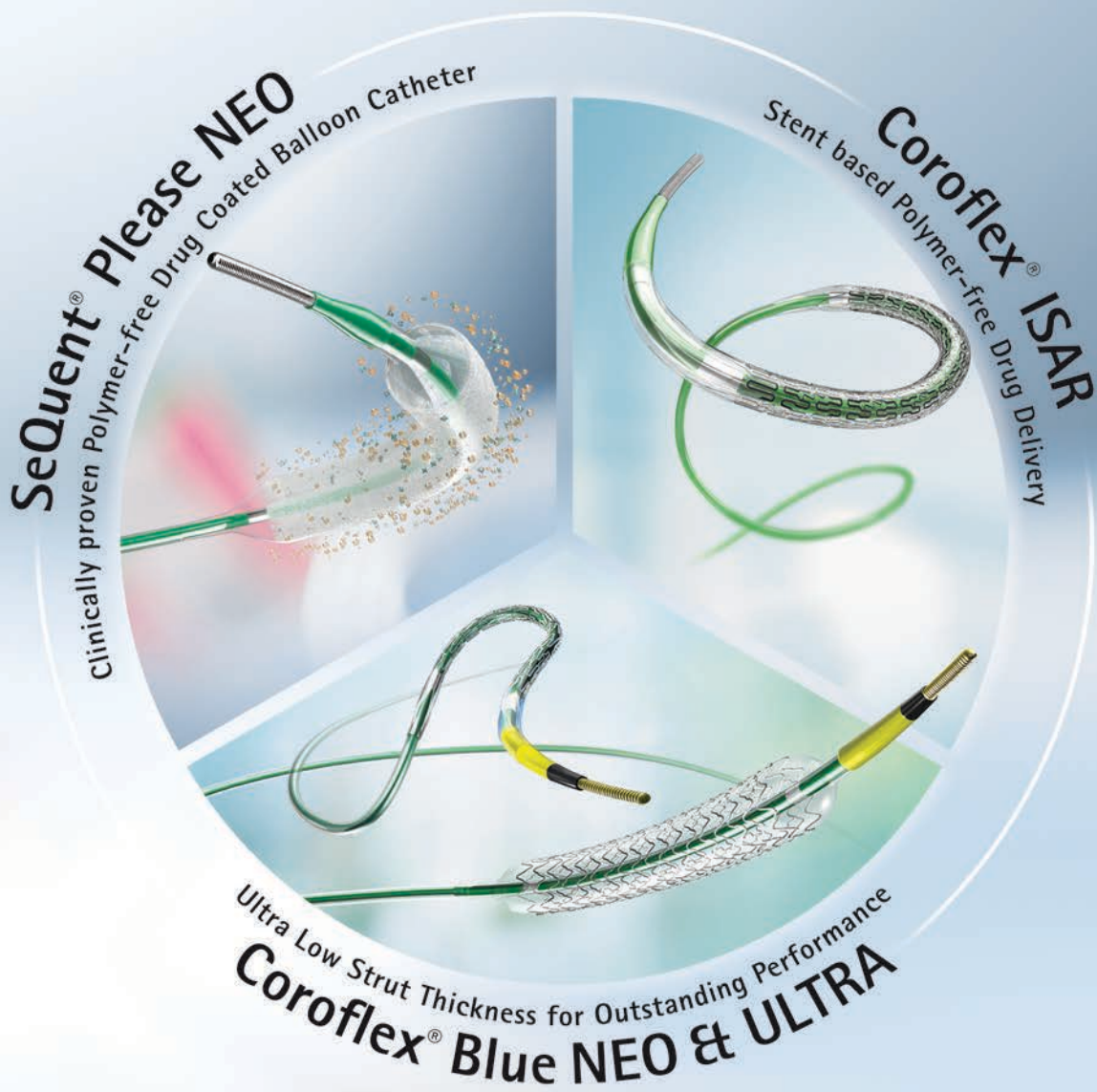




# B. Braun Vascular Systems

## Solution Oriented Angioplasty

# ANGIOPLASTY

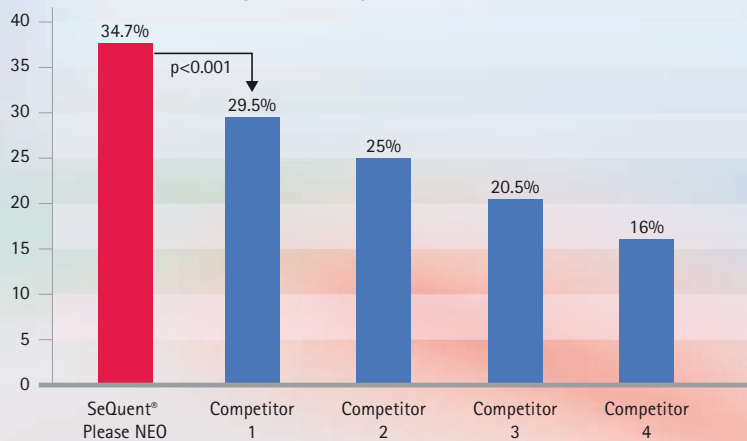


# SeQuent<sup>®</sup> Please NEO

## Advanced Crossing Performance

# IMPROVED FLEXIBILITY SUPPORT YOUR

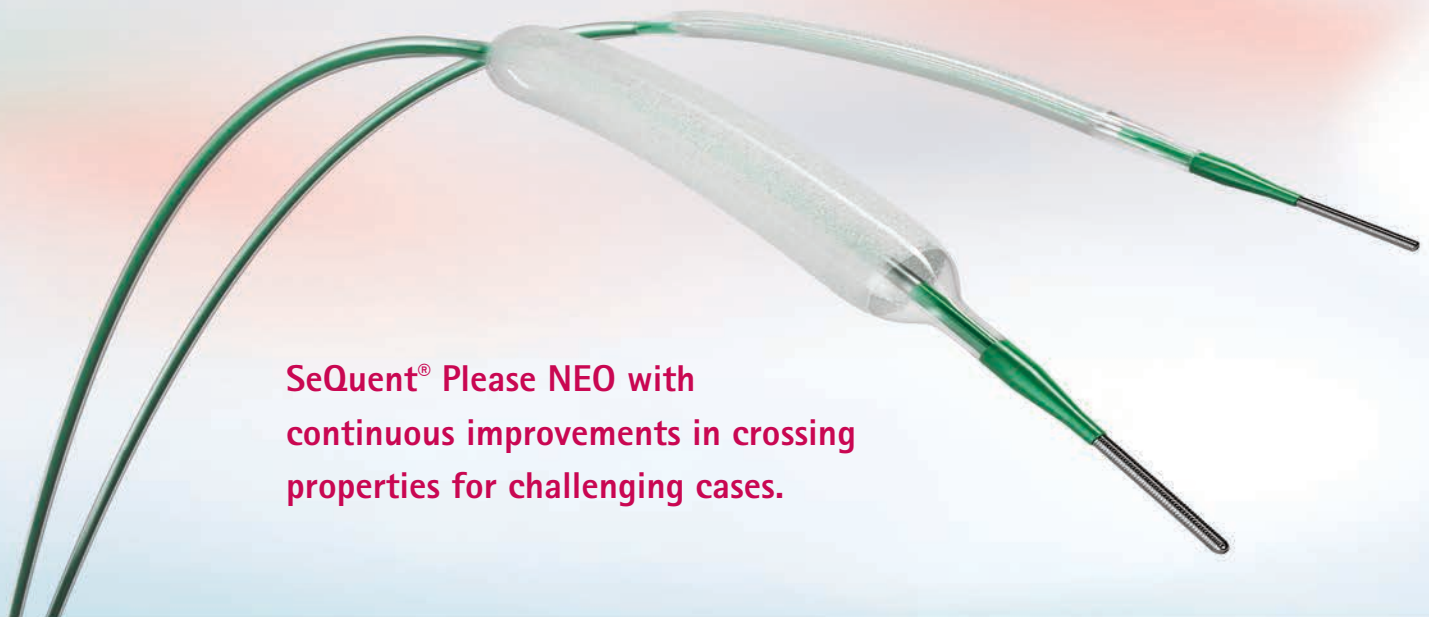
Best pushability to cross a lesion



Pushability is the ratio between the force that the user has to apply at the proximal catheter shaft and the force that arrives at the stenosis.

SeQuent<sup>®</sup> Please NEO gives the user the perfect combination with a small profile, high flexibility and high pushability.

**SeQuent<sup>®</sup> Please NEO with continuous improvements in crossing properties for challenging cases.**



# SeQuent® Please NEO

## Product Portfolio and Technical Data

# FEATURES TO DAILY ROUTINE

Balloon diameter	Balloon length							Nominal Pressure	Rated Burst Pressure (RBP)
	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 profil	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

Distributor

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