

# *OPN NC*®

Super High Pressure PTCA Balloon

Power meets precision,  
the basis for optimal lesion  
preparation and sustainable  
stent results.



### Long-term Prognostic Implications of Coronary Calcification

- Pooled analysis data of 6 296 patients enrolled in seven clinical drug-eluting stents trials were analysed to understand effects of severe coronary calcification.
- Patients with severe lesion calcification with 3 years followup showed:
  - Lower rates of complete revascularization
  - Increased mortality

| Endpoints                                                       | Patients with severe calcification | Patients without severe calcification |
|-----------------------------------------------------------------|------------------------------------|---------------------------------------|
| Mortality                                                       | 10.8%                              | 4.4%                                  |
| HCombined Endpoint:<br>MI & Death MI, Death & Revascularization | 22.9%<br>31.8%                     | 10.9%<br>22.4%                        |

\*Bourantas, et al. Prognostic implications of coronary calcification in patients with obstructive coronary artery disease treated by percutaneous coronary intervention: A patient level pooled analysis of 7 contemporary stent trials. BMJ 2014; 100: 1158-1164.

A Swiss Technology that shall  
redefine the strategies of  
plaque modification.

## ... AND ISSUES ...

### Lesion Preparation the "Need of the hour"

**Incomplete and/or asymmetrical stent expansion can lead to increased risk of restenosis or thrombosis.<sup>1</sup>**

- Can lead to increased risk of acute and sub-acute stent failure.<sup>2</sup>
- Associated with increased rate of ischemic events at 1 year.<sup>2</sup>
- Difficulty in stent delivery, may lead to damage of the polymer/drug coating leading to impaired drug delivery.

1. Mintz G. Intravascular Imaging of Coronary Calcification and its Clinical Implications. J Am Coll Cardiol Imaging 2015;8(4): 461-71.

2. Chambers JW, et al. Pivotal Trial to Evaluate the Safety and Efficacy of the Orbital Atherectomy System in Treating De Novo, Severely Calcified Coronary Lesions (ORBIT II). J Am Coll Cardiol Intv 2014; 7:510-8.

3. Généreux P, et al. Ischemic Outcomes After Coronary Intervention of Calcified Vessels in Acute Coronary Syndromes: Pooled Analysis From the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) and ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) Trials. JACC 2014; 63(18): 1845-54.

4. Fujii K, Carlier SG, Mintz GS, Yang YM, Moussa I, Weisz G, Dangas G, Mehran R, Lansky AJ, Krebs EM, Collins M, Stone GW, Moses JW, Leon MB. Stent underexpansion and residual reference segment stenosis are related to stent thrombosis after sirolimus-eluting stent implantation: an intravascular ultrasound study. J Am Cardiology. 2005 Apr 5; 45 ( 7 ) : 995-8.

### Become OP(E)N minded

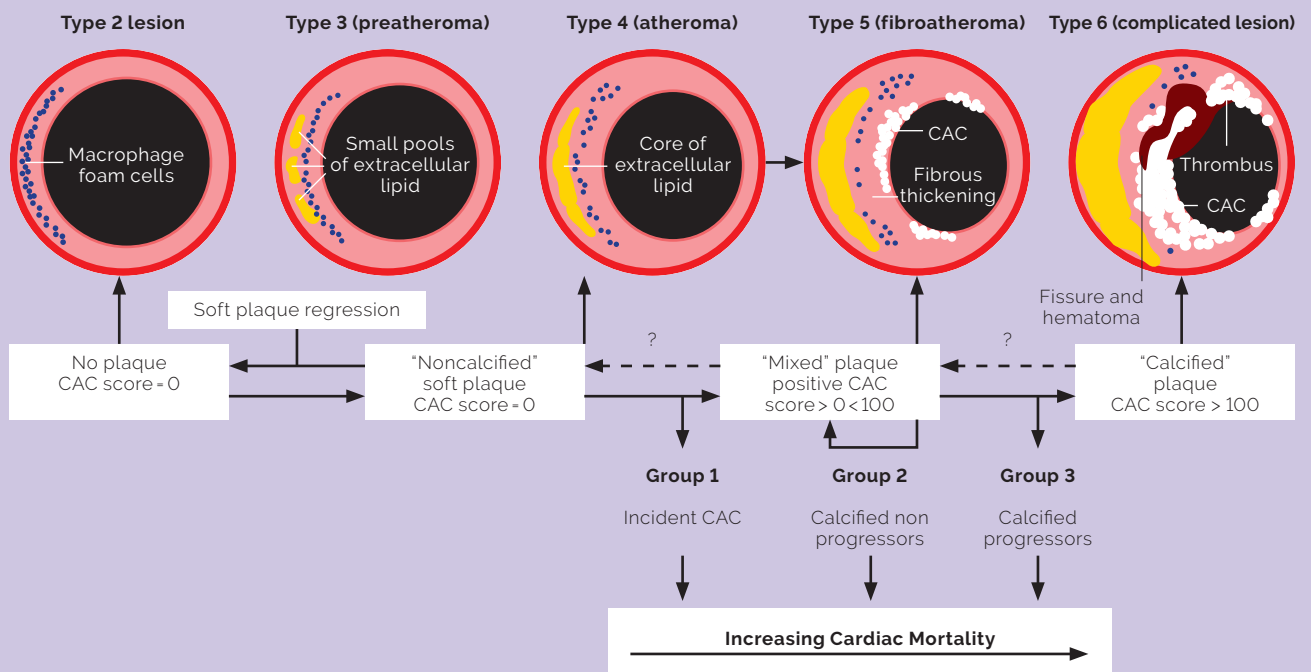
"Why should you use an OPN NC balloon only for post dilatation of a stent or for the treatment of instent restenosis caused by underexpanded stents when you potentially could avoid most of these cases by using the OPN NC for predilatation directly in order to achieve optimal lesion preparation prior stenting?"



### Coronary Artery Calcification (CAC)

- CAC is a large and growing problem.
- Advanced age, diabetes and renal insufficiency are leading risks for the development of calcified lesions.

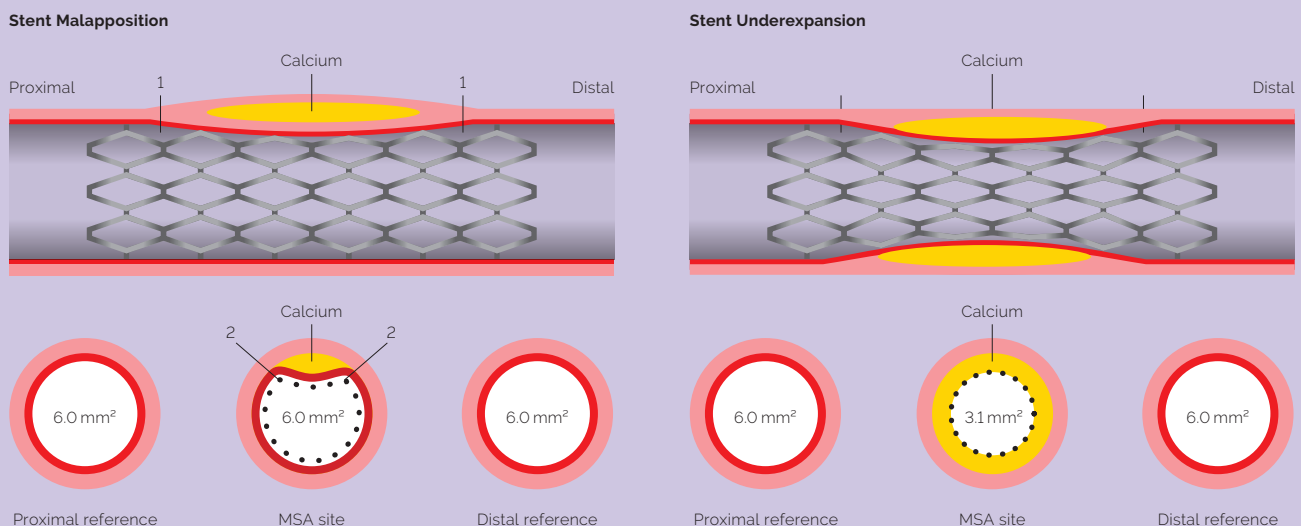
- Increasing calcium burden is associated with complex interventions, higher risk for complications and increasing mortality.



## ... POTENTIAL CONSEQUENCES ...

### CAC-Effect on Stent Expansion

- With increased calcium volume and bulk the chances of stent under expansion are greater.<sup>1</sup>
- Asymmetrical stent expansion is seen up to 50% of stents deployed in calcified lesions in several trials.<sup>2</sup>
- Stent under expansion causes an increase in ischemic events at 1 year.<sup>3/4</sup>



1. Mintz, G. Intravascular Imaging of Coronary Calcification and its Clinical Implications. J Am Coll Cardiol Imaging 2015;8(4): 461-71.
2. Chambers JW, et al. Pivotal Trial to Evaluate the Safety and Efficacy of the Orbital Atherectomy System in Treating De Novo, Severely Calcified Coronary Lesions (ORBIT 11). J Am Coll Cardiol Interv 2014; 7:510-8.
3. Genereux P, et al. Ischemic Outcomes After Coronary Intervention of Calcified Vessels in Acute Coronary Syndromes: Pooled Analysis From the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) and ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) Trials. JACC 2014; 63(18):1845-54.
4. Vavarunakis et al. Stent deployment in calcified lesions: Can we overcome calcific restraint with higher pressure balloon inflations? Catheter Cardiovasc Interv 2001;52:164-172.

... THE MOST ECONOMICAL AND  
BEST TECHNICAL SOLUTION  
TO AVOID AND TREAT ...

# OPN NC<sup>®</sup>

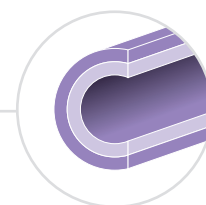
Super High Pressure PTCA Balloon

## OPN NC

The proven best economic and technical solution in the armentarium of tools in order to help you to overcome a great number of your daily interventional challenges successfully.

## Double Layer for Double Power

- Unique balloon in balloon technology to withstand highest pressures.
- Increased tensile strength.
- Uniform expansion.



## New Integrated Hub

- For easier handling and better visibility of size.



## Markers

- Dual platinum markers for all balloon sizes.

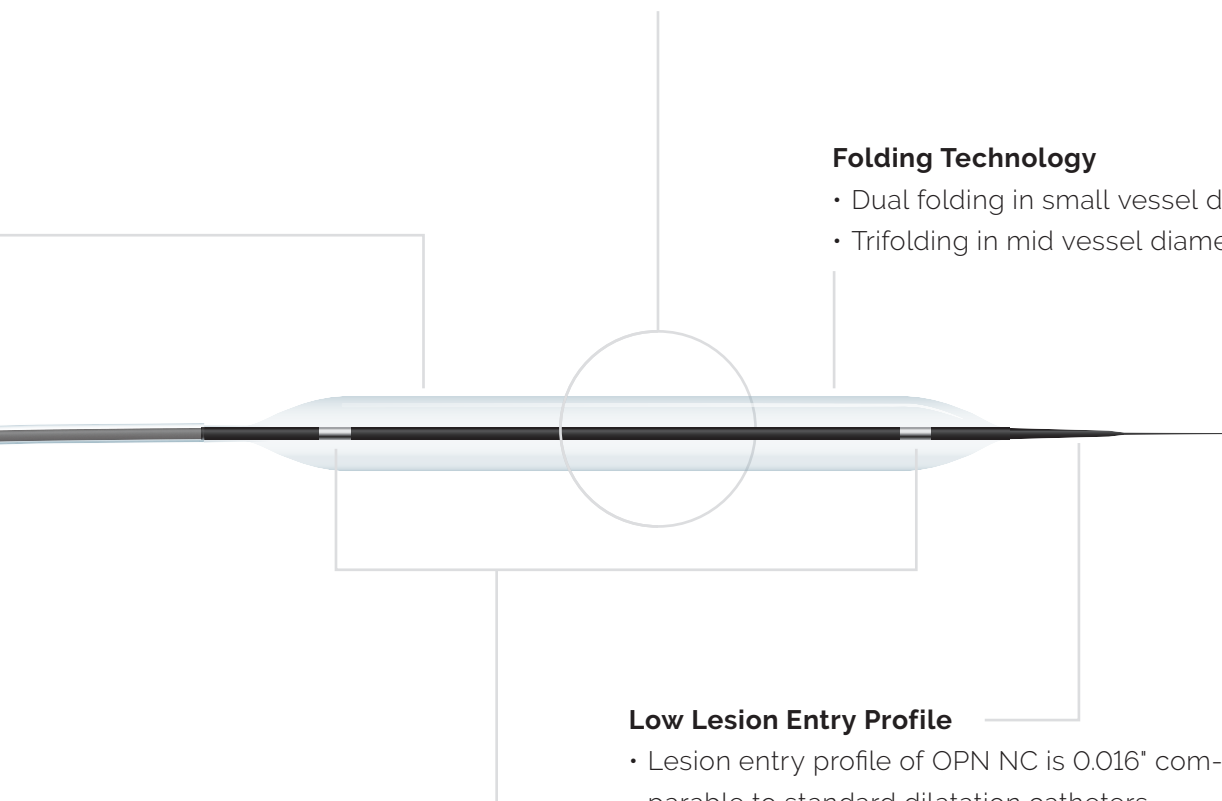


### **Low Balloon Profile**

- Crossing profile of 0.028" despite of dual layer comparable to conventional dilatation catheters.

### **Folding Technology**

- Dual folding in small vessel diameters.
- Trifolding in mid vessel diameters.



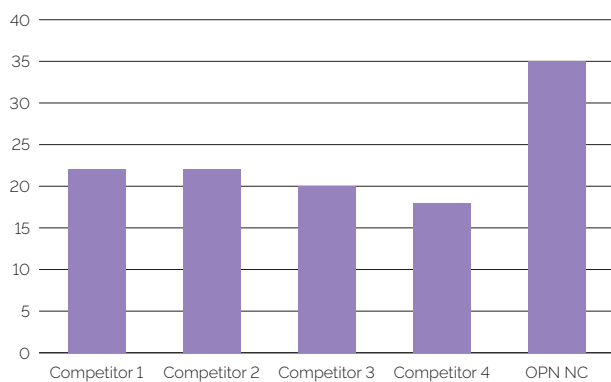
### **Low Lesion Entry Profile**

- Lesion entry profile of OPN NC is 0.016" comparable to standard dilatation catheters.
- Lesion entry profile measured at the centre of the 4 mm tip.

### Super High Pressure for Super Performance, Highest Safety and Efficacy

- OPN NC offers a rated burst pressure of 35 bar for unmet performance in cracking tough calcified lesions.

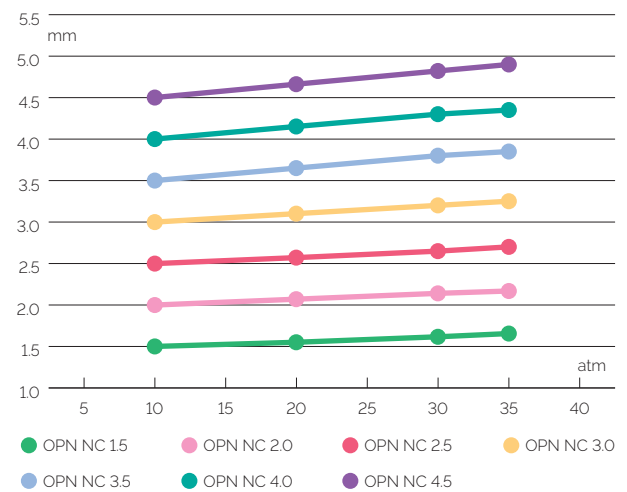
Highest Pressure Resistance: 35 bar



- The device has proven its safety and efficacy by successful treatment of calcified, highly calcified and very complex lesions in over 60 000 patients.

### Compliance Curve OPN NC

- Lowest diameter compliance rate over the largest pressure range of any PTCA balloon on the market.

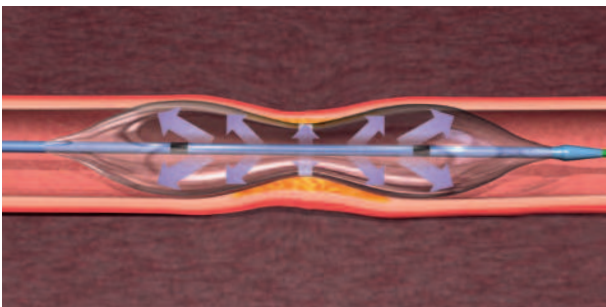


- The OPN NC device has a linear compliance because of its twin layer construction.
- The OPN NC device has less than 10% growth even at pressures as high as 35 atm.

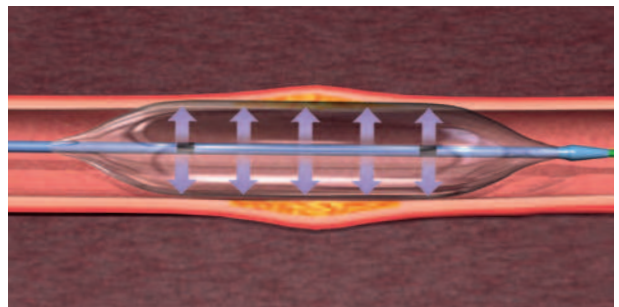


### **Dog Boning – No more an issue**

- Conventional non compliant balloons at high pressures cause dog boning.
- OPN NC at a pressure of 35 bar has a linear compliance and cause no dog boning.



Standard non compliant balloons tend to be oversized at the edges, with less dilatation at the obstructive segment of the lesion (dog boning).



OPN NC provides a predictable amount of pressure at the lesion without uncontrolled radial and longitudinal growth. Hence, eliminating dog boning.

## **Be Mindful!**

- Workers performing fluoroscopically guided cardiovascular procedures are at a significantly higher risk of a diverse array of health disorders compared to the non exposed subjects.

## **Save Time, every minute counts!**

- The OPN NC reduces the overall procedure time. Thus, saving long hours of standing at the patient table.

## **Reduce Radiation**

- A shorter procedural time will further reduce the level of radiation exposure.

## **Reduce Contrast Media**

- A reduction of fluoro time leads to a lower use of contrast media.
- Contrast media in excess causes nephrotoxicity and AKI.



Become and remain  
OP(E)N minded.

## Ordering Matrix

OPN NC

| Article Number | Balloon Diameter | Length | RBP    | Min. Guiding |
|----------------|------------------|--------|--------|--------------|
| 150-010-004    | 1.5 mm           | 10 mm  | 35 atm | 6F           |
| 150-015-004    | 1.5 mm           | 15 mm  | 35 atm | 6F           |
| 150-020-004    | 1.5 mm           | 20 mm  | 35 atm | 6F           |
| 200-010-004    | 2.0 mm           | 10 mm  | 35 atm | 6F           |
| 200-015-004    | 2.0 mm           | 15 mm  | 35 atm | 6F           |
| 200-020-004    | 2.0 mm           | 20 mm  | 35 atm | 6F           |
| 250-010-004    | 2.5 mm           | 10 mm  | 35 atm | 6F           |
| 250-015-004    | 2.5 mm           | 15 mm  | 35 atm | 6F           |
| 250-020-004    | 2.5 mm           | 20 mm  | 35 atm | 6F           |
| 300-010-004    | 3.0 mm           | 10 mm  | 35 atm | 6F           |
| 300-015-004    | 3.0 mm           | 15 mm  | 35 atm | 6F           |
| 300-020-004    | 3.0 mm           | 20 mm  | 35 atm | 6F           |
| 350-010-004    | 3.5 mm           | 10 mm  | 35 atm | 6F           |
| 350-015-004    | 3.5 mm           | 15 mm  | 35 atm | 6F           |
| 350-020-004    | 3.5 mm           | 20 mm  | 35 atm | 6F           |
| 400-010-004    | 4.0 mm           | 10 mm  | 35 atm | 7F           |
| 400-015-004    | 4.0 mm           | 15 mm  | 35 atm | 7F           |
| 400-020-004    | 4.0 mm           | 20 mm  | 35 atm | 7F           |
| 450-010-004    | 4.5 mm           | 10 mm  | 35 atm | 7F           |
| 450-015-004    | 4.5 mm           | 15 mm  | 35 atm | 7F           |
| 450-020-004    | 4.5 mm           | 20 mm  | 35 atm | 7F           |

## SIS Medical Inflation Devices

|                            | SIS Medical 40 atm Inflation Devices             | SIS Medical 55 atm Inflation Devices      |
|----------------------------|--------------------------------------------------|-------------------------------------------|
| Description                | For standard and high pressure PTCA up to 40 atm | For super high pressure PTCA up to 55 atm |
| Ordering Information (REF) | 96346                                            | 96463                                     |
| Units per Pack             | 1                                                | 1                                         |
| Volume (ml, cl)            | 25                                               | 14                                        |



### Important Information

Refer to the Instructions for Use supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions.



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Be and remain OP(E)N  
minded.