

naviscore

Coronary scoring balloon dilatation
catheter



iVascular[®]
therapies for living

naviscore

A new player in calcified lesions

Naviscore is an **innovative coronary scoring balloon dilatation catheter**.

iVascular breaks new ground by developing a product with a **hybrid design** that combines the benefits of scoring and cutting balloons.



BEST OF CUTTING

Axial filaments orientation:

Ensures greater cross capacity and a 90° axial plaque modification.

BEST OF SCORING

Nitinol wires flexibility:

Ensures better navigability and low perforation risk while modifying the plaque.

When to use Naviscore

Naviscore is indicated in significant lesions, including in-stent restenosis and especially in complex lesions with:



Long length



Severe calcification



Significant bifurcation

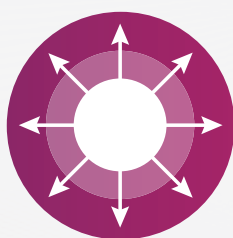


Why Naviscore



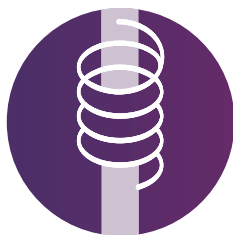
Optimal trackability

Naviscore easily crosses the lesion



Enhanced scoring capacity

Naviscore performs an effective plaque modification



Excellent rewrap and recross capabilities

Naviscore inflates as many times as you need



Low profiles and no deformation ensured by axial structure.

Low artery wall friction due to proprietary hydrophilic coating.



The smallest diameter available in the market.

Ø1.50 mm

6 times larger scoring surface than competitor*.

21x more force than conventional balloons**. Uniform axial force at 90° offers more control on plaque modification.

20 atm of RBP. High-resistant semi-compliant balloon.

Excellent balloon folding due to its memory shape nitinol structure.

Optimized profile rewapping thanks to unique scoring structure.

* Data on file, comparison vs Angiosculpt, Phillips

** Data on file at iVascular. Naviscore vs semi-compliant balloon

Severely calcified lesion treated with Naviscore

Patient profile

- Male, 76 years old
- CRF: HTA, Ex-smoker, CKD
- NSTEMI 2018. BAV.

Lesion type

- Angiography showing the LCx chronically occluded, severely calcified.
- Also the LAD have a severe plaque and extremely calcified.

Procedure

- During the procedure a 6F guiding catheter was used.
- The lesion observed was severely calcified but **Naviscore 3.0 x 6mm could advance without difficulties** (Figure 1).
- **Naviscore crossed the calcified plaque easily** (Figure 2).
- Once **Naviscore crossed the lesion at the 1st attempt** (Figure 3), it was inflated progressively.
- First inflation was up to 18 atm, a deformity was noted on the proximal part.
- **On a second inflation, the balloon was inflated up to 20atm. The plaque broke and the vessel was opened with an optimal result.**
- Finally, an Angiolite stent was implanted. **Angiolite expanded and apposed correctly** showing an optimal angiographic result (Figure 6).

CRF: Cardiovascular risk factors, HTA: hypertension, CKD: Chronic kidney disease, NSTEMI: non-ST segment elevation myocardial infarction



Fig 1. LCx chronically occluded and LAD severely calcified

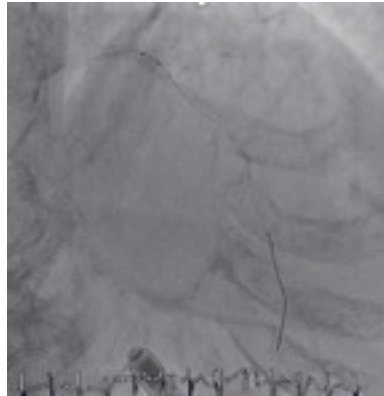


Fig 2. Naviscore penetrating the lesion at 1st attempt

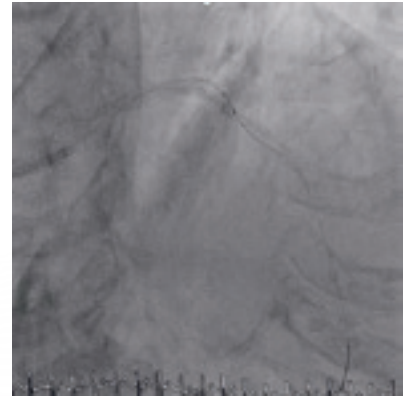


Fig 3. Naviscore crossed the lesion

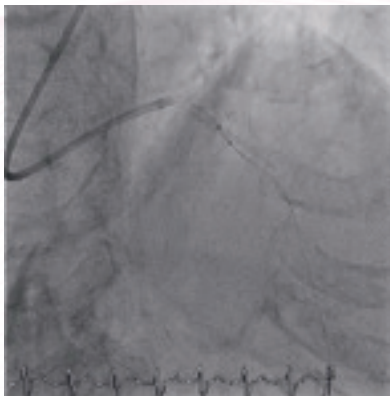


Fig 4. Naviscore inflated breaking the plaque

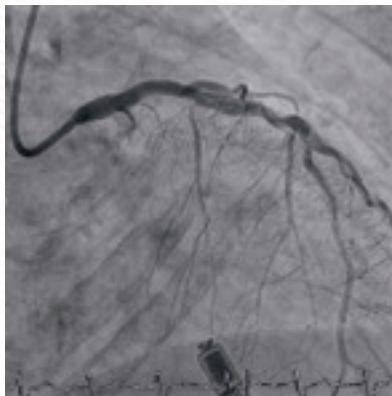


Fig 5. Angiographic result after Naviscore

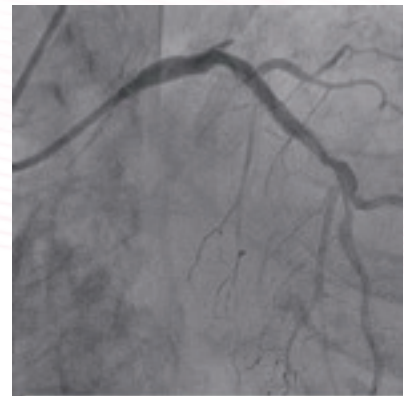


Fig 6. Final angiographic result

Conclusions

“Naviscore is a very powerful device with more pushability than the other competitors, easier entry into the lesions, and greater plaque modification.”

Naviscore should be the FIRST CHOICE DEVICE for the treatment of these difficult and complex lesions thanks to its crossing capacity of severely calcified lesions at the 1st attempt and the effectiveness of opening the vessel.”



Dr. Antoni Serra, Hospital
Sant Pau, Barcelona, Spain

Naviscore features

- Rapid Exchange catheter (RX)
- Guidewire compatibility: max. 0,014"
- NP: 8 atm | RBP: 20 atm
- Pt/Ir radiopaque markers
- Proprietary hydrophilic coating Hydrax plus
- 6F compatibility

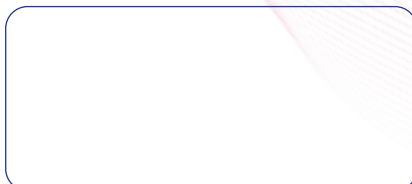
Product with CE mark, certified by Notified Body 0318

Balloon diameter (mm)	Effective length 142 cm				
	Balloon length (mm)				
	6	8	10	12	15
1.50	BCSR14150150006	BCSR14150150008	BCSR14150150010	BCSR14150150012	BCSR14150150015
2.00	BCSR14150200006	BCSR14150200008	BCSR14150200010	BCSR14150200012	BCSR14150200015
2.50	BCSR14150250006	BCSR14150250008	BCSR14150250010	BCSR14150250012	BCSR14150250015
3.00	BCSR14150300006	BCSR14150300008	BCSR14150300010	BCSR14150300012	BCSR14150300015
3.50	BCSR14150350006	BCSR14150350008	BCSR14150350010	BCSR14150350012	BCSR14150350015



The availability of each reference for the sale is linked to the authorization of commercialization in the country of destination

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iCover

Peripheral balloon expandable
PTFE covered stent system

**Designed to
cover all needs**



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iVascular[®]
therapies for living

Able to treat the most tortuous arteries

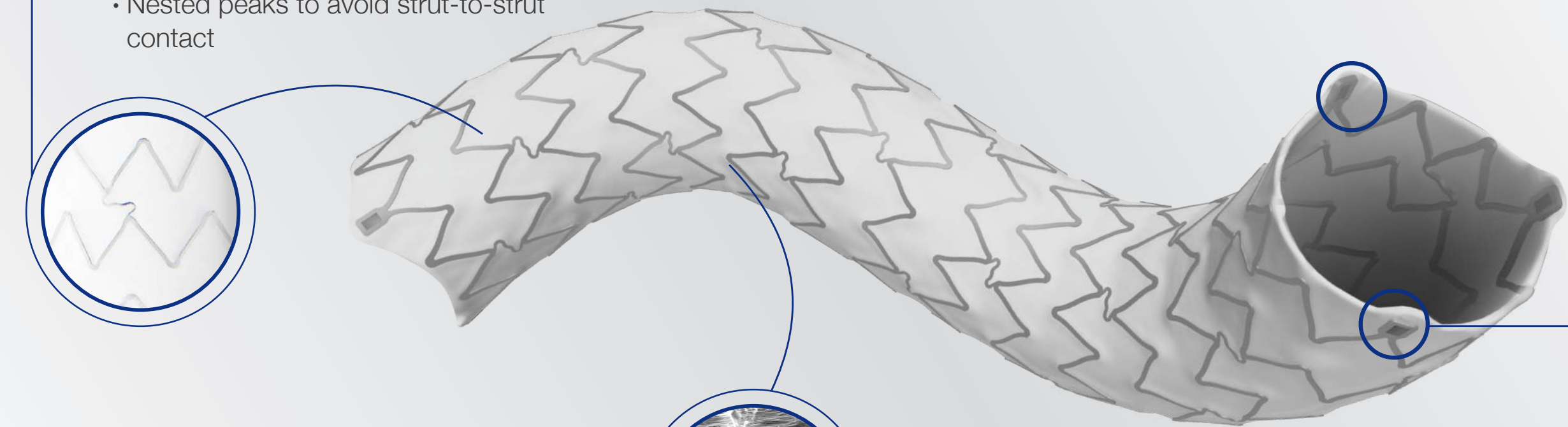
iCover
Designed to cover all needs

Enhanced visibility

Unique stent with radiopaque markers to facilitate the implantation and the post-dilation

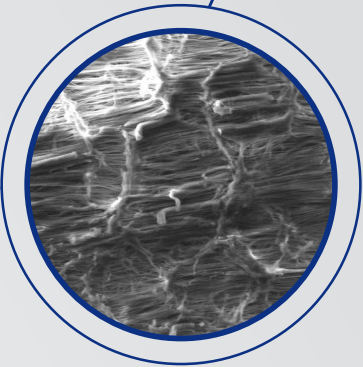
ePTFE covered stent with high flexibility

- Due to:
- Open cell design and alternated links
 - Nested peaks to avoid strut-to-strut contact



Best in class post-expansion capacity (≥2mm)

High ePTFE porosity to ensure covered stent post-expansion capacity



MAXIMUM POST-EXPANSION DIAMETERS						
STENT DIMENSIONS		STENT DIAMETERS (mm)				
		5	6	7	8	9 10
STENT LENGTH (mm)	17	≤10mm				≤12mm
	27					
	37					
	57					

Excellent navigability and easy to implant

iCover
Designed to cover all needs

Outstanding flexibility

of the crimped stent, avoiding the kinking during navigation

Small profiles:

6F introducer compatibility up to 8mm*

- **Crimped on an Oceanus 35 PTA balloon, offering:**

- Short deflation times
- Good pushability and trackability

INTRODUCER COMPATIBILITIES							
STENT DIMENSIONS		STENT DIAMETERS (mm)					
		5	6	7	8	9	10
STENT LENGHT (mm)	17	6F			7F		
	27						
	37						
	57						

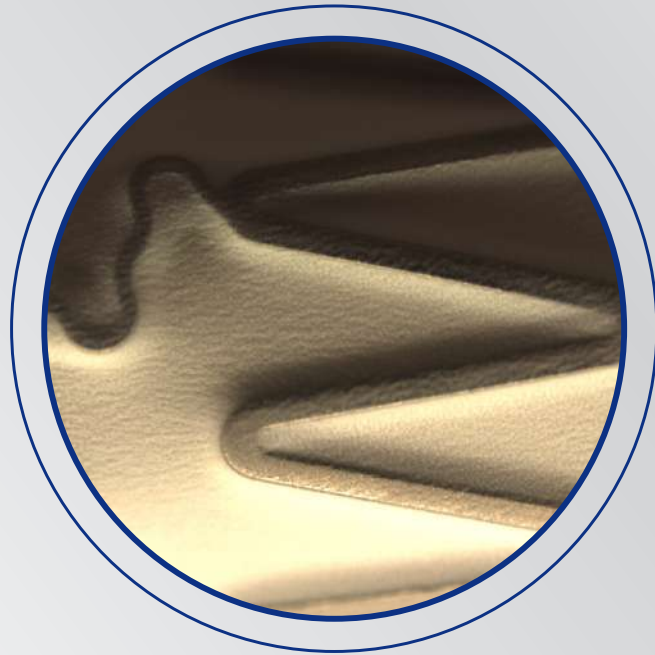
* 6F up to 8x17 mm and 7F from 8x27mm up to 10 mm.

iVascular proprietary encapsulation technology

iCover
Designed to cover all needs



Specific ePTFE laser cutting technology



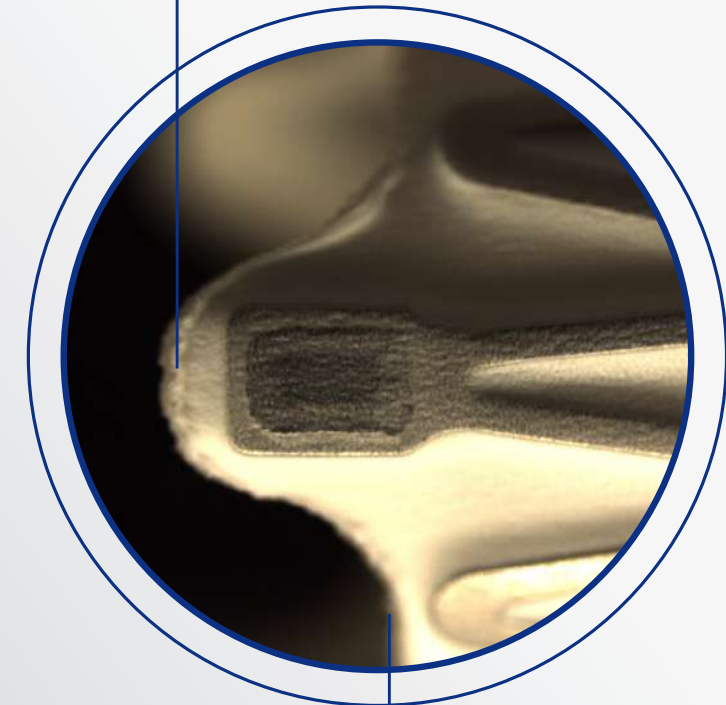
Encapsulation technology

iCover is a stent completely encapsulated with 2 ePTFE layers



Proprietary technology to encapsulate the stent into an inner and outer ePTFE layer

Ensures complete encapsulation avoiding delamination



• **Perfect sealing**

The laser follows the stent outline while cutting the contour

iCover features

- > Over the wire catheter (OTW)
- > Guidewire compatibility: **0.035"**
- > Catheter length: **80** and **140** cm
- > NP: 9 atm
- > RBP:
 - Ø 5-7mm: 15 atm
 - Ø 8mm: 14 atm
 - Ø 9-10mm: 13 atm
- > Maximum post-expansion:
 - Ø 5-8mm: ≤10mm
 - Ø 9-10mm: ≤ 12mm
- > CoverTech encapsulation technology
- > Introducer compatibility
6F (up to Ø8mm, L 17mm), **7F** (≥8mmØ, L27mm)
- > **3 radiopaque markers** at each stent end
- > Stent material: CoCr L605
- > Graft material: ePTFE
- > Recoil: ≤ 10 %
- > Shortening:
 - Length 17mm: ≤ 12 %
 - Length 57mm: ≤ 8 %

Product with CE mark, certified by Notified Body 0318

Effective catheter length (cm)	Stent diameter (mm)	Stent length (mm)			
		17	27	37	57
80	5	SPCBCC35080050017	SPCBCC35080050027	SPCBCC35080050037	SPCBCC35080050057
	6	SPCBCC35080060017	SPCBCC35080060027	SPCBCC35080060037	SPCBCC35080060057
	7	SPCBCC35080070017	SPCBCC35080070027	SPCBCC35080070037	SPCBCC35080070057
	8	SPCBCC35080080017	SPCBCC35080080027	SPCBCC35080080037	SPCBCC35080080057
	9		SPCBCC35080090027	SPCBCC35080090037	SPCBCC35080090057
	10		SPCBCC35080100027	SPCBCC35080100037	SPCBCC35080100057
140	5	SPCBCC35140050017	SPCBCC35140050027	SPCBCC35140050037	SPCBCC35140050057
	6	SPCBCC35140060017	SPCBCC35140060027	SPCBCC35140060037	SPCBCC35140060057
	7	SPCBCC35140070017	SPCBCC35140070027	SPCBCC35140070037	SPCBCC35140070057
	8	SPCBCC35140080017	SPCBCC35140080027	SPCBCC35140080037	SPCBCC35140080057
	9		SPCBCC35140090027	SPCBCC35140090037	SPCBCC35140090057
	10		SPCBCC35140100027	SPCBCC35140100037	SPCBCC35140100057

● Introducer compatibility: **6F** ● Introducer compatibility: **7F**

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iVascular[®]
therapies for living

navitian

Coronary microcatheter



The navigation you need



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Navitian, the needed microcatheter to arrive to the most challenging lesions.

Its exceptional design brings benefits as:

Outstanding trackability through the small and tortuous arteries due to hydrophilic coating HYDRAX PLUS

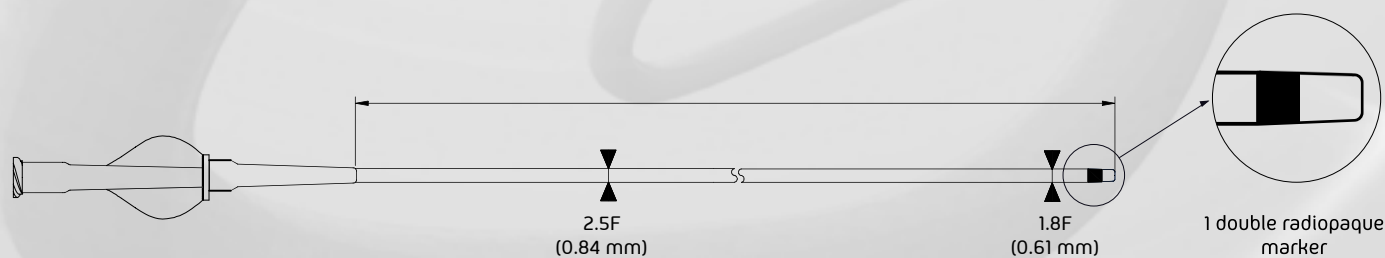
Optimal flexibility, pushability and resistance to kinking provided by a full length variable braided pattern

Complete guidewire control ensured by its conical transition

Superior crossability and penetration capacity due to its optimized tip profile and shape with a double c-cut radiopaque marker

navitian features

- > **Over the wire catheter (OTW)**
- > **Guidewire compatibility** 0.014"
- > **Usable catheter length** 135 and 150 cm
- > **1 double radiopaque marker**
- > **Internal PTFE layer**
- > **Hydrophilic coating:** 70 and 90 cm



Product with CE mark, certified by Notified Body 0318

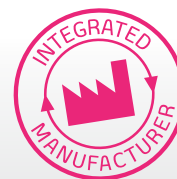
References

Usable length 135 cm
Usable length 150 cm

MCC C14 135 001
MCC C14 150 001

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