

naviscore

Coronary scoring balloon dilatation catheter







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

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



Enhanced scoring capacity

Naviscore performs an effective plaque modification

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 rewrap and recross capabilities

Naviscore inflates as many times as you need

Excellent balloon folding due to its memory shape nitinol structure.

Optimized profile rewrapping 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 plague 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).

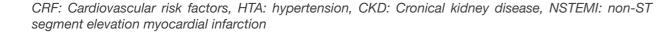




Fig 1. LCx chronically occluded and LAD severely calcified

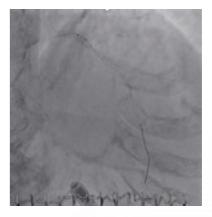


Fig 2. Naviscore penetrating the lesion at 1st attempt

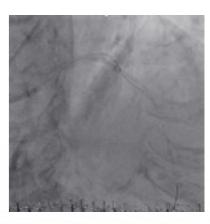


Fig 3. Naviscore crossed the lesion



Fig 4. Naviscore inflated breaking the plaque



Fig 5. Angiografic result after Naviscore



Fig 6. Final angiografic 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."



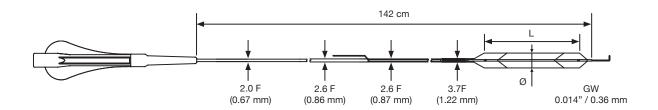
Dr. Antoni Serra, Hospital Sant Pau, Barcelona, Spain



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





