

naviscore

Coronary scoring balloon dilatation
catheter

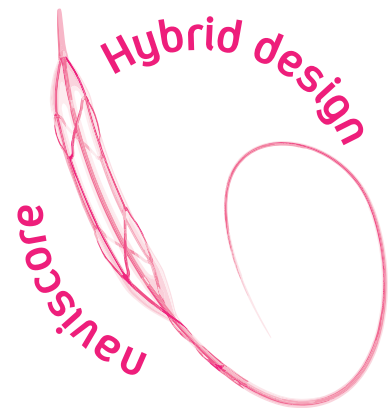


iVascular[®]
therapies for living

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

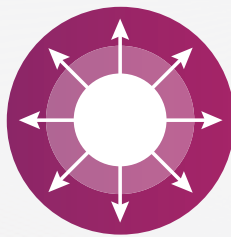


Why Naviscore



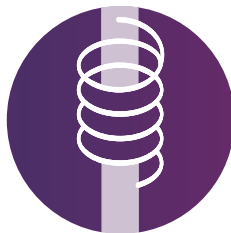
Optimal trackability

Naviscore easily crosses the lesion



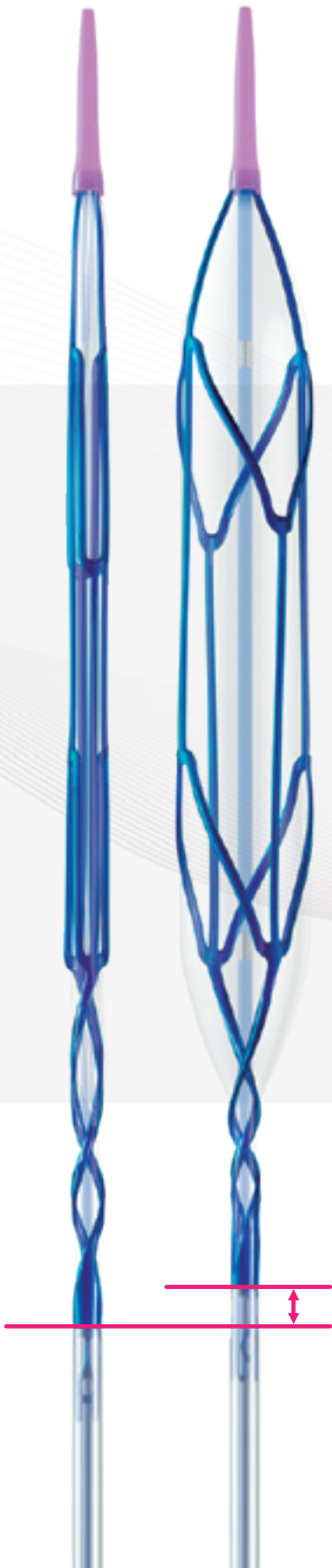
Enhanced scoring capacity

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: Cronical kidney disease, NSTEMI: non-ST segment elevation myocardial infarction



Fig 1. LCx chronically occluded and LAD severely calcified

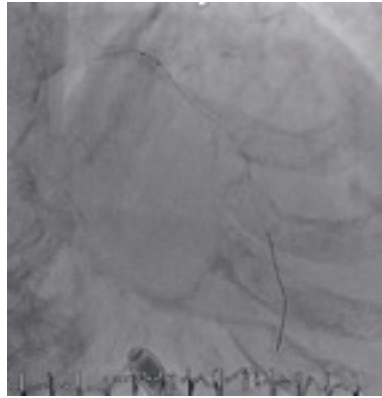


Fig 2. Naviscore penetrating the lesion at 1st attempt

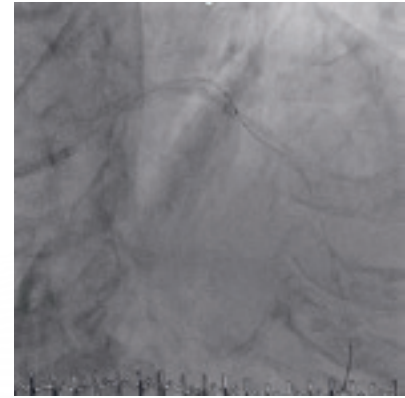


Fig 3. Naviscore crossed the lesion

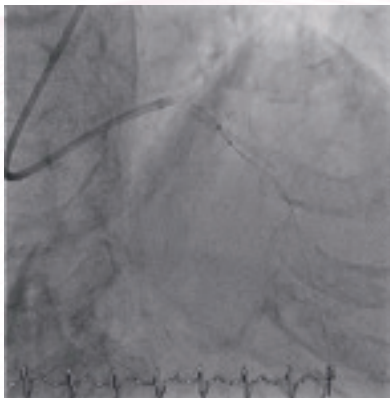


Fig 4. Naviscore inflated breaking the plaque



Fig 5. Angiographic result after Naviscore

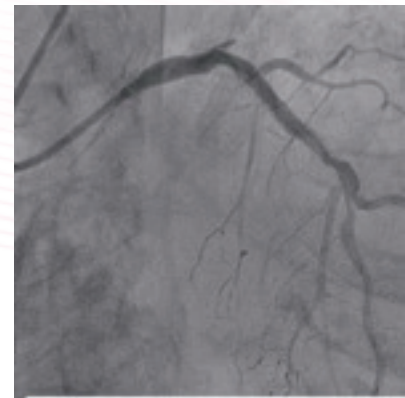


Fig 6. Final angiographic result

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

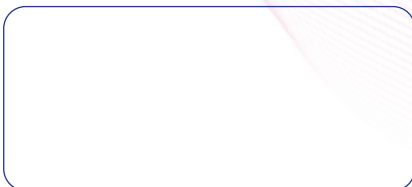
Product with CE mark, certified by Notified Body 0318

| 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 |



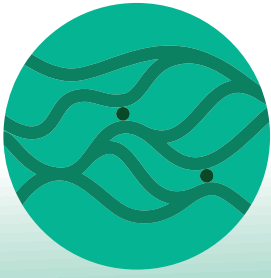
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iNtercept

Stent retriever

Designed to restore the blood flow

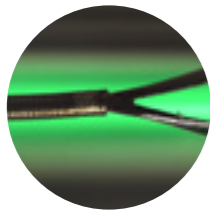


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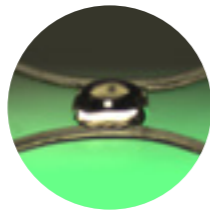
iNtercept, nitinol basket designed to facilitate release and maximise thrombus recovery

Accuracy in the implantation

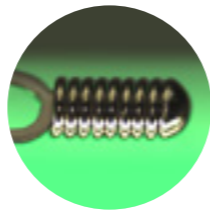
Excellent visibility with:



1 Proximal gold marker



2 Central gold markers arranged in a helical pattern along the length of the basket



3 Distal platinum markers

Compressed

Deployed

Proximal central marker to help position the retriever relative to the thrombus

Excellent conformability

- The axial slit allows a high adaptability
- Closed cells ensure optimal position in the removal

Outstanding pushability and navigability

- Pusher with distal tapered design reinforced by a coil
- Two pushers designed for the different vessels to be treated

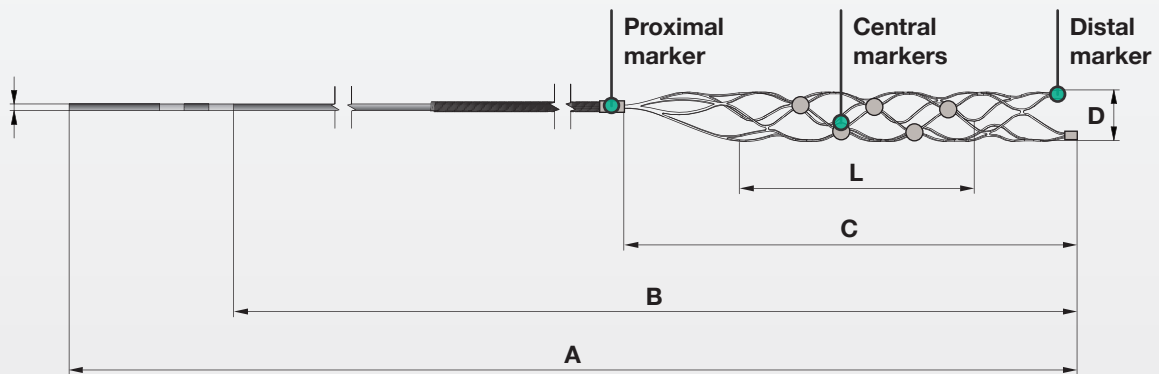
iNtercept features

- > Self-expandable nitinol basket
- > Closed cells
- > Distal radiopaque markers:
Platinum coil → 2 markers in 3mm diameter and 3 markers in diameters 4 and 6mm
- > Central gold radiopaque markers along the basket

- > Proximal gold radiopaque marker at the junction of the pusher and the basket
- > Tapered pusher design at distal level reinforced by a stainless steel coil

Includes

- Torque device



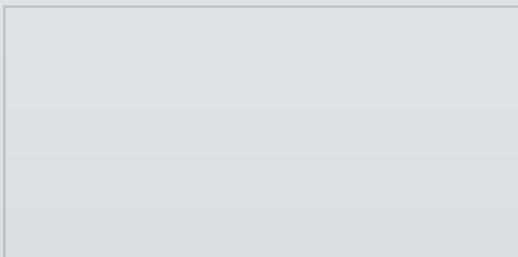
CE mark product. Certified by Notified Body 0318

| iNtercept | | | | | | | | |
|----------------|--------------|--------|--------|--------|--------|--------------------------------------|----------------------------------|----------------------------------|
| References | Nominal size | | | | | Microcatheter compatibility (inches) | Vessel to treat (minimum Ø) (mm) | Vessel to treat (maximum Ø) (mm) |
| | A (cm) | B (cm) | C (mm) | D (mm) | L (mm) | | | |
| DETNS195030015 | 195 | 152 | 28 | 3 | 15 | 0,017 | 1,5 | 2,5 |
| DETNS195030020 | 195 | 152 | 32 | 3 | 20 | 0,017 | 1,5 | 2,5 |
| DETNS195040020 | 195 | 152 | 33 | 4 | 20 | 0,021 | 1,5 | 3,5 |
| DETNS195040030 | 195 | 152 | 42 | 4 | 30 | 0,021 | 1,5 | 3,5 |
| DETNS195060030 | 195 | 153 | 53 | 6 | 30 | 0,021 / 0,027 | 2,0 | 5,5 |
| DETNS195060050 | 195 | 155 | 69 | 6 | 50 | 0,021 / 0,027 | 2,0 | 5,5 |



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