DOMINUS-AB DEVICE: Expectation of a branched device for use in aortic arch aneurysms *(on the shelf)*

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting: BRAILE MEDICAL DEVICES
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
With the Braile Medical Devices from SP/Br, we are working on development of the DOMINUS ARCH-BRANCHED device

**DOMINUS A-B**
This device has been tested since 2016 and it consists in
A single module of endoprosthesis with 03 inner branches
01 to the braquio-cephalic trunk (BCT)
01 to the left common carotid artery (LCCA)
01 to the left subclavian artery (LSA)
And 02 fenestrations
For these branches
It is built on a platform of "Z" stents in nitinol recovered with dacron of low porosity, without proximal free stent or active fixation.
The **proximal** sealing zone is in the **ascending aorta**.
The distal sealing zone is in the descending aorta and
When the **covered stents** are accommodated to the respective supra-aortic trunks.
The submodule to BCT and LCCA is like a "mini bifurcated endoprosthesis". They are 2 independent trunks (12 and 7mm) with "Z" stent structure, covered with a low porosity dacron.
Which are internally sutured to the main module and externalized by a single fenestra in the main body of the endoprosthesis, receiving anterograde flow.
The other submodule to LSA has the same characteristics (7mm) and is exteriorized 2 cm below, positioned to receive retrograde flow.
Each of these internal branches have 34mm, sufficient to promote sealing with the covered stents.
Currently, the delivery system is 24F. We know this is big for this moment but we are working to reduced it to 22F or 20F.
The delivery of the main body will be a safe and precise process controlled by a ratchet system.
It’s INDICATED TO TREAT:
- Aneurysms and / or dissections involving aortic arch and supra aortic trunks from the zone 0, especially when there is a high-risk or unfit for open repair.
- compassionate cases.
- emergencies
This design allows us to expect one “of the shelf” device able to adapt to a variety of anatomies. We used the concepts of parallel stent techniques (chimney and sandwich) and customized devices (fenestrated and branched). Its implantation is independent of the aortic arch segment impaired.
However, the launching of the module and its branches with our purpose depends on a special device developed by our production engineer, able to prevent the interlacing of the guidewires inside the aorta.
This device (8F compatible) has 5 independent internal channels:
With different output positions of the guidewires
1 Central to Extra Stiff guidewire
ES guidewire

1 to BCT guidewire
ES guidewire

BCT guidewire

1 to LCCA guidewire
ES guidewire

BCT guidewire

LCCA guidewire

1 to LSA guidewire
All branches will have their paths pre-identified by independent guidewires without possibility of interlacing, allow a quick accommodation of the covered stents, thus reducing surgical time.
The main module releasing point will be identified through the specific marks in the endoprosthesis. After its releasing we will have flow through the the main body of the endoprosthesis, and from each of its branches and we will not have ischemia of the supra-aortic trunks.
We will insert one introducer for each of the pre-cannulated guidewire, one by one, and we will have each of the target branches individualized.
Externally of the endoprosthesis, in the arterial lumen or aneurysmal sac, the covered stents have free path and they will accommodate according to the patient’s anatomy - as in the parallel stents technique.
CONCLUSION:

This device has advantage over the parallel stents technique or customized technique because:

- there are no gutters between the stents,
- only one main module is used,
- the technique uses pre-catheterization of the target branches
- the exact positioning of the fenestration is not necessary during release – possibility to an "of the shelf" device
- can be fully applied through endovascular technique,
- no hybrid revascularization or interventions are necessary.
- no temporary cerebral ischemia.

- A multi-center study is necessary to prove the applicability and efficiency, and then we hope to return soon to demonstrate this application results.
Thank you.

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