# Large-bore Arterial Access in the Era of Structural Cardiovascular Disease

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July 9, 2020

**Abstract**

Over the last two decades, the medical community witnessed an outstanding and accelerated development on minimally invasive therapies. With the dorsal spine of supportive data from large randomized control trials, transcatheter aortic valve replacement (TAVR), aortic and mitral valve-in-valve, mechanical circulatory support and peripheral endovascular interventions all share the need of accessing a vascular bed with a large bore catheter. Nevertheless, to date, there has yet to be a universal consensus on defining large-bore vascular access (LBVA) in the world of transcatheter therapies. We explore the evolution, characteristics and vascular compatibility of the current commercially available devices, analyze the devices along with access site-specific complications rates and finally review the present methods for percutaneous vascular closure.

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`LBVA_Arterial_Maindocument.docx` available at https://authorea.com/users/341322/articles/468305-large-bore-arterial-access-in-the-era-of-structural-cardiovascular-disease

Table 1. Large Bore Vascular Devices with Minimal Vessel Size

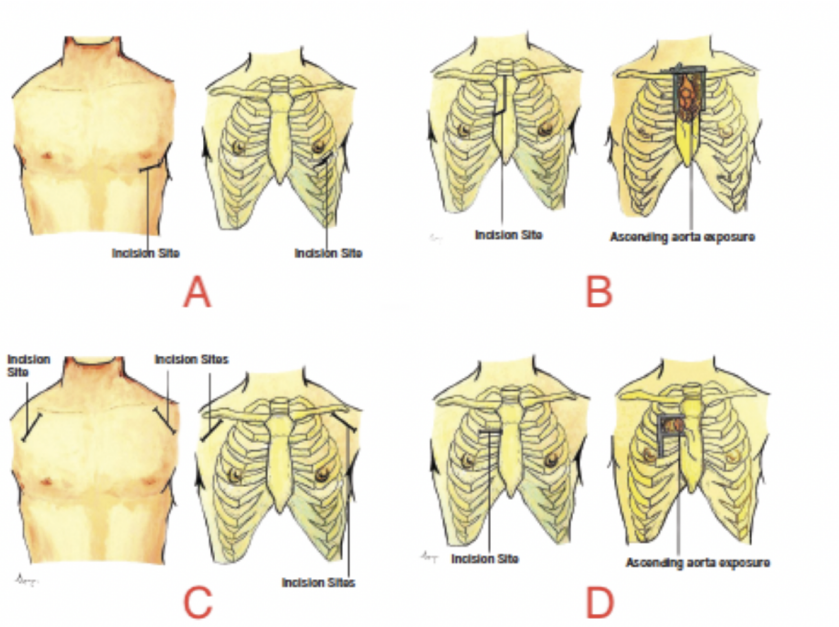
| **Delivery Device** | **Vascular Access Site** | **Procedure** | **Size in Fr** | **Recommended Minimal Vessel Size/mm** |
|---|---|---|---|---|
| Sapien 3 Commander Delivery System | Femoral Artery | Transcatheter aortic valve replacement | 14-16 | 5.5-6.0 |
| Edwards Axela Sheath | | | 14 | 5.5 (6.0 with subclavian/axillary access) |
| Evolut R/EnVeo R | | | 14-16 | 5.0 |
| Evolut Pro/Enveo Pro | | | 14-16 | 5.0 |
| Evolut Pro + | | | 14-18 | 5.0 (5.5 for 16 Fr and 6.0 for 18 Fr) |
| Lotus Edge/iSleeve-Lotus Introducer Set | | | 15 | 6.5 with Lotus Introducer Set/5.9 with iSleeve |
| Acurate Neo Aortic Valve System | | | 18 | 5.9 with the iSleeve introducer |
| JenaValve Pericardial TAVR System | | | | Class III investigational device undergoing clinical trials in the US (not yet FDA approved) |
| Venus Valve | | | | |
| Allegra Valve | | | 18 | |
| Impella CP | Femoral Artery | Mechanical Circulatory Support (Left Ventricle to Aorta Assist Device) | 14 (23 Fr for axillary access) | |
| Impella 5 | | | 21 | |
| Impella RP | | | 22 | Body Surface Area $\geq 1.5 m^2$ |
| TandemHeart | Femoral Artery | Mechanical Circulatory Support (Left Atrium to Aorta Assist Device) | | |

Table 2. Currently Available, FDA-Approved Stent Grafts for Treatment of Thoracic Aortic Pathology.

| **Product Name (Manufacturer)** | **Available Graft Sizes (mm)** | **Proximal Neck Diameter (mm)** | **Sheath/Introduction System Diameter (F)** |
|---|---|---|---|
| TAG conformable thoracic endoprosthesis (Gore and Associates | 21-45 | 16-42 | 18-24 (inner diameter; sheath required) |
| The RelayPlus System (Bolton Medical, Inc.) | 22-46 | 19-42 | 22-26 (outer diameter) |
| Valiant thoracic stent graft (Medtronic) | 22-46 | 18-42 | 22-25 (outer diameter) |
| Zenith Alpha thoracic device (Cook Medical) | 24-46 | 20-42 | 16-20 (inner diameter) |
| Abbreviations: FDA, US Food and Drug Administration | | | |

Table 3. Examples of Endovascular Aneurysmal Repair Delivery Diameters.

| **Device** | **Manufacturer** | **Outer Diameter (F)*** | **CE Mark Approval** | **FDA Approval** |
|---|---|---|---|---|
| Incraft | Cordis Corporation | 14 | Yes | No |
| Ovation | Endologix | 14 | Yes | Yes |
| Nellix | Endologix | 17 | Yes | No |
| AFX | Endologix | 17 | Yes | Yes |
| Zenith Alpha AAA | Cook Medical | 18 | Yes | No |
| Endurant II | Medtronic | 18 | Yes | Yes |
| Excluder | Gore & Associates | 20.4† | Yes | Yes |
| Abbreviations: CE, Conformité Européenne; FDA, US Food and Drug Administration<br>* Size represents the majority of the main body devices in the product range.<br>† Outer diameter of 18-F introducer sheath. | | | | |



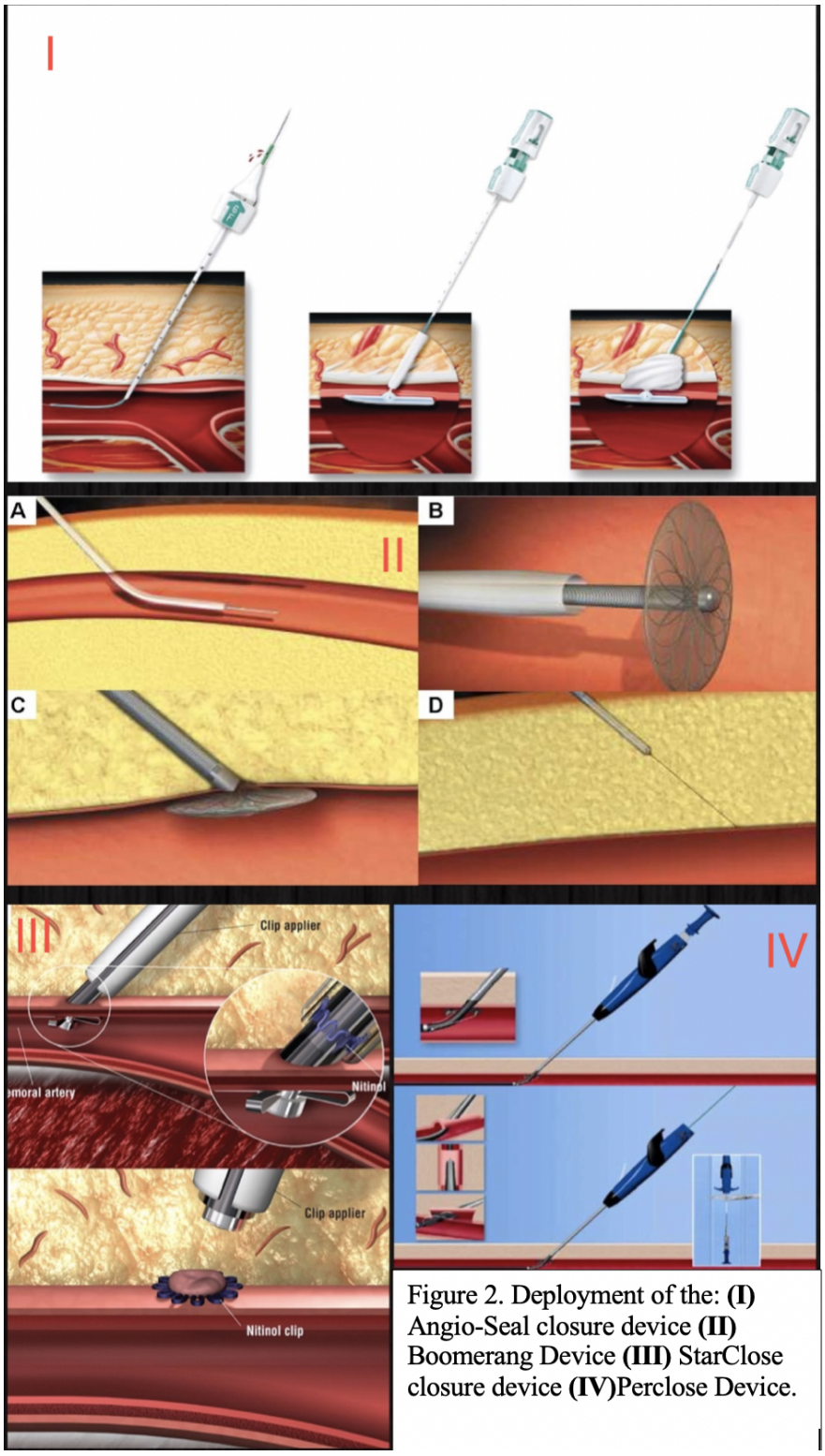



Figure 2. Deployment of the: **(I)** Angio-Seal closure device **(II)** Boomerang Device **(III)** StarClose closure device **(IV)**Perclose Device.