

# Custom-Made Devices: Current State of the Art

An overview of available technologies, how we got here, and what might be coming next.

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Endovascular repair of aortic pathologies has become increasingly utilized over the past 3 decades. What started as a disruptive technology for the treatment of infrarenal aneurysms with physician-made or -modified devices has rapidly expanded into treatment options including virtually every section of the aorta, from the aortic valve to the iliac bifurcations. The evolution of endovascular devices has always been a balanced “tug-of-war” between available commercialized devices provided by industry and physician-modified devices and techniques to achieve technical solutions in areas in which no dedicated device currently exists. Devices that were yesterday’s “out-of-the-box” solution have now become somewhat established techniques in everyday practice. The quest to discover readily available technical solutions that provide endovascular treatment options for the entire aorta is consistently ongoing. The optimal balance between off-the-shelf, universally applicable technologies and custom-made, patient-tailored devices is constantly shifting in a search for optimal patient outcomes.

## CURRENTLY AVAILABLE CUSTOM-MADE DEVICES

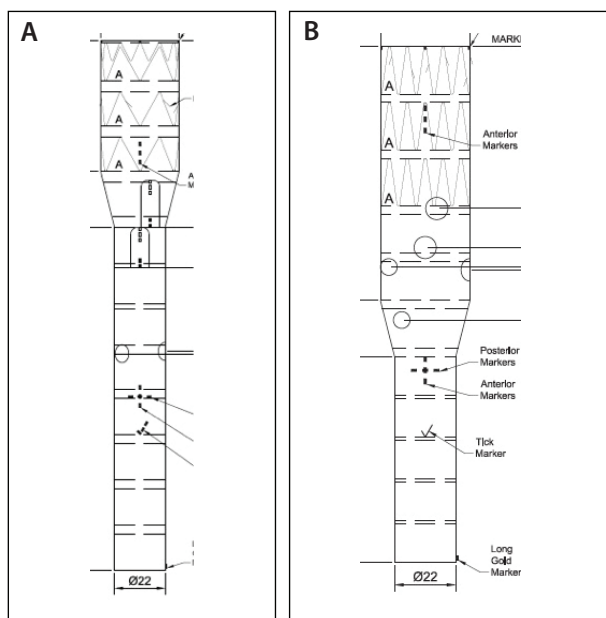
Speaking broadly, the most commonly used standard devices for endovascular aneurysm repair (EVAR) and thoracic endovascular aneurysm repair (TEVAR) are, in some aspects, custom-made. Although each individual component in infrarenal EVAR or TEVAR is standardized, the in vivo assembled device is a composite of these components into a complete endograft that is, by some means, custom-made for each patient. The practice of combining different components from various device manufacturers to achieve a repair in the individual patient is sometimes applied off-label and takes this “customization” one step further.<sup>1</sup>

However, for the purposes of this article, the term custom-made is used for the description of specifically ordered endografts that are tailored to the individual patient’s anatomy and that cannot be achieved by simply combining standard available devices. In most cases, this will involve endovascular stent grafts used to treat areas of the aorta involving side branches (eg, thoracoabdominal, juxtarenal, and suprarenal aneurysms) and aortic arch repair. Although, in some cases, customization will only involve making the diameter larger or smaller or changing the overall length of the endograft. We discuss several stent graft manufacturers that will provide customized devices upon request.

## COOK MEDICAL

Cook Medical provides custom-made devices based on the Zenith platform (Figure 1). Cook was the first company to take this path, with reports from the late 1990s outlining the first cases of implanted physician-made or -modified devices that evolved into custom-made devices, which later provided the platform for the European CE Mark and US Food and Drug Administration–approved Cook fenestrated devices. A similar pathway was seen in the thoracoabdominal branch devices<sup>2</sup> that comprised the foundation of the branch device<sup>3</sup> and the iliac side branch device that was originally conceptualized by using a standard infrarenal Zenith device in the iliac bifurcation.<sup>4</sup> Currently, aside from the approved platforms of fenestrated stent grafts for juxtarenal aneurysms, iliac side branches for aortoiliac aneurysms, and the standard t-Branch stent graft (Cook Medical) for thoracoabdominal aneurysms, custom-made designs based on a combination of these technologies are available for the treatment of juxtarenal and suprarenal, as well as thoracoabdominal, aneurysms. Clinical data from individual centers’ trials have suggested that depending on patient anatomy, the use of fen-

Courtesy of Cook Medical.



**Figure 1.** A low-profile device with two branches for the celiac and superior mesenteric artery and two fenestrations for the renal arteries (A). An endograft with five fenestrations for a patient with two right renal arteries (B).

fenestrations versus caudally oriented cuffs or directional cuffs in different anatomic scenarios might provide different outcomes regarding side branch patency.<sup>5,6</sup> In individual cases, stent grafts with combinations of fenestrations and branches purposely designed to match individual patient designs can be manufactured. A number of studies have shown excellent outcomes using this approach.<sup>6</sup> Physicians are able to plan a design with the help of dedicated planning centers where dedicated planners can review the patient anatomy, oversee the planning request, and, in dialogue with the treating physician, come up with a plan. Cook Medical also manufactures custom-made devices for the treatment of the aortic arch<sup>7</sup> and ascending aorta, but these devices are used only within clinical trials.

## JOTEC

Other than the standard infrarenal EVAR and TEVAR devices, Jotec currently only supplies custom-made devices, including designs with branches, fenestrations, or a combination of the two for the treatment of thoracoabdominal, juxtarenal, and suprarenal aneurysms, as well as aortoiliac aneurysms (Figure 2). Very limited data are available in the literature regarding the outcomes of these devices. In a series of eight patients with thoracoabdominal aortic aneurysms (TAAAs),



Courtesy of Jotec GmbH.

**Figure 2.** Jotec custom-made devices.

Kinstner et al<sup>8</sup> reported a 100% implantation success rate and 29 of 32 visceral arteries were successfully catheterized; two patients required open iliorenal bypasses. At 18-month follow-up, four patients needed treatment for endoleaks, and one type V endoleak with sac expansion was observed.

## VASCUTEK

The Anaconda AAA stent graft (Vascutek Ltd, a Terumo Company) has been available in Europe for more than a decade for EVAR. The Fenestrated Anaconda stent graft (Vascutek Ltd, a Terumo Company) is based on the same platform and is provided as a custom-made device (Figure 3). The design features of the fenestrations are similar to those on the Cook Medical device, but due to the unsupported proximal design of the stent graft, the constraints on fenestration placement with regard to the metal framework of the device are less limiting. The shape of the proximal portion of the endograft offers the possibility to use it as a scallop for a target vessel during repair and, like the infrarenal counterpart, it offers the possibility of constraint and repositioning during delivery, thus potentially overcoming mismatch in planning versus in vivo positioning of the device. The published outcomes are very limited; however, the largest published series of 25 patients with an 11-month median follow-up reported a 96% target vessel patency and 4% operative mortality.<sup>9</sup>

Courtesy of Vascutek Ltd, a Terumo Company.

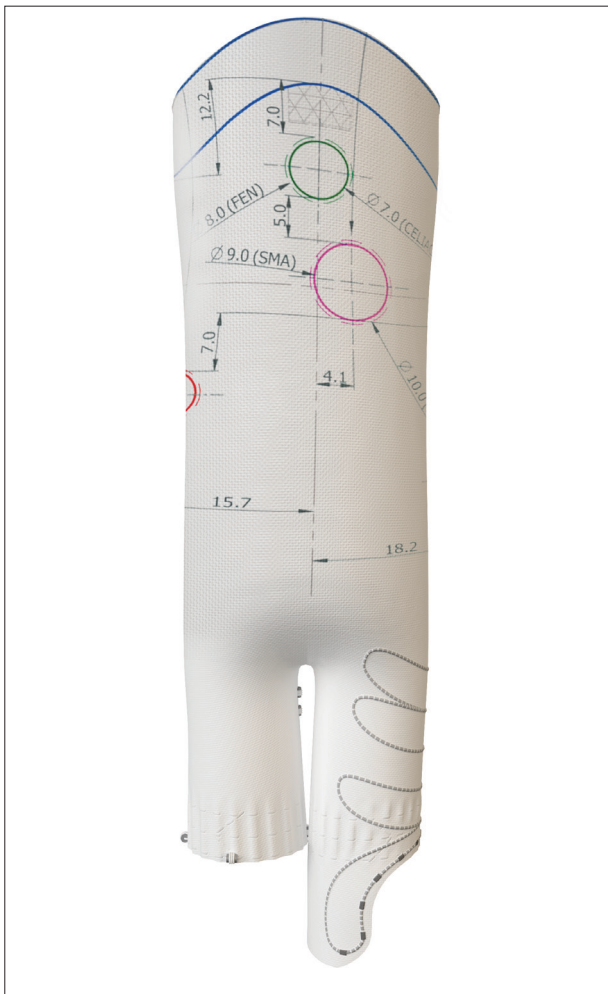


Figure 3. The Vascutek Fenestrated Anaconda stent graft.

### BOLTON MEDICAL

For aortic repair, Bolton Medical offers the infrarenal Treovance and Treo stent grafts, as well as the Relay Thoracic endograft. Based on these platforms, the company has the possibility of supplying custom-made devices for the abdominal and thoracic aorta and the aortic arch. The Bolton Medical dual-branch aortic arch stent graft has a large opening on the convex portion of the graft, which serves as the external opening for two internal branches in the main stent graft (Figure 4). It has a fixed configuration with locking barbs in both internal tunnels to prevent component disconnection and migration. The preliminary results of the global experience of this stent graft in 26 patients showed a perioperative mortality of 11.5% and a stroke rate of 3.5%.<sup>10</sup> Further publications and details regarding the outcomes are awaited.



Figure 4. The Bolton Medical dual-branch aortic arch stent graft.

Courtesy of Bolton Medical.

The Bolton Medical Thoracic Relay graft can also be customized with scallops on the distal and proximal aspects to accommodate arch vessels (proximally) and the celiac and superior mesenteric arteries (distally). This technique has been evaluated by Dr. Rimbau and colleagues in Barcelona, Spain, with great success.<sup>11</sup>

### CONCLUSION

The field of EVAR has grown rapidly since the initial treatment of simple infrarenal aortic aneurysms. New devices currently allow for the endovascular treatment of the entire aorta, including challenging areas of branching vessels, such as the visceral aorta and the aortic arch. However, the variability in anatomy in these challenging areas of the aorta requires extensive customization to allow for individual graft design and treatment. Furthermore, branch vessel anatomy

is very diverse. Preliminary data suggest that the outcome when using directional branches versus “simple” fenestrations and scallops to revascularize target vessels is important for long-term patency and outcomes. These anatomic challenges have made the quest for readily available, standardized off-the-shelf devices difficult to bring into clinical practice.

At present, the only available off-the-shelf device is the Cook Medical t-Branch device for the treatment of TAAAs. With its four caudally oriented directional cuffs, it is quite versatile, but studies indicate that the device can only be used in approximately 50% of patients presenting with TAAAs.<sup>12</sup> In addition, universal application of this device, including use in off-label anatomy, has shown a significant increase in renal branch complications. Several other off-the-shelf grafts are currently in trials, including the Cook p-Branch<sup>13</sup> device for juxtarenal and suprarenal aneurysms, the Gore Thoracoabdominal Endoprosthesis device (Gore & Associates) for TAAAs, and the single-branch devices for the aortic arch, such as the Medtronic Valiant Mona LSA and the Gore single-branch thoracic device.

Early clinical results have been presented and are promising, but the applicability in a real-world setting and the long-term outcomes are currently unknown. In parallel to the development of dedicated off-the-shelf devices, the use of innovative hybrid techniques with chimney grafts, sandwich grafts, periscopes, and snorkels is widely used and reported.<sup>14,15</sup> These techniques are appealing at first sight, as they offer immediate treatment options using standard materials for complex clinical scenarios; however, a complete lack of stringent preclinical and clinical testing and trials for these devices makes the true scientific results difficult to interpret.

At present, it is likely that the off-the-shelf grafts and alternative parallel graft techniques will continue to develop and have a role when approved devices, such as the Cook t-Branch or standard fenestrated grafts, are not suitable. However, with the present technologic platforms, it is unlikely that these techniques will suffice to treat all of the available scenarios. Thus, custom-made devices are likely to continue to play a significant role in the treatment of complex aortic disease for the foreseeable future. Although difficult to study (every device is unique and thus, potentially, has a unique set of problems), large prospective registries have the possibility of evaluating these devices more stringently. Improved production and streamlining of planning procedures will likely make custom-made devices more available as well.

An interesting step in this direction is the concept of standardizing physician-modified devices, as proposed by Dr. Starnes in Seattle, Washington.<sup>16</sup> By using three-dimensional templates created from individual patient CT scans, in combination with computerized planning software, individualization potentially becomes rapid and precise, and is the ultimate individualization. If this can be combined with improved production capabilities, the ultimate custom-made stent graft could become available expeditiously. ■

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*Disclosures: Consultant, speaker, and holds intellectual property with Cook Medical.*