

Arterial Coupler Re-Design for Anastomosis

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Arterial anastomosis is the surgical connection of two blood vessels to restore or redirect blood flow. Despite its importance, current techniques remain highly dependent on surgeon skill and are time intensive. The global anastomosis device market was valued at \$4.41 billion in 2025 and is projected to reach \$7.07 billion by 2033 (Anastomosis Devices Market Size | Industry Report, 2033, n.d.).

Microsurgical procedures represent only 1-2% of over 300 million annual surgeries but carry high technical complexity and risk (Hinds et al., 2017). Individual centers perform approximately 80-120 microsurgical free flap procedures annually, highlighting both the specialized nature of these operations and the limited opportunities for standardization and skill acquisition (Kovatch et al., 2019). Across surgical anastomosis procedures, clinically significant complication rates persist, including anastomotic leakage rates around 6.3% and postoperative mortality rates near 5.6% in high risk surgical settings (Kilaviz et al., 2025). These outcomes reinforce the need for more reliable and standardized anastomosis techniques.

Manual microsuturing remains the primary method for arterial anastomosis. It is technically demanding, time-consuming, and highly dependent on surgeon experience, typically requiring 30 to 60 minutes per procedure. Even in expert hands, complication rates such as thrombosis, leakage, or anastomotic failure can reach up to 8%, reinforcing the need for a more consistent alternative (Pafitanis et al., 2021).

The GEM Microvascular Anastomotic Coupler (Synovis/Baxter) is widely used for venous anastomosis, achieving patency rates above 95% and reducing operative time to approximately 7.5 minutes (Ohayon et al., 2025). However, no comparable device exists for arterial anastomosis. Arteries present additional challenges due to thicker vessel walls and higher intraluminal pressures, which can lead to misalignment and leakage (Mercadante & Raja, 2025). There are currently no commercially available devices for arterial anastomosis, and suturing remains the standard of care. Existing designs and patents have not produced a clinically adopted arterial solution.

To address this gap, we developed a mechanical stent-like device that reduces reliance on suturing, designed to improve procedural speed, consistency, and reliability. The device everts one arterial end over a cuff and secures the opposing vessel over it, forming a sealed connection through external wall apposition. The nitinol composition provides circumferential compression, enabling secure fixation and alignment of thicker arterial walls under physiological pressures.

The design was validated through benchtop testing using biological vessel models to assess leak resistance, alignment, and time efficiency. Testing demonstrated a 40% reduction in anastomosis time compared to traditional suturing, while maintaining acceptable sealing performance under physiologic pressure conditions. Overall, this approach offers a scalable solution to reduce operative time, improve consistency, and minimize complication risk in arterial anastomosis procedures. This device is designed to integrate into existing surgical workflows without requiring significant changes to current techniques, improving accessibility to reliable arterial anastomosis across varying levels of surgical expertise.