



devices for use in microsurgical applications. MSI's first product for commercialization, a Vascular Coupling System (VCS), is intended to replace the hand suturing technique currently used to

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The current state-of-the-art procedure in microsurgical vascular anastomosis is hand-suturing the two cut ends of an artery or vein together using ultrafine techniques with the assistance of an operating microscope. Hand suturing is time consuming (30-60 minutes depending upon the surgeon's ability), requires expertise, and is prone to human error. Sutures must penetrate through the wall of the vessel and can damage the vessel intima or inadvertently catch the vessel backwall, both of which can lead to thrombosis. The added time of manually hand-suturing vessels translates to significant cost in the operating room which are further exacerbated if complications such as thrombosis, leakage, or stenosis occur. There have been many attempts to improve the current manual suturing technique, all of which have fallen short. Venous coupling devices like the Synovis GEM offer a competing technology; however, these devices do not work well with thick walled arteries. Researchers at the University of Utah's Agarwal Research Lab have developed a vascular coupling system (VCS) that is

leaving foreign material in the lumen to come in contact with blood flow. This patented device has been licensed to Microsurgical Innovations who is in the process of bringing its VCS device to market in collaboration with **Microsurgical Innovations**. Market size estimates are based on the number of

microsurgery operations performed each year, including plastic surgeries, reconstructive surgery after injuries or disease, replantation of severed appendages, and organ transplants. This total is estimated to surpass 100,000 procedures. Each microsurgery involves at least two anastomoses, thereby doubling the number of devices required. Due to the ease of use, reliability, and ability to couple arteries, this device has the potential for expanding the number of microsurgeries performed by enabling less experienced surgeons to undertake such procedures. It could also be used in



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other surgical disciplines, including non-vascular procedures such as bile duct repair (laparoscopy) and reversal of tubal ligation or vasectomy procedures. Typically, microsurgeries are carried out in tertiary care settings, and a successful VCS that does not require additional physician training has the potential to expand these microsurgeries into the community hospital and battlefield settings. Future growth opportunities lie in Asia, as most Asian countries perform many more microsurgical procedures than are performed in the US. To effectively position this technology for market entry, the VCD addresses the needs of the market and provides compelling value. The VCD improves workflow efficiency by reducing surgery time, decreasing human technical error, and making the procedure much easier than suturing. Ease of use, time savings, and the ability to be used with arteries as well as veins will be validated through comparison to manual suturing and procedures with the comparable Synovis coupler.

7 Preliminary projection of revenue of the VCD are based upon an assumed per unit price of \$350 and a price of \$3,000 for the instruments; both prices of which are based upon comparable prices for the Synovis GEM line of anastomosis coupling products. The size and engineering requirements for these devices are similar, as are their intended use propositions. The Financial Model assumes that the total addressable market in this segment is approximately 100,000 units per year with a yearly market growth rate of 3%. The Financial Model also assumes a penetration rate for the VCD and its instruments of only 5% per year, which then drives the unit sales numbers for the forecast. With those as inputs, the Model generates revenue projections of \$3.9 million in the first year of sales (2022), \$10.3 million in 2023, and \$17.0 million in sales in 2024.

7 The MSI founders have extensive experience working with each other over the last five years, completing foundational research for the VCD they developed, along with various other collaborative research efforts involving other medical devices. The MSI founders also have a track record for receiving federal funding from various agencies including SBIR/STTR funding for other projects. Additionally, the founders have developed an accomplished entrepreneurial track record, founding startup companies and delivering products to market. Based on invitro, animal, and early i



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MSI's founders and staff are all from the University of Utah and have successfully worked together on this and other projects:

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- Dr. Jay Agarwal is the Chief of Plastic Surgery Division and is the President for MSI. Dr. Agarwal is a microsurgery specialist and experienced in animal models of nerve and vascular
- Dr. Bruce Gale is Professor and Chair, Mechanical Engineering, and Vice President of Engineering for MSI. He has successfully commercialized a high throughput microfluidic based protein printing technology through his company Wasatch Microfluidics with \$2 million/
- Dr. Himanshu Sant, Research Associate Professor, is the Vice President of Operations at MSI.

