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Integrally Joined Stainless Steel-NiTi Medical Devices

A method for manufacturing surgical tools and implants with strong, gapless joints between NiTi (Nitinol) and stainless steel to capitalize on the best properties of both materials. One example is a cardiology guidewire featuring a stainless steel shaft to give the surgeon good control and a NiTi pigtail tip which recovers an optimal shape after insertion to prevent damage to nearby tissue.

- ***Patent Status: Patent Pending***

LEAD INVENTORS

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Prof. Dapino is the Honda R&D Americas Designated Chair at The Ohio State University, where he is a professor and director of the National Science Foundation Industry-University Cooperative Research Center on Smart Vehicle Concepts. Prof. Dapino's expertise is in smart materials and structures, advanced manufacturing, and system integration.

Prof. Panton is the Lincoln Electric Company Endowed Professor at the Ohio State University. Prof. Panton's expertise is in laser welding, microwelding, and processing of shape memory alloys. Prof. Panton has experience in medical devices, medical guidewire manufacturing, and an entrepreneurial background that have given him the drive to develop new technologies.

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Market Need

NiTi (Nitinol) is widely accepted and used for medical devices such as surgical tools and implants due to its biocompatibility and unique thermal-mechanical properties which provide superelastic or shape memory responses. However, there are currently no commercial solutions for joining of NiTi to other metals such as stainless steel (SS) without deterioration of the NiTi properties or the joint interface. This limits the ability to capitalize on the properties of different metals for different functions in medical devices. Current methods for mechanically joining NiTi and SS severely limit design freedom. Therefore, many surgical tools must be either all NiTi or all SS.

According to a BCC Research report (HLC051H), Minimally invasive surgical (MIS) techniques correspond to a $21-billion USD global market with a CAGR of 7.1% and estimated market size of $29.6-billion USD by 2024. Guidewires are one example of an MIS device for which no adequate method of joining NiTi and SS currently exists. As a result, current guidewires are made entirely from either SS or NiTi. SS tools are stiff enough to give the surgeon good control of the tool but the pigtail tip plastically deforms during insertion through the catheter, losing its optimal shape and risking damage to nearby tissue. Superelastic NiTi tools provide an optimal shape after insertion through the catheter, but the flexibility of the shaft makes it difficult for the surgeon to control. Therefore, there is a need for a method to produce strong, gapless joints between NiTi and SS to capitalize on the advantages of both materials. For example, a pigtail guidewire with a SS shaft and NiTi pigtail tip would provide both good controllability and the safe, optimal shape of the inserted pigtail.

Technology

Our team at The Ohio State University have developed a method to seamlessly join NiTi and SS using ultrasonic consolidation. This process produces solid-state welding of metals at low temperatures, preventing degradation of the NiTi properties while retaining the temper of the SS and providing robust, gapless joints. Figure 1 shows an optical micrograph of a NiTi wire embedded in 410 SS at OSU.

In order to overcome the limitations of current all-NiTi or all-SS cardiology pigtail guidewires (e.g., Figure 2), the team has developed a SS-NiTi guidewire with a SS shaft and a NiTi pigtail tip to provide both control and optimal tool shape after insertion. A NiTi wire is seamlessly embedded in the end of a SS shaft and extending out to form the tool. The NiTi tip can be shaped into any desired tool geometry, such as a pigtail as illustrated in Figure 3.

The inventors have reached the proof-of-concept stage with this technology and a provisional patent has been filed. The team is looking for a co-development partnership capable of helping them move the project forward into the next stages of design and execution.

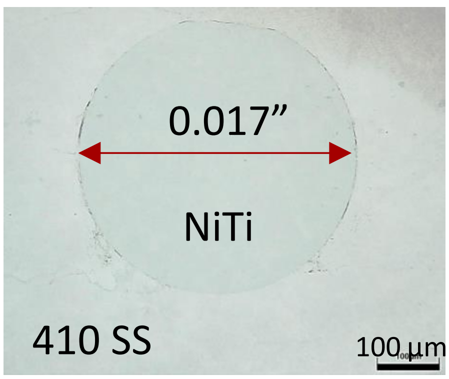

Figure 1: *Example of a NiTi wire embedded in 410 SS at OSU using ultrasonic consolidation. The NiTi wire extends from the SS shaft and can be shaped into the desired tool tip geometry, such as a pigtail.*

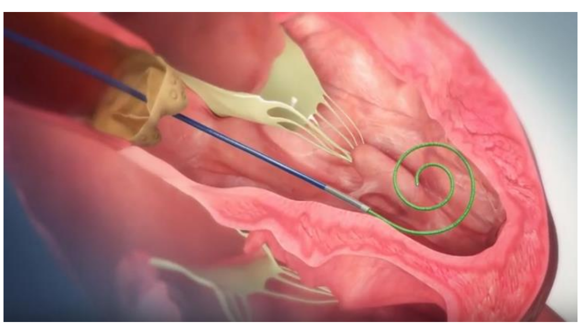

Figure 2*: Commercial SS cardiology pigtail guidewire.*
[“SAFARI2TM”, Boston Scientific, 2019. Web. <https://www.bostonscientific.com/en-US/products/guidewires/safari2-preshaped-guidewire.html> Accessed 20 Aug 2019.]

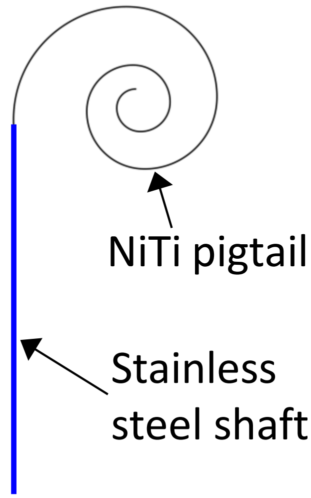

Figure 3: *NiTi-SS pigtail guidewire: an example of what can be manufactured using this technology.*

Commercial Applications

- Tools for minimally invasive surgery
- Medical implants
- Robotic actuators
- Deployable space structures

Benefits/Advantages

- Capitalize on the best properties of both NiTi and SS for medical tools and implants
- Strong, seamless interface eliminates gaps that can trap contaminants
- Technology can be applied to wires, plates, and other 3D shapes