Case Study

Liquidmetal® Alloys in Minimally Invasive Medical Devices

Industry
Medical

Challenge
Produce a high performance medical device that meets extreme demands in an economically sensitive market.

Millions of minimally invasive surgical procedures are performed every year in the United States. These procedures are commonly performed by, but not limited to: Gastroenterologists, Internists, Gynecologists, Cardiovascular Surgeons, Plastic and Reconstructive Surgeons, Orthopedic Surgeons, and Veterinarians. Of the dozens of different procedures performed using minimally invasive techniques, most of them utilize at least one piece of equipment that contains a component suitable for the Liquidmetal technology. These components could currently be CNC machined, injection molded, investment cast, stamped, or fine blanked. While Liquidmetal alloys are not limited to applications currently utilizing another metal, many metal components could be improved by this technology.

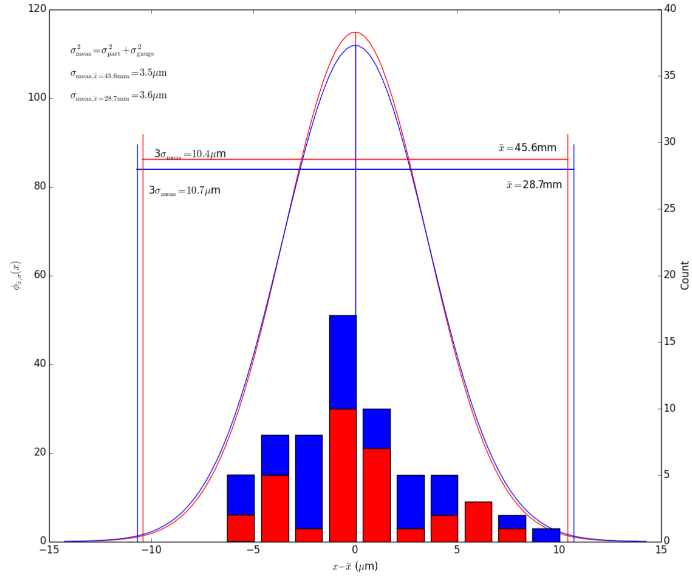
As the number of minimally invasive surgeries increases, the complexity of the medical devices used continues to increase as well. The demand for equipment that is highly precise, complex, durable, and price sensitive is rapidly growing as a result. This case study will examine each category individually, and reveal how Liquidmetal alloys could be a novel technology advancement in the industry.

Precision and Repeatability

Since the upsurge of minimally invasive procedures in the early 1990's, devices have continued to become smaller and more complex. The goal is to minimize tissue trauma, decrease surgery time, decrease patient recovery time, and improve equipment and surgeon performance. Expensive processes are often used in order to ensure medical device components are manufactured to exact specifications on a consistent basis.

Liquidmetal alloys have a particularly unique characteristic that crystalline metals lack. When molten, prior to being injected into molds, Liquidmetal alloys are amorphous. What's interesting is that when they are cooled in the mold they maintain their amorphous structure in the solid state. There is no phase transformation like that which occurs in crystalline metal alloys. Additionally, very little shrinkage occurs (<0.5%). These two unique characteristics contribute to the remarkable dimensional control and repeatability of the Liquidmetal manufacturing process. Following extraordinary documented results on a recent customer application where surface profiles where critical to the performance of a part, Liquidmetal engineers have been collecting additional process variation data, which will be reported in an upcoming white paper. The Liquidmetal team is using a Hexagon Metrology, Optiv Classic 321 tp coordinate-measuring machine (CMM) to evaluate the precision of a Liquidmetal test part. Preliminary data collected from a sample size of 32 parts has demonstrated remarkable results. No part differed from the next by more than 16μm (0.0006") for two different dimensions on the part, which were 28.7mm (1.13") and 45.6mm (2.03"). Like the recent customer experience, the Liquidmetal process and alloys can achieve tight tolerances that rival many production CNC machining processes.

The chart below displays a histogram of data collected from the 32 piece sampling of the Liquidmetal test part. You will note the three standard deviations for the two dimensions 28.7mm and 45.6mm respectively.



The chart below contains a generalized comparison breakdown of CNC machining, investment casting, MIM and Liquidmetal dimensional variation capabilities for critical part dimensions.

	CNC MACHINING	MIM	INVESTMENT CASTING	LIQUIDMETAL
Part-to-part variation	± 13-25 μm (0.0005-0.0010")	± 51-254 μm (0.002-0.010")	± 127-254 μm (0.005-0.010")	± 8-14 μm (0.0003-0.0006")
Dimensional tolerances	± 18-38 μm (0.0007-0.0015")	± 76-381 μm (0.003-0.015")	± 127-254 μm (0.006-0.015")	± 13-38 μm (0.0005-0.0015")

Durability

A significant part of the performance that medical professionals rely on in a device is its durability through its life of use regardless if it is a reusable or disposable device. Whether or not a component can withstand its procedural environment could possibly impact the patient's wellbeing and recovery. Highly common materials used for metal components in minimally invasive devices currently include 17-4PH, 316L, and 420 stainless steels. With the reduction in the size of parts, along with increased complexity, there is an increasing need and opportunity for high performance alloys.

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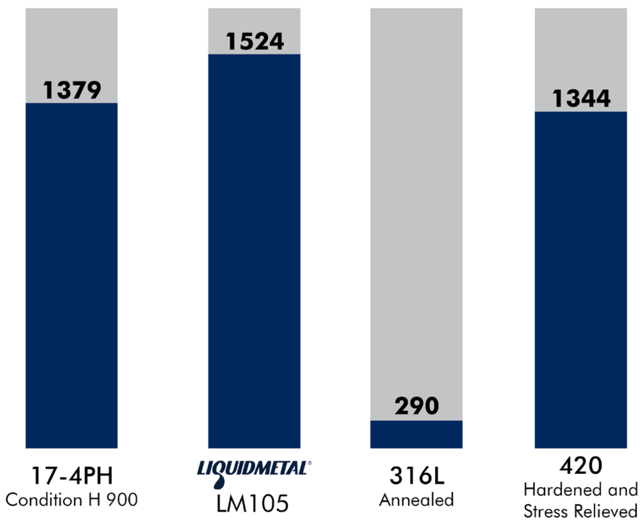
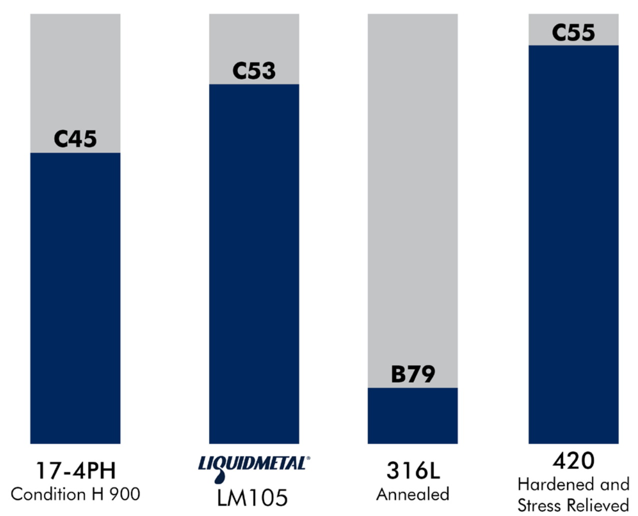
Because device failure in a patient is not an option, strength is a critical property. Liquidmetal LM105 boasts a 1524 MPa yield strength, which is 11% better than stainless steel 17-4PH, its nearest competitor.

Yield Strength (Mpa)



Liquidmetal LM105 also boasts an impressive 563 Vickers hardness, or 53 Rockwell C out of the mold.

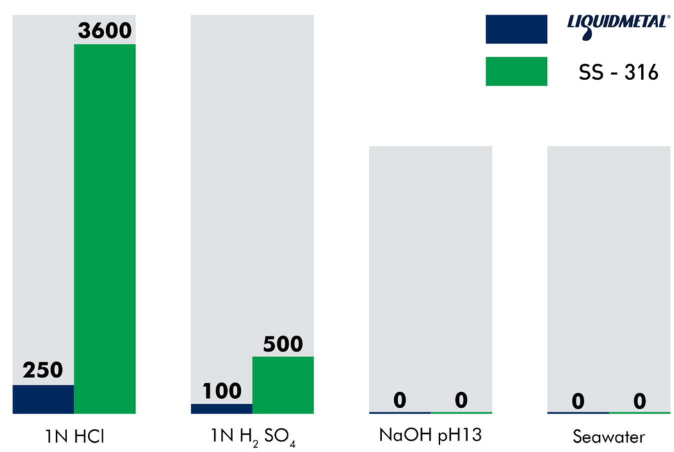
Hardness (Rockwell)



In Liquidmetal alloys, these properties are formed by the amorphous material composition. Additionally, no post mold processing is required to achieve final properties. Crystalline metals like 17-4 PH and 420 stainless steel require heat-treating to attain final properties, which can cause distortion, reduction of dimensional precision, and create quality problems if they are not processed correctly.

Liquidmetal alloys have been through extensive corrosion tests showing excellent performance throughout. ASTM B117 salt spray data showed no visual signs of corrosion for 336 hours, even up to 5,000x magnification in a Scanning Electron Microscope. In a 30-day immersion test, solutions were analytically diluted to 1L and inductively coupled plasma mass spectrometry was performed to determine elemental concentrations. In comparison with stainless steel, the Liquidmetal alloy experienced less than 10% the dissolution in 1N HCl, and 20% the dissolution in 1N H2 SO4.

Total Dissolution Concentration (PPM)



Factoring in an elastic limit of 1.80% (as a percentage of its original shape), LM105 presents a truly unique combination of material properties. Now you can give the end user full confidence in the product, and manufacture a part with properties that normally require extensive post processing, all in one step.

Economic Sensitivity

Pressure to cost reduce surgical procedures and surgical devices is ongoing and intense. Most traditional metalworking technologies have been cost reduced to the point where only minor improvements are achieved from time to time. Alternatively, switching from one technology to another is not often a simple proposition as there are usually capital costs associated with tooling, along with product qualification costs to keep in mind. Meaningful future reductions will come from innovative processes and device designs. Liquidmetal Technologies' approach is to provide both an innovative process and materials, while giving customers engineering support to develop parts that leverage the technology's maximum benefits.

Providing downstream product cost improvements can come from the ability to design parts previously uneconomical to produce by other processes such as CNC machining, eliminating part assemblies, achieving a range of properties without post processing requirements, and reducing inventory costs through the reduced total process cycle times achieved by the Liquidmetal single process step.

The Liquidmetal one-step part forming process starts with a crystalline ingot. The material is melted under vacuum and injected into highly precise molds. Within a couple minutes a fully amorphous part tree is ejected from the mold and placed on a cooling belt for de-gating. This results in down to 2.0 Ra μin. surface finish, 563 Vickers hardness, and exceptional corrosion resistance right out of the mold, among other extraordinary properties.

Previously, engineers were forced to manufacture parts knowing the restrictions and costs of a process, and working within them. Valuable consistency and performance properties are often only available at high costs, especially in the custom union necessary for your specific part. With Liquidmetal alloys, now you can design like you've always dreamed, attain a rare combination of material properties, manufacture in one step, and secure economic gains through the entire product life cycle.

Design Guidelines, Welding, and Biocompatibility

The Liquidmetal process provides an extremely unique combination of material properties and shape making capabilities that are uncommon in traditional metalworking processes, even when those primary processes include post processing steps. At a basic level, here are a few design guidelines for Liquidmetal parts:

- Part weight up to 80 grams
- Maximum dimension of 100mm
- Outer draft angles of 0.5° to 3°
- Inner draft angles of 1° to 5°
- Wall thickness of 0.6mm to 4.0mm
- Dimensional tolerance of ±0.025mm or better for critical dimensions
- Mold cavities up to 64

Most principles of good plastic part designs also apply to Liquidmetal parts. The injection molds used to produce Liquidmetal parts are also similar to those used for injection molding thermoplastics.

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One distinct difference between plastic parts and Liquidmetal part design is the gate size used. Generally, gates for Liquidmetal parts are larger. Our engineering team can help specify these requirements for your specific parts.

Liquidmetal alloys can be welded together, allowing for increased part size and complexity. Liquidmetal engineers have had excellent success welding with an electron beam, and micrographs of the results are promising. Maintaining amorphous structure throughout the part is critical to preserving Liquidmetal alloys' remarkable properties. In one case, a 9.6mm wide specimen was electron beam welded and there were no signs of crystallization in the fusion zone.

The self-welding properties of some Liquidmetal alloys in the right conditions are remarkable, creating a weld that is hard to differentiate from virgin material. The weld illustrated in the photograph below was performed by e-beam welding.

The Liquidmetal team is continuing extensive research into welding Liquidmetal alloys to one another and dissimilar alloys. Future reports will detail this work.
Liquidmetal LM105 has also recently completed its first round of ISO 10993 biocompatibility testing. While each individual device must undergo its own ISO certifications to account for its specific processing methods, this information serves to give potential customers confidence that LM105, is highly promising as a biomedical device material. The results from a third-party laboratory for sensitization, irritation, systemic toxicity, hemocompatibility, and cytotoxicity are below. Both in vivo and in vitro tests were conducted on 45x45x2.1mm3 plates molded from the ENGEL Liquidmetal e-motion injection molding machine.

Completed Biocompatibility Tests for Liquidmetal As-Molded LM105 Alloy
From Table A.1 - Evaluation tests for consideration from ISO 10993-1

[shaded] Required   X = Completed and passed

Device Categorization By			Biological Effect				
Nature of body contact		Contact duration **A** - Limited (<24 hrs.) **B** - Prolonged (>24 hrs. to 30 d.) **C** - Permanent (>30 d.)	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Systemic toxicity	Hemocompatibility
Category	Contact						
Surface Device		A	x	x	x		
		B	x	x	x		
		C	x	x	x		
	Mucosal membrane	A	x	x	x		
		B	x	x	x		
	Breached or compromised surface	A	x	x	x		
		B	x	x	x		
External Communicating Device	Blood path, indirect	A	x	x	x	x	x
		B	x	x	x	x	x
	Tissue/Bone/ Dentin	A	x	x	x		
	Circulating blood	A	x	x	x	x	x
Implant Device	Tissue/Bone	A	x	x	x		

In conclusion, Liquidmetal's LM105 as-molded commercial alloy produced on the ENGEL Liquidmetal injection molding machine is non-sensitizing, non-irritating, non-systemic-toxic, hemocompatible, and non-cytotoxic, making it a promising biocompatible material for biomedical device applications.

LIQUIDMETAL® TECHNOLOGIES

Wrapping Up

The medical device industry, especially minimally invasive devices, faces an extra challenge when manufacturing parts. Equipment failure is not an option, and could impact the patient's wellbeing and recovery. Liquidmetal technology offers solutions to many common manufacturing roadblocks that force medical device manufacturers into expensive or inconvenient processes with extraordinarily long cycle times in order to compensate for this.

Whether a surgeon is performing aortic valve surgery, a carotid angioplasty, or rotator cuff repair, the challenge is still the same for reliable and consistently performing equipment. Liquidmetal alloys offer precision equal to and sometimes better than CNC machining. Considering their extraordinary as-molded strength (1524 MPa) as well, Liquidmetal alloys offer a truly unique advantage to medical device manufacturing. The opportunity is now, to design like you have always dreamed, overcome traditional manufacturing obstacles, and produce a part in one step. In many ways the remarkable material properties come "free" with the part. In conclusion, the Liquidmetal process and alloys improve part performance, reduce liability, and maintain overall price sensitivity while upgrading downstream economic advantage.