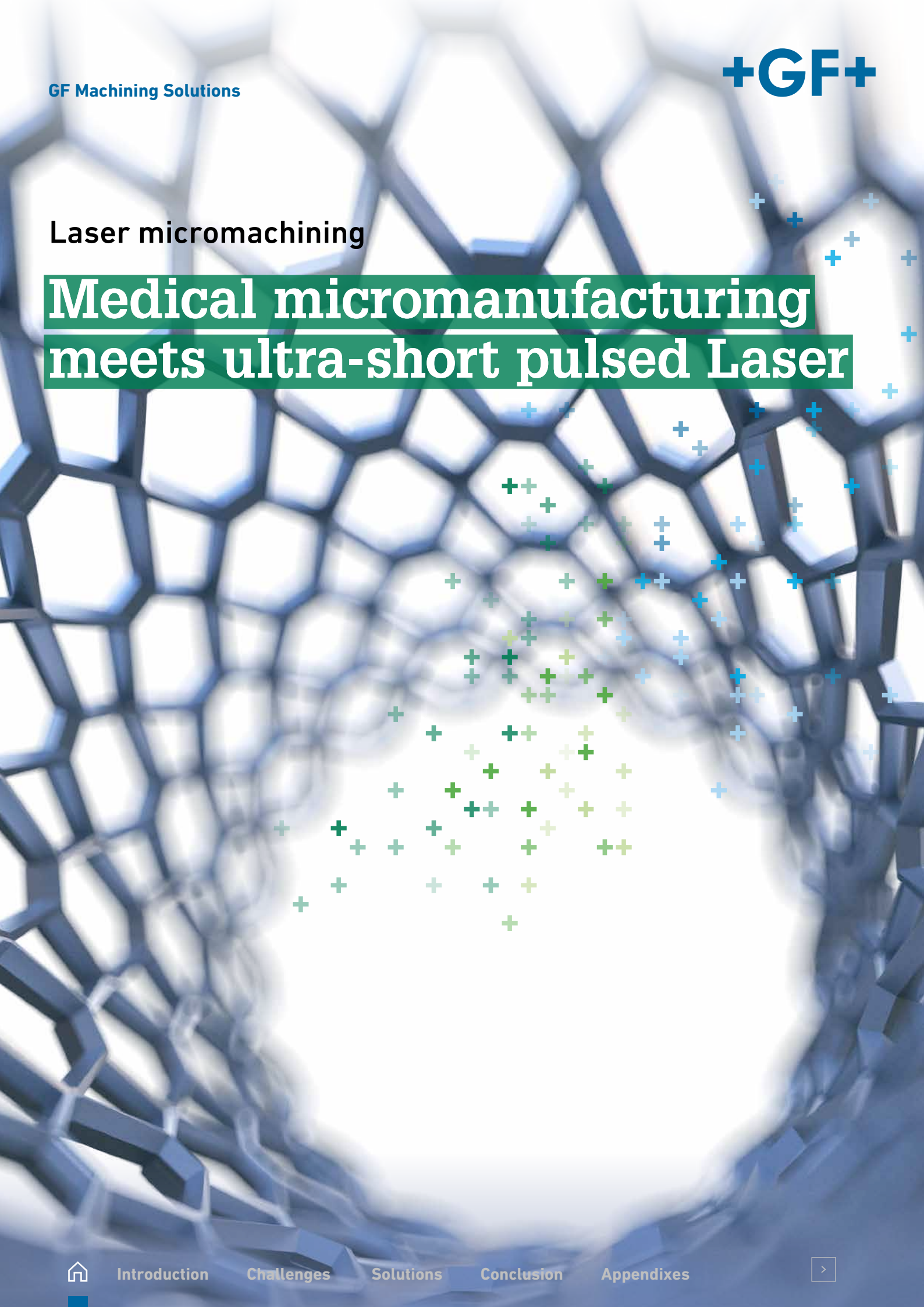
Laser micromachining

Medical micromanufacturing meets ultra-short pulsed Laser



Introduction

Medical devices have made great advances over the last two centuries. Alexander Wood's popularization of the first generation of hypodermic needles in the 1800's, the first implantable pacemakers in the late 1950's, the first human use of an ablation catheter in 1981 by Dr. Melvin Scheinman; all impossible without micro-manufacturing.

Implantable medical devices

have a strong trend towards miniaturization to reduce invasiveness and increase effectiveness. This requires the manufacturers to constantly expand their capabilities; be it through advances in process engineering, purchase of newer capital, or changeover to new technologies. One of the technologies that OEMs and job-shops have been utilizing to keep up with new medical device designs is Ultra-Short Pulsed (USP) lasers, or lasers with pulse widths ranging from tens of femtoseconds to hundreds of picoseconds.

Challenges

There are numerous challenges faced by medical device manufacturers. Devices implanted into the human body, whether temporarily or permanently, receive a high level of scrutiny to ensure the best patient prognosis possible. Two big questions are asked before a new design is to be manufactured: What will be the cost per part? And can the design be manufactured with the required quality?

Understanding the cost per part before part production starts is critical for each manufacturer. Contributors to the cost/part are the costs of the equipment, maintenance and consumables such as electrodes or grinding wheels. The cycle time per part is another critical constituent.

The topic of whether or not a new part design can be produced at the required quality is not at all trivial. The trend of miniaturization pushes manufacturers to either expand the capability of their current process, or invest in new equipment to achieve the required results. For micro-machining of medical parts, the manufacturing difficulties include defects such as HAZ (Heat Affected Zone), burrs, recast, and debris, as well as accurate and repeatable positioning.

Fortunately for parts manufacturers, providers of manufacturing equipment have evolved to work closely with their customers and take many of the risks out of purchasing capital through providing turnkey solutions that address both the productivity and process sides of the equation.

Solutions

A number of solutions have been developed over the years to address the manufacturing need for smaller and higher quality medical devices.

This trend of miniaturization, and therefore the change in required tooling, is best exemplified by the work at GF Microlution, which started as a mechanical micromachining solutions provider and has evolved into an USP laser micromachining solutions provider. GF Microlution's USP laser machines come standard with femtosecond lasers, solid granite foundation, high precision motion platform, built in metrology, automation, and high-end optics.

MLTC – Simplify complex tube cutting with Laser

Production-oriented solutions

When producing parts in large series, and what is more in the medical industry, beyond the notion of costs, the notion of repeatability is critical. It is therefore important to design equipment that ensures very high quality stability along the production batches. It is in accordance with this imperative that both ML5 and MLTC were developed. This is part of their DNA with, first of all, a granite base allowing great acceleration while maintaining the same level of quality. Other additional elements such as the use of linear axes are also the best choices for series production.

Some unique options, like the MLTC's sealed cut box, which captures and drains water as part of closed-loop wet cutting system creating minimal mist and keeping the rest of the machine dry, ensure to avoid part damage and loss, especially when it comes to very small tubes.

Granite base construction –
Best in class thermal stability

ML5 – Achieve excellent edge and
surface quality and straight sidewalls

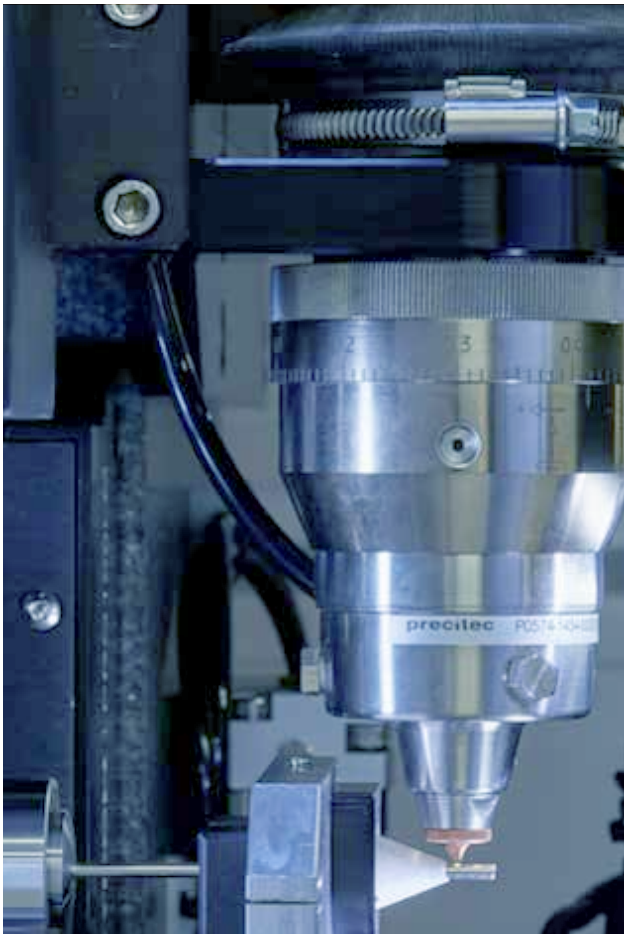
Femtosecond Laser and flexibility of delivery

Medical parts require tight process control to ensure the safety of the patients. Often times this requires complex post processing of parts to remove recast material, burrs, and machining debris. Even with precautions in place to prevent defects, the scrap-rates are often high. Because of this, many producers of these parts have implemented 100% inspection. Using USP lasers greatly increases the quality of the features and therefore removes many of the down-stream processes that add significant costs for manufacturers.

The beam delivery utilized in laser machines is important for both productivity and quality. The Microlution MLTC is a 4 axis tube-cutter which uses an adjustable beam expander through a fixed optics delivery system to allow for controlling of the laser kerf and divergence.

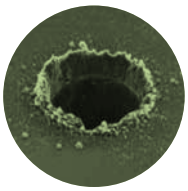
The Microlution ML5 is a 3 or 5 axis general micro machining center often machines thicker materials which require taper control. Therefore the ML5 allows the process engineer to choose the features' taper via a 5-axis scanning unit.

Both the MLTC and ML5 solutions are optimized for their respective use cases to give the process engineers the flexibility they need to achieve their quality of parts and to reduce their cycle times.

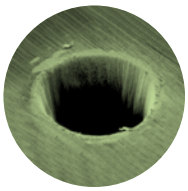


MLTC – Special-designed spindle for very small delicate tube handling

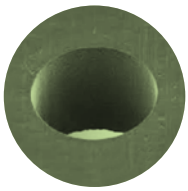
Laser performance compared



Nanosecond
HAZ
(Heat Affected Zone)
Melt zone adds variability



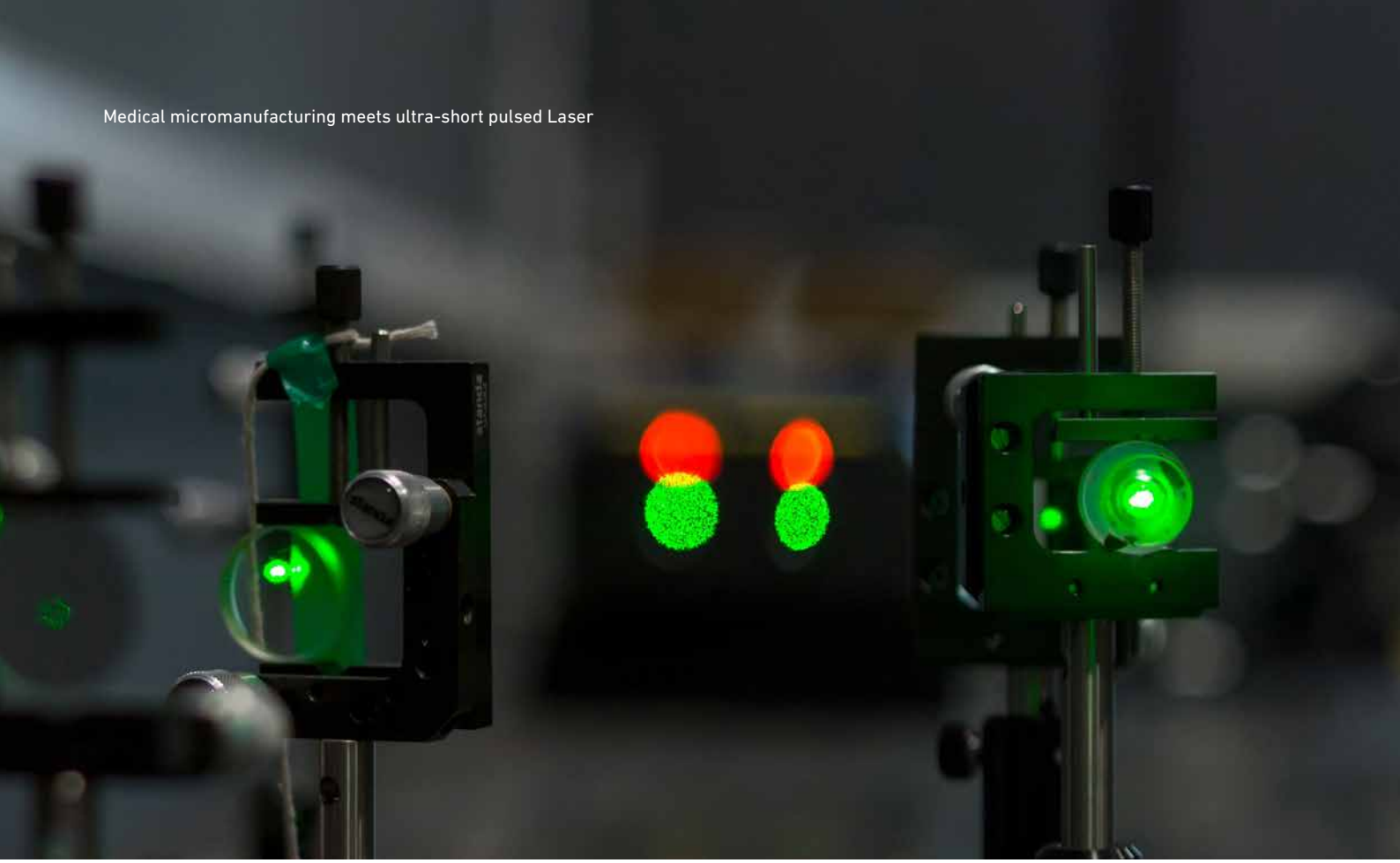
Picosecond
Less HAZ
Rough surface adds variability



Femtosecond
No HAZ
Low variability

Experience the 5-axis femtosecond difference

When combined with its 5-axis scanning solution, manufacturers can leverage advanced micromachining capabilities that can produce negative tapered holes and slots, drill arbitrarily shaped through-holes and contour with even smaller inside radii. With the click of a button, shops can easily achieve near-perfect machining quality, even for complex geometric features that were all but impossible to cut only a few years ago.



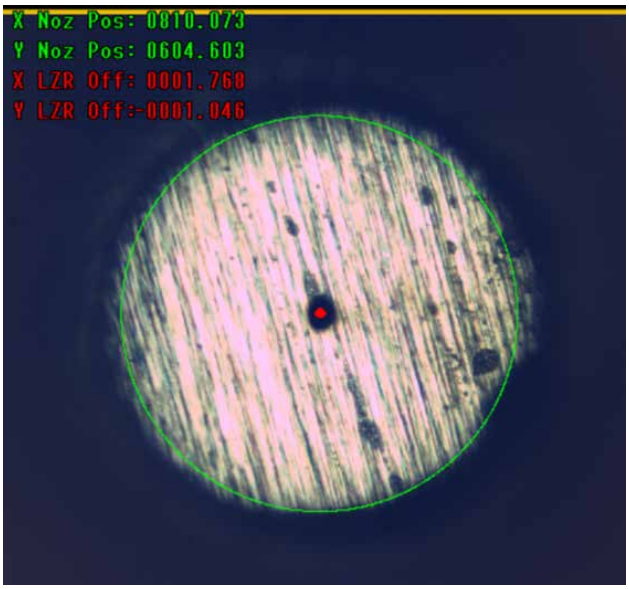
Metrology – Built-in Vision Systems

Visual checks have been a mainstay in verifying that the machined medical parts pass the required standards. Not only is the cost of visual inspection expensive but it is also prone to human error; which is especially exacerbated in small medical components. Vision systems have become an essential tool for offloading some of the inspection workload and therefore reducing overall costs.

Both the ML5 and the MLTC have built in vision systems to both set up the parts and machine, as well as to provide an additional layer of inspection.

The MLTC has a programmable camera through the optics and an "end-on" camera trained on the end of the tube to be machined. Utilizing the cameras at these two angles gives quick feedback of the machine and stock positions to the engineer through the changeover process (whether the laser is on the centerline of the stock, for example). Another use case is to check the outer diameter and inner diameter of tubing before each part is machined to ensure that the correct stock is loaded and that there is no damage to the material.

The ML5 also comes with a fully integrated vision system. A common use case on this platform is for initial part setup relative to the fixture or other features on the incoming part. The machine is programmed to identify certain features and compensate locations to ensure that errors in part loading or sizing does not affect the machined features' locations.



ML5 – Automated inside and outside for the highest productivity

Automation

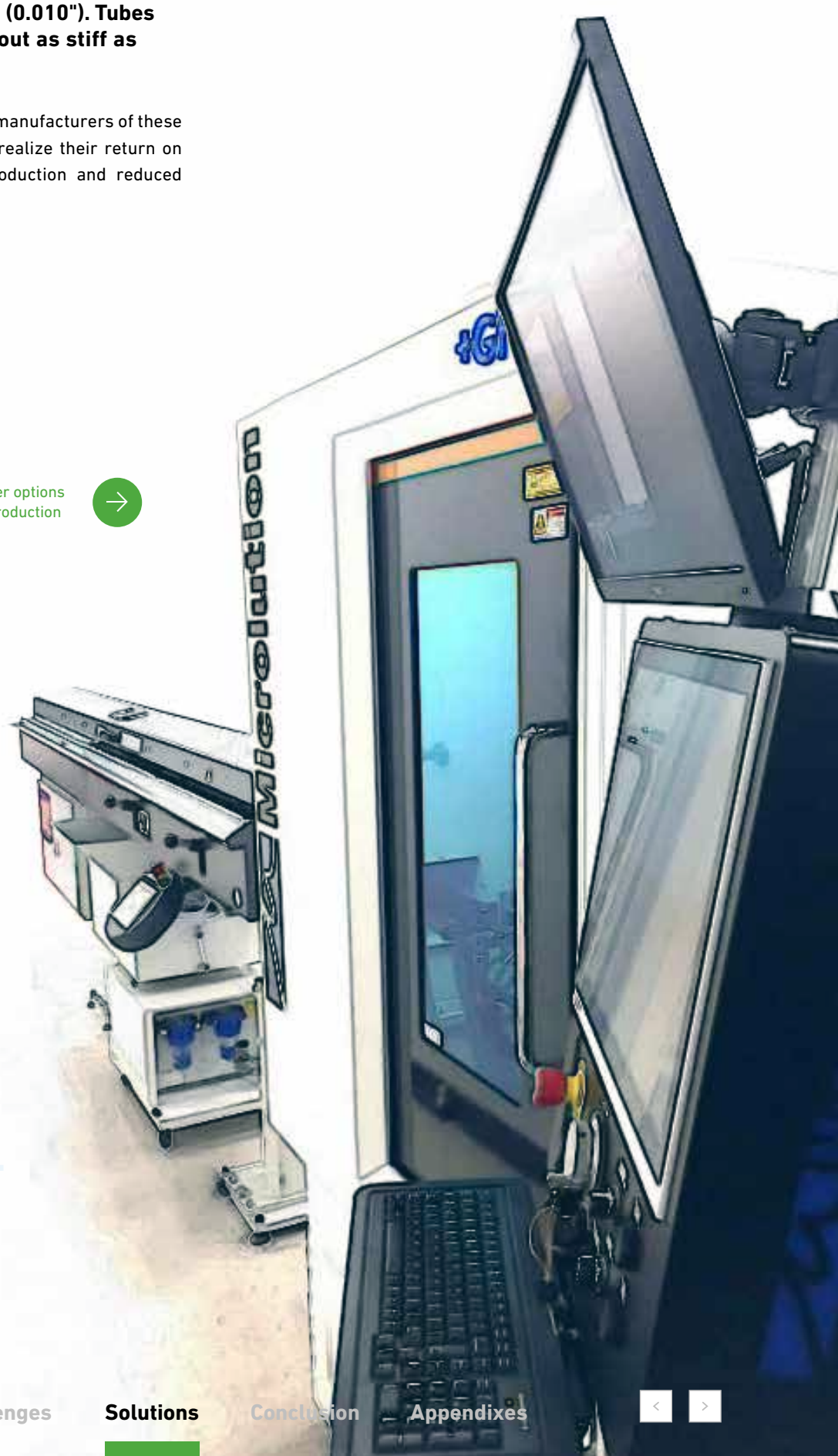
The cost per part is greatly reduced with the use of automation throughout a part's manufacturing and verification process. Loading/unloading parts, cleaning processes, flow rate verification, and feature measurements are examples of commonly automated process that bookend an operation. Equipment providers have become adept at working with manufacturers on either providing flexible interfaces for connecting to automation or by providing automated solutions directly with the equipment.

One of the most commonly automated processes is a bar feeder for tube cutters. Bar feeders allow 'lights out' production by drastically increasing the amount of time between operator interventions to load new material. In the past, however, these bar feeders were unable to handle small diameter tubing which are often required by medical device manufacturers.

In 2021, GF Microlution released their first bar feeder which is compatible with tubing diameters as small as 254µm (0.010"). Tubes at this diameter are often about as stiff as cooked spaghetti!

Small-tube automation has allowed manufacturers of these small components to more quickly realize their return on investment through "lights out" production and reduced workload per operator per machine.

MLTC - Bar Feeder options for high series production



Conclusion

Ultra-Short pulsed lasers have left the R&D optical benches and have matured into an integral tool for the medical micro-manufacturing industry over the past two decades. These advances in manufacturing equipment help us reduce costs per part (and ultimately per medical intervention) as well as gives the design engineers more flexibility to create the next generation of medical components.

Appendix 1: Marker band

In order to identify the location of a catheter tip under fluoroscopy, the use of marker bands is commonplace in medical applications. These bands are typically platinum iridium metals that are easily detectable on the technology used during the surgeries. The marker bands are put on the catheter, either through swaging or embedding, as a shiny indicator to the surgeon of directly where in the body the tip is located.

- The MLTC small tube handling system can handle 0.25mm to 0.76mm OD
- Standard MLTC can handle marker bands larger than 0.76mm OD
- Standard wall thickness is down to around 50um for STH materials

Marker band

Technologies	+ MLTC with 4-axis motion platform + Femtosecond Laser + Two measurement cameras (coaxial and on-end) for in-process measurements and defect detection + Bar feeder for full automation
Market Segment	Medical
Material	Radiopaque precious metals (mostly PtIr)
Machining Time	~ 2 seconds
Diameter/slot accuracy	~ ±10µm (general customer request) ~ ±5um (our capability)

Key advantages

+ Reduced cycle time
+ Reduced post processing activities thanks to Femto Laser capabilities
+ Reduced costs of consumables
+ Increased productivity thanks to the bar-feeder

Appendix 2: Flexible catheter

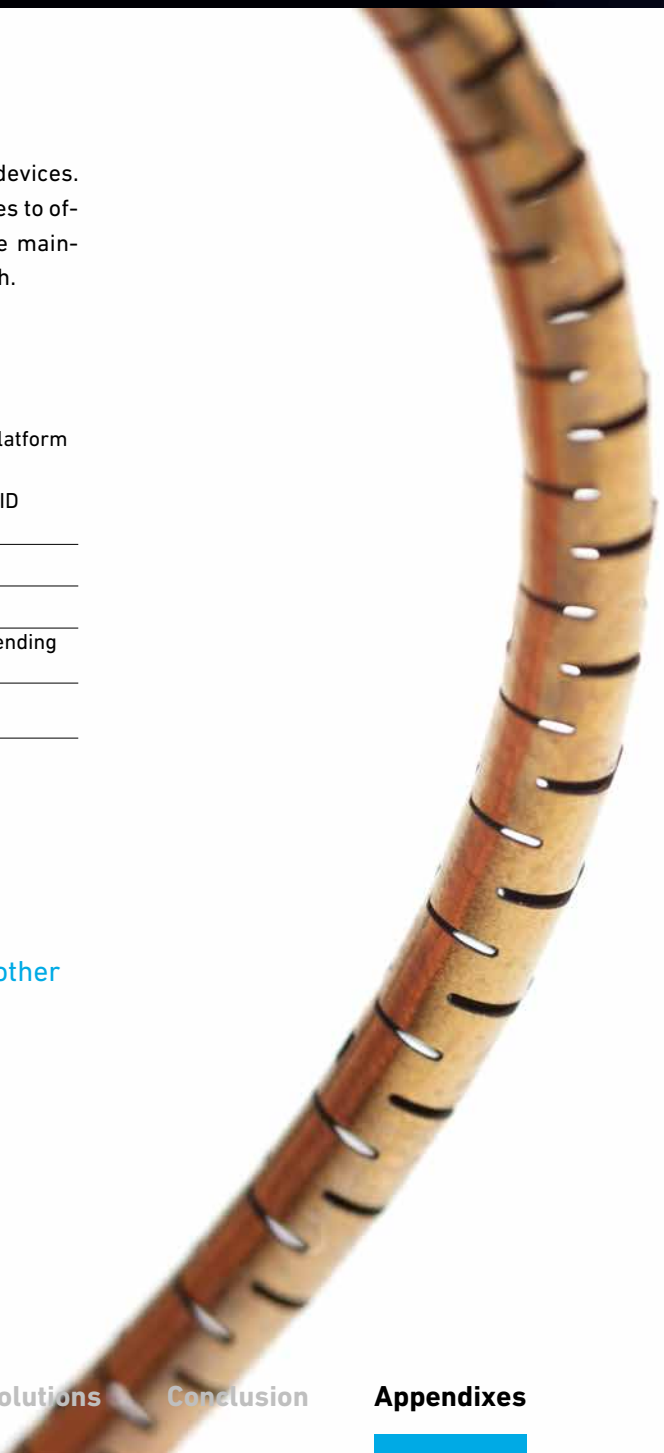
Catheter guidewires support in positioning medical devices. The guidewires have specific features and geometries to offer enough rigidity to reach the final location while maintaining flexibility to countour along the required path.

Catheter guidewire

Technologies	+ MLTC with 4-axis motion platform + Bar feeder + Vision system for part OD/ID verification
Market Segment	Medical
Material	Precious metals, Nitinol
Machining Time	~1-10 minutes per part (depending on complexity and length)
Diameter/slot accuracy	±10µm requested ±5µm held

Key advantages

+ Burr/HAZ free machining
+ Reduced post processing
+ Reduced cycle times compared to other technologies
+ Reduced costs of consumables



Appendix 3: Ablation catheter tips

Ablation catheter tips are used in medical procedures to correct heart arrhythmias.

Ablation catheter tips

Technologies	+ 5 axis motion platform (±1µm repeatability) + Femtosecond laser + On-end vision system (2µm repeatability to compensate part runout) + 3 axis touch probe (XYZ repeatability < 2µm)
Market Segment	Medical
Material	Precious materials
Machining Time	~ 1 seconds per feature ~ 1 minute per part (for part measurement and drilling 35 features)
Hole diameter	~ 80µm diameter

Key advantages

+ Overall increased in process repeatability with high precision motion platform
+ Burr free features thanks to Femtosecond laser and 5 axis scanhead
+ Faster cycle time than EDM
+ Reduced costs of consumables

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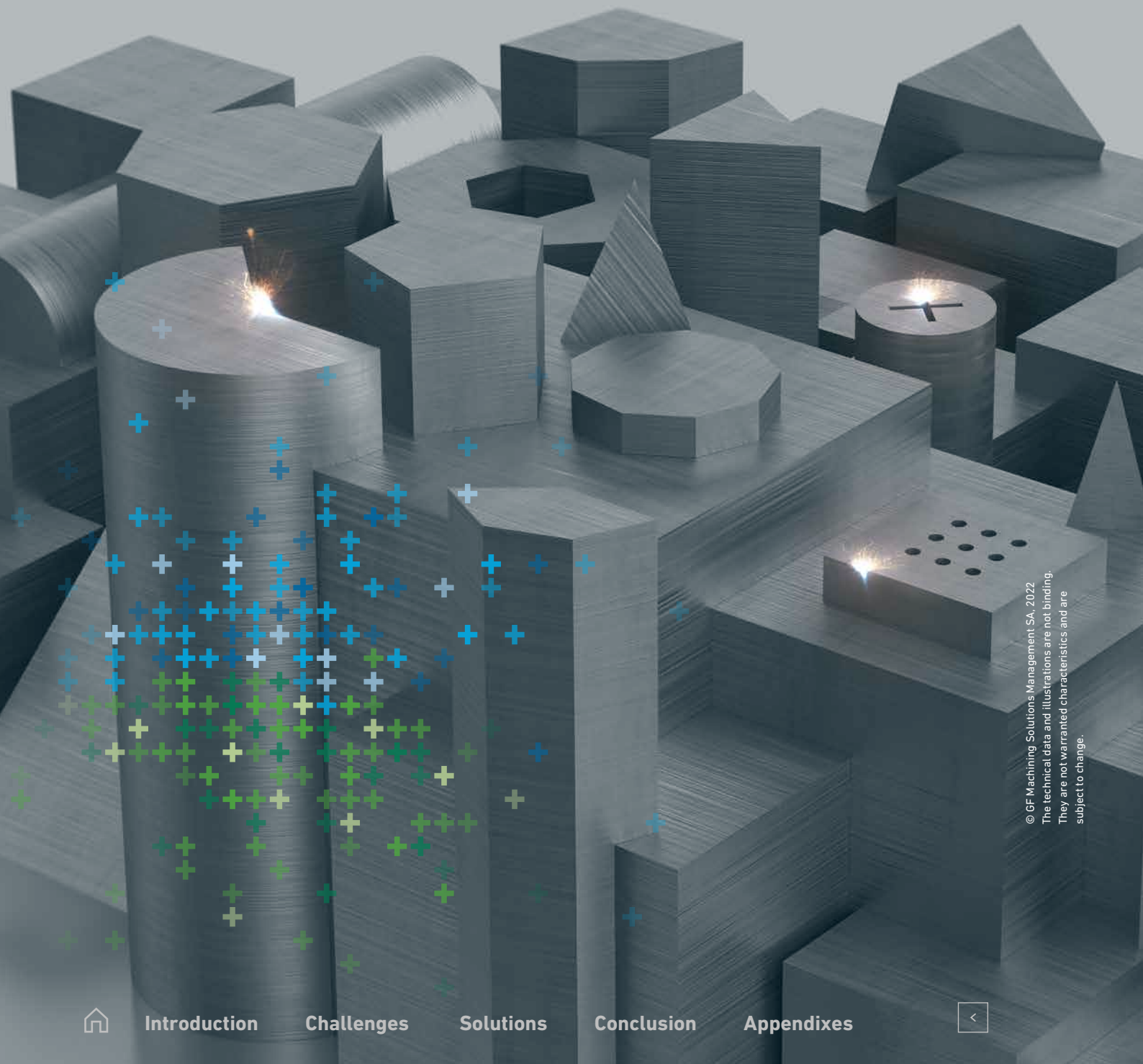

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