

Marking Considerations for Medical Devices

We are regularly asked about marking medical devices ranging from surgical tools, instruments and even implants. The following note explains factors that you need to consider when specifying TherMark as a marking solution.

FDA Approval

A common question is “do your products have FDA approval?” Unfortunately, we cannot give a definitive yes/no answer to this question as it depends of the individual circumstances of how the product is going to be used and what materials and process are involved in its manufacture. Firstly, the FDA do not generically approve a process such as laser bonding; what we do know is that we have multiple customers that have used the TherMark laser bonding process and have had their instruments with our marks successfully approved by the FDA. We can also provide MSDS that denote the materials contained in our products.

Permanence of Mark

One of the most important considerations is the permanence of the mark. This will depend on the processes the product is expected to withstand such as cleaning, passivation and multiple sterilization cycles in an autoclave. Among our customer base, we have many people marking surgical tools that have passed different tests such as those listed below:

Passivation – ASTM A967 Citric
Corrosion – ASTM A380



Common Applications and Substrates

The most common application we encounter is marking surgical tools. In most cases these will be made from high grade stainless steels. Other common applications include products such as dental equipment that has an anodized aluminum finish. We recommend using our LMM14 material for stainless steel and our LMM6018.LF tape for anodized aluminum. Full product details and laser settings can be found at www.thermark.com



Laser Bonding versus Direct Laser Marking

Historically, instrument makers have used laser engravers such as diode pumped YAG systems to produce direct marks by annealing the substrate. This process can be very sensitive to the substrate material and can also lead to corrosion of the mark after multiple cleaning cycles or passivation. The TherMark laser bonded mark can be achieved using a lower cost CO₂ laser and will offer better protection against corrosion, UV and abrasion than many direct marks.

Customer Testimonial

The testimonial below is feedback from one of our customers on the performance of the TherMark process:

“I would like to mention how pleased we are with the results of the LMM14 marking spray. We use a CO₂ laser to mark our stainless steel products used in vascular surgeries...The majority of medical device manufacturers in the industry use YAG lasers to engrave marks onto stainless steel, but through our testing, they would fail 100% due to rusting. I have tested your product against chipping, rubbing, corrosion (ASTM A380), visual inspection and cytotox. Marks using LMM14 passed 100%. Even through Citric Passivation (ASTM A967 Citric) the laser mark would not fade or come off, unlike the YAG mark. The LMM14 outperforms the competition and yields a finer, sharper and smoother mark. TherMark has made it possible for us to use a much less expensive laser marking process”

If you have any further questions on marking surgical tools, please contact TherMark customer support on +1 (323) 344 9500 or review our information at www.thermark.com