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Back to the Source….The Importance of Material Traceability in the Medical Device Industry

Introduction

The FDA continues to exert regulatory pressure on OEM's and Contract Manufactures which supply complete medical implant products or components. A common area of scrutiny is the requirement to maintain material traceability for the life of the device. Material traceability (and other critical supply chain and process information) is recorded and maintained in a document package named the Device History Record (DHR). Per the FDA, all medical implant devices and select instrument products must have recorded material tractability throughout the supply chain and production process. Specifically, FDA 820.60 states "each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mix-ups." Furthermore, FDA 820.65 states "manufacturers shall maintain procedures for identifying with a control number each unit, lot, or batch of finished devices."

Similar regulatory standards exist globally through the World Health Organization, ISO 13485, and most recently ISO 14971 (applies to OEM's selling product into Europe) which calls for the implementation of a risk management system that requires the manufacturer to determine the safety of the medical device during the life cycle of the product. A key element in this risk mitigation system is the ability to track raw material to melt source and all the way through the manufacturing process.

While the vast majority of material suppliers strive to provide 100% traceability to the melt source, few offer the capability of physically marking and labeling each piece of material in addition to providing the material certifications of compliance required. For round bar and flat type material, this process is known as "Line Marking."

What is Line Marking?

Line marking is a process which physically labels the material with select information required by the customer. This information can be as simple as material grade, mill name, and heat number. Or, additional information may be displayed that includes, but is not limited to; customer P.O. number, component part number, processing date (outside processing), heat number, etc. Figure #1 provides an illustration of a typical Line Marked bar.

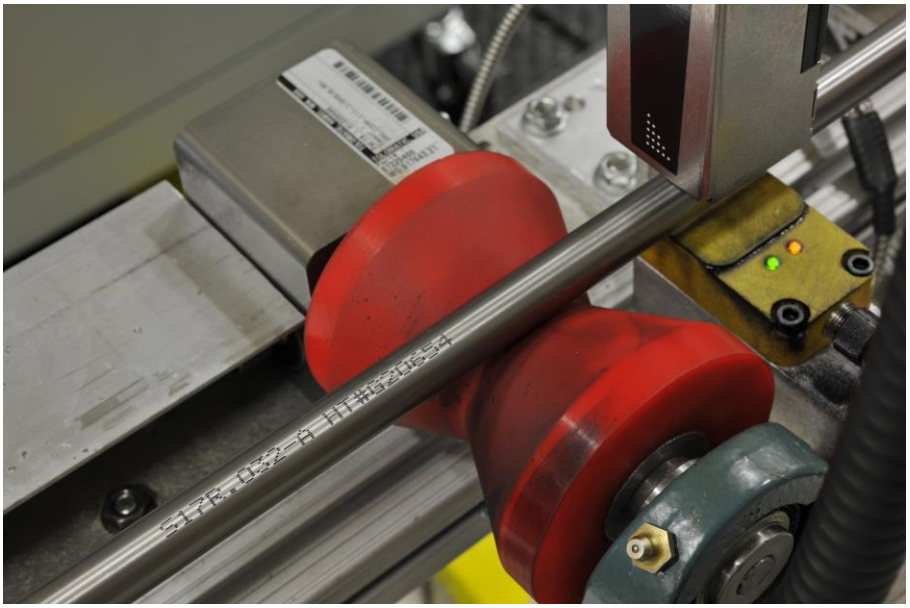

Figure #1: Banner Medical Line Marking with Banner Product Code and Heat Number

Why is Line Marked Material Useful?

Line marking material provides distinct features and benefits to OEM's and Contract Manufacturer's serving the medical device industry. Some of these are listed below:

Features	Benefits
Provides immediate ID of material upon receipt	Prevents mixing of material being stored
Positive identification throughout product realization	Prevents the wrong material from being used
Allows easy sorting should material ever get mixed	Reduces sort and stowage time of material
Can be used on various grades: Stainless, CoCr, Ti	Flexibility and coverage across all grades consumed
Information is customizable to customer requirement	No limit to information displayed. Info can repeat.
Ink is bio-degradable	Ink used will not contaminate material
Large size range: 3/16" O.D. through 1.50" O.D. std.	Flexibility and coverage across the majority of sizes
No delay in delivery time	Line marking is done in process. No delay in delivery
Bolsters quality management system	Marked material reduces risk on many levels
Eliminates individual tagging or painting of material	Saves handling and labor associated with traceability

Conclusion

Material traceability is a key element of every good quality management system employed in the medical device industry. Having the ability to immediately I.D. material upon receipt and throughout the supply chain process is not only important; it's a regulatory requirement that protects you and the end user. The ability to line mark various grades of material in a myriad of sizes provides risk mitigation throughout the manufacturing process. Even the most meticulous quality systems have shortfalls. Adding this layer of cost effective risk mitigation into your system provides supplementary support and peace of mind.

Please contact Banner Medical for additional information on this and other value-added services we offer.

Sources:
FDA 820.60
FDA 820.65
ISO 13485
ISO 14971