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Using Radiopaque Coatings to Design Smarter, Safer Surgical Products

(Credit: Proplate)

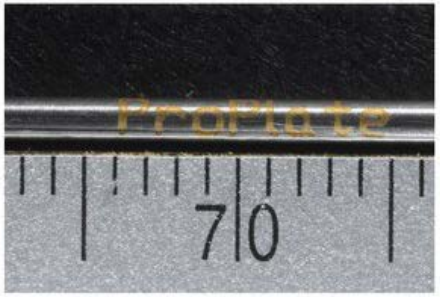
By Ross Peterson, Marketing Manager, ProPlate and Craig Ingalls, Owner and President, ProPlate

Radiopaque marker bands are visible under fluoroscopy and are used by doctors to guide and place catheters and other devices during medical procedures. Other common applications include ring electrodes, stents, guide-wires, hypotubes, and cardiac rhythm management devices. Typical processes to enable traditional marker bands involve swaging, embedding, reflowing, crimping, and the welding of marker bands to catheters and other devices.

An innovative technology has recently emerged to eliminate these processes, along with known risks and performance drawbacks, while still competing at a cost level. This new technology is a unique metal coating process that atomically bonds directly to a catheter, guide wire, hypotube, stent, or similar component. The process has been coined, Vizi-Band®. Vizi-Band® was pioneered by ProPlate®, a company that is based out of the Minneapolis-St. Paul, Minnesota greater metropolitan area.

This biocompatible and radiopaque metal coating allows for endless design customization, meaning that marker bands no longer need to be limited to bands. Unlike conventional machined marker bands, coating markers to tight tolerances can create radiopaque features that are conformal to very complex geometries. Installing radiopaque markers in certain regions where it was once highly difficult or impossible to do so successfully, is now possible through coating them. The coating can be applied selectively and precisely to the component in different areas, such as specific legs of a stent, or particular regions of a catheter hypotube. The process also allows the use of different shapes or patterns, such as dots and lines, and can even be applied in the form of numbers or letters. This advantage can help a doctor accurately determine the direction of the device while it is twisting and winding through the patient's body. It also has potential to make communication amongst doctors more clear during a procedure if the use of numbers or letters are implemented, as opposed to markers without identification or labels.

The thickness of the radiopaque markers can also be customized due to it being an additive manufacturing process, like 3D printing, as opposed to subtractive manufacturing processes such as turning or stamping. Being an additive process allows the innovative coated markers to be thinner than traditional machined and crimped on bands, depending on the level of brightness needed under the fluoroscopy. The layer is built up from zero thickness and can be performed at a very slow rate. The coating rate can be easily adjusted depending on certain process and component variables, which are dialed in for optimum precision and productivity. Layers measuring as thin as 0.000003 inches can be easily accomplished. However, it is important to know that the radiopacity brightness directly correlates to the coating thickness. The reduction of marker thickness can allow the catheter or device to have an overall lower profile, which will in turn produce a performance advantage. This is crucial for applications such as micro catheters and stents, and helps to meet the constant demand to make medical devices smaller and even more complex.



ProPlate Hypotube Vizi-Bands (Credit: ProPlate)

Additionally, the elimination of known risks for traditional marker bands is achieved through this coating technology. Machined, swaged, crimped, and welded markers all carry risks during a medical procedure. These processes can cause device failures for a myriad of reasons. Component parts can separate, welds on dissimilar or even similar materials can break, and mechanical crimps can weaken and detach. These failures could potentially turn a minimally invasive procedure into an invasive operation and cause many complications. Employing the unique metal coated markers enables manufacturers to avoid these failure modes due to the bond between the radiopaque material and the device components being at an atomic level. Long-term storage of radiopaque metal filled polymers is another known risk of traditional markers due to degradation over time. This risk is also eliminated because of the coated marker technology's unlimited shelf life.

Current machined marker bands are laboriously installed by crimping, sometimes individually by hand, whereas coating markers to the component can be accomplished in high volumes simultaneously for maximum efficiency. This allows the process to remain a cost effective alternative. With the combined elimination of risks and enhanced performance, while still competing with the current industry standard costs Vizi-Band® can help produce better outcomes for hospitals, doctors, patients and medical device manufacturers. MDT

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