EXXELIA MICROPEN

ARTICLE

A safer, more precise radiopaque (RO) marker: The case for direct-writing RO markers on medical devices.

Introduction.

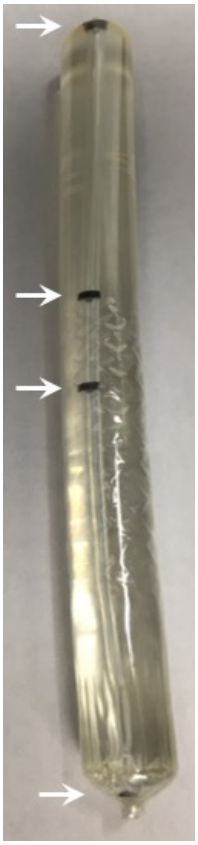
Medical devices often incorporate a radiopaque (RO) marker in key spots so the position of these devices can be seen in real time during surgery with fluoroscopy, X-rays, or other imaging techniques. Traditional markers are small bands that are affixed to the device through swaging. Within the past few years, the FDA has issued Class I recalls for a variety of medical devices with swaged radiopaque markers, because sometimes these markers were loosened on the device after implantation, with the potential of causing “serious adverse health consequences or death.”

Conventional swaged marker bands in 4 locations

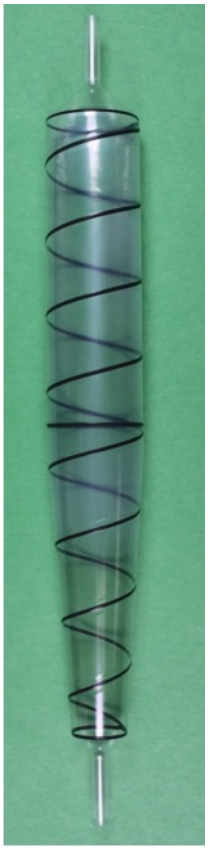
Micropenned radiopaque markers are safer.

Safety alone is an excellent reason to evaluate an alternative to swaged radiopaque markers, but there are other benefits that are more important from a functional standpoint. Micropenning is an extremely precise form of direct-write printing where radiopaque inks can be deposited on the medical device. In Micropenning, we use inks made from materials with a pedigree of medical device use and FDA approvals. Then we put them through toxicity tests as well as a torture test to be certain there can be nothing left behind. The inks have been chosen also for electrochemical stability, materials conflicts, and biocompatibility. Inks that are approved for both 30-day and permanent implants are available.

Torture test to examine ink adhesion on a medical balloon



Conventional swaged marker bands in 4 locations



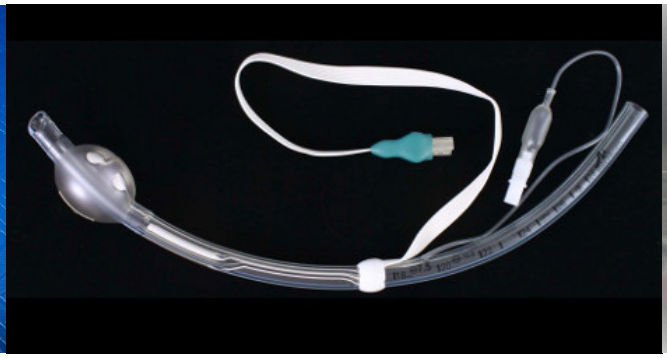
Balloon after Micropen printing with a helical design RO marker

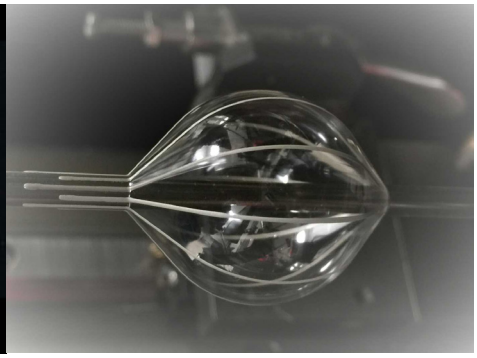
Micropenned radiopaque markers give you more flexibility and precision.

With Micropen there are very few restrictions on the position of the markers, the size of the marks, or the pattern printed. Unlike swaged bands that are small and must be used in number to provide accurate positional information, radiopaque Micropenned markers can be written end-to-end for total visualization of the device's position.

Micropenning can “pen” on virtually anything

Micropenning can direct-write a radiopaque material on virtually any substrate or device configuration—inside or outside—making it a good choice as a direct replacement for swaged markers on devices like catheters, tubes, and sensors. But a unique advantage of Micropen printing is that the RO design can be applied to expandable structures like balloons, something that is not possible for traditional markers.





Micropen can combine radiopaque markers with other sensors as you require.

We can also Micropen a wide variety of the sensors you may require in your device—visual, thermal, chemical, pressure, magnetic, or electrical. Since our pioneering beginnings in 1982 we have developed a family of inks that work as an ink-system to combine marker and sensor functionality in the most streamlined manner possible.

“...excellent visualization of the extent, position, and unfurling of the balloon and completely eliminated the cost and labor of RO bands.” [1]

Micropen can work with you to build a rapid prototype. Then we can help fine-tune your design for scale.

We can take your design and provide advice as to how we can add RO positioning to your device. A half-hour conversation is often enough for us to let you know if Micropenning can help you.

Contact us at **585-624-2610** or email us at **micropensales@exxelia.com** to schedule a quick, free conversation with one of our engineers about your design.

1.Grande, W.J. (2016). Direct Capillary Printing in Medical Device Manufacture. In Medical Coatings and Deposition Technologies (eds D.A. Glocker and S.V. Ranade). https://doi.org/10.1002/9781119308713.ch9

Why Exxelia Micropen?

Exxelia Micropen has been a pioneer in medical device development with Micropen- printed electronics technology for 25+ years. We are ISO 13485 certified, and we have the expertise to collaborate with you end-to-end from initial design concept through production.

Links to Exxelia Micropen resources:

Overview Video

Substrates & Inks

Medical Applications

Contact Us:

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