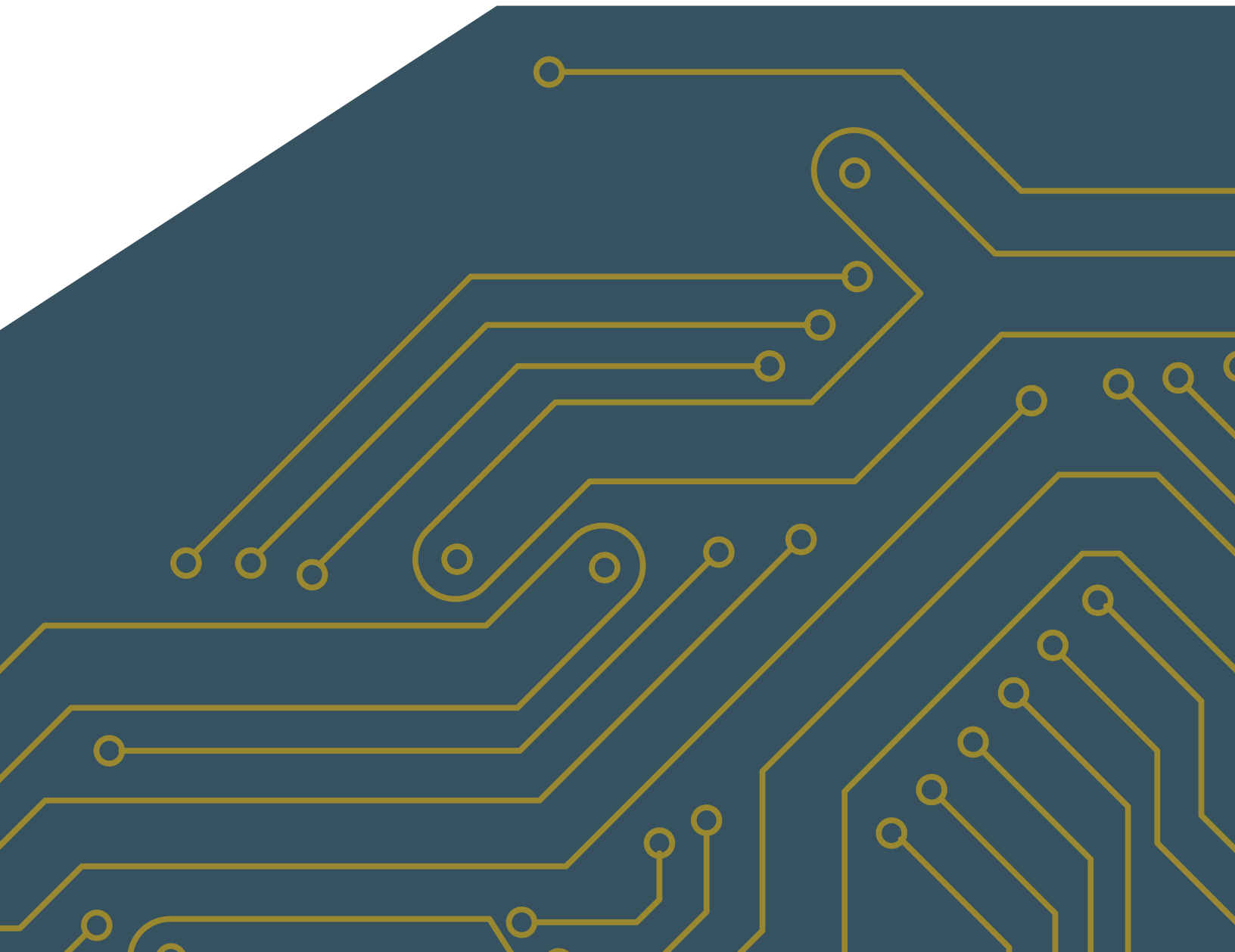
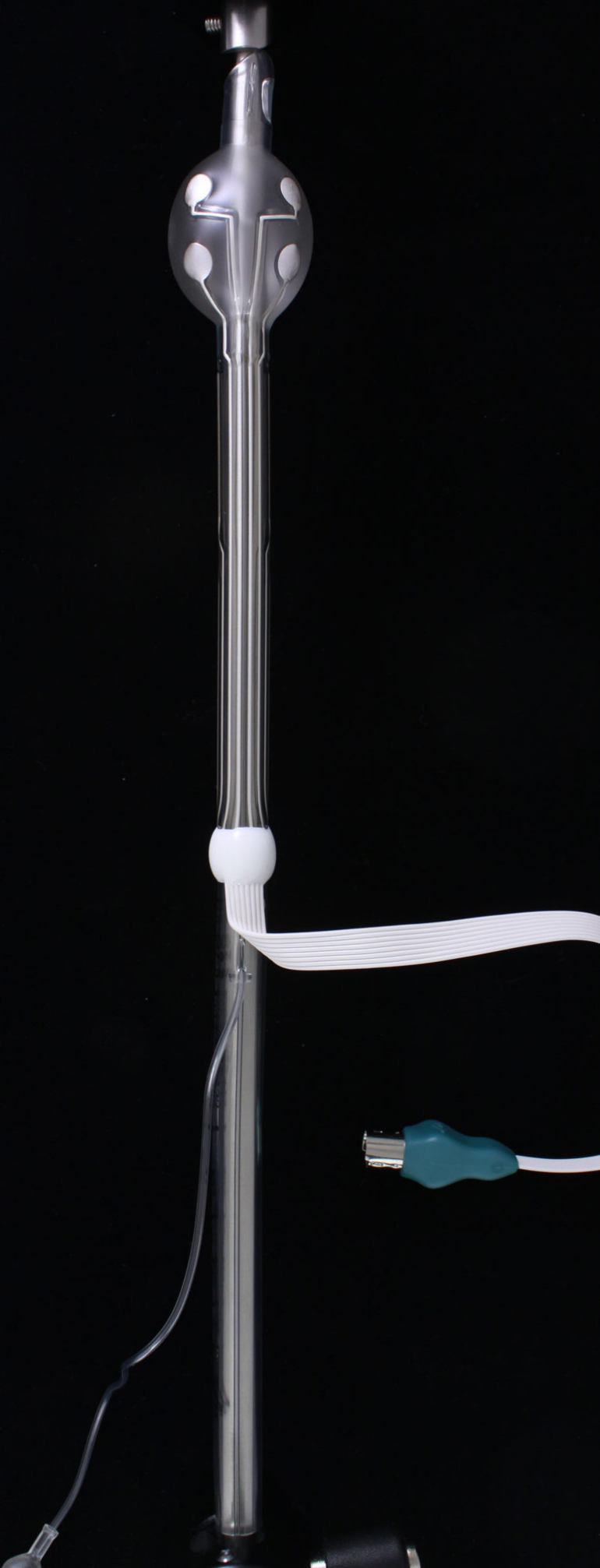


WHITEPAPER

Printed Electronics on Medical Devices

Choosing the right technology PLUS five criteria for a successful project



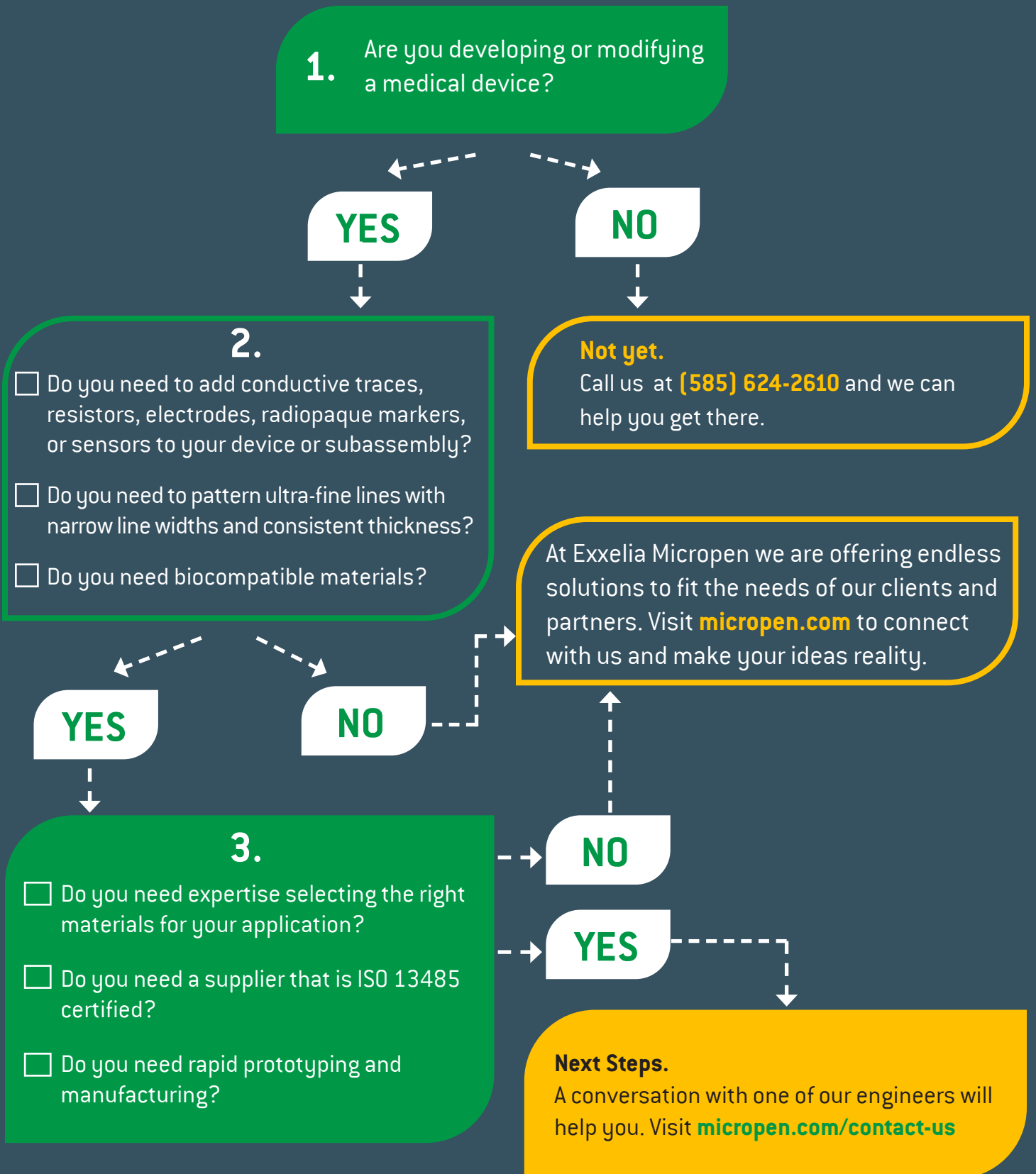


Introduction.

Traditionally passive medical devices are becoming smarter. Examples include disposable ETT and catheters and temporary implantables that would reside in the body for less than 30 days, all the way to permanent implant devices like orthopedic hardware and bone repair kits. Today, they are providing surgeons with functionality and data that even a decade ago would have been regarded as science fiction. This trend, however, poses a particular challenge to device designers: To increase functionality while keeping the device small and safe for the patient. Of course, this is especially important for any device that is implantable.

Exxelia Micropen has been in on the development of many of these exciting devices. We are an organization with extensive expertise in developing, prototyping, and manufacturing medical tech. We have pioneering experience in direct write printed electronics technology, which we call Micropenning. Micropenning is an additive process (no wasted material) that writes fine-line conductive traces, sensors, and radiopaque markers directly onto a surface without the need for masks, appliques, or screens. What a decade ago might have been created with wires and attached sensors we can design today with printed electronics on the surface of the medical device substrate itself, thus adding desired functionality while saving valuable space and being safe for the patient. The printing can be done on just about any 3-dimensional shape and substrate with a variety of biocompatible inks to suit a particular requirement. The design can be configured to deliver heat, monitor vital signals, measure pressure, or other desirable properties.

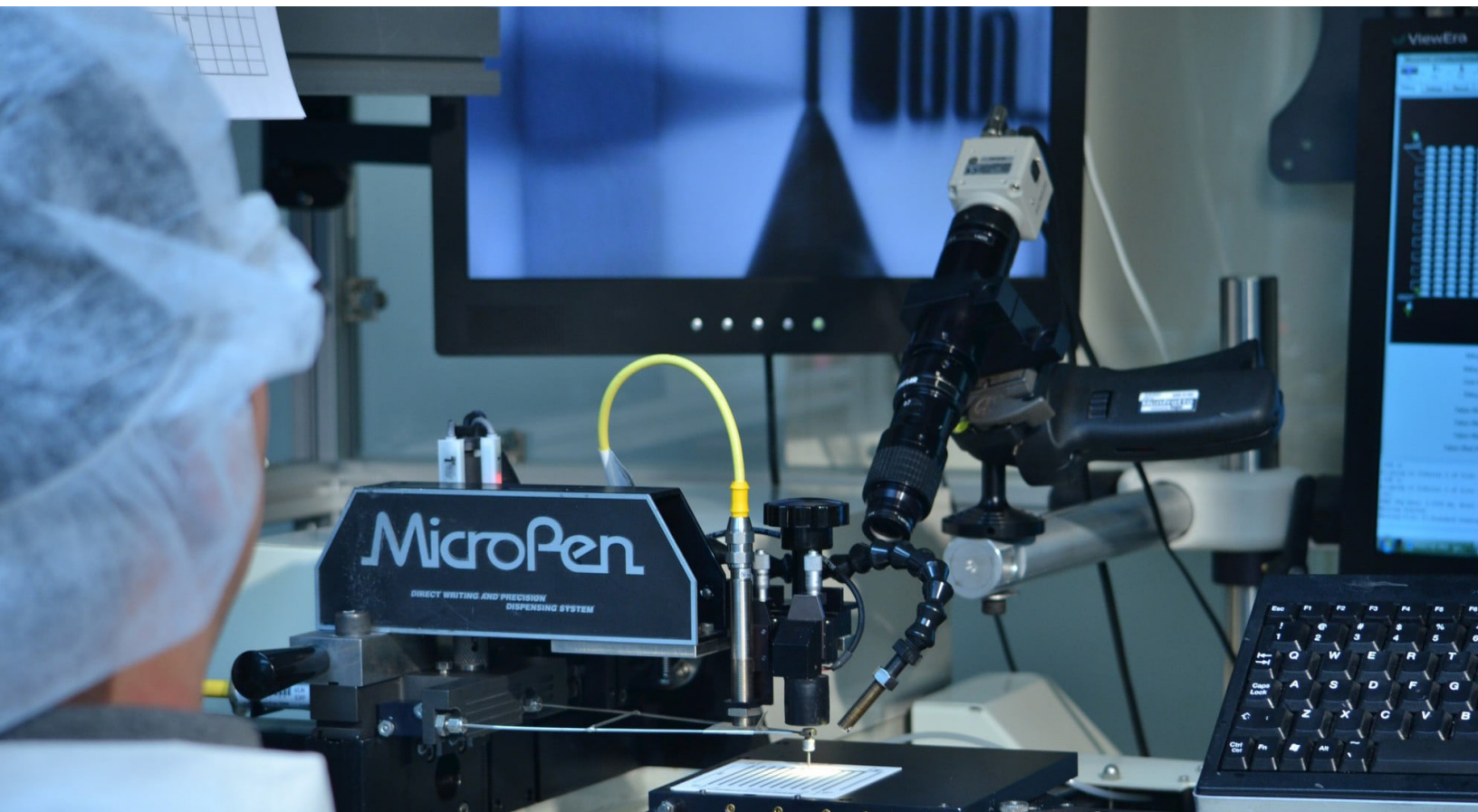
How to determine if you should explore Micropen Direct Write additive printing.



Medical device design considerations: wear, duration, prototype cost, production quantity, unit cost (at scale) and medical device certification

As you proceed along your development journey, these design considerations/parameters are all important.

- Of course, wear goes hand-in-glove with duration of the device as a key property for the design. Exxelia Micropen has experience with devices on every side of this scale, from disposable one-use devices to permanent implants designed for longer-term use.
- Prototype/development cost and speed of prototyping are strong points for Exxelia Micropen as our technology lends itself to rapid prototyping. Micropenning requires no screens, masks or appliques, which can be costly and time consuming to setup. Since it is an additive process, there is no material wasted, so Micropenning can represent a substantial cost savings when expensive materials (like gold) are required.
- Talking to us early can help us design your prototype with scale in mind, so there is no need for a major redesign once the prototype is approved.
- Exxelia Micropen is ISO 13495 certified with years of medical device manufacturing experience, which means we have highly stringent quality systems in place and the expertise to ensure a successful project.



Tech review:

Exxelia Micropen has helped many medical device manufacturers with the design, prototyping, testing, and volume-conductive ink printing of devices such as ablation probes, instrumented endotracheal tubes, radiopaque markings, balloon catheters, and more.

Our Micropen technology is an additive process: no stencil, screen, or photomask is needed. We store the pattern for your device in a CAD system and print it directly onto the surface of the device. We can print on virtually any material you would want to use, and onto virtually any shape—flat, curved, inside or outside of your device. We invite you to check out some of our applications, and even to visit us in person to see how we do it!

Micropenning is particularly well suited to printing electronics on the surface of medical devices, especially those that go inside the body.

These include:



Printing on thin, flexible, and irregular substrates that are highly 3-dimensional



Patterning fine lines (50 μm) with small spacing (25 μm)



Printing on a variety of substrate materials with a variety of inks



Assuring that materials and process steps are biocompatible



Tailoring production volume and unit cost to meet your targets

5 criteria for a successful path to printing electronics on a medical device.

1

When considering a partner, do you sense their passion for quality?

Your design and manufacturing partner should have a culture throughout the entire organization of maintaining the highest level of quality. (It helps if they are certified ISO 13485, the medical device international standard for quality management.) This ensures that there are robust processes in place, from initial validation through qualification and production manufacturing. It also means that the organization can discover opportunities for improvement that can lead to greater efficiency and cost savings. Exxelia Micropen is certified as a contract manufacturer specializing in high-



precision electronic printing of critical functional materials of medical devices and components. The Micropen team is always looking for ways to improve on process and productivity.

2

Do they have relevant experience in medical device design, prototyping, and production?

There are complex requirements in the healthcare industry, and a proven track record in the understanding of proper documentation, revision control, and maintenance of device history records and safety regulations will go a long way to ensure that your project is successful. An experienced partner can provide advice on design, suitable inks, techniques, and steps to optimize the process. This can lead to valuable time and cost savings over the course of the project. There is no substitute for experience in partnering on the design and manufacturing of printed electronics for the implantable medical device market. Exxelia Micropen has over 25 years of experience in working with top-tier medical device companies, printing electronics on endotracheal tubes, ablation devices, balloon catheters, etc. Our engineering and development teams have the necessary technical expertise, and our production, test, and quality teams understand what it takes to manufacture volume devices while maintaining competitive pricing. We understand that we are adding value to devices that will be used to save or enhance a patient's life.

3

Could you envision them as a long-term partner and collaborator?

The most successful partnerships are long-term and collaborative. The resources on each team should have a shared understanding of the objectives and requirements, and the chosen supplier should be seen as an extension of your team. This allows challenges to be solved quickly and assures that the project will be completed on time and within budget. Regular meetings, passing files back and forth, and engaging experts in different functions of the organization are all elements of a partnership and lead to the success of the project. Your partner should be proactively communicating throughout the product lifecycle. Your partner may also consider investing in the partnership for the long-term. Over time, as you work together, you'll be able to apply learnings and efficiency to not only one product but a portfolio of products in a cost-effective and optimized way.

At Exxelia Micropen, we are committed to working collaboratively, starting early in the product design stage. We will share with you our accomplishments, manufacturing controls, and quality assurance process steps. We want you to get to know us, and the earlier we can engage with you as an integrated partner to your design team, the better. Most of our customers have been with us for years and we value a platform approach where we can apply our learnings to product extensions and next-generation designs.

4

Can they scale and respond to demand changes?

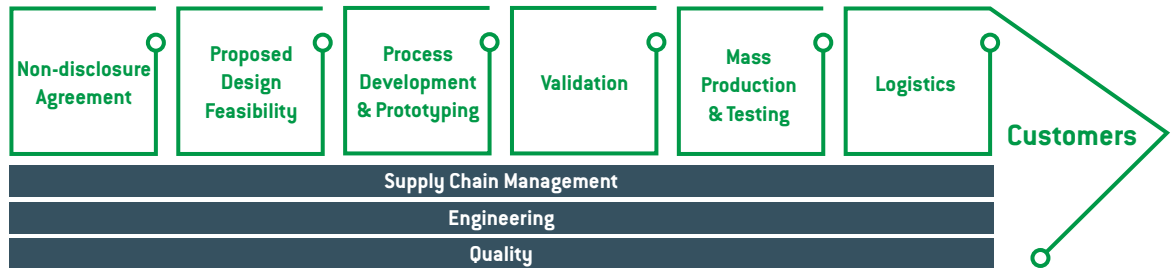
It is important to choose a partner who can meet your production requirements now and into the future. The manufacturer should be agile and flexible in regard to your demand changes and able to meet your deliveries as agreed. This requires that they have a well-understood supply chain of raw materials and lead times. Make sure to ask about this when selecting a partner. At Exxelia Micropen we have the resources and experience to respond to growth and demand increases.

This is especially important in today's roller-coaster supply chain economy. We have excellent partnerships with suppliers of ink, substrates, and other raw materials and have a well-established process for supply chain management and production scheduling.

5

Do they have an end-to-end process?

A full-service partner who can collaborate on product design, rapid prototyping, manufacturing, testing, and supply chain services is ideal. Consolidating all activities under one roof can reduce costs and time to market. It also allows for problems to be addressed quickly and eliminates the finger-pointing when multiple suppliers are involved. You should choose a partner who will complement your own team, adding value end-to-end.



At Micropen we have expertise from design through manufacturing and responsive support throughout the product lifecycle. Our flexible printing manufacturing services can meet the needs of any company, from a start-up to a major OEM.

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](#)

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