

Caerus helps create lives through fertility diagnostic enabled by laser technology

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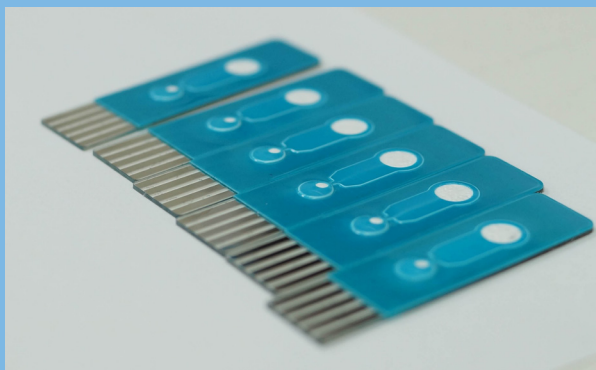
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SUMMARY STATEMENT

Headquartered in Europe, Caerus Biotech is a research and development company specializing in next-generation fertility solutions. The company needed a partner that is equally innovative to support the production of their flagship product MiOXSYS, an in-vitro diagnostic (IVD) tool for male infertility.

CHALLENGE

- Develop robust and agile manufacturing program for next-generation male infertility diagnostic system MiOXSYS

SOLUTION

- Partner with MicroMed Solutions to ensure proprietary device features are achieved through ISO 13485:2016 compliance and cutting-edge laser converting technologies

RESULT

- Established manufacturing program for MiOXSYS, resulting in commercial launch, clinical adoption, and recognition by the World Health Organization

The Technology Partnership

01

Challenge

Designing a next-gen diagnostic tool

Caerus was founded upon a mission to revolutionize infertility therapy. And a worthy mission it is. Infertility is estimated to impact around 190 million people worldwide. Of that total, up to 55 million are men facing oxidative stress infertility. As a subsidiary of GryNumber Health Group, Caerus championed a flagship technology called MiOXSYS—the only patented in-vitro diagnostic (IVD) system to deliver the complete measurement of seminal oxidation-reduction potential. This next-generation diagnostic tool plays a critical role in providing answers to male infertility diagnosis and management.

Why is this measurement important?

The link between oxidation-reduction imbalance within the male reproductive tract and semen and fertility has been investigated for decades. Excessive levels of reactive oxygen species can affect sperm functions and thus reproductive outcomes.

How does the system work?

MiOXSYS technology leverages the latest advancements in medical science, electrochemistry, and nano-engineering. The system involves an electrometer and disposable sensor consisting of a 3-electrode system. After sample equilibration, a current is applied to the electrode measuring the balance between all oxidants and antioxidants in a patient's sample. The result provides a strong indication of semen quality.

02

Solution

Deploying innovative tech to meet a dual goal

Caerus knew they needed a production partner as cutting edge as they are. And an organization that shared the same mission to improve patient outcomes.

Headquartered in Minnesota, USA, MicroMed Solutions is an engineering firm committed to advancing medical care through microfluidic technology and thin-film laser converting. Caerus chose MicroMed for its track record in navigating device compliance and ISO quality management standards. “We knew we wanted an expert in ISO requirements to help guide the manufacturing process of the diagnostic and take into account any critical changes,” explained Martynas Linkevičius, CCO of Caerus Biotech.

“We also knew we wanted transition experts,” added Linkevičius. Working closely together, MicroMed acts as a full CDMO production provider from ordering materials, to dispensing chemistry, to packaging tens of thousands of consumer-ready units per year, with the ability to scale as demand increases.

Plus, MicroMed's cutting-edge laser converting technologies are the perfect complement to Caerus' cutting-edge MiOXSYS diagnostic system. Laser ablation is deployed to create the electrodes and laser through-cutting for membrane components, features, and patterns.

03

Result

Providing answers to complex fertility issues

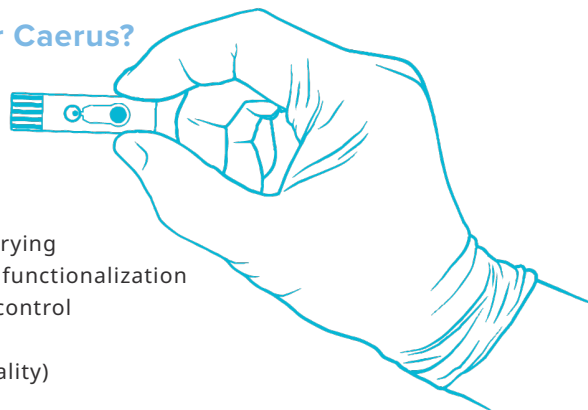
Caerus' MiOXSYS diagnostic tool is currently market-ready and available for consumers looking for solutions to their infertility challenges. The IVD tool is quickly building momentum in fertility/IVF clinical settings in Europe and Japan, and is available as a 'research use only' (RUO) device in the USA, as Caerus seeks FDA approval.

“Our company manages a complex IP portfolio in the male fertility field, and we needed a partner with world-class engineering acumen to help us translate a proprietary concept into a market-ready, patient-friendly device,” says Valdemaras Rodzko, CEO of Caerus Biotech.

“We're happy to have chosen MicroMed Solutions. They are the right company to help us solve design and manufacturing challenges, scale production to hundreds of thousands of sensors annually, and ensure compliance from the earliest stages”, Rodzko concludes.

What services does MicroMed provide for Caerus?

- + material management
- + assembly
- + laser cutting
- + laser ablating
- + mixing chemistry
- + chemistry dispensing and drying
- + precision electrode surface functionalization
- + humidity and temperature control
- + custom die cutting
- + lot testing (i.e. controls, quality)
- + pouching
- + packaging and labeling



“The real challenge was tuning in the science from an environmental perspective. We needed to understand how humidity and temperature during manufacturing impacted the function of the device. Now, we have a robust manufacturing program to build reliable MiOXSYS sensors to meet the strict requirements needed for test protocol.”

— Tom Daul, Director,



MicroMedSolutions