

BiBB receives first order for EndoDrill GI from a university hospital in the US

The cancer diagnostics company BiBBInstruments AB ("BiBB or the "Company"), the developer of EndoDrill®, the world's first market-cleared, electric-driven biopsy instrument for endoscopy, announces that the first order for EndoDrill® GI has been received from the university hospital UC Davis Health in the USA. This initial order has a small order value but holds great significance, as UC Davis Health becomes BiBB's first paying customer.

"It feels fantastic to now have our first customer in the USA, and the order is proof that we have developed an innovative biopsy product that benefits cancer care. This is just the beginning of our commercial journey and a small reward for the investors participating in the ongoing rights issue," says Fredrik Lindblad, CEO of BiBB.

The university hospital UC Davis Health in Sacramento, California, conducted a clinical evaluation of EndoDrill® GI in 2024. The evaluation initially resulted in a scientific publication on the first eight patient cases. Tissue sampling with EndoDrill® GI achieved 100% diagnostic accuracy after only one pass, and the co-authors concluded that sampling with EndoDrill® GI is both effective and safe. This successful clinical evaluation has now been converted into the first order of single-use instruments.

EndoDrill® GI is also being evaluated at several hospitals in Europe, while the production of single-use instruments is being transferred to a new contract manufacturer to enable scaling up. Furthermore, discussions are ongoing with potential distribution partners in preparation for a broader market launch, planned to take place after production capacity has been increased.

About EndoDrill® GI

EndoDrill® GI is the world's first market-cleared electric-driven biopsy instrument for endoscopic ultrasound (EUS). The instrument is used for EUS-guided tissue sampling for all indications in the gastrointestinal tract, e.g. pancreas, stomach, esophagus, lymph nodes, and liver. EndoDrill® GI received FDA 510(k) clearance in the US in 2023 and CE approval in Europe in early 2024. The product is currently being clinically evaluated in the US and Europe.

This is a translation of the Swedish press release. If there should be any discrepancies, the Swedish language version prevails.

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This disclosure contains information that BiBBInstruments AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 11:30 CET on January 24, 2025.

About BiBB

The cancer diagnostics company BiBBInstruments AB develops and manufactures EndoDrill®, a patented product line of electric-driven endoscopic biopsy instruments. The EndoDrill® instruments take high-quality tissue samples with high precision with the goal of improving the diagnosis of several serious cancers, such as stomach, pancreas, liver, lung, and bladder. The product portfolio is aimed at the global market for ultrasound-guided endoscopic (EUS/EBUS) biopsy instruments, which constitute the most advanced and fast-growing area of endoscopy. BiBB received 510(k) clearance from the US FDA for the lead product EndoDrill® GI in 2023. At the beginning of 2024, CE marking according to MDR was also obtained for all three product variants: EndoDrill® GI, EndoDrill® EBUS and EndoDrill® URO. Thus EndoDrill® is the first cleared powered endoscopic biopsy system in both the US and Europe. The EndoDrill® system includes sterile disposable biopsy instruments with associated drive system. The company was founded in 2013 by Dr. Charles Walther, cancer researcher at Lund University and senior consultant in clinical pathology at Skåne University Hospital in Lund. BiBBInstruments is based at Medicon Village in Lund and the BiBBInstruments share (ticker: BIBB) is listed on Spotlight Stock Market.