
Clinical evaluation at Karolinska University Hospital is progressing

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 Company's clinical evaluation is proceeding at Karolinska University Hospital in Stockholm. During the Company's visit to the hospital, Dr. Fredrik Swahn performed biopsy sampling using EndoDrill[®] GI on three patients with suspected pancreatic tumors, resulting in visible core biopsies in all cases. The hospital was provided with more disposable instruments to complete the evaluation. Expanded market studies at a growing number of hospitals in Europe and the US are an important part of the Company's strategy and constitute the first step in the launch of EndoDrill[®] GI.

"It is gratifying to see that the evaluation at Karolinska continues with additional patient cases and that we received positive feedback." says Dr. Charles Walther, founder and CMO at BiBB.

Just after last week's introduction of EndoDrill[®] GI at Sahlgrenska University Hospital in Gothenburg, BiBB's founder Dr. Charles Walther visited Karolinska University Hospital in Stockholm once again. He participated in three patient cases with biopsy sampling of suspected pancreatic tumors under the leadership of Dr. Fredrik Swahn. In all cases, visible core tissue biopsies were taken and Charles Walther received valuable feedback from the team in the examination room. Finally, Karolinska Hospital received additional disposable instruments to be able to complete the evaluation.

There is ongoing collaboration and information exchange between the various hospitals in Europe and the US that participate in the evaluation of EndoDrill[®] GI. These market studies aim to collect user feedback and clinical data as well as increase product awareness, and they constitute the final step before a directed launch of EndoDrill[®] GI to selected hospitals.

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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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.