
First liver cases with EndoDrill GI performed in the USA

The cancer diagnostics company BiBBInstruments AB ("BiBB" or the "Company"), the developer of EndoDrill® – the world's first market-cleared powered biopsy instrument for endoscopy – announces that Dr. Mohammed Barawi, Medical Director of the Endoscopy Unit at Henry Ford St. John Hospital & Medical Center, has initiated a clinical evaluation of EndoDrill® GI. With support from BiBB's team, Dr. Barawi performed tissue sampling in the liver and pancreas on three patients. Liver biopsy is a rapidly growing indication within endoscopic ultrasound (EUS), while pancreatic biopsy is currently the largest indication. In all patient cases, high-quality core biopsies were obtained, and Dr. Barawi will continue evaluating EndoDrill® GI.

"It was inspiring to see Dr. Barawi and his team successfully perform examinations with EndoDrill® GI, including the first liver biopsies with the instrument in the United States. Our international introduction of EndoDrill® GI is now continuing, and we are grateful for the positive response we have received in the U.S.," says Dr. Charles Walther, founder and CMO of BiBB.

Henry Ford St. John Hospital in Detroit is the second hospital in the USA, after UC Davis Health in Sacramento, to initiate a clinical evaluation of the powered biopsy instrument EndoDrill® GI. After a brief introduction to EndoDrill® GI by BiBB's on-site representative, Dr. Barawi was able to perform biopsies on three patients, one in the pancreas and two in the liver. The samplings resulted in true core tissue biopsies, i.e., intact tissue samples with preserved architecture. These samples will now be evaluated to determine diagnostic outcomes.

Endoscopic ultrasound-guided liver biopsy (EUS-LB) is an emerging indication for liver biopsy. A week ago, BiBB announced that the first liver cases using EndoDrill® GI had been performed in Europe, and now, one week later, the first liver biopsies with the instrument have been conducted in the United States.

About EndoDrill® GI

EndoDrill® GI is the world's first market-cleared powered biopsy instrument for endoscopic ultrasound (EUS). The instrument is used for EUS-guided tissue sampling for various indications in the gastrointestinal tract, e.g. pancreas, stomach, esophagus, lymph nodes, and liver. EndoDrill® GI received FDA 510(k) clearance in the USA in 2023 and CE approval in Europe in early 2024. The product is currently undergoing clinical evaluation in both the USA and Europe. The commercialization phase began in early 2025 when a first order was received from UC Davis Health in the United States.

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.