
First clinical cases with EndoDrill® GI successfully performed at Karolinska University Hospital in Sweden

The cancer diagnostics company BiBBInstruments AB ("BiBB" or the "Company"), the developer of the world's first market-cleared electric-driven biopsy instrument for endoscopy, announces that the first clinical tissue acquisition procedures with EndoDrill® GI at Karolinska University Hospital in Stockholm have been successfully performed. BiBB is now planning to initiate more evaluations at a series of Scandinavian hospitals.

In February, BiBB announced that the entire EndoDrill® product portfolio had received CE certification in accordance with MDR, i.e. market approval for the European market. This meant that the Company could begin clinical evaluations of the first product variant, EndoDrill® GI, which is used for sampling in the GI tract, e.g. pancreatic tumors, and submucosal tumors in the stomach. This pre-commercial evaluation has now been initiated at Karolinska University Hospital in Stockholm.

In late March, doctors at Karolinska University Hospital performed tissue samplings on two patients with tumors in the pancreas and stomach, respectively. In both cases, histological core biopsies (CNB, Core Needle Biopsy) were taken, which have now been shown to provide diagnoses in both cases. The instrument was called "FNB on steroids" in the endoscopy room as a sign that it takes larger, more informative, biopsies compared to the latest generation of existing manual EUS biopsy instruments (EUS-FNB). High-quality biopsies are essential to establish a complete diagnosis for personalized treatment. The evaluation at Karolinska University Hospital has continued and the doctors have now independently performed another successful patient case without on-site support. The trials in Stockholm will be followed by more evaluations at a series of Scandinavian hospitals. The launch of EndoDrill® GI in Sweden is expected to take place later this year.

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, oesophagus, lymph nodes and liver. EndoDrill® GI received FDA 510(k) clearance in the US in 2023 and CE approval in Europe in early 2024.

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

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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 electric 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.