BiBBInstruments AB
Press release, April 17, 2024

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Successful clinical pilot study with EndoDrill GI published in peer reviewed scientific journal

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 pilot study EDMX01 with EndoDrill® GI has been published in the peer reviewed Scandinavian Journal of Gastroenterology. The study results show 100 percent diagnostic accuracy when sampling with EndoDrill® GI and superseded samples taken in the same tumors with a leading standard biopsy instrument. The authors concluded that the EndoDrill device was safe and easy to use, could obtain true core biopsies in a single pass, with a potential of reducing the need of multiple samplings. Currently, FDA-cleared, and CE-marked EndoDrill® GI is being evaluated at hospitals in the US and Sweden.

The results from BiBB's Swedish clinical pilot study, EDMX01, with EndoDrill® GI, were announced in the form of a poster presentation at Digestive Disease Week (DDW) in San Diego on May 21-22, 2022. Now, an original article with more details has been published in the **peer reviewed** Scandinavian Journal of Gastroenterology titled "The advent of the first electric-driven EUS-guided 17-gauge core needle biopsy – A pilot study on subepithelial lesions" (F. Swahn et al.).

" We are very grateful for the convincing results. It is a very good effort that has been carried out by the participating clinics. An acknowledgment of the solid effort is that the study is published as a peer reviewed original article in a respected medical journal," says Dr. Charles Walther, CMO at BiBB.

About study EDMX01

The pilot study compared tissue sampling using the EndoDrill® GI vs. standard fine needle instrument in deeply situated gastric tumors in 7 patient cases. In each tumor, tissue samples were taken in randomized order with electric-driven EndoDrill® GI and with leading fine needle instruments, EUS-FNB (Medtronic, SharkCore™). With the EndoDrill® GI, a rotating needle cylinder cuts out tissue samples, and with the standard EUS-FNB, samples are taken with a manual stabbing motion. It was a broad group of patients (n=7, 28-75 years) with 6 different types of tumors in the upper gastrointestinal tract and with a tumor size from 17 mm to 90 mm, i.e. a significant challenge for endoscopic sampling.

For EndoDrill®, samples of visible "core biopsies" were obtained in 7/7 cases (100%) while manual EUS-FNB resulted in 5/7 (71%) samples of ditto. Histological diagnosis was obtained in 7/7 cases (100%) with EndoDrill® and in 6/7 cases (86%) with EUS-FNB. No serious complications were noted after the examinations. EndoDrill® was rated as "simple" or "very simple" in terms of handling (7/7), preparation (7/7), adjustment of the needle (7/7), and sampling performance (6/7, one difficult case).

The research team concludes that the pilot study has shown that EndoDrill® GI can safely be used to obtain true core biopsies (CNB, Core Needle Biopsy) in a single needle puncture, reducing the need for a second sampling. The authors write that the EndoDrill® GI obtained coherent histological tissue samples that superseded conventional FNB samples, in both amount and quality. It is also noted that the EndoDrill® needle is hyperflexible, which was particularly beneficial in one of the cases. The

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researchers write that EndoDrill® GI takes core biopsies that resemble the tissue samples taken with rigid core needles in breast and prostate cancer. If this can be applied to other tumor areas, EndoDrill® will also have the potential to become a valuable tool for effective tissue sampling and precise diagnostics beyond the gastrointestinal tract. The authors conclude by stating that they are confident that the learning curve to use EndoDrill® GI is relatively short and that the technology can be applied in routine clinical practice. The article is ”peer reviewed” meaning that experts and researchers in the field have reviewed the study and its scientific quality before it is accepted for publication.

Link to the scientific publication: https://doi.org/10.1080/00365521.2024.2336611

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 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.