BiBBInstruments AB
Press release, October 2, 2024

Scheelevägen 2
Medicon Village
SE-223 81 Lund
www.bibbinstruments.com

New Peer-Reviewed Clinical Case Series in the U.S. Shows 100% Diagnostic Accuracy with EndoDrill GI

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 eight patient cases using EndoDrill® GI in the U.S. have been scientifically published in Endoscopy International Open. Biopsies were sampled in the pancreas, esophagus, stomach, and small intestine. In all cases EndoDrill® GI obtained 100% diagnostic accuracy after only one needle pass. In four patients, both EndoDrill® GI and conventional needles were used to sample the same lesion, in which EndoDrill® GI showed superior tissue samples. The authors summarize that these initial patient cases indicate that sampling with EndoDrill® GI is effective and safe.

"*The scientific review of eight completed cases at UC Davis Health in California using EndoDrill® GI demonstrates the method's broad application and diagnostic accuracy. It is particularly interesting that in four cases where both EndoDrill® GI and conventional needle instruments (EUS-FNA/FNB) were used in the same patient, EndoDrill® GI provided a diagnosis, while comparative sampling with standard needles failed to produce diagnostic material*," says Dr. Charles Walther, founder and CMO of BiBB.

In January 2024, Dr. Antonio Mendoza Ladd, medical director of endoscopy at UC Davis Health in Sacramento, California, started a clinical evaluation of the FDA-cleared EndoDrill® GI, which is still ongoing. The results from the first eight patient cases have now been published in the article "*Initial Experience With The Transmural Use Of A New Endoscopic Ultrasound Electric Core Needle Biopsy Device: A Case Series*" in Endoscopy International Open[1].

These patient cases represent the first transmural (through the wall of the gastrointestinal tract) biopsies using an EUS-CNB instrument (EndoDrill® GI) on tumors in the pancreas (n=5), retroperitoneum (n=2), and mediastinum (n=1). In all eight patient cases, a diagnosis was achieved using tissue biopsies taken with EndoDrill® GI (100% diagnostic accuracy) after a single needle pass. In four of these cases, patients had first undergone biopsies using manual EUS-FNA/FNB needle instruments (the current "gold standard"), which provided insufficient tissue samples for diagnosis. In all these cases, tissue samples obtained with EndoDrill GI resulted in a complete diagnosis. The samples from EndoDrill® GI showed less blood contamination, fewer artifacts, and more intact tissue cores compared to what is typically seen with standard EUS-FNA/FNB instruments. The only noted adverse effect was one case of mild bleeding, which was successfully controlled.

The authors' impressions after the initial cases with EndoDrill® GI are that the tissue sampling method is effective, safe, and easy to install and use. They conclude by recommending a randomized clinical study comparing EndoDrill GI with standard EUS-FNA/FNB needle instruments to further assess the product's efficacy and safety.

1 Mendoza Ladd A, Alsamman A, Meiklejohn K et al. Initial Experience With The Transmural Use Of A New Endoscopic Ultrasound Electric Core Needle Biopsy Device: A Case Series. Endoscopy International Open 2024. doi: 10.1055/a-2427-2311

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Link to the article https://www.thieme-connect.de/products/ejournals/abstract/10.1055/a-2427-2311

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.

For more information about BiBB, please contact:

Fredrik Lindblad, CEO
E-mail: fredrik.lindblad@bibbinstruments.com
Phone: +46 70 899 94 86
www.bibbinstruments.com

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.