

## **Henry Ford St. John Hospital Reports First U.S. Liver Biopsy Cases with EndoDrill® GI**

The cancer diagnostics company BiBBInstruments AB ("BiBB" or the "Company") today announces that Henry Ford St. John Hospital & Medical Center in Detroit has reported the first U.S. case series with EndoDrill® GI that includes endoscopic ultrasound-guided (EUS) liver biopsies. The evaluation, led by Dr. Mohammed Barawi and conducted with his team at Henry Ford St. John Hospital, was presented at a regional medical conference and demonstrated the device's ability to obtain diagnostic tissue from both the liver and pancreas.

The series comprises four patients, three with suspected liver conditions and one with a suspected pancreatic tumor, who underwent EUS-guided biopsy. In all cases, the motorized 17G instrument yielded diagnostic tissue samples, including one case where prior percutaneous tissue sampling had been non-diagnostic. Diagnoses included autoimmune hepatitis, cirrhosis, and pancreatic adenocarcinoma.

*"These early results support the value of EndoDrill® GI in achieving reliable core biopsies for demanding indications,"* said Dr Charles Walther, Founder and CMO of BiBBInstruments. *"We are especially encouraged by the positive feedback from the experienced team at Henry Ford St. John Hospital. Their findings help pave the way for our upcoming U.S. launch in partnership with TaeWoong Medical USA."*

Dr. Barawi's team highlighted both the diagnostic performance and procedural safety of EndoDrill® GI in their abstract. The authors concluded: *"The use of the EndoDrill device demonstrated strong diagnostic utility across an array of clinical presentations. Due to the clinical necessity for adequate tissue samples to establish molecular pathology, EndoDrill yielded safe and effective results in this limited sample size."*

Henry Ford St. John Hospital is the second U.S. center to evaluate EndoDrill® GI, following initial clinical use at UC Davis Health in California. BiBB is currently finalizing its U.S. commercial launch preparations together with TaeWoong Medical USA, who in June 2025 signed an exclusive distribution agreement for the U.S. market. The first commercial deliveries are expected later this year.

### **About EndoDrill® GI**

EndoDrill® GI is the world's first FDA-cleared powered biopsy instrument for endoscopic ultrasound (EUS). Unlike conventional manual FNA/FNB needles, it features a motorized rotating tip that extracts intact core tissue samples, improving histological yield and enabling molecular analysis. The system received 510(k) clearance in the U.S. in 2023 and CE marking in Europe in 2024. It is currently undergoing clinical evaluation in both regions, with a U.S. launch in collaboration with TaeWoong Medical USA set to begin during the autumn.



BiBBInstruments AB  
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*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**

BiBBInstruments AB is a cancer diagnostics company that develops and manufactures EndoDrill®, the world's first line of electric-driven endoscopic biopsy instruments. EndoDrill® is designed to collect core tissue samples (CNB) with high diagnostic accuracy. The instruments aim to improve the diagnosis of several serious cancers, including those of the stomach, pancreas, liver, lung, and bladder. The product portfolio targets the global market for ultrasound-guided endoscopic biopsy instruments (EUS/EBUS), one of the most advanced and rapidly growing segments of endoscopy. BiBB received 510(k) clearance from the U.S. FDA for its lead product, EndoDrill® GI, in 2023. In early 2024, CE marking under the EU Medical Device Regulation (MDR) was granted for all three product variants: EndoDrill® GI, EndoDrill® EBUS, and EndoDrill® URO – making EndoDrill® the first powered endoscopic biopsy system cleared in both the U.S. and Europe. The U.S. launch of EndoDrill® GI is set to begin during the autumn in collaboration with the company's new distribution partner, TaeWoong Medical USA. The EndoDrill® system includes sterile, single-use biopsy instruments along with a proprietary motorized drive unit. The company was founded in 2013 by Dr. Charles Walther, a cancer researcher at Lund University and senior consultant in clinical pathology at Skåne University Hospital. BiBBInstruments is headquartered at Medicon Village in Lund, Sweden, and is listed on Spotlight Stock Market (ticker: BIBB).