
BiBB has initiated a collaboration with Swedish contract manufacturer Cenova

The cancer diagnostics company BiBBInstruments AB ("BiBB" and the "Company"), the developer of EndoDrill®, the world's first market-cleared electric-driven biopsy instrument for endoscopy, informs that the Company has initiated a collaboration with the Swedish contract manufacturer Cenova. The transfer of the production of disposable instruments to Cenova is planned to be completed by mid-2025. This enables a quality-assured production tailored for commercial volumes, which is a requirement from potential distribution partners

"With the plans for strategic collaboration with one or more distribution partners, we need to increase production capacity for our sterile single-use instruments to meet a rise in demand. Therefore, we have chosen to switch to a Swedish contract manufacturer with extensive experience in volume production and the ability to meet stringent regulatory requirements from various markets. The transition is expected to be completed by mid-2025 and represents an important step toward commercial success," says Fredrik Lindblad, CEO of BiBB.

BiBB has so far collaborated with a smaller development and manufacturing partner. This partnership has been highly fruitful during the company's development phase, resulting in the first ultrasound-guided biopsy instrument with clinically proven ability to obtain core tissue samples (EUS-CNB). For the upcoming commercialization of EndoDrill® GI, in collaboration with one or more distribution partners, the production capacity for sterile single-use instruments must be increased. BiBB has chosen to initiate a partnership with Cenova from Mjölby. Cenova is a contract manufacturer with 50 years of experience in producing innovative and complex medical devices in cleanroom environments. They have a robust quality system that meets the toughest market requirements and collaborates with both innovation-driven companies and large multinational corporations.

In connection with the kickoff for the transfer project, BiBB has strengthened its development department with a senior project manager experienced in working for a major global medical technology company. The goal is for the project to be completed by mid-2025, ensuring BiBB achieves higher production capacity, which is required by potential sales partners. To meet demand until the production transfer is completed, BiBB has built up a finished goods inventory of sterile single-use instruments for planned clinical marketing activities, evaluations, and sales to selected customers.

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 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 undergoing clinical evaluation in the USA and Europe in preparation for a planned directed launch.

About Cenova AB

Cenova is a full-service contract manufacturer with 50 years of experience in innovative and complex clean plastic products, specializing in injection molding, vacuum forming, assembly, packaging, and sterilization. Cenova offers the entire process chain, from development through industrialization and assembly to the distribution of products manufactured in ISO-classified cleanrooms. This work is supported by a top-tier quality system that meets the requirements of ISO 9001, ISO 14001, ISO 13485, and FDA 21 CFR Part 820 QSR. Cenova's clients are based both in Sweden and internationally. Cenova, part of the Gepe Group headquartered in Switzerland, has its production facility in Mjölby, Sweden.

This is a translation of the Swedish press release. If there should be any discrepancies, the Swedish language version prevails.

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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 an 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.