
U.S. Tour Fall 2025 – BiBB Strengthens Its Presence in the American Market

BiBBInstruments AB (“BiBB” or the “Company”), a cancer diagnostics company, has recently completed a successful tour across the United States – an important step in the initial commercialization of EndoDrill® GI in the world’s largest market for ultrasound-guided endoscopic tissue sampling (EUS/EBUS). During the trip, BiBB met with representatives from six leading hospitals and supported TaeWoong Medical USA (“TaeWoong”) in education and clinical introductions of EndoDrill® GI. The Company also received further confirmation of the clear clinical need for high-quality core biopsies, while both ongoing studies and a planned randomized multicenter study were discussed. The targeted launch has now begun, and TaeWoong has already sold EndoDrill® GI to four university hospitals ahead of a broader rollout in 2026.

“The strong response from U.S. hospitals confirms both the need for better biopsies and EndoDrill®’s potential to improve current practice – and to meet future demands for more informative tumor samples,” says Charles Walther, CMO and founder of BiBB.

Strong Interest from U.S. Hospitals

During the two-week U.S. tour, BiBB and TaeWoong Medical USA visited several leading hospitals. The visits included staff training, demonstrations of EndoDrill® GI, and clinical introductions in real-world cases. Several hospitals expressed strong interest in the product, particularly given the need for more robust and reproducible core biopsies in EUS-guided sampling. The team also noted that EndoDrill®’s unique ability to obtain high-quality tissue samples in one or only a few needle passes is a key differentiating feature compared with today’s manual FNB needles.

BiBB’s representatives also reconfirmed the significant unmet need for improved biopsies in both endoscopic ultrasound (EUS – gastrointestinal tract) and endobronchial ultrasound (EBUS – lungs/airways). This applies both to current clinical practice, where adequate diagnostic material is critical for treatment decisions, and looking ahead, where biopsies increasingly need to enable tumor genetic analysis to support individualized therapy. This is an area where EndoDrill® is clearly at the forefront, illustrated by the ongoing project at Mayo Clinic in Jacksonville, FL, which aims to determine whether core biopsies such as those obtained with EndoDrill® can become key enablers within the rapidly growing field of precision oncology.

Clinical Studies as Value Drivers

During the trip, BiBB discussed both its ongoing clinical collaborations and the planning of a forthcoming randomized multicenter study of EndoDrill® GI in the U.S. and Europe. This study, coordinated by BiBB’s new advisor, Professor Peter Vilmann, is planned to begin in 2026 to further strengthen the clinical evidence for EndoDrill® ahead of broader adoption and represents a central part of the Company’s long-term market strategy.

Beyond the GI area, discussions also included the upcoming product variants EndoDrill® EBUS and EndoDrill® URO. These will enable future expansion into the diagnosis of lung cancer and bladder cancer, two large and globally growing markets with significant commercial potential.

Launch Gaining Clear Momentum

The targeted U.S. launch of EndoDrill® GI is now underway, with TaeWoong focusing on establishing regular use at five major reference hospitals. These centers will form the foundation for a broader nationwide rollout in 2026.

TaeWoong has already sold EndoDrill® instruments to four U.S. university hospitals, and additional installations are expected according to the joint launch plan. BiBB continues to support TaeWoong with training, clinical support, and evidence-building activities to ensure a successful commercial introduction of EndoDrill® GI in the U.S. market.

About EndoDrill® GI

EndoDrill® GI is the world's first powered biopsy instrument for endoscopic ultrasound (EUS) with both FDA clearance and CE marking. Unlike conventional manual FNA/FNB needles, the instrument features a powered rotating needle tip that retrieves intact core tissue cylinders, providing very high histological yield and enabling molecular analysis. The system received 510(k) clearance in the United States in 2023 and CE marking in Europe in 2024. It is currently in clinical use in both regions, and a targeted U.S. launch began in the fall of 2025 in collaboration with TaeWoong Medical USA.

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 series of market-cleared powered endoscopic biopsy instruments. EndoDrill® is designed to obtain core tissue samples (core needle biopsies, CNB) with high diagnostic accuracy and aims to improve the diagnosis of cancers in the stomach, pancreas, liver, lungs, and urinary bladder. The product portfolio targets the global market for ultrasound-guided endoscopic biopsy instruments (EUS/EBUS), one of the most advanced and fastest-growing segments in modern endoscopy. BiBB received FDA 510(k) clearance for its first instrument, EndoDrill® GI, in 2023 and CE marking under the EU Medical Device Regulation (MDR) in 2024 for all three product variants – EndoDrill® GI, EndoDrill® EBUS, and EndoDrill® URO. EndoDrill® is thus the first motor-driven biopsy system approved in both the U.S. and Europe. The U.S. launch of EndoDrill® GI began in fall 2025 in collaboration with TaeWoong Medical USA. The EndoDrill® system consists of sterile single-use instruments and a proprietary drive system. BiBB was founded in 2013 by Dr. Charles Walther, cancer researcher at Lund University and senior consultant in clinical pathology at Skåne University Hospital. The Company is headquartered at Medicon Village in Lund and is listed on Spotlight Stock Market (ticker: BIBB).