

Case Study

Workshop and Expert Meeting with BEGO Implant Systems

In February 2020, **BEGO Implant Systems** invited Climedo Health to Bremen to take part in a two-day workshop with leading **dentists and implantologists**. The main objective of the expert meeting was to discuss the challenges of the new **EU Medical Device Regulation (EU MDR)** and to exchange views on how to jointly manage the new requirements. The feedback from the participating doctors and BEGO employees was consistently positive and BEGO Implant Systems subsequently decided to use Climedo Health to carry out their planned **Clinical Survey** project.

About BEGO Implant Systems

With over **200 employees**, **BEGO Implant Systems GmbH & Co. KG** is one of four business divisions of the BEGO Group. It manufactures more than 1 million **implant components** with over 50 international product approvals for the **global dental market** per year. As an innovative company, it holds over 30 patents and reinvests a large part of its turnover in **research and development** to provide its patients with a healthy, attractive smile and an improved quality of life. Just like thousands of other European medical device manufacturers, **BEGO Implant Systems** is confronted with the requirements of the new **EU MDR**.



Source: BEGO Implant Systems

Challenge

The implementation of the EU MDR has presented medical device manufacturers with significant challenges. The new regulation's objective is to ensure **patient safety** and **transparency**. Therefore, a continuous and structured Post-Market Clinical Follow-up of the medical devices is absolutely necessary.

- BEGO Implant Systems GmbH & Co. KG has planned and already taken a number of measures to meet the increased requirements for **Post-Market Surveillance (PMS)** and **Post-Market Clinical Follow-up (PMCF)**.
- It is often **challenging** for medical device manufacturers to continuously monitor and document the operations performed by doctors in the context of studies and patient cases. They are therefore dependent on the cooperation of the operating physicians. Since **doctors** are generally short of time, they must be **motivated** to **participate** in the clinical data collection for the medical devices used. A data collection process must be designed to be **efficient** and **automated** in order to use as little of the doctors' valuable time as possible.
- **Traditional survey and data collection tools** are of limited use for clinical surveys and are unsuitable for clinical trials, not least for data protection reasons. Many functions (such as **dynamic filters**) are not available, and evaluations must be created manually, which is very **time-consuming**. An interface to other systems and file types is also missing in most cases.

"Accompanying and documenting clinical studies and patient cases for a wide range of products is very important for a manufacturer like BEGO Implant Systems. That's why we were looking for a system that would allow us to collect clinical data in the most efficient way and to monitor the progress of PMS activities per product. We are glad to have discovered Climedo."

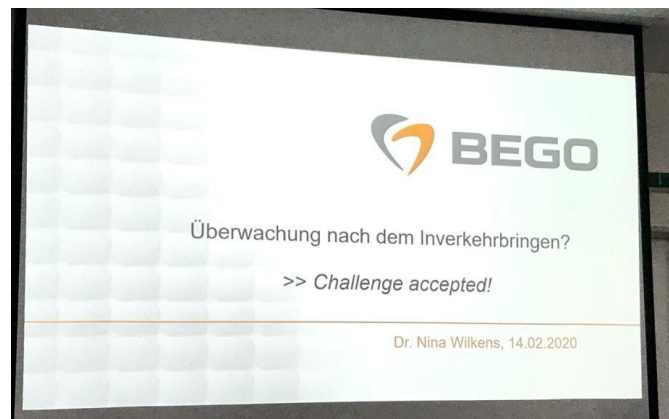
Dr. rer. nat. Nina Wilkens, Clinical Affairs Manager, BEGO Implant Systems

Solution

In order to meet the requirements, BEGO Implant Systems invited Climedo to Bremen in **February 2020** to conduct a joint workshop and to give a presentation at the **annual expert meeting** with selected renowned **dentists** and **implantologists**. The aim of the meeting was to discuss the **new requirements** that will affect doctors and medical device manufacturers in the light of the upcoming **EU MDR**.

In addition to individual presentations by employees of BEGO Implant Systems and Climedo, there was plenty of time for questions, comments and a lively exchange between the participants.

Climedo's solution **facilitates and automates** the entire process of **proactive, structured data collection** in the context of the required product monitoring and collection of clinical data (PMS and PMCF measures).



Source: BEGO Implant Systems

- The Climedo platform enables customers to **document** and **provide clinical data more quickly**. This way, doctors can participate in the required PMS and PMCF measures in a simple and time-saving manner. As such, every practice and clinic can make a valuable contribution to meeting the EU MDR requirements and the growing demands on medical device manufacturers in order to benefit from high-quality products in the future.
- Participating practices and clinics have access to their own data for **internal analysis** at all times. On request, **anonymous comparisons** with other users can be made, for example to **identify** frequently occurring problems or application errors at an **early stage** and thus **improve** patient safety and quality.
- Thanks to dynamic filter views, collected data can be **statistically processed** and **visualized** in flexible dashboards at any time.
- Both open **API interfaces** and imports of existing data from other systems are possible.

- Climedo enables the compliant collection of data, even within the framework of **strictly regulated clinical studies**. The **data protection** measures and software security precautions required for this have been confirmed by external auditors.
- By simply scanning a **QR code** during the expert meeting, the doctors were able to take part in a **live survey** on their own **smartphones** and get an impression of Climedo's **user-friendliness**.

"I was immediately impressed by the ingenuity of the platform. That's why I am now using Climedo for quality management of my surgical work as an oral surgical implantologist. In particular, I appreciate the intuitive usability, which minimizes training costs for employees."

Dr. med. dent. Wolfgang Maas, Oral Surgeon, Practice for Implantology

Results and Outlook

The reactions of the participating doctors and BEGO employees were consistently positive:

- The advantages of Climedo for **efficient and user-friendly data entry** were quickly recognized and immediately confirmed by the active participation in the live survey.
- The possibility of easily **evaluating the survey and study results** was particularly well received by the doctors.
- During and after the workshop, some doctors expressed their **interest in further usage of Climedo** in their practices to **document their treatments and operations internally and to evaluate them statistically**.
- Without exception, **all doctors** expressed their **willingness to participate** in the planned project of a **Clinical Survey** using Climedo's solution.

BEGO Implant Systems subsequently decided to **use Climedo to carry out the planned project of a Clinical Survey**. The aim is to systematically collect data and to **collect clinical data in the context of PMS and PMCF activities**.

"Thank you very much for the great workshop and the productive collaboration so far! The participating doctors were convinced by the Climedo system and we are looking forward to using it for our PMS activities. What we particularly like are the ease of use and the flexible options for configuring the clinical surveys. We can make any changes to the input masks ourselves in a very short time, without the necessary support from IT."

Dr. med. dent. Nina Chuchracky, Product Marketing Director, BEGO Implant Systems

Want to digitalize your PMS processes in time for the EU MDR and learn how to better incentivize your product users? Get in touch for a quick chat or a demo!

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About Climedo

Climedo's mission is to bring the best treatment to every patient by empowering healthcare professionals with intelligent software solutions. Together with Europe's leading hospitals, we have developed a cloud-based platform for cutting-edge clinical validation of medical devices and pharmaceutical products. By digitally connecting all stakeholders (medical device manufacturers, pharma companies, CROs, hospitals and patients), Climedo allows for increased performance, better cost-efficiencies – and ultimately – accelerated medical innovation. Learn more at www.climedo.com.

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