

Advancing endoscopy with Blackbox Innovations

PENTAX Medical's **Harald Huber** and **Michael Unger** discuss key trends and innovation in endoscopy, with *The Clinical Services Journal*. They highlight some of the key developments that are expected to advance endoscopy in terms of safety, productivity, and clinical outcomes.

There are a number of key trends shaping the endoscopy market – patient safety and hygiene, artificial intelligence (AI), and the need to balance a degree of single-use provision with sustainability. These trends are fuelling innovation in endoscope design and PENTAX Medical has been working closely with clinicians to understand and respond to these drivers.

“Our main objectives are to minimise the risk of infection, improve clinical outcomes, and enhance the professional's experience and healthcare productivity within endoscopy. With this in mind, we are looking further ahead at what endoscopy could look like in 5-10 years,” explains Michael Unger, general manager marketing, product and business development. “Through our Blackbox Innovations programme, we work closely with physicians and invite them at an early stage into our R&D processes. It is our aim to learn about challenges in daily clinical practice and then brainstorm with physicians on the development of solutions,” he explains.

Since its introduction in 2016, the Blackbox Innovations programme has become an important part of the company's approach to R&D. The dedicated workshops take place at one of four global R&D sites which provide the ideal environment for innovation. An integral function of these sessions is to provide a forum for detailed discussion of unmet needs and challenges in clinical practice and collaborative exploration of potential solutions. Finally, the users have a chance to try out early prototypes and provide real-time feedback during a hands-on session. To date, a number of new developments have resulted from this approach. One of these has been the the PENTAX Medical Video Duodenoscope ED34-i10T2 which features a sterile disposable elevator cap (DEC) for single-patient use and simple disposal. This



was developed to address the increasing incidences of cross-contamination with different types of pathogens that may be linked to improper cleaning or disinfection of the elevator mechanisms of duodenoscopes used in endoscopic retrograde cholangiopancreatography (ERCP) procedures. Feedback from key opinion leader customers at these workshops was instrumental in the development of the final concept.

“Cleaning a duodenoscope is a complex task – there are more than 120 steps for an individual to remember. We have considered: ‘how can we make life easier for people at the forefront of endoscopy safety – to make our scope easier to use and to clean?’ One of the biggest pain points is how to clean the elevator. We have redesigned the mechanics and made it disposable. There is also a more open design to allow access for a brush, enabling easier cleaning. This type of thinking is being adopted for all of our developments. It is about

considering every stakeholder involved and making the processes easier,” comments Harald Huber, global vice president for product and category management. Huber points out that over the past decades, the focus has been on improving endoscope technology. However, there is still a need for improvements in the field of hygiene.

“Our R&D is developing packages that focus on how to clean the scope, improve patient safety, and deliver more effective treatment. We are listening to physicians through the Blackbox Innovations programme, but the patient is also a key stakeholder for PENTAX Medical. In terms of hygiene, we have been making some important improvements to our existing technology to improve patient safety – including the development of semi-disposable devices, such as the DEC Duodenoscope.”

Another important development to emerge from the Blackbox Innovations discussions has been the ONE Pulmo ►

single-use bronchoscope – the pandemic was a key driver in the development of this disposable device.

“During COVID there was a need for immediate availability in ICU, so single use was identified as the ideal option,” explains Unger. This led to the launch of a single use bronchoscope, with HD image quality.”

Ultimately, single use scopes eliminate wait times between procedures, simplifying overall workflow and patient throughput. The sterile-packed scopes are ready to use anytime, anywhere, allowing quicker care delivery to the most vulnerable patients. However, the ONE Pulmo has also broadened the clinical applications beyond the standard disposable scope, without compromising on high quality pulmonary care.

The ‘Power of Choice’

As developments, such as this, successfully tackle the challenges of availability and infection prevention, will single use



endoscopes increasingly become the norm? Unger and Huber state that this is unlikely to happen in the foreseeable future.

“We do not believe there will only be single use in the future,” comments Unger. “Some areas of endoscopy require the best possible image and haptic feedback. This is not yet available with single use. We believe in ‘the Power of Choice’ – providing a complete portfolio of solutions for the

physician so they can choose the best option for the individual patient. This includes reusable scopes with a reprocessing strategy with the highest margin of safety; semi-disposable scopes with the disposable elevator cap, and single use where necessary – such as in the ICU, where it is vital for the scope to be available at any time.”

“In the early days, there was a lot of interest in single use endoscopes, and it looked like every scope might become single use in the future,” comments Huber. “Now the topic has settled, and it is clear from discussions with physicians that the hype is not as strong as it was before – reality has kicked in.

“There are questions around cost and what are we going to do with the waste? Our view is that there needs to be a balance – a mix between single use and reusables. It doesn’t make sense to go 100% single use for all cases. Every patient is different. Every medical situation is different. That is why we have the ‘power of choice’ concept.”

“We don’t want to force customers into a specific direction. We want them to be able to select the right piece of equipment for the situation,” adds Huber. “There are patients who are more vulnerable from a health perspective, and it may make sense to use a single use scope for these individuals. However, we believe the market will move towards a mix of single use and reusable as sustainability issues come to the fore – every physician will need to consider balancing cost, patient safety and the environment before going into a procedure.”

Drying and storage

There are other ways in which healthcare providers can be supported to improve hygiene in endoscopy. This includes a focus on developing solutions for drying and storage.

“If you simply wash an endoscope, reprocess it, and hang it in a drying cabinet to dry, there is a risk of biofilm formation during the process. Even if you follow the first part of the process perfectly, there are risks in the second part. This is why the portfolio also includes solutions for fast drying and the safe storage of scopes,” comments Unger.

The PlasmaTYPHOON+ and PlasmaBAG system is an example of an innovation that emerged in response to this challenge. The new endoscope drying and storage solution is capable of drying endoscopes even faster – in just 1-3 minutes. The system uses two types of airflow to ensure each individual channel is perfectly dried: a laminar flow to eliminate the residual fluid in the channel, and a turbulent heated flow to completely dry the channel walls. Boosting the efficiency of drying cycles directly impacts endoscope availability and therefore patient procedures.

Advancing proficiency in innovative endoscopic techniques

To help advance endoscopy further, PENTAX Medical is also investing in education – this is especially important in helping to spread expertise in new approaches and endoscopic procedures that can improve outcomes. Huber points out that there is a move from open surgery to endoscopy and more minimally invasive techniques, which includes procedures such as endoscopic submucosal dissection (ESD).

“Japan is leading on this approach but there are not so many specialists in Europe right now. This means we need to educate physicians on this sophisticated procedure,” he explains. “In each region, we have local training programmes, but we don’t want to just focus on the professors; we also want to focus on the young and emerging physicians. There is a need to improve access to training for this group which is why Pentax is positioning itself in the market as one of the leading providers of this education.”

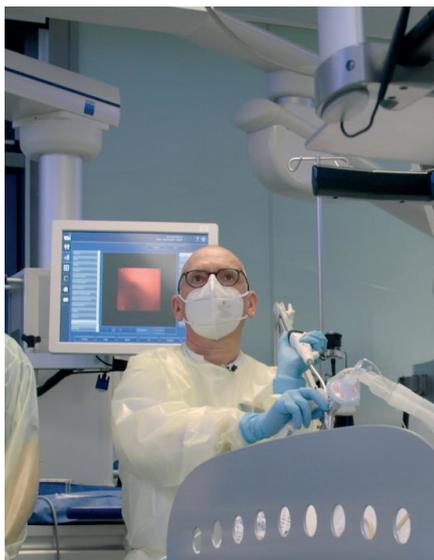
The PENTAX Medical forward Academy gives promising clinicians, new to the field of endoscopic therapeutic procedures, the chance to work one-to-one with ESD experts, who personally mentor and provide valuable hands-on training in advanced level therapeutics.

The programme offers a comprehensive one-year training curriculum based on ESGE Guidelines outlining how to achieve proficiency in performing ESD. The in-depth programme has been developed in

partnership with internationally recognised ESD training experts, including Dr. Amyn Haji (King’s College, London, UK), Dr. Arjun Koch (Erasmus MC Rotterdam, Netherlands), Dr. Michael Haefner (Ospedale di Bolzano, Austria), Dr. Ken Ohata (NTT Medical Centre, Tokyo, Japan) and Dr. Hideyuki Chiba (Omori Red Cross Hospital, Tokyo, Japan). This exciting training initiative also creates a valuable knowledge and information exchange network between Europe and Japan where ESD was first developed.

The training programme entails a structured series of steps devised to guarantee the development of the trainee’s core skills. Over the year, they are directly supported by both European and Japanese mentors who are highly experienced in a variety of advanced endoscopic therapeutic techniques, having performed thousands of procedures over many years. The training involves ESD basics lectures and guided self-study, observing experts performing ESD in European tertiary referral centres, as well as performing ESD cases under the direct supervision of the expert European and Japanese mentors. Core to the programme’s success is also the ability to formally evaluate learning progress and share feedback within it.

PENTAX Medical has also launched an Endoscopic Ultrasound (EUS) course with a mentor group led by several of the world’s top experts in Europe and has plans for further such courses, in the near future.



In combination with complete drying, storage of the endoscope in the single-use carbon-neutral PlasmaBAG ensures the preservation of its disinfected state for up to 31 days.* To provide a safe and active storage environment, the PlasmaBAG is insufflated with plasma containing ozone molecules, and then sealed. By maintaining the disinfected state, the need to reprocess endoscopes after storage is reduced and the risk of recontamination during transport is further eliminated. As a result, the reprocessed endoscopes are available anywhere, anytime.

Artificial intelligence

While safety, hygiene and usability have been key drivers in R&D in endoscopy in recent years, the market is also now seeing increasing interest in the use of AI, according to Unger and Huber.

“When face-tracking first emerged in airports, we thought ‘if you can track a face, why not a polyp?’ This is where the journey in AI first started in for Pentax endoscopy,” explains Huber. “The detection of polyps is really important, and our AI system is helping physicians in their daily practice to increase their normal detection rate, particularly when they become fatigued,” explains Unger.

“In our fight against colorectal cancer, we have already achieved a great deal. We have increased the adenoma

detection rate (ADR) by up to 11% with digital and optical enhancement technology. We have also increased ADR by up to 28% by mechanical devices to examine blind spots. However, up to 26% of lesions are still missed in examinations, which is why we are committed to developing solutions to overcome daily challenges in colonoscopy routines,” adds Huber.

This has led to the introduction of the development of an AI-assisted ‘smart assistant system’ designed to support endoscopists in finding potential polyps during a colorectal examination. ‘DISCOVERY’ is the outcome of a close cooperation between the company’s research centre located in Augsburg, Germany, and expert clinical partners from six of the leading medical institutions across the world. For this next generation development, a total of more than 120,000 files from approximately 300 clinical cases were used for the software training. By leveraging artificial intelligence, the system is able to assist endoscopists in finding potential polyps during a colorectal examination.

“When driving, from A to B, we now turn on our GPS system. Much like this, I believe that in 5-10 years from now, we will see AI used as a ‘smart assistant’ to help guide physicians. This will not only be used for detection, but also in supporting decision-making, as well as focusing on different areas and different diseases,” comments Unger.

“Currently, the focus area is colonoscopy, but – in the future – this will expand into other areas of the body. One of the barriers that still needs to be overcome is convincing the physician that they need this help, however.

“Some believe they are so experienced in detecting polyps that they don’t need this technology. People were not convinced that they needed a navigation system in their car, at first. But after 6 hours of working, physicians can become tired, or the conditions in the colon may be challenging. AI can really help increase the adenoma detection rate,” he asserts.

“In the past, there was a real fear that this type of technology would de-skill endoscopy and that physicians may be out of a job in ten years. Now, people realise that there will always be a need for the physician,” Huber concludes. “There is no ambition to replace the physician with an AI system. The goal is not about de-skilling but about re-skilling – it is about learning to incorporate the benefits of AI into the workflow. This is becoming the main opportunity in this field.”

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*Validated for up to 744 storage hours (31 days) according to NF EN 16442 norm. The maximum storage time may be subject to local regulations on endoscope storage.



Harald Huber

Harald Huber is the global vice president for product and category management, at PENTAX Medical. He is an expert in medical product & programme management, with key knowhow in artificial intelligence, single use devices and infection prevention. With 15 years of experience in global medtech and the management of global initiatives, with teams from multiple sites and cultures, he combines deep technology understanding and commercial knowhow to establish successful marketing strategies for highly innovative products.



Michael Unger

Michael Unger is the general manager marketing, product and business development, at Pentax Medical. He leads the marketing communications and product management team in EMEA. He is also responsible for business development within the region. He has 20 years of experience in sales, marketing and business development within the healthcare industry, with roles in EMEA and Asia.

