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Consure wins USFDA clearance for Qora

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The company announced that it has received 510(k) clearance from the US Food and Drug Administration (FDA) to market three devices under its novel Qora Stool Management Kit (SMK) platform, to help manage faecal incontinence (FI) in non-ambulatory patients.

FI is the inability to control bowel movements, leading to the involuntary and untimely release of faeces or flatus.

It is an especially embarrassing and distressing condition for nearly 10 million US hospitalized patients and their caretakers.

With current management options, patients are more likely to acquire bedsores, dermatitis, nosocomial infections and extend their length of stay in the hospital.

Such facility acquired complications impact the CMS reimbursement received by these healthcare facilities, costing nearly 2 billion dollars annually.

Qora paves the way for an entirely new approach in the management of faecal incontinence, representing a $5 billion dollar market opportunity.

Designed with the patient and user in mind, the Qora is the most comfortable, cost-effective, simple to use and versatile FI management device.

With its patented technology, Consure brings together highly-motivated and capable team members, clinicians and investors focused on improving care for more than 100 million patients worldwide.

The Qora SMK suite of devices comprising Qora Aeon, Qora AIM and Qora Arida, is designed to cover the spectrum of clinical needs observed in institutionalized FI patients.

Consure's flagship product, Consure 120 SMS, had previously received clearance in 2014.

Consure adds to this product line by introducing a short-term product, Qora Arida, and two long-term products, Qora Aeon and Qora AIM, which is MRI-compatible.

These three line extensions offer an expanded faecal management portfolio for complex critical care patients and long-term acute or nursing care patients.

Additionally, the new clearance allows for expanded use period for these devices, for up to 29 days.

Qora uses proprietary technology that enables the device to safely divert liquid to semi-formed stool without interfering with patients' normal physiological function.

The innovative design ensures hygienic device placement and dignified patient care.

Consure Medical has received wide patent protection for its proprietary technology in key markets and continues to expand its patent portfolio.

"We see our FDA clearance and successful product pilots at partner health centres as key milestones in helping manage faecal incontinence in a safer, more hygienic and compassionate manner," said Mr Nishith Chasmawala, CEO, Consure Medical.

Backed by strong clinical evidence and supported by a talented team, Consure Medical is ready to scale up the product's commercialization in key geographies and establish Qora SMK as a new standard of care.

"With our entirely novel approach to managing faecal incontinence, Qora is the first product that can be used beyond the critical care setting, offering a much needed management option for millions of patients suffering from faecal incontinence outside the ICU. The elegance of our novel technology is in its versatility and simplicity of use. Since Qora can be used with patients who have semi-formed stool or are being managed in step down facilities like LTACs, SNFs, and nursing homes, the market expansion opportunity is tremendous, nearly tripling the current number of addressable patients," Mr Chasmawala added.

With the current reimbursement scenario, 20% of all US hospitals are being penalized for completely avoidable clinical complications like pressure ulcers and nosocomial infections.

Medical device innovation targeted at improving healthcare quality outcomes, as well as the proactive adoption of such technology, will be instrumental in helping improve quality of healthcare around the world.

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