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Medspira Receives FDA 510K Clearance for mcompass Anorectal Manometry Device

Makes Testing Practical for a Wide Range of Medical Specialists

May 21, 2012—Minneapolis—Medspira has received U.S. Food and Drug (FDA) 510K clearance for its innovative mcompass anorectal manometry device. Anorectal manometry testing evaluates pelvic floor function in patients with constipation or fecal incontinence.

Incorporating a range of unique features, mcompass is designed to make testing highly accurate, easy to perform and practical for a broad range of medical specialists. In addition to colorectal surgeons and gastroenterologists, Medspira will market the device to primary care physicians, gerontologists, URO/GYNs and OBGYNs.

“Fecal incontinence and related chronic constipation are major medical problems and growing significantly with today’s aging population,” says Jim Quackenbush, CEO of Medspira. “Yet, despite the health and lifestyle consequences, only one in 13 patients with fecal incontinence or chronic constipation is tested to determine the cause of their disorder. Often, sufferers are provided a range of treatments that fail to address the root of their problem.”

Unlike today’s more complex and cumbersome anorectal devices, mcompass is portable, compact and weighs only three pounds. Other systems usually require a cart and dedicated room, while mcompass can be set up anywhere in minutes. Testing can be easily conducted in nursing homes or other community locations.

Intuitive and user-friendly, mcompass comprises three simple components—a disposable catheter, mobile tablet PC and wireless portable manometer. Built-in software prompts guide even inexperienced users through the testing process. The device is ready for use within seconds due to an innovative priming method, and results display in real time on the device’s tablet PC workstation. The full encrypted data packet can be emailed to specialists for interpretation, if needed, in a few clicks using the device’s built-in Wi-Fi connectivity.

In addition, mcompass features an innovative, disposable catheter for enhanced testing accuracy and a proprietary single-connector to streamline set-up. The catheter comprises a central rectal balloon and four radial anal canal balloons at 90 degree relative positioning. Each balloon provides independent measurement. The device’s anal canal balloon is 20 mm long, enabling one or

two positioned full anal canal measurements. A non-compliant rectal balloon supports true rectal compliance testing.

“Most manometry devices on the market today handle a range of motility exams in addition to anorectal testing, making them costly and complicated for anorectal use,” explains Quackenbush. “Therefore, anorectal testing is typically performed by gastroenterologists or colorectal specialists, when it is performed at all. Because mcompass is dedicated to this one function, Medspira is able to offer the device for a far more affordable purchase price and to simplify the design so that testing can even be performed by a nurse or physician’s assistant. Anorectal testing is crucial to appropriate diagnosis and efficient treatment of fecal incontinence and related problems. Finally, mcompass has broken down all the barriers to testing.”

“Fecal incontinence commonly affects the elderly. Now, with mcompass, gerontologists can provide these exams,” says Quackenbush. “Additionally, women with pelvic floor damage in child birth often suffer this problem and their first stop is often a URO/GYN. But, until now, few of these specialists offered a manometry exam. We believe another mcompass user will be an OB/GYN, who can conduct a five-minute test to ensure a women’s sphincter muscles remain intact following vaginal birth.”

Because of the stigma attached to the fecal incontinence, many people suffer in silence. Medical experts have found that patients are often more comfortable talking to a familiar primary care physician about their problem than an unfamiliar specialist. With mcompass, these physicians can now conduct appropriate testing and move patients along the path to appropriate treatment.

Anorectal manometry measures the pressures of the anal sphincter muscles, the sensation in the rectum, and the neural reflexes that are needed for normal bowel movements.

About Medspira

Since 2009, Medspira has worked with leading medical institutions to develop and market medical devices that provide cost effective diagnosis and treatment for a variety of conditions. Its highly focused distribution model addresses United States and worldwide markets. Products are produced in partnership with world-class, FDA approved and ISO 13485 registered manufacturing facilities. Medspira was originally formed through the acquisition of product lines and technologies developed by Mayo Clinic. The company also maintains close relationships with major research organizations to track products that will fulfill its mission to bring important tools to more physicians, clinics and patients.