FOR IMMEDIATE RELEASE

FDA clears CystoSure® Urinary Access Catheter System for Female Cystoscopy

System Represents the First New Approach for Cystoscopy in Decades

Boston, Ma. – January 5, 2015 – Emmy Medical, LLC announced today that the U.S. Food and Drug Administration (FDA) has cleared its CystoSure® system for female cystoscopy. CystoSure® provides a simple, safe and efficient means for conducting cystoscopy at the office, in the operating Room, or at the bedside.

Cystoscopy is a commonly performed procedure used in hospitals and office to diagnosis lower urinary tract conditions. Traditional cystoscopy is complicated and cumbersome, preventing widespread use even when indicated. CystoSure®’s patent pending design, specifically designed for the female patient and their care providers, reinvents the game – providing a technique which is safe, simple, and standardized.

“Over a million gynecologic and urogynecologic procedures are performed annually in this country which have a risk or urinary tract injury but few undergo routine cystoscopy despite recommendations from our professional societies,” according to Jim Greenberg, MD and inventor of CystoSure®. “Nothing has changed for female cystoscopy in the last 100 years so I created CystoSure® to be easier for doctors and safer for patients.”

The CystoSure® system consists of two components: an 18 French 4-Way catheter and a small scope. CystoSure’s proprietary design allows multiple passes of the scope to visualize the bladder while lowering risk of trauma or infection to the urethra/bladder and improving patient comfort. In addition, the catheter design allows full and consistent bladder evaluation with a simple 360 degree rotation of the scope, obviating the need for a learning curve or cystoscopy experience. According to Neeraj Kohli, MD, MBA, Chief Medical Officer, “CystoSure® is a game changer. It makes cystoscopy more accessible to physicians and patients alike while making the procedure safer, faster, and easier while saving doctors and hospitals valuable time and money.”

“FDA clearance of CystoSure® represents a new era of choice for clinicians who are uncomfortable with the traditional cystoscopy systems being employed today and need to evaluate the bladder in patients with hematuria, overactive bladder, and other urinary tract disorders in the office or the OR,” said Ron Adams, Emmy Medical president and CEO. “Emmy Medical is committed to improving the health and quality of life of women who are experiencing the challenges of managing urinary tract conditions. CystoSure® is a big step towards meeting that commitment.”
CystoSure® will be commercially available to medical professionals in the United States in the first half of 2015.

About Emmy Medical LLC

Emmy Medical LLC, based in Boston, MA, has developed the world’s first female specific cystoscopy system. The CystoSure® system utilizes a flexible urinary catheter to establish an access pathway and incorporates a proprietary scope port which enables the clinician to conduct diagnostic cystoscopy without needing to remove the drainage catheter. Emmy Medical was formed in August, 2013 by a team of forward thinking doctors and seasoned medical device executives. Visit us on the web at www.cystosure.com.

Safety information for CystoSure® therapy is provided at www.cystosure.com. CystoSure® is not for everyone. Information at this site should not be used as a substitute for patients talking with their doctor. Patients are encouraged to review this safety information and talk with their doctor about diagnosis options.

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