



## American Medical Systems Announces 1,000th Patient Enrolled in PROPPER Registry

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*Largest Prospective, Multi-Year, Penile Prosthetic Registry Advances Understanding of Real-World Satisfaction with Penile Prostheses For Erectile Dysfunction Patients*

MINNEAPOLIS, Feb. 19, 2015 /PRNewswire/ -- American Medical Systems Inc. (AMS), a subsidiary of Endo International plc (NASDAQ: ENDP) (TSX: ENL) and leading provider of medical technologies for pelvic health, today announced the enrollment of the 1,000th patient in the largest prospective, multi-year, global registry study of penile prosthetic outcomes in the world.

The study, entitled PROPPER (Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration), is sponsored by AMS and is being conducted by a team of experienced urologists at 11 North American sites. It aims to better characterize real-world patient satisfaction and other outcomes among men who are receiving prosthetic implants to treat their erectile dysfunction (ED). All patients enrolled in the registry will be implanted with penile implants manufactured by AMS, the majority of whom will receive the three piece inflatable penile prosthesis (IPP), the AMS 700.

Using data from the registry, ten abstracts have been presented at several medical meetings since 2013. Additionally, a peer reviewed study titled *Reservoir Alternate Surgical Implantation Technique: Preliminary Outcomes of Initial PROPPER Study of Low Profile or Spherical Reservoir Implantation in Submuscular Location or Traditional Prevesical Space* authored by Edward Karpman, et al, was published in the Journal of Urology in January 2015. The study illustrates how reservoir placement has evolved to support greater utilization of three piece devices as well as confidence in treating men post robotic radical prostatectomy. "PROPPER is the first-of-its kind observational registry that captures critical data about real-life outcomes to aid patients and their doctors in making important decisions about their ED treatment options," said Karpman. "This is an ongoing process, and we expect the database to continue to grow as more men, with the support of their partners, consider penile implants."

"We are pleased to be able to partner with an outstanding group of physician investigators in order to add to the understanding of the safety and performance of our devices as they are utilized in clinical practice. We anticipate that the large number of men enrolled in this study will yield robust results that, once published, will be informative for implanting physicians, referring physicians and for patients," said Dr. Ronald Morton, Chief Surgical Officer, AMS.

Previous clinical research showed that of ED patients who received a penile implant, 93 percent were satisfied with their device<sup>1</sup>. Furthermore, in a study of both patients and partners, 92 percent of patients and 96 percent of their partners reported excellent or satisfactory sexual activity<sup>2</sup>.

"American Medical Systems, an established world-leader in treatments for ED and other pelvic health disorders, is committed to advancing the treatment of ED, to give men and their partners effective, world-class treatment options," said Dev Kurdikar, Senior Vice President and General Manager, Men's Health, AMS. "We're very pleased to reach this milestone in the PROPPER registry - the largest prospective study of its kind. Such investments are aligned with our strategic intent of being able to provide physicians, patients and other healthcare system stakeholders with impactful data."

For more information about American Medical Systems' pelvic health solutions for men, visit [www.visitams.com](http://www.visitams.com).

### **About PROPPER Registry**

The registry (ClinicalTrials.gov Identifier NCT01383018) uses questionnaires as well as direct physician to patient physical examination and history taking, enabling the investigating physicians to prospectively measure patient responses at regular intervals over a one-to five-year period. Several key metrics are being analyzed, including device effectiveness, durability, complications and patient satisfaction; quality of life will also be analyzed, as defined through several validated patient questionnaires.

### **About Erectile Dysfunction**

About 1 in 5 American men over the age of 20 experience some degree of ED<sup>3</sup>, adding up to an estimated 30 million men<sup>4</sup>. For many patients, drugs and other therapies are not a satisfying option with treatment discontinuation rates of up to 60%. Penile implants, first invented and developed at AMS, have helped more than 300,000 men return to an active and satisfying sex life<sup>5</sup> over the past 40 years<sup>6</sup>.

### **About the AMS 700™ Series Penile Prosthesis Product Line**

The AMS 700™ Series Penile Prosthesis product line is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). These devices are contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery or (for the AMS 700™ Penile Prosthesis with InhibiZone™ Antibiotic Surface Treatment) have a known sensitivity or allergy to rifampin, minocycline, or other tetracyclines. Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries or open sores may have an increased risk of infection.

## **About American Medical Systems**

American Medical Systems (AMS), headquartered in Minnetonka, MN, is a diversified supplier of medical device technology to treat incontinence, sexual dysfunction, benign prostatic hyperplasia (BPH) and other pelvic disorders. AMS is focused on improving access and outcomes with the goal of restoring patient quality of life. AMS is an operating company of Endo International plc (NASDAQ: ENDP) (TSX: ENL), a global specialty healthcare company focused on improving patients' lives while creating shareholder value. Learn more at [www.endo.com](http://www.endo.com).

## **About Endo International plc**

Endo International plc is a global specialty healthcare company focused on improving patients' lives while creating shareholder value. Endo develops, manufactures, markets, and distributes quality branded pharmaceutical, generic pharmaceutical, over the counter medications and medical device products through its operating companies. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at [www.endo.com](http://www.endo.com).

## **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect Endo's current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Although Endo believes that these forward-looking statements and information are based upon reasonable assumptions and expectations, readers should not place undue reliance on them, or any other forward-looking statements or information in this news release. Investors should note that many factors, as more fully described in the documents filed by Endo with securities regulators in the United States and Canada including under the caption "Risk Factors" in Endo's Form 10-K, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and with securities regulators in Canada on System for Electronic Document Analysis and Retrieval ("SEDAR") and as otherwise enumerated herein or therein, could affect Endo's future financial results and could cause Endo's actual results to differ materially from those expressed in forward-looking statements contained in Endo's Annual Report on Form 10-K. The forward-looking statements in this press release are qualified by these risk factors. These are factors that, individually or in the aggregate, could cause Endo's actual results to differ materially from expected and historical results. Endo assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities law.

## **References**

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