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**Contact:**

Karen Whelan, Communications Manager

[kwhelan@mpathymedical.com](mailto:kwhelan@mpathymedical.com)

(866) 319-8820

**Smartmesh™ Technology Offers Low Complication Profile for Pelvic Floor Repair**

*~ New Restorelle™ Series Demonstrates Near Zero Mesh Erosion Rate ~*

**Raynham, MA, November 17, 2008** - Mpathy Medical, a rapidly growing medical device company which has developed and brought to market a range of surgical solutions used to restore pelvic health to women, today announced the findings of a retrospective cohort study carried out by Red Alinsod, MD, FACOG, FACS, ACGE, Laguna Beach, CA. This study demonstrates a low complication profile for Restorelle™, the company's pelvic floor restoration product line, which is constructed with its ultra lightweight Smartmesh™.

In a series of 201 patients and 360 total mesh implants<sup>i</sup>, carried out from November 2005 to October 2008, the results report that the use of Restorelle™ is associated with a 0.28% erosion rate and a 99.5% cure rate based on POP-Q assessment of the enrolled patients. The follow up time for this series ranged from 36 months to 2 months, resulting in a mean follow up of 22 months. Important factors regarding patient quality of life were measured and included:

- No new occurrence of dyspareunia (painful intercourse) attributable to prolapse repair.
- Non-palpability of the mesh throughout - neither the patient nor partner could feel the implant postoperatively in uncomplicated repairs.
- 93% patients reporting that their quality of life was "good" or "very good" postoperatively compared to "poor" or "fair" preoperatively.

“The results from this substantial series clearly demonstrate the low complication profile associated with Mpathy Medical’s ultra lightweight mesh material when used to surgically manage pelvic organ prolapse,” stated Dr. Red Alinsod, South Coast Urogynecology, Laguna Beach, CA. “I have been extremely pleased with the fully functional and restored anatomy which Restorelle™ products help me to deliver to my patients. I have consistently been able to achieve these positive results without my patients or their partners experiencing dyspareunia, which was often present after using previous surgical solutions.”

The Food and Drug Administration recently issued a public health notification which reported serious complications associated with transvaginal placement of mesh in the repair of urinary stress incontinence (USI) and pelvic organ prolapse (POP). This announcement came following over 1,000 reports of adverse events associated with mesh from nine manufacturers. These complications ranged from issues that negatively affect the patient’s quality of life, such as dyspareunia or narrowing of the vaginal wall, to more serious problems that can include chronic pain and require additional surgery to correct.

“We are pleased to share the results from Dr. Alinsod’s study,” stated Ian Stevens, Chief Executive Officer, Mpathy Medical. “We believe that the recent FDA announcement raises important issues relating to the use of mesh for this type of surgery. We are very confident that Smartmesh™ is the right solution for women and their surgeons, since it is the only product which has been designed specifically with the female anatomy and physiology in mind.”

To review the abstract from Dr. Alinsod’s series, [click here](#).

#### **Facts on Pelvic Health Conditions:**

- The prevalence of USI and POP increases with age<sup>ii</sup>.
  - USI affects approximately 1 in 4 women while POP affects up to half of all women over the age of 50.
  - Approximately 20% of women who have symptoms of POP also experience USI.
- Approximately 200,000 procedures are performed each year to correct USI and POP<sup>iii</sup>.
- Women who are obese have a 40-75% increased risk of POP<sup>iv</sup>.

- Many women who suffer from USI or POP are unaware of the procedures that are available to correct these problems. A recent study indicated 2/3 of women were not aware of sling procedures to treat USI<sup>v</sup>.
- Depression is a common resulting factor of pelvic health conditions. The risk of depression is 40% higher for incontinent women. Women with severe incontinence are 80% more likely to experience depression<sup>vi</sup>.

### **About Mpathy Medical**

Mpathy Medical is a rapidly growing medical device company which has developed and brought to market a range of surgical solutions used to restore pelvic health to women. Mpathy Medical's core product lines - Minitape® and Restorelle™ - are used by surgeons specializing in urogynecology, gynecology, and urology to treat female urinary stress incontinence and pelvic organ prolapse. Founded in 2003 by a surgeon, Dr. James Browning, Mpathy Medical supplies the only mesh solutions designed specifically for the female anatomy and physiology. The mesh - branded Smartmesh™ - is a physiologically compatible, ultra lightweight polypropylene mesh which encourages superior collagen growth and works in concert with the patient's own natural tissue for optimum safety and results. The company is headquartered in Glasgow, Scotland with US operations in Raynham, MA and has received 510(k) clearance to market by the FDA in the US and CE marking in the UK for all its medical devices. To learn more about Mpathy Medical, visit [www.mpathymedical.com](http://www.mpathymedical.com).

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<sup>i</sup> Many patients received a multi-compartment vaginal repair; therefore, requiring more than one piece of Restorelle™ mesh.

<sup>ii</sup> Nygaard, I. et al (2008). Prevalence of Symptomatic Pelvic Floor Disorders in US Women. *Journal of American Medical Association*; 300, 1311-1316.

<sup>iii</sup> American Urogynecologic Society.

<sup>iv</sup> American Urogynecologic Society.

<sup>v</sup> American Academy of Gynecologic Laparoscopists.

<sup>vi</sup> Nygaard, I. et al (2003). Urinary Stress Incontinence and Depression in Middle-Aged United States Women. *The American College of Obstetricians and Gynecologists*; 101,149-156.