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Long-Term Data Proves Safety and Efficacy of GYNECARE TVT Tension-free Support for Treating Stress Urinary Incontinence

Somerville, NJ (August 20, 2001) – The first long-term study of GYNECARE TVT Tension-free Support for Incontinence, a minimally-invasive surgical option for stress urinary incontinence (SUI), shows that five years after treatment nearly 85 percent of women treated reported that they remain dry. Another 10 percent still report significant improvement in their condition. While previous studies of GYNECARE TVT Tension-free Support have suggested similar success rates, these long-term data published in International Urogynecology Journal, (volume 12; 2001 supplement 2), suggest there is no significant decline in efficacy over an extended period.

“Five year data is significant for an incontinence surgical device,” said Dr. Carl Gustaf Nilsson, the study’s lead author and OB/GYN at the Helsinki University Central Hospital. “This study validates that GYNECARE TVT is a simple, safe and effective treatment option for women suffering with SUI.”

The long-term follow-up study, conducted at three Finland centers, followed 90 women suffering from SUI for five years after they were treated with GYNECARE TVT Tension-free Support. Of the 85 patients who completed the study, 72 (84.7%) remained completely dry and nine (10.6%) remained significantly improved. Researchers regarded patients as dry if they had a negative stress-test result (i.e., no urine loss while coughing), a negative 24-hour pad-weighting test result and if quality-of-life improved by at least 90 percent.

GYNECARE TVT Tension-free Support was successfully placed under local anesthesia, and the majority of patients were ready to be released from the hospital on

the day of surgery. Post-operative complications were few and required no surgical intervention.

More than 13 million Americans suffer from incontinence, and women account for 85 percent of cases. One of four types of incontinence, SUI typically is caused by a weakening of the pelvic floor muscles that support the urethra. As a result, patients experience an involuntary loss of urine during physical activities such as coughing, sneezing, laughing and exercise. This embarrassing condition can significantly inhibit a woman's quality of life, often causing her to avoid an active lifestyle or to shy away from social situations.

GYNECARE TVT Tension-free Support is part of a simple, outpatient, minimally invasive procedure to treat SUI. The TVT device uses a mesh sling to provide support to the middle of the urethra, the section that is strained during physical activities. This positioning of the device provides support only when needed and creates a "tension-free" treatment solution that reduces the risk of over-correcting. The study found that none of the patients complained of difficulties urinating at the long-term follow-up visit.

"A key benefit of the treatment is that it can be performed under local anesthesia," said Dr. Nilsson. "Since the patient is awake, the surgeon can perform a 'cough test' and evaluate the placement of the mesh sling and make any adjustments during the procedure."

To date, more than 150,000 women worldwide (more than 40,000 in the United States) have been treated with GYNECARE TVT Tension-free Support. As with any surgery of this kind, the procedure should not be performed in pregnant patients or patients who plan future pregnancies. Although rare, complications associated with the device



include injury to blood vessels of the pelvic sidewall and abdominal wall, difficulty urinating and bladder and bowel injury.

ETHICON Women's Health & Urology, a division of JOHNSON & JOHNSON MEDICAL LIMITED is a global health care company dedicated to advancing healthcare for women worldwide. The company offers less-invasive options for the treatment of menorrhagia (excessive menstrual bleeding), fibroids, pelvic adhesions, and female urinary incontinence.

Visit www.womenshealthsolutions.co.uk to learn more about the conditions we treat and GYNECARE TVT Tension-free Support For Incontinence.