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New Study Shows Uterine Balloon Therapy Helps Women Avoid Hysterectomy Over the Long Term

SOMERVILLE, N.J. May 30, 2003 – A new study shows that nearly 9 out of 10 women who underwent treatment for menorrhagia (heavy menstrual periods) with the GYNECARE THERMACHOICE* Uterine Balloon Therapy System five years ago have avoided hysterectomy. The study, published in the journal of Human Reproduction (Vol. 18, No. 5, 2003), proves that endometrial ablation performed with uterine balloon therapy offers a viable alternative for a woman seeking to avoid major surgery and preserve her uterus.

The study followed up with 260 women from 10 participating centers in Europe and Canada who underwent treatment with uterine balloon therapy between 1994 and 1996. Of the 188 (72%) women that responded to the questionnaire, 25 had undergone hysterectomy and 21 had a repeat endometrial ablation procedure. Among the respondents, hysterectomy was avoided in 86%, and, among those women, 88 % did not undergo a second ablation procedure.

“The high rate of hysterectomy avoidance over five years or more is very encouraging for uterine balloon therapy,” said lead study author, Nazar N. Amso, M.D., Department of Obstetrics and Gynaecology, University of Wales, College of Medicine. “Uterine balloon therapy is much less traumatic for the patient compared to hysterectomy and easier for the physician to perform than first generation ablation techniques, such as rollerball.”

Menorrhagia affects 1 out of 5 women and is the cause for approximately 20 percent of the 600,000 hysterectomies performed annually in the United States. The GYNECARE THERMACHOICE Uterine Balloon Therapy System is used in a simple outpatient procedure that can be completed in under 30 minutes.

During the procedure, a balloon catheter is inserted into the uterus and inflated with a small amount of sterile fluid that is heated for eight minutes to break down the uterine lining. When the treatment cycle is completed, the fluid is withdrawn from the balloon and the catheter is removed. Nothing stays in the uterus. The uterine lining has been treated and will slough off like a period in the next seven to 10 days. Women often return to their normal activity the day after treatment.

GYNECARE THERMACHOICE has been used to treat more than 250,000 women worldwide. In most women, the treatment will reduce menstrual bleeding to a moderate or light, manageable flow. Some women may experience spotting, while other women may stop bleeding altogether (amenorrhea). Also, clinical studies show that 78% of women evaluated three years after treatment with the device are free from significant menstrual pain and cramping.

GYNECARE THERMACHOICE is indicated to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia due to benign causes that have completed childbearing. Rare, but possible safety risks include blood loss, burn of internal organs, perforation (hole) or rupture of the wall of the uterus, and leakage of heated fluid from the balloon or tissue into the cervix.

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.

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