

# Thermachoice® III

## Time

## Temperature

## Pressure

## Make it your choice...

  
**Thermachoice® III**  
Uterine Balloon Therapy System

### ORDERING INFORMATION:

#### GYNECARE THERMACHOICE® III

Uterine Balloon Therapy Catheter    Sterile, single use catheters

TC003 ..... Box of 5

TC013 ..... Single pack

#### GYNECARE THERMACHOICE® III

Uterine Balloon Therapy System

00825..... Controller

01105..... Umbilical Cord

04995..... Power Cord

TO ORDER CALL:

# 1-800-255-2500

#### ESSENTIAL PRODUCT INFORMATION:

**INDICATIONS:** The GYNECARE THERMACHOICE® UBT System is a thermal balloon ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete. **CONTRAINDICATIONS:** The device is contraindicated for use in a patient: who is pregnant or who wants to become pregnant in the future; with known or suspected endometrial carcinoma (uterine cancer) or premalignant change of the endometrium, such as unresolved adenomatous hyperplasia; with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transverse myomectomy; with active genital or urinary tract infection at the time of procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis); with an intrauterine device (IUD) currently in place. **ADVERSE EVENTS INCLUDE:** rupture of the uterus; thermal injury to adjacent tissue; heated liquid escaping into the vascular spaces and/or cervix, vagina, fallopian tubes, and abdominal cavity; electrical burn; hemorrhage; infection or sepsis; perforation; post-ablation-tubal sterilization syndrome; complications leading to serious injury or death; complications with pregnancy (Note: pregnancy following ablation is dangerous to both the mother and the fetus); vesico-uterine fistula formation; cramping/pelvic pain; nausea and vomiting; endometritis and risks associated with hysteroscopy. **WARNINGS:** Failure to follow all instructions or to heed any warnings or precautions could result in serious patient injury. If uterine perforation is present, and the procedure is not terminated, thermal injury to adjacent tissue may occur if the heater is activated. Endometrial ablation is not a sterilization procedure. Patients who have previously undergone tubal ligation are at increased risk of developing post-ablation-tubal sterilization syndrome which can require hysterectomy. Endometrial ablation procedures using the GYNECARE THERMACHOICE® UBT System should be performed only by medical professionals who have experience in performing procedures within the uterine cavity, such as IUD insertion or dilation and curettage (D&C), and who have adequate training and familiarity with GYNECARE THERMACHOICE® UBT System. **PRECAUTIONS:** Never use other components with the GYNECARE THERMACHOICE® UBT System. Refer to package insert for complete product information including warnings, precautions, and adverse reactions. RX Only.

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 **ETHICON**  
Women's Health & Urology  
A division of ETHICON, INC.  
a Johnson & Johnson company

TC3-0194-09-10/11

# Did you know

studies show

# up to 93%

of Women with menorrhagia

suffer from both

# Bleeding and Pain?<sup>(2,6,7)</sup>

  
**Thermachoice® III**  
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# It's Time For Thermachoice® III

	An Effective Solution To Help <b>Stop Heavy Bleeding.</b>		Reduction In Pain at one year.
Patients report comparisons*	Patients experiencing amenorrhea at 12 months	Patients with normal levels or less	Patients experiencing reduction in dysmenorrhea (Pain)
GYNECARE THERMACHOICE® III <sup>(1)</sup>	<b>37%</b>	<b>81%</b>	<b>89%</b>
NovaSure® <sup>(2)</sup>	36%	78%	63%
Her Option® <sup>(3)</sup>	22%	67%	88% <sup>(4)</sup>
HTA System® <sup>(5)</sup>	35%	68%	N/A

\*Not based on a head to head clinical study.

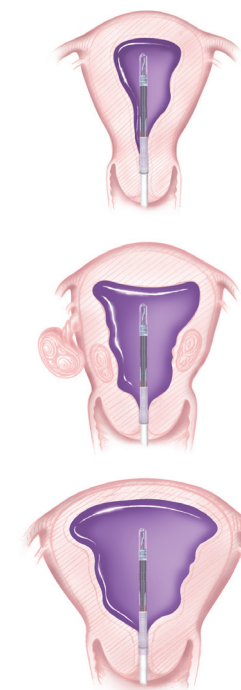
\*Based on intent-to-treat population (1) GYNECARE THERMACHOICE® III. Instructions for use. ©2008 Ethicon, Inc. (2) NovaSure. Instructions for use. ©2004 Cyt Corporation. (3) Her Option. Instructions for use. ©2006 American Medical Systems, Inc. (4) Antoni J. Duleba, M.D., Martha C. Heppard, M.D., Richard M. Soderstrom, M.D. A Randomized Study Comparing Endometrial Cryoablation and Rollerball Electroablation for treatment of Dysfunctional Uterine Bleeding. *The Journal of the American Association of Gynecologic Laparoscopists* 2003;10:17-26 (5) Hydro ThermAblator System. Instructions for use. © 2005 Boston Scientific Corporation. N/A = not available (6) NovaSure. Instructions for use. © 2004 Cyt Corporation. Summary of Safety & Effectiveness Data: GYNECARE THERMACHOICE® Uterine Balloon Therapy System. PMA970021. 1997 (7) Summary of Safety & Effectiveness Data: CryoGen Her Option Uterine Cryoablation Therapy System. PMA P000032, version 8.0. September 14, 2002

Make **GYNECARE THERMACHOICE® III** your choice...  
for customized coverage...to help end heavy periods.

**89% OF PATIENTS** in a study  
had a reduction in menstrual  
**PAIN AND CRAMPING.**<sup>(1)</sup>

(1) GYNECARE THERMACHOICE® III, IFU, ETHICON, Inc.

Gynecare  
**Thermachoice® III**  
Uterine Balloon Therapy System



Conforms to most uterine shapes and  
sizes with no reduction of efficacy

Delivers more even necrosis of tissue  
throughout the entire endometrium  
(Based on ex vivo studies versus previous balloon)

Requires minimal dilation for greater  
patient safety and comfort