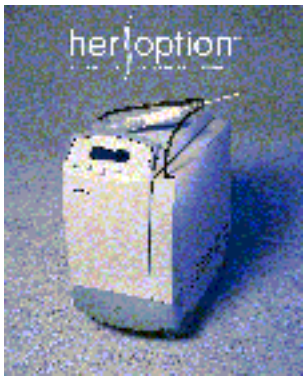
HerOption™ Uterine Cryoblation Therapy™ System
P000032



Product Name: HerOption™ Uterine Cryoblation Therapy™™™ System
Manufacturer: CryoGen, Inc
Address: 11065 Sorrento Valley Court, San Diego, California 92121
Approval Date: April 20, 2001
Approval Letter: **http://www.fda.gov/cdrh/pdf/p000032a.pdf**

What is it? The HerOption™ Uterine Cryoblation Therapy™ System is a surgical device used to treat excessive menstrual bleeding by destroying certain tissue in the uterus (womb). It consists of a console, probe and a single-use disposable Control Unit which covers the probe during use.

How does it work? The System destroys tissue by the application of extreme cold. After the patient has received appropriate anesthesia, the probe (with the disposable Control Unit placed over it) is introduced through the vagina into the uterus. The probe is angled to one side of the uterus and is placed in contact with the endometrial (innermost) layer of the uterus. This is the layer of fluffy tissue that is discarded with the blood when women menstruate. The device is turned on for 4 minutes, and cooled air flows into the uterus The probe is then repositioned to the other side of the uterus, and the device is turned on for 6 minutes. A "CryoZone" or "freeze zone" is created at the tip of the probe. As the CryoZone grows, its leading edge advances through tissue. Tissue contacted by that portion of the CryoZone colder than -20 °C (-4° F) is destroyed.

When is it used? This device is intended for women who have not yet reached menopause, whose child-bearing is completed and who have a condition called "menorrhagia," or excessive uterine bleeding. The device is only used in women whose menorrhagia is due to benign or non-cancerous causes.

What will it accomplish? The HerOption™ Uterine Cryoblation Therapy™ System reduces excessive menstrual bleeding. In a randomized, clinical study, this device was used to successfully reduce

menstrual bleeding 1 year after the procedure in approximately 68% of the women enrolled. In approximately 22% of the women, menstrual bleeding was totally eliminated at one year. The most frequently observed side effects were pain, cramping, nausea, and vomiting.

When should it not be used? This device should not be used in a patient: who is pregnant or who desires to become pregnant in the future; has a known or suspected endometrial carcinoma (uterine cancer); has an active genital or urinary tract infection at the time of the procedure; has active pelvic inflammatory disease (PID); has an intrauterine device (IUD) currently in place; or who has had a classical cesarean section. This procedure is not a sterilization procedure.

Additional information:

- Summary of Safety and Effectiveness and labeling will be available at: http://www.fda.gov/cdrh/pdf/p000032.html

Other: FDA's Office of Women's Health web site : http://www.fda.gov/womens/default.htm

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