

ATTACHMENT B

Patient Brochure

Now,
there's more
than one
option for
excessive
menstrual
bleeding.

HTA Therapy: The New Choice For Excessive Menstrual Bleeding...

1. WHAT IS ENDOMETRIAL ABLATION?

Endometrial ablation is a procedure to treat abnormal uterine bleeding. The procedure is intended to destroy all or most of the tissue that is responsible for menstrual bleeding (the endometrium). After the procedure, you may never bleed again or if you do, your bleeding should be reduced. Not all patients experience a satisfactory reduction in bleeding so all treatment options should be discussed with your doctor.

2. WHAT IS THE HYDRO THERMABLATOR® (HTA®)?

The Hydro ThermAblator® is a device that allows your gynecologist to perform endometrial ablation on an outpatient basis. This outpatient procedure allows your doctor to insert a probe into your uterus that includes a tiny telescope for viewing the lining of the uterus. Heated saline is circulated and is intended to destroy the lining of the uterus, even in an abnormal sized or shaped uterus, to eliminate or reduce bleeding to normal levels or less.

3. HOW WILL I BE EVALUATED TO DETERMINE IF ENDOMETRIAL ABLATION WITH THE HTA® IS THE RIGHT PROCEDURE FOR ME?

Your gynecologist will do some pretreatment tests that may include a Pap smear, an ultrasound, or a hysteroscopy (look inside the

uterus with a tiny telescope) to see why you are having excessive menstrual bleeding.

4. HOW DOES THE HYDRO THERMABLATOR® WORK?

First, your cervix will be slightly dilated to allow the introduction of the telescope through the vagina, into the cervix and then into the uterus. This gives your gynecologist a view of the inside of your uterus to assure proper positioning. Then, your uterus will be filled with room temperature saline solution to gently clean and flush the uterus.

The fluid will be heated to 90°C and circulated in the uterus for ten minutes in order to treat the endometrium (lining of the uterus).

When the treatment is complete, the uterus will be flushed with room temperature saline to cool the uterus and the probe. All of the saline will be removed after the cooling phase is completed.

Your uterine lining has been treated and will slough off similar to a menstrual period over the next few weeks.

5. WILL I FEEL ANYTHING DURING THE PROCEDURE?

Your physician may give you pain medication before the procedure to minimize cramping during or after the procedure. You and your physician will decide what anesthesia will be best for you to receive during the procedure. Your options are to be fully asleep so you

won't feel anything during the procedure, or to receive some medication to be sedated (sleepy) during the procedure or to receive only a local anesthesia injection and be fully awake. If you choose to be awake, you may feel some discomfort, such as mild cramping, during the procedure but it should not be painful.





H[®] Therapy: The New Choice for Excessive Menstrual Bleeding...



6. WHAT SHOULD I EXPECT AFTER MY TREATMENT?

You should be able to return home on the day of your procedure. You may experience some light cramping that should go away by bedtime. Most women should be able to return to normal activities the next day. You will probably have a pink or yellow watery discharge for a few weeks after your treatment. If you experience 2 days of heavy bleeding, abdominal or pelvic pain, a fever, or pain that increases over time beyond 24 hours after the procedure, call your physician.

7. I SHOULD EXPECT AFTER I GO HOME?

Most women should be able to return to normal daily activities the next day. You should speak with your physician about the resumption of sexual activity. Most patients experience a pink or yellow, watery discharge for a few weeks or longer after the procedure. You should not use tampons for up to seven days after the procedure to reduce the potential risk of infection. Your monthly menstrual bleeding, may be heavy for a few months after the treatment as a part of the healing process, and should improve after a few months.

8. CAN I GET PREGNANT AFTER TREATMENT WITH THE HTA[®]?

You should not have this procedure if you desire pregnancy in the future. Endometrial ablation, however, does not prevent you from becoming pregnant and such a pregnancy would be high risk for both mother and fetus.

Contraception or sterilization should be used after this treatment since pregnancy can still occur. Please discuss the different options with your physician.

9. WHAT ARE THE RISKS OF TREATMENT WITH THE HYDRO THERMABLATOR[®]?

Treatment with the HTA[®] may involve some rare but potential risks that include perforation (creation of a hole) in the wall of the uterus, a hot fluid bowel or other internal organ burn or leakage of hot fluid into the cervix or vagina. Collection of blood and/or tissue in the uterus post procedure (hematometra) may occur and may require another outpatient procedure to correct the problem.

WHAT OTHER TREATMENTS ARE AVAILABLE TO TREAT EXCESSIVE MENSTRUAL BLEEDING?

- **Medication** - Hormonal therapy, sometimes as simple as birth control pills, may be prescribed for women who experience heavy menstrual bleeding due to a hormonal imbalance and who wish to preserve their fertility after treatment.
- **Dilation and Curettage (D&C)** - This surgical procedure may provide a temporary solution to heavy menstrual bleeding. The top layer of the lining of the uterus (the endometrium) is scraped away, often under general anesthesia in an outpatient setting. Risks include perforation of the wall of the uterus, injury to the bowel or other internal organs, bleeding, or infection. A D&C provides a tissue sample to help your doctor

determine the cause of excessive bleeding and to rule out any abnormalities.

- **Endometrial Ablation**
 - **Balloon therapy** - This outpatient procedure allows your doctor to insert a probe with a balloon into your uterus that will allow the lining of your uterus to be heated with hot fluid to reduce excessive menstrual bleeding. This treatment is most successful when the shape and size of the uterus are normal. Risks include perforation of the wall of the uterus and possible injury to the bowel or other internal organs.
 - **Hysteroscopic Endometrial Ablation** - This procedure involves the use of a surgical instrument that gives the doctor a view of the inside of your uterus. This instrument allows the doctor to remove all or the majority of the endometrial lining using electrocautery or a laser. This surgical procedure is often performed under general anesthesia and is intended to eliminate or reduce bleeding to normal levels or less. The recovery from endometrial ablation is much shorter and generally less painful than a hysterectomy.
 - **Hysterectomy** - The complete surgical removal of the uterus provides a final cure for excessive menstrual bleeding. The procedure is considered major surgery and is performed under general anesthesia. A hospital stay is generally required and recovery may take several weeks. Hysterectomy may be performed when other forms of therapy have failed or are not an option.

H. Therapy: The New Choice For Excessive Menstrual Bleeding...

If you feel controlled by heavy bleeding during your periods and believe your options are to wait until menopause or to have a hysterectomy, there may be another choice for help without major surgery.

A new minimally invasive choice is available for your consideration for the treatment of excessive menstrual bleeding; HTA® has the potential to offer:

- An alternative to hysterectomy or other major surgical procedures
- An outpatient procedure
- Decreased recovery period and less need for general anesthesia
- ~~Return to normal activity within a few days~~
- Fewer significant harmful side effects

Speak with your doctor if you have questions about the Hydro ThermAblator® and to understand this new treatment for excessive menstrual bleeding.

For more information call:

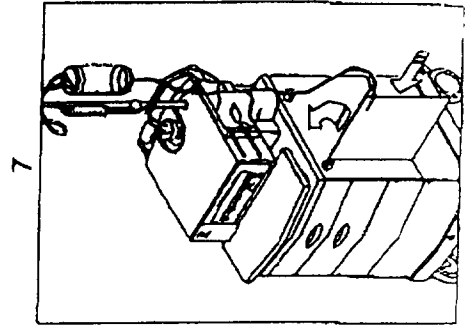
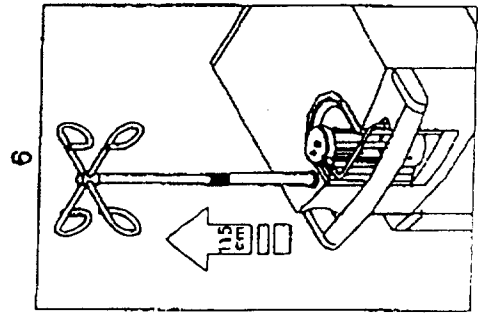
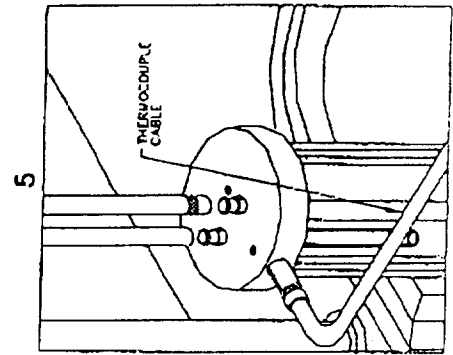
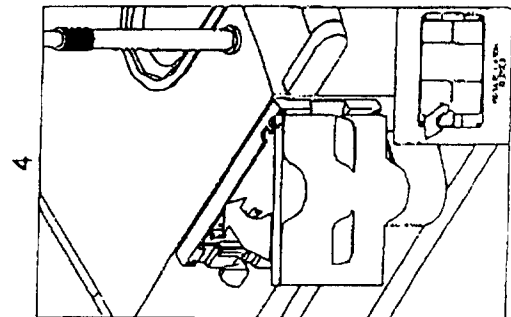
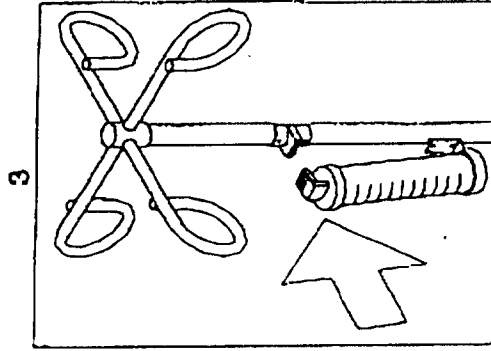
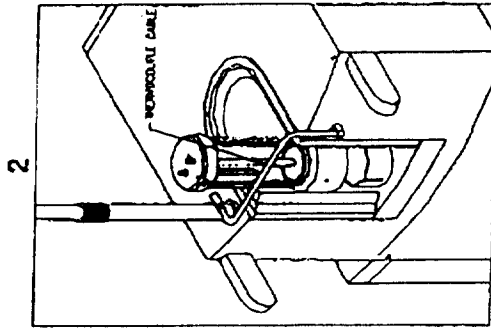
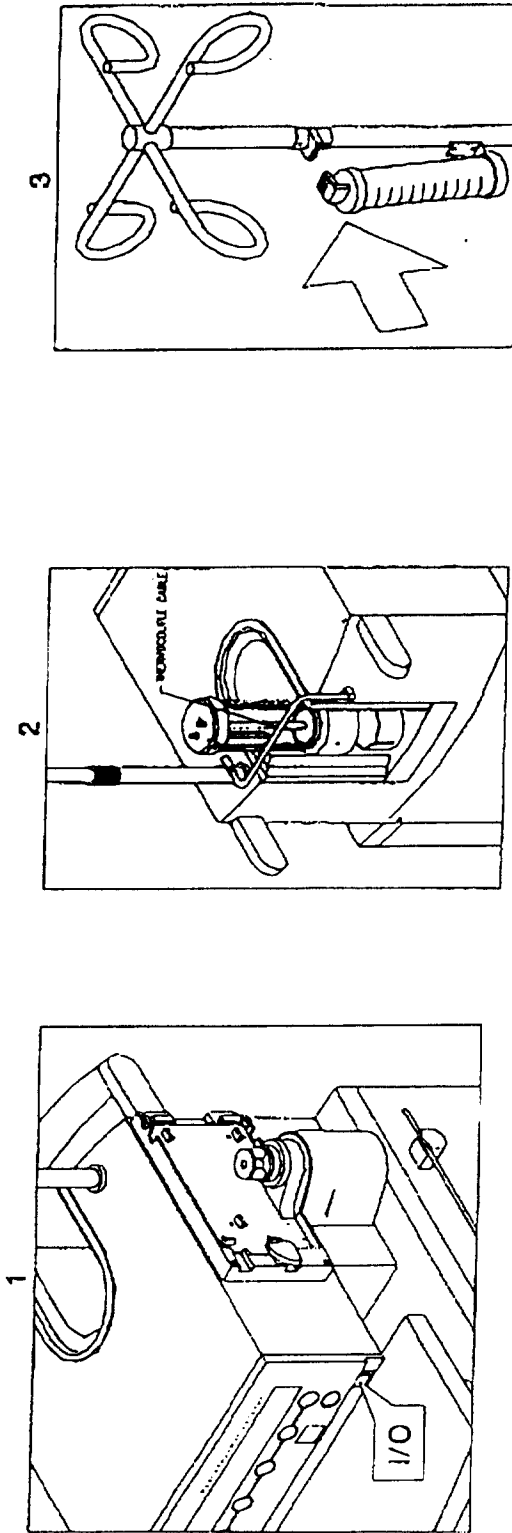
BEI Medical Systems
100 Hollister Road
Teterboro, NJ 07608
Telephone: 201-727-4900
Fax: 201-727-4998
Website: www.beimedical.com



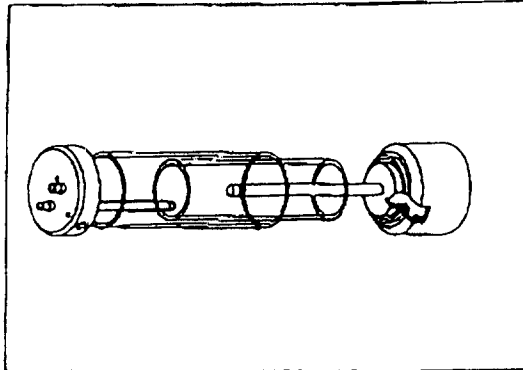
M E D I C A L
S Y S T E M S

REFER TO THE HYDRO THERMABLATOR® (HTA®) INSTALLATION & OPERATORS MANUAL FOR PROPER SETUP & USE

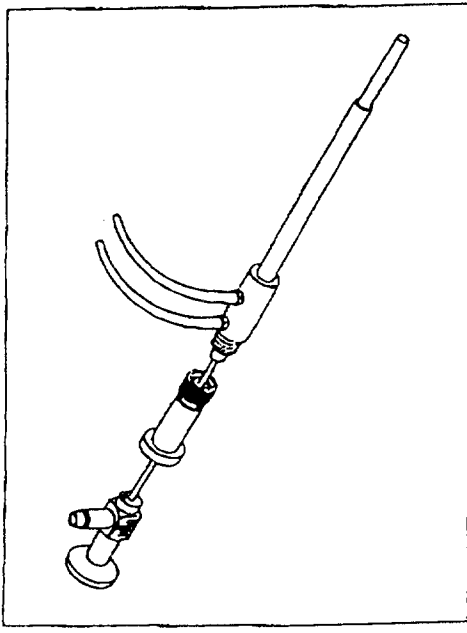
HTA® QUICK SETUP GUIDE



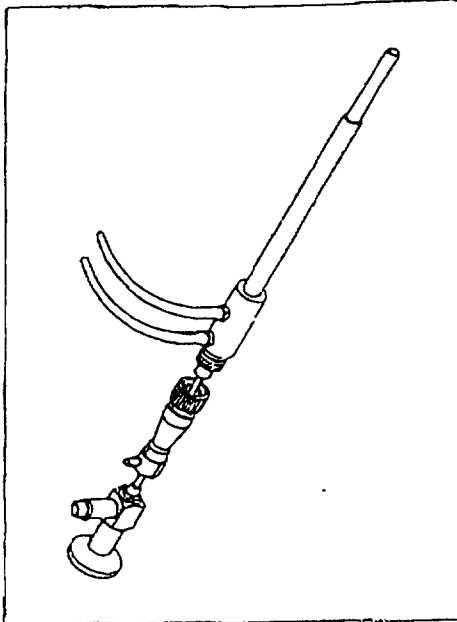
INDICATIONS



BEI



STORZ



<p>Contents:</p> <ul style="list-style-type: none"> 1 Sheath Assembly 1 Cassette and Reservoir 1 Drain Collection Bag <p>Additional Materials Required:</p> <ul style="list-style-type: none"> 1. 3 Liters Sterile Normal Saline (0.9%) 2. HTA® Operator's Manual 3. Sterile Heater Canister 4. 3 mm Hysteroscope Telescope 5. Hysteroscope to Sheath Adapter 	<p>Contenido:</p> <ul style="list-style-type: none"> 1 Baïna para histeroscopia 1 Cartucho y reservorio 1 Bolsa recolectora de drenaje <p>Otros Materiales Necesarios:</p> <ul style="list-style-type: none"> 1. Bolsa de 3 litros de suero salino al (0,9%) 2. Manual de uso del H.T.A. 3. Unidad calentadora esteril 4. Histeroscopia maximo 3 mm 5. Adaptador para baïna e histeroscopia 	<p>Contenu:</p> <ul style="list-style-type: none"> 1 Ensemble gaine 1 Cassette avec r�servoir 1 Sachet r�cup�ration liquide <p>Mat�riel suppl�mentaire requis (non-inclu):</p> <ul style="list-style-type: none"> 1. 3 litres de solution saline � 0,9% 2. Manuel de l'utilisateur HTA 3. Thermostat st�rile 4. Hyst�roscope de 3 mm 5. Raccord hyst�roscope - gaine
<p>Inhalt:</p> <ul style="list-style-type: none"> 1 Schaft system 1 Kassette und fl�ssigkeitsreservoir 1 Drainageauffangbeutel <p>Zus�tzlich Ben�tigte Materialien/Dinge:</p> <ul style="list-style-type: none"> 1. 3 Liter sterile normale kochsalzl�sung (0,9%) 2. HTA Gebrauchsanweisung 3. Sterile heizbeh�ller 4. 3 mm hysteroskopie-optik 5. Hysteroskop passend zum shaftadapter 	<p>Contenuto:</p> <ul style="list-style-type: none"> 1 gruppo guaina 1 cassetta e serbatoio 1 sacca di raccolta drenaggio <p>Altri materiali necessari:</p> <ul style="list-style-type: none"> 1. 3 litri soluzione fisiologica sterile (0,9% Na Cl) 2. Manuale di istruzione H.T.A. 3. Riscaldatore sterile 4. Telescopio per isteroscopia da 3mm 5. Adattatore per isteroscopia 	<p>Conte�do:</p> <ul style="list-style-type: none"> 1 Unidade de baïna 1 Cartucho e reservatorio 1 Saco de coleta de drenagem <p>Materiais Requeridos Adicionalmente:</p> <ul style="list-style-type: none"> 1. 3 litros de soro fisiologico (0,9%) 2. Manual de instrucoes do HTA 3. Unidade de aquecimento esterelizada (canistrel) 4. Histeroscopia de 2,7 mm a 3 mm (max.) 5. Adaptador para a baïna do histeroscopia

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STERILE EO

⊗ SINGLE USE

Contents:

- 1 Sheath Assembly
- 1 Cassette and Reservoir
- 1 Drain Collection Bog

Conteúdo:

- 1 Unidade de bainha
- 1 Carlucho e reservatório
- 1 Saco de coleta de drenagem

Contenido:

- 1 Baño para histeroscopia
- 1 Carlucho y reservorio
- 1 Bolsa recolectora de Drenaje

Inhalt:

- 1 Schaft system
- 1 Kassette und Flüssigkeitsreservoir
- 1 Drainageauffangbeutel

INDICATIONS
 The Hydro Thermablator[®] is a hysteroscopic endometrial ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive menstrual bleeding) due to benign causes for whom cryotherapy is contraindicated.

Read package insert before using.

Lire les instructions avant utilisation.

Vor gebrauch packungsbeilage sorgfältig lesen!

Leggere il foglio illustrativo prima dell'uso.

Lea las instrucciones antes de usar

Leia o impresso contido no interior da embalagem antes de usar

This set may only be used in conjunction with the Hydro Thermablator[®] system. Refer to the Hydro Thermablator[®] Installation & Operators Manual for proper setup & use.



LOT Lot Number

📅 Manufacture Date

🕒 Expiration Date

CE 0088

REF 55015

CAUTION- Federal Law restricts this device to sale by or on the order of a physician. The physician using the device must be trained in diagnostic hysteroscopy.

BEI Medical Systems

Teterboro, NJ 07608
Tel: 201-727-4900
Fax: 201-727-4998

DI Authorized Representative
NOT FOR SALES OR CUSTOMER SERVICE
QUALITY FIRST. CUSTOMER SERVICE LAST

20 Century Road
East Saddle River, NJ
Tel: + 1 (201) 708-5173 (937)
Fax: + 1 (201) 728-5113 (937)



BEI MEDICAL SYSTEMS

P/N 55015C / Rev. D

e-mail: service@beimedical.com

INDICATIONS

The Hydro ThermAblator® is a hysteroscopic endometrial ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive menstrual bleeding) due to benign causes for whom childbearing is complete.

**Instructions
for
Hydro ThermAblator® Heater Canister Assembly**

This Heater Canister may only be used in conjunction with the Hydro ThermAblator® System. Refer to the Hydro ThermAblator® Installation and Operator's Manual for proper set-up and use.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician. The physician using the device must be trained in diagnostic hysteroscopy.

Note: Heater Canister is provided non-sterile.

Instructions below apply to Heater Canister Assembly Post-Sterilization.

Heater Canister Assembly

IMPORTANT: Heater Canister is supplied non-sterile and must be cleaned and sterilized prior to use by following steps 1 (a) through 5 on page 61 of the Installation and Operator's Manual. The steps shown below pertain to the assembly of heater canister post-sterilization.

1. Open the package containing the sterilized Heater Canister. Assemble the Heater Canister using sterile technique, maintaining sterility of the inner fluid pathways.
2. Place the inner cylinder onto the base, seating the cylinder properly on the orange "O" ring.
3. Place the outer cylinder over the inner cylinder, seating it properly over the base (no "O" ring).
4. Place the lid over the inner and the outer cylinders while fitting the steel rod into the threaded opening on lid. Screw down to compress the "O" rings. Do not over tighten.

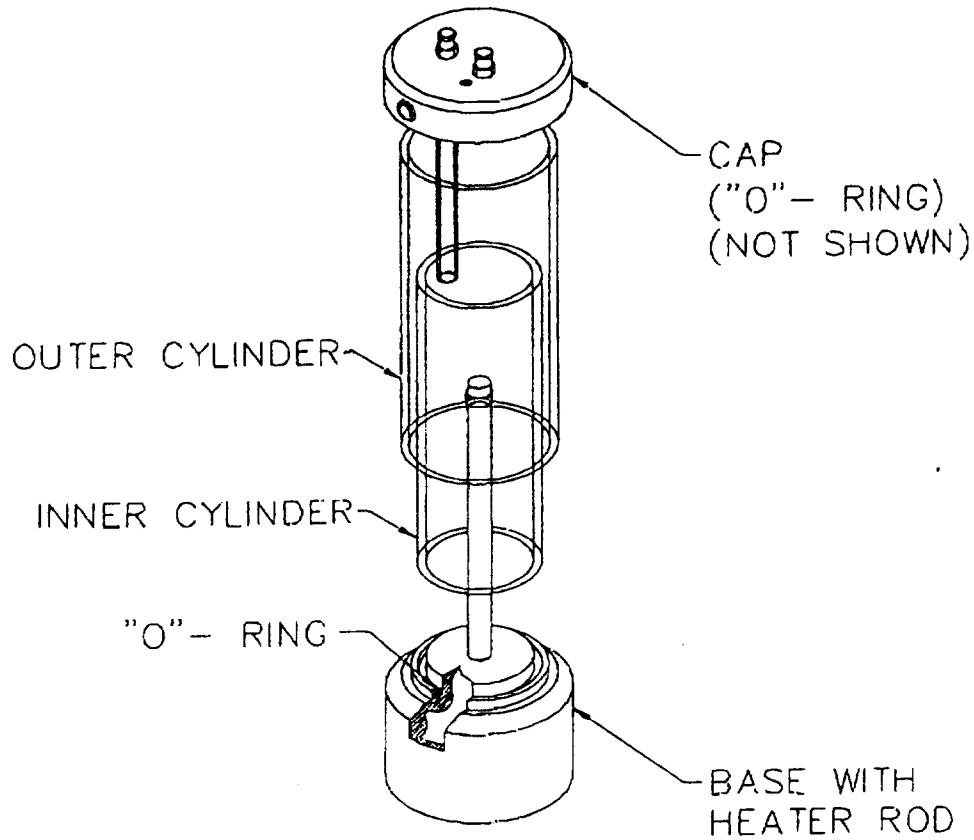
NOTE: Inner cylinder will be tight between the two orange "O" rings. Outer cylinder will be loose and will spin freely between lid and base. The outer cylinder only serves as a protective thermal cover for the inner cylinder that will be hot during operation.

PRECAUTION: The heater canister must not be used after 10 autoclave cycles.

NOTE: Inner cylinder will be tight between the two orange "O" rings. Outer cylinder will be loose and will spin freely between lid and base. The outer cylinder only serves as a protective thermal cover for the inner cylinder which will be hot during operation.



MEDICAL
SYSTEMS



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