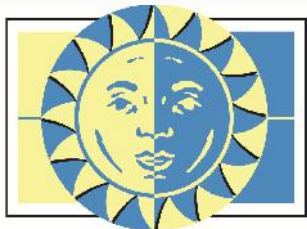


# An Introduction to MEA

It's about *knowledge*. It's about MEA



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For Educational Use Only.

Indications: MEA is indicated for ablation of the endometrial lining of the uterus in premenopausal women with menorrhagia (Excessive Uterine Bleeding) due to benign causes for whom childbearing is complete. For product demonstration, product discussion, to schedule training in the use of MEA for treatment of eligible patients, or to obtain additional information concerning the clinical experience of MEA, consult your Microsulis clinical specialist or sales representative for assistance. Document Number 150-017-1

# The Simple, Effective Treatment of MEA

MEA is a highly effective, minimally invasive treatment for heavy periods

## The Basics

- Average 3-4 minute treatment
- Local or IV sedation anesthesia for most patients
- Suitable for in-office treatments

## The Facts

- Over 30,000 treatments completed throughout the world
- High amenorrhea, success and satisfaction rates
- Potential for greater effectiveness due to physician control



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# Endometrial Ablation Techniques

## MEA (Microwave)



### Advantages

- Most effective treatment
- Highest patient satisfaction
- Widest population applicability
- Short procedure time

### Drawbacks

- Larger dilation required

## Thermachoice (Thermal balloon)



- Market pioneer in endometrial ablation
- Minimal dilation required
- Easy to use

- Lower efficacy
- Not as effective in fibroid populations
- Not as effective in irregular and large cavities

## NovaSure (Radio frequency)



- Slightly improved efficacy over ThermoChoice
- Short procedure time
- Easy to use

- Not as effective in fibroid populations
- Not as effective in irregular and large cavities
- Larger dilation required

## HTA System (Heated free fluid)



- Comparable efficacy to NovaSure
- Direct visualization

- Extended procedure time
- Hot fluid leakages
- Complex device set-up

## Her Option (Cryotherapy)



- Pioneer in office treatments
- Minimal dilation required

- Lower efficacy
- Extended procedure time
- Continuous ultrasound required



# Why Switch to MEA?

## Ensure the most effective treatment for more of your patients

- 96%: Bleeding reduced to normal or better
- 61%: Amenorrhea

## Satisfy more of your patients

- Over 98%: Patient Satisfaction

## Treat more of your patients

- Equally effective in cavities with fibroids
- (61% amenorrhea)\*\*

\* Relative to other thermal EA techniques, the MEA treatment is more successful in producing amenorrhea, is effective in a wider population, and achieves the highest patient satisfaction rate (Data on file from PMA Clinical Trials. Evaluable population one-year post-treatment)

\*\* Not fully evaluated in patients with submucosal fibroids that distort the endometrium more than 3 cm or that obstruct access to the uterine cavity



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# Success and Satisfaction\*

**Failures** in Reduction  
to Normal Bleeding  
%

MEA

4

NovaSure

13

HTA System

23

Thermachoice

20

Her Option

27

1 failure  
in

25

8

5

5

4

**Unsatisfied** patient rates  
%

1.5

8

NA

14

14

1 failure  
in

65

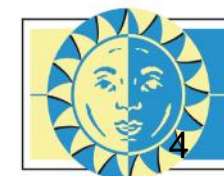
13

NA

8

8

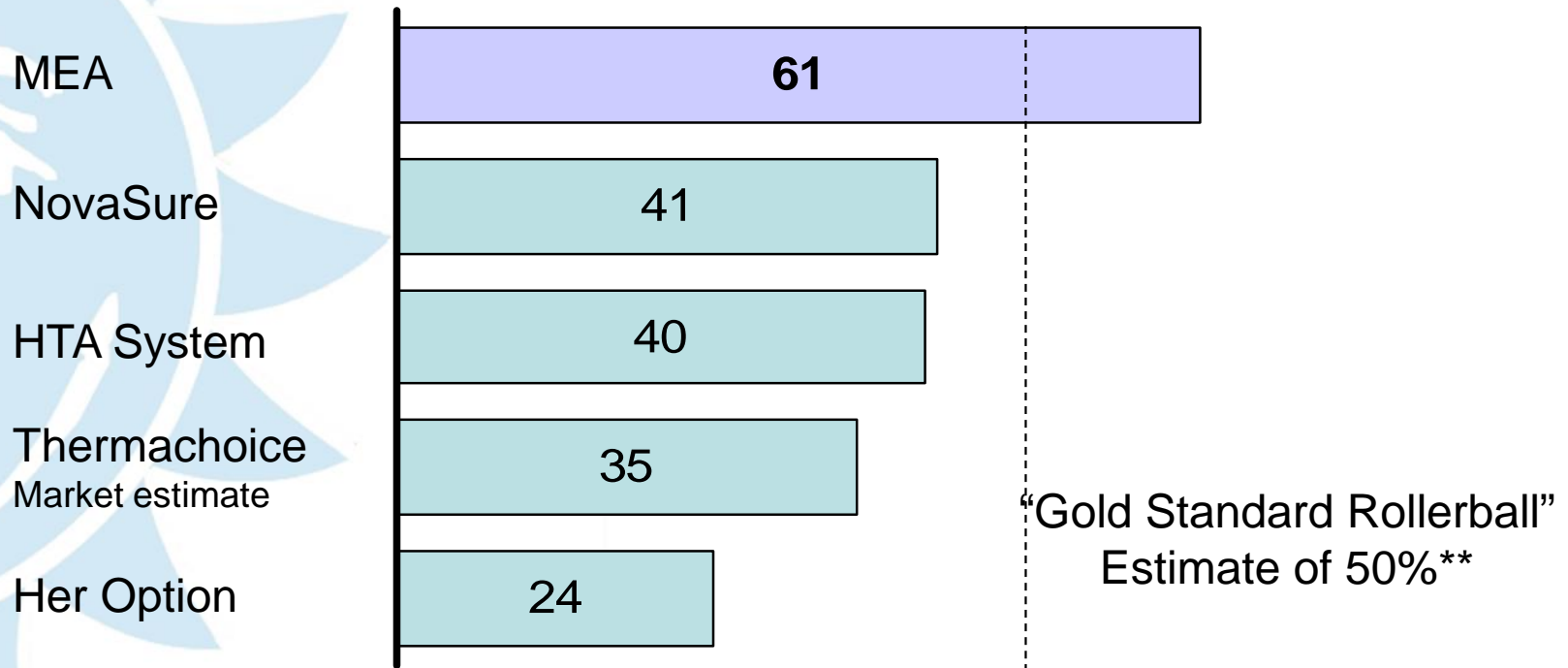
\* Data on file from PMA Clinical Trials. Evaluable population one-year post-treatment



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# Comparison of Effectiveness

Amenorrhea Rates\*  
%



\* Data on file from PMA Clinical Trials. Evaluable population one year post-treatment

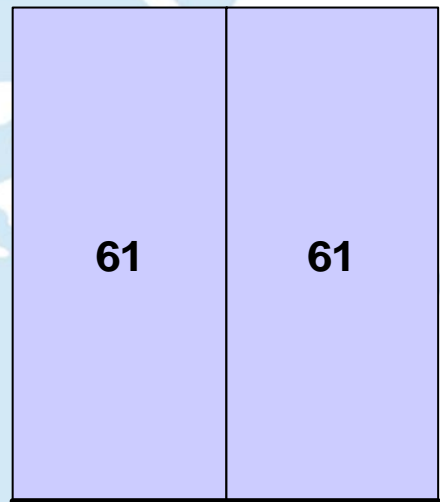
\*\* As seen in the majority of PMA Thermal Endometrial Ablation Clinical Trials



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# The Ability to Treat a Wider Population

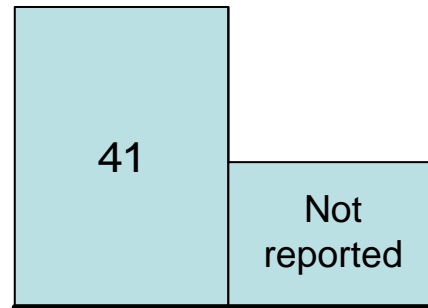
Amenorrhea Rates\*  
%



Normal      Fibroid populations\*\*

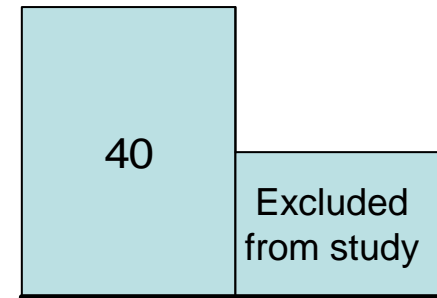
**MEA**

Only Endometrial Ablation Proven  
in Fibroid Populations



Normal      Fibroid populations

**HTA**



Normal      Fibroid populations

**Novasure**

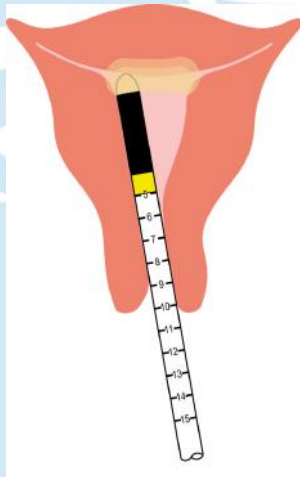
\* Data on File from PMA Clinical Trials. Evaluable population one-year post-treatment

\*\* Not fully evaluated in patients with submucosal fibroids that distort the endometrium more than 3 cm or that obstruct access to the uterine cavity



# Physician Directed MEA Treatment

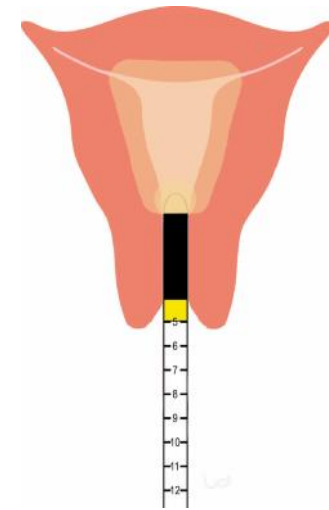
Unlike global modalities,  
the physician controls the MEA treatment



Continuous sweeps to  
treat fundus



Applicator placed near cornua  
(Direct tissue contact not required)



Entire uterine body  
treated all the way to  
internal cervical os

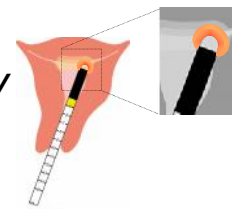


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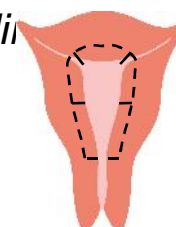
# Advantages of MEA

Precise depth of thermal effect  
*5-6 mm for optimized efficacy and safety*



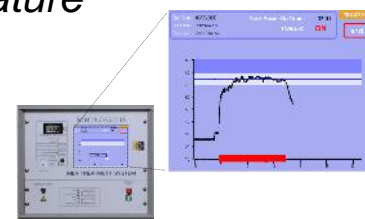
Consistent coverage throughout  
cavity

*Physician controlled without need for direct  
tissue contact*



-- Region of  
controlled MEA  
thermal penetration

Real-time treatment “visualization”  
*Continuous monitoring through temperature  
feedback*



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# MEA Treatment Effect

Before an MEA treatment

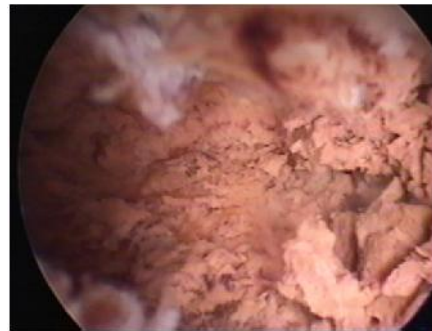


After an MEA treatment

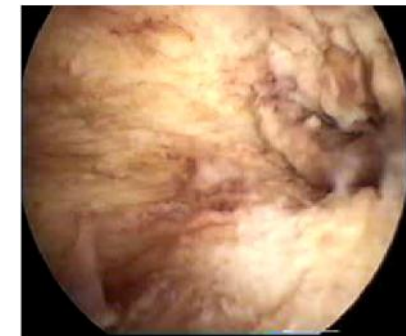
*Right cornua*



*Corpus*



*Left cornua*

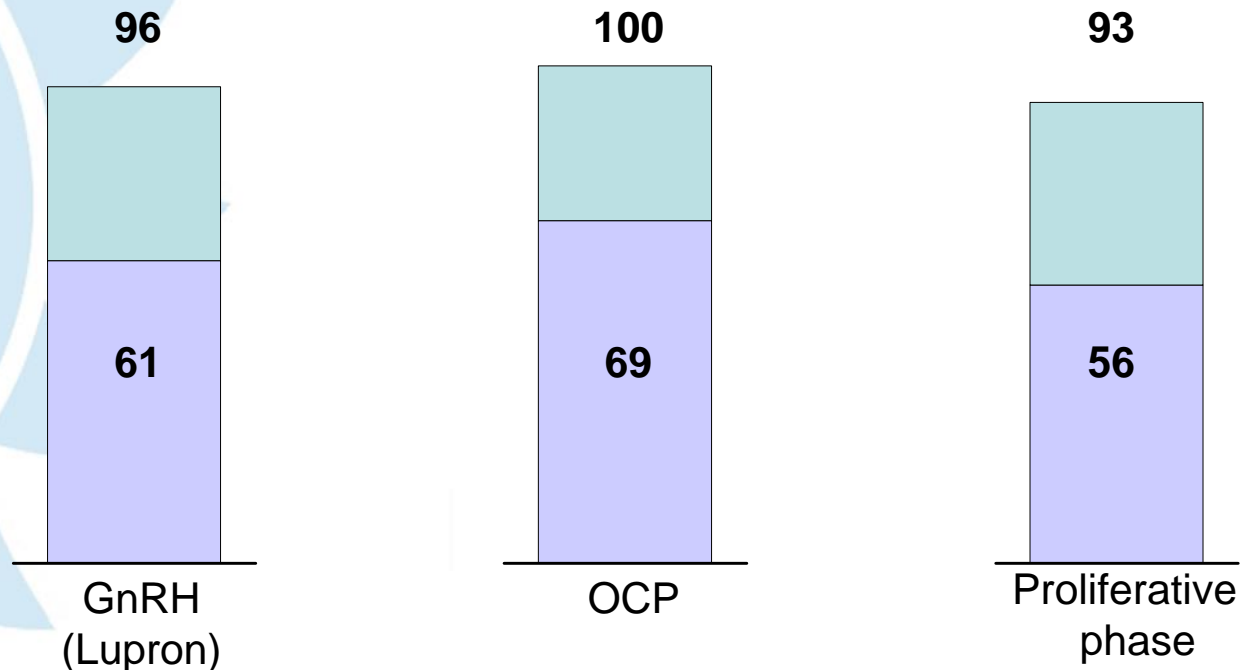


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# Effective Across Pre-Treatment Options

Effectiveness rates\*  
%

Additional reduction  
to normal bleeding  
Amenorrhea



\* Evaluable population one year post-treatment, Lupron: Cooper JM, J Am Assoc Gynecol Laparosc 2004, 11(3):394-403.  
OCP: Fortin CA, J Am Assoc Gynecol Laparosc 2003, 10(3) S15. Proliferative Phase: Jack SA, BJOG (In Press)



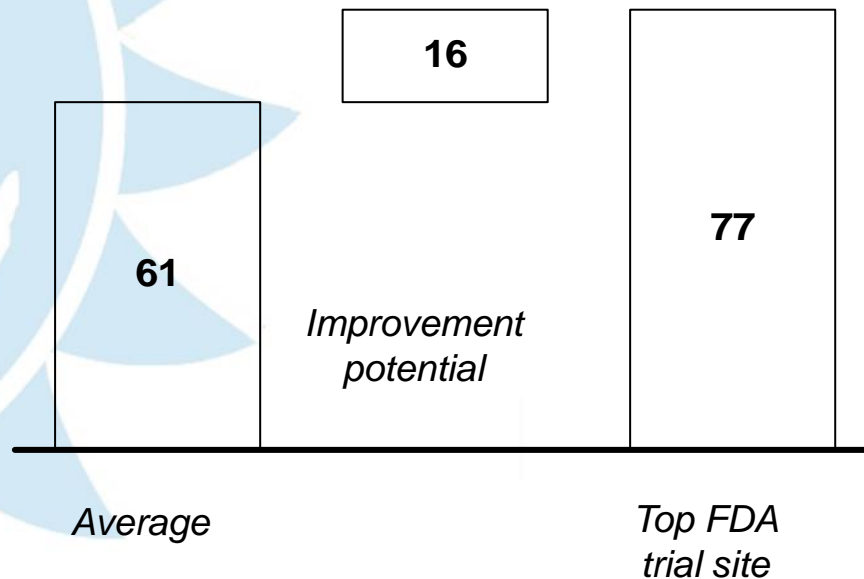
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# The Opportunity for Even Better Results

Unlike global modalities, MEA provides the potential to achieve greater effectiveness

## Amenorrhea Rates\*

%



## Consistencies among most effective treatments

- Treatment of each cornua
- Continuous sweeping of entire corpus
- Continued treatment in lower segment

\* Data on file from PMA Clinical Trials. Evaluable population one year post-treatment



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# MEA Thermal Effect

Gentle, therapeutic microwaves used to heat the uterine lining to resolve heavy periods

## MEA clinical treatment

- *5-6 mm: MEA treatment*

## Theoretical worst case simulation

- *8 mm: MEA applicator held in one place in non-perfused tissue for 8 minutes at 90°C*



**Comparable to the 4-9 mm range of normal case thermal effects reported for other thermal endometrial ablation modalities\***

- Novasure: 9 mm maximum--Based on data reported from simulated uterine cavity animal studies (Summary of Safety and Effectiveness)
- HTA: 4 mm--Based on data reported from testing (Summary of Safety and Effectiveness)
- Thermachoice: 5.8 mm--Based on data reported from testing (Neuwirth, et.al.)



# A Safer Alternative to Surgery

	Risk of adverse effects*	Recovery time
<b>Hysterectomy</b>	<b>10%</b>	<b>1 to 6 weeks</b>
<b>RollerBall</b>	<b>2.1%</b>	<b>1 to 3 days</b>
<b>Endometrial Ablation</b>	<b>&lt; 0.07%</b>	<b>Less than 1 day</b>

\* Hysterectomy: Value Study—2002

RollerBall: Mistletoe Study--1997

Endometrial Ablation: Duleba, AJ. "Review of Major Complications Related to Devices Used to Treat Abnormal Uterine Bleeding." November 2004, AAGL.



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