

# VAGINAL REJUVENATION DEVICE OVERVIEW

Jocelin Sisto, MA, MMS, PA-C

Director of Aesthetics and Research at aFresh Med Spa & Plastic Surgery

Adjunct Faculty Member at Rush University Medical Center and Midwestern University PA Programs

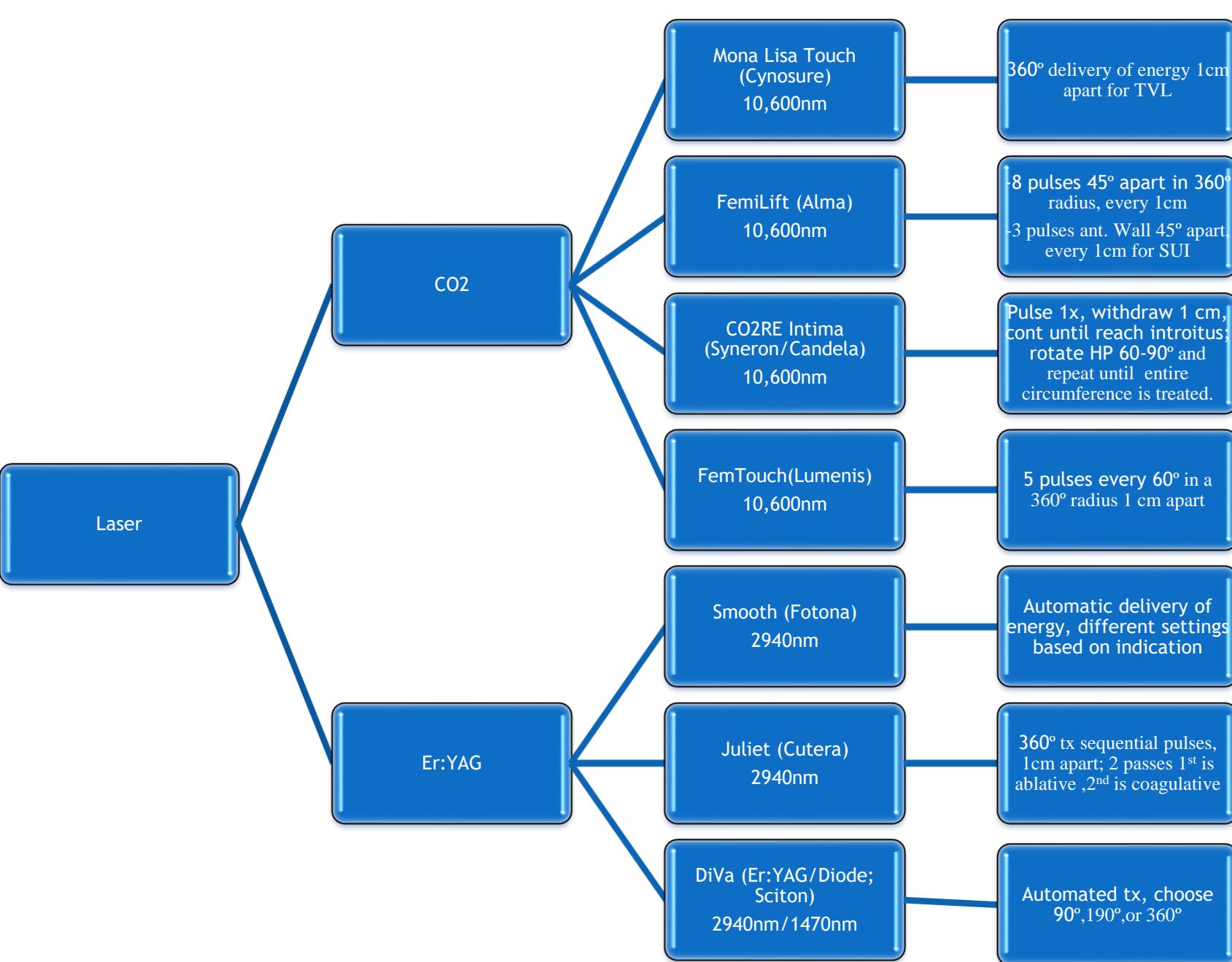
# DISCLOSURES

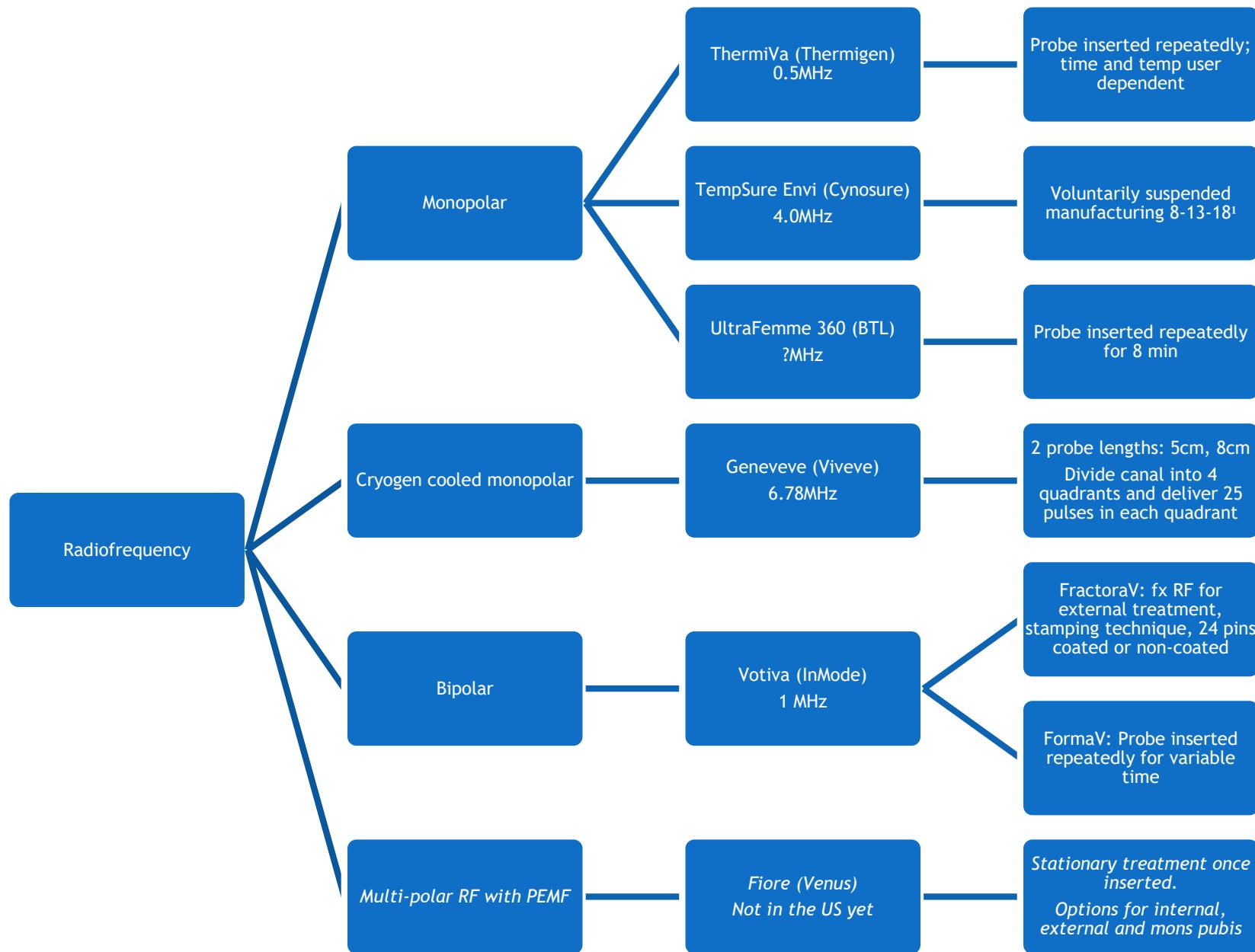
- ◉ FDA Status - Variable
- ◉ Levels of Evidence - Variable
- ◉ Disclosures - Consultant, Clinical trainer,  
Speaker for InMode Aesthetic Solutions

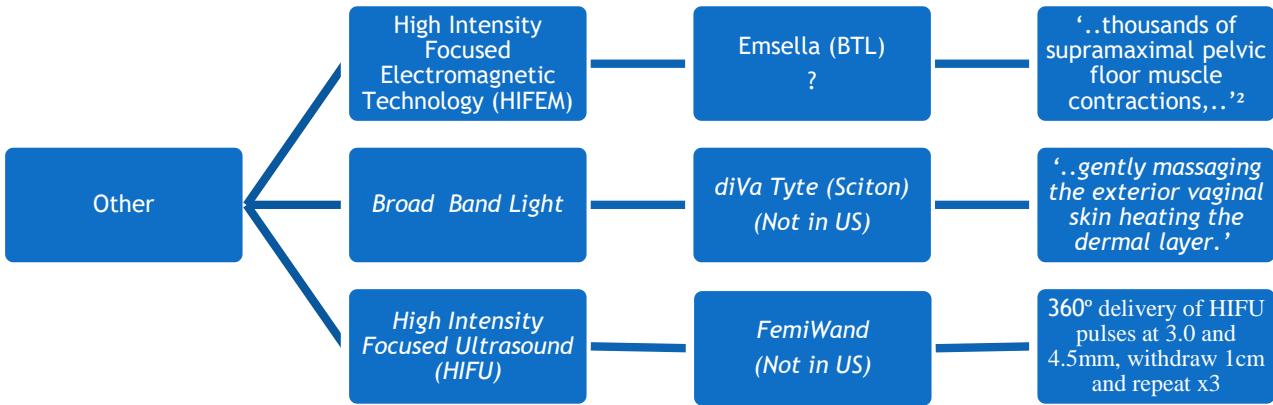
# OBJECTIVES

- Summary of energy devices currently on the market by energy source
- Review indications and differences among Laser, Radiofrequency, and other devices
- Review of recent FDA warnings and what this means
- Summary of reported adverse events related to vaginal rejuvenation devices
- Supplemental FDA warning letters per manufacturer





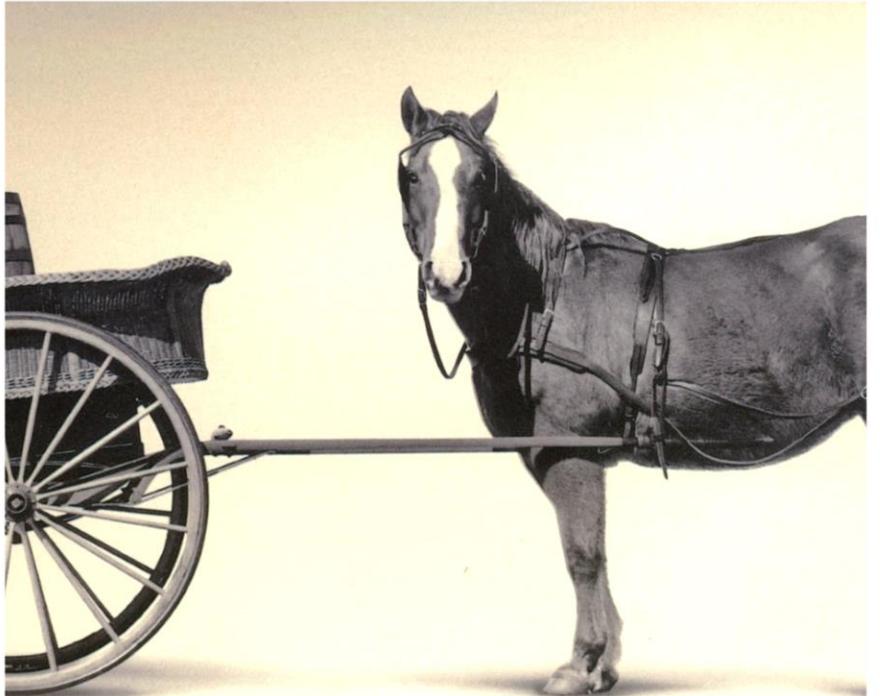




## LASER INDICATIONS BY DEVICE

# RF/OTHER INDICATIONS BY DEVICE

RF/other	SUI/uri-nary inconti-nence	dryne ss	Adjunct to Kegel's	Muscle pain relief	Muscle relaxation	Vaginal laxity	Tissue tightenin g	Generate collagen	Increase blood flow/circulation	Decrease in recurring infections	Decrease in mons
ThermiVa <sup>17</sup>							✓				
*TempSure Envi <sup>16</sup>	n/a										
<i>UltraFemm e 360<sup>19</sup></i>									✓		
Geneveve <sup>15</sup>								✓			
Votiva <sup>20</sup>			✓	✓	✓				✓		
<i>FemiWand<sup>21</sup></i>	✓	✓				✓	✓			✓	
Emsella <sup>18</sup>	✓						✓				
<i>Fiore<sup>22</sup></i>							✓				✓



## WHAT HAPPENED WITH THE FDA?

“In reviewing adverse event reports and published literature, we have found numerous cases of vaginal burns, scarring, pain during sexual intercourse, and recurring or chronic pain.”<sup>23</sup>

- “We are aware that certain device manufacturers may be inappropriately marketing their energy-based medical devices for the uses noted above that are outside of their cleared or approved intended uses.”<sup>25</sup>
- 7 companies were sent letters of communication
  - Venus Concept, Ltd
  - BTL Industries, Inc.
  - Cynosure, Inc
  - Alma Lasers
  - Sciton, Inc
  - Thermigen, Inc
  - InMode MD, Ltd
  - <https://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm111104.htm>
- “Understand that the FDA has not cleared or approved any energy-based medical device for vaginal “rejuvenation” or cosmetic procedures, or for the treatment of vaginal symptoms related to menopause, urinary incontinence or sexual function”<sup>24</sup>

## MANUFACTURER AND LASER FACILITY DEVICE EXPERIENCE (MAUDE)

- “The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters <sup>1</sup>(manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.”<sup>4</sup>
  - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>
- Search results were conducted first by manufacturer then by brand name..

**NUMBER OF EVENTS REPORTED BY MANUFACTURER 8-1-08  
THROUGH 8-31-18**

Manufacturer	Total AE (1827)	AE sp. Vag. Device (17)
Lumenis	500	6
Hologic	500	1
Cynosure	203	3
Candela	148	0
Cutera	120	0
Venus Concept	95	0
Alma	77	0
DEKA	66	2
Syneron	55	0
Sciton	31	0
BTL	20	0
Viveve	5	5
Fotona	4	0
Almirall	1	0
InMode	1	0
Invasix	1	0

## NUMBER OF EVENTS REPORTED BY BRAND 8-1-08 THROUGH 8-31-18

Brand name	Total AE (1909)	AE sp. to vag. Device (21)
Smooth	500	0
Intima	500	0
Core	500	0
Co2re	0	0
Diva	388	0
Mona Lisa Touch	10	10
FemTouch	5	5
Thermiva	4	4
Geneveve	2	2
Femilift	0	0
Juliet	0	0
UltraFemme 360	0	0
Emsella	0	0
TempSure Envi	0	0
Fiore	0	0
Votiva	0	0

# ADVERSE EVENTS SUMMARY FROM MAUDE DATABASE<sup>26</sup>

- Neurologic
  - Pain
  - Burning
  - Numbness
- Gynecologic
  - Dyspareunia
    - New onset
    - Worsening symptom
  - Prolonged menses
  - Inability to conceive
  - Scarring
  - Disfigurement
  - Cyst formation
- Urologic
  - Urinary incontinence
    - Worsening symptoms
  - Burning with urination
  - Frequent urination
  - Sensation of incomplete voiding (4-6 week duration)
- Ophthalmic
  - Operator report: Facial burning sensation during treatment with subsequent bacterial conjunctivitis

# SUMMARY

- Devices for women's health have significant potential for positive impact.
- Education is key in treating appropriate candidates with the correct device.
- Risks need to be clearly reviewed by device.
- Further study on long term sequelae would be beneficial.
- Accurate reporting of AE is needed to learn the limitations and full risk/benefit profile of these treatments.

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# THANK YOU!

This presentation will be posted at:

[www.drgutowski.com](http://www.drgutowski.com)

Contact information:  
[jocelin@afreshmedspa.com](mailto:jocelin@afreshmedspa.com)