

ENDOMETRIAL ABLATION

TREATMENT COMPARISON¹⁴

	minerva ^{ES} [®]	NovaSure [®]	HTA [®]	Her Option [®]	Mara [™]	Cerene [®]
Hysterectomy Rate 3-Year follow up	0.9% ¹ (7X Reduced Rate) ¹⁴	6.3% ⁵	10.2% ⁷	No Data Available	No Data Available	No Data Available
Success Rate (≤ normal bleeding) 1-Year follow up	93% ²	77.7% ⁵	68% ⁷	67.4% ⁸	78.7% ¹¹	76.9% ¹²
Amenorrhea Rate (zero bleeding) 1-Year follow up	72% ²	36% ⁵	35% ⁷	22.2% ⁸	19.4% ¹¹	10% ¹²
Ablation Method	Plasma Thermal Conduction ³ (3 Mechanisms of Ablation)	RF Energy ⁵ Impedance Terminated (1 Mechanism of Ablation)	Hot Saline ⁷ (Circulating)	Cryothermic Energy ⁸ (Creates Iceballs)	Water Vapor ¹¹ (Steam)	Cryothermic Energy ¹² (Liquid N ₂ O)
Power Delivered	Max. 40 Watts ³ Declines during treatment	Max. 180 Watts ⁵ Constant during treatment	N/A	N/A	N/A	N/A
Energy Delivery Time	120 seconds ³	Avg. 90 seconds ⁵	Avg. 10 minutes ⁷	10 - 34 minutes Range ⁹	120 seconds ¹¹	150 seconds ¹²
Avg. Procedure Time (Insertion to removal)	3.1 minutes ²	5 minutes ⁶	26.4 minutes ⁷	20 - 30 minutes ¹⁰	4.2 minutes ^{11,13}	6.9 minutes ¹²

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Soft Silicone Array	Yes ³	No ^{5,13} Metalized Mesh	N/A	N/A	N/A	N/A Polyurethane Liner
Cervical Seal Position in the Cervix	Internal Os ³ Intracervical Sealing Balloon	External Os ⁵ Cervical Collar	N/A	N/A	Internal Os ¹¹ Intracervical Sealing Balloon	N/A
Cervical Seal CO ₂ Flow Indicator	Yes ³	No ¹³	No ¹³	No ¹³	No ¹³	No ¹³
CO ₂ Extension Tubes	Yes ⁴	No ¹³	N/A	N/A	N/A	N/A
Uterine Perforation Detection Test	Yes ³ 2-Stage (Before treatment)	Yes ⁵ 1-Stage (Before treatment)	Yes ⁷ Fluid Pump & Valves (During treatment)	Ultrasound Monitoring ⁸ (During treatment)	Yes ¹¹ 2-Stage (Before treatment)	Yes ¹² 2-Stage (Before treatment)
Vacuum to Remove Moisture/ Steam/N ₂ O	Not Necessary	Required ¹³	Not Necessary	Not Necessary	Not Necessary	Not Necessary

REFERENCES: (1) FDA Approved Labeling: Minerva Endometrial Ablation System [Operator's Manual, Sect 8.1]. Redwood City, CA: Minerva Surgical, Inc; L0001. (2) FDA Approved Labeling: Minerva Endometrial Ablation System [Operator's Manual, Sect 8.2]. Redwood City, CA: Minerva Surgical, Inc; L0001. (3) FDA Approved Labeling: Minerva Endometrial Ablation System [Operator's Manual]. Redwood City, CA: Minerva Surgical, Inc; L0001. (4) Minerva[®], 180-Day Device Modification Supplement: P140013/S005. (5) FDA Approved Labeling: NovaSure[®] Impedance Controlled Endometrial Ablation System [Instructions For Use and Controller Operator's Manual]. Marlborough, MA: Hologic, Inc; 2014. (6) NovaSure[®]. Web, <<http://www.NovaSure.com>>. Accessed 17 May 2019. (7) FDA Approved Labeling: Genesys HTA[™] System [Genesys HTA ProCerva[™] Procedure Set]. Marlborough, MA: Boston Scientific Corporation; 2014. (8) Her Option[™] Uterine Cryoablation Therapy[™] System. PMA P000032: Summary of Safety and Effectiveness Data: CryGen, Inc. San Diego, CA; 2001. (9) Her Option[®], Cryoablation Therapy System User Manual. 030-02096-001 Rev. W. Cooper Surgical. 2/15. (10) Patient Benefits." Her Option[®]. Cooper Surgical, n.d. Web. <<http://www.herooption.com/Professionals/Benefits/PatientBenefits.aspx>>. Accessed 24 Feb. 2017 (11) FDA Approved Labeling: AEGEA Vapor Endometrial System [Instructions For Use AEGEA Vapor System[™] Model # GEA-SYS-12-0400]. Redwood City, CA: AEGEA Medical; AEGEA IFU. (12) Cerene[®] Cryotherapy Device, PMA PI80032: Summary of Safety and Effectiveness Data: Channel Medsystems, Inc; 2019. (13) Summarized based on data provided in IFU/SSEDs. (14) Based on Comparing Operators Manuals /SSEDs - Not based on head-to-head studies