HOLOGIC®

ACESSA SYSTEM CLINICAL COMPENDIUM

2020

Executive Summary

Laparoscopic Radiofrequency Ablation (also referred to as Lap-RFA or RFVTA) of Uterine Fibroids with the Acessa® system provides significant reduction in heavy menstrual bleeding and fibroid volume while preserving the uterus. Results from clinical trials show high patient satisfaction and low surgical reintervention rates.

Results from additional clinical trials also found that Lap-RFA for Uterine Fibroids using the Acessa system has a low adverse event rate as well as lower intraoperative blood loss, shorter hospital stay, and faster recovery times compared to hysterectomy and myomectomy3.

In conclusion, Lap-RFA for Uterine Fibroids using the Acessa system in a safe and effective alternative to hysterectomy and myomectomy.



250 Campus Drive, Marlborough, MA 01752 USA +1.508.263.2900 | Hologic.com

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OVERVIEW OF CLINICAL EXPERIENCE WITH ACESSA PROVU

The Acessa system is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The Acessa Procedure (Lap-RFA) is minimally invasive, outpatient procedure that preserves the uterus and is a safe and effective alternative to hysterectomy and myomectomy.

- Over 4,000 patients treated with the Acessa system since 2012¹⁴
- 900+ patients studied and actively being studied under various protocols
- 47+ peer reviewed publications to date that include safety and efficacy data on 475 unique patients
- Long term clinical outcomes reported at 3-6-12-24-36 months¹

Key publications in support of Lap-RFA with the Acessa system are summarized on the following pages. Please contact <u>SURGICALMEDICALAFFAIRS@HOLOGIC.COM</u> for additional information on clinical data for the Acessa system.





SUMMARY OF PEER-REVIEWED PUBLICATIONS

CLINICAL STUDIES	PATIENTS STUDIED	STUDY DESIGN
I. INVESTIGATIVE DEVICE EXEMPTION (IDE) TRIAL IDE TRIAL: 12 MONTHS IDE TRIAL: 36 MONTHS IDE TRIAL: OBSERVATIONS IDE TRIAL: OBSERVATIONS IDE TRIAL: OBSERVATIONS	135	NON-COMPARATIVE PROSPECTIVE STUDY, COHORT STUDY, WITH OBSERVATIONS
II. RANDOMIZED CONTROLLED TRIAL (RCT) COMPARING LAPAROSCOPIC RADIOFREQUENCY ABLATION (LAP-RFA) WITH LAPAROSCOPIC MYOMECTOMY (LM) • RCT COMPARING LAP-RFA WITH LM: 12 MONTHS • RCT COMPARING LAP-RFA WITH LM: 24 MONTHS	50	COMPARATIVE PROSPECTIVE STUDY RCT
III. META-ANALYSES • META-ANALYSIS: LIN • META-ANALYSIS: HAVRYLIUK • META-ANALYSIS: BRADLEY • META-ANALYSIS: SANDBERG	N/A	META-ANALYSES AND SYSTEMATIC REVIEWS
IV. FEASIBILITY STUDIES PHASE I 	31	FEASIBILITY STUDY
V. TRUST STUDYTRUST CANADA	105	POST MARKET, PROSPECTIVE, MULTI- CENTER LONGITUDINAL

ACESSA PIVOTAL IDE CLINICAL TRIAL: 12-MONTH RESULTS

Chudnoff, SG, et al. Outpatient Procedure for the Treatment and Relief of Symptomatic Uterine Myomas. Obstetrics and Gynecology, 2013;121(5):1075–82.

	Objective	To estimate the safety and efficacy of laparoscopic ultrasound-guided radiofrequency volumetric thermal ablation of uterine myomas in symptomatic women.
Outpatient Procedure for the Treatment and Relief of Symptomatic Uterine Myomas Sout G. Chudoff, and, MS, John M. Branaw, MD, David J. Levine, MD, Mitah Harris, MD, Ridord S. Guida, MD, and His Bank, MD	Trial Design	Prospective, multicenter, interventional clinical trial with primary outcome measures of change from baseline to 12 months and ongoing qualitative follow- up of women for 3 years posttreatment.
<text><text><footnote><footnote><text><footnote><text></text></footnote></text></footnote></footnote></text></text>	Endpoints	Adverse events Reduction in menstrual blood loss Symptom severity score (SSS) and Health-related Quality of Life (HRQL) Myoma volume reduction Patient satisfaction Surgical reintervention
individual read from and for a factor of a factor	Enrollment	135 patients enrolled 127 patients in the full analysis and 12-month follow- ups 640 fibroids treated
	Conclusion	Radiofrequency volumetric thermal ablation of myomas is well tolerated and results in rapid recovery, high patient satisfaction, improved quality of life, and effective symptom relief.

Key patient outcomes at 12 months

- ♦ 81.9% of patients reported a reduction in their menstrual bleeding
 - ♦ 103.6 mL mean decrease in alkaline hematin from baseline
 - 40.2% experienced at least a 50% reduction from baseline to 12 months post treatment in their menstrual blood flow
- ♦ 45.1% mean myoma volume reduction
- ♦ 24.3% mean uterine volume reduction
- 98% of patients responded that they would recommend the treat to a friend with the same health problem
- ♦ 94% of patients responded that they were satisfied with the treatment

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- Mean 35.2- and 41.2-point improvements in SSS and HRQL scores
- 1 serious adverse event reported

ACESSA PIVOTAL IDE CLINICAL TRIAL: 36-MONTH RESULTS

Berman, J., Guido, R., Garza, L. J., Robles, P. R., Whaley, F., & Chudnoff, S. (2014). Three Years' Outcome from the Halt Trial: A Prospective Analysis of Radiofrequency Volumetric Thermal Ablation of Myomas. Journal of Minimally Invasive Gynecology, 21(6). doi: 10.1016/j.jmig.2014.08.072

	Objective	To analyze the clinical success of radiofrequency volumetric thermal ablation (RFVTA) at 3-year follow-up in terms of subject responses to validated questionnaires and surgical repeat intervention to treat myomas.
Original Article Three-Year Outcome of the Halt Trial: A Prospective Analysis of Radiofrequency Volumetric Thermal Ablation of Myomas Jay M. Berman, MD ⁺ , Richard S. Guido, MD, José Gerardo Gaza Leal, MD, Rodolfo Robels Penueller, MD, Predrick S. Whaley, FhD, and Scott G. Chudonff, MD, MS, for the Halt Study Group The Delayer of the State o	Trial Design	Prospective follow-up of patients for 36 months after treatment in a multicenter international trial of outpatient, laparoscopic ultrasound-guided RFVTA of symptomatic uterine myomas
nocejne theisened paided BFVTA of typeptomatic article sympasma (Candian Taki Tone classification II-1). Setting: University looping and private suggicatorents. Paintext: One hundred dirty dive premn operated worm (mean IQD) age, 42.5 (4.6) years, body mass index, 30.5 (6.1) with programma ward adjusteding variatorized paint paints. Paintext: One hundred dirty dive premn operative paints in the state of the	Endpoints	Symptom Severity Score (SSS) and Health-related Quality of Life (HRQL) score Reintervention rate
Exposed: Ablation, Fibrick L Laporocepic obmound, Mysour, Dakomer, Ealindingersy volument in form al abusin Supported by for mady groune (MM Maladi, Inc., Resettence), CAL Consequently allower: DM Maladi, Inc., Resettence), CAL Supported by for mady groune (MM Maladi, Inc., Resettence), CAL Consequently allower: DM Maladi, Inc., Resettence), CAL Supported by for mady groune (MM Maladi, Inc., Resettence), CAL Consequently allower: DM Maladi, Resettence), CAL Madation (MM Maladi, Inc., Resettence), CAL Consequently allower: DM Maladi, Resettence), CAL Madation Consequently and the optical and plot of the optical and plot optical and plot of the optical and plot of the optical and plot of the optical and plot optical and plot of the optical and plot optical and pl	Enrollment	135 patients enrolled 104 patients in the full analysis and 36- month follow-ups
	Conclusion	RFVTA of uterine myomas resulted in sustained relief from myoma symptoms and continued improvement in health- related quality of life through 36 months after ablation.

Key patient outcomes at 36 months

- ♦ 11% cumulative surgical reintervention rate
- ♦ Mean 32.6-point decrease in SSS
- ♦ Mean 38.6-point improvements in and HRQL score
- ◊ Improvements in SSS and HRQL scores at 12 months were also observed at 36 months

ACESSA PROCEDURE IDE CLINICAL TRIAL: OBSERVATIONS

Galen, D. I., Isaacson, K. B., & Lee, B. B. (2013). Does Menstrual Bleeding Decrease After Ablation of Intramural Myomas? A Retrospective Study. Journal of Minimally Invasive Gynecology, 20(6), 830-835. doi: 10.1016/j.jmig.2013.05.007

JMIG Part of the second	Objective	To evaluate the effect of radiofrequency volumetric thermal ablation (RFVTA) on menstrual bleeding in patients with intramural myomas
Original Article Does Menstrual Bleeding Decrease After Ablation of Intramural Myomas? A Retrospective Study Donald I Galen, MD*, Keith B. Isaccon, MD, and Bruce B. Lee, MD Pouck Repeaters in a fore of set of Poucke Repeaters in Stress (Series), Series (Series)	Trial Design	Retrospective analysis of a recently completed prospective trial of laparoscopic ultrasound-guided RFVTA
patients with hierarchi process. Being Rotopolous analysis of neutrity completed properties that of layers acple alterward-patient RPV 34 is which 135 subjects and objects by meanward heavy meaning heaving $(\geq 1000 \pm 500 \pm 300 \pm 1000 \pm 10000\pm 1000\pm 10000\pm 10$	Endpoints	Reduction in menstrual blood loss (MBL)
Setting: Characteristic to optical and private surgery surgers. Notices: Constrained thirty-fore proceedings of the formation of the set of t	Enrollment	 135 premenopausal symptomatic women with uterine myomas and heavy menstrual bleeding confirmed by alkaline hematin analysis 122 patients in the full analysis at 12 months
 De Geneven a prindjel sverigere in de exploj oddy. Espensorie, Nikajev Berkele NCTROFERSY, wich is spennechly field berkel. Bearwood, C.A. De Gien arm en Hit Matche Scientific Adato Bearwood, C.A. De Gien arm en Hit Matche Scientific Adato Scientific Adato Device (1) Successful and Charl Media of Charl Composition of Charl Media of Charl Device (1) and a field field field field of Charl Device (1) and a field fie	Conclusion	Although it has been known that the treatment of submucous myomas results in a reduction of MBL, this is the first study to show that radiofrequency ablative therapy for intramural myomas without a submucosal component will also
		result in a significant reduction in menstrual blood loss

Key patient outcomes based on observational study data

- ♦ All 122 subjects had clinically and statistically significant decrease in MBL
- ♦ Lap-RFA resulted in 103.6 mL mean reduction in menstrual blood flow at 12 months post-treatment
- 91.8% of subjects had 1 or more intramural myomas, but submucous myomas were present in fewer than half of the subjects
- 10 subjects had submucousal but no intramural fibroids and the most significant posttreatment decrease in monthly bleeding (-45.1%)
- 63 subjects had intramural myomas but no submucosal myomas, and their posttreatment decrease in MBL was also clinically and statistically significant (-31.8%)
- 27 of these 63 subjects did not have myomas abutting the endometrium or submucous myomas and experienced clinically and statistically significant reduction in MBL (-25%)

ACESSA IDE CLINICAL TRIAL: OBSERVATIONS

Galen, D. I., Pemueller, R. R., Leal, J. G., Abbott, K. R., Falls, J. L., & Macer, J. (2014). Laparoscopic Rafrequency Fibroid Ablation: Phase II and Phase III Results. JSLS: Journal of the Society of Laparoendoscopic Surgeons, 18(2), 182-190. doi:10.4293/108680813x13693422518353

	Objective	To review phase II and phase III treatments of symptomatic uterine fibroids using laparoscopic radiofrequency volumetric thermal ablation (RFVTA).
SCIENTIFIC PAPER Laparoscopic Radiofrequency Fibroid Ablation: Phase II and Phase III Results Donald I. Galen, MD, Rodolfs Robles Pemueller, MD, José Gerardo Garza Leal, MD, Karen R. Abbott, MD, Janice L. Folls, MD, James Macer, MD	Trial Design	Retrospective, multicenter clinical analysis of results from two phase II studies and 2 sites and one phase III study at 11 sites
AISTRACTIACKground and Objectives: To review phase II and and using lagurancepts radiofrequency volumetric ther and abasis (DFVTA).Index analysisInteractive constraints of the phase II and and abasis of DFVTA does not require any uterim individual time ad abasis of DFVTA does not require any uterim individual statement of the phase II and at 2 also ($n = 60$) and one phase II and at 11 size ($n = 52$). Bushly statement in quality of II.Rothods: We performed a retraportive, making the quark of the parasceptic RNTA of symptomatic myormas or at 2 also ($n = 60$) and one phase III study at 11 size ($n = 61$).Rothods: Teom baseline to 12 months were applied.Rothods: Teom baseline to 12 months and the phase II study at 11 size ($n = 60$) and one phase III study at 11 size ($n = 60$).Rothods: Teom baseline to 12 months are physical study at 11 size ($n = 60$) and one phase III study at 11 size ($n = 60$).Rothods: Teom baseline to 12 months are physical study at 11 size ($n = 60$).Rothods: Teom baseline to 12 months are physical study at 11 size ($n = 60$).Rothods: Teom baseline to 12 months and the physical study at 11 size ($n = 60$).Rothods: Teom baseline to 12 months and the physical study at 11 size ($n = 60$).Rothods: Teom baseline to 12 months and their transport merely study at the physical study at the	Endpoints	Symptom severity score (SSS) and Health- related Quality of Life (HRQL) Decreased uterine volume Return to normal activity Device-related adverse events Decreased menstrual blood loss
tients in place III missed a metion of 5 days of weak (mage, 1-20 days). The net of peripose-discal devices related adverse events was 35% (5 of 137). Despite the neurons that of discrements in discrement in disc	Enrollment	206 patients who received Lap-RFA treatment for uterine fibroids
 Andre creecing websit crant, aven, ave, no tracketti, and the second crant of the second cran	Conclusion	RFVTA does not require any uterine incisions and provides a uterine-sparing procedure with rapid recovery, significant reduction in uterine size, significant reduction or elimination of myoma symptoms, and significant improvement in quality of life.

Key patient outcomes based on observational study data

- ♦ Mean 25.9% reduction in uterine volume
- ♦ Mean 45.1 point decreased in SSS
- ♦ Mean 43.5 decreased in HRQL scores
- ♦ Patients returned to work with 4-5 days
- ♦ 1.4% rate of possible device-related adverse events

ACESSA IDE CLINICAL TRIAL: OBSERVATIONS

Levine, D. J., Berman, J. M., Harris, M., Chudnoff, S. G., Whaley, F. S., & Palmer, S. L. (2013). Sensitivity of Myoma Imaging Using Laparoscopic Ultrasound Compared with Magnetic Resonance Imaging and Transvaginal Ultrasound. Journal of Minimally Invasive Gynecology, 20(6), 770-774. doi: 10.1016/j.jmig.2013.04.015

IMIG the land of t	Objective	To determine the eficacy of laparoscopic ultrasound (LUS) as compared with contrast-enhanced magnetic resonance imaging (CE-MRI) and transvaginal ultrasound (TVUS) in detection of uterine myomas
Original Article Sensitivity of Myoma Imaging Using Laparoscopic Ultrasound Compared With Magnetic Resonance Imaging and Transvaginal Ultrasound David J. Levine, MD*, Jay M. Bernan, MD, Micah Harris, MD, Scott G. Chudnoff, MD, MS, Fredrick S. Whaley, PhD, and Suzame L. Palmer, MD Inneh Department of Mericin and Geneology, Sciolari More, The planer, MD Inneh Department of Mericin and Geneology, Sciolari More, The planer, MD Inneh Department of Mericin and Geneology, Sciolari More, Sciolari Matanet (Dr.Letter), Department of Observict and Geneology Distance, Attorney (Theris), Department, Sciolari More, Sciolari Matanet, Sciulified, Michigan (Dr. Branz), Worney Todalo Barench, Prince, Attorney (Theris), Department, Schweidt Matanet, Sciulified, Michigan (Dr. Branz), Moldan (Dr. Branz), Department Calleger of Moldan, Bonz, New York (Dr.C. Chadog), Downey & Additional Change, Calleging (Dr. Branz), Department Calleger of Moldan, Bonz, New York (Dr.C. Chadog), Downey & Additional Change, Calleging (Dr. Branz), Calleging (Dr	Trial Design	Retrospective study of imaging methods used in a trial of LUS-guided radiofrequency volumetric thermal ablation in women with symptomatic myomas
ABSTRACT Study Objective: To determine the efficacy of laparancopic ubmound (LUS) is compared with contrast-columed magnetic resonance imaging (CEMRI) and transmignia ubmound (TVUS) in detection of tarine aryonas. Designe, Recruptor for study off the imaging are dood were the sould in the study off. Typic ide adals for query volumentic thermal ablation in women with symptomatic myomas (Canadam Tak Fare elastification II-2). Softing Elsever model and wersity optivate angularization usyop official for the study of the stu	Endpoints	Number of myomas found in CE-MRI, TVUS, and LUS
 radiolequery volumente thermal ablation. The imaging methods and their yields in terms of number of nymons (notal per subject were as follows TUS, 4d Bynossi (notal SD 1(3), map., 1-3) (is CE-MM 2, 53 runnal (4 (5) 2), map., 0-20); and LUS, 818 myonso (6) [49], map., 1-20 (is C. MM 2, 4d neural number of a substantial transmission of the substantial substantial transmission (4 (5) 2), map., 0-20); and LUS, 818 myonso (6) [49], map., 1-20 (is C. MM 2, 3d neural number of the substantial transmission (4 (5) 10). LUS was superior to TUS, CB (55 5%) by its CE-MM 2, 200 (4.7%) by thecentral male, and 386 (44.5%) by LUS. Condensitions the maximum promas, regardless of size or type. Journal of Minimally Invasive Gynecology (2013) ■, ■ ■ © 2013 AAGL. All rights meared. Strandomia threasent, Lapanoung's ultrassant, Magnetic meaness imaging. Moras: Radiofungancy witestife thermal ablatine; Three goal threasent, Lapanoung's ultrassant, Magnetic meaness imaging. Moras: Radiofungancy witestife thermal ablatine; Three goal threasent is a transmission. Strandomia threasent, Lapanoung's ultrassant, Magnetic meaness imaging. Moras: Radiofungancy witestife thermal ablatine; Three goal threasent is a transmission. Strandomia threasent, Lapanoung's ultrassant, Magnetic meaness imaging. Moras: Radio fungancy witestife thermal ablatine; Three goal threasent is a transmission. Strandomia threasent, Lapanoung's ultrassant, Magnetic meaness imaging. Moras: Radio fungancy witestife thermal ablatine; Three goal threasent is a transmission. Strandomia threasent, Lapanoung's ultrassant, Magnetic meanes ablatine; Three goal threasent is a transmission. Strandomia threasent, the strandomia and the strandomia threasent is a transmission to the strandomia threasent. 	Enrollment	135 women with symptomatic myomas and objectively conFIrmed moderate to severe heavy menstrual bleeding
Www.AAGL.org/joing-204-5.JMICL-D-13-00159R1 Functional and the set of the set	Conclusion	Compared with CE-MRI and TVUS, LUS demonstrates the most myomas, regardless of size or type

Key findings based on observational study data

- ♦ Laparoscopic ultrasound identifies 2x more fibroids than transvaginal ultrasound
- Laparoscopic ultrasound identifies 1.4x more fibroids than contrast-enhanced magnetic resonance imaging
- LUS detected a larger number of serosal, intramural, and submucosal myomas and intramural myomas abutting the endometrium than did the other methods
- ♦ LUS picked up smaller (< 1 cm³) fibroids than TVUS and CE-MRI
 - ♦ 10% of fibroids imaged with TVUS were small, 21% of fibroids images with CE-MRI were small, and 39% of fibroids imaged with LUS were small

RCT COMPARING LAP-RFA WITH LAPAROSCOPIC MYOMECTOMY: 12 MONTHS

Brucker, S. Y., Hahn, M., Kraemer, D., Taran, F. A., Isaacson, K. B., & Krämer, B. (2014). Laparoscopic radiofrequency volumetric thermal ablation of fibroids versus laparoscopic myomectomy. International Journal of Gynecology & Obstetrics, 125(3), 261-265. doi: 10.1016/j.ijgo.2013.11.012

		Objective	To compare the mean hospital discharge times and perioperative outcomes for radiofrequency volumetric thermal ablation (RFVTA) of Flbroids and laparoscopic myomectomy (LM)
Litteria CLINCAL ARTICLE Laparoscopic radio frequ versus Laparoscopic my Sara Y, Brucker*, Markes Hahr Keith B, Isaacon ¹⁶ , Bernhard Y ¹⁰ 	Converts lass available as financed/twot tional Journal of Gynecology and Obstetrics Journal homeseage; www.elieviar.com/ficesta/Ego ency volumetric thermal ablation of fibroids meetcomy ^{All} . Dout Kraemer ^A . Proin Andrei Taran ^A . Kitaner ^d ^{All} thore Grame ^{All} thore Grame ^{All} thore Grame ^{All} thore Grame ^{All} thore Grame	Trial Design	Post market, randomized, prospective, single- center, longitudinal, comparative study to evaluate the outcomes of RFVTA and the current standard of care (LM) for symptomatic uterine fibroids in women who desired uterine conservation
A ETICLE INFO Methoday Constraints Records in August 2013 Records in Augus	A BITRACT Objector To rough of the mean burghtlick Large times and perspectate autiones for tal despect volu- ments of merrical actions (BMA), and means and a lansmaph of memory meaning (MA). Methadis to the perspect despectation of the mean sector of the MA and the sector of the memory means (MA) and the MA and the perspect despectation of the mean sector of the MA and the means and the mean sector of the burden means (MA) and the mean of the MA and the mean sector of the means burden means (MA) and the MA and burden means (MA) and the MA and the burden means (MA) and the MA and the land the MA and		Surgeons were blinded to the treatment until all fibroids had been mapped by laparoscopic ultrasound
 Introduction Derive fibriek are the most common they work by just the quality of last a hydrenchamy (12) Hydrenchamy is the and derive to cover be the firsting of speptraulic fibries and undir most procession hydrencham and the set of the start of the speptraulic fibries and undir most processions may expend the site system and the set of the property of the set of the set of the set of the spectra of the set of the set of the set of the set of the set of the set of the set of the set of the set of the set of the set of the set of the metanty of an indire related block in the set of the set of the metanty of an indire related block in the set of the set of the metanty of an indire related block in the set of the metanty of an indire related block in the set of the se	<text><text><text><text><text><text><text><text><text><text></text></text></text></text></text></text></text></text></text></text>	Endpoints	Mean hospitalization time Mean intraoperative blood loss (mL) Percentage of fibroid treated
¹ Comparing a the at Dynamic and Symposium Terms and the symposium of the symposium of the Symposium of the symposium of the symposium of the symposium of the Symposium of the symposium of the symposium of the symposium of the Symposium of the symposium of the symposium of the symposium of the Symposium of the symposium of the symposium of the symposium of the Symposium of the symposium of the symposium of the symposium of the symposium of the Symposium of the symposium of		Enrollment	51 patients randomized to the 2 interventions Final analysis included 25 patients in the RFVTA group and 25 patients in the LM group
		Conclusion	Radiofrequency volumetric thermal ablation resulted in the treatment of more Flbroids, a significantly shorter hospital stay, and less intraoperative blood loss than laparoscopic myomectomy.

Key patient outcomes based on RCT study data

- ♦ Median surgery time for Lap-RFA is comparable to LM
 - ♦ 1.1 hours for Lap-RFA
 - ♦ 1.2 hours for LM
- \diamond $\$ Lap-RFA results in reduced hospitalization stay compared to LM
 - ♦ Median 7.8 hours for Lap-RFA
 - ♦ Median 22.6 hours for LM
- \diamond Lap-RFA results in lower intraoperative blood loss compared to LM
 - ♦ Median 20 mL for Lap-RFA
 - ♦ Median 35 mL for LM
- ♦ Lap-RFA results in treatment of more fibroids compared to LM
 - ♦ 71 fibroids treated with Lap-RFA (98% rate of treated/excised fibroids)
 - ♦ 49 fibroids treated with LM (80.3% rate of treated/excised fibroids)

RCT COMPARING LAP-RFA WITH LAPAROSCOPIC MYOMECTOMY: 24 MONTHS

Krämer, B., Hahn, M., Taran, F., Kraemer, D., Isaacson, K. B., & Brucker, S. Y. (2015). Interim analysis of a randomized controlled trial comparing laparoscopic radiofrequency volumetric thermal ablation of uterine fibroids with laparoscopic myomectomy. International Journal of Gynecology & Obstetrics, 133(2), 206-211. doi: 10.1016/j.ijgo.2015.10.008

LINCULARICLE Interim analysis of a rand radiofrequency volumet	Contentials and all Queening and Obsertin 133 (2016) 287-211 Contentialities and adde at ScienceOrect tional Journal of Gynecology and Obstetrics [aurnal homespage: www.elsevier.com/focater/jgo	Objective	To compare 24-month patient-reported outcomes following laparoscopic radiofrequency volumetric thermal ablation (RFVTA) and laparoscopic myomectomy in patients with uterine fibroids
La paroscopic myomector Bernhard Kaimer, "Andruss Hai Keith B. Isascon"-S. Sra Y. Bun - Department of deates and Corporatio, Internet * Wrengin Branch Kanger, Menn - Brand Markathinel, Jones, and Mark - Reference of the state of the state - Reference of the state of the state of the state - Reference of the state of the state of the state - Reference of the state of the state of the state - Reference of the state of the state of the state of the state - Reference of the state of the state of the state of the state of the state - Reference of the state o	ny n ^{Na} , Florin-Andrei Taran ^A , Dorit Kraemer ^A , et mene Taran ^A , Borin Kraemer ^A , et mene Mater A B ST R A C T Objetter To anyor 23-enseth patient-separated nationals following by answerption of the Math. Mitch An Interin anyolicity of a set of the set of the set of the mathematical set of the set of the set of the set of the set of the set	Trial Design	Interim analysis on data from an ongoing randomized, prospective, single-center, longitudinal trial of laparoscopic myomectomy and RFVTA
Legaranty (crayondorsy Legaranty) (clamand Radolingancy dolton Radolingancy dolton Radolingancy visionistic the nail dolton	messary requirements to wild ad a generation and in tage terms and adjust from day for which of spatients (1 at 0 2 V/V) and (1 person per spatient) in the V/V (1 at 0 (1 and per spatient)) and (1 and per spatient) in the V/V) and (1 per spatient) and (1 and V/V), completed 3 H and (1 and D and V/V) and (1 per spatient) and (1 and V/V). A spatient (1 and V/V) and (1 per spatient) and (1 and V/V) and (1 per spatient) and (1 and V/V). A spatient (1 and V/V) and (1 per spatient) and (1 and V/V) and (1 per spatient) and (1 and V/V). A spatient (1 and V/V) and (1 per spatient) and (1 and V/V). A spatient (1 and V/V) and (1 per spatient) and (1 and V/V). A spatient (1 and V/V) and (1 per spatient) and (1 and V/V). A spatient (1 and V/V) and (1 per spatient) and (1 and V/V) and (1 per spatient) and (1 and V/V). A spatient (1 and V/V) and (1 per spatient) and (1 per	Endpoints	Symptom severity score (SSS) and Health- related Quality of Life (HRQL)
 Instructure and one of the second seco	 A statistic statisti statisti statistic statistic statistic statistic statistic s		51 patients randomized to the 2 interventions Final analysis included 21 patients in the RFVTA group and 22 patients in the LM group
• corresponding antibury at: Department of Ober of Table app, Weinstein Hoggs, A., Dienerstein, M., Standard, M., Sandard, M., Sandard, M., Sandard, M., Levin and antibury for the Manuskul Antiburg, and the Antiburg Antiburg and Standard and Standard and Standard Mathematical Standard and Standard and Standard (http://www.sminister.gl.toms.shy-sec.sl.(40).)			24-month data suggest equivalence in safety and patient-reported efficacy of RFVTA and laparoscopic myomectomy

Key patient outcomes based on RCT study data

- ♦ Improvements in SSS were found in both Lap-RFA and LM patients
- ♦ Improvements in HRQL were found in both Lap-RFA and LM patients
- Similar scores show durability of Lap-RFA as an alternative to LM

META-ANALYSIS: QUALITY OF LIFE, ADVERSE EVENTS, AND REINTERVENTION OUTCOMES AFTER LAPAROSCOPIC RADIOFREQUENCY ABLATION FOR SYMPTOMATIC UTERINE FIBROIDS

Lin, L., Ma, H., Wang, J., Guan, H., Yang, M., Tong, X., & Zou, Y. (2019). Quality of Life, Adverse Events, and Reintervention Outcomes after Laparoscopic Radiofrequency Ablation for Symptomatic Uterine Fibroids: A Meta-Analysis. Journal of Minimally Invasive Gynecology, 26(3), 409-416. doi: 10.1016/j.jmig.2018.09.772

	Objective	To review short and long-term outcomes from patients after Lap-RFA for uterine fibroids
	Trial Design	Meta-analysis
Laparoscopic Radiofrequency Ablation for Symptomatic Uterine Fibroids: A Meta-Analysis Letao Lin, MD, Haocheng Ma, MD, Jian Wang, MD, Haitao Guan, MD, Min Yang, MD, Xiaoqiang Tong, MD, and Yinghma Zou, MD Irente Departed Intermediation of Warded Interview Free Regid, Joing, Chea (al adors)		Symptom Severity Score (SSS) and Health- related Quality of Life (HRQL)
ABSTRACT In this eview, we assessed the short-term (3 and 6 months) and long-term (12, 24, and 36 months) symptom relief and quality of life improvement, procedure-related advente event net, restorvention mite, and days missed from work after lapmonoperior randorsquerey shafts. Disky disk Bayework's traine thereoff and "adding the thinkings," a systematic senseth was performed in PMMed, Ovid, Tanhan, Cacheme Lhowy, and Chickelmidgev. Studies con- sisting of tweire theory symptom and quality of the scores were considered eligible. Both comparison and non- sisting of tweire theory symptom and quality of the Scores were considered eligible. Both comparison and non-	Endpoints	Procedure-related adverse events
comparine funds, were included. Uning a randow-effection model, a non-analysis was performed. Flight mindes represent the state of the improvement (behalt-Related Quality of 116; 1980;QUI questionniae score of +4164 4976 on onfoldence interval (CT), 38.9-4434 and as its unarisential Springer State of the state of th		Reintervention rate
change remained adults in biogeness. Otherwy, The overall evidence resists and a 20% (20% CL 1.16% – 4-45%), and the mode metrics towards 0.17% (0.05% - C.12.46.46%). The commit proce- duce-chand advence overas in two 1.17% (0.5% CL 0.02% - 3.3%), and particle mixed as average of 4.35 days (0.9% CL 3.25% - 6.4 day) of works. In conclusion, lipsware-participation distribution for the conclusion (0.9% CL 3.25% - 6.4 day) of works. In conclusion, lipsware-participation distribution for the conclusion (0.9% CL 3.25% - 6.4 day) of works. In conclusion, lipsware-participation distribution for the conclusion of the concl		Days missed from work
erdel and quality of the improvement with a low risk of adverse events and statewestion and just a low days of mission dwork. Journ of Marianity Browstee Openology (2019), 52, 649–614. O 2018, ARL, All rights merved. Keywords: Laparencopic mdo/topacacy ablation; Mets-analysis; Quality of life;Symptomatic sterime Broid	Study Size	8 studies
Uterine fibroids are the most common benign tumors of the female reproductive system, with a cumulative incidence of 2016 [12]. Approximately 50% of a cumulative ine fibroids become symptomatic, returning in abnormal stretrine before heavy mercurated before the system of the particulation of the intervention become symptomatic, returning in abnormal stretrine before heavy mercurated before the system of the particulation of the system is the system of the system of the system of the system of the system is the system of the system is the system of the syst		581 total patients studied
 The direct order that by the number of transmission of the direct order ordero	Conclusion	Lap-RFA is an efficacious way to treat small- sized and nonpedunculated symptomatic uterine fibroids, providing stable long-term symptom relief and quality of life improvement with a low risk of adverse events and reintervention and just a few days of missed work.

Key findings from meta-analysis

- HRQL after Lap-RFA improved significantly up to 36 months
- ♦ Overall reintervention rate of 4.39%
- ♦ 69.17 cm³ median reduction in uterine volume
- Patients return to work in 4.35 days on average
- 1.78% procedure related adverse event rate

META-ANALYSIS: SYMPTOMATIC FIBROID MANAGEMENT

Havryliuk, Y., Setton, R., Carlow, J. J., & Shaktman, B. D. (2017). Symptomatic Fibroid Management: Systematic Review of the Literature. JSLS: Journal of the Society of Laparoendoscopic Surgeons, 21(3). doi:10.4293/jsls.2017.00041

	REVIEW ARTICLE JSLS	Objective	Determine whether recommendations can be made regarding best practice for symptomatic uterine fibroid surgical treatment	
Symptomatic Fibroid Mana of the Li	gement: Systematic Review iterature	Trial Design	Systematic review and meta-analysis	
Yelena Havryliuk, MD, Robert Setton, MD, John	J. Carlow, EdD, MPH, Barry D. Shaktman, MD		Intraoperative blood loss	
ABSTRACT Background and Objectives: Symptomatic stering fi-	roscopic radiofrequency ablation, and magnetic reso- rance-guided focused ultrasound). Conclusion: We explored ironds that might outle clini-		Length of stay	
broke are a societal and healthcare burden with no clear consensus among medical professionals as to which pro- cedural treatment is most appropriate for each symptom- atic patient. Our purpose was to determine whether rec-	cians when courseling patients who need treatment of symptomatic fibroids. We found that fibroid therapy is trending toward uterine-conserving treatments and cat- conserve commended areas them independently for min-		Complications	
ommendations can be made regarding bost practice based on review and analysis of the literature stree 2006. Database: A systematic search of journal articles relevant	timally involve options are increasing, it is important for the clinician to provide the patient with evidence-based therapeutic strategies.	Endpoints	Operating time	
to the treatment or symptomatic themic threads was per- formed within PubMed, clinical society websites, and medical device manufacturen' websites. All clinical trads published in English, representing original research, and	Kcy Words: Intervention, Leiomyoma, Symptomatic fi- broid, Utertne.	Enapoints	Reintervention rate	
reporting clinical outcomes associated with interventions for the management of symptomatic uterine fibroids were considered. Each article was screened and selected based on study type, content, relevance, American College of	INTRODUCTION		Readmission rate	
Obstitutions and Gynacologius acces, and internal/conte- nal validip. Outcomes of interest were patient haushes characteristics, Illevial characteristics, procedural distato, complexations, and longer fuero follow-up. Incodess-efforts meta-analyses were used to test the quantitative data. Assessment of 140 full-length articles through January 2016 produced 45 atticles for the quantitative analysis.	sympositiants actions and approximate the imposition present is algorithmat social and his highly are burdlen, and there is no clear consensus among medical performation at to which treatment is appropriate for their sympositic patients. These burdles, solid myometrial tamons are the most consensor tamons found in women. They have an ostimated cumulative incidence of up to 70% in white women and 80% in black women during the promenon-		Symptom Severity Score (SSS) and Health- related Quality of Life (HRQL)	
The weighted combined results from hysterectority trais were compared with these from uterine-preserving fibroid studies (myomectomy, uterine artery embolization, lapa-	pausal years. ¹ Severe symptoms may develop in 15 in 30% of cases, and the extent of symptoms depends on fibroid location, number, and size. Submucosal and inframual fibroids truncally manifest with abroarmal uterities bleed-	pausal years. ¹ Severe symptoms may develop in 15 to 30% of cases, and the extent of symptoms depends on fibroid location, rumber, and size. Submucosal and intramunal fibroids typically manifest with abnormal uterine bleed-		Complete assessment of 142 articles
Department of Charitan and Dynamidag, Well Canad Bachal Edilage, New York, New York, 1930. One Narophel, Steiner, and Madamard. Discourse Statistics, San Classonic, California, 1930. On Ladows The advest facels worked student Andro Classic for contributions to the total research.	ing, whereas subscraal and pedanculated fibroids usu- ally present with bulk-related symptoms of polytic pain and lowed to bladder dydanction. Symptomatic patients may miss work and, overall, have lower quality of the than sevenetomatic rations? a 'm addition, the messence of fi-	Study Size	45 used in quantitative analysis	
Hai Muhu, Yuo, Denizowa Ji, Zilkiwa, Hui Ji, and Jiao Lindong Lio menuch and nanical and an interpretation startaneous levels for the deal of the mesoning the states are part on mellinear of startaneous startaneous and the states are part on mellinear data. Only, it that and disk starts, had to (10), free hardpalling with Cloud Muhal Olikay, 19 Km and Muhal Muha. Ji Km Muhal Muham mengena and an anti-startaneous for the start and part hardpalling and an anti-startaneous for the start and particular bardpalling and an anti-start and of dispensationages. Integrations: Muhalud Sys. 2019;51:2232-2232020	has for search and symptomizing particular. In addition, the presence of 11- tors and the search of 12- tors and 12- ma additional direct and indirect costs of symptomatic filterable in a star 13- most and 12-main addition of the search of the search of the second search of the search of the search of the second search of the search of	of may find is infertily and adverse (negrouncy cod- us). ⁵ and divers and indivers cause of symptomatic (Breads in United States may coursed §34 (Blacs, col Glass more 400,000 mpatient hydroxycol State). The symptomic of the sympto- physical (Endos) there coverside sing inclusions are spinnaric (Endos) that hydroxycol manage- physical (Endos) that hydroxycol manage-		Fibroid therapy is trending toward uterine- conserving treatments and outcomes are comparable across those treatments.
july-September 2017 Volume 21 Ionae 3 e2017/00041 1	jii jii ji	Conclusion	Lap-RFA is associated with low complication rates, minimal EBL, and low reintervention rates. In addition, patients reported major improvement in their HRQL and symptom severity scores compared to reports of more traditional interventions, such as hysterectomy, myomectomy, and UAE.	

/	Key findings from meta-analysis				
		Lap-RFA	Myomectomy	UAE	Hysterectomy
	Procedure Details & Early Follow Up				
	Blood Loss	35.4 mL	175.5 mL	NA	269.3 mL
	Length of Stay	0 days	2.0 days	2.4 days	2.2 days
	Complications, (major)	1.7%	3.5%	2.7%	2.1%
	Long Term Follow Up				
	Duration of follow up	27.0 months	34.7 months	13.5 months	11.2 months
	Number of patients	209 pts	689 pts	1423 pts	334 pts



META-ANALYSIS: CLINICAL PERFORMANCE OF RADIOFREQUENCY ABLATION FOR TREATMENT OF UTERINE FIBROIDS

Bradley, L. D., Pasic, R. P., & Miller, L. E. (2019). Clinical Performance of Radiofrequency Ablation for Treatment of Uterine Fibroids: Systematic Review and Meta-Analysis of Prospective Studies. Journal of Laparoendoscopic & Advanced Surgical Techniques, 29(12), 1507-1517. doi:10.1089/lap.2019.0550

	Objective	To review evidence regarding typical patient outcomes for RFA
Some of Landoncoccare & Journed Burdel, Technoles Trave B, Harrier T, 2019 To The Description Of The Description Clinical Performance of Radiofrequency Ablation for Treatment of Litering Ethnolds:	Trial Design	Meta-analysis Systematic review of prospective studies for treatment of uterine fibroids with RFA
<section-header><section-header><section-header><text><text><section-header><text><text><text><text><text><text><text><text><text></text></text></text></text></text></text></text></text></text></section-header></text></text></section-header></section-header></section-header>	Endpoints	Mean procedure time Return to work timeline Time to discharge Fibroid volume reduction Symptom Severity Score (SSS) and Health-related Quality of Life (HRQL) Reintervention rate
medicatine or Unitery in modification is common, but offer medicatine or Unitery in modification is common by the original original original original original original attributed is a straight to strength the presenter properties much resolution at a straight and a straight original original attributed is a straight original original original original original original original original original original original	N=	32 studies 1283 patients
	Conclusion	RFA of uterine fibroids significantly reduces fibroid volume, provides significant durable improvements in fibroid-related quality of life, and is associated with favorable reintervention rates.

Key findings from meta-analysis

- Mean 73 minutes Lap-RFA procedure time
- ♦ Mean 10.7 hours Lap-RFA hospital stay
- ♦ 3.8% reintervention rate at 14 months for Lap- RFA
- Mean 66% fibroid volume reduction at 12 months for RFA
- Mean 6.5 days to return to work after Lap-RFA
- ♦ Reduced SSS
- Improved HQRL

META-ANALYSIS: REINTERVENTION RISK AND QUALITY OF LIFE OUTCOMES AFTER UTERINE-SPARING INTERVENTIONS FOR FIBROIDS

Sandberg, E. M., Tummers, F. H., Cohen, S. L., Haak, L. V., Dekkers, O. M., & Jansen, F. W. (2018). Reintervention risk and quality of life outcomes after uterine-sparing interventions for fibroids: A systematic review and meta-analysis. Fertility and Sterility, 109(4). doi: 10.1016/j.fertnstert.2017.11.033

Reintervention risk and quality of life outcomes after uterine-sparing	Objective	To compare uterine-sparing treatment options for fibroids in terms of reintervention risk and quality of life
interventions for fibroids: a systematic review and meta-analysis Balances 4.0.** of addition M. M. P. Tarrier, "Safety JColors, M.D., M	Trial Design	Systematic review and meta-analysis
Brighten and Worden't Higher's Under UberGeldback, Botten, Mannahouth, "Darp drever of Chinal Editorishing Engineering, Darit Lichnergy of Technology, Darit Lichner, Mannahouth," and Providence of Editorishing Engineering, Darit Lichnergy of Technology, Darit Lichnergen (State Participant), and Technology, Barter Darity, State State (State Participant), and the Interfordance State (State Participant), and the Interfordance of the Interfordance Interfordance (State Interfordance of the Interfordance of the Interfordance of the Interfordance of the Interfordance Interfordance (State Interfordance of the Interfordance of	Endpoints	Reintervention outcomes Symptom Severity Score (SSS) and Health-related Quality of Life (HRQL)
Result(s): There were'n winders include to includy the spectrating (7.2.9) wereas. Straffed by the street spins, interventions that after the method wave (100, 190, 190, 190, 190, 190, 190, 190,	Study Size	85 studies 17,789 total patients studied
Provide the first manuary of the f	Conclusion	This study demonstrates that long-term data, particularly for the newest uterine- sparing interventions, are urgently needed.

Key findings from meta-analysis

- Lap-RFA results in the lowest reintervention rate at 6 months when compared to cryotherapy ablation, myomectomy, HIFU, and UAE
- ♦ Lap-RFA resulted in improved SSS and HRQL at 12 months
- Limited data for Lap-RFA at 60 months

FEASIBILITY STUDY: LAPAROSCOPIC ULTRASOUND-GUIDED RADIOFREQUENCY VOLUMETRIC THERMAL ABLATION OF SYMPTOMATIC UTERINE LEIOMYOMAS: FEASIBILITY STUDY USING THE HALT 2000 ABLATION SYSTEM

Leal, J. G., Leon, I. H., Saenz, L. C., & amp; Lee, B. B. (2011). Laparoscopic Ultrasound-Guided Radiofrequency Volumetric Thermal Ablation of Symptomatic Uterine Leiomyomas: Feasibility Study Using the Halt 2000 Ablation System. Journal of Minimally Invasive Gynecology, 18(3), 364-371. doi:10.1016/j.jmig.2011.02.006

TIE JONNAL OF MINIBALLY INVARVE OTNEDUCOT	Objective	To assess the safety and efficacy of the Halt 2000 Radiofrequency Ablation System
ELSEVIER Instruments and Techniques Laparoscopic Ultrasound-Guided Radiofrequency Volumetric Thermal Ablation of Symptomatic Uterine Leiomyomas: Feasibility Study Usine the Halt 2000 Ablation System	Trial Design	Prospective, single-center, longitudinal, open-label, single-arm, feasibility study
<text><text><text><text><text><text><footnote><footnote><footnote><footnote></footnote></footnote></footnote></footnote></text></text></text></text></text></text>	Endpoints	Patient safety Adverse events Reintervention rate Uterine volume changes Symptom Severity Score (SSS) and Health-related Quality of Life (HRQL)
	Enrollment	31 patients
	Conclusion	Volumetric thermal ablation using the Halt 2000 System produced significant reduction in symptoms and improvement in quality of life at 1 year after treatment, with an excellent safety profile.

Key findings from feasibility study

- Mean SSS improvement by 82% at 12 months
- ♦ Increased HRQL by 37.65 points at 12 months
- No procedure-related repeat hospitalizations, repeat treatments, or any procedures related to symptoms of myoma after radiofrequency ablation
- ♦ Mean uterine volume decreased from 105.9 cm³ to 53.5 cm³ at 12 months

TRUST STUDY: CLINICAL OUTCOMES AND HEALTH CARE UTILIZATION PRE- AND POST-LAPAROSCOPIC RADIOFREQUENCY ABLATION OF SYMPTOMATIC FIBROIDS AND LAPAROSCOPIC MYOMECTOMY: A RANDOMIZED TRIAL OF UTERINE-SPARING TECHNIQUES (TRUST) IN CANADA.

Rattray, D. D., Weins, L., Regush, L. C., Bowen, J. M., O'reilly, D., & Thiel, J. A. (2018). Clinical outcomes and health care utilization pre- and post-laparoscopic radiofrequency ablation of symptomatic fibroids and laparoscopic myomectomy: A randomized trial of uterine-sparing techniques (TRUST) in Canada. ClinicoEconomics and Outcomes Research, Volume 10, 201-212. doi:10.2147/ceor.s155038

Outstathsouth end Darmen America America America America American Society Contrastructures (2014) for 17 Apr 2014 Toronton America	ClinicoEconomics and Outcomes Research Dovepress	Objective	To compare laparoscopic ultrasound-guided radio frequency ablation of fibroids (Lap-RFA) and laparoscopic myomectomy in terms of 1) healthcare utilization and 2) serious complication rates.	
	Clinical outcomes and health care utilization pre- and post-laparoscopic radiofrequency ablation of symptomatic fibroids and laparoscopic myomectomy: a randomized trial of uterine-		Trial Design	Post-market, randomized, prospective, multicenter, longitudinal, noninferiority interventional comparative evaluation
	<text><text><text><text><text><text><text><text></text></text></text></text></text></text></text></text>	Endpoints	Healthcare utilization Serious complication rates Symptom Severity Score (SSS) and Health-related Quality of Life (HRQL)	
		Enrollment	45 patients 23 in Lap-RFA group 22 in myomectomy group	
	Generation-face (ahr A Third (643) 2014 Annue, Fern Statchwer 1906, Cocket Par (ab da bit) and (characteristic) and (characteristic) and (characteristic) Annue (ab da bit) and (characteristic) Annue (ab da bit) and (characteristic) Annue (ab da bit) Annue (ab da b	and the first sector of the se	Conclusion	Compared to myomectomy Lap-RFA is associated with significantly lesser intraoperative blood loss, shorter procedure and hospitalization times, lesser consumption/use of disposable and reusable surgery equipment, reduced health care resource utilization, and faster return to work through 3 months post-treatment. Direct and indirect costs of Lap-RFA and myomectomy are comparable.

Key findings from TRUST study

- Lap-RFA results in shorter hospitalization stay than myomectomy \diamond
 - o Mean 6.7 hours for the Lap-RFA group, 9.9 hours for the myomectomy group
- Lap-RFA results in shorter procedure time than myomectomy \Diamond
- Mean 70 minutes for Lap-RFA, 86.5 minutes for myomectomy \diamond Lap-RFA resulted in less intraoperative blood loss than myomectomy
 - Mean 25.2 mL blood loss for Lap-RFA, 82.4 mL for myomectomy
 - Lap-RFA symptom severity reduction is comparable to myomectomy
- \diamond Lap-RFA results in guicker return to work than myomectomy \diamond
 - Mean 11.1 days for Lap-RFA, 18.5 for myomectomy
- \diamond Lap-RFA combined per patient direct and indirect costs comparable to myomectomy (Canada)

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IMPORTANT SAFETY INFORMATION The Acessa ProVu system is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The Acessa ProVu system is contraindicated for patients who are not candidates for laparoscopic surgery and/or patients with a uterus adherent to pelvic tissue or viscera. The Acessa ProVu system's guidance system is not intended for diagnostic use. Please read all instructions for use of the Acessa ProVu system prior to its use. Safe and effective electrosurgery is dependent not only on equipment design but also on factors under control of the operator. Rare but serious risks include, but are not limited to, skin burns, mild inter-operative bleeding, post-procedural discomfort (cramping, pelvic pain), infection, vaginal bleeding, blood loss and complications related to laparoscopy and or general anesthesia. If you or someone you know has possibly experienced a side effect when using our product please contact your physician. Insufficient data exists on which to evaluate the safety and effectiveness of the Acessa ProVu system in women who plan future pregnancy, therefore the Acessa ProVu system is not recommended for women who are planning future pregnancy.

This is a general information tool for medical professionals and is not a complete representation of the product Instructions for Use (IFU). It is the medical professional's responsibility to read and follow the IFU. The information may suggest a particular technique or protocol however it is the sole responsibility of the medical professional to determine which technique or protocol is appropriate. Sound patient evaluation and selection is the responsibility of the medical provider.

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