Zacks Small-Cap Research

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Viveve Medical (VIVE-NASDAQ)

VIVE: Unit Placements On A Tear. Add'l Approvals / Distribution Should Further Steepen Placement Rate

We use a 10-year DCF model to value VIVMD. We have revenue growing from $5.7M in 2016 to $22.0M in 2019 and to approximately $78M in 2026. Other key inputs to our DCF include a 11% discount rate and 2% terminal growth rate. Based on our DCF model, VIVMD is valued at approximately $11/share.

Current Price (08/16/16)	$7.32
Valuation	**$11.00**

OUTLOOK

Viveve's flagship product, the Viveve System, is used to treat vaginal laxity and sexual function, a condition which is often caused by vaginal childbirth and one in which about 50% of women that have undergone normal vaginal delivery hold as a concern. Other methods exist to address vaginal laxity although they suffer from certain drawbacks.

VIVEVE I large, randomized clinical study results confirmed earlier findings that Viveve System significantly improves sexual function and reduces vaginal laxity. This marketing study, along with data from previous studies and the recent significantly beefed-up distribution is expected to help accelerate the roll-out of the Viveve System. Brazil and U.S., which lead the world in vaginal rejuvenation procedures, could come online in the near term. Next steps are to conduct U.S. study in support of FDA filing for treatment of vaginal tissue to improve sexual function – study could initiate this year. In the meantime, will look to initially commercialize in U.S. under general surgical indication

Our DCF-based valuation values the company at $11/share.

SUMMARY DATA

52-Week High	**$10.50**
52-Week Low	**$4.02**
One-Year Return (%)	**11.19**
Beta	**0.82**
Average Daily Volume (sh)	**33,732**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$79**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**44**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-0.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Instruments**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	38 A	73 A	584 A	752 A	1447 A
2016	1284 A	1556 A	1322 E	1493 E	5655 E
2017					11017 E
2018					16492 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$1.10 A	-$0.68 A	-$0.50 A	-$0.54 A	-$2.48 A
2016	-$0.55 A	-$0.66 A	-$0.39 E	-$0.40 E	-$1.71 E
2017					-$1.94 E
2018					-$1.37 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Q2 Financial Results…*Unit Placements On A Tear. Add'l Approvals, New Territories Coming Online*

Viveve reported financial results for the second quarter ending June 30. Unit placements and related revenue remain on a tear with sales up 21% sequentially to $1.56M, a new record and ahead of our $1.12M estimate by almost 40%. Viveve System placements, which included 40 in Q2 (vs. our 28 estimate), up from 33 in Q1 (the prior record) and almost 18% more than the 34 sold in all of 2015, continue to drive the vast majority of the top-line. However, we continue to expect consumables (i.e. treatment tips) sales to accelerate from a growing installed base (currently at 115) and increased utilization as a result of greater awareness, including clinical evidence, supporting the benefits of Viveve System therapy.

VIVE sold 402 treatment tips in Q2, compared to 474 in Q1 and 615 for all of 2015. And while below our 649 unit estimate, as we have noted in prior updates we had expected consumables sales to be variable, lumpy and tough to model on a quarter-to-quarter basis, particularly during the early years when growth (on a percentage basis) of the installed base is so rapid (installed base grew 53% during Q2).

We expect growth to be further facilitated by several catalysts which have come online over the last few months including the highly positive results of the VIVEVE I study, regulatory approval in new territories including Singapore and S. Korea (both in August), new distribution agreements and a restocked cash balance to help fund additional sales, marketing and general awareness-building efforts. Additional regulatory approvals, potentially including Brazil and the U.S. which are the top two markets for vaginal rejuvenation, could come in the near-term and provide another significant tailwind to revenue.

GEOGRAPHIC REGION	DISTRIBUTION COVERAGE	REGULATORY CLEARANCE
North America	1	1
Latin America	15	2
Europe	28	18
Asia Pacific	11	6
Middle East	10	-
TOTAL	**65**	**27**

SOURCE: VIVE Q1 10-Q

Recent and Expected Upcoming Milestones…

- Results of the randomized, sham-controlled VIVEVE I study, announced in April, showed a highly statistically significant difference between the active and sham arms on the VSQ (i.e. laxity) primary endpoint as well as the FSFI (i.e. sexual function) secondary endpoint. In addition, safety was considered excellent with no difference in adverse event rates between the treatment and sham cohorts
- Viveve now has distribution in 65 countries and regulatory approval in 27, this is up from 51 and 22, respectively, as of March. Recent distribution and regulatory additions include S. Korea and significant footprint expansion in Latin America - both markets which we expect to hold significant opportunity given the relative high rates of cosmetic procedures in those areas
- Management expects the Viveve System to gain regulatory approval in another 4 to 6 countries by the end of 2016. This includes Brazil which, according to data from the International Society of Aesthetic Plastic Surgeons (ISAPS), is the country with the most vaginal rejuvenation procedures performed annually (the U.S. is second)
- June equity raise netted ~$13.9M. Also in June VIVE secured a $10M term loan ($$4.5M of which was used to retire prior debt). The restocked cash balance, which stood at $19.9M at Q2 quarter-end, will be used to further steepen the unit placement curve, build awareness and distribution and for regulatory activities, including in the U.S.
- U.S. commercialization could commence as early as late this year under the existing 510(k) for either general surgery or an enhanced label including gynecological tissue. Longer-term plan continues to be an indication for improvement of sexual function (VIVEVE II study could commence in 2017). IDE to commence pivotal U.S. study in support of treatment of vaginal tissue to improve sexual function indication expected to be filed in near-term.

Q2 also marked a highlight in gross margin. Gross margin at 34.3% was also a new record, up from 27.1% in Q1 and an average 31.9% in all of 2015. Management noted on the call (which we missed due to a time conflict) that they expect GM to remain relatively elevated and trend between 35% and 45% through the remainder of 2016 as a result of development updates to the treatment tips and improved pricing (particularly if U.S. launch occurs in 2016).

Cash
VIVE used approximately $4.3M ($4.7M ex-changes in working capital) of cash in operating activities in Q2 and $6.3M ($8.4M ex-changes in working capital) in the first 6 months of 2016. Cash balance stood at $19.9M at quarter-end which, at the recent burn rate, represents approximately 16 months worth of operating capital.

U.S. Regulatory Update…
Management provided an update to their U.S. regulatory plan on the Q2 call. As a reminder, VIVE is following a two-pronged approach - initially hoping to commercialize the Viveve System under a general surgery or enhanced general surgery indication and later for a more substantive 'improvement of sexual function' indication supported by data from the upcoming pivotal U.S. VIVEVE II study.

Existing 510(k): Earlier this year VIVE submitted a special 510(k) seeking expanded labeling for general surgical procedures for coagulation and hemostasis, including gynecological tissue for their current device, which already has FDA clearance for general surgical procedures. Management noted on the call that the application was accepted by FDA for review in late May, VIVE received questions from the agency in mid-July and the company subsequently submitted their response. VIVE expects to hear back from FDA in the fall (Sept). If clearance is granted with the expanded label, VIVE would then prepare to commercialize. If not, they will look to update their current 510(k) for general surgical procedures via a design history file update (essentially updating the file to include any changes to the device/technology) - VIVE believes that they could have clearance under the general surgical procedures indication prior to current year end. As we have noted in our ongoing coverage of VIVE, this will provide VIVE will some early revenue opportunity but, perhaps more importantly, initial awareness building in the U.S. as they pursue a sexual function indication

De novo 510(k): encouraged by the positive results of VIVEVE I, particularly highly statistically significance on the Female Sexual Function Index (FSFI) endpoint, the company will seek labeling for the treatment of vaginal tissue to improve sexual function. Next steps including submitting an IDE to FDA - which VIVE expects to do following response from FDA on their general surgical procedures filing. If all goes well, management believes the pivotal VIVEVE II study (more details below) could commence in early 2017. If eventually approved, the Viveve System would be the only therapy approved for the treatment of vaginal tissue to improve sexual function and could be a game-changer in our view

Highly Positive VIVEVE I Study Results…
In April Viveve announced positive top-line results of VIVEVE I (VIveve Treatment of the Vaginal Introitus to EValuate Effectiveness), its sham-controlled clinical trial assessing safety and efficacy of the Viveve System in more than 150 patients at 9 sites in Europe, Canada and Japan. While results of two previous smaller studies (one in U.S.: n = 23, one in Japan: n = 30) had already demonstrated that treatment with the Viveve System can significantly reduce vaginal laxity and improve sexual function, this VIVEVE I study is the largest to-date and the first sham-controlled study evaluating the Viveve System for the treatment of vaginal laxity as well as for sexual function.

VIVEVE I Design / Protocol…
Enrollment was initially expected to be 113 patients - the study protocol was subsequently updated (per clinicaltrials.gov) to enroll an expected 145 – final enrollment ended up being 174 patients (117 active, 57 sham) with vaginal laxity efficacy data on a 'per-protocol' population of 155. Subjects were randomized 2:1 (active:control) - patients were blinded, treating personnel were not. The treatment group received 90 Joules/cm2 of RF energy delivered via the Viveve System while the sham group received <1 Joule/cm2. Subjects were followed through the six month follow-up period with assessments at day 10 and months 1, 3 and 6.

Key inclusion / exclusion criteria included;[1]
- Inclusion:
    - pre-menopausal and ≥ 18 years of age
    - had least one full term vaginal delivery (>37 completed weeks) at least 12 months prior to enrollment date
    - experienced vaginal looseness (i.e. VSQ < 4) during vaginal intercourse
- Exclusion:

[1] Clinicaltrials.org. ClinicalTrials.gov Identifier: NCT02261974. VIveve Treatment of the Vaginal Introitus to EValuate Effectiveness (VIVEVE I)

- Pregnant or planning to become pregnant within the next 12 months or has had a delivery within the last 12 month
- currently meets the criteria for a female sexual disorder including DSM V, FSAD, FOD, Genitopelvic Pain, Sexual Aversion, Dyspareunia or Vaginismus and has not been treated for this condition within the past 12 months
- taking SSNRI or SSRI drugs

Primary efficacy endpoint was the proportion of women in the treatment arm as compared to the proportion of women in the sham (i.e. - control) arm that report no vaginal laxity six months following treatment as measured by Viveve's specially designed questionnaire, VSQ ("Viveve System Questionnaire"). VSQ, which is similar to the VLQ questionnaire used in the two prior studies, is based on a seven point scale (1:very loose, 2:moderately loose, 3:slightly loose, 4:neither loose nor tight, 5:slightly tight, 6:moderately tight, 7:very tight). "No vaginal laxity", as defined in the VIVEVE study protocol, is a VSQ score of >4.

Secondary efficacy endpoints were the percentage change in mean score from baseline to six months following treatment of the active arm as compared to the control arm in 1) the Vaginal Laxity Inventory (VALI), 2) Total FSFI and 3) FSDS-R. See our Appendix for detailed description of these secondary measures.

Study Results: Primary and FSFI Endpoints Highly Statistically Significant….

Results were positive, showing a highly statistically significant difference between the active and sham arms on the VSQ (i.e. laxity) primary endpoint as well as the FSFI (i.e. sexual function) secondary endpoint. In addition, safety was considered excellent with no difference in adverse event rates between the treatment and sham cohorts.

VSQ

Of the 174 subjects enrolled and randomized, 19 were not evaluable for efficacy purposes due to not completing the 6-month follow-up or for other protocol violations. The per-protocol population included 103 active and 52 sham subjects. At the 6-month follow-up, 41.7% (43/103) of active subjects reported having no vaginal laxity (i.e. VSQ > 4) compared to just 19.2% (10/52) of subjects that received sham treatment. The difference was highly statistically significant with a Chi-squared p-value of 0.005. Active subjects were 3.05x more likely to achieve 'no vaginal laxity' at 6 months than were sham subjects (95% confidence interval, p-value = 0.006).

Mean VSQ score at the 1, 3 and 6 month follow up periods were;

- 1-month: 3.9 active vs. 3.8 sham (difference of 0.1)
- 3-month: 4.1 active vs. 3.9 sham (difference of 0.2)
- 6-month: 4.1 active vs. 3.4 sham (difference of 0.7)

The mean difference at 6 months of 0.7 is statistically significant at a 95% confidence interval (p=0.007). The widening difference in mean VSQ over the course of the assessment periods is believed to be representative of weakening of a placebo effect in the sham arm.

FSFI

Similar to the two prior studies, VIVEVE I demonstrated that treatment with the Viveve System is associated with a significant increase in sexual function. FSFI is a brief, 19-item self-report measure of female sexual function that provides scores on six domains of sexual function as well as a total score. It was developed for the specific purpose of assessing sexual functioning in clinical trials. These 19 items include: desire (2 items), arousal (4 items), lubrication (4 items), orgasm (3 items), satisfaction (3 items), and pain (3 items) and are scored from 0 to 5. The FSFI total score is a weighted average of the six domains with each contributing a maximum of six points to the total (maximum score of 36). Wiegel, Meston and Rosen demonstrated that a cutoff of 26.55 discriminates between women with and without sexual dysfunction.[2]

103 (71 active, 32 sham) patients were included in the FSFI per-protocol population. Of the six domains, two (sexual arousal and orgasm) were statistically different favoring the active arm. And while the other four were not statistically different, there was a positive response favoring the active group. The individual p-values were (p-value < 0.05 is considered statistically significant);

- desire 0.081
- arousal 0.007
- lubrication 0.095
- orgasm 0.004
- satisfaction 0.097
- pain 0.122

[2] Wiegel M1, Meston C, Rosen R. The female sexual function index (FSFI): cross-validation and development of clinical cutoff scores. J Sex Marital Ther. 2005 Jan-Feb;31(1):1-20.

But while just two of the six individual domains hit statistical significance, the weighted average of the six domains of the active arm (27.5) was statistically different from that of the sham arm (24.3) at the 6-month follow-up. In addition, the weighted average scores of the six domains on the active arm at 1-month (27.0), 3-month (27.6) and 6-month (27.5) follow up were all above 26.55 (i.e. considered sexually functional) while the scores of the sham arm at each of these timepoints (1-month: 25.5, 3-month: 25.9, 6-month: 24.3) were all below 26.55 (i.e. considered sexually dysfunctional). Similar to the VSQ measure, there was some placebo effect in the sham arm that began to wane at about 3 months following initiation of treatment.

Importantly, the expectation is that the weighted average total score, as opposed to individual domain scores, is what FDA will be looking for as an endpoint in VIVE's proposed pivotal U.S. study. And while it is uncertain as to whether FDA will accept FSFI as a primary endpoint in VIVEVE II, we are encouraged that this is a clinical industry metric which has already been well-validated and documented. We think if accepted by FDA, that these VIVEVE I results, coupled with similarly positive FSFI results in the prior two studies, bode well for chances that VIVEVE II also hits statistical significance on FSFI.

VALI and FSDS-R
Vaginal Introitus Laxity Inventory and Female Sexual Distress Scale-Revised were the other two secondary endpoints. VALI relates to the respondents' concern of laxity and how that may affect sexual functioning while FSDS-R relates to a respondents' feelings of sexual activity-related distress based on a 13-item questionnaire.

While neither VALI or FSDS-R scores were statistically different between active and sham arms in VIVEVE I, we do not view this as problematic as it relates to the proposed U.S.-based controlled study as they have no cross-over relevance to the expected primary (FSFI) or secondary (VSQ) endpoints for VIVEVE II (i.e. – upcoming study). We think VIVE likely included VALI and FSDS-R in VIVEVE I in order to stack in additional metrics so as to offer other options in the event FSFI and/or VSQ failed to show statistical significance.

SAFETY
Similar to the two prior studies, safety was considered excellent in VIVEVE I. All 174 (117 active, 57 sham) enrolled and randomized patients underwent a safety evaluation. There was no statistical difference in safety measures between the two arms;

- treatment-emergent adverse events; 32.5% active vs. 35.1% sham
- related treatment-emergent adverse events; 11.1% active vs. 12.3% sham
- serious treatment-emergent adverse events; 0% active vs. 1.8% sham

NEXT STEPS

U.S. IDE: VIVE has now completed the final analysis and packaged the data for an expected upcoming IDE submission in anticipation of conducting a U.S.-based pivotal study in support of an eventual de novo 510(k) filing. On the Q2 call management noted that they expect to submit the IDE following response from FDA on the general surgical procedure filing - which could happen later this year.

VIVE intends to seek an indication for 'the treatment of vaginal tissue to improve sexual function', with (weighted average total) FSFI as the primary endpoint. While 'vaginal laxity' as measured by VSQ (or a version of) was the primary endpoint in all three of Viveve's clinical trials, VSQ is a proprietary metric developed by Viveve and may not be deemed acceptable to FDA without further scrutiny and validation. By contrast, FSFI is a clinical industry metric which has already been well-validated and documented. Management has also previously noted that they hope to incorporate VSQ as a secondary endpoint.

So assuming FDA concurs with a proposed FSFI endpoint and eventual FDA clearance for the treatment of vaginal tissue to improve sexual function indication, the Viveve System would be the only therapy approved for that claim providing significant and substantive difference from all other vaginal laxity-related devices. This, in our opinion, could be a game-changer for Viveve.

Marketing Message: VIVE will also likely look to have the VIVEVE I data published. They will also certainly be incorporated into the current marketing message outside of the U.S. We think this data could be potent – while the two prior studies provided evidence of significant efficacy of the Viveve System in both vaginal laxity and sexual function, the larger size and sham-controlled nature of VIVEVE I should provide clinicians with a much more definitive conclusion to the device's effectiveness.

U.S. Study: assuming IDE approval, VIVE will move towards clinical trial site selection and IRB approvals. While the company has yet to offer specifics in terms of expected design / size of a U.S.-based study, given that VIVEVE I was able to hit highly statistically significant results with enrollment of less than 200 patients, we don't expect VIVEVE II would be significantly different in size – although with the possibility of slightly greater enrollment (~10% - 20%) to provide an additional cushion. VIVEVE I was conducted at nine sites – expect a similar number, possibly one or two additional, for VIVEVE II.

We expect additional interaction between VIVE and FDA leading up to and following the IDE submission. Discussions should include finalizing clinical trial design including size, endpoints and indications. We note that VIVEVE I was obviously not a U.S. or in any way an FDA-affiliated study – as such, design, size, endpoints and other components of VIVEVE II could differ from that of VIVEVE I, and potentially meaningfully so. We may know more in the coming few months.

In the meantime….VIVE will continue to seek labeling for general surgical procedures for coagulation and hemostasis, including gynecological tissue for their current device, which already has FDA clearance for general surgical procedures. Management noted on the Q2 call that the application was accepted by FDA for review in late May, VIVE received questions from the agency in mid-July and the company subsequently submitted their response. VIVE expects to hear back from FDA in the fall (Sept). If clearance is granted with the expanded label, VIVE would then prepare to commercialize if not, they will look to update their current 510(k) for general surgical procedures via a design history file update (essentially updating the file to include any changes to the device/technology) - VIVE believes that they could have clearance under the general surgical procedures indication prior to current year end. As we have noted in our ongoing coverage of VIVE, this will provide VIVE will some early revenue opportunity but, perhaps more importantly, initial awareness building in the U.S. as they pursue a sexual function indication

BACKGROUND

Vaginal Laxity: *under-reported and associated with significant quality-of-life issues…*

Vaginal laxity, or a feeling of looseness, is a result of the introitus (i.e. - vaginal opening) collagen tissue losing some of their resilience and contractibility. Often this is a result of severe stretching caused by vaginal childbirth. And while other occurrences can result in vaginal laxity, including advanced age, certain genetic disorders and sexual activity, vaginal childbirth is the most common cause with subsequent deliveries increasing the risk and extent of looseness.

Vaginal laxity is often associated with reduced sensation and sensitivity during sexual intercourse, resulting in a decrease in sexual satisfaction. A study published in October 2006 in the Journal of Obstetrics and Gynecology which assessed the sexual satisfaction of a population of women post-delivery found a significant decrease in sexual satisfaction scores (as measured by a questionnaire) among women who underwent normal vaginal delivery as compared to those who delivered via caesarean section.[3]

The prevalence, consequences and potential demand to address vaginal laxity has garnered little attention or study, likely at least in part due to women being embarrassed to discuss it. In that regard Viveve has been somewhat of a pioneer, sponsoring several studies in order to better understand the thoughts of women and physicians on the subject. The evidence, garnered through Viveve's own research as well as studies unrelated to the company, suggest that vaginal laxity is under-reported, is of significant concern to women and is associated with lower sexual satisfaction. And in our opinion, this supports the potential demand for a therapy that can effectively address vaginal laxity and the adverse quality-of-life issues with which it is associated.

A study that Viveve sponsored titled *A Cross-Sectional Survey to Assess the Prevalence and Symptoms Associated with Laxity of the Vaginal Introitus*[4] queried 421 women ages in order to assess the prevalence of vaginal laxity and its effect on sexual satisfaction. Women aged 25 - 55 who had at least one vaginal delivery completed a questionnaire which included questions about interaction with their OB/GYN regarding sexual function, sexuality following childbirth and potential benefits to improving vaginal laxity. Results of the survey were that 48% (201 of 421) expressed laxity of the vaginal introitus as a concern ("some" or "a little" or "a lot), 80% (n=335) had not discussed vaginal laxity with their OB/GYN and only 48% (n=204) though Kegel exercises were effective.

A second study that was sponsored by Viveve, which was in collaboration with the OBGYN Alliance, surveyed 525 practicing OB/GYNs had a more distinct focus on what the potential demand might be for a procedure that would effectively address vaginal laxity. The survey found that 84% (n=441) of the OB/GYNs queried believed that vaginal laxity is the most common physical change in women after childbirth - ahead of weight gain, urinary incontinence and stretch marks. Additionally, the survey found that OB/GYN's believe vaginal laxity is under-reported.

The notion that the condition is under-reported as well as negatively effecting sexual satisfaction is further supported by a study published in the International Urogynecology Journal in October 2012 titled *Vaginal laxity: a poorly understood quality of life problem; a survey of physician members of the International Urogynecological Association (IUGA)*. A survey of 563 members of the IUGA included 27 questions related to attitudes and practices related to vaginal laxity. Among the findings were that 83% (n=467) believed that vaginal laxity was under-reported, and that the majority viewed vaginal laxity as something that adversely impacts sexual function.

Inadequate Means to Address Vaginal Laxity…

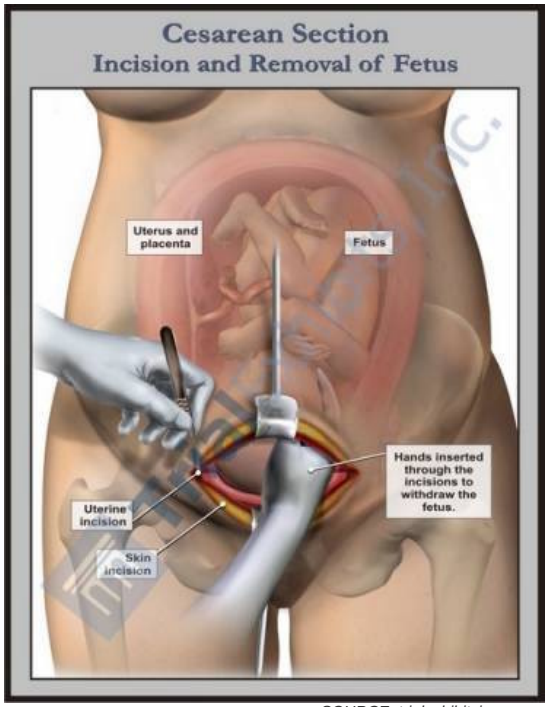
Options to address vaginal laxity include avoidance through elective cesarean section in lieu of normal vaginal delivery or through post-delivery treatment. However, given the certain risks, scarring and recovery time associated with a cesarean section (c-section) and various drawbacks of the most common treatment regiments, these may not be considered the most ideal options.

In a **c-section**, the baby is delivered through the mother's abdomen. It is a major surgical procedure which involves cutting through the abdomen, muscle and then into the uterus and adjusting organs for access. Risks of the surgery include major bleeding, infection, blood clots and damage to nearby organs. These risks increase with

[3] Griffiths A, et al. *Female genital tract morbidity and sexual function following vaginal delivery or lower segment caesarean section.* J Obstet Gynaecol. 2006 Oct;26(7):645-9

[4] http://www.ics.org/Abstracts/Publish/105/000206.pdf

subsequent cesarean sections. In fact, research has shown that approximately 40% of women that have three or more c-sections will experience complications. And since many doctors will recommend against vaginal delivery after a woman has already had a c-section, the risks of complications can become even greater. Recovery time is also longer with c-section versus vaginal delivery with the former requiring hospital stays averaging about twice that (4 days vs. 2 days) of normal vaginal delivery and relegating the mother to mostly inert activities for several weeks after discharge. And finally, c-sections can be cosmetically unpleasing, leaving a several inch scar on the lower abdomen.



SOURCE: trialexhibitsinc.com

There is also recent evidence that suggests babies born by c-section are more likely to be overweight or obese as adults. The study, titled *Mode of Delivery and Offspring Body Mass Index, Overweight and Obesity in Adult Life: A Systematic Review and Meta-Analysis*[5], was published in PLoS ONE in February 2014. The study, which analyzed data from 15 studies on more than 38k women from ten countries, suggests that babies born by c-section have a 26% greater chance of being overweight as adults compared to those born vaginally. But while study did show an association between c-section births and risk of being overweight, for which the authors hypothesized certain reasons including differences in stomach bacteria of babies born by c-section versus vaginally, the study did not prove a cause-and-effect. So while adult obesity may be another risk of c-section, more research would need to be done to determine if this should be considered a functional concern.

But despite the known risks and drawbacks of c-sections, these have not reduced the procedures' popularity. The rate of c-section procedures have doubled over approximately the last ten years and now accounts for 32% of all births in the U.S. and about 25% in the U.K. And while some of this increase can be attributed to clinical reasons and changes in clinical practice patterns, increasing concern over vaginal laxity is also likely to be a contributing factor and prompting women to choose elective (as opposed to emergency or physician-recommended) c-sections. In fact a U.K. survey of 282 obstetricians found that 31% would choose elective c-section in lieu of vaginal delivery in order to avoid certain pelvic floor dysfunction and quality-of-life issues associated with vaginal delivery, including vaginal laxity.[6]

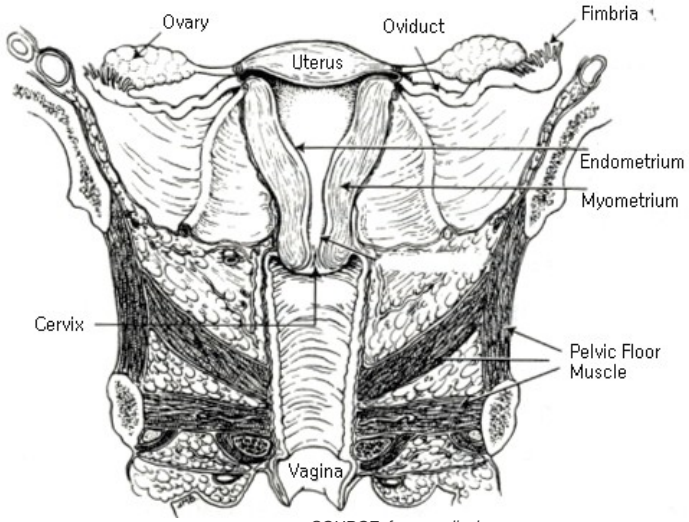
Barring avoidance through c-section, the most common methods to address vaginal laxity are pelvic floor exercises such as Kegels or reconstructive vaginal surgery.

[5] Darmasseelane, K., Hyde MJ, Santhakumaran S., Gale C., Modi N. *Mode of Delivery and Offspring Body Mass Index, Overweight and Obesity in Adult Life: A Systematic Review and Meta-Analysis.* PLoS ONE. 2014 Feb

[6] Al-Mufti R., McCarthy A., Fisk NM. *Survey of obstetricians' personal preference and discretionary practice.* Eur J Obstet Gynecol Reprod Biol. 1997 May;73(1):1-4

Kegel exercises involve rapid and repeated active contraction of the muscles that surround the pelvic floor, specifically the pubococcygeus. Kegels are designed to strengthen the pelvic muscles in order to address urinary incontinence and improve sexual function. And while Kegels are often recommended to address vaginal laxity, particularly following childbirth, and have shown to be effective in tightening the muscles around the vagina, scant evidence suggests that they are effective in improving the resilience or contractibility of the vaginal collagen tissue (i.e. - vaginal introitus). In fact, since Kegels only work the pelvic floor muscles, which surround the vaginal entrance but are not part of the vaginal canal, anatomy would support the evidence that suggest these exercises have little or no effect on tightening the vaginal opening.

Position of pelvic floor muscles in relation to vaginal introitus



SOURCE: furunmedical.com

An option to address introital laxity that has largely proven effective is **vaginal rejuvenation surgery**. Laser vaginal rejuvenation (LVR) is the most common female genital plastic surgery performed. According to the International Society of Aesthetic Plastic Surgeons (ISAPS), in 2011 there were 56k vaginal rejuvenation procedures performed worldwide (Brazil, with over 9k, is the country with the most procedures performed), including over 2k in the U.S.[7] LVR is a relatively new procedure, the rate of which has been increasing rapidly. According to the American Society for Aesthetic Plastic Surgery, there were over 5k vaginal rejuvenation procedures performed in the U.S. in 2013, an increase of 44% from the 3.5k performed in 2012.[8]

Vaginal rejuvenation is a surgical procedure performed under local anesthesia which tightens and restores the aesthetics of the vagina. It improves vaginal muscle tone and reduces internal and external vaginal diameters. Most commonly, women elect to have LVR following childbirth in order to improve the appearance of the vagina, restore tightness and to improve sexual satisfaction.

While several studies[9,10,11] have indicated that vaginal rejuvenation surgery is effective in restoring vaginal tightness and in improving sexual function/satisfaction, there are significant drawbacks to this procedure. Cost, which can vary between $4k and $10k, can be a serious impediment, particularly for those in lower income brackets. And with almost any surgery, complications can be a concern. Specific to vaginal rejuvenation, bladder injury, excessive bleeding and infection are potential procedural complications. There is also risk of loss of clitoral sensation and potential for scarring. Recovery is also longer (i.e. 5 - 6 days) and more uncomfortable (bruising, swelling, pain) compared to less invasive methods.

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[7] ISAPS International Survey on Aesthetic/Cosmetic Procedures Performed in 2011

[8] The American Society for Aesthetic Plastic Surgery. 2013 Cosmetic Surgery National Data Bank

[9] Goodman MP, et al. *A Large Multicenter Outcome Study of Female Genital Plastic Surgery.* Journal of Sexual Medicine (Impact Factor: 3.51). 11/2009; 7(4pt1):1565 - 1577.

[10] Pardo, J. S., Solà, V. D., Ricci, P. A., Guiloff, E. F. and Freundlich, O. K. (2006), *Colpoperineoplasty in women with a sensation of a wide vagina.* Acta Obstetricia et Gynecologica Scandinavica, 85: 1125–1127

[11] Goodman, M. P. (2011), *Female Genital Cosmetic and Plastic Surgery: A Review*. Journal of Sexual Medicine, 8: 1813–1825. doi: 10.1111/j.1743-6109.2011.02254

Viveve System

The minimally invasive, non-ablative Viveve System uses patented, reverse-thermal radio frequency (RF) technology to tighten vaginal tissue. Viveve has a perpetual, fully paid, royalty free license to the patents behind the technology from Solta Medical, Inc. Solta was formerly known as Thermage, Inc. (founded by Edward Knowlton) and was acquired by Valeant Pharmaceuticals in 2014. Thermage had designed the technology for use in tightening skin on the face and certain areas of the body such as the legs and stomach.

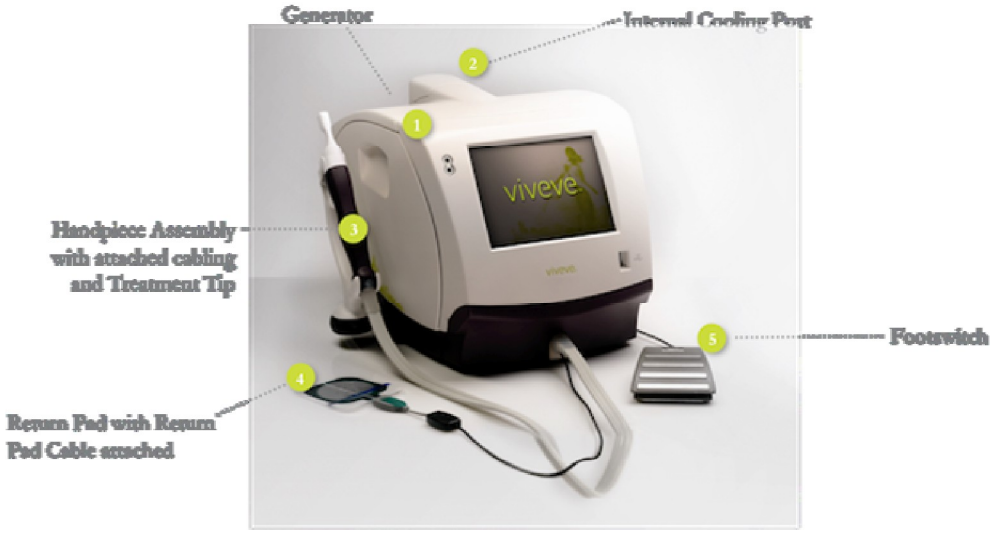
The Viveve System was designed using the same technology as that of Thermage's ThermaCool System, which has been used in over 280k procedures for skin tightening - mostly for facial skin. Slight modifications were made to the software of the RF generator as well as to the design of the handpiece and treatment tips in order to optimize the system for vaginal treatment. The Viveve System is currently manufactured by Stellartech Research Corporation, the original manufacturer of the Thermage device.

The Viveve System consists of three components; a small table-top console, a handpeice and a single-use (consumable) treatment tip. The monopolar RF energy generated by the console sends an electrical current through an electrode contained in a handpiece that was specially designed for use on vaginal tissue. The RF energy produces heat which is delivered to the body via the treatment tip at the end of the handpiece. The capacitive coupling mechanism inherent in the technology creates an electrical field where the treatment tip contacts the body, producing a current throughout the surrounding tissue and resulting in uniform heating of the area. Heating shrinks and shortens the fibrous saptae, collagen fibers which connect the dermis to the muscle, which results in tightening of the tissue. In addition, over several (1 - 3) months following the procedure, new collagen strands may form as a result of the application of the RF energy, providing further tightening of the tissue.

Viveve Treatment Tip



Viveve Console

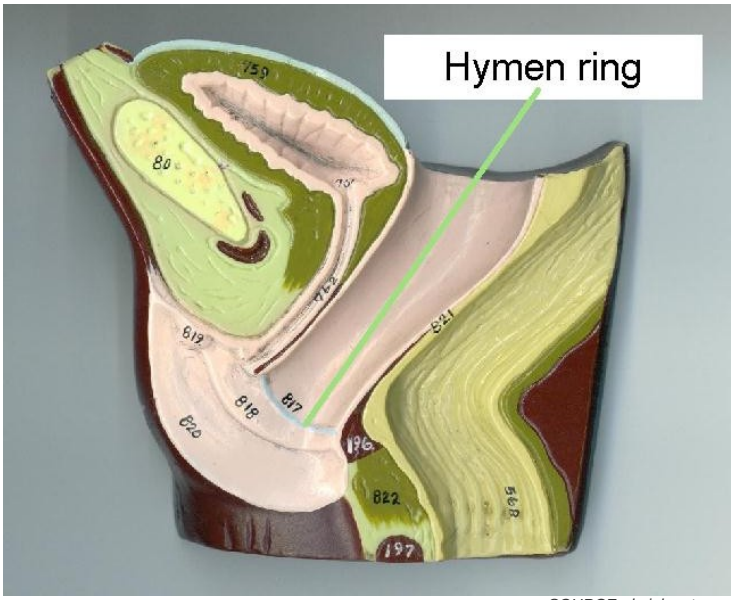


The RF generator produces a six megahertz signal. Also housed in the console is a special coolant and coolant system, which is also licensed from Solta. The coolant is delivered through the handpiece to the tissue immediately before and after the application of heat in order to cool and protect the tissue.

List price for the Viveve System console is approximately $60k while total selling price for the aggregate consumables, including the treatment tip, used in each treatment is approximately $600. The treatment tips have been designed as single-use with a memory chip that disables the tip after a pre-programmed number of pulses. In addition to the single-use tips, Viveve sells other consumables including cooling fluid (~5 - 6 procedures per canister), single-use return pads which are adhered to the body during the procedure and viscous fluid, which is used to ensure proper current flow from the treatment tip to the body.

The Viveve treatment is done on an outpatient basis in a physician's office without the need for anesthesia. During the ~30 minute procedure the physician delivers pulses in a horseshoe-type pattern from the 1:00 o'clock to the 11:00 o'clock positions inside the hymenal ring in three phases; cooling, heating (of 90 Joules/cm^2) and then cooling with each sequence lasting approximately eight seconds. Each sequence is repeated for a total of five times with overlapping pulses. In total, a typical procedure will consist of approximately 105 pulses over the five passes. The

patient typical experiences only warming and cooling but no pain. Efficacy has been demonstrated to last for 12 months.



SOURCE: drcink.net

As the Viveve procedure is minimally invasive, non-ablative and does not require anesthesia, recovery is essentially instantaneous and few complications have been reported. Of the complications that patients have experienced, almost all have been mild and consisted of slight vaginal discharge, redness/swelling and mild abdominal discomfort. No permanent complications have been reported.

CLINICAL DATA

Effective in Treating Introitus Laxity and Improving Sex Without the Drawbacks of Surgery

The Viveve System has been evaluated in a preclinical study and two clinical trials, all of which have indicated that the Viveve treatment significantly improves vaginal laxity. In addition, positive top-line results of a third clinical trial (the only sham-controlled trial to-date) were announced in April 2016. In all clinical trials to date, there have been no treatment-related adverse events.

> Preclinical Study

Viveve, in collaboration with West Virginia University, conducted a preclinical study on sheep to assess safety and to help determine the optimal level of RF energy delivery. The study, conducted in 2010, treated five sheep with the Viveve System at RF energy levels ranging from 75 to 90 Joules/cm^2. Following treatment, at one week, one month, three months and six months, vaginal biopsies were performed with 4 to 5 samples taken from each. These were compared to a control cohort of three sheep. Biopsies examined vaginal mucosa and connective tissue for changes associated with the RF treatment over the six month evaluation period.

Results determined the optimal RF energy delivery level to be 90 Joules/cm^2 (which is the level used in clinical practice) and tissue heating via RF energy appears to promote tightening of fibrous saptae and collagen production. Investigators also concluded a strong safety profile due to the absence of damaged tissue.

> U.S. Study

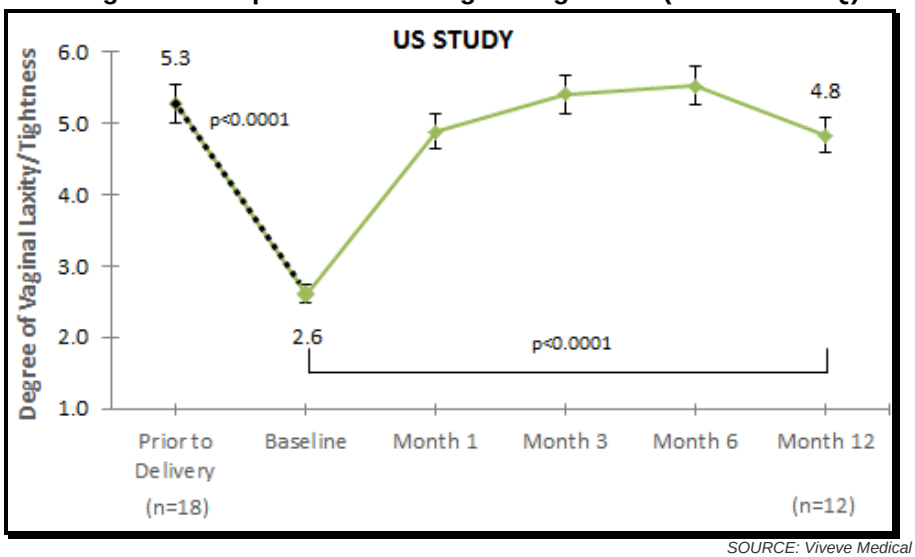
The single-center, single-arm U.S. study, which commenced in 2008, enrolled 24 women ages 25 - 44 years old which had had at least one vaginal delivery. All subjects were treated once with RF energy at various levels delivered via the Viveve System through the vaginal mucosa. The first three women received 60 Joules/cm^2, the next three received 75 Joules/cm^2 and the remaining 18 received 90 Joules/cm^2. Outcomes were measured at five time points; day zero (i.e. - prior to treatment), one month, three months, six months and 12 months. Outcomes were measured using self-reporting questionnaires (with questions focused on level of vaginal tightness and sexual satisfaction), modified Female Sexual Function Index (mFSFI), Female Sexual Distress Scale-Revised (FSDS-R)

and the Global Response Assessment (see Appendix for a detailed description of the outcomes). Pelvic exams were performed to assess safety.

At baseline, all of the women in the study expressed significant vaginal laxity (based on a Vaginal Laxity Questionnaire or VLQ) with an average score of 2.6 on a 1.0 - 6.0 scale (higher = tighter). In addition, approximately 50% of the study population conveyed reduced sexual satisfaction (based on a Sexual Satisfaction Questionnaire or SSQ) as compared to prior to giving birth.

23 (of 24) of the subjects completed the three and six month evaluations, 18 the nine month evaluation and 17 the twelve month evaluation. A 95% confidence interval was used to designate statistical significance on all measures. Results showed rapid and prolonged improvement in vaginal laxity with a statistically significant ($p<0.0001$) increase in tightness to pre-childbirth levels occurring by the one-month assessment point in all 24 women. This tightness level was sustained through to the final 12-month assessment time point. In addition, at every assessment point there was a statistically significant ($p>0.0001$) improvement in vaginal laxity.

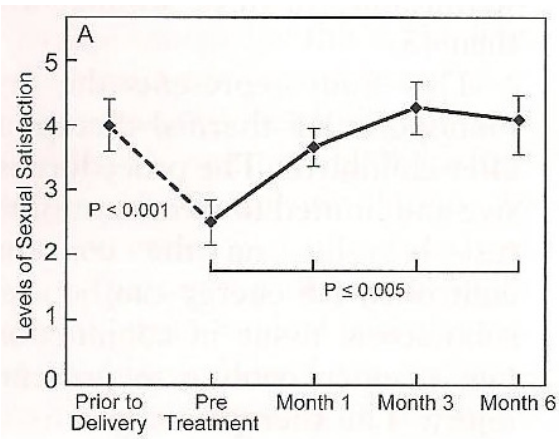
Significant Improvement in Vaginal Tightness (based on VLQ)

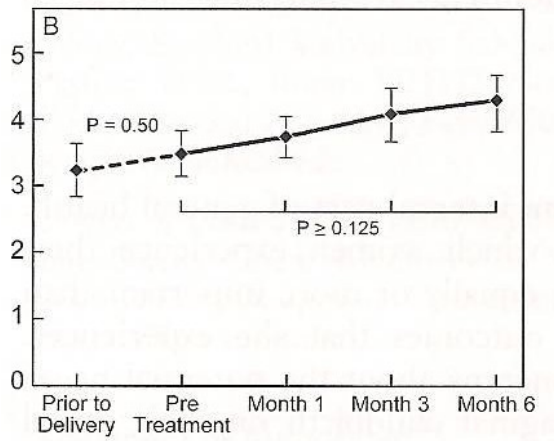


SOURCE: Viveve Medical Inc.

Top-line results, through the six-month evaluation period, were published in the Journal of Sexual Medicine in September 2010 and presented at the American College of Obstetricians and Gynecologists annual meeting earlier that year.

Sexual satisfaction also improved with treatment. Prior to treatment, 12 (of the 24) women expressed a diminished level of sexual satisfaction after their vaginal deliveries. The other 12 women reported either no change in sexual satisfaction or an increase in sexual satisfaction after their vaginal deliveries. SSQ scores significantly improved for all of the women who had reported a diminished level of sexual satisfaction (chart A below)[11] at six months following treatment (from an average of 2.5 to 4.1). There was no significant change in SSQ scores of the women who had reported no change in sexual satisfaction (chart B below)[11].





The FSFI and FSDS measures are used to assess changes in sexual function and sexually related distress, respectively. These showed the study participants did not experience any negative effects related to sexual function related to the RF treatment. In addition, throughout the six-month evaluation period, all FSFI scores (other than pain) significantly improved and personal distress (measured by FSDS) decreased significantly for all 24 patients at one month and all 23 patients at three and six months.

FSFI and FSDS Scores Indicate Treatment Improved Sexual Function and Reduced Distress[12]

Table 2 Changes in sexual function (mv-FSFI) and sexually related personal distress (FSDS-R) scores before and after RF treatment

Questionnaire	Possible score (range)	Pre-treatment N = 24	Month 1 N = 24	*P* value	Month 3 N = 23	*P* value	Month 6 N = 23	*P* value
mv-FSFI								
Desire	(1.2–6)	4.1 ± 0.9	4.7 ± 0.9	0.008	4.8 ± 0.8	0.002	4.8 ± 0.8	0.002
Arousal	(0–6)	4.5 ± 0.9	5.2 ± 0.8	<0.001	5.5 ± 0.5	<0.001	5.5 ± 0.5	<0.001
Lubrication	(0–6)	4.6 ± 1.1	5.3 ± 0.8	<0.001	5.3 ± 0.9	0.010	5.5 ± 0.8	0.001
Orgasm	(0–6)	4.1 ± 1.2	5.0 ± 1.2	0.001	5.4 ± 0.9	<0.001	5.3 ± 1.1	<0.001
Satisfaction	(0.8–6)	4.4 ± 1.0	5.1 ± 1.0	0.002	5.3 ± 0.7	<0.001	5.3 ± 0.7	<0.001
Pain	(0–6)	5.9 ± 0.5	5.8 ± 0.5	0.354	5.8 ± 0.4	0.732	5.6 ± 0.9	0.255
Total score	(2–36)	27.4 ± 3.6	31.1 ± 3.0	<0.001	32.2 ± 2.7	<0.001	32.0 ± 3.1	<0.001
FSDS-R								
Total score	(0–52)	13.6 ± 8.7	7.0 ± 6.5	0.001	4.4 ± 5.9	<0.001	4.3 ± 5.0	<0.001

Data are mean ± SD.
P value determined by paired *t*-test at months 1, 3, and 6 compared with pretreatment.
N = number of subjects; mv-FSFI = modified Female Sexual Function Index; FSDS-R = Female Sexual Distress Scale-Revised; RF = radiofrequency.

There were no treatment-related adverse events during either the treatment phase or throughout the 12-month follow-up period. Most of the women experienced a sensation of warmth during treatment but no significant pain.

> Japan Study

In March 2010 the Viveve System commenced evaluation in a second clinical trial, this time in Japan. The study design was very similar to that of the U.S. trial, with the most significant exception being no variability in the treatment dose with the Japan study.

The single-arm, single-site study enrolled 30 women ages 21 - 55 years old which had had at least one vaginal delivery. All women were treated once with RF energy of 90 Joules/cm^2. Outcomes were measured at baseline (i.e. - prior to treatment), one month, three months, six months and 12 months. Outcome measures were also similar to the U.S. study and included questionnaires related to vaginal tightness (VLQ) and sexual satisfaction (SSQ), mFSFI, FSDS-R and Global Response Assessment.

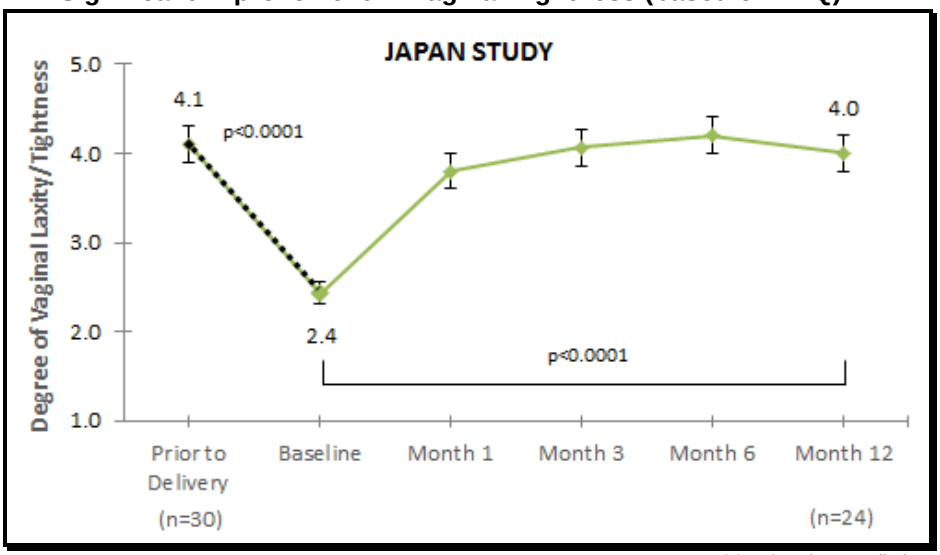
All 30 women completed the one month, three month and six month evaluations. At 12 months, 23 women completed the VLQ and SSQ questionnaires and 22 women completed were evaluable in FSFI and FSDS.

Results were published in the Journal of Women's Health in September 2013. At baseline 17 of the 30 subjects reported a decrease in sexual satisfaction with 13 reporting no change or decrease in sexual satisfaction since their last vaginal delivery. Average vaginal laxity of all the women prior to treatment was 2.4 on a 1.0 - 6.0 scale (higher = tighter).

A 95% confidence interval was used to designate statistical significance on all measures. Results showed statistically significant improvement in vaginal laxity within one month of treatment and throughout the 12-month evaluation period. The pre-treatment mean score of 2.4 increased to 4.2 at six months and was 4.0 at twelve months (23 patients were evaluable at 12 months).

[12] Millheiser LS. et al. *Radiofrequency Treatment of Vaginal Laxity after Vaginal Delivery: Nonsurgical Vaginal Tightening.* Journal of Sexual Medicine. Sept 2010

Significant Improvement in Vaginal Tightness (based on VLQ)

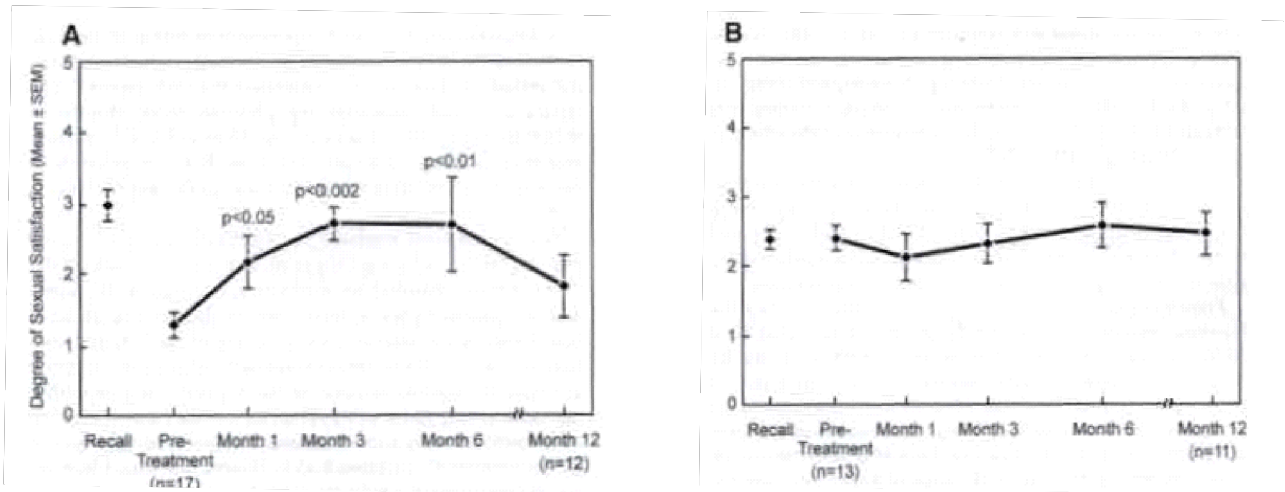


SOURCE: Viveve Medical Inc

Also, similar to results of the U.S. study, sexual satisfaction improved significantly. As reported by the Sexual Satisfaction Questionnaire (SSQ), sexual satisfaction improved at each follow-up period in 13 of the 17 women who expressed decreased sexual satisfaction at baseline. SSQ assesses sexual satisfaction using six levels of response (none, poor, fair, good, very good or excellent), with a higher score reflecting more satisfaction. SSQ scores of the 13 women who expressed decreased sexual satisfaction prior to treatment increased from an average of 1.29 at baseline to 2.71 at six months. At 12 months only 13 of these 17 women remained evaluable.

The SSQ scores of the 13 women who expressed no change (or no decrease) in sexual satisfaction prior to treatment remained significantly unchanged throughout the treatment period.

SSQ Improved in Those Expressing Sexual Dissatisfaction (A), No Change in Those Expressing No Dissatisfaction (B)[13]



[13] Sekiguchi Y. et al. *Laxity of the Vaginal Introitus After Childbirth: Nonsurgical Outpatient Procedure for Vaginal Tissue Restoration and Improved Sexual Satisfaction Using Low-Energy Radiofrequency Thermal Therapy.* Journal of Women's Health. Vol 22. Number 9 2013

Sexual function, as measured by FSFI showed significant improvement through the six month evaluation period, although not through 12 months (note that all 30 women were evaluable at six months while 22 were evaluable at 12 months). FSFI improved from a mean of 22.4 prior to treatment to 26.0 (p=0.002) at six months. Five of the six FSFI measures showed statistically significant improvement (all but "desire") at six months. At 12 months mean FSFI was 26.0 (p=0.080).

Distress related to sexual activity, as measured by FSDS-R, also significantly improved. Mean FSDS-R prior to treatment of 15.8 decreased to 9.8 at one month (p<0.001) and remained statistically lower throughout the evaluation period. At 12 months mean FSDR-R (for the remaining 22 evaluable subjects) was 10.3 (p<0.005).

Significant Improvement in Sexual Function (FSFI) and Sexually-Related Distress (FSDS-R)[12]

TABLE 2. CHANGES IN SEXUAL FUNCTION (FSFI) AND SEXUALLY-RELATED PERSONAL DISTRESS (FSDS-R) SCORES AFTER RF THERAPY FOR VAGINAL INTROITAL LAXITY

	Possible Score (Range)	*Baseline N=30*	*1M N=30*	*P*	*3M N=30*	*P*	*6M N=30*	*P*	*12M N=22*	*P*
FSFI										
Desire	(1.2–6)	3.3±0.8	3.0±0.8	0.043	3.1±0.9	0.190	3.2±1.0	0.310	3.25±1.0	0.741
Arousal	(0–6)	3.2±1.3	3.2±1.2	0.873	3.7±1.0	0.023	3.7±0.5	<0.01	3.6±1.6	0.363
Lubrication	(0–6)	4.5±1.5	4.7±1.5	0.219	5.0±1.1	0.089	5.1±1.3	<0.01	4.6±1.5	0.271
Orgasm	(0–6)	3.4±1.5	3.8±1.5	0.082	4.4±1.1	<0.002	4.2±1.4	<0.002	4.2±1.2	0.080
Satisfaction	(0.8–6)	3.6±1.5	4.1±1.2	0.052	4.5±1.1	<0.001	4.4±1.1	0.001	4.2±1.3	0.119
Pain	(0–6)	4.5±1.7	5.1±1.8	<0.01	5.3±1.3	<0.02	5.3±0.9	0.005	4.8±1.8	0.503
Total Score	(2–36)	22.4±6.7	23.9±6.7	0.038	26.0±5.1	0.002	26.0±5.8	0.002	26.0±5.2	0.080
FSDS-R										
Total Score	(0–52)	15.8±11.7	9.8±8.0	<0.001	8.9±7.4	<0.001	9.9±8.2	0.002	10.3±8.7	<0.005

Data are mean±SD.
P value determined by Wilcoxon signed rank test for paired samples, months 1, 3, 6, and 12 compared to pretreatment.
N, number of subjects.

Relative to safety, there were no serious treatment related adverse events. On a visual analog (VAS) pain scale of 1 - 10 (10 most pain) the average score was 1.5 with seven subjects reporting sproadic pain in the range of 5 - 7. All women reported returning to their normal activities when questioned at 72-hour follow-up. Subjects reported that they returned to vaginal intercourse within 10 days post-treatment.

> Sham-Controlled, Larger Study Reports Positive Top-Line Results

While the studies that have been completed so far have been relatively small and single-arm, a much larger and sham-controlled clinical trial recently reported highly positive data.

Viveve announced positive top-line results of VIVEVE I (VIveve Treatment of the Vaginal Introitus to EValuate Effectiveness), its sham-controlled clinical trial assessing safety and efficacy of the Viveve System in more than 150 patients at 9 sites in Europe, Canada and Japan. While results of two previous smaller studies (one in U.S.: n = 23, one in Japan: n = 30) had already demonstrated that treatment with the Viveve System can significantly reduce vaginal laxity and improve sexual function, this VIVEVE I study is the largest to-date and the first sham-controlled study evaluating the Viveve System for the treatment of vaginal laxity as well as for sexual function.

VIVEVE I Design / Protocol…

Enrollment was initially expected to be 113 patients - the study protocol was subsequently updated (per clinicaltrials.gov) to enroll an expected 145 – final enrollment ended up being 174 patients (117 active, 57 sham) with vaginal laxity efficacy data on a 'per-protocol' population of 155. Subjects were randomized 2:1 (active:control) - patients were blinded, treating personnel were not. The treatment group received 90 Joules/cm2 of RF energy delivered via the Viveve System while the sham group received <1 Joule/cm2. Subjects were followed through the six month follow-up period with assessments at day 10 and months 1, 3 and 6.

Key inclusion / exclusion criteria included;[14]

- Inclusion:
  - pre-menopausal and ≥ 18 years of age
  - had least one full term vaginal delivery (>37 completed weeks) at least 12 months prior to enrollment date
  - experienced vaginal looseness (i.e. VSQ < 4) during vaginal intercourse
- Exclusion:
  - Pregnant or planning to become pregnant within the next 12 months or has had a delivery within the last 12 month

[14] Clinicaltrials.org. ClinicalTrials.gov Identifier: NCT02261974. VIveve Treatment of the Vaginal Introitus to EValuate Effectiveness (VIVEVE I)

- currently meets the criteria for a female sexual disorder including DSM V, FSAD, FOD, Genitopelvic Pain, Sexual Aversion, Dyspareunia or Vaginismus and has not been treated for this condition within the past 12 months
- taking SSNRI or SSRI drugs

Primary efficacy endpoint was the proportion of women in the treatment arm as compared to the proportion of women in the sham (i.e. - control) arm that report no vaginal laxity six months following treatment as measured by Viveve's specially designed questionnaire, VSQ ("Viveve System Questionnaire"). VSQ, which is similar to the VLQ questionnaire used in the two prior studies, is based on a seven point scale (1:very loose, 2:moderately loose, 3:slightly loose, 4:neither loose nor tight, 5:slightly tight, 6:moderately tight, 7:very tight). "No vaginal laxity", as defined in the VIVEVE study protocol, is a VSQ score of >4.

Secondary efficacy endpoints were the percentage change in mean score from baseline to six months following treatment of the active arm as compared to the control arm in 1) the Vaginal Laxity Inventory (VALI), 2) Total FSFI and 3) FSDS-R. See our Appendix for detailed description of these secondary measures.

Study Results: Primary and FSFI Endpoints Highly Statistically Significant….
Results were positive, showing a highly statistically significant difference between the active and sham arms on the VSQ (i.e. laxity) primary endpoint as well as the FSFI (i.e. sexual function) secondary endpoint. In addition, safety was considered excellent with no difference in adverse event rates between the treatment and sham cohorts.

VSQ
Of the 174 subjects enrolled and randomized, 19 were not evaluable for efficacy purposes due to not completing the 6-month follow-up or for other protocol violations. The per-protocol population included 103 active and 52 sham subjects. At the 6-month follow-up, 41.7% (43/103) of active subjects reported having no vaginal laxity (i.e. VSQ > 4) compared to just 19.2% (10/52) of subjects that received sham treatment. The difference was highly statistically significant with a Chi-squared p-value of 0.005. Active subjects were 3.05x more likely to achieve 'no vaginal laxity' at 6 months than were sham subjects (95% confidence interval, p-value = 0.006).

Mean VSQ score at the 1, 3 and 6 month follow up periods were;
- 1-month: 3.9 active vs. 3.8 sham (difference of 0.1)
- 3-month: 4.1 active vs. 3.9 sham (difference of 0.2)
- 6-month: 4.1 active vs. 3.4 sham (difference of 0.7)

The mean difference at 6 months of 0.7 is statistically significant at a 95% confidence interval (p=0.007). The widening difference in mean VSQ over the course of the assessment periods is believed to be representative of weakening of a placebo effect in the sham arm.

FSFI
Similar to the two prior studies, VIVEVE I demonstrated that treatment with the Viveve System is associated with a significant increase in sexual function. FSFI is a brief, 19-item self-report measure of female sexual function that provides scores on six domains of sexual function as well as a total score. It was developed for the specific purpose of assessing sexual functioning in clinical trials. These 19 items include: desire (2 items), arousal (4 items), lubrication (4 items), orgasm (3 items), satisfaction (3 items), and pain (3 items) and are scored from 0 to 5. The FSFI total score is a weighted average of the six domains with each contributing a maximum of six points to the total (maximum score of 36). Wiegel, Meston and Rosen demonstrated that a cutoff of 26.55 discriminates between women with and without sexual dysfunction.[15]

103 (71 active, 32 sham) patients were included in the FSFI per-protocol population. Of the six domains, two (sexual arousal and orgasm) were statistically different favoring the active arm. And while the other four were not statistically different, there was a positive response favoring the active group. The individual p-values were (p-value < 0.05 is considered statistically significant);

- desire 0.081
- arousal 0.007
- lubrication 0.095
- orgasm 0.004
- satisfaction 0.097
- pain 0.122

[15] Wiegel M1, Meston C, Rosen R. The female sexual function index (FSFI): cross-validation and development of clinical cutoff scores. J Sex Marital Ther. 2005 Jan-Feb;31(1):1-20.

But while just two of the six individual domains hit statistical significance, the weighted average of the six domains of the active arm (27.5) was statistically different from that of the sham arm (24.3) at the 6-month follow-up. In addition, the weighted average scores of the six domains on the active arm at 1-month (27.0), 3-month (27.6) and 6-month (27.5) follow up were all above 26.55 (i.e. considered sexually functional) while the scores of the sham arm at each of these timepoints (1-month: 25.5, 3-month: 25.9, 6-month: 24.3) were all below 26.55 (i.e. considered sexually dysfunctional). Similar to the VSQ measure, there was some placebo effect in the sham arm that began to wane at about 3 months following initiation of treatment.

Importantly, the expectation is that the weighted average total score, as opposed to individual domain scores, is what FDA will be looking for as an endpoint in VIVE's proposed pivotal U.S. study. And while it is uncertain as to whether FDA will accept FSFI as a primary endpoint in VIVEVE II, we are encouraged that this is a clinical industry metric which has already been well-validated and documented. We think if accepted by FDA, that these VIVEVE I results, coupled with similarly positive FSFI results in the prior two studies, bode well for chances that VIVEVE II also hits statistical significance on FSFI.

VALI and FSDS-R

Vaginal Introitus Laxity Inventory and Female Sexual Distress Scale-Revised were the other two secondary endpoints. VALI relates to the respondents' concern of laxity and how that may affect sexual functioning while FSDS-R relates to a respondents' feelings of sexual activity-related distress based on a 13-item questionnaire.

While neither VALI or FSDS-R scores were statistically different between active and sham arms in VIVEVE I, we do not view this as problematic as it relates to the proposed U.S.-based controlled study as they have no cross-over relevance to the expected primary (FSFI) or secondary (VSQ) endpoints for VIVEVE II (i.e. – upcoming study). We think VIVE likely included VALI and FSDS-R in VIVEVE I in order to stack in additional metrics so as to offer other options in the event FSFI and/or VSQ failed to show statistical significance.

SAFETY

Similar to the two prior studies, safety was considered excellent in VIVEVE I. All 174 (117 active, 57 sham) enrolled and randomized patients underwent a safety evaluation. There was no statistical difference in safety measures between the two arms;

- treatment-emergent adverse events; 32.5% active vs. 35.1% sham
- related treatment-emergent adverse events; 11.1% active vs. 12.3% sham
- serious treatment-emergent adverse events; 0% active vs. 1.8% sham

NEXT STEPS

U.S. IDE: VIVE has now completed the final analysis and packaged the data for an expected upcoming IDE submission in anticipation of conducting a U.S.-based pivotal study in support of an eventual de novo 510(k) filing. On the Q2 call management noted that they expect to submit the IDE following response from FDA on the general surgical procedure filing - which could happen later this year.

VIVE intends to seek an indication for 'the treatment of vaginal tissue to improve sexual function', with (weighted average total) FSFI as the primary endpoint. While 'vaginal laxity' as measured by VSQ (or a version of) was the primary endpoint in all three of Viveve's clinical trials, VSQ is a proprietary metric developed by Viveve and may not be deemed acceptable to FDA without further scrutiny and validation. By contrast, FSFI is a clinical industry metric which has already been well-validated and documented. Management has also previously noted that they hope to incorporate VSQ as a secondary endpoint.

So assuming FDA concurs with a proposed FSFI endpoint and eventual FDA clearance for the treatment of vaginal tissue to improve sexual function indication, the Viveve System would be the only therapy approved for that claim providing significant and substantive difference from all other vaginal laxity-related devices. This, in our opinion, could be a game-changer for Viveve.

Marketing Message: VIVE will also likely look to have the VIVEVE I data published. They will also certainly be incorporated into the current marketing message outside of the U.S. We think this data could be potent – while the two prior studies provided evidence of significant efficacy of the Viveve System in both vaginal laxity and sexual function, the larger size and sham-controlled nature of VIVEVE I should provide clinicians with a much more definitive conclusion to the device's effectiveness.

U.S. Study: assuming IDE approval, VIVE will move towards clinical trial site selection and IRB approvals. While the company has yet to offer specifics in terms of expected design / size of a U.S.-based study, given that VIVEVE I was able to hit highly statistically significant results with enrollment of less than 200 patients, we don't expect VIVEVE II would be significantly different in size – although with the possibility of slightly greater enrollment (~10% - 20%) to provide an additional cushion. VIVEVE I was conducted at nine sites – expect a similar number, possibly one or two additional, for VIVEVE II.

We expect additional interaction between VIVE and FDA leading up to and following the IDE submission. Discussions should include finalizing clinical trial design including size, endpoints and indications. We note that VIVEVE I was obviously not a U.S. or in any way an FDA-affiliated study – as such, design, size, endpoints and other components of VIVEVE II could differ from that of VIVEVE I, and potentially meaningfully so. We may know more in the coming few months.

In the meantime….VIVE will continue to seek labeling for general surgical procedures for coagulation and hemostasis, including gynecological tissue for their current device, which already has FDA clearance for general surgical procedures. Management noted on the Q2 call that the application was accepted by FDA for review in late May, VIVE received questions from the agency in mid-July and the company subsequently submitted their response. VIVE expects to hear back from FDA in the fall (Sept). If clearance is granted with the expanded label, VIVE would then prepare to commercialize if not, they will look to update their current 510(k) for general surgical procedures via a design history file update (essentially updating the file to include any changes to the device/technology) - VIVE believes that they could have clearance under the general surgical procedures indication prior to current year end. As we have noted in our ongoing coverage of VIVE, this will provide VIVE will some early revenue opportunity but, perhaps more importantly, initial awareness building in the U.S. as they pursue a sexual function indication.

COMPETITION

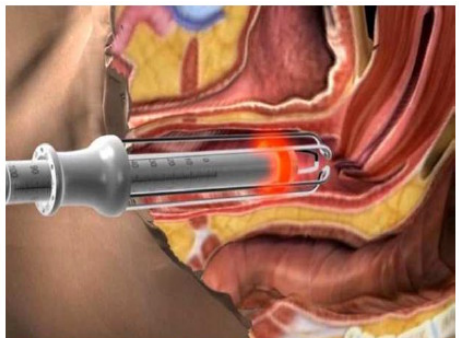
Aside from Kegel's and vaginal surgery, which we believe suffer from significant drawbacks, the Viveve System will face other competition. Our due diligence uncovered two therapies that are aimed specifically at treating vaginal laxity by non-invasive means. These are IntimaLase, a 2940nm Er:YAG "non-contact, non-invasive" laser made by Fotona, a significant laser manufacturer based in California and FemiLift, a CO_2 laser manufactured by Alma Surgical, a medical laser company based in Illinois.

IntimaLase

Treatment with IntimaLase consists of two treatment sessions, spaced approximately 15 - 30 days apart. No anesthesia is required. Per Fotona, the laser tightens the walls of the vagina through precisely placed non-ablative laser pulses which heat the collagen in the vaginal tissue.

IntimaLase was used in a 21-patient pilot study[13] from June 2011 to January 2012. The subjects, aged 21 -61 years old, all reported suffering from vaginal looseness. Only 10 of the patients had had one or more vaginal deliveries, with three having deliveries via c-section and eight never having had children.

IntimaLase Procedure[16]



A specially designed laser vaginal tightening questionnaire was used to assess vaginal tightening - which was given to both the patient and their partners. This questionnaire also included one question to assess the subject's perception of changes in their sexual gratification following treatment. Follow-up occurred at 48 hours following each treatment, prior to the second session and three months after completion of treatment.

Results on the laser vaginal tightening questionnaire showed that all 21 patients reported improved vaginal tightness with one reporting mild improvement, 16 as moderate and 4 as strong. 20 of the 21 patients responded to

[16] Gaviria P, JE, Lanz L, JA. *Laser Vaginal Tightening (LVT) - evaluation of a novel noninvasive laser treatment for vaginal relaxation syndrome.* Journal of the Laser and Health Academy. Vol. 2012, No.1 www.laserandhealth.com

the questionnaire with 3 reporting mild improvement, 10 moderate and 7 strong improvement. In terms of changes in sexual gratification, 20 of the 21 patients reported improvement in sexual gratification following treatment. Pain was assessed using a VAS scale. 10 of the 21 patients reported the procedure was totally painless (score of 0) with 11 reporting mild pain (scores of 1 and 2). No treatment related serious adverse events were reported and patients returned to normal daily activities within three days of treatment.

We note that given the very small study populations of both the Viveve System and IntimaLase, coupled with the subjectivity of questionnaires and inherent non-comparability of the studies based on differences in study designs (including outcome measures), that it is not possible to make a scientific comparison between the efficacy of the two devices. We think it is relevant to note, however, that follow-up with the Viveve studies was up to 12 months, while this IntimaLase study follow up was only up to three months.

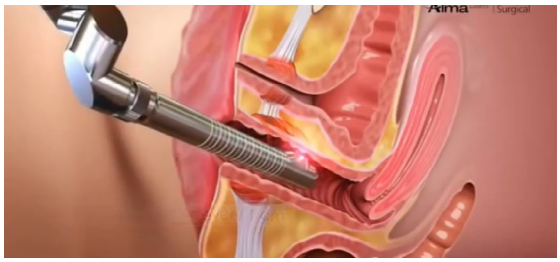
Aside from potential differences in efficacy (or safety) - which, again we do not think is currently possible to confidently ascertain, competitiveness may favor the Viveve System due to a lower treatment burden. Treatment with the Viveve system consists of one ~30-minute session while treatment with IntimaLase requires two sessions spaced 15 - 30 days apart.

FemiLift

Alma Lasers' FemiLift uses a 30W CO_2 laser. Similar to IntimaLase, the laser is non-invasive and is used to heat the vaginal tissue to tighten it. Per Alma, the procedure can be done in one 30 minute session, does not require anesthesia and is virtually painless.

CO_2 lasers have been used for a decade or more for the treatment of skin conditions including wrinkles, sun exposure and acne. More recently they have been used for rejuvenation of vaginal tissue, although most of which appears to be focused on symptoms such as dryness, urinary burning and itching, as opposed to vaginal laxity. We have found no clinical studies which evaluate CO_2 lasers in the treatment of vaginal laxity - although we are not implying that they may potentially be efficacious or safe in that application.

FemiLift Procedure



SOURCE: Alma Surgical

REGULATORY / COMMERCIALIZATION

Distribution

We think it is clear that the aggressive onboarding of third party distribution over the last several months is paying dividends and should bode well for further unit placement and revenue growth. VIVE now has distribution in 65 countries - this is up from only about 20 in mid-2015, and regulatory approval in 22. We expect more territories and distribution agreements to come online in 2016 including potentially in Brazil and the U.S., the two leading markets for vaginal rejuvenation procedures.

As of June 2016

GEOGRAPHIC REGION	DISTRIBUTION COVERAGE	REGULATORY CLEARANCE
North America	1	1
Latin America	15	2
Europe	28	18
Asia Pacific	11	6
Middle East	10	-
TOTAL	**65**	**27**

Valuation / Recommendation

We think it is relevant to look at Thermage, Inc.'s (Thermage was acquired by Valeant Pharmaceuticals in early 2014) ThermaCool system as a rough guide on which to base a forecast for the roll-out and economics of the Viveve System. The Viveve System is based on the same technology as the ThermaCool system, which launched in late 2002 for the treatment of wrinkles and skin tightening on the face and other parts of the body. The ThermaCool revenue model is also similar to that of the Viveve System - essentially to build a sufficient installed base of consoles which will then feed an ever-growing revenue stream of consumables. The consumables are also very similar and include a treatment tip, return pad, coolant and other small accessories.

The potential market size for skin tightening is many multiples larger than that for vaginal tightening. According to ISAPS there were 309k facelift procedures and 56k surgical vaginal rejuvenation procedures performed in 2011. Using these as rough proxies for the respective U.S. markets for non-invasive skin tightening and vaginal tightening, implies the former is 5x - 6x the size of the latter.

Another difference related to the end-user markets, which we account for in our financial projections, is that the availability of facial and body non-invasive skin tightening is almost certainly much more common knowledge than it is for non-invasive vaginal tightening. Also, while there is little embarrassment associated with inquiring about addressing facial wrinkles, uptake of cosmetic vaginal procedures has been hampered as a result. We think these differences will be reflected in a more moderate adoption curve of the Viveve System as compared to that of ThermaCool.

In addition to selling to a significantly larger target market, Thermage has had the benefit of a highly scaled distribution platform. Their distribution as of the end of 2006 (ThermaCool's fourth year on the market), the earliest period in which we were able to find this information, included sales through 29 distributors in 70 countries and a direct sales force in the U.S.

In the first full year on the market (i.e. - 2003) 587 ThermaCool consoles and 40k treatment tips (including the other consumables) were sold. Thermage notes in their filings that each treatment tip represents approximately one treated patient. Thermage averaged annual sales of over 500 consoles and almost 100k per-patient consumables during the first six years following ThermaCool launch and had an installed base of approximately 525k consoles at the end of that period (i.e. - 2008). Their total installed base at the end of 2012, which includes complementary products acquired since 2009, was approximately 9,300 units.

	ThermaCool Years on the market						
	1	2	3	4	5	6	**Avg**
Tips/Cons Sold	40,233	94,099	83,662	130,690	136,000	112,000	**99,447**
Consoles Sold	587	612	408	437	633	478	**526**
Tips sold to-date	40,233	80,466	174,565	258,227	388,917	524,917	
Consoles sold to-date	587	1,199	1,607	2,044	2,677	3,155	

In terms of pricing and utilization, Thermage averaged approximately $30k per console and $300 of consumables per-patient during the first six years. Utilization per console averaged approximately 5x per month over the same period.

	ThermaCool Years on the market						
	1	2	3	4	5	6	Avg
Sale price / tip	$180	$321	$323	$301	$332	$370	**$304**
Sale price / console	$29,705	$32,104	$30,886	$30,435	$25,750	$28,452	**$29,555**
Average Monthly Utilization per console	5.7	6.5	4.3	5.3	4.2	3.0	**4.9**

Our Financial Model Assumptions…

So while certain differences in Thermage's product, target market, competitive landscape and early distribution capabilities may not provide a specific template for what to expect with the roll-out of the Viveve System, we think it is a useful gauge, at least in terms of illustrating the potential demand for the technology (which is essentially the same), pricing and utilization in the respective end-user markets.

We currently model a unit placement rate of about 12 per month in 2016 (compared to about 8 per month in 2H 2015) and estimate utilization at ~2- 3x per month. Entry into other countries and onboarding of additional distribution should push the installed base higher and similarly benefit utilization. Leveraging the positive clinical data from VIVEVE I should also be a meaningful catalyst to the placement and utilization rates.

Entry into the U.S. market could come as soon as 2017 (with a general or enhanced general surgery label) and in 2018 - 2019 for a more substantive 'treatment of vaginal tissue to improve sexual function' indication. Coupled with a greater marketing push, expanded OUS distribution and additional clinical data to support sales, we think it is reasonable that Viveve could increase the unit placement rate by approximately 15 - 20 consoles per year from 2018 to 2024. This results in a total installed base of almost 1,700 units after ten years on the market, which compares to ~9,300 units with Thermage's products over roughly the same period of time. Again we account for the much more moderate roll-out with the Viveve System and much smaller market as compared to Thermage. We also think that a reasonable case would be made that our forecasted unit placement rate is conservative, particularly given that competition in Thermage's target market is much more intense and widespread than that of Viveve's.

We model utilization to improve with greater awareness of the benefits of non-invasive vaginal tightening and, potentially with a generation of women that may feel less embarrassed about broaching the subject of vaginal laxity with their physician. Our modeled utilization improves from 2x - 3x per month to just over 5x per month at year 2024.

Relative to pricing, we again may be erring on the side of conservatism. While list price of the Viveve console is $60k and per-patient consumables are estimated to sell for approximately $600, we use initial pricing of $30k and $350, respectively. This more closely mirrors Thermage's legacy pricing over the first six years - although inflation and less competition in the vaginal tightening space may imply that these estimates are on the low end, particularly given the potential for higher pricing in the U.S. market.

DCF Values VIVE at $11/share

We use a 10-year DCF model to value VIVE. Using the inputs discussed above, we have revenue growing from $5.7M in 2016 to $22.0M in 2019 and to approximately $78M in 2026 (for reference, Thermage's sales were $50M+ at second year after ThermaCool launch). .

Other key inputs to our DCF include a 11% discount rate and 2% terminal growth rate. Based on our DCF model, VIVE is valued at approximately $11/share. Our outlook and financial estimates are subject to change based on progress with expansion of distribution, results of clinical trial data and regulatory approvals, among other events.

APPENDIX

VIVEVE I Secondary Outcome Measures

Female Sexual Function Index (FSFI)
FSFI is a brief, 19-item self-report measure of female sexual function that provides scores on six domains of sexual function as well as a total score. It was developed for the specific purpose of assessing sexual functioning in clinical trials. These 19 items include: desire (2 items), arousal (4 items), lubrication (4 items), orgasm (3 items), satisfaction (3 items), and pain (3 items) and are scored from 0 to 5. The FSFI total score is a weighted average of the six domains with each contributing a maximum of six points to the total (maximum score of 36). Wiegel, Meston and Rosen demonstrated that a cutoff of 26.55 discriminates between women with and without sexual dysfunction.[17]

Female Sexual Distress Scale-Revised (FSDS-R)[Error! Bookmark not defined.]
FSDS-R is a patient-reported outcomes measure consisting of 13 items assessing different aspects of sexual activity-related distress in women. It has a high degree of discriminative sensitivity to distinguish between sexually dysfunctional and normal functional women and is sensitive to therapeutically inducted changes in function. Items are scored on a five-point Likert-type scale as never (0), rarely (1), occasionally (2), frequently (3), or always (4). A total score, ranging from 0 to 52, can be computed by adding all 13 item scores. Higher scores indicate higher levels of sexual distress. The provisional cut-off score of $\geq$15 reliably identifies over 90% of women who are currently experiencing sexually related personal distress (Derogatis et al 2008).

Vaginal Introitus Laxity Inventory (VALI)[18]
Vaginal Introitus Laxity Inventory is a 12-item patient reported outcome measure (i.e., PRO) designed to describe and quantify the nature of a female respondent s concern with the perception of laxity (looseness) and its impact on the qualities of satisfaction and enjoyment of her sexual functioning. Items of the VALI address the impact of laxity on the major aspects of the female sexual response cycle (i.e., sexual desire, arousal and orgasm), and quantify the patient s experience of sexual pleasure, sensitivity and satisfaction. The VALI items also address the potential impact of vaginal introitus laxity on sexual confidence and the patient s partner. All 12 items are measured on 5-point Likert scales and scores are summed to achieve a VALI Total score, range 0-48).

[17] Wiegel M1, Meston C, Rosen R. The female sexual function index (FSFI): cross-validation and development of clinical cutoff scores. J Sex Marital Ther. 2005 Jan-Feb;31(1):1-20.
[18] Description taken verbatim from Viveve's Protocol Report for the VIVEVE 1 study

FINANCIAL MODEL

Viveve Medical, Inc

	2015 A	Q1A	Q2A	Q3E	Q4E	2016 E	2017 E	2018	2019
Total Revenues	$1,447.0	$1,284.0	$1,556.0	$1,322.1	$1,493.0	$5,655.1	$11,016.9	$16,491.7	$21,462.0
YOY Growth	*1507.8%*	*3278.9%*	*2031.5%*	*126.4%*	*98.5%*	*290.8%*	*94.8%*	*49.7%*	*30.1%*
Cost of Goods Sold	$985.0	$936.0	$1,022.0	$856.3	$944.6	$3,758.8	$6,589.8	$8,712.7	$9,355.1
Gross Income	$462.0	$348.0	$534.0	$465.8	$548.4	$1,896.2	$4,427.1	$7,779.0	$12,106.8
Gross Margin	*31.9%*	*27.1%*	*34.3%*	*35.2%*	*36.7%*	*33.5%*	*40.2%*	*47.2%*	*56.4%*
SG&A	$7,464.0	$2,548.0	$2,615.0	$2,555.0	$2,794.0	$10,512.0	$12,228.7	$13,853.0	$14,594.1
% SG&A	*515.8%*	*198.4%*	*168.1%*	*193.3%*	*187.1%*	*185.9%*	*111.0%*	*84.0%*	*68.0%*
R&D	$4,988.0	$1,796.0	$2,463.0	$1,881.0	$1,864.0	$8,004.0	$8,615.0	$5,544.0	$4,789.0
% R&D	*344.7%*	*139.9%*	*158.3%*	*142.3%*	*124.9%*	*141.5%*	*78.2%*	*33.6%*	*22.3%*
Operating Income	($11,990.0)	($3,996.0)	($4,544.0)	($3,970.2)	($4,109.6)	($16,619.8)	($16,416.6)	($11,618.0)	($7,276.3)
Operating Margin	*-828.6%*	*-311.2%*	*-292.0%*	*-300.3%*	*-275.3%*	*-293.9%*	*-149.0%*	*-70.4%*	*-33.9%*
Total Other Income (Expense)	($436.0)	($110.0)	($772.0)	($197.5)	($197.5)	($1,277.0)	($741.2)	($513.6)	($178.7)
Pre-Tax Income	($12,426.0)	($4,106.0)	($5,316.0)	($4,167.7)	($4,307.1)	($17,896.8)	($17,157.8)	($12,131.6)	($7,455.0)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-
Net Income (continuing ops)	($12,426.0)	($4,106.0)	($5,316.0)	($4,167.7)	($4,307.1)	($17,896.8)	($17,157.8)	($12,131.6)	($7,455.0)
YOY Growth	*101.1%*	*135.6%*	*-14.0%*	*65.1%*	*43.3%*	*44.0%*	*-4.1%*	*-29.3%*	*-38.5%*
Net Margin	*-858.7%*	*-319.8%*	*-341.6%*	*-315.2%*	*-288.5%*	*-316.5%*	*-155.7%*	*-73.6%*	*-34.7%*
EPS (continuing ops)	($2.48)	($0.55)	($0.66)	($0.39)	($0.40)	($1.94)	($1.37)	($0.89)	($0.52)
YOY Growth	*-75.5%*	*-73.9%*	*-93.5%*	*-64.3%*	*-40.4%*	*-21.9%*	*-29.3%*	*-35.5%*	*-41.5%*
Diluted Shares O/S	5,000	7,493	8,081	10,600	10,700	9,218	12,500	13,700	14,400

Brian Marckx, CFA

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