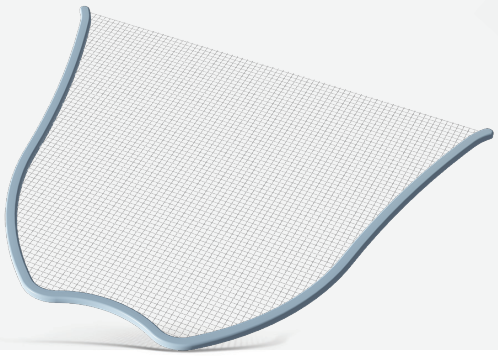
lyra medical

Brilliantly Simple

The **safe**, **easy** and **effective** way to restore organ support in women suffering from advanced anterior vaginal wall prolapse with or without apical prolapse

IT'S SIMPLE.
IT'S SAFE.
IT WORKS.

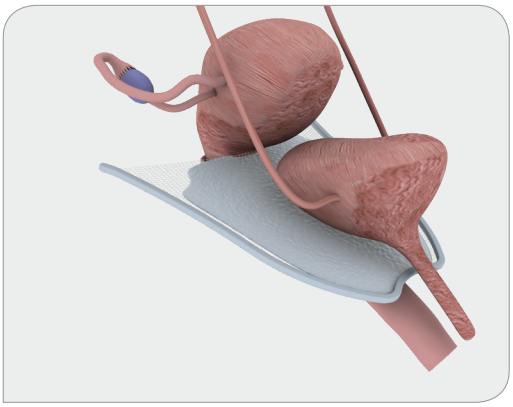


Lyra Medical's implant is a revolutionary surgical treatment for women suffering from advanced anterior vaginal wall prolapse with or without apical prolapse. The Self-Retaining Support (SRS) technology eliminates the need for complex anchoring techniques delivering a safe and long-term treatment solution.

Lyra's technology mimics the physiologic pubocervical fascia and restores pelvic organs to their anatomical and functional location. This anchorless technique restores transvaginal implants as a viable, safe and effective treatment that far surpasses current mesh kits, sacrocolpopexy and native-tissue repair procedures.

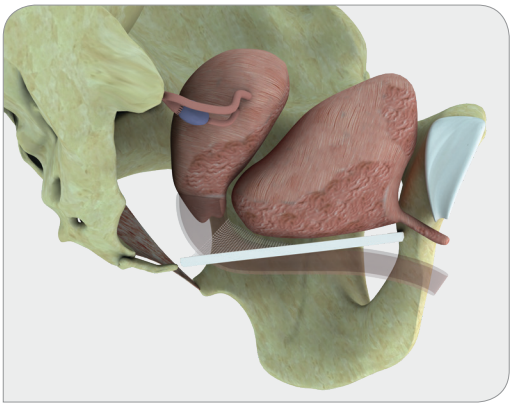
Safe

- Eliminates mesh complications
- Frame retains mesh tension and prevents folding, eliminating the risk of erosion
- Frame prevents mesh contraction and over-time tension, eliminating failures, pain and dyspareunia
- No blind insertion of trocars, eliminating the risk of bleeding or organ perforation



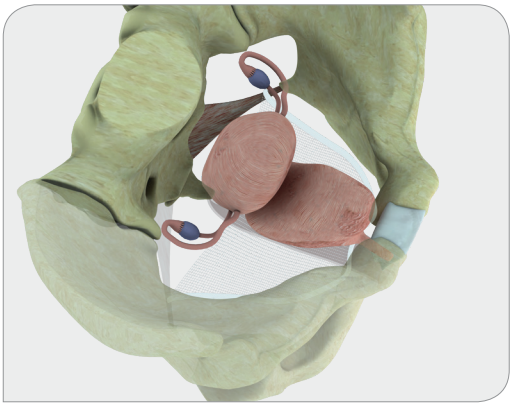
Easy to Use

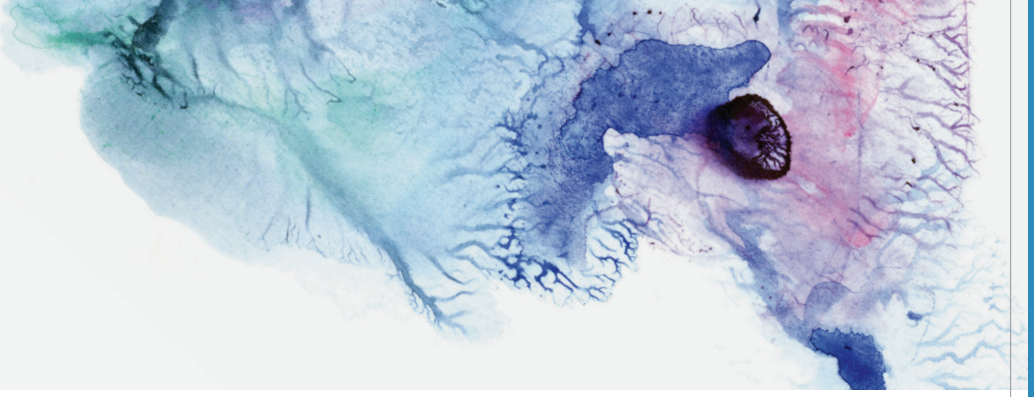
- Identically follows current surgical techniques while eliminating the need for complicated fixation steps
- Simplifies the procedure
- Short operation time
- Short learning curve



Long-term Efficacy

- Accurately imitates physiologic support
- Trampoline-like concept accommodates dynamic intra-abdominal pressures
- Offers complete anatomical cure for women suffering from symptomatic anterior vaginal with or without apex / uterine apical POP-Q grade ≥2 prolapse
- Conclusive, anatomical cure maintained at all follow-up visits





Ongoing Clinical Trials

70 patients were recruited and treated in international multi-center studies. As of August 2019, available data includes a follow-up period of 27.7 (range 11.4-41) months.

Lyra's first-in-women trial was initiated in September 2014, at three Medical Centers in Israel and Europe followed by an additional study initiated in March 2016 in three study centers in Israel. Both studies include patients suffering from symptomatic ≥2 degree anterior vaginal with/without apical prolapse. The vast majority of patients (90%) were stages 3 and 4. As of August 2019, 27 (39%) patients completed their 36-month follow-up, 33 (47%) completed their 24 month follow-up and 10 (14%) patients completed their 12 month follow-up. Only one patient refused vaginal examination after the 12 month follow-up visit, but was still followed-up for subjective results. This patient reported no AEs, no symptoms and no other changes from her previous (12 mo.) follow-up visit.

Variable	Baseline	Post-Operative
POP-Q:		
Stage 0	0	57 (81.4%)
Stage 1	0	9 (13%)
Stage 2	7 (10%)	4 (5.7%)
Stage 3	51 (73%)	0
Stage 4	12 (17%)	0
Mean point Aa (cm)	2.0 (-1 to 3)	-2.9 (0 to -3)
Mean point Ba (cm)	3.1 (-1 to 6)	-2.8 (0 to -3)
Mean point C (cm)	0.4 (-8 to 6)	-6.9 (-10 to 1)

* Values given as # of patients (%), mean cm (range)
** Last follow-up visit for each patient [N=70]. As of December 2018: 19 patients (27%) completed their 36 months FU; 24 patients (34%) completed their 24 months FU; 26 patients (37%) completed their 12 months FU; all the patients completed their 6 months FU;

All procedures have been carried out uneventfully. No mesh erosions or chronic pelvic pain were observed in any patient until now. One patient experienced a frame erosion which was solved by partial removal of the implant bridge under local anesthesia without any further consequences. This was the only patient implanted with a large implant.

To date, objective anatomical, subjective and safety results are similar in both studies. One patient (1.4%) had a symptomatic recurrence of her apical prolapse (C=0), two patients (2.8%) had an asymptomatic recurrence of their apical prolapse, representing 91.4% anatomical success.

Results suggest that the safety profile and clinical outcome of an anchorless implant is potentially better than that reported for other trans-vaginal surgical meshes, sacrocolpopexy or native tissue repair procedures.

For further details refer to these studies in the white paper available on Lyra Medical's website (www.lyramedical.com), under the resources tab.

The Lyra SRS Implant is available for sale under CE.

> "SRS technology provides the ultimate implant for the treatment of anterior wall vaginal prolapse. The ease of use and the impressive anatomical and subjective outcomes are far superior to any other mesh implants ever used.I am confident that SRS-based solutions will revolutionize the treatment of prolapse, the same way that TVT did to treating incontinence. I have no doubt that SRS will become the next gold standard for reconstructive pelvic surgery."
>
> **Prof. Mauro Cervigni, Professor Urogynecology,** Dept. Urology "La Sapienza" Univ.-Polo Pontino, ICOT-Latina, Italy

> "My previous experience with vaginal mesh made the Lyra SRS implant procedure easy to adopt. The surgery itself was short and the postoperative recovery was without any noticeable adverse events. At the follow-up visits, I was very satisfied when patients expressed their gratitude on the outcome and from the short and painless recovery period. Overall, the anatomical and subjective results are excellent."
>
> **Dr. Anna Padoa,** Assaf Harofeh Medical Center, Israel, Editor: "The Overactive Pelvic Floor"

> "While carrying out my first procedure I realized that the device can provide an excellent solution for pelvic organ prolapse. The simplicity of the Lyra SRS insertion makes it the most straightforward implant I have ever used. The anatomical and subjective results are very promising in comparison to mesh solutions I have used in the past. I hope that more of my patients will get the chance to benefit from the Lyra SRS solution in the future."
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> **Dr. Zoltán Fekete** Head of Urogynecology Division, Szeged University Hospital, Szeged, Hungary

> "When you examine a happy patient with optimal anatomy 24 months after SRS implantation, you realize that this unique design provides perfect results even in the most advanced prolapse cases. The Lyra SRS is optimal: short procedure, painless recovery and superior subjective and anatomical results. It is hard to use any other implant after you see the results of the Lyra SRS."
>
> **Dr. Gil Levy,** Director Devision of Female Pelvic Medicine, University Hospital, Assuta Ashdod, Israel

> "The Lyra SRS implant is very friendly and easy to use. With an overall operating time of 12 minutes from start-to-end, it's the fastest procedure that I have ever done. So far the anatomical results are very promising."
>
> **Dr. Na'ama Marcus,** Head of Urogynecology Unit, Ziv Medical Center, Israel

About Lyra Medical

Lyra Medical has developed a new implant for the surgical treatment of pelvic organ prolapse (POP).

The company's self-retaining support (SRS) technology eliminates the need for complex anchoring techniques to assure a safe and long-term treatment solution. The company's SRS technology is presently being applied for the treatment of advanced anterior vaginal wall prolapse with or without apex / uterine prolapse.

Lyra's technology mimics the natural anatomy and restores pelvic organs to their functional and physiological location. It represents a new anchorless method that significantly improves current transvaginal mesh (TVM) solutions. SRS technology was developed to eliminate the high complication rate associated with current anchored TVMs and reverse the low success rate associated with native-tissue repair. Lyra's solution is being proven in clinical trials to deliver exceptional safety and long-term efficacy. For more information, please visit www.lyramedical.com

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