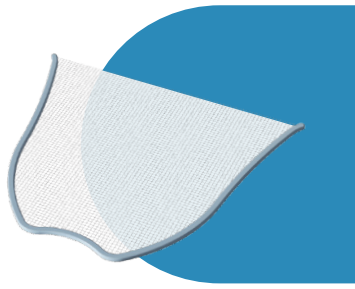
Anchorless, Self-Retaining Support (SRS)



A new anchorless implant for the surgical treatment of Pelvic Organ Prolapse (POP)

Existing transvaginal implants (TVM) are associated with severe safety risks, to the extent that they have been banned in the US. At Lyra Medical we understand that these risks stem from the need to anchor these implants into the pelvic structure, regardless of the specific anchoring method or the implant's material. Lyra Medical's Self-Retaining Support (SRS) technology addresses this safety issue by eliminating the need to anchor the transvaginal implant. Additionally, this transformative technology provides durable mechanical support that restores pelvic organs to their anatomical and functional location, thereby addressing the efficacy issues of non-implant procedures (Native Tissue Repair).

This simple, proven solution provides a safe, effective and long-term treatment that far surpasses existing treatment options.

SOLUTION HIGHLIGHTS

Safe and easy to insert via simple transvaginal approach

Eliminates mesh complications (contraction and erosion)

Provides **long-term organ support** (clinically proven over a 3-year period)

Shortens procedure time and surgeon's learning curve

LYRA'S FOUNDATIONS

2012 Company established.

2013 Cadaver & animal studies.

2014 SRS-I First in-women clinical trial, including 20 women with a three-year follow-up. Excellent and conclusive results show 100% success rate with a single transient adverse event.

2016 SRS II Multi-center clinical trial initiated with 50 patients.

2018 Interim results after a two-year follow-up showed 95.7% anatomical and 98.5% subjective success.

MARKET UNREST

2008 FDA shares initial concerns about Transvaginal Mesh (TVM) safety.

2011 FDA convenes advisory panel to discuss TVM complications and the types of clinical studies necessary to better assess the risks.

2014 FDA adopts modified success criteria for assessing Native Tissue Repair (NTR) vs. TVM, improving NTR success definition while compromising anatomical outcomes.

2019 TVM manufacturers Boston Scientific and Coloplast fail to meet FDA requirements and are ordered to stop distributing their solutions immediately.

DATA SPEAKS LOUDER THAN WORDS

Lyra Medical is the only manufacturer to provide clinical data prior to its approval for clinical use in Europe and Israel. The available data clearly shows compliance with FDA requirements, which will be demonstrated at scale in the near future.

The company is certain of its ability to demonstrate a benefit/risk profile that will position it as the first-line of treatment for anterior vaginal wall and uterus prolapses.

	SUCCESS RATE	COMPLICATION RATE
Lyra Medical's SRS Implant*	**97.2%**	**4.2%**
Native Tissue Repair (including SSF)**	73.8%	22%
Other TVM Implants**	83.3%	25%

1 Success Rate: as defined by the FDA - a combination of anatomical and subjective results, and the need for retreatment

2 Complication Rate: complications relating to the implant/procedure

* Lyra Medical Ltd. proprietary information

** Extracted from an executive summary report delivered by Boston Scientific as part of an FDA panel

FAVORABLE LANDSCAPE & BUSINESS OPPORTUNITY

LOW RISK, PROGRESSIVE STAGE

- Obtained excellent clinical data.
- Secured mass production capabilities and an alliance with a strategic partner for fast sales growth.
- Successfully passed regulatory and market penetration milestones (Europe and Israel).

GREAT BUSINESS OPPORTUNITY

- Currently there is not a single transvaginal device available in the US market; a company entering this market will practically be operating alone.
- Available treatments are insufficient; the FDA's 2019 decision strengthens and highlights this unmet need.
- Lyra provides a solution for a real need, targeting a large and growing market.
- SRS offers an attractive business model with a high gross margin.

LYRA'S KEY ACHIEVEMENTS

Clinical
Two clinical trials, including 70 patients and a three-year follow-up.

R&D
Flagship product, the SRS implant, completed R&D process; new product in the pipeline.

Production
Fully-functional production line with mass production capabilities.

Regulations
CE certified and Israeli MOH approved since September 2018.

IP
2 US and 1 EU patents approved (granted); new applications are in progress.

Sales
Over 850 implants sold during first twelve months.

Business Development
International distribution agreement with a strategic partner in place, and cooperation with seven training facilities throughout Europe.

Capital
US$4.1M raised from private investors in three fundraising rounds.

Recognition
Presentation in leading international conferences (including videos and live surgery broadcasts) since 2015.

ENTHUSIASTIC & EXPERIENCED TEAM

Lyra Medical was founded by experienced and successful entrepreneurs, whose expertise in the field of medical devices and clinical practice combine to create a strong technology that answers the need to improve POP treatment.

Shaul Shohat, Chairman
A serial entrepreneur with over 20 years of experience in the medical device arena. Over the span of his career Mr. Shohat has introduced several medical devices into the market, two of which have been acquired (OrthoSpace and Eon Surgical).

Iram Levit, Founder & CEO
An experienced entrepreneur with a successful track record of founding, launching, managing, raising funds and bringing medical device companies to fruition, Mr. Levit has led Lyra Medical's operations from its incorporation.

Dr. Gil Levy, MD, Founder & CMO
A recognized and distinguished urogynecologist, researcher, author of numerous publications, and an experienced entrepreneur with a successful track record of establishing a medical device company within this field of expertise.

INVESTMENT OPPORTUNITY

Lyra Medical is currently seeking US$16M in capital. Investment will fund:

- Global operations
- FDA clearance (including a large-scale regulatory clinical study)
- EU and Israel sales growth
- Commercialization in other territories (Asia, Latin America)

MARKET POTENTIAL

50% of women who have given birth have some degree of genital prolapse.

10-20% of women who have given birth experience symptoms that may require surgery.

7M women are candidates for surgical POP repair in the US and Europe alone.

600K+ women undergo surgical repair each year in the US and Europe.

$600M estimation US & EU Markets POP market (direct implant cost).

No transvaginal implant is currently available in the US. Strong indications suggest that the SRS Implant will meet FDA requirements.

ROADMAP

1 Expanding global operation to the US, China, Latin America and India.

2 Exploring anchorless technology's applicability to other pelvic disorders (Incontinence, Rectocele) and other surgical fields

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