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Issued by	**Title**	**Date**	**Signature**
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Marco Tuturici	Chief Operation Officer, MD-Clinicals	05/03/2026	

Rev.	Name	Date	ECO/CAPA	Modification Description
01	Rachel Weiss-Hersh	26.5.2022	ECO-22-03	Initial release
02	Rachel Weiss-Hersh	27.11.2023	ECO-23-02	Update data 2022
03	Rachel Weiss-Hersh	27.02.2024	ECO-24-03	Update data 2023
04	Rachel Weiss-Hersh	8.5.2025	ECO-25-02	Update data 2024
05	Yael Hod, Catalin Pepe	23 Feb2026	CAPA-25-06	Update of data from 2025 and updating format due to NC from NB Audit Oct 2025

ORIGINAL
Date 8.3.2026
Signature

Contents

1 Introduction

According to the medical device regulation (MDR) manufacturers are requested to prepare comprehensive safety reports in addition to other obligated evaluation reports. These reports are part of the post-market surveillance system (PMS) after a medical device has been placed on the market. For higher risk devices, classified as Class IIb or III, the manufacturer has to issue reports for the safety and performance, such as Periodic Safety Update Report (PSUR) and a Summary of Safety and Clinical Performance report (SSCP), which are updated annually. These reports are to be transmitted to the EUDAMED database and are partially available for the public. The aim of these reports is to provide authorities or notified bodies a quick overview of post-market activities, in particular of the implementation of the plan, data collected, conclusions and actions taken if events have been found. The SSCP report is issued by the manufacturer to transparently inform the public on high-risk products. This "summary of safety and clinical performance" contains all required contents according to the guidance document *"MDCG 2019-9 Summary of safety and clinical performance – A guide for manufacturers and notified bodes"* of the medical device coordination group (MDCG). These guidelines provide advice to the European Commission and assists the Member States in ensuring a harmonized implementation of medical devices Regulations (EU) 2017/745 and 2017/746.

This "summary of safety and performance" report is deemed to provide sufficient information for the **SRS Implant**, a permanent implant for the treatment of **anterior based pelvic organ prolapse** with or without uterus\apical prolapse.

2 Abbreviations

CAPA	corrective and preventive action
EU	European Union
EUDAMED	European database on medical devices
FSCA	field safety corrective action
FSN	field safety notice
IFU	instructions for use
MDCG	medical device coordination group
MDR	Medical Device Regulation
NB	notified body
PFDI- 20	Pelvic Floor Distress Index - 20
PMCF	post-market clinical follow-up
PMS	post-market surveillance
PSUR	periodic safety update report
SRN	single registration number for an economic operator
SSCP	summary of safety and clinical performance
UDI-DI	Unique Device Identification – device identifier
URL	Uniform Resource Locator (internet address)

Part A – SSCP intended for users/healthcare professionals

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the SRS implant of Lyra Medical.

The SSCP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for healthcare professionals.

Translations:

The language of the master SSCP and the available translations is given in the history and version section of this Document.

Device identification and general information

1.1 Device trade name(s)

SRS Implant

1.2 Manufacturer´s name and address

Lyra Medical Ltd.

HaMelacha 3, Binyamina

Israel, 3057324

+972-4-9921100

lyramedical.com

1.3 Manufacturer´s SRN (single registration number)

IL-MF-000020804

1.4 Basic UDI-DI

7290017797SRSDE (Assigned by Lyra Medical. Not registered at EUDAMED yet)

1.5 Medical device nomenclature description

Device	Code	Scope Expressions
SRS	**GMDN** 60842	Pelvic organ prolapse surgical mesh, synthetic polymer
	MDN 1104	Non-active soft tissue and other implants (MDCG 2019-14)
	MDS 1005	sterile condition
	MDT 2002	manufactured using plastic processing
	MDT 2008	manufactured in clean rooms and associated controlled environments
	MDT 2011	require packaging, including labelling
	CND P900202	SURGICAL MESHES, POLYPROPYLENE
	EMDN P0899	UROGENITAL PROSTHESES - OTHER

1.6 Class of device/Classification

According EU MDR 2017/745 [1], Rule 8, the SRS Implant is classified as a class III device, belonging to the highest risk class.

1.7 Year when CE was issued

The device was initially issued for CE in 2018 under MDD 93/42“

1.8 Authorized representative (if applicable: name and SRN number)

MedNet EC-REP III GmbH, DE-AR-000011191

[1] MDR Annex VIII (1.3.)

1.9 NB's name and the NB's single identification number

SZUTEST- 2195

2 Intended purpose of the device

The SRS Implant is intended for the treatment of anterior vaginal wall prolapse with/without apex/uterine prolapse. The SRS Implant is indicated for use in adult females (>21 years) suffering from anterior POP-Q ≥ grade 2 (point Ba ≥-1 cm).

2.1 Indications

Pelvic organ prolapse, anterior with and without apical descent, POP-Q ≥ grade 2

2.2 Contraindications

- Pathology of the pelvic soft tissue.
- Pregnant patients, or patients who are considering future pregnancies.
- Below 21 years of age
- Any pathology, including known or suspected uterine/cervical/vaginal/bladder pathology, which would compromise placement (e.g. anatomical distortion or abnormalities).
- Any pathology that would limit blood supply and compromise healing (e.g. decreased blood supply to organs as a result of treatments such as radiation therapy, chemotherapy).
- Presence of known or suspected cancer of the vagina, cervix, bladder or uterus.
- Blood coagulation disorder.
- Autoimmune connective tissue disease.
- Renal insufficiency and urinary tract obstruction.
- Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before placing the SRS Implant.
- Sensitivity/allergy to polypropylene or titanium-dioxide or PEEK

2.3 Target populations

The device is intended for the treatment of patients older than 21 years that suffer from anterior prolapse (bladder prolapse) with or without an apical prolapse (uterus prolapse) of stage 2 and worse.

3 Description of the device

This device is a small, sterile, single-use implant. It is placed in the body using a minimally invasive procedure. Once implanted, it remains in place permanently. It does not need anchors or screws.

The implant has two parts: a firm frame and a soft surgical mesh. The frame is made from a strong, medical-grade plastic called PEEK. This material is durable and safe for use on the body. The frame has two side arms connected by a middle bar. It can be compressed into a smaller shape for insertion. This allows placement through a small opening. After placement, it returns to its original shape (Figure 1).

The size and shape were chosen based on medical research and cadaver studies. The design fits normal pelvic anatomy. The device is available in one standard size.

Figure 1: SRS implant

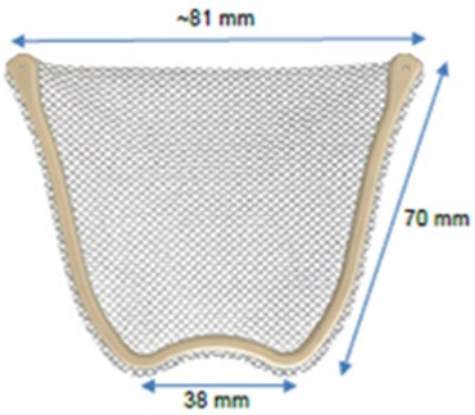
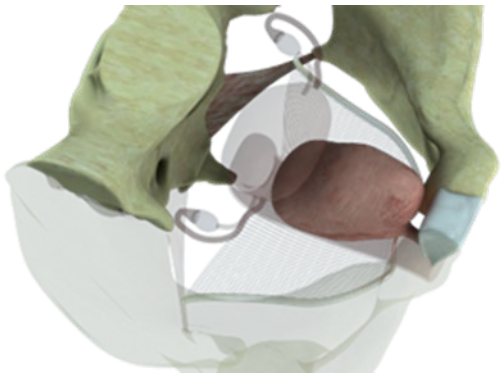


Figure 2:Location in the Pelvic



3.1 Device concept

The SRS Implant is designed to incorporate the advantages of pelvic organ prolapse (POP) meshes while eliminating the risks for complications associated with other mesh products. It is believed that the main reason for post-op complications with this mesh is the fact that the mesh has to be fixed within the pelvic floor. Lyra's SRS Implant mimics the natural anatomy and is designed to restore and maintain pelvic organs in their normal physiological location. A surgical mesh is attached to a solid flexible frame, which allows the mesh to remain in a flat orientation at the desired location and provide a 'trampoline-like' support for the prolapsed pelvic organs. The SRS's frame is designed to prevent mesh folding and allow flat placement of the mesh within the pelvic floor. The frame itself is not fixed to the surrounding tissue and keeps the o in position. This anchorless concept was designed to reduce common complications such as pain and mesh erosions.

3.2 Description of how the device is achieving its intended mode of action

The device is placed surgically in between the bladder and the vagina for the treatment of anterior and apical vaginal compartments advanced prolapse. The device is inserted between the bladder and the vaginal mucosa with the lateral arms following the anatomy of the arcus-tendineus-fascia-pelvis (ATFP) and the connecting bridge positioned under the lower edge of the pubic symphysis. The surgical technique includes central dissection of the bladder from the vagina which extends to the paravesical space for direct palpation of the ischial spines bilaterally. After the surgical space is prepared, the device is inserted. The appropriate location is confirmed by visualization of a symmetrically positioned device and fully stretched mesh under the bladder. No surgical anchoring techniques are used. The vaginal incision is closed under no tension and vaginal packing is used for 24 hours. Lyra's SRS Implant is similar to commercially available transvaginal POP products as it uses a similar mesh material and transvaginal

surgical technique. Similar to other POP repair products, the implant is inserted via trans-vaginal approach using standard surgical tools. The SRS implant is designed to treat pelvic organ prolapse by providing structural support to weakened pelvic floor tissues without the use of fixation anchors. The device is made of biocompatible, porous synthetic mesh that allows for tissue ingrowth after implantation. Once placed in the appropriate anatomical position, it acts as a supportive scaffold, redistributing mechanical forces and reinforcing native ligaments and fascia. Over time, host tissue integration stabilizes the implant, restoring normal pelvic anatomy and improving organ support while minimizing complications associated with anchored fixation systems.

3.3 Reference to previous generation(s)

This is the first generation of this device.

3.4 Accessories

There are no accessories for this device.

3.5 Usage

☒ Single use ☐ Multiple use (re-use)

3.5.1 Mode of sterilisation

☐ Gamma sterilisation ☒ Ethylene oxide sterilisation ☐ Autoclave

3.5.2 Constituents (as required in the IFU):

The materials of construction for the Lyra SRS Implant are further described in the following table:

Component Name	Raw Materials in Component/ Grade	Type of Patient Contact
Frame	PEEK-OPTIMA LT1/Implant Grade	Direct, Tissue/Bone, Permanent
Mesh	non-absorbable monofilament polypropylene with covalently bonded titanium surface coating (TiLOOP Mesh)	Direct, Tissue/Bone, Permanent

3.6 Previous generation(s) or variants and description of the differences

Not applicable.

3.7 Description of any accessories which are intended to be used in combination with the device

Not applicable.

3.8 Description of any other devices and products which are intended to be used in combination with the device

The SRS Implant is inserted via vaginal approach using standard surgical tools.

4. Information on any residual risks and any undesirable effects, warnings and precautions

A risk is defined in the MDR as the combination of the probability of occurrence of harm and the severity of that harm. According to the standard ISO 14971:2019 harm is defined as physical injury or damage to the health of people, or damage to property of the environment.

During the clinical evaluation of the SRS Implant, several risks have been discussed that might lead to harm of the patient, meaning that a physical injury or damage might occur. These risks include frame erosion or prolapse recurrence, which have been found in a low occurrence, but have a high severity meaning the patient might require a re-surgery. Other risk factors might be vaginal bleeding, pelvic pain, de novo dyspareunia, de novo voiding dysfunction and neuromuscular problems, none of these risks occurred in a considerable rate. Hematoma and bleeding as well as urinary tract infection might occur as post-surgical complications using the SRS Implant, but rates were found similar or less compared to other products.

4.1 How potential risks have been controlled or managed

The manufacturer has initiated strategies to mitigate these risks as far as possible. Surgeons that seek to be trained for the usage of the SRS implant are required to be experienced in minimal transvaginal surgery for the correction of pelvic organ prolapse. They receive an extended training including a hands-on training from qualified proctors provided by the manufacturer. Only surgeons successfully pass the training are allowed to use the SRS Implant.

4.2 Remaining risks and undesirable effects

Potential risks, associated with this medical device, are controlled and managed by using a standardized procedure. Some risks cannot be completely avoided. These are called remaining risks. Undesirable effects to this device can happen. The Instructions for Use identifies that a patient may experience the following typical remaining risks, interactions and undesirable effects in conjunction with the SRS implant.

The following main risks were detailed in the literature for mesh implants:

Risk	Device or Procedure Related	Timing	Range in SOTA 2019-2025	Reported Rates for Lyra in clinical studies
Mesh erosion and mesh exposure	Both	36M	Reported range in the SOTA For all mesh POP implants (0.8%-13%)	0%
Frame exposure	Device	12M	No reports for this in the literature since this design is specific to Lyra Medical	1.4% (1/70)
Mesh Folding	Device	36M	Reported range in the SOTA For mesh POP implant	0%
Organ Injury	Procedure	During procedure	Reported range in the SOTA For mesh POP: Faioli R, et al (2021), Yeung E, et al (2024) 1-4 %-4% Ulrich D, et al (2020) – Full art NA Sacrocolpopexy, no specific mesh, laparoscopic/robotic/laparotomy Bladder injury - 2.7% Bowel injury – 1%	0%
Organ perforation by mesh extrusion or migrating device post-op	Both	24M	0.42%-9%	0%
Mesh contraction	Device	12M	0%-7.2%	0%
Reoperation Prolapse (Recurrence)	Both	24M	5.5-8.5%	0% (1/70 (1.4%) treated with Pessary)

Dyspareunia	Device	24M	5.8%-7.6% Vaginal prolapse FU – NA Anterior compartment – 6.1% Multicompartment mesh – 10.2% Total – 7.6%	1.4% (1/70)
Infection	Both	30 days	0.5%- 10%	5.7% (4/70):
Sepsis/abscess formation	Both	After procedure	Less than 1%	0%
Urinary tract infection (UTI)	Procedure	30M	3.1%	12.8% (9/70)
Pain (vaginal or pelvic)	Both	24- 36M	1.4%- 14%	0%
Discomfort / irritation	Device	24-36M	7.1%	0%
Hematoma and bleeding	Procedure	Up to 30 days after Op	1.7%-7%	1.4% (1/70)
De novo Stress Urinary Incontinence	Device	12-36M	Native: 9.6% Mesh: 13.3%- 25.6%	2.8% (2/70)
Ureteric injury;	Procedure	12M	Less than 1%	0%
Ureter obstruction;or difficulty empting bladder	Both	During procedure	2-6%	See Urinary retention
Urinary incontinence;	Procedure	0.5-7 years	0.5%-11.2%	See DE Novo SUI

Urinary retention;	Both	Up to 7 days	21%	2.8% (2/70)
Neuro-muscular problems;	Both	24M	3%	0%
Vaginal tightening	Both	24M	1.2-3.6%	0%
Allergy, hypersensitivity or other immune reaction; Retained foreign body (foreign body reaction);	Device	NA	Regarded as rare in FDA report	0%
Adhesion formation;	Both	After surgery	4.2%	0%
Inflammation (acute or chronic);	Both	After surgery		0%
Vaginal discharge;	Both	12-24M	10%	0%
Dehiscence and/or necrosis;	Both	Less than 3 M	0.3-3-5%	0%
Wound dehiscence;	Procedure	Less than 3 M	Reported as case report-rare less than 1%	0%
Constipation/defecatory dysfunction;	Both	5 Years	7.9%-8.5%	0%
Granulation tissue formation;	Both		Less than 1%	0%
Surgical site wound irritation, erythema, edema;	Procedure	30 days	2-2.5%	0%

Lyra developed an implant for the treatment of anterior vaginal wall and uterine prolapse, named Self-Retaining Support (SRS) Implant. The SRS Implant incorporates the advantages of commercially available POP meshes while eliminating the need for mesh fixation, which is believed to be the main cause for both intra and post-operative adverse events in currently available techniques.

The SRS technology was designed to ensure a safe treatment that addresses the root cause of current mesh-related complications.

INHIBITS MESH EROSION –

The solid frame enables the use of an ultra-light (16 gr.\m2), extra-thin mesh (65µm fiber). It also retains the mesh tension and prevents it from folding, which can lead to erosion.

PREVENTS MESH CONTRACTION –

The solid frame acts as an opposing mechanical force that prevents the mesh from contracting, preventing pain and improving long-term efficacy.

REDUCES RISK OF BLEEDING & ORGAN PERFORATION –

The SRS concept eliminates the need for blind insertion of surgical instruments (trocars, anchoring instruments, etc.), reducing the risk of damage to surrounding anatomical structures.

MINIMIZES RISK OF PAIN & DYSPAREUNIA –

The SRS Implant ensures bladder support without causing tension across the vagina. The frame maintains the original tension-free, flat configuration therefore prevent pelvic pain.

MAINTAINS MACRO-POROUS MESH STRUCTURE (reduce risk of mesh stiffness which may lead to pain, discomfort, dyspareunia and vaginal shortening)

The solid frame maintains the implant's flat orientation and the macro-porous structure of the supporting layer.

4.3 Warnings

- Patient counseling should include a discussion that the mesh to be implanted is a permanent implant and that some complications associated with implanted mesh may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh.
- In the event of a post procedure infection, the entire mesh may have to be removed or revised.
- Like all foreign bodies, the mesh may potentiate an existing infection reaction or sepsis.

- Tissue responses to the implant may include: local irritation at the wound site, erosion or exposure vaginally or through other surrounding tissue, migration of the device from the desired location, fistula formation, foreign body reaction and inflammation. The occurrence of these responses may require removal or revision of the mesh.
- The Mesh is considered a permanent implant. Removal of the mesh or correction of mesh-related complications may involve multiple surgeries.
- Complete removal of the mesh may not be possible and additional surgeries may not always fully correct the complications.
- Mild to moderate incontinence may occur due to incomplete support.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Perforations or lacerations of vessels, nerves, bladder, urethra, or bowel may occur during placement and may require surgical repair.
- Do not use a product that has damaged or opened packaging, as sterility may be compromised; Use of a non-sterile product may result in patient injury.
- Do not use a product that has expired. Use of an expired product can lead to infection or degradation and the product may not function as intended.
- The SRS Implant is supplied sterile for single use only. The device should not be re-sterilized. In the event that the product becomes contaminated prior to use, immediately return the device to Lyra Medical for replacement. Re- sterilizing the product may result in patient injury.
- Each device should be carefully examined prior to surgery and continuously monitored throughout the surgical procedure to ensure the structural integrity and sterility of the device has not been compromised in any way. In case a fault with device integrity is noted, immediately return the device to Lyra Medical for replacement. Using a damaged device may result in patient injury.
- DO NOT use excessive force while compressing the device for insertion as this may cause breakage or compromise device integrity.
- An implant which has been damaged or on which repairs have been attempted should not be implanted; failure to follow this instruction may result in patient injury.
- Surgical treatment of female pelvic organ prolapse should be performed ONLY by physicians with the appropriate training and experience in the use of the device as well as in minimally-invasive placement of surgical mesh devices for treatment of pelvic floor disorders

and in management of complications resulting from procedures. Failure to follow this instruction can result in patient injury.

- Training on the use of the SRS Implant is mandatory. Contact your company sales representative to arrange for this training.
- Prior to use, consult this IFU. Failure to follow this instruction can result in patient injury.
- Disposal: Follow all applicable national local laws and guidelines regarding the disposal of the SRS Implant. Use caution when handling contaminated items in order to prevent the spread of contamination.
- In case of surgical extraction, photographs and a detailed description of the extracted device should be sent to Lyra Medical before disposal.
- Individual patients' anatomy may vary. In each procedure it is important that the intended anatomical plane for the SRS Implant placement is planned and known for each individual patient. Employment of imaging methods before and after mesh placement may aid in proper mesh placement and confirm absence of injury to non-target anatomical structures.
- Standard surgical practices should be followed for pelvic floor procedures as well as for the management of contaminated or infected wounds.
- Ensure that the SRS Implant is positioned symmetrically with no pressure on surrounding tissues, the solid frame is not flexed, the SRS Implant is in the horizontal position and the mesh is fully stretched.
- The titanium Dioxide surface of the synthetic material will not affect radiological diagnostic techniques (X-ray, CT, MRI and US investigations).
- Follow up is advised throughout the patient's life time.

As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation by the transvaginal route.

4.4 Precautions

Since previous and currently available anchor-based implants have raised many safety concerns, surgeons shall obtain the patient consent prior to surgery to ensure that the patient understands the postoperative risks and potential complications of transvaginal mesh surgery.

- The patient counseling should include a discussion that the mesh to be implanted is a permanent implant and that some complications associated with implanted mesh may require additional surgery. Serious adverse tissue responses or infection may require removal of mesh.
- Any onset of bleeding, pain, abnormal vaginal discharge or signs of infection occurring at any time should be reported by the patient immediately.
- Patients should be counseled to refrain from heavy lifting, exercise and intercourse for a minimum of six (6) weeks after the procedure. A Physician should determine when it is suitable for each patient to return to normal activities.
- In the event of a post procedure infection, the entire mesh may have to be removed or revised.
- Like all foreign bodies, the mesh may potentiate an existing infection reaction or sepsis.
- Tissue responses to the implant may include local irritation at the wound site, erosion or exposure vaginally or through other surrounding tissue, migration of the device from the desired location, fistula formation, foreign body reaction and inflammation. The occurrence of these responses may require removal or revision of the mesh.
- The mesh is considered a permanent implant. Removal of the mesh or correction of mesh-related complications may involve multiple surgeries.
- Complete removal of the mesh may not be possible and additional surgeries may not always fully correct the complications.

4.5 Summary of any field safety corrective action, (FSCA including FSN) if applicable

- There were no reports on FSCA or FSN for the SRS implant

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to equivalent device

Lyra Medical does not claim equivalency for any available device for the treatment of Pelvic Organ Prolapse.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking

Initially safety and performance were demonstrated in a first-in-women study, the SRS-I, following with the SRS-II study with altogether 70 patients and 6 months follow-up. Patients were implanted with the SRS Implant and followed for 2, 6, 12, 24 and 36 months. Measurements were obtained for the performance of the device by POP-Q (standardized measurements for prolapse severity) and questionnaires (how does the patient feel about the prolapse and the prolapse related symptoms). Safety included any event and complaint that occurred over the observation period of three years and are connected to the device or the implantation procedure.

SRS-I:

Study Title	International, multicenter, prospective, non-randomized, single-arm, interventional clinical investigation. Study objectives were to demonstrate the safety of the SRS Implant, to evaluate its performance in improving POP grade and urinary system function and to assess the level of difficulty of the implantation technique.
Study Rationale and Justification	Following Pre-clinical assessment, Lyra medical performed this pilot study to establish the initial safety and feasibility of the implant while identifying any immediate intra-operative risks. The pilot study is aimed to provide enough data to evaluate anatomical success and can allow the refinement of surgical techniques and device sizing before larger trials. In addition, the aim is to recognize potential complications early, ensuring patient safety is prioritized during the introduction of new technology.3 sizes of SRS Implant were used.
Objectives	To demonstrate the safety of the SRS Implant To evaluate the performance of the implant in improving POP-Q grade of the anterior vaginal wall and vaginal apex To evaluate the performance of the urinary system after device implantation To evaluate the difficulty level of the surgical procedure To assess the ease of use of physicians
Methodology	20 patients suffering from anterior POP-Q grade 2 (point Aa or Ba ≥-1) and above, who were scheduled for POP surgery, were screened and enrolled to the study in 2 sites in Israel and one in Hungary. First patient was enrolled on September 16, 2014, last patient finalized the last follow-up on 12 of March, 2018. Data was collected at baseline (pre-surgery) and at 2 weeks and at 2, 6, 12, 24 and 36 months post-operative follow-up visits. The following parameters were collected and evaluated at each follow-up visit: POP-Q measurements, physical examination, urinary cough test, QOL questionnaires (except 2 weeks and 2 months follow-up visits), concomitant medication and AE evaluation. No patients were lost to follow up. One patient did not consent for the extension of the follow up period and did not participate in the last follow-up (36 mo.) visit. This report refers to all screened and enrolled patients. The overall mean follow-up period was 36.96 months (range 12.5-41). At follow up, all women had completed anatomical cure with POP-Q measurements of the anterior and apical compartment at normal values (Aa/Ba=-2/-3).
Inclusion Criteria	1. Patient has signed the informed consent form and is willing to participate in the clinical study and data collection. 2. Patient's age is between 18 and 75 years old

	3. POP-Q: Aa and/or Ba is at least -1cm
Exclusion Criteria	1. Patient is pregnant or breastfeeding 2. Patient suffering from active infection (on antibiotic therapy) 3. Patient planning vaginal delivery 4. Previous vaginal mesh surgery 5. Patient is in high risk for surgery (evidence of clinically significant cardiovascular, renal, hepatic or respiratory diseases). 6. Any condition that, in the judgment of the investigators, would interfere with the subject's ability to provide informed consent, comply with study instructions, place the subject at increased risk or which might confound interpretation of study results. 7. Malignancy 8. Known hypersensitivity to PEEK and polypropylene materials. 9. Participation in another investigational trial that has not completed the primary endpoint or interferes with study participation 10. Tendency for hyper-scaring reaction 11. Diagnosed with mental or emotional disturbance.
Main Results	All women demonstrated 100% study success, where their POP-Q grade improved from stages 2, 3 or 4 to stages 0 or 1 following the SRS Implantation procedure. These results were found to be statistically significant (P Value<0.001). At 36 months follow-up (N=19), the QOL questionnaires' score has showed improvement, where PFDI-20 questionnaire's relevant sub-sections: Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6), Colorectal Anal Distress (CRAD-8) and Urinary Distress Inventory (UDI-8) scores, showed a decrease of 39.8 (p<0.0001), 13.0 (p=0.011) and 34.1 (p<0.001) points, respectively. All three sub-sections were found to be statistically significant. The total PFDI-20 scores improved with a statistically significant (p<0.0001) decrease of 86.9 points. Due to the intimate nature of the sexual function questionnaire (PISQ-12) and therefore low compliance rate, not enough data for a valid and reliable conclusion has been collected. Nevertheless, available data shows improvement in sexual function. No events of urinary retention nor de-novo Stress Urinary Incontinence (SUI), mesh erosions or pelvic pain related to the implant were documented at follow up visits. One SADE was documented as an erosion of a part of the device's frame through the anterior vaginal wall. No other device related AEs were reported during the follow up period. Participating surgeons expressed their impression of the ease of use of the SRS

	Implantation procedure. All involved personal stated that the fact that the SRS eliminates the need of complex fixation maneuvers, makes it the most straight forward, easy to adapt, easy to use implant until today. As compared to the literature (FDA Meta-analysis of surgical POP devices), the safety profile of the SRS Implant is potentially better than that reported for traditional surgical meshes. 36 months follow up performance-wise reveals comparable results to existing Pelvic Organ Prolapse treatment devices.This study results suggest that the benefits of the use of the SRS Implant outweigh the risks.

SRS-II:

A second study - the SRS-II clinical trial with similar study design and objectives was initiated in 2016 and finalized by December 2020 including another 50 patients:

Study Title	International, multicenter, prospective, non-randomized, single-arm, interventional clinical investigation. Study objectives were to demonstrate the safety of the SRS Implant, to evaluate its performance in improving POP grade and urinary system function and to assess the level of difficulty of the implantation technique.
Study Rationale and Justification	A pivotal study with 50 subjects is justified to confirm long-term clinical efficacy and safety with greater statistical power. In this study the device included only one specific mesh size can streamline the surgical procedure and can ensure highly standardized outcomes across the study group. By removing alternative sizes, researchers can isolate the performance of the most versatile design, which can simplify manufacturing and can provide a clear, predictable benchmark for anatomical success.
Objectives	Study objectives were to demonstrate the safety of the SRS Implant, to evaluate its performance in improving POP grade and patients' quality of life, the performance of the urinary system after device implantation and to assess the difficulty level of the surgical procedure.
Methodology	Between March 22nd, 2016 to July 19th, 2017, 50 patients were screened and enrolled to the study in 3 sites in Israel. All patients were diagnosed with symptomatic anterior POP-Q grade 2 and above (point Ba ≥ -1) and were scheduled for POP surgery regardless of this study. Two patients were lost to follow-up after their two-year visit. This report refers to all screened and enrolled patients. As of Dec 20th, 2020, the mean of the follow up period was 39.3 months post operation (range 26.1-51.3). This study is a multi-center, prospective, non-

	randomized, single-arm, interventional clinical investigation designed to demonstrate the safety and performance of the SRS device. Data was collected at baseline (pre-surgery) and at 2 weeks and at 2, 6, 12, 24 and 36 months post-operative follow-up visits. The following parameters were collected and evaluated at each follow-up visit: POP-Q measurements, physical examination, urinary cough test, QOL questionnaires (except 2 weeks and 2 months follow-up visits), concomitant medication and AE evaluation
Inclusion Criteria	1. Patient has signed the informed consent form and is willing to participate in the clinical study and data collection. 2. Patient's age is between 18 and 75 years old 3. POP-Q: Aa and/or Ba is at least -1cm
Exclusion Criteria	1. Patient is pregnant or breastfeeding 2. Patient suffering from active infection (on antibiotic therapy) 3. Patient planning vaginal delivery 4. Previous vaginal mesh surgery 5. Patient is in high risk for surgery (evidence of clinically significant cardiovascular, renal, hepatic or respiratory diseases). 6. Any condition that, in the judgment of the investigators, would interfere with the subject's ability to provide informed consent, comply with study instructions, place the subject at increased risk or which might confound interpretation of study results. 7. Malignancy 8. Known hypersensitivity to PEEK and polypropylene materials. 9. Participation in another investigational trial that has not completed the primary endpoint or interferes with study participation 10. Tendency for hyper-scaring reaction 11. Diagnosed with mental or emotional disturbance.

Main Results	As of December 20th, 2020, 49 patients (98%) completed their 1-year FU (one patient attempted the 2y FU), 44 patients (88%) completed their 2-year FU, and 48 patients (96%) completed their 3-year FU. Two patients were lost to follow-up after their 2-year visit. At final follow up 46 (92%) patients had complete anatomical cure with POP-Q measurements of the anterior compartment at normal values (Ba=-2/-3). Two patients were measured with Ba of -1 cm and a C at normal level (n=1 C -9cm, n=1 C—10cm). Two other patients presented with C=0, while Ba remained at -3 cm in their final visit. Only one patient with C=0 described the symptomatic feeling of a bulge (PFDI-20 question3 score2) and was retreated by pessary, reaching a subjective success of the study of 98%. The composite success (including objective and subjective success) of this study was 92%. The Quality of Life (QOL) questionnaires' data show an improvement in the PFDI-20 scores for all domains at final visit: Pelvic Organ Prolapse Distress Inventory (POPDI-6), Colorectal Anal Distress (CRAD-8), Urinary Distress Inventory (UDI-8) and Total scores show an average decrease of 27.2, 6.6, 18.7 and 52.5 points, respectively. Post-operative decrease of the POPDI-6, UDI-8 and Total scores were found to be clinically meaningful (referring to Minimum Clinical Important Difference (MCID) >15 points per domain and MCID >45 for total score) and statistically significant. The PISQ-12 questionnaire is designed for sexually active, heterosexual, partnered women and as such is irrelevant in many of the elderly patients. Additionally, due to the intimate nature of the sexual function questionnaire, which resulted in poor response rates, data was insufficient for a valid and reliable conclusion. Nevertheless, available data shows improvement in sexual function. There were two events of transient urinary retention, four cases of de-novo Stress Urinary Incontinence (SUI) and one case of urinary voiding dysfunction. Other adverse events (AEs) included UTI, post-surgery hematoma and general AEs which were unrelated to the device or the procedure. No mesh erosions or pelvic pain related to the implant were documented at follow up visits. No unexpected adverse device event (USADE) or death had occurred. The participating surgeons described their experience with the SRS as an easy-to-use device and as non-complex surgical procedure. All surgeons stated that the fact that the SRS eliminates the need for complex fixation maneuvers, makes it a straightforward, easy to adapt, easy to use vaginal mesh implant. As compared to the literature (Meta-analysis of surgical POP devices), the safety profile of the SRS Implant is potentially better than that reported for other transvaginal implants. The performance of the SRS Implant after mid-term follow up reveals results comparable to existing Pelvic Organ Prolapse mesh kits.

5.3 Summary of clinical data from other sources

- A usability study was initiated by local distributer in Germany to gain information from the user (surgeon) using the SRS Implant. 174 patients were recruited for this study and implanted with the SRS Implant. During the follow-up until the discharge of the patient collected all data regarding success of treatment, complications and complaints and user evaluation. Results revealed that patients were hospitalized for an average of 3.4 days, 99.6% achieved complete prolapse correction (POP-Q stage 0/1) and only one patient (0.4%) had a stage 2 prolapse. There were no prolapse of stage 3 or 4 at discharge. The main complications were 2.3% hematoma, 1.7% organ puncture during the procedure, stress incontinence (0.6 %), and urinary retention (1.7 %). Surgeons were altogether greatly satisfied with the usage of the SRS Implant and the outcome of the surgery.

-An investigator-initiated study was initiated in 2022 to investigate the Quality of Life in patients implanted with the SRS over a 24 months observation period. This study remained ongoing and no results are available by the time this report was written.

Other PMCF activities included the analysis of complaints and any unknown risks by literature search. No new risks were identified, that might affect the patient by SRS implantation.

-Long term follow up-Lyra medical is conducting a study with survey to subjects who were treated in the first study, approximately 10 years ago, to assess long terms success.

The clinical evidence demonstrates safety and beneficial performance of the SRS Implant. As a result of our analysis, the benefits of the product outweigh the possible risks, that were identified for the usage of the device.

5.4 Overall summary of the clinical performance and safety

5.4.1 Clinical Benefits

The Pelvic Floor Distress Inventory-20 (PFDI-20) is a validated patient questionnaire used to measure the severity of symptoms and the degree of distress caused by pelvic floor disorders. It consists of 20 questions categorized into three subscales that evaluate pelvic organ prolapse, urinary, and colorectal symptoms. Clinicians use this tool to assess the subjective success of a procedure by comparing how a patient's quality of life has improved from before surgery to long-term follow-up.Verified by clinical examination.

1. Subjective Success- PFDI-20 question No. 3 "Usually have a bulge or something falling out that you can see or feel in your vaginal area? Lyra medical claims that in 36M at least 90% of the subjects will answer no to this question.

2. The Total score of the questionnaires which measures the degree of distress caused by pelvic floor disorders is expected to reduce in at least 23-45 points after 36Mfor 90% of the subjects.

3. Subjective Improvement in Urinary Symptoms - For 80% of the subjects after 36M form the surgery there will be reduction of 11 points in the sub questionnaire for these symptoms.

5.4.2 Clinical Performance Claims

1. Lyra Medical claims that in at least 95% of the subjects after 12M and 85% of the patients after 36M the POP-Q score will be reduced to stage 0 or 1 with C≤ -5, meaning miminal or no prolapse.

2. Shorter Operation Time- it is also claims that the operation time (from incision to completion of final mucosal suture) with e SRS implant is in the range of 24-39 min.

3. Ease of Use- 80% will rate improvement in Ease of use, i.e. above 5 in Likert scale.

5.4.3 Clinical Safety Claims

Lyra Medical showed an excellent safety profile compared to the reported rates in the SOTA. For clinical safety claims, the following measures were chosen:

Risk	Claim	Timing
Mesh erosion and mesh exposure	Up to 3% of reported cases	36M
Frame exposure	Up to 3% of reported cases	12M
Mesh Folding	Up to3% of reported cases	36M
Organ Injury	Up to 1% of reported cases	During procedure
Organ perforation by mesh extrusion or migrating device post-op	Up to 1% of reported cases	24M
Reoperation of anterior or apical compartment	up to 3%	36M

5.4.4 Benefit-risk assessment and acceptability of the benefit-risk ratio

The safety and clinical performance of the SRS implant have been demonstrated in more than 300 patients enrolled in several pre-market trials, PMCF-studies and investigator-initiated trials with thousands of units sold since 2018.

The SRS can achieve high anatomical success rates, with clinical data suggesting it can restore the organs to a near-natural physiological position over long-term follow-up. Due to its unique PEEK frame, the system can provide simultaneous and stable support to both the vaginal apex and the anterior wall,

which can prevent the common recurrences seen in traditional tissue repairs. Furthermore, the structural design can ensure the mesh remains flat and tension-free, which can effectively avoid the mesh folding and contraction that are known to cause chronic pain in other products.

Functionally, the improvement in a patient's quality of life can reach highly significant levels, as scores on standardized distress questionnaires can demonstrate a reduction in symptoms. Because the system uses a Titanized mesh and an anchorless approach, it can minimize the chronic inflammatory response and can significantly reduce the risk of mesh erosion. Ultimately, these integrated properties can lead to durable, long-term outcomes and can enhance the overall safety profile for the patient.

By design, the SRS Implant is inserted transvaginal using standard surgical tools and positioned between the anterior vaginal wall and the bladder.

The placement technique prevents the need for blind, complicated fixation techniques, thus simplifying and shortening the entire procedure.

This streamlined process can provide surgeons with better visualization throughout the procedure and can minimize the manual dexterity required to achieve anatomical success. Ultimately, the simplicity of Lyra's method can lead to more consistent surgical results and can enhance the efficiency of the operating room environment

All the known risks to health observed with POP surgery are controlled by the SRS Implant's design as demonstrated by bench tests, pre-clinical studies, and clinical studies. The clinical studies demonstrate, as expected, a reduced incidence of many of the known risks of POP surgery (including pain, incontinence, dyspareunia, organ injury) and excellent device performance in providing an anatomic and subjective cure for POP, with reduced recurrence of POP and reduced requirement for repeat surgery. Surgeons also expressed satisfaction with the ease of use and short surgery time.

Based on the review of the risk management process and the compliant file, the procedures in place are adequate to protect patient's safety and the risks associated with the use of the device are acceptable when weighed against the benefits to the patient.

5.5 Ongoing or planned post-market clinical follow-up

The main ongoing and planned post-market clinical follow-up (PMCF) activities are as follows:

1. Long-term data collection as part of a planned PMCF study to assess safety and efficacy in the long term.
2. Collection of Distributer and investigator-initiated study
3. Continuous collection and analysis of complaints, vigilance data for the market
4. Training users and collecting active feedback from the users
5. Inspection of regulatory clearance in other markets

6. Possible diagnostic or therapeutic alternatives

6.1 Non-Surgical-Conservative treatment

Nonsurgical (conservative) management of pelvic organ prolapse is recommended and should be attempted before surgery is contemplated. Conservative management confers several advantages: it is safe and inexpensive, it is not usually associated with morbidity and mortality, it is not invasive, it can lead to high patient satisfaction, and it may be used for patients awaiting surgery or patients who are not interested in or candidates for surgical management The main options are:

- Pelvic muscle exercises (PMEs) - Pelvic Floor Muscle Training (PFMT), commonly known as **Kegel exercises**, consists of repeated voluntary contractions of the levator ani muscles to strengthen the pelvic "hammock." This treatment is relevant for stage 1 or 2 POP score.
- Vaginal support devices (pessaries)- a removable, medical-grade silicone device inserted into the vagina to provide structural support for pelvic organ prolapse. It acts as a mechanical "shelf" or "plug" that holds the descending organs (bladder, uterus, or rectum) in their natural position, effectively relieving symptoms like pressure and bulging without surgery.
- Life style changes- weight loss and reducing weight from the pelvic floor

6.2 Surgery

Two major choices can be made according to the patient's needs when POP repair is required- Native tissue repair or mesh repair. Native tissue repair aims to correct the prolapse using the tissue itself obliterative procedure or reconstructive surgery.

- Obliterative surgery narrows the opening of the vagina, preventing the organs from slipping out. This may eliminate the ability to have penetrative sex- Colpocleisis is an obliterative procedure obliterative procedures are that they typically have a short operative duration, low risk of perioperative morbidity, and low risk of prolapse recurrence. that results in a shortened vagina. It prevents any organs from bulging outside the body [18]
- Reconstructive surgery repairs the weak parts of the pelvic floor and moves the organs back to their typical position,

<u>With mesh:</u>

  - Transvaginal Mesh (TVM): These procedures are performed through an internal incision in the vaginal wall. Traditional Anchored Kits: These use "arms" or sharp anchors to fix the mesh into pelvic ligaments. While effective for support, the "blind" anchoring process led to the 2019 FDA ban on many of these products due to nerve pain and organ injury. In the case of Lyra medical the procedure is

anchorless and without trocars. The SRS implant is anchorless and still performs the same structural support role as traditional transvaginal meshes — distributing load across weakened tissue planes to reduce prolapse recurrence. Similar Trans Vaginal devices share common or analogous biomaterials (e.g., polypropylene, PVDF, lightweight knit structures, titanized variants) with a spectrum of mesh weights and porosities that are representative of the state-of-the-art in pelvic floor support.

- Sacrocolpopexy :treats uterine prolapse and vaginal vault prolapse using a mesh material to attach the vagina to a ligament by the tailbone. It's usually performed through small incisions in the abdomen through laparoscopy, also treats uterine prolapse. With surgical mesh, the cervix and vagina are attached to the tailbone, lifting the uterus into place
- Colporrhaphy: treats anterior and/or posterior vaginal wall prolapse. With colporrhaphy, the surgeon performs the procedure through the vagina. The vaginal walls are reinforced with dissolvable sutures to support the bladder and rectum or with a mesh
- Uterosacral or sacrospinous ligament fixation uses the patient's tissues to treat uterine prolapse or vaginal vault prolapse. The surgery is performed through the Vagina (like colporrhaphy). During the procedure, the top of the vagina is attached to a ligament or muscle in the pelvis, using dissolvable sutures.

*Table 1**: Summary of alternative treatments***

Category	Colpocleisis	TVM	Sacrocolpopexy	Colporrhaphy	Uterosacral / Sacrospinous Fixation
Approach	Obliterative	Reconstructive	Reconstructive	Reconstructive	Reconstructive
Access	Vaginal	Vaginal	Abdominal (lap.)	Vaginal	Vaginal
Mesh	No	Yes	Yes	No	No
Main Use	Advanced POP, no sexual activity	Vaginal prolapse support	Apical prolapse	Ant./post. wall prolapse	Apical prolapse
Key Note	Short surgery, low morbidity	FDA limits on anchored kits	Durable, gold standard	Native tissue possible	Native tissue repair

6.3 Operational types of approaches

Surgical management of pelvic organ prolapse (POP) can be broadly classified based on the surgical route: vaginal or abdominal.
Vaginal approaches are the most performed, as they are generally associated with shorter operative times, faster recovery, and lower postoperative morbidity. Vaginal procedures include native tissue repairs (such as anterior or posterior colporrhaphy), sacrospinous ligament fixation, and obliterative procedures like colpocleisis for women who do not desire future vaginal intercourse. Vaginal approaches can be performed with or without concomitant hysterectomy, depending on uterine pathology and patient preference[11]
Abdominal approaches include open, laparoscopic, or robotic-assisted sacrocolpopexy, which involves suspending the vaginal apex or cervix to the sacrum using mesh. Abdominal approaches are typically associated with lower long-term recurrence rates, particularly in apical prolapse, but generally require longer operative times and hospitalization.[20]
Abdominal sacrocolpopexy may be performed with or without hysterectomy, and uterine preservation is increasingly considered safe and effective in selected patients[21]
When hysterectomy is performed as part of pelvic organ prolapse (POP) surgery, apical suspension is required. Non-mesh (native tissue) procedures include vaginal hysterectomy with uterosacral ligament suspension or sacrospinous ligament fixation, often combined with anterior and/or posterior colporrhaphy. Mesh-based procedures include abdominal or laparoscopic hysterectomy with sacrocolpopexy, in which synthetic mesh is used to suspend the vaginal cuff to the sacrum. Transvaginal mesh was previously used in conjunction with hysterectomy but is now subject to significant regulatory restrictions due to safety concerns.
When hysterectomy is not performed, POP surgery involves uterine-sparing apical support. Non-mesh options include sacrospinous or uterosacral hysteropexy with native tissue repair of affected compartments. Mesh-based options include abdominal or laparoscopic sacrohysteropexy, in which mesh is used to suspend the uterus or cervix to the sacrum. Transvaginal mesh hysteropexy has also been described historically but is now limited or discontinued in many regions due to mesh-related risks.

Table 2:POP surgery with or without Hysterectomy

Category	With Hysterectomy	Without Hysterectomy
Procedure Names	Vaginal hysterectomy + USLS / SSLF, Hysterectomy + Sacrocolpopexy	Sacrospinous hysteropexy, Uterosacral hysteropexy, Sacrohysteropexy, Colporrhaphy
Approach	Reconstructive (except colpocleisis, obliterative)	Reconstructive (except colpocleisis, obliterative)
Access	Vaginal or Abdominal / Laparoscopic	Vaginal or Abdominal / Laparoscopic

Mesh	Yes (sacrocolpopexy) / Historically Yes (TVM, restricted)	Yes (sacrohysteropexy) / Optional (colporrhaphy) / Historically Yes (TVM, restricted)
Main Use	Apical prolapse, combined compartment repair	Apical prolapse, anterior/posterior compartment repair, uterine preservation
Keynote	Apical suspension required to prevent vault prolapse	Provides uterine preservation, comparable short- to medium-term outcomes

The choice of surgical route and whether to perform a hysterectomy depends on prolapse severity, patient comorbidities, sexual activity, and patient preference, with both approaches showing high anatomical and functional success when appropriately selected.

6.5 Suggested profile and training for users

As a prerequisite, the SRS Implant should only be used by physicians trained in pelvic reconstructive surgery in a fully equipped operating room. Physicians should be trained in the minimally-invasive placement of surgical mesh devices for treatment of pelvic floor disorders and in management of complications resulting from procedures prior to using this device.

Additionally, the surgeon needs to pass successfully an established, documented training program This training program includes a theoretical and a practical, hand-on clinical sessions. The practical part consists of two sections of which one is a hands-on training at a suitable facility in real surgery and in the second part the surgeon has to perform the surgery independently under supervision of a qualified trainer/proctor. Only surgeons that successfully finalized all training parts can be certified and are allowed to use the device. Instruction for the usage of the device and training of new surgeons is only allowed by a representative of the manufacturer or a dedicated proctor, which has been certified by the manufacturer.

7. Reference to any harmonized standards and CS applied

a. MDR (2017/745)

This SSCP has been conducted according to description in the MDR Chapter III, Article 32 article. The MDR requires that the SSCP is conducted for “implantable devices and for class III devices”, is written in a clear way for the intended user and if relevant for the patient and shall be available for the public.

b. MEDDEV (2.7.1 Rev 4, 2016)

The MEDDEV is the basic standard describing the conduct of a clinical evaluation for any medical device. The current applicable version is MEDDEV 2.7.1 Rev 4 (2016) which is complemented by MDCGs issued as guidance to implement the MDR.

c. EN ISO 13485 (2016)

This standard defines the specific requirements for a suitable quality system that a manufacturer has to provide to assure that constantly customer and regulatory requirements are met. The latest update of this standard was released in 2016.

d. EN ISO 14197 (2019)

This standard specifies terminology, principles and a process for risk management of medical devices, including software as medical device and in vitro diagnostic medical devices. The process assists the manufacturer to identify any hazard that might occur by the usage of the device and provides tools for estimation, evaluation and control of associated risks.

8. Revision History, Data Sources and Release

Revision History			
SSCP rev. number	**Date issued**	**Change description**	**Revision and translations sent to Notified Body**
A 5.0		Initial Release	☐ sent to NB: Date ☐ Validated language of the master SSCP: English ☐ Other validated languages: ☐ No (only applicable for class IIa or some class IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

Part B – SSCP intended for patients/lay persons

This summary gives a simple overview of how safe and effective the SRS Implant is. This summary is for patients, for the public and for anyone without a medical background.

This summary does not offer medical advice. If you have questions about your health please talk to your healthcare provider. This summary does not replace the implant card nor the Instructions For Use.

What the device is designed to do:

- This implant is for adult women who have a moderate to severe case when the front part of the vagina weakens and bulges. They need surgical support to move those organs back into their proper place.

- **Who this device is for and what problems it treats:**

  The front wall of your vagina has dropped. It is now at or past the opening of your body. The top of the vagina may or may not have dropped too.

- **Who should NOT get this device:**
  - You should NOT get this device if you have any of the following:
  - You are pregnant or planning to have a baby in the future.
  - You are under 21 years old.
  - You have an infection in the area (this must be treated and cleared first).
  - You have cancer (or possible cancer) in the vagina, cervix, bladder, or uterus.
  - You have had radiation or chemotherapy in the past that damaged blood flow in the area.
  - You have a blood clotting disorder.
  - You have a disease that affects your body's connective tissue (like lupus or scleroderma).
  - You have kidney problems or trouble urinating.
  - You are allergic to polypropylene, titanium dioxide, or PEEK (the materials in the device).

- You have any other medical issue that makes the tissue in the pelvis weak, damaged, or oddly shaped.

4 Device description

- **What the device is made of and what touches your body?**

  It is a small implant placed inside the body to fix prolapse. It stays in the body from surgery.

  The basics:

  No big cuts: Doctors do not need to cut you open wide to put it in.

  Clean and safe: It comes sterile (germ-free).

  One time use: It is made just for you and cannot be used on another person.

  No stitches: It holds itself in place without anchors or stitches.

  Permanent: It does not come out.

  What is it made of?

  It has two parts:

  A plastic frame: Made from a strong medical plastic called PEEK.

  A mesh: A screen-like material that helps hold tissue in place.

  Shape and size:

  The frame has two side bars and a bridge that connects them.

  It can fold down small so doctors can put it in easily.

  It only comes in one size. It was designed to fit most women based on studies and research.

- **Does this device contain any medicine or drugs?**

  There are no medicinal substances in the SRS Implant.

- **How the device is put in:**

  This implant is placed inside the body to fix a dropped bladder and a dropped top of the vagina.

  Where it goes:

  It sits in the small space between the bladder and the vagina.

The steps of the procedure:

1. **The cut:** The doctor makes a small cut inside the vagina.
2. **Making space:** They gently separate the bladder from the vagina to create a pocket for the device.
3. **Placement:** The device is inserted into this pocket.
4. **Checking the fit:** The doctor looks to make sure the device is centered and lying flat under the bladder.
5. **No stitches to hold it:** The device stays in place on its own. It is not stitched or tacked down.
6. **Closing up:** The cut in the vagina is closed gently. A soft pack may be placed inside the vagina for one day to help with healing.

How it is like other treatments:

This device is put in using the same basic method and tools as other vaginal prolapse repairs.

- **Description of accessories, if any:**

  There are no accessories to be used with the device.

5 What you need to know about possible problems, side effects, and safety steps:

This sheet is to help you learn. It does not replace a visit with your doctor. If you have any worries or questions, please call your healthcare provider.

- **How we lower the chances of problems:**

  The company studies the device ahead of time to find possible problems. They list what could go wrong and why. The doctor gets safety instructions to help prevent issues. If a new risk is found later, the company will act fast to keep patients safe.

- **Risks and side effects that may still happen:**

  This implant has some risks. We follow strict steps to control these risks, but some cannot be completely removed.

  You probably already know the normal risks of surgery, so we won't list them here.

  The SRS Implant is made by Lyra to fix vaginal or uterine prolapse. Unlike other implants, it does not need stitches to hold it in place. Doctors believe those stitches often cause problems during or after surgery.

Because this implant doesn't need stitches, it is designed to be safer and avoid the issues that other meshes can cause. However, some side effects are still possible, and those are listed in the instruction booklet.

- Prevents mesh from cutting through tissue: The mesh is very thin and light. A solid frame keeps it flat so it cannot fold or bunch up. Folding causes damage.

- Prevents mesh from shrinking: The frame holds the mesh open so it cannot shrink. Shrinking causes pain.

- Lowers bleeding risk: Doctors do not need to push sharp tools blindly into the body. This means they are less likely to hit something they should not.

- Lowers pain risk: The implant supports the bladder without pulling on the vagina. No pulling means less pain.

- Keeps mesh holes open: The frame keeps the mesh flat. Flat mesh has open holes, which helps the body heal properly.

- **How the Numbers Work**

- **Range in other meshes:** This shows the lowest and highest rates reported for older, similar implants.
- **Lyra's rate:** This is the rate seen so far in studies for the new Lyra implant. If a number is not listed, it means it was not reported in the table.
  - **Erosion and Wearing**
- **Mesh erosion (mesh wears through tissue):** This happened in **1.4%** of Lyra patients. For other meshes, it happens in up to **13%** of patients.
- **Frame exposure (the plastic frame pokes through):** This is a new design, so there are no other meshes to compare it to.
  - **Pain**
- **Pain during sex (Dyspareunia):** This happened in **1.4%** of Lyra patients. For other

meshes, it happens in up to **7.6%** of patients.

- **General pain (pelvic or vaginal):** Other meshes report this in up to **14%** of patients.
- **General discomfort/irritation:** Other meshes report this in about **7.1%** of patients.
- **Mesh shrinking (causes pain):** Other meshes report this in up to **7.2%** of patients.
    - **Bladder and Urination**
- **New incontinence (leaking urine after surgery):** This happened in **2.8%** of Lyra patients. For other meshes, it happens in up to **25.6%** of patients.
- **Difficulty emptying the bladder:** This happened in **2.8%** of Lyra patients. Other meshes report this in up to **6%** of patients.
- **Urinary tract infection (UTI):** Other meshes report this in about **3.1%** of patients.
- **Urinary retention (cannot pee):** Other meshes report this in up to **21%** of patients (usually in the first week).
- **Ureter injury (damage to the tube from kidney to bladder):** Other meshes report this in less than **1%** of patients.
    - **Bleeding and Injury**
- **Bleeding or hematoma (blood collecting under tissue):** Other meshes report this in up to **7%** of patients.
- **Organ injury (damage during surgery):** Other meshes report this in up to **4%** of patients.
- **Organ perforation (mesh pokes an organ later on):** Other meshes report this in up to **9%** of patients.
    - **Infection**
- **General infection:** This happened in **5.7%** of Lyra patients. For other meshes, it happens in up to **10%** of patients.
- **Serious infection (abscess or sepsis):** Other meshes report this in less than **1%** of patients.
    - **Bowel and Digestion**
- **Constipation or trouble pooping:** Other meshes report this in up to **8.5%** of patients.
    - **Surgical Healing Issues**
- **Prolapse returning (needs another surgery):** Other meshes report this in up to **8.5%** of patients.
- **Wound issues (dehiscence/necrosis/tissue death):** Other meshes report this in up

to **3.5%** of patients.

- **Scar tissue (adhesions):** Other meshes report this in about **4.2%** of patients.
- **Granulation tissue (extra healing tissue):** Other meshes report this in less than **1%** of patients.
- **Surgical site irritation (redness/swelling):** Other meshes report this in up to **2.5%** of patients.
    - **Other Issues**
- **Vaginal discharge:** Other meshes report this in up to **10%** of patients.
- **Vaginal tightening:** Other meshes report this in up to **3.6%** of patients.
- **Nerve or muscle problems:** Other meshes report this in about **3%** of patients.
- **Mesh folding:** This can happen with other mesh implants.
- **Allergic reaction:** This is considered very rare.
- **Inflammation:** This can happen after any surgery.

About the Mesh Implant:

- This mesh is **permanent**. It stays in your body from surgery.
- If problems happen, you may need **more surgery**. Sometimes, even repeat surgery cannot fix the problem completely.
- If the body has a bad reaction or gets infected, the mesh may need to be removed.
- It may not be possible to remove all of the mesh.

Possible Body Reactions

- The body may react to the mesh. This can cause:
    - Redness or irritation where the cut was made
    - Mesh wearing through the skin or tissue (erosion or exposure)
    - Mesh moving from where it was placed
    - An abnormal tunnel forming between organs (fistula)
    - Swelling or a reaction to a foreign object

- These problems may require more surgery or mesh removal.

Risks During or After Surgery

- You may have mild leaking of urine if support is not complete.
- If the mesh is too tight, you may have trouble peeing. This can be temporary or permanent.
- During placement, the doctor could accidentally poke or cut:
    - Blood vessels
    - Nerves
    - Bladder
    - Urethra (tube that carries pee out)
    - Bowel
- These injuries may need surgical repair.
- Infection may happen. If it does, the whole mesh may need to be removed.

Important Rules for Doctors and Hospitals

- **Check the package:** Do not use if the package is open or damaged. It might not be sterile (germ-free).
- **Check the date:** Do not use if the product has expired. It may not work right and could cause infection.
- **One time use only:** The device is sterile for one patient, one surgery. Do not re-sterilize or reuse.
- **Inspect the device:** Check it before and during surgery to make sure it is not broken.
- **Do not force it:** Do not use too much force when folding or inserting the device. It could break.
- **Damaged devices:** Do not use a device that is damaged or has been repaired.

Doctor Training

- Only doctors with **special training** should perform this surgery.
- Doctors must be trained on how to use this specific device (SRS Implant).
- Doctors must also know how to manage problems if they happen.

Before Surgery

- Your doctor should plan where the mesh will go. Your body shape is unique.
- Imaging (like ultrasound) may be used before or after to help place the mesh and check for injury.

During Surgery

- The mesh should be placed flat and smooth.
- It should not pull on nearby tissue.
- The frame should not be bent.
- The mesh should be fully stretched out.

After Surgery

- The mesh has a titanium coating, but it **will not** affect X-rays, CT scans, or MRIs. You can still have these tests.
- You should see your doctor for check-ups for the rest of your life.

Things That Increase Risk

Some patients have a higher risk of problems. Tell your doctor if you:

- Have diabetes
- Smoke
- Have gone through menopause (low estrogen)
- Have had radiation near your pelvic area
- Are older
- Have pelvic muscle pain
- Heal slowly
- Take steroids
- Have an active infection

Your doctor will consider these things to decide if this surgery is right for you.

Disposal

- If the mesh is removed, the hospital must follow local rules to throw it away safely.
- If it is removed, the doctor should take photos and write a description to send to Lyra Medical.

- **Safety notices or actions taken since the device was approved**
  There were no negative reports for the SRS implant

6 Summary of clinical studies and what we learned before and after the device was on the market

- **The proof from studies that allowed this device to be approved.**

  Before the SRS Implant could be sold in Europe (CE Mark), Lyra Medical needed to prove it was safe and that it worked. They did two main studies to check:
- **Safety:** Did patients have problems or side effects?
- **Performance:** Did the implant fix the prolapse? Did patients feel better?

Study 1: The SRS-I Study (The First Small Study)

This was the very first test in humans. Think of it as a "pilot test" to make sure the idea was safe before trying it on more people.

- **Who was in it?** 20 women with prolapse.
- **How long were they watched?** They were checked for 3 years after surgery.
- **What was measured?** Doctors measured the prolapse (using POP-Q scores) and asked women how they felt (using questionnaires).

Key Findings:

- **It worked:** All 20 women were cured. Their prolapse improved from stage 2, 3, or 4 down to stage 0 or 1.
- **They felt better:** Women filled out questionnaires about their symptoms. Their scores improved significantly, meaning they had less discomfort and bother from their prolapse.
- **Sexual function:** Not enough women answered questions about sex to draw firm conclusions, but the data that was collected showed improvement.
- **Good safety results:**
  - No problems with urine retention (cannot pee).

- No new cases of stress incontinence (leaking urine when coughing/sneezing).
- No mesh erosion (mesh wearing through tissue).
- No pelvic pain related to the implant.

- **One serious problem:** In one patient, a small part of the *frame* poked through the vaginal wall.
- **Doctor feedback:** The surgeons said the device was very easy to use because it does not require complex stitching.

Conclusion of SRS-I: The study suggested the benefits of using this implant are greater than the risks.

Study 2: The SRS-II Study (The Larger Follow-Up Study)

This was a bigger study to confirm the results from the first study with more patients.

- **Who was in it?** 50 women with prolapse.
- **How long were they watched?** They were checked for over 3 years after surgery (average 39 months).
- **What was measured?** The same things: prolapse measurements and patient questionnaires.

Key Findings:

- **It worked:** 46 out of 50 women (92%) were completely cured.
- **Success rate:** 98% of women felt their symptoms were successfully treated. Only one woman still felt a bulge and needed a pessary.
- **They felt better:** Women's questionnaire scores improved significantly. The improvement was big enough to be considered "clinically meaningful," meaning it actually made a real difference in their daily lives.
- **Sexual function:** Again, not enough data for a strong conclusion, but the available data showed improvement.
- **Side effects seen:**
  - 2 cases of temporary trouble emptying the bladder.
  - 4 cases of new stress incontinence (leaking urine).
  - 1 case of problems with urination.
  - Some urinary tract infections (UTIs) and post-surgery hematomas

(bruising/blood pockets) that were not related to the device itself.

- **Good news:** No mesh erosion. No pelvic pain related to the implant. No unexpected serious problems. No deaths.
- **Doctor feedback:** Again, surgeons said it was easy to use.

Conclusion of SRS-II: The study confirmed that the SRS Implant is likely safer than other vaginal mesh implants on the market, and it works just as well as them.

Simple Summary of Both Studies

Feature	What They Found
Did it fix the prolapse?	**Yes.** The vast majority of women were cured (92-100%).
Did women feel better?	**Yes.** Their symptoms bothered them much less after surgery.
Was it safe?	**Generally, yes.** There were no cases of mesh erosion or implant-related pain. Some women had temporary urine problems or UTIs.
Any serious problems?	In the first study, one patient had the frame poke through tissue. In the second study, there were no serious device problems.
What did doctors think?	They found it very easy to use because it doesn't need complicated stitching.

- **More Proof That the Device Works**

Lyra continues to collect information to make sure the SRS Implant is safe and works well, even after it was approved. Here is what they found:

Study in Germany (Usability Study)

A local distributor in Germany wanted to see how well the implant worked in real-life use. Surgeons used the SRS Implant on **174 patients** and tracked what happened until the patients went home from the hospital.

Results:

- **Short hospital stay:** Patients stayed in the hospital for about **3.4 days** on average.
- **Very high success rate:** Almost all patients (**99.6%**) had their prolapse completely fixed.
- **Only one patient (0.4%)** still had some prolapse left, but it was mild.
- **No patients** had a severe prolapse when they left the hospital.

Side effects seen:

- **2.3%** had a hematoma (blood pocket under the skin)
- **1.7%** had an organ puncture during surgery (accidental poke)
- **1.7%** had trouble emptying their bladder (urinary retention)
- **0.6%** had stress incontinence (leaking urine)

Doctor satisfaction: The surgeons were very happy with how easy the device was to use and how well it worked.

Ongoing Studies

- **Quality of Life Study (started 2022):** This study is checking how patients feel over 24 months after getting the implant. It is still happening, so no results are available yet.
- **Long-Term Follow-Up (10 years):** Lyra is contacting patients from the very first study (about 10 years ago) to see how they are doing now. This will show if the implant keeps working well over a long period of time.

Watching for Problems

Lyra also keeps an eye on complaints from doctors and patients. They search medical literature to see if any new risks have been discovered.

Good news: No new risks have been found that would affect patients with the SRS Implant.

The Bottom Line

All of this information—from the original studies, the Germany study, and ongoing monitoring—shows that:

- The SRS Implant is **safe**.
- The SRS Implant **works well**.
- The **benefits** of using this implant are greater than the **risks**.

- What Are the Clinical Benefits? (How Do Patients Feel Better?)

  To measure success, Lyra does not just look at the prolapse itself. They also ask patients how they feel. They use a questionnaire called the PFDI-20, which asks 20 questions about prolapse symptoms, bladder problems, and bowel problems.

  Here are the specific goals Lyra set for the SRS Implant, based on what patients reported 3 years (36 months) after surgery.

  -Benefit 1: No More Bulge

  The Question: "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?"

  The Goal: Lyra wants at least 90% of patients to answer "No" to this question 3 years after surgery.

  This means the implant is holding everything in place, and patients do not feel that bothersome bulge anymore.

  -Benefit 2: Less Distress from Symptoms

  What is measured: The total score of the questionnaire. This score shows how much the pelvic floor problems are bothering the patient in daily life. A lower score means less bother.

  The Goal: Lyra wants 90% of patients to have their total distress score drop by at least 23 to 45 points 3 years after surgery.

  This means patients are significantly less bothered by their symptoms than they were before surgery.

  -Benefit 3: Better Bladder Control (Urinary Symptoms)

  What is measured: The part of the survey that asks about bladder problems (like leaking

or feeling the urge to go often).

The Goal: Lyra wants 80% of patients to have their bladder symptom score drop by at least 11 points 3 years after surgery.

This means most patients have fewer and less bothersome bladder symptoms.

- **Safety Parameters (How Safe Is the Implant?)**

  Lyra Medical compared its SRS Implant to other mesh devices on the market (called the State of the Art, or SOTA). They wanted to show that their device is safer. Here are the goals they set and the timeframes for tracking them.

Safety Goals for the SRS Implant

Risk (What could go wrong?)	Lyra's Safety Claim (Their Goal)	When is this measured?
Mesh erosion or exposure (Mesh wears through or pokes through tissue)	**Less than 3%** of patients will have this problem.	3 years after surgery
Frame exposure (The plastic frame pokes through tissue)	**Less than 3%** of patients will have this problem.	1 year after surgery
Mesh folding (Mesh bunches up instead of lying flat)	**Less than 3%** of patients will have this problem.	3 years after surgery
Organ injury (Accidental damage to bladder, bowel, or	**Less than 1%** of patients will	During the surgery itself

Risk (What could go wrong?)	Lyra's Safety Claim (Their Goal)	When is this measured?
other organs during surgery)	have this problem.	
Organ perforation later on (Mesh pokes into an organ after surgery)	**Less than 1%** of patients will have this problem.	2 years after surgery
Need for another prolapse surgery (Prolapse comes back and needs to be fixed again)	**Less than 3%** of patients will need repeat surgery.	3 years after surgery

Simple Summary

For each of these risks, Lyra promises that the number of patients affected will be very low—**3% or less** for most problems, and **less than 1%** for the most serious ones like organ injury or perforation.

7 Other treatment options you can discuss with your doctor

Talk to your doctor about other treatment options. Your doctor can help you choose what is best for you.

8 Suggested training for users

This SRS implant can only be used by trained pelvic surgeons. The surgery must take place in a fully equipped operating room.

Doctors must be trained in minimally invasive mesh placement. They also need to know how to manage any problems.

Before using this device, the surgeon must pass a formal training program. This program is documented and approved. It includes both classroom learning and hands-on clinical training.

The practical training has two parts. First, the surgeon practices real surgeries at an approved location. Then, they operate on one's own under a proctor.

Only surgeons who complete all training are certified. Only certified surgeons are allowed to use this device.

Only certified proctors or producer reps can train surgeons.