

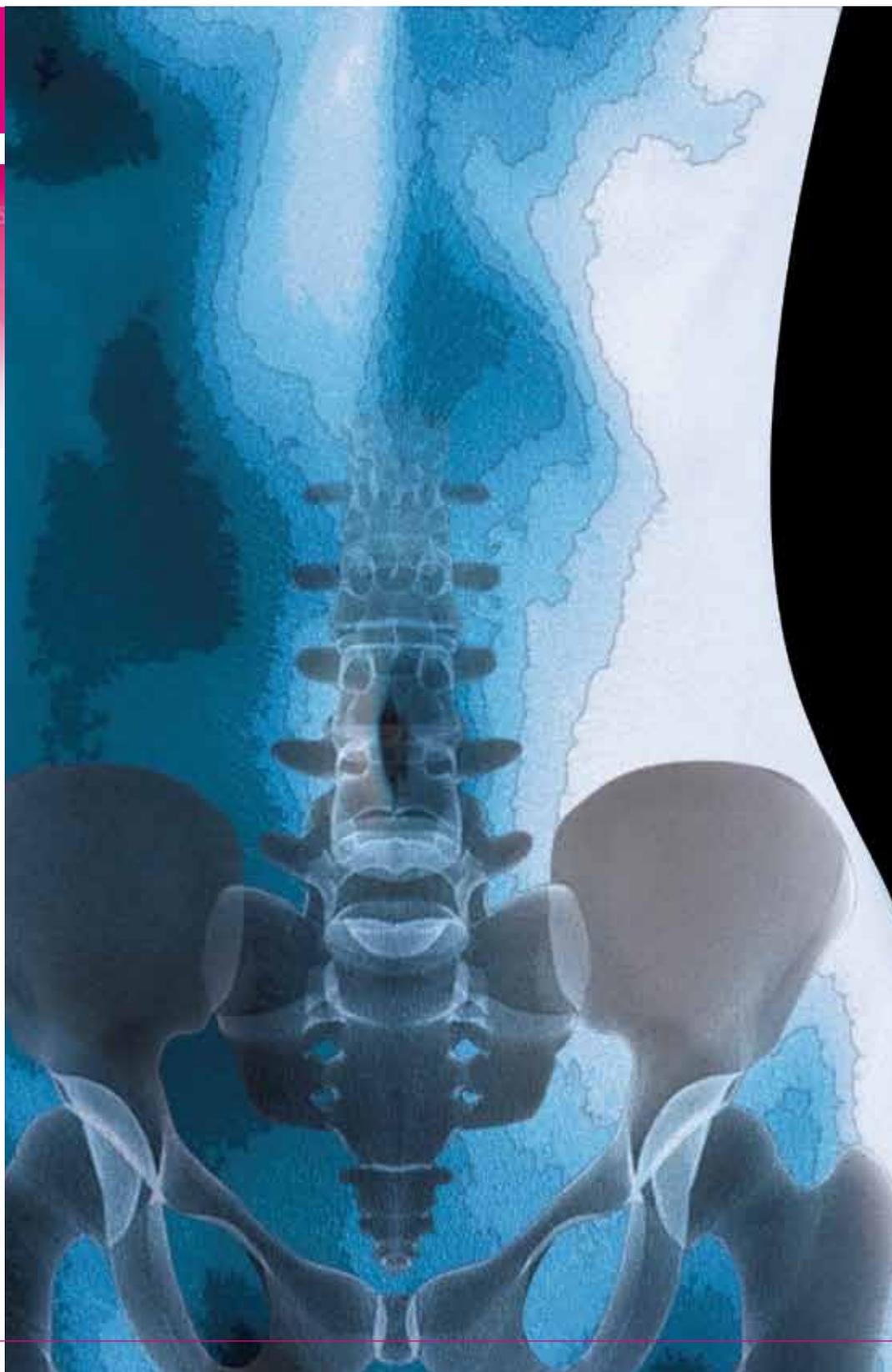
Systems for

UROGYNAECOLOGY

Textile
implants



Safety
with method



150
YEARS
1866 - 2016



SERAG
WIESSNER



Innovation and tradition

Decades of experience

High-tech and craftsmanship

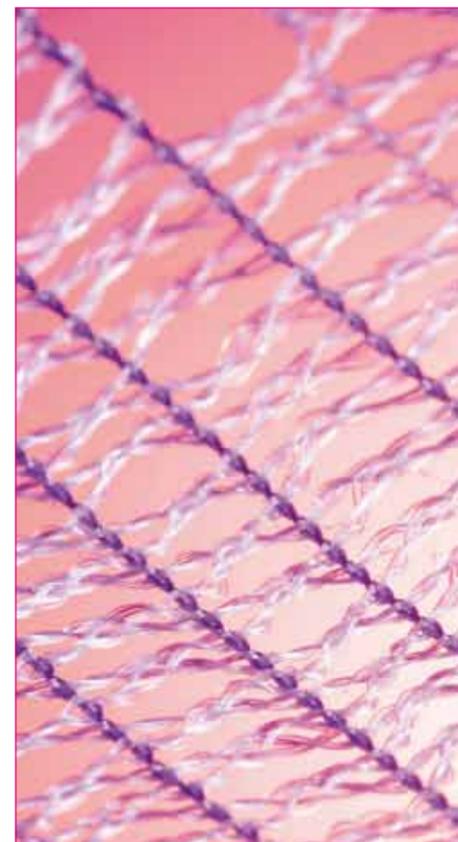
Interdisciplinary research

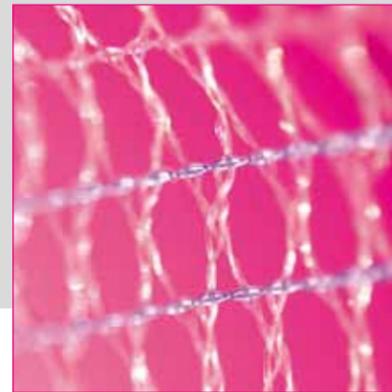
As the oldest German manufacturer of surgical suture material, SERAG-WIESSNER combines many decades of experience with the latest medical know-how. More than a hundred years ago the company began manufacturing sterile catgut and later also successfully established itself as the producer of sterile liquid medicinal products. Production efficiency at the plant in Naila, Upper Franconia, is not only a tradition but also future orientated: the combination of precise craftsmanship and high-tech industrial manufacturing processes meets the highest quality demands in routine production, small-scale production and special designs. In our 2000 m² cleanroom area, more than 200 employees manufacture textile implants, surgical suture material, infusion and rinsing solutions, as well as reusable instruments, bringing together the latest research

and state-of-the-art technology. In addition, interdisciplinary teams of in-house and external doctors, pharmacists, biologists, chemists and engineers develop new, improved and better-tolerated materials, as well as novel methods of treatment. This cooperation has already produced the successful SERASIS[®] system for the treatment of stress incontinence in women. SERATOM[®] provides systems offering a whole range of technical options for treating prolapses and sets new benchmarks in urogynaecology. And in addition to the continuous development of the tried and trusted systems, comes the new SERATEX[®] range of products. These textile implants have been developed mainly for laparoscopic surgery.

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Product range





Safety meets comfort

State-of-the-art composite material

Minimally invasive procedures

Economic and efficient surgical techniques

There are always high expectations placed on surgical procedures: as little stress for the patient as possible, short treatment times, the best possible prognosis of cure, to mention just the most important. SERATOM® PA, SERASIS® PA and SERATEX® PA were developed to fulfil these expectations. Their ease of handling results from the complex structure of the textile implants. The mesh consists of partially absorbable bicomponent fibres - a unique combination of two tried and tested materials, polypropylene (PP) and the segmented copolyester of polyglycolic acid and caprolactone (PGACL). Both materials

have been used in surgery for a long time and are well known and clinically proven as surgical suture material. The two components are combined into a monofilament fibre structure by extrusion. Absorption of PGACL into the body usually takes 90 to 120 days, during which time the body's cells grow into the mesh. The remaining colourless PP meshwork is a stable and permanent implant made of thin individual filaments. It forms an extremely soft mesh implant that is very comfortable for the patient. As distinct from other partially absorbable implants, the original mesh structure of SERATOM® PA,

SERASIS® PA and SERATEX® PA is completely maintained even after partial absorption. During the absorption process, the implant decreases in weight by about two-thirds. Less foreign material in the body, but still of sufficient strength, means the greatest possible safety and tolerability for the patient. In addition, the surgical instruments developed for this method can be reused. Comparison with existing methods and products confirms the advantages of SERATOM® PA, SERASIS® PA and SERATEX® PA for all concerned.

Advantages for the doctor:

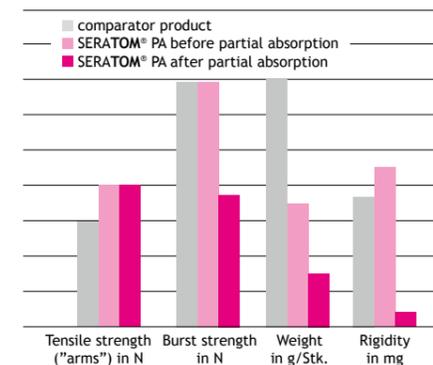
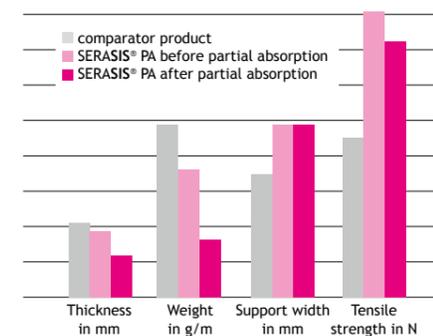
- High initial rigidity for optimal handling
- Cost-saving, minimally invasive surgical procedure
- Unique stability of shape
- Novel composition of tried and trusted materials with macroporous mesh structure to allow optimal ingrowth of cells
- Hydrophilic surface of the fibres for secure adhesion

Benefits for the patients:

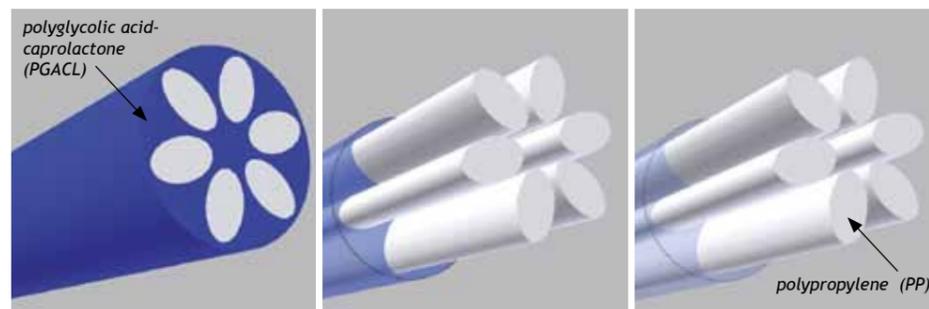
- Minimally invasive surgical procedure
- Reduced risk of infection due to monofilament structure
- Minimum foreign body presence
- Anatomically adapted elasticity
- Excellent patient comfort thanks to optimised softness

Less is more

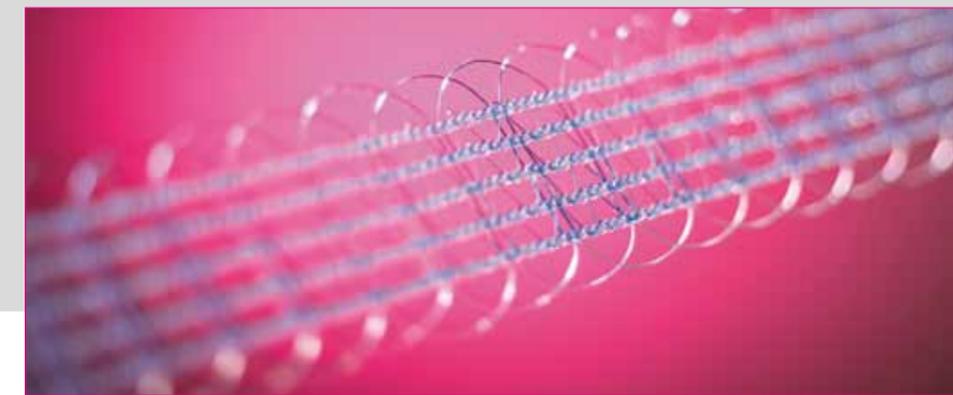
Convincing facts



Partial absorption



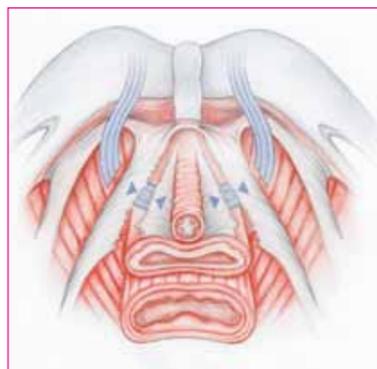
Fibre before partial absorption ... during partial absorption ... just before partial absorption has finished.



Retropubic approach



Paraurethral approach



The advantages of flexibility

The SERASIS® systems are particularly suitable for the treatment of patients with genuine stress incontinence, those with intrinsic sphincter dysfunction and those undergoing pelvic floor reconstruction (e.g. prolapse surgery with SERATOM®). Tape implants with monofilament non-absorbable polypropylene or partially absorbable bicomponent material (hexafilament with a monofilament character) are available for tension-free applications. Besides standard TVT use, the extensive range of surgical instruments and implant programmes also allow the surgeon to use the transobturator, paraurethral or posterior approaches. All the possible routes of access (vaginal, abdominal, outside in and inside out) are thus completely covered.

Retropubic approach

This procedure became known throughout the world as the tension-free vaginal tape (TVT) method. With a 1.5 cm long anterior colpotomy and two abdominal incisions, the SERASIS® tape is pulled through the body with the aid of the two SERASIS®/SERAPRO® instruments. This permanent implant holds up the urethra as a tension-free support and the tape can be adjusted in both directions after the vaginal incision has been sutured. The blue colour makes it easier for orientation in the tissues and allows a sure transection in cases of over-correction.

Paraurethral approach

In addition to simple fixation with the retropubic SERASIS®, a supporting tape can also be implanted using a paraurethral approach if the vaginal suspension is defective. With severe suspension defects, however, anterior SERATOM® fixation is to be preferred.

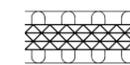
Transobturator approach

The transobturator SERASIS® offers greater scope with respect to the access and the indications for surgery. Unlike the two techniques mentioned previously, the route followed is through the obturator foramen. The vaginal incision is the same but two stab incisions are made over the obturator foramen close to the groin. With SERASIS® PA ADAPT, an additional central thread loop allows subsequent adjustment of the tape without any further aids.

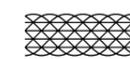
With the various reusable helical instruments, the route from the inside to the outside or from the groin down to the vagina may be selected. The risk of injury to internal organs is reduced still further by this procedure.

Posterior approach

Slight defects in vaginal suspension can likewise be treated with an ischioanal SERASIS® tape. A SERATOM® implant using the posterior approach is the technique of choice for large prolapses.



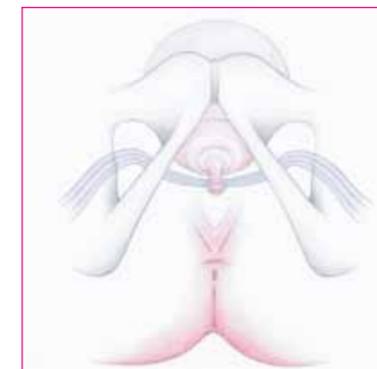
SERASIS® -tape
Article No: IS55MR



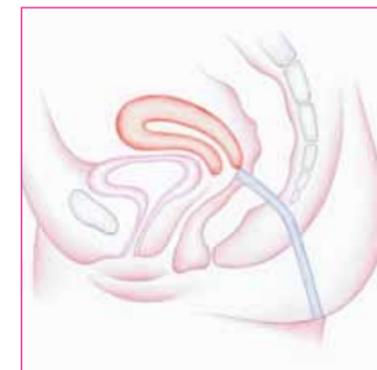
SERASIS® PA-tape
Article No: IS56MR

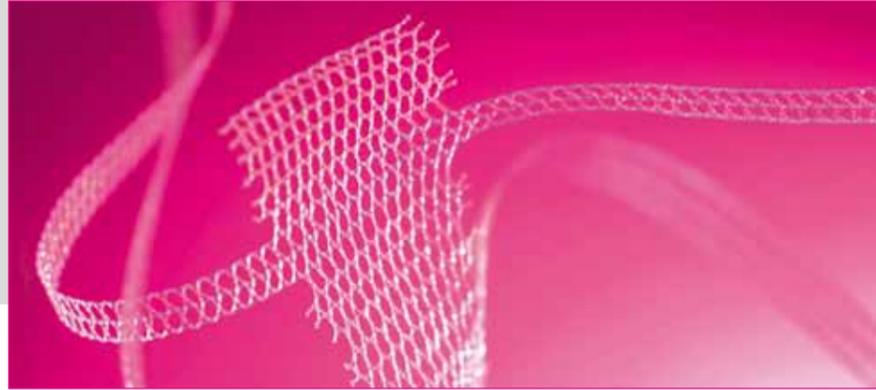
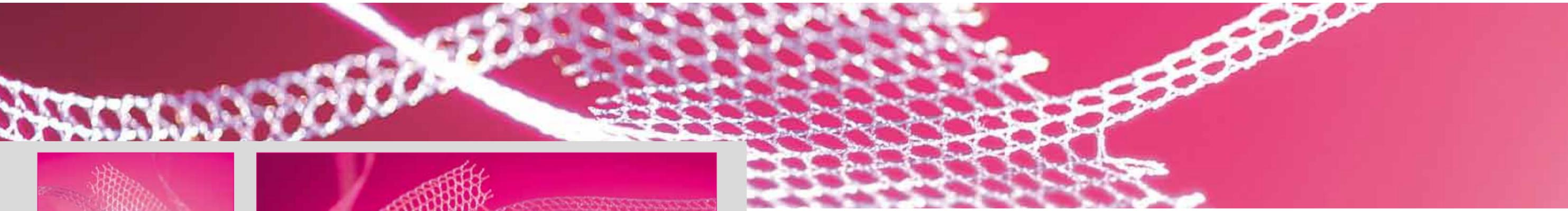
SERASIS® PA ADAPT
Article No: IS58MR

Transobturator approach



Posterior approach





Safety with method

Textile implants specially for the pelvic floor

Developed together with surgeons

SERATOM®

The SERATOM® system offers various meshes for the reconstruction of the pelvic floor, together with the appropriate introducers. The different options allow optimal repair of defects in the pelvis, both in the anterior and posterior regions. The unique macroporous mesh provides optimal suspension of the vaginal vault or the uterus. Implantation of a SERATOM® mesh elevates the prolapse and at the same time stabilises the tissues. The supportive mesh is fixed to stable structures in the pelvis by means of angled and individually tensioned tapes. This results in an anatomically correct, lasting reconstruction of the pelvic floor - an important prerequisite for the recovery of bladder and bowel function. The tolerability of these materials has been continually improved in recent

years. The latest development is a mesh made out of partially absorbable fibres, so that the quantity of foreign material can be kept to a minimum. These materials allow the surgeon to bring the vagina, bladder and bowel back to their original positions and fix them permanently in place. In addition, an expert team of experienced surgeons is continuing to develop the SERATOM® system even further. In this way, as far as the stability of the implants is concerned, it has been possible to increase the success rate considerably from the previous average of 60-70% with classic surgical techniques.

The use of SERATOM® allows a minimally invasive, tension-free, surgical concept that can be performed via the vagina. Its use is indicated with findings of traction cystoceles in need of surgical

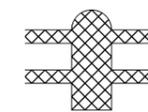
correction, with or without a stable cervix and also as part of an overall concept for transvaginal surgery in cases of incomplete or complete prolapse.

4-point fixation

When the cervix itself still has sufficient stability, even though there are anterior compartment prolapses, the use of a 4-point fixation SERATOM® is recommended. The implant is also inserted via an anterior colpotomy in this surgical procedure.

The "arms" (tapes) of the SERATOM® mesh are positioned in such a way that the textile implant spans the pelvic floor and provides the bladder with a hammock-like support. With this technique, the tapes of the implant are brought out by the transobturator route and both the upper and lower mesh

edges are fixed with sutures. The sets include a full range of half-curved and helical instruments. Surgeons are already familiar with their use from operations with SERASIS®.

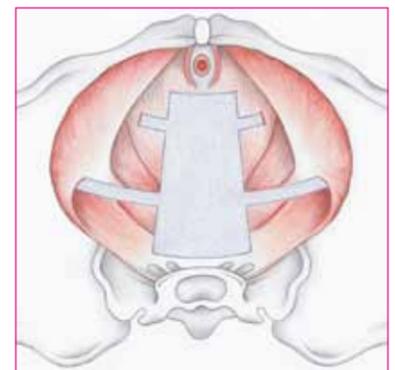


SERATOM® A PA
Article No: SN205MR

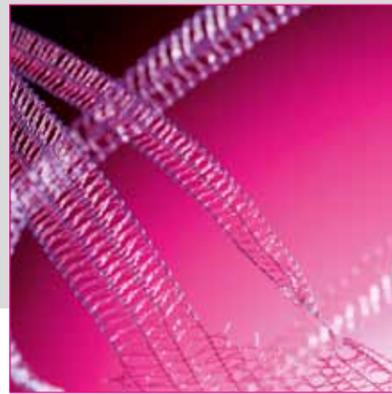
4-point fixation



Lateral view of the implant, which is stretched out between the bladder and the vagina and fixed beneath the bladder and to the cervix.



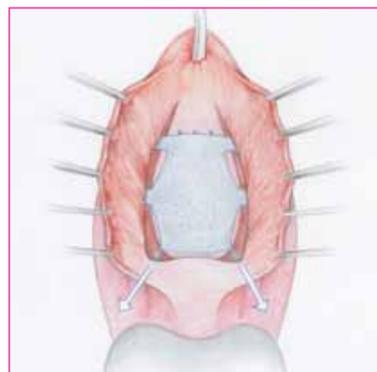
View of the pelvic floor from above, showing the permanently supporting SERATOM®.



6-point fixation



The individually adapted implant provides stability and security.



View from below, showing the SERATOM® mesh stretched out under the bladder and the posterior fixation.

6-point fixation

Bringing the tapes out via the trans-obturator route also applies to 6-point fixation. This method is recommended if there is an "unstable cervix" and/or when the uterus has been removed. It also allows the options of organ-sparing surgery and lengthening the tapes or reducing the implant surface through an incision in a stable area. Potential problems with defaecation are avoided by angulation of the tapes and adjustment of the tension to suit the individual. As distinct from the 4-point fixation option, 6-point fixation has an additional pair of arms. The bladder load is thus distributed over a wider area which, apart from making it more comfortable for the patient, also increases the loading capacity of the mesh implant. Two further sacrotuberal/sacrospinous attachment points are required for additional fixation. The third tapes on

each side can be positioned in the gluteal region or by using the SERAPRO® RSD Ney in a single-incision technique. It is important that the upper and lower edges of the mesh are fixed loosely to prevent any downwards slipping or sintering of the implant. SERATOM® E PA and SERATOM® P PA have considerably greater load-bearing capacity and stability because of their narrower stitches and additional fixation. These properties make the mesh implants entirely suitable for this surgical implementation, depending on the patient's anatomy and the surgeon's preference.

SERATOM® E PA
Article No: SN215MR

SERATOM® P PA
Article No: SN845MR

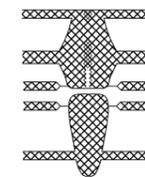
Posterior SERATOM®

Defects in the posterior compartment are also dealt with by means of a specially designed textile implant. The implant is put into position through a posterior colpotomy and the arms brought out through the gluteal region. The ends of the "upper" tapes are attached in such a way as to allow hinge-like movement, thus ensuring that sufficient freedom remains for the intestines. The implant is stretched out easily, without wrinkles, by the four tapes. Its use in the posterior compartment crosses the border between gynaecology and proctology. With interdisciplinary cooperation of these two specialities, SERATOM® can also be used by proctologists. SERATOM® F PA is the standard implant for posterior use; however, SERATOM® L PA is also available for patients with large defects. This

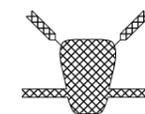
flexibility is another of the advantages offered to the surgeon. Attention should also be paid to fixing the mesh edges when using a posterior SERATOM®. Alternatively, the SERAPRO® RSD Ney can be used instead of the gluteal incisions and the operation performed with a single-incision technique. Please note that we offer special training in this technique.



SERATOM® F PA
Article No: SN245MR



SERATOM® E PA +
SERATOM® F PA +
Article No: SN265MR



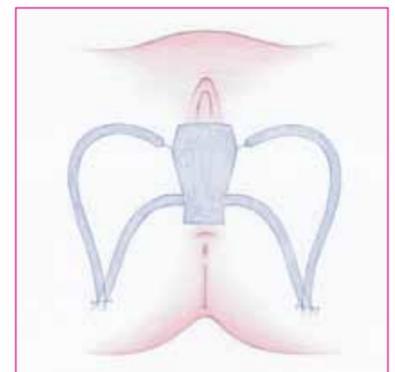
SERATOM® L PA
Article No: SN295MR

Other articles can be found in the full catalogue.

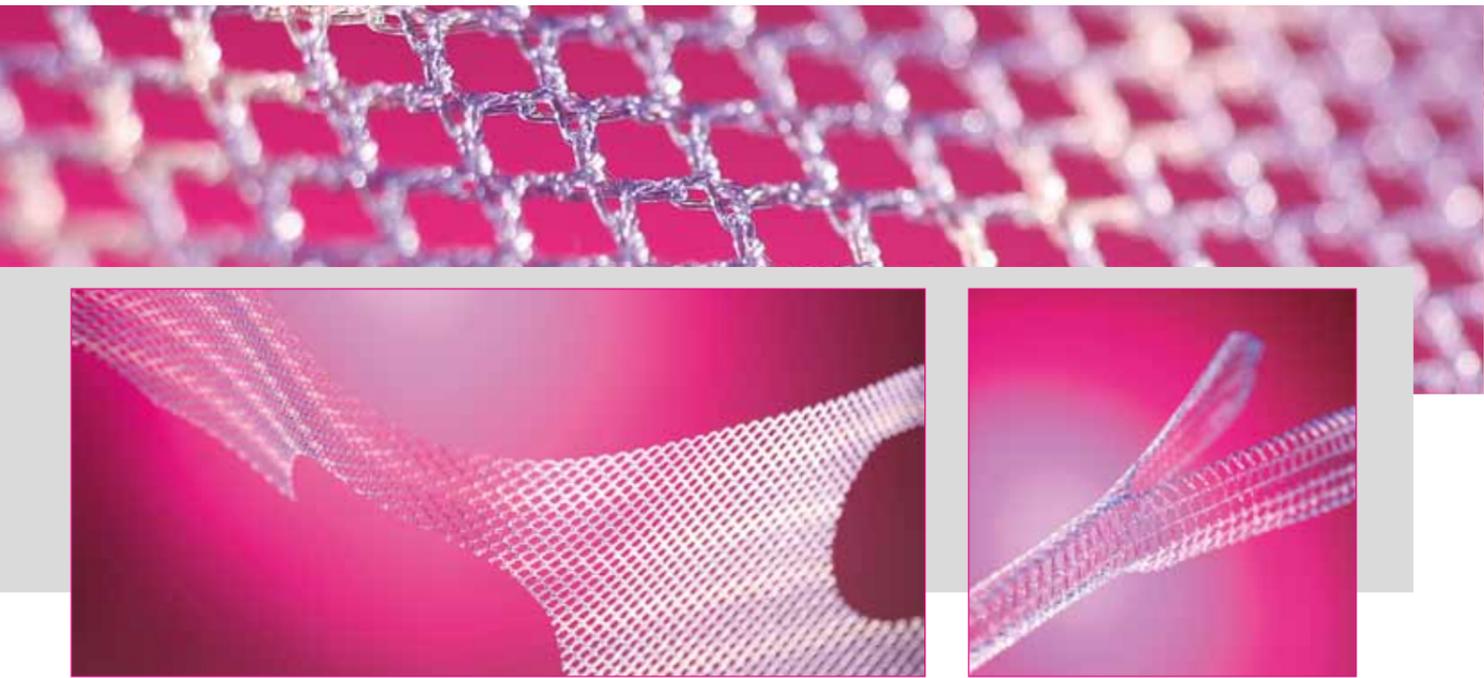
posterior



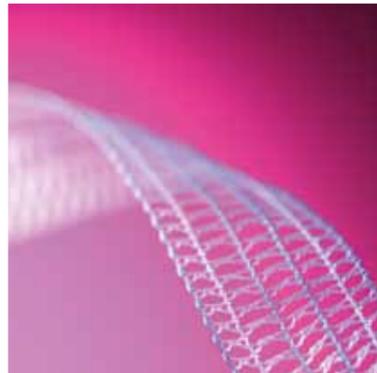
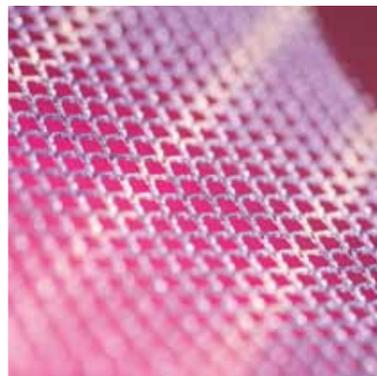
Fixation of a rectocele in the posterior compartment with gluteal attachment.



View from below, showing the angled and fixed gluteal tapes.



Sacrocolpopexy



SERATEX®

With SERATEX®, we have further expanded our product range of partially absorbable mesh implants for laparoscopic surgery.

The advantages of partial absorption, less foreign material permanently in the body but still with adequate strength, remain just as important as the stable structure of the mesh.

The SERATEX® E series meets demands for greater elasticity.

-  SERATEX® A PA
Article No: STA01401
-  SERATEX® B1 PA
Article No: STB01001
-  SERATEX® B2 PA
Article No: STB01002
-  SERATEX® E1 PA
Article No: STE01001
-  SERATEX® E2 PA
Article No: STE01002
-  SERATEX® E3 PA
Article No: STE01003
-  SERATEX® F1 PA
Article No: STF01001

Practical experience centres in Europe

The best way of finding out about the considerable advantages of our mesh implants and surgical instruments - e.g. shorter and more minimally invasive procedures, handling, the operating and healing process - is through practical experience. For this reason we offer you the opportunity of working with experienced surgeons in selected clinical centres, to follow their work with our products at first hand. These experts will impart their knowledge to you in a clear manner and you will gain insight into

the clinical work with patients and their follow-up care. In addition, you will benefit from lively discussion and the exchange of views. Are you interested in learning more about our mesh implants and the associated surgical techniques? Please contact one of our in-house product consultants or sales representatives. We will be pleased to tell you more about our practical experience centres in Germany and in Europe, and suggest available dates for your visit.

Informational material

Surgical materials and instruments developed by SERAG-WIESSNER are renowned for their reliability and precision of use and are extremely well tolerated. Our films of operations show details of comprehensive

examples of the products' use in surgical practice. We have also prepared clear and easily understandable leaflets and brochures to help your patients understand the individual possibilities and benefits of our products.



Implant pass
Art. No. 801034

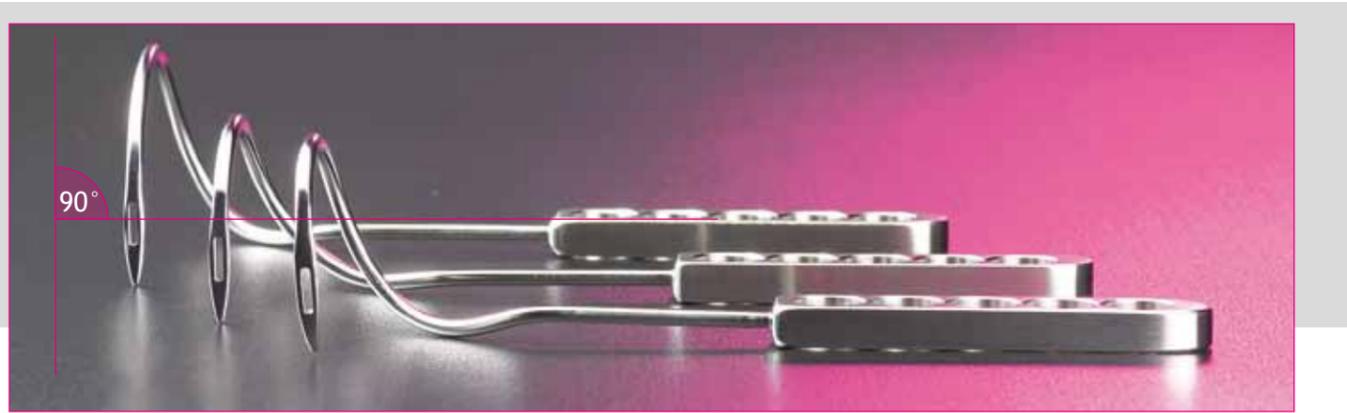
Surgical training films:
SERASIS® / SERASIS® TO -
Stress incontinence system
(CD German/English), Art. No. VF15

SERATOM® (DVD - English), Art. No. VF17

SERATOM® - Infracoccygeal colpopexy
(DVD - German/English), Art. No. VF18

SERATOM® E PA - 6-point fixation
(DVD - German/English), Art. No. VF21

Further brochures and overviews can be found at www.serag-wiessner.com



Instruments

SERAPRO®/SERASIS®

The SERAPRO®/SERASIS® instruments have been developed over many years in cooperation with surgeons in gynaecological and urological practice. Taking into account the precision and stability required, we decided right from the start that all our first-class reusable instruments would be made from high quality surgical steel. This decision resulted in superior handling and costs that are much lower than for disposable instruments. The instruments designed for specific purposes (e.g. SERASIS® trocar sets) can be used for all applications depending on the surgeon's preferences and the anatomical conditions presented by the patient: they can, for example, be used for SERASIS® TO, XXL, SL.

Possible access routes:

- vaginal - abdominal
- retropubic - transobturator
- outside-in - inside-out
- single-incision

Further improvements in the possibilities for use and the ergonomic handling are continually being developed, with the aim of making it possible for all surgeons to select the safest and best method for themselves and their patients.

SERAPRO® RSD-Ney

Developed together with Dr Jörg Neymeyer, these suturing forceps can be used for many indications, using a single-incision technique to place surgical sutures or insert mesh implants.

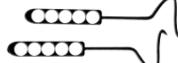
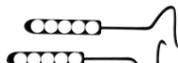
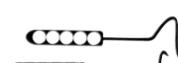


Reusable instruments made from surgical steel, with integrated safety features.

Integrated safety

A wide range of experts in various disciplines have contributed to the development of each instrument so that it meets the highest standards in every respect. For optimal surgical procedures, the axis of the instrument and its penetrating part are aligned vertically. The penetrating part is in a vertical plane and the axis of rotation of the instrument is in the centre of the helix. The handle is deliberately designed with cut-outs. Less material means a considerable reduction in weight. This makes a noticeable difference to the ease of handling and precision of use - even when wearing wet surgical gloves. The German instrument makers in Tuttlingen are responsible for design as well as for ensuring that the instruments are easy to clean, so as to guarantee optimally safe sterilisation.

These and many other factors contribute to the integrated safety, both in passing the instruments and in the processes involved in their reuse.

-  SERASIS® TO Set
Article No: IS50
-  SERASIS® TO XXL Set
Article No: IS60
-  SERASIS® TO SL Set
Article No: IS70
-  SERASIS® V
Article No: IS40
-  SERASIS® V2
Article No: IS80
-  SERAPRO® V3
Article No: IS85
-  SERAPRO® VT1
Article No: IS90
-  SERAPRO® RS
Article No: IS91
-  SERAPRO® RSD/Ney
IS200

Top quality reusable surgical instruments



Quality German engineering in all its aspects allows individual use in accordance with the surgeon's preferences and the patient's anatomy.



150
YEARS
1866 - 2016



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