

## A.M.I. BSC Mesh

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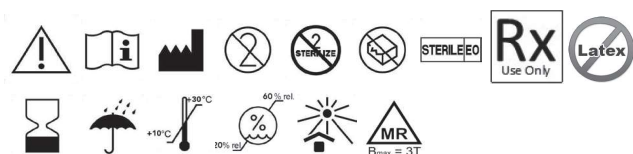


REF	Product name
BSC5001	BSC Mesh PP 0

**Operating manual**  
**Gebrauchsanweisung**  
**Manuale operativo**

**Manual de instrucciones**  
**Manual operacional**  
**Návod k používání**  
**Návod na používanie**

**C€0297** PFR5551



**A.M.I.®**

## 1. Terminology & abbreviations

POP	–	pelvic organ prolapse
PP	–	polypropylene

## 2. Product description

The BSC Mesh (BSC = Bilateral Sacrospinous Colposuspension) is made of an ultralight monofilament polypropylene mesh with hexagonal structure. It is designed to induce the formation of neo-ligaments by establishing symmetrical, bilateral suspension of the vaginal vault from the sacrospinous ligament. It recreates the support previously provided by the natural ligaments, which are no longer functioning. The BSC Mesh is considered a minimally-invasive form of correction for pelvic organ prolapse, as a vaginal dissection of just the size of the surgeon's finger is necessary to position the implant and fix it to the sacrospinous ligament by means of suitable suture instruments (e.g. A.M.I. i-stitch).

The BSC Mesh is offered with a ready-to-use set of PP-sutures (blue) loaded onto stainless steel devices for surgical suture attachment, which are intended to be used in combination with the mesh implant during implantation.

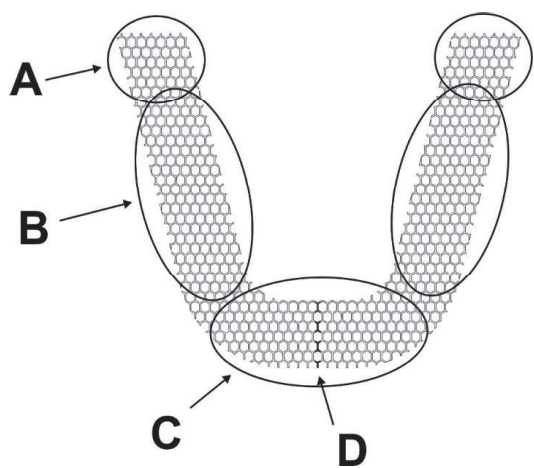
REF	Name	Component	Description
BSC 5001	BSC Mesh PP 0	BSC Mesh implant	Mesh implant
		i-stitch loading unit PP 0 (2x)	Loading unit to use with the A.M.I. i-stitch instrument

## 3. Intended use

Transvaginal mesh implant for surgical treatment of female pelvic organ prolapse (POP).

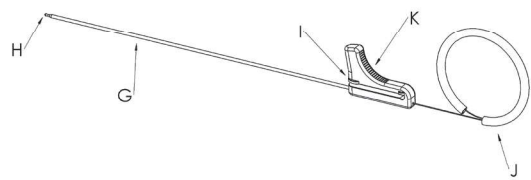
4. Definition

BSC Mesh implant:



No.	Description	Function
A	Mesh suspension zone	Prolapse re-suspension
B	Free mesh section	Space for the rectum
C	Central mesh section	Attachment zone to apical vagina
D	Midline marker	Positioning aid

i-stitch loading unit:



No.	Description
G	Cannulated needle
H	Blunt suture tip
I	Sliding guide
J	Suture dispenser
K	Needle slider

## 5. Product features and clinical benefits

- Implantation via transvaginal approach
- Implant is made of lightweight, wide-pore, biocompatible monofilament mesh material
- BSC Mesh features a circular-shaped cut-out in the proximal part to ensure the mesh fits properly around the rectum

## 6. User group/ user qualifications

The products are intended for use by qualified and expert medical specialists. An understanding of the principles of the appropriate surgical techniques is a prerequisite.



**Warning!** Pelvic reconstructive surgery with and without implants requires knowledgeable (e.g. anatomy) and experienced surgeons as pointed out in various guidelines and recommendations of medical societies (e.g. SCENIHR, FIGO, AGUB, EAU/EUGA):

- Especially the use of surgical meshes for POP surgery is only advised for trained surgeons who are educated in the surgical technique of this treatment.
- Furthermore, the surgeons should be trained on the usage of the specific mesh products.
- It is strongly advised to perform such complex surgeries in specialized and experienced multidisciplinary medical centres or hospitals only.

A.M.I. GmbH offers and highly recommends workshops wherein the usage and handling of the product in question is shown. Please contact the local distributor or the manufacturer to get the details/ information about the workshops.

## 7. Patient group

Physically mature, at least 18 years old female patients with symptomatic genital prolapse with or without urinary incontinence.

## 8. Indications

BSC Mesh is indicated for transvaginal reconstructive surgery of symptomatic pelvic organ prolapse (POP) with or without urinary incontinence, restricted to

- (a) cervical-,
- (b) uterine-, or
- (c) vault prolapse
- (i) in complex cases,
- (ii) as secondary surgical treatment or
- (iii) in case of high risk of POP recurrence.

## 9. Contraindications

The use of the product is contraindicated in case of:

- pregnancy and/or patients who consider future pregnancies
- adolescent/ pubescent patients
- existence of a known sensitivity/ allergy against plastic materials such as polypropylene, polyester, etc.
- any pathology, including known or suspected uterine pathology, which would compromise placement of the implant/mesh (e.g. anatomical distortion or abnormalities)
- known anticoagulation disorder
- anticoagulant therapy
- autoimmune connective tissue disease
- renal insufficiency and upper urinary tract obstruction
- cancer illnesses of the vagina / cervix / rectum
- undergone radiation therapy on the vagina, cervix, rectum
- planned or emergency opening of the gastro-intestinal tract, as this could cause a risk of product contamination that could lead to infection that would require removal of the implant/device
- active or latent infection especially of the genital system and/or urinary tract

The use of the product is generally deemed contraindicated, if the method as such or the use under consideration of the patient's general condition is seen as contraindicated by decision of the attending physician.

## 10. Patient information

The surgeon performing the implantation should ensure that patients or their representatives, are correctly and comprehensively informed on the benefits and risks associated with the use of synthetic non-absorbable polypropylene meshes. Before the mesh procedure, the patient must be informed of the following additional issues:

- Mesh placement route (abdominal, transvaginal)
- Mesh is considered a permanent implant; removal of mesh or correction of mesh-related complications may involve subsequent surgery/surgeries
- Surgeon's assessment of risk-benefit ratio taking into consideration patient age, severity of prolapse, severity of symptoms, possible future complications that are specific to mesh explantation
- Limitations of mesh removal and correction of post-operative complications
- Specific complications/ residual risks associated with the proposed procedure
- Suitability of the patient's condition for mesh implantation
  - Patients with family planning completed (i.e. exclusion of pregnant patients and/or patients with planned pregnancy)
  - Level of sexually activity
- Evidence/ level of experience of the performing surgeon with the surgical procedure
- Alternative treatment options (advantages and disadvantages in relation to specific patient condition)
  - Non-surgical treatment as primary treatment before surgery
  - Different surgical treatment options (including native tissue repair)
  - Different implantation routes for mesh implants (abdominal and trans-vaginal)
- Education of the patient about the fact that all publications about outcome of surgical and non-surgical treatment may have a bias that complications are underrepresented since there is an increased likelihood that patients with complications will not attend (voluntary) follow-up visits in conjunction with studies. Therefore, the possibility of a complication / adverse event is likely to be higher than reported in studies.

## 11. Possible complications / adverse events

Possible complications include but are not limited to:

### **Frequently or (implant) specific reported complications:**

- de novo urge urinary incontinence,
- post-op bowel obstruction/ constipation,
- dyspareunia,
- prolapse/ recurring prolapse,
- de novo urinary incontinence,
- mesh erosion, mesh extrusion,
- pain (acute or chronic),
- faecal incontinence,

### **Additional reported complications:**

- hematoma,
- hemorrhage,
- post-operative bleeding,
- inflammation (acute or chronic),
- infection,
- abscesses,
- fistulae development/ formation,
- wound dehiscence,
- reaction against foreign body,
- adhesion formation,
- ischuria,
- difficulties while urinating / dysuria,
- urinary retention,
- contractions,
- nerve damage,
- perforation of vessels, nerves, bladder, urinary tract, large bowel and other structures,
- vaginal shortening/ stenosis,
- necrosis,

- mesh or tissue contraction,
- vaginal discharge
- scar tissue formation
- emotional and psychological condition

Pain can be experienced in the area of the product in the early post-operative phase.

Continuous persisting pain in the area of the mesh requires a more detailed medical clarification.

The effectiveness of the product is greatly affected by applied surgical techniques, the inter-operative maintenance of sterility, the correct dimensions and positioning.

Any incontinence which might already have existed can become obvious following the rectification of the incident.

Unwanted tissue reactions can require a part or complete explanation of the product.

When securing the product, care needs to be taken not to damage (e.g. cut or rip) the mesh implant with the means of fixation being used (e.g. surgical sutures).

## 12. Safety related information

### **Danger**



The keyword „danger“ indicates a hazard with a potentially high risk, which if the hazard is not avoided, the consequences are severe injuries or death

### **Warning**



The keyword „warning“ indicates a hazard with a medium risk, which if the hazard is not avoided, the consequences are severe injuries

### **Caution**



The keyword „caution“ indicates a hazard with a low risk, which if the hazard is not avoided, the consequences are minor or moderate injuries


















### **Note**










The keyword „note“ indicates a safety information which shows a condition which has to be complied, information for understanding, as well as tips and recommendations for the effective use of the product



## 13. Warnings and precautions

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-  **Danger!** Pelvic reconstructive surgery (implantation and explantation of mesh implants) requires knowledgeable (e.g. anatomy) and highly experienced surgeons as pointed out in various guidelines and recommendations of medical societies (e.g. SCENIHR, FIGO, AGUB, EAU/EUGA)  
Implantation and explantation of mesh implants should only be done in specialized medical centres or hospitals with sufficient expertise.
- 
-  **Warning!** The information in the current instructions for use, as well as the information accompanying the products used in combination must be adhered to. 
- 
-  **Warning!** The product must not be used for any purposes other than the purpose mentioned above.
- 
-  **Warning!** Do not attempt to alter this product in any way. Doing so may endanger the patient and / or user.
- 
-  **Warning!** The use of damaged products or products which do not function perfectly is to be avoided.
- 
-  **Warning!** Do not re-sterilize or reuse disposable products   

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-  **Warning!** Do not use the product after the expiry date. 
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-  **Warning!** Do not use products that have open or defective sterile barrier packaging 
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-  **Warning!** The mesh has to be fixed in a way that the suture runs in a rectangular way according the direction of load. A distance of a minimum of 1 pore needs to be ensured between the threaded sutures.
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-  **Warning!** In case of any explantation, the product holds a biological hazard. The disposal has to be carried out according to current national laws and recommendation guidelines (e.g. RKI recommendations) for clinical waste.
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-  **Warning!** Vaginal or urinary tract infections should be cured completely prior to implantation of the product.
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-  **Warning!** The product is only to be used in case of patients who have been classed as suitable following a medical examination carried out in advance.
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	<b>Warning!</b> The implanted product must not have any direct contact to intestine or other intra-abdominal organs and must therefore always be covered by the peritoneum.
	<b>Warning!</b> The product should be placed without tension.
	<b>Warning!</b> The implantation of the mesh requires an extensive dissection of the pelvis, vagina and rectum including the paravesical and pararectal space. This can cause complications such as bleeding and others (see section 11 Possible complications / Adverse events) requiring immediate surgical intervention and repair.
	<p><b>Warning!</b> Mesh implantation can cause or lead to various complications (see 11 Possible complications/ Adverse events)</p> <p>All publications about outcome of surgical and non-surgical treatment may have a bias that complications are underrepresented since there is an increased likelihood that patients with complications will not attend (voluntary) follow-up visits in conjunction with studies.</p>
	<b>Warning!</b> Patients must be advised accordingly to seek immediate medical attention in case of the occurrence of unusual post-operative pain.
	<p><b>Warning!</b> The user has to come to a joint decision in a medical multidisciplinary board of a specialized pelvic floor centre where the benefit-risk-ratio for the individual patient is in focus that the surgical treatment of the patient is appropriate.</p> <p>The following issues have to be considered:</p> <ul style="list-style-type: none"> <li>• Conservative treatment options</li> <li>• Degree of suffering is present</li> <li>• Severity of prolapse</li> <li>• Consideration of patient-specific surgical details</li> <li>• Appropriate pre-operative diagnostics</li> <li>• Comprehensive patient information, incl. e.g. different treatment options, impact of patient age corresponding to risk of explantation and the related complications/ adverse events</li> <li>• Follow-up and medical care till freedom of symptoms</li> </ul>
	<b>Note:</b> The product is suitable for MRI examination up to 3 Tesla.

#### 14. Product combinations and accessories

The BSC Mesh PP 0 is principally suitable to be used in combination with the A.M.I. i-stitch suture instrument system.

For more detailed information regarding the products used in combination with the BSC Mesh PP 0 please refer to the specific instructions for use of these products.

#### 15. Surgical instructions

##### Checklist before use:

The product has to undergo a visual check before use whereby attention must be paid to the following:

- Integrity of the sterile barrier packing
- Expiry date on the sterile barrier packing
- Damage due to inappropriate transport or storage

The U-shaped form of the mesh re-suspends the apical vaginal vault bilaterally to the sacrospinous ligaments in case of vaginal prolapse, or uterine prolapse, level I defect according DeLancey.

In case of uterus preserving surgery, the BSC Mesh can be fixed at the anterior or posterior cervix.

The BSC Mesh is applied via anterior colpotomy to the anterior part of the vaginal vault/anterior cervix or via posterior colpotomy to the posterior part of the vaginal vault/posterior cervix.

The BSC Mesh is used for suspension of vaginal vault or uterine prolapse only, it is not designed to treat cystoceles, rectoceles or enteroceles.

Any colporrhaphy within the same surgery is advised to be performed prior to the final bilateral fixation of the BSC Mesh to the sacrospinous ligaments.



**Warning!** If the BSC Mesh is fixed to the sacrospinous ligament before the colporrhaphy is performed this could lead to an increased tension on the organs and therefore the associated complications / adverse events

1. The mesh midline marker on the BSC Mesh is an orientation guide.
2. After single dose antibiotic prophylaxis and thoroughly disinfection of the vagina pull down the cervix or vault. Infiltrate the incision line with normal saline (with or without adrenalin) to the surgeons discretion., make an at least 2 cm longitudinal

vaginal incision 3 cm distal to the vaginal apex/ cervix. By keeping the vaginal skin at the apex intact, a later overlapping of mesh and suture line are avoided to reduce the risk of erosion/ inflammation. From the upper end of the longitudinal vaginal incision, the tissues of the cysto- or rectovaginal septum are dissected off the anterior resp. posterior aspect of the cervix or vaginal wall.

3. Advance a Metzenbaum scissors under the vaginal wall horizontally in the direction of the pelvic side wall. Use a single index finger to probe the dissection aiming in the general direction of the ischial spine which should be palpable through the fascial tissues overlying the pelvic sidewall. Perform the digital examination until the ischial spine can be felt clearly together with the sacrospinous ligament.
4. Use the index finger to sweep up and down over the lateral sacrospinous ligament until a pararectal tunnel is created in the fascia. Resist the temptation to use excessive force or sharp dissection. If the finger dissection proves to be unsuccessful then introduce a pair of scissors into the dissection on each side and open the fascia with the scissors by using a push-open withdraw technique. Use the index finger to open up the fascial defect created by the scissors. Create access for sacrospinous fixation with the A.M.I. i-stitch instrument.
5. Repeat the dissection and identification of the ischial spine and the sacrospinous ligaments on the other side.
6. Apical attachments of polypropylene suture USP 2-0 are placed on each side in the medial posterior aspect of the sacrospinous ligament immediately adjacent to the sacrum/coccyx with the i- stitch instrument. The sutures are not knotted but guided laterally to the thighs of the patient where they are held i.e. by short Kocher clamps. (See surgical instructions in the i-stitch IFU).
7. Make sure that both sutures are firmly placed in the sacrospinous ligament.
8. Suture the central section of the BSC Mesh with two U-stitches, to the cervix/ apical anterior or posterior cervix resp. vaginal wall (in case of hysterectomy) and an additional suture fixation 2-3 cm lateral to the central fixation sutures ("turning point sutures") on each side. It is to the physicians discretion to use resorbable or permanent suture USP 2-0 or 3-0.
9. Pass both ends of the sacrospinous sutures from the rear to the front through the BSC Mesh at the end of U point (A). The exact longitudinal position of the passage is determined according to the anatomy and is at the discretion of the physician.
  - Leave at least one pore of the mesh between the two threads.
  - Leave at least two complete pores to the apical BSC Mesh end
  - Make sure that the BSC Mesh is not twisted.
  - Make sure the sutures run in a rectangular way according the direction of load.

10. Make sure that the BSC Mesh lies flat at the vagina wall/ cervix.
11. The BSC Mesh is now knotted directly onto the sacrospinous ligament. Before tying the I-Stitch-sutures it might be helpful to place and tie a braided resorbable suture USP 2-0 across the cranial angle of the colpotomy facilitating later closure after the prolapse is resolved
12. Closure of the vaginal incision, insert a urethral catheter and apply a vaginal tamponade.

#### 16. Explantation of the product

##### **Patient information**

Transvaginal / open or laparoscopic mesh removal is a technically complex surgical procedure that requires qualified surgeons with appropriate experience and skill in surgery and knowledge in pelvic anatomy.

Because transvaginal mesh is considered a permanent implant, surgery to remove the mesh can be difficult and may increase a woman's risk of additional complications.

Mesh removal surgery may not address all of the symptoms that a patient may be experiencing. For this reason, mesh removal may not always be the appropriate treatment of symptoms.

Due to tissue growth into and around the mesh, removing the mesh without damaging the surrounding tissue and organs may not always be possible.

Depending on potentially affected organs, surgical mesh removal should be carried out in a multidisciplinary approach, potentially comprising of urologists, colorectal surgeons, pain specialists and specialist pelvic floor physiotherapists.

## 17. Partial resection (e.g. erosion, pain, dyspareunia, p.v. discharge, bleeding)



**Warning!** Pelvic reconstructive surgery with and without implants requires knowledgeable (e.g. anatomy) and experienced surgeons as pointed out in various guidelines and recommendations of medical societies (e.g. SCENIHR, FIGO, AGUB, EAU/EUGA):

- Especially the use of surgical meshes for POP surgery is only advised for trained surgeons who are educated in the surgical technique of this treatment.
- Furthermore, the surgeons should be trained on the usage of the specific mesh products.
- It is strongly advised to perform such complex surgeries in specialized and experienced multidisciplinary medical centres or hospitals only.

Patient is in dorsal lithotomy position. Apply an intravenous single- shot antibiotic. Place a Foley catheter before the beginning of the procedure to prevent bladder and urethra injury.

It is advised not to use electrocautery instruments in the vaginal space for surgical mesh removal.

Sharp dissection around the affected area depending on the size of the erosion. In regard to a small exposure, it is sufficient to grasp the mesh with a clamp, pull it carefully within the vaginal cavity and cut it below the level of the vaginal skin. In case of pain due to too much tension, it is sufficient to transect the fixation point.

Reconstruct the defect and close the incision with sufficient overlap of vaginal tissue.

Ensure at all times that structures / organs are unimpaired. Depending on the surgical site, potentially use cystoscopy, urethroscopy and / or rectoscopy.

In case of perforation of adjacent viscera search collaboration with other medical specialties, such as urology or colorectal surgery. Consider referral to a clinician with appropriate training and experience.

## 18. Total resection (e.g. pain, inflammation, abscess)



**Warning!** Pelvic reconstructive surgery with and without implants requires knowledgeable (e.g. anatomy) and experienced surgeons as pointed out in various guidelines and recommendations of medical societies (e.g. SCENIHR, FIGO, AGUB, EAU/EUGA):

- Especially the use of surgical meshes for POP surgery is only advised for trained surgeons who are educated in the surgical technique of this treatment.
- Furthermore, the surgeons should be trained on the usage of the specific mesh products.
- It is strongly advised to perform such complex surgeries in specialized and experienced multidisciplinary medical centres or hospitals only.

Patient is in dorsal lithotomy position. Apply an intravenous single- shot antibiotic. Place a Foley catheter before the beginning of the procedure to prevent bladder and urethra injury.

It is advised not to use electrocautery instruments in the vaginal space for surgical mesh removal.

Identify the mesh via a vaginal incision along the relevant landmarks by aqua dissection (additionally with adrenaline, if needed).

Once the mesh is detected, remove / excise as much of the exposed mesh material as possible.

Depending on the indication for surgery, it may not necessarily be advisable to excise the entire mesh.

Reconstruct the defect and close the incision with sufficient overlap of vaginal tissue.

Ensure at all times that structures / organs are unimpaired. Depending on the surgical site, potentially use cystoscopy, urethroscopy and / or rectoscopy.

In case of perforation of adjacent viscera search collaboration with other medical specialties, such as urology or colorectal surgery. Consider referral to a clinician with appropriate training and experience.

## 19. Disposal of the product



After the usage of the product (explantation, removal etc.) it bears a potential biological hazard and has to be disposed according to current national laws and recommendation guidelines (e.g. RKI recommendations) for clinical waste.

## 20. Storage and transport conditions

Avoid strong vibrations during transport. Transport and storage should be in a dry and clean environment, protected from water and other fluids, sunlight, dust, salt and other substances.

Storage temperature: max. +25°C

## 21. Return and repair

Return consignments are only accepted if all components have been cleaned and sterilized beforehand. Contaminated components must be correspondingly labeled for the return consignments.

In the event of a defect, the entire product including the description of the defect must be sent back to the manufacturer.

## 22. Additional information

This description is only a guide for the proper and safe use of this product by the user (medical staff / surgeon or their representation in the form of a health care facility). It does not constitute as a recommendation for surgical procedures. By using this product, the user declares and warrants that it is familiar with the operating method described here and that all regulations applicable in the country concerned with respect to this method are complied with. Care must be taken to ensure that this product is prepared and used appropriately by qualified staff. The institution (hospital, health care facility) and the surgeon performing the surgery are jointly responsible for ensuring that the qualified infrastructure necessary is in place and that only surgeons qualified in mesh POP surgery perform the surgery.











A.M.I. GmbH recommends that pelvic reconstructive surgery incl. mesh implantation and explantation is only performed in specialized medical centers or hospitals with sufficient expertise.







Defects and damages due to natural wear and tear, improper use, or modifications to the product which do not correspond to the user information are excluded from warranty. A.M.I. GmbH or its authorized specialist dealers are neither responsible for, nor obliged to compensate the surgeon or health care facility for incidental or causally determined losses, damages, or expenses arising directly or indirectly from the use of this product. A.M.I. GmbH will assume liability for product defects that existed before the product was shipped only if these defects are determined and reported before the product is used. Such cases will constitute only as a claim for replacement of the defective product.



All major incidents in relation to the product must be reported to the manufacturer and the appropriate authorities of the member state in which the user and/or patient is registered/located.

### 23. Symbols

Symbol	Description
	Refer to instructions for use
	Caution! Follow the accompanying documents
	Do not use if packaging is damaged
	Manufacturer
	Date of manufacture
	Do not reuse
	Do not re-sterilize
	Sterilized using ethylene oxide
	Latex free
	The US Federal Law restricts this product to be sold by or ordered by an approved physician
	Batch code (The first two digits indicate the year of manufacture)
	Reference number (order number)

	Expiry date
	This product complies with the applicable European Directives. The trailing four-digit number identifies the Notified Body.
	Keep dry
	Keep away from sunlight
	Temperature limit (high)
	This product is compatible with MRI with magnetic field strengths of up to 3 Tesla

## 24. Specifications

BSC Mesh Implant		
Dimensions:	Width	91 mm
	Height	75 mm
Weight:		0.05 g
Sterilization method:		Ethylene Oxide (EO)

General mesh specifications:	
Grammage:	21 g/m <sup>2</sup>
Thickness:	0.38 mm
Diameter of thread:	76 µm
Shape of mesh weave:	Hexagonal
Volume material fraction:	< 10 %
Stitch width:	2.2 mm lengthwise
	2.4 mm crosswise
Interstitial pore size:	100 -150 µm

i-stitch loading unit:	
Suture material, thread size	PP, monofilament USP 0
Needle length	166,5 mm
Needle diameter	1,5 mm
Needle tip type	Blunt tip
Total suture length	700 mm

## 25. Materials

Material	Mass, surface area etc.	Type of contact
Polypropylene (mesh implant)	0,05g	Implanted device
Polypropylene (suture)		Implanted
Silicone (NuSil MED-6608-2)		implanted

## 26. Conformity

The product complies with the requirements of Medical Device Directive 93/42/EEC and is labelled with the CE mark accordingly.

**CE0297**