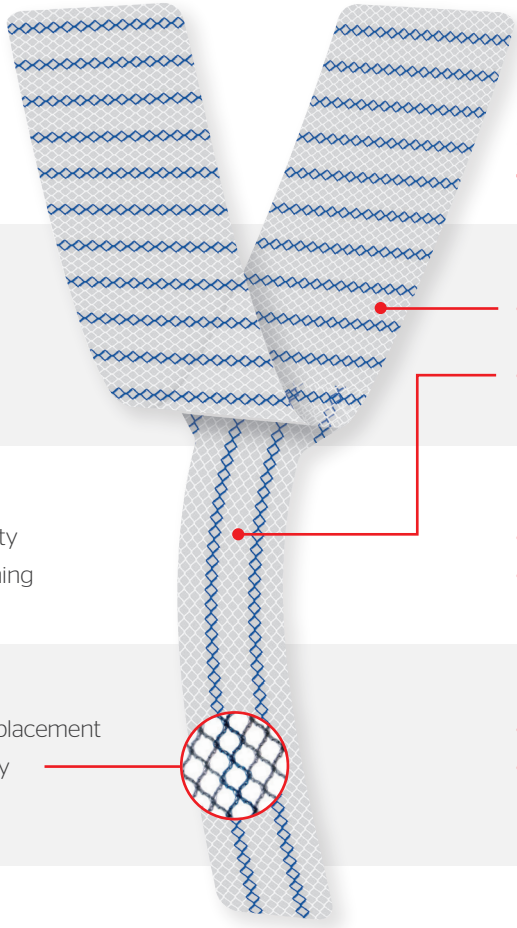
ARTISYN®

You understand that caring for your patient means using a mesh that complements your technique and her anatomy[1,2]

Indicated for Sacrocolpopexy[2]

ARTISYN® Y-Shaped Mesh, the only Y-shaped mesh designed to provide efficiency and support while evolving to leave less mesh behind[1,2]



Efficiency
for the Surgeon[1,3]

Excellent Intraoperative Handling[3]
- Mesh optimized to resist wrinkling and folding[3]
- Precreased vaginal flaps designed to reduce steps[1]

Easy Mesh Placement[1]
- Blue lines aid orientation and visibility
- Sacral arm tapered to reduce trimming

Precision During Fixation[1]
- Blue lines facilitate accurate suture placement
- Large pore size makes suturing easy

Support with Less Mesh
for the Patient[1,2]

Unique Bidirectional Design[1]
- Vaginal flaps designed to accommodate lengthening and distention
- Sacral flap designed to limit elongation

Mesh Is Designed to Be Strong[4]
- Strongest mesh tear strength*
- Strongest suture pullout strength in the sacral flap†

Mesh Evolves Over Time[2]
- 46% of the mesh absorbs by 84 days[1,2]
- Remaining mesh stays strong after tissue integration[1,3]

*ARTISYN Mesh displayed strongest mesh tear strength at implantation compared to Coloplast Restorelle® Y and JUNE MEDICAL ALYTE™ Y-Mesh Graft in benchtop testing.

†ARTISYN Mesh displayed strongest suture pullout strength at implantation compared to Coloplast Restorelle® Y and JUNE MEDICAL ALYTE™ Y-Mesh Graft in benchtop testing.

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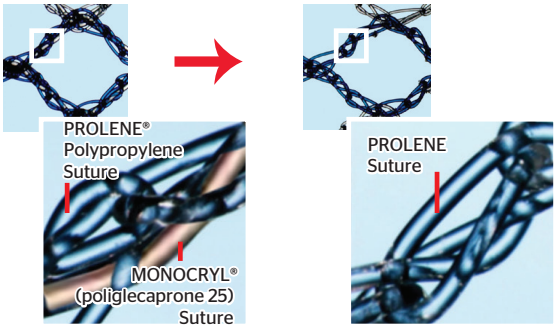
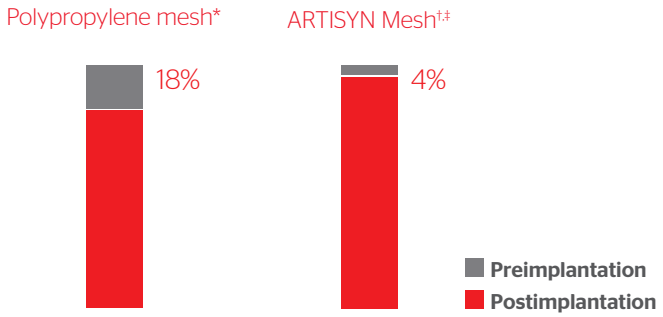
The mesh in ARTISYN® Y-Shaped Mesh evolves over time... with less tissue-mesh contracture postintegration[2,5]



Preimplantation — 84 days postimplantation[2]

Tissue-mesh contraction postintegration at 120 days[5]



In animal studies it was shown that the mesh material used in ARTISYN Mesh:

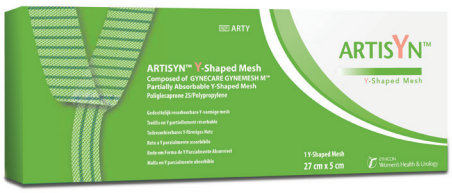
- Demonstrated significantly less tissue-mesh contracture vs. another lightweight mesh postintegration[5]
- Remained pliable[2,3]

Mesh used in experiment:

*PP-8 (polypropylene of 7.6 g/m²)

†PP-32 (polypropylene with absorbable fibers; 32 g/m²)

‡In an internal Ethicon animal study, the mesh used in ARTISYN Mesh led to 8% tissue-mesh contraction 140 days postimplantation, while polypropylene mesh led to 21.2% tissue-mesh contraction 182 days postimplantation[6]



Ordering Information

Description	Ordering Code	QTY	Dimensions Length	Dimensions Width
ARTISYN® Y-Shaped Mesh	ARTY	1 unit	27 cm	5 cm
Virtual Code	ARTY5L	5 units	27 cm	5 cm

To order, call 1-800-255-2500.
To locate your local representative, call 1-877-ETHICON.

ESSENTIAL PRODUCT INFORMATION

INDICATIONS

ARTISYN™ Y-Shaped Mesh is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (laparotomy or laparoscopic approach) where surgical treatment for vaginal vault prolapse is warranted.

CONTRAINDICATIONS

ARTISYN™ Y-Shaped Mesh should not be used in infants, children, pregnant women, or in women planning future pregnancies, because the mesh will not stretch significantly as the patient grows. ARTISYN™ Y-Shaped Mesh should not be used in the presence of active or latent infections or cancers of the vagina, cervix, or uterus.

WARNINGS & PRECAUTIONS

Patients who are on anticoagulation agents and undergoing surgery using ARTISYN™ Y-Shaped Mesh must have their anticoagulation therapy carefully managed. Postoperatively, refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until your physician determines when it is suitable for you to return to your normal activities. The safety and effectiveness of this product has not been validated in clinical trials.

PATIENT FACTORS

Physicians should use their surgical experience and judgment to determine if ARTISYN™ Y-Shaped Mesh is appropriate for certain patients. Patient-specific factors may impair wound healing, which may increase the likelihood of adverse reactions.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, bleeding including hemorrhage or hematoma, urinary incontinence, urge incontinence, urinary frequency, urinary retention or obstruction, voiding dysfunction, acute and/or chronic pain, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring and mesh extrusion, exposure, or erosion into the vagina or other structures or organs. As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation. Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse, which in some patients may not resolve. Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time. Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening may occur. As with all surgical procedures, there is a risk of infection. As with all foreign bodies, ARTISYN™ Y-Shaped Mesh may potentiate infection. Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair. Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur. These adverse reactions may require surgical treatment. As with any surgery, one or more revision surgeries may be necessary to treat these complications. ARTISYN™ Y-Shaped Mesh is a permanent implant that integrates into the tissue. In cases in which the ARTISYN™ Y-Shaped Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

Seroma. Adhesion formation. Atypical vaginal discharge. Exposed mesh may cause pain or discomfort to the patient's partner during intercourse. Death. Consult your doctor to discuss the potential benefits and risks of your treatment options and whether ARTISYN™ Y-Shaped Mesh is appropriate for you.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full Instructions for Use.

References

1. Amarasinghe C. Surgeon design validation completion report. ARTISYN™ Y-Shaped Mesh. DVCR0000031 version A. June 20, 2012. Ethicon, Inc. **2.** ARTISYN® Instructions for Use. Somerville, NJ: Ethicon, Inc. **3.** Cobb WS, Burns JM, Peindl RD, et al. Textile Analysis of Heavy Weight, Mid-Weight and Light Weight Polypropylene Mesh in a Porcine Ventral Hernia Model. *J Surg Res.* 2006;136(1):1-7. **4.** Flint J. Assessment of competitive Y-mesh devices. PE Study File AST 2012-0142. May 22, 2012. Ethicon, Inc. **5.** Ozog Y, Konstantinovic ML, Werbrouck E, et al. Shrinkage and biomechanical evaluation of lightweight synthetics in a rabbit model for primary fascial repair. *Int Urogynecol J.* 2011;22(9):1099-108. Epub 2011 May 12. **6.** Holste J. Final report PD 01 / 3-2-1. ETHICON GmbH. Norderstedt, Germany. Aug. 14, 2003. Ethicon, Inc.

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