

## VIDEO DEMONSTRATION OF VAGINAL SURGERY FOR PROLAPSE USING MESH IMPLANTS AND A VAGINAL SUPPORT DEVICE

### Introduction

The GYNECARE PROSIMA® Pelvic Floor Repair System (Ethicon, Somerville, NJ) was developed to surgically treat pelvic organ prolapse. The kit comes with similarly pre-shaped mesh implants, a vaginal support device (VSD), a balloon, an anterior inserter, a posterior inserter and a 60 ml syringe. PROSIMA is a trocar-less surgical system that employs a vaginal approach to prolapse surgery using monofilament polypropylene mesh implants that are held in position for 3 to 4 weeks by a VSD. A balloon is attached to the VSD and is inflated with up to 90ml of air. The balloon is used instead of the traditional vaginal pack and is deflated and removed 24 hours after surgery. The aim of this video is to demonstrate vaginal surgery for prolapse augmented by mesh implants using a trocar-less system and a vaginal support device (VSD).

### Design and Results

Video taping of prolapse surgery, using the PROSIMA system, was performed on 6 consecutive cases. A final version was made from the first 3 cases. This video demonstrates the surgical technique used for the PROSIMA procedure. It demonstrates, firstly, the anterior vaginal repair. The vesicovaginal plane is exposed by dissecting the vaginal epithelium off the underlying pre-vesical tissue. Anterior channels for the mesh implant straps are made on each side by creating a space immediately anterior and superior to the ischial spine and superficial to the parietal fascia of the obturator internus muscle. The anterior mesh implant is introduced into the vesicovaginal plane. The mesh straps are placed into the anterior channels with the aid of the anterior inserter instrument. The vaginal epithelium is closed in two layers. The deeper fibromuscular layer is closed using a continuous non-interlocking stitch. The superficial squamous epithelial layer is closed by a non-interlocking continuous everting mattress stitch. Non-interlocking stitches are used to avoid de-vascularizing the vaginal epithelium along the incision line. The two-layered closure, including the everting mattress stitch, is used to obtain a relatively thick suture line at the site of the vaginal incision. This closure technique is used to reduce mesh exposure. The video then demonstrates the posterior vaginal repair with the rectovaginal plane being exposed by dissecting the vaginal epithelium off the underlying pre-rectal tissue. Posterior channels for the mesh implant straps are created on each side by dissection through the rectal pillars to each ischial spine and sacrospinous ligament. The posterior mesh implant is introduced into the rectovaginal plane. The mesh straps are placed into the posterior channels with the aid of the posterior inserter instrument so that the mesh implant straps about the sacrospinous ligaments. The epithelium is closed in the same fashion as the anterior vaginal epithelium. The VSD can be modified into three sizes: large, medium and small. At the completion of surgery an appropriately sized VSD with attached balloon is placed in the vagina and sutured in place to prevent dislodgement. The balloon is inflated with air using the 60 ml syringe. After deflation, the balloon is removed at 24 hours. The VSD is removed 3 to 4 weeks after surgery.

### Concluding message

The surgery presented in this video demonstrates a novel and innovative approach to prolapse surgery. This vaginal approach uses mesh implants via a trocarless system to improve durability, a VSD to support the positioning of the mesh and prevent vaginal wall adhesions during healing, and a balloon that replaces the traditional vaginal pack. The two-layered technique used to close the vaginal epithelium is aimed at reducing the risk of mesh exposure along the suture lines.

<b><i>Specify source of funding or grant</i></b>	<b>Video taping of prolapse surgery, using the PROSIMA system, was performed on all six subjects after obtaining written consent from each subject in compliance with local IRB guidelines</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>Video taping of prolapse surgery, using the PROSIMA system, was performed on all six subjects after obtaining written consent from each subject in compliance with local IRB guidelines</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>