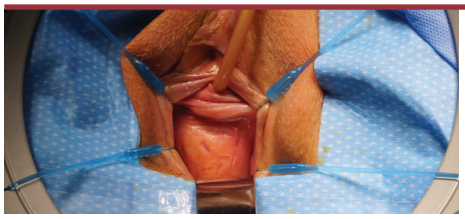
ARMS MEDICAL

DERMA [PURE] dCELL technology

TECHNIQUE GUIDE

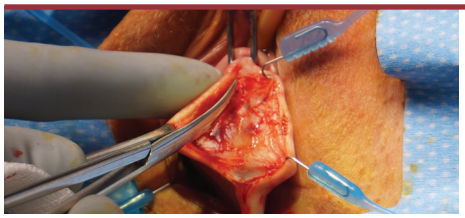
Treatment of Cystocele and Vaginal Vault Prolapse

PROCEDURE

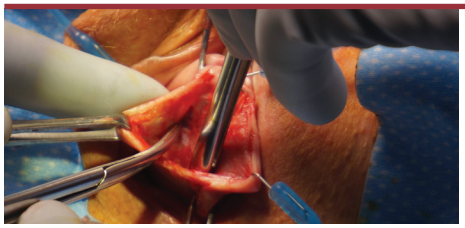


Place the patient in dorsal lithotomy position with care to avoid flexion of the thighs upon the hips beyond 90° to avoid femoral neuropathy. Care must also be taken to avoid external rotation of the thighs to avoid obturator neuropathy.

Place a 16 French Foley catheter. A self-retaining perineal retractor may be used. Place longitudinal traction along the anterior vaginal wall to separate the vagina from the bladder. Inject local anesthesia with epinephrine into the vesicovaginal space to provide hydro-dissection and hemostasis.

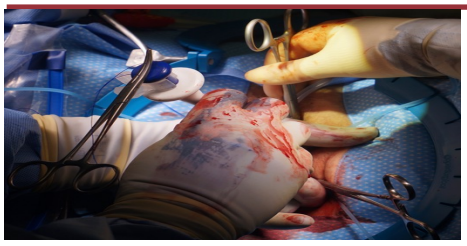


Make an incision from the bladder neck to the vaginal apex with a full-thickness dissection and separate the pubovesical fascia from the anterior vaginal wall to the level of the sulci bilaterally.



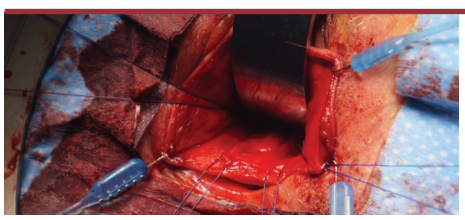
Enter the paravesical space to identify the ischial spine and sacrospinous ligament surrounded by the coccygeus muscle (CM – SSL) on either side.

Clear digitally 3 cm of soft tissue overlying the CM - SSL.



Employing an anchoring device deliver 0 PDS or 0 permanent Prolene suture through the inferior margin of the CM – SSL 3 cm medial to the ischial spine. Confirm placement through the ligament by applying traction to the suture as proper placement will yield firm resistance to suture traction without elevation of surrounding coccygeus musculature.

Perform rectal exam to confirm absence of suture penetration in the rectal wall.



Place PDS or Prolene suture approximately 1 cm lateral of the midline bilaterally through split thickness vaginal cuff (2-0 suture) in post-hysterectomy patients or anterior cervix (0 suture). Plicate the pubovesical fascia with delayed absorbable suture.

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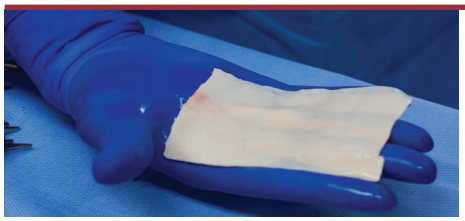
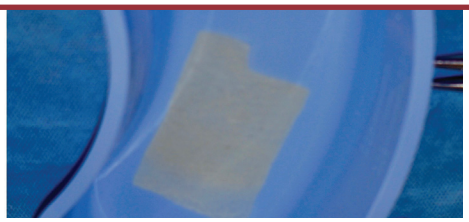
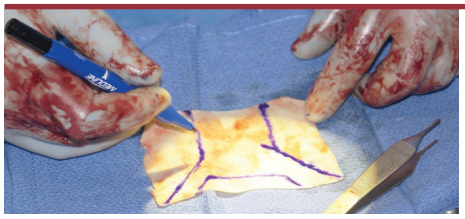
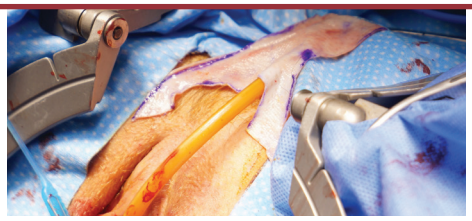


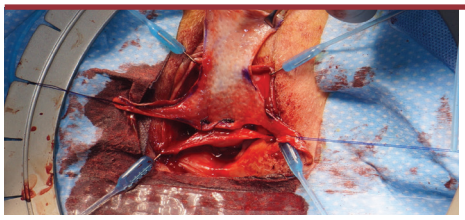


Take a 7 cm X 10 cm DermaPure dermal allograft and fill a sterile basin with enough room temperature sterile saline to completely cover the DermaPure.

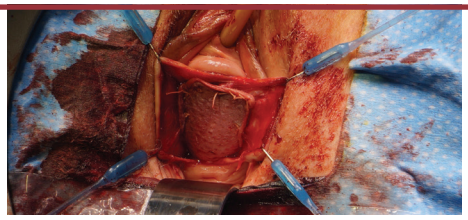




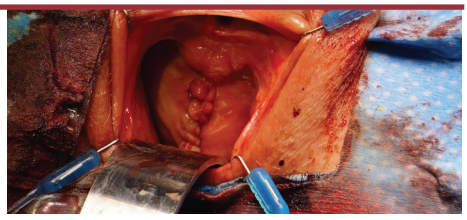
The concave cutout along the 10 cm proximal edge is to prevent banding across the rectum once suspended between the sacrospinous ligaments.



The graft should be oriented with the lamina propia against the vaginal wall. Attach the proximal edge of the DermaPure to the vaginal apex using the previously placed apical sutures. Attach the distal 4 cm edge to split thickness distal vagina employing 3 separate delayed absorbable sutures.



Attach the DermaPure laterally to the vaginal sulci using 3-0 Vicryl suture as needed.



Perform cystoscopy to the bladder with instillation of D-10 to ensure absence of trauma and to allow for visualization of ureteral jets. Empty the bladder followed by 2 consecutive 300 cc aliquots of sterile water to remove the sugar content from the bladder.

Irrigate the vagina with gentamicin-laden saline solution and then pack vagina with saline-soaked sterile vaginal packing.

Surgeon Perspective:

"Since learning about DermaPure® from ARMS Medical, I have been very impressed by its advantages over synthetic mesh and competitive biologics. It offers good handling characteristics, is easy to place, incorporates well into surrounding tissue and has a negligible exposure rate. The proprietary dCELL® technology promotes tissue growth and healing more effectively than cross-linked products. I believe in this unique biologic platform and its usefulness in pelvic organ prolapse and mesh removal surgery."

- James Chivian Lukban, DO, FACOG, FACS, FFPMRS
Colorado Pelvic Floor Consultants, Englewood, Colorado

DermaPure® Decellularized Dermal Allograft		
030400HD	3 cm x 4 cm	DermaPure® Decellularized Dermal Allograft
040600HD	4 cm x 6 cm	DermaPure® Decellularized Dermal Allograft
071000HD	7 cm x 10 cm	DermaPure® Decellularized Dermal Allograft

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ARMS Medical provides advanced surgical technologies and tools for pelvic floor issues, including organ prolapse and incontinence. Our goal is to help patients, surgeons and hospitals by optimizing outcomes, maximizing safety and minimizing complications.