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FDA Decision Regarding Transvaginal Mesh for Pelvic Organ Prolapse

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Dear Valued Customer,

We are disappointed by the FDA decision which requires withdrawal of our surgical transvaginal mesh product and removes this treatment option for women suffering from pelvic organ prolapse (POP).

In May 2018, we submitted our PMA to the FDA for Restorelle® DirectFix Anterior mesh with the goal of providing our customers with an important treatment solution in the women's health space. Upon conclusion of the PMA review, the FDA determined that there was not sufficient evidence to assure that the product worked better than surgery without the use of mesh to repair pelvic organ prolapse in the long-term.

As a result, FDA regulations require that all anterior transvaginal mesh products, including Restorelle® DirectFix Anterior mesh, can no longer be commercialized in the U.S. Therefore, we will cease distribution immediately and conduct a market withdrawal.

Steffen Hovard
President & Senior Vice President

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It is important to note that this is not a recall, it is a product withdrawal. Also, this only impacts the Restorelle DirectFix Anterior transvaginal mesh. Our other products are not impacted, including Allograft tissue, Transabdominal mesh, and Stress Urinary Incontinence (SUI) mesh.

The following products in the Women's Health portfolio (mesh and tissue products) remain available for use in treating POP and SUI.

- **Axis™ Dermis** – Tutoplast® Processed Omni-directional Allografts
  (4 x 7 cm, 6 x 8 cm, 6 x 12 cm, 6 x 16 cm, 8 x 12 cm)
- **Suspend® Fascia Lata** – Tutoplast® Processed Uni-directional Allografts
  (2 x 7 cm, 2 x 12 cm, 2 x 24 cm, 4 x 7 cm, 6 x 8 cm)
- **Restorelle® Y** – Ultra Lightweight Mesh (24 x 4 cm, 27 x 4 cm)
- **Restorelle® Y Contour** – Ultra Lightweight Mesh (24 x 3 cm)
- **Restorelle® Flat Mesh** – Ultra Lightweight Mesh
  (M - 15 x 10 cm, L - 24 x 8 cm, XL - 30 x 30 cm)
- **Altis®** – Single Incision Sling System
- **Aris®** – Transobturator Sling Kit
- **Supris®** – Retropubic Sling Kit

No action is required from you regarding this communication. Further information regarding the market withdrawal will be communicated after we review our plans with the FDA.

While we are disappointed with the FDA's decision regarding our PMA, we are fully committed to women's health and will continue to explore new solutions that meet patients' needs and improve their quality of life. We regret any inconvenience this matter may have caused. We sincerely appreciate your partnership.

If you have further questions, please contact Coloplast Customer Service directly at (800) 258-3476, or by email urology@coloplast.com.

Sincerely,

Steffen Hovard
President and Senior Vice President
Coloplast Interventional Urology