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Coloplast A/S  
Holtedam 1  
3050 Humlebæk  
Denmark  
Tel: +45 4911 1111  
[www.coloplast.com](http://www.coloplast.com)  
CVR-nr. 69749917

**Coloplast responds to FDA's decision to remove Surgical Transvaginal Mesh as Treatment Option for Pelvic Organ Prolapse**

Coloplast was informed yesterday by the FDA that the PMA for Restorelle DirectFix Anterior is not approved and the company must cease marketing and distribution immediately.

As a result, FDA regulations require that all anterior transvaginal synthetic mesh products, including Coloplast's Restorelle DirectFix Anterior device, can no longer be commercialized in the U.S., effective immediately. Coloplast will work with the FDA and other relevant authorities to ensure the orderly removal of these devices from customer inventories.

In accordance with the FDA guidance, Coloplast recommends that women who have received transvaginal mesh for the surgical repair of pelvic organ prolapse should continue with their annual and other routine check-ups and follow-up care. There is no need to take additional action if you are satisfied with your surgery and are not having any complications or symptoms. However, any patient with questions or concerns should speak to her healthcare provider. Please refer to the full statement on the [FDA website](#).

Coloplast is disappointed by the FDA decision to remove surgical transvaginal mesh as a treatment option for women suffering from pelvic organ prolapse. Coloplast has been committed to working with the FDA on the 522 clinical studies to document the long-term efficacy and safety of the products.

Restorelle DirectFix Anterior accounts for approximately 0.2% of group revenues, and therefore the financial impact is immaterial and does not impact our financial guidance.

- "Our mission at Coloplast is making life easier for people with intimate healthcare needs. Pelvic organ prolapses (POP) can be a painful, embarrassing, and a debilitating issue for the women who suffer from it. While mesh sales to treat POP in women account for approximately 0.2% of our global revenue, we firmly believe that patients and their physicians should have a choice of therapies. We are disappointed with the FDA's decision because it reduces the treatment options for women with POP. We remain committed to providing alternative therapies." says CEO Kristian Vil-lumsen, Coloplast.

Coloplast has alternative solutions for the same type of products including tissue products as well as alternative procedures for pelvic organ prolapse. The FDA's decision is limited to mesh for the transvaginal repair of pelvic organ prolapse and does not extend to mesh used to treat stress urinary incontinence.

Coloplast does not expect the FDA decision to impact the US product liability case regarding transvaginal surgical mesh products. Coloplast has provisioned DKK 5.25bn for the product liability case and settled more than 95% of the known lawsuits. Coloplast continues to see the female pelvic mesh mass tort litigation mature towards conclusion.

**Coloplast A/S**

## For more information, please contact:

### Investors and analysts

Anders Lonning-Skovgaard  
Executive Vice President, CFO  
Tel. +45 4911 1111

Ellen Bjurgert  
Vice President, Investor Relations  
Tel. +45 4911 1800 / 4911 3376  
E-mail dkebj@coloplast.com

Rasmus Sørensen  
Senior Manager, Investor Relations  
Tel. +45 4911 1800 / 4911 1786  
E-mail dkraso@coloplast.com

### Press and the media

Lina Danstrup  
Senior Media Relations Manager, Corporate Communications  
Tel. +45 4911 2607  
E-mail dklina@coloplast.com

### Website

[www.coloplast.com](http://www.coloplast.com)

### Address

Coloplast A/S  
Holtedam 1  
DK-3050 Humlebæk  
Denmark

Business reg. (CVR) no. 69749917

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Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare.

Our business includes Ostomy Care, Interventional Urology, Continence Care and Wound and Skin Care. We operate globally and employ about 12,000 people.