



To whom it may concern

Priv.-Doz. Dr. med. Sebastian Ludwig
Chief of Division
Urogynecology and Plevic Floor Reconstructive Surgery
Department of Obstetrics and Gynecology
phone: [REDACTED]
telefax: [REDACTED]
[REDACTED]@uk-koeln.de

Cologne, 8th August 2023

PFAS Statement

In our tertiary University department of Obstetrics and Gynecology, we perform around 120 surgeries annually to treat pelvic organ prolapse. For these procedures, we rely on the use of polyvinylidene fluoride (PVDF) meshes, which have proven to significantly reduce the risk of recurrence and reoperation. In addition to the classic apical fixations, we also perform an innovative technique to mimic the pelvic floor anatomy. In the so-called CESA/VASA operations, both uterosacral ligaments are mimicked in their anatomical course using specially developed PVDF meshes. In comparison, only a minimum of PVDF material is used. Compared to the classical unilateral mesh sacropexy (with PP or PET), less than one third of PVDF material is used (for example 16 cm²). Banning PVDF meshes bears the risk to leave no equivalent alternative available to treat our patients.

As a university hospital, we have also tested the biomechanical properties of implanted PVDF meshes in animal models and together with the clinical application, an exceptional tolerance of these products is convincing.

Over the years, our clinical experience has emphasized the importance of stable and non-degradable mesh materials for long-term implantation within the body. This is especially crucial as materials like polypropylene

Tel. Nr.: 0221 / 478 –	
Privatambulanz	-4900
Operative Gynäkologie	-4959
Brustzentrum	-86545
Minimal – invasive Chirurgie	-4959
Kreisssaal	-4965
Geburtsanmeldung Risikosprechstunde	-6847
Pränatalmedizin und gynäkologische Sonographie	-4975
Reproduktionsmedizin und Gynäkologische Endokrinologie	-4959
Gynäkologische Onkologie	-4900
Ambulante Chemotherapie	-4945
Beckenbodenzentrum	-4900
Dysplasie- und Vulva- Sprechstunde	-4959



and inflammatory responses. In contrast, PVDF has emerged as a superior choice, remaining stable without signs of degradation, making it an innovative polymer endorsed by various surgical societies.

In addition, we use a variety of PVDF products in our interdisciplinary Continence and Pelvic Floor Centre at the University of Cologne. Together with the Clinic for Urology and Visceral Surgery/Proctology, we perform a large number of interdisciplinary operations (more than 300 per year) in which we use PVDF products, as they are often the only option for long-term and effective, but also safe reconstruction of the patients' pelvic floor.

We join other medical professionals in urging the expert committees and decision-makers to consider time-unlimited exceptions for surgical meshes made of PVDF and other PFAS materials. Such exceptions are vital for the well-being of our patients, as banning these materials would lead to increased complications and reduce treatment options. We must safeguard patients' health by prioritizing mesh materials with optimal biocompatibility and long-term stability in pelvic floor surgeries.

Additionally, a nationally established urogynecological registry, where every patient who has received such a PVDF product is registered with preliminary and, above all, follow-up data, contributes to this. This provides additional security, transparency and offers a certain degree of protection for the patients.

Sincerely,

Priv.-Doz. Dr. med. Sebastian Ludwig

Chief of Division
Urogynaecology and Pelvic Floor Reconstructive Surgery,
University Hospital of Cologne, Dept. Obstetrics and Gynecology