Statement of the International Society for Gynecologic Endoscopy and ISGE – Accreditation on the total ban of PFAS.

We recently became aware of a restriction proposal by a number of EU-member's national chemical agencies to indiscriminately ban all poly- and perfluorated alkyl-substances (PFAS), including polymeric materials. This ban would affect a number of urogynaecological treatment options as well as implants that have been established in the field for decades.

Durability of the material, the very property that has led to the proposed ban of PFAS, is paramount to guarantee implant stability over a patient's lifetime. The problem of degradation of some non-fluorinated mesh-materials has been recognized by international guidelines.

According to the current state of research, the use of mesh materials is undisputed necessary in order to enable patients to receive adequate therapies. For years there have been successful efforts to minimize the use of mesh materials. Ultimately, however, the use of small amounts remains imperative in order to achieve the decisive apical stabilization (1-3). There is published evidence that the proposed restrictions would pertain to implants with the lowest recurrence rates and lower complication rates.

We strongly suggest the ECHA and the European Commission to not adopt the proposed legislation in its entirety. Unique devices as well as treatment alternatives would be lost to affected patients.

Especially devices made for a particular surgical technique (e.g., bilateral sacrocolpopexy or pectopexy for pelvic organ prolapse) would considerably limit therapeutic options available to the surgeon.

In general, we agree to imposing restrictions on substances with environmental risks and have long-term effects on human health. However, an informed decision on a ban should be based on critical assessment of risks as well as medical benefits, in particular to the patients. We therefore appeal to the ECHA to not unduly limit the therapeutic options in the field of urogynaecology.

For the International Society for Gynecologic Endoscopy – ISGE Accreditation

Immediate Past President

Günter Noé

Medical Director

Bruno J van Herendael

Frans Adriaenssensstraat, 54,
2170 Merksem Belgium
[redacted]@gmail.com

Products containing PFAS

For example, Omyra mesh by B.Braun, DUALMESH by Gore, DynaMesh®-CESA/ DynaMesh®-VASA/ DynaMesh®-PR/ DynaMesh-SIS by FEG Textiltechnik, Composix E/X mesh by Becton Dickinson, ventrio hernia patch by Becton Dickinson, Ventralex by Becton Dickinson

References

2. The HerniaSurge Group. International guidelines for groin hernia management. Hernia (2018) doi:10.1007/s10029-017-1668-x. „Over time, most polymers do show alteration or degradation of their polymeric structure." "It may be prudent to assume that hernia mesh implant instability can occur after several decades. " "Under electron microscopy, human mesh explants all show signs of degradation. PVDF has the highest resistance to degradation."

3. Noé GK, Barnard A, Spüntrup C, Schiermeier S, Soltécz S, Anapolski M, et al. Laparoscopic versus vaginal native tissue repair in combination with pectopexy. Sub-analysis from an international, prospective, and multi-centre study: short term results. Minim Invasive Ther Allied Technol. 2021:1-7.

4. Noé; G. Genital Prolapse Surgery: What Options Do We Have in the Age of Mesh Issues? . Journal of Clinical Medicine. 2021;10(2).

5. Noé GK, Schiermeier S, Anapolski M. Defect Oriented Strategy Reducing mesh in pelvic floor surgery by laparoscopic approach thetrocar. 2020;1(1):6-9.

6. Karalis T, Tsiapakidou S, Grimbizis GF, Mikos T. Surgical results in POP/UI surgery after using PVDF compared to other materials. A systematic review and meta-analysis. Eur J Obstet Gynecol Reprod Biol. 2023 May;284:110-119.

Frans Adriaenssensstraat, 54,
2170 Merksem Belgium
[redacted]@gmail.com