Fluoropolymers for medical use are essential

The draft restriction on the use of PFAS is causing concern. It is feared that surgical meshes made of PVDF could be banned after a short transition period.

For 30 years, the investigation of textile implants for the treatment of tissue defects has been a central focus of clinical and experimental research in the Department of Surgery at RWTH Aachen University. Within this framework, I have worked intensively with my colleagues on improving implant safety and have acquired numerous third-party funded research projects. With this research activity, which has now lasted 30 years, with more than140 publications (see Appendix 2) on the subject of mesh implants, more than 250 invited lectures on implants and numerous book contributions, it was possible to significantly improve the previously predominant oversized materials by introducing the concept of large-pored lightweight meshes. I was able to contribute this expertise as an expert witness for courts in the USA and Australia in numerous proceedings.

Medical implants must basically have a high stability and resistance to degradation if they have to function for years or decades in the tissue and the aggressive cellular environment of the biological foreign body reaction. This is all the more true if they have a large contact surface area, as is the case with "Surgical Meshes". These textile implants made of different materials are recommended for tissue reinforcement by all professional societies [Appendix 1: 1-4] as the therapy of choice and are routinely used as standard worldwide.

Among the currently used polymers, PVDF fulfils the requirements for textile medical implants in an outstanding way as it shows no signs of degradation after implantation and induces a low inflammatory and fibrous reaction due to its hydrophobic surface. In contrast, the alternative polymers available show dramatic disadvantages in some cases, which have led to over a hundred thousand documented court cases worldwide [Appendix 1: 6]. Among other things, the hydrophilic polymers made of polyester are subject to rapid hydrolytic degradation, while those made of polypropylene are subject to oxidative surface decay with the release of micro-particles and increased cellular activation of the inflammation and scarring processes [Appendix 2: 1,29].

In the past 30 years of intensive research activity with more than 140 publications (see Appendix 2) on the subject of "Mesh" it has become clear that PVDF is currently the best polymer for use in textile fabric reinforcement [Appendix 2: 1-140].
The production of PVDF mesh implants is currently a core technological competence built up over decades within the EU, a migration of production facilities to non-EU countries would be regrettable. A ban on PVDF as an implant material in the EU would mean an increased use of polypropylene (PP) or polyester (PET) meshes along with the increase of associated risks for thousands of patients if they do not have the option of obtaining PVDF implants outside the EU.

The development of hernia meshes made of PVDF began more than 20 years ago in 1998 which, with an increasing number of experimental and clinical studies (see ref. list Appendix 2 with the published results of our own studies), became increasingly clear when comparing implant

materials that the conventional mesh implants made of polypropylene (PP) and polyester (PET) are associated with a pronounced inflammatory foreign body reaction, and with the millions of mesh implants in use, new, more compatible polymers were required. Initial trials confirmed the possibility of using PVDF for mesh constructions and also confirmed the superior compatibility after insertion into the tissue (see e.g. [Appendix 2: 118]). In the following years, more and more surgeons were convinced to the use of PVDF implants through publications and presentations at national and international conferences, even though large mesh manufacturers continued to stick to their standard materials of polypropylene (PP) and polyester (PET) against better knowledge and in part against the warning of the polymer manufacturer [Appendix 1: 7].

The positive experience of surgeons, as well as first long-term registry studies with indisputable benefits for PVDF meshes in the long-term course [Appendix 1: 5] currently support the increasing use of PVDF mesh implants, and give hope that implants made of PVDF will increasingly replace implants made of risky polypropylene (PP) and polyester (PET) in the coming years.

Appendix 1

1: The HerniaSurge Group (2018) International guidelines for groin hernia management. Hernia. https://doi.org/10.1007/s10029-017-1668-x

2: Bittner R, Bingener-Casey J, Dietz U, et al (2014) Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society [IEHS])—Part 1. Surg Endosc 28:2–29. https://doi.org/10.1007/s00464-013-3170-6

3: Henriksen NA, Montgomery A, Kaufmann R, et al (2020) Guidelines for treatment of umbilical and epigastric hernias from the European Hernia Society and Americas Hernia Society: Guidelines for treatment of umbilical and epigastric hernias. Br J Surg. https://doi.org/10.1002/bjs.11489

4: SAGES Guidelines Committee, Kohn GP, Price RR, et al (2013) Guidelines for the management of hiatal hernia. Surg Endosc 27:4409–4428. https://doi.org/10.1007/s00464-013-3173-3
Simons MP, Aufenacker T, Bay-Nielsen M, et al (2009) European Hernia Society guidelines on the treatment of inguinal hernia in adult patients. Hernia 13:343–403. https://doi.org/10.1007/s10029-009-0529-7

5: Baker JJ, Öberg S, Rosenberg J. Reoperation for Recurrence is Affected by Type of Mesh in Laparoscopic Ventral Hernia Repair: A Nationwide Cohort Study. Ann Surg. 2023 Feb 1;277(2):335-342. doi: 10.1097/SLA.0000000000005206

6: https://www.meshmedicaldevicenewsdesk.com/articles/100-thousand-mesh-defective-product-cases-now-filed-as-mesh-makers-assure-shareholders

7 https://www.meshmedicaldevicenewsdesk.com/articles/mesh-polypropylene-resin-not-

meant-human-implants

中文翻译文本：

主题：关于使用 PFAS 的限制草案引起了关注。人们担心，由 PVDF 制成的手术网可能会在短暂的过渡期后被禁止。

30 年来，用于治疗组织缺陷的纺织品植入物的研究一直是亚琛工业大学外科系临床和实验研究的中心焦点。在这个框架内，我与同事密切合作，以提高移植体的安全性，并获得了许多第三方资助的研究项目。这项研究活动已经持续了 30 年，有 140 多篇关于网状植入物主题的出版物（见附录 2），250 多场关于植入物的特邀讲座和大量书籍投稿，通过引入大孔轻质网的概念，可以显着改善以前占主导地位的超大尺寸材料。我能够在众多诉讼中作为美国和澳大利亚法院的专家证人贡献这些专业知识。

医疗植入物基本上必须具有很高的稳定性和抗降解性，如果它们必须在组织和生物异物反应的侵袭性细胞环境中发挥作用数年或数十年。如果它们具有较大的接触表面积，则更是如此，例如“手术网”的情况。这些由不同材料制成的纺织植入物被所有专业协会推荐用于组织加固 [附录 1：1-4]作为首选疗法，并在全球范围内常规用作标准治疗。

在目前使用的聚合物中，PVDF 以出色的方式满足了纺织医疗植入物的要求，因为它在植入后没有降解迹象，并且由于其疏水表面而诱导低炎症和纤维反应。相比之下，可用的替代聚合物在某些情况下显示出明显的劣势，这导致全球超过十万起记录在案的法庭案件 [附录 1：6]。除其他外，由聚酯制成的亲水聚合物会受到快速水解降解的影响，而由聚丙烯制成的亲水聚合物会随着微粒的释放和炎症和疤痕过程的细胞活化增加而受到氧化表面衰变[附录 2：1，29]。

在过去 30 年的深入研究活动中，有 140 多篇关于“网格”主题的出版物（见附录 2），很明显 PVDF 是目前用于纺织织物增强的最佳聚合物[附录 2：1-140]。
PVDF 网状植入物的生产目前是欧盟内部数十年来建立的核心技术竞争力，将生产设施迁移到非欧盟国家将是令人遗憾的。欧盟禁止 PVDF 作为植入材料将意味着聚丙烯（PP）或聚酯（PET）网的使用增加，如果成千上万的患者无法选择从欧盟以外获得 PVDF 植入物，则相关风险也会增加。

由 PVDF 制成的疝补片的开发始于 20 多年前的 1998 年，随着越来越多的实验和临床研究（见参考文献列表附录 2 和我们自己的研究结果的公开），在比较植入材料时变得越来越清楚，由聚丙烯（PP）和聚酯（PET）制成的传统网状植入物与明显的炎症异物反应有关，随着数以百万计的网状植入物的使用，需要新的、更兼容的聚合物。初步试验证实了将 PVDF 用于网状结构的可能性，并且还证实了插入组织后的优越相容性（参见例如[附录 2：118]）。在接下来的几年中，越来越多的外科医生通过国家和国际会议上的出版物和演讲被说服使用 PVDF 植入物，尽管大型网状制造商继续坚持使用聚丙烯（PP）和聚酯（PET）的标准材料，而不是采用更好的知识，部分反对聚合物制造商的警告[附录 1： 7].

外科医生的积极经验，以及首次长期注册研究，在长期过程中对 PVDF 网状物具有无可争议的好处[附录 1：5]目前支持 PVDF 网状植入物的使用增加，并给人们带来了希望，由 PVDF 制成的植入物将在未来几年越来越多地取代由危险的聚丙烯（PP）和聚酯（PET）制成的植入物。

U. 克林格教授博士

附录 1

1: The HerniaSurge Group (2018) International guidelines for groin hernia management. Hernia. https://doi.org/10.1007/s10029-017-1668-x

2: Bittner R, Bingener-Casey J, Dietz U, et al (2014) Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society [IEHS])—Part 1. Surg Endosc 28:2–29. https://doi.org/10.1007/s00464-013-3170-6

3: Henriksen NA, Montgomery A, Kaufmann R, et al (2020) Guidelines for treatment of umbilical and epigastric hernias from the European Hernia Society and Americas Hernia Society: Guidelines for treatment of umbilical and epigastric hernias. Br J Surg. https://doi.org/10.1002/bjs.11489

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6: https://www.meshmedicaldevicenewsdesk.com/articles/100-thousand-mesh-defective-product-cases-now-filed-as-mesh-makers-assure-shareholders

7 https://www.meshmedicaldevicenewsdesk.com/articles/mesh-polypropylene-resin-not-meant-human-implants

由于根据第三部分（ECHA 对附件 XV 限制报告的评论）提交的字符数有限（最多 9000），完整的附录 2 仅包含在第四部分（ECHA 对附件 XV 限制报告的评论）之下的上传附件中。

Due to the limited number of characters (max. 9000) in the submission under Section III (ECHA Comments for Annex XV restriction report), the complete Appendix 2 is only included in the uploaded attachment under Section IV (ECHA Comments for Annex XV restriction report).