

CLINIC FOR GENERAL, VISCERAL AND TRANSPLANT SURGERY

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Subject: 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 > 140 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 > 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.



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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>
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- 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>

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).

Appendix 2

- 1: Wang H, Klosterhalfen B, Klinge U, Müllen A, Jockenhoevel S. Influence of polypropylene mesh degradation on tissue inflammatory reaction. *J Biomed Mater Res A*. 2022 Dec 30. doi: 10.1002/jbm.a.37494. Epub ahead of print. PMID: 36583666.
- 2: Klinge U, Dievernich A, Stegmaier J. Quantitative Characterization of Macrophage, Lymphocyte, and Neutrophil Subtypes Within the Foreign Body Granuloma of Human Mesh Explants by 5-Marker Multiplex Fluorescence Microscopy. *Front Med (Lausanne)*. 2022 Feb 15;9:777439. doi: 10.3389/fmed.2022.777439. PMID: 35242772; PMCID: PMC8887619.
- 3: Dievernich A, Achenbach P, Davies L, Klinge U. Characterization of innate and adaptive immune cells involved in the foreign body reaction to polypropylene meshes in the human abdomen. *Hernia*. 2022 Feb;26(1):309-323. doi: 10.1007/s10029-021-02396-7. Epub 2021 Mar 31. PMID: 33788008; PMCID: PMC8881270.
- 4: Heise D, Mirlas Y, Helmedag M, Eickhoff R, Kroh A, Lambertz A, Klink CD, Neumann UP, Klinge U, Tolba R. Two Polyurethane Adhesives for PVDF Fixation Show Superior Biocompatibility in a Rat Model. *J Invest Surg*. 2022 Jan;35(1):233-239. doi: 10.1080/08941939.2020.1833261. Epub 2020 Oct 14. PMID: 33535001.
- 5: Eickhoff RM, Kroh A, Eickhoff S, Heise D, Helmedag MJ, Tolba RH, Klinge U, Neumann UP, Klink CD, Lambertz A. A peritoneal defect covered by intraperitoneal mesh prosthesis effects an increased and distinctive foreign body reaction in a minipig model. *J Biomater Appl*. 2021 Jan;35(6):732-739. doi: 10.1177/0885328220963918. Epub 2020 Oct 8. PMID: 33331198.
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