



Magenta,
September 5th 2023

To whom it may concern,

It is with great concern that I have learned about the PFAS restriction proposal published by the European Chemicals Agency, with the potential ban of well-established hernia mesh implants with unique properties for which there are currently no alternatives.

As hernia implants are designed to reinforce soft tissue, high stability and resistance to degradation are essential requirements for long-term function with retention times in the body of up to 60 years to minimize health costs and health risks for individual patients. Among the polymers currently in use, PVDF has been proven to meet these requirements particularly well. Mesh implants made of polypropylene (PP) or polyester (PET) as the only available alternatives to fluoropolymers do not represent an adequate substitute due to clinically relevant deficits in long-term stability [1–7].

I am director of the Department of General Surgery of ASST Ovest Milanese – Hospitals of Magenta & Abbiategrasso, Italy. Since 2015 we have been using fluoropolymers (PVDF and PTFE) successful for hernia repair in the Division of Oncologic and Minimally Invasive Surgery at the Niguarda General Hospital in Milan, Italy [8, 9]. After a huge experience of more than 10 years with other mesh materials, in 2015 we switched to PVDF mesh due to excellent clinical results. With regard to parastomal hernias (PSH), in the last five years we have moved from the keyhole technique with PTFE mesh to the sandwich technique due to unsatisfactory results after repair [9], and for prevention we have started to use the chimney technique [10]. Both the sandwich and chimney techniques are based on the intraperitoneal placement of meshes, which require the overlapping of two open-porous meshes or one open-porous mesh with a highly elastic funnel, respectively. So far, these requirements can only be met by meshes made of PVDF [11]. Therefore, I fear that a ban of PVDF for the use case of hernia mesh implants would significantly limit the available treatment options, which would have a direct negative impact on therapeutic outcomes for patients.

In addition to the aforementioned better long-term stability, which is of utmost importance for optimal patient care in hernia surgery, PVDF is also known for its high purity, i.e. it can be used without additives, which reduces the risk of allergic and autoimmune diseases [12], as well as by its low foreign body reaction, which is also a desirable fundamental property of a hernia mesh material and enables its use in the abdominal cavity without additional coating [13]. In contrast, direct contact of internal organs with PP and PET usually leads to formation of many adhesions to the mesh, increasing the risk of intestinal injury, which is why these materials require an additional barrier to shield the mesh.

For the above reasons and in the interest of patient safety, I strongly call on the European Chemicals Agency to grant an exclusion from the scope of the restriction proposal or an exemption by way of a time-unlimited derogation for hernia meshes made of fluoropolymers, in particular PVDF, from the ban.



If you have any questions, please do not hesitate to contact me.

Sincerely,

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REFERENCES

1. Farr NTH, Roman S, Schäfer J, et al (2021) A novel characterisation approach to reveal the mechano–chemical effects of oxidation and dynamic distension on polypropylene surgical mesh. *RSC Adv* 11:34710–34723. <https://doi.org/10.1039/D1RA05944K>
2. Farr NTH, Rauert C, Knight AJ, et al (2023) Characterization and quantification of oxidative stress induced particle debris from polypropylene surgical mesh. *Nano Select* nano.202200243. <https://doi.org/10.1002/nano.202200243>
3. Iakovlev VV, Guelcher SA, Bendavid R (2015) Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients. *J Biomed Mater Res Part B Appl Biomater*. <https://doi.org/10.1002/jbm.b.33502>
4. Warren JA, McGrath SP, Hale AL, et al (2017) Patterns of Recurrence and Mechanisms of Failure after Open Ventral Hernia Repair with Mesh. *Am Surg* 83:1275–1282
5. O'Dwyer PJ, Chew C, Qandeel H (2022) Long term outcome and elasticity of a polyester mesh used for laparoscopic ventral hernia repair. *Hernia* 26:489–493. <https://doi.org/10.1007/s10029-021-02486-6>
6. Maskal S, Miller B, Ellis R, et al (2023) Mediumweight polypropylene mesh fractures after open retromuscular ventral hernia repair: incidence and associated risk factors. *Surg Endosc*. <https://doi.org/10.1007/s00464-023-10039-4>
7. Baker JJ, Öberg S, Rosenberg J (2023) Reoperation for Recurrence is Affected by Type of Mesh in Laparoscopic Ventral Hernia Repair: A Nationwide Cohort Study. *Annals of Surgery* 277:335–342. <https://doi.org/10.1097/SLA.0000000000005206>
8. Ferrari G, Bertoglio C, Magistro C, et al (2013) Laparoscopic repair for recurrent incisional hernias: a single institute experience of 10 years. *Hernia* 17:573–580. <https://doi.org/10.1007/s10029-013-1098-3>
9. Bertoglio C, Morini L, Maspero M, et al (2021) From keyhole to sandwich: change in laparoscopic repair of parastomal hernias at a single centre. *Surg Endosc* 35:1863–1871. <https://doi.org/10.1007/s00464-020-07589-2>
10. Bertoglio CL, Maspero M, Morini L, et al (2020) Permanent end-colostomy parastomal hernia prevention using a novel three-dimensional mesh. *Hernia*. <https://doi.org/10.1007/s10029-020-02326-z>
11. Berger D (2023) Perspectives of prevention and treatment of parastomal hernia-what do we really know and where should we go? *Mini-invasive Surg* 7:24. <https://doi.org/10.20517/2574-1225.2023.30>
12. The HerniaSurge Group (2018) International guidelines for groin hernia management. *Hernia* 22:1–165. <https://doi.org/10.1007/s10029-017-1668-x>
13. 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 3. *Surgical Endoscopy* 28:380–404. <https://doi.org/10.1007/s00464-013-3172-4>