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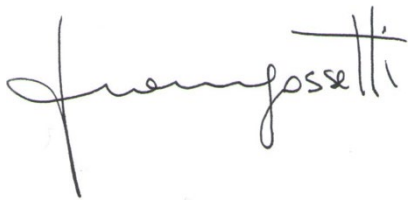
Dear Members of the European Chemicals Agency,

I am very concerned about the published PFAS restriction proposal, which include mesh materials that have been used successfully in hernia surgery for decades, namely fluoropolymers. Of particular concern to me is the possible ban of polyvinylidene fluoride (PVDF), a fluoropolymer that is the material of choice for the treatment of ventral hernias in the Department of Cardiothoracic-Vascular and Transplant Surgery, Abdominal Wall Surgery Unit, Policlinico Umberto I – Sapienza University of Rome, Italy for over 10 years [1].

I have been focused on the topic of hernia surgery since 1990 and also specifically on meshes. Until December 31 st, 2022 I was Director of the Abdominal Wall Surgery Unit at Policlinico Umberto I – Sapienza University of Rome. During this time, I explanted and analyzed over 75 meshes in patients with mesh-related complications. I never had to remove any PVDF mesh from retromuscolar position implanted by myself or other colleagues (also in different position). I have published over 80 publications that are listed on Pubmed, most of them on the topic of hernias or meshes. In the past 10 years, I have operated on over 160 patients with PVDF meshes and can confirm the excellent results and uniqueness of these meshes.

PVDF is a synthetic, non-absorbable, highly non-reactive fluoropolymer of high purity with excellent mechanical, chemical and biological properties [2–4]. Meshes made of PVDF have good biocompatibility; they elicit a minimal foreign body reaction with much smaller foreign body granulomas compared to meshes made of polypropylene (PP) and polyester (PES) [4–9]. This, in combination with mesh designs with high effective porosity, reduces the risk of “bridging” scar reactions, i.e. complete filling of the mesh pores with fibrous tissue and associated mesh contraction/shrinkage, which can be monitored by the availability of MRI-visible variants in vivo [10–13]. These excellent, partly unique properties in combination with the superior biostability/aging resistance compared to PP and PES [3, 14, 15] make PVDF meshes in our opinion currently the best solution for the treatment of hernia patients with the aim of achieving lasting treatment success.

A ban of currently the best material for hernia treatment, namely PVDF, would be a big setback for hernia surgery in general and would force physicians to use less suitable materials. Therefore, I call on the European Chemicals Agency to grant a time-unlimited exemption for PVDF. Please do not hesitate to contact me if you have any questions.



Rome, 23 August 2023

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