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Dear Members of the ECHA,

With great concern I have learned about the potential ban of some irreplaceable mesh implants in the course of the PFAS restriction proposal currently under discussion in the European Chemicals Agency. While I support the main goal of the proposal, I'm convinced that there is also need for wise exceptions. The ban would affect well established and in many ways unique implants for which there are no alternatives available on the market yet.

I have been focused on the topic of hernia surgery since 2005 and also specifically on meshes. Until 2017 I was head of the section of abdominal wall reconstruction and hernia surgery at the University of Würzburg (Germany). During this time, I explanted and analyzed over 300 meshes in patients with mesh-related complications. I have contributed to over 95 Pubmed listed publications, most of them on the topic of hernias. In the past 5 years, since my move to Olten (Switzerland), I have operated on over 1000 patients with PVDF meshes with robotic approach and can confirm the excellent results and uniqueness of these meshes. Allow me to point out to 3 reasons for the uniqueness and necessity of these meshes for patient care:

First, the availability of long-term stable medical devices is of utmost importance for optimal patient care in hernia surgery, to minimize healthcare costs and health risks for the individual patients over their life-time. Mesh implants made of PP and PET as the only available alternatives to mesh implants made of fluoropolymers do not represent an adequate substitute due to clinically relevant deficits in long-term stability. [1-6] We are currently seeing an increasing number of cases of degradation of PET meshes already after 2-4 years of implantation, with deleterious consequences to patients. It should not be needed to be reminded, that patients continue living up to 60 years after mesh implantations, so very long-term stable meshes are crucial.

Second, there are even important surgical techniques ("funnel technique") that can only be performed with dedicated mesh implants made of fluoropolymers (DynaMesh-IPST). In the case of a ban, these important surgical procedures can no longer be performed, as there are no alternatives to these unique fluoropolymer mesh implants available on the market. These meshes have proved clinical safety for over two decades. To find an alternative to PVDF and to clear its medical use under medical devices regulations will take a long time.

Thirdly, PVDF hernia implants are available as MRI-visible variants. There are no other mesh implants on the market with this specific feature, which represents a clinically relevant improvement in terms of patient safety. [7-11]

For these reasons and in the interest of patient safety, I strongly call on the European Chemicals Agency to grant a time unlimited exemption for mesh implants made of fluoropolymers, in particular PVDF. Should you have further questions I would be glad to answer and assist you.

Kindest regards,



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Excerpt of the Literature

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