

European Chemicals Agency
PFAS consultation

Villalobos Mori, Rafael
Chief of the Abdominal Wall Unit Surgery, Arnau de Vilanova University Hospital
Spain

Dear Members of the European Chemical Agency,

I have become aware that the proposed PFAS ban may have unintended consequences on well-established and irreplaceable mesh implants used for hernia treatment, which are made of Fluoropolymers. This concern has prompted me to compose this letter.

As a dedicated hernia surgeon for over 13 years, I can attest that all relevant medical guidelines recommend the use of mesh implants as the gold standard for hernia treatment. These implants serve a permanent load-bearing function and typically remain in the patient's body for an average of 25 years, and in some cases, up to 60 years. In the event of a mesh implant failure, reoperation is required in the majority of cases, which always carries higher risks of complications compared to the initial intervention.

I have 8 years of experience using polyvinylidene fluoride (PVDF) meshes in different abdominal wall surgery techniques. I have used this material in different locations of the abdominal wall of my patients with a very long follow up and I've never had problems related to this material. That results that I and my team have obtained reflect the excellent utility and safety. In fact, the PVDF meshes are the most important material to repair the abdominal wall defects in my Unit.

The main focus of the discussion concerning a potential PFAS ban is the substances' extreme durability ("forever-chemicals"). However, this very characteristic is the strongest argument against banning these substances for specific long-term medical implants, especially for hernia meshes. There is currently no equivalent alternative to fluoropolymers that meets the essential requirement of long-term stability.

Considering the relatively small quantities of material used (only a few grams per mesh implant) and the significant patient and socio-economic benefits, a ban on hernia meshes made of Fluoropolymers would be disproportionate and lead to severe negative consequences for patients and the healthcare system.

I acknowledge the environmental concerns related to different PFAS materials and support the initiative to critically assess their widespread use and seek alternatives. However, it is crucial to weigh these environmental concerns against the immediate negative impact a ban on certain medical devices could have on patients' health.

With patient safety in mind and in the spirit of proportionality, I urge the European Chemicals Agency to grant an indefinite exemption for mesh implants made of fluoropolymers, particularly PVDF. If you have any further inquiries, please feel free to contact me.

Sincerely yours,



1. Villalobos Mori Rafael, Maestre Yolanda, González-Barranquero Alberto, Olsina Kissler Jorge.
HERNIA LUMBAR DERECHA: DOCKING POSTERIOR COMO NOVEDAD EN EL ABORDAJE DEL eTEP
ROBÓTICO CON MALLA PVDF
Video ATLAS de la AEC
2. González Barranquero Alberto, Espert JJ, Maestre Y, Llompert M, Gas C, Olsina J, Villalobos Mori Rafael
ANALYSIS OF RECURRENCE AND RISK FACTORS IN LAPAROSCOPIC SANDWICH TECHNIQUE FOR
PARASTOMAL HERNIA REPAIR.
Surgical endoscopy. Accepted in Sep 2023
3. Villalobos Mori, Rafael, Madrazo Z, Maestre Y, Gonzalez Barranquero A, Gas C, Olsina J
OMEGA trial: A multicenter randomized controlled non-inferiority trial of Only MESH fixation with
a Glue Applicator comparing traumatic vs atraumatic fixation of the mesh in ventral/incisional
laparoscopic repair.
Trial running