19 June 2023

To whom it may concern

PFAs restriction proposal

It is with great concern that we (the European Hernia Society, www.europeanherniasociety.eu) have received information of a potential ban of numerous surgical mesh implants in the course of the PFAS restriction proposal currently under discussion by the European Chemicals Agency. Surgical mesh implants are used in the repair of abdominal wall hernias, a common condition throughout the world. The proposed ban would affect well established implants (see list in footnote [1]) that have been used very successfully for years. Furthermore, some have unique properties for which there are no alternatives available at present.

The availability of medical devices with durable characteristics is of utmost importance for optimal patient care in abdominal wall surgery, to minimize health risks for the individual patients over their life-time, and the real risk of hernia recurrence and need for further surgery as a result. The relevance of long-term stability of implant materials is also discussed in international guidelines (see footnote [2]):

> *"Over time, most polymers do show alteration or degradation of their polymeric structure. […]It may be prudent to assume that hernia mesh implant instability can occur after several decades. […] Under electron microscopy, human mesh explants all show signs of degradation. PVDF has the highest resistance to degradation."*

Only recently, a hernia registry study was published[3] which clearly reports that products affected by restriction are associated with the lowest recurrence rates in the long term.

We ask the Agency and the European Commission to consider the serious implications for patients with a hernia of banning a number of high quality products in health care that do not have alternatives with proven equivalent outcomes. Equally important, among the mesh implants affected by the ban are many devices directly linked to a surgical technique (e.g. funnel-technique in case of parastomal hernia repair) for which there are no alternatives on the market. A ban of these meshes would limit medical treatment options and could lead to inferior therapeutic outcomes for patients.

We therefore call on the European Chemicals Agency and the European Commission to not restrict important mesh choices for surgeons in relation to their patients. The ability to choose the best medical device for the individual patient is key. We are aware of the burden of surgery and medicine in general, in contributing to the risk of global warming and other risks to this planet. However, the hernia mesh industry contributes a tiny fraction of the PFAs issue. Researching, developing and attaining the appropriate for human use approval for new hernia meshes is a lengthy process. A stay on any ban of PFA hernia mesh products is crucial, until effective alternatives can be found. It is likely that the environmental burden of a second open for hernia recurrence would outweigh the risk of a small volume of PFA related hernia meshes.

We would be happy to respond to any queries as necessary related to this area of PFA use.

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[1] Omyra mesh by B.Braun, DUALMESH by Gore, DynaMesh IPST by FEG Textiltechnik, DynaMesh CICAT by FEG Textiltechnik, DynaMesh ENDOLAP 3D by FEG Textiltechnik, Composix E/X mesh by Becton Dickinson, ventrio hernia patch by Becton Dickinson, Ventralex by Becton Dickinson

[2] The HerniaSurge Group. International guidelines for groin hernia management. Hernia (2018) doi:10.1007/s10029-017-1668-x.

[3] Baker, J. J., 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) doi: 10.1097/SLA.0000000000005206

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