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To whom it may concern,

I am a specialist in the surgical treatment of the sensitive entity of hiatal hernia patients. To date, I have surgically treated more than 1,500 patients with hiatal hernia using the so-called DELTA OP method. There is only one mesh implant on the market that can be used for this special surgical method. This mesh implant (DynaMesh-DELTA) is made of the fluoropolymer PVDF and is also to be banned in the course of the PFAS ban. The loss of this mesh implant and the subsequent loss of the surgical operation method "DELTA" would be a severe restriction of the treatment options in the treatment of hiatal hernias.

Preventing the further spread of PFAS is an understandable and sensible aim, which I fully support. Nevertheless, there are essential uses for which no alternatives are available. In these cases, the harm caused by the ban rapidly becomes a much greater risk than the continued use of the product. In the case of essential medical devices for which no alternatives are available (as in the case of the hernia mesh for the surgical treatment method "DELTA"), this is exactly what I see.

Therefore, and in the interest of patient safety I call on the European Chemicals Agency to grant a time unlimited exemption for essential medical devices as the hernia mesh implant "Dynamesh-DELTA" made of PVDF.

I will be happy to answer any questions you may have.

Sincerely yours,

Florian Thomas,

  
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