

Prof.Dr.Metin Ertem

Acibadem Kozyatagi Hospital

Istanbul – Türkiye

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With great concern I recognized the potential ban of PVDF (DynaMesh) and ePTFE (e.g. DUALMESH, Ventralex) mesh implants in the course of the PFAS restriction proposal. These implants have been used by many of our surgeons for years with the best clinical success and highest patient satisfaction.

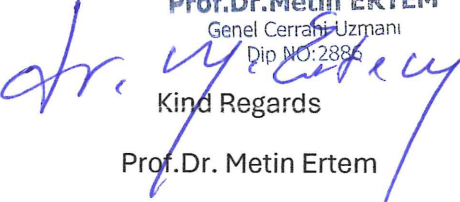
Some of the implants affected by the ban are unique and without alternatives like the tunnel-shaped DynaMesh-IPST mesh for the repair of parastomal hernias /1/ or the DynaMesh-HIATUS mesh made of PVDF /2/, specially designed for the treatment of hiatal hernia.

Additionally I will lose beneficial diagnostic techniques like the postoperative visualisation of PTFE implants in CT /3/ or of Dynamesh PVDF-visible implants in MRI /4/. There are no other mesh implants on the market with this specific feature, which represents a clinically relevant improvement in terms of patient safety.

Especially the durable characteristics of the used fluoropolymers are of utmost importance for optimal patient care in surgery, avoiding health risks and recurrences by polymer degradation for the individual patients over their life-time /5-7/.

A ban of these meshes, that do not have alternatives with proven equivalent outcomes, would limit medical treatment options and could lead to inferior therapeutic outcomes for patients.

I therefore call on the European Chemicals Agency and the European Commission to grant a time unlimited exemption for mesh implants made of fluoropolymers and to not restrict surgeons' therapy freedom to choose the best medical device for the individual patient according to their best medical knowledge and according to patient- and indication-related criteria.


Prof.Dr.Metin ERTEM
Genel Cerrahi Uzmanı
Dip NO:2886
Kind Regards
Prof.Dr. Metin Ertem

Acibadem Kozyatagi Hospital Head Of Surgery

President Turkish Fight Against Cancer Foundation

Literature

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