

European Chemicals Agency
P.O. Box 400,
FI-00121 Helsinki,
Finland

Vienna, May 19, 2023

Statement of the Austrian Society for Hernia Surgery (ÖHG) on the discussed ECHA restriction proposal regarding the ban on fluorinated polymers in hernia surgery

The board members of the ÖHG have been working intensively on abdominal wall hernia surgery for many years. My name is Gernot Köhler and I am the acting president of the Austrian Hernia Society (ÖHG). I have the privilege of writing this letter on behalf of our board members. I certified a reference center for hernia surgery in the Congregation Hospital Linz in 2014 and I am an accredited European specialist in abdominal wall surgery (FEBS AWS).

Polyvinylidenfluorid (PVDF) has been a standard material for us in many areas of abdominal wall surgery for many years and is indispensable in our daily practice. We have written numerous „peer reviewed“ publications in surgical top journals worldwide on this topic [1-11], which contribute to the excellent evidence regarding the clinical suitability of PVDF meshes.

Some of the implants are unique and without alternatives, for example with regard to the tunnel-shaped IPST mesh for the repair of parastomal hernias [1-6] and enabled the development of a new technique that is now widely used. In addition, such three-dimensional tunnel-shaped implants play a major role in the prevention of parastomal hernias [7]. Funnel meshes can be used in an open and laparoscopic-assisted approach and cover the inner margin of the hernia defect with their specially designed funnel-shaped part. Due to their intraperitoneal position, a sufficient overlap of the defect can be reached without the need of separation of abdominal wall layers. Furthermore, concomitant incisional hernias in midline position can be reinforced by the implants flat part itself or with an additional flat mesh. An often present stoma prolapse can be managed very easily by resection of redundant bowel. Same-sided stoma reposition does not cause any further destabilization of the abdominal wall. The specially designed elastic and flexible funnel part fits the diverted bowel accurately and gives protection against stoma prolapse. The dual-layer composite structure of funnel meshes with polyvinylidene fluoride and polypropylene promotes antiadhesive properties and provides safe and rapid ingrowth in the abdominal wall. We observed no mesh-related complications such as bowel erosions or stoma stenosis in our own collective of about 200 patients, who underwent either PSH prevention or repair with 3D funnel meshes. Meshes usually cannot be imaged directly.

In view of the unique „MR visible technology“ using a mesh with enhanced signal through the addition of iron particles into the polyvinylidene fluoride base material provides detailed mesh depiction.

We expect opportunities for better understanding of mesh integration and researching time-dependent changes of meshes such as shrinkage, deformation, and migration and their clinical relevance by the control of long-term outcome parameters. We have published the successful clinical use of such implants and the impressive imaging capability [8-11].

The wide range of products consisting of PVDF are designed for intraperitoneal and extraperitoneal placement, thereby ensuring that almost the entire range of hernia surgery problems can be covered. A ban on such polymers (PTFE and PVDF) would be disastrous in many medical fields (suture material, vascular prostheses, sterile filters, medical seals....), but especially in the field of hernia surgery.

The purity of the material with the corresponding implications in terms of excellent biocompatibility, best tolerability and almost no toxicological or allergenic potential has been proven for PVDF in comparison to alternatives. The antislip surface ensures stable positioning of the mesh. It also facilitates handling and fixation and the high effective porosity allows direct contact of the tissue layers through the mesh and promotes rapid incorporation.

The extremely slow material degradation of monofilamentous PVDF for example in comparison with polyester but also with polypropylene, causes the necessary long-term stability for permanently recurrence-free hernia care. PVDF appears to be very resistant to hydrolysis and degradation. All properties of modern implants are met (mechanical characteristics like tear strength, tensile strength, burst resistance and suture retention). All of this indicates the resilience, strength and rigidity of the mesh material i.e. deformability and elasticity, pliability (flexibility) and extensibility. Even the anisotropy (directional extensibility) of Dynamesh cicat ® for example is provided by incorporated green orientation strips into the mesh material. They must always run in the craniocaudal direction. This is future oriented, because the anisotropy factor of the body is longitudinal to transversal about 8 to one, that means the linea alba is 8 times more elastic stretchable and loadable in the longitudinal direction before it tears, so meshes should be stretchable in the longitudinal direction but stronger in the transversal direction. This is the research field of the future to better understand which mech properties best meet the requirements of the individual abdominal wall (age, gender, BMI) and the respective defect (size, location, tissue composition). Attempts will be made to better harmonize the textile properties of mesh implants with the physiological properties of the abdominal wall. The PVDF material is indispensable for optimal, comprehensive, individualized and sustainable care for patients with all types of abdominal wall, inguinal and diaphragmatic hernias.

For all these reasons, we ask the ECHA and the European Commission to refrain from banning fluoropolymers for the use in hernia mesh implants and to grant instead a time unlimited exemption for mesh implants made of fluoropolymers.”

Gernot Köhler on behalf of the board members of the Austrian Hernia Society (ÖHG)

- 1) Parastomal hernia repair with a 3- D mesh device and additional flat mesh repair of the abdominal wall. Köhler G, Koch O.O, Antoniou S, Lechner M, Mayer F, Klinge U,; Emmanuel K. Hernia. 2014 Oct;18(5):653-61; PMID: 25112385
- 2) Single-Port Parastomal Hernia Repair by Using 3-D Textile Implants. Köhler G, Emmanuel K, Schrittwieser R. JSLS. 2014 Jul-Sep; 18(3); PMID: 25392655; PMC: 4208891;
- 3) Changes in the Surgical Management of Parastomal Hernias Over 15 Years: Results of 135 Cases. Köhler G1, Mayer F, Wundsam H, Schrittwieser R, Emmanuel K, Lechner M. World J Surg. 2015 Nov;39(11):2795-804; PMID: 26264458
- 4) A Novel Technique for Parastomal Hernia Repair Combining a Laparoscopic and Ostomy-Opening Approach. Köhler G, Fischer I, Wundsam H J Laparoendosc Adv Surg Tech A. 2017 Jun 27. doi: 10.1089/lap.2017.0313. PMID: 28654318
- 5) [Principles and parallels of prevention and repair of parastomal hernia with meshes]. Köhler G. Chirurg. 2019 Sep 30. doi: 10.1007/s00104-019-01047-z. [Epub ahead of print] Review. German. PMID: 31570963
- 6) Parastomal Hernia Repair with a 3D Funnel Intraperitoneal Mesh Device and Same-Sided Stoma Relocation: Results of 56 Cases. Fischer I, Wundsam H, Mitteregger M, Köhler G. World J Surg. 2017 Jul 24. doi: 10.1007/s00268-017-4130-4. PMID: 28741192
- 7) Prevention of parastomal hernias with 3D funnel meshes in intraperitoneal onlay position by placement during initial stoma formation. Köhler G1, Hofmann A, Lechner M, Mayer F, Wundsam H, Emmanuel K, Fortelny RH. Hernia. 2016 Feb;20(1):151-9; PMID: 25899106
- 8) Magnetic resonance visible 3-D funnel meshes for laparoscopic parastomal hernia prevention and treatment. G. Köhler · H. Wundsam · L. Pallwein-Prettner O.O. Koch · K. Emmanuel Eur Surg. 2015 June 2. DOI 10.1007/s10353-015-0319-7
- 9) First human magnetic resonance visualisation of prosthetics for laparoscopic large hiatal hernia repair. Köhler G1, Pallwein-Prettner L, Lechner M, Spaun GO, Koch OO, Emmanuel K. Hernia. 2015 Dec;19(6):975-82; PMID: 26129921
- 10) Laparoscopic stoma relocation for parastomal hernia treatment by using a magnetic resonance visible 3D implant. Köhler G, Emmanuel K. ANZ J. Surg 2014 Nov 3. doi: 10.1111/ans.12899; PMID: 25366333

- 11) Magnetic resonance-visible meshes for laparoscopic ventral hernia repair. Köhler G, Pallwein-Prettner L, Koch OO, Luketina RR, Lechner M, Emmanuel K JSLS. 2015 Jan-Mar;19(1); PMID: 25848195

Sincerely on behalf of the ÖHG Board

Prim. Priv. Doz. Dr. Gernot Köhler



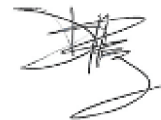
Präsident

Dr. Nikolaus Hartig



Schriftführer

Univ.-Prof. Dr. René Fortelny



Kassier