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Briefempfänger-Firmenname

Committee for PFAS – European Chemicals Agency

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www.godeshoehe.de**Betreff:** PFAS restriction proposal currently under discussion in the European Chemicals AgencyDatum
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Dear Members of the ECHA,

Based on a long history of experience with PVDF meshes in pelvic floor surgery I am truly concerned about the potential ban of some irreplaceable mesh implants. I can follow the main goal of the proposal but for good patient care there must be time unlimited exceptions.

Since 2006 I was head of the continence clinic at the Aachen University clinic and from 2012 up to 6/2023 I was the coordinator of the interdisciplinary continence centre at the University hospital in Bonn. I am following the discussion about sling material since 2010 ^{1,2,3}

PFAS restriction proposal currently under discussion in the European Chemicals Agency would limit the choices of material used for incontinence and prolapse procedures.

Although there is some debate about superficial degradation of PP Mesh as one factor leading to complications, most authors, concluded that Polypropylene degradation may play a role in the continuous inflammatory response, mesh hardening and late deformations. ^{4,5,6,7}

In a comparative study Gerullis et al. ⁸ looked at inflammatory infiltration, amount of macrophages and connective tissue reaction to investigate whether mesh material could be improved by highly aligned collagen threads crosslinked using either genipin or 1-ethyl-3-(3-dimethylaminopropyl) carbodiimide and N-hydroxy succinimide (EDC/NHS). The authors concluded for all tested materials that Polyvinylidene fluoride (PVDF) performed better than Polypropylene (PP – TVT) or reinforced PP (UltraPro) even not coated.

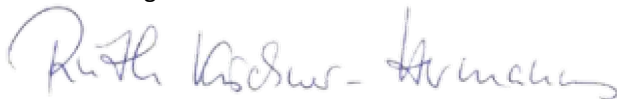
Slings and other meshes used in pelvic floor made entirely of PVDF are in many ways beneficial for the patients. PVDF is a material with proven excellent biocompatibility, good mechanical and chemical properties, high hydrolysis resistance and compared with other materials such as for example Polypropylene demonstrate a slow aging process. In polypropylene aging results in post-crystallization leading to a reduction in strength of up to 47%, whereas with PVDF this is only up to 4,7 %. Mesh implants made of PVDF benefit from the good material properties. In conjunction with optimally adapted mesh parameters, this leads to unsurpassed properties in terms of tissue integration and sustainability. PVDF is associated with a considerable reduction of the risk of erosions, inflammations, fibrosis and hematomas. ⁹

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The PVDF mesh implant is directly warp knitted and not cut from a surface area. This gives it edges, which allow easy, atraumatic insertion and adjustment without irritation of the surrounding tissue (no "saw teeth"). Even under load, the geometry is not changing significantly. The effective porosity remains maintained; permanent changes in mesh geometry do not occur, handling becomes easier and undesirable curling of the tapes is prevented.

Mit freundlichen Grüßen

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Name Prof. Dr. Ruth Kirschner-Hermanns
Leitung der Neuro-Urologie

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