Replacing PTFE with UHMW-PE: A High-Performance, PFAS-Free Approach to Medical Component Design

Scherer Manuel, Technical Marketing Manager, CELANESE

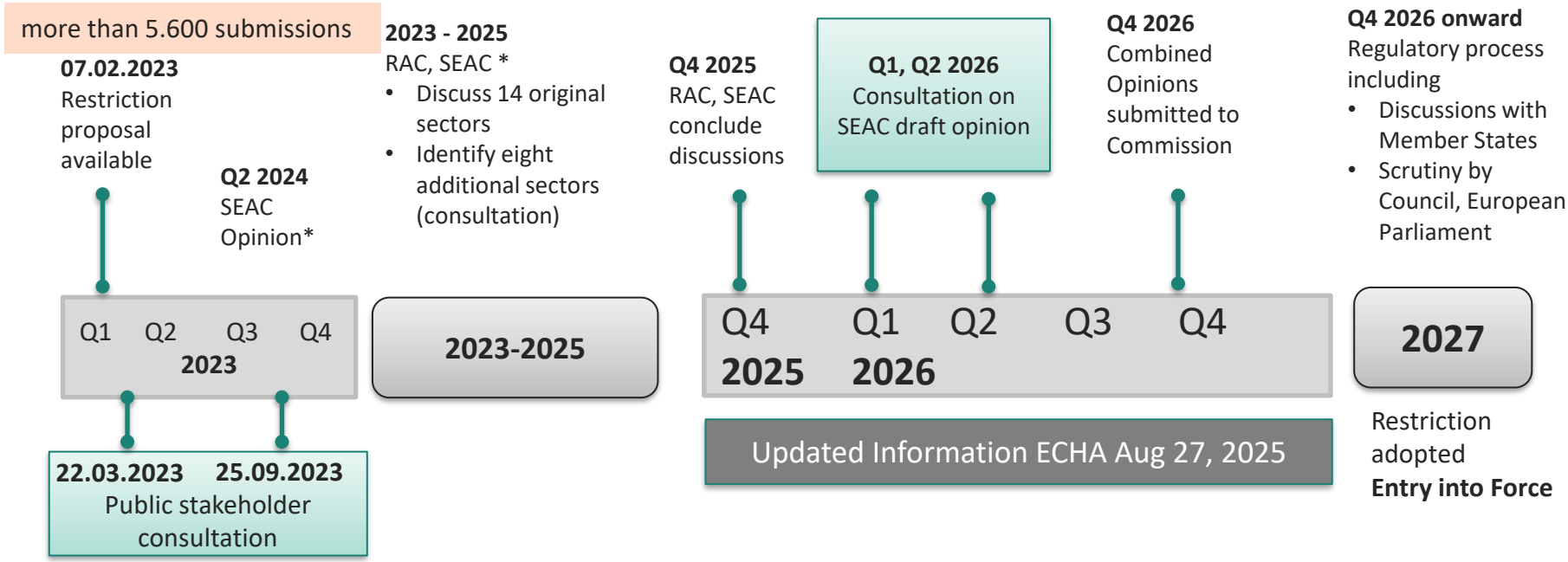
Balloffet Cécile, Application Development Engineer, CELANESE



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1. The Challenge: Regulatory Pressure around PFAS



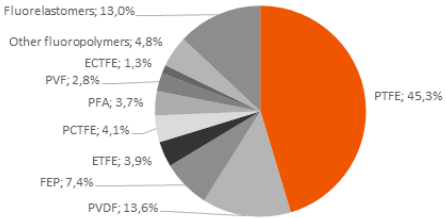
Regulation still evolving, but the direction is clear: PFAS restrictions will tighten, making proactive planning essential

* RAC, SEAC: Adoption of opinions at Risk Assessment Committee (RAC) and Committee on Socio-Economic Analysis (SEAC)

2. The Unmet Need: What Medical OEMs and Specifiers Are Looking For…

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Fluoropolymers Market



PTFE Property Profile

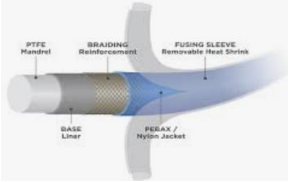
Property	Standard	Typical Values
Coefficient of friction (COF)	stick slip test - steel ball vs polymeric plate	0,1
Wear resistance	relative wear volume on a rotating steel shaft test	
Impact strength	double-notched Charpy impact strength	15-25 kJ/m2
Melting point	Tm in °C	330°C
Chemical resistance		excellent
Purity and Biocompatibility	chemically inert - permanent implant quality grades available	
Hydrophobicity	lowest surface energy in thermoplastics	<20 Dyne/cm
Electric insulation	low dielectric constant and high dielectric strength	Dk of 2.0 (100H
Porosity and pore sizes*	tunable to cover a broad range of application needs	
UV resistance		excellent
Carbon footprint	kg CO2 emission used in the production of each kg resin	6-60
Shore hardness	D hardness scale	55
Density	volumetric mass in g/cm3	2,2

*Processing dependant properties

PFS Plungers Coating



Vascular Catheter Liner



Medical Lubricant



Bioprocessing Vent Filters



Vascular Grafts



Anchoring for IOL



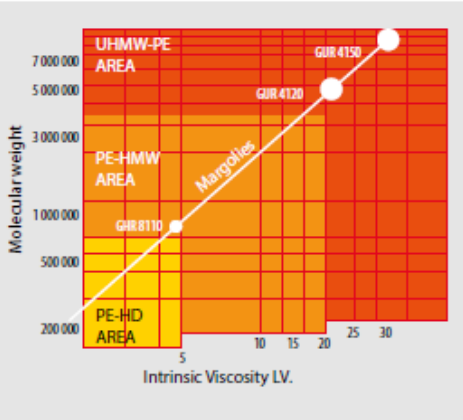
The medical industry is looking for PTFE performance- and safety profile - without intentionally added PFAS in a diverse field of applications

General Business Information

3. The Solution: what is UHMW-PE?

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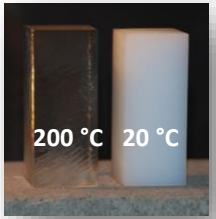
The Polyethylene Family



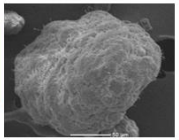
$CH_2=CH_2$ (Ethylene) —Heat, Pressure, Catalyst→ $-CH_2-CH_2-$, $-CH_2-CH_2-$, etc. (Rearrangement of primary covalent bond)

(H) $^{***}CH_2-CH_2-CH_2-CH_2-CH_2-CH_2-CH_2-CH_2-CH_2-H$

Polyethylene Polymer

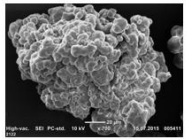


Grain morphology (bulk density)



"Potato" with bulk density ≈ 0.45 g/cm³

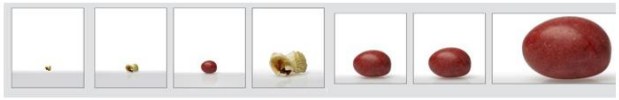
Less interaction area



"Popcorn" with bulk density < 0.3 g/cm³

More interaction area

Grain size (d50)



Surface energy (hydrophobic, hydrophilic)

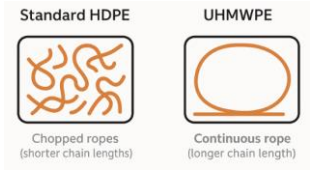


GUR® UHMW-PE powders dispersed in water

- Left: normal GUR® UHMW-PE is hydrophobic and phase-separates immediately
- Right: modified GUR® UHMW-PE is hydrophilic and can be dispersed in water for some time

Typical Molecular Weight Ranges of Low-Pressure PE

HDPE:	**30 000 – 300 000**
HMW-PE:	**300 000 – 3 Million**
UHMW-PE:	**3 – 12 Million**



Definition of UHMW-PE:

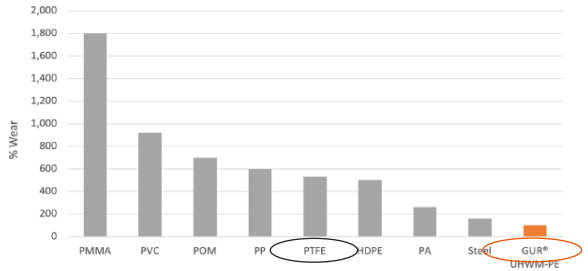
- ISO 11542-1: MFR<0.1 g/10min (190°C / 21.6 kg)

GUR® UHMW-PE contains no intentionally added PFAS and inherently has significantly lower CO_2 footprint and density compared to PTFE

3. The Solution: what is UHMW-PE Footprint in Medical?

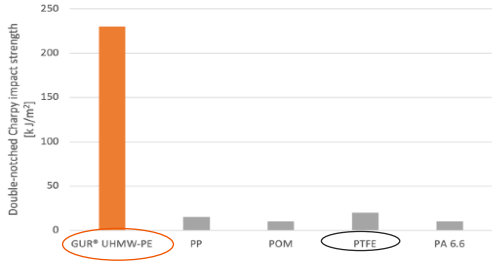
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Abrasion resistance



Material loss performance is relative to GUR® UHMW-PE grade 4120 (=100) for different materials determined by the sand slurry method. The sand slurry method rotates specimens in a sand-water mixture under defined conditions for several hours.

Impact strength



The double-notched Charpy impact strength test results show the amount of energy absorbed by a material at the breakpoint. This graph illustrates that the impact strength performance of GUR® UHMW-PE is much higher than that of other thermoplastic polymers.

Conformity Data	GUR® (UHMW-PE)
FDA Regulation	21 CR 177.1520
EU FC Regulation	EC 1935/2004
USP Class VI (ISO 10993-6, -10, -11)	Yes
Cytotoxicity (ISO 10993-5)	Yes
Hemolysis (ISO 10993-3)	Yes
Device Master File (MAF)	588
Drug Master File (DMF)	10904
Physicochemical Test (USP 661.1)	Yes
Applicable ASTM Materials Standards	F648-21, F2759-19, F2848-21, F755-19, F2695-12
International Pharmacopeia Standards	EP 3.3.2- Containers for Human Blodd & Blood Components
Sterilization	
Steam (121°C/ 134°C	No
E-Beam/ Gamma irradiation	Yes
EtO	Yes





UHMW-PE provides significantly better abrasion resistance and impact than PTFE

UHMW-PE has decades' worth of clinical history in permanent implant applications

General Business Information

3. The Solution: UHMW-PE, a Good Candidate to Displace PTFE in (Traditional PTFE) Spaces?

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Typical values	GUR® UHMW-PE	PTFE
Wear resistance	++	+
Impact Strength	++	o
Carbon footprint [kg/kg product]	~2	6 - 60
Density [g/ml]	0.93	2.2
Purity, FDA approval	++	++
Processing	-	-
Minimum Usage Temperature [°C]	-270	-270
Shore Hardness	D60	D55
Coefficient of Friction		
Chemical Resistance	+	++
Maximum Usage Temperature [°C]	80	260
UV Resistance	-	++
Flammability	-	++

With innovation, UHMWPE can penetrate into traditional PTFE spaces

UHMWPE has a clear advantage over PTFE

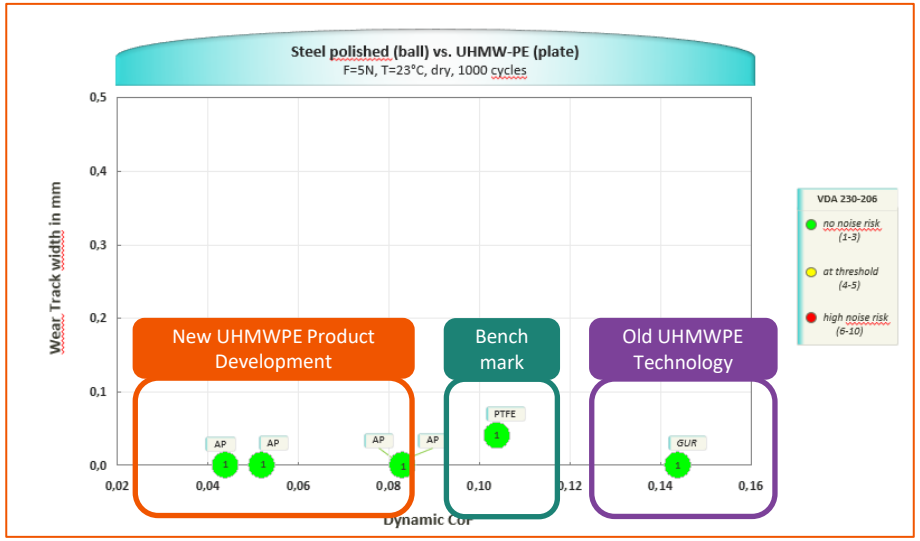
UHMWPE and PTFE coexist

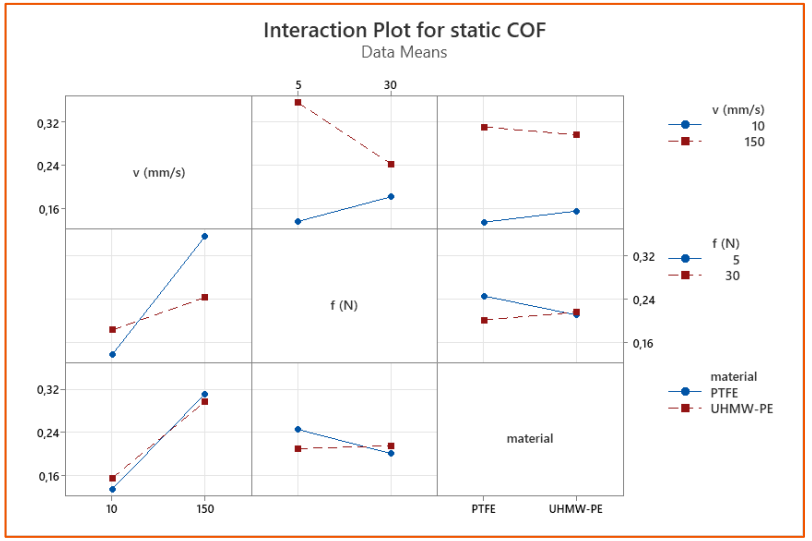
PTFE has historic advantage over UHMWPE

Innovation on UHMW-PE as a mean to tap into new applications, addressing the spaces where PTFE used to have clear advantages over UHMW-PE

General Business Information

3. The Solution: UHMW-PE, a Good Candidate to Displace PTFE in Low-Friction (Traditional PTFE) Spaces?





With new generation of products, UHMW-PE has overcome the historic drawback vs. PTFE on stick-slip performance

4. Application Case #1: UHMW-PE as PTFE Alternative in Syringe Plungers

validation stage

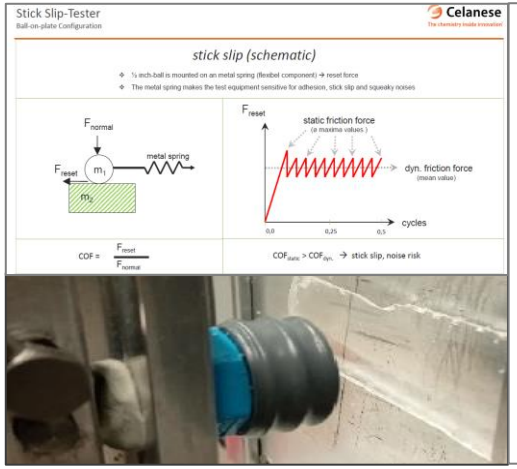
Application

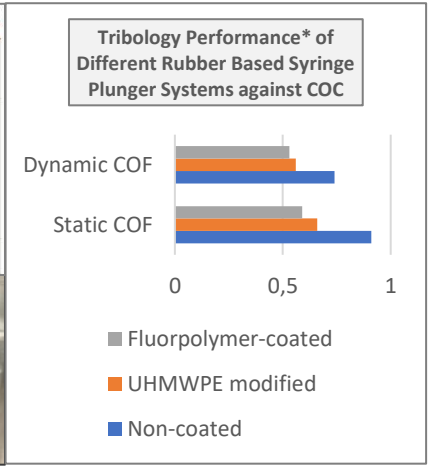
- UHMW-PE as tribology additive used in rubber formulations for syringe plungers
  - PTFE/ETFE coatings are used in rubber industry to provide lubricious layer to halobutyl rubber-based syringe plungers
  - The coating's main function is to achieve low initiation- and insertion forces during application and assembly, respectively

Requirements

- Low coefficient of friction
  - Especially at low speeds and applied forces (stick slip phenomenon)
- Biocompatibility and chemical inertness
  - ISO-10993 protocols
  - Low extractables profile (lengthy drug contact)
- Steam sterilization







* Results after 1 cycle at stick slip tester b/w syringe body and plunger at F = 10N, v= 10mm/s, oscillating movement

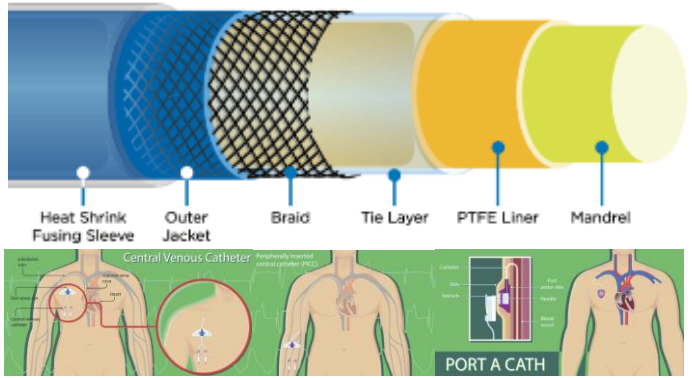
General Business Information

4. Application Case #2: UHMW-PE as Alternative to PTFE in Catheter Liners

validation stage

Application

- Catheter: Multilayered structures
  - PTFE liner creates a lubricious tube that allows for guide wires and instruments to pass through without tearing or large amounts of resistance
  - Inner layer is typically composed of PTFE
  - Lined catheters used for endoscopic surgery have higher requirements than other medical tubing



Requirements

- Low Coefficient of friction: similar feel to surgeons guiding tools with existing tubes
- Biocompatibility: Tube liner not directly in contact with body, but wires that pass through them are
- Mechanical integrity: must not be torn by wires/ tools
- Electrically Insulative

- Why UHWMPE should be considered moving forward in catheter liners
  - Thin-wall processing (dip coating)
  - Low coefficient of friction (comparable surgeon feel)
  - Higher shore D hardness (translating into higher scratch resistance)
  - Electric insulation (Dk = 2.1 100Hz, IEC 60250)

General Business Information

4. Application Case #3: UHMW-PE as PTFE Alternative in Medical Membranes

conceptual stage

Application

- Gas- and vent filtration membranes for biopharma processing: nano-/microporous membranes for air, gas and solvent applications
- For use in bioreactors, storage tank venting, filling equipment venting
- Main job of the membrane is to prevent contamination and maintain process security
- Main formats cartridges and capsules







Requirements (PTFE)

- Pore sizes of 0,2 - 0,5 µm
- Bacterial retention (aerosol challenge tests) and airflow rates at certain pressures
- Biocompatibility (USP Class VI) and extractables
- Hydrophobic (and oleophobic)

- **GUR® UHMW-PE membranes can cover the property range of ePTFE membranes**

Property	GUR® membrane	ePTFE membrane
Thickness	2-250 µm	25-250 µm**
Porosity	40-85%	65-85**
Pore size	0.02-15 µm	0.05-5 µm**
Tensile strength	100-170MPa*	20-120MPa**
Puncture strength	750-1500 mN/µm*	
Hydrophobic	✓	✓
Chemical resistance	✓	✓

Typical values

*Internal values, resin/processing dependent
**Literature-based values

General Business Information

4. Application Case #4: (U)HMW-PE as ePTFE Alternative in Endoprosthesis

conceptual stage

Application

- Endoprosthesis: to treat aneurysms such as vascular grafts
- A bulging or balloon-like swelling in the wall of an artery, caused by weakening of the vessel wall
- As vessel wall becomes progressively weaker, increasing the risk of rupture (bursting) or dissection (a tear in the wall), both of which are life-threatening emergencies

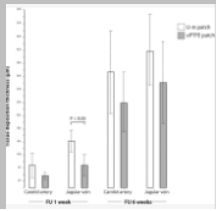




Requirements

- Patency
- Hemocompatibility
- Histology
  - Thrombus formation
  - Tissue deposition
- Mechanical stability
  - Support suture lines and prevent rupture
  - Prevent leaks and pseudoaneurysms

- A proof-of-concept study in a sheep model demonstrated that vascular patches made from woven ultra-high-molecular-weight polyethylene (UHMWPE) fibers exhibited non-inferiority in patency and hemocompatibility compared to expanded polytetrafluoroethylene (ePTFE) patches at up to 6 weeks*



*A Novel Cardiovascular Prosthesis Made from Woven Ultrahigh-Molecular-Weight Polyethylene Fibers, Proof of Concept in a Sheep Model - Annals of Vascular Surgery

Key Takeaways on UHMW-PE GUR® as a PTFE Alternative

- UHMW-PE addresses the challenge of PFAS restrictions as it contains ***no intentionally added PFAS,*** addressing environmental and regulatory concerns
- It offers ***similar properties to PTFE,*** like ***low coefficient of friction***
- ***Innovation on UHMW-PE*** to tap into new spaces, addressing the applications where PTFE used to have clear advantages over UHMWPE
- Suitable solution for ***demanding medical applications*** such as syringes stoppers, membranes, functional additives, catheters liners…

Now, it's your turn! Let's work together on your future applications!

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