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PFAS in the Medical Technologies Sector

Roumiana Santos, Chemicals Manager
MedTech Europe
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About the medical technology sector

About MedTech Europe

The European trade association for the medical technology industry including diagnostics, medical devices and digital health.

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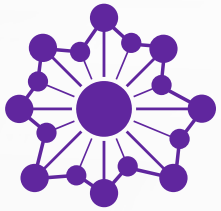
OUR MEMBERS

140+ multinational corporations*



50 medical technology associations

*medical devices, diagnostics and digital health

About medical technology

Medical technology is any technology used to **save** and **improve** lives of individuals suffering from a wide range of conditions.

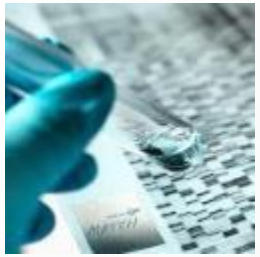
There are more than **500,000 products, services and solutions** currently available


















In Vitro Diagnostics (IVDs)

What are IVDs?

- IVDs are devices that provide diagnostic information by examination of a specimen derived from the human body.
- Specimens include blood, urine, tissue

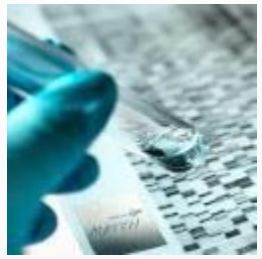
Why are they useful?

- Major source of information to determine the healthcare pathway
- They also monitor, screen, manage and assess predispositions to diseases

Examples of IVDs

- Pregnancy tests
- Blood glucose monitoring
- HIV tests
- Cancer screenings
- Blood type identification
- TB testing
- DNA genotyping & analysis
- Companion diagnostics



Medical Devices (MDs)

What are MDs?

- They are products, services or solutions that prevent, diagnose, monitor, treat and care for human beings.
- They are innovative engineered technologies available to hospitals, physicians and patients.

Why are they useful?

- They save lives, replace & restore body functions, prevent diseases development, monitor patients conditions and equip health institutions and home.

Examples of medical devices

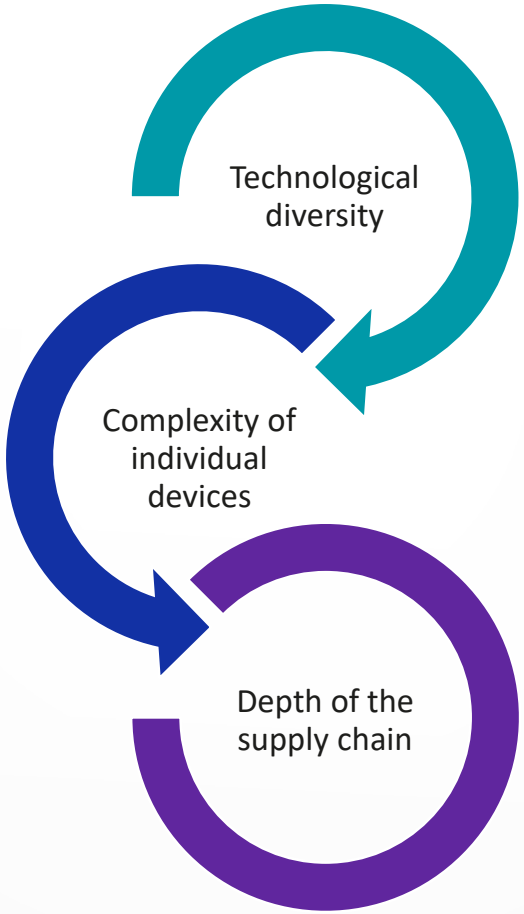
- Hospital beds, mattresses, sheets
- Surgical tools, gloves, tables
- Bandages
- Wheelchairs
- Surgical robots
- Pacemakers, defibrillators, stents
- Artificial hip, knee, legs.
- Eye lenses
- Hearing aids







Complexity of the medical technologies' supply chain



Medical technology industry embraces materials science, biochemistry, metallurgy, robotics, advanced textiles, all forms of electronic and IT systems.

Individual devices differ greatly in complexity; it is not uncommon for routinely used devices to have **hundreds and thousands of components and parts** → E.g. laboratory/diagnostic machines for blood testing and analysis.

Supply chains of up to **30 tiers from materials to the final device** exist.

The average depth is smaller (e.g., **four to six tiers** for a seemingly simple product like an elastic bandage).

Relying on suppliers to provide upstream traceability information can be lengthy, intensive, and can put a strain on business relationships.

Uses of PFAS in medical technologies

Where can PFAS be found in Medical Devices and IVDs? Representative examples

- IVD instruments: tubing, O-rings, coating of dispenser tips, seals and gaskets, syringe pump valves
- Manufacturing of reagents (Oligo production and enzyme purification) (as PFAS are used in a very early stage of production, only traces of PFAS are expected to be found in the final product)
- Ophthalmic endotamponades
- Medical tapes and wound dressings'
- Surgical drapes and gowns;
- Dental abrasives and orthodontics
- Medical imaging devices such as MRI, X-Ray, CT, ultrasound and molecular imaging devices
- Blood contact invasive devices (Catheters- Venous, Arterial, Urinary/ Guidewires / Introducers/ Dilators/ Stents)
- Fluid path filters and separators (Air selective vents for drip chambers / IV sets/ Fluid filters for infusates)
- Specialty coatings (Syringe stoppers)
- Surgical sutures
- Vascular grafts
- Cardiac occluders
- Implantable biomaterials
- Ophthalmic products (Eye drops, Tamponades for intraocular use)
- Infusion filters
- Peripheral venous catheters
- Catheters for peripheral regional anaesthesia
- Devices for ultrasound supported needle tip tracking
- Capillary part of an arterial catheter for invasive monitoring of blood pressure and blood sampling using the Seldinger technique
- Vessel dilatators (part of introducer) and basic kits for anaesthesia and intensive care
- Guidewires for introduction, stabilisation and positioning of angiographic catheters
- PTCA catheters, drug eluting stent catheters, drug coated balloon catheters
- Radiopaque, pre-formable peel-away introducer sets
- Invasive use device components materials commonly used and applications:
- PTFE: Invasive tubing (Urinary catheter tubing, PIVC catheter tubing, Arterial catheter tubing, Introducer tubing, Dilators) to name a few; PTFE coated guidewires – Low friction coating; PTFE tapes; Surgical mesh (hernia); Balloon expandable (vascular) covered stents; Grafts; Aortic stent grafts; Peripheral stent grafts; Sutures
- FEP: PIVC catheter tubing, Shrink tubing
- Non-invasive device use components – PTFE - Hang tag
- Infusion – non-invasive but fluid path device components materials commonly used and applications:
- Fluorinated silicone lubricant; To lubricate silicone-based valves in needleless connectors. Does not dissolve into the silicone matrix so remains as a surface lubricant; Hydrophobic fluorinated filter coatings; PTFE - air and moisture vapour selective membranes and filters
- Critical care non-invasive but fluid path device components materials commonly used and applications
- Surgical sutures e.g. for cardiovascular surgery containing polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF)

What are the types of PFAS/groups thereof used (non-exhaustive list)

IVD instruments & reagents

- PTFE
- FEP
- PCTFE
- ETFE
- PVDF
- FKM/FPM fluoroelastomers
- FFKM/FFPM perfluoroelastomers
- Hexafluor propanol
- Triflouracetic acid
- Triflouracetic acid anhydride
- Triflourmethane-sulfonic acid anhydride
- Triflourtoluene
- Methyl trifluoromethanesulfonate

MDs

- PTFE
- FEP
- Perfluoropolyether
- PVDF
- PVDF-HFP
- Perfluorinated acrylates (C6 – C14)
- Hydrophobic surface treatments – surface bound or reacted fluoropolymers of undisclosed composition
- PTFE coatings
- Specialty fluorinated lubricants
- FKM/FPM fluoroelastomers
- FFKM/FFPM perfluoroelastomers
- PTFE and PVDF suture materials
- Semifluorinated alkanes (for example 1-(Perfluorhexyl)octane and 1-(Perfluorobutyl)pentane)

Why PFAS – properties & functions fulfilled by PFAS

- Properties such as **chemical** and **heat resistance**, **lubrication** and **biocompatibility**
- PFAS is either a **component** of the final medical device or IVD, or a **processing aid** used during upstream manufacturing
- PFAS substances are often key to achieving the required high **performance** and **durability** of the products in the various use areas

What typical essential functions do PFAS fulfill in medical technologies? 1/2

Medical Devices

Ophthalmic endotamponades - in **surgery** to reposition a detached **retina**

Blood contact invasive devices – e.g. grafts/covered stents, catheter tubings for infusion of medication and IV fluids and drug eluting stent (DES) – **blood flow** within/between **arteries** and **veins** and for DES to control drug release to inhibit the vessel re-narrowing

Medication contact components - **minimise drug-device interactions**

Surgical sutures: pledgets made of PTFE serve as suture abutments when suturing soft tissue. They are essential in **heart valve operations**

Fluoropolymers, like PTFE and PVDF, are used in several components for the **treatment of serious acute and chronic diseases**

In hernia meshes for rapid **healing** of **hernia**

Cleaning of medical devices as cleaning solvents in vapor degreasing applications

What typical essential functions do PFAS fulfill in medical technologies? 2/2

In Vitro Diagnostic Reagents & Instruments

IVD testing kits for hemostasis products which **detect blood coagulation**

Heat-transfer agent in IVD clinical chemistry diagnostic testing instruments, which is essential to the **functioning** of the instrument

Surfactant properties in *in vitro* diagnostic assays, which allow **measures of various parameters** such as magnesium concentration in serum, plasma and urine

Fluoropolymers like PTFE and PVDF are used in several components for **analytical instruments**

Other: Coating on the dispense tip, tubing and tubing connectors, distributors, seals and gaskets, syringe pump valves, O-rings and sealants

Substitution – availability and assessment of alternatives

Challenges with alternatives to PFAS

Without PFAS, these medical technologies would not be able to perform their intended purpose

Sometimes, the alternative is another type of PFAS

- Apart from PFAS, it is unlikely that any alternative would have similar or superior functions.

The functionalities of PFAS make them preferred over alternatives

- At the same time, some of the intrinsic properties which render these substances the preferred choice are the very same that create a burden on the environment.

A non-PFAS replacement would likely lead to:

- less lubricity → increased **incidence of puncture wounds, no deliverability of the guidewire or catheter to the target lesion** or other adverse events.
- reduced chemical inertness and hydrophobicity → increased incidence of **device malfunction** and **inability of the surgeon** to sufficiently visualize the surgical site.

Examples of applications of PFAS where alternatives are not feasible

FEP capillary of peripheral venous catheters:

- Technically can be replaced with PUR, but this may affect **diagnostic performance** and patient well-being.

Devices for ultrasound supported needle tip tracking:

- No alternative since the **main function** of the device is based on this material.

PTFE – Guidewires or delivery device catheter:

- PTFE coating on the guidewire or PTFE component in the catheter is essential for the **delivery** of the guidewire or the device to **the treatment site**.

For PFAS in *in vitro* diagnostic assays:

- there is no other **class of surfactants** that represent a direct replacement.

In filters for critical care medications, such as antineoplastic drugs

Alternatives assessment under sectoral legislation

Medical technologies are invasive and/or come into contact with the human body and are strictly regulated

- **Medical Devices Regulation and *In Vitro* Diagnostic Regulation** have stringent:
  - **risk management**
  - **design**
  - **safety**
  - **quality**
  - **performance** and
  - **alternatives validation** requirements.
- Manufacturers of IVD reagents and systems fluids must proceed to design change procedures under specific regulations that can take between **3 to 12 years to complete.**
- For Fluoropolymers in components of analytical modules, all products would require **new qualification** according to e.g. certain IEC standards.
- Materials with contact to blood or similar criticality require a **minimum approval time** in case of is approximatively 3 years and can further exceed this range.

Risk management under sectoral legislation

- Where a **CMR 1A/1B and/or endocrine-disrupting** substances is used, it **triggers a justification procedure**, which includes a risk-benefit analysis (Section 10.4 of the MDR).

- Most applications are medical devices that end up as **clinical waste which is**
  - collected separately
  - treated in accordance with applicable legislation (e.g. WEEE Directive)
  - by licensed waste operators

- Healthcare institutions as a major user of medical devices represent a **strictly regulated**, professional work environment.

Conclusions

Concluding remarks

- We have been doing a survey of our uses since the summer of 2022
- PFAS are used in a range of critical medical technologies
- Due to the expected broad impact of a future PFAS restriction, numerous technologies and services could be affected in parallel
- PFAS often have no alternative, and where there is, it tends to be another PFAS
- When considering a transition to a potential non-PFAS alternative, it is important to consider patient well-being and the timeline and requirements under sectoral legislation

Thank you!

Roumiana Santos

rr.santos@medtecheurope.org

www.medtecheurope.org

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