Public comment for PFAS restriction about the medical wire

1. endoscopes
2. catheters
3. ultrasonic probes

Comments

Our company have been actively working to comply with chemical regulations in various countries. Furthermore, we support the ambitious efforts of the European Union (EU) to reduce risks posed by hazardous substances and have earnestly taken measures to meet the requirements of EU chemical regulations such as REACH. In addition
we would like to emphasize that from an environmental and health perspective, we are fully committed to replacing PFAS in our products.
However, there are no alternatives available for some applications that are essential to society.
Therefore, we suggest an exemption for some essential uses.

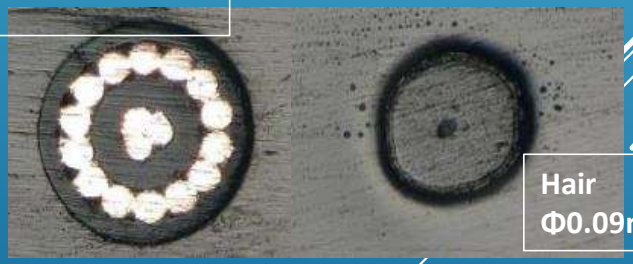
Medical cables are connected to medical equipment and sometimes used inside the human body. These cables require heat resistance, thin extrudability, low dielectric property and flexibility. There is no alternative material to meet these all characteristics.
Medical devices can endanger human life if they do not function properly.
To avoid these risks, we need to continue to use Fluorine insulation wire for medical application.

Medical cable (Endoscope)

■ Usage

A medical device that allows examination and treatment while viewing images of the inside of the body. The cable consists of a multi-core cable and uses FEP/PFA for the insulation of each coaxial line/insulated line inside and the final jacket.

Cable Diameter: 0.3~5.0mm
Number of cores： 3C~200C



■ Disposal method

Endoscopic cables are primarily heat sterilized after one use and reused many times.
Estimated world PFAS use：about 1800kg/year
Estimated EU PFAS use: about 450kg/year

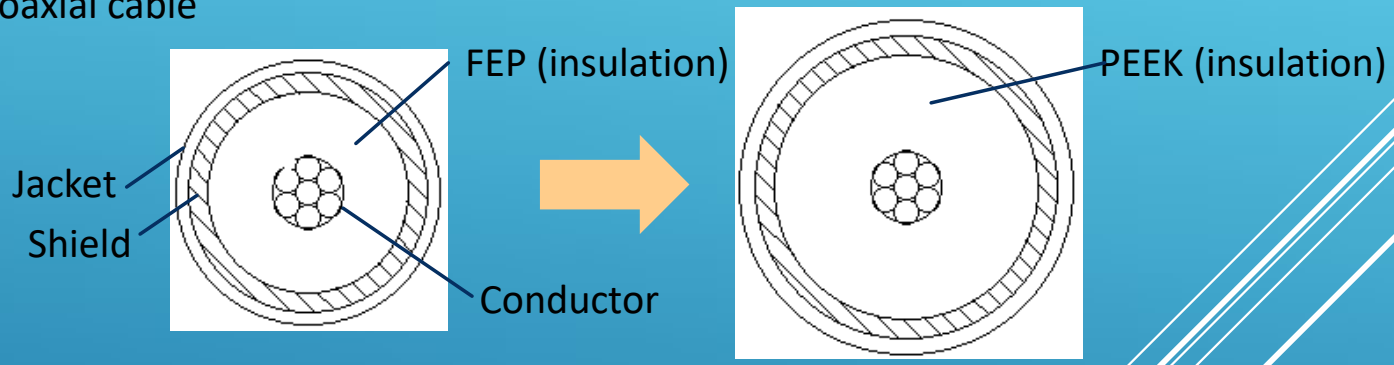
Medical cable (Endoscope)

Required material properties	Reason
• Low dielectric • Low loss tangent	Endoscope cables require high-resolution image transmission, and it is essential to use materials with low dielectric constant and low dielectric loss tangent. If the material properties deteriorate, the transmission performance may deteriorate and accurate image transmission may not be possible.
• High heat resistance	Endoscope cables are heat sterilized at a high temperature of about 130°C after use. Therefore, it is necessary to use highly heat-resistant materials.
• Thin extrusion (small diameter)	It is very important to reduce the diameter of endoscope cables that are inserted through the throat or nose to observe the inside of the body. In order to reduce the diameter, it is necessary to make each signal line thinner. Thicker cables are likely to increase patient burden.
• Flexibility	Cables for endoscopes used to observe the inside of the body are bent and used, so the flexibility of the cables is important.

Medical cable (Endoscope)

■ Example of impact

AWG40 50Ω Coaxial cable



	FEP (PFAS)	PEEK (PFAS Alternatives)
Cable diameter	0.33mm	0.42mm (+27%)
Attenuation (@400MHz)	-3.2dB/m	-3.4dB/m (+6%)
Material price	-	4 times

Thicker cables are likely to increase patient burden.
The transmission performance may deteriorate and accurate image transmission may not be possible.

Medical cable (Endoscope)

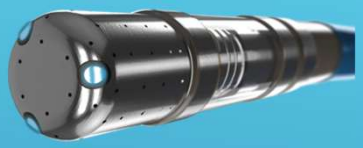
-	PFAS		PFAS Alternatives in the Proposed Restrictions						
Materials	FEP	PFA	EPDM	Silicone	PEEK	Mica	Polyvinyl chloride	Polyethylene	Ceramic Based
Dielectric constant (ε)	2.1	2.1	>2.5	>3.5	3.4	>4.5	>2.8	2.3	>4.0
Loss tangent (tanδ)	＜0.0002	＜0.0002	-	0.001~ 0.02	0.0035	0.01~ 0.02	0.01～0.1	＜0.0005	0.0005~ 0.003
Continuous use temperature (Heat resistance)(℃)	200	260	90	200	260	＞500	100	120	＞500
Thin extrusion	Good	Good	Poor	Poor	Poor	Poor	Poor	Poor	Poor
Flexural modulus (Flexibility)(Mpa)	610	590	10	16	3700	17000	2400	100~ 1500	2800~

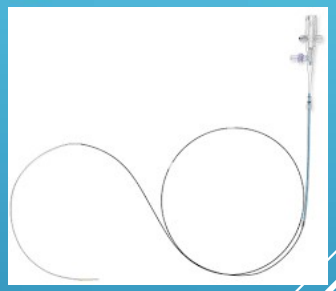
Fluorine is the only material that satisfies all the required properties

Medical cable (Catheter)

■ Usage

A medical device that can pass through blood vessels to perform examinations, treatments, and procedures. The cable has a structure that bundles multiple cores, and uses FEP/PFA for the insulation of each internal coaxial line/insulated line and the final jacket.





Cable Diameter: 0.1~2.0mm
Number of cores： 1C~20C

■ Disposal method

・Basically disposable.
・it is a medical device, it will be properly disposed of in accordance with the Waste Disposal Law.

Medical cable (Catheter)

Required material properties	Reason
・High heat resistance	The coaxial wire used for the catheter cable is soldered at high temperature(>200℃) during processing.
・Thin extrusion (small diameter)	It is very important to reduce the diameter of catheter cables that are inserted through blood vessels. In order to reduce the diameter, it is necessary to make each signal line thinner. Thicker cables are likely to increase patient burden.
・Flexibility	Cables for catheter that pass through blood vessels are bent and used, so the flexibility of the cables is important.

Medical cable (Catheter)

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Medical cable (Ultrasonic probe)

■ Usage

A medical device that can perform examinations by projecting ultrasonic waves that bounce back from the inside of the body. The cable consists of a multi-core cable, and uses FEP/PFA for the insulation of each coaxial line/insulated line inside.

Cable Diameter: 3.0~10mm
Number of cores： 10C~400C

■ Disposal method

Ultrasonic probe cables are mostly wiped with chemicals after one use and reused many times
Estimated world PFAS use：about 3100kg/year
Estimated EU PFAS use: about 780kg/year

Medical cable (Ultrasonic probe)

Required material properties	Reason
• Low dielectric • Low loss tangent	Ultrasonic probe cables need to transmit and receive ultrasound signals, and it is essential to use materials with low dielectric constant and low dielectric loss tangent. If the material properties deteriorate, the transmission performance may deteriorate and accurate image transmission may not be possible.
• High heat resistance	The coaxial wire used for the ultrasonic prove cable is soldered at high temperature(>200℃) during processing.
• Thin extrusion (small diameter)	Ultrasonic probe cables require ease of handling by the user and flexibility as a coaxial core, so it is very important to reduce the diameter. In order to reduce the diameter, it is necessary to make each signal line thinner. Thicker cables are likely to increase patient burden.
• Flexibility	Ultrasonic probe cables are bent and used, so the flexibility of the cables is important.

Medical cable (Ultrasonic probe)

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Fluorine is the only material that satisfies all the required properties