Appendix 1

Uses and substitutions of PFAS for Specialist Equipment

This document is the appendix 1 of the general comment to the Restriction report on Per- and polyfluoroalkyl substances (PFAS) from

JAIMA (The Japan Analytical Instruments Manufacturers' Association)

submitted on 25 September 2023

Table of content

The characteristics and functions of PFAS

Summary

PFASs have many functions. The characteristics and functions of PFAS which are mainly used in Specialist equipment are described in this section.

PFAS has excellent properties such as, chemical resistance, electric insulation, heat resistance, repellency from water and oil, non-adhesion, weatherability, and others. PFASs are used where multiple of these properties are required simultaneously. We recognize that the ability to provide these various properties in a single material is the most important property of PFAS, and at present we do not have information on any other substance with this function other than PFAS.

Chemical resistance

Fluoropolymers compared to other general-purpose resins

Table 1 Classes of Substances at 20° C, Chemical Compatibility Chart - LDPE, HDPE, PP, Teflon Resistance (calpaclab.com) [1]

	ETFE	FEP/TFE/FPA	FLPE	FLPP	HDPE	LDPE	PC	PETG	PP	PVC	TPE***
Acids, Dilute or Weak	E	E	E	E	E	E	E	G	E	E	G
Acids, **Strong/Concentrated	E	E	G	G	G	G	G	N	G	G	F
Alcohols, Aliphatic	E	E	E	E	E	E	G	G	E	G	E
Aldehydes	E	E	G	G	G	G	G	G	G	G	G
Bases/Alkali	E	E	F	E	E	E	N	N	E	E	F
Esters	G	E	G	G	G	G	N	G	G	N	N
Hydrocarbons, Aliphatic	E	E	E	G	G	F	G	G	G	G	E
Hydrocarbons, Aromatic	G	E	E	N	N	N	N	N	N	N	N
Hydrocarbons, Halogenated	G	E	G	F	N	N	N	N	N	N	F
Ketones, Aromatic	G	E	G	G	N	N	N	N	N	F	N
Oxidizing Agents, Strong	E	E	F	F	F	F	F	F	F	G	N

*Not for tubing chemical resistance (except PVC) **Except for oxidizing acids (See oxidizing agents, strong) ***TPE gaskets

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Excellent: 30 days of constant exposure causes no damage. Plastic may tolerate for 30 years.
Good: Little or no damage after 30 days of constant exposure for the regent
Fair: Some effect after 7 days of constant exposure to the reagent. The effect may be crazing, cracking, loss of strength or discoloration.
Not recommended: Immediate damage may occur. Depending on the plastic, the effect may be severe crazing, cracking, loss of strength or dis coloration, deformation, dissolution or permeation loss.

Table 2 Property Comparison of Fluoroelastomers (FKM) with Other Rubbers [1]

Type / Properties	Fluoroelastomer	Silicon rubber	Acrylic rubber	Nitrile rubber	Ethylene propylene rubber
	FKM	MQ, VMQ	ACM	NBR	EPDM
Specific gravity	1.8～2.0	1.0	1.0	1.0	0.9
Heat resistance	◎	◎	○	△	○
Low temperature resistance	△	◎	○	◎	◎
Electrical properties	○	○	△	△	◎
Solvent resistance	◎	◎	○	△	○
Flame resistance	◎	○	▲	▲	▲
Ozone resistance	◎	◎	◎	×	◎
Steam resistance	◎	○	×	△	○
Acid resistance	◎	○	△	○	◎
Alkaline resistance	◎	◎	△	○	◎
Oil resistance	◎	△	○	○	×
Permeability resistance	◎	▲	○	○	△

◎ : Excellent ○ : Good △ : Fair ▲ : Marginal × : Poor

"Cleanliness" is defined as the fact that fluoropolymers are not easily eluted by acids, alkalis, or solvents (chemical resistance), do not contain other materials such as plasticizers in the molding process, and do not contain products that would thermally decompose during the material molding process.

Ozone resistance

Ozone is known to degrade plastic materials in two ways:

A: Substances with double bonds (C=C) in their structures (such as natural rubber, chloroprene rubber, butadiene rubber, etc.) undergo decomposition in which ozone reacts with the double bonds to produce ketones, when they come into contact with ozone.

B: When ozone exists in water, peroxy radicals are generated. Non-fluorine materials (eg polyethylene, polypropylene, etc.) deteriorate even if they do not have double bonds.

Fluoropolymers does not have decomposition pathways such as A and B even if it comes into contact with ozone, so it can be used for a long time without deterioration.

[1] https://www.daikinchemicals.com/library/pb_common/pdf/catalog/RC-1L.pdf translated from the document in Japanese. Last accessed on 14 July, 2023

Table 3 Comparison of ozone resistance properties of plastics

Thermoplastic resin		Ozon Resistance
Soft vinyl chloride	PVC	○
Rigid vinyl chloride	PVC	○
Vinylidene chloride resin	PVdC	◎
ABS	ABS	△
Polyethylene	PE	△
Nylon	N	×
Acrylic resin	PMMA	△
Fluoropolymer resin	PTFE	◎
Phenolic resin	PF	△
Melamine resin	PVC	○
Furan resin	FF	○
Epoxy resin	EP	△
Unsaturated polyester resin	UP	×

◎ : Excellent ○ : Good △ : Fair ▲ : Marginal × : Poor

Repellency from water and oil / non-adhesion

Since the fluoropolymers have a small polarizability, the intermolecular force is small. Because of its characteristics, fluoropolymers have repellency and non-adhere properties on the surface. In general, the repellency from various liquids is evaluated by the contact angle, and the larger the contact angle, the higher the repellency.

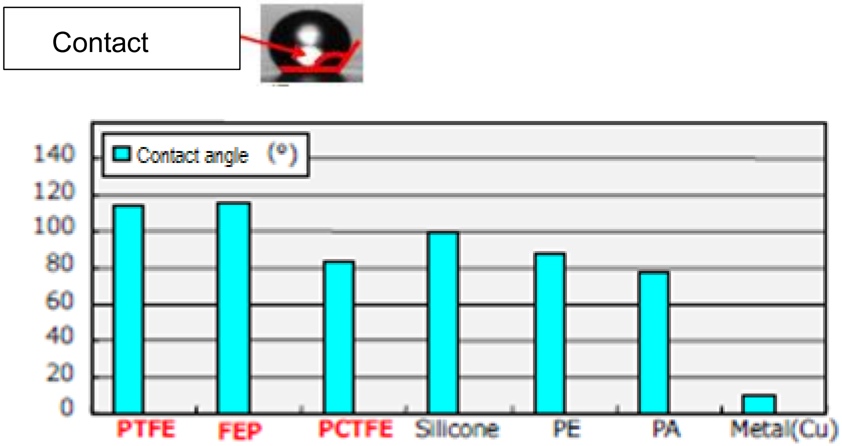

Figure 1　Contact angles with water

Adhesion energy refers to the amount of work required to pull a liquid contacting a solid away from the solid. The larger the contact angle, the smaller the adhesion energy. It means that a liquid in contact with a small adhesion energy solid easy to separate from the solid.[2]

Table 4　Surface properties of various plastics and metals

Material name	Contact angle with water (°)	Adhesion energy (dyn/cm)
PTFE	114	43.1
FEP	115	42.0
Silicone resin	90~110	47.8~72.7
Paraffin	105~106	52.7~53.8
PE	88	75.2
PCTFE	83	-
PA	77	97.7
Phenolic resin	60	109.0
Copper(electropolishing)	9.6	144.2
Aluminium(electropolishing)	4.6	145.0

This characteristic is sometimes called "mold releasability". It can also be expressed as antifouling because it does not easy to adhere.

[2] Japan Fluoropolymers Industry Association(2020), ふっ素樹脂ハンドブック, 14th edition. Page 34 Translated from Japanese.

Heat resistance

Fluoropolymers have high heat resistance as follows. They have higher heat resistance compared to other general-use resins

Table 5 The heat resistance of Fluoropolymer [3]

	Fluoropolymers						Other general-use resins	
Heat resistance : maximum operating temperature (C)	PTFE	PFA	FEP	ETFE	PCTFA	PVdF	PP	PVC
	260	260	205	150	120	120	100	60

Electric insulation

When the dielectric constant is low, the insulation in electrical components can be made thinner, leading to downsizing and weight reduction of the equipment. In applications where downsizing and weight reduction are necessary, it is an essential feature

Table 6 The dielectric constants of various resins

	Fluoropolymer				Fluorine rubber	
	PTFE	FEP	PFA	ETFE	FKM	FEPM
Dielectric constant	◎ 2.1			○ 2.3～2.8	△ 3～4	△～○ 2.5～3.5
	Non-fluoropolymer				Non-fluorine rubber	
	PVC	PEEK	TPI (Thermoplastic Polyimide)	Polyolefin	Silicone rubber	EPDM
Dielectric constant	△ 4～6	△ 3.2～4.5	△ 2.8～3.2	△～○ 2.3～4	△ 3.2～10	△ 2.5～3.5

◎ : Excellent ○ : Good △ : Fair ▲ : Marginal × : Poor

Low friction, self lubrication

Friction coefficient of fluorine resin is lower than that of other resins. It is because polarizability (Mobility of electrons in an electric field) of C-F bonding is low (0.68) and the intermolecular force is weak. (Reference: polarizability of C-Cl bonding is 2.59) [4]

[3] DAIKIN INDUSTRIES, LTD. (2009) ダイキン フッ素樹脂ハンドブック，Page 4

[4] Japan Fluoropolymers Industry Association(2020), ふっ素樹脂ハンドブック, 14th edition. Page 9 Translated from Japanese.

Table 7 Comparison of friction coefficient among PTFE and other materials [5]

Types of plastic	Plastic / Plastic	Plastic / Steel	Steel / Plastic
PTFE	0.04	0.04	0.10
PE	0.10	0.15	0.20
PS	0.50 *)	0.30	0.35
PMMA	0.80 *)	0.50 *)	0.45 *)

*) indicates occurrence of stick-slip motion.
Measurement condition: Bowden-Laden type measurement equipment, load: 9.8-39.2N, sliding speed: 0.01cm/s
Plastic/Steel indicates sample material/pin material
PE: polyethylene PS: polystyrene PMMA: polymethylmethacrylate

As an example of low friction, Table 8 shows friction coefficient of PTFE.

Table 8 Comparison of static friction coefficient among PFA, PTFE and FEP[6]

Type	ASTM test method	Measurement condition		Unit	PFA	PTEF	FEP
Coefficient of static friction	-	Against polished steel		-	0.05	0.02	0.05

One of the characteristics related to friction is “self lubrication”. The molecules of PTFE separate from molding of PTFE due to friction. The molecules in crystals of PTFE separate easily because intermolecular forces are weak. PTFE moves and attaches to the friction mating surface and generates friction between them. It lowers friction coefficient. [7]
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[5] Japan Fluoropolymers Industry Association(2020), ふっ素樹脂ハンドブック, 14th edition. Page 24 Translated from Japanese.
[6] DAIKIN INDUSTRIES, LTD. (2009) ダイキン フッ素樹脂ハンドブック，Page 53
[7] Japan Fluoropolymers Industry Association(2020), ふっ素樹脂ハンドブック, 14th edition. Page 24 Translated from Japanese.

Gas barrier properties/Gas permeation properties

Fluoropolymer film are less steam permeability.

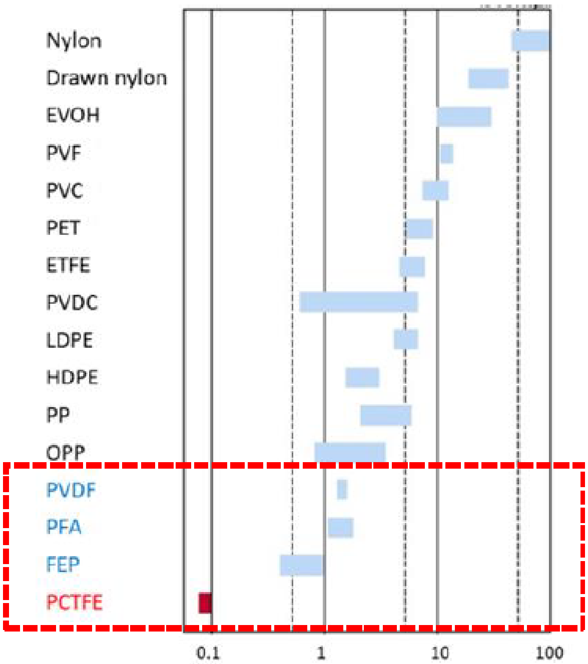


Figure 2 The degree of steam permeability [8]

[8] DAIKIN INDUSTRIES, LTD. (2009) Daikin Fluoropolymers Handbook, Page 109

Fluorine elastomers are less atmospheric (nitrogen, oxygen) permeability.

Table 9　Comparison of gas permeability of elastomer [9]

Material	Temperature degree Celsius	He	H_2	O_2	N_2	CO_2	CH_4	C_2H_2	C_3H_8
Vinyl methyl silicone rubber（VMQ）	25	N/A	400	400	200	1600	N/A	N/A	10000 or more
	50		570	500	280	1550			
Ethylene propylene rubber（EPDM）	25	N/A	N/A	16.5	5.90	79.2	N/A	N/A	91.2
	50			46.6	13.7	183			246
Perfluoro-elastomer（FFKM）	25	10.3	8.25	2.5	8.1	28.7	3.3	N/A	N/A
Styrene butadiene rubber（SBR）	25	17.5	30.5	13	4.8	94	N/A	N/A	N/A
	50	42	74	34.5	14.5	195			
Vinylidene fluoride fluororubber（binary FKM）	25	2.95	4.6	1.0	0.8	3.9	0.6	N/A	N/A
Vinylidene fluoride fluororubber（Ternary FKM）	25	2.64	4.13	1.7	0.7	1.6	0.4	N/A	N/A
Chloroprene Rubber（CR）	25	N/A	10.3	3.0	0.89	19.5	2.5	N/A	N/A
	50		28.5	10.1	3.55	56.5	9.8		
nitril-butadiene rubber（Mid-high NBR）	25	9.32	12.1	2.94	0.81	23.5	N/A	18.9	26.9
	50	23.4	33.7	10.5	3.58	67.9		68.3	78.3
nitril-butadiene rubber（High NBR）	25	5.2	5.42	0.73	0.18	5.67	N/A	8.25	11.2
	50	14.2	17.0	3.5	1.08	22.4		19.8	33.1
butyl rubber（IIR）	25	6.4	5.5	0.99	0.25	3.94	0.6	1.28	N/A
	50	17.3	17.2	4.03	1.27	14.3	3.2	5.82	

（$\times 10^{-8}$ ｃｃ，ｃｍ/ｃｍ^2,sec,atm）

[9] DAIKIN INDUSTRIES, LTD. (2009) Daikin Fluoropolymers Handbook，Page 78

Property of Gas Permeability

Table 10　Gas Permeability of FEP film [10]

Property			Standard Test method	Unit	FEP film
Gas Permeability	Gas permeability coefficient	N_2	ASTM D1434	$cm^3 \cdot cm/cm^2 \cdot s \cdot atm$	120×10^{-10}
		O_2			370×10^{-10}
		H_2			$1{,}080\times10^{-10}$
		CO_2			970×10^{-10}
		CH_4			66×10^{-10}
		C_2H_4			44×10^{-10}
	Water-vapor permeability		JIS Z0208	$g/m^2 \cdot 24h$	1.6
	Water Absorption		ASTM D570	%・24h	<0.01

Fluoropolymers permeate small molecular gases, such as oxygen and nitrogen, conversely, large molecular gases do not permeate. Fluoropolymer properties are used in permeate membranes for measurement and analysis.

Table 11　Comparison of gas permeability of various materials [11]

Gas	Gas Permeability		
	FEP	PTFE	Low Density Polyethylene
N_2	1.2×10^{-8}	1.1×10^{-8}	0.74×10^{-8}
O_2	3.7×10^{-8}	3.2×10^{-8}	2.2×10^{-8}
CO_2	9.7×10^{-8}	8.9×10^{-8}	9.6×10^{-8}
CH_4	0.66×10^{-8}	—	2.2×10^{-8}
CH_3	0.66×10^{-8}	—	5.2×10^{-8}
C_3H_8	0.11×10^{-8}	—	7.2×10^{-8}
C_2H_4	0.48×10^{-8}	—	—

Temperature: 25 degree Celsius(77°F)　Units: cm^3 (ST P) $cm/cm^2 \cdot atm$

[10] DAIKIN INDUSTRIES, LTD. (2009) Daikin Fluoropolymers Handbook, Page 78
[11] DAIKIN INDUSTRIES, LTD. (2009) Daikin Fluoropolymers Handbook, Page 80

Low refractive index

Amorphous fluoropolymer resin has high transmittance. This is utilized for optical components and optical fibers.

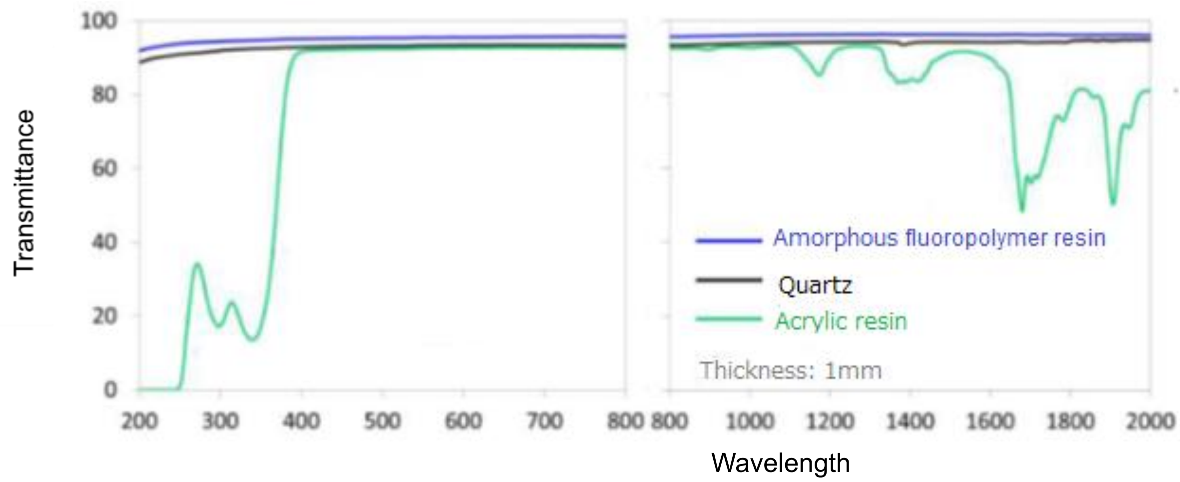


Figure 3　Comparison of transmittance [1]

Weatherability

Fluoropolymer resin has high weatherability and can be used outdoors. It does not react to sunlight such as ultraviolet rays. It is not susceptible to oxidizing effects of atmospheric oxygen and other substances (see “chemical resistance”). It can be used in a wide temperature range from low to high (see “heat resistance”). It has high water repellency and does not absorb water, so it is not affected by humidity changes. It can be said that fluoropolymer resin has high weather resistance because it has the above points.

Table 12　Fluoropolymer resin weatherability comparison [12]

	Fluoropolymer resin						General resin	
	PTFE	PFA	FEP	ETFE	PCTFE	PVdF	PP	PVC
Weatherability	◎	◎	◎	◎	◎	◎	×	×

◎ Excellent, ○ Good △ Not very good ▲ Needs attention × Not good

Regarding the graph below, it can be seen from the accelerated weatherability test with the

[12] DAIKIN INDUSTRIES, LTD. (2009) ダイキン フッ素樹脂ハンドブック，Page 4

Sunshine Weather Meter that the gloss retention rate decreases by no more than 10% even after 4000 hours of exposure. [13]

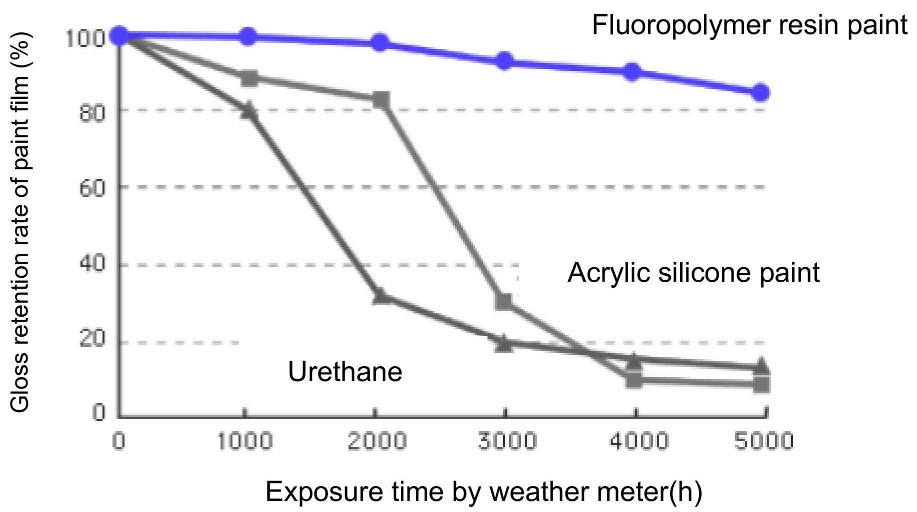


Figure 4 Accelerated weatherability test of paint [13]

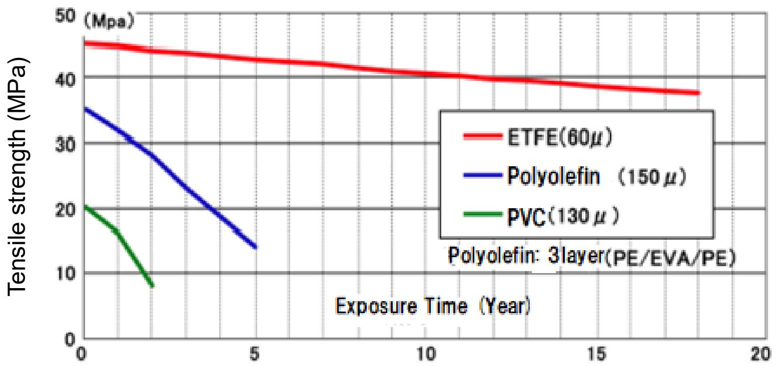


Figure 5 Outdoor exposure test Comparison of tensile strength between ETFE and other materials [14]

Durability

It means that it can be used for a long time. Due to its high chemical resistance and high weatherability, PFAS can achieve high durability.

Resistance to creep / Compression set

When a constant load is applied to a polymeric material, creep occurs, in which deformation progresses over time. Similarly, compression set occurs where the deformation does not

[13] https://www.kyoeishoji.co.jp/business/chemical/fusso_toryo.html translated from the document in Japanese. Last accessed on 21 July, 2023
[14] https://www.taiyokogyo.co.jp/feature/etfe_film.html translated from the document in Japanese. Last accessed on 21 July, 2023

recover when the force is removed. Both properties are known to be correlated. When rubber materials are used in elastic applications such as packings or diaphragms, it is required to minimize the effects of both properties.
Experimental examples of "30% creep time (Hour)" for major rubber materials are shown below. Creep is known to be worse at higher temperatures, Experiments have shown that FKM and silicon exhibit good properties.

Table 13

	50 degree Celsius	70 degree Celsius	100 degree Celsius	120 degree Celsius	150 degree Celsius
NR	190	103	3.8	–	–
SBR	1250	203	14	–	–
CR	4200	550	45	7.4	–
NBR	3900	380	41	12.2	–
IIR	–	–	2.7	–	–
FKM	–	–	1650	305	180
Silicon	–	–	–	1550	190

Quoted from the journal of “the Society of Rubber Science and Technology, Japan”, 1960(Vol33), P882-892, “Stress relaxation and creep properties of various vulcanized rubbers”.

Examples of compression set test results are shown below. In general, it is difficult to quantitatively compare materials because the measured values differ depending on the compounding and hardness of the rubber. Here, the compression set of the materials was compared by comparing the minimum value of each material in the database. FKM and silicon showed relatively good properties, showing the same tendency as creep.

Table 14

	Compression set JISK6301 100 degree Celsius×70h
NR	–
SBR	Min 20%
CR	Min 23%
NBR	Min 9%
IIR	–
EPDM	Min 23%
FKM	Min 11%
Silicon	Min 6%

The minimum value of each material was quoted from the data described in "Material Database / Organic Materials" (1989), The Nikkan Kogyo Shimbun”.

Uses of PFAS in Specialist Equipment

Summary

PFAS are a very important group of substances for Specialist Equipment, which depends on these uses to maintain safety, as they are highly effective in chemical resistance, Repellency from water and oil, and electric insulation.

PFAS polymer resins are two to ten times more expensive than other commodity plastics. There is no use other than where the equipment does not work without the use of PFAS.

General electronics components are not covered in this document. However, since our equipment also uses common electronic circuit parts, we also use parts common to information equipment and general consumer EEE. For usage and non-substitutable information for such parts, please refer to Japan 4EE Opinion RCOM21, No.4543 and additional Opinion Information and Non-Substitutable Information to be submitted in September 2023. Semiconductors are also used in our products. Many PFASs are used in semiconductors and semiconductor manufacturing equipment. Comments on most of the items in this section have been submitted by industry associations that specialize in the respective items. We hope that dossier submitters consider the manufacturer's opinions.

electric wires and insulation

An electric wire is a linear member for transmitting electricity. Metal, which is a good conductor, is used for the part that transmits electricity, and plastic resin that has electric insulation is used around the wire in order to block the influence on anything other than the transmission destination of electricity.

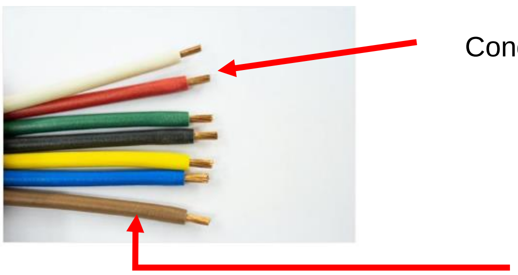


Figure 6

Polyvinyl chloride is generally used for covering parts where plastic resin is used, which is called as sheath, but PTFE, PFA, FTPE, etc. are selected depending on the suitability of use and electric insulation requirements. Since these are more expensive than polyvinyl chloride, they are used only when it is difficult to use other materials such as polyvinyl chloride.

PFAS functions required by PFAS wires and availability of alternatives.

Wires using PFAS for coating have high electrical insulation when the coating is thin (100 μm or less). PFAS also has a high heat resistance of 150-200°C. In addition, PFAS wires can be used even when there are chemicals around the device because PFAS has chemical resistance.

Examples of devices equipped with electric wire and insulation

Medical cables of probe cable for ultrasound diagnostic equipment

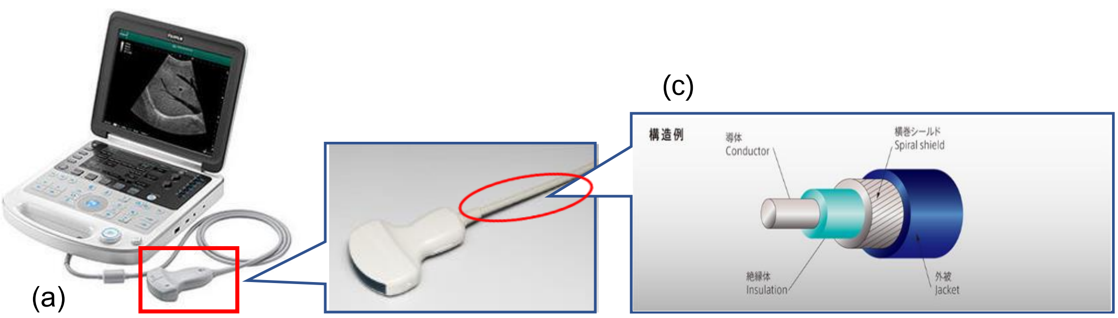


Figure 7

The ultrasonic diagnostic device is shown in Figure 7(a) and consists of an image analysis unit and a cable with a transducer.

The cable with transducer shown in Figure 7(b) is composed of about 200 coaxial wires in order to transmit and receive about 200 signals.

The inside of the red circle cable in Figure 7(b) is as shown in Figure 7(c).

Figure 8 shows a cross-sectional view of one of Figure 7(c).

The performance required for these coaxial wires is (electric insulation / low dielectric constant), heat resistance, and extrusion suitability. PFA/FEP is used as a material that satisfies these three elements.

Table 15 shows the comparison results with the alternative candidate material PEEK.

In order to obtain a diagnostic image with high accuracy, the attenuation of coaxial wire must be 2 dB / m or less in terms of the size shown in Table 15 Comparison with alternative candidate material PEEK, and the required performance is not satisfied unless PFA/FEP is applied.

In order to satisfy the attenuation, it is necessary to reduce the capacitance, and for this purpose, the dielectric constant must be 2.1 or less.

The cross-sectional view of one coaxial wire is shown in Photo 4, and the red arrow part is the insulating layer and the green arrow part is the outer skin layer.

Both layers require thickness control of 0.05 mmt or less, and PEEK cannot be controlled, especially for the outer layer because it does not stretch.

In order to evenly cover the outer layer without destroying the shield layer, stretching is necessary.

PEEK meets only heat resistance requirements.

Table 15 Comparison with alternative candidate material PEEK

		PFA		PEEK		Required characteristics
electrical characteristics	dielectric constant	2.1	○	3.15	×	≦2.1
	Attenuation*1	1.75	○	≧2	×	@10MHz ＜2 d B/m
heat resistance	Rated temperature	≧200	○	≧200	○	200° C or higher
extrusion suitability	Coating thickness control	GOOD	○	BAD	×	≦0.05mmt
	Non-stop extrusion time	GOOD	○	BAD	×	≧2hr

*1Conductor 48AWG (7/0.012), OD 0.18mmΦ

◎ : Excellent ○ : Good △ : Fair ▲ : Marginal × : Poor

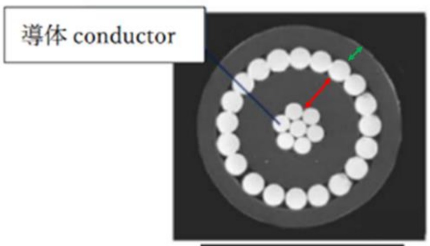


Figure 8 Cross-sectional view of one coaxial wire

Board terminals of Luminance meter

The luminance meter uses PFAS for the optical sensing substrate, which handles currents as extremely small as a few pA (10^{-12} A). Since the extremely small current output from the optical sensor is measured and used, even if a tiny amount of current leaks out from the original path onto the substrate, it is a critical error factor. Since leakage current values must be controlled to be sufficiently smaller than pA units, electronic components are wired floating off the substrate, as shown in the following figure9. However, since it is inevitable that the soldered part comes in contact with the substrate, a PTFE terminal with high insulation properties is used as a prop for connection (connection prop), and soldering is performed there to ensure high insulation to the substrate. Then, leakage current generation is controlled. Without PTFE terminal, the product doesn't satisfy its function.

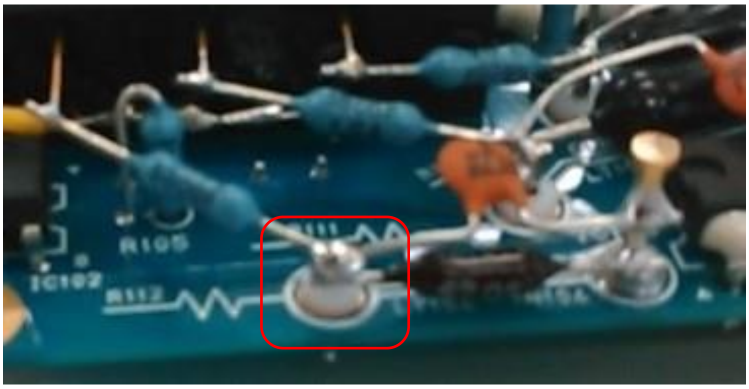


Figure 9

In circuits that handle very small currents at the several pA level, leakage current must be controlled as described above, and the connecting pillar must have very high insulation (about $10^{15}\Omega$) under all environmental conditions (temperature, humidity, etc.).

Surgical power cord

Figure 10

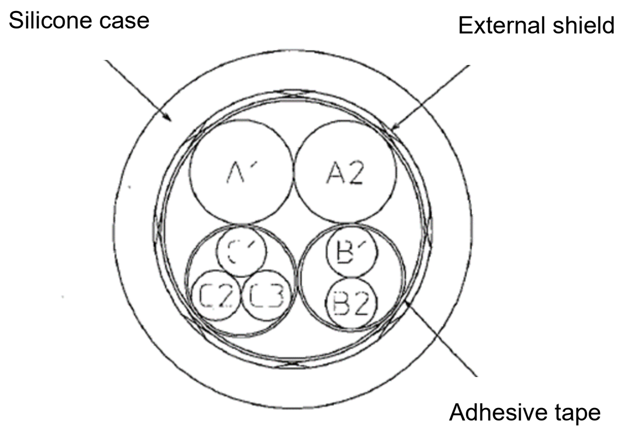


Figure 11

The surgical treatment tool shown in the above Figure 10has a structure in which the tip of the treatment part can be rotate. The power supply cord twists according to the rotation of the treatment part. Since the resistance and hardness of the rotation of the tip treatment tool due to this twist greatly hinder the operation of the surgeon, it is essential to maintain the flexibility of the cord in surgical treatment tools especially which need delicate operation. It is necessary to maintain electric insulation between each bundled cord, but the flexibility is not maintained when it becomes thicker. So it is essential that each cord is covered with PFA.

In addition, since surgical devices conduct high-frequency currents, they are affected by the capacitance between each cord. In addition to suppressing changes in capacitance due to changes in the position of the cord internally, the suppression tape for regulating the position of each cord must have flexibility with the function of preventing the increase of capacitance between cords by autoclave, which is a sterilization process, and it is essential to be EPTFE.

RF- generators electrical insulation of patient treatment circuit to mains and other electrical circuits

Figure 12 RF- generators electrical insulation of patient treatment circuit to mains and other electrical circuits [RF = radio frequency current]

RF- generators used in the transformer for wire insulation so it is inside the generators . It is used in wire and tubes.Electric insulating and non-adhesion are required. All electrical tests according to IEC 60601-2-2 have to be repeated. It is a high risk that leakage current limits cannot be kept

PI and PEEK is not flexible enough. PET chemical resistance is to low, not sufficient heat resistance.

US(Ultra Sonic)- generators also used it.

Cable for Sapphire Capacitance Diaphragm Gauge

The components use electric insulation with PFAS.

・Temperature sensor for control

・Heater board connection cable and thermistor

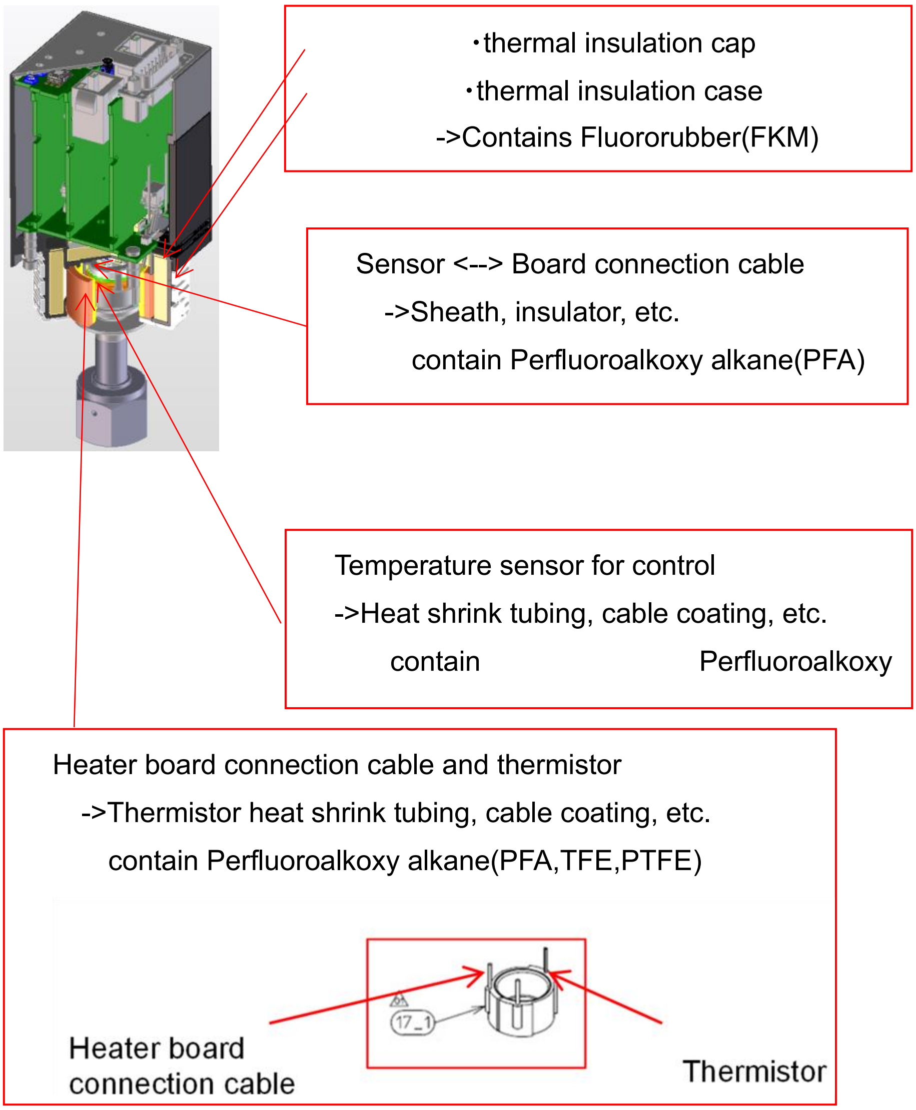


Figure 13

There is no fluorine-free material with equivalent heat resistance.

<u>Gas Chromatograph (GC)</u>

PTFE is used for covering the high voltage cable which can be applied to the flame ionization detection part of GC. Since high insulation and elasticity are required, materials other than PTFE do not satisfy the performance.

PTFE is used as the insulator between the core and the shield of the signal coaxial cable of the GC flame ionization detector. Because the signal is a minute f (femto) A-level current, the insulator must be highly insulated. Materials other than PTFE have large leakage current and do not satisfy the performance.

Mass spectrometer (MS)

MS is a device that ionizes an analysis object by various methods, separates the produced ions by their masses, and measures them. A portion for separating and detecting ions is incorporated into a vacuum vessel which is kept in high vacuum so as not to interfere with the movement of ions. High voltages ranging from several hundred V to 3000 V are applied to electrodes and detectors arranged in a vacuum chamber. High insulation, flexibility, and low outgassing in vacuum are required for the coating of electric wires supplying high voltage. Fluororesin is the only material that satisfies these requirements.

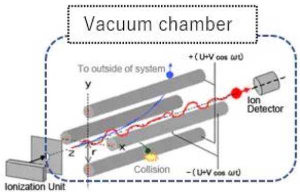


Diagram of Quadrupole MS

Figure 14

Analytical robot

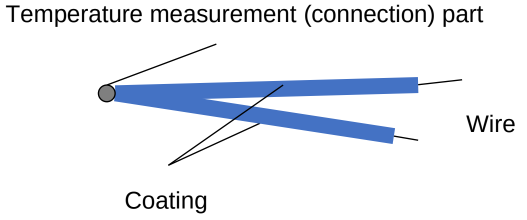
In the analytical instrument, a robot with various movements is used for the pretreatment to analyze the sample. Electric wires with excellent chemical resistance, bending resistance and durability are used for the moving parts. Fluororesin is the only material that satisfies these requirements.

Figure 15

Temperature sensor (thermocouple)

A thermocouple is a temperature sensor that measures using the principle that a thermoelectromotive force is generated by connecting the tip of a metal wire made of different materials and the temperature difference between the tip and the other end.

Temperature sensors can measure a wide range of objects, including acids, alkalis, and organic solvents, and can also measure a wide range of temperatures, including applications that measure chemicals at 100°C or higher. The thermocouple wires are coated with FEP and PFA to ensure accurate measurement without negative effects from chemicals or high temperatures. There is no material other than fluoropolymers that combines chemical resistance and heat resistance to realize such applications, and it is difficult to replace them.



Coated temperature sensor wire

Figure 16

Heat shrink tubing

By putting a thin and long object to be covered in a tube, heating it, and shrinking the tube, the object is covered. It prevents parts from coming off or falling off, and strengthens the covered part. Fluoropolymer resin heat-shrink tubing is thin but has high electric insulation performance. PTFE and PFA are used as fluoropolymer resins.

Functions of PFAS required by heat-shrinkable tubing and availability of alternatives

Fluoropolymer resin heat-shrink tubing is thin but has high electric insulation performance. It can be used in applications where there is not enough space for electric insulation, and there is no alternative material available for applications that require tight spaces.

Examples of the products which incorporate heat shrinking tubes

Thermistor protection for Sapphire Capacitance Diaphragm Gauge

Components corresponding to a heater operating temperature of MAX 250°C

For the picture of this products, please see the explanation in electric wires and insulation.

Fluoropolymer resin is used in the heat-shrinkable tube to protect the thermistor

There is no fluorine-free material with equivalent heat resistance.

Sealing materials

Parts description

Packings, gaskets, and O-rings

Packings and gaskets exist to connect and seal by placing/placing them between parts. As an example, they are used in piping and pipe connections. Gases and liquids that pass through pipes leak out through the smallest gaps, and packing gaskets exist to prevent this. Packing in the narrow sense is used for power system parts, and those used for non-moving parts are called gaskets. Various innovations have been made in molding and realizing functions, such as spiral gaskets made of alternating layers of thin metal strips and PTFE sheets, and wrapped gaskets made of 0.4~0.8 mm hot PTFE, covering gaskets of metal or other materials.

Those with a circular/round cross section are called O-rings.

In addition to PTFE, fluoropolymer rubbers such as FKM and FFKM are also used for this application.

Fluoroelastomer O-rings with X-ray resistance as well as characteristics of PFAS are used in X-ray equipment. No alternative to such a multi-resistant material has been found yet.

Figure 17　Packings, gaskets, O-rings

Bearings

A bearing reduces friction between two parts to make movement smoother. Bearings are classified into radial bearings, thrust bearings, and linear bearings, depending on whether rotational or linear motion is involved. A bush is also a type of bearing.

Fluoropolymer bearings such as PTFE have a low coefficient of friction and can maintain a constant torque within various tolerances, while minimizing rattling and noise. In particular, PTFE must be used for bearings near chemical fluids such as acids, alkalis, organic solvents, and ozone, and for food contact applications, where oil is not preferred.

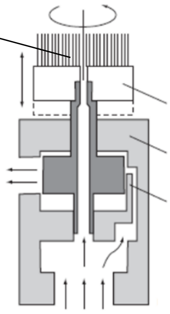


Figure 18 Bearing used for the rotating shaft sliding part of the sensor cleaning brush

Sealing tape

Sealing tape, made of PTFE material, is an adhesive tape used to secure parts within equipment. It is employed to fasten parts that could pose safety risks if dislodged, as well as to seal mounting parts. Additionally, the tape serves as a filler to address gaps in the joints or connections of pipes for flowing liquids or gases, such as water pipes, air pipes, and hydraulic pipes. Notably, the tape can establish liquid- or gas-tight connections with tapered pipe threads by directly filling the voids between the threads.

Figure 19

The functions of sealing materials of PFAS and alternatives

Functions of PFAS Required by Sealing Materials and the Feasibility of Alternatives to PFAS

Required Functions for Sealing Materials

Liquids and gases flowing in pipes, or near parts, often consist of strong acids, alkalis, or organic solvents. Therefore, the sealing materials used must be resistant to these chemicals. Fluoropolymer is highly resistant to such chemicals, and additionally, it is ozone-resistant, making it an ideal choice when ozone is present in the piping.

If the liquid or gas in the piping, or the equipment itself, operates at high temperatures, PTFE or PFA are good options due to their high heat resistance of up to 260°C, a limit higher than other resins. FFKM and FKM rubbers also exhibit high heat resistance, withstanding temperatures up to 250-300°C.

For applications where sealing materials, such as gaskets, are used on sliding surfaces, where lubricating oil is unsuitable (particularly in contact with food), or where play and noise must be avoided, sealing materials must also possess low friction and self lubrication properties.

In the restriction report on seal tape, paste-like sealing materials are mentioned as alternative materials. However, if these sealing materials contain hydrocarbon substances, reactive functional groups may decompose. This could pose a risk of contamination in the surrounding area due to the produced decomposition products. For sealing tape used for equipment operating in clean environments, where such contamination is unacceptable, paste-like sealing materials cannot be used as alternatives.

As a sealing material that combines outstanding chemical resistance, ozone resistance, heat resistance, water and oil repellency, low friction, self-lubrication, and cleanliness, there is no substitute for fluoropolymers. The substitution of fluoropolymers with other materials poses a significant challenge. Non fluorine elastomers might be considered as potential replacements for fluorine rubbers like FKM rubber. However, their heat resistance, low friction, and chemical resistance do not measure up to those of fluorine-rubbers like FKM rubber. Therefore, substituting fluorine -rubbers with non fluorine elastomers is unfeasible.

Examples of the products which uses sealing materials

Pressure Transmitter:

Pressure transmitters are measuring instruments mainly used in factories and plants. It measures pressure for process fluids such as liquids, gases and steam and outputs analog or digital signals corresponding to the measurement results. It is also used to measure flow rate and liquid level based on measured pressure.

The process fluid to be measured has various characteristics such as temperature, pressure, and properties. If the sealing performance is not maintained, not only correct measurement results not be obtained, but the factory or plant may stop. In addition, if the process fluid is high temperature, extremely low temperature, or toxic or corrosive, the outflow of the fluid may cause great damage to the surrounding environment and workers, so the sealing performance is very important.

Many sealing materials that use PFAS materials have excellent heat resistance and chemical resistance, and it is considered difficult to replace them when considering the above safety assurance.

- O-Rings
- It is used for sealing the mating part of the product.

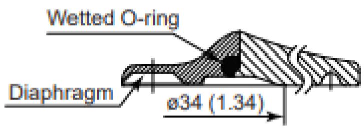


Figure 20　Wetted O-RING

- Gasket
  - Seal a product and pipe fittings. Fluid leak prevention.

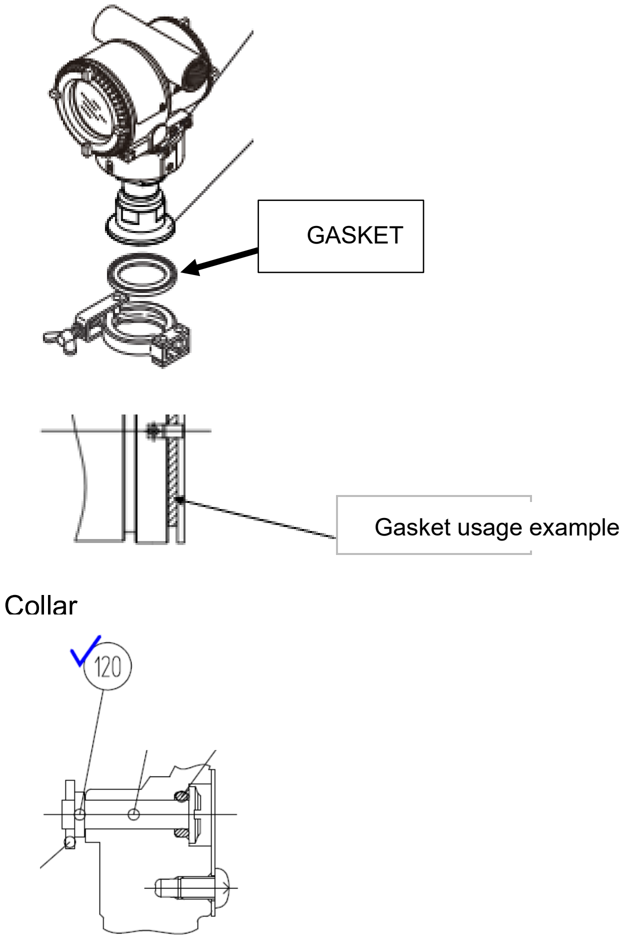


Figure 21

Adjustment seal between two prisms for projector (PTFE adhesive tape)

A projector is a device that uses light to project an image. They use high intensity light to form a clearer image. High-intensity light generates heat, so heat-resistant components are required. In addition, the device requires very delicate adjustment to form an image. To create the gap for adjustment, PTFE tape is used, which has high heat resistance, high chemical resistance, and excellent sliding properties.

The prism unit for the projector consists of two types of prisms, and PTFE tape is used between the two prisms to allow position and spacing adjustment after manufacturing.

PTFE tape is used with the adhesive to bond around the optical path between the two prisms to prevent dust, and the water-repellent effect of PTFE allows air to pass through but prevents water from entering.

Since projectors are used indoors and outdoors, they must be able to withstand temperature changes. The dimensions of glass change slightly with temperature, but if a tape with low slipperiness is used, the lens will be damaged by friction. So, slipperiness is necessary. Slipping between the tape and the prism glass prevents the prism glass from being scratched when the prism posture is adjusted (assembly process) or when it is vibrated from the external environment (during projector movement or transportation vibration).

There is no other material other than PTFE that has heat resistance, chemical resistance, and excellent sliding properties.

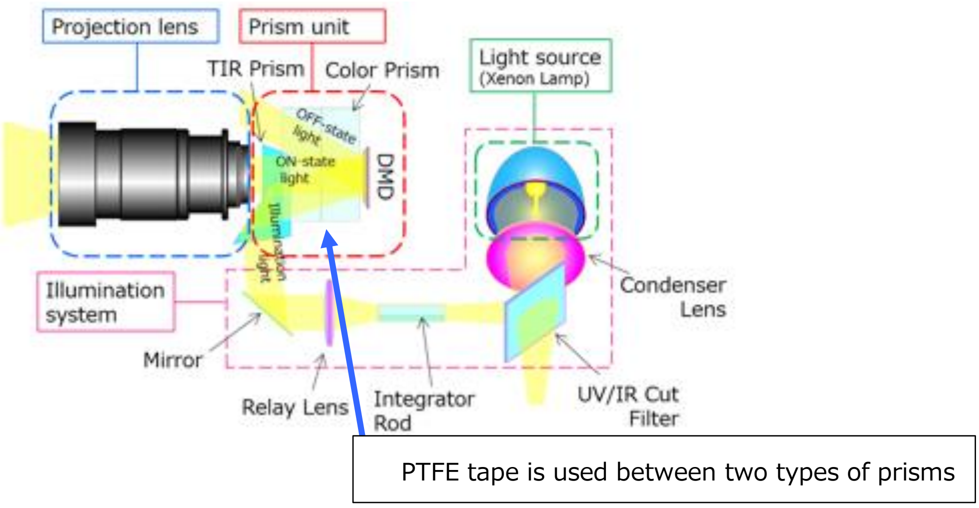


Figure 22　Image of light path inside the projector

Required specifications

- Environmental humidity　40 degree Celsius/90%
- Heat resistance: about 100 degree Celsius

(GB lasers, laser phosphors, and xenon lamps are used as light sources, resulting in high temperatures inside the equipment. Higher brightness requires more light sources, resulting in higher temperatures inside the equipment. Therefore, higher temperature heat resistance is required. Without heat resistance, the tape would fire or emit smoke.)

- Chemical resistance/ Organic solvent resistance (IPA, ethanol, acetone, etc.)

(Organic solvents are used in the production process, especially for cleaning prisms. Because PTFE tape is bonded to the prism, the tape must also be chemical resistant.)

- High sliding properties /Low friction properties

static friction coefficient Approx. 0.12

Polyester mesh cloth with PFAS coating is placed at the air outflow inlet and outlet in the lens barrel, which changes in volume due to lens focusing and zooming. By sealing with the cloth, it allows air to pass through but prevent water and dust from entering the barrel.

Junction unit for vacuum environment / O-ring for seal for air and vacuum environment

Optical Junction unit for vacuum enviroment is used for a photoelectric sensor that enables detection inside a vacuum chamber by transmitting light from a fiber amplifier through a fiber unit.

The optical coupler is provided with sealing ability to pass the detection light through the wall of the vacuum device.

The O-ring for sealing are made of fluorine rubber to keep high temperature , high seal and high cleanliness

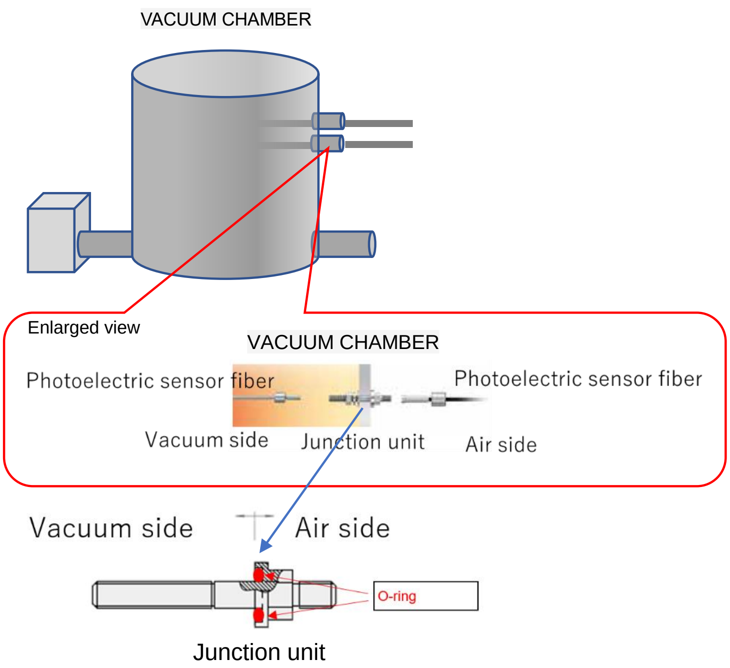


Figure 23

To keep high temperature, high seal, and high cleanliness in a vacuum environment, materials other than fluorocarbon rubber are not appropriate.

O-rings are used as sealing parts to prevent external leakage at joints between different parts.

Mass Flow Controller / Mass Flow Meter

O-rings are used as sealing parts to prevent external leakage at joints between different parts.

<Mass flow controller usage

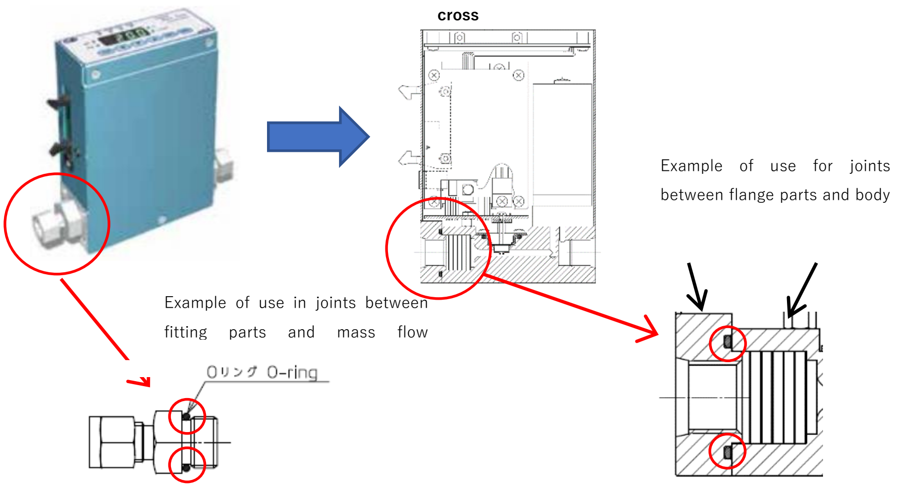


Figure 24

FKM is used for various gases with excellent heat resistance, chemical resistance, ozone resistance, etc., especially when using flammable oxygen gas, it is used due to its high heat resistance and ozone resistance, and the alternative product is a special rubber material, but it becomes a fluorine-based rubber material and the use of fluorine-based substances is unavoidable.

If fluorine-based materials are not used, safety is significantly impaired.

endoscope reprocessor

The endoscope reprocessors use a variety of chemical solutions such as acids, alkalis, and alcohols to clean and disinfect the endoscopes after use. Some of these solutions may cause health hazards such as chemical burns if they come into direct contact with the human body, and sealing materials in the endoscpe reprocessor are required to have chemical resistance to withstand these chemical solutions and prevent leakage.

Therefore, fluoropolymers such as PTFE, FKM, FFKM, and FEPM, which have high chemical resistance to various chemical solutions, are used for sealing materials such as packing, gaskets, O-ring and sealing tape.

Other substances such as EPDM and silicone are not sufficiently resistant to these solutions, especially the peracetic acid used for endoscopes disinfection, because these substances deteriorate in a short period of time. Therefore, it is impossible to substitute other substances.

Endoscope

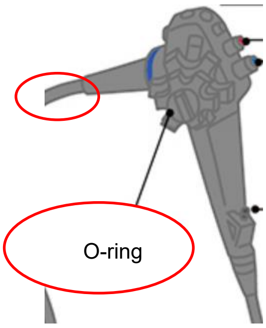


Figure 25

A medical device that is inserted into the body through the oral cavity to observe and treat the inside of a lumen. FKM is necessary because the O-ring provided in the sliding part must have chemical resistance and low friction. Chemical resistance is a property necessary for sterilization, disinfection, and cleaning after use to prevent infection. As a sterilization method, there is a method using gas such as EOG or hydrogen peroxide, and the sterilization gas penetrates the interior of the product, so chemical resistance is a necessary characteristic even for internal parts. The sterilization methods that can be used are limited depending on the region, and it is not enough for a product to be compatible with just one, but it is necessary to have resistance to all sterilization methods. There is no material with chemical resistance equivalent to that of FKM and low friction.

Computed Radiography (CR) for Non-Destructive Testing

CR generates an X-ray image by converting the X-ray information recorded on an imaging plate (IP), a type of X-ray detector used in X-ray photography, into an electrical signal by exciting it with a laser beam.

The durable life of a CR is about 6 years. In order to achieve this, it must be durable enough to withstand 540,000 times of IP loading from the assumed frequency of use of CR. In order to achieve this durability, the sliding and wear resistance of PTFE are essential, and there is no material that has the same sliding and **wear resistance** as PTFE.

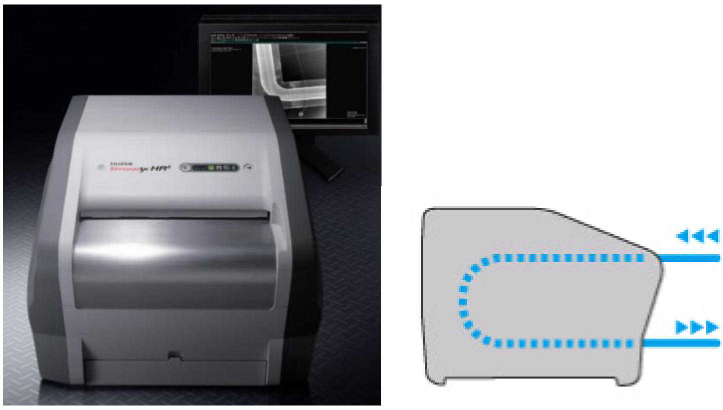


Figure 26

Plumbing

Plumbing is any system that convey fluids or energy for any application. Pipes, tubes, joints, fittings, are used for plumbing. Fluoropolymer resins, such as, PTFE, PFA, PVDF, are used. Some international standards mention uses of fluoropolymer resins for plumbing. [15]

- Tubes (not heat shrink tubes)
  Tubes are used for convey fluids to the places.

Figure 27

- Joints / fittings
  Joints / fittings are components to connect tubes to units and/or tubes to tubes.

Figure 28

[15] Example of international standards: ISO 12039:2019 mentions that the sampling line shall be made of PTFE, PFA.

The functions and alternatives which plumbing requires:

The material of plumbing is determined by the types of fluids flowing through tubes. Fluoropolymers can be used as piping for fluids in the temperature range of -10°C to 200°C (PTFE) and about -40°C to 160°C (PFA), including acids, alkalis, organic solvents, ozone, and oils. Fluoropolymers (PTFE, PFA, PVDF) are the only plumbing materials that can be used when the fluids of flowing the tubes meets one or more of these characteristics.

Fluoropolymer resins are the only materials that can simultaneously provide and express multiple functions required for the proper functioning of chemical resistance/ cleanliness, repellency from water and oil, and heat resistance.

Since PTFE, ETFE and FEP have transparent resin, it is possible to visually check whether liquid is flowing in the piping or whether there are air bubbles in the liquid. This is an important characteristic in analytical instruments.

Examples of the products which incorporate plumbing

Magnetic Flowmeter

An Electromagnetic Flowmeter is a type of flow meter that applies a magnetic field in the perpendicular direction to the flow of the measured fluid. As a result of the flow and the magnetic field, an electromotive force is generated in directions perpendicular to both the flow and the magnetic field. This electromotive force is extracted by a pair of electrodes, and the output signal is sent to a converter. The electromagnetic flow meter is a flow meter that applies Faraday's law of electromagnetic induction to moving objects.

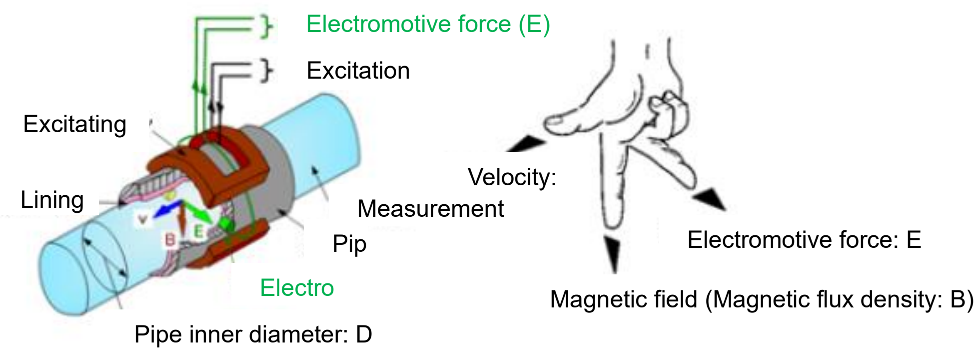


Figure 29

The resin lining, known as lining, is applied to pipes (metal piping), and materials such as PFA and PTFE are used.

The purposes of this lining are as follows:

Electrical insulation: The lining ensures electrical insulation between the measured fluid and

the electrodes or the pipe, preventing electrical short-circuiting of the signal electromotive force.
Chemical resistance: The lining provides resistance to chemical substances such as acids and alkalis when the measured fluid contains them. This prevents corrosion and degradation caused by the fluid's characteristics and the environment, thereby improving the accuracy and reliability of the measurement.
Wear protection: The lining plays a role in protecting the pipe from internal friction and impacts. It reduces wear and damage caused by solid particles and abrasives in the fluid, maintaining measurement performance over an extended period of use.
Heat resistance: The lining exhibits stable performance even in high-temperature environments. It resists degradation when exposed to high-temperature fluids and environments, ensuring consistency and reliability in the measurements.

NOx measuring equipment

For accurate measurement, dehumidify the sample with a dryer unit before measuring. It is dehumidified by the Flemion tube of the dryer unit, but it is necessary to purge dry gas around the Flemion tube. Cover the Flemion tube with a PFA tube, purging dry gas in between.
Also, PFA tubes are used to connect the dryer unit and piping.
Since NOx is highly adsorbable, PTFE, which does not easily adsorb, is used as a sampling tube.
Used to connect flow sensor and PTFE tube.

Total Nitrogen analyzer

Oxides of nitrogen analyzer
In a Total Nitrogen analyzer, when a sample is injected into a high-temperature combustion tube, Total Nitrogen is decomposed into nitric oxide. Nitric oxide concentration is measured using the chemiluminescent reaction produced when nitric oxide and ozone are mixed.
The NOx meter measures nitrogen oxides, which are a combination of nitric oxide and nitrogen dioxide in exhaust gas. In this process, several percent of nitrogen dioxide are converted to nitric oxide by a high-temperature catalyst. Nitric oxide concentration is measured using the chemiluminescence reaction produced when nitric oxide and ozone are mixed.
Since sealing properties are required for the flow path (tube and contact) of ozone, PTFE with excellent ozone resistance is the most suitable material.

Gas Chromatograph (GC)

In a sulfur chemiluminescence detector (SCD) which is one of GC detectors, samples (sulfur compounds) eluted from a GC column are injected into a burner to cause oxidation and reduction reactions. Then the samples (SO radicals) are sent to a reaction cell, where they collide with ozone, which generates light emission that is detected by a photomultiplier. According to the measuring principle, SCD is sensitive only to sulfur compounds and can selectively detect trace amounts of sulfur compounds in complex sample matrixes.

Ozone channels and reaction chambers must use PTFE, which has excellent ozone resistance.

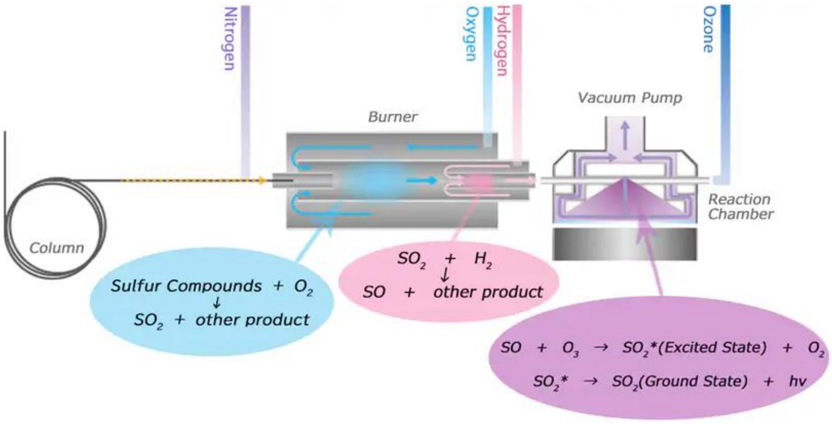


Figure 30

Differential scanning calorimeter

Tubes to flow the liquid nitrogen below -196 degrees C.

Flexible pipes made of metals other than resin cannot be used because of possible cracking due to cold embrittlement. In addition, because metals have high thermal conductivity, there is a greater risk of low-temperature burns during unintended contact and frost due to their high thermal conductivity.

Less flexible. Tubes with an inner diameter of 16 mm are commercially unavailable.

Inductively Coupled Plasma Mass Spectrometer (ICP-MS)

To suck the liquid sample

To flow the sample for the nebulize

Chemical resistance against xylene, Kerosene, MIBK, DMF

Total Organic Carbon analyzer(TOC)

Oxides of nitrogen analyzer

Tube to flow the ozone gas.

ozone gas

Tubes and contacts must be airtight

Micro flow rate liquid flow meter

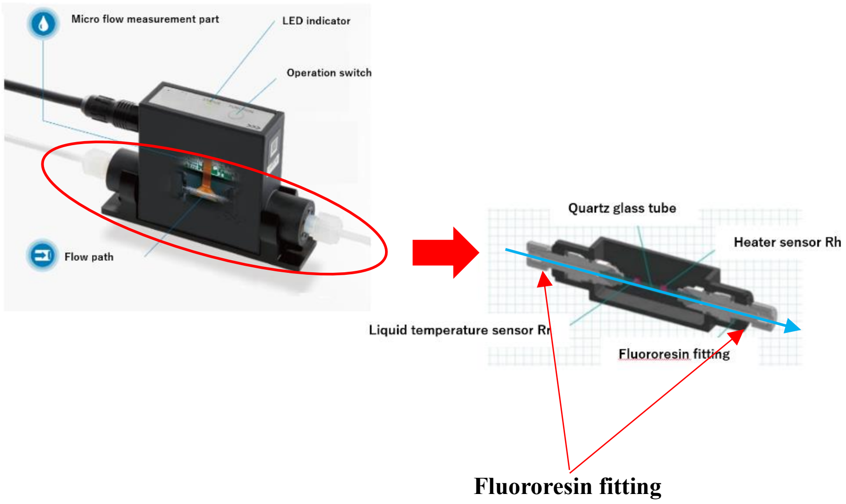


Figure 31

◆Characteristics of PFA,PTFE

・Excellent chemical resistance

・Excellent weatherability

・Soft

・Easy to process

◆Benefits of using PFA,PTFE

Semiconductor manufacturing process is required high level chemical controls, due to chemical contamination makes negative influences on quality of products. PTFE and PFA which are inert to various chemicals and also include low additives, are suitable materials for flow paths in semiconductor manufacturing process.

◆Impact of prohibition using PFA,PTFE

It will be impossible to keep miniaturization technology used in current semiconductor manufacturing process.

To avoid this problem would require a great deal of effort and technical innovation.

Endoscope

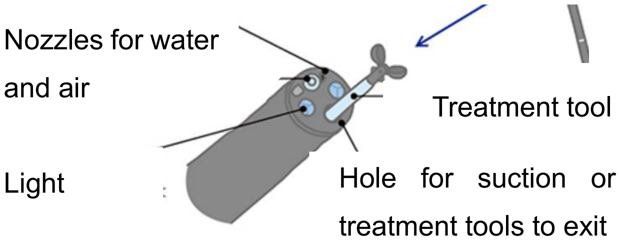


Figure 32

A medical device that is inserted into the body from the oral cavity to observe and treat the inside of the lumen. A flow path of an air and water supply for passing water, air, or the like through a tip, a flow path of a forceps for inserting a treatment tool, and a flow path of a suction for sucking a body fluid or the like need to follow a complicated lumen shape.
Among flexible materials, chemical resistance, low friction, heat resistance, and non-adhesion are required, and PTFE and PFA are used.
Flexibility is a property necessary for insertion into complex lumens. Chemical resistance are necessary characteristics for disinfection and cleaning to prevent infection after use.It is a necessary characteristic for resistance to body fluids such as stomach acid. Low friction is a characteristic necessary for inserting a treatment tool for collecting tissue and performing surgery in the lumen, from the operation part to the tip. Heat resistance is a necessary characteristic to perform autoclave sterilization at 136 °. Non-adhesiveness is a characteristic necessary for mucosa and the like not to stick in the flow path when inserting into a living body or sucking. PE can be mentioned as an alternative material, but it cannot be substituted because it is inferior in chemical resistance and heat resistance, so the quality of sterilization, disinfection, and cleaning is reduced, and the risk of infection increases.
In addition to these properties, biocompatibility is required. Biocompatibility means that the risk of toxicity such as allergic reactions, chronic toxicity, and genotoxicity is small.
Due to the chemical properties of fluorine compounds, the effect on living organisms is small, the purity of the material is high and the possibility of containing impurities is low, and the durability against chemical treatment is excellent and the possibility of unexpected deterioration is low.
When alternative materials other than PFAS, only bench test evaluation cannot adequately evaluate safety, and based on ISO 10993-1, biologically safe such as cytotoxicity, sensitization, irritant or intradermal reaction, systemic toxicity, subchronic toxicity, genotoxicity, implantation, hemocompatibility, etc. are evaluated again.
* Hereafter, the above idea is used for application examples for biometric contact points.

Figure 33

In addition, The exteriors that contain these flow paths and other components inside and are inserted into the body also require chemical resistance, low friction, heat resistance, and non-adhesion in a flexible material, and PVDF (polyvinylidene fluoride) is used. The reasons for the need for each characteristic are the same as above.

Insulating tubes for surgical treatment tools

In surgical procedures, high-frequency currents are applied to cauterize tissues and prevent bleeding. In order to cauterize only the intended portion, especially in the treatment tool called bipolar, a two-pole electrode is provided in the treatment tool. Therefore, pipes and rod-shaped members (ultrasonic drive members) serve as electrical paths, but heat shrinkable tubes by FEP are indispensable for insulating pipes and rod-shaped members and preventing short circuits in the electrical path between the two poles. In addition, in order to stabilize ultrasonic vibration, a function to attenuate unnecessary vibration is also essential.

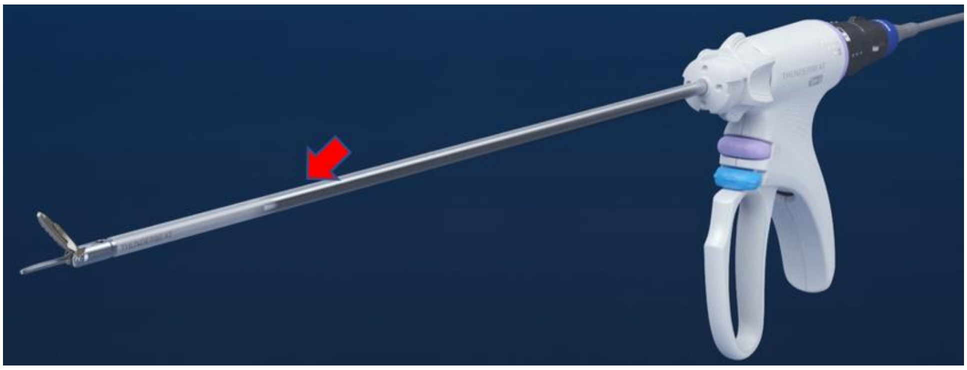


Figure 34

This is due to the chemical resistance, heat resistance, electrical insulation, and low friction required for surgical treatment tools. In addition to these properties, biocompatibility is required.

See "Biocompatibility" in the endoscope section of "Plumbing" for details.

bipolar surgical RF instruments

PFA CAS: 30525-89-4

Figure 35

Arc resistance to RF- plasma; Cleanability of surfaces; safe dielectric strength at small layer thickness; Non- Slip- Stick effect for movement; low friction for moving parts (after cleaning cycles- grease would be removed); heat resistance for steam cleaning and disinfection; high chemical resistance for cleaning and disinfection (Peroxide, etc.)

PI is not flexible, has high slip- stick behavior

PEEK will burn down under RF- plasma (arc)

PET chemical resistance is to low, slip- stick behavior, non sufficient heat resistance

There is no hazard and exposure risk. All materials in contact are controlled via ISO 10993. This product is single used

All Cleaning disinfection tests have to be requalified, since low surface energy of PFA is unmatched it can be estimated that cleaning procedures have to be harsher in the future

Endoscopic treatment tool

Figure 36

A medical device for performing endoscopic procedures. In order to insert into the channel of the endoscope inserted into the body, it is necessary to follow the complex shape, and among flexible materials, PTFE and PFA are used because of their acid resistance, low friction, heat

resistance, and non-adhesiveness requirements.
Flexibility is a property necessary for insertion into complex lumens. Acid resistance is a necessary characteristic for resistance to body fluids such as stomach acid. Low friction is a characteristic necessary for insertion into the endoscope channel to the distal end. Heat resistance is a necessary property in devices that use high-frequency energy to prevent damage to the device or/and endscopes during treatment. Non-adhesiveness is a characteristic necessary for mucosa and the like not to stick in the flow path when inserted into a living body or sucked.
PE can be mentioned as an alternative material, but since it is inferior at least in low friction, the treatment property is reduced due to the deterioration of insertability, so it cannot be substituted.
In addition to these properties, biocompatibility is required. See "Biocompatibility" in the endoscope section of "Plumbing" for details.
1 Description : Fluoropolymers for use in medical devices Endoscope Applications
2 PFAS substance(s) used: name and CAS number (If known):
PFAS substances including but not limited,
Poly(1,1,2,2-tetrafluoroethylene), CAS # 9002-84-0
Perfluoro-alkoxy polymer, CAS # 26655-00-5
Copolymer of hexafluoropropylene and tetrafluoroethylene CAS # 25067-11-2
3. It is well known that C-F bonding energy is much higher energy than C-C bonding energy, the unique crystal structure of fluoropolymers, lower surface energy, hydrophobic as well. Due to its unique microstructure structure, and repellency from water, fluoropolymers have been used in medical device , such as endoscope with many benefits, including but not limited, 1. excellent biocompatibility, biostability, and patient safety history. 2.resistant to chemical, enzyme, and microbiological attacks while eliminating biodegradation issues. 3. low friction allows moving parts to slide with ease, generating less heat, and undergoing less wear and tear. 4. low surface energy or hydrophobic makes it non-adhesion material combined with its moisture barrier and chemical resistance, makes it a valuable polymer for medical device industry especially for patient safety with reusable endoscope application which involves cleaning and disinfecting the devices so that they can be reused.
4. These unique chemical-physical characteristics of fluoropolymers make medical devices safer to use for patients. However, the unique properties of fluoropolymers make them difficult to replicate with other non-fluoropolymers. For instance, To the best practices in polymer industry, the alternative materials for fluloropolymers are proposed as follows: Chlorotrifluoroethylene (E-CTFE), Ethylene Tetrafluoroethylene (ETFE), and so on and so furth. However, the proposed alternative materials are still under the umbrella of 2021 OECD definition of PFAS “Any substance that contains at least one fully fluorinated methyl (CF3-) or

methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it)" Silicone rubber could be proposed as an alternative substances for certain applications but not suitable for endoscope application because of its higher on coefficient of friction, especially to tackle a surgical procedure with difficulty anatomy conditions.

Fuel Cell Performance Testing Equipment

Fuel cells generate electricity and heat through a chemical reaction between hydrogen and oxygen. Fuel cell performance testing equipment evaluates the performance and durability of fuel cells. Fuel cells contribute to carbon neutrality by improving energy efficiency and reducing CO_2 emissions.

The following characteristics are required for the piping of the fuel cell performance testing equipment.

- The piping serves as a flow path for alkaline substances used as materials for hydrogen and acidic substances produced as a result of the reaction. (Chemical resistance)
- Since the polymer membrane used in the fuel cells requires wet condition, water vapor is added to the hydrogen. The flow path is heated to approximately 150°C to prevent condensation of water vapor in the piping. (Heat resistance)
- Hydrogen in the exhaust gas after the reaction may be reused, which requires an additional supply of hydrogen, resulting in large pressure changes inside the piping. Therefore, the piping needs to be strong. (Durability).

In case of condensation in the piping, the concentration of water vapor added to hydrogen cannot be maintained at the required level and normal operation will be disturbed. In addition, a transparent pipe with chemical resistance may be used as a liquid level gauge to check the liquid level in the tank where the alkali solution is stored.

For these reasons, the fuel cell performance testing equipment needs to be made of transparent, chemical (acid, alkali) resistant, heat resistant, and durable materials. Currently, PTFE and PFA are the only such materials available, and they are difficult to replace.

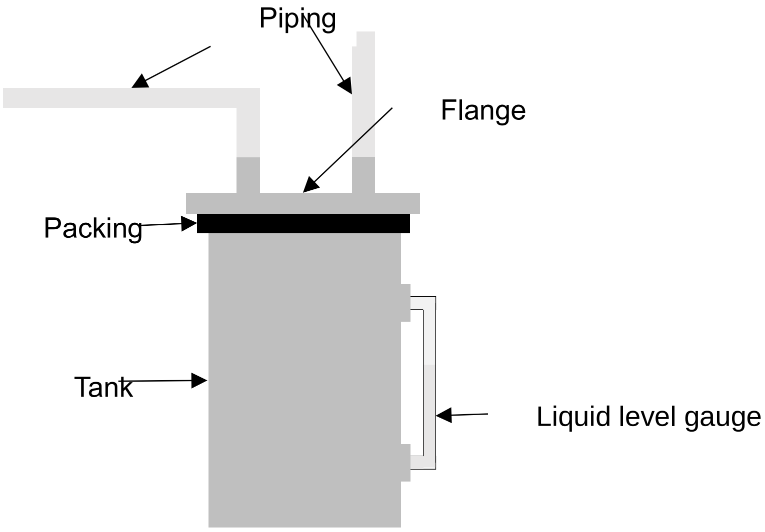


Figure 37

Valves

Valves are general for equipment with a movable mechanism that can open and close flow paths in order to go through, stop, and control the flow of fluids. They are used in a wide variety of products, from relatively small devices with flow paths and valves to large-scale manufacturing processes and chemical plants. There are many types of valves. Some valves, which are often incorporated in specialist equipment, are discussed. They are not exhaustive.

The functions and alternatives which valves require:

The chemical resistance against acids, alkalis, organic solvents oils, and ozone, which flows through valves, is essentially required. Valves, which opens and close frequently required the property of low friction, repellency from water and oils, non-adhesion. Any failure of valves can cause serious accidents. therefore, the durability of fluoropolymer resin is required for valves PTFE and other fluoropolymer resins are frequently used. Fluoropolymer resins, such as, PTFE are the only materials that can simultaneously provide and express multiple functions required for the proper functioning of valves.

- Solenoid valve

  A solenoid valve is electromehanically operated. One of the operations is to open and close a valve using the principle that when an electric current is applied to an electromagnet (solenoid), an iron piece called a plunger is attracted and released when the electric current is cut off. Diaphragms divide into a valve compartment that opens and closes flow paths and a functioning compartment that drives. Fluoropolymer resins, such as, PTFE, FKM, FFKM, and FEPM, are frequently used for flow paths, diaphragms, and sealing materials in solenoid valves. Solenoid valves have wide variety of types, such as, liner action, pilot operated, the combination of liner action and pilot operated.

- Ball valves

  A ball valve opens and closes a flow path by rotating a hollow ball. In automatic valves, an electric motor is used to rotate the ball. A large cross-sectional area of the flow path can be obtained, and the resistance of the path can be kept low. Fluoropolymer resins, such as, PTFE, are frequently used

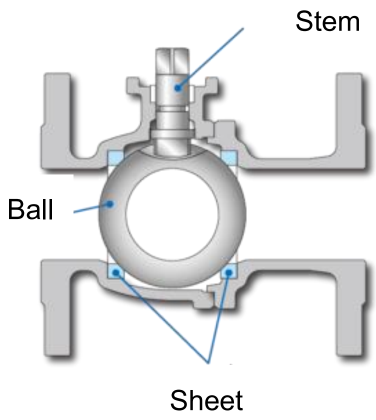


Figure 38

- Check valve

  A check valve is installed on gas or liquid piping where the fluid back pressure closes the valve plug to prevent reverse flow. A check valve is called as non-return valve, reflux valve, retention valve, foot valve, or one-way valve There are disc check valves that blocks backflow by closing the O-ring valve with a disc and duckbill check valves that uses a valve plug shaped like a duck's beak. Fluorinated materials such as PTFE, FKM, FFKM and FEPM are used for the valve plug and the sealing materials of the housing.

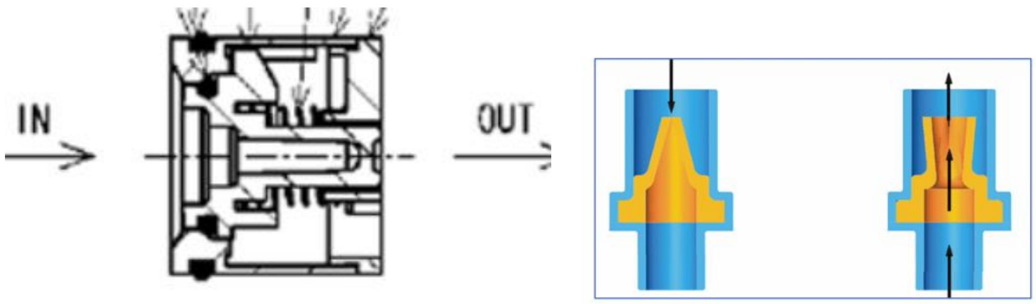
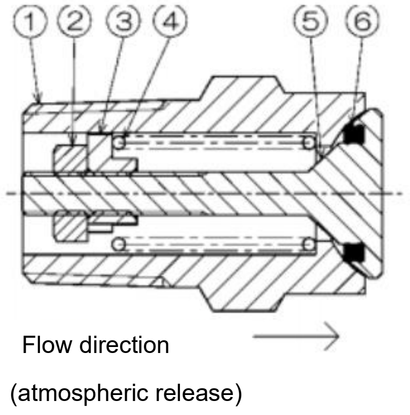


Figure 39

- Relief valves/safety valves

A relief valve is a valve that automatically releases pressure when excessive pressure occurs in the pipes. A spring keeps the valve plug such as O-rings or diaphragms closed, and it opens (released) when a pressure exceeding the spring force occurs.
Fluorinated materials such as PTFE, FKM, FFKM and FEPM are used for the valve plug and the sealing materials of the housing.



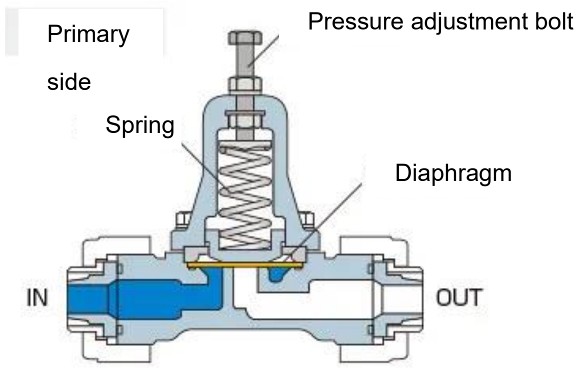


Figure 40

Examples of the products which incorporates valves

Mass Flow Controller（MFC)

Elemental analysis is a method of complete combustion of organic compound samples, and high-purity oxygen gas and argon gas are introduced. (see below)

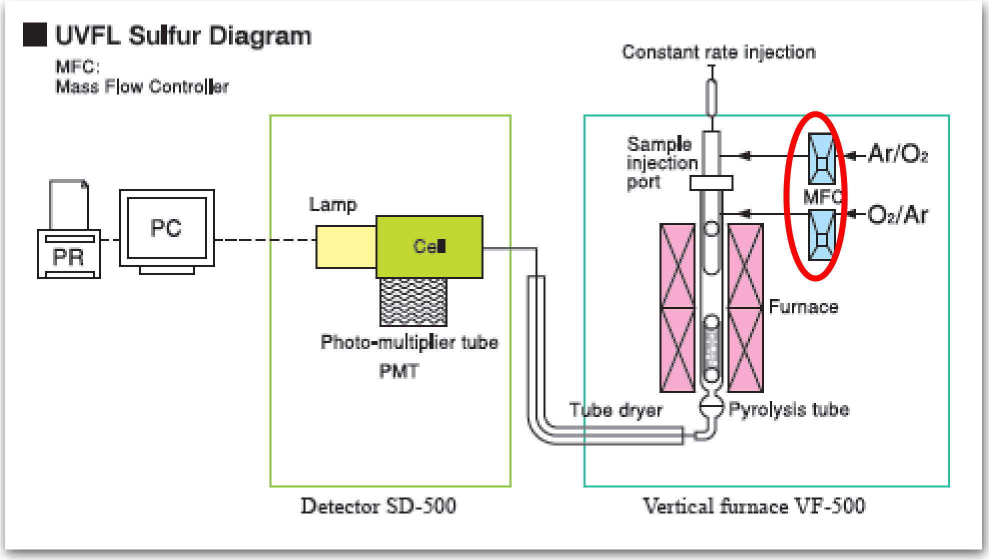


Figure 41

The switching valve of the mass flow controller is a diaphragm type, and PTFE is used to provide flexibility to withstand repeated operation and durability against oxygen gases. PTFE is difficult to find replacement. Because it is highly non-adhesion and the substance does not stick to it like other fluoropolymers, and it has overwhelmingly low friction and excellent durability compared to other resins.

Control valve of mass Flow Controller

Mass flow controllers are used for flow control of various industrial gases.

PTFE is used as the material of the valve body of the flow control valve of mass flow controller.

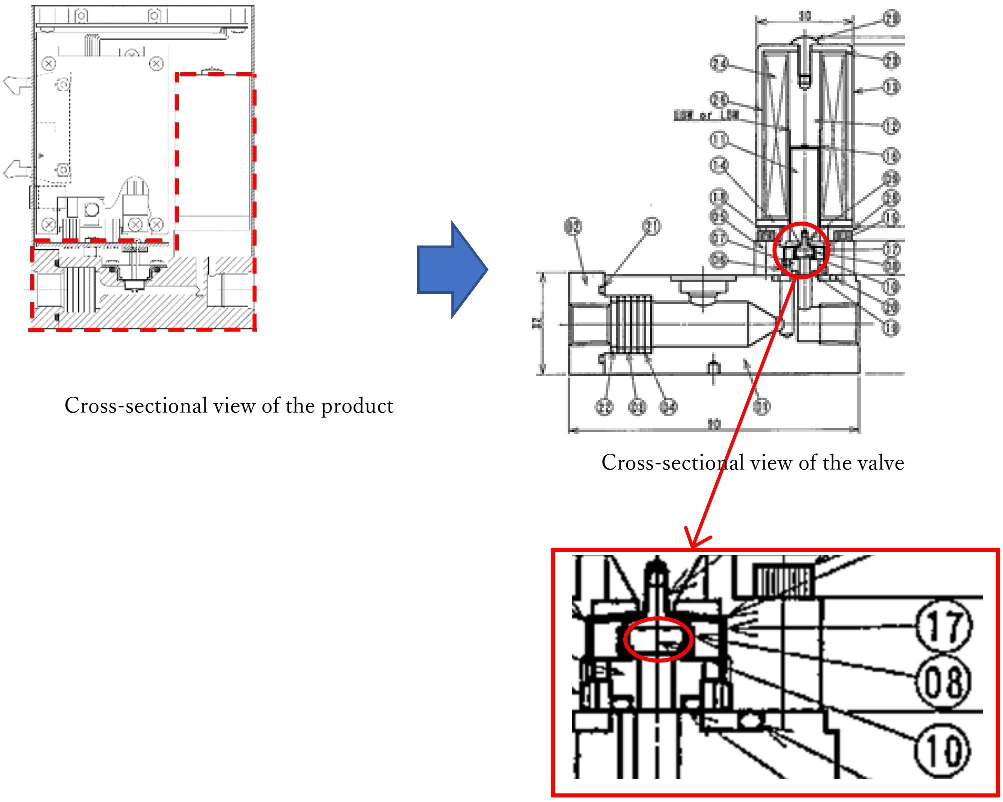
See part (10) in the figure39 below (the right is a partial enlarged view).

Performance requirements for materials.

・Heat resistant to withstand operation from -10°C to +60°C.

・Chemical resistance to withstand components contained in combustible gases.

・Resistant to ozone gas.



Cross-sectional view of the product

Cross-sectional view of the valve

Enlarged view

Figure 42

Mass flow controller for semiconductor manufacturing

PFA coating is applied to the valve that functions to accurately supply the amount of etching gas in the etching equipment for semiconductor manufacturing. When the valve is closed, it must be tightly closed and impermeable to gas. Low friction is necessary because it must not wear out even with the impact of continuous opening and closing of the valve.

The friction ecoefficiency of silicone is low, and silicone cannot be used for this application.

Fluoride ion measuring equipment

This equipment is mainly used to measure the concentration of fluoride ions in factory wastewater. Fluoride ions are detected by an ion electrode, and the concentration can be monitored continuously by sending the sample to the flow cell holding the ion electrode with a liquid sending pump. The sample water is an aqueous solution such as factory wastewater. Various ionic components and insoluble solids are included depending on the type of production.

Used as a switching valve for the solution feed channel

The valve is used as a switching valve for the solution feeding flow path, and the body and diaphragm valve are PTFE solenoid valves.

<u>NOx measuring equipment</u>

NOx meter utilizes chemiluminescence generated in the process that NO and ozone react to produce NO2. Since the emission intensity is proportionally related to NO concentration, NO concentration is obtained by measuring the emission intensity. Since NO2 does not emit light, it is converted into NO by a converter, and NOx(NO+NO2) is measured, and then NO2 concentration is obtained from the difference between NOx density and NO density. So the NOx meter requires switching between the NO measurement line and the NOx measurement line. Also, during calibration, it is necessary to switch between the sample line and the calibration line. Since NOx has high adsorptivity, PTFE is required for NOx passing part, and therefore, a solenoid valve is used for switching.

(Flow diagram）

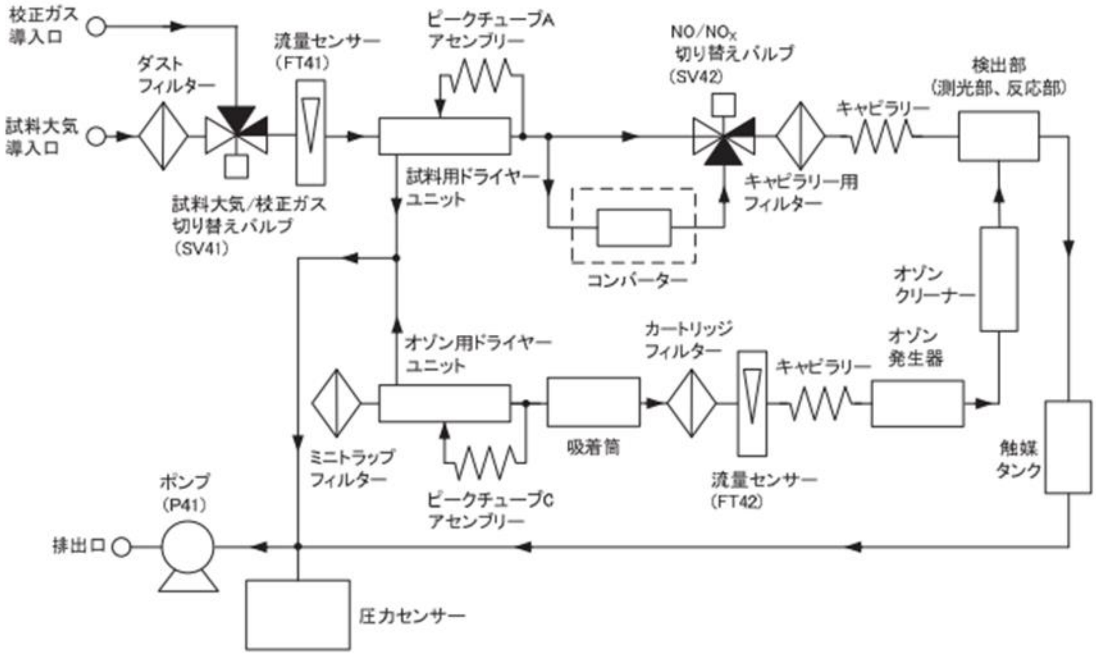


Figure 43

The NOx meter requires switching between the NO measurement line and the NO2 measurement line. Also, during calibration, it is necessary to switch between the sample line and the calibration line. A solenoid valve is used for switching.

Control valves

Control valves are used in a variety of different markets that controls fluid flows in plumbing installed in air conditioning system of building, and Industrial plants, for example petrochemical and power plant.

Examples of control valve products

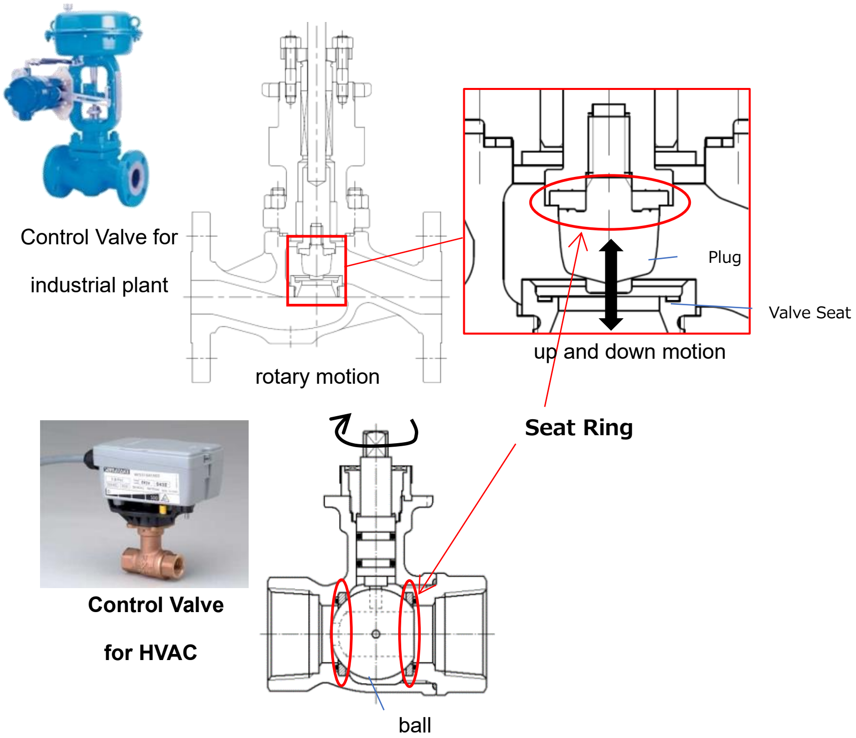


Figure 44

PTFE seat ring is a component of control valves that has a function of stopping the flow by contacting with the plug when it is fully closed.

In general, the friction coefficient of PTFE (0.1 or less) is approximately 1/5 that of metal (approximately 0.5), and the torque required to rotate the plug is approximately 1/5 in proportion to the friction coefficient.

Add that, corrosive and high temperature fluid flows through control valves. So, excellent chemical and heat resistance are required to control valves. PTFE fills all of characteristics aforementioned. Furthermore, it has proven track record of long-term use in various fields.

Material for scraper rings in industrial control valves

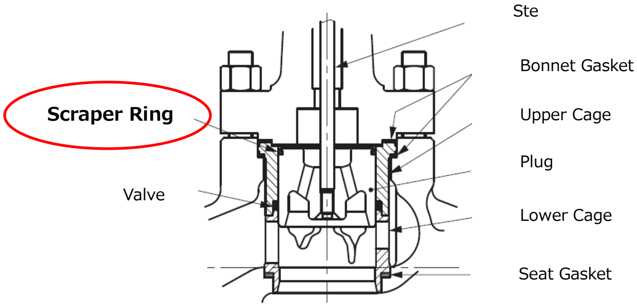


Figure 45

The PTFE scraper ring scrapes off the fluid adhering to the cage of the control valve and prevents sticking of the plug and cage.
Industrial control valves are used to control corrosive fluids such as chemicals, and are required to have performance that can withstand the control of corrosive fluids.
On the other hand, in identifying corrosive fluids, there are many fluids that are difficult to determine physical properties such as intermediates of chemical substances, and materials that have a wide range of chemical resistance are required.

In order to control corrosive fluids with industrial control valves, scraper rings made of PTFE are required in the flow passages where corrosive fluids come into contact.
Other polymer materials, such as rubber and resin, might be able to substitute for PTFE as the material of scraper rings. However, it is considered that the alternative materials are not suitable, because they do not have enough resistance to various chemicals of chemical plants.

Lining and throttling mechanism materials for industrial control valves.

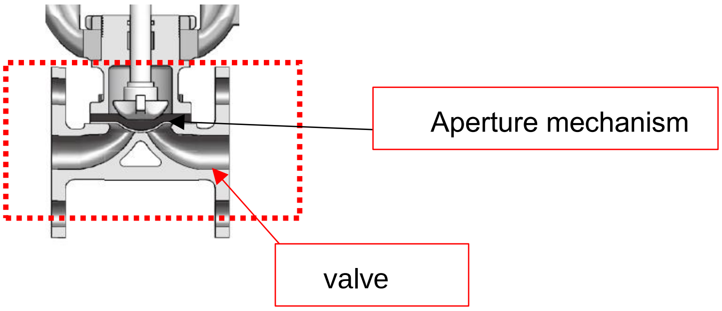


Figure 46

Industrial control valves are installed in pipes of various industrial plants, that are used to control flow of fluids. Industrial control valves are used to control corrosive fluids such as chemicals.

Industrial control valves are required to be able to withstand the control of corrosive fluids at high temperatures (approximately 140°C).

In order to control corrosive fluids with industrial control valves, main body linings and throttle mechanisms made of PFA, ETFE and PTFE are required in the flow passages where corrosive fluids come into contact.

Depending on the fluid used, PFA and ETFE are used in the body lining, and PTFE is used in the throttle mechanism.

- It is possible that other polymer materials such as rubber and resin can be used as alternative materials for body lining and throttle mechanism using PFA, ETFE, and PTFE. However, alternative materials have poor resistance to a wide variety of chemicals in industrial chemical plants and cannot withstand corrosive fluids.
- If it is assumed that metal materials such as chromium and nickel alloys will be substituted, it is necessary to periodically stop the equipment and check the corrosion status of the control valves connected to the pipes. When corrosion occurs, fluid control becomes impossible, so it is necessary to replace the industrial control valve itself.

endoscope reprocessor

The endoscope reprocessors use a variety of chemical solutions such as acids, alkalis, and alcohols to clean and disinfect the endoscopes after use.

Various valves such as solenoid valves, ball valves, check valves, and relief valves are used to switch the solutions and control the flow. If the performance of the valve is degraded or broken, the cleaning and disinfection of the endoscope may be inadequate, leading to cross-infection. Therefore, fluoropolymers such as PTFE, FKM, FFKM, and FEPM, which have high chemical resistance to various chemical solutions, are used for the valve discs, diaphragms, and sealing materials between housings in each valve.

Other substances such as EPDM and silicone are not sufficiently resistant to these solutions, especially the peracetic acid used for endoscopes disinfection, because these substances deteriorate in a short period of time. Therefore, it is impossible to substitute other substances.

Pumps

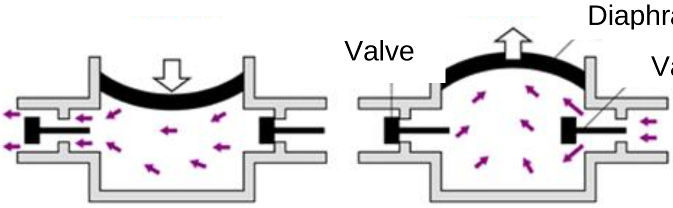


Figure 47 Explanation on Pumps [16]

A pump is a device that transfers, pumps, and stirs liquids and gases under the action of pressure.
It is divided into two types according to the difference in structure: non-positive displacement pumps and positive displacement pumps. Non-positive displacement pumps are pumps that impart energy to liquids by rotating impellers, and include centrifugal pumps, propeller pumps, and viscous pumps. A positive displacement pump is a pump that pressurizes and energizes a liquid that is within a certain volume, and there are plunger pumps, diaphragm pumps, gear pumps, etc. In pumps, fluorine rubber such as FKM, FFKM, and FEPM is used for the sealing members and diaphragms of the housing. PTFE is used for the impeller bearings.

PFAS functions which pumps require and alternatives

Pumps used to transfer fluids such as acids, alkalis, organic solvents, oils, and ozone require high chemical resistance for each member in contact with the fluid. Especially in the case of diaphragms, durability that can withstand repeated bending are also required. Fluorine materials such as FKM, FFKM, and FEPM are used as materials to satisfy these requirements, and it is difficult to replace them with other materials.
In the case of bearings, low friction, self-lubrication, and wear resistance are also required. Fluorine materials such as PTFE are used as materials to satisfy these requirements, and it is difficult to replace them with other materials.
The analyzer may also pump low-temperature liquefied carbon dioxide (minus 57°C). Fluorine materials such as FKM, PTFE and FFPM are used, and it is difficult to substitute other materials.

[16] https://www.monotaro.com/note/cocomite/525/

Examples of the products which incorporate pumps

endoscope reprocessor

The endoscope reprocessors use a variety of chemical solutions such as acids, alkalis, and alcohols to clean and disinfect the endoscopes after use.

And the endoscope reprocessors use internal pumps to deliver these solutions to the outer surfaces and channels of the endoscope.If the performance of the pump deteriorates or breaks down, the cleaning and disinfection of the endoscope may be insufficient, leading to cross-infection. Therefore, fluoropolymers such as PTFE, FKM, FFKM, and FEPM, which have high chemical resistance to various chemical solutions, are used for sealing materials, diaphragms, and bearings in these pumps.

Other substances such as EPDM, silicone and POM don’t have sufficient chemical resistance to these solutions, especially to the peracetic acid solution which used to disinfect endoscopes, because these substances deteriorate in a short period of time. Therefore, it is impossible to substitute other substances.

Coating/Lining

Part Description

A surface treatment in which the surface or inner surface of a base material is covered with a fluoropolymer is called a coating or lining. A relatively thick covering is often referred to as a lining, while a thin covering is often referred to as a coating. There are various methods such as molding, bonding a sheet to the base material, bonding powder, or covering with a liquid. Fluoropolymers used include PTFE, PFA, PCTFE, FEP, and ETFE.

Metal plating and surface treatment containing fluoropolymer resins are used to adhere to metals.

Coatings and linings are applied to parts in contact with fluids. The parts include the inner surface of the piping and parts in contact with the fluid. Coatings may be applied to areas where water repellency to water and oil, low friction, self lubrication, and non-adhesion are desired.

Examples of coating / lining

Piping inner surface

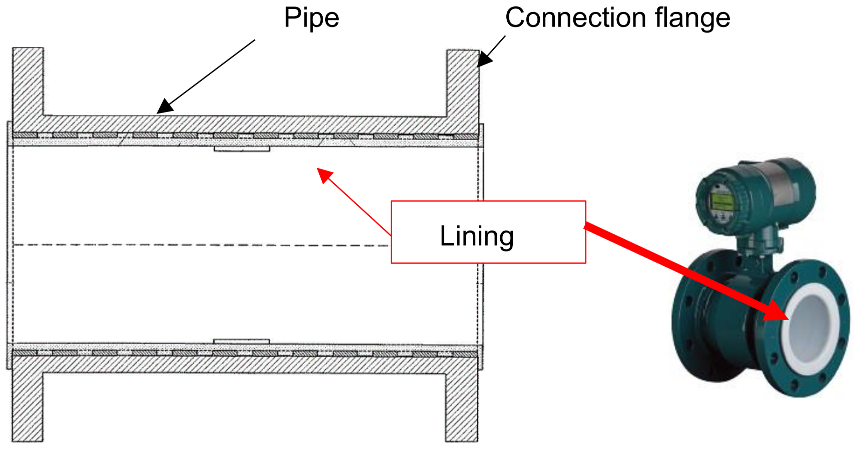


Figure 48

Coating and lining section of parts (diaphragm) in contact with fluid

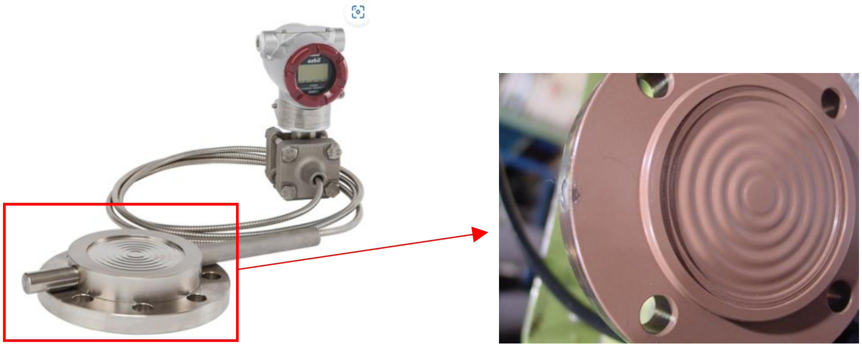


Figure 49

PFAS functionality required by coating/lining and possible substitutions

By covering the surface with a fluoropolymer, PFAS gains chemical resistance/cleanliness and mold-releasing properties that the base material does not have. Coatings and linings in contact with fluids can withstand corrosion and operate stably without maintenance for long periods of time (10 years). For example, fluorine coatings and linings on low-hardness rubber materials provide both high flexibility and chemical resistance. When the fluid is a powder, it is difficult for the fluid to adhere to the coating/lining area due to non-adhesion of fluoropolymers.

Coatings for instruments and tools for analysis and measurement

Analysis and measuring instruments are required to have chemical resistance because they may analyse and measure any kinds of chemical substances, including strong acids, strong alkalis, organic solvents, and oils, as samples. For correct analysis and measurement, no specimens or reference materials should remain in instruments or pipettes, tubes, etc. If residues remain, subsequent analysis and measurement will not be accurate. In order to prevent residues from remaining, coating should be applied to the areas where the specimens and reference materials are likely to remain. The fluoropolymer resins have the functions, such as, repellency from water and oils, and non adhesion. These functions can prevent residues from remaining, which resulting in accurate analysis and measurement.

Examples of Parts and Equipment Using Lining and Coating

There are a great many devices that coat base materials that come in contact with fluids.

Lining for fluid contact parts of electromagnetic flowmeters and pressure transmitters

Equipment around piping such as electromagnetic flowmeters and pressure transmitters cannot maintain their performance without fluoropolymer resin linings and coatings in order to withstand various fluids such as acids and alkalis.

Linings using ETFE or PFA can operate stably for 10 years without maintenance.

Accidents may occur if the equipment continues to operate with the fluid flowing through the piping without noticing that it has been corroded by the fluid.

In order to maintain the work environment and safety management, it is necessary to use fluoropolymers that can be safely used for a long period of time without replacement for devices that pass corrosive fluids.

Surface coating of the rubber roller (see photo below) that feeds the film in the thermal developing section of the laser imager

A laser imager is a device that outputs various image data (general radiography, CT, MRI, etc.) taken by an X-ray machine onto DRY film, and doctors use these medical images to diagnose patients. The film with the image data output is fed by rollers. Image data is output by thermal processing (temperature 126°C), so the rollers must be heat resistant. In addition, the material generated during thermal processing adheres to the rollers, causing image defects, feeding failures, and other problems, so releasability is necessary. Therefore, fluoropolymer coated rollers with heat resistance and releasability are required. Defects in the image may result in misdiagnosis or oversight.

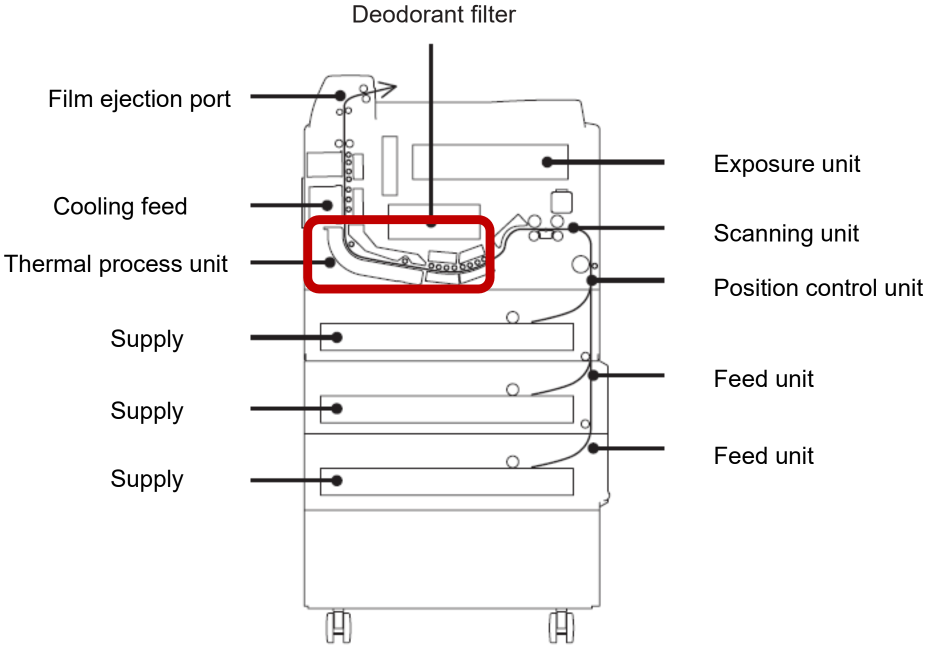


Figure 50

<u>Coating in the chemiluminescence cell of the nitrogen detector.</u>

Elemental analysis is a method of complete combustion of organic compound samples, introducing high-purity oxygen gas and argon gas. In order to observe luminescence from chemicals which were introduced into the cell of the detector, anti-reflection and anti-corrosion properties are necessary. Fluoropolymer resin materials are required as coating materials in cells with low refractive index and chemical resistance.

In the nitrogen detector, the nitrogen compound in the sample is combusted and oxidized and reacted with ozone gas in the cell. Therefore, ozone resistance is required in the cell.

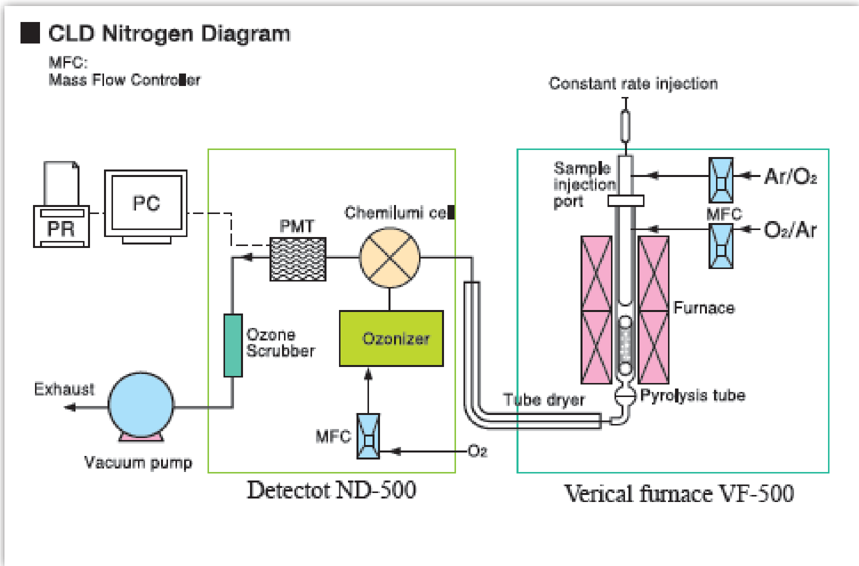


Figure 51

On the other hand, in the sulfur detector, when the sulfur compound in the sample is combusted and oxidized, most of it becomes SO_2 . When the generated SO_2 is irradiated with ultraviolet light (190-230 nm) of a xenon lamp in the cell, fluorescence is emitted. Therefore, the inside of the cell is required durability against ultraviolet rays.
Fluoropolymer materials meet each required specification at a high level. They are practically non-fungible.
Please see the diagram of Mass flowmeter of UVFL diagram

Imaging Plate (IP) for Non-Destructive Testing and Medical Image Diagnosis

IP consists of a 350μm-thick polyethylene terephthalate (PET) material with excellent flatness and flexibility, coated with a special phosphor that produces photoluminescence. When an X-ray is taken, the radiation passing through the object to be inspected is temporarily stored in this "phosphor layer" in the form of electronic energy distributed over the entire surface in proportion to the dose. The surface (white side) of the IP has a transparent "front protective layer" that prevents dirt and scratches from the "phosphor layer", and the back side has a "back protection layer" that covers the layer (black) that has a light blocking.
Fluoropolymer is used for "front protective layer".
X-ray information recorded in IP is read by Computed Radiography (CR) and CR generates X-ray image. After reading with CR, the X-ray information recorded in IP can be erased by irradiating white light and can be used repeatedly.
As IP is conveyed repeatedly within the CR, there is a risk that the surface will become dirty or scratched.

Dirt and scratches on the surface of the IP will cause defects in X-ray images, making accurate inspections and diagnoses impossible. Therefore, the surface of IP is required to be antifouling and low-friction.

Fluoropolymer is the only material that satisfies the following property (antifouling, low-friction) and manufacturing suitability for coating.

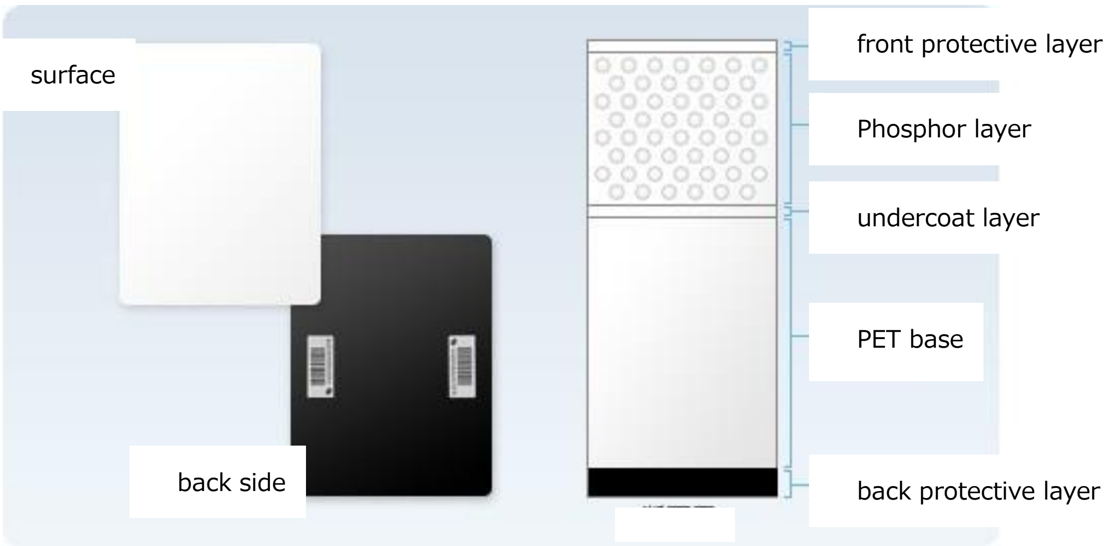


Figure 52

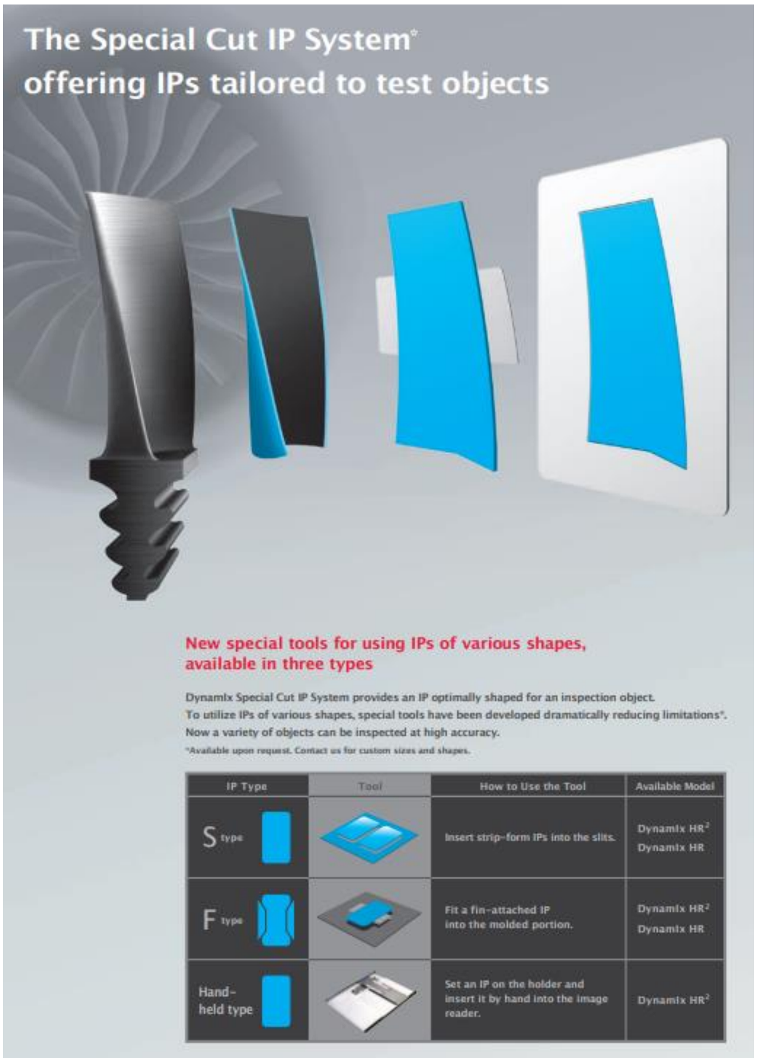


Figure 53

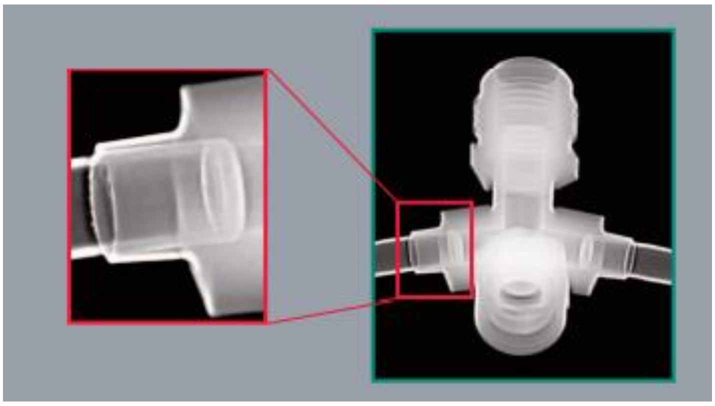


Figure 54

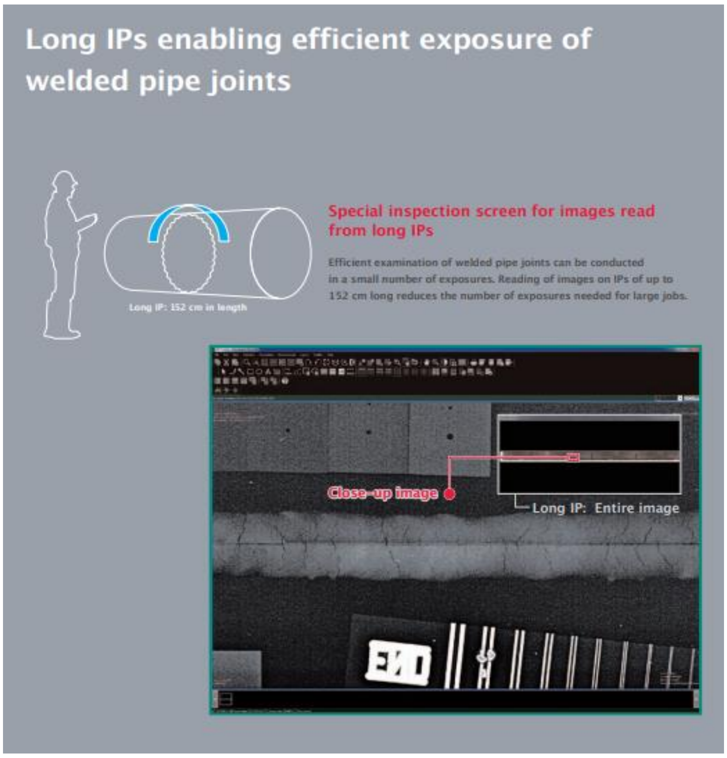


Figure 55

<u>Environment-resistant photoelectric switch with built-in amplifier.</u>

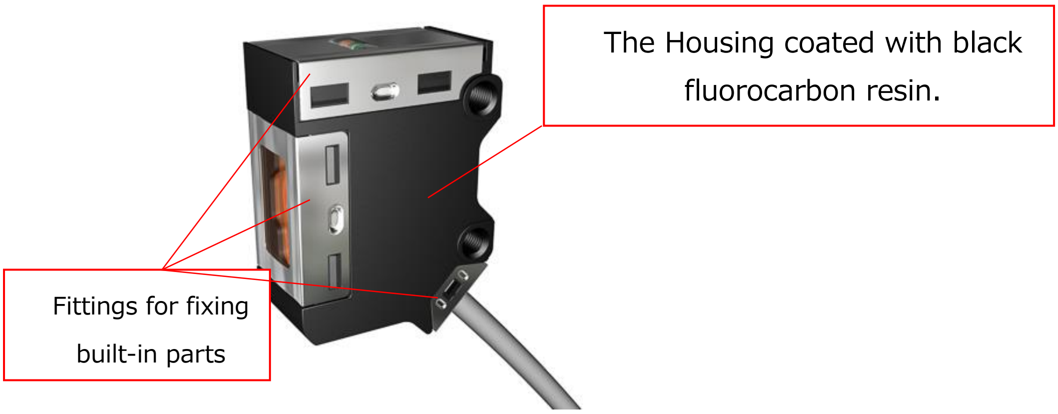


Figure 56　External View/ Detection of workpiece seating in machine tool

Improved corrosion resistance of housing

The housing of Environment-resistant photoelectric switch is made of zinc die-cast. Zinc die-casting has advantages such as high fluidity, easy dimensional accuracy, low molding temperature, and long service life of metal mold, but it has low chemical resistance.

Therefore, it cannot be used in machine tools and automobile parts machining lines, which are users of this switch, unless corrosion resistance is improved by painting and plating. Water-soluble coolant (basic) is often used in machine tools and automobile parts machining lines, and zinc die-cast housing is highly likely to be corroded unless surface treatment such as painting is performed (Figure 56).

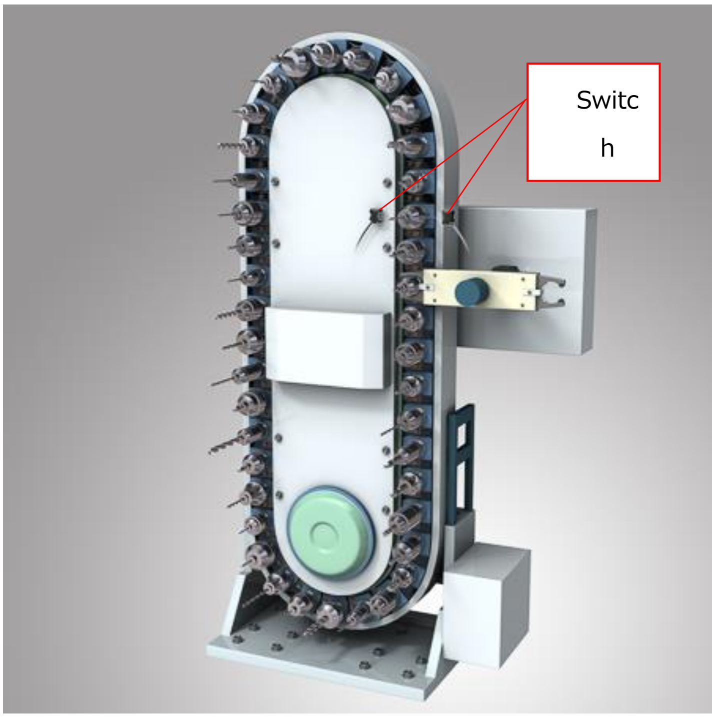


Figure 57　Confirmation of Existence of Tool in Machine Tool

Prevention of crevice corrosion and dissimilar metal contact corrosion

The H2B housing is assembled with a metal stopper (SUS plate (zinc plated)) (Figure 56) and attached to an accessory SUS bracket or the mounting surface of the user side (metal, resin, etc., materials cannot be specified) (Figure 57). Therefore, it is necessary that the metal surface of the housing is not exposed in order to prevent electrolytic corrosion due to gap corrosion and contact between different metals.

The former model number of this switch had adopted acrylic coating, but it was changed to fluorine coating due to low resistance to water-soluble coolant. The surface of the housing must be free from exposed metal. Therefore, coating by coating is necessary instead of plating. For the same reason, coating is necessary even if the housing is changed to a highly chemical resistant metal material such as SUS.

There are concerns about the following impacts due to the unavailability of this technology

- Affects machining with machine tools that use water-soluble coolant and parts machining and production on automotive parts production lines
- There is no alternative technology. When a switch without fluorine coating is used, corrosion of the switch causes contamination of corrosion products (foreign matter) into

parts, generation of rust in processed parts, and increase of stoppage period of machine tools and production lines due to increase of sensor replacement frequency.

For the above-mentioned reasons, the prohibition of coatings with fluorine-based paints should be exempted indefinitely from this restriction because of the economic burden due to the increased frequency of replacement and the serious degradation to the finished product.

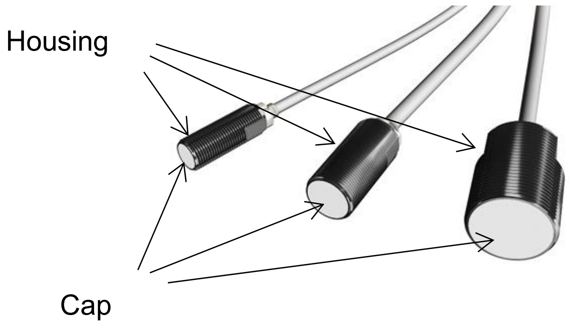
In terms of disposal, restrictions should not be applied as coatings by fluorinated paints generally lead to a reduction in waste.

Spatter-guarded proximity switch

Part of the housing of the spatter-guarded proximity switch used in a welding environment.

Cap：Fluoropolymer resin PFA sensing surface

Housing：Coated with fluoropolymer resin.



Spatter-guarded proximity

Figure 58

The following features can be obtained by using Fluoropolymer resin.

Cap：It can withstand the heat of welding spatter. It is difficult for spatter to stick.

Housing：It is difficult for spatter to stick.

Endoscope(Coating)

Figure 59

A guidewire used to secure the insertion route of the treatment tool when performing procedures for periods that are difficult to approach, such as the pancreatic bile duct. By coating fluoropolymer resin on the surface of a substrate such as metal, it acquires acid resistance, low friction, and non-adhesiveness that cannot be possessed by the base material alone. Biocompatibility and chemical resistance are also important characteristics for use as medical devices.

Chemical resistance is a necessary characteristic for resistance to body fluids such as stomach acid. Low friction is a characteristic necessary for smoothly guiding the treatment tool and inserting the treatment tool into the target site. Non-adhesion is a characteristic necessary for the mucous membrane and the like to not stick when inserted into a living body. There is no coating material other than fluoropolymer resin that satisfies all of these properties. Aliphatic urethane has poor low friction, and the necessary quality cannot be ensured, such as deterioration of treatment performance due to deterioration of insertability.

In addition, there is a method of using a gas such as EOG or hydrogen peroxide as a sterilization method, and since it is exposed to sterile gas, chemical resistance is a necessary characteristic. There is no material that has chemical resistance equivalent to fluoropolymer resin and has low friction.

In addition to these properties, biocompatibility is required. See "Biocompatibility" in the endoscope section of "Plumbing" for details.

■*Endoscope*

A medical device that is inserted into the body from the oral cavity to observe and treat the inside of the lumen.

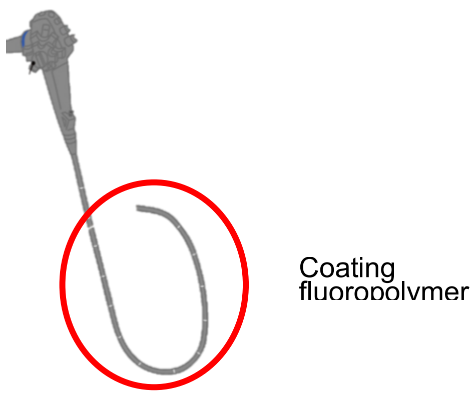


Figure 60

By coating fluoropolymer (PTFE etc.) on the surface of base materials such as resin or rubber , chemical resistance, acid resistance, alkali resistance, heat resistance, low friction, and non-adhesiveness that cannot be possessed by the base material alone are acquired. In addition, flexibility is a necessary characteristic for insertion into complex lumens. Chemical resistance , acid and alkali resistance are necessary characteristics for disinfection and cleaning to prevent infection after use. Acid resistance is a characteristic that is also necessary for resistance to body fluids such as stomach acid. Low friction is a characteristic necessary for smooth insertion into the lumen to reduce pain. Heat resistance is a necessary characteristic to perform autoclave sterilization at 136 °C. Non-adhesiveness is a characteristic necessary for the mucous membrane and the like to not stick when inserted into a living body. There is no coating material other than fluoropolymer that satisfies all of these properties. Aliphatic urethane has poor heat resistance, chemical resistance, and low friction, and the quality of sterilization, disinfection, and cleaning decreases, increases the risk of infection, and increases patient pain. For example, in hydrogen peroxide sterilization, which is currently becoming mainstream, it has been confirmed that the coating surface easily deteriorates, and coating peeling occurs in less than half the cases compared to fluorine-based coatings.

As a sterilization method for endoscopes, there is a method of using gases such as EOG and hydrogen peroxide, and since sterile gas also penetrates the inside of the product, chemical resistance is a necessary characteristic even for internal parts. Sterilization methods are limited by the methods that can be used depending on the region, and it is not enough to be able to correspond to any one as a product, but it is necessary to be resistant to all sterilization methods. Furthermore, in metal mechanical parts such as O-rings provided on sliding parts and curved operation wires built-in, in addition to chemical resistance, low friction is required to reduce friction between members, so similarly, coatings containing fluoropolymer such as PTFE and PTFE-Ni plating are required. For example, when the coating of the operation wire is replaced with a non-PFAS member such as boron nitride, carbon, and silicone, which are general coating agents, the frictional resistance between the members increases, and the bending operation of the endoscope requires 2~5 times greater traction force than the fluorinated coating. In addition, there is molybdenum disulfide as another non-PFAS material, but although the lubrication performance is relatively excellent, it is difficult to replace it due to the risk of toxic substances generated in hydrogen peroxide sterilization. As described above, PFAS materials are indispensable because there is no material having chemical resistance equivalent to fluoropolymer and low friction.

In addition to these properties, biocompatibility is required. See "Biocompatibility" in the endoscope section of "Plumbing" for details.

1. Description : Fluoropolymers for use in medical devices Surgical Guidewire Applications

Figure 61

2. PFAS substance(s) used: name and CAS number (If known):

PFAS substances, including but not limited,

- Poly(1,1,2,2-tetrafluoroethylene), CAS # 9002-84-0
- Perfluoro-alkoxy polymer, CAS # 26655-00-5
- Copolymer of hexafluoropropylene and tetrafluoroethylene CAS # 25067-11-2

3. It is well known that C-F bonding energy is much higher energy than C-C bonding energy, the unique crystal structure of fluoropolymers. lower surface energy, hydrophobic as well. Due to the unique microstructure structure, and hydrophobic characteristics, fluoropolymers have been used in medical device, such as endoscope with many benefits, including but not limited, i. excellent biocompatibility, biostability, and patient safety history. ii.resistant to chemical, enzyme, and microbiological attacks while eliminating biodegradation issues. iii. low co-efficient of friction allows moving parts to slide with ease, loading device effectively as well. iv. low surface energy or hydrophobic makes it nonstick material combined with its moisture barrier and chemical resistance, makes it a valuable polymer for medical device especially for physician to tackle a surgical procedure with difficulty anatomy conditions.

4. These unique chemical-physical characteristics of fluoropolymers make medical devices safer to use for patients. However, the unique properties of fluoropolymers make them difficult to replicate with other non-fluoropolymers. For instance, to the best practices in polymer industry, the alternative materials for fluloropolymers are proposed as follows: Chlorotrifluoroethylene (E-CTFE), Ethylene Tetrafluoroethylene (ETFE), and so on and so furth. However, the proposed alternative materials are still under the umbrella of 2021 OECD definition of PFAS “Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it)”

■ *Coating of surgical instruments*

The tissue gripping part consists of two parts. (Electrode member in contact with tissue and jaw holding electrode member)

Figure 62

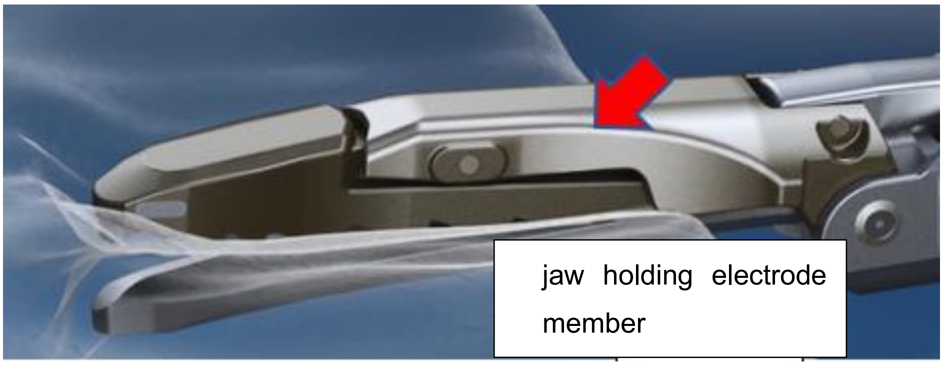


Figure 63

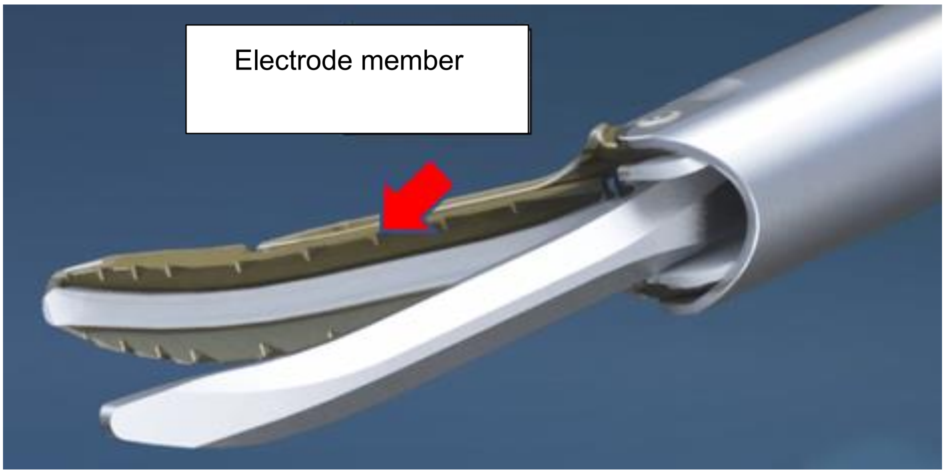


Figure 64

Since the tissue gripping surface of the electrode part is a part where burnt tissue tends to stick very easily because of the high-frequency current being passed through it, it is especially essential for gripping surface to be non-sticking. This is because if they don't have the non-stickness, the bleeding that has been stopped will be re-bleeding due to the operation when releasing the adhesion, which is very dangerous. In addition to chemical resistance, heat

resistance, electrical insulation, and low friction required for surgical treatment tools, Ni-PTFE plating is essential because mechanical properties that can withstand heat, pressure, and mechanical damage when assembling pads are required at a particularly high level and have electrical conductivity.
In order to prevent unnecessary energy from acting on the living body, the outer surface of the jaw does not conduct electricity (has insulating properties) and becomes hot due to the heat generated during treatment, so it is very important to be non-adhesion like the electrode part.
PFA coating is indispensable for biocompatibility, chemical resistance, heat resistance, electrical insulation, and low friction required for surgical treatment tools.
In addition to these properties, biocompatibility is required. See "Biocompatibility" in the endoscope section of "Plumbing" for details.

Flame arrestor (sintered metal) surface

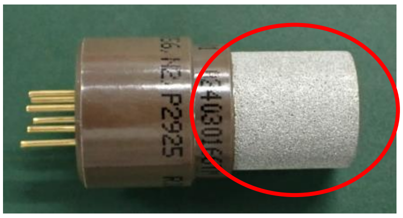


Figure 65

Sintered metal flame arrestor is used to prevent the internal gas sensor element from becoming an ignition source. Surrounding gas reaches the sensor element through fine gaps in the sintered metal, but when water is adsorbed on the sintered metal, the flow path of the gas narrows. Therefore, in order to prevent water adsorption and corrosion on sintered metal, a fluorine coating is applied for the purpose of adding repellency from water and chemical resistance.

- Inside the metal nipple

Figure 66

Fluorine coating is applied to the inside of the metal nipple which is part of the gas flow path for the purpose of adding non adhesion in order to prevent the gas concentration from decreasing due to the adsorption of highly adsorptive gases.

Repellency from water

The flame arrester (sintered metal) is given water repellency by applying a fluorine coating to prevent clogging due to water adsorption and corrosion.

Non-adhesion

Fluorine coating is applied to parts of metal pipes that cannot be used due to insufficient strength of fluoropolymer resin pipes, such as when it is necessary to cut threads to fix them.

Chemical resistance

Fluorine coating is applied to the parts used in the gas flow path to provide chemical resistance. Fluorine coating can be used in acids, alkalis, organic solvents, ozone, and oils.

Fuel Cell Performance Testing Equipment:Coating of tank

Fuel cells generate electricity and heat through a chemical reaction between hydrogen and oxygen. Fuel cell performance testing equipment evaluates the performance and durability of fuel cells. Fuel cells contribute to carbon neutrality by improving energy efficiency and reducing CO2 emissions.

The Fuel cell performance testing equipment supplies hydrogen obtained from an alkaline substance to the fuel cell. It stores the alkaline liquid to obtain hydrogen in a stainless steel tank, which cannot be used for a long period of time because the stainless steel is corroded by the alkali. Therefore, the tank surface is protected by coating with PTFE. Moreover, hydrogen gas used for fuel cell is necessary to add water vapor. The tanks for to control the dew point of the added water vapor can reach temperatures above 150°C. Thus the coating material must be heat resistant. So far, PTFE is the only material which has both chemical and heat resistance.

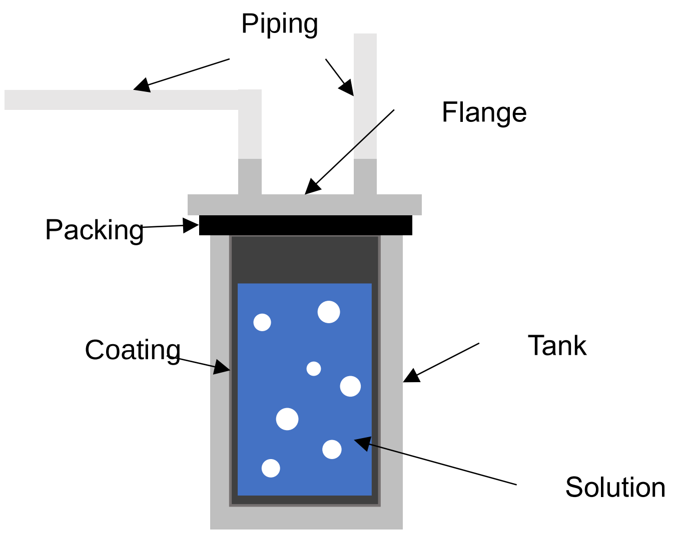


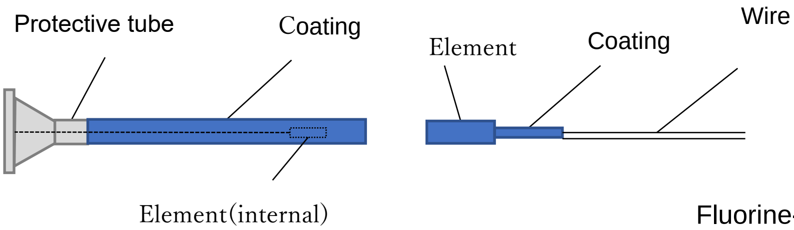
Figure 67

Temperature sensor

Contact type temperature sensors can measure temperature by contacting the object to be measured and reaching to the same temperature. The sensor measures the temperature using the element itself or an element inserted into a protective tube for strength.

Temperature sensors can measure a wide range of objects, including acids, alkalis, and organic solvents, and can also measure a wide range of temperatures, including applications that measure chemicals at 100°C or higher. Therefore, sensor elements, wires themselves, and protective tubes are coated with FEP or PFA to eliminate the adverse effects of chemicals and high temperatures and realize accurate measurement.

There is no material other than fluoropolymers that combines chemical resistance and heat resistance to realize such applications, and it is difficult to replace them.



Fluorine-coated temperature sensor

Figure 68

Coatings for the interior of X-ray analysis detector

Fluorescence X-ray analysis (XRF) is designed to analyze elements by measuring the X-ray fluorescence produced after each element is excited by X-rays. X-rays generated from components close to the sensor are also detected, so that X-rays of fluorescence generated from sources other than the sample being measured interfere with accurate analysis.

The lower the atomic number, the lower the energy of the X-ray fluorescence. Conversely, elements with higher atomic numbers tend to absorb X-rays more easily.

Therefore, metallic materials such as Nickel, which are the internal components of the detector, are coated with a metal with a lower atomic number, such as Aluminum (Al), and then coated with a fluoropolymer resin less than 100 µm thick to absorb the fluorescent X-rays generated from Al. Fluoropolymers also emit fluorescent X-rays, but their low energy has no effect on the analysis.

If coatings other than fluoropolymers are used, epoxy resins and carbon coatings are available. But these have a lower X-ray absorption than fluoropolymers. For the same absorption capacity, a coating three times thicker for graphite (C) and seven times thicker for polypropylene (C3 H6) is required to absorb the fluorescence X-ray from Al (See the figure). The thicker coating interferes with the sensor, reducing detection sensitivity and increasing analysis time.

For accurate X-ray fluorescence analysis, it is difficult to use anything other than fluoropolymers for the internal coating of the detector.

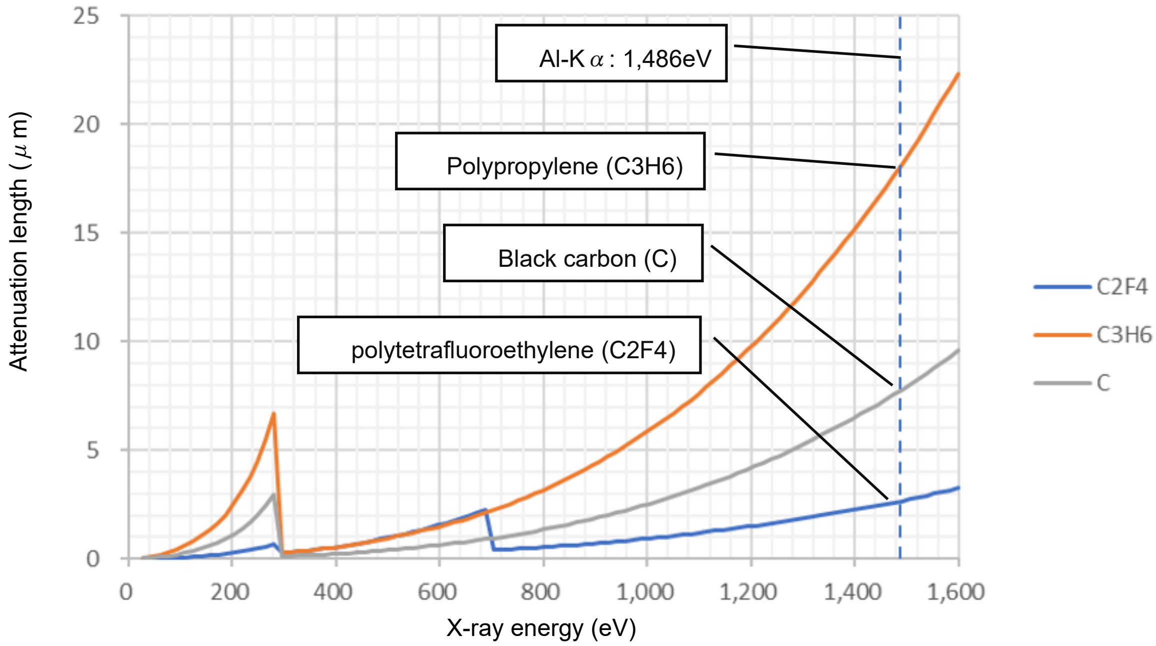


Figure 69 X-ray attenuation lengths of X-ray [17] : Dashed line is fluorescence X-ray energy from Aluminum.

Membrane filters

Membrane filters are to remove and separate specific substances or objects from fluids. A wide variety of materials are used. If fluorine compounds are necessary, PTFE, FEP, ETPE and PFA are frequently used.

Membrane | Electrolyte

Dissolved oxygen electrode | Electrochemical gas

Figure 70

[17] It is calculated with CXRO X-Ray Interactions With Matter, https://henke.lbl.gov/optical_constants/ accessed on 25 August 2023

Measurement method of pH meter and diagram of membrane filter

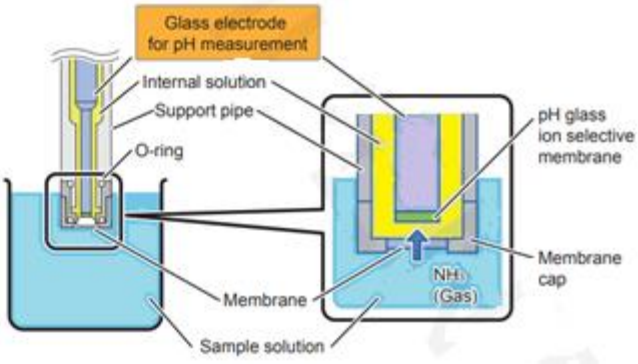


Figure 71

1. Gas components in the sample are go into the electrode through the membrane.
2. The pH of the internal solution changes according to the amount of the gas taken in, and the change of pH is read by a glass pH electrode.
3. The pH change of the internal solution is converted to gas concentration in the sample.

The following properties are required for the membrane used in this application.
There is currently no other material that possesses these properties at a level that can be used in products.

・Gas permeability
  Membrane must have sufficient gas permeability even under conditions of no pressure.
・Chemical resistance
  Membrane must have sufficient chemical resistance that will not deteriorate after immersion in various samples.
・Repellency from water
  Repellency from water is required in order not to permeable water.

PVC, glass and PEEK are too high much gas barrier property to separate gases. PE is weak for acids. Glass is melt down by hydrogen fluoride and some gases. Fluorine compounds such as PFAS are the only materials that can simultaneously provide and express multiple functions required for the proper functioning of membrane filters.

PTFE filter used in the ozone decomposition catalyst unit of NOx measuring equipment
A NOx meter needs to generate ozone to measure NOx by the chemiluminescence method. For accurate measurements, ozone is generated in excess of NOx in the sample. An ozone decomposition catalyst is used to decompose ozone remaining after NOx measurement, and a PTFE filter is used to remove the catalyst powder.

PTFE filter is a filter with little adsorption and decomposition. Use is recommended in the Environmental Air Constant Monitoring Practices Promotion Manual. It also has better ozone-resistance than PVC and PE and is less priced than PEEK.

PTFE porous membrane Electrochemical gas sensor

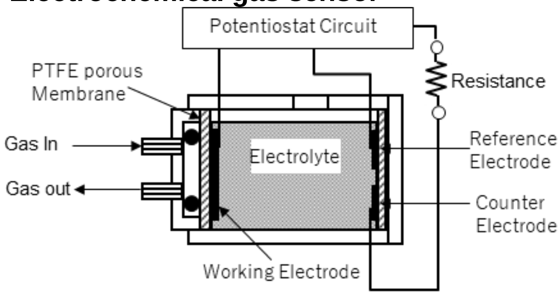


Figure 72

1. Electrochemical gas sensor is constituted by a working electrode formed on a PTFE porous membrane, a reference electrode, a counter electrode, electrolyte and a housing which is holding other components.
2. Every electrode is connected to a potentiostat circuit and the working electrode is implied fixed potential to that of the reference electrode.
3. The PTFE porous membrane is in contact with atmosphere which may contain intended gas to be detected.
4. The gas to be detected goes through by diffusion in the membrane and reaches the interface of the working electrode and the electrolyte.
5. The gas is electrochemically oxidized or reduced.
6. The oxidized or reduced reaction involves transfer of electrons between chemical species and the working electrode, hence current flows in the circuit.
7. The current is measured to determine the concentration of the gas to be detected

The following properties are required for the membrane used in this application.

There is currently no other material that possesses these properties at a level that can be used in products.

・Gas permeability

The membrane must have gas permeability at atmospheric pressure.

・Water resistance

The membrane must have sufficient water resistance not to leak electrolyte.

・Corrosion resistance

The membrane must have corrosion resistance. Examples of corrosive gases are NOx, SOx, halogen and halogen halide.

・Chemical resistance

・Heat resistance

The membrane must have sufficient heat resistance over 150 degree Celsius to coat electrocatalyst.

・Non-adsorptive

The membrane must have sufficient non-adsoptive. If the gas to be detected is adsoabed on the membrane, the gas can’t go through the membrane, or it takes time to go through the membrane.

Galvanic oxygen sensor

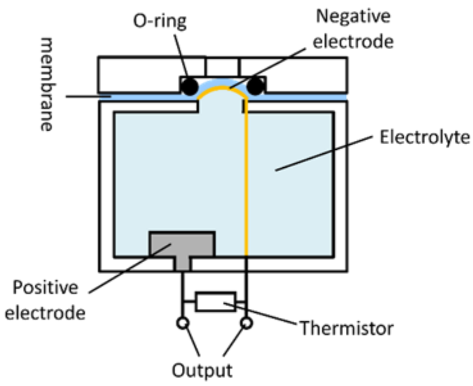


Figure 73

1. Oxygen gas in the sample reaches through the membrane into the sensor.
2. The oxygen gas taken in is reductively decomposed at the cathode. A current flows according to the oxygen amount taken in.
3. The current is read as a voltage through a resistor such as a thermistor.

The following properties are required for the diaphragm used in this application.

・Gas permeability

The gas to be measured is taken into the electrode. This measurement is not possible without sufficient oxygen permeability even under conditions of no pressure. Among fluorine compounds, FEP has superior oxygen permeability compared to other polymer membranes.

・Chemical Resistance

FEP is used in environments where it is in constant contact with various gases (acids, alkalis, organic solvents, etc.). The membrane filter does not deteriorate in these environments, does not elute components of the membrane filter when in contact with any sample, and must be resistant to chemicals.

・Water repellency and water resistance

The membrane filter must be hydrophobic and water resistant to prevent water from permeating into the electrode.

The material must not change after 10 years of exposure test as a material.

Other examples

Endoscope(Electrical Contact Unit)

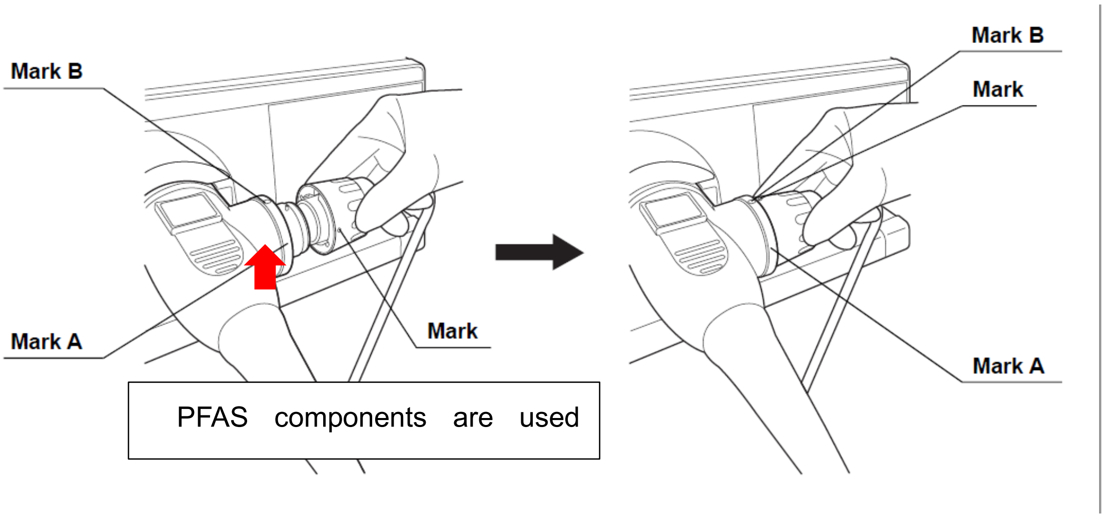
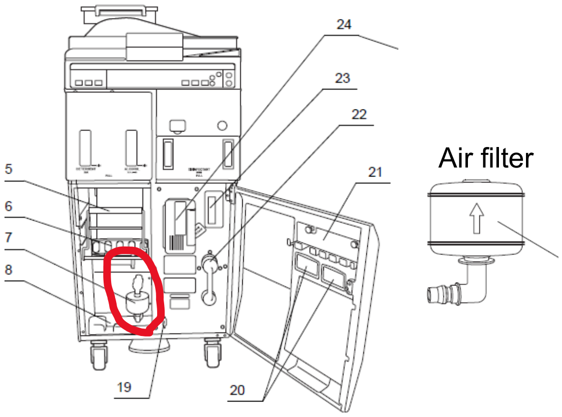


Figure 74

In the electrical contact unit of the endoscope, ePTFE sheet is used for parts that require ventilation while waterproofing. When connecting watertight with a plug and receptacle, an air escape path is secured inside. Otherwise, high pressure will occur between the plug and the receptacle, causing poor work or damage. Since the air escape path at this time is connected to the inside of the product, waterproof performance is required as a protection of the electric parts. Therefore, by utilizing the porous structure of ePTFE, it is waterproof and moderately breathable. There is no substitute material that is resistant to deterioration by chemicals and gases and is both waterproof and breathable.

Endoscope Reprocessor



Filter for air delivery.
Filters out airborne bacteria and microscopic debris.

Figure 75

After cleaning and disinfection the endoscope, a PTFE membrane filter is used as an air filter for compressed air to remove water from the endoscope channels. The filter must have filter sterilization properties (pore size of 0.2 μm) to prevent recontamination of the endoscope after cleaning and disinfection. It must have biocompatibility so that there is no risk of toxicity if debris remains the endoscope and is used in the patient.

Furthermore, for sterilization of the air filter itself, it is necessary to have heat resistance and chemical resistance that can withstand autoclaves and EtO. And it is necessary to have repellency from water so that moisture in the air that condenses during compression does not adhere to the endoscope. Fluoropolymers such as PTFE are used as materials that satisfy these characteristics. and there is no substitute materials

Figure 76

a PTFE filter is used as a ventilation filter for disinfectant bottles such as peracetic acid solutions. Since the peracetic acid disinfectant generates peracetic acid gas over time, the gas need to be released by the PTFE filter that is moisture-permeable and waterproof with a porous structure to prevent bursting the bottle . In addition, this filter is required to have high chemical resistance to prevent deterioration by the internal disinfectant. PTFE are used as materials that satisfy these characteristics, and there is no substitute materials.

Electrode

-Parts in contact with liquid other than electrodes in electrode structure (of instrument that measures the physical quantity of a liquid by electrical means)-

The electrode in a measuring instrument is a part to be electrically contacted with an object and to measure for the purpose of measuring the electrical signal of the measurement object.

The instrument to measure the physical quantity of a liquid by electrical means is equipped the electrode(s).

In that type of instrument, the purpose of the electrodes is to detect the electrical potential or charge at limited area in the liquid. Therefore, （In the electrode and surrounding structure,） parts in contact with liquid other than electrodes must be non-conducting.

For non-conducting material, high hardness materials such as glass or ceramics can be used only very limited usage. because these high-hardness materials are inferior in workability and impact resistance. Therefore, in many cases, resin is used for parts in contact with liquid other than electrodes. And there is no resin material other than PFAS that can withstand the temperature and corrosiveness of liquids.

Internal junction and filers in electrodes for pH liquid measurement

Internal solution determines the standard of electric potential for pH liquid measurement.

Small amount of internal solution is diffused in the sample. It is necessary to reduce the amount of diffusion of the internal solution to reducing the impact to samples, and stable measurement. Fluoropolymer gels and porous resins which impregnant fluoro-monomer internal solution minimise the amount of the diffusion.

Samples could be strong acids, alkalis, organic solvents, and others. The liquid junction of electrodes requires chemical resistance. PFASs are chosen for internal solutions, gels and porous resins in the liquid junction for pH measurement. PFASs have repellency from water and oils, which resulting in less stains in the electrodes. This is particularly useful for continuous operations. Internal junctions require PFASs which have the function of chemical resistance and repellency from water and oils for accurate and stable measurement.

Optical coating

A water-repellent coating layer which contains Perfluoroalkyl or perfluoropolyether compounds is formed with a thickness of less than tens of nm on the outermost surface of coating layers of the ophthalmic lens surfaces.

The water repellent coating provides superior properties such as water repellency, oil repellency, lubricity, smoothness and chemical resistance to the ophthalmic lens. These properties improve prevention of water discoloration on anti-reflection coatings, scratch resistance, ease of wiping off stains (fingerprints, sebum, etc.) on the lens surface and maintainability. As the results, these high performances enable to extend substantially the product life of lenses.

And the water-repellent coating layer is coated on anti-reflection coating layers to eliminate the ghost and flare phenomena in lens optical systems.
The one of valuable features is having both properties of low refractive index (n<=1.40) and high transparency of the coating layer which composed of perfluoroalkyl or perfluoropolyether compounds.

*1 Ghosting/flare: Reflected light generated on the lens surface is repeatedly reflected in complex ways, resulting in the appearance of light images that are not actually there. The higher the reflectivity of the lens surface, the more likely it is to appear.

*2 Anti-reflection coating: A film with a function to reduce reflected light. In ophthalmic lenses, reflection is reduced by alternately layering materials with different refractive indices to utilize light interference.

*3 Low refractive index: Since the lower the refractive index of the film of the top surface layer of an antireflection coating, the greater the effect of reducing reflections from the lens surface, a film material with a lower refractive index is required. The refractive index of general glass is 1.52, and the refractive index of base materials for eyeglass lenses is 1.50~1.90 (including plastic and glass).

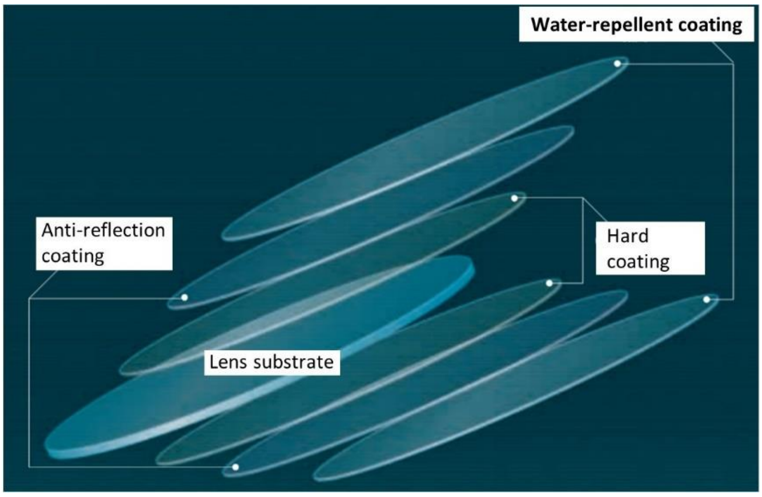


Figure 77

Functions of PFAS that required for lens coating and their alternatives.

Ophthalmic lenses

Ophthalmic lenses are daily exposed to sunlight, rain, sweat, and washed with detergents. So, high level repellency from water and oil are required for the coating of ophthalmic lenses. PFAS-based coatings are widely used because of their excellent weatherability, low friction, and repellency from water and oil. The water-repellent coatings have been developed since the 1980s, but it is still very difficult to achieve the target performances with non-fluorine compounds. Even after more than 30 years effort, no coating without PFAS, which can pass abrasion resistance, chemical resistance, and weather resistance tests assuming everyday use, has been developed yet.

As the proposal alternatives, silicone-based water repellents are representative material, though they can achieve fluorine-based equivalents in terms of contact angle to water, they have not been able to achieve fluorine-based equivalents in terms of contact angle to oil, chemical resistance, and low refractive index.

＜Test results＞

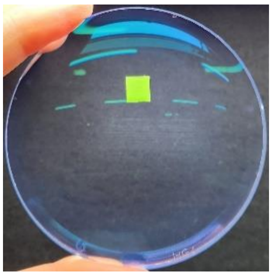
Performance comparison of fluorine-based perfluorinated polyether water-repellent coating and silicone-based polydimethylsiloxane water-repellent coating

Table 16

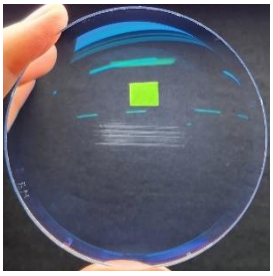
		Perfluorinated polyether	Polydimethylsiloxane
Contact angle	To water (H_2O)	108°	104°
	To oil (Oleic acid $C_{18}H_{34}O_2$)	80°	52°
Scratch resistance	Steel wool load 500g 50 round-trip	Good	Bad
Chemical resistance	After 6hr dipping in alkali（NaOH aq. pH:11）	Good	Bad
	After 6hr dipping in acid（HNO_3 aq. pH:1）	Good	Bad

＜Details＞

Pictures of appearance after scratch test



perfluorinated polyether



polydimethylsiloxane

Figure 78

Contact angle change in chemical resistance test

Table 17

		Alkali		Acid	
		Water	Oleic acid	Water	Oleic acid
Perfluorinated polyether	Before	108°	80°	108°	80°
	After	105°	70°	104°	70°
Polydimethylsiloxane	Before	105°	52°	105°	52°
	After	42°	40°	48°	31°

Water repellent effect by coating

Without coating With Coating

Figure 79 Difference among lens with coating and without coating [18]

Period required for replacement: About 1.5 to 2 years, if a non-fluorine material with PFAS-equivalent performance is produced.
Volume of PFAS to be placed on the EU market : car camera 0.32μg/year
Amount of PFAS entering in the EU as water-repellent coating materials on ophthalmic lenses

The amount of PFAS entering the EU as water-repellent coatings on ophthalmic lenses is estimated to be 300 kg/year*1. The amount of PFAS entering the EU through water coating*2 is much smaller (1 ppm to 2 ppm) than the total amount of PFAS entering the EU through all applications (140,000 to 310,000 ton/year).

<Explanation for estimating the amount of PFAS entering the EU as water-repellent coating materials of ophthalmic lenses>.

The amount of PFAS entered in the EU as ophthalmic lenses was calculated from the product of the annual sales volume of eyeglass lenses in the EU and the amount of PFAS coated as hydrophobic coating film per lens.

1. Hypothesis

・Assume that all vision corrective spectacle lenses sold in the EU have a hydrophobic coating

[18] Cannon optron https://optron.canon/ja/evaporation/pickup01.html accessed on 31 May 2023.

on both sides.

2. Estimate

1) Annual sales volume of eyeglass lenses in the EU
   200,000,000 pcs/year (200 million pcs/year) *1,*2
2) Amount of PFAS per lens (both sides) **
   1.5 x 10-3 g/pcs
3) Amount of PFAS entering the EU through spectacle lenses
   1) × 2) = 300 kg/year
4) Total amount of PFAS entering the EU
   140,000 to 310,000 tons/year *3
5) PFAS content ratio by spectacle lens
   9.7E-07～2.1E-06 (1ppm～2ppm)

**The net PFAS amount a is the solid content coated as the water-repellent coatings on both sides of the lens, excluding the solvent. Assuming that the total amount a is deposited on the total number of lenses b that are put in. The amount of PFAS per lens is calculated as a/b.

Therefore, The PFASs amount entering in EU countries as water-repellent coating materials for ophthalmic lenses is much smaller than that entered in EU as other industrial application.

3. Reference

*1 WORLD LENS AND FRAME DEMAND STUDY 2022, SWV
https://www.ewintelligence.com/world-lens-and-frame-demand-study-2022/98489.article
*2 Spectacle Lenses – Europe
https://www.statista.com/outlook/cmo/eyewear/spectacle-lenses/europe
*3 ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION, P.22/224, Socio-economic analysis, “For the EU, this resulted in an estimated amount of 140 000 to 310 000 t of PFASs introduced to the market in 2020,"
https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea

Examples of devices with lenses

PFAS is mainly used for outdoor sensors, lenses of surveillance cameras, etc., and protective panels on the surface of smartphones and other devices.
Without the use of PFAS, it would not be possible to meet the required specification of water contact angle (100° or more). As a result, the visibility of the image will be poor, and the function

of the sensor or surveillance camera will not be established.

Examples

Anti-fog and anti-smudge coating for endoscope tip lenses

Figure 80

Material:Organofluorine compound

It is an organic fluorine compound and has good hydrophilicity and water repellency, so it is highly effective in preventing dirt and water droplet adhesion. Inorganic MgF_2 and SiO_2 are used as lens coatings, but they have insufficient hydrophilicity and repellency from water, and dirt and water droplets stick to the lens during diagnosis, hindering diagnosis.

Anti-reflective coating material for endoscopes

Material:4,5-Difluoro-2,2-bis(trifluoromethyl)-1,3-dioxole,polymer with Tetrafluoroethylene （CAS RNo：37626-13-4）

Since it is a fluorine resin and has good elasticity, it has high chemical resistance and heat resistance even when coated on the WLO resin lens part. Inorganic materials such as MgF2 and SiO2 are used as lens coatings, but their elasticity is insufficient, and in reflow resistance and reusable endoscope resistance tests, coating cracks occur on the WLO resin lens, resulting in defects.

Optical fibers are embedded inside the endoscope to transmit illumination light and images of the inside of the body. As shown in the figure below, an optical fiber consists of a core and cladding made of multi-component glass, with a coating containing PFAS (fluorinated silane coupling agent) on the outside.

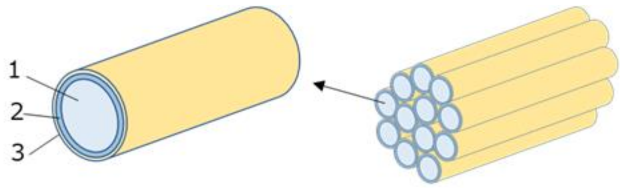


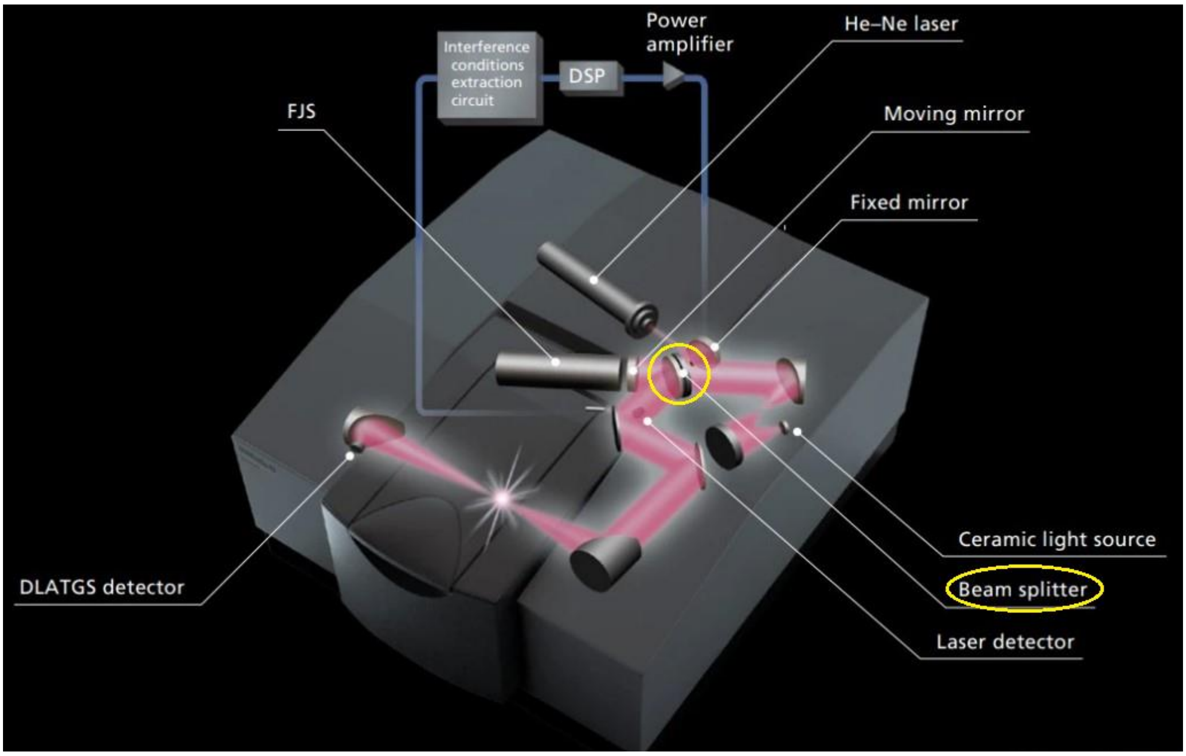
Figure. Optical fiber for endoscope
1_Core, 2_Cladding, 3_PFAS coating

Figure 81

A PFAS coating is applied to the fiber surface to ensure chemical resistance to withstand disinfection and sterilization of the endoscope, and sliding to reduce friction between members that occurs during pulling and bending operations. As a substitute, when non-PFAS materials such as boron nitride, carbon, and silicone, which are general lubricants, are used, the frictional resistance between the fibers and other materials increases when the endoscope is repeatedly bent, and more than half of the fibers break. In the worst case, there is a risk that all the fibers break and the illumination light will not reach the body cavity during the use of the endoscope, resulting in a loss of observation, which is extremely dangerous. Molybdenum disulfide is another non-PFAS lubricant, which has relatively good lubrication performance, but it is difficult to replace molybdenum disulfide because of the risk of generating toxic substances in hydrogen peroxide sterilization, which is now becoming mainstream.

Fourier transform infrared spectrophotometer (FTIR)

The interferometer inside a Fourier transform infrared spectrophotometer (FTIR) uses an optical element called a beam splitter, and potassium bromide (KBr) is commonly used as the material. Because KBr is deliquescent, humidity must be kept low. It is also necessary that dirt does not adhere to the surface. Fluororesin is indispensable as a coating material for a beam splitter because it has both moisture resistance, antifouling property, and flat transmission characteristics in the wavelength region of infrared rays.



Fiber unit for Measurement use

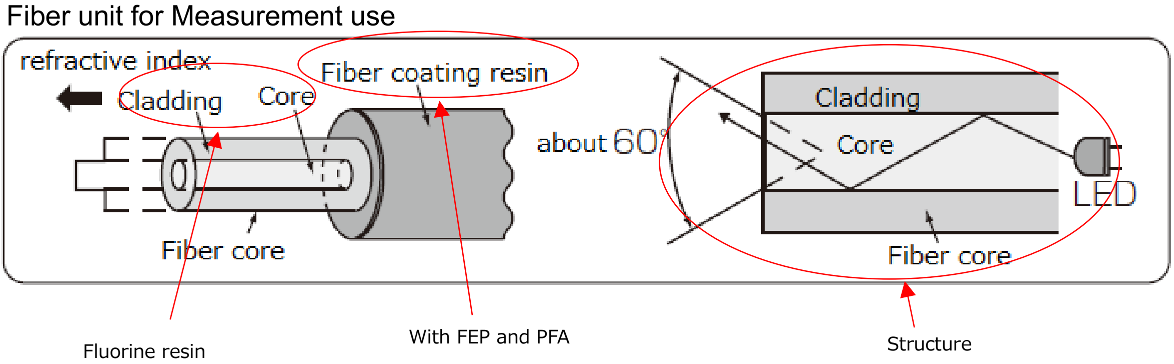
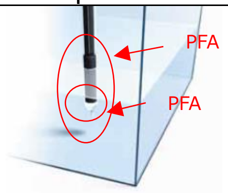
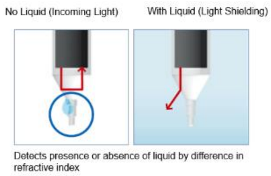


Figure 82

・This is a step index type multimode fiber (using the refractive index difference between core and clad). Fluorine resin is used for the clad. No alternative material has been proposed by the manufacturer at present. In this type of fiber, the basic optical characteristics of the fiber are determined by the refractive index difference between core material and clad material, and the material is selected by the manufacturer in consideration of the manufacturing method. Users use commercially available fiber. FEP is used for the clad and jacket, and PFA is used for the jacket and outer coating.

	Detection method and part of use	Purpose and materials used	Principle using PFA characteristics
Liquid level detection		The tip detection part is made of PFA, and the tube material which may come into contact with liquid is also covered with PFA, a material which is easily fused with the tip. In order to make the tip small and non-electric, a commercially available plastic optical fiber cable is used for guiding the detection light, and fluorine resin (specific material is not disclosed by the manufacturer) is also used as the clad material.	Use refractive index difference between PFA and liquid  **PFA is used for the detector** It uses the difference in refractive index between liquid and liquid. Detection principle ・ It utilizes the return light difference due to the refractive index difference (hereinafter referred to as n) between the material of the tip cone and the external contact material. ・ Without liquid : In a state of lower refractive index than PFA (n ≒ 1.35) (air n ≒ 1), most of the light emitted from the projection is reflected by the inner surface of the cone and returns to the light receiving portion to enter. ・ Liquid : The liquid has a large refractive index equal to or higher than that of PFA (water n ≒ 1.33, ethyl alcohol n ≒ 1.36), and the amount of light that is substantially transmitted through the conical surface and returns to the light receiving portion decreases. ・ The presence or absence of liquid is

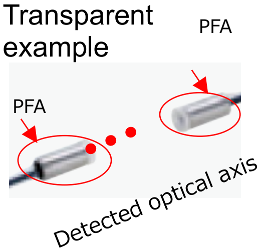
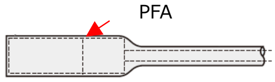
			determined by this light amount difference.
Leak detection		The detection head and cable, which may come into contact with liquid, are covered with PFA.	Use refractive index difference between PFA and liquid  Detection principle is the same as "liquid level detection"
Chemical resistance	Transparent example 	The detection head and cable, which may come into contact with liquid, are covered with PFA.	Sealing performance is ensured by fusing the tip of the PFA detection head and the tube. 

Figure 83

Due to the housing made of PFA resin, this fiber unit has higher stability against organic solvents than other products.

- The following characteristics can be obtained by using PFA resin for the fiber unit.
  - This fiber unit functions stably for the detection of organic solvents.
  - There is no alternative to this function
- This leakage sensor is used for the following applications.
  - Liquid leakage detection in semiconductor wafer cleaning and developing processes
  - Detection of tank leakage
- There are concerns about the following effects due to the unavailability of this technology :
  - Cleaning and development of a semiconductor wafer using an organic solvent cannot be carried out safely.
- For the above reasons, the prohibition of PFA resin in leakage sensors affects safety and should be exempted from this restriction indefinitely.

Optical fiber for data communication

(End products: LC, LCMS, protein sequencer protein sequencer, ICPMS, ICP, GC)

VDF plastic is used for the clad of optical fiber.VDF plastic has a lower refractive index than that of PMMA which is used for the core, and VDF is clear plastic.
https://www.pofeska.com/index.html
Its use is for data communication between devices. LED with a wavelength of 660 nm is used for the light emitting device for transmission.
https://www.broadcom.com/products/fiber-optic-modules-components/industrial/industrial-control-general-purpose/650nm/hfbr-1532etz

Figure 84

Even if there is an alternative material that meets some of the properties, we believe that it is almost impossible to cover all the properties, including optical, mechanical and environmental properties.

Medical Fiber Optics

1.Fluoropolymers used in medical optical fibers for medical devices

Applications

Figure 85

2. PFAS substance(s) used: name and CAS number (If known):

PFAS substances, including but not limited,

Poly(1,1,2,2-tetrafluoroethylene), CAS # 9002-84-0

Perfluoro-alkoxy polymer, CAS # 26655-00-5

Copolymer of hexafluoropropylene and tetrafluoroethylene CAS # 25067-11-2
Poly(ethene-co-tetrafluoroethene CAS # 25038-71-5

…

3. It is well known that C-F bonding energy is much higher energy than C-C bonding energy, the unique crystal structure of fluoropolymers, lower surface energy, hydrophobic as well. Due to the unique microstructure structure, fluoropolymers have been used in medical device, such as endoscope with many benefits, including but not limited, i. excellent biocompatibility, biostability, and patient safety history. ii.resistant to chemical, enzyme, and microbiological attacks while eliminating biodegradation issues. iii. low co-efficient of friction allows moving parts to slide with ease, loading device effectively as well. iv. low refractive index (RI), 1.3 - 1.4, makes it valuable low refractive index polymer for optical fiber application used in medical device, in which cladding materials have to be lower refractive index than core materials in order to meet total internal reflection specification through Snell's law.

4. These unique chemical-physical characteristics of fluoropolymers make medical devices safer to use for patients. However, the unique properties of fluoropolymers make them difficult to replicate with other non-fluoropolymers. For instance, to the best practices in polymer industry, the alternative materials of fluloropolymers for Polymer Optical Fiber (POF) applications are proposed as follows: Chlorotrifluoroethylene (E-CTFE), Ethylene Tetrafluoroethylene (ETFE), and so on and so furth. However, the proposed alternative materials are still under the umbrella of 2021 OECD definition of PFAS “Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it)” Silicone rubber, RI about 1.4 at 819 nm, could be proposed as an alternative substances for limited POF applications but POF need another jacket layer with lower RI materials such as fluoropolymers beyond its limitation mechanical behavior for medical optical fiber applications.

Heat medium

Refrigerators, compressors, centrifuges

Refrigerators are used for the units require temperature control, and pretreatment for measurement and analysis. Fluorinated gases are the only materials that can simultaneously provide and express multiple functions required for the proper functioning of refrigerators, such as, thermodynamic efficiency, surface tension, electrical insulation, inactivity, heat conductivity, and a wide range of operating temperature.

HFCs as F-gas will be restricted by the EU F-gas regulation and international treaties. HFCs will be replaced by organic fluorine compounds that their GWP are smaller than carbon dioxide. In that case, the substituted organic fluorine compounds (GWP>1) will be further substituted.

A succession of substitutions in a short period shortens the lifetime of specialist equipment, which is originally long-life. Refrigerators, compressors, centrifuges are used as units of specialist equipment, the derogation as spare parts should be considered. Specialist equipment cannot be repaired, it will be discarded and its lifetime will be shortened.
Refrigerants must not leak from the unit, the units that uses refrigerants such as refrigerators, compressors, and centrifuges requires the sealing materials mentioned in this document.
5(f), (g), and (h) of proposal wordings are written in Annex A of the restriction report. Specialist equipment with a long Lifetime cannot be sufficient grace periods. The grace periods should be examined.

Lubricating oil

Lubricating oil is used to control friction and wear of metal contacting parts when machines are combined to rotate, reciprocate, or otherwise operate. In addition to suppressing friction and wear, this oil also suppresses corrosion and frictional heat, and its sealing and cleaning properties allow the machine to operate smoothly.
Lubricating oil formulated with PFAS have the following characteristics

- Low friction: Reduces the adverse effects of friction on the lifetime and performance of components.
- Heat resistance: Resistance to chemical changes even when used in high-temperature environments. Resistance to ignition.
- Weatherability: Excellent oxidation stability and resistance to adverse effects of oxygen. Not decomposed by moisture.
- Chemical resistance: Resistant to chemicals such as acids and alkalis.
- Chemical resistance/cleanliness: Almost no deterioration of rubber and plastic materials.

There is no other lubricant besides fluorinated synthetic lubricants that can satisfy all of the above characteristics.

Lubricant oils in the products.

Mass Flow Controller / Mass Flow Meter

Mass flow controllers and mass flow meters are used for flow control and flow measurement of various industrial gases.
Lubricating oil is applied to joint screws and O-rings to prevent screw galling and improve the assembly of O-rings.

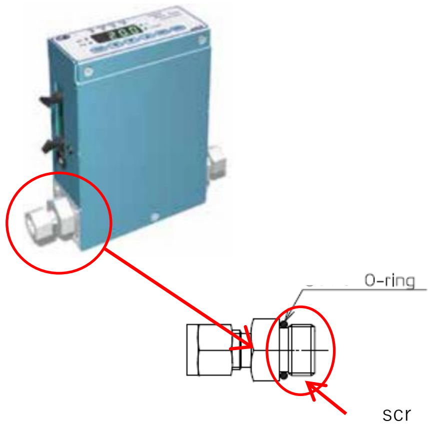


Figure 86

Ordinary grease and oil cannot be used because they may become a source of ignition when flammable oxygen gas is used, so their safety is significantly impaired.

Computed Radiography (CR) for Non-Destructive Testing

PTFE is used for the coating of parts inside the solenoid of the lock mechanism of the IP loading part of CR.

The durable life of CR is about 6 years. In order to achieve this, it must be durable enough to withstand 540,000 times of IP loading from the assumed frequency of use of CR. PTFE's low friction property is essential, and replacing it with nickel plating reduces the durability to about 1/6, reducing the durable life of the equipment from 6 years to 1 year.

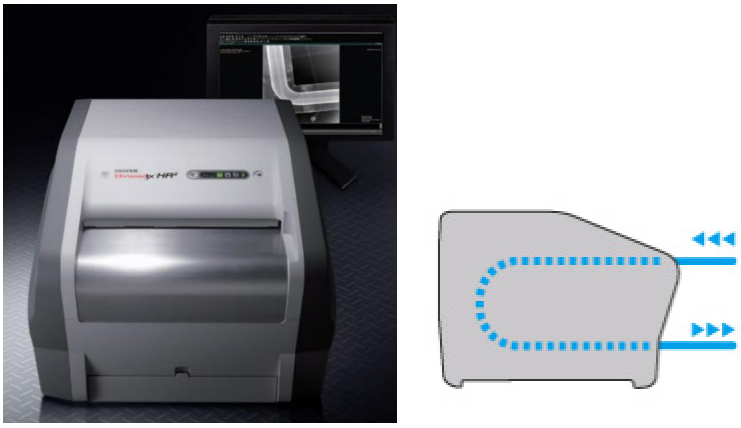


Figure 87

Pressure Transmitter

1)Measuring Principal

A pressure transmitter consists of a barrier diaphragm that contacts the process pressure, a center diaphragm that protects the sensor, and a sensor that detects the pressure.

If there is a difference in pressure on each barrier diaphragm, the fill fluid that carries the pressure creates a pressure difference on either side of the sensor, which distorts the sensor and changes its resistance.

Measure the pressure by converting the resistance change of the sensor.

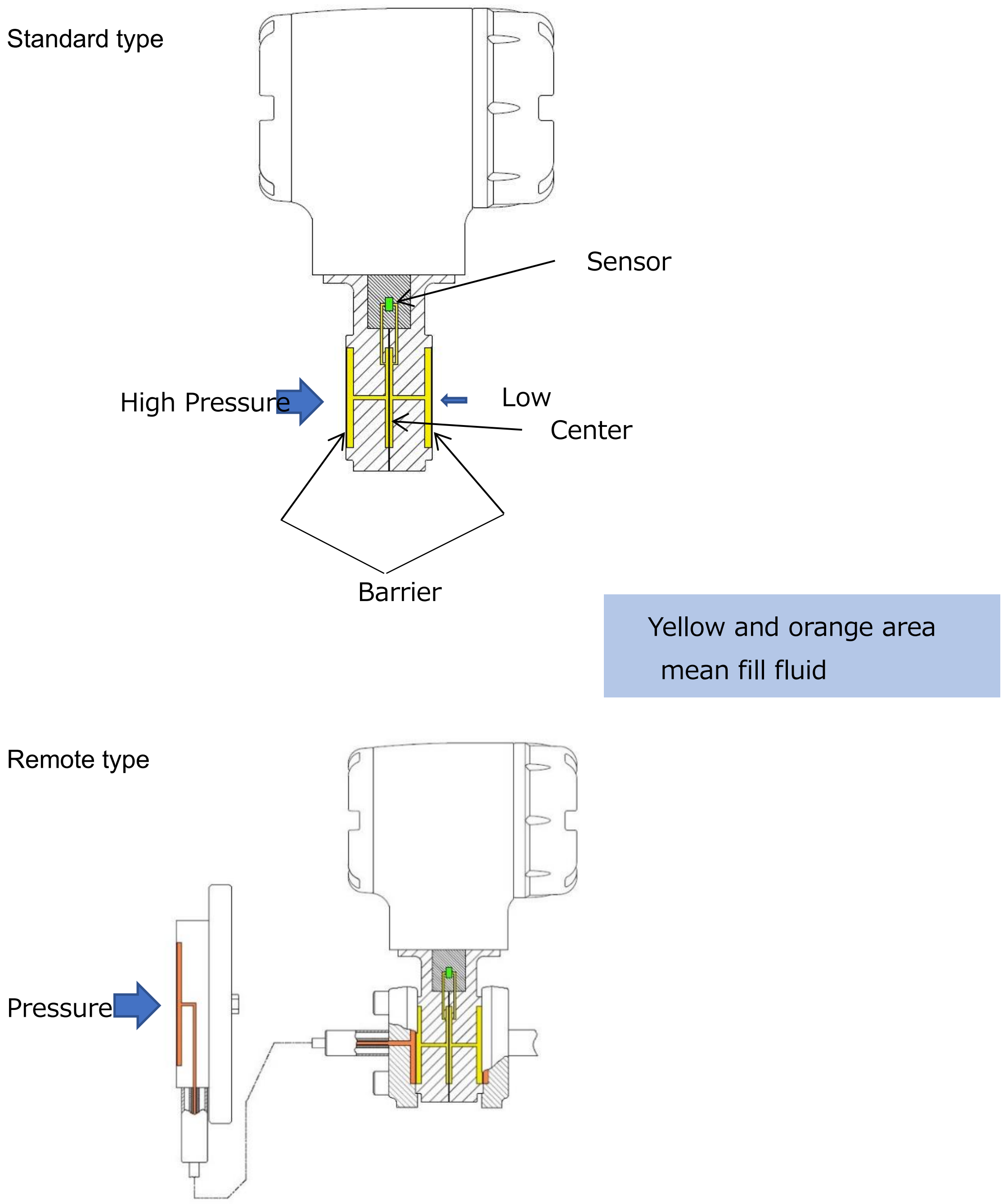


Figure 88

In addition to the following items, the properties required for the fill fluid include fluidity even at low temperatures, low viscosity, and nonflammability. The only fill fluid that offers all of these is the fluorinated fill fluid, and there is no alternative.

The diaphragms that come into contact with process fluids may be damaged due to corrosion or abrasion during use. When broken, the fill fluid comes into direct contact with the process fluid, but otherwise does not leak into the environment. This product is a WEEE target model and is in a controlled state for disposal.
Since the fill fluid is in direct contact with the sensor, high electrical insulation performance is required.
PCTFE can use up to 120 degree Celsius, Perfluoropolytrimethyleneoxide can use up to 260 degree Celsius.
Stable against strong corrosive acids and alkalis.
Does not react with chlorine and oxygen even under high temperature and pressure.
Surface tension:26～28ｍN/m
Silicon oil: Most likely fill fluid but reacts with chlorine and oxygen at high temperatures and pressures, and in the worst cases explodes.

Coding for sliding rubber parts of industrial controllers

A PTFE-coated lubricant is applied to the outer circumference of the packing to make it easier to separate the front bezel from the case. Since the housing is made of resin, there is a risk of solvent cracking, and grease cannot be used.

Figure 89 Overall product

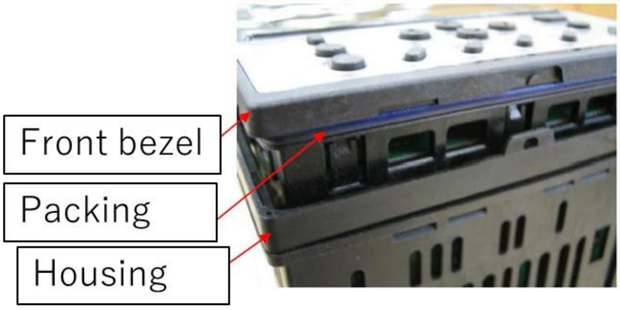


Figure 90 Packing installation explanatory diagram

Inductively Coupled Plasma Mass Spectrometer (ICP-MS)

In ICP-MS, a sample introduced into an inductively coupled plasma is ionized, and selected ions are detected by a mass spectrometer in a vacuum vessel. It is necessary to keep the vacuum degree of about 0.0001 Pa for passing ions in the vacuum vessel.

The O-ring used for the vacuum vessel is coated with grease. It is necessary to use a grease containing PFPE with a low saturated vapor pressure because the outgas from the grease interferes with the sample analysis.

In ICP-MS, an oil rotary vacuum pump is used to maintain the vacuum. PFPE is used as the sealing and working fluid of the oil rotary vacuum pump. PFPE is chemically stable and does not deteriorate and fail due to chemical reaction even when gas containing acid is evacuated under vacuum. When conventional synthetic oil is used, the period of stable analysis is shortened and the frequency of pump oil disposal will be increased.

Energy dispersive X-ray fluorescence analyser (EDXRF)

In EDXRF, the apparatus may be vacuumed in order to analyze light elements. In the apparatus, there is a driving mechanism for switching the X-ray irradiation diameter according to the shape of the sample and switching the filter to improve the detection sensitivity. It is necessary to use grease containing PFPE with low vapor pressure so that grease used for these driving mechanisms does not scatter in vacuum and contaminate the equipment.

Others

Solvent for oil content analyzer

Solvent for oil content analyzer is chlorotrifluoroethylene (CAS RN 9002-83-9). (hereinafter "specific chlorotrifluoroethylene solvent")

Solvent extraction-nondispersive infrared absorption method is used for oil content measurement. The light from the light source enters the cell filled with the oil-extracted solvent. After that, an interference filter introduces only the absorption wavelength range (3.4 to 3.5 μm) attributed to stretching vibration between carbon-hydrogen bonds (C-H) into a detector (pyrosensor). As the oil content in the oil extracting solvent increases, the light transmitted through the cell is decreased, and the current value generated by the pyroelectric effect decreases. The oil content can be calculated using this current value.

Infrared absorption method for oil content analysis is standardized in ASTM standard D7066-4.

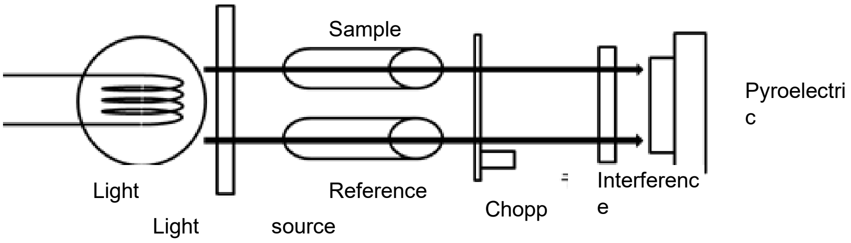


Figure 91 Oil content analyzer bench structure

Extraction of oil from solid samples is performed by immersion as shown in the figure below.

Figure 92 Method for extracting oil from solid samples

Functions of PFAS required by solvent for oil content analyzer and substitutability.

The oil content is quantified by Beer-Lambert law using absorption attributed to carbon-hydrogen stretching vibration at 3.4 to 3.5 μm (2941 to 2857 cm^{-1}). Therefore, the extraction solvent must not have absorption in this wavelength range. Chlorotrifluoroethylene has no carbon-hydrogen bond (C-H) in its molecular structure and has no absorption at 3.4 to 3.5 μm, so it is suitable as a solvent for oil content measurement using the solvent extraction-nondispersive infrared absorption method.

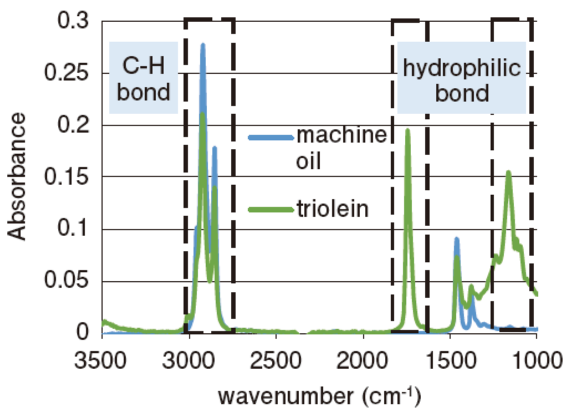


Figure 93 IR spectrum of oil

Existing solvents used for cleaning parts and general reagents that do not have carbon-hydrogen bond (C-H) in their molecular structures were verified, but it could not be adopted because it did not meet the following performance requirements.

- Influence of infrared absorption

From the principle of the analyzer, it is necessary to have no absorption higher than that of the specific chlorotrifluoroethylene solvent in the wavelength range of 3.4 to 3.5 μm (2941 to 2857 cm^{-1}).

- Safety

The specific chlorotrifluoroethylene solvent is not listed in the Montreal Protocol and the Kigali Amendment and are not classified in the EU CLP Regulation Hazard Classification.

With a boiling point of 134°C and a vapor pressure of 1.33 (kPa), it does not easily volatilize during use, so it can be used with normal ventilated environment. Similar safety and operability are required for alternative material.

- Analyzer performance cannot be achieved

The measurement range of the oil content analyzer is 0-200 mg/L. The light source and the detector are designed and adjusted to achieve the specified performance in the range of 0-200 mg/L when measured using the specific chlorotrifluoroethylene solvent.

Therefore, as with the influence of infrared absorption, a low absorption rate equivalent to that of the specific chlorotrifluoroethylene solvent is required for measurement in the analyzer range of 0-200 mg/L

Table 18　comparison of solvents

Composition	Specific Chloro trifluoro ethylene	1-bromo propane + stabilizer	aliphatic hydro carbon + ester	Decane	Undecane	1-bromo propane	Trichloro-ethylene	tetrachloro-ethylene
Name	Chloro-trifluoro-ethylene polymer			Decane	Undecane	1-bromo-propane	Trichloro-ethylene	tetrachloro-ethylene
(CAS RN)	9002-83-9	106-94-5 stabilizer: unknown	unknown	124-18-5	1120-21-4	106-94-5	79-01-6	127-18-4
Boiling point（degree Celsius）	134	48	174	172	196	71	87	121
Classification of EU CLP Regulation	Not Classified			Not Classified	Not Classified	Flam. Liq. 2 Skin Irrit. 2 Eye Irrit. 2 STOT SE 3 STOT SE 3 STOT RE 2 Repr. 1B	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3 Muta. 2 Carc. 1B Aquatic Chronic 3	Carc. 2 Aquatic Chronic 2
Montreal Protocol and Kigali Amendment	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Absorption around 3.4-3.5 μm	Small	Large	Large	Large	Large	Large	Large	Middle
KB value	31	13	-	-	-	121	130	90
400 mg oil solubility	Possible	-		-	-		Possible	Possible
Alternative?	-	Unsuitable	Unsuitable	Unsuitable	Unsuitable	Unsuitable	Unsuitable	Unsuitable

Solvent PFAS Release Risk

Using: With a boiling point of 134°C and a vapor pressure of 1.33 (kPa), it does not easily volatilize during use. And the specific chlorotrifluoroethylene solvent is not listed in the Montreal Protocol and the Kigali Amendment and are not classified in the EU CLP Regulation Hazard Classification, so safe to use.

After use: Only the oil can be removed from used specific chlorotrifluoroethylene solvent with a dedicated equipment and can be reused

Existence and Possibility of Alternatives: There is no alternative solvent that can ensure the same performance and safety as the current one.

Period required for substitution when a substitute material is developed: 4-5 years

Solvent: There is no alternative solvent that can ensure the same performance and safety as the current one.

X-ray Film for Non-Destructive Testing

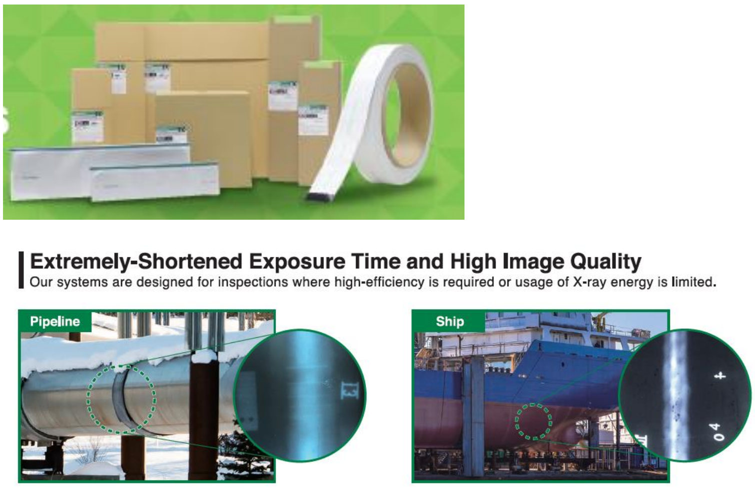


Figure 94

X-ray film for non-destructive testing is widely used for the following inspections.
Pipelines, Aircraft engines, Nuclear power plants, Bridges, Structures, Fine ceramic parts, Electronic parts, Castings, Welds

The following properties of PFAS are essential for X-ray films, and PFAS (particularly fluorosurfactants) is the only material that can provide these properties with a single material, and at present there are no substitutes.

- Surfactant

  Strong hydrophobicity of the perfluoroalkyl group is required in the coating manufacturing process.

  By using a perfluoroalkyl group as the hydrophobic group of the surfactant, the surface activity is strengthened, and the surface tension of the coating liquid is lowered, thereby improving the coating performance.

- Antistatic agent

  In order to achieve the performance required for X-ray films for NDT, the strong electronegativity of fluorine atoms is necessary.

  Due to the strong electronegativity of the fluorine atom, perfluoroalkyl groups tend to be negatively charged.

  The gelatin used in the film is naturally prone to positive charging, and PFAS is used as a material to lower it to the negative side in order to adjust this to an appropriate charging characteristic (charging series).

  Proper electrification makes the film less likely to be charged with static electricity during X-ray photography, reducing the risk of blackening (image defects) due to discharge.

<Example of application＞

Pipeline inspection

Aircraft and engine inspection

Nuclear power plants

Bridges

Structures

Fine ceramic parts

Electronic components

Castings

Welded parts

(Technical Explanation of Non-Substitutability)

Controls the surface tension of the coating solution as a coating aid.

Stabilizes dispersion of hydrophobic functional materials as an emulsion dispersing agent.

As a conductive material, it adjusts the electrostatic charge of the coating film and suppresses statics.

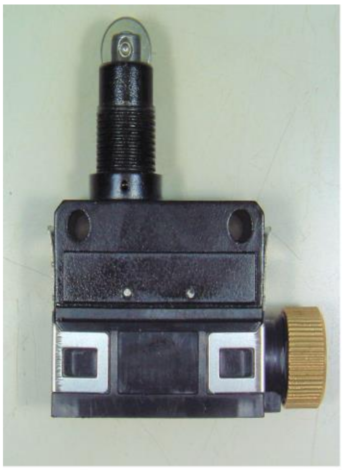
As a lubricant, it imparts slipperiness to the surface of the material.

Adding anti-fouling property to the surface as a surface modifier

PFAS (especially F element surfactant) is the only compound that can provide many of these functions in a single material, and there are no alternative candidates at this time.

Limit switch button, housing and rubber seal

1. Internal switch button
2. Painting the housing
3. Used for each rubber seal of limit switch



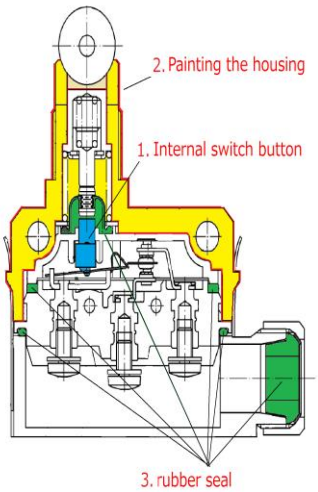


Figure 95

Although the exterior coating can be changed to other coatings, fluorine is the lowest and most suitable for internal sliding properties.
Sliding：plunger and housing
Sliding: internal switch button and internal switch cover
Addition of fluorine improves slidability.

Table 19 [19]

	Fluoropolymer	Resin	
	PTFE	PE	POM
Dynamic friction coefficient (ud)	0.09	0.13	0.18
Heat-resistant(degree Celsius)	260	70-110	80-120

The retention of seals at high temperatures is superior to other rubbers.

Switching to silicone rubber is difficult to adopt because of the risk of contact failure.
In addition, it is often used for applications such as cutting fluid that damage silicon rubber, so it cannot be used.

High-Speed Impact Testing Machines

To absorb shock

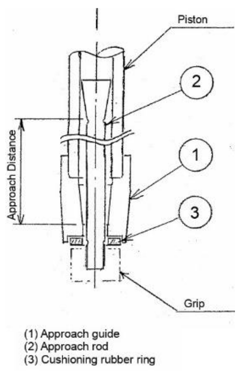


Figure 96

Strength, shock absorption capacity (speed 20 m/sec)
It is used in a thermostatic bath. It must withstand temperatures between -40 and 150 degrees Celsius.

[19] https://www.y-skt.co.jp/magazine/coating/lowfriction/

Liquid leak sensor

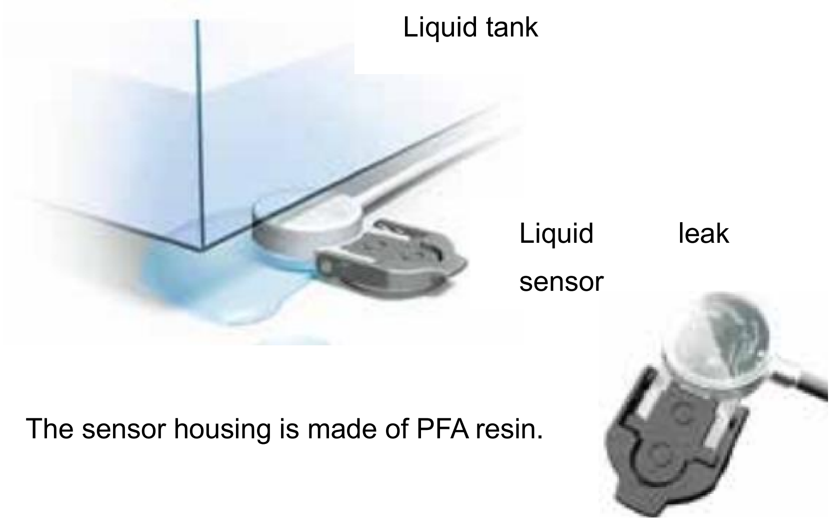


Figure 97

Schematic diagram of sensor structure
The sensor housing cover, case and tube are made of PFA resin.

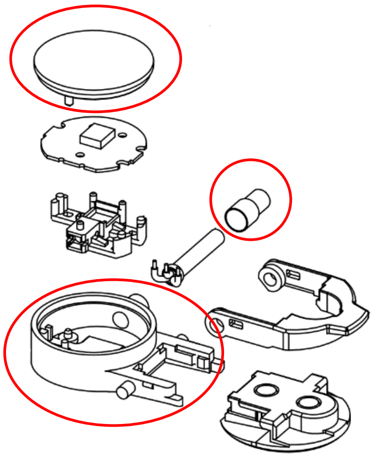


Figure 98

Due to the housing made of PFA resin, this leakage sensor has higher stability against organic solvents than other products.

- The following characteristics can be obtained by using PFA resin for the leakage sensor.
  - This leakage sensor functions stably for the detection of organic solvents.
- This leakage sensor is used for the following applications.
  - Liquid leakage detection in semiconductor wafer cleaning and developing processes
  - Detection of tank leakage
- There are concerns about the following effects due to the unavailability of this technology :
  - Cleaning and development of a semiconductor wafer using an organic solvent cannot be

carried out safely.

Mold release coating for the injection molding of plastic lenses

In the injection molding of plastic lenses and lens unit housings, we use a mold release coating on the surface of the mold to prevent the plastic from sticking to the mold during removal from the mold (mold release) after filling the mold with plastic. Thereby, it can improve moldability.

The type of PFAS for the release coating is not disclosed due to confidential information. If this release film is not coated, the yield of the molding process will be less than 10%.

The reasons why release coating is especially necessary for plastic lenses and lens unit housings are as follows.

1. Effect on lens optical performance

   If the next injection molding is performed with plastic adhering to the mold, the part of the molded product corresponding to the part of the mold to which the plastic has adhered will be transferred in the shape of the adhered plastic, creating a dent in the molded product. Especially in the case of lenses, if even a part of the lens is dented, optical performance is greatly affected and the product becomes defective.

2. Decreased production efficiency

   When resin adheres to the mold, molding must be stopped and the adhered resin removed from the mold. If this frequency is high, production efficiency will decrease. Plastic lenses also tend to adhere, mainly because of the following reasons:

   2-1. Since the required shape accuracy is very strict, the pressure to transfer to the mold must be high. As a result, the resin tends to stick to the mold during mold release more than other plastic parts.

   2-2. Dirty mold surfaces due to continuous molding make it easy for resin to adhere to the surface.

Standard white calibration plate (Colorimeters)

Colorimeters, which measure and quantify color, are widely used for quality control of "color" of products and materials in various industries, such as automobiles, information appliance (IA), cosmetics, and apparel, to improve management efficiency and quality.

A high-performance colorimeter measures the reflectance at each wavelength (360 to 740 nm for visible light) by spectroscopy of the light reflected from the object being measured at each wavelength.

To obtain accurate measured color values, it is necessary to calibrate the measurements when starting up the colorimeter and in some cases once every few hours, and a white calibration plate is used for this purpose.

A white calibration plate is a standard reflector with a pre-valued reflectance, which must have

a reflectance of at least 95% (ideally 100%) at all measurement wavelengths.
Crystalline PTFE is used as the standard reflective calibration plate.

PFAS functions required by standard reflective calibration plates and the possibility of alternatives
White calibration plates (standard reflectors) need lots of requirements as follows; high reflectance (95% or higher) in all visible light ranges as described above, as well as material stability, such as stability under various conditions of use, suppression of surface degradation (decrease in reflectance) due to light exposure and aging, and no change in reflectance due to cleaning using chemical products (e.g. silicone solvent).

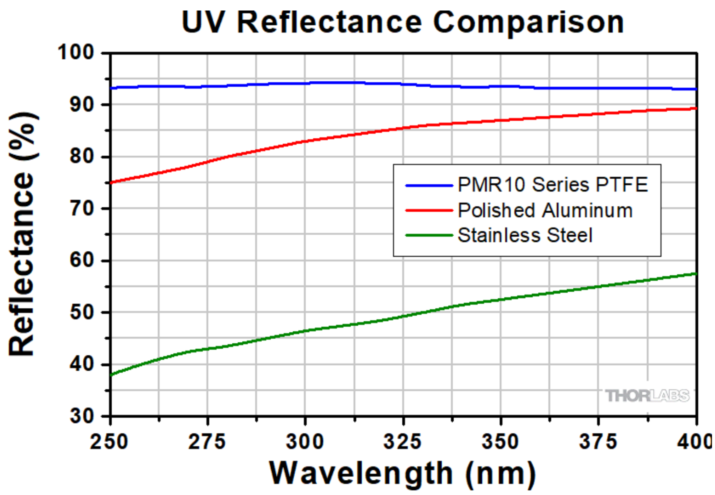


Figure 99　UV Reflectance Comparison [20]

Most of the white reflective calibration plates used in current products are made of leaded ceramics. Lead is an exempted use (category 9, 13b) of the RoHS Directive, but this is expected to expire soon. After the expectation, we have searched for an alternative for a long time, and PTFE is the only material that satisfies the requirements. There are currently no alternatives to PTFE, except for leaded ceramics, which will be regulated by the RoHS Directive.

UV-visible spectrophotometer、Fluorescence spectrophotometers

20 https://www.thorlabs.co.jp/newgrouppage9.cfm?objectgroup_id=13871#:~:text=%E3%83%9D%E3%83%AA%E3%83%86%E3%83%88%E3%83%A9%E3%83%95%E3%83%AB%E3%82%AA%E3%83%AD%E3%82%A8%E3%83%81%E3%83%AC%E3%83%B3(PTFE,%E3%82%88%E3%82%8A%E3%82%82%E5%84%AA%E3%82%8C%E3%81%A6%E3%81%84%E3%81%BE%E3%81%99%E3%80%82 last accessed on June 11 2023

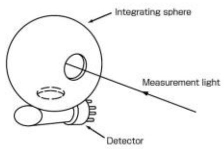


Figure 100

Integrating spheres have a spherical-shaped inner surface and inner wall made of light scattering material. Integrating spheres are effective in causing a light beam (measurement light) entering the sphere to scatter uniformly.

Integrating spheres have a hole (aperture) at the position irradiated by the measurement light. When measuring the measurement light which passes through the sample and enters the sphere, the sample is placed at this aperture. The detector is installed at an aperture (mainly, at the top or bottom of the integrating sphere) where it is not directly irradiated by the measurement light.

It is recommended to use an integrating sphere when measuring samples, such as semi-transparent or opaque solutions and lenses, that change the direction of light.

PTFE has a reflectance of 95% or more in visible light and a reflectance of 90% or more in near infrared, and is suitable for integrating sphere materials. Moreover, it has a characteristic that does not easily affect fluorescence analysis. On the other hand, the reflectivity of BaSO4, which is often used, is reduced in the near-infrared region, and it is inferior to that of PTFE, and has the disadvantage that the coated surface of BaSO4 is easily peeled off, so it cannot replace PTFE.

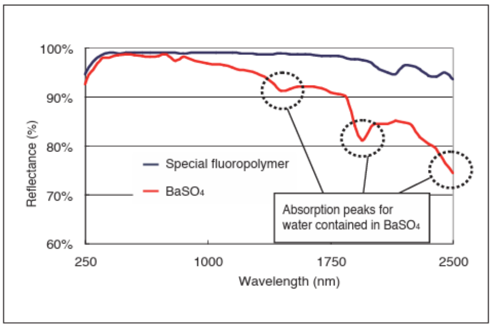


Figure 101

Cutting parts

(Example of finished products: diaphragm galvanic oxygen sensors, oxygen detectors)

It is a part manufactured by cutting a block of resin. Because it is a small-lot production product, it is produced by cutting that does not require mold costs. Another reason for cutting is that there are places where sealing properties are required.

Here, I will touch on the machined parts used in the casing of the galvanic oxygen sensor. There are various materials, but we will describe the case where PTFE and PFA, which have higher chemical resistance, are used.

Figure 102 Example of Fluoroplastic Cutting Parts

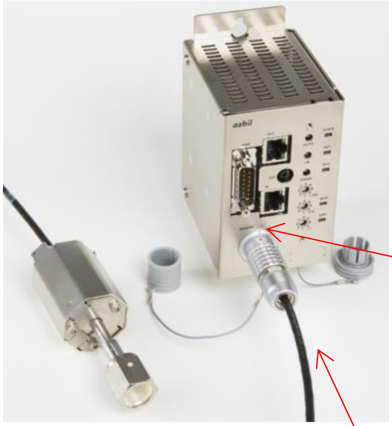
Please see "Membrane filters" for galvanic oxygen sensors

Fluoropolymer casing are required when parts require chemical resistance. There is a need to measure oxygen concentration even in places where acids, alkalis, and organic solvents are always present. In this application, it is necessary to have chemical resistance such that it does not deteriorate even when it comes into contact with various gases (acids, alkalis, organic solvents), does not elute components even when it comes in contact with any sample.
Also, as a material, it is necessary to have weather resistance properties such as not changing in a 10-year exposure test and not softening or deforming in the surrounding environment of -40 to 70 °C.
If you try to perform the same function with other materials, for example, phenolic resins and polyamide resins can be mentioned as resins that are resistant to acetone as a general organic solvent, but phenolic resins are resistant to strong alkalis. Polyamide-based resins cannot be used as a substitute because they do not have durability against strong acids.

Sapphire Capacitance Diaphragm Gauge

Components corresponding to a heater operating temperature of MAX 250°C
For the picture of this products, please see the explanation in electric wires and insulation.

Components compatible with gauge head operating temperature of MAX 250°C



LEMO connector ⇔
Board connection cable
→
Cable jacket and dielectric
contain Perfluoroalkoxy

Sensor, Temperature sensor for control ⇔ Board connection cable
→ Sheath, insulator, etc.
contain Perfluoroalkoxy alkane(PFA)

Figure 103

Humidity element for humidity sensor and dew point temperature sensor

Sector "Electronics and semiconductors (Annex E.2.11.)" "Construction products (E.2.13.)"

Sub uses :Monitoring and control instruments Heating, Ventilation and Air Conditioning(HVAC)

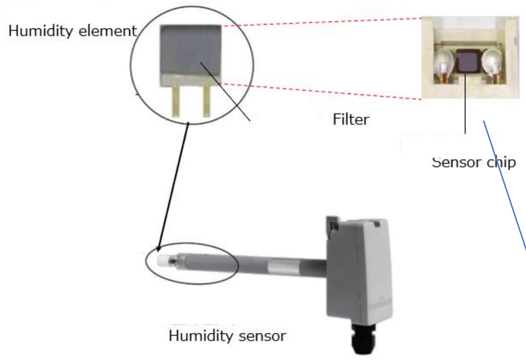
Polymeric PFAS /Fluorinated polyimide

Generic name for the final product: Humidity sensor, Dew point temperature sensor

Common name for application parts: Humidity element

Detailed application description:

The humidity sensor chip used for a humidity sensor and a dew point temperature sensor measures humidity by capacitance change between electrodes sandwiching the moisture sensitive film. The thickness of the moisture sensitive film is several μm.



Schematic diagram of sensor chip structure

Polymer moisture-sensitive membrane is made of fluorinated polyimide

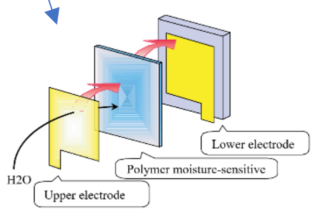


Figure 104

This humidity sensor is used for the following purposes

- Humidity sensor installed in an environment in which condensation appears on the sensor itself, such as inside the HVAC duct and the outside air intake section.

The following features can be obtained by using fluoride polyimide for humidity sensor

- The humidity sensor works stably for a long period in an environment where the sensor is condensed (100% humidity).
- Nothing to replace this function.

The humidity sensor has higher stability under high temperature, high humidity and condensation than other products due to the humidity sensitive membrane using fluorinated polyimide.

The prohibition of this technology is concerned about the following effects.

- It won't be able to properly measure and control humidity on HVAC system in an environment in which condensation appears on the sensor itself.
- Other polymer materials such as methyl methacrylate resin (PMMA), polyimide, polysulfone, etc. can be candidates as alternative technologies and materials.
- However alternative technology requires replacement of the sensor every time condensation occurs. For example, it is known that condensation appears on a humidity sensor which is inserted into an outside air intake duct several times a year depending on the weather. Humidity sensors without moisture sensitive membrane using fluorinated polyimide for this application will require replacement at least once a year. Moisture sensitive membranes using fluorinated polyimide can withstand at least 8 years of use.

Performance requirements for materials (PFAS)

Heat-resistant: 180 degree Celsius as a humidity sensitive element

Repellency from water: Electrical insulation in condensing environments

Chemical resistance: Resistant to organic solvent atmosphere

Alternative Considerations: No substitute material

Required derogation period: 13.5 years or more

Valve for air volume and room pressure control

Materials for ensuring sliding, **corrosion resistance**, chemical resistance, and solvent resistance for air volume valves.

Use sector: "Medical devices (Annex E.2.9.)", "Construction products (E.2.13.)"

sub-uses: Control valve, Heating, Ventilation and Air Conditioning(HVAC)

PFA：26655-00-5

PTFE：9002-84-0

PVDF：24937-79-9

ETFE：25038-71-5

Generic name for the final product: Valve for air volume and room pressure control

Common name for application parts: Body, Pivot arm, S-link, Shaft, Spring, Cone, Brackets, Seal), Tap, e-crip), Bush, Slider, Sleeve, Cap, Bolt

Detailed application description

The two main applications of valves are below.

(1) To be installed as a local exhaust ventilation system to prevent workers from being exposed to substances harmful to the human body, such as in chemical manufacturers and biotechnology research laboratories.

For example, when a worker opens or closes the door of the local exhaust device (red dotted frame in Figure 106), the differential pressure across the valve suddenly changes, but by taking advantage of the good sliding property, the valve can be instantly changed to the appropriate valve opening position to maintain exhaust at a constant air volume.

In addition, since valves must control fluids containing various chemicals and solvents, they must be resistant to corrosion, chemicals, and solvents.

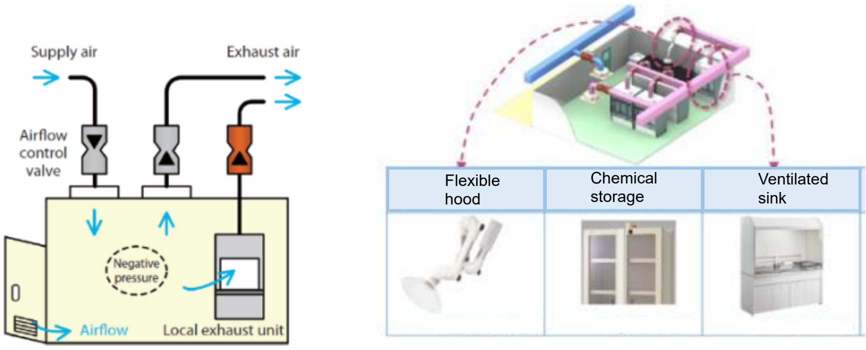


Figure 105　Example of air volume control in a chemical/ Other exhaust applications

(2) The device is installed in hospital rooms and wards as a negative-positive pressure control device to secure hospital beds for patients with infectious diseases and to protect healthcare workers from infection risk.

Even when the differential pressure across the valve suddenly changes due to the opening and closing of the hospital room entrance door, etc., the air supply and exhaust valves respond instantly by taking advantage of their good sliding characteristics and change to the appropriate opening position, thereby always maintaining the pressure difference between the room and outside.

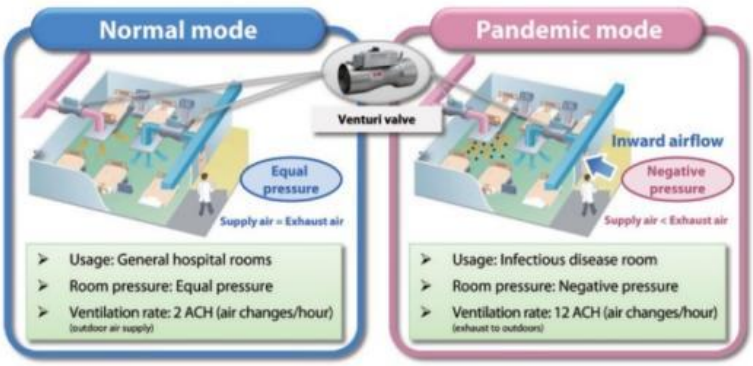


Figure 106　Image of negative and positive pressure control in a hospital room

The parts used in valves that include candidates for regulation are below.

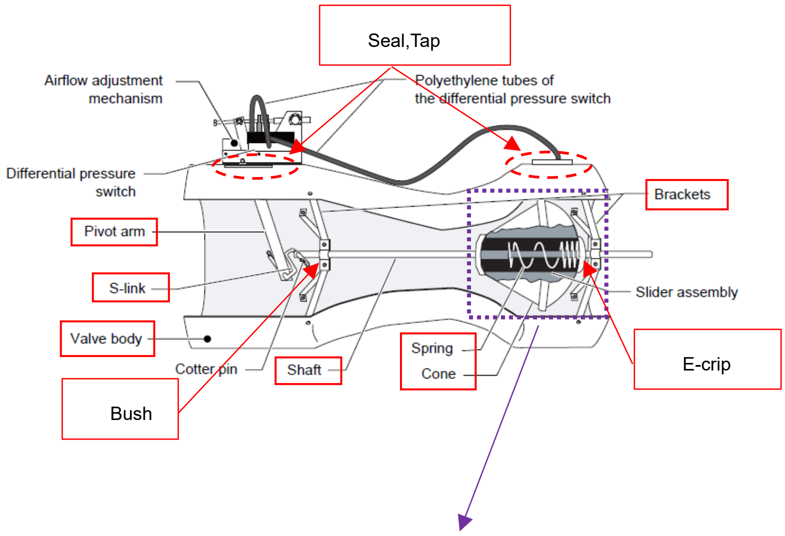


Figure 107 Valve image

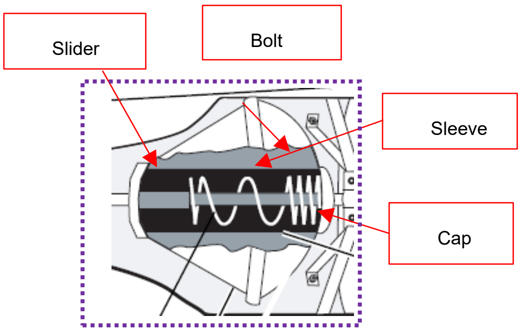


Figure 108 Slider assembly

(1) For valves that do not require corrosion resistance, chemical resistance, or solvent resistance, parts (Slider, Sleeve, Cap) containing PTFE should be used to ensure sliding properties.

(2) Valves that require corrosion resistance, chemical resistance, and solvent resistance use the following parts to ensur

e the above three functions and sliding properties.

・Parts containing PTFE (Slider, Sleeve, Cap, Bush, Seal, Tap)

・Parts containing PFA (Shaft, Spring)

・Parts containing PVDF or ETFE (Body, Pivot arm, S-link, Cone, E-crip, Bolt)

Technical Description of Essential Uses

As mentioned above in “Detailed application description”, valves must have the sliding property required to respond instantly to sudden disturbances, and the corrosion, chemical, and solvent resistance required to control fluids containing various chemicals and solvents.

Therefore, it is necessary to place parts containing PTFE, PFA, PVDF, and ETFE for mechanisms that need to ensure sliding properties and for channel parts that are in contact with the control fluid.

(1) Ensure sliding properties

Other polymeric materials may be used as an alternative to PTFE for ensuring sliding properties. However, since there is no material with lower sliding resistance than PTFE, the sliding resistance force will increase and the sliding performance required for valves cannot be ensured.

(2) Ensure sliding properties, corrosion resistance, chemical resistance, and solvent resistance

Other polymeric materials, such as rubber and resin, may be used as alternatives to PFA, PTFE, PVDF, and ETFE for the purpose of ensuring the above four functions.

However, the alternative materials cannot ensure the sliding properties, corrosion resistance, chemical resistance, and solvent resistance required for valves due to the deterioration of sliding properties as described in (1) and the lack of resistance to various chemicals and solvents.

The following effects are feared as a result of the unavailability of these technologies.

The inability to use PFA, PTFE, PVDF, and ETFE for valves will make it impossible to carry out normal operations at chemical manufacturers, biotechnology research facilities, hospitals, and other facilities.

This will have a profound impact on the production and supply of medicines, the progress of research in biotechnology, and isolated medical treatment, including coronas.

For the above reasons, the prohibition of the use of parts containing PFA, PTFE, PVDF, and ETFE in valves should be exempted from this restriction in terms of ensuring safety for the human body.

In terms of disposal, the restriction should not be applied to valves containing PFA, PTFE, PVDF, and ETFE, since these components can be used until the product reaches its original service life, leading to a reduction of waste in general.

Performance requirements for materials (PFAS)

Heat-resistant: Heat-resistant max93 degree Celsius

chemical resistance: Resistant to chemicals, solvents and corrosive fluids

Sliding performance: Wear resistance due to sliding, sliding performance

Non-adhesion: Non-adhesion of foreign matter

Mechanical parts for sliding or releasing applications used in "Specialist equipment"

Fluoropolymers with excellent low friction, and self-lubrication and mon-adhesion. properties are often used in mechanisms that require sliding with plastic and metal parts or releasing from sticky materials.. The following common characteristics are related to the reason why fluoropolymers are particularly selected for "Specialist equipment".

1) Some final products handled by "Specialist equipment" require use in special environments. For example, in facility environments where foods, liquids, powders, etc. are handled, consideration must be given to high temperature, high humidity, generation of dust, or hygiene management.
2) Equipment used in social infrastructure such as factories is required to have performance such as automatic operation, trouble-free operation, easy preparation and setup changes. This enables us to provide society with high-quality, low-cost products and services.
3) When handling products with equipment, it is required to minimize the impact on product quality, such as damage or adhesion of foreign matter.

From the above, the mechanical parts for sliding applications used in " Specialist equipment " are required to have the following properties.

- Repellency from water and oil / non-adhesion
- Low friction, self lubrication
- Heat resistance
- Chemical resistance (Acid resistance, Alkali resistance, Oil resistance, Ozon resistance)

Table 20 summarizes the performance of major alternative materials with respect to the required performance.

Table 20

Material		PTFE	POM	HDPE	PA66
Material or Coating		Material/ Coating	Material	Material/ Coating	Material/ Coating
Low friction	Coefficient of friction	0.04	0.2~0.3	0.2~0.3	0.18~0.4
Repellency from water and oil	Contact angle of water [deg]	114	（Equivalent to PA66）	88	77
	adhesion energy [dyne/cm]	43.1		75.2	97.7
Oil resistance	Contained in food	◎	〇	◎	◎
Acid resistance	Contained in food	◎	×	◎~〇	△~×
Alkali resistance	Contained in detergents, etc.	◎	×	◎	◎
Ozon resistance	Special cleaning	◎		△	×
Heat resistance	Hot food	◎	△	△~×	△

* Non-adhesion and Repellency from water and oil are according to the above-mentioned property table. Others are summarized by the author of this section based on multiple documents.

Appropriate materials are selected and used according to the required performance that varies depending on the work environment and target product. From the table, PFAS shows good properties with respect to water/oil repellency and heat resistance. Cases where PFAS is used as an irreplaceable material include, for example, use in environments where food and liquids are handled, as well as guide parts or blade surface coatings where adhesion is undesirable.

Heating pressure bar with knife of packaging machine (with PTFE Coating)

Instrument example (Packaging machine for food industries)

Figure 109

Food Contact Parts of Measuring Instruments

The following performances are required for the food contact parts of measuring instruments for pre-packaging food.

1) Conformity with (EC) No 1935/2004, (EU) No 10/2011, etc. is required for safety when materials used are exposed to the body through food.
2) For the purpose of reducing food waste and cleaning burden, and ensuring supply by automating production, it is required that food does not adhere easily.

There are two technical approaches to the anti-adhesion performance of 2). The first is "a) reducing the contact area with food" and the other is "b) using water- and oil-repellent, non-adhesive materials." The Table 21 summarizes the performance of the main means currently in practical use considering the operating environment conditions. Each means is provided in the form of material or coating.

Table 21

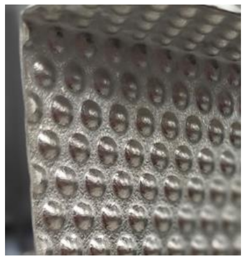
Technical approach		(1)contact area	(2) water- and oil-repellent, non-adhesive materials		
Means		Stainless steel embossed structure	PFAS(PTFE,PFA)	Ceramic	HDPE
Material or Coating		Material	Material/Coating	Coating	Material
Repellency from water and oil	Does not adhere to water or oil	× Oil hardens and accumulates.	◎	◎~○	○
Non-adhesion (for hard foods)	Food does not remain on equipment.	◎~○	◎	○~△	○
Non-adhesion (for soft foods)		△~×	◎	○~△	○
Oil resistance	Contained in food	◎	◎	◎	◎
Acid resistance	Contained in food	◎	◎	◎	◎~○
Alkali resistance	Contained in detergents, etc.	◎	◎	○	◎
Ozon resistance	Special cleaning	◎	◎	◎	△
Heat resistance	Hot food	◎	◎	◎	○
Durability	Hard to wear	◎	△	○	△

*PFAS and PE are according to the above-mentioned property table. SUS and ceramics are summarized by the author of this section based on multiple documents.

In terms of technology in the practical stage, PFAS is superior in all items except durability. Since the required performance differs depending on the type of food and the factory environment, means other than PFAS may be selected. However, it is clear from the above table that substitution is not possible in all cases, which is the reason why exclusion is necessary. Also, the determination of substitutability must be tried in all cases using actual food in a real working environment, which is why the substitution period is necessary.

Instrument example (Weigher for food industries)

Example of oil accumulation (Food contact part is a flat stainless steel without coating)



Example of stainless steel embossed structure

Figure 110

Atomic Absorption Spectrophotometer

There is a furness method as a method to atomize a sample. The element in the sample is atomized by the heat generated by injecting the sample into a graphite tube and passing a current through the tube. The material constituting the heating section is required to have mechanical strength, electrical insulation for passing electric current, heat resistance to high temperatures of the heating section, and chemical resistance not to be degraded by vaporized sample vapor. Materials other than fluororesin cannot satisfy all these characteristics.

Protein sequencer

Protein sequencers transfer proteins to hydrophobic membranes for analysis. At this time, chemical resistance to acidic/basic gases and organic solvents and binding ability to proteins are required for the membrane. PVDF (polyvinylidene fluoride) membrane is used as a material satisfying these characteristics.

Fourier transform infrared spectrophotometer (FTIR)

Since the optical components inside the FTIR tend to deteriorate due to humidity, humidity must be kept low using a dehumidifier. Among dehumidifiers, those that electrolyse moisture with a perfluorocarbon solid polymer electrolyte membrane (Nafion) have features such as noise-free, no water droplets, small size, light weight, and long life, and are indispensable parts for FTIR. For example, silica gel desiccants need to be replaced frequently, and if they are forgotten, the moisture absorption capacity is lost and FTIR cannot be used.

Gas Chromatograph (GC)

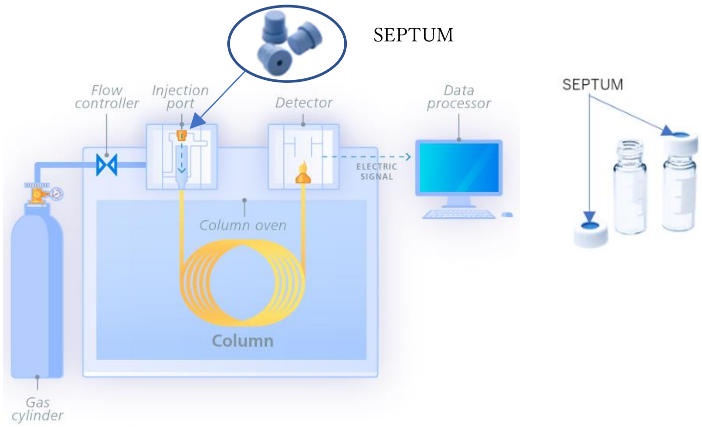


Figure 111

In GC, a liquid sample is injected and heated, and the vaporized component is separated by a column and detected.
In the sample injection port, a needle is inserted through a plug called a septum to inject the sample. The sample injection port is heated up to 350°C. The septum must have elasticity, airtight, chemical resistance, and heat resistance so that the vaporized sample does not leak. No SEPTUM material other than PTFE satisfies these conditions.
If silicon rubber or butyl rubber is used instead of PTFE, the target sample component cannot be correctly detected because the volatile component from the rubber is large.
The septum of PTFE is also used for the lid of the vial for the sample. If air tightness is not maintained, the concentration of the solvent changes by vaporization, and the accuracy of the analysis cannot be ensured.

Connectors for high voltage

Apply a high voltage from 500V to 5,000V to measure a high resistance or a signal by an ionization effect.

Use a connector for high voltage to connect a probe or a detector from a power generator by using a cable.

PTFE insulation materials demonstrate high insulation resistances even at high voltages. They are extremely excellent while being strongly heat-resistance and non-hygroscopic.

Therefore, substitution is difficult.

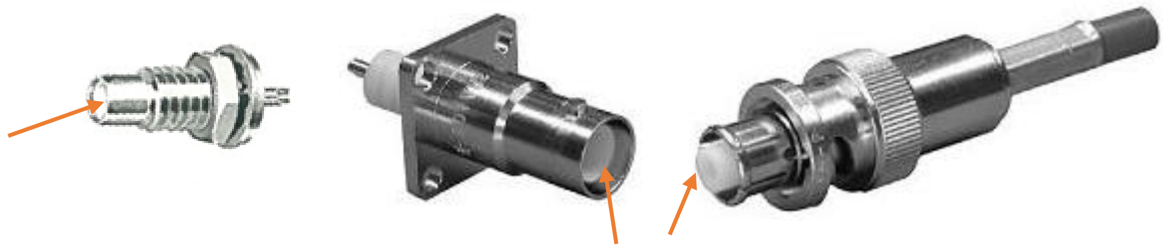


Figure 112

Use example

Figure 113 shows the example of a connector for applying a high voltage to a probe for high resistance measurement.

Connect the equipment (the probe and the main unit) by using a small-diameter cable for the contact of the probe with a sample.

Use a compact and high voltage-resistant connector.

Also use PTFE materials which are light, non-hygroscopic, and high-insulation.

Though ceramic materials are possible alternatives, they cannot be substituted because of the difficulties in processing into small shapes and the fragility.

Figure 113　Probe connector for resistivity meter