

Non-confidential attachment of PFAS public consultations

PP-SFP-IPD-Med

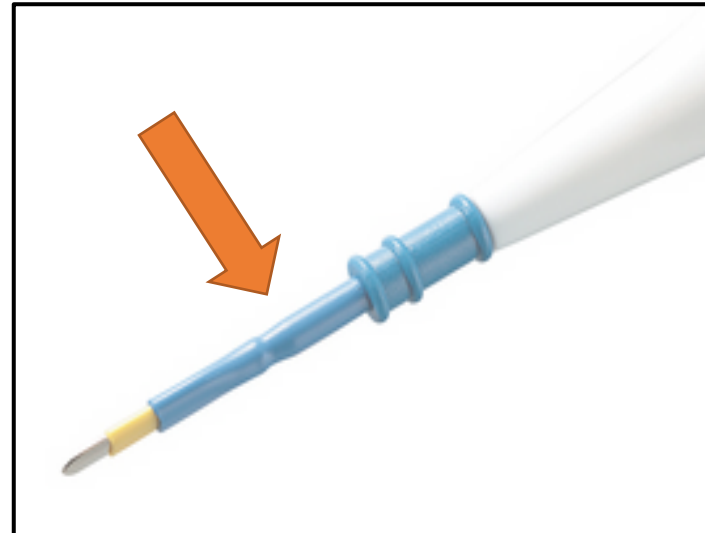
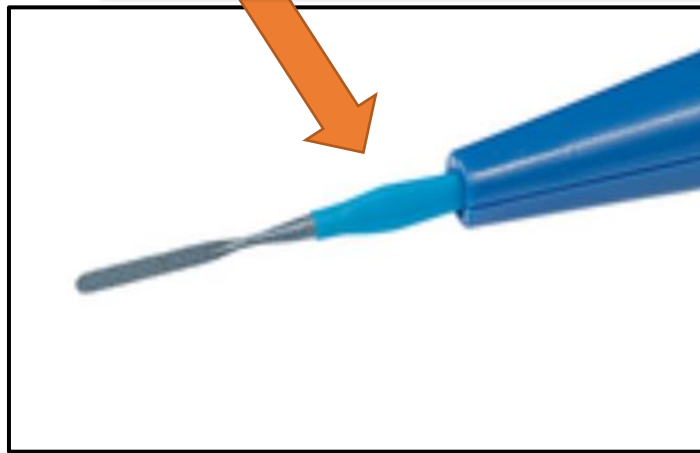
24/Aug/2023

Irradiated Products Division

Sumitomo Electric Fine Polymer, Inc.

Typical application of heat-shrinkable tubing for electric scalpel

Typical application for medical electric scalpel



Comparison table of PFAS(PVDF) and its alternatives in the proposed restrictions

Materials	PVDF		EPDM	Silicone	PEEK	Mica	Polyvinyl chloride	Polyethylene	Ceramic Based
Flexibility	Semi rigid		Flexible	Flexible	Rigid	Rigid	Flexible~ Semi rigid	Flexible~ Semi rigid	Rigid
Continuous use temperature(°C)	180		90	180	260	> 500(Mica)	100	120	> 500
Oil resistance	Excellent		Poor	Poor	Excellent	Excellent	Poor	Good	Excellent
Abrasion resistance	Excellent		Poor	Poor	Excellent	Excellent	Good	Good	Excellent
Flame-retardancy	Excellent		Poor	Good	Excellent	Excellent	Good	Poor	Good
ISO10993	Yes		No	No	Yes	No	No	Yes	No
Heat Shrinkable Tubing (Shrink ratio)	Possible (min.50%)		Possible (50%)	Possible (50%)	Possible (40%)	Impossible	Possible (min.50%)	Possible (min.50%)	Impossible

Comparison of properties between [PVDF] and other PFAS alternatives. Gray shaded cells are issues when substituting PVDF heat-shrink sleeve. "ISO10993" is a standard for medical equipment, basically no additives required. As for the alternative of PVDF heat shrink sleeve for medical equipment (electric scalpel), PEEK could be candidate for alternative, but PEEK has only 40% shrink ratio (inside diameter 1.4:1 shrink) to have following difficulties

- 1) narrow range of size for fittable to an object
- 2) less clearance between inside diameter of sleeve and an object, which give difficulty in inserting the object into sleeve especially in long length

Shrink ratio:
 $(D-d)/D * 100 (\%)$

where as D: Inside diameter before shrink
d: Inside diameter after shrink

Shrink ratio
50% = 2:1 shrink
67% = 3:1 shrink



An example of fire accident while operating with electric scalpel

(*)<https://pubmed.ncbi.nlm.nih.gov/17571619/>, non-confidential attachment

Case Reports > Masui. 2007 Jun;56(6):718-9.

[Fire caused by a spark of electric scalpel igniting alcoholic antiseptic containing chlorhexidine]

[Article in Japanese]

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Affiliations + expand

PMID: 17571619

Abstract

Fire accident is one of the most severe complications that can occur in the perioperative period. We report a case of an episode of electrosurgical burn. An 80-year-old woman was scheduled for ascending colectomy due to ascending colon carcinoma. The skin of the surgical site was sterilized with alcoholic antiseptic containing chlorhexidine before the operation. On coagulating the bleeding point of the subcutaneous fatty tissue, a spark of the electric scalpel ignited the alcoholic antiseptic. She had burn on her right thorax, lower abdomen and femoral region. Two-degree burn occupied 2% of the body surface and three-degree burn 3%. She underwent dermatoplasty 14 days later. Postoperative course was uneventful and she left the hospital on the 58th postoperative day. An alcoholic antiseptic is the most useful and has an immediate effect for preoperative disinfection of the skin according to the CDC guideline. However, electric scalpel and alcoholic use are always accompanied with the risk of ignition and sufficient caution is required.

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Abstract

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Typical PEEK heat-shrinkable tubing in the market



Features:

- Continuous service temperature 500°F/260°C
- Translucent recovery shrink temperature 572°F - 644°F (300°C - 340°C)
- Opaque recovery shrink temperature 680°F - 725°F (360°C - 385°C)
- Recovered wall range of 0.004" to 0.010" (0.102 to 0.254 mm)

Benefits:

- Excellent abrasion resistance
- Extends life of the protected item
- Adhesion to metals
- Available in colors

Applications:

- Electrical component covering
- Protective jacketing
- Wire Splicing
- Reusable medical devices

Technical Notes:

- Zeus will assist in developing custom heatshrink processes
- Class VI approved materials

PEEKshrink® 1.4:1 Heat Shrinkable AWG Tubing

Zeus P/N	Ordered as AWG Size	As Supplied Inside Diameter Min	Recovered Dimension After Shrinking Wall Thickness			
			Recovered ID Max	Minimum	Nominal	Maximum
85322	17	0.038	0.027	0.005	0.007	0.009
85318	16	0.045	0.032	0.005	0.007	0.009
85184	15	0.055	0.039	0.005	0.007	0.009
85204	14	0.085	0.060	0.005	0.007	0.009
85197	13	0.092	0.065	0.005	0.007	0.009
85189	12	0.101	0.072	0.005	0.007	0.009
85313	11	0.112	0.080	0.005	0.007	0.009
85310	10	0.125	0.089	0.005	0.007	0.009
85298	9	0.137	0.098	0.005	0.007	0.009
85294	8	0.160	0.114	0.005	0.007	0.009
85146	7	0.174	0.124	0.005	0.007	0.009
85063	6	0.200	0.143	0.005	0.007	0.009
85213	5	0.221	0.158	0.005	0.007	0.009
85236	4	0.252	0.180	0.005	0.007	0.009
85243	3	0.277	0.198	0.005	0.007	0.009
85246	2	0.316	0.226	0.005	0.007	0.009
85255	1	0.349	0.249	0.005	0.007	0.009
85326	0	0.392	0.280	0.005	0.007	0.009

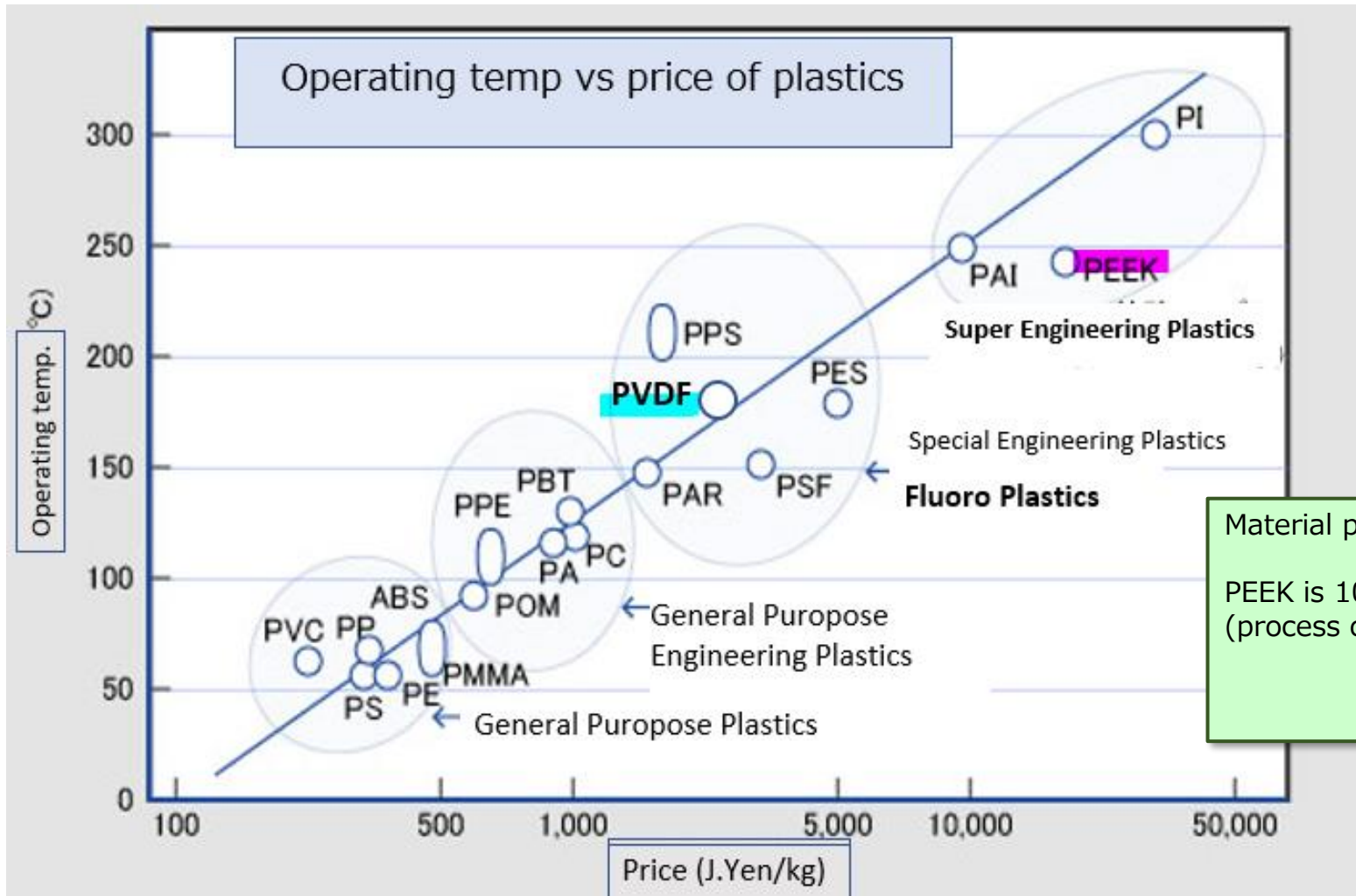
PACKAGING: Standard 4ft lengths. Custom sizes and lengths available upon request.

Catalog from Zeus:

<https://www.zeusinc.com/wp-content/uploads/2023/03/Zeus-Catalog-G-V1R6.pdf>

showing PEEK shrink tube has [1.4 : 1] shrink ratio = 40% shrink ratio

Material price comparison between PVDF and PEEK



Material price comparison between PVDF and PEEK

PEEK is 10 times higher than PVDF in raw material.
(process cost is not displayed here)