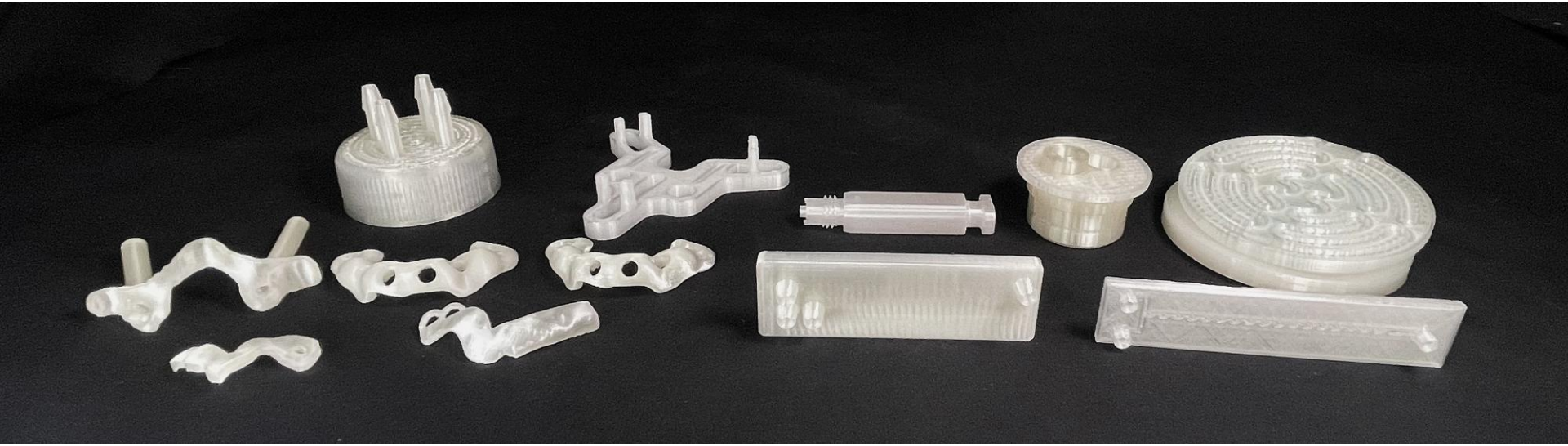
Unlocking Untapped Markets in 3D-Printing

Engineered Polyester Filaments for Pharma, Chemical & Beyond



Kurt Chiang, PhD
FLXR Engineering Co., Ltd
April/2025

PROVIDING ENGINEERING SOLUTIONS

Value Delivery Through Deep Customer Understanding

- We **begin by thoroughly understanding customer needs**; then develop 3D printing solutions that are functional, cost-effective, and consistently high quality.
- Deliver the **right product at the right price** for engineering applications in the biochemical, chemical, and pharmaceutical industries, as well as medical instruments and electronics.

Expertise in Precision Manufacturing

- Manufacture filaments using **automated, life-science-grade** extrusion lines with tight tolerance (**<±0.03mm**) for exceptional print quality.
- In-house rheology lab to optimize polymer flow for 0.20~0.25 mm nozzles, enabling intricate prints with **exceptionally smooth surfaces.**

FLXR Engineering Co., Ltd.

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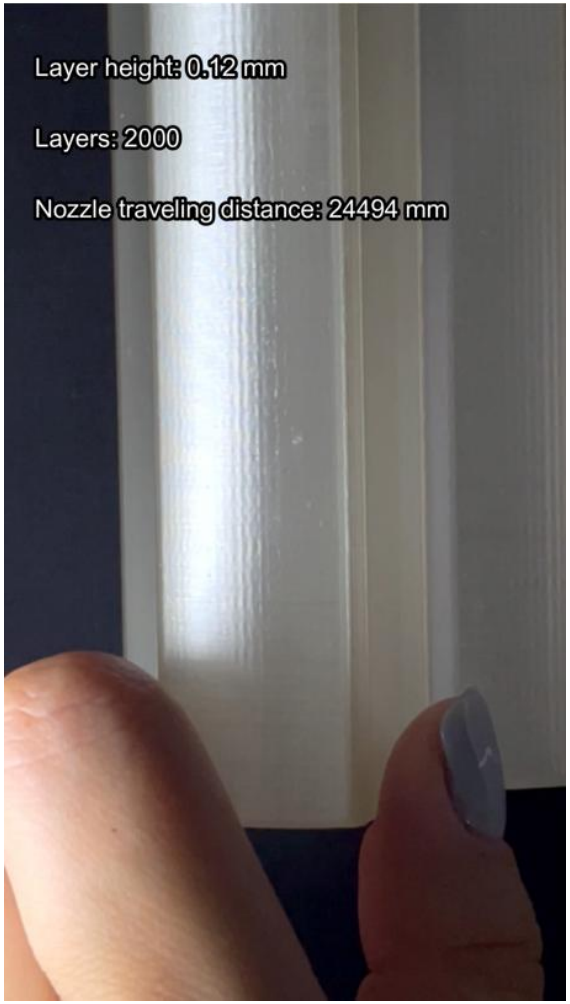
W www.flxr.engineering // hello@flxr.engineering

T +886-2-2290-1122

FILAMENT QUALITY DEMO



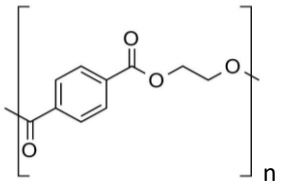
Material: PEN-Natural
Part Dimension: H: 240mm
Printed using: 0.25 mm nozzle intamsys pro310

WHAT IS PEN POLYMER?

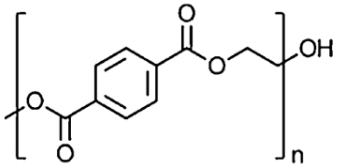
PEN is the highest-grade polyester engineered for demanding conditions, providing exceptional chemical resistance along with strong heat and hydrolysis resistance.

POLYESTERS

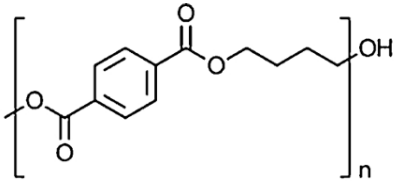
Highest strength, chemical & temperature resistance, insulating, and scratch-resistant in polyester family



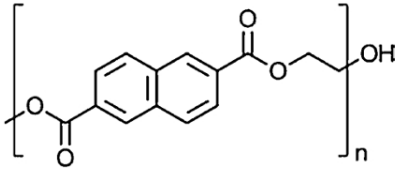
PETG



PET



PBT



PEN

Increasing engineering performance / value-add

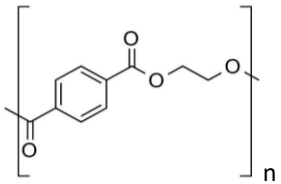
Signage

Fibers

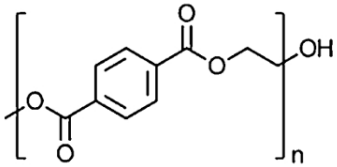
Electrical connectors

Medical bottles

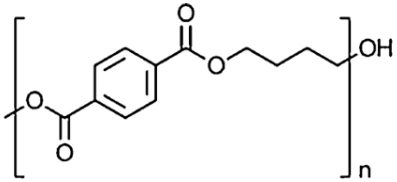
POLYESTERS IN 3DP



PETG



PET



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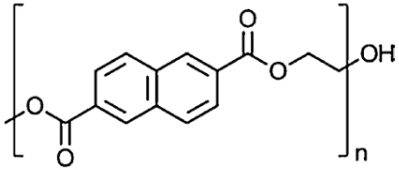


PEN

Suitable for 3DP

Less desirable for 3DP

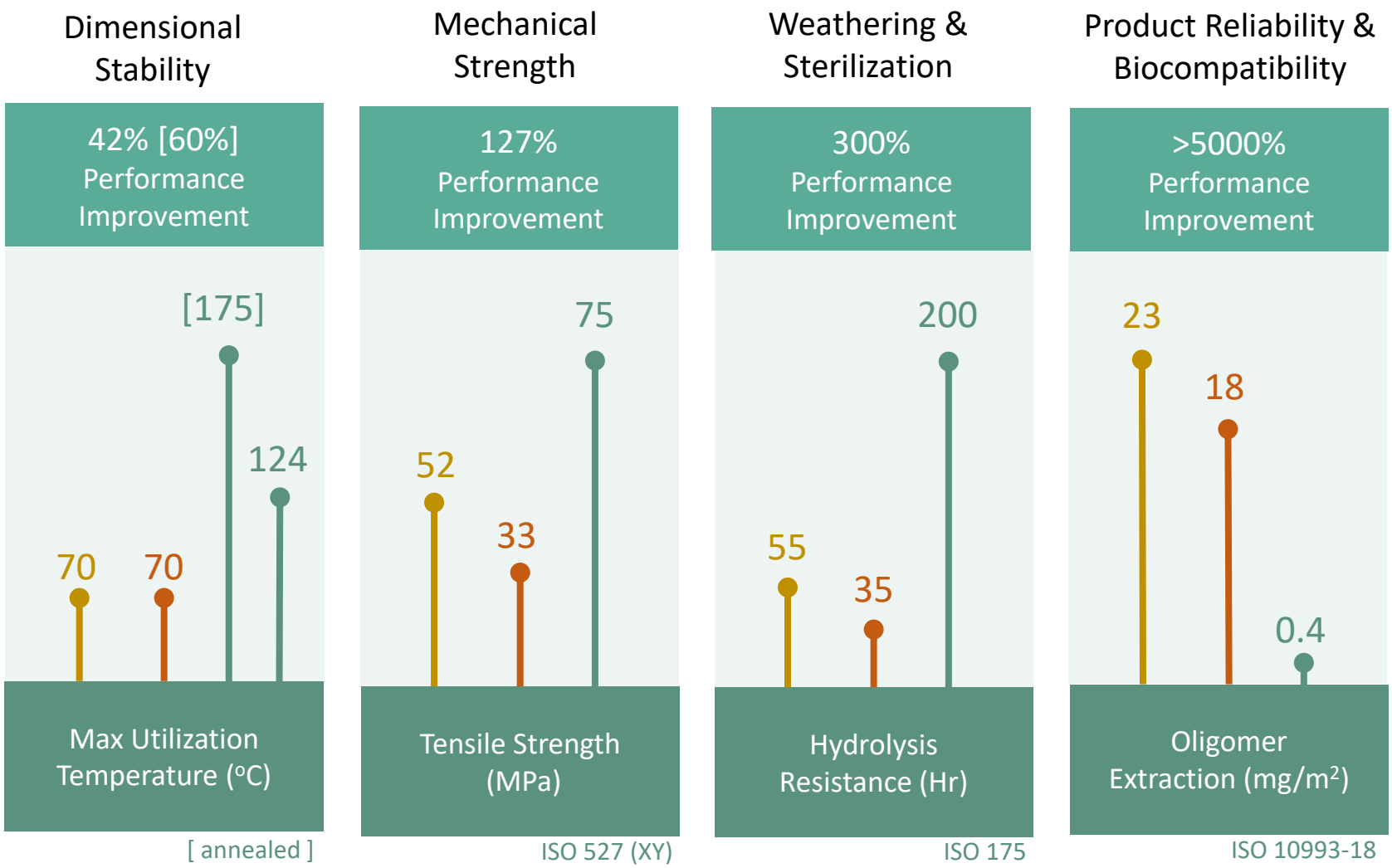
Suitable for 3DP

- Minimal warping
- Very affordable
- High gloss

- High tendency to warp
- Problem with layer adhesion
- Highly sensitive to moisture

- Minimal warping
- High performance
- Least sensitive to moisture in polyesters

POLYESTER FILAMENT PERFORMANCE



APPLICATIONS OF PEN

Anesthetic injection pen cartridge

Medical bottles
Cosmetic bottles

Blister packs
Pharma

Dielectric films (capacitors)
Optical films (monitors displays)

Plastic bottles
Alcohols, juices, soups

Nespresso coffee capsules
60/40 PEN/PET

FLXR PEN FILAMENTS

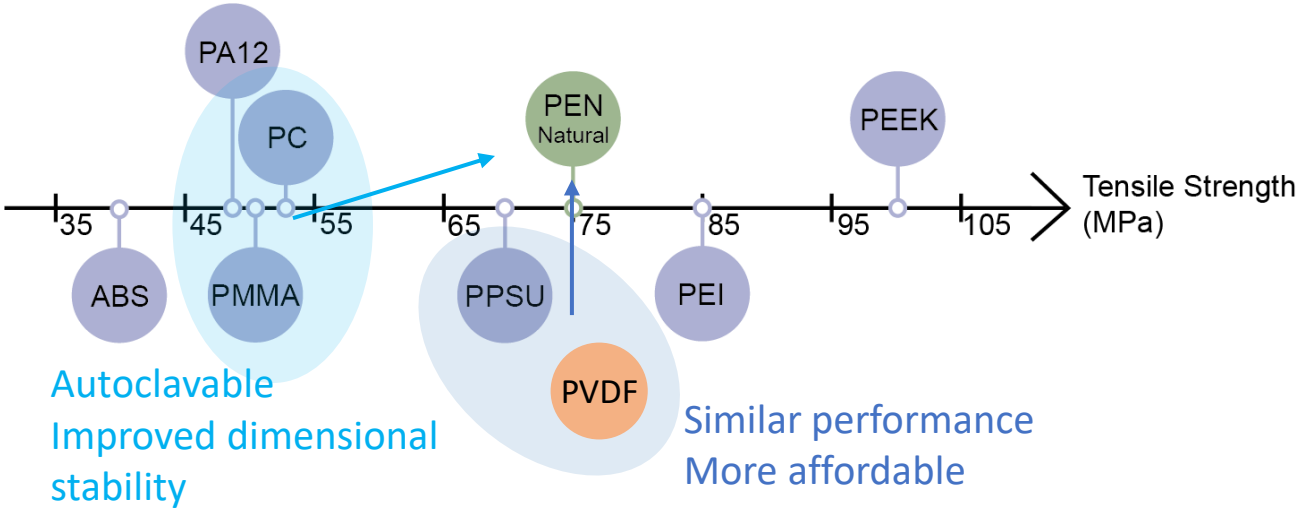
PEN-Natural
(Biocompatible)

w/ all catalyst, oligomers, etc removed.

PEN-HF
(Engineering / Food-safe)

Base Resin Use	Vaccine & anesthetic bottle	Cosmetic & premium food ware
User base	Biotech, Pharma, Medical, Chemical	Industrial, Engineering, Food processing
Application	Consumables (surgical guides, fluidics, labware, medical containers)	Consumables & Parts (jigs, food processing equip., disposable nozzles)
MSRP ($USD/kg roll)	160 ~ 170	130 ~ 140
Mechanical strength	++++	+++
East of printing	++++	+++++
Print speed	Up to 140 mm/s	Up to 300 mm/s
End of life	Recycle w/ PET up to 6%	

PEN Natural
(Biocompatible)

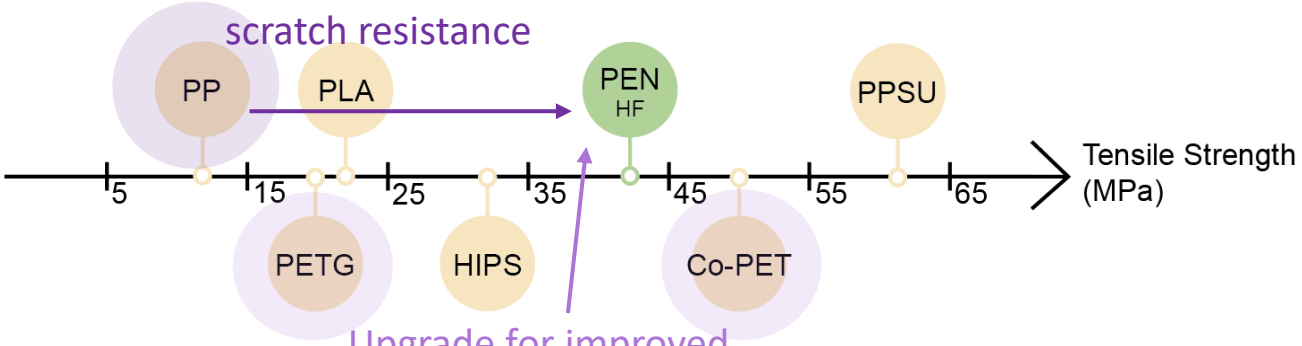


Autoclavable
Improved dimensional stability

Similar performance
More affordable

Upgrade for improved chemical resistance & scratch resistance

PEN HF
(Engineering)



Upgrade for improved heat resistance

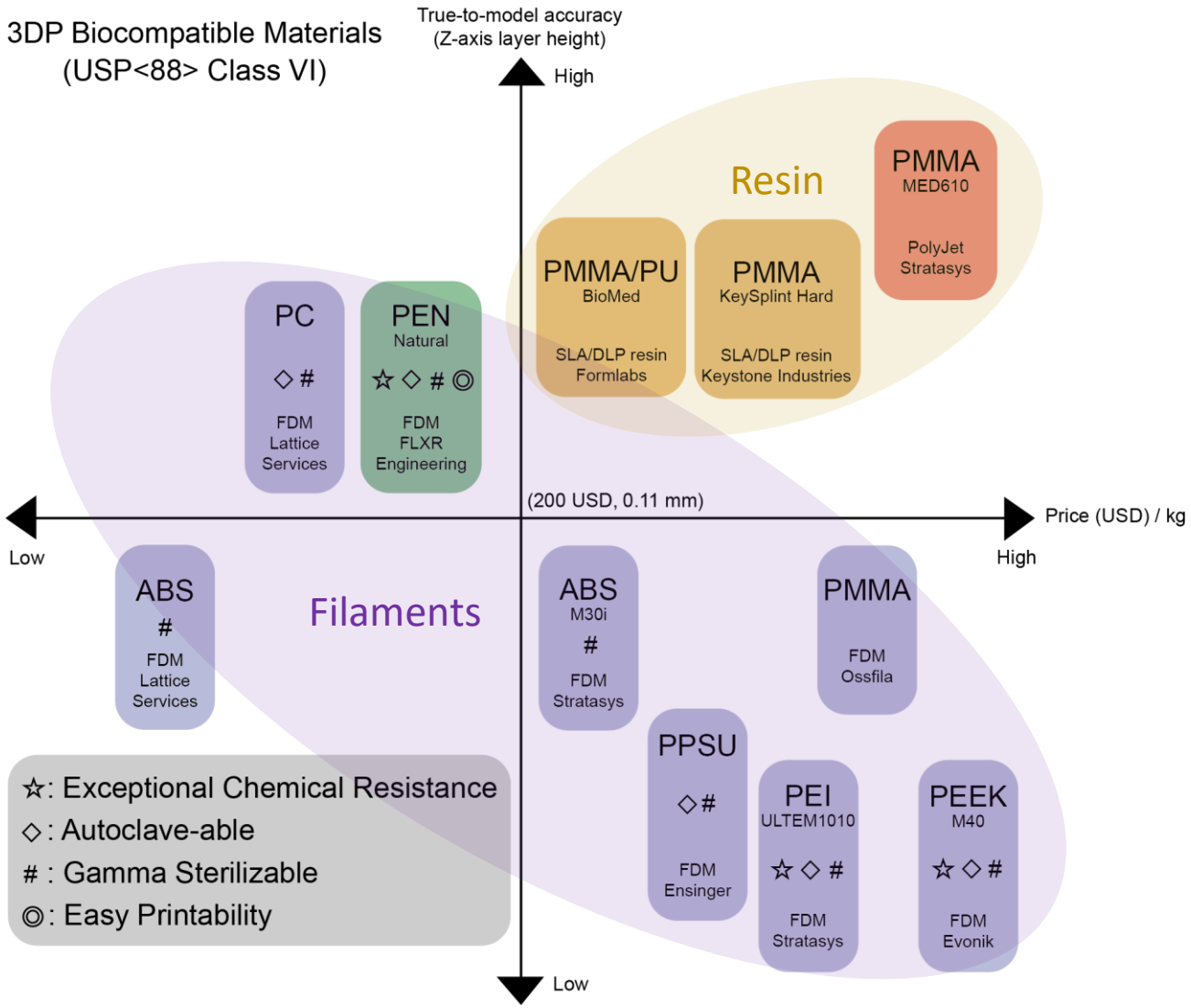
DIFFERENTIATING FACTORS

1. Cost Effective:
    - PEN is very affordable compared to other biocompatible, engineering materials on the market without sacrificing key performance metrics. The saving comes from a larger commercial production of PEN polymer compared to PEEK, PPS, PPSU etc.
2. Chemical resistance:
    - PEN is among the most chemical-resistant, biocompatible 3D-printing materials available – surpassed only by PEEK and PPS* and on par with PVDF, with very low extractable potential.
3. Regulatory (*PEN-Natural*):
    - PEN meets regulatory requirements for biotech, pharma, medical, and chemical applications. *(USP 88 Class VI, USP 87, ISO 10993-4, -10, -17, ADCF, FDA 21 CFR 177)*
4. Compatible to client workflow:
    - Compatible with autoclave, EtO, gamma and e-beam sterilization methods and no messy resins and extensive post-processing required.

*(*note: Although PPS is biocompatible, no commercially available filament remains so, because 3D printing requires carbon fiber, which negates its biocompatibility.)*

PEN NATURAL

*If you're looking for a biocompatible, chemically-resistant, and cost-effective option, **PEN-Natural** is a strong offering.*



FLUIDIC DEVICES

3D-printed reactors as an alternative to traditional glassware.

Mr. W
RD Manager
Chem. Eng. Co.

PEN enables more available chemical reactions for the system with material prices lower than PVDF

1. Exceptional chemical resistance
2. Low-extractable potential
3. Temperature resistance to 120 °C

MIXING DEVICES

CFD-optimized PEN 3DP magnetic stir bar

3D-Printed Soln.* @ 600 RPM

Coven. Mag. Stir @ 600 RPM

Dr. S
Principle Scientist
Electronic Chem.

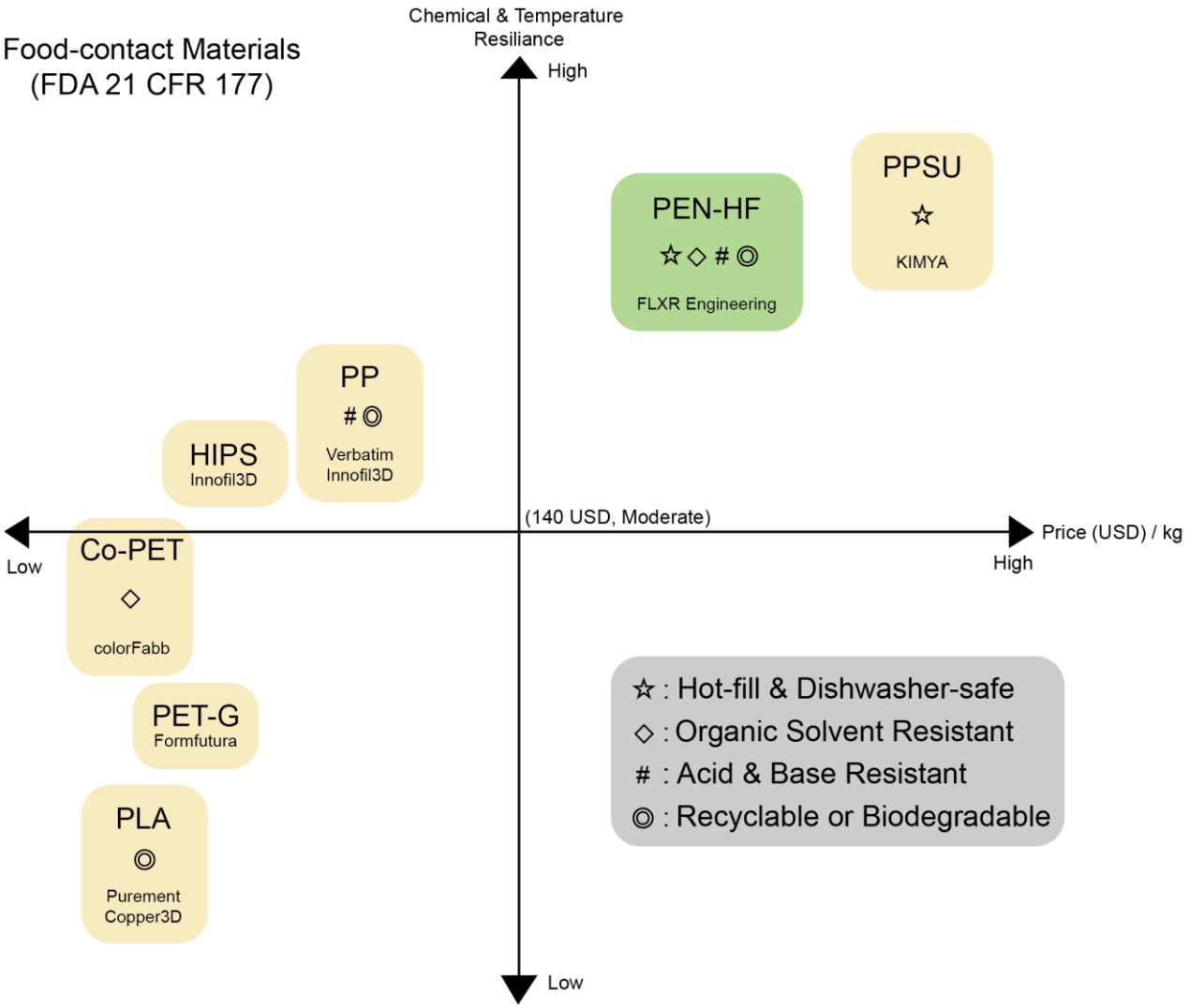
1. 3D-printing solved quality misalignment issue with TSMC, an annual $8 mil USD business.

2. Safe & reliable material:
   Analytical testing revealed no contamination of CMP slurry from 3D-printed PEN mixing device.

3. Material is PFAS-free, in alignment with ESG policies set by *company*.

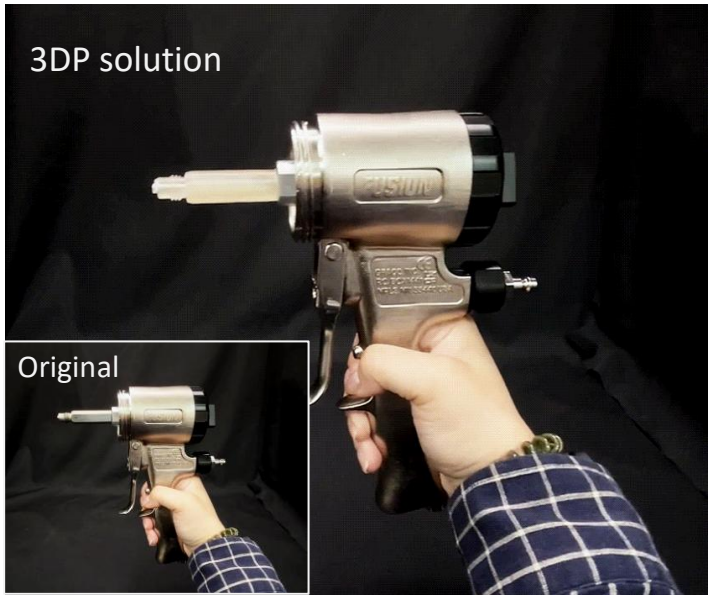
PEN-HF (HIGH FLOW)

***PEN-HF** delivers near-PPSU levels of chemical, heat, and moisture resistance at just 50% of the cost, without requiring an industrial FDM printer.*



INDUSTRIAL COMPONENTS

Mr. C
Managing Director
Hardware factory



Conversion of stainless-steel parts to single-use components for chemical spray guns

1. 3D-printing solved my problem on the production line, quality of painted products improved and workers are happy not to deal with cleaning nozzles.

2. Material cost for the disposable nozzle is $1.2 USD, very affordable and resistant to solvents in paint.

Original stainless-steel component: $32 USD/pc

SCIENTIFIC COMPONENTS

Caps and components for commercial electro-chemical analytical cell

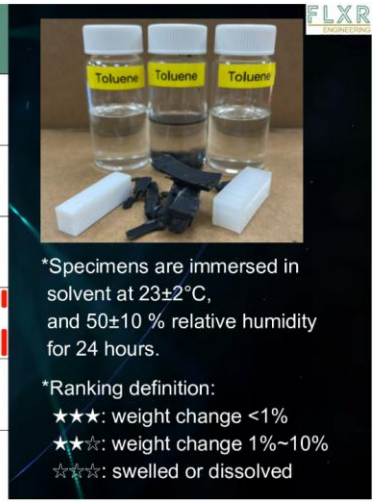
Mr. W
Senior R&D Manager
Electro-chemical Co.

1. PTFE machining is getting expensive, so I'm pleased to learn that PEN can be 3D-printed. PEN has excellent dielectric strength and we already use it in our other products.

2. The cost of a 3D-printed PEN part is half that of a PTFE part, and it's also PFAS-free—an extra selling point for our customers.

CHEMICAL RESISTANCE DEMO

Chemical/Filament	FLXR-PEN Natural	PC	PA66 Natural
Distilled water	★★★	★★★	★★☆
5% Acetic acid	★★★	★★★	★★☆
Acetone	★★★	☆☆☆	★★★
Toluene	★★★	☆☆☆	★★☆
10% Nitric acid	★★★	★★☆	★★☆
Ethyl acetate	★★★	☆☆☆	★★☆



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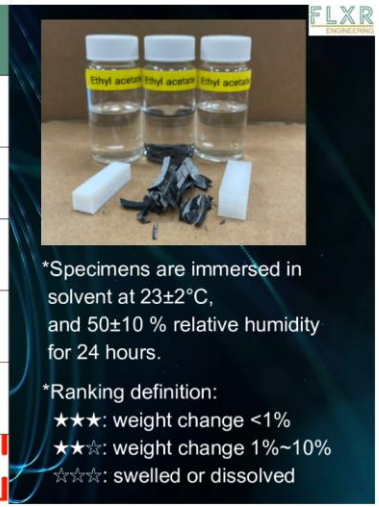
10% Nitric acid	★★★	★★☆	★★☆
Ethyl acetate	★★★	☆☆☆	★★☆



Parts printed using BambuLab X1E

CHEMICAL RESISTANCE OF MATERIALS

FLXR ENGINEERING

Resistance at 23 °C, 30 days	PEN Natural (~165USD/kg)	PEEK (~650USD/kg)	PPS (~240USD/kg)	PVDF (~250USD/kg)	PPSU (~370USD/kg)	PP (~80USD/kg)	BioMed Clear (~349USD/L)
HNO_3(20%)	A	A	C	A	B	A	B
Acetone	B	A	A	D	D	A	D
Chloroform	D	A	A	A	D	C	B
Cyclohexane	A	A	A	A	A	D	B
Ethyl acetate	A	A	A	D	A	A	-
MEK	A	A	A	C	D	B	D
THF	B	B	A	B	D	C	-
NaOH (30%)	A	A	A	C	A	A	B
EtO	A	A	D	A	A	D	A

Test specimen submerged for 30 days in solvent; ranking definition:
A: weight change <1%, tensile strength retained >95% to standard.
B: weight change between 1~10%, tensile strength retained >75%
C: weight change >10%, tensile strength retained <75%
D: dissolved and softened within 120 hours.

SORPTION STUDY OF PEN

In collaboration and tested by:

Safe: **>5mg /g polymer** potentially leads to cross contamination and compromises product integrity.

Sample ID	Material	**Acetaminophen** (amide/phenol)	**Camphor** (ketones)	**Ibuprofen** (carboxylic acid)	**Menthol** (alcohol)	**Methyl Salicylate** (ester)
A5	**PEN**	0.9	3.2	1.7	0.2	1.0
B2	**PEN**	1.6	2.3	0.6	0.8	0.7
A4	**PTFE**	<0.1	0.2	<0.1	<0.1	0.2
B4	**PTFE**	0.1	0.1	<0.1	0.1	0.2
A3	**PVDF**	0.9	3.2	0.5	3.5	0.8
B3	**PVDF**	0.7	1.4	0.7	4.9	0.3
A2	**TPX**	0.2	36.9	0.3	0.4	0.5
B1	**TPX**	0.9	25.0	0.8	1.1	0.9
A6	**PET**	8.5	27.2	11.9	22.9	488.5
B6	**PET**	25.6	18.4	7.2	39.9	625.6
A1	**PC**	10.3	18.2	8.3	712.30	34.7
B5	**PC**	25.9	37.1	18.4	561.80	21.8

Units: mg chemical / g of polymer

MIGRATION STUDY OF PEN

FLXR ENGINEERING

In collaboration and tested by:

國立陽明交通大學 NATIONAL YANG MING CHIAO TUNG UNIVERSITY

Clean: No anti-oxidants, processing aids, oligomers to risk contamination of diagnostic results

Sample ID	Material	**Toluene** (non-polar aromatic)	**Ethyl acetate** (polar aprotic)	**n-Hexanes** (non-polar aliphatic)	**Ethanol** (polar hydrophilic)	**Dichloromethane** (polar halogenated)
C1	**PEN**	0.14	<0.05	<0.05	<0.05	0.31^
D3	**PEN**	0.19	<0.05	<0.05	<0.05	0.18^
C6	**PTFE**	<0.05	<0.05	<0.05	<0.05	<0.05
D5	**PTFE**	<0.05	<0.05	<0.05	<0.05	<0.05
C2	**PVDF**	<0.05	0.82^	<0.05	<0.05	0.16
D1	**PVDF**	<0.05	0.35^	<0.05	<0.05	0.09
C3	**TPX**	3.92^	<0.05	0.11	<0.05	1.87^
D6	**TPX**	4.76^	<0.05	<0.05	<0.05	2.12^
C5	**PET**	3.38^	0.72	1.51	0.12	17.80^
D2	**PET**	5.69^	1.22	1.91	0.15	10.91^
C4	**PC**	9.30^	6.07^	0.19	0.10	23.19^
D4	**PC**	8.50^	9.69^	0.38	0.07	21.03^

^material not resistant to solvent

Units: mg chemicals / g of polymer

PEN NATURAL 3DP FILAMENT

FILAMENT SPECIFICATIONS

Diameter	: 1.75 ± 0.03 mm
	2.85 ± 0.06mm
Color	: translucent
Net filament wt.	: 200g, & 1,000g
MSRP	: USD$ 160~170/kg

USP<87>
USP<88>Class VI

UL94 HB
UL94 HV2

ISO 10993-4
ISO 10993-10

FDA 21 CFR 177.1637

Base resin uses a US-patented process that removes residual catalysts, oligomers, and low molecular weight polymers – ensuring suitability for medical and pharma applications

ORIGINAL SPOOL DESIGN

- ✓ Smooth reliable release for material stations
- ✓ Eliminate the need for tape removal or filament cutting
- ✓ Tested >100 times and 100% jam-free

US Patent Pending: 63/595.978

MECHANICAL PROPERTIES

	Test Method	FLXR PEN-Natural				BASF Ultrafuse PPSU		
	ISO 527-2/1A G.L=50.0 mm	INJ	XY (Flat)	YZ (Side)	ZX (Up)	XY (Flat)	YZ (Side)	ZX (Up)
Tensile strength (MPa)	5 mm/min	73.7	75.2	51.9	22.2	74.5	-	49.0
Elongation (%)	5 mm/min	10.6	10.1	2.4	0.5	7.3	-	2.9
Tensile modulus (MPa)	1 mm/min	2796	2717	2435	2534	2221	-	2150
	ISO 178:2019							
Flexural Strength (MPa)	2 mm/min	107	100.3	-	43.1	105	114	88.9
Flexural Modulus (MPa)	2 mm/min	2299	2263	-	1976	1940	1910	1700
	ISO 180:2019							
Izod Impact Strength kJ/m^2	Notched	9.6	3.1	-	1.9	13.7	15.8	5.3

Note: All sample are printed with 100% infill
Sample conditioned 88h at (23 ± 2)°C and (50 ± 10) % relative humidity

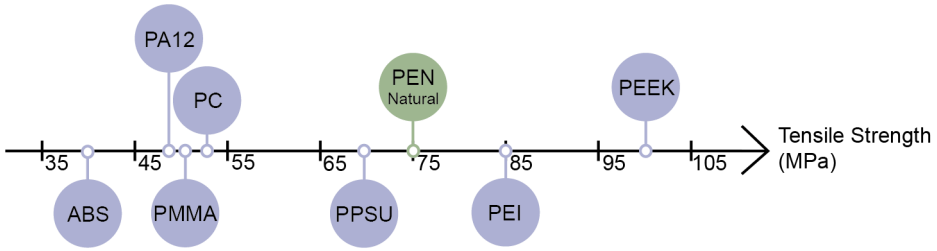
3rd party testing done by: SGS

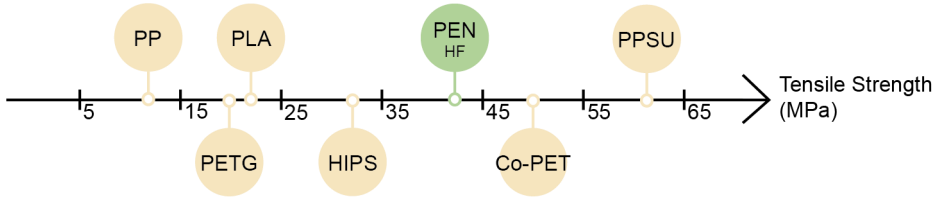
MECHANICAL PROPERTIES

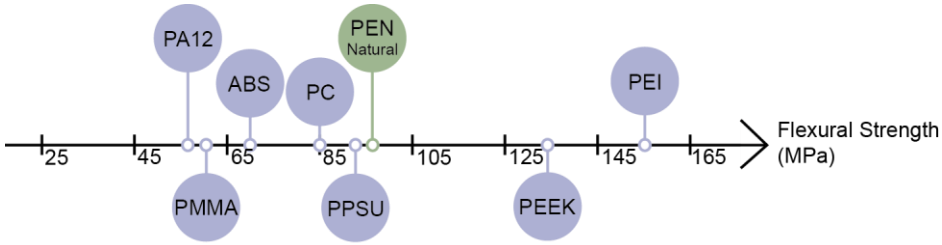
PEN Natural
(Biocompatible)

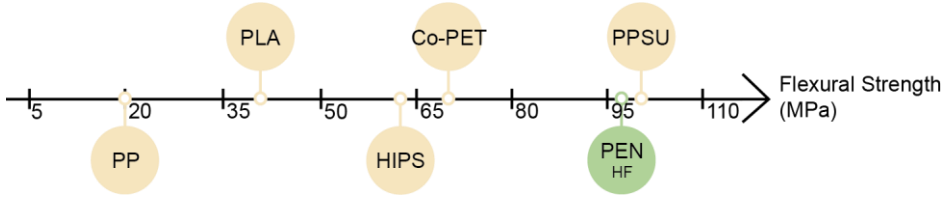
w/ all catalyst, oligomers, etc removed.

PEN HF
(Engineering)

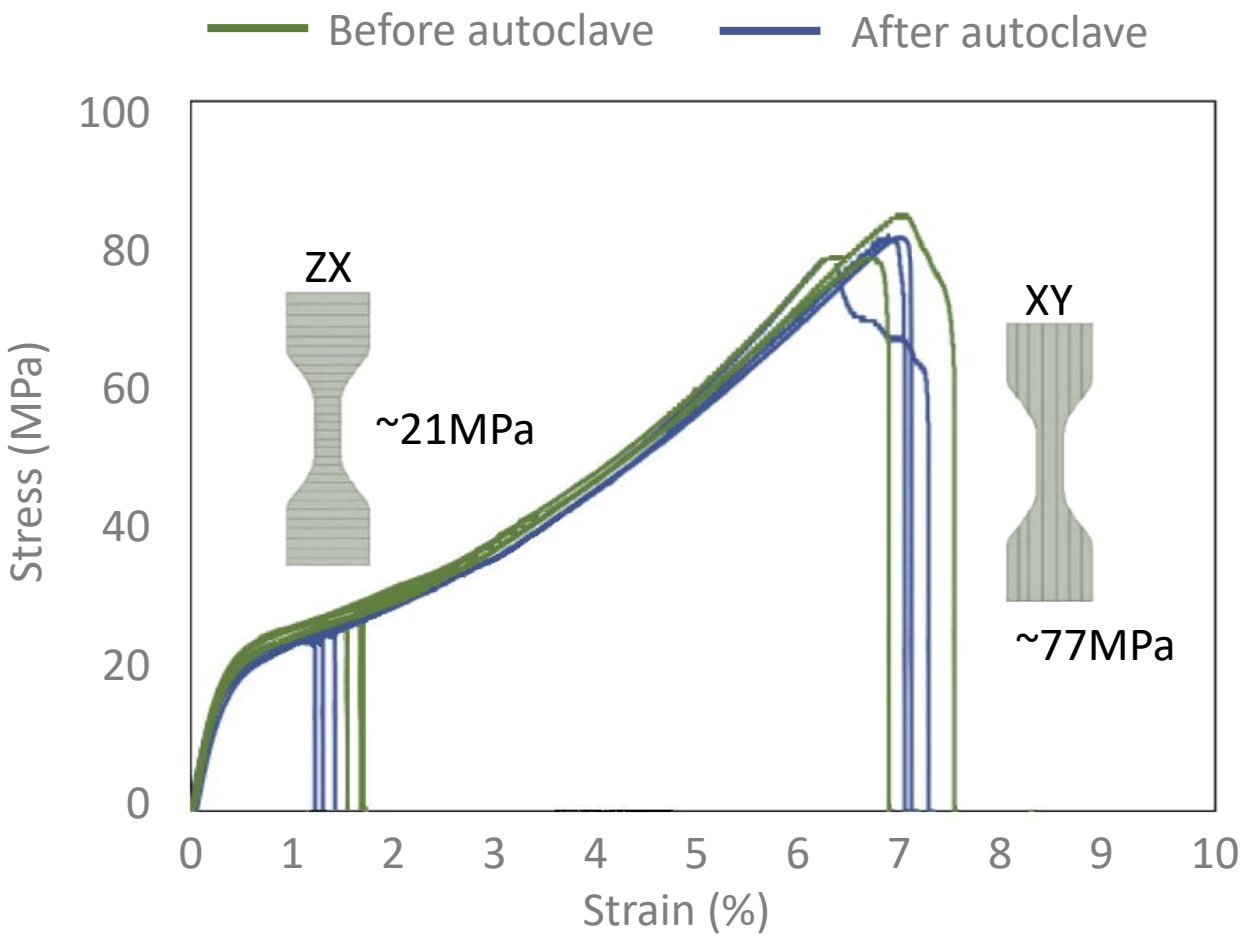








AUTOCLAVE STERILIZATION



PEN Natural
(Biocompatible)

Method:

1. Pre-vacuum
2. Autoclave ~132 °C for 4 minutes
3. Drying cycle
4. ISO 527 mechanical testing

✓ PEN retains its dimensional accuracy and mechanical strength after autoclave sterilization

FDA 21 CFR 177 FILAMENTS

Filament registered to FDA
Base resin listed on: EU 10/2011, SEPA(CHINA), ECL(KOREA), MITI(JAPAN)

Material	Manufacturer	Aqueous	Alcoholic	Acidic	Fatty	High-Temp	Frozen
PEN	FLXR Eng	Yes	Yes	Yes	Yes	Yes	Yes
PPSU	KIMYA	Yes	Yes	Yes	Yes	Yes	Yes
PP	Verbatim	Yes	Yes	Yes	Yes	No	Yes
	Innofil3D	Yes	Yes	Yes	Yes	No	Yes
HIPS	Innofil3d	Yes	Yes	Yes	No	No	Yes
PLA	Purement	Yes	No	No	No	No	No
	Copper3D	Yes	No	No	No	No	No
Co-PET	colorFabb	Yes	Yes	Yes	No	No	Yes
PET-G	Formfutura	Yes	Yes	Yes	No	No	Yes

PEN: PEN is completely tasteless and odorless; can be sanitized by multiple methods (steam, chemical, peroxide and more)

Source: FDA U.S. FOOD & DRUG ADMINISTRATION

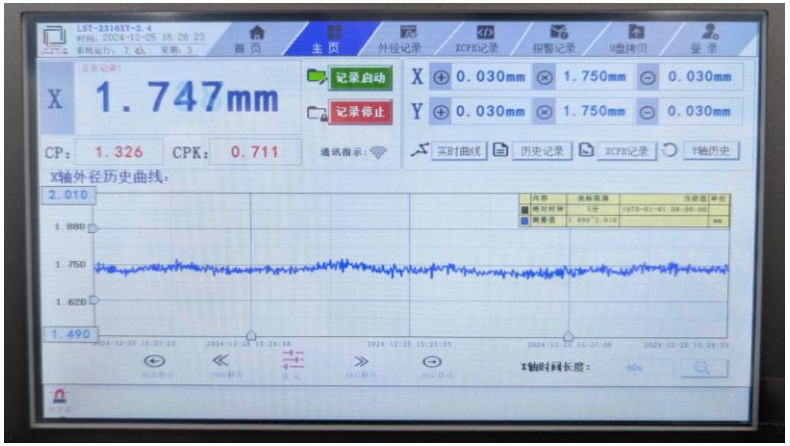
ELECTRICAL PROPERTIES

PEN provides similar electrical insulation to PTFE but is easier to process, 3D-print, more cost-effective, and more environmentally friendly.

Material (20 μm film)		PEN	PET
Breakdown Voltage kV/mm		300	280
Dielectric Constant (Permittivity)	25 °C / 60 Hz	3.0	3.2
	25 °C / 1 kHz	2.9	3.1
	25 °C / 1 GHz	2.9	3.0
	125 °C / 1 kHz	3.1	3.5
Dissipation Factor	25 °C / 60 Hz	0.003	0.002
	25 °C / 1 kHz	0.005	0.006
	25 °C / 1 GHz	0.005	0.008
	125 °C / 1 kHz	0.006	0.014
Volume Resistivity	25 °C 10/Ω	10	7
Surface Resistivity	25 °C 10/ Ω·cm	2	6

Source: Dupont Teijin

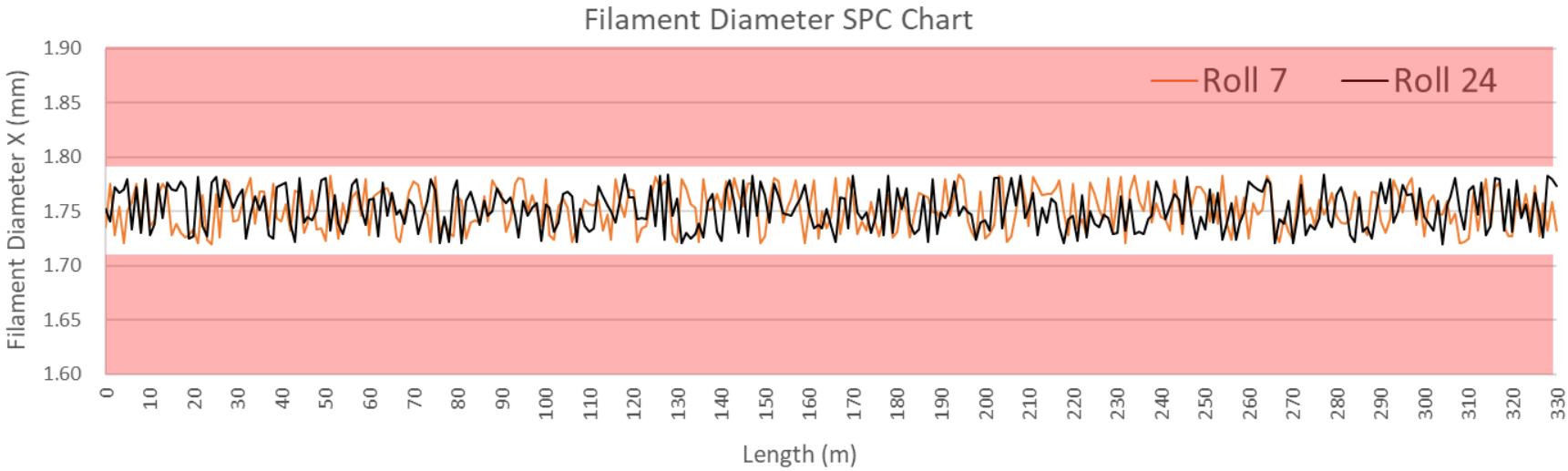
FILAMENT DIAMETER



Online XY Laser Accuracy: ±0.003 mm
Data date: 2024.12.25

Precision Matters & Reliability:

- Automated extrusion line ensures diameter tolerance of <±0.03mm
- Eliminates human variability, delivery consistent quality necessary for medical applications



USP CERTIFICATIONS

FLXR ENGINEERING

SGS

PEN
<Lot No.: 240419-04>
USP <88> Class VI Study

Client:	**FLXR Engineering Co., Ltd.**
Institution:	**SGS Taiwan Industrial Service Ltd.** **Health Industry Service**
Test Article No.:	**PSG24900064**
Date Received:	2024.10.08
Final Report No.:	113A001-D210709-FRE

CONCLUSION

The test article "PEN" extracts of normal saline, olive oil, 1:20 ethanol and polyethylene glycol 400 (PEG 400) did not produce a significantly biological responses either in mice acute systemic toxicity test or in white rabbit intracutaneous irritation test. Besides, the test item "PEN" did not produce a significantly biological response in intramuscular implantation test in rabbits neither. Therefore, the test item "PEN" meets the requirements of the USP guidelines, for Class VI plastics.

Authorized by

Wu Ping-Hsuan
Study Director
Biomedical Verification Lab.
Plastics Industry Development Center

Date (YYYY.MM.DD) 2025.01.08

Wei Chi-Chen
Management
Biomedical Verification Lab.
Plastics Industry Development Center

Date (YYYY.MM.DD) 2025.01.08

For Test Report ONLY

SGS

STUDY SCHEDULE
PEN
<Lot No.: 240419-04>
In Vitro Cytotoxicity Test- Elution Test

Report No.:	PUB24800022
Test article received date:	2024.08.05
Experimental Starting Date:	2024.08.15
Experimental Completion Date:	2024.08.18
Study Completion Date:	See Study Director's signature date in the report
Name of Study Personnel:	Momo Shih

RESULTS

1. **Appearance**
   The extract of the test article contained suspension.
   The precipitate occurred in test article extracts.

2. **Cell biological reactivity**
   As shown in Table 3 and Figures, the cells exposed to negative control extracts showed no significant change in cell morphology and monolayer cell confluency compared to blank control. The grade was 0 which meant none of cell reactivity. The positive control extracts caused severe cellular damage and destroyed nearly complete destruction of the cell layers. Therefore, the positive control experiments were scored as grade 4 meant severely reactivity. The cells treated with test article extracts showed nearly complete or complete destruction of the cell layers., scored as grade 4, meant severe of cell reactivity.

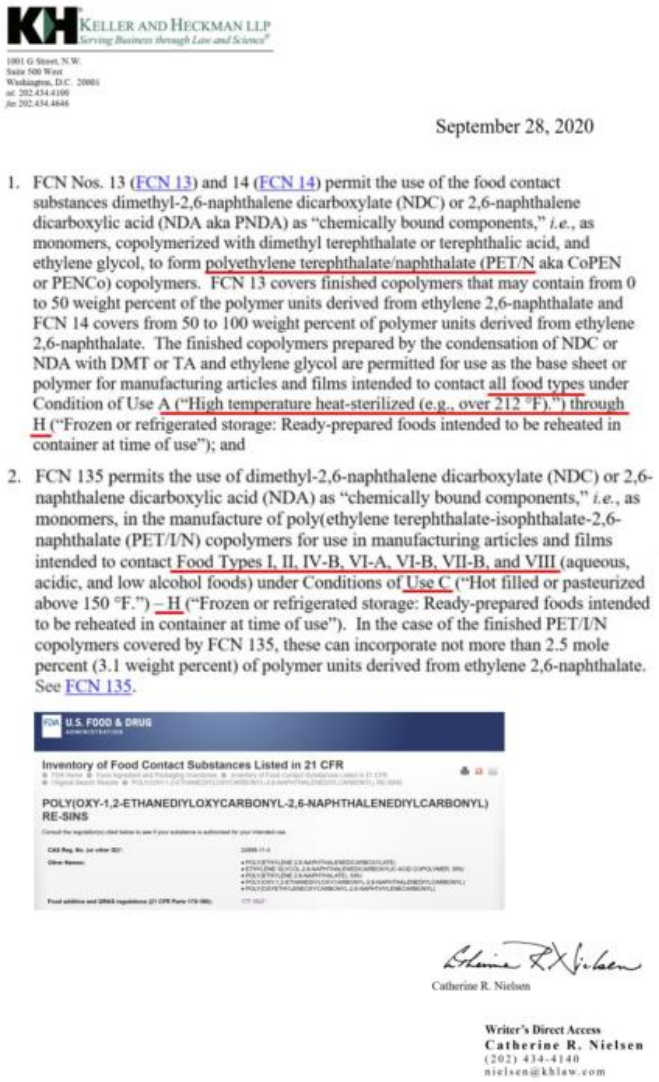
CONCLUSION

The results of biological reactivity were listed in Table 3. The cell morphology and monolayer cell confluency as shown in Figures. Based on the grades, the "PEN" extract had none cell reactivity. The test article extracts did not induce cytotoxic effect in L929 cells, according to USP<87>.

Approval Signatory: Benson Liu / SGS Taiwan Ltd. Date 2024.09.11

Laboratory Head: Shin Jyh Chen / SGS Taiwan Ltd. Date 2024.09.11

FDA 21 CFR 177



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September 28, 2020

1. FCN Nos. 13 (FCN 13) and 14 (FCN 14) permit the use of the food contact substances dimethyl-2,6-naphthalene dicarboxylate (NDC) or 2,6-naphthalene dicarboxylic acid (NDA aka PNDA) as "chemically bound components," *i.e.*, as monomers, copolymerized with dimethyl terephthalate or terephthalic acid, and ethylene glycol, to form polyethylene terephthalate/naphthalate (PET/N aka CoPEN or PENCo) copolymers. FCN 13 covers finished copolymers that may contain from 0 to 50 weight percent of the polymer units derived from ethylene 2,6-naphthalate and FCN 14 covers from 50 to 100 weight percent of polymer units derived from ethylene 2,6-naphthalate. The finished copolymers prepared by the condensation of NDC or NDA with DMT or TA and ethylene glycol are permitted for use as the base sheet or polymer for manufacturing articles and films intended to contact all food types under Condition of Use A ("High temperature heat-sterilized (e.g., over 212 °F).") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use"); and

2. FCN 135 permits the use of dimethyl-2,6-naphthalene dicarboxylate (NDC) or 2,6-naphthalene dicarboxylic acid (NDA) as "chemically bound components," *i.e.*, as monomers, in the manufacture of poly(ethylene terephthalate-isophthalate-2,6-naphthalate (PET/I/N) copolymers for use in manufacturing articles and films intended to contact Food Types I, II, IV-B, VI-A, VI-B, VII-B, and VIII (aqueous, acidic, and low alcohol foods) under Conditions of Use C ("Hot filled or pasteurized above 150 °F.") – H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use"). In the case of the finished PET/I/N copolymers covered by FCN 135, these can incorporate not more than 2.5 mole percent (3.1 weight percent) of polymer units derived from ethylene 2,6-naphthalate. See FCN 135.

Catherine R. Nielsen

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177.1637:

Used in contact only with food of Types I, II, IVB, VIA, VIB, VIIB, VI and VIII identified in table 1 of § 176.170(c) of this chapter, under conditions of use A through H described in table 2 of § 176.170(c) of this chapter; and with food of Types III, IVA, V, VIC, VIIA, and IX identified in table 1 of § 176.170(c) of this chapter, under conditions of use C through H described in table 2 of § 176.170(c) of this chapter;