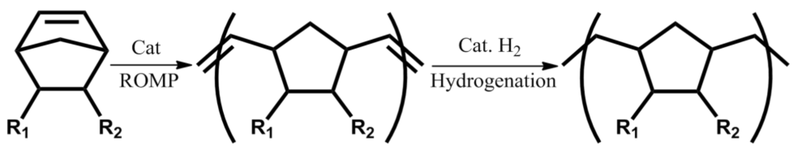
Introduction to Cyclo Olefin Polymer (COP)
- Key Properties Update -

S. Suzuki, T. Katayama, K. Arai, T. Sawaguchi, ZEON CORPORATION

1. What is Cyclo Olefin Polymer ?

◆ **COP polymers (ZEONEX®, ZEONOR®) were commercialized in 1990 and have found increasing use in pharmaceutical syringes and vials due to COP's unique benefits vs glass and other plastics.**



Product Grade	Water Absorption (%)	Light transmittance (%)	Glass Transition Temp (℃)	Elongation at break (%)
ZEONEX® 5000	<0.01	92	69	120
ZEONOR® 1020R	<0.01	92	102	90
ZEONEX® 690R	<0.01	92	136	20
ZEONEX® 790R	<0.01	92	163	10

Passes US/EU/Japan Pharmacopoeia, ISO 10993, DMF listed

2. Benefits of COP for pre-filled syringe

Syringes made of ZEONEX® offer :

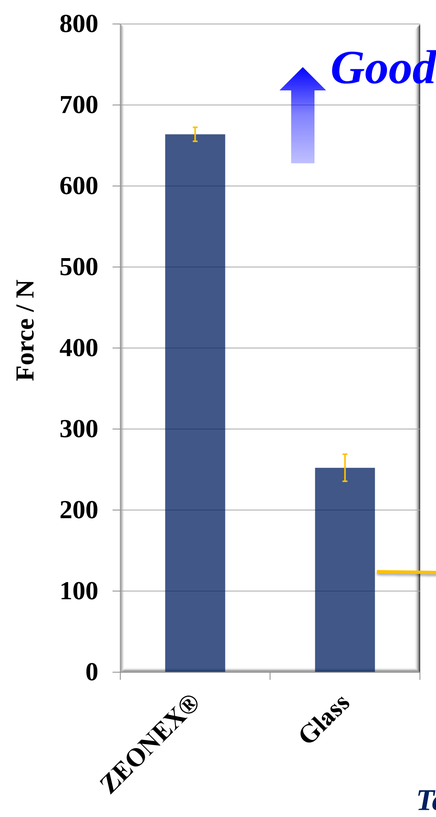
- ✓ **High transparency** — *- Easy to inspect the drug*
- ✓ **Low impurities** — *- Very low residual metals*
- ✓ **Sterilization** — *- Gamma, EB, Steam*
- ✓ **No delamination** — *- No flakes and particles*
- ✓ **Drug compatibility** — *- Acids, alkalis and alcohols*
- ✓ **High break resistance** — *- Improved drop tolerance*
- ✓ **Low E / L** — *- Very low elution*
- ✓ **High moisture barrier** — *- Long-term drug storage*
- ✓ **Low adsorption** — *- Keep drug activity*
- ✓ **Silicone oil free** — *- No aggregation*

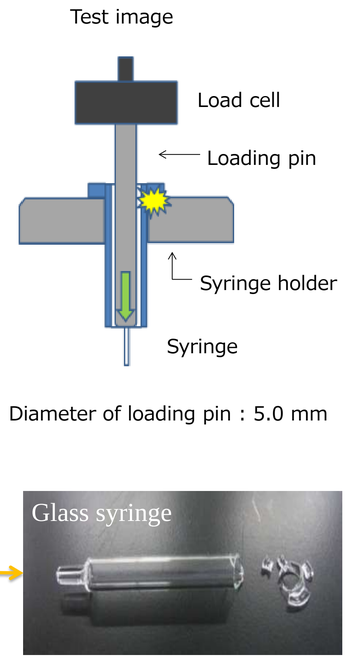
Typical devices where ZEONEX® is used:

- *Pre-Filled syringes*
- *Pre-Filled cartridges*
- *Vials and bottles for long-term storage of biologics*
- *IV and Total Parenteral Nutrition (TPN) bags*
- *Bio-reactors*
- *High pressure injection syringes (Needle-free, viscous drug, and large dosage injection)*

3. Tough Material

In case of syringe shape, ZEONEX® has high strength compared with glass.





Test speed of 1.0 mm/min

4. Safe Material

- **High Purity**
- **Residual metals less than 0.02 ppm**
- **Contains no lubricants/process aids**
- **Low outgas**

Residual metals of ZEONEX® 690R

Al	V	Zr	Mg	Ti	Pd
<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Cr	W	Fe	Ni	Zn	Cd
<0.02	<0.02	<0.02	<0.02	<0.02	<0.02

Unit: ppm

Measures by ICP-MS analysis

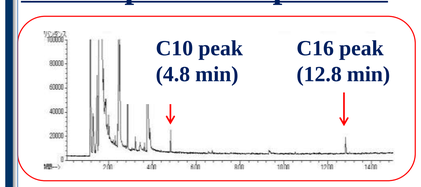
Very low residual metals (vs. other plastics)

Measurement method: ICP-MS

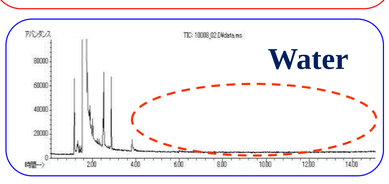
Analysis of metal species : Al, Cu, Fe, Mg, Pb, Ti, Zn, Zr, Li

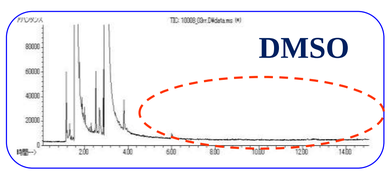
5. Low Extractables / Leachables

◆ **Non-polar components**

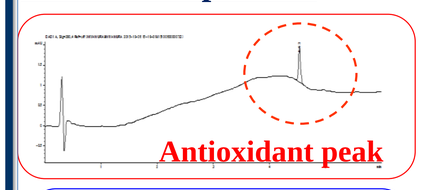


Reference chart : GC
Measurement of C10 and C16 materials as internal standard

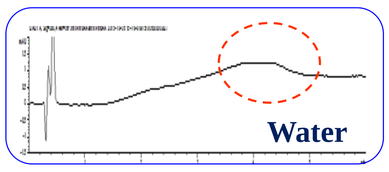


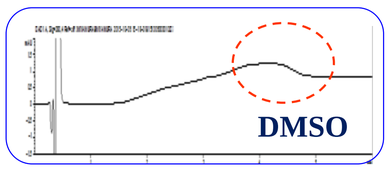


◆ **Polar components**



Reference chart : HPLC
Only A. O.





Non-polar and polar components are not detected from ZEONEX® syringes.

Test conditions : **Storage temp. : 40℃, Storage time : 3 months (approximately equal to storage of 3 years at 5℃)**

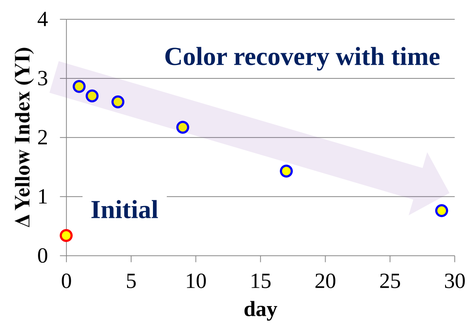
6. Sterilize with Gamma, EB, Steam

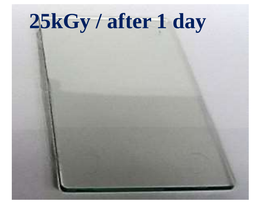
ZEONEX® is minimally influenced by exposure to standard sterilization methods.

ZEONEX® Properties	Unit	Initial	Sterilization *2			
			Steam	EOG	Gamma 25 kGy	EB 20 kGy
Light Transmittance *1	%	91	91	91	87	88
Yellow Index (⊿YI) *1	-	0.3	0.8	0.3	4.1	5.8
HAZE *1	-	0.1	0.6	0.2	0.1	0.2
Tensile Strength	MPa	68	74	68	67	67

***1 Test piece: injection-molded plate (3 mm in thickness)**
***2 Sterilization conditions**
Steam: 121 deg.C, 20 min. EOG: 50° C, 6 hours, EOG conc. 600 mg/l

Color shift occurs after irradiation sterilization but quickly recovers

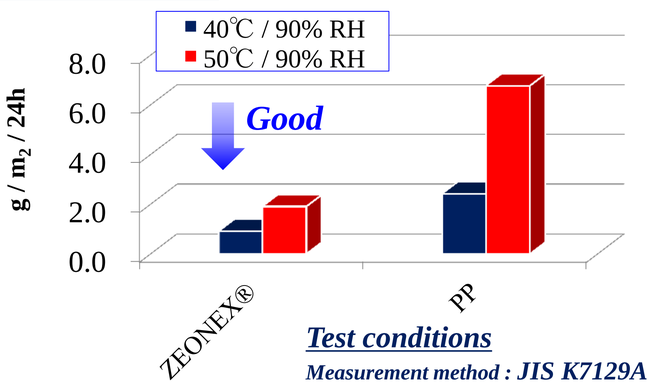




7. Low Moisture Pass - Thru

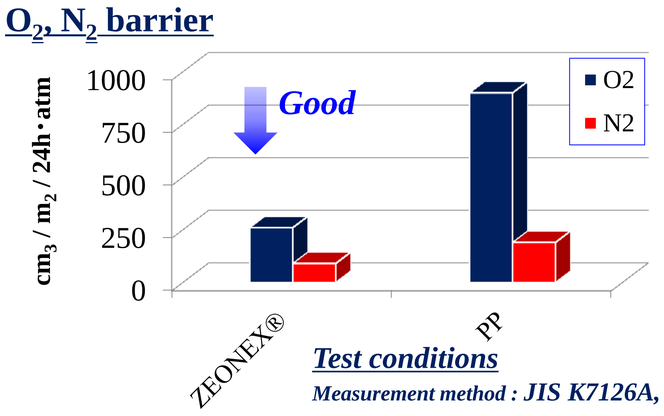
- **Excellent moisture barrier ➔ prolong drug shelf life**
- **3x better gas barrier vs polypropylene (PP)**

Moisture barrier



Test conditions
Measurement method : JIS K7129A

O_2, N_2 barrier



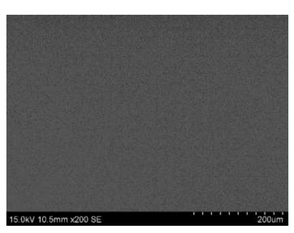
Test conditions
Measurement method : JIS K7126A, at 23℃

8. No Delamination - No flakes and particles -

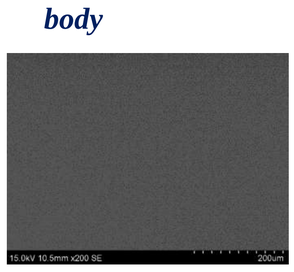
- **Delamination most commonly occurs at the tip of glass syringe where process heat history exposure is the highest.**
- **Particles are observed with glass syringes.**
- **No particles are observed in ZEONEX® syringe.**

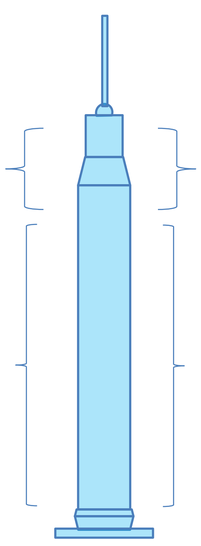
Syringe made of ZEONEX®

tip



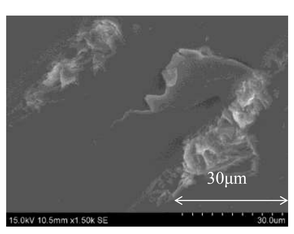
body





Glass syringe

tip



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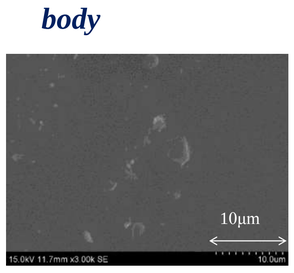
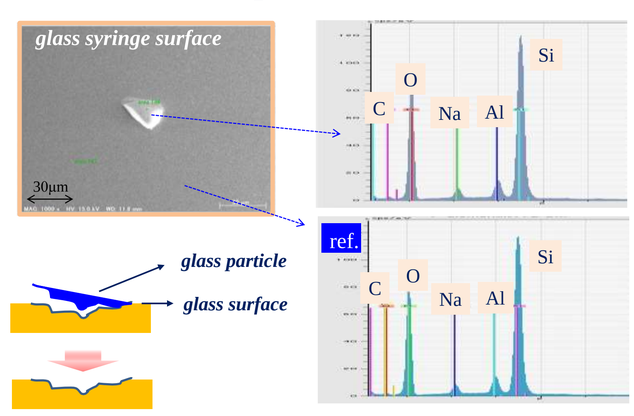


Test conditions
3.0 % Citric Acid, pH : 10.0, Storage temp. : 80 ℃, Storage time : 28 days

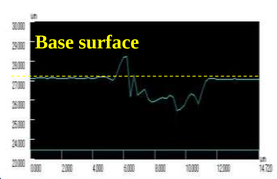
More details

Identification of particles



Measurement method : EDX (Energy Dispersive X-ray)

Glass surface profile after testing



The particles may be generated from the cavities observed on the glass surface.
- Identification of the particles
- Capture of the particles.