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.

![Diagram of Cyclo Olefin Polymer](Image)

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
- High moisture barrier
- No delamination
- Drug compatibility
- High break resistance
- Improved drop tolerance
- Very low residual metals
- Very low elution
- Long-term drug storage
- Low adsorption
- Keep drug activity
- Silicone oil free
- Acids, alkalis and alcohols
- No aggregation

Typical devices where ZEONEX® is used:

- Pre-Filled syringes
- Pre-Filled cartridges
- Vials and bottles for long-term storage of biologicals
- 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.

![Graph showing strength comparison](Image)

4. Safe Material

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

![Residual metal analysis](Image)

5. Low Extractables / Leachables

- Non-polar components
- Polar components

Reference chart:

- GC: Measurement of C10 and C16 materials as internal standard
- HPLC: Only A. O.

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

![Extractables analysis](Image)

6. Sterilize with Gamma, EB, Steam

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

<table>
<thead>
<tr>
<th>Sterilization</th>
<th>Unit</th>
<th>Initial</th>
<th>Steam</th>
<th>EO</th>
<th>Gamma</th>
<th>EB</th>
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<tbody>
<tr>
<td>Light Transmittance</td>
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<td>95</td>
<td>95</td>
<td>96</td>
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<tr>
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</tr>
<tr>
<td>O2%</td>
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</tr>
</tbody>
</table>

![Sterilization graph](Image)

7. Low Moisture Pass - Thru

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

Moisture barrier

![Moisture barrier analysis](Image)

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®

Glass syringe

![Comparison of glass and ZEONEX® syringe](Image)

More details

Identification of particles

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

Glass surface profile after testing

![Glass surface analysis](Image)