Fluoropolymers in Healthcare
Daikin Overview

- Daikin America, Inc. is a wholly owned subsidiary of Daikin Industries, Ltd. Headquartered in Osaka, Japan.
- Fluorochemical-based business focusing on air conditioning and chemicals.
- Manufacturing locations in Japan, China, France, Netherlands, and USA.
- Est. Corporate global sales ~$14BB; Fluorochemical division ~ $2.9 BB.
First Fluoropolymer (PTFE) Was Discovered in 1938.

Carbon Backbone Surrounded by Fluorine Atoms.

Family Includes PTFE (non-melt), Melt Processable Resins Such As PFA, FEP, ETFE, PVDF, and Fluoroelastomers.
Fluoropolymers 101

- Typical Properties Include
  - Low Coefficient of Friction (Lubricity)
  - Low Water Absorption, Excellent Moisture Barrier
  - Low Surface Energy (Oil/Water Resistance)
  - Excellent Chemical Resistance, Insolubility
  - Superior Electrical Properties (Low Dielectric)
  - High Service Temperatures
  - Good Mechanical Properties at Low Temperatures, and Weather Resistance, etc.
Fluoropolymers 101

- Applications Include
  - Catheters
  - Sutures
  - Dental Floss
  - Heat Shrink Tubing
  - Weather Resistant Coatings
  - Release Films, Tapes
  - Fuel Tubes
  - Seals
  - Insulators for High End Cables, etc.
PTFE: Polytetrafluoroethylene
Helical Structure of PTFE Chain
Healthcare’s Love of Fluoropolymers

- Chemical Resistance
  - Stable in severe environments such as strong bases, acids, and various solvents
- Low Surface Energy
  - Oil/Water Repellency
- Low Coefficient of Friction
  - Lubrication, Non-Stick Properties
- Biological Inertness
- Low/No Extractables
- Excellent Moisture Barrier
Benefits of FP in Healthcare

- Biocompatible / USP/Cytotoxicity Tested
- Lubricity (Dynamic Coef. Of Friction) – Lowest of Any Thermoplastic
  - PTFE: 0.02
  - PFA: 0.04 - 0.06
- Almost Inert
- Low/No Extractables or Leachables
- Moldable by Injection, Extrusion and Other Thermoplastic Processing Techniques
Myths about Fluoropolymers

- Limited Product Offerings
- Must Be Sintered/Machined (PTFE Only)
- Specialty Applications Only
- Difficult to Process
- Complex Injection Molded Parts Are Not Possible
Industry Issues

- Extractables
- Barrier Properties
- Chemical Resistance
- Glass Replacement
- Stick-Slip
- Silicone Toxicity
- Catheter Construction
- Sterilization
Addressing Industry Issues - Extractables

Extractable Fluoride Ion Comparison

Conventional Grade PFA

AP 211 SH
Addressing Industry Issues - Moisture Barrier Properties (WVTR)

- Chart Showing Moisture Barrier Properties of Various Thermoplastics
- PFA Among The Best
- PFA’S WVTR Values Between 2-3 g/m²/day (for 4 mil thick film at 40°C and 95% RH)
- PCTFE the Best Among Organic Films. It Is Being Used in Blister Packs for Pharmaceuticals.
Addressing Industry Issues - Chemical Resistance

- Percent Weight Change After Chemical Immersion
- 7 Days @ 75°C-80°C
- Stable in Strong Acids and Bases
- Insoluble in Almost All Solvents

<table>
<thead>
<tr>
<th>Chemicals</th>
<th>NEOFLON PFA</th>
<th>NEOFLON FEP</th>
<th>NEOFLON ETFE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric acid (35%)</td>
<td>0.0</td>
<td>0.0</td>
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<tr>
<td>Sulfuric acid (95%)</td>
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<td>Nitric acid (60%)</td>
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<tr>
<td>Fluoric acid (50%)</td>
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<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Acetic acid (50%)</td>
<td>0.0</td>
<td>0.0</td>
<td>+0.2</td>
</tr>
<tr>
<td>Sodium hydroxide (50%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Ammonia hydroxide (28%)</td>
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<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Sodium chloride (30%)</td>
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<td>0.0</td>
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<tr>
<td>Methyl alcohol</td>
<td>0.0</td>
<td>+0.1</td>
<td>+0.5</td>
</tr>
<tr>
<td>Ethyl alcohol</td>
<td>+0.1</td>
<td>+0.1</td>
<td>+0.7</td>
</tr>
<tr>
<td>Acetone</td>
<td>+0.4</td>
<td>+0.3</td>
<td>+3.5</td>
</tr>
<tr>
<td>Carbon tetrachloride</td>
<td>+2.3</td>
<td>+1.9</td>
<td>+6.0</td>
</tr>
<tr>
<td>Chloroform</td>
<td>+1.6</td>
<td>+1.6</td>
<td>+6.8</td>
</tr>
<tr>
<td>Toluene</td>
<td>+0.5</td>
<td>+0.5</td>
<td>+2.8</td>
</tr>
<tr>
<td>Xylene</td>
<td>+0.4</td>
<td>+0.4</td>
<td>+2.2</td>
</tr>
<tr>
<td>Benzene</td>
<td>+0.7</td>
<td>+0.7</td>
<td>+3.4</td>
</tr>
<tr>
<td>n-Hexane</td>
<td>+0.7</td>
<td>+0.6</td>
<td>+1.1</td>
</tr>
<tr>
<td>Methyl ethyl ketone</td>
<td>+0.4</td>
<td>+0.4</td>
<td>+3.7</td>
</tr>
<tr>
<td>Ethyl acetate</td>
<td>+0.6</td>
<td>+0.6</td>
<td>+4.0</td>
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<tr>
<td>Aniline</td>
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<td>+0.1</td>
<td>+0.6</td>
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<tr>
<td>Diethylamine</td>
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<td>+2.4</td>
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<tr>
<td>Phenol</td>
<td>+0.1</td>
<td>+0.1</td>
<td>+0.4</td>
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</tbody>
</table>

Note: Immersing conditions: For 7 days at 75–80°C (167–176°F). In case of Fluoric acid and Ammonia hydroxide, immersing conditions are for 7 days at room temperature.
Addressing Industry Issues - Glass Replacement

- Non Breakable/Durable (When Dropped)
- Clarity
- Moisture Barrier Properties
- High Purity
- Chemical Resistance
- High Impact Strength Even at -60 °C or Lower
Addressing Industry Issues - Stick-Slip

- Common Problem with Syringes
- Caused By Friction of Plunger Against Syringe Barrel
- Often Results In Improper Dosages
- Inherent Lubricity of Fluoropolymers Helps to Address Problem
Addressing Industry Issues - Silicone Toxicity

- Silicone Often Used To Combat Stick-Slip Issues
- Widely Used in Medical Industry
- Frequently Seen As A “Necessary Evil”
- Silicone Can Cause Toxic Reactions In Patients
- Fluoropolymers Mitigates The Need For Silicone Lubricants
Addressing Industry Issues - Catheter Construction

- Current Catheter Construction Methods Are Labor Intensive and Expensive
- Current Catheters Are Often Unreliable and Delaminate.
- Current Catheters Require a Toxic Etch Compound to Facilitate Bonding
- Use of EFEP in Co-Extrusion with (Modified) PEBA Eliminates Historic Problems
Addressing Industry Issues - Sterilization

- Fluoropolymers Traditionally Difficult to Sterilize (PTFE)
- Melt Products Show Promise (EFEP)
- Daikin Plans To Characterize Material Sample Across Range of Sterilization Methods
Addressing Industry Issues - Inertness

- Fluoropolymers Are Very Inert
- USP/Cytotoxicity Testing Results Are Proof
- Acceptable For Wide Range Of Healthcare Applications
Daikin Innovations

- Reactive Polymers; ETFE, EFEP, CPT
- Bonding with Nylon, PEBA, EVOH
- EFEP vs. FEP in Catheters
  - Co-Extrusion
  - No Successive Layer Build-up
  - No Chemical Etch Needed
  - Multi-Layer Construction in One Step Process
Co-extrusion of Reactive Resins to Achieve Strong Interlayer Adhesion

Summary of Results

<table>
<thead>
<tr>
<th>Extruder</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resin</td>
<td>EFEP</td>
<td>EFEP</td>
<td>M-PEBA</td>
</tr>
<tr>
<td>Melt Temp, °F</td>
<td>490-510</td>
<td>490-510</td>
<td>370-420</td>
</tr>
<tr>
<td>Pressure, psi</td>
<td>1000-1200</td>
<td>1000-1200</td>
<td>500-900</td>
</tr>
</tbody>
</table>

Adhesion strength is excellent: 30 – 40 N/cm
What the Future Holds

- Polyurethane Bonding
- Expansion of Reactive Polymers Offering
- Higher Reduction Ratio, Lower Pressure, Thinner Tubing, Longer Runs
- Daikin is Receptive to The Needs of Our Customers – Ideas are Welcome!
Possible Applications

- Pre-Filled Syringes
- Lined Catheters Allowing Deep Vascular Access
- Inhaler Device Components
- Bio-Containment Vessels
Daikin Products

- PTFE – Molding Powders, Fine Powders, and Dispersions
- Melts – PFA, FEP, CPT, ETFE, and EFEP
- Fluoroelastomers – Whole Range of DAI-EL Products
- Surface Coatings – Unidyne, Zeffle, and Optool
Summary

- Fluoropolymers Offer A Wide Variety of Applications in the Medical Industry.
- Fluoropolymers May Solve Many Long-Standing Industry Issues.
- Fluoropolymers Can Be Processed Via A Number of Common Plastics Processing Equipment.
Thank You

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