Watson-Marlow Fluid Technology Group

Effects of Sterilization on Peristaltic tube Properties

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Today’s Presentation

- Overview of Watson Marlow
  - Technology Groups
  - Our Factories
  - Market Sector
- How Peristaltic Pump Works
- Critical Properties for Peristatic Tubing
- Sterilization Studies
- Cure Mechanisms
- Conclusion
- Questions?
Watson-Marlow Fluid Technology Group

Our organisation at a glance

10 factories

34 countries with direct sales operations

1330 employees
Our factories – centre of excellence

- Each factory is a centre of excellence for its own particular part of the product range
- Improvement driven by the Global Excellence in Manufacturing program (GEM)
- All factories accredited to ISO9001 and 14001
Sales by market sector

42% BioPharm/Pharmaceutical
Sterile pumping, filling, transfer tubing and connections. Applications include fermentation, filtration, aseptic filling, and tablet coating

27% Industrial
Wide chemical compatibility, flow rate ranges and control options. Ease of use ensures rapid acceptance by operators

10% Water & Wastewater
Abrasion-resistant pumping of solids-laden fluids. Accurate and controllable chemical metering

8% Food & Beverage
Accurate, repeatable dosing with low-shear pumping action. No damage to solids and soft fruit. CIP and SIP. MasoSine: gentle, low shear, EHDGE

8% Medical & Clinical Diagnostic OEM
All Watson-Marlow and Alitea

5% Mining
Rugged pumps required to reliably handle aggressive flocculent chemicals and abrasive slurries 24/7

OEM route to market accounts for 26% of sales
How a Peristaltic Pump Works

The animation shows the fluid being drawn into a pump, trapped between two rollers and being expelled from the pump. The complete closure of the tube which is squeezed between the track and the rollers gives the pump the positive displacement action, preventing back flow and eliminating the need for check valves when the pump is not running.

Nothing but the tube touches the fluid-minimising validation
Flow stability and metering accuracy
Critical Performance Properties

- Life in Pump
- Flow stability
- Burst Pressure
- Shelf Life
- Particulate generation

- Unsterilized
- Autoclaved 131°C for 3 minutes
- Gamma Irradiated 50kGy
Life in Pump / Flow Stability
Life in Pump / Flow Stability

Silicone A

Silicone B

Key
- Green = unsterilized
- Blue = Autoclave
- Red = Gamma irradiated
Shelf Life

Silicone A unsterilised

Silicone A Gamma irradiated
## Burst Pressure

<table>
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<tr>
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<th>Max pressure (Bar)</th>
<th>Burst pressure (Bar)</th>
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<tbody>
<tr>
<td>Silicone A</td>
<td></td>
<td></td>
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<tr>
<td>Unsterilized</td>
<td>6.27</td>
<td>4.43</td>
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<tr>
<td>Autoclave</td>
<td>6.89</td>
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<td>Gamma</td>
<td>8.23</td>
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<tr>
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<th>Max pressure (Bar)</th>
<th>Burst pressure (Bar)</th>
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<tr>
<td>Silicone B</td>
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<tr>
<td>Unsterilized</td>
<td>9.16</td>
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<tr>
<td>Autoclave</td>
<td>7.32</td>
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<tr>
<td>Gamma</td>
<td>10.66</td>
<td>5.01</td>
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Burst Pressure- Failure Modes

Silicone A

UNSTERILE

AUTOCLAVE

GAMMA

Silicone B
Particulate Generation

- Closed loop system using Dreschel flask
- DI water
- Running continuously for 24 hours at high speed
- The water filtered using 1.5 micron glass fibre filter paper (Whatman 934-AH filter paper)
- The filter paper is dried at 60 °C in an oven for 1 hour before weighing

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<tr>
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<th>Unsterilized</th>
<th>Autoclaved</th>
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<td>Silicone A</td>
<td>11.9</td>
<td>10.0</td>
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<tr>
<td>Silicone B</td>
<td>3.8</td>
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Addition Cure Mechanism

Polydimethyl Siloxane

Cross linker

N=250-900 g/mol
Effects of Gamma Irradiation

\[ \text{CH}_3 \sim \text{O-Si-O} \sim \text{CH}_3 \]

\[ \text{Gamma} \to \text{CH}_3 \sim \text{O-Si-O} + \sim \text{O-Si-O} + \text{CH}_3 \sim \text{O-Si-O} \bullet + \text{Si-O} \sim + \text{H} + \text{CH}_3 \]

- \( (A) \quad \text{C+B} \quad \text{A+D} \quad \text{A+B} \quad \text{A+A} \)
- \( \text{Hyperoxides} \)
- \( \text{Inactive chains} \)
Conclusions

• Sterilisation has a positive effect on the critical properties of peristaltic tube
• Gamma irradiation has more of an effect on the tube properties than Autoclave
• Different Silicone materials are affected in different ways
• Selecting material formulation for tube need to understand and consider the effect of different sterilization techniques