How to Bring SAFER BLOOD BAGS to Healthcare

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Webinar: How to Bring Safer Blood Bags to Healthcare
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- Short company intro
- Compounding
- Experience on PVC replacement
- Material
- First test feedback
Privately owned

Founded 1979 in Sweden / 1986 in Denmark

Focus on packaging/process technology for pharmaceutical industry

Polymer & Compound sales and marketing (>25 years)

Production of compounds dedicated to medical market (1998)

Production at new high efficiency plant in Denmark (2003/2008/2014)

Total capacity: 25,000 tons

**meliflex**: new standard of compounds to healthcare industry

Global sales to healthcare companies

Dedication to healthcare through innovation, quality and service!
25,000 tons

= 2bn IV bags
= 5bn infusion sets

80,0000 blood bags @ Karolinska University Hospital
~1 ton
Specialty compounds and polymers for healthcare
COMPOUNDING

- Technology used to melt blend polymers and additives to obtain stable homogeneous mixture
- Design customized materials blends with unique mix of properties
- Scalable – no critical mass
SUSTAINABLE POLYMER SOLUTIONS FOR HEALTHCARE

Sustainable material technology
- Polyolefin based (vs. PVC, engineering resins, glass, steel)
- Customized to specific needs
- Extensive application know-how

Sustainable in quality
- Medical service concept
- Regulatory compliance

Sustainable supply
- Dedicated to Healthcare
- No critical mass
- Small, fast, flexible
- Logistics
Supplied leading OEM with PVC replacement since mid 1990-ies

- IV bags
- PD bags
- Nutrition bags
- Infusion sets
- Catheters
- Drainage applications
- Drug packaging & delivery devices
MELIFLEX XT TUBING MATERIALS

KINK RESISTANCE

SOFTNESS

CLARITY
meliflex XP
TPE/TPO for PVC replacement in healthcare applications

Environmental and Health benefits with Polyolefin base Elastomer (TPE/TPO)
Based on well established and documented polymers

→ polyethylene (PE) - in market since 1930-ies

→ polypropylene (PP) - in market since 1950-ies

→ synthetic rubber (TPE) - in market since 1950-ies

![Polymers used in Healthcare market (2007)]
- Easy processing / extrusion $\rightarrow$ high yields
- Less temperature sensitive $\rightarrow$ retain its properties over wide temp. span
- Easy recycling
- Good chemical resistance
- No use of plasticizers
- Residual product from incineration $\rightarrow$ CO$_2$ + H$_2$O
- Low density
- Good availability
- Low prices
- REACH compliant / no **Substances of Very High Concern**
- PVC free → chlorine free → dioxin free
- Approx. 25-30% lower density (0.90 vs. 1.25 g/cm³)
  → lower material consumption
  → reduced waste in hospitals
  → reduced waste after incineration
- Better environmental profile (vs. PVC and TPU/PUR)
  → Life Cycle Analysis / Environmental Product Declaration
  → Journal of Cleaner Production (vol 16 nr 16 2008 - issn 0959-6526)
ENVIRONMENTAL PROFILE FOR SOFT MATERIALS

TPO       PolyOlefin
TPE       Styrene Block Copolymers
TPV       TPO/EPDM-Vulcanized
PVC-S     PVC/DEHP
TPU       PolyUrethanes

* Rating based on LCA evaluation by Nordic Ecolabelling
(Swan labelling of peritoneal dialysis and intravenous sets; 2007)
• **meliflex** is safe:
  → Latex-free
  → BPA-free
  → phthalate-free
  → free from animal based additives (BSE/TSE free)
  → free from any **Substances of Very High Concern**

• Low migration → no plasticizer migration

• Low drug absorption → due to high chemical resistance

• Regulatory compliance to ISO 10993, USP and European Pharmacopeia
PVC FREE BLOOD BAGS
EU Life+ program
with Karolinska University Hospital, Stockholm, Sweden
www.PVCfreeBloodBag.eu
MELIFLEX XF FILM MATERIALS FOR PHARMACEUTICAL PACKAGING

KEY FEATURES

- Enhanced soft polypropylene
- Excellent flexibility (>50 MPa)
- Excellent clarity / low haze
- Excellent impact / drop resistant
- Fast sealing / peal seal
- Sterilisation @ 121°C
- Complete range for multilayer films
- USP 87, 88, 661, ISO 10993, EP compliant
<table>
<thead>
<tr>
<th>Multilayer coextruded film featuring:</th>
<th>Multilayer coextruded tubes featuring:</th>
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<tbody>
<tr>
<td>§ Sterilizable</td>
<td>§ Sterilizable</td>
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<tr>
<td>§ No blocking / stickiness</td>
<td>§ No blocking / stickiness</td>
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<tr>
<td>§ Softness</td>
<td>§ Softness</td>
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<tr>
<td>§ Toughness</td>
<td>§ Kink resistance</td>
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<td>§ Strong sealing</td>
<td>§ Resist centrifuge</td>
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<td>§ Freezable / defrezzing</td>
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<td>§ Clarity</td>
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<tr>
<td>§ Freezable / defrezzing</td>
<td>§ Sealable (tube to tube)</td>
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<td>§ Clarity</td>
<td>§ Regulatory compliance</td>
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PVCfreeBloodBag - 1st prototype test results w/ placebo (water)

- Sterilizable: OK
- No blocking / stickiness: OK, better than anticipated for non-embossed film
- Softness: OK, tube to be slightly softer for better curling into cups
- Toughness: OK, no film or tube failures
- Strong sealing: OK, no seal failures
- Drop resistance: OK during ‘normal’ handling
- Clarity: OK, very good
- Kink resistance: OK, acceptable, softer tube w/ more kink resistance
- Resist centrifuge: OK, some marks from ‘wrong’ clams
- Freezable / defrezzing: OK
- Regulatory compliance: OK – blood testing pending!!
Thank you!

Questions?

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