

How to Bring **SAFER BLOOD BAGS** to Healthcare

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With financial support from
EU's Life+ programme



Webinar: How to Bring Safer Blood Bags to Healthcare

22 October 2015

- Short company intro
- Compounding
- Experience on PVC replacement
- Material
- First test feedback



With financial support from
EU's Life+ programme



- 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



- 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 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 XF FLEXIBLE FILM MATERIALS

meliflex



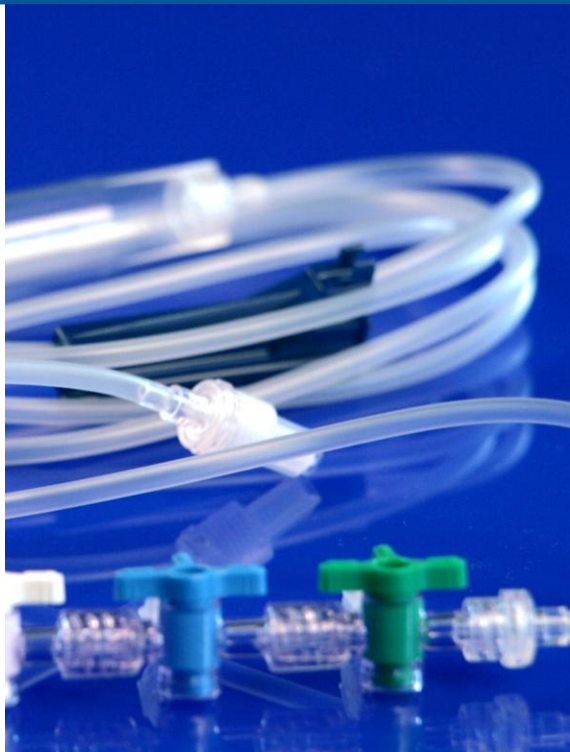
FILM



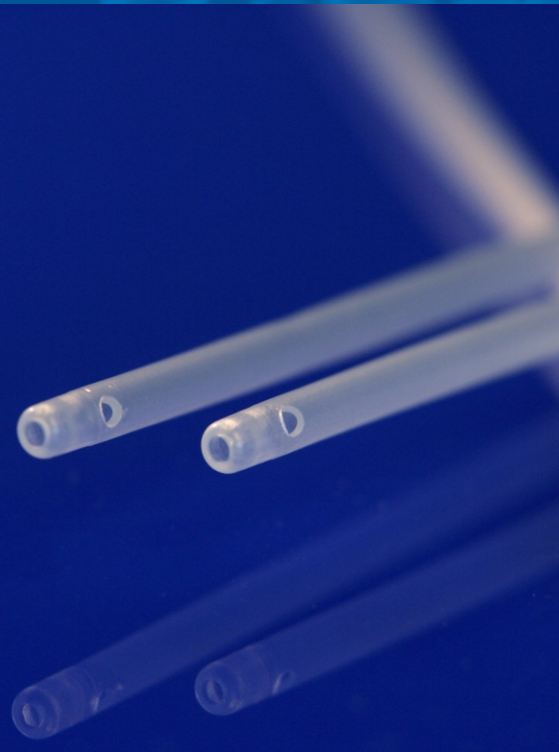
TUBES



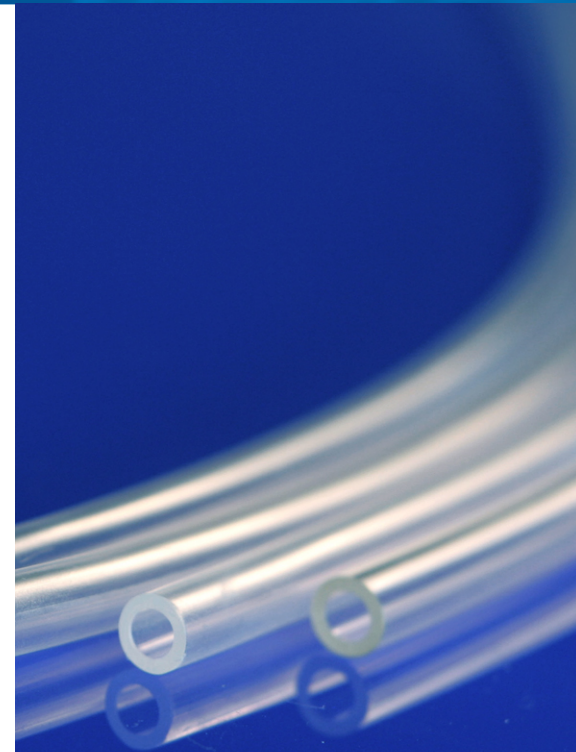
PORTS



KINK RESISTANCE



SOFTNESS



CLARITY





CUSTOMIZED



ENHANCED



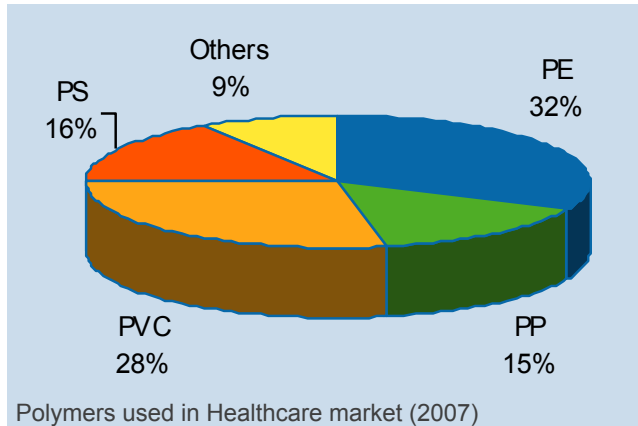
VALUE-ADDED

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



- Easy processing / extrusion → high yields
- Less temperature sensitive → retain its properties over wide temp. span
- Easy recycling
- Good chemical resistance
- No use of plasticizers
- Residual product from incineration → $\text{CO}_2 + \text{H}_2\text{O}$
- 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)

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 **S**ubstances of **V**ery **H**igh **C**oncern
- Low migration → no plasticizer migration
- Low drug absorption → due to high chemical resistance
- Regulatory compliance to ISO 10993, USP and European Pharmacopeia



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- **PVC FREE BLOOD BAGS**

EU Life+ program

with Karolinska University Hospital, Stockholm, Sweden

www.PVCfreeBloodBag.eu

KEY FEATURES

- Enhanced soft polypropylene
- Excellent flexibility (>50 MPa)
- Excellent clarity / low haze
- Excellent impact / drop resistant
- Fast sealing / peel seal
- Sterilisation @ 121°C
- Complete range for multilayer films
- USP 87, 88, 661, ISO 10993, EP compliant



PVCfreeBloodBag prototype made from:

Multilayer coextruded film featuring:

- Sterilizable
- No blocking / stickiness
- Softness
- Toughness
- Strong sealing
- Resist centrifuge
- Drop resistance
- Freezable / defreezing
- Clarity
- Regulatory compliance

Multilayer coextruded tubes featuring:

- Sterilizable
- No blocking / stickiness
- Softness
- Kink resistance
- Resist centrifuge
- Freezable / defreezing
- Clarity
- Sealable (tube to tube)
- Regulatory compliance

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 / defreezing OK
- Regulatory compliance OK – blood testing pending!!

Thank you!

Questions?

Oct'2015

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