

Substitution of hazardous chemicals in medical devices

09.11.2016

© MELITEK A/S

Webinar | The new Medical Devices Regulation - An engine for EDC substitution?

@ HCWH on 9.11.2016

Jesper Laursen | Business Director

Webinar:

Substitution of hazardous chemicals in medical devices

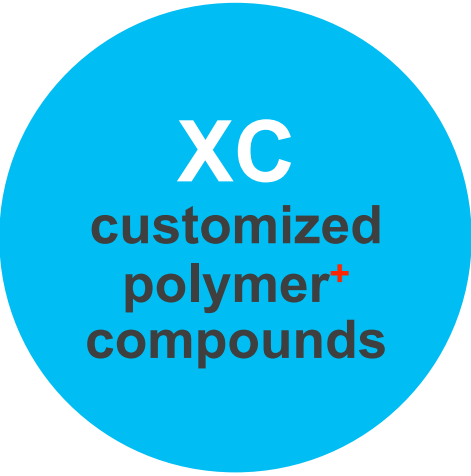
9 November 2016

- Short company intro
- Experience on PVC replacement
- Update on PVC Free Blood Bags

- Founded 1979
- Private owned and located in Denmark
- Offer Elastomer and Polymer Compounds
- Dedicated and devoted to service Healthcare market (>95%)
- Production at 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



XP
polyolefin
compounds



XC
customized
polymer⁺
compounds



XR
elastomer
compounds

meliflex is used in...

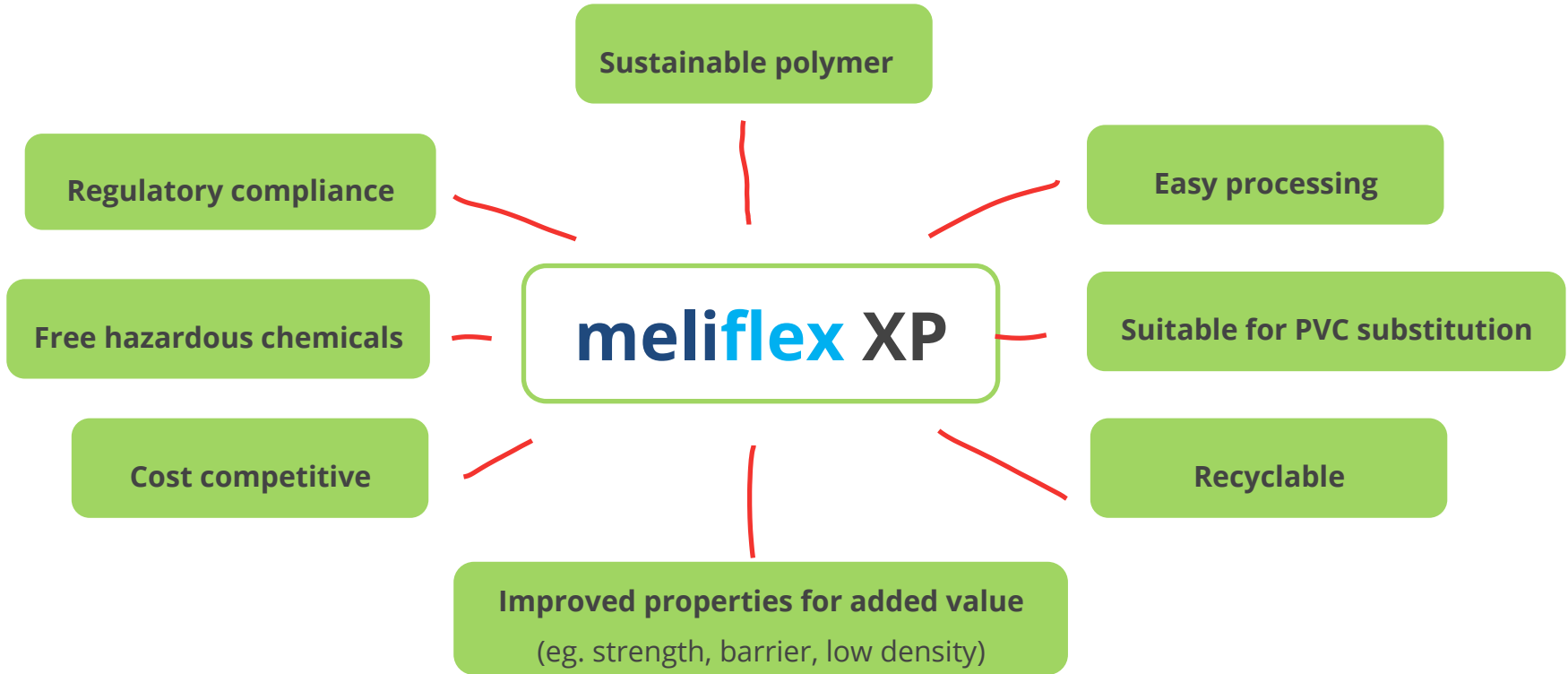
MELITEK



meliflex XP

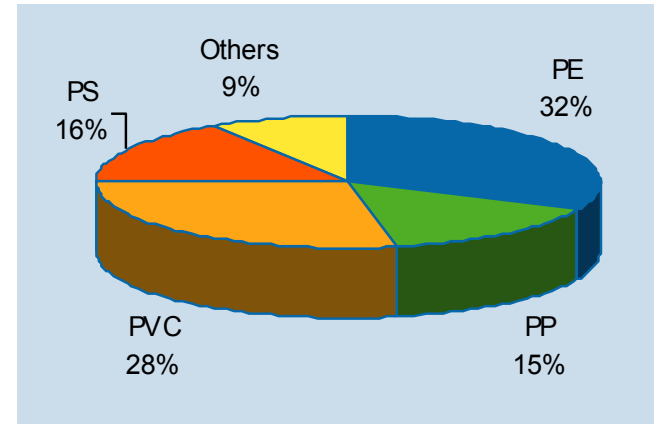
Substitute for soft PVC in healthcare applications

Environmental and Health benefits with
Polyolefin base Elastomer (TPE/TPO)



Based on well established and documented polymers:


- polyethylene (**PE**) - in market since 1930s
- polypropylene (**PP**) - in market since 1950s
- synthetic rubber (**TPE**) - in market since 1950s



Polymers used in Healthcare market (2007)

- 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 **S**ubstances of **V**ery **H**igh **C**oncern
- 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 and free from hazardous chemicals !

- + 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 chemical migration → no plasticizer migration
- + low drug absorption → due to high chemical resistance
- + compliance to ISO 10993, USP and European Pharmacopeia



With financial support from
EU's Life+ programme



- **PVC FREE BLOOD BAGS**

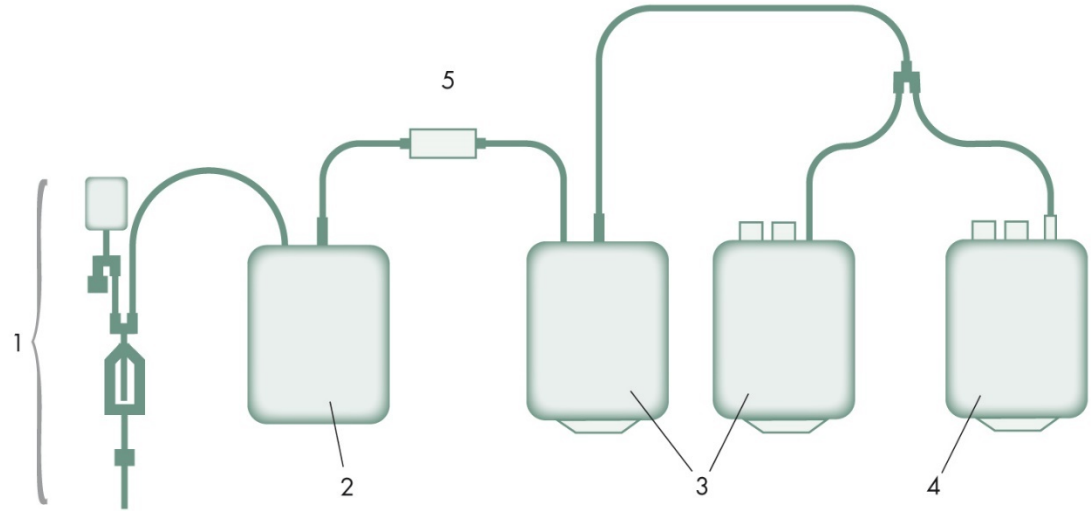
EU Life+ program

with Karolinska University Hospital, Stockholm, Sweden

www.PVCfreeBloodBag.eu

Multilayer film & tubing

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



KEY

1. Sampling device
2. Collection bag

3. Empty transfer bag
4. Transfer bag with additive solution
5. Leucocyte filter



**Karolinska
Institutet**

KAROLINSKA
University Hospital



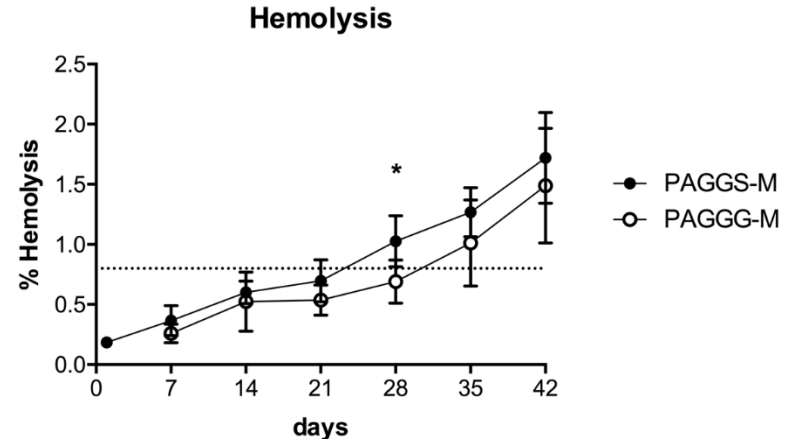
Conclusions from in vitro testing:

- + The results are promising.
- + The quality of the stored red blood cells was higher with PAGGG-M.
- + Haemolysis was problematic with both solutions.
- + Other additive solutions could improve the quality of red blood cells stored in the new blood bags.



Karolinska
Institutet

KAROLINSKA
University Hospital



PVCfreeBloodBag – pending

- Softer tubing
- Sterilisation validation
- CE mark
- User instructions / centrifuge cup loading
- Improved stabilizing solution (PAGGG-M)
- User testing at 4 hospitals in Sweden

More on www.pvcfreebloodbag.eu



**AKADEMISKA
SJUKHUSET**



Thank you!

Questions?

Nov'2016

©MELITEK

MELITEK A/S

Hartvig Jensensvej 1
DK-4840 Nr. Alslev
Denmark

Tel. +45 70 250 255
Fax +45 70 250 277
E-mail: sales@melitek.com

www.melitek.com

Follow us on :

