Presentation of Polymedics Innovations GmbH (PMI) – Wound Healing Company I Germany
Company profile at a glance

PolyMedics Innovations GmbH

- Foundation: 2001
- 5 shareholders / associates
- Products: SUPRATHEL® # SUPRATHEL® CW
- CE approval in 2004 & FDA (510K) in 2009
- Sales & distribution in 20 countries worldwide
- own facilities (2008): production, logistics, sales, R&D
- 15 employees (2014)
Company activities, expertise, skills

**activities**
- Sales & Distribution
- Marketing
- QS / QM / RA
- Prod. clean rooms (ISO 146441-1; class D # 100.000)
- R & D (wounds, hernia, stents, anti-adhesion)

**expertise**
- Resorb. polymers
- Textile technologies
- Chemical & physical process technologies
- Tissue engineering
- Interdisc. team of chemists, biologists, engineers, physicians

**skills**
- Design & realisation animal & human studies
- MD development from screening to final product
- Market launch & access
- HEOR, Cost eff., Reimbur.
QS / QM system: certificate DIN EN ISO 13485 : 2012
EC certificate, conformity
EC certificate, product class III (UMDNS 17-670)

Polymedics Innovations GmbH
Hearweg 15 D
73770 Dossenheim
Germany

Certificate

EC-Certificate
(quality assurance system)
according to Annex II (existing section) of Medical Devices Directive 93/42/EEC.
It is issued by the:

BSI Group Deutschland GmbH
11999 Berlin
Germany

Certificate

Certificate

Certificate

Certificate

Certificate
Company network & relations

**Research Institutions:**
- ITV / ITVP
- NMI
- FHG

**Advisory board:**
- KOL / HoD
- Physicians
- Clinical staff

**Institutional Network:**
- AFBW
- BioRegio
- BioPro

**Clinical Network:**
- Burn Centers
- Univ. hospitals
- Wound care centers
**SUPRATHEL® - Epithelial Skin Substitute**

- **Material:** Poly-DL-lactid, Trimethylencarbonate, Caprolactone
- **Aspect:** white smooth sheet, microporous membrane

**Key Properties**
- **Thickness:** 50-150 µm
- **Transepidermal water loss (TEWL):** 40-70 ml/m²*hour
- **Porosity:** 70 - 80%
- **Pore size:** 2 - 40µm (av. < 10µm)

→ *temporary second skin*
Significant reduction of pain (wound pain)
Rapid / accelerated epithelization
No change of the direct (Suprathel) wound dressing
Undisturbed wound healing
Optimal adaptable to all body regions
Physiological adapted moisture vapour permeability
Transparency, wound bottom is visible during the healing time
Minimal risk of infection, no allergenic potential
No additional OP, no narcotic bath
No Sedativa, less (or no) Analgetica
Excellent cosmetic results
Synthetic product, no biological risks
Reducing nursing time
Increasing patients convenience
### Countries
- **Europe:**
  - Austria, Germany, Switzerland, Finland, Poland, Sweden, Great Britain, Netherlands, Belgium, Spain, Denmark, Italy
- **Africa:**
  - South Africa
- **Asia:**
  - Turkey, South Korea, Pakistan
- **America:**
  - Dom Republic, Mexico, Costa Rica, USA

### Approvals
- **Europe CE:** approval 2004
- **USA FDA:** approval 2009
- **S-Korea KFDA:** approval 2010
- **Mexico & Dom Rep.:** registration 2009
- **Australia TGA:** approval 2012

### Applications in hospitals
- > 300 hospitals worldwide
- > 150,000 applications
- > 15,000 patients

- ➔ no notifiable occurrences or incidences
chronic wounds (CW)
✓ multicenter study 2011-2013
✓ SUPRATHEL® CW launch 2014

Adhesion prophylaxis
✓ animal study, clinical appl. trials

„Tissue engineering“ material
✓ „Matrices“ or „Scaffolds“ for cells via spay techniques (BG Berlin)

Synthetic Dermal Skin Substitute
✓ animal studies finished
◆ human multicenter trial in 2015

SUPRATHEL® plus
- Future projects, needs, offers

**Future proj.**
- Adhesion barriers
- Hernia repair (mesh, patch)
- Vascular patches
- Stents (vascular, gastrointestinal)
- Tissue eng.
- Surface modif. MD

**needs**
- Clinical advisory
- CRO (study design, biometry, monitoring)
- HEOR
- Consultants, reimbursement, cost eff.
- Animal study (team, facilities)
- Biology, Pathology, Histology

**offers**
- Collaboration international projects and studies
- Partner in R&D projects or studies
- Test lab (phys. chem. mechan.)
„medicus curat – natura sanat“
(Hippokrates, 460-370 b.c.)
“The physician treats, nature cures”

Thank you very much for your attention!