



Fraunhofer ISC

**RENACER® - a natural, plastic-free
and bioactive material platform**

RENACER® Materials

Platform Technology

RENACER® - the next generation of *ortho*-silicic acid releasing biomaterials

A **unique liquid raw material** is developed at Fraunhofer ISC that...

- ... can be processed into **particles, fibers** and **coatings**,
- ... is **fully resorbable** into *ortho*-silicic acid and **free of microplastics**,
- ... is *bioactive* impacting regeneration of e.g. skin and bone,
- ... is shown to be **biocompatible** and **safe**, (former developed product based on silica gel is **approved as a CE-certified medical product class III**),
- ... can be **manufactured** and **scaled up under GMP conditions**

patented technology

priority date: 2017

DE, US, EP – granted

Silicic Acids in Humans

Bioactivity

» silicic acids are omnipresent in nature

natural,
microplastic-free

sea water and minerals

plants, fruits, plankton

human tissues and body fluids

» silicic acids are bioactive

impact
on health

Boosting wound regeneration

Promoting bone healing

Alzheimer prevention



sea water and minerals



plankton



bamboo



rice



potatoes



skin tissue

aim: Creating eco-friendly and effective products by patented silicic acid technology

Inspired by Nature

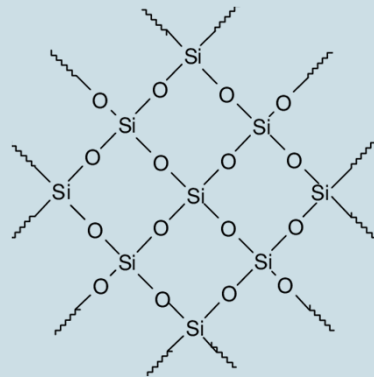
RENACER® Materials

High condensation grade

- high mechanical stability
- low solubility into *ortho*-silicic acid (oSA)



incorporation of
poly-(silicic acids)



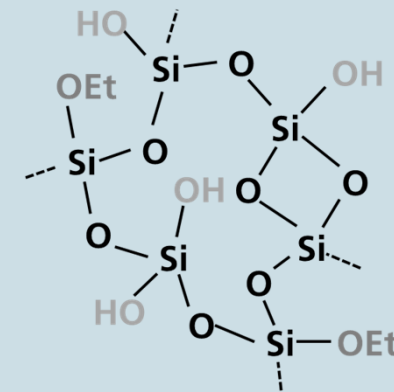
idealized structure

Know How
Fraunhofer ISC

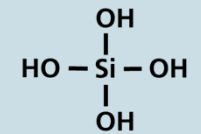
RENACER®

Adjustable condensation grade

- degradation into bioactive *ortho*-silicic acid (oSA)
- release of bioactive amounts of *ortho*-silicic acid (oSA)



degradation into:

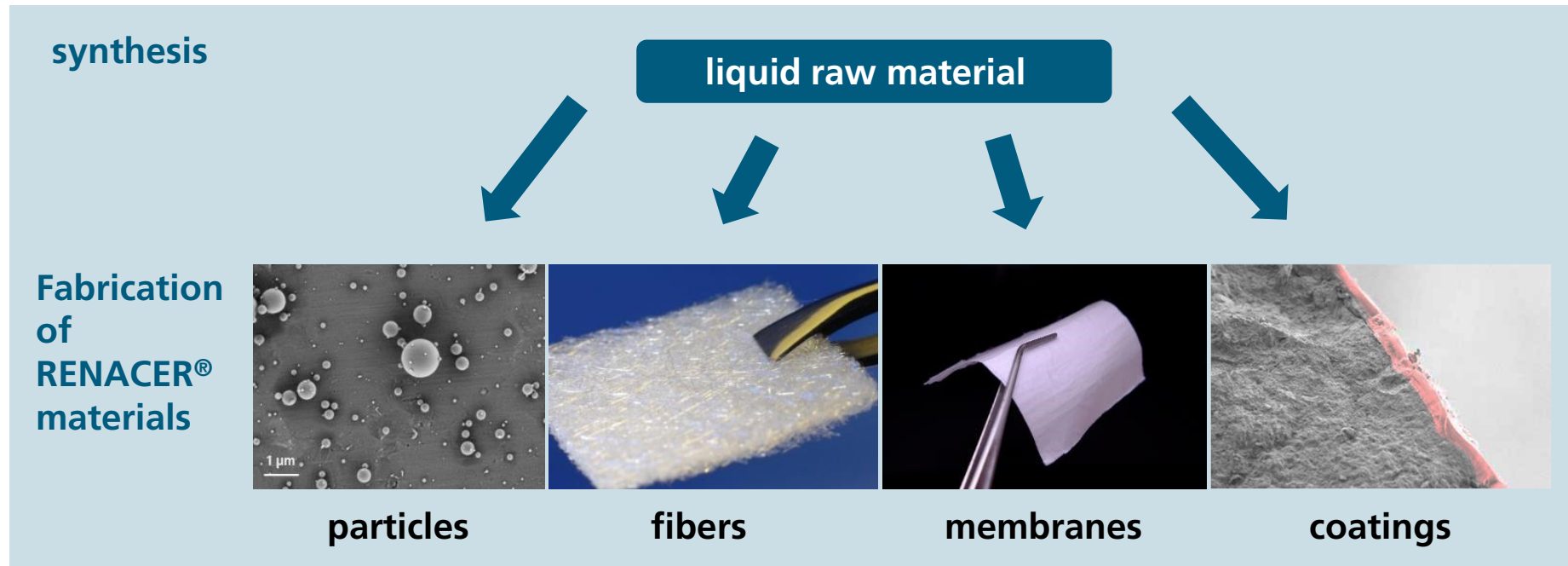


oSA

natural &
bioactive

RENACER® Materials

Platform Technology



➔ resorbable, bioactive and plastic-free biomaterials inspired by nature

RENACER® Materials

Markets

medical products



examples:

- wound regeneration
- scaffolds
- barrier membranes
- coatings of medical products
- customized developments

pharmacy



examples:

- drug encapsulation
- drug protection
- coating of oral dosage forms
- mucoadhesive particles
- (controlled) drug release

cosmeceutical



examples:

- ointments
- cremes
- nail care
- hair care
- food supplements

RENACER® Fibers

Application Fields



- **fully *in-vivo* resorbable** into natural α -silicic acid
- **Silica Gel – the underlying material class:**
CE-approved as a medical product class III
for the regeneration of chronic skin diseases
(diabetic ulcers, 2nd degree burns)

Ongoing product developments and improvements:

» ... next generation wound healing applications

» ... advanced therapeutic medicinal products (ATMPs)

» ... drug encapsulation

» ... resorbable scaffolds

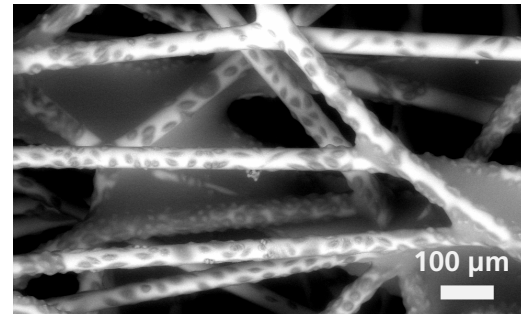
» ... fiber reinforcement

Fiber Fleece based on Silica Gel

Successful In-house Development

Silica Gel Fiber Fleeces for the Treatment of Chronic Wounds

- fully resorbable material with optimized mesh sizes
- form stability while resorption into non-toxic *o*-silicic acid – $\text{Si}(\text{OH})_4$
- migration of healthy cells into the scaffold
- healing period: approx. 2 months
- established GMP-process
- CE-certification (diabetic ulcer and 2nd degree burns)



KEMA Quality

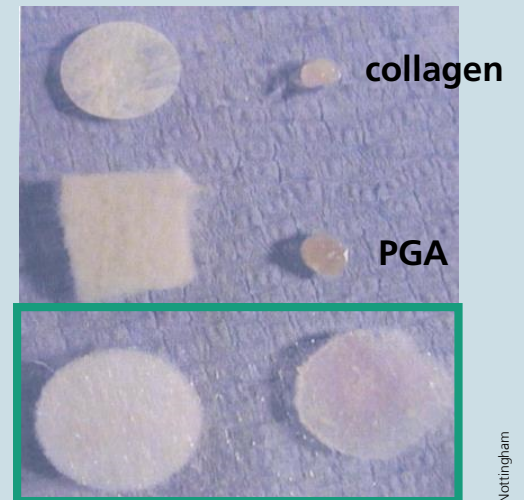
CERTIFICATE

Number: 2108976CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES



before culturing after 4 weeks



silica gel
fiber fleece

2 cm

University of Nottingham

Biodegradable Fibers and Membranes

Fabrication Techniques of RENACER®



μ -fibers

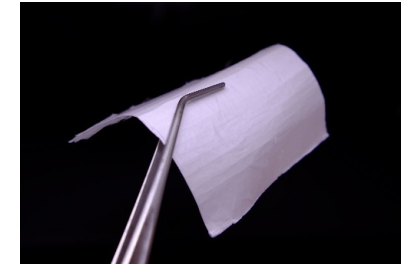
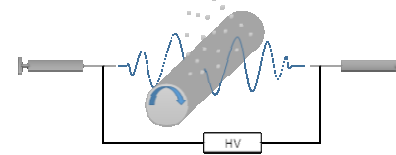
fiber diameter:
20 – 120 μm

- non-wovens or endless fibers
- different nozzle geometries
- fleece or cotton ball-like structures

Pressure spinning



Electro spinning



sub- μ -fibers

fiber diameter:
0.1 – 5 μm

- planar or tubular membranes
- possibility of co-spinning

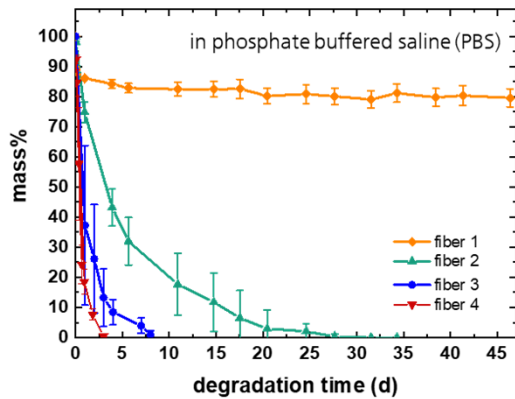
Biodegradable Fibers and Membranes

Property Profile and USPs of RENACER®

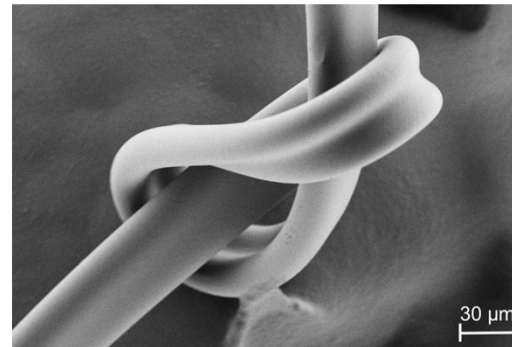
Adjustment of:

- fiber diameter
- mesh sizes
- fiber orientation
- degradation profiles
- fiber flexibility
- drug incorporation

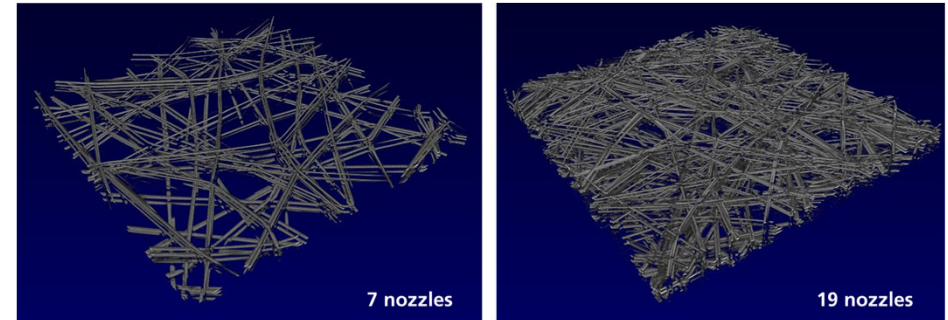
adjustment of degradation profile



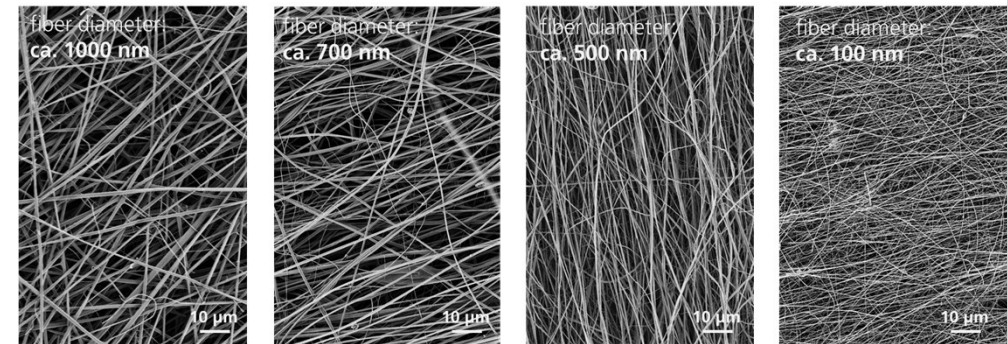
adjustment of fiber flexibility



adjustment of mesh size (OCT)



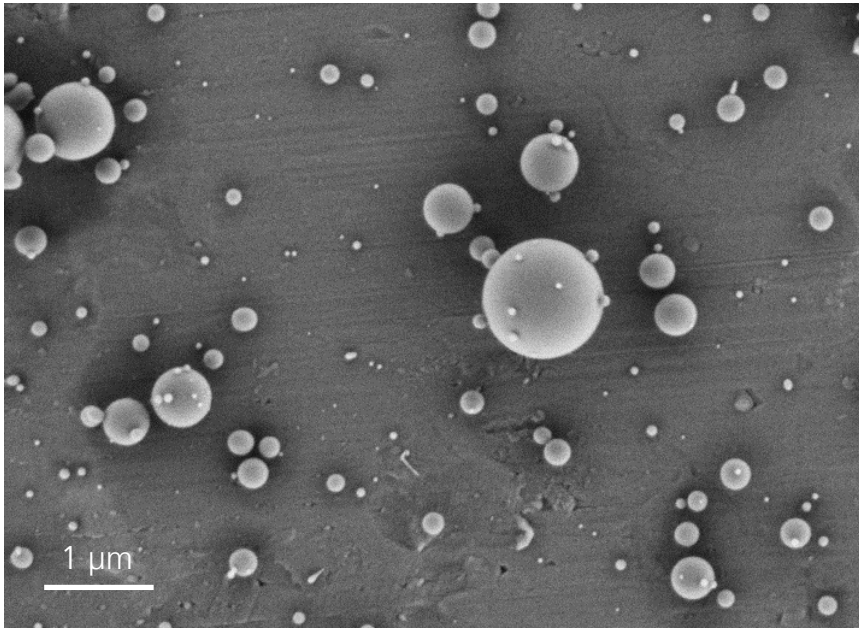
adjustment of fiber diameters (electrospinning)



decrease in fiber diameter

RENACER® Particles

Application Fields



Ongoing developments:

» ... drug delivery and therapy

» ... mucoadhesive properties

» ... small molecule, protein & plant extract encapsulation

» ... drug protection and release

» ... particulate filler and flow agents

RENACER® Particles

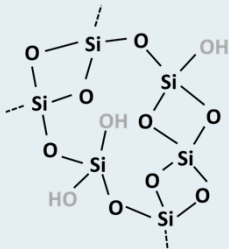
Property Profiles and USPs

drug protection:

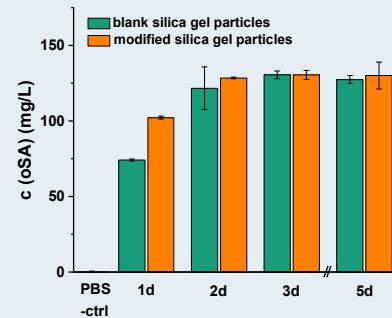


★ = drug molecule

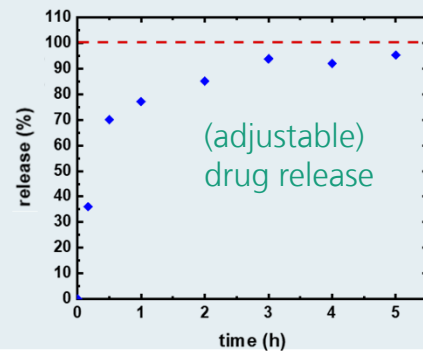
■ = silica gel matrix



particle dissolution:



drug release during dissolution:

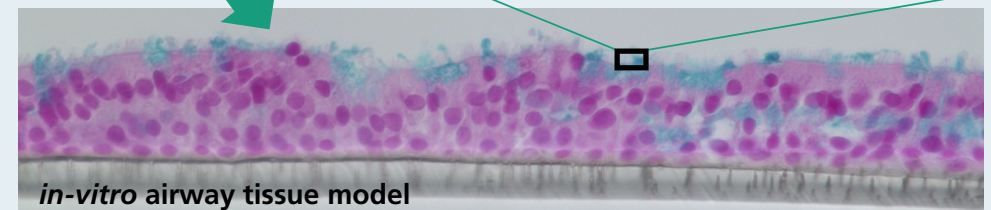
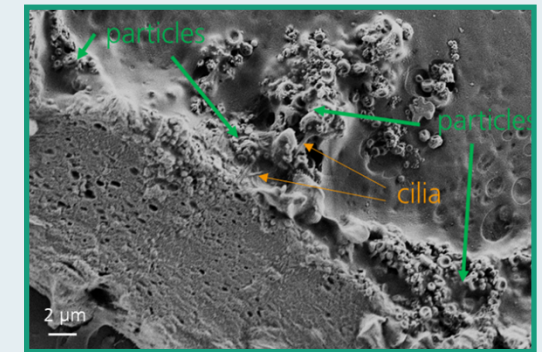


Spraying techniques:

- Spray drying
- Electro spraying
- Granulation
- Precipitation

In-vitro experiments – mucus affinity:

application of drug-loaded silica gel particles on *in-vitro* airway model with mucus



RENACER® Coatings

Application Fields

Ongoing developments:

» ... (nano)topographic coating

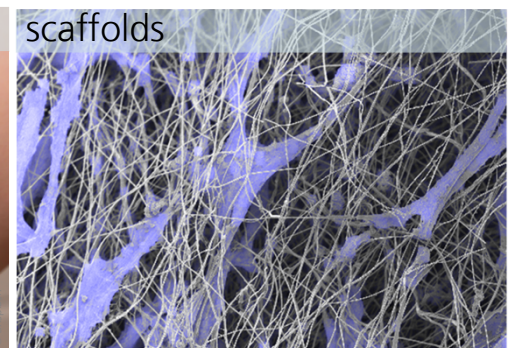
» ... coatings of oral dosage forms

» ... coating of medical products

» ... surface chemical functionalization

» ... surface biologization

Functional coatings on:



Biocompatible Coating Systems

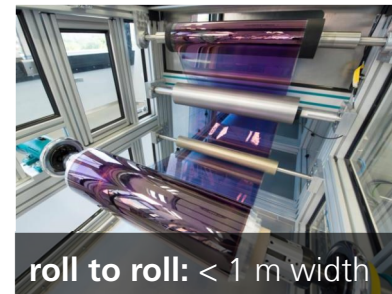
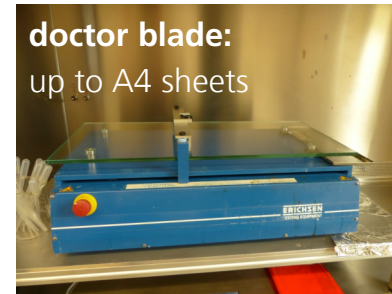
Coating Techniques

Coating Techniques:

- fluidizing bed
- dip coating
- rotational coating
- spray coating
- roll-to-roll coating
- roller coater
- doctor blade

Pretreatments:

- annealing
- plasma activation
- etching
- chemical treatment



customized coating techniques including first **up-scaling** processes

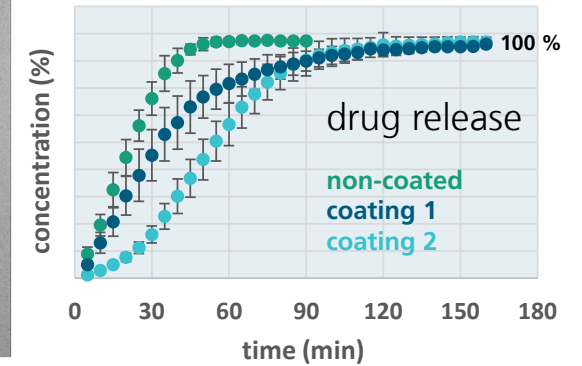
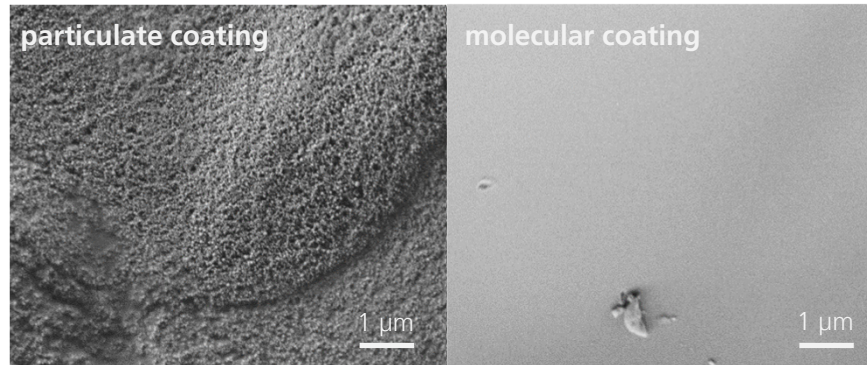
Biocompatible Coating Systems

Property Profiles and USPs

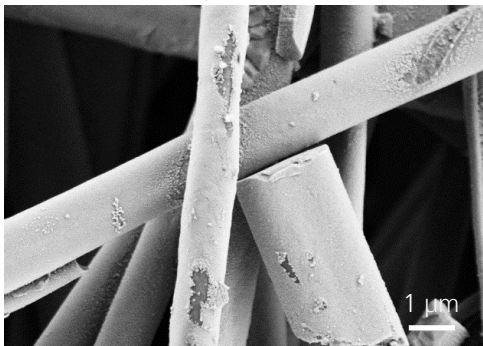
Substrates:

- planar
- topographic
- fibers
- tablets

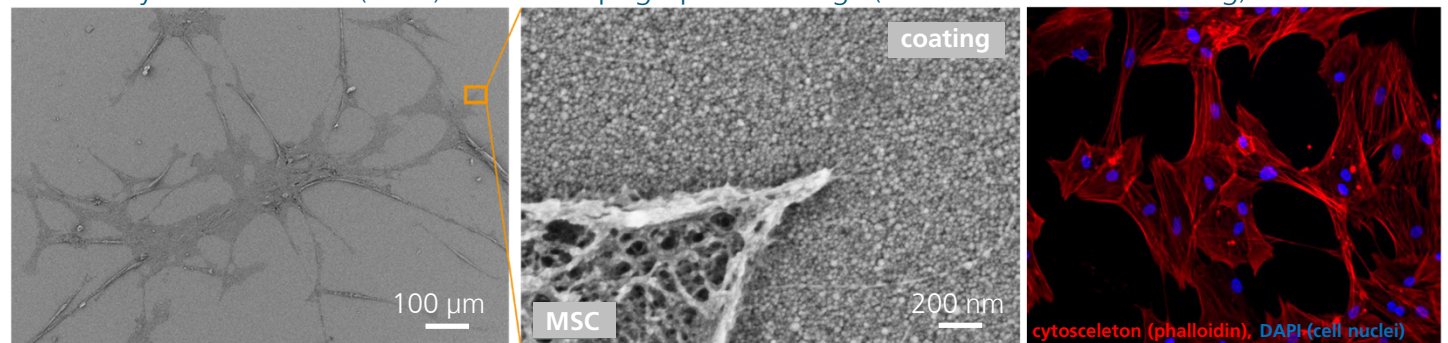
coatings on oral dosage forms (SEM):



protein coatings in medical products:

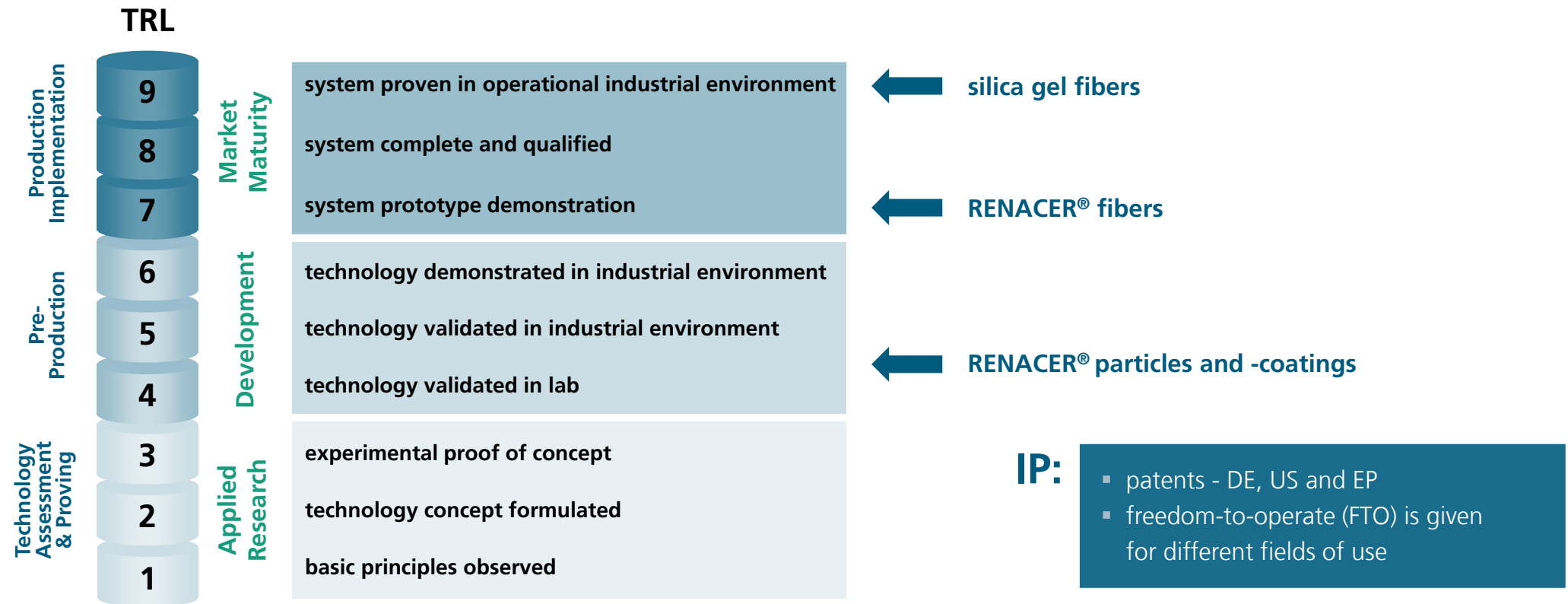


mesenchymal stem cells (MSC) on nanotopographic coatings (SEM and immunostaining):



Technology Readiness Level (TRL)

RENACER®



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