

SchurSign ■

Bio-absorbable, pain free, and precise tissue marking

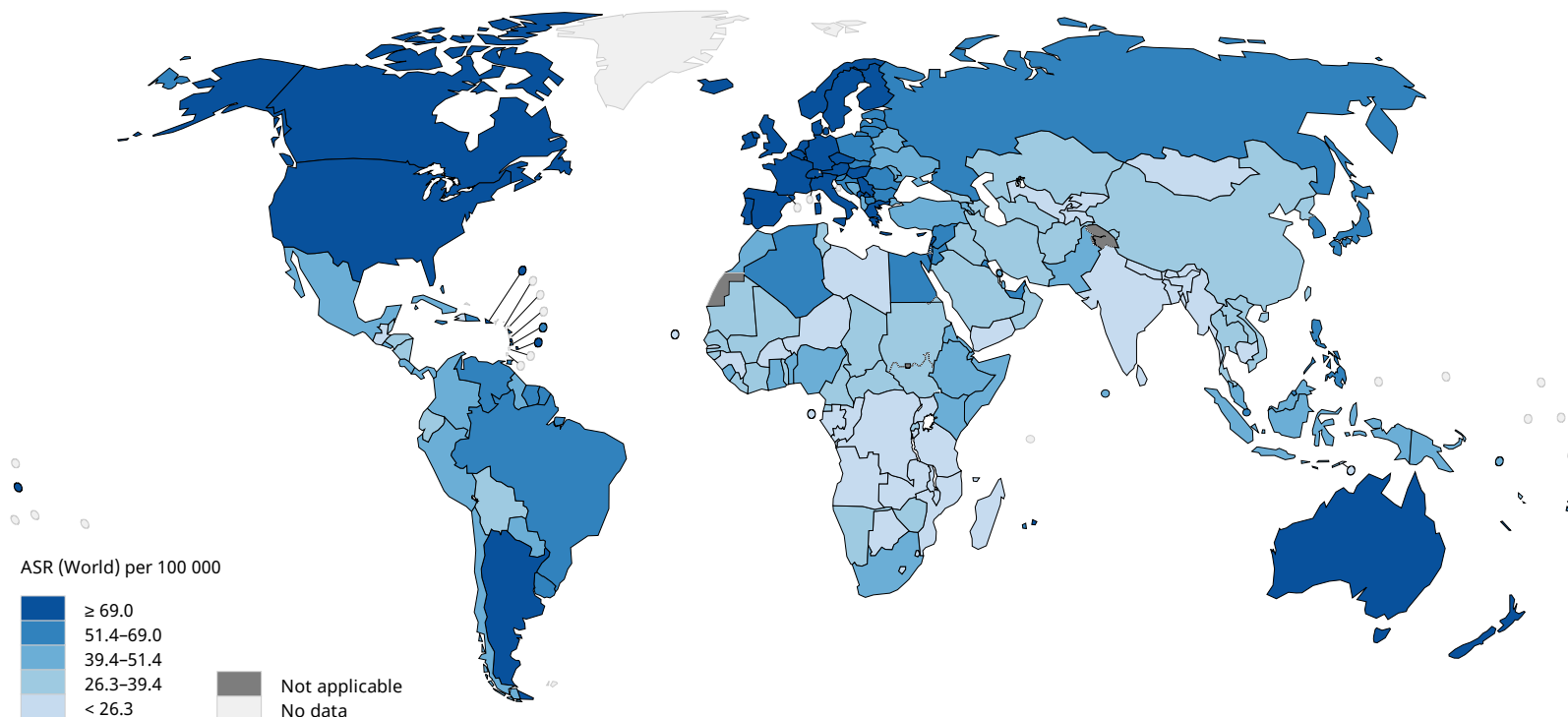
Dr. Christine König, CEO

Sino-German Health Industry Weeks Roundup 2021

SurgMark ■

2 M cases of breast cancer per year

Estimated age-standardized incidence rates (World) in 2018, breast, all ages



All rights reserved. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization / International Agency for Research on Cancer concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate borderlines for which there may not yet be full agreement.

Data source: GLOBOCAN 2018
Graph production: IARC
(<http://gco.iarc.fr/today>)
World Health Organization

 **World Health Organization**
© International Agency for
Research on Cancer 2018

Incidences are rising, because many of us now regularly go to mammography screening programs

Many of us now routinely receive tissue markers, especially **small lesions** are often only marked first.


Less invasive treatments are available, it doesn't always have to be mastectomy!

Breast cancer is the most common form of cancer in women!



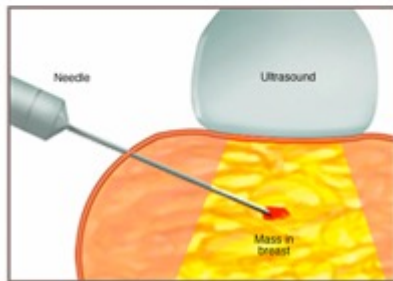
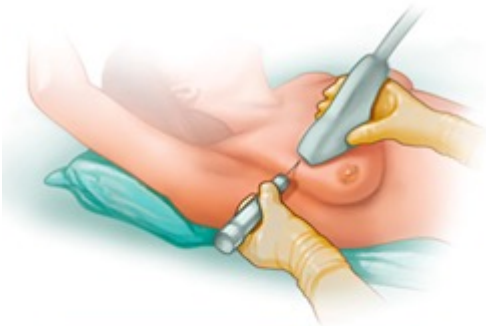
Trends in treatment

- Breast cancer detection and treatment is continuously improving and has become more sensitive, more specific and less invasive.
- In most practices patients routinely receive markers/clips, i. e. tiny ($\approx 5\text{mm}$) metal based implants, as part of the biopsy procedure, either,
 - prior to surgery and during neoadjuvant therapy to mark a tumor,
 - or to mark a suspicious lesion for follow-up,
 - or after tumor resection to mark the area where a tumor was removed.

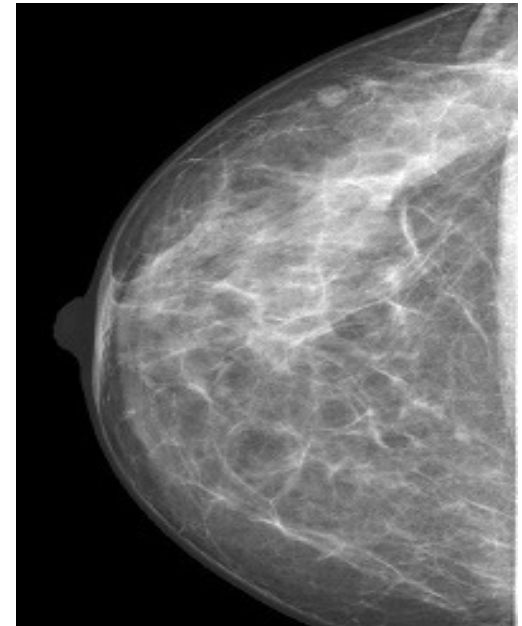


Exact marking is crucial for a proper evaluation of surgery outcome, follow-up routine, and diagnosis of cancer recurrence.

Tissue markers in diagnosis & therapy



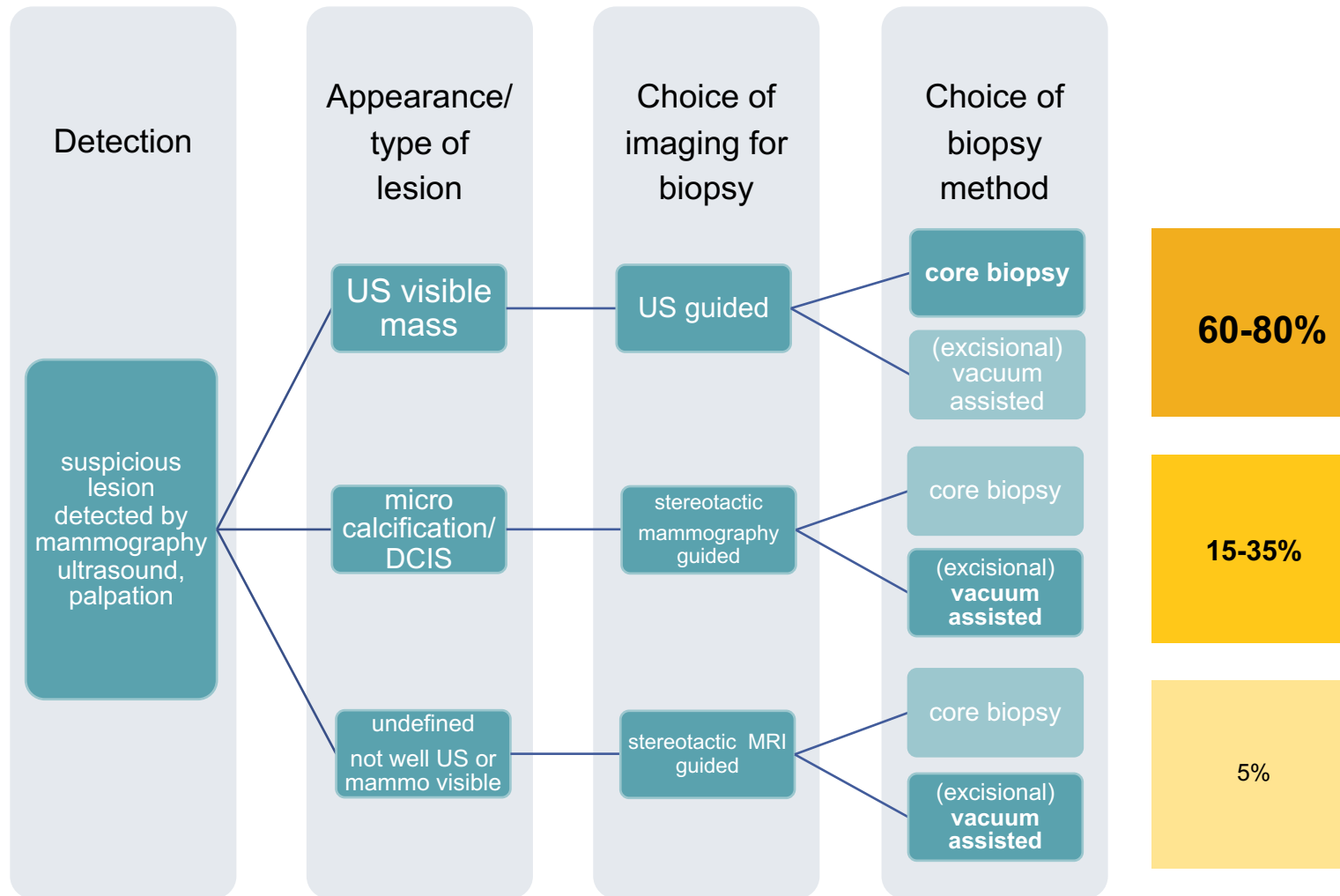
© BMFQ FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH. ALL RIGHTS RESERVED.



Main competitors in the field of tissue marking are:

Hologic, Cook Medical Inc., Argon Medical Devices, C. R. Bard (BD), SOMATEX Medical Technologies GmbH, and Mammotome (Devicor Medical Products, Inc).

Ultrasound guided core biopsy is the most frequently applied biopsy procedure



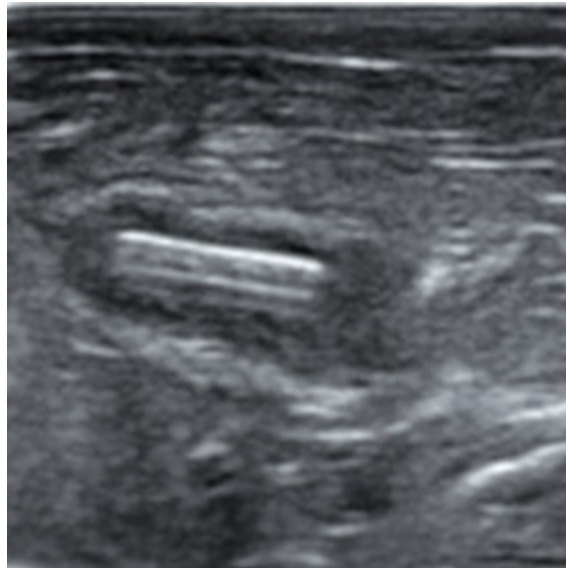
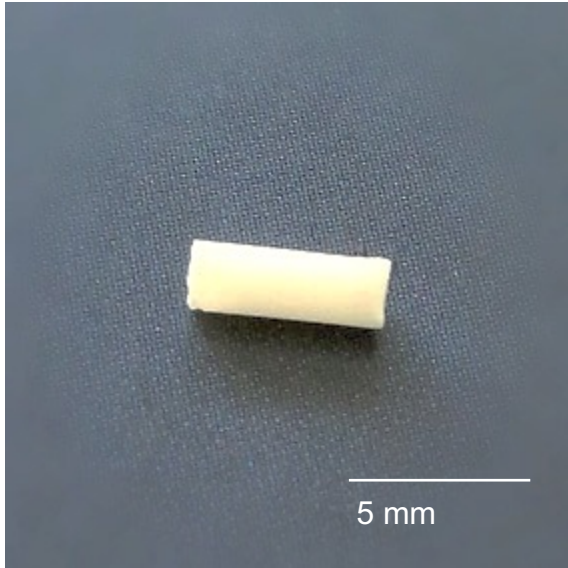
The problem with today's markers - an unmet medical need

- Poor Ultrasound visibility.
- Permanent implant.
- Discomfort and pain.
- Migration and failure to dislodge from applicator.

Hesitation to use markers even though recommended

Our solution for patients and doctors is:

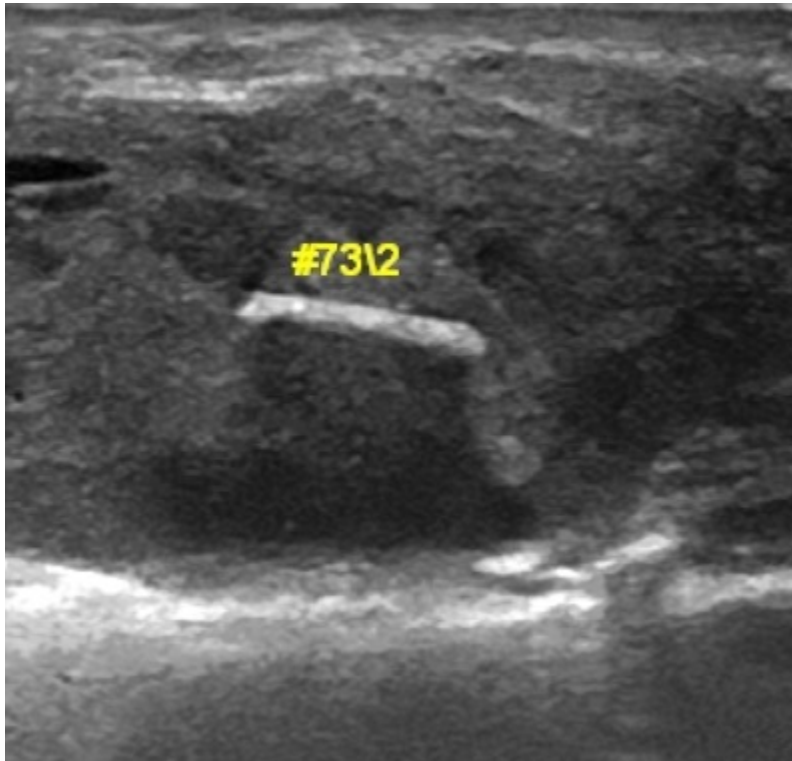
SchurSign ■



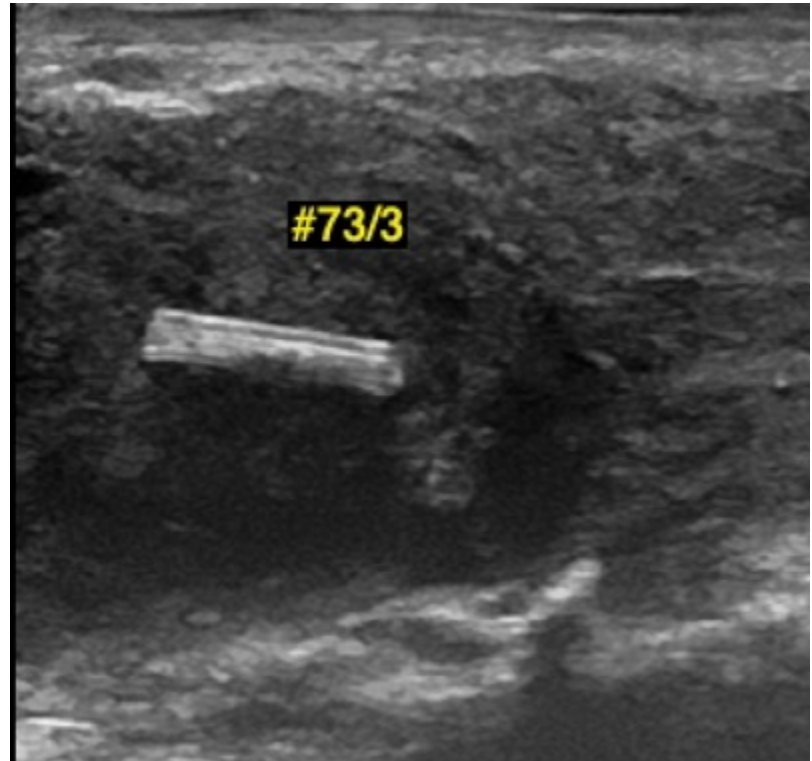
A biomaterial based,
fully resorbable,
and **pain free tissue**
marker with
outstanding US
visibility!

SurgMark ■

Convincing echogenicity in ultrasound



A) Ultrasound visibility of SchurSign in human breast tissue immediately after insertion



B) Ultrasound appearance of SchurSign 2h after insertion

SchurSign® advantages for doctors and patients

- Immediate ultrasound visibility.
- Biocompatible, fully resorbable.
- Flexible material, pain free.
- Adheres to tissue and doesn't migrate.
- Excellent visibility with all standard systems.



Impact of increased marking on treatment costs

Savings in breast cancer treatment are expected to be high due to:

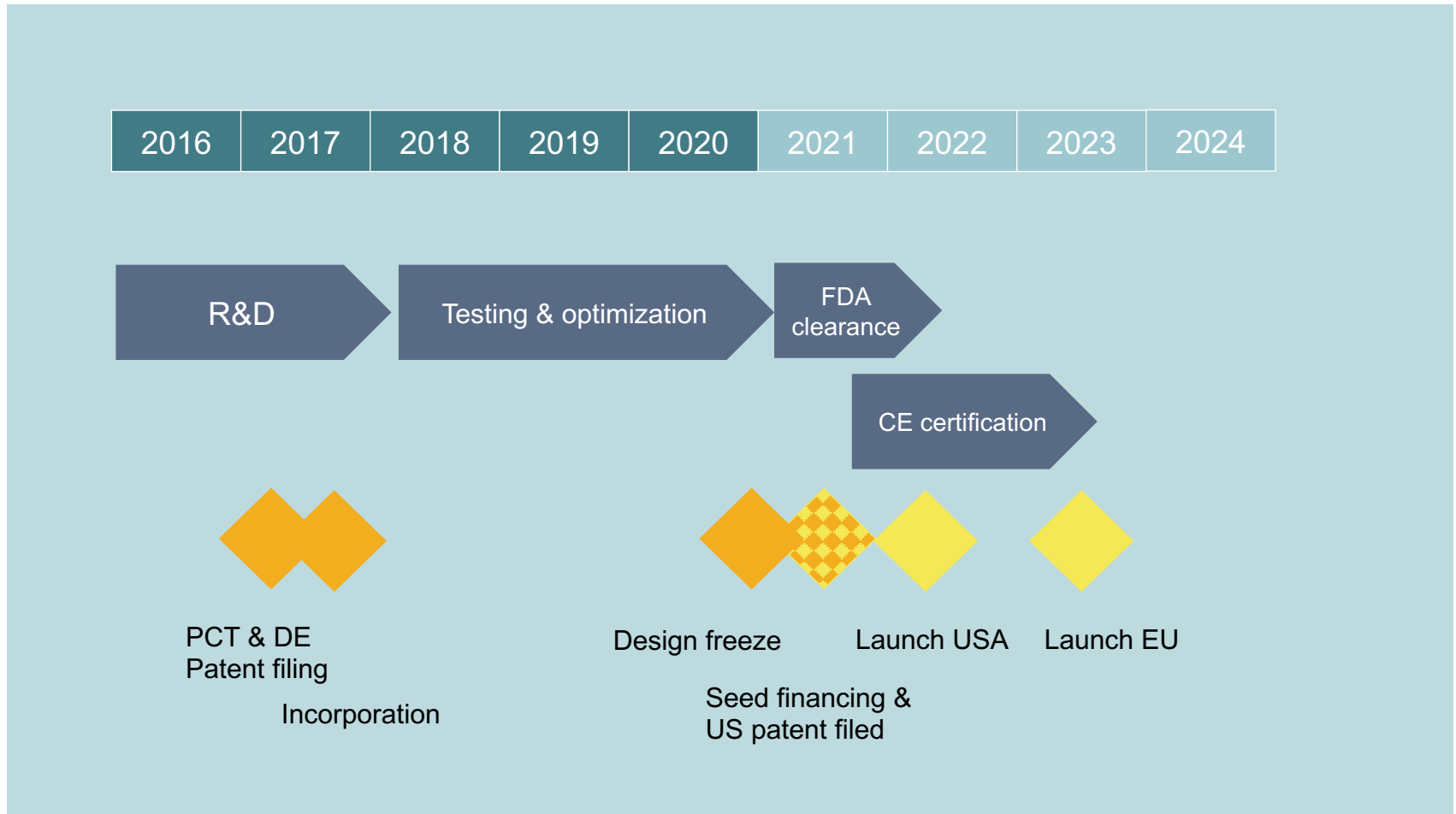
- early stage, small lesion detection leads to lower treatment costs²
- less use of mammography as follow-up imaging technology, due to better ultrasound visibility of our markers
- reduction of overtreatment (estimated at 30% in US today¹), less unneeded surgical procedures and chemotherapy

							over-treatment
	# cases	mammo- graphy	surgery	chemo- therapy	costs/patient	total (in millions)	10%
DE	69000	100 €	2.500 €	15.000 €	17.600 €	1.214 €	121 €
US	230000	200 \$	100.000 \$		100.200 \$	23.046 \$	2.305 \$

¹ P. Gøtzsche, M. Nielsen, *Cochrane Database Syst Review*, 2013 Jan 19; (1)

² H. Blumen, K. Fitch, V. Polkus, *American Health & Drug Benefits*, 2016 Feb (9) 1

Development timeline



Price, Product, Placement...

Pricing/Reimbursement

- Markers will NOT be sold at a premium price
 - 70 - 90 € per marking in the EU
 - 80 -100 \$ per marking in the US
- several codes for reimbursement in USA and Europe available

Distribution

- A specialized wholesale partner for medical supplies to clinics, mammography centres and interventional radiologists in the US has been identified. A term sheet is under negotiation.

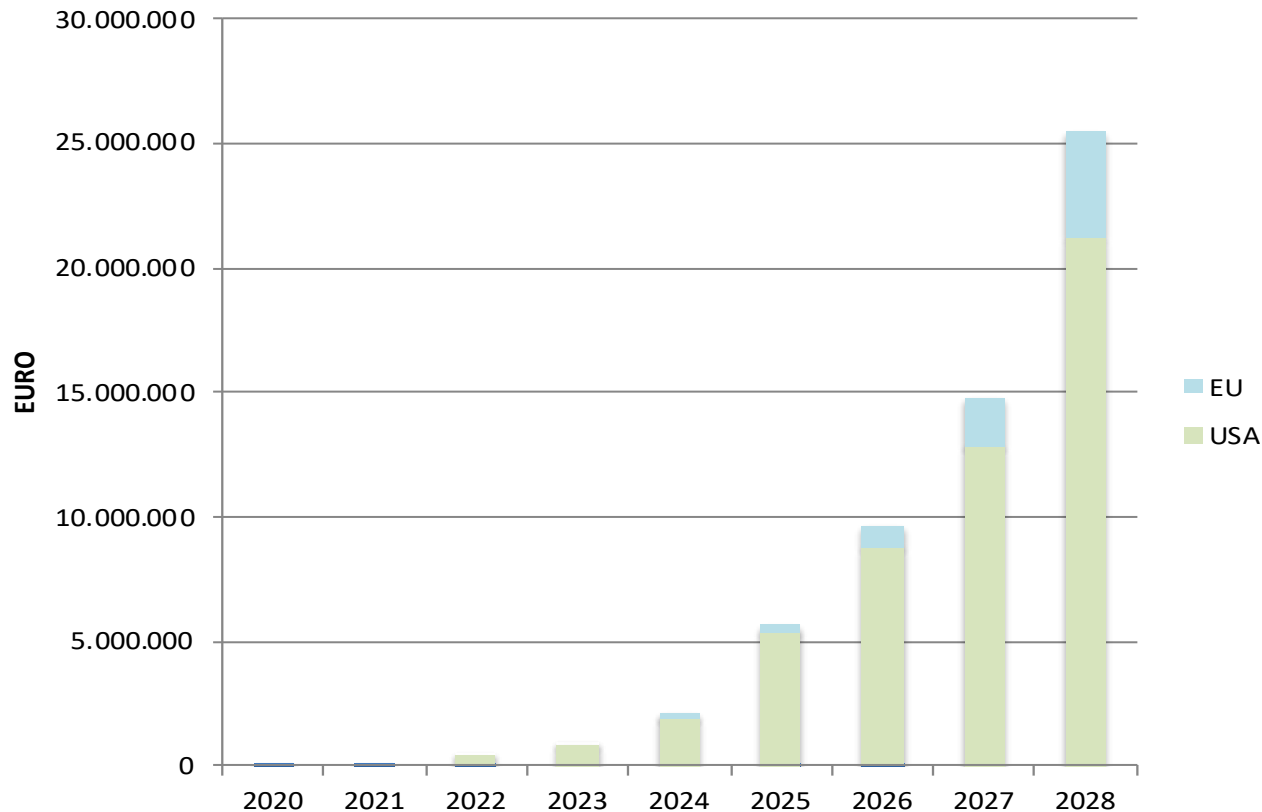
Production

- An FDA certified CMO has been identified for production.
- SurgMark owns exclusive production know-how.

By 2024 breast lesion localization is expected to hit the US\$ 1.0 Billion threshold

The Global Breast Lesion Localization Methods Market was valued at US\$ 323.43 million in 2015 and is projected to expand at a CAGR of 11.0% during the forecast period (2016–2024), **as highlighted in a recent report by *Coherent Market Insights*.**

We will earn our first million € between 2023-24, selling approx. 30.000 markers, or 1-2% of US market shares.



Fundraising Strategy

500 kEUR

short term:

- convertible notes
- investors pool
- using INVEST program
- **closing 1st quarter 2021**



500+ kEUR

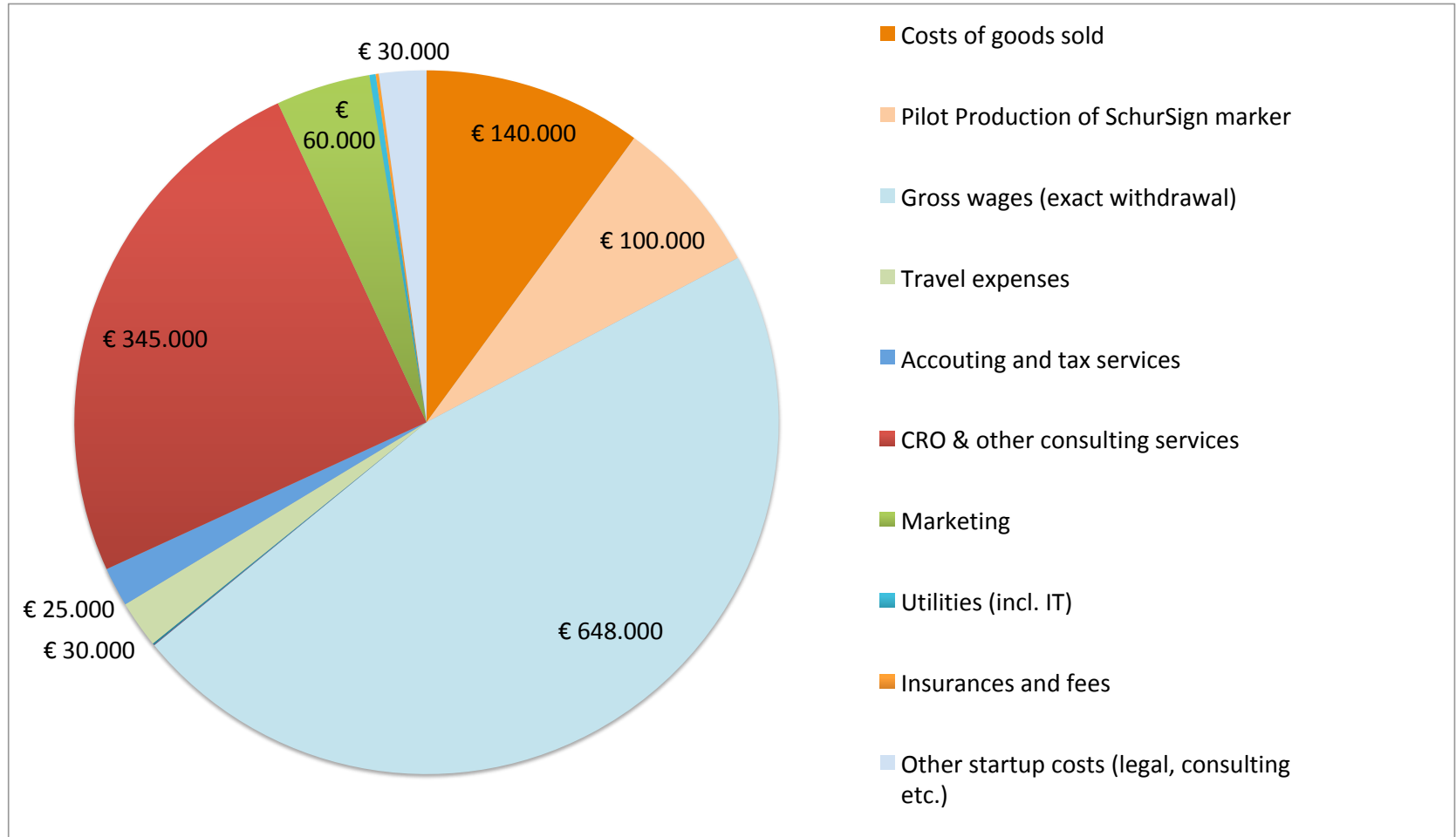
mid term:

- conversion and capital raise
- strategic and/or institutional investor
- move into accelerator
- 1st quarter 2022

Status:

- to date commitment of ~ 330 kEUR convertible notes by private investors (INVEST program)
- promising discussions with strategic investors
- expecting to receive 250+ kEUR from the Corona Recovery Fonds

3 Years Cash Flow*



total ~1.4 MEUR
includes ~ 380 kEUR revenues in 2 half of 2023
monthly burn rate 28 kEUR
annual spending 330 kEUR

The Management Team

Dr. Christine König, PhD

CEO, experienced founder and CEO in the life sciences industry, >20 years experience as serial entrepreneur and international top management consultant.



Dr. Thomas Freier, PhD

Sen. VP, product development and quality assurance, chemist and serial entrepreneur in the biomaterials- and medical sciences.



Dr. Rivelino Montenegro, PhD

Sen. VP, regulatory affairs and chemistry, multiple times entrepreneur in the medical field and experienced chemist in materials science



Dr. Frank Schure, MD


CCO, >30 years experience as a surgeon in oncology, specialist in obstetrics and gynecology, ultrasound diagnostics expert



Dr. Peter A. Meier, MD, MBA

CMO, entrepreneur and advisor with >20 yrs. senior management and business development experience in the medical device industry



A large, dense group of women of various ethnicities and ages, all smiling and wearing professional business clothing like blazers and scarves. They are arranged in several rows, filling the frame. The text "Thank you for your interest !" is overlaid in the center in a white, bold, sans-serif font.

**Thank you
for your
interest !**

SchurSign® – a sure sign!

contact:

Dr. Christine König, CEO

Maria-Louisen-Str. 122

22301 Hamburg

+49-(0)177-4075795

christine.koenig@surgmark.com

www.surgmark.com

Investment with clear exit opportunity

what we are looking for	what we are offering
~ 1 MEUR to cover the next 3 years, i.e. obtaining FDA clearance and market launch in US	convertible note or equity, access to INVEST 20% refund
One or more investors, with a good understanding of medical devices market	up to 30% equity in SurgMark, or equity at conversion (current pre-money evaluation is ~3 Mio. EUR)
Early stage/angel investors, with short-term investment horizon	Seed investment into up-to-date self-funded, non-diluted company, only founders and CEO on Cap Table
	exit opportunity in 3-4 years, corresponding term sheet offered by VC, or trade sale

Exit opportunities for investors

- The typical exit strategy for a medical device startup such as SurgMark is via the acquisition by a market leader (e.g. Bard/BD, J&J, Hologic, or Metronic a.o.).
- Pre-market start-ups with approved devices in growing markets historically have been valued in multiples of anticipated annual returns, i.e. in the area of €10 to 50 million.
- IPOs have also been shown to be successful exit strategies within the 5 year term.

Exits by similar MedTech companies



Company	Product	year	buyer	value
ForSight Vision5	Peri-ocular ring for drug delivery and reducing intraocular pressure (IOP) in glaucoma	2016	Allergan	\$95M + undisclosed milestone payment
Sequent Medical, Inc.	Aneurysm embolization system	2016	MicroVention Inc, (Terumo)	\$380M
Medovent GmbH	Reaxon, chitosan implant for nerve repair	2018	KeriMedical	Undisclosed
Somatex Medical Technologies	Tumark family of tissue markers	2021	Hologic	\$64M

Current equity/shares distribution

<i>Equity</i>	<i>36.630,00 €</i>	<i>100,00%</i>
Frank Schure	13.300,00 €	36,31%
Peter Meier	10.000,00 €	27,30%
Rivelino Montenegro	5.000,00 €	13,65%
Thomas Freier	5.000,00 €	13,65%
Christine König	3.330,00 €	9,09%

Our realistically addressable market in the US and Europe will be approximately 100 MEUR at launch in 2023

USA	CAGR biopsy and marker	10%						
			2022	2023	2024	2025	2026	2027
	Breast Biopsy		1331000	1464100	1610510	1771561	1948717,1	2143588,81
	marker used	80%	1064800	1171280	1288408	1417249	1558974	1714871
	marker/patient	1	1064800	1171280	1288408	1417249	1558974	1714871
	costs per marker in EUR	75						
EU	total market vol		79.860.000 €	87.846.000 €	96.630.600 €	106.293.660 €	116.923.026 €	128.615.329 €
	CAGR NACT	10%						
			2022	2023	2024	2025	2026	2027
	Cancer diagnosis in Europe		500000	500000	500000	500000	500000	500000
	neoadjuvant chemo	25%	166375	183013	201314	221445	243590	267949
	marker used	90%	149738	164711	181182	199301	219231	241154
	marker/patient	1	149738	164711	181182	199301	219231	241154
	costs per marker in EUR	100						
	total market vol		14.973.750 €	16.471.125 €	18.118.238 €	19.930.061 €	21.923.067 €	24.115.374 €
	EU plus US		94.833.750 €	104.317.125 €	114.748.838 €	126.223.721 €	138.846.093 €	152.730.703 €

Own estimation of realistically addressable market. CAGR is based on own and others' research and here estimated at 10%, no increase in breast cancer incidences in EU is anticipated, rather growth driven by increasing numbers of NACT.

NACT: neoadjuvant chemotherapy

Milestones, tasks, status of delivery on way to NA market

Complete market study (US)

Q2 2021

- interviews with KOLs
- desktop research (ABC target list)
- online survey
- refinement of USP



FDA clearance for minimal viable product

Q4 2021

- complete design freeze
- set up production and decide for inserter supplier
- tests and documentation
- submission under 510 (k) process



First sales of SchurSign® in the US

Q2 2022

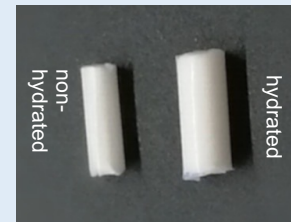
- sign contract with sales partner for US target groups
- detail the market access plan
- execute plan and ramp up marketing efforts
- find clinical partners for studies



From prototype to design freeze - development, studies, and optimization to date

- Optimization of ultrasound visibility immediately after implantation and during follow-up periods
- Design variants testing (in phantoms, animal models, human mastectomy material) and optimization (tubes, threads, etc.)
- Optimization of surface chemistry
- Testing of various chemical additives and coatings.

- Tube shaped
- non-hydrated dimensions:
 - Length: 5 or 8 mm
 - Thickness: 14 gauge
- Contains BaSO_4
- Patent blue coloring possible
- Can be delivered with different resorption times, depending on application:
 - < 6 month
 - 6 to 24 months
 - > 2 years.



Importance of product features according to interviewees

Product feature	Interventional radiologist	breast surgeon	patient
Ease of deployment	+++	o	++
Visibility in ultrasound, mammography, MRI, CT ★	+++	+++	+++
Tissue adherence, non-migrating ★	+++	+++	+++
Soft, flexible material ★	o	+	+++
Fully resorbable ★	+	+	+++
Removable by vacuum biopsy, ablation ★	+	o	+++

★ = SchurSign® unique selling proposition