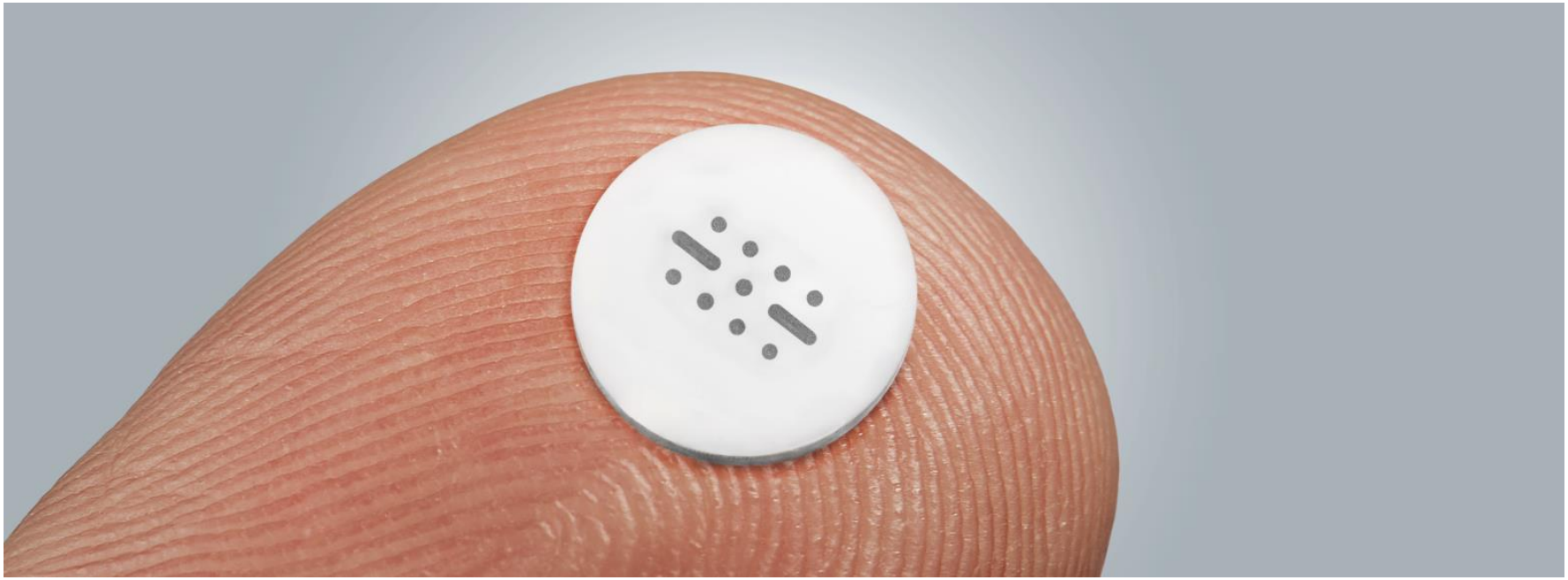

Innovative Cermet Ceramic Components for Medical Devices

Dr. Robert Dittmer, Ulrich Hausch, Maximilian Göhler, Bilge Kaya, Jens Trötzschel

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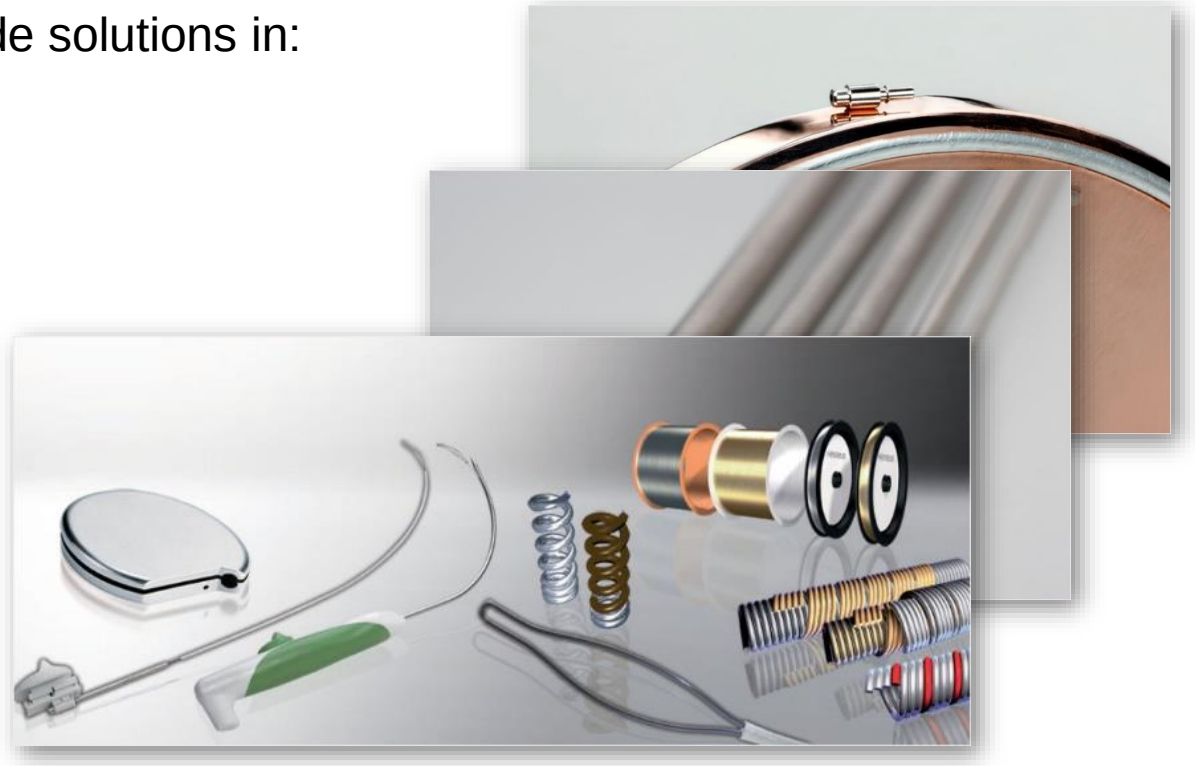
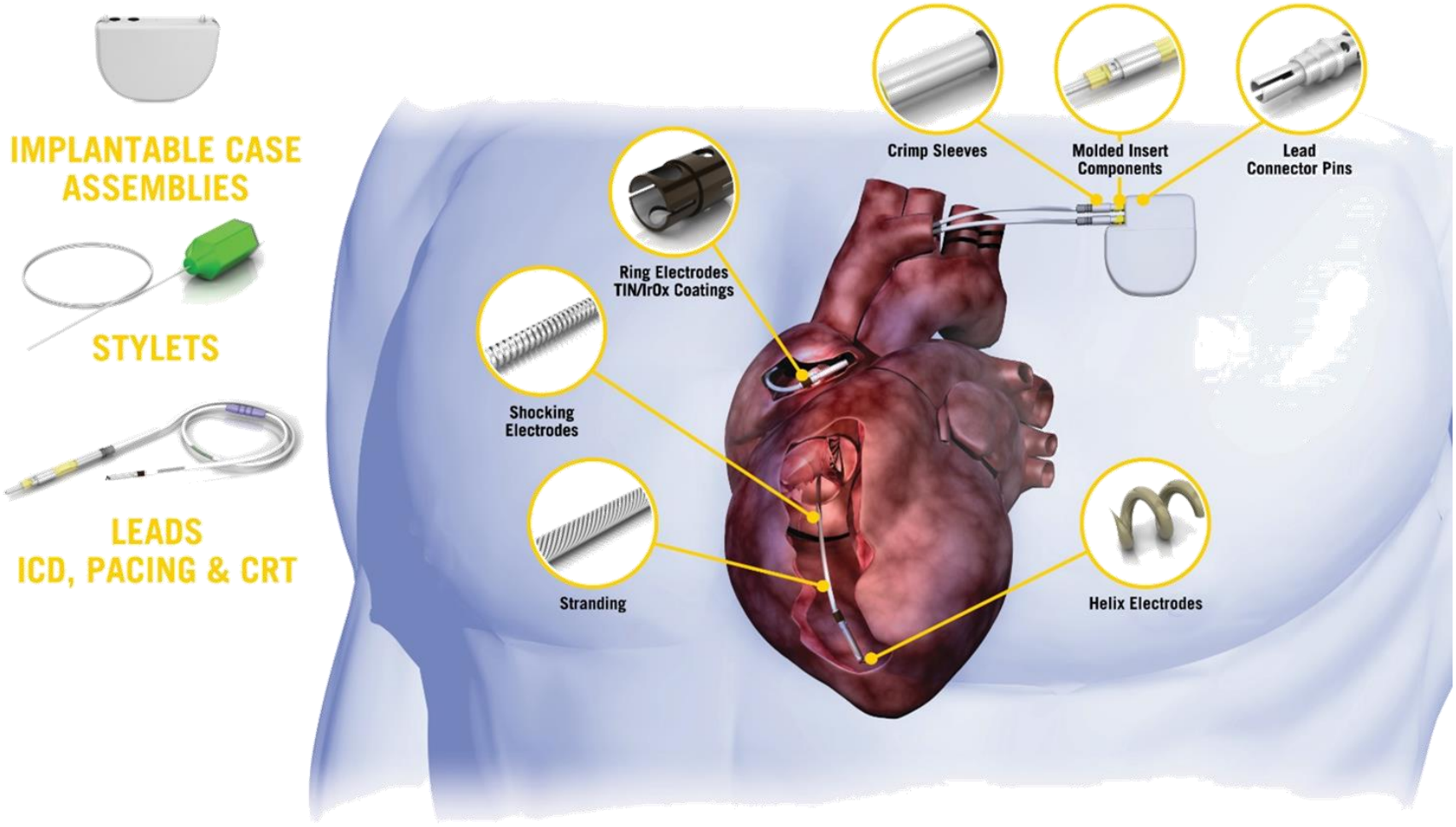
1. Heraeus Medical Components at a Glance

- HMC is the leading source of metal components for medical devices
- based on our technological excellence in R&D, product development and manufacturing we provide solutions in:
  - materials
  - micro components
  - wires and tubes
  - coiling
  - assemblies
  - cases



Heraeus Components for Implantable Devices



Heraeus Medical Components Worldwide

St. Paul

Germany

Switzerland

Plymouth

Puerto Rico

Tokyo

Shanghai

Costa Rica

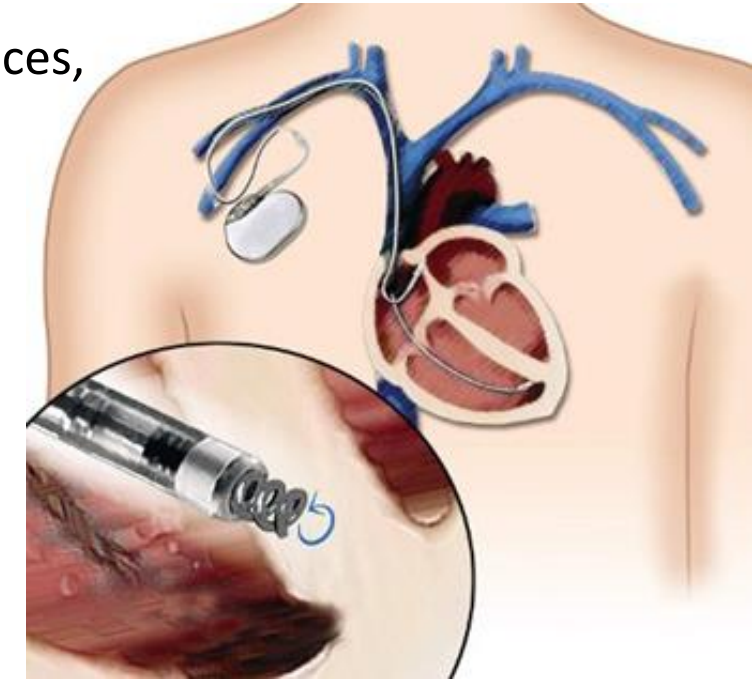
Singapore

Asia Sales:

- Tokyo, Japan
- Shanghai, China

2. Feedthroughs for Medical Implants

- Cardiac Arrhytmias
  - Pacemaker, Defibrilator, CRT-Devices, Biomonitors
- Incontinecy
- Pain Therapy
- Parkinson, Epilepsy
- Sleep Apnea
- Deafness or Hearing Loss
- Patient Monitoring Needs



Active implantable devices of high importance for manifold medical therapies!

Requirements for Feedthroughs

- devices typically with 4-16 channels
  → feedthrough required to couple electrical signals in and out
- requirements for feedthroughs
  - hermetic sealing – no fluid must enter/exit
  - conductivity and insulation in one part
  - high reliability for 10+ years

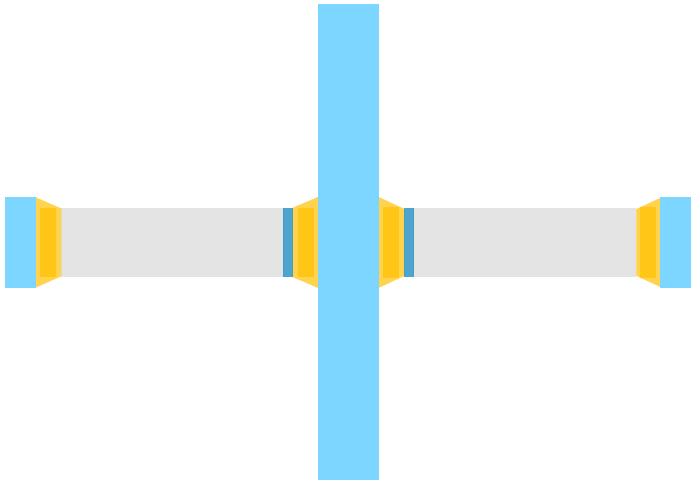
Every active implantable medical device requires feedthrough technology!

[9]

Conventional Feedthrough Assembly

- many single parts reduce overall reliability and robustness
- labor-intense assembly
- expensive parts especially for many channels
- limitation of maximum number of pins per part
- only straight through-channels (no bifurcations, etc.)

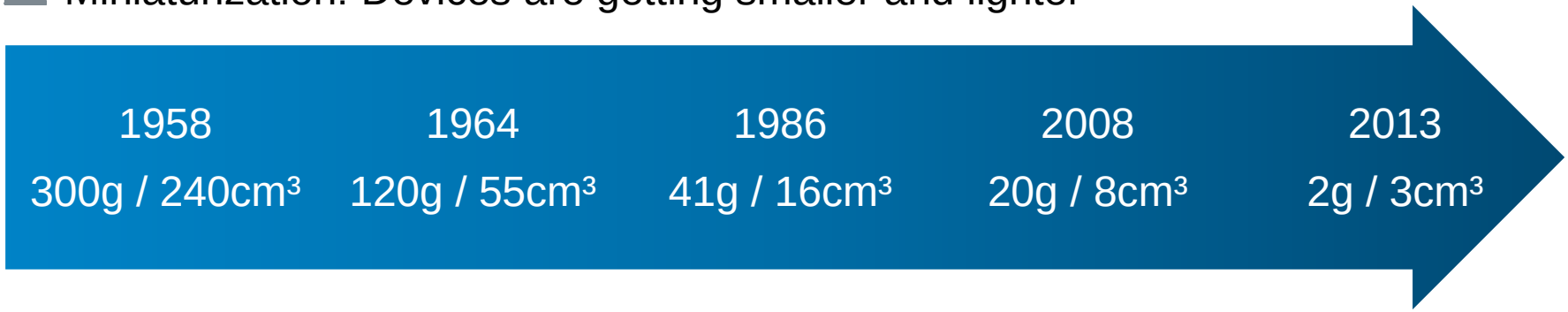
Simpler and more flexible design highly desirable!



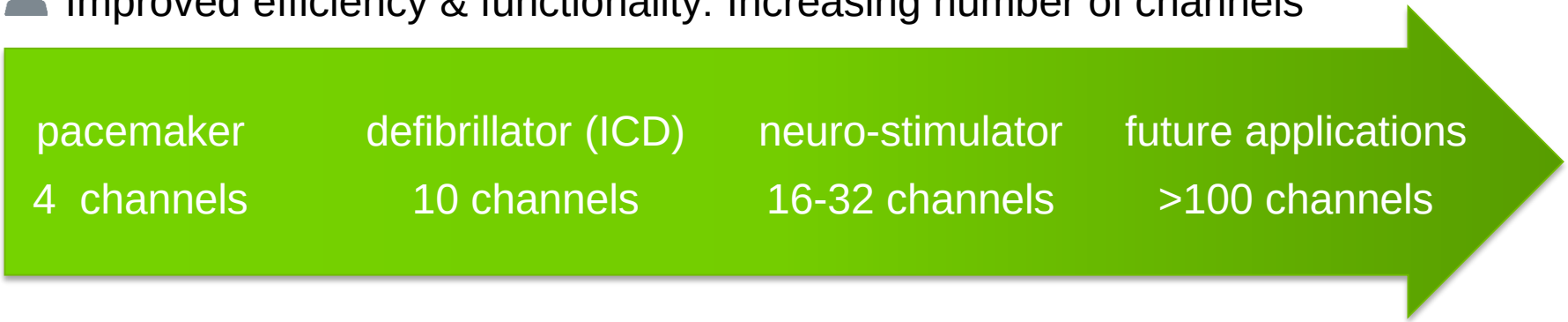
1. alumina insulator with core hole
2. sputtercoat inside w/ Nb coating
3. slide brazering in
4. slide feedthru Pin in
5. slide ferrule over
6. slide ferrule braze in
7. braze

Megatrends in AMI

- Miniaturization: Devices are getting smaller and lighter



- Improved efficiency & functionality: Increasing number of channels



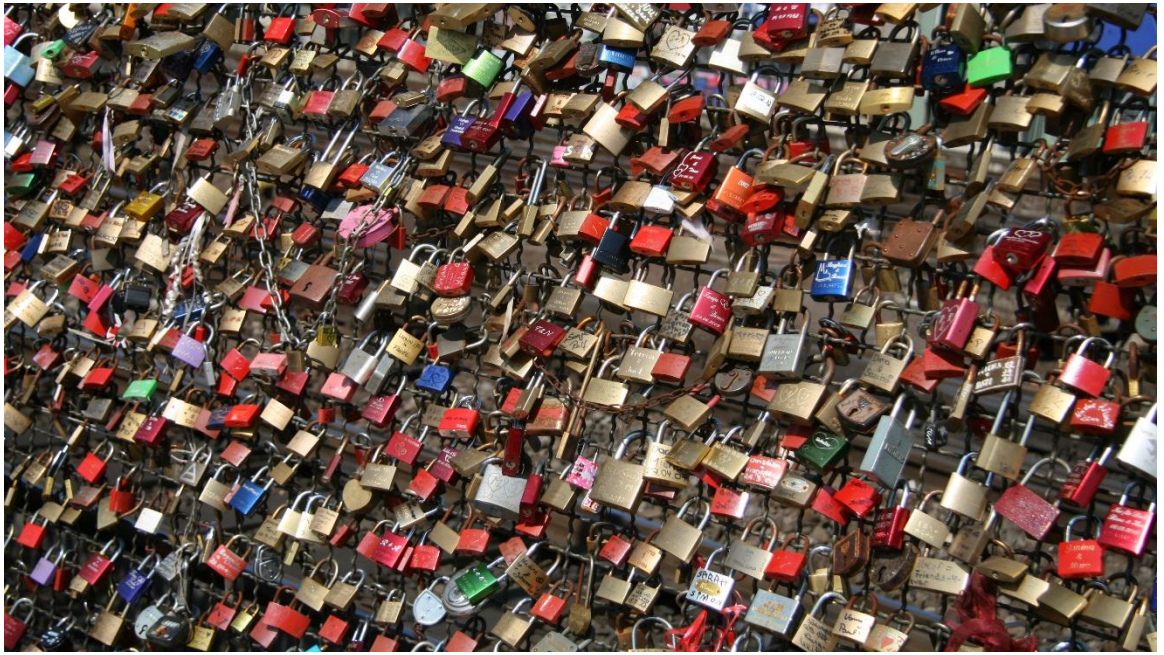
Current feedthrough technology fails to support these trends!

The benefit of high resolution

- effective therapy requires pin-point stimulation and sensing
- the higher the resolution of the therapy, the better the effect for the patient
- comparable with TVs: the higher the resolution, the better the picture

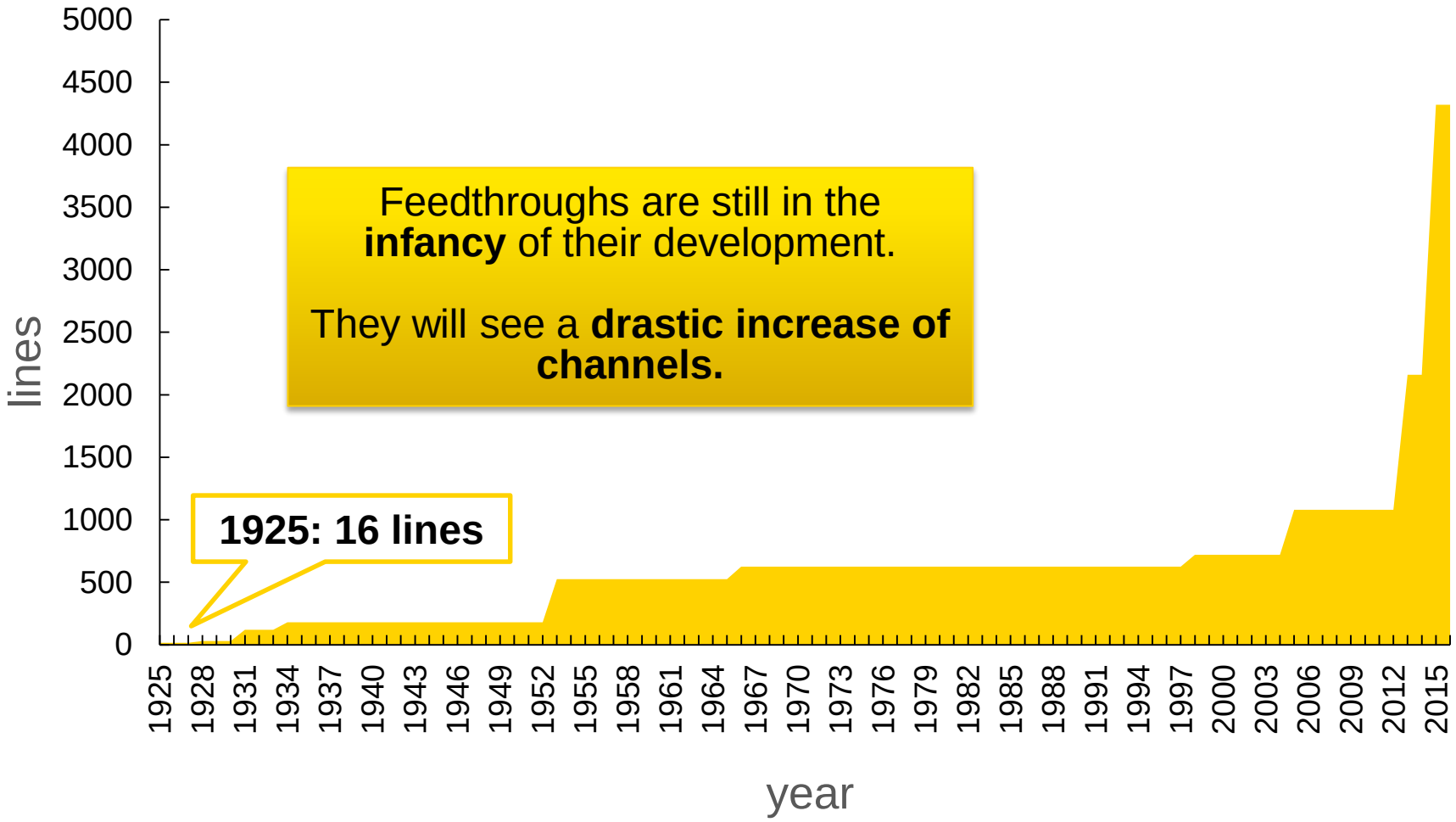
1995

2015



Higher resolution in future AMIs essential for effective therapies: hearing, seeing, neurostimulation, brain reader,… .

Evolution of TV resolution

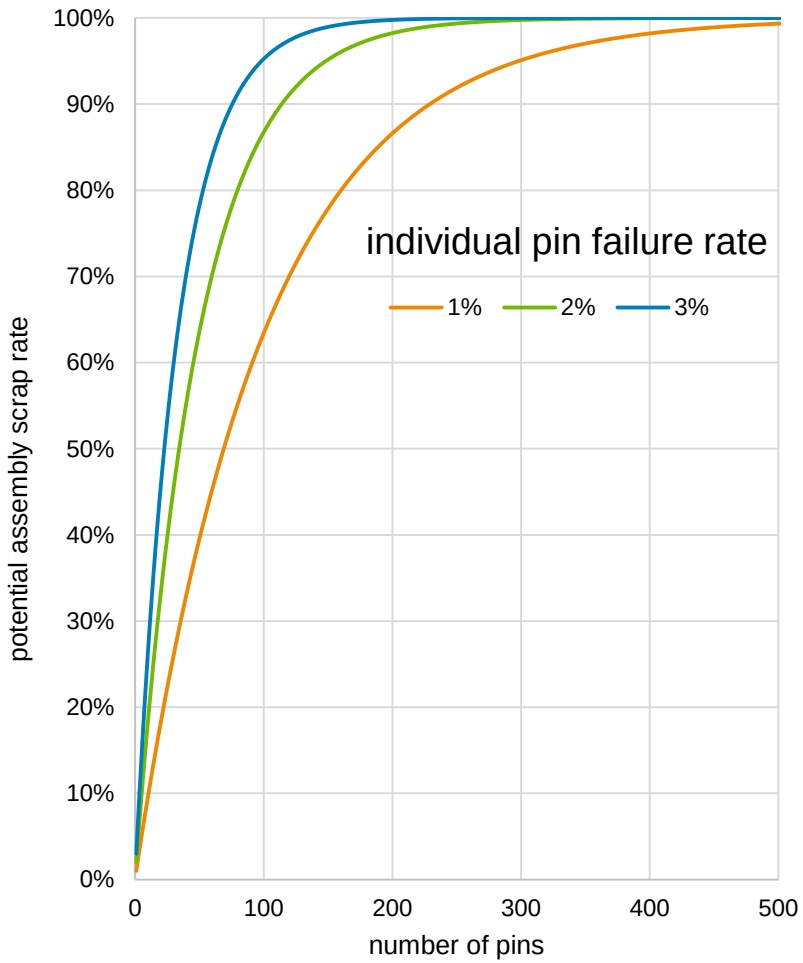


Heraeus

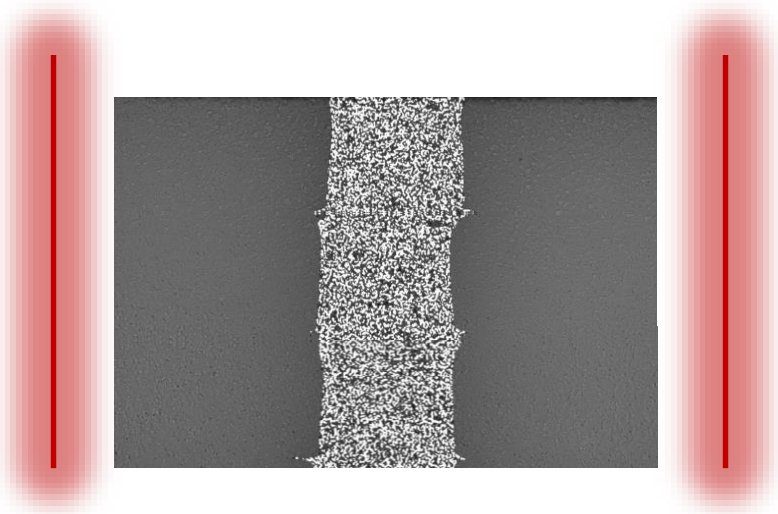
Challenge of many channels

Pin-based feedthroughs limit future development of active medical implants.

- conventional technology is cumber-some and requires many single parts
- a feedthrough with hundreds or thousands of channels:
  - technologically highly challenging
  - too large due to limited miniaturization potential of pin-based approach
  - economically impossible
    - failure of one single pin causes failure of whole feedthrough
    - even for low individual pin failure rates the scrap rate adds up fast for >100 channels
  - risk associated with such a part is not acceptable for the patient



3. A New Feedthrough Concept for Medical Implants



layered feedthrough structure

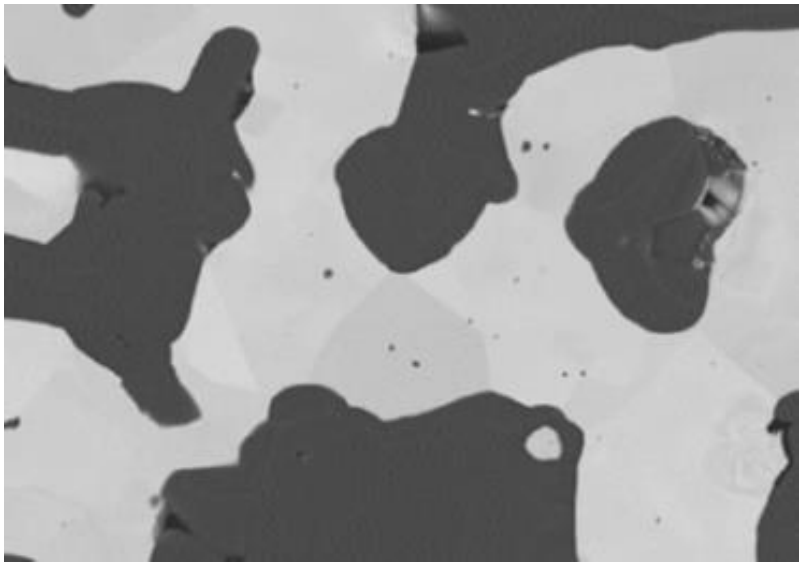
- using high-temperature co-fired ceramic (HTCC) technology
  → established method of mass production in electronics industry
- ceramic green tape gets punched according to desired design
- filling of conductive paste into ceramic tape by a printing process
- stacking several individual layers
- co-firing for densification

Comparably simple process adapted that had been used successfully for decades to produce robust, reliable parts.

Cermet as an Enabler

- our solution: use a microstructural composite to overcome mismatch
- cermet = CERamic + METal
- used in many industries such as aerospace, lighting, machining, etc.
- combines the advantages of ceramics with the advantages of metals
  - high hardness
  - superior wear resistance
  - high heat resistance
  - metallic conductivity despite ceramic
  - low density for lightweight designs

Mixing platinum and alumina for bio-compatible Cermet in the medical field!



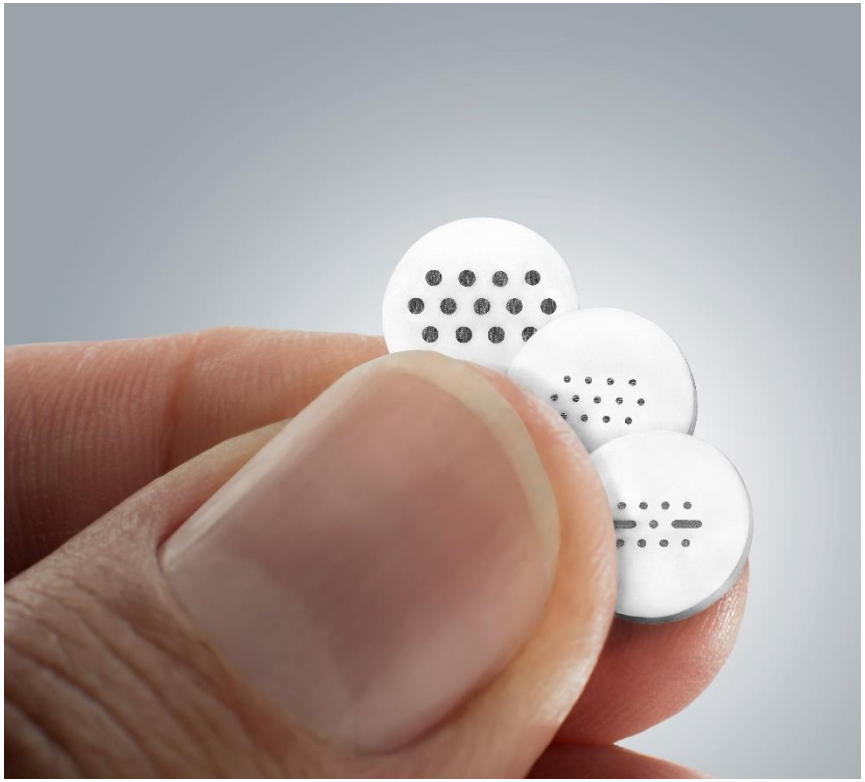
Paradigm change: No more pins in feedthroughs

Conventional technology → New CerMet Technology

Almost 100 patents and patent applications protect the Cermet Technology.

Features of the Heraeus CerMet Technology

- **Hermeticity:** absolutely leak-tight feedthroughs
- **Conductivity:** channels with metal-like conductivity
- **Insulation:** high electrical insulation resistance between vias
- **Biocompatibility:** platinum and alumina with excellent biocompatibility and successfully used for decades in implants
- **Cost Efficiency:** HTCC technology can be scaled up easily

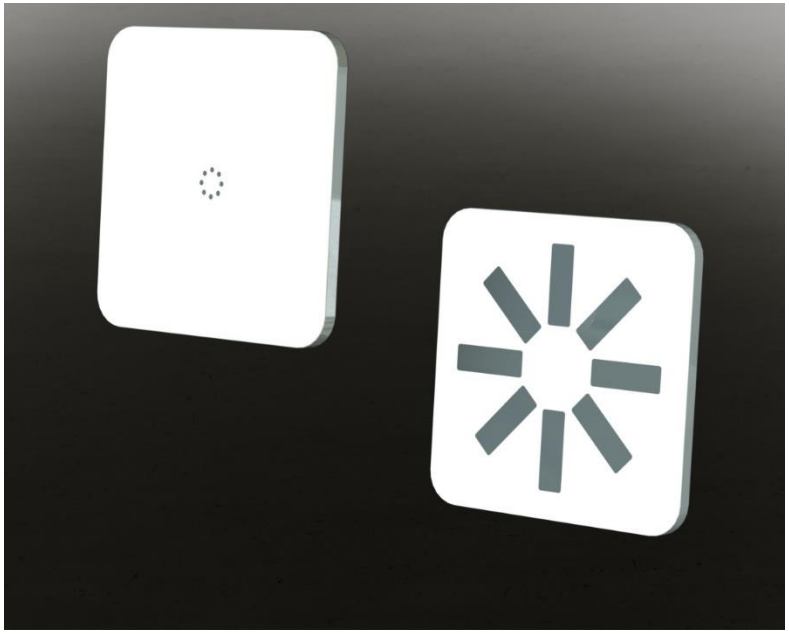


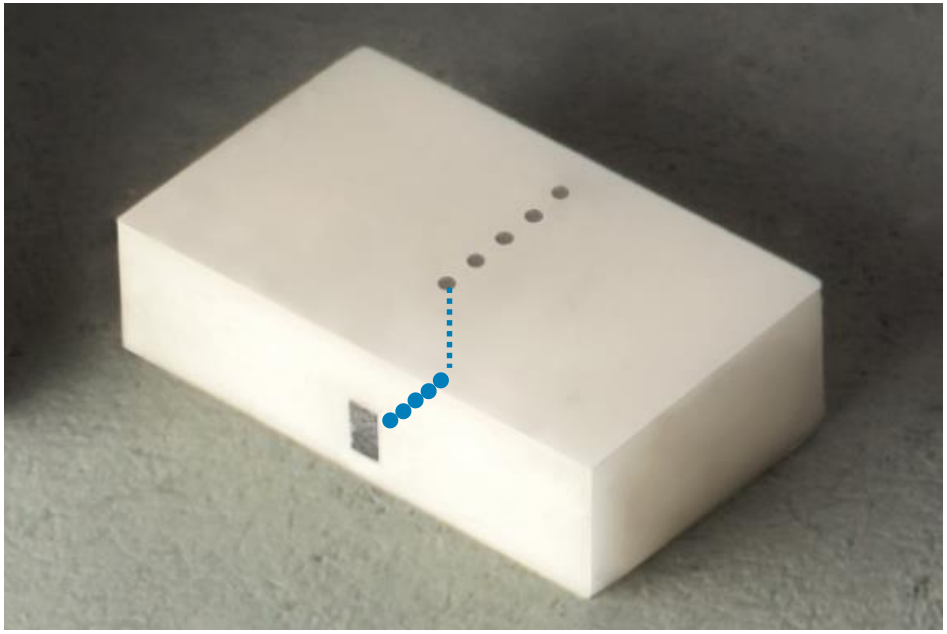
Cermet Technology fulfills all requirements!

Freedom to Invent

- enables more complex designs with a much higher degree of freedom
  - internal bifurcations and steps of vias
  - internal re-routing
  - non-circular cross-sections
  - 3-dimensional shapes

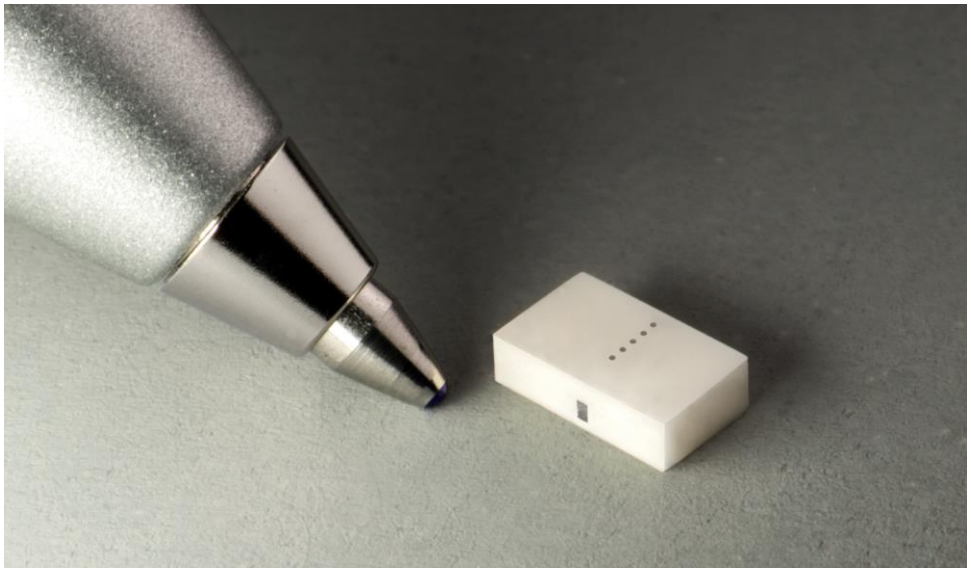
Unprecedented design freedom!





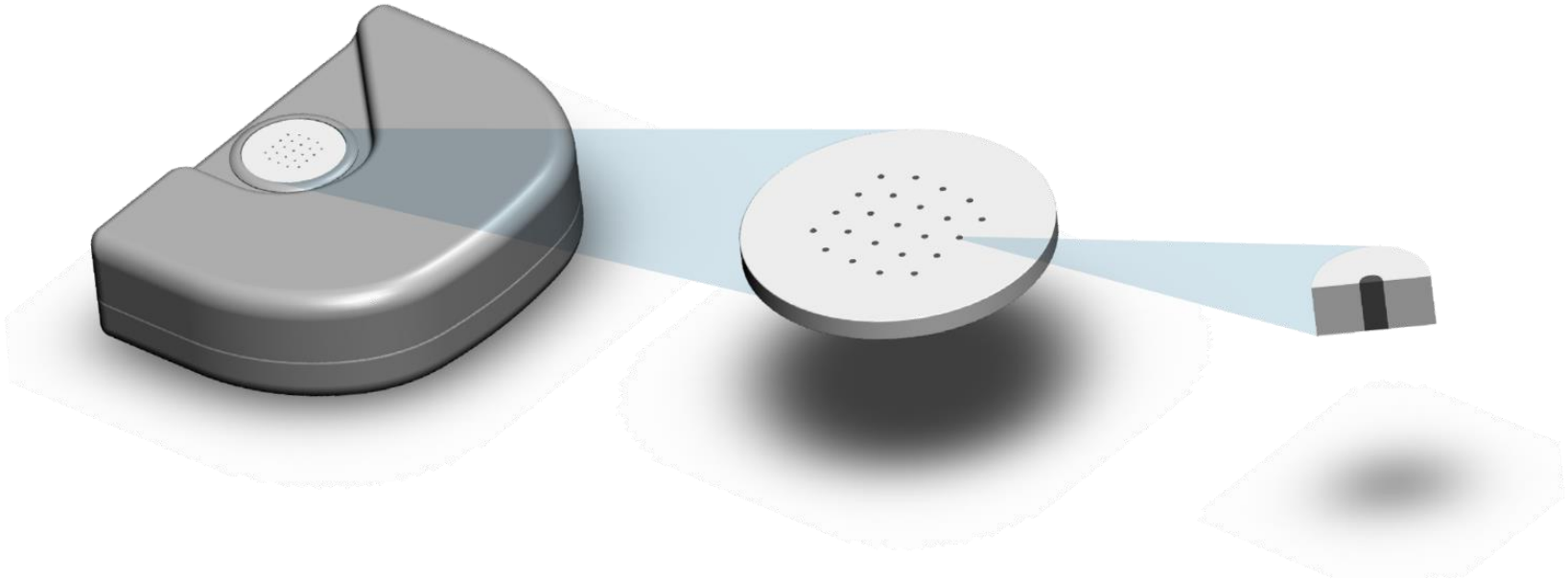
Freedom to Invent

- offers unparalleled miniaturization potential
- vias as small as 150 µm in diameter
- up to 800 vias per cm² possible
- drastic downscaling of today's feedthroughs or increase of via count



Cermet Benefits

- **Generation of additional cost savings**
  - costs are reduced significantly, especially for parts with a high number of channels
- **Development of devices with integrated functionality**
  - amount of components and assembly steps of device reduced, eventually reducing the assembly costs



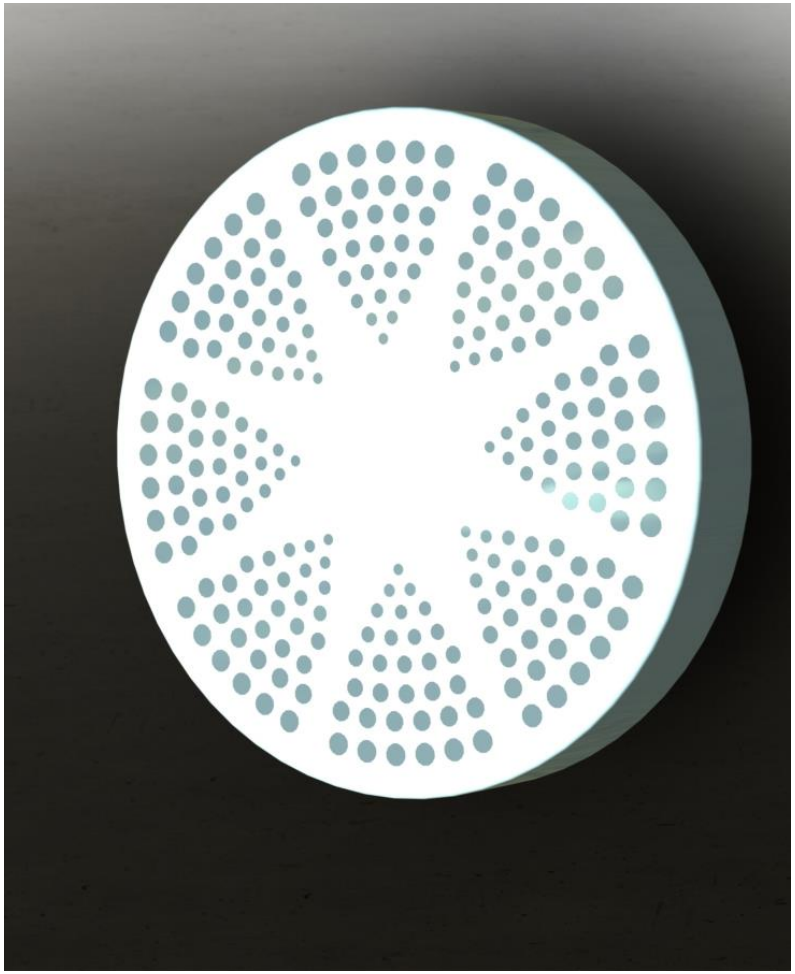
Cermet Benefits

Design more efficient devices

- significantly increased number of channels for sensing and stimulating
- more reliable, more accurate, and more efficient therapy
- reduced number of unintended stimulation

Production of safer devices

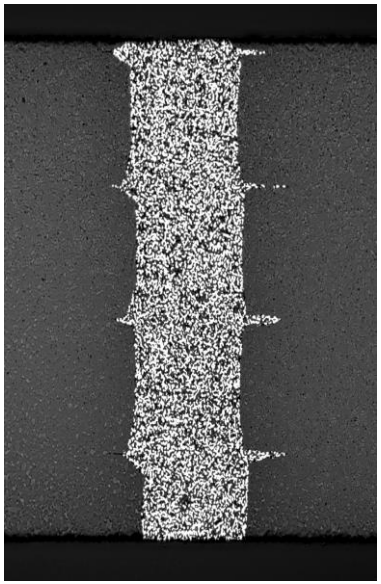
- one monolithic composite part instead of a plethora of single parts
- potential reason for leaks is eliminated, yielding more robustness and reliability
- risk for failure is significantly reduced as there is no macroscopic interface between conductor and insulator



The Dual Composite on Different Size Scales

1,000 µm scale

100 µm scale



10 µm scale

1 µm scale

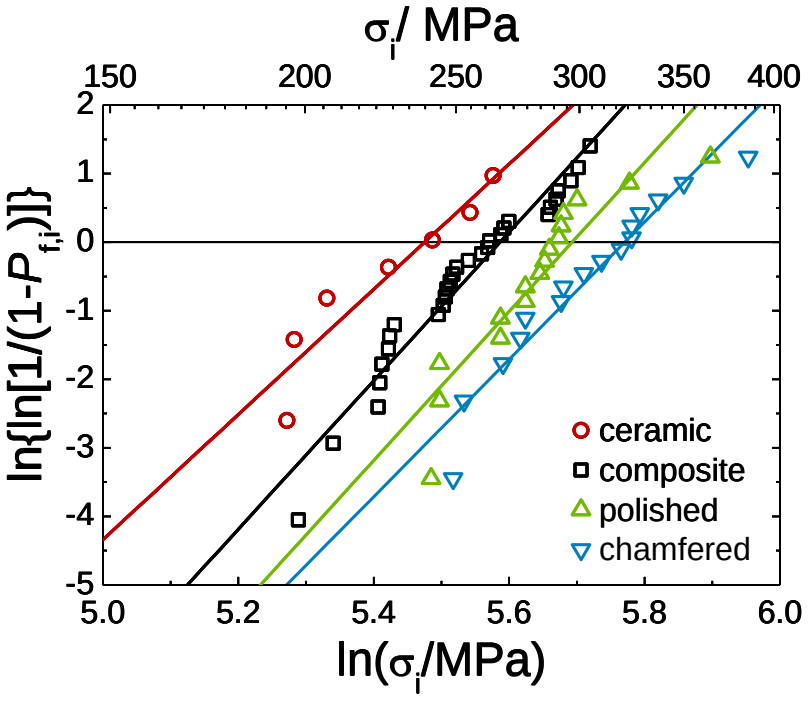
- interpenetrating network microstructure within cermet via
- no interface between matrix and via but interconnected ceramic phase

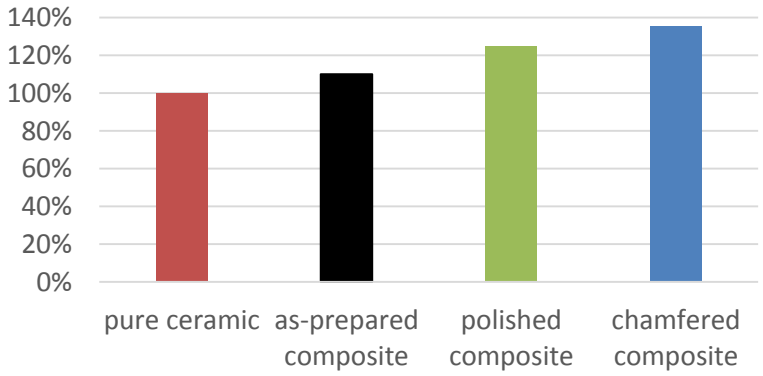
Is strength of composite affected by via?
Is conductivity of via sufficient?
Is the composite leak-tight?

4. Physical Properties

- pure ceramic sample with a characteristic strength of 232 MPa
- as-prepared composite around 10 % (24 MPa) stronger than ceramic!
  → cermet yields strengthening!
  → fractography reveals that failure occurs mostly in ceramic matrix
- further mechanical enhancement of composite by
  - polishing: +36 MPa (+14 %)
  - chamfer: +60 MPa (+23 %)

Composite unexpectedly more robust than pure ceramic!

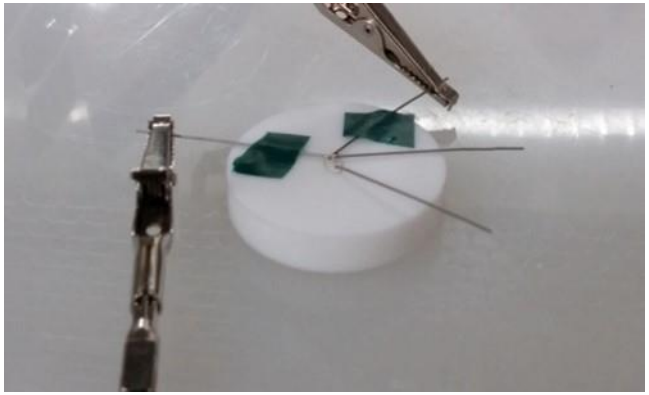


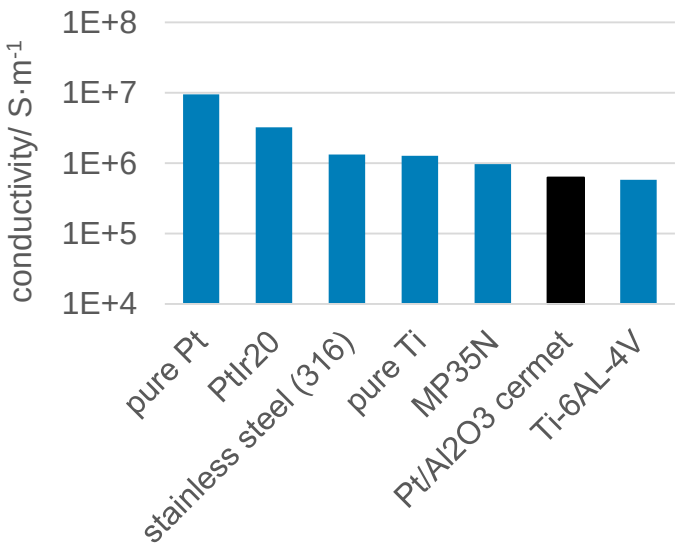


Electrical properties

- insulation resistance at 1 kV_{DC}
  - between two adjacent vias with ca. 1mm pitch
  - only minute currents on the order of 10^{-11} A
  - insulation resistance of 10.000 GΩ
    → as high as expected for pure alumina
    → great potential to further decrease pitch
- conductivity of the vias on the order of 10^5...10^6 S/m
  - comparable to some metal conductors such as titanium, stainless steel, and other alloys
  - great potential to further decrease via diameter

Insulative and conductive properties of composites much better than currently necessary!





4. Summary and conclusions

1) innovative new method introduced to produce feedthroughs for implants

2) material system with unique property profile
   - biocompatible
   - conductive
   - insulating
   - hermetic
   - mechanically robust
   - non-magnetic (MRT)
   - heat-resistant
   - easy to integrate

3) more flexible, miniaturized design with higher number of vias feasible

4) highly robust composite with strength exceeding pure ceramic

5) also non-medical application possible, *e.g.*, for harsh thermal/chemical conditions

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Thank you for listening!