# Electronics Packaging Methods and Materials for Implantable Medical Devices

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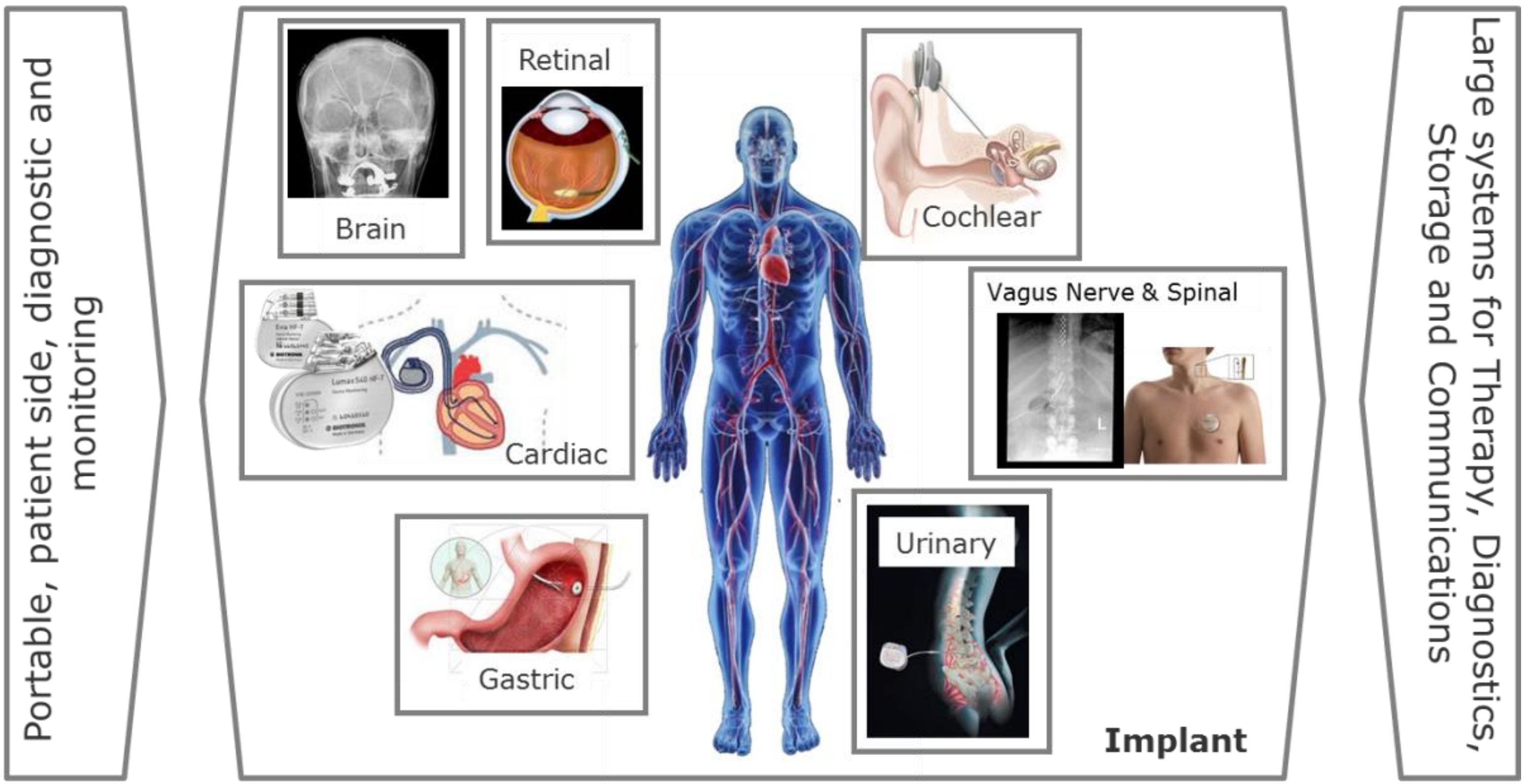
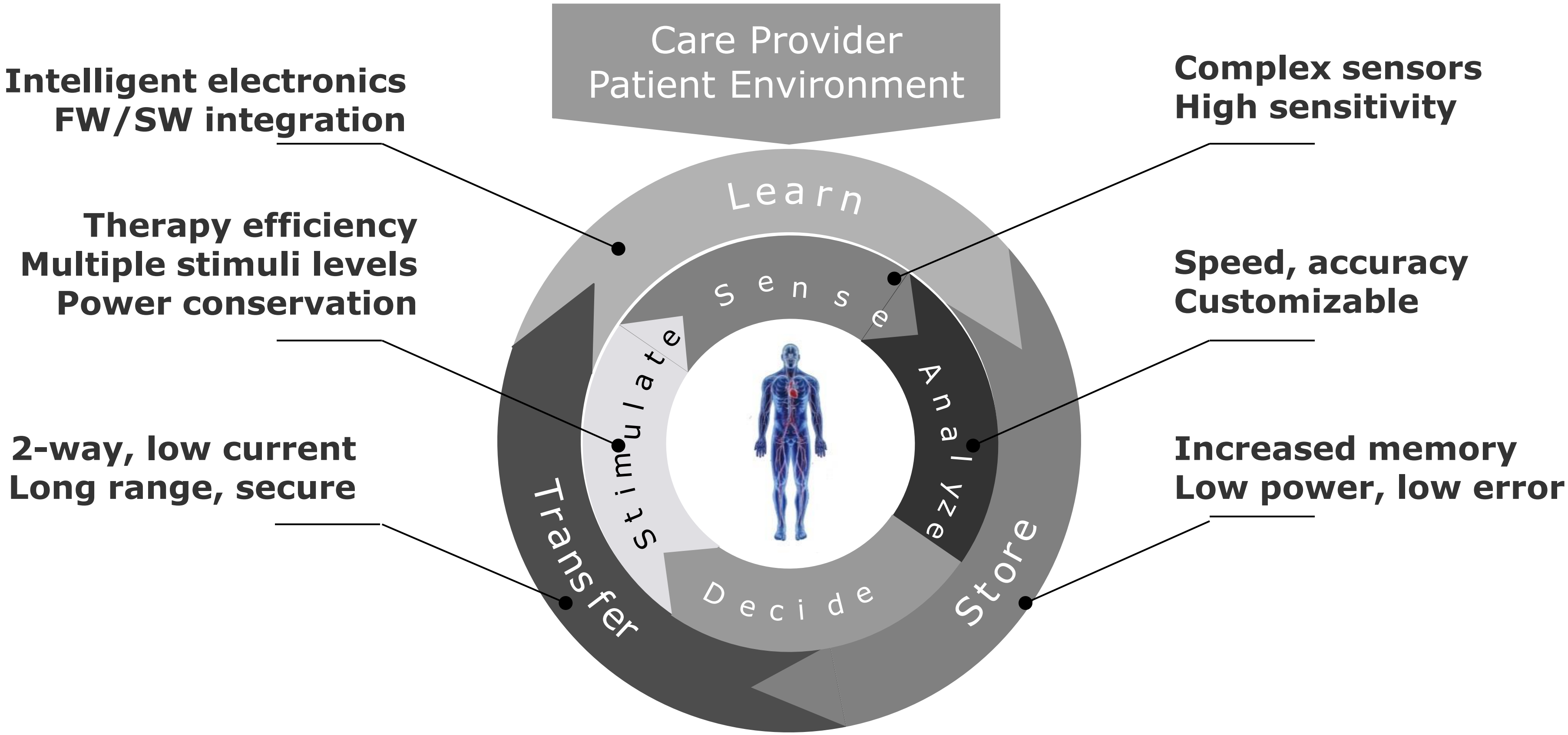
# Medical Microelectronics – Situation




**Technology use from other industry segments not always feasible**

- Miniaturized form factors - Flat, cylindrical, body conforming
- Medical requirements – Low power, Reliability, cost, and supply continuity

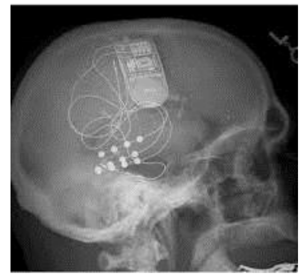
# Smart Medical Microelectronics – Trends

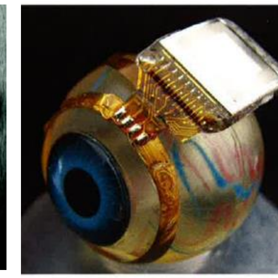


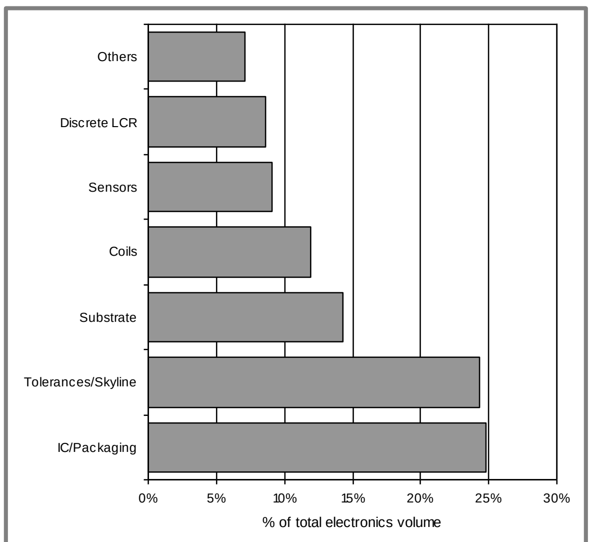

Increased functionality (patient centric, connected, mobile)
drive miniaturized wireless topologies

**Smart Devices require Smart Solutions !**

# Design Strategies – Challenges



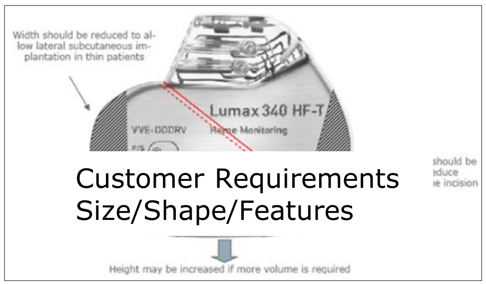


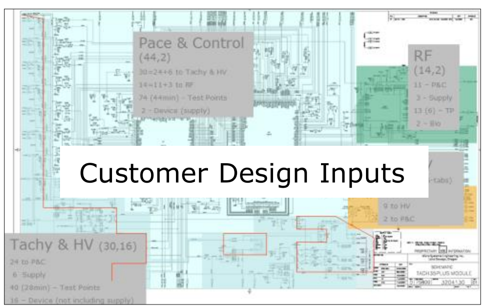

- **Ultra Low power, high voltage, high frequencies**
- **Physiological shape → unique electronics form factors**
  - **Flat/folded, cylindrical/annular, body conforming/spherical**
- **Non-uniform component “skyline” → 3D density <65%**
- **Ultra-miniaturization requires flexible 3D interconnects**

**A comprehensive design approach required**

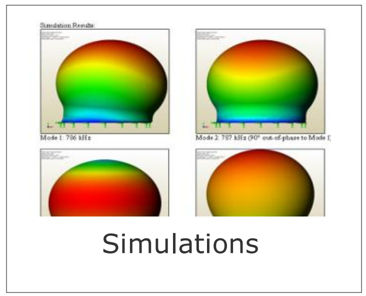
# Design Strategies – A Comprehensive Approach

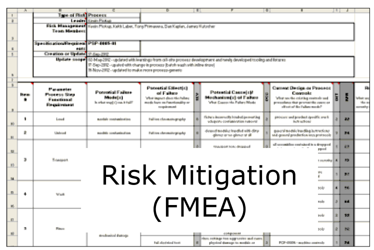
**Design Inputs**

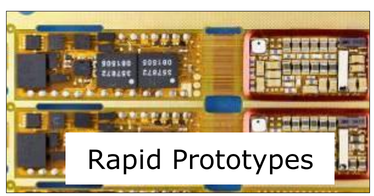


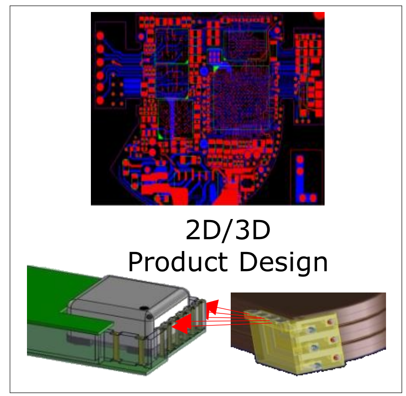



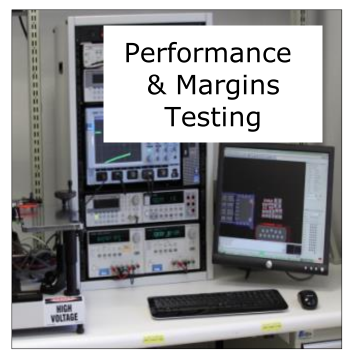

**Design Iterations**



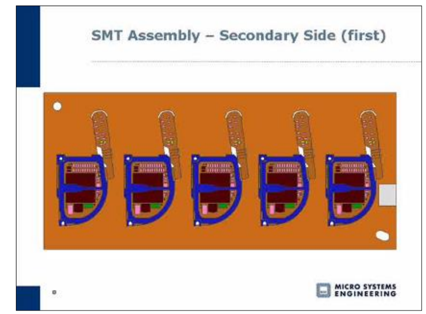



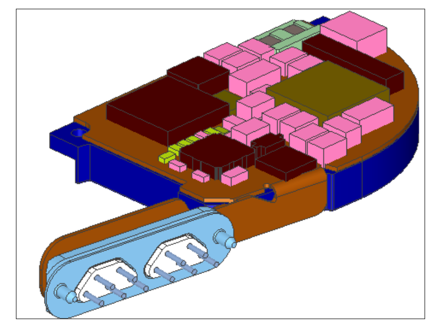



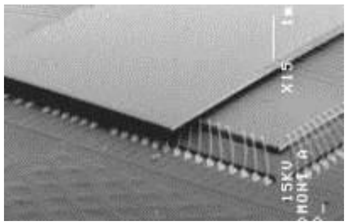

**Module/Assembly Solutions**



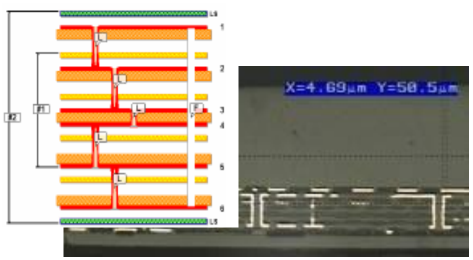



**Methodology (FMEA, Dfx), Simulation, Platforms/Knowledge base**

# Design Strategies – Key Miniaturization Solutions

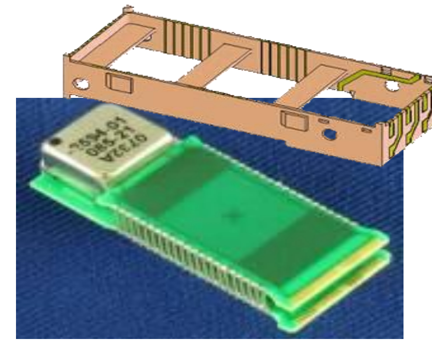


**Stacked ASIC Die**

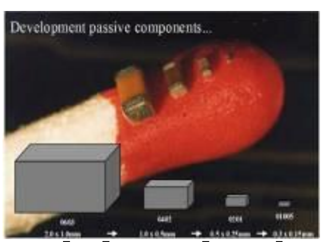



**High Density Interconnects**

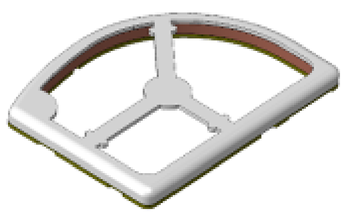
- **Early adoption of advanced packaging and interconnects**
- **Leverage of strategic partnerships**
- **Integrated development of assembly/ test from prototype to manufacturing**
- **Comprehensive focus on reliability from design to manufacturing**



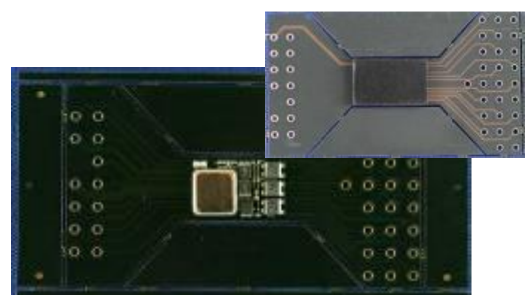
**Advanced 3D Interconnects**




**Miniaturized Components**



**Communication coil integration**



**System-in-Packages**

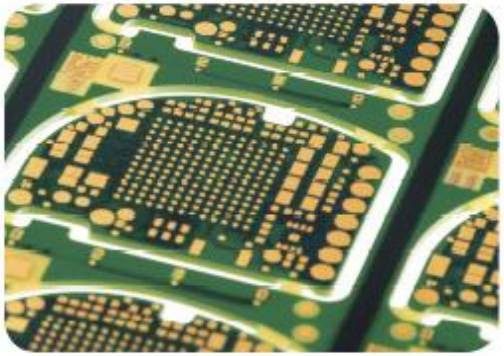
**Fold/nest solutions**

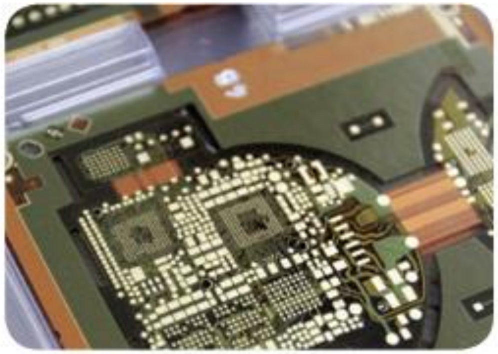
# Substrates

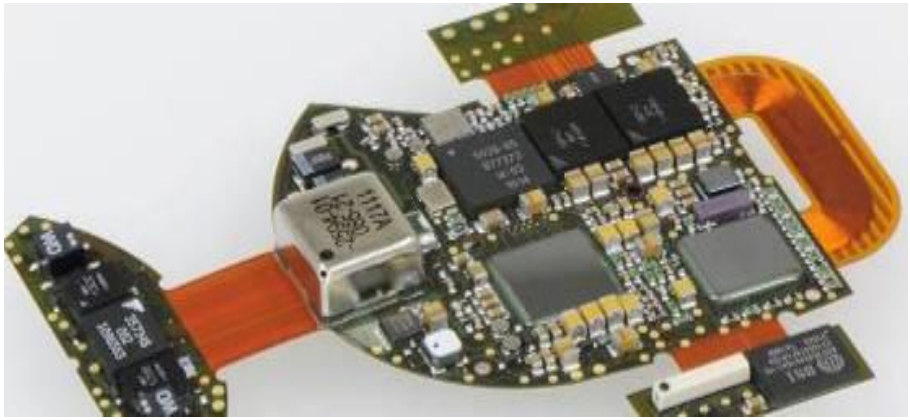
- **The substrate is the backbone of an electronic device**
  - It interconnects all components electrically
  - It is the mechanical carrier for the components
- **Substrate technology has a direct impact on**
  - Achievable form factors
  - Available assembly processes
  - Reliability and performance of the device
- **Substrate technologies**
  - Rigid Substrates → based on glass reinforced materials
  - Full Flex Substrates → based on flexible polymer films
  - Rigid-Flex Substrates → a combination of the above
  - **New Substrates → Biocompatible**

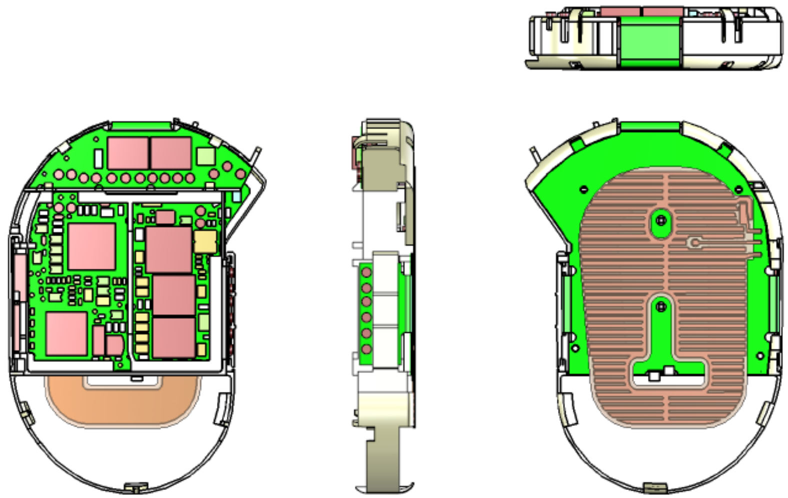
# Substrates to Achieve Various Form Factors

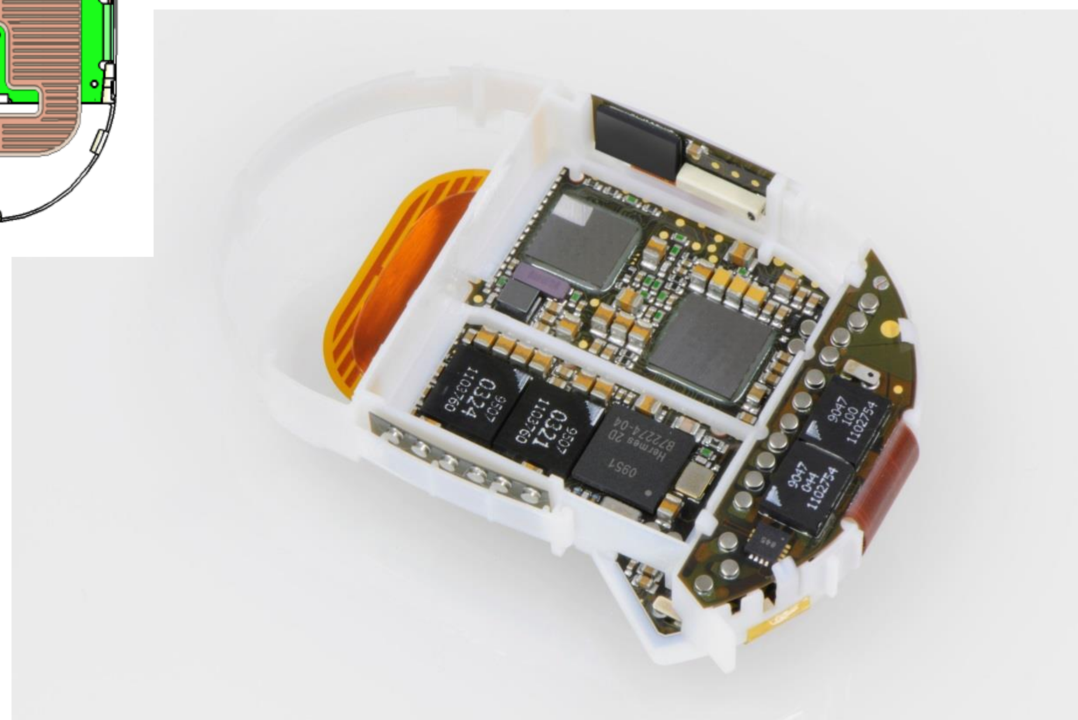






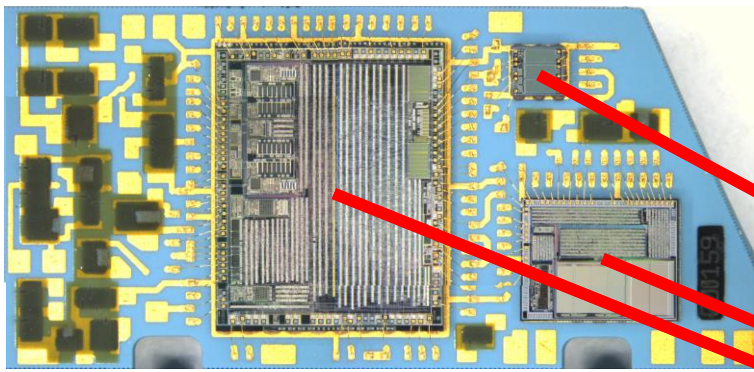
# Folded Module



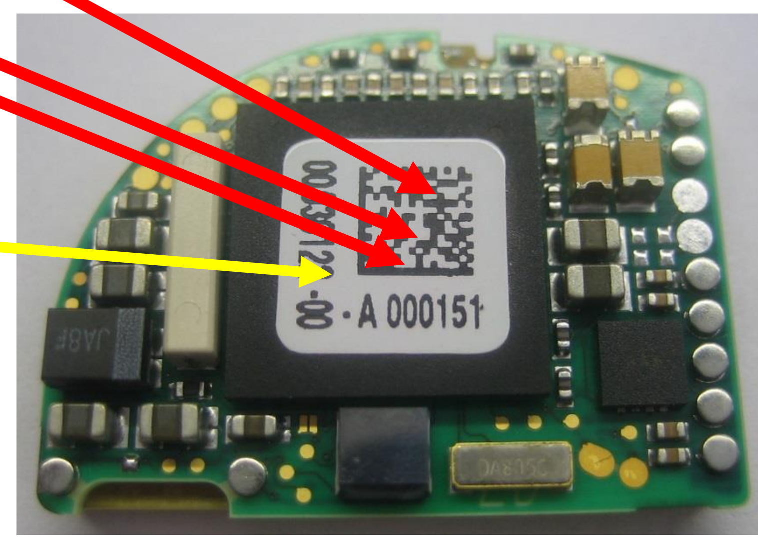


# Progression of Packaging

## Active Medical Implant Buildup (Cardiac Pacemaker)



**Functionality is distributed among three ASICS; COB-Assembly**

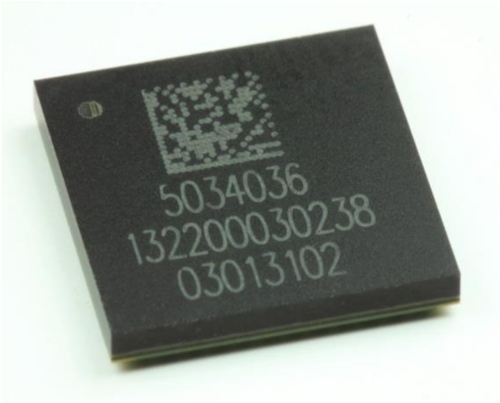


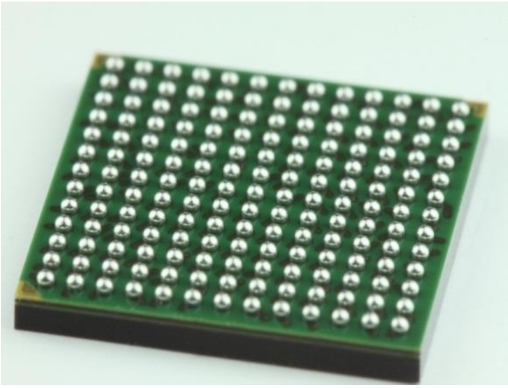
**Functionality in one SDBGA (Stacked Die Ball Grid Array)**

**Improvement in the Level of Integration**

# SDBGA Packages

- *Robust Package*
- Package is mounted in a Standard-SMT-Process
- Parallel (=faster) Assembly Process
- Complete electrical Test after Packaging

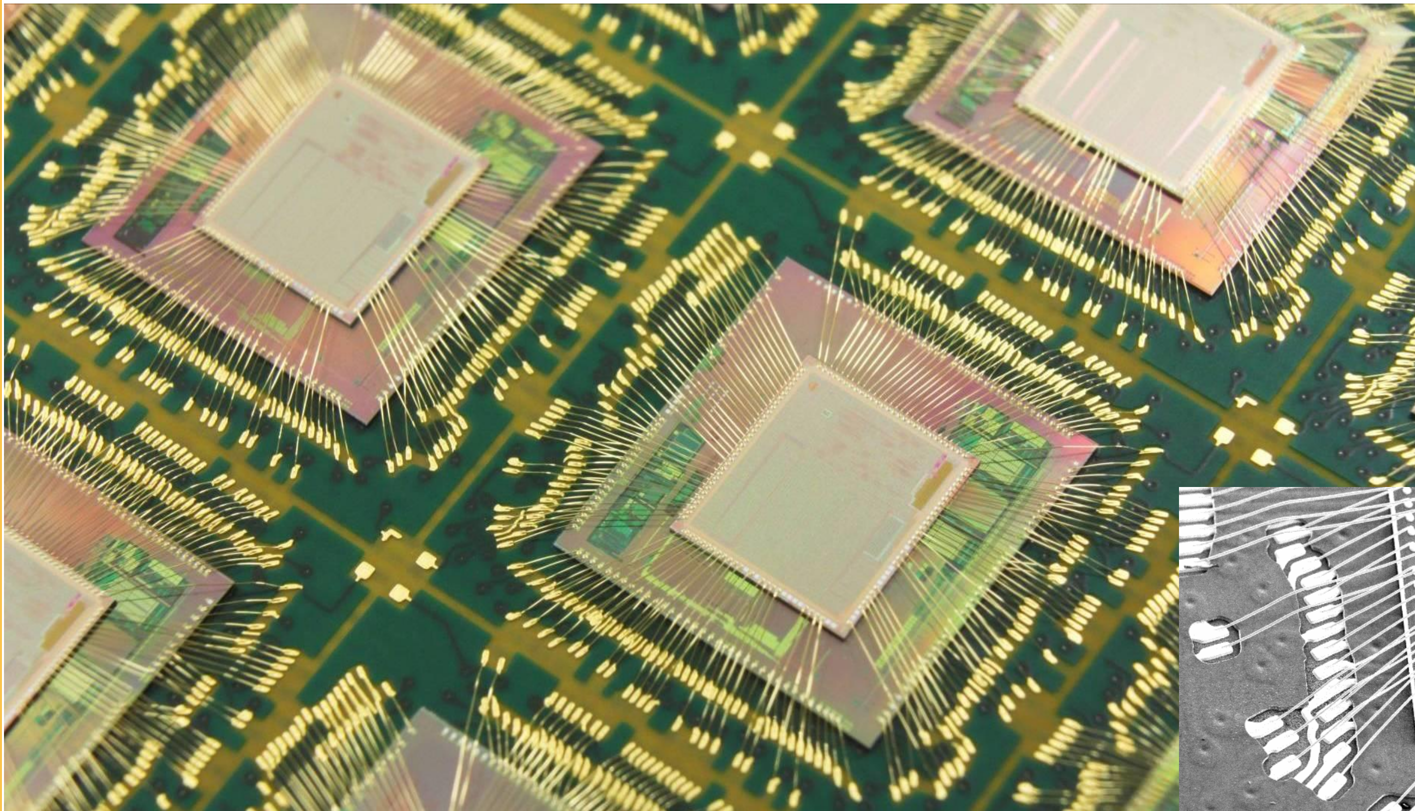


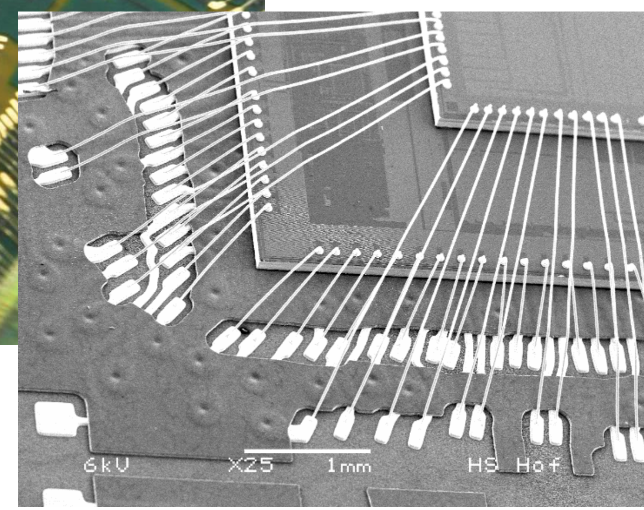



# SDBGA Packages for Medical Implants

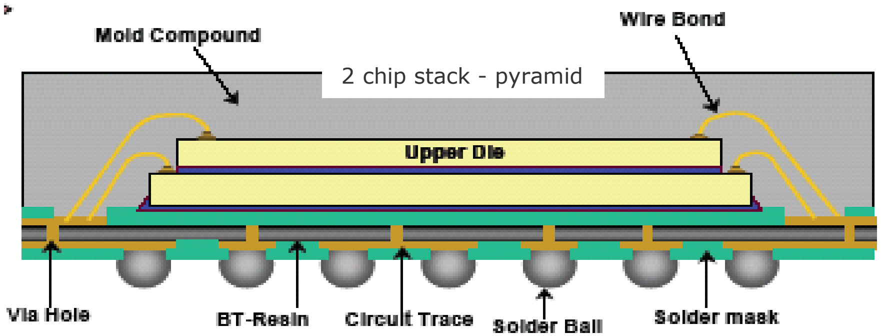
- Material and Process Traceability
- Traceability of the assembled dice down to their x-y position on the wafer
- Assembly of Known Good Die; complete electrical test is performed on wafer level
- Small to Mid Volumes
  - Limited Availability from Packaging Companies

# SDBGA Packaging

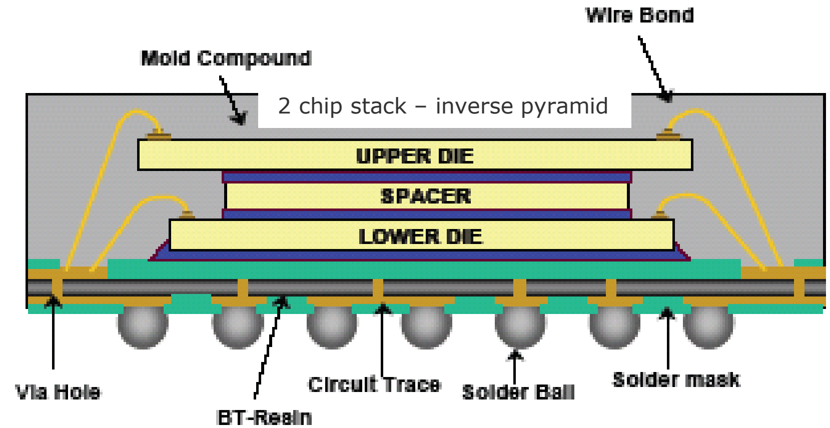




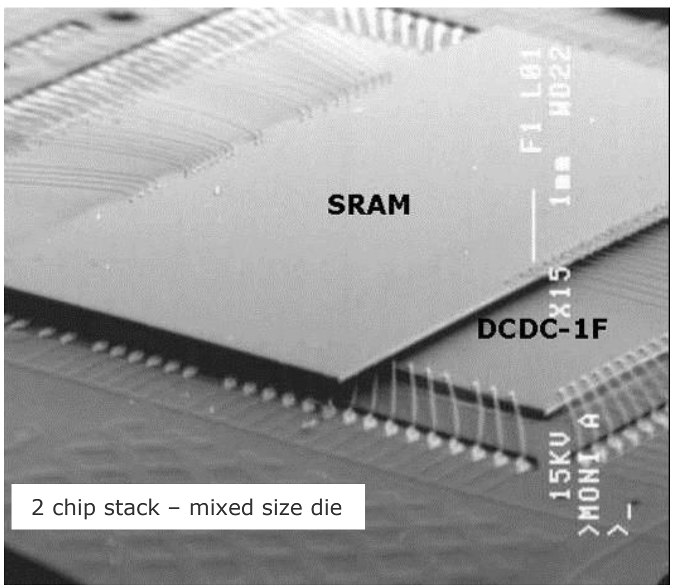
# SDBGA Solutions



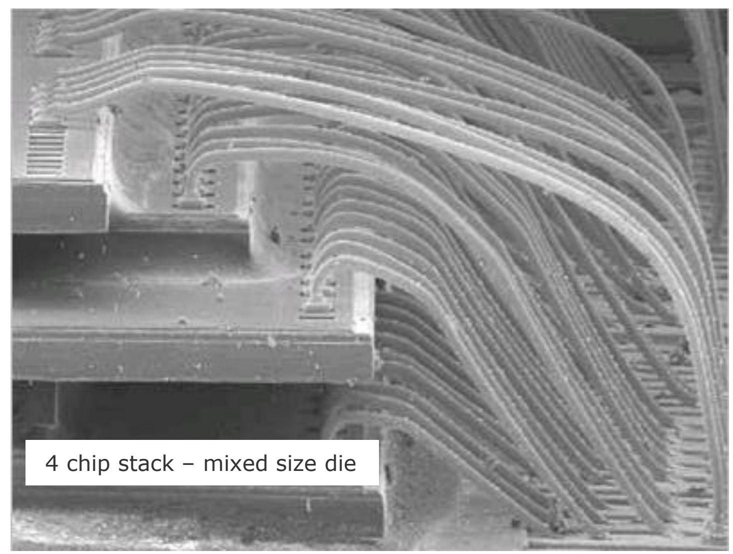

2 chip stack - pyramid




2 chip stack – inverse pyramid

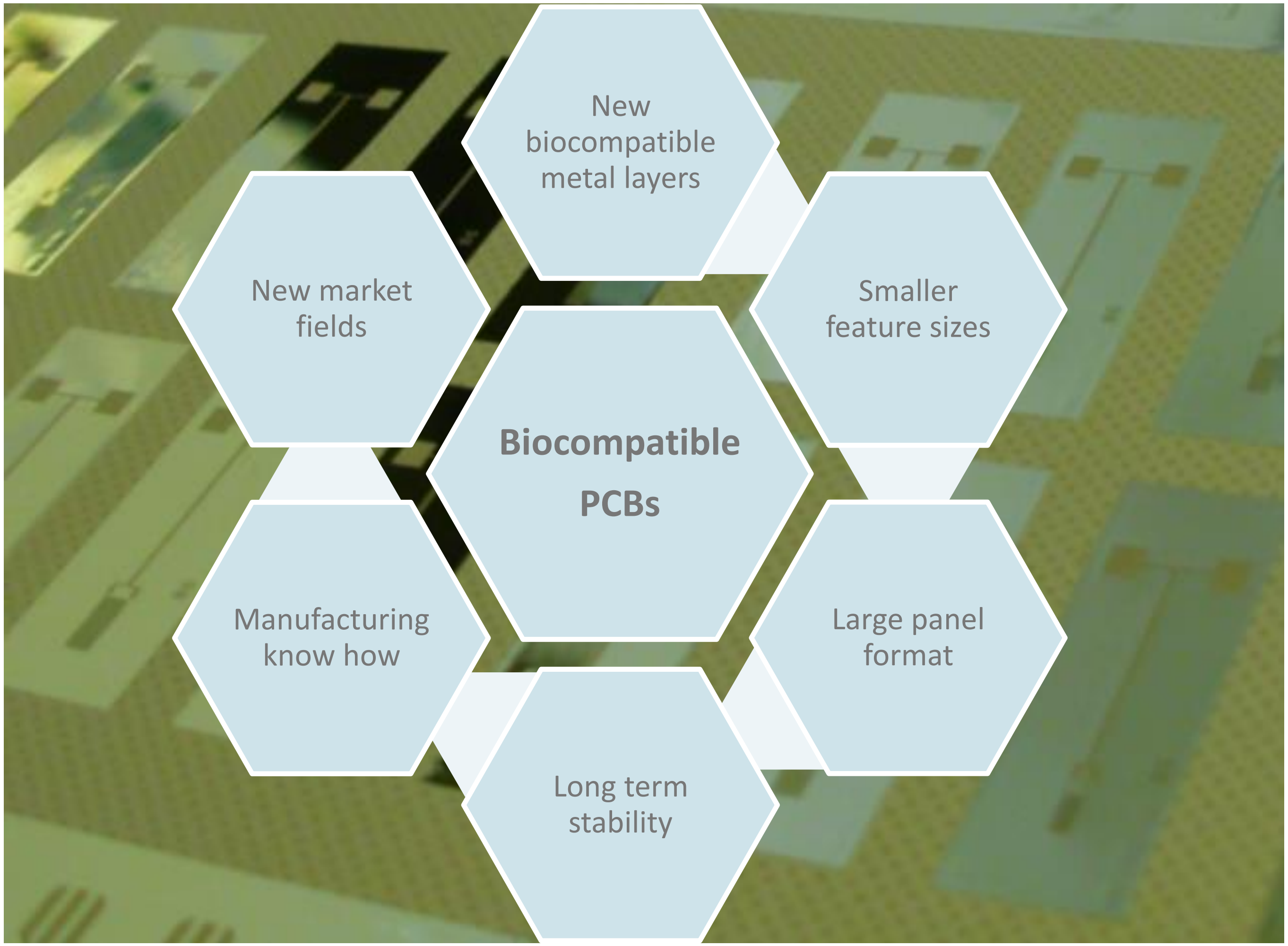



2 chip stack – mixed size die



4 chip stack – mixed size die

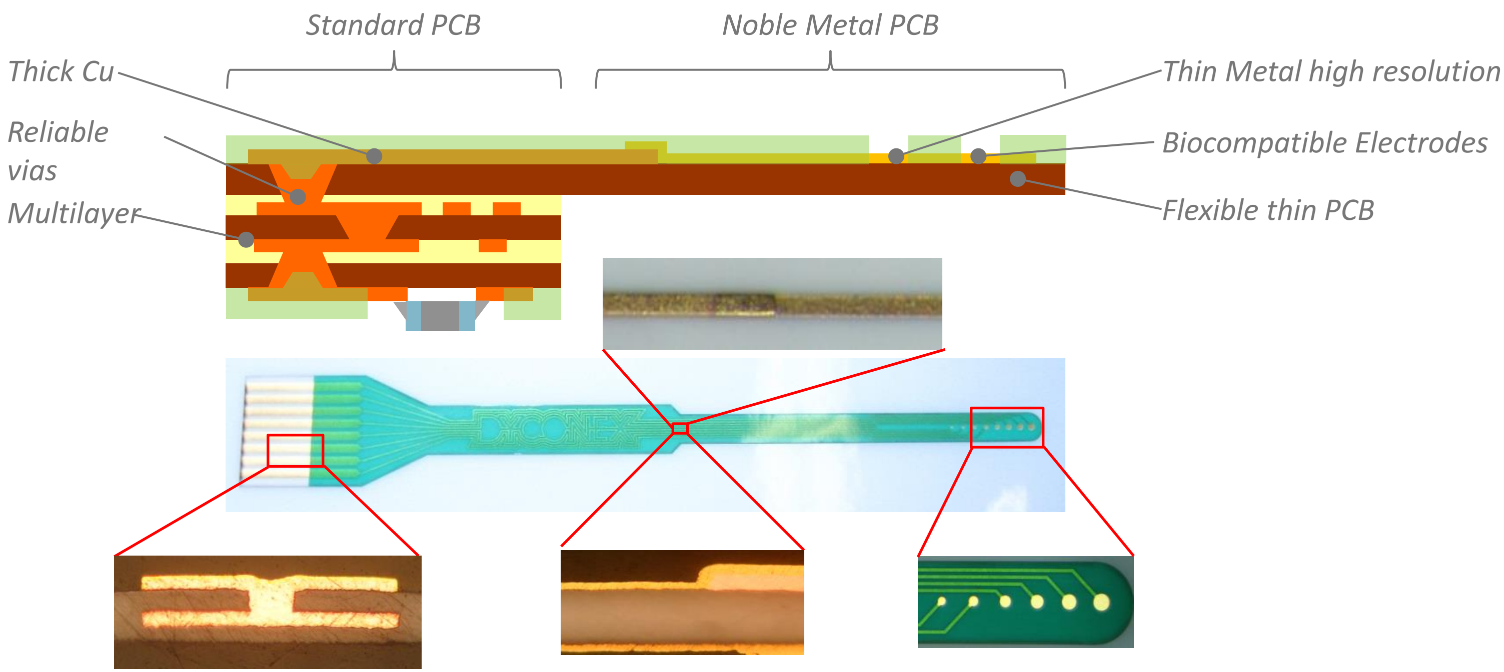
# Biocompatible Substrates



# COMPARISON: Standard PCB vs. Noble Metal PCB

**Standard PCB subtractive copper etching**
- Thick metal
- Line / Space: > 25 µm
- Reliable z-axes connection (via)

**Noble metal PCB additive technology**
- Thin metal
- Line / Space: < 25 µm
- Challenging z-axes connection




*Typical build up of a sensor*

# ISO 10993-1:2009 + Cor 1:2010 Regulation

Definition of biocompatibility:

"The quality of not having toxic or injurious effects on biological systems." *

The ISO 10993-1:2009 + Cor 1: 2010 set a series of standards for evaluating the biocompatibility of a medical device prior to a clinical study. **

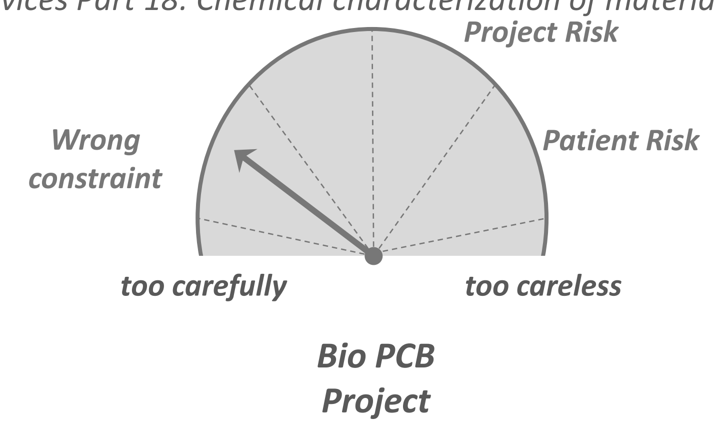
- 18 different specification points
  - *ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process*

  to

  - *ISO 10993-18:2009 Biological evaluation of medical devices Part 18: Chemical characterization of materials*

*"There is no bio-incompatible material....*

*.... the dose makes the poison"*





** Dorland's Medical Dictionary ; ** Wikipedia*

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engineering for life

DYCONEX
an MST company

# ISO 10993-1:2009 + Cor 1:2010 Biological Evaluation Tests

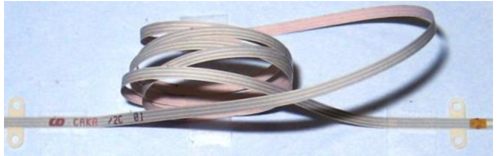
- Not all tests are essential but a base knowledge of ISO 10993 is mandatory
- Substrates processed by DYCONEX have been successfully tested for *ISO 10993-5 Test for in vitro cytoxicity*


| Medical Device Category | | | Biological Effect | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Nature of Body Contact: Category | Contact | Contact Time<br>A- limited (< 24 h)<br>B- short term (24h - 30 d)<br>C - permanent (> 30 d) | Cytoxiticity | Sensitization | Irritation or intra cutaneous reaction | Systematic Toxiticity | Subacute and subchronic toxiticity | Genotoxiticity | Implantation | Hemocompabtibility | Chronic toxiticity Carcinogenicity |
| Surface Device | Skin | A | x | x | x | | | | | | |
| | | B | x | x | x | | | | | | |
| | | C | x | x | x | | | | | | |
| | Mucosal menbrane | A | x | x | x | | | | | | |
| | | B | x | x | x | o | o | | | | |
| | | C | x | x | x | o | x | x | o | | o |
| | Breached surface | A | x | x | x | o | | | | | |
| | | B | x | x | x | o | o | | o | | |
| | | C | x | x | x | o | x | x | o | | o |
| External Device | Blood Path Direct | A | x | x | x | x | | | | x | |
| | | B | x | x | x | x | o | | | x | |
| | | C | x | x | o | x | x | x | o | x | o |
| | Tissue bones dentin | A | x | x | x | o | | | | | |
| | | B | x | x | x | x | x | x | x | | |
| | | C | x | x | x | x | x | x | x | | o |
| | Circulating blood | A | x | x | x | o | | | | | |
| | | B | x | x | x | x | x | x | x | | |
| | | C | x | x | x | x | x | x | x | | o |
| Implant Device | Tissues bones | A | x | x | x | o | | | | | |
| | | B | x | x | x | x | x | x | x | | |
| | | C | x | x | x | x | x | x | x | | o |
| | Blood | A | x | x | x | x | x | | x | x | |
| | | B | x | x | x | x | x | x | x | x | |
| | | C | x | x | x | x | x | x | x | x | o |

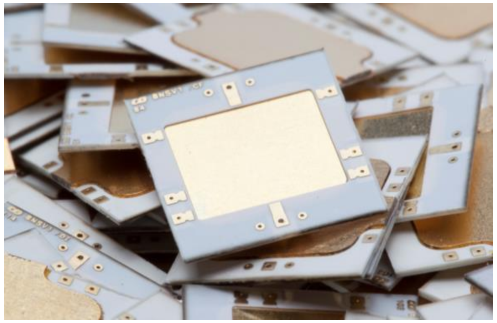
x - Test according ISO 10993-1
o - Additional Tests (USA)

# Material – Available Options

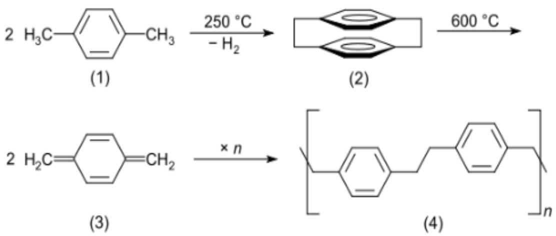
- **For flexible applications:**
  - Polyimide
  - LCP



- **For rigid applications:**
  - Glass
  - PEEK
  - Flexible material with a rigid stiffener

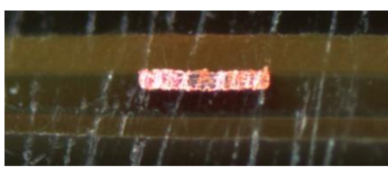


- **Cover materials:**
  - For flexible applications:
    - Solder mask (can be used for short term implants)
    - LCP
  - Parylene coatings

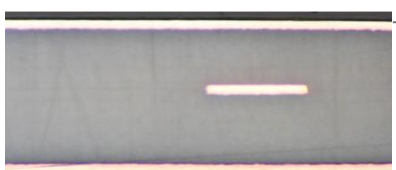


# LCP – Liquid Crystal Polymer - Properties

- Very flexible thermoplastic base material
- Biocompatible properties
- High temperature stability (Tg > 280°C, Td > 320°C)
- Very low water absorption (0.04 %) in comparison to standard acrylic adhesives (8%)
- Excellent high frequency properties ($\varepsilon_R$= 2.9, tan θ = 0.0025)
- Low weight (3.2 g/cm$^3$)
- For multilayer one homogeneous material

Pi
Adhesive
Pi

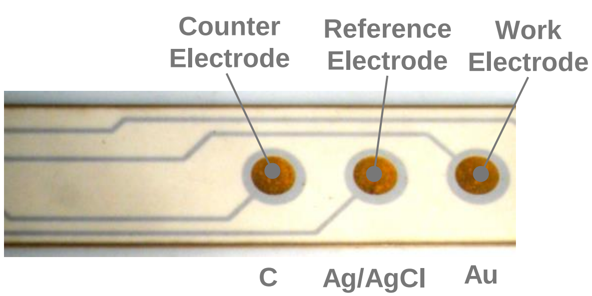


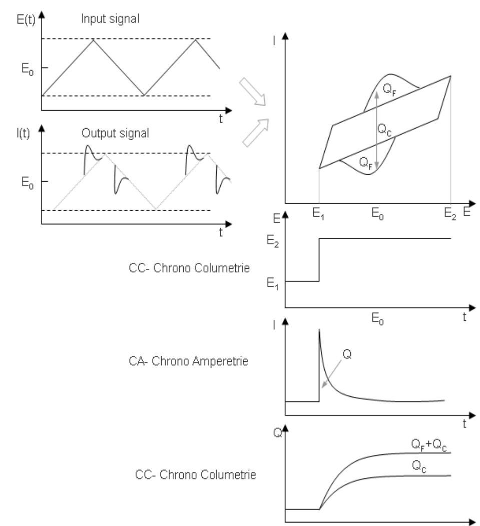
Only LCP

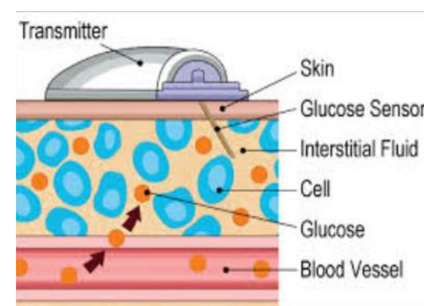
# Application: Short Term Blood Glucose Sensors

- Compact, handheld, portable device, which measures blood glucose levels as part of a diabetes management regimen for the chronic diabetic
- Direct implantable bio sensor with clinical approved studies
  - flexible PCB substrate
  - flexible cover mask
- 30 days in human body
- Measures capacitive electric charge current
- Typical 3-electrode system


*Source: http://diabeteshealth.com/media/images/article_images/5060.jpg*



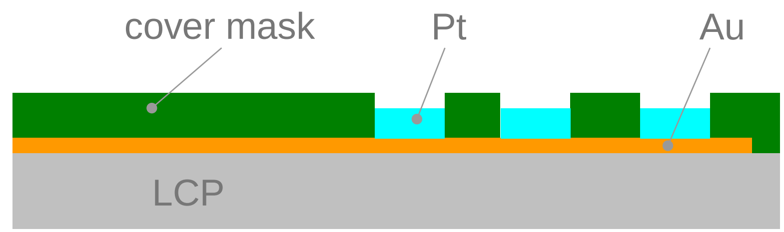



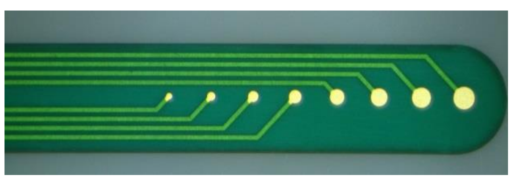

*Source: www.medtronicdiabetes.com*

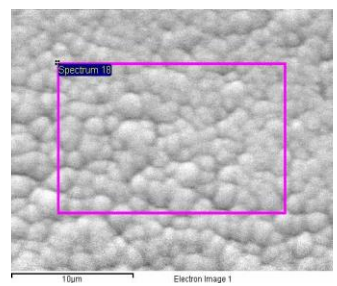
# Application: Permanent Implant Cochlear Electrodes

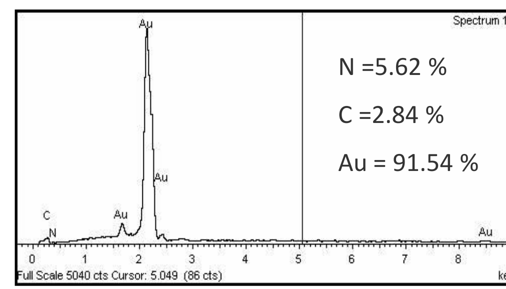
- Need of pure biocompatible materials without copper for long term implant
  - LCP for excellent biocompatible properties
  - Au for good adhesion and flexible properties
  - Pt for selective electrodes robustness
- Test design with 125 µm traces on 250 µm pads
- Test structures with 15 µm Line / Space demonstrated



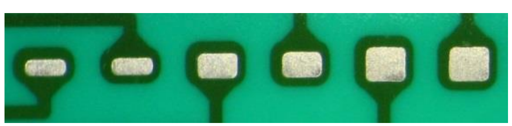

pure gold electrodes

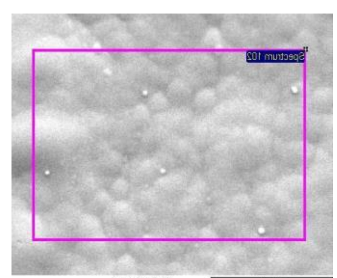


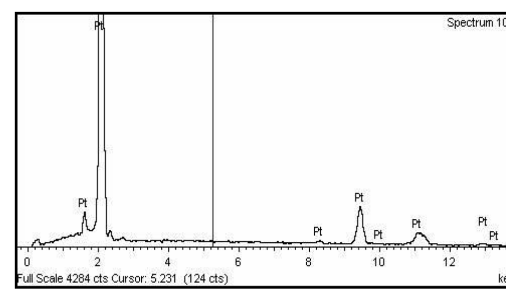



gold + platinum electrodes

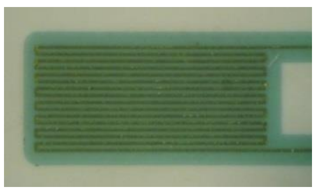




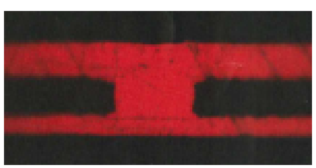


# Application: Thermistors For Heat Measurements

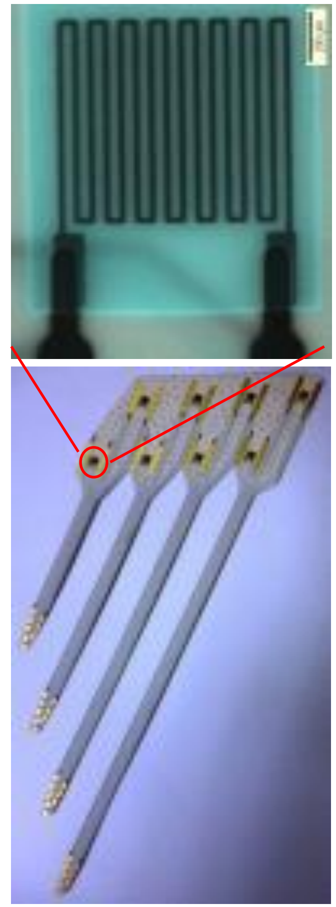
- Balloon catheters with electrodes for neuro-stimulation or ablation
- Invasive surgical procedure
- Extremely flexible ultra thin 2-layer LCP build up with 50 µm final thickness
- One thermistor per electrode couple with thin film layer

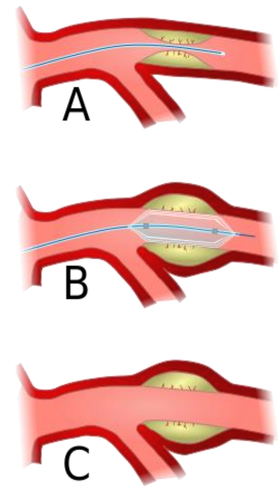


- 25 µm Line / Space
- One sided copper plating with 100% via-fill

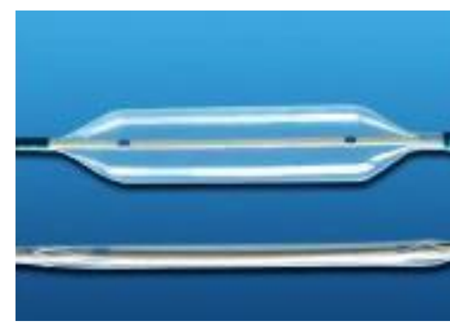


- Surface finish: electroplated gold on copper for short term implant



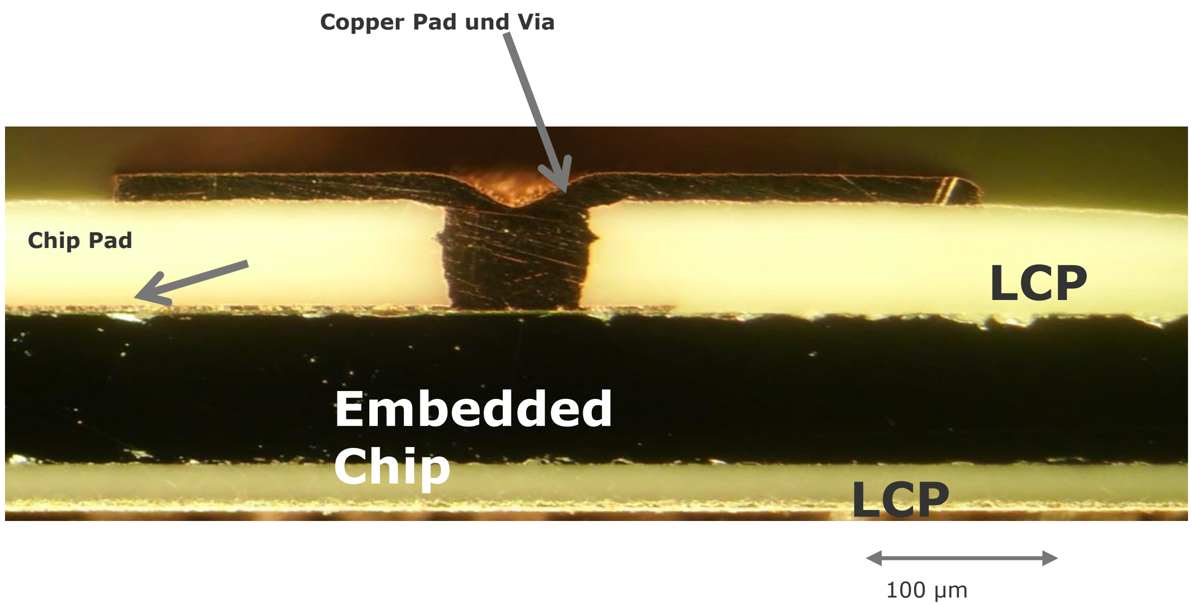



Source: http://de.wikipedia.org/wiki/Angioplastie



Source: http://www.p-wholesale.com/

# Smart Electrodes: Embedded Die



# Summary

- Electronics packaging for complex medical devices demands innovation and advanced capabilities, but achieved in a manner which ensures reliability and performance.

- This can be realized through adoption of multiple approaches including:
  - Substrates to accommodate unique form factors.
  - 3D packaging approaches like SDBGA.
  - Migration to biocompatible substrates where appropriate to enable new applications.