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

Intelligent electronics
FW/SW integration

Therapy efficiency
Multiple stimuli levels
Power conservation

2-way, low current
Low range, secure

Care Provider
Patient Environment

Complex sensors
High sensitivity

Speed, accuracy
Customizable

 Increased memory
Low power, low error

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**

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A comprehensive design approach required
Design Strategies – A Comprehensive Approach

**Design Inputs**
- Customer Requirements
  - Size/Shape/Features

**Design Iterations**
- Simulations
- Risk Mitigation (FMEA)
- Rapid Prototypes

**Module/Assembly Solutions**
- 2D/3D Product Design
- Performance & Margins Testing

Methodology (FMEA, Dfx), Simulation, Platforms/Knowledge base
Design Strategies – Key Miniaturization Solutions

- 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

Stacked ASIC Die

High Density Interconnects

Miniaturized Components

Communication coil integration

System-in-Packages

Fold/nest solutions

Advanced 3D Interconnects
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 in one SDBGA (Stacked Die Ball Grid Array)

Improvement in the Level of Integration

Functionality is distributed among three ASICS; COB-Assembly
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

- New biocompatible metal layers
- Smaller feature sizes
- New market fields
- Manufacturing know how
- Large panel format
- Long term stability
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

- **Thick Cu**
- **Reliable vias**
- **Multilayer**

- **Thin Metal high resolution**
- **Biocompatible Electrodes**
- **Flexible thin PCB**

New England 43rd Symposium & Expo
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
  to

"There is no bio-incompatible material.... .... the dose makes the poison"

*Dorland’s Medical Dictionary; **Wikipedia
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 cytotoxicity.
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 ($\varepsilon_R = 2.9$, $\tan \theta = 0.0025$)
- Low weight (3.2 g/cm$^3$)
- For multilayer one homogeneous material
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

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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

Smart Electrodes: Embedded Die

Copper Pad und Via

Chip Pad

Embedded Chip

LCP

100 μm
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.