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Hermetic packaging of implantable devices: How did we get here? And where are we going?

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ADVANCED OUTSOURCING SOLUTIONS FOR ACTIVE IMPLANTS AND MINIMALLY INVASIVE DEVICES

What is hermeticity?

hermeticity (ˌhɜːməˈtɪsɪtɪ)

▸ Definitions

noun

the state of being airtight or gastight

Implantable devices really should be both…

- Water tight
- Ion tight

But nothing is really hermetic…

VARIAN

IT'S A GIVEN THAT EVERYTHING LEAKS…THE QUESTION IS HOW MUCH?

LEAK RATE CONVERSION TABLE

Leak rate (atm-cc/sec)	Leak rate (cc/time)	Time required to form one bubble (1/8" dia) under water
10-1 atm-cc/sec	1 cc/ 10 sec	Steady stream
10-2 atm-cc/sec	1 cc/ 100 sec	1.5 seconds
10-3 atm-cc/sec	1 cc/ 17 min	15 seconds
10-4 atm-cc/sec	1 cc/ 3 hours	150 seconds
10-5 atm-cc/sec	1 cc / day	25 minutes
10-6 atm-cc/sec	1 cc/ 12 days	Bubbles are too infrequent to be observed
10-7 atm-cc/sec	1 cc/ 17 weeks	
10-8 atm-cc/sec	1 cc/ 3 years	
10-9 atm-cc/sec	1 cc/ 32 years	
10-10 atm-cc/sec	1 cc/ 318 years	

TYPCICAL LEAK RATE SPECIFICATIONS BY APPLICATION

Application	Leak rate (atm-cc/sec)	comment
Torque converter	10-3 to 10-4	Retention of liquid
Beverage can end	10-6 to 10-7	Retention of CO2
Auto air bag	10-5 to 10-8	Guaranteed operation
Vacuum furnace	10-6 to 10-8	Leak tight
IC package	10-7 to 10-8	Prevent ingress of moisture
Implantable medical device	10-9 to 10-10	Prevent ingress of moisture

Devices should be sufficiently hermetic to ensure function and safety.

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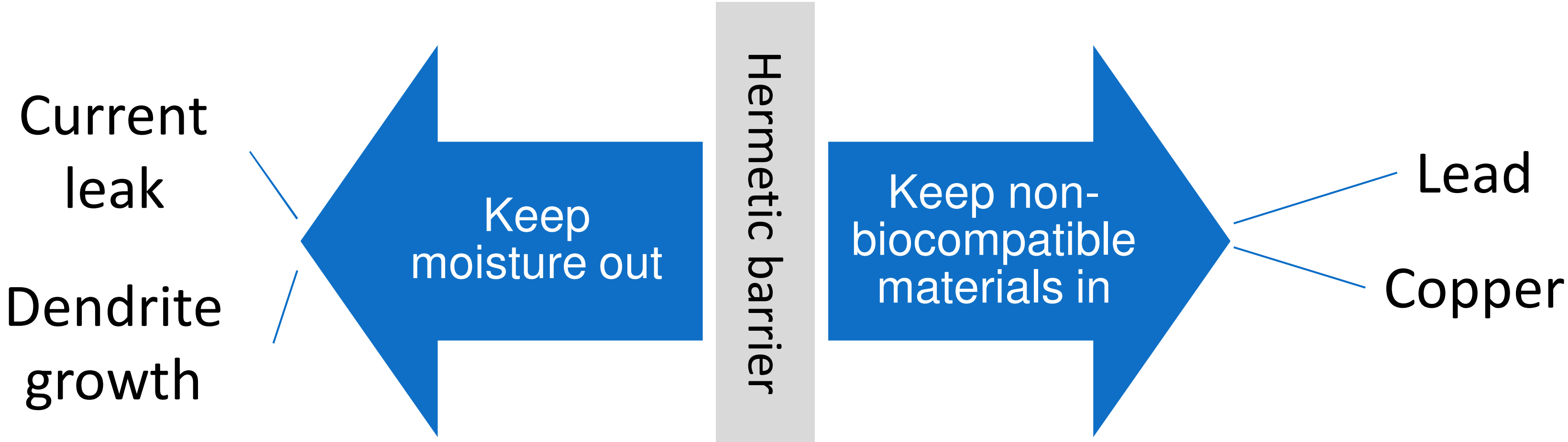
Why does hermeticity matter?



Moisture can lead to…

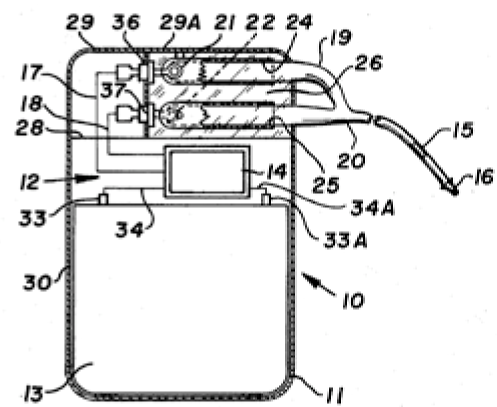
- Power drain
- Non-function
- Unpredictable or unintended function

Hermeticity in history…

Siemens pacemaker (First implanted 1958)

Chardack-Greatbatch (First implanted 1960)

Cardiac Pacemakers, Inc. (Patented 1974)



Architecture evolution?

Determining acceptable leak rate

- How much moisture is acceptable in the device?
  - MIL-STD vs EN 44502 vs 5000 ppm vs 3 monolayers of water…
- How much moisture will be sealed into the device?
  - Moisture in the components (Handling, environmental humidity, etc.)
  - Vacuum bake
  - Desiccants
- How long does the device need to survive?
  - How long is therapy required?
  - How long will the power source last?
  - How complicated is it to remove the device?
- How much tracer gas do you have?
  - Internal free volume
  - Helium concentration

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Determining acceptable leak rate

Determination of Helium Tracer Gas Leak Rates to Support Hermeticity Requirements		
LEAK RATE SUMMARY (REFERENCE TD110492 FOR BACKGROUND & DETAILED METHODOLOGY)		
Approach #1: Leak rate based on European Standard EN 45502-2-3:2010		
Measured helium leak rate:	1.23E-08	atm-cc/sec
Approach #2: Leak rate based on MIL-STD-883H, Method 1014.13		
Measured helium leak rate:	6.82E-08	atm-cc/sec
Approach #3: Typical leak rates reported by the Leak Detection Equipment Manufacturers		
Leak rate specification based on chart:	10^{-9} to 10^{-10}	atm-cc/sec
Approach #4: Determining an acceptable leak rate based on the device life and the maximum acceptable internal relative humidity		
Measured helium leak rate:	9.91E-11	atm-cc/sec
Approach #5: Determining an acceptable leak rate based on water vapor ingress resulting in the accumulation of 3 monolayers of water over the specified device life		
Measured helium leak rate:	1.62E-11	atm-cc/sec

Risk should help drive specification development.

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Measurement methods

In-process testing

- Gross leak
- Fine leak

Most typically used, but limited for low leak rates

Developing test methods

- Cumulative helium
- Optical

Allows lower leak rates, but not production ready

Monitoring

- Electrical characteristics
- Moisture sensors

Monitoring rather than screening could result in latent failure

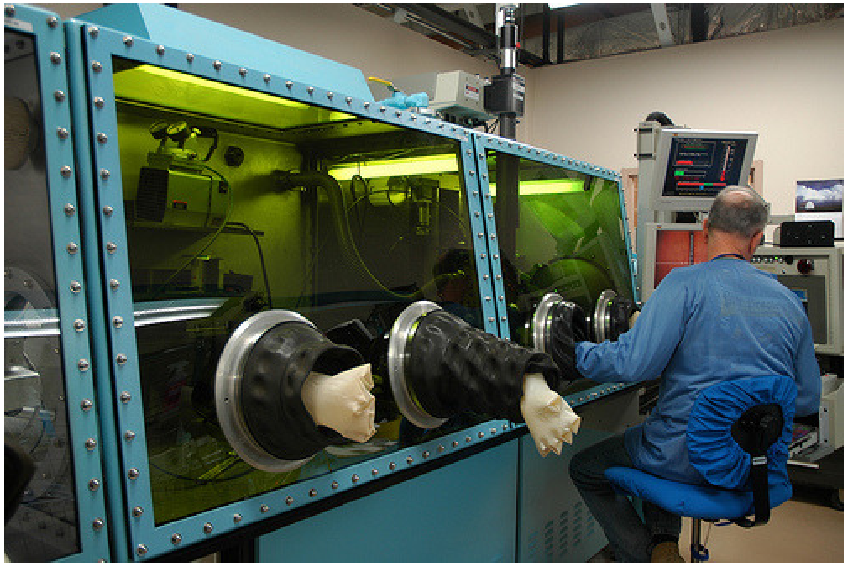
Measurement methods

Most fine leak test methods use helium tracer gas…

- Inert
- Small molecule
- Easy to detect
- Low levels in background atmosphere

Helium bomb

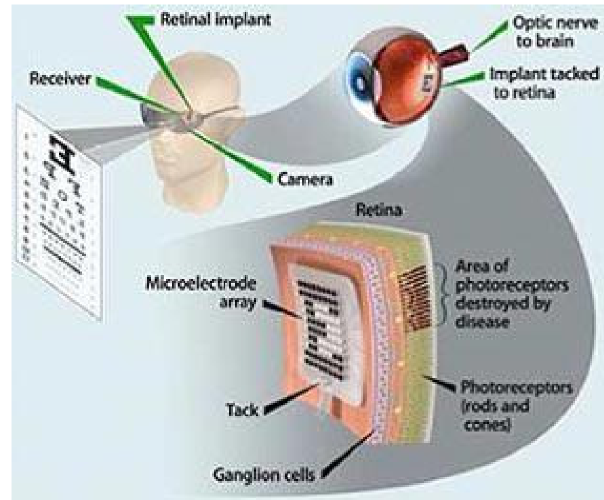
Tracer gas sealed into device

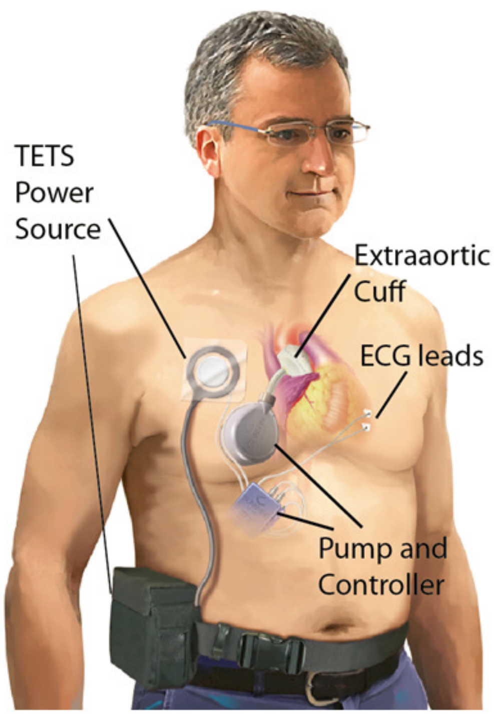


Industry trends

New and expanding therapies

- Monitoring devices
- Sensory prosthetics
- Mechanical circulatory support
- Peripheral nerve stimulation





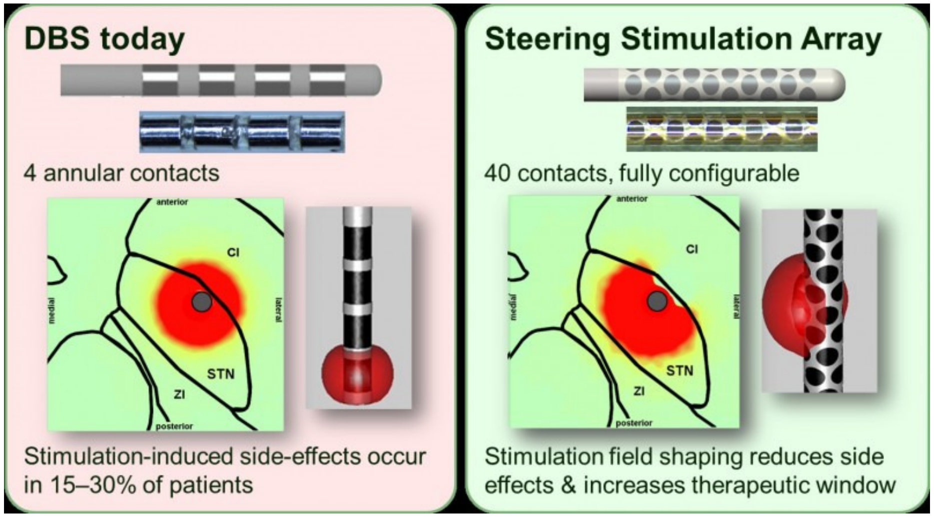
Industry trends

New and expanding therapies

- Monitoring devices
- Sensory prosthetics
- Mechanical circulatory support
- Peripheral nerve stimulation

Therapy improvements

- DBS: Increased specificity
- SCS: Minimally invasive
- CRM: Failure reduction



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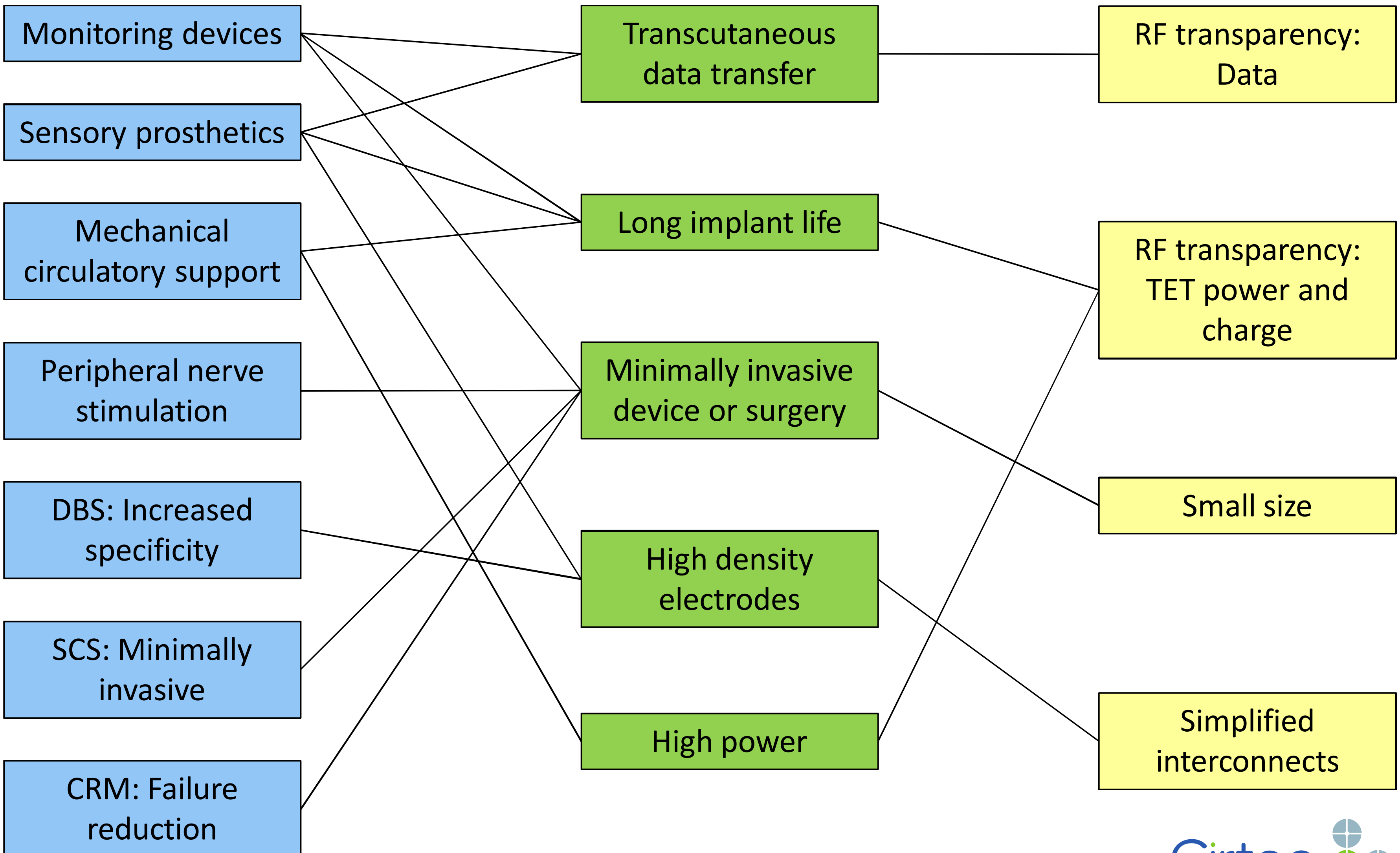
Industry trends



Ceramic packaging

RF transparency: Data

RF transparency: TET

- Established implant use
- Good hermeticity
- Thicker walls than metals
- High temperature sealing
- Mechanical impact challenges

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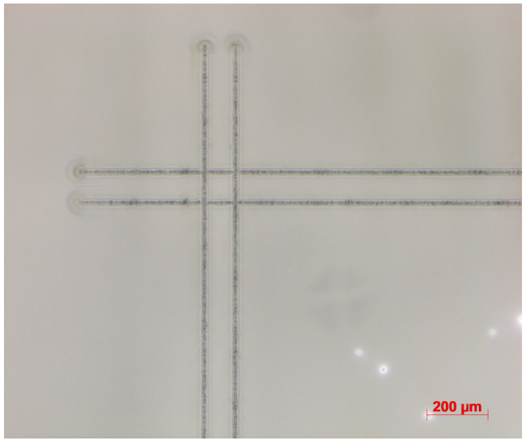
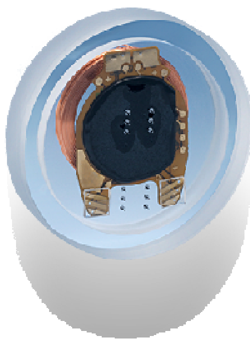
Glass packaging



Images courtesy of GlencaTec.



RF transparency: Data

RF transparency: TET

- Good hermeticity
- Proprietary materials or sealing processes
- Vias/feedthroughs require device-by-device development

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Ambient Temperature Bonding

Images: Invenios

RF transparency: Data

RF transparency: TET

Simplified interconnects

- Ambient temperature process
- Glass, silicon, ceramics, metals
- Small bond zone
- Incorporate electrical leads into bond

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Polymer encapsulation

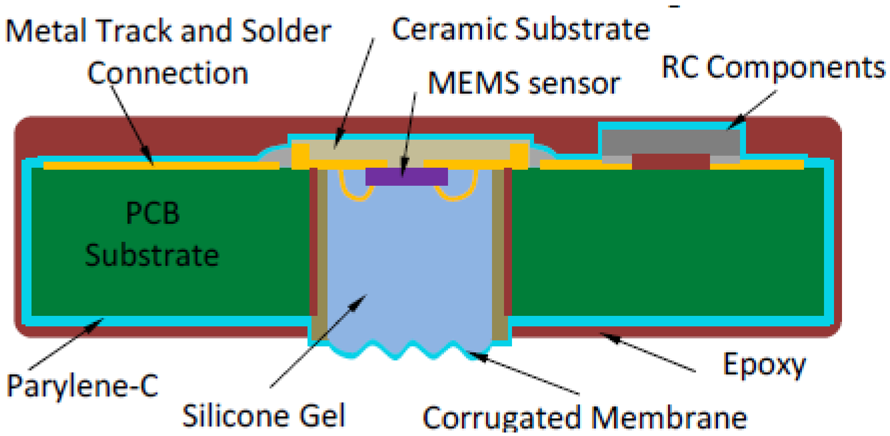


Figure 1: Cross-sectional schematic diagram of a micropackaged MEMS pressure sensor. The corrugated membrane is designed to minimize drift in sensitivity and nonlinearity during long-term implantation.

P. Wang et al., Transducers 2015, Anchorage, AK

RF transparency: Data

RF transparency: TET

Small size

Need for small size and RF transparency is driving some implant designers back to polymer encapsulants.

Polymer encapsulation

Desired properties of encapsulants

- Cured without voids
- Low modulus or designed to withstand thermal stress
- Hydrolytic stability (long term adhesion in water)
- Cures at moderate temperatures

Desired properties of encapsulated materials

- Corrosion resistant or passivated by oxide
- Good adherend for encapsulant

Adapted from material presented by Dr. Nick Donaldson of University College London at University of Washington on 10/26/2015.

Chemical vapor deposition

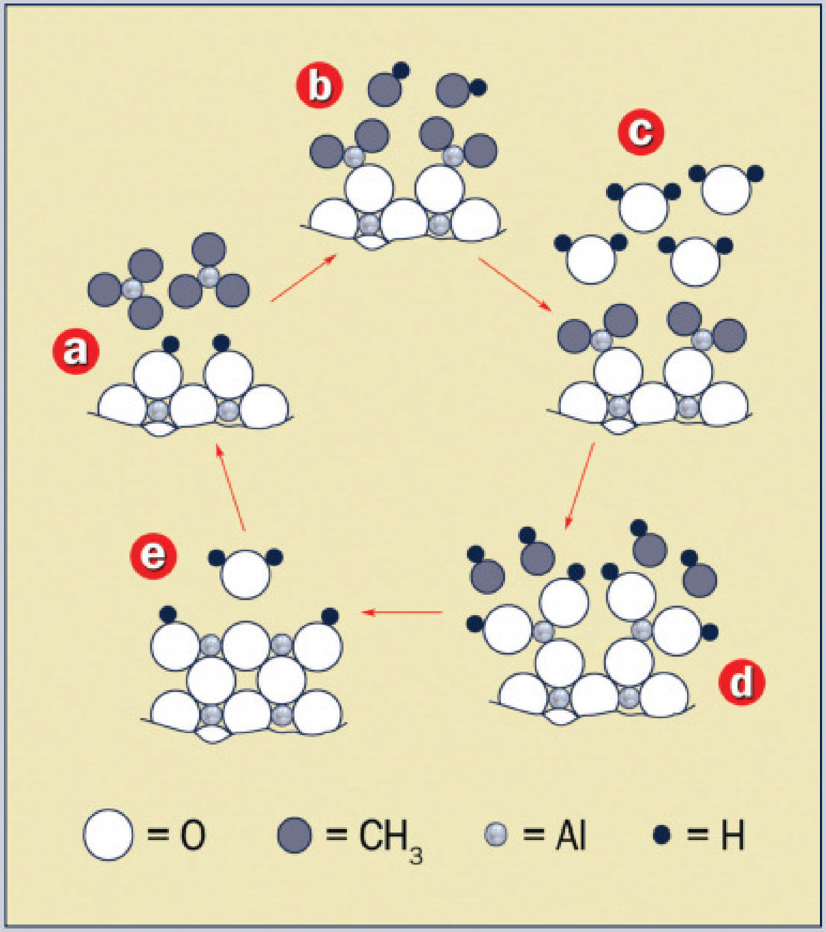


Figure 1-1: Five-step cycle (a through e) to produce one monolayer of Alumina ceramic (Al_2O_3) on a surface. Image courtesy of Sundew Technologies LLC.

RF transparency: Data

RF transparency: TET

Small size

- Conformal coating of ceramic
- In theory, can be truly hermetic
- Cannot be tested by traditional hermetic test methods

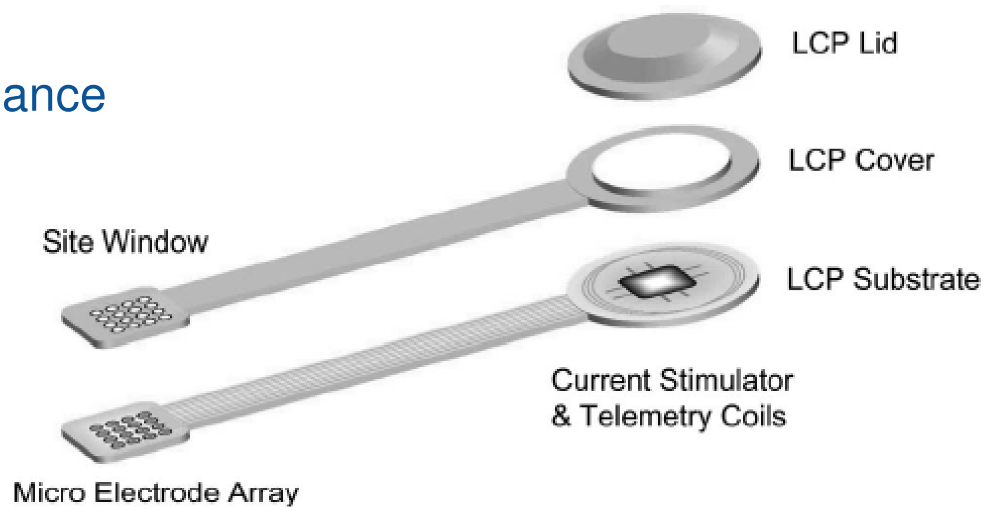
Liquid crystal polymer

- High temperature and low temperature LCP laminated to allow fusion bonding
- Requires moderately high process temperatures, which may limit electronic component selection
- Promising fluid ingress performance

RF transparency: Data

RF transparency: TET

Simplified interconnects



"Monolithic Encapsulation of Implantable Neuroprosthetic Devices Using Liquid Crystal Polymers", Kim S-J, et al., IEEE Trans BME, 58(8) 2255-2263, 2011.

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