DRAPER

Advancement in Microelectronics Packaging for Medical Implants: *Solving the Need for "More" with "Less" Space*

Caroline Bjune

07 May 2019

What Does Medical Device Packaging Mean?

- Packaging in the traditional sense in the medical community pertains to the external package housing the device.
  - *Subjected to and required to meet transport and shelf-life specifications*
  - *Typically requires custom designed trays and sealing process*

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  - *Electronics (internal guts of the device) – components (ASICs, SMTs, discrete); circuit board (rigid, flex, rigid-flex)*

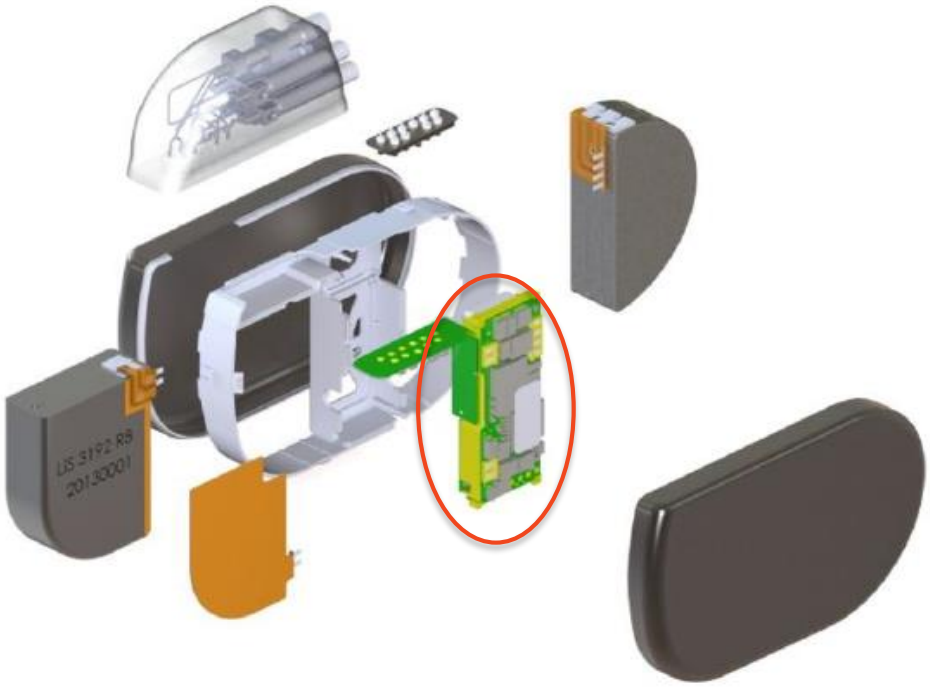

Photo: MST/Dyconex, https://www.mst.com/dyconex/

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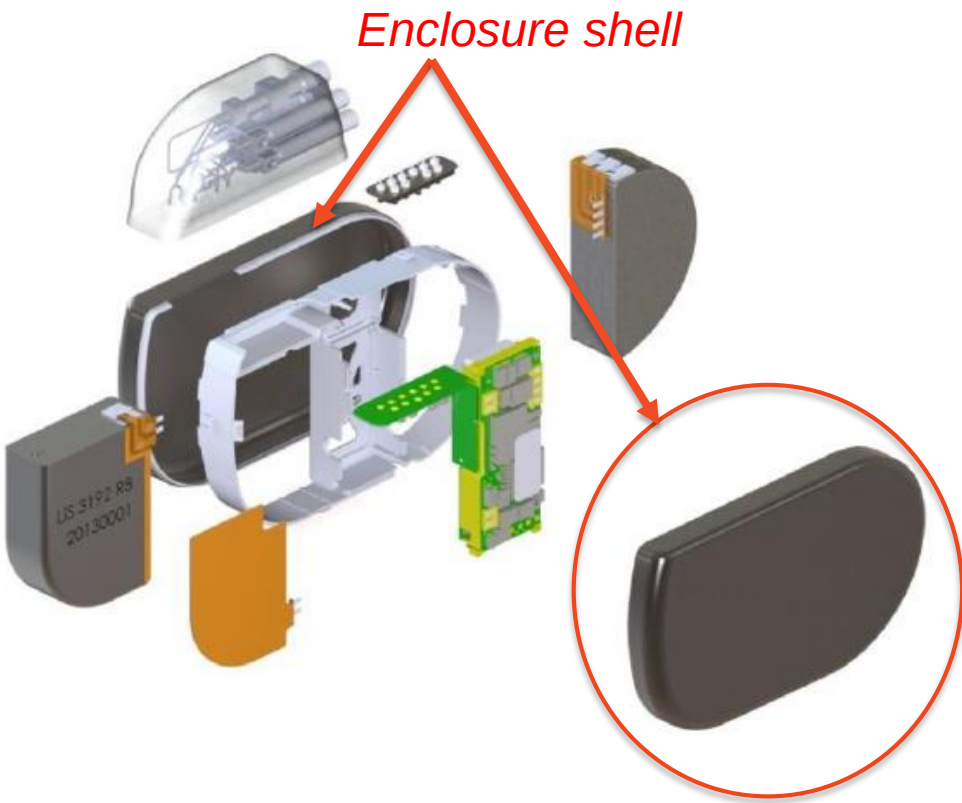

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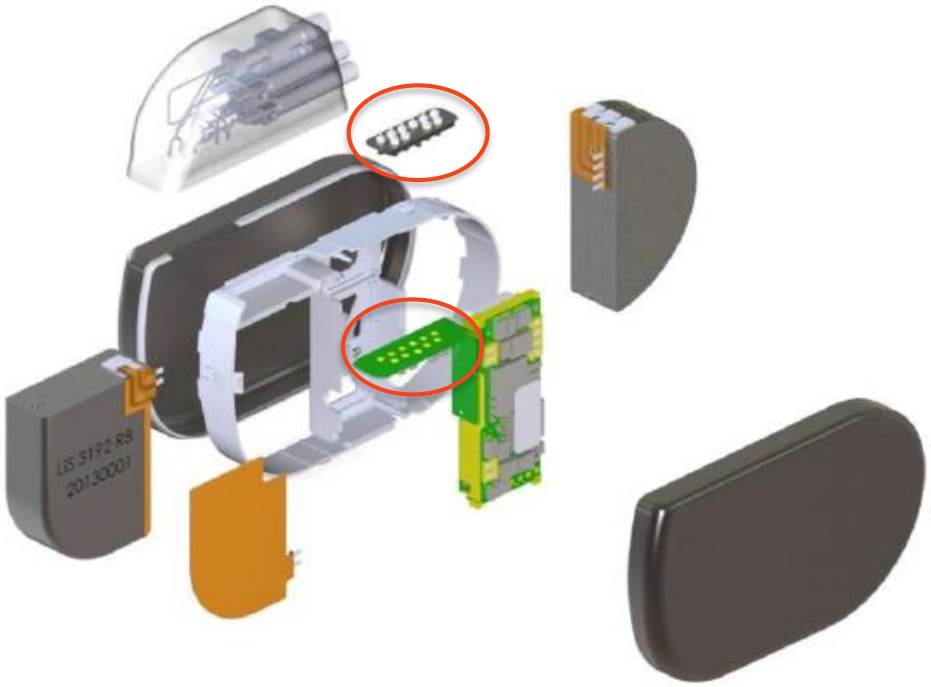

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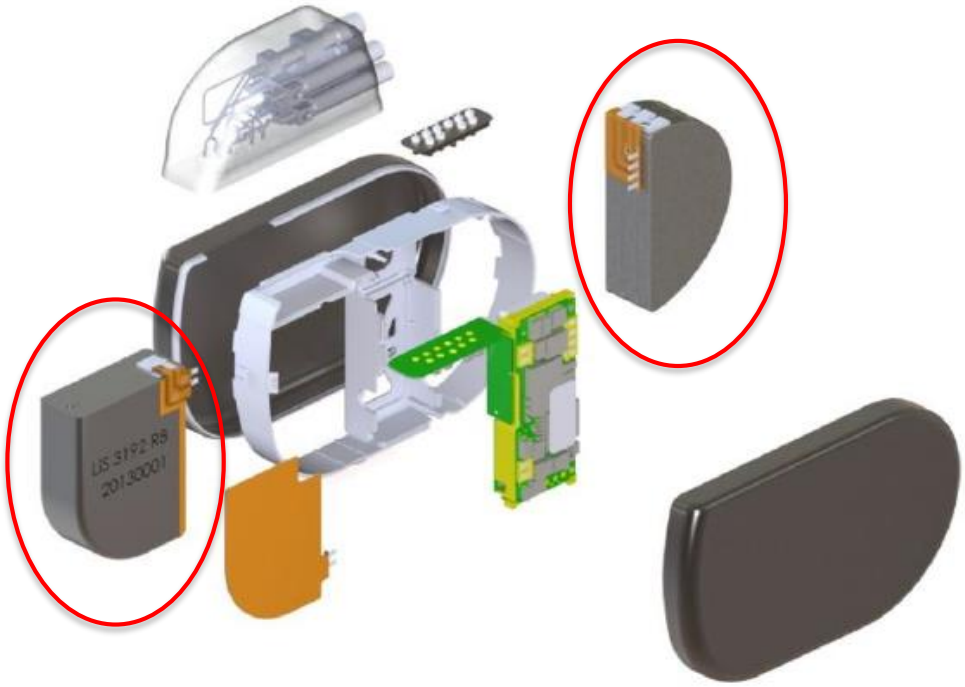

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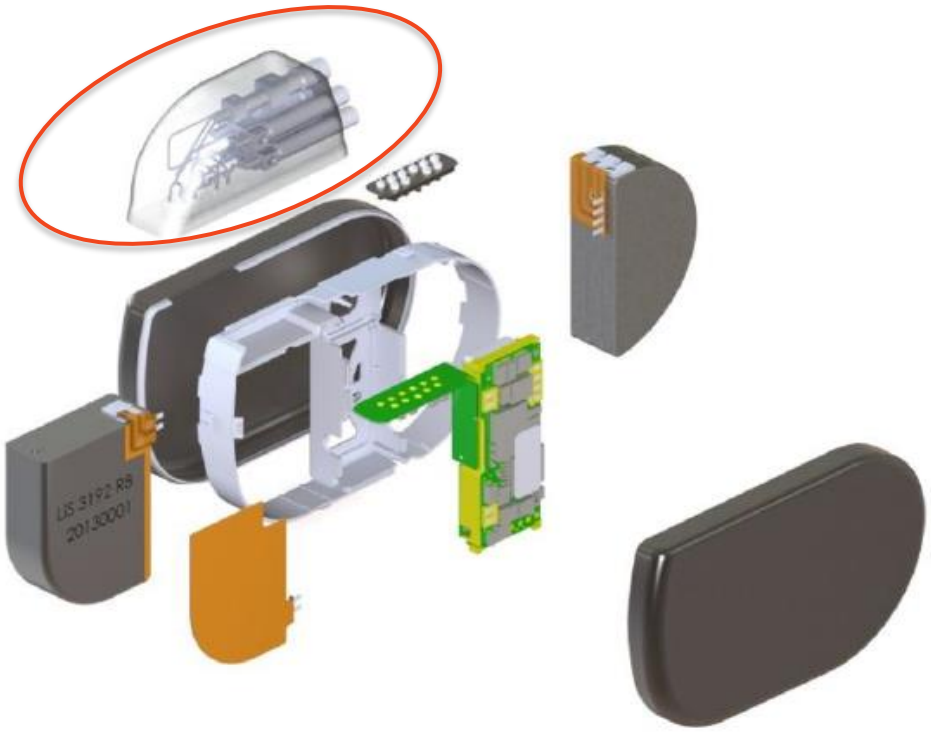
  - *Interconnect (how to bring the functions from the inside out to world, i.e. communication)*
  - *Power (battery within the implant; wirelessly powered)*
  - *Interfaces with other sub-systems (i.e. leads, controller)*



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The Evolution of Neuromodulation

From cardiac to neuro: variations on a common theme

1960s
Pacemaker

1970s
Pacemaker

1980s
Cochlea

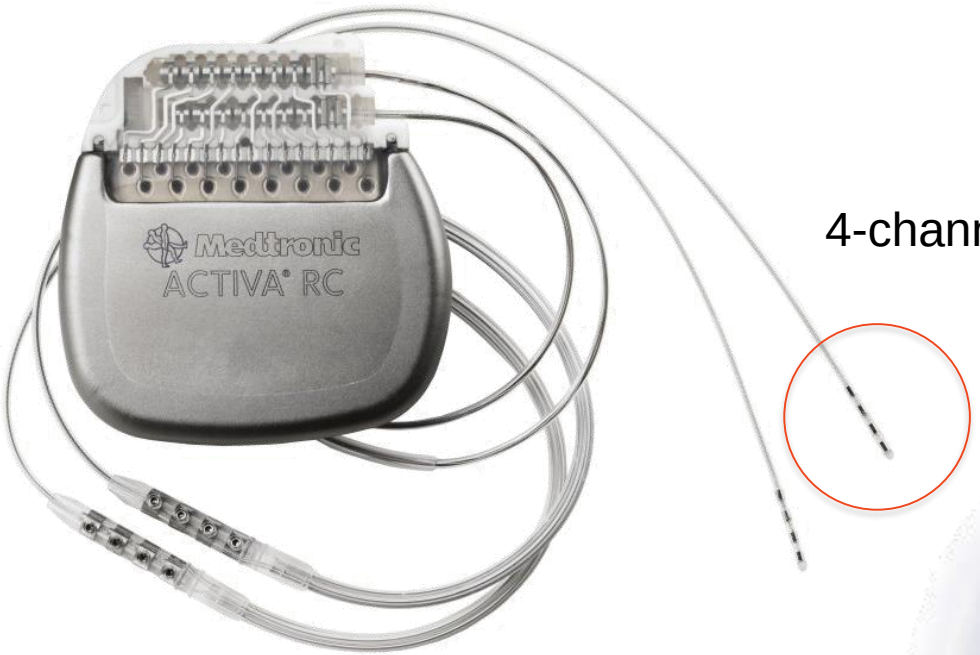
1990s
Spinal Pain

2000s
DBS

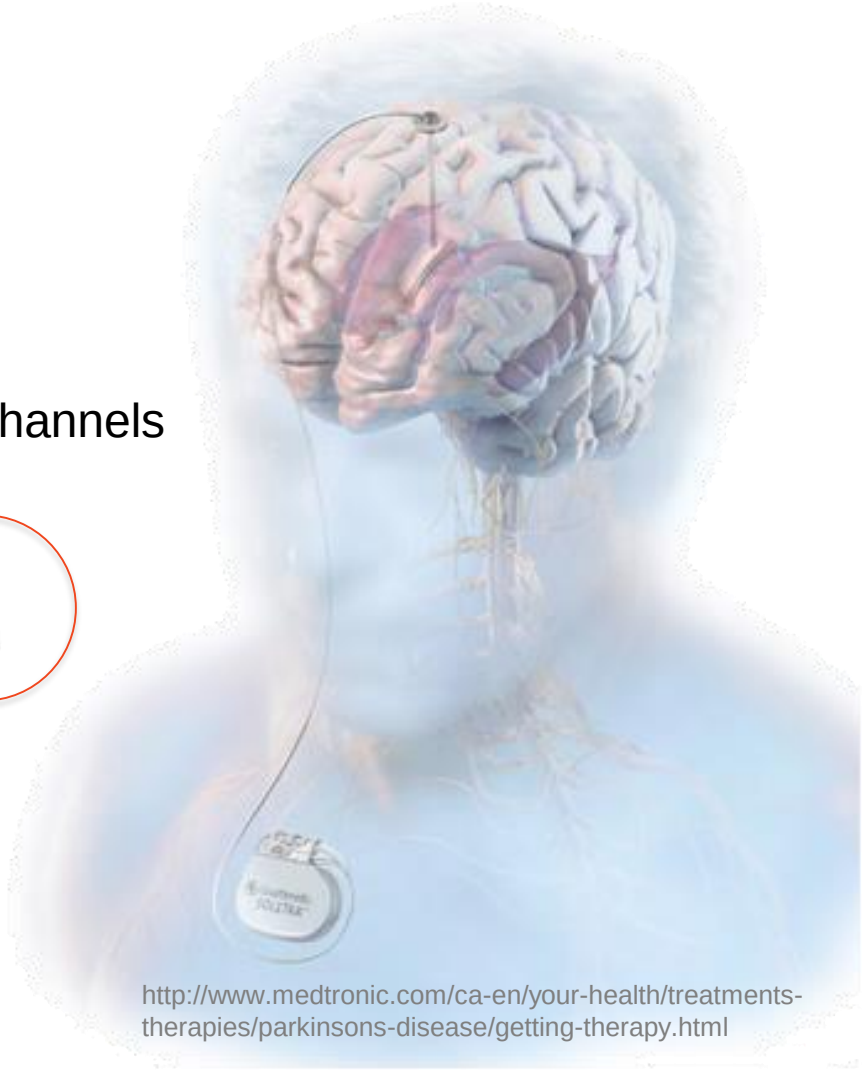
2010s
Epilepsy

Deep Brain Stimulation (DBS)

Implantable Pulse Generator (IPG)



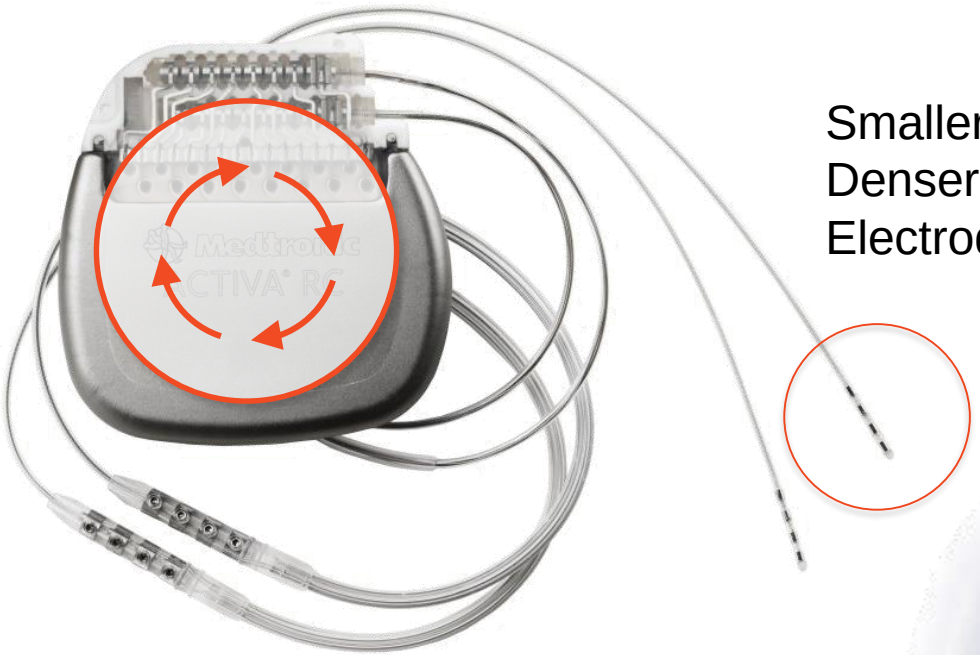
4-channels



http://www.medtronic.com/ca-en/your-health/treatments-therapies/parkinsons-disease/getting-therapy.html

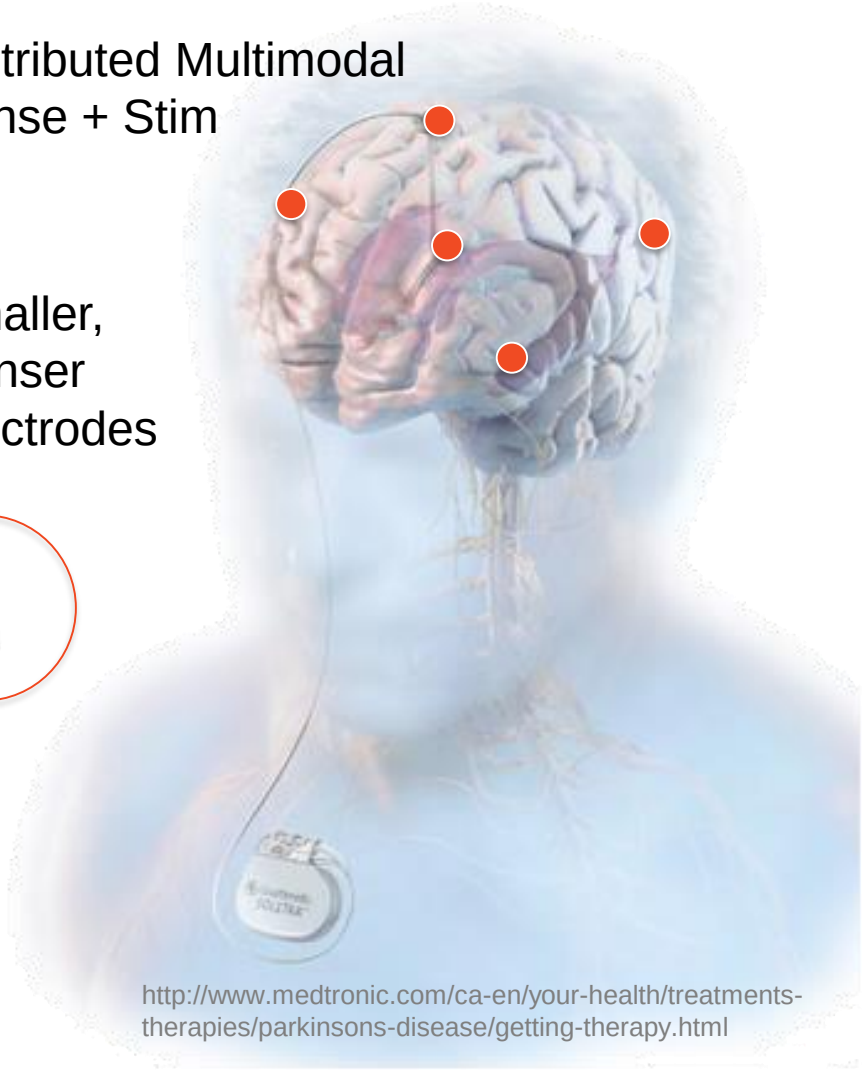
Personalized Responsive Therapies

Smarter, Responsive
Closed-loop Therapies



Distributed Multimodal
Sense + Stim

Smaller,
Denser
Electrodes



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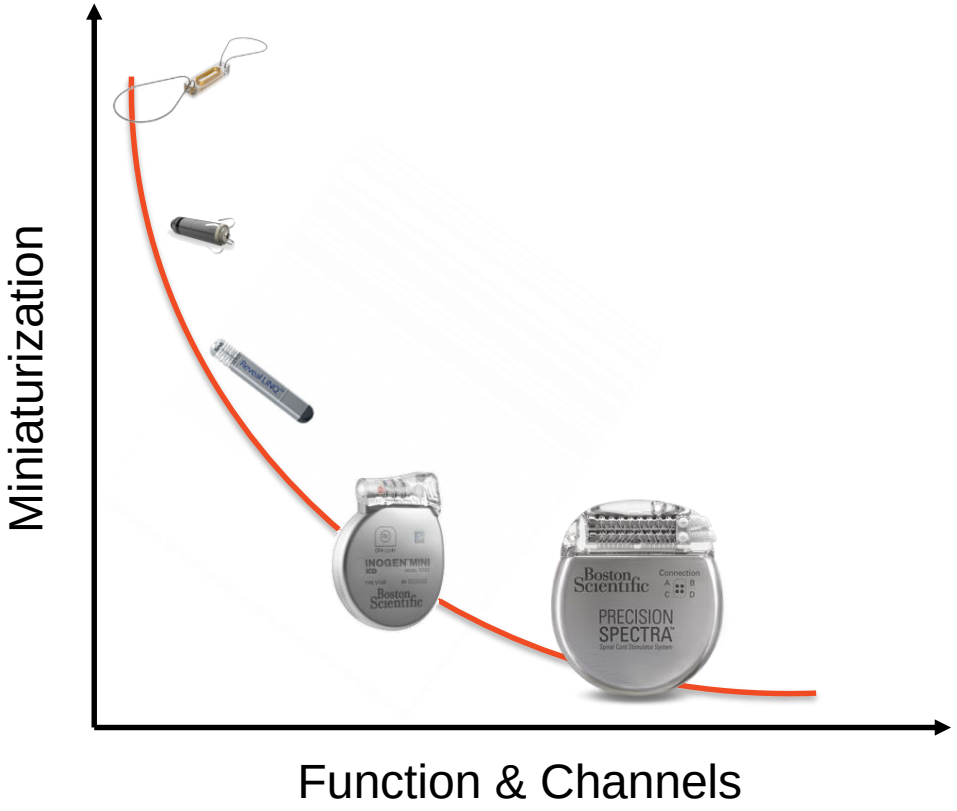
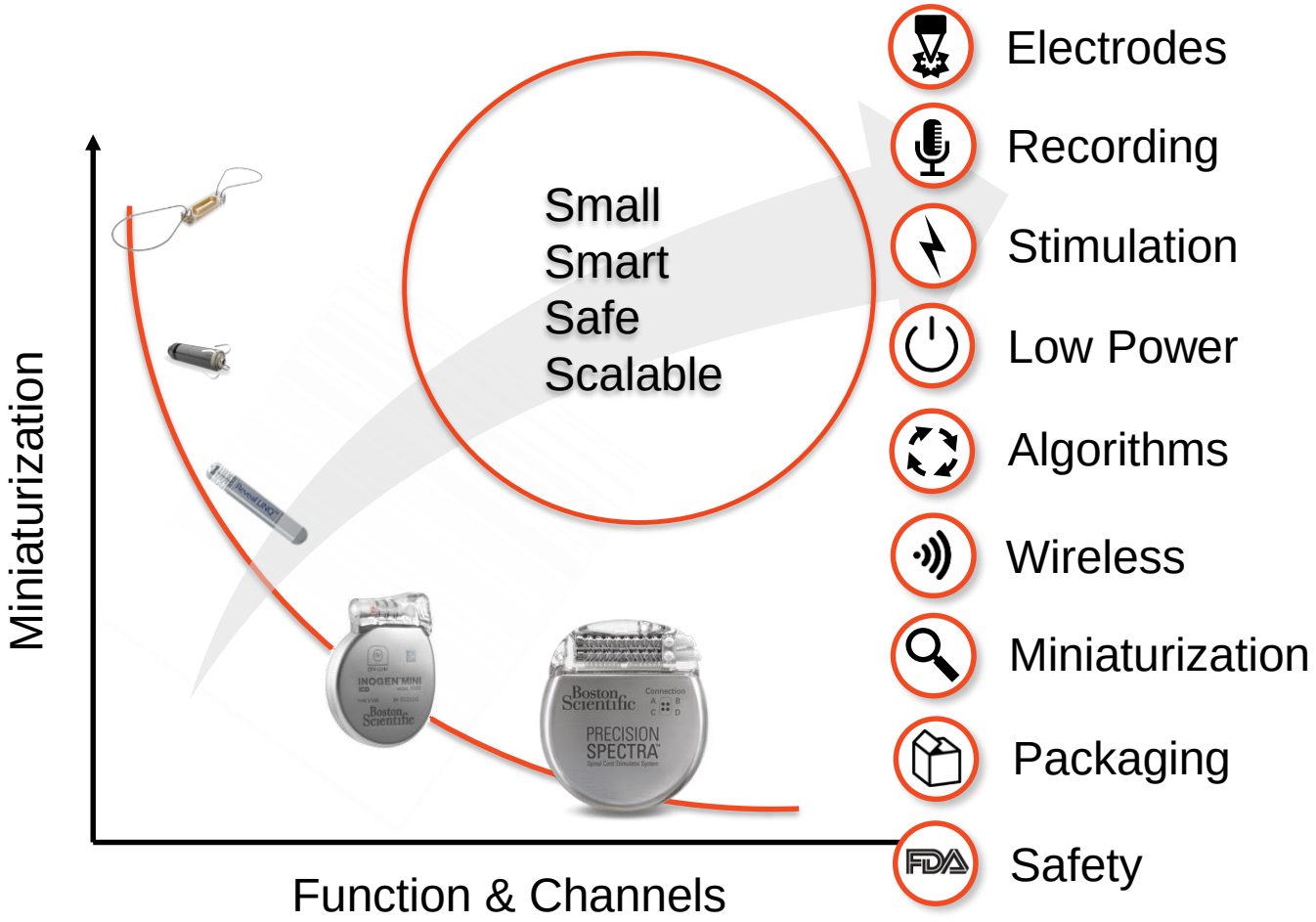
Limitations of Current Technology

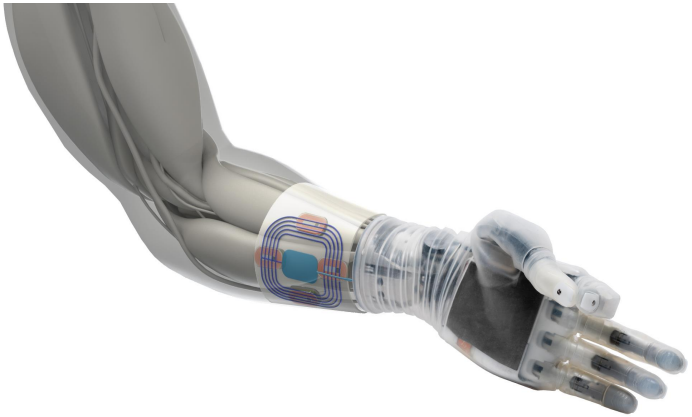


Miniaturization without Compromise

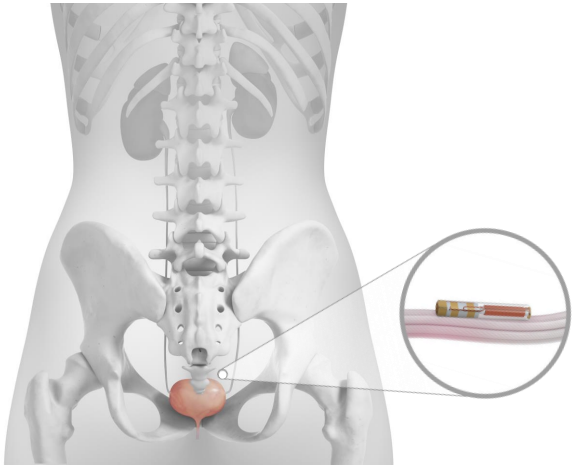


Neurotechnology Development at Draper

Deep Brain Stimulation (DBS)



Peripheral Nerve Stimulation



Stimulation Particle

TRANSFORM DBS

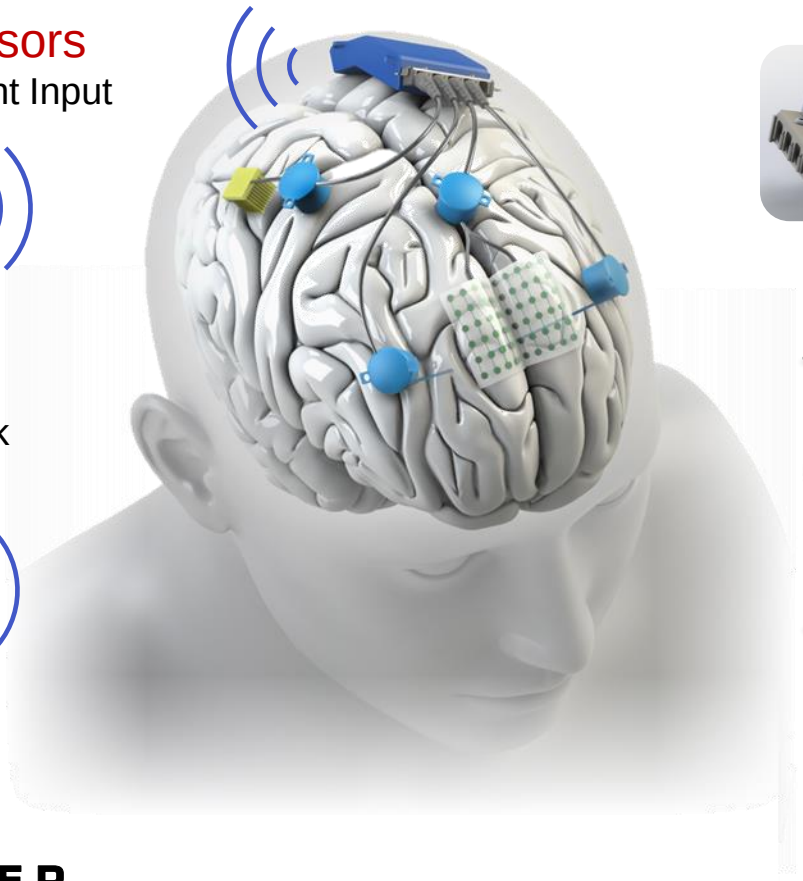
Distributed, multi-modal, closed-loop neuromodulation

Central Hub
Closed-loop Processing

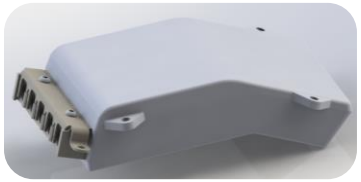
5 Satellites
Record + Stim

Wireless Sensors
Biometrics + Patient Input

Base Station
Streaming + PC Link



TRANSFORM DBS



- 320 channels
- Responsive stimulation
- Record Spikes + LFP
- Multi-modal data fusion
- Wireless data streaming
- ***PERSONALIZED TREATMENT***

Neuropace

- 8 channels
- Responsive stimulation
- Record LFP only

Medtronic PC+S

- 4 channels
- Constant stimulation
- Record LFP only
- Leads/cables transverse through neck

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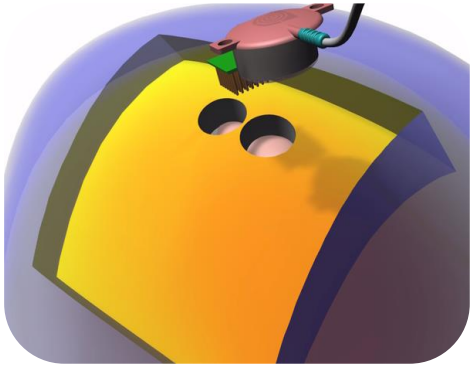
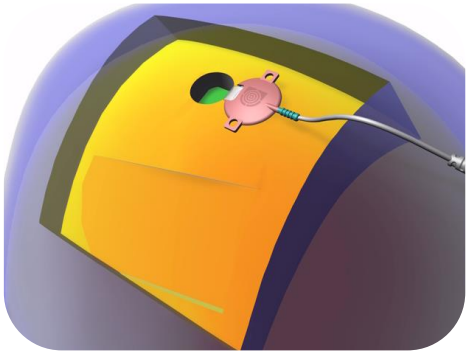
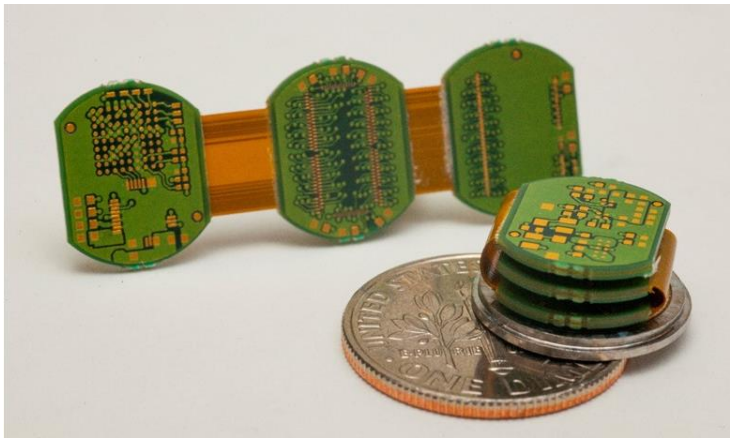
Satellite System

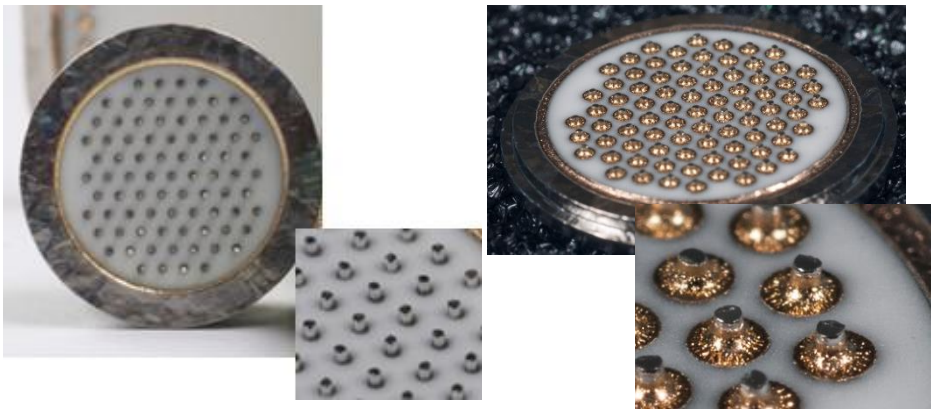




Miniaturized Hermetic Enclosure:

- Designed to fit within a within a 14mm diameter surgical burr hole
- Rigid-flex board – enables folding of electronics
- 81-pin high density ceramic feedthrough plate and titanium enclosure
- Each satellite can accommodate up to 64 channels (electrodes; COTS connectors); connects to hub cable





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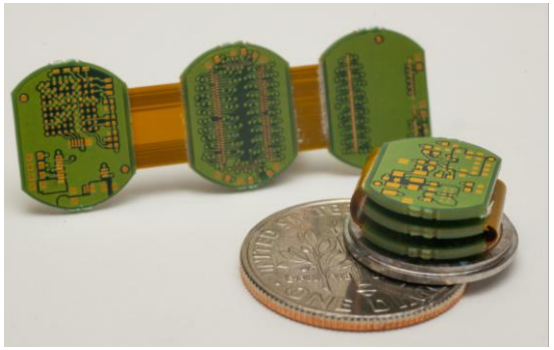
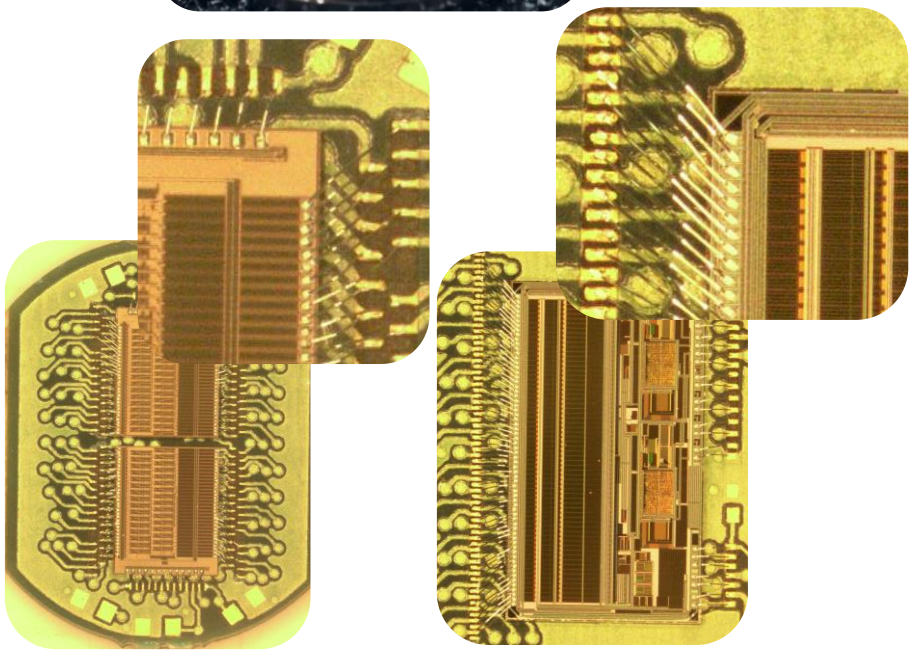
Satellite – Miniaturization



- Increasing functionality in a limited footprint required:
  - *Custom designed ASIC's*
  - *Combination of traditional rigid with flex → Rigid-flex design*
  - *Dual sided design for each*
  - *Low profile BGA-style attached*

- Challenges:
  - *Incorporating COTS components*
    - Amplifier (die)
    - FPGA (SMT)
    - Passives
  - *Size limitation prohibited blocking capacitors for all channels*
  - *Complex design*
    - Increase design time
    - Vendor sourcing (fab and assembly)



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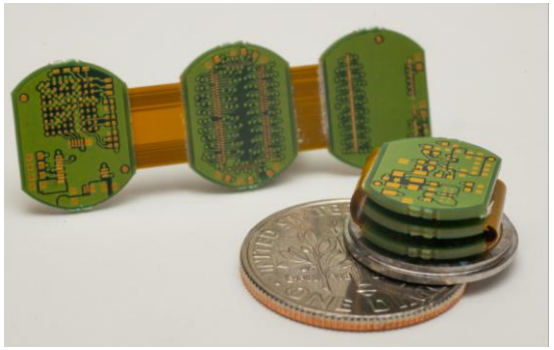

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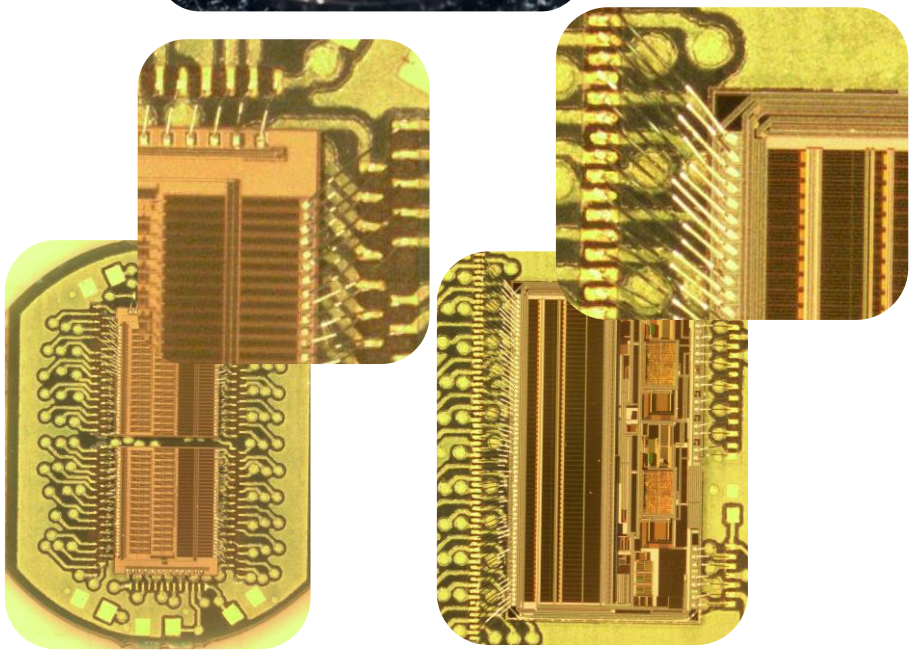
- Improvements in the future
  - *Reduction of COTS components where possible*
  - *Flip chip and/or die stacking approach (interposer)*
  - *Decrease pin (d) and/or increase pin pitch*
  - *Goal to simply PCB design*
    - Reduce number of pedestals
    - Increase feasibility of manufacturing and assembly
    - Decrease fabrication time
    - Increase feasibility of testing



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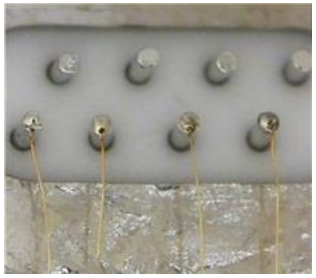
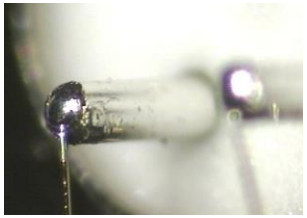
Satellite – Connecting to the Outside

- Development process for each wire type
  - *Various wire diameter (pin d = 10mil)*
  - *Dissimilar materials (pin = 90/10 Pt/Ir)*
- To strip or not too strip?
  - *Bond strength and robust*
  - *Method, potential damage, time*

External Side (electrodes/hub cable)



Hub cable (5mil Pt/Ir wire)



ECOG, DBS Electrodes (1mil Pt/Ir wire)

Microelectrode array (1mil Au wire)

Wire bundles to COTS connectors (2mil Pt/Ir wire)

Feedthrough Interconnection Challenges

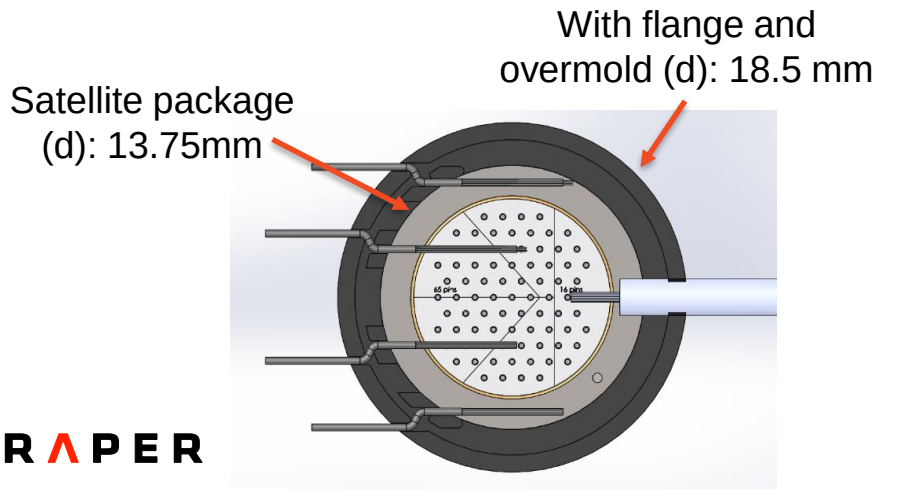
Challenge #1 – Laser welding of EACH INDIVIDUAL wire to pin

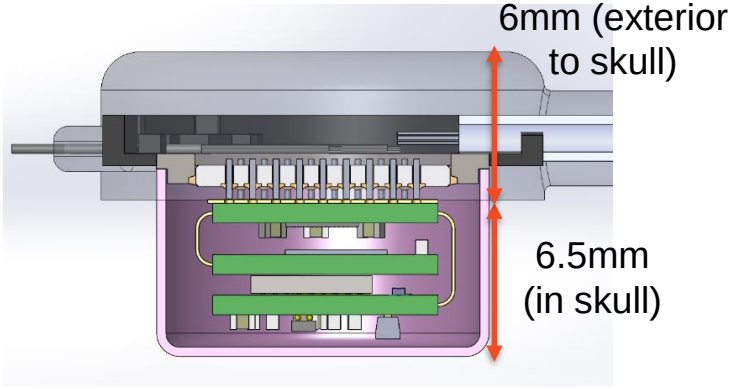
- Labor intensive; process development often required
- As number of channels per electrodes increase, proper handling and tracking of each electrode wire to pin becomes more of a challenge.

Feedthrough Interconnection Challenges

Challenge #2 – Splitting and re-bundling 64 channel electrode was required

- Resulted in an increase to satellite size
  - *Too large for implanting high channel electrodes into animals for clinical research*
- Ultimately need scales with wire counts.
  - *As channel count increase, so does this problem*

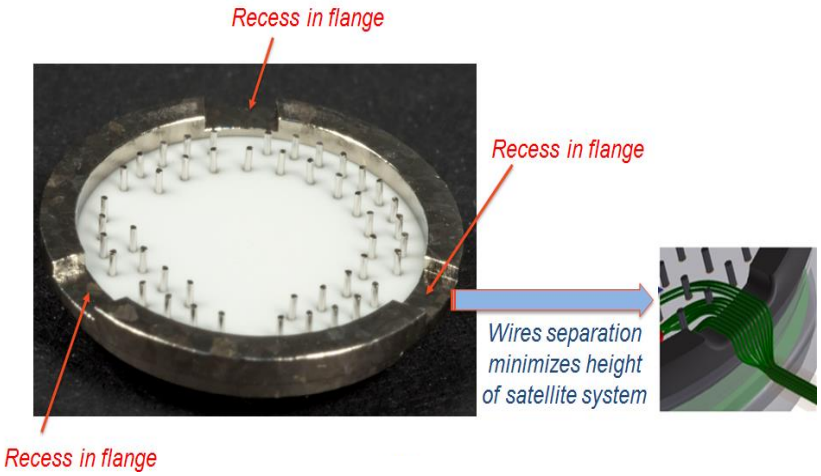




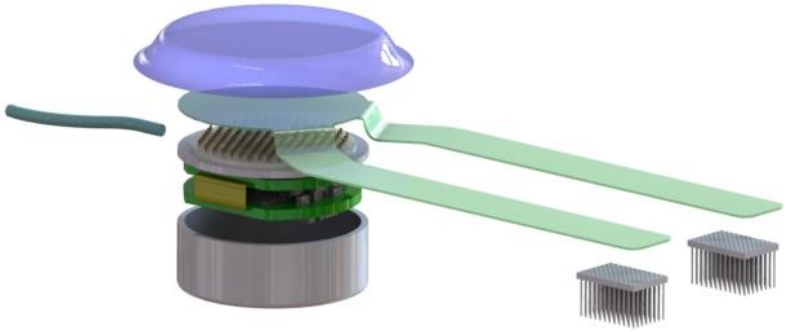
Feedthrough Interconnection Solutions

Potential Solutions:

- Recesses in feedthrough flange
  - *Enables wires splay when exiting*
  - *Provides specific entry points for each cable/bundle*



- Design a flex interconnect cable
  - *Interface between feedthrough and electrodes*
  - *Integrate electrode contacts (i.e. flex electrode) or interconnects to components/system*



Central Hub System - Modular

- Three discrete subsystems:
  - *Electronics system – PCB's, antenna*
  - *Rechargeable battery*
  - *High density custom connector*

- Flex cable integrate electronics and battery to connector

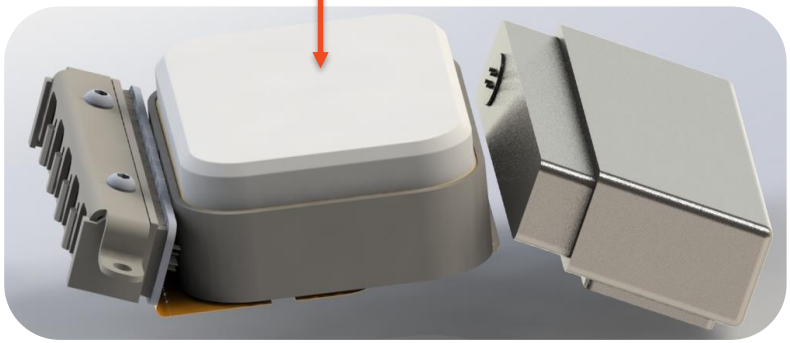
- System's curvature can be set by encapsulation tool

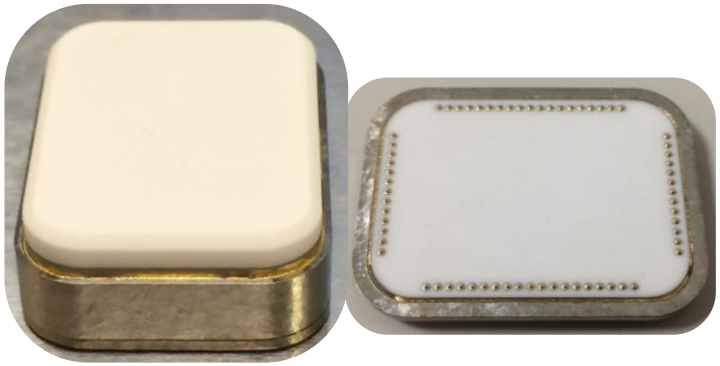
- Advantages of modular approach
  - *Custom design curvature to meet specific patient's requirements*
  - *Discrete battery enables introduction of new battery without the need for redesigning the entire package/housing*
  - *Each subsystem can be tested and validated individually → reducing the risk of losing the entire system*

Central Hub System

- Electronics system– PCBs, antenna with ferrite
  - *64-pin ceramic feedthrough plate with titanium flange*
  - *Alumina cover (RF transparent) with a titanium flange (hermetic seal)*

Hub Electronics Subsystem



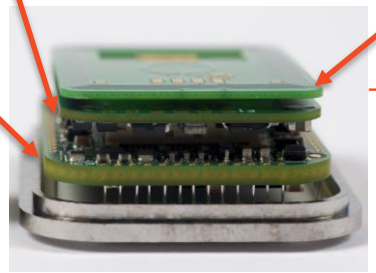


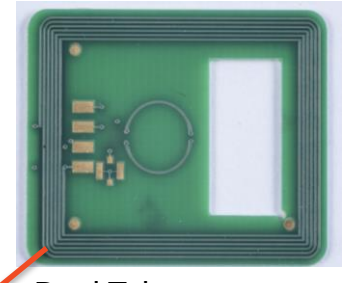
Low-Power Processor & Stimulator ASICs:

- *Neural signal processing and stimulation control*

AC Power Management:

- *Power conversion and distribution to satellites*





Dual Telemetry:

- *Long-range controller link for reprogramming & high-bandwidth link for neural data to an external base station*

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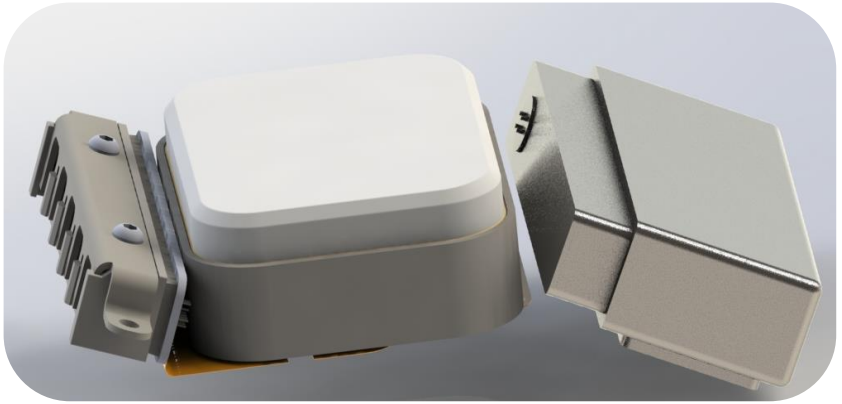
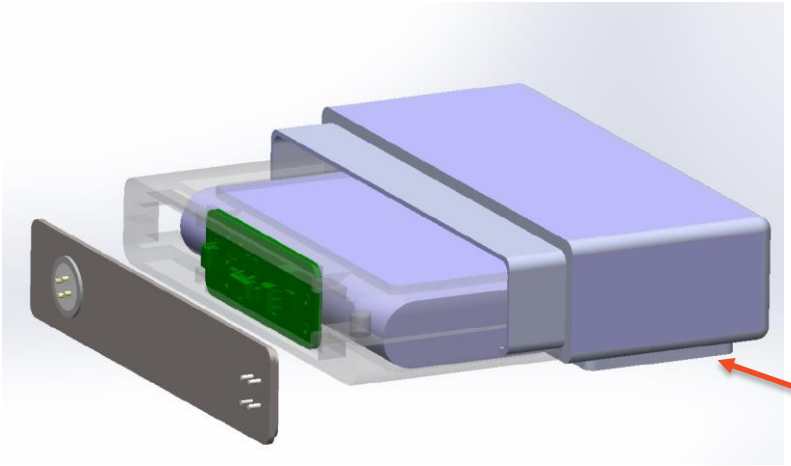
Central Hub System

- Electronics system– PCBs, antenna with ferrite
- Rechargeable battery
  - *Medical, implantable grade cell*
  - *Protection PCB*
  - *Hermetically sealed (Ti to Ti)*
  - *Titanium housing also serves as system's ground*

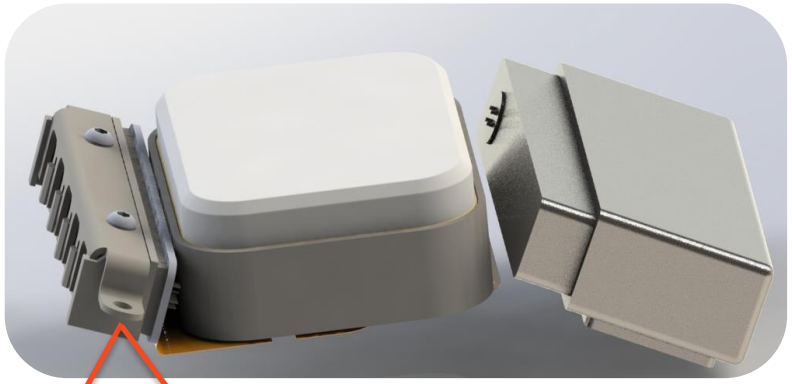




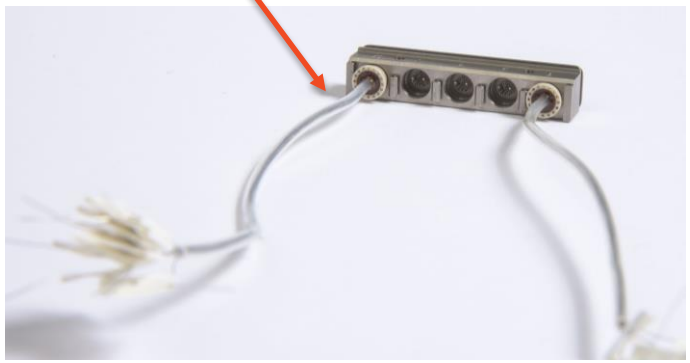
Ground contact for Hub system

Central Hub System

- Electronics system– PCBs, antenna with ferrite
- Rechargeable battery - Housing also serves as system's ground
- High density custom connector system
  - *~ 5x volume reduction compare to traditional connector systems*
  - *Housing contains 5 x 10 contacts sockets (50 contacts total)*
  - *Locking clip secures each plug/cable to housing*
  - *Each cable is hardwired to a satellite*



High density custom connector system



Central Hub System

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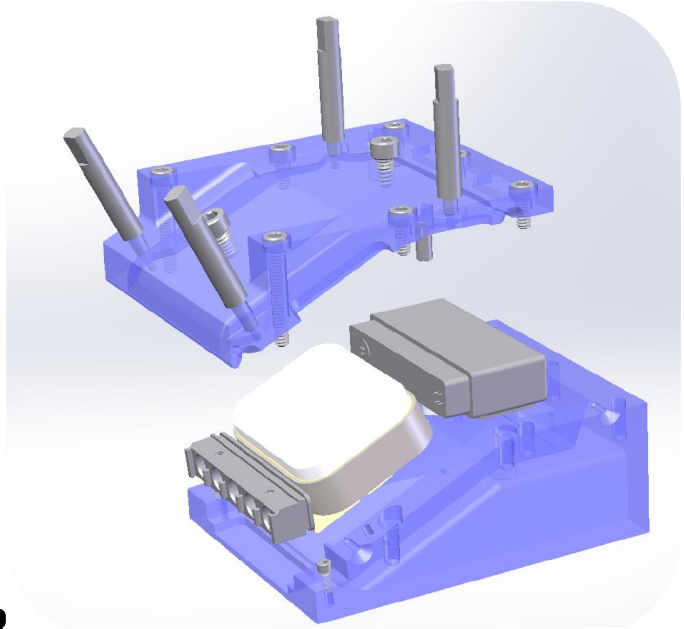
- Rechargeable battery - Housing also serves as system's ground
- High density custom connector system
- Flex cable integrate electronics to connector pins
- System's curvature can be set by encapsulation tool

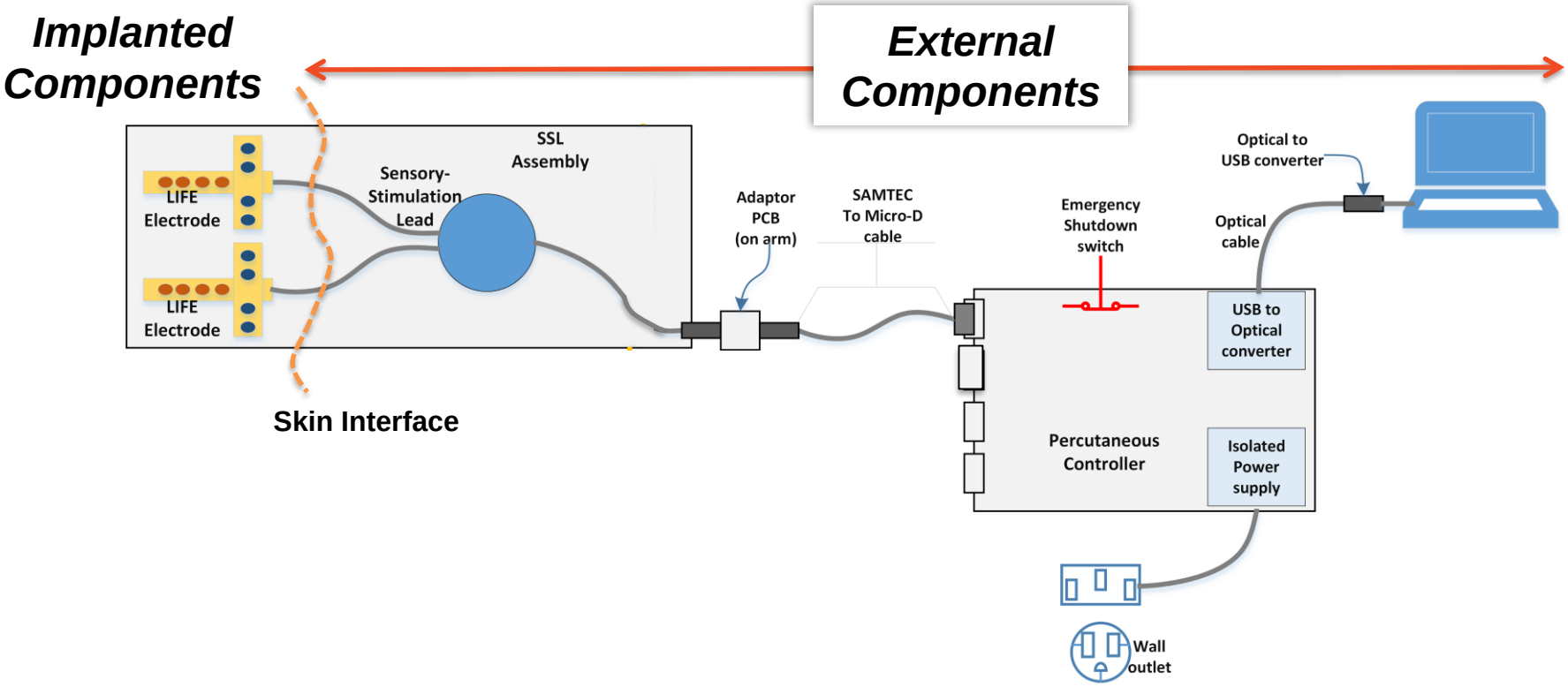


Peripheral Nerve Stimulation - HAPTIX

- More than 185,000 amputations are performed annually in the US.
- Lack of realistic sensations of touch hampers effective use of prosthetic limbs.

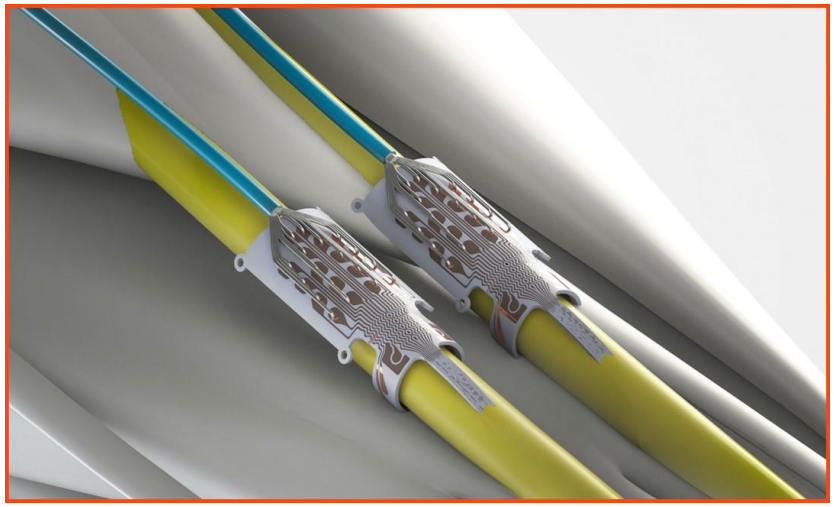
- Program's Objective - Create a prosthetic hand system that could move and provide sensory feedback like a natural hand would do
  - Requires development of next generation neuro-technologies to provide sensory stimulation (touch and proprioception) for enhanced prosthetics.

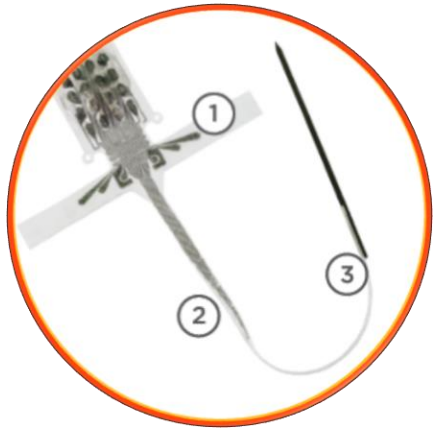
HAPTIX Passive System Overview

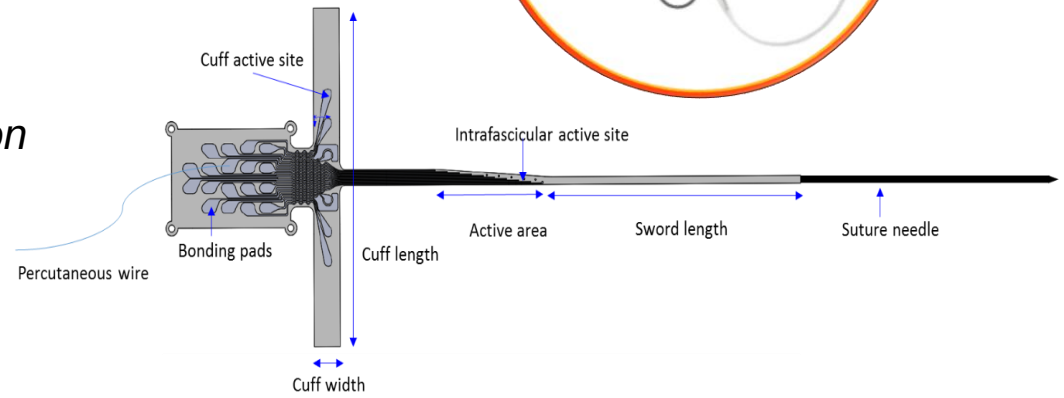


L.I.F.E. Electrodes – Validated as a Passive System

- Longitudinal Intra-Fascicular electrodes (LIFE) → fine featured electrodes designed to be implanted within the body of the peripheral nerve.
- Allows interrogation and stimulation of both sensory and motor nerve fascicles with the same device.
  - *6 cuff electrodes (1) for macro recording, stimulation, and a secure anchoring point around the nerve*
  - *9 intra-neural electrodes (2) for micro recording and stimulation for more precise motor control and sensory perception*
  - *A needle at the tip (3) allows for easy implantation and simplifies implantation within individual motor and sensory fascicles for safer and more reliable access to targeted neurons*







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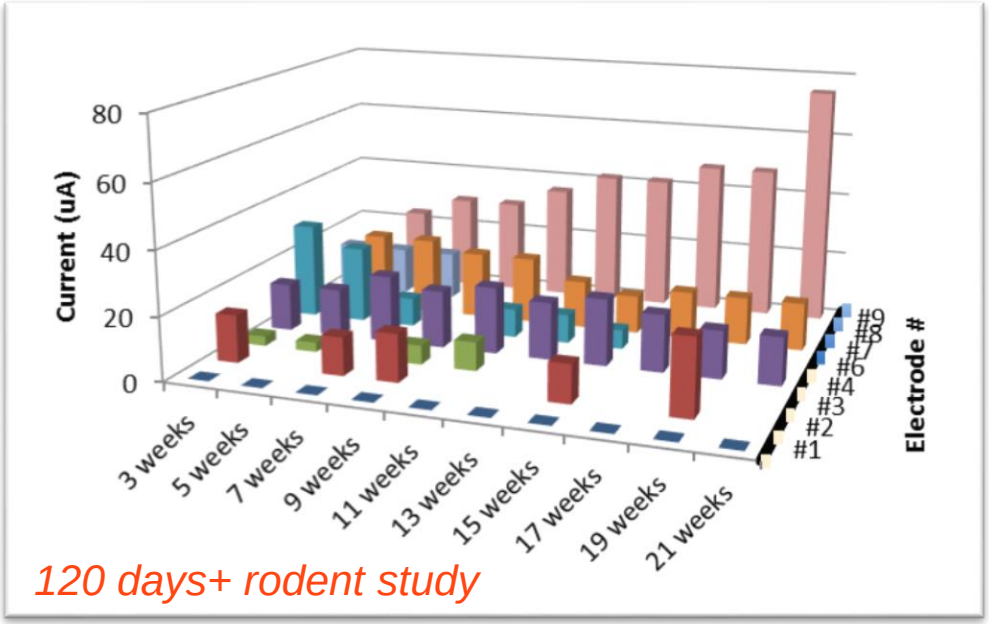
Electrodes Percutaneous Leads

- Use for connecting each electrode to the external system
- Arranged as bundles of four wires (quads).
- Each quad consist of a section of helical coil - allows for the movement of the cable without breakage.
  - *Also aids in forming closure around the tunnel opening where the bundles exit the skin to plug into the connector.*
- Bundles and individual wires are color coded with biocompatible heat shrink tubing for signal identification.
- The bundles separate out into individual wires once outside the skin.
  - *Proximal and Crimp Pins inserted into a connector block for interfacing with external controller.*

Passive Leads – Animal and Cadaver Implants

- Verification of the nerve interface:
  - *Histology of tissue response and stimulation threshold stability*
  - *Stimulated on different electrode sites*
  - *120 days+ of rodent studies*
  - *Acute NHP studies*
- Cadaveric assessment of electrodes placement for surgical optimal position for human clinical studies

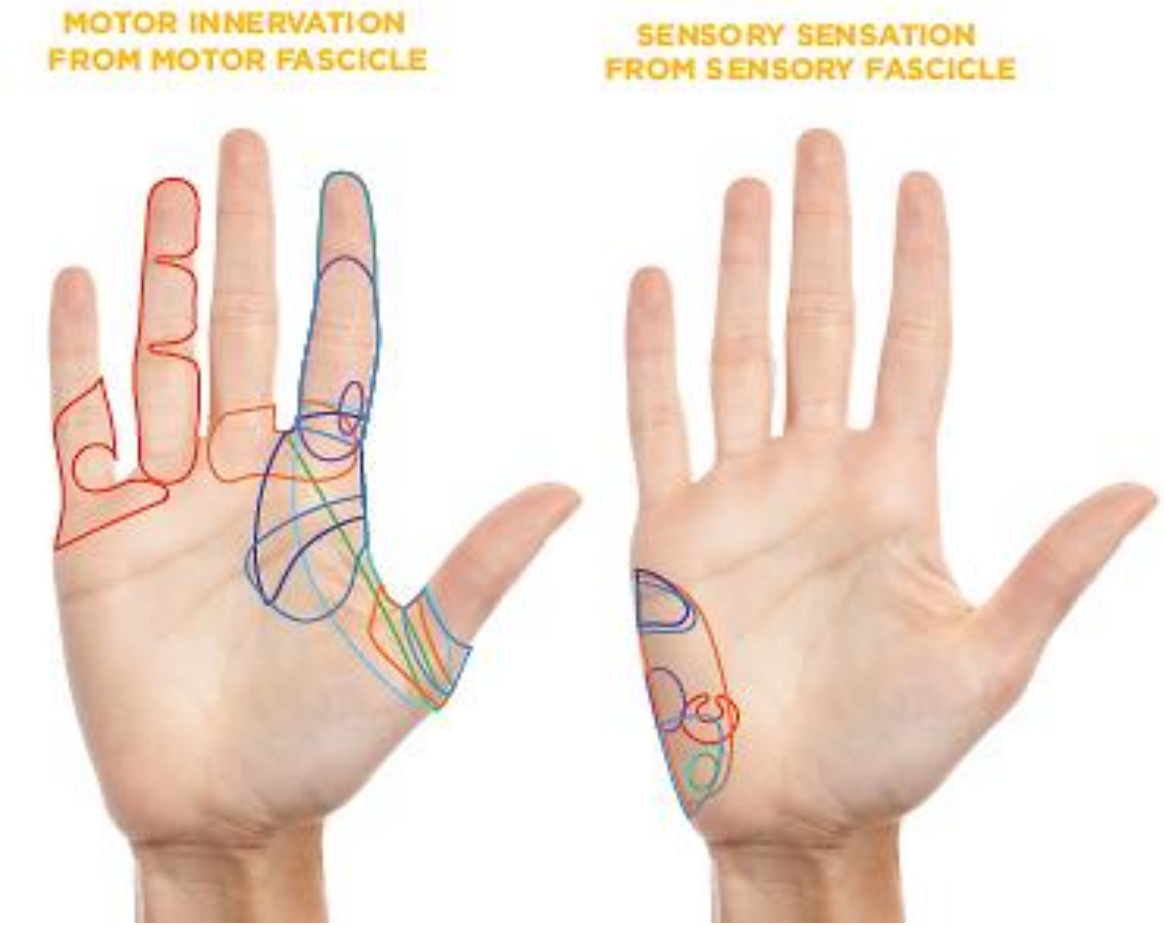


120 days+ rodent study

Passive Leads – Clinical Outcome

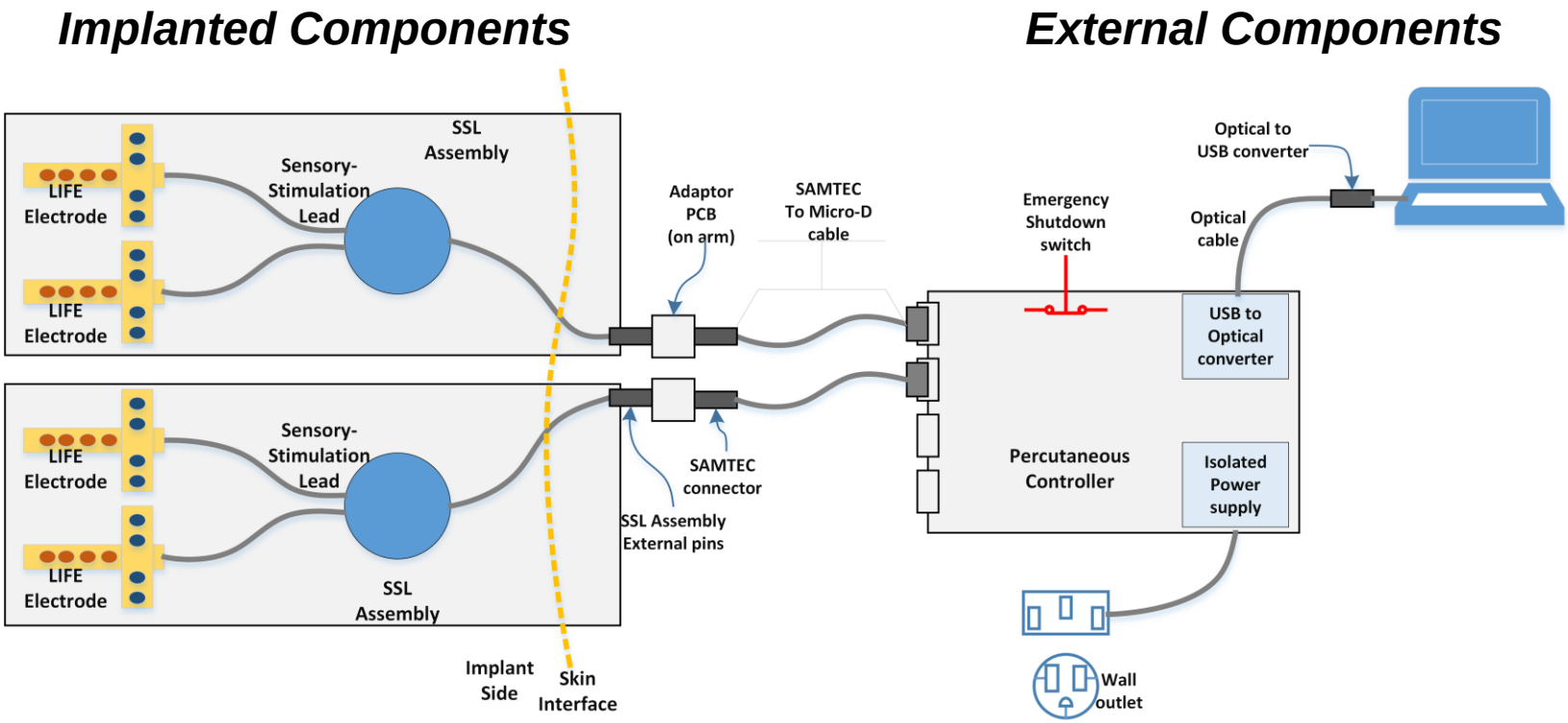
Passive Implants

90-day implants in 2 human patients



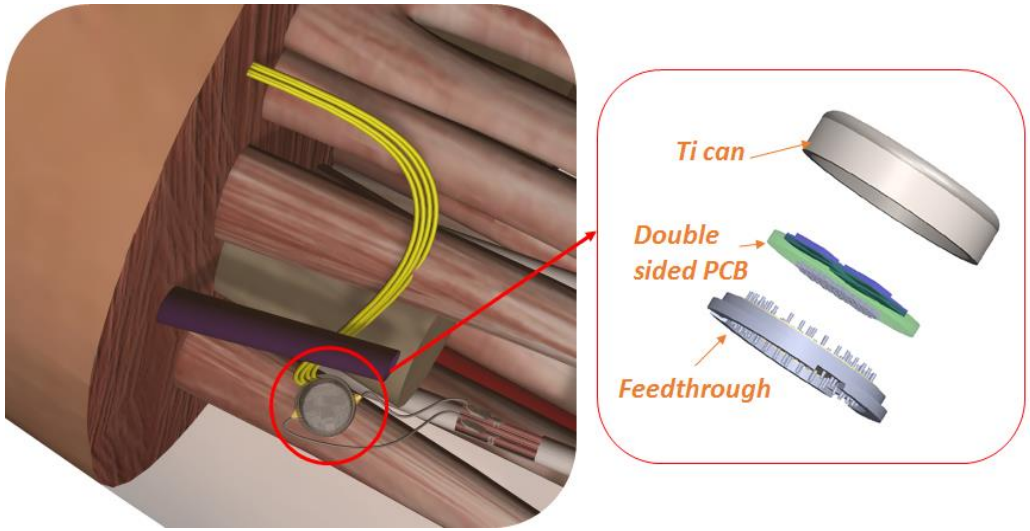
HAPTIX Active System Overview

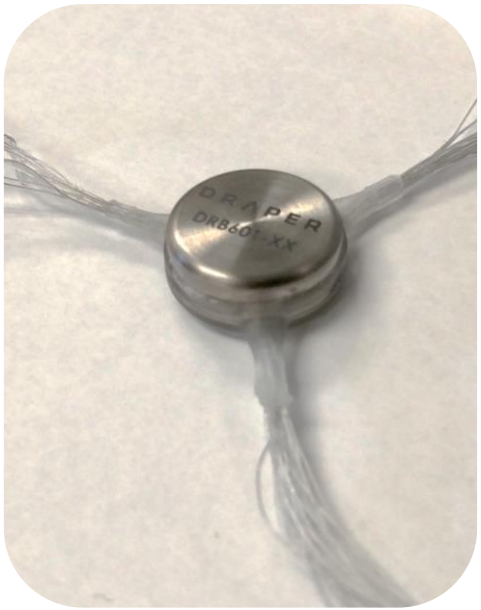
L.I.F.E. Electrodes Combined with Implant Device for Recording and Stimulation



SSL Satellite - Overview

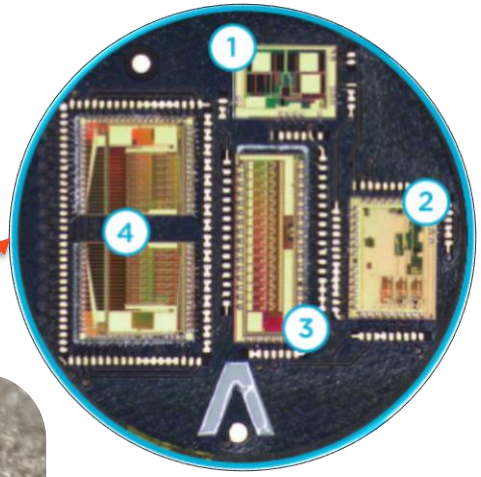
- Active electronics → interfaces with the electrodes and controller system (via percutaneous leads).
- Consists of:
  - *Ceramic feedthrough substrate*
  - *Titanium can*
  - *Double sided PCB*
- Electrodes hardwired to the satellite (feedthrough)
  - *LIFE*
  - *EMG's*
- Satellite device size:
  - *~ 14mm (diameter), < 5mm (height)*

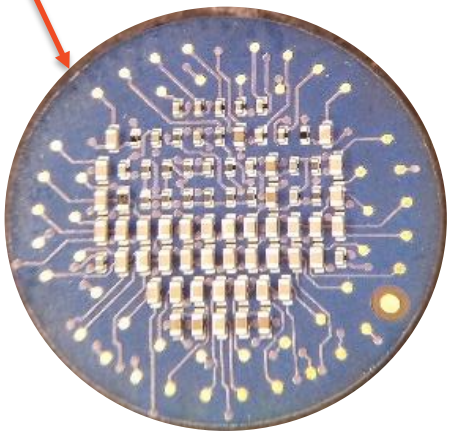




Active Electronics – Draper Designed ASIC's

Height < 5mm





Callout #	Draper ASIC
1	High Voltage Charge Pump
2	AC-to-DC Power Conversion
3	Neural Amplifier
4	Cross-point Switch

Function	Description
Recording	• 30 recording channels • Multiplexed up to 30 kHz • 1.5 µV RMS noise (700 Hz – 5 kHz) • 36 dB gain
Stimulation	• 30 stimulation channels • 2 simultaneous stimulation pulses • Multiplexing capable on all channels • Pulse resolution of 1 µA and 1 µs
Bottom side	• Double capacitors for protection (0201, 01005) • Contact pads for feedthrough attachment (testing prior)

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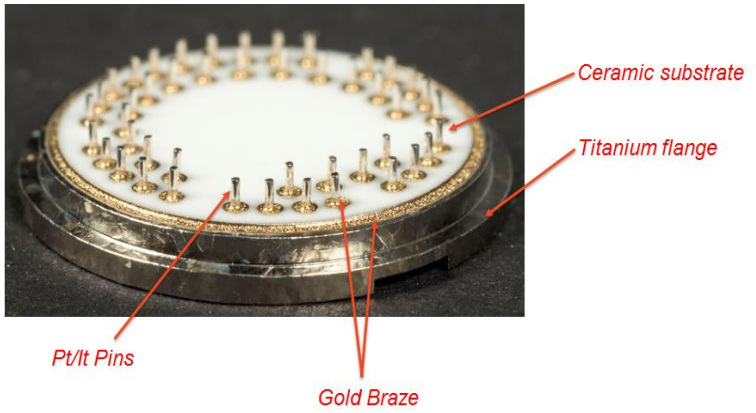
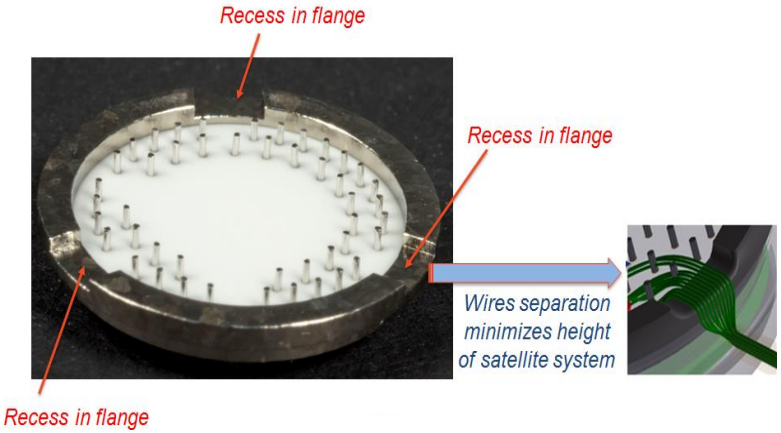
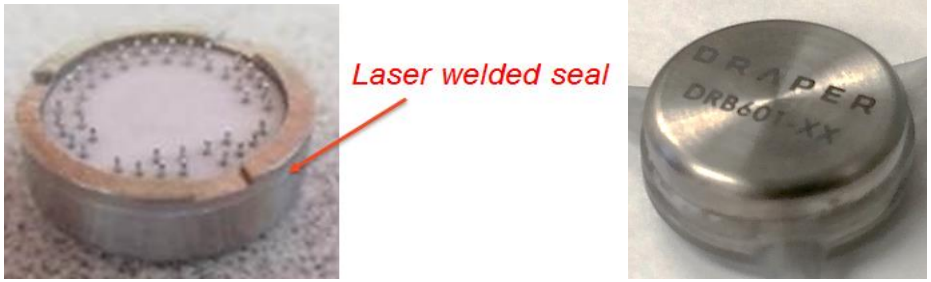
SSL Satellite Enclosure

- Alumina feedthrough substrate
  - *Pt/Ir pins*
  - *Arrayed in sections for each electrodes and bundles of percutaneous leads*
  - *Alumina substrate brazed to Ti flange*
  - *SMT component size on the pin side of the board drives internal pin height*
  - *Recesses in flange provides entry points for each electrodes and percutaneous leads*
    - Enables wires to spread out, thus reducing excess height from the bundling of wires
- Titanium cover
  - *Laser welded to feedthrough flange (hermetic)*
  - *Laser marking on surface for system serialization and traceability*







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Leads Attachment to SSL Satellite

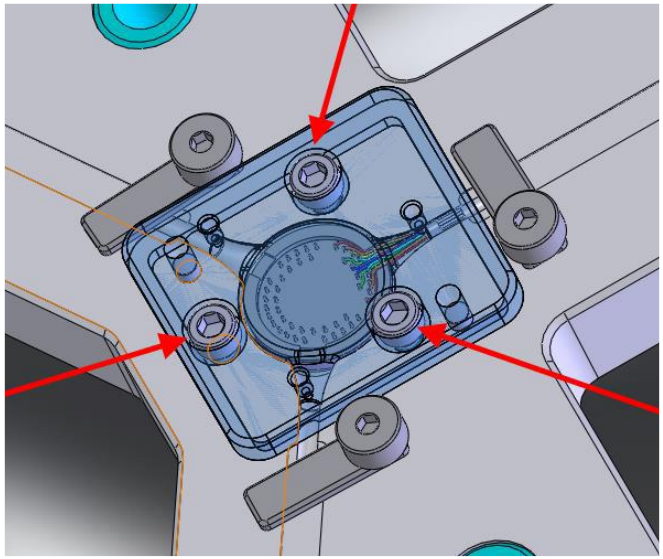
- Dissimilarity in materials (stainless steel wires and Pt/Ir pins) → Pt sleeves were used in early feasibility studies.
  - *Provides additional thermal mass*
  - *Provides additional support at the weld joint.*
- Additional refinement in welding parameters
  - *Weld joints and pull strength of wires same, if not more, than with sleeve (≥ 1 lb force)*
- Advantage of not using the sleeves:
  - *Ability to observe wire contact during welded*
  - *Ability for rework if needed*

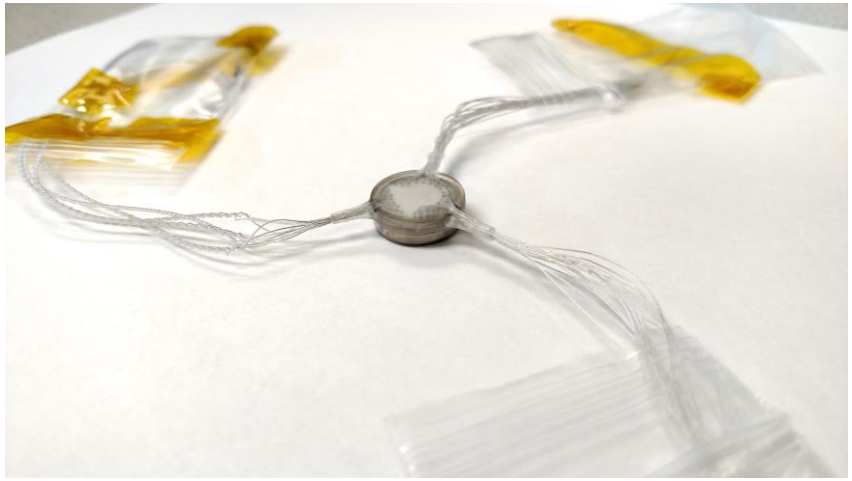
Welded with Pt sleeves

Welded without Pt sleeves

SSL Overmolding

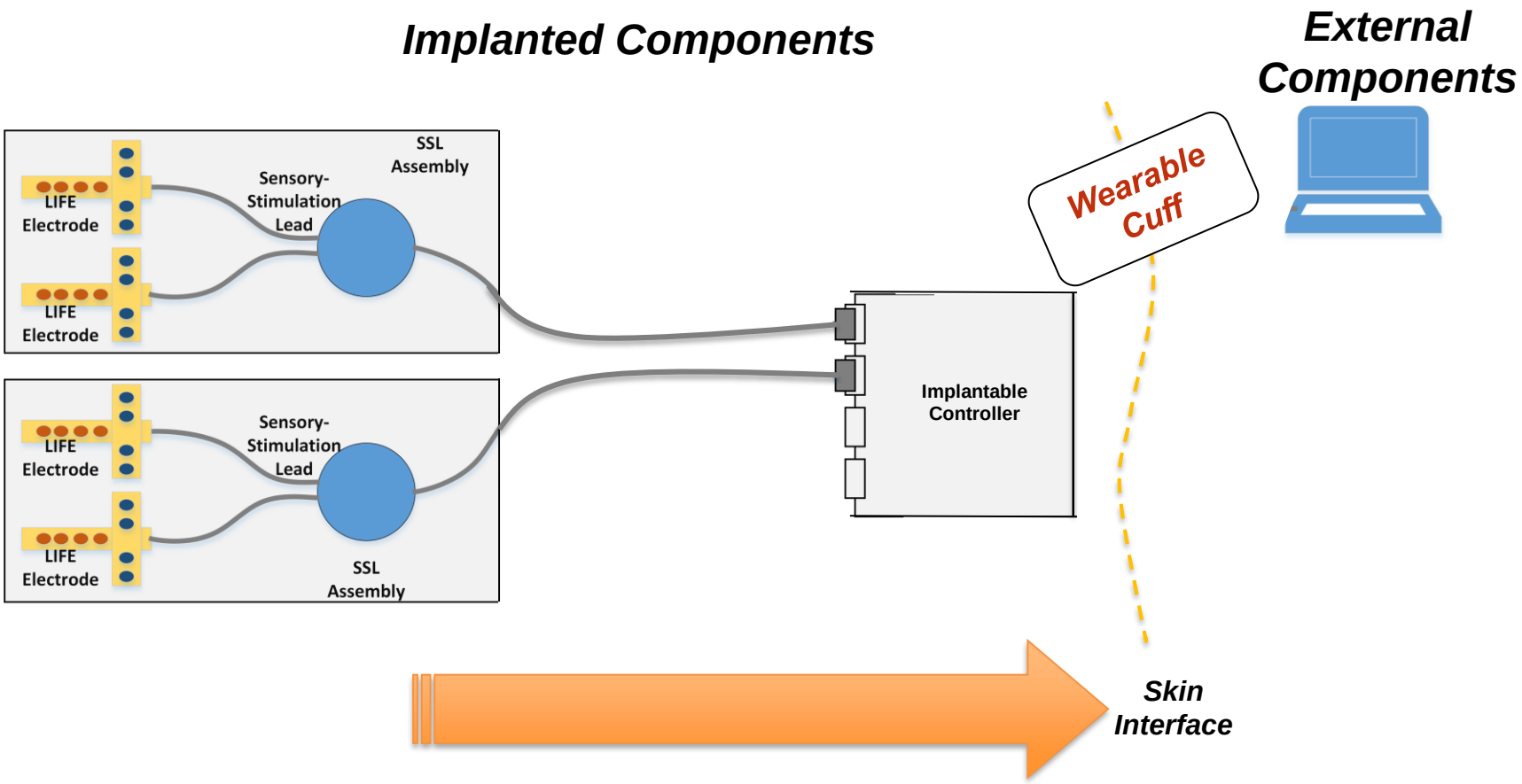
- Custom designed encapsulation tool for overmolding the satellite
  - *Dual layer process: epoxy followed by silicone.*
  - *“Boot” design for cable strain relief*



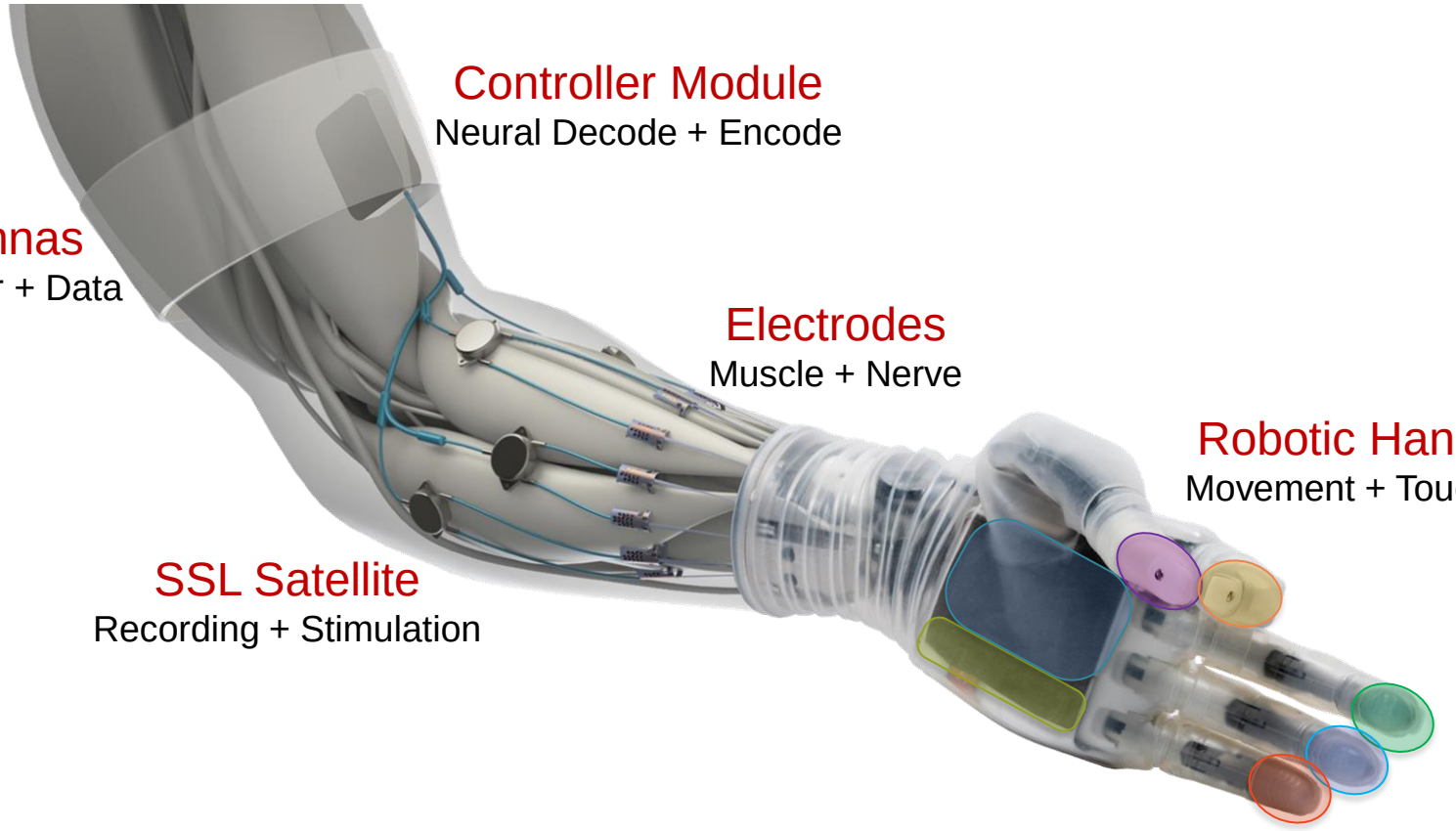


Backer card for shipping

Networked Active Leads System Overview

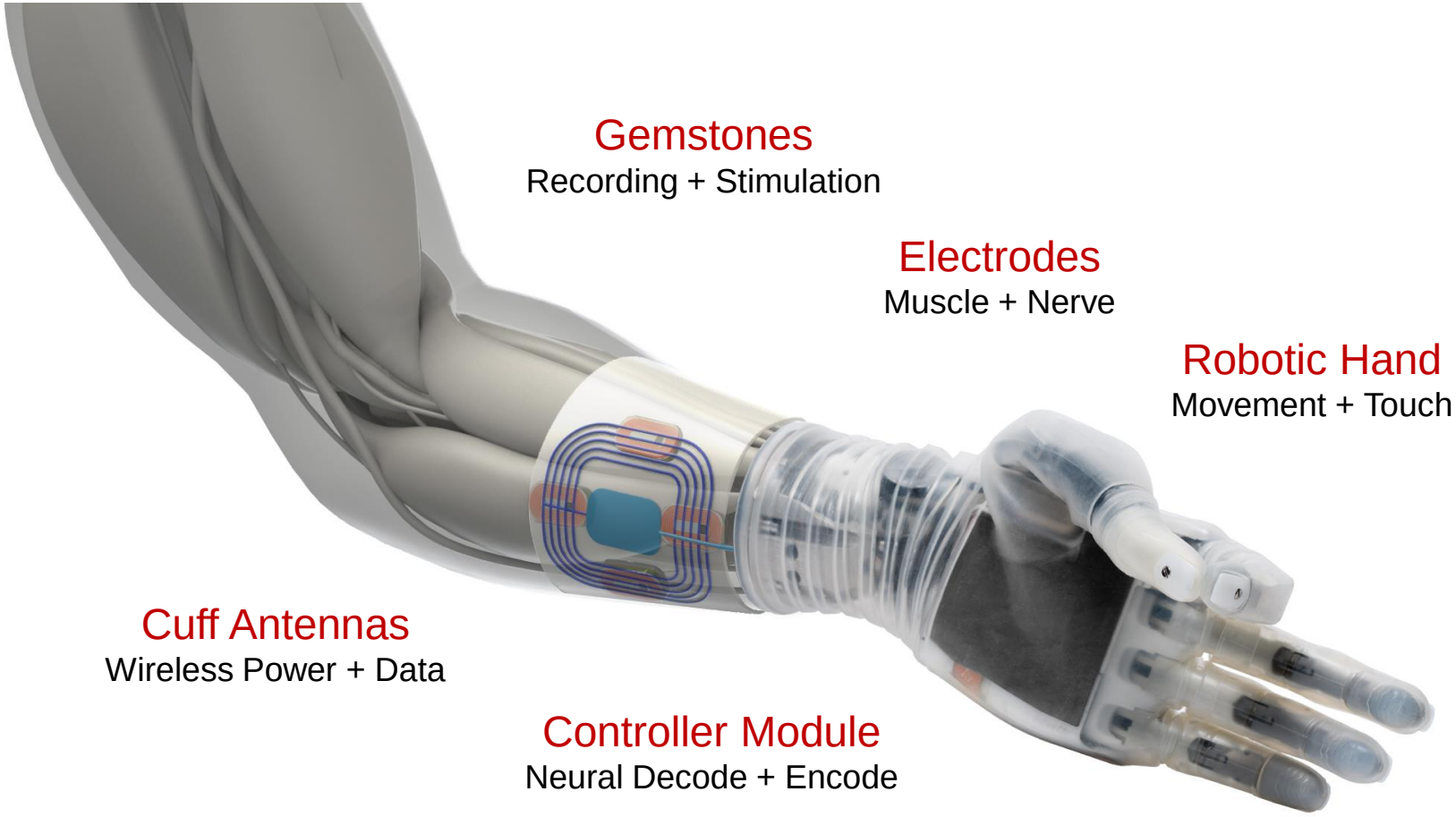


Networked Active Leads System



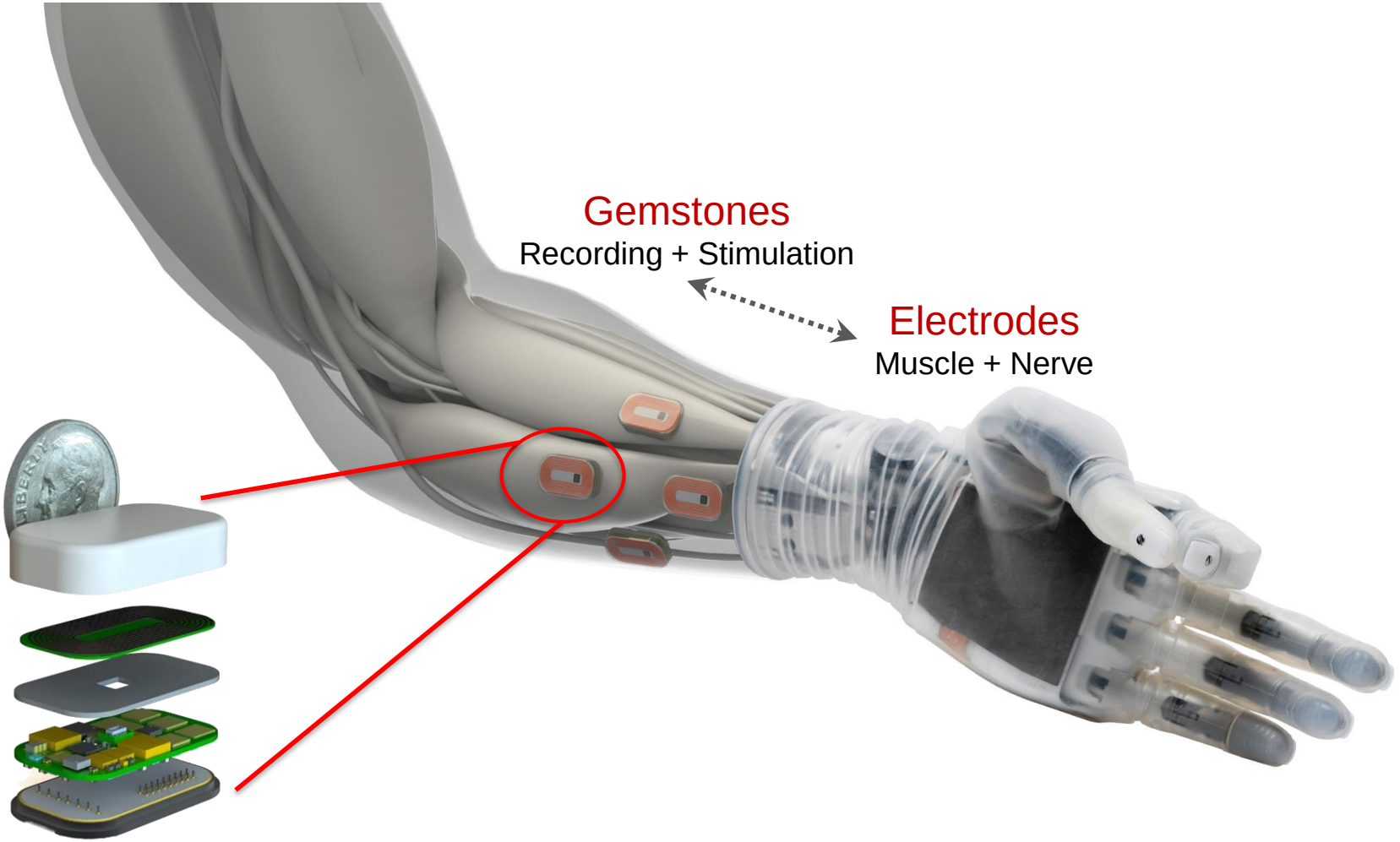
Leadless System

Leadless implants improve scalability and flexibility



Leadless Gemstone Device

Implanted Gemstone Device Connected to Electrodes



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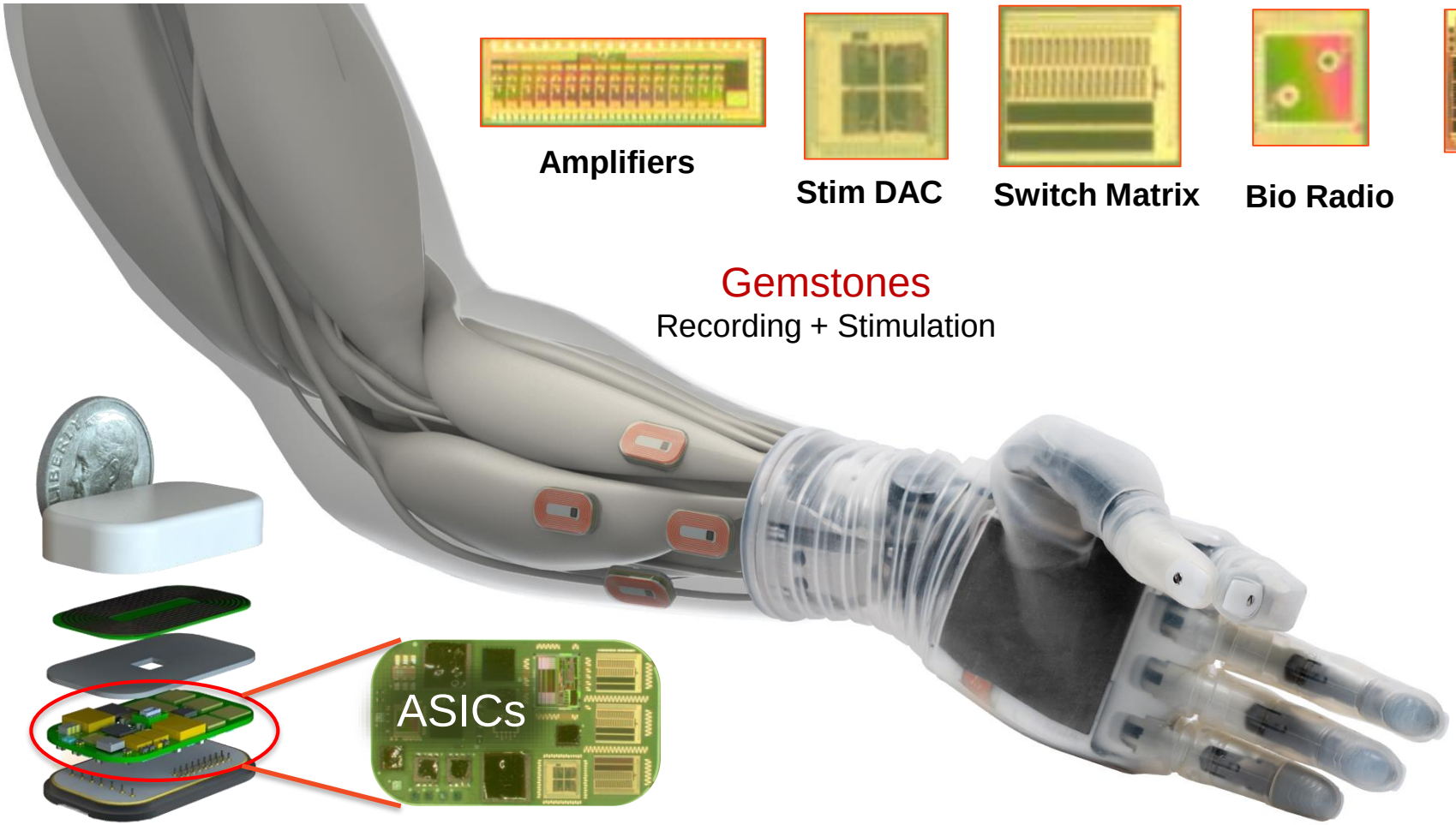
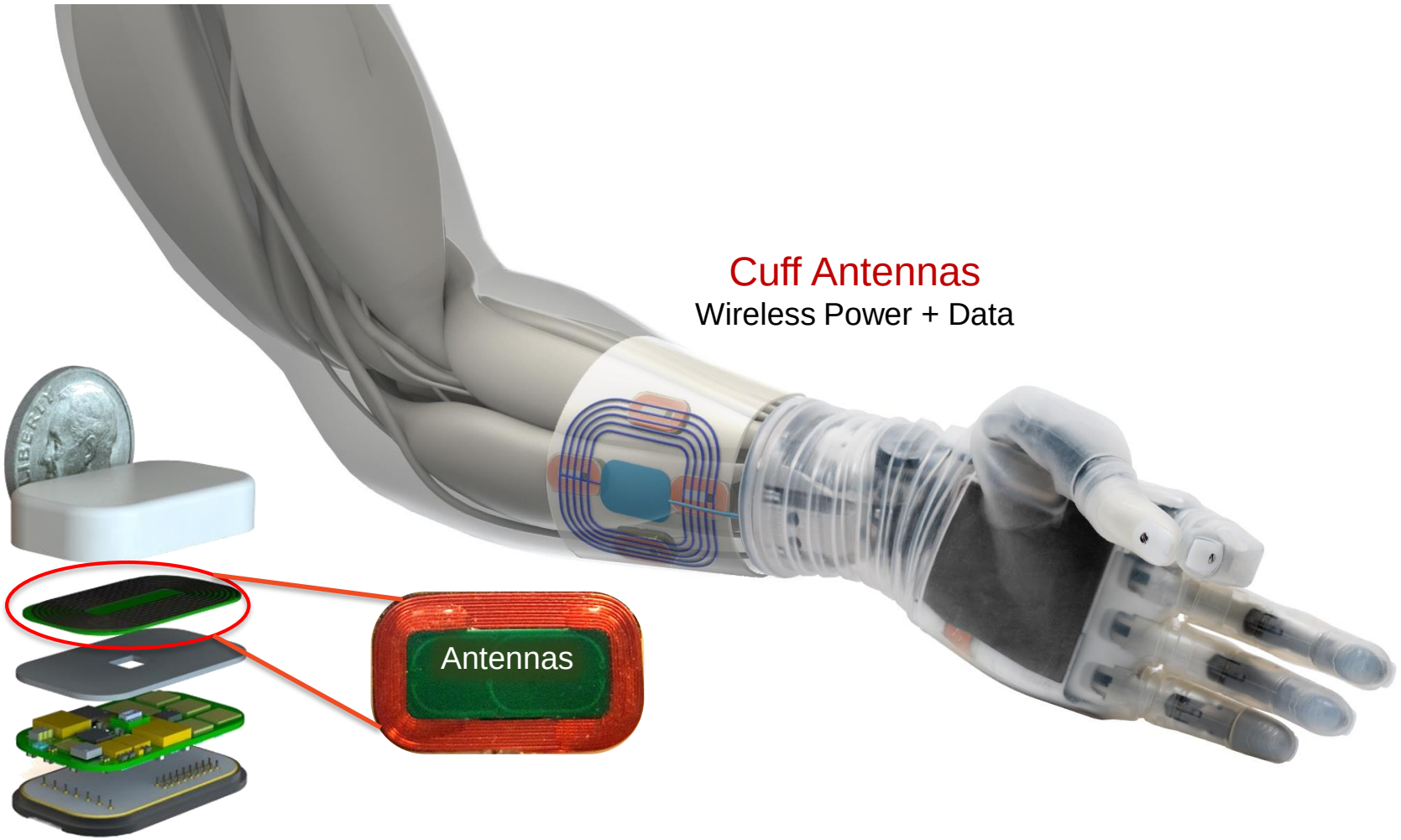
Wireless Gemstone Device

Draper Custom Designed ASIC's Enable Efficient Microelectronics Packaging



Wireless Gemstone Device

Gemstone to Wearable Cuff Antennas Communicates and Powers



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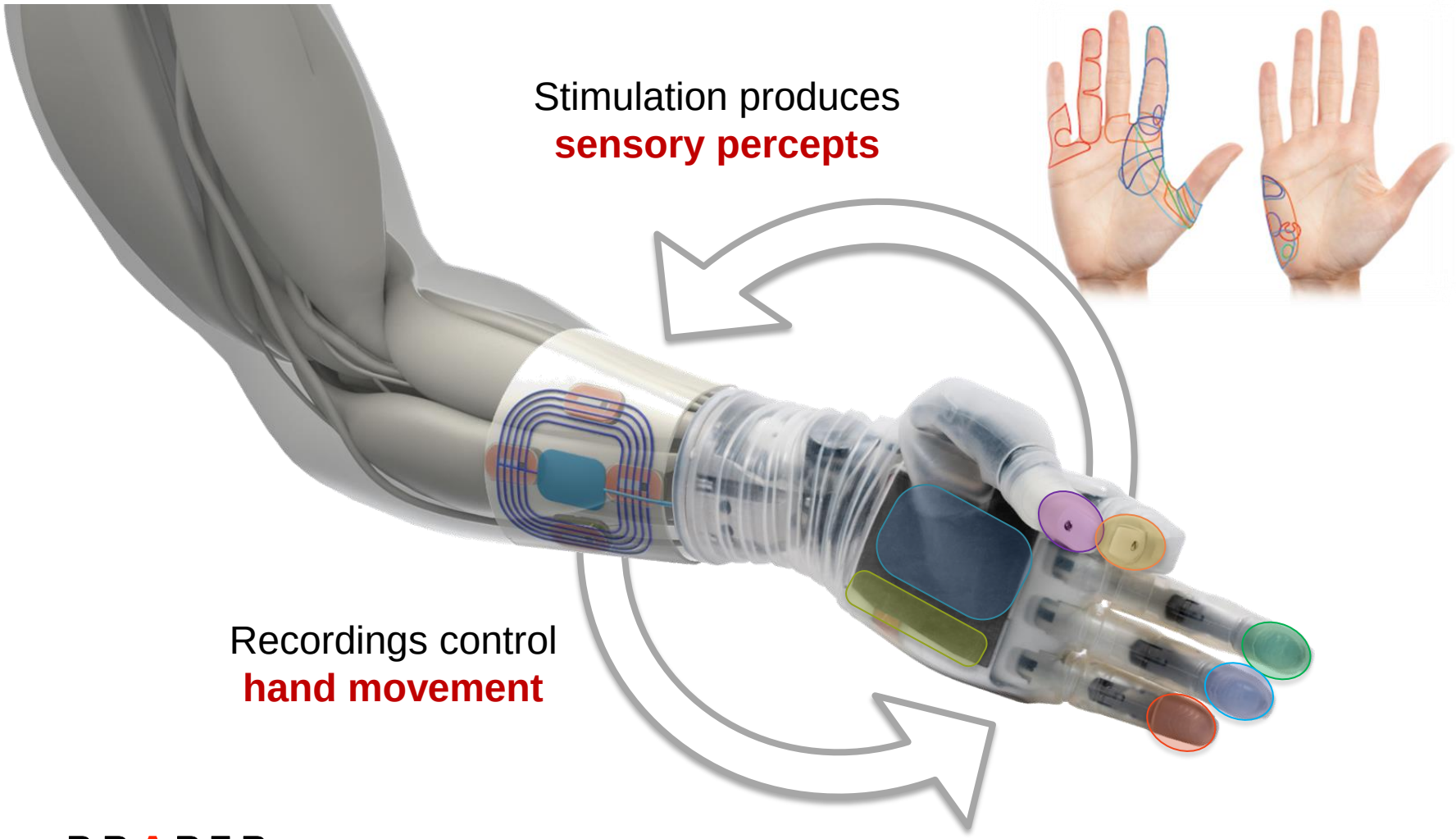
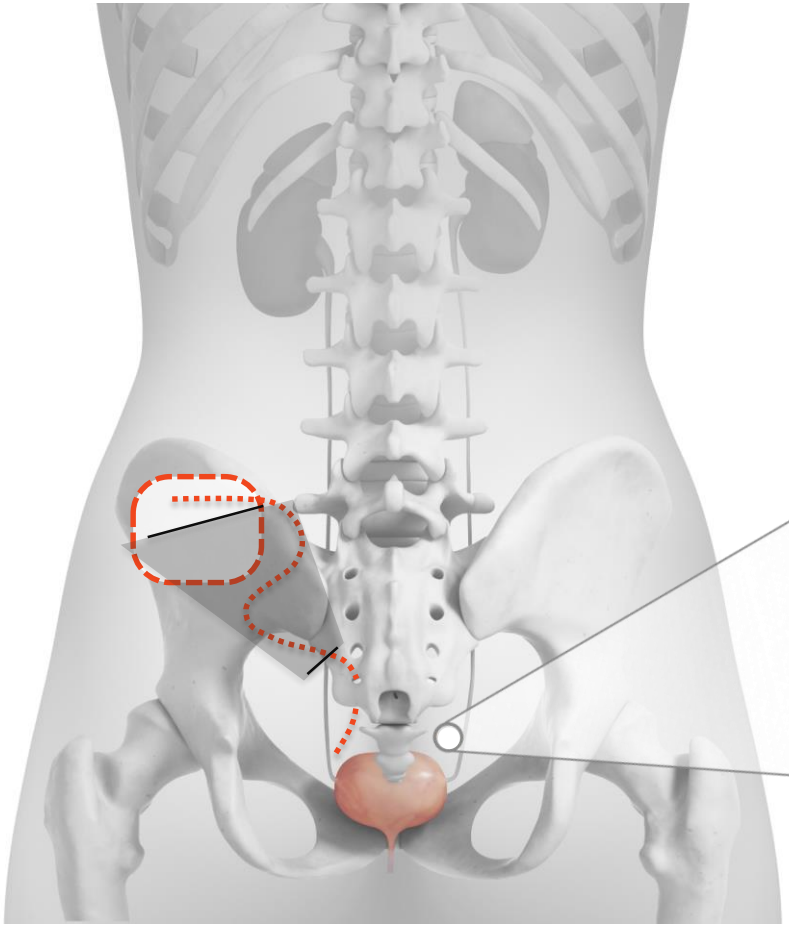
Leadless and Wireless System

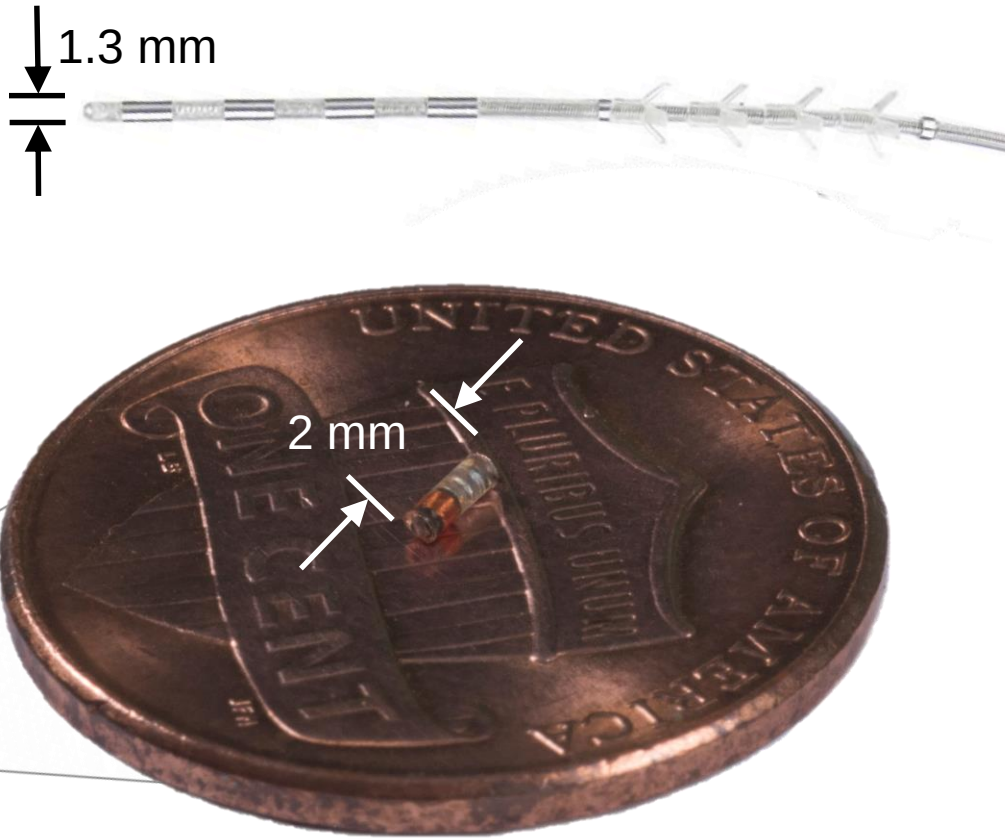
Leadless implants improve scalability and flexibility



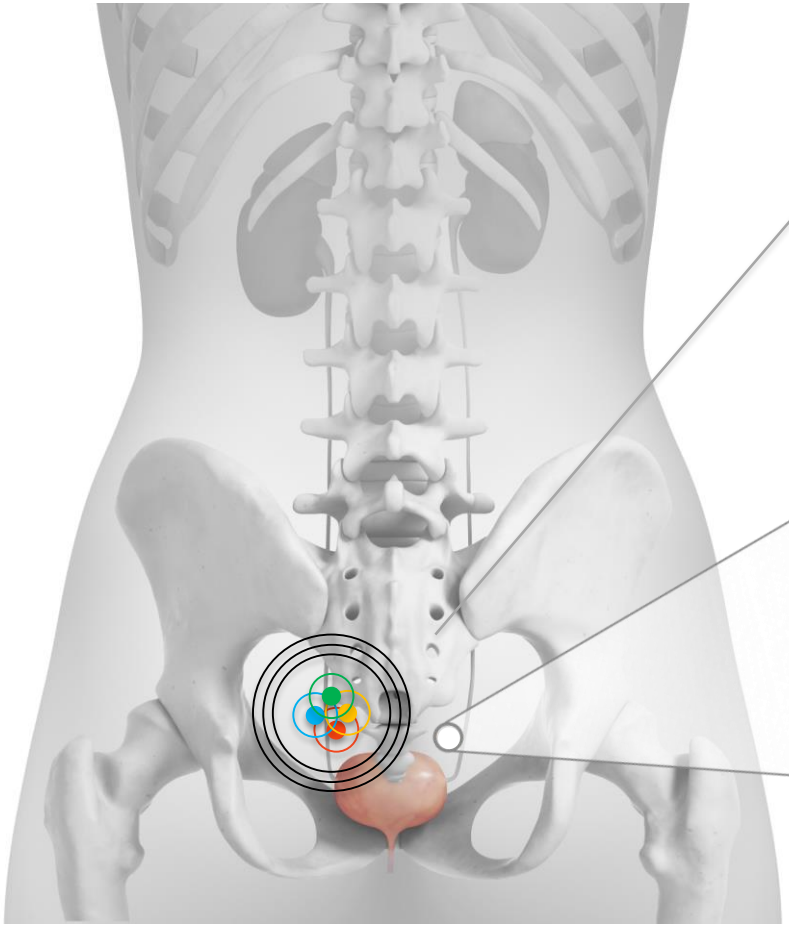
Stimulation Particles

Sacral Nerve Stimulation

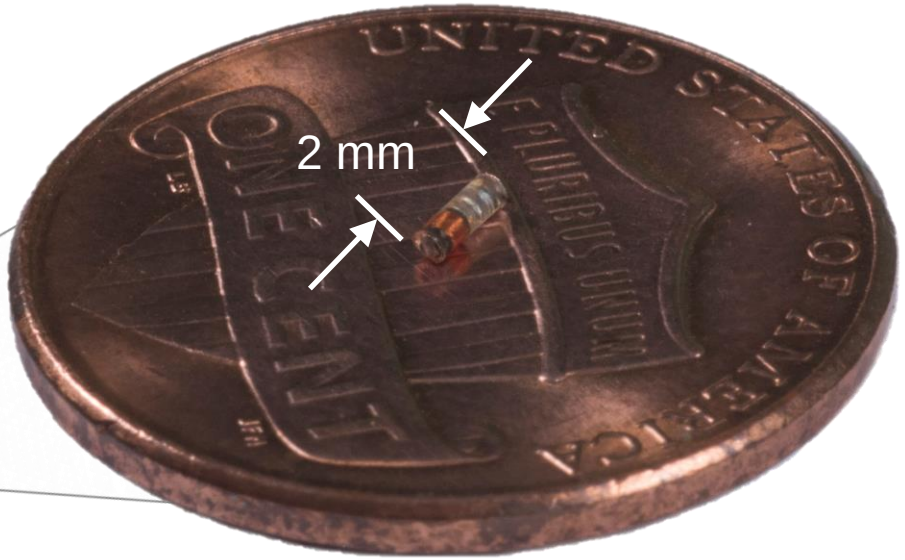




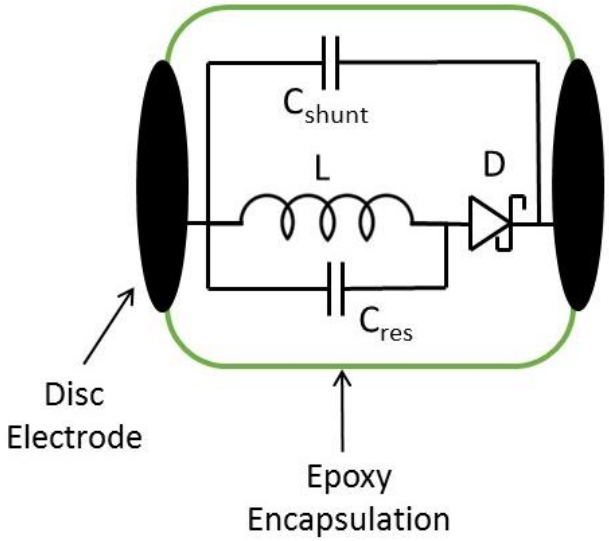
Stimulation Particles

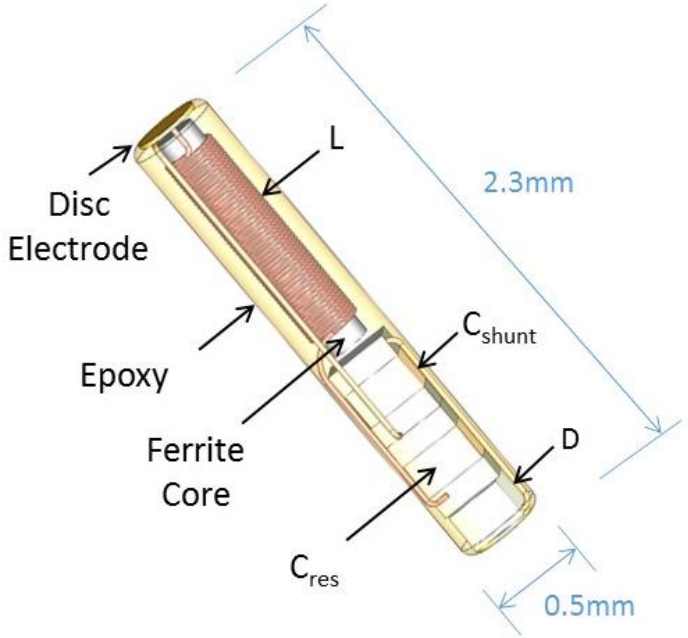


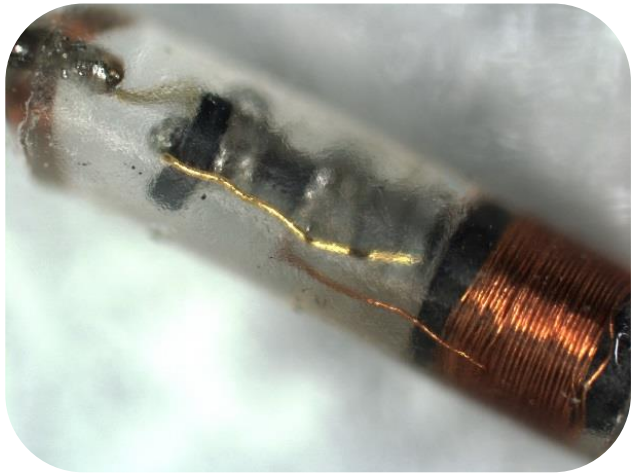
Single wearable antenna patch can coordinate therapies on up to 10 particles



Draper's Neurostimulator Particle







Future for Advanced Microelectronics Packaging and Assembly

Medical Device and Diagnostic Industry (MDDI) article *"How FDA Hinders Medical Device Innovation" (2015)*

> *"FDA is slow to adopt evaluation guidelines for novel medical device technologies… small companies are paying the price"*

Unique Challenges:

- ✓ Robust Design for Daily Use
- ✓ Hermetic
- ✓ Mechanical and Thermal Stability
- ✓ Biocompatibility (novel materials – leachable, delamination)
- ✓ Sterility and Packaging
- ✓ EMC Compatibility

System Safety and Reliability Designs

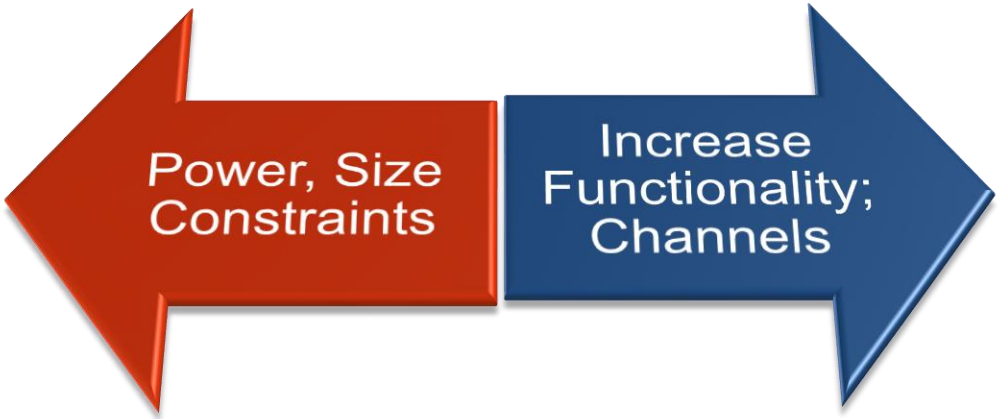
- Biocompatible, non-cytotoxic materials
  - *Chemically stable in in vivo environment*
  - *Metals and ceramics exposed to in vivo environment: Ti, Alumina for package body, Pt/Ir for electrodes, SS316 LVM, Pt/Ir, Au for lead wires*
  - *Insulators: Silicone, epoxy*

- Mechanical stability, reliability
  - *TRANSFORM – Impact resistance*
  - *HAPTIX - reliable against muscular motion, pistoning of electrodes at the percutaneous interface*

- Safety
  - *Intrinsically safe electrical design (i.e. power consumption vs. T rise)*
  - *Electronics safe during surgical insertion (against electrocautery etc.)*
  - *HAPTIX - minimal damage to nerve during electrode insertion*

Future for Advanced Microelectronics Packaging and Assembly

- Increase functionality → Increase power requirement and/or space (volume, footprint)
- Increase channel sites → Increase feedthrough I/O and connector

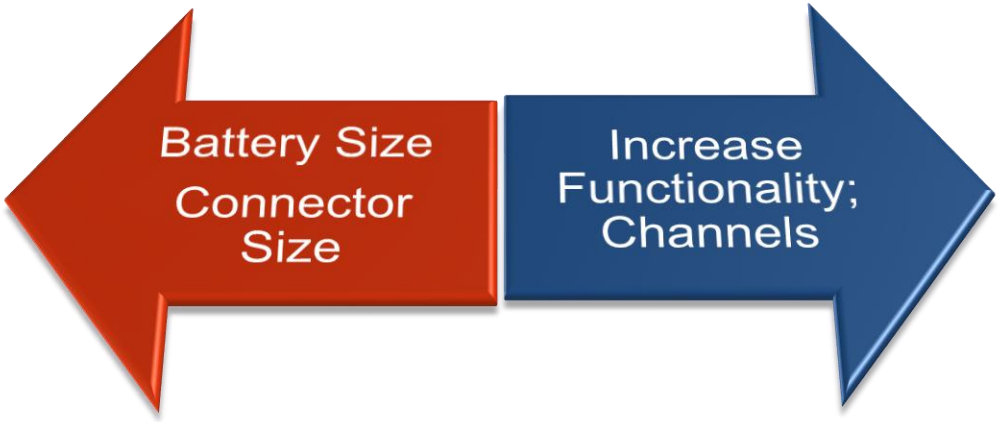


Unique Challenges:

- ✓ Efficient Electrical Design
- ✓ Wireless Design
- ✓ Battery Technology
- ✓ Connector Technology

Future for Advanced Microelectronics Packaging and Assembly

- Increase functionality → Increase power requirement and/or space (volume, footprint)
- Increase channel sites → Increase feedthrough I/O and connector



Areas for Innovation

- ✓ Custom Designed ASIC's → Miniaturization, Performance
- ✓ Wireless Design → Reduction in connection cables, Removal of battery
- ✓ Battery Technology
- ✓ Connector Technology

A Vision for Next-generation Therapies

- **Informed decisions**
  - *Systems-level view of disease*
- **Precise & coordinated therapies**
  - *Exactly the right place*
  - *Exactly the right time*
- **Personalized care**
  - *Responsive feedback to patients and clinician*

Acknowledgements

- TRANSFORM DBS and HAPTIX work was supported by the Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO).
- Neurostimulation Particle work originated as a Draper's Internal Research and Development Program. Current work supported by AHA and NIH.
- Collaborative effort with:
  - *Massachusetts General Hospital*
  - *Nerves, Inc.*
  - *University of Texas-Southwestern*
  - *Arizona State University*
  - *University of Texas – Dallas*
  - *Numerous members at Draper*

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Questions?