Packaging Architecture for an Implanted System that Monitors Brain Activity and Applies Therapeutic Stimulation

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Abstract

Deep brain stimulation therapies for Parkinson's disease utilize hardware, which from a packaging perspective, resembles that used in cardiac pacemakers. A hermetic package that contains stimulation electronics and a primary battery supply is implanted under the scalp in a recess cut into the skull. Stimulation probes, each with up to four electrodes, are inserted into the brain and connected to the electronics package via a plug and cable system. Unlike single-target devices like cochlear implants and pacemakers, achieving this neuropsychiatric therapy requires the ability to record and stimulate in multiple and distributive areas of the brain, both cortical and subcortical. By contrast, the closed loop neural stimulator being developed under the DARPA SUBNETS program utilizes probes, which each carry up to 64 electrodes that can be switched between recording and stimulation functions. This capability necessitates locating low noise amplifiers, switching and communication electronics in close proximity to each probe site. Each of these satellite electronics packages requires ten electrical connections to the hub package, which significantly increases the complexity of the interconnect system relative to current practice. The power requirements of this system preclude the use of a primary battery supply so instead, a large lithium ion battery is used with a recharging coil and electronics. The hub system is fabricated as a separate connector header, electronics package and battery pack that are interconnected by a flex circuit to allow it to conform to the skull for implanting. The standardized feedthrough substrate on the satellite, which can interface with multiple types of electrodes, along the system being reconfigurable, enables the our architecture to support new clinical research. It also allows the clinician to select satellite-electrode system based on a patient's needs, thus providing a customized, patient-specific therapeutic system. In this paper, we will describe the various packaging components of this system and the design considerations that drove our technology choices.

Keywords: neural stimulator; closed loop system; distributive architecture; implantable systems

I. INTRODUCTION

In response to the DARPA BAA-14-09 for Systems-Based Neurotechnology for Emerging Therapies (SUBNETS) [1], we developed packaging solutions for our system architecture with the goals of inquiring new understandings of complex, systems-based disorders of the brain, as well as creating new close-

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loop therapies for neuropsychiatric and neurologic disease. The platform for our system is one which senses brain and body's electrical activity, correlates that activity to a patient's psychiatric symptoms, and as a result delivers electrical stimulation to alleviate those symptoms. Achieving this form of neuropsychiatric therapy requires the ability to record and stimulate in multiple and distributive areas of the brain, both cortical and subcortical.

II. ARCHITECTURE PLATFORM

Our architectural approach for this close loop system is a cranially mounted system which contains multiple satellite connecting to a single central hub, as shown Figure 1.

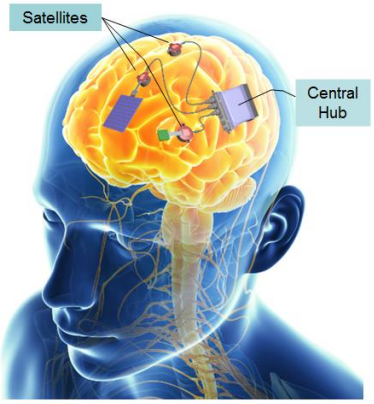


Figure 1: Illustration of the Packaging Architecture

This architecture enables access to a distribution of neural sites. The use of satellite systems also enables noise-sensitive electronics to be placed in closed proximity to the neural sites, thus providing high fidelity signals for subsequent processing. Each satellite contains electronics for both recording and stimulation and connect to a high density electrode (up to 64 channels per satellite). The standardized satellite interface can mate to microelectrode arrays, electrocorticography (ECoG) arrays, and deep brain stimulation (DBS) electrodes. Our satellite design can also accommodate commercial connector blocks, which would allow our system to interface with existing lead sets. The hub, which contains the centralized processing, power, communication, and stimulus pulse generator, can support up to 5 satellite systems. Thus providing our system the capability of 320 reconfigurable channels. This system design approach allows the surgeons to select and place the satellite-electrode system(s) based on the individual patient's needs, are therefore provides a customized system for each patient. The satellite/hub system is implanted but can wirelessly communicate with a base station which is external to the patient, for data streaming, reprogramming, and wireless recharge, as shown in Figure 2.

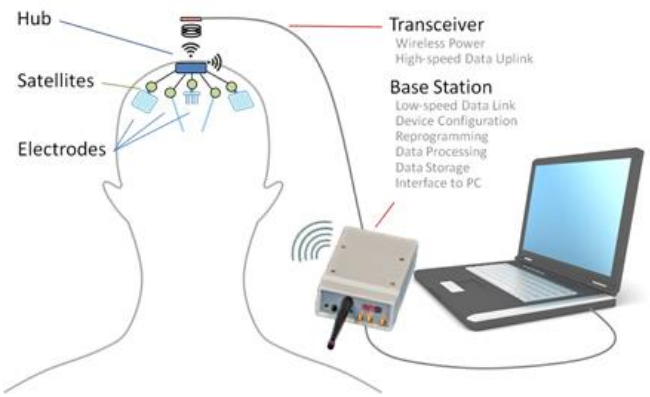


Figure 2: Illustration of the Overall System

III. SYSTEM REQUIREMENTS

There are several requirements which this system must address related to packaging and materials for this program, some of which are shown in Table 1 [1].

Table 1: System Requirements For Phase 1

Parameter	Phase One
Number of sites	4 recording, 1 stimulating
Electrodes per site	25 recording, 25 stimulating
Duration of implant	90 days
Time between recharge/battery replacement	30 days
Size of implant	40 mm x 40 mm
Weight of implant	35 g

Other requirements that the design needs to address when the system is being used in an implanted state [2]. Table 2 highlights some of these requirements related to materials and packaging that pertains to our system architecture, along with specification from the FDA concerning implantable devices [3]. The two primary references which relate to our system are, The International Organization for Standardization (ISO) 14708 which details regulations for *"Implant for Surgery – Active Implantable Medical Devices"*. The second is the *"Technical Standards for the Safety and Effectiveness of Medical Electrical Equipment"* published by the International Electrotechnical Commission (IEC). This series is specified in IEC 60601.

Table 2: List of Materials/Packaging Related FDA Specifications

Description (specification)	Value	Reference
The assembled device shall be	sterile	ISO 14708-1 / 14.1
Implanted device shall be	biocompatible	ISO 14708-3 / 14.3
Rough surfaces, sharp corners and edges shall be	avoided or covered	IEC 60601-1 / 9.3
Implantable device shall have no features that cause	reaction or inflammation	ISO 14708-3 / 15.2
No surface shall exceed temperature of surrounding body by	2°C	ISO 14708-3 / 17
Long term changes in materials shall not	cause a hazard	ISO 14708-3 / 19.1
Multiple conductor junctions of implantable leads shall be	Strain relieved	ISO 14708-1 / 23.4

IV. HUB SYSTEM

A. *Overview*

The central hub consists of four distinct components; an electronics system enclosed in a ceramic package, a rechargeable battery/housing, a customized high density connector, and a flex substrate(s) which integrate the first three components together, as shown in Figure 3.

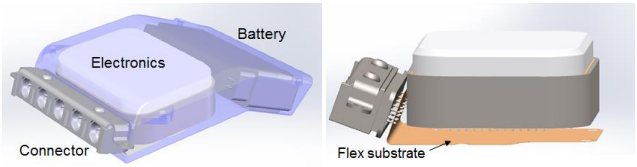


Figure 3: Illustration of the Major Packaging Components Comprising the Central Hub

Table 3: Hub System Packaging Specification

Feature	Value	Comments
I/O	64 on 0.050in pitch Material: 90/10 Pt/Ir D = 0.010in	Value dependent on number of I/O between Hub and satellite; battery and ground contact
Package materials	Alumina plate and cover; titanium seal rings; liquid crystal polymer flex; titanium battery housing	To meet hermeticity, biocompatibility spec. Ceramic cover for RF transparency
Flex to package attachment	Conductive silver epoxy	Based on discussion with assembly houses
Package seal	Titanium band for laser welding	To meet hermeticity spec.
Package overmold	Silicone rubber	To meet hermeticity, impact spec; strain relief/device comfort;
Battery encapsulation	Titanium can	Biocompatibility and impact spec.

B. *Hub System Electronics Package*

As shown in Table 3, the feedthroughs for connecting to the electronics within the Hub system consists of a 95% alumina substrate with a brazed titanium flange. An array of 64 platinum/iridium pins, 90/10% respectively, are gold brazed into the ceramic, as shown in Figure 4.

Figure 4: Images of the Hub electronics 64-pin Feedthrough Plate. External side (left), internal side (right)

All of the materials selected for the feedthrough plate are known for their biocompatibility [4]. The electronics housing cover is comprised of the same 95% alumina material which is gold brazed to a titanium flange. The titanium flanges on the feedthrough plate and cover provides the hermetic seal for the electronics by laser welding the two flanges.

The external footprint of the enclosure is 30mm x 40mm, with the overall height of the package dictated by the internal height needed for accommodating the necessary electronics. In this design, as shown in Figure 5, the bottom printed circuit board containing the majority of the electrical components attaches to the feedthrough substrate. This board will contain holes allowing it to drop into the pins of the feedthrough plate. A second component attaches to the bottom board via a board-to-board connector. The top board contains the antennas with a ferrite material attached to its bottom side.

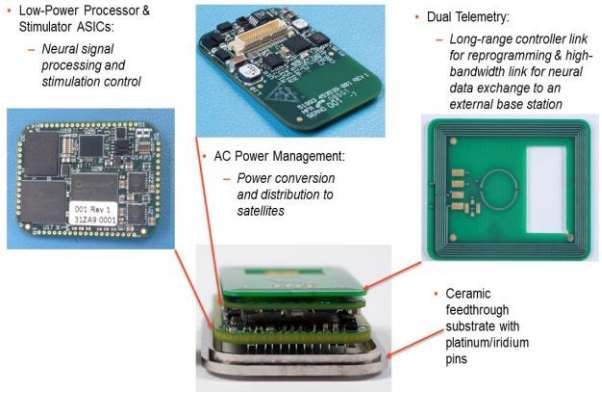
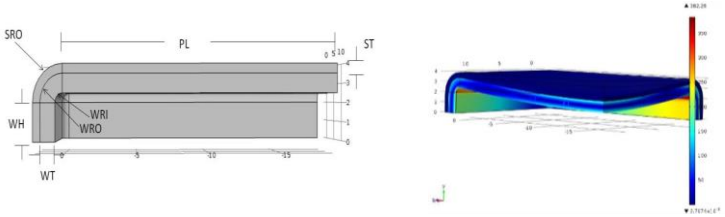


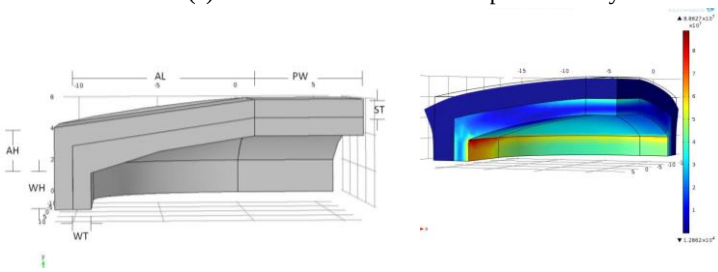
Figure 5: View of the central hub electronics stack-up mounted onto the ceramic feedthrough substrate.

In this design, the bulk of the cover height is comprised of the titanium flange/side wall. With the ability to trim the titanium as needed, there is flexibility within the one cover design to accommodate the current internal height needed as well as the providing the ability to decrease the overall package height with a reduction of the electronics.

Alumina was selected as the cover material for its RF transparent properties [5]. One of the electrical requirement of the hub system is wireless communication to the antennas located on the top circuit board within the enclosure. Traditionally, this form of wireless communication is provided by incorporating a RF transparent window (i.e. sapphire) within a titanium cover or enclosure. However, due to the limited footprint of the overall system, the use of an all-ceramic cover provides the maximum allowable area for the antenna within the enclosure. Before finalizing the design of the cover, finite element model analysis was conducted to look at the stresses within the alumina materials when subjected to impact. Several documents (ISO14708-1/23.2, IEC60068-2-47, IEC60068-2-64, IEC60068-2-75:1997) states that a design must absorbs 2.5 Joules in mechanical impact energy [6]. As shown in Figure 6, the influence of the ceramic thickness and the internal cover's curvature has on the ability of the alumina cover of absorbing this impact.



(a) Rounded wall with silicone protective layer



(b) Arched wall with silicone protective layer

Figure 6: Finite Element Model Parameters and Results for (a) Curved Wall Ceramic Cover and (b) Arched Wall Ceramic Cover.

Results from the FEM analysis showed that using a ceramic cover with an arched transition between the top and side wall, along with a wall thickness of 1.5mm (compared to 1.0mm) provided the best strength and thus is better equipped for meeting the impact specification.

C. Rechargeable Battery Enclosure

The selection of the rechargeable battery for this system was based on both its physical and electrical properties. Due to the size and weight limitation for an implantable system, the goal was to incorporate a battery no larger than 710mm^2 and 6mm thick, with a weight less than 10g based on the size and weight estimates for the remaining portion of the system. After research into commercially available rechargeable batteries appropriate for implantable applications, the Quallion QL0200I-A cell was chosen. The battery is housed in a separate titanium case, as shown in Figure 7.

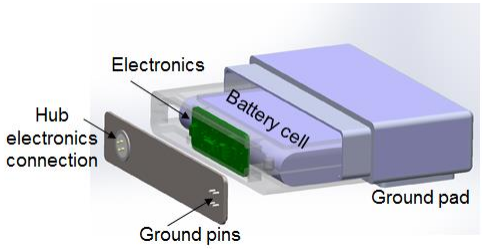


Figure 7: Illustration of the Rechargeable Battery and Housing.

The battery is integrated into the hub system with the use of quad feedthrough pins brazed into the cover plate for the housing. The use of this secondary housing allows for additional electronics to be placed with the battery. The housing itself provides additional protection for hermeticity, the impact specification of 2.5 Joules, as well as serving as the overall ground for the hub.

D. Plug and Socket Connector

The connection between the individual satellites and the main hub systems must withstand up to 6 connect/disconnect cycles. To achieve this, the satellites will be connected to the hub using plugs that are inserted into a single socket which is bonded to the hub flex circuit. Due the high number of contacts between the hub system and satellites, 10 contacts per satellite, commercial connection systems designed for

medical implant applications exceeded the targeted footprint of 10mm x 40mm. Based on commercial circular connector system, a modified and custom design concept was developed for a nano-circular connector system.

The housing consists of a titanium shell and five discrete sockets, one per satellite, as shown in Figure 8.

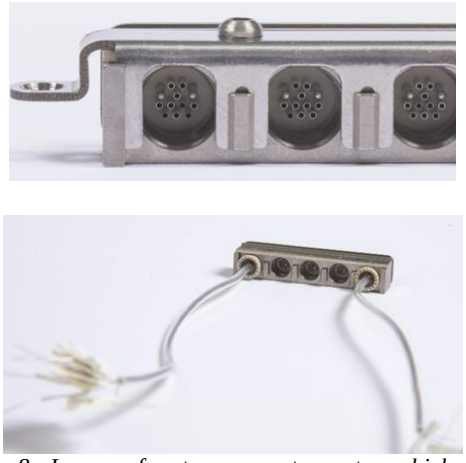


Figure 8: Images of custom connector system which connects the central hub system to up to 5 satellites. The custom plug and play cables are shown in the lower image.

A biocompatible insulator material encapsulates each individual stainless steel pin within the socket, and guiding pins to ensure the plug is inserted in the correct orientation. The mating plug has a silicone overmold which seals the connector housing to the cable, provides strain relief, and increases the strength and durability of the connector. The design incorporates dual O-rings for additional protection against fluid ingress and increase seal integrity, which could be incorporated into the socket or plug.

E. Hub System Integration

The central hub is a modular system that is integrated together using a liquid crystal polymer flex substrate shown previously in Figure 3. The interconnect layer comprises of gold metallization. Both the feedthrough pins for the hub electronics, as well as the pins on the connector housing will be attached to the flex using a biocompatible, silver conductive epoxy. After integration, the system is them placed in an encapsulation tool for an over molding process, as shown in Figure 9.

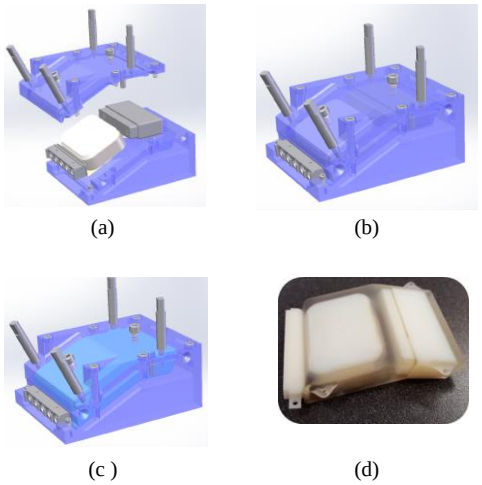


Figure 9: Illustration of the Hub System Encapsulation Tool (a-c) and Final Form Factor of the Central Hub (d).

V. Satellite System

A. Overview

The central hub system can connect up to 5 satellite systems. Each of these systems contain front end electronics for the electrode array, power conversion, and communications with the hub controller. This is a significantly more complex electronics package than used in other implanted stimulating and recording systems [7],[8]. The package for the satellite was design with the goal to fit within a 14mm diameter bur hole created by the surgeon. The bulk of the package would sit within this hole, and a top cap would hold the connections to the system hub and electrodes in place. The cap would also include capture holes to allow the surgeon to anchor the cap to the skull and provide a smooth surface interface to the skin. An overview of the satellite package design connected to a microelectrode array and the cable for connecting to the hub system is shown in Figure 10 and details illustrated in Table 4.

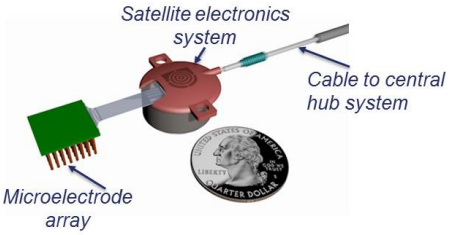


Figure 10: Illustration of an Individual Satellite System Connected to a Microelectrode Array and Hub Cable.

Table 4: Physical Design Specifications of the Satellite System Per System Requirements

Feature	Value	Comments
Size	13.74mm diameter, 8mm tall	Fits within a 14mm diameter surgical burr hole (neurosurgeon input)
I/O	81 pins on 0.970mm pitch	64 for electrode; 10 for hub
Package (enclosure) materials	Alumina base feedthrough plate; Titanium cover	To meet hermetic; biocompatibility specification
Package seal	Titanium seal ring on feedthrough plate for laser welding	To meet hermetic specification
Wire attachment	Thermo-sonic bond	Assembly vendor will determine best practice
I/O encapsulation	Epoxy filled plastic shell	Provides strain relief for the wires

B. Satellite Device Enclosure

The satellite enclosure consist of a 81-pin feedthrough plate and a titanium can. The same materials (95% alumina, gold brazed to a titanium flange) that is used for the hub electronics feedthrough plate is used for the 81-pin feedthrough. The pins also consists of the same material composition (90% platinum/10% iridium) and the same 0.010in diameter that is used on the hub. These pins provide the electrical connection between the interior electronics and the electrode and hub cable attached on the exterior side of the plate, as shown in Figure 11.

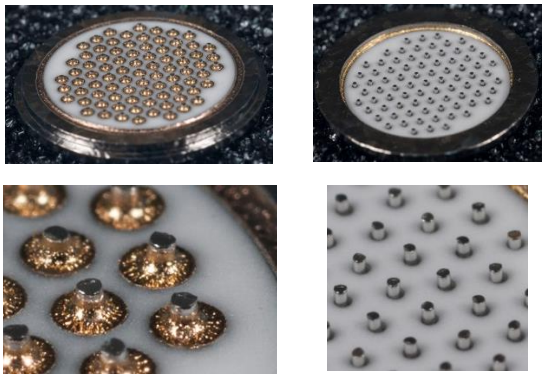


Figure 11: Images of the Satellite 81-pin Feedthrough Plate. Internal Side (left), External Side (right).

The hermetic seal of the package is achieved by laser welding the can to the titanium flange that is brazed onto the ceramic feedthrough plate.

C. Rigid-Flex Physical Design and Assembly

The satellite electronics board is a rigid-flex design comprised on three rigid boards with flex connection, as shown in Figure 12.

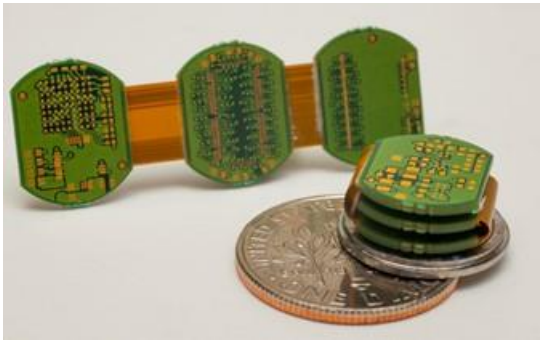


Figure 12: Optical Images of the Fabricated Rigid Flex Board, as-received and folded onto the feedthrough plate.

This design allows for the board to be folded upon itself to fit within the internal dimensions of the satellite enclosure of a 12.8mm diameter and approximately 7mm height. Titanium cans of different heights can be machined to accommodate taller rigid-flex designs, for example if a double sided board were required.

The circuit board contains four bare dies, a chip-scale package, and several passive components. Due to the fine pitch of the contacts on several of the bare dies, sub 25µm diameter wire bond attachment is required. The bare dies would be attached first. A glob top layer would then be applied to protect the bare dies and wire bonds during the surface mount attachment and reflow process of the remaining components. The assembly process of the rigid-flex board would be conducted in the flat configuration.

The rigid-flex board is attached to the pins of the feedthrough plate by solder attachment. Nonconductive epoxy is then applied and wicked into the area between the board and feedthrough plate for additional reinforcement of the bond. Once the board is attached to the feedthrough plate, the first flex bend is formed and secure using conductive epoxy. The second bend is then formed. Once the rigid-flex board is attached and folded, the satellite package is hermetically sealed by laser welding. Images of the satellite electronics system is shown in Figure 13.

Figure 13: Images of the satellite electronics system. Exploded view of the folded board mounted to the feedthrough substrate (left), Enclosed system (right).

D. Cable Attachment and Encapsulation

A cable for connecting the hub and up to four different styles of electrodes/leads would be hardwired to the external side of the satellite feedthrough plate. Laser welding, resistance welding, or peg bonding would be used for the cable attachment process. Wire diameter ranging from 0.001in to 0.005in core, plus insulation have been evaluated. Wire composition of 100%Pt, 90%/10% Pt/Ir, and 99% Au, as shown in Figure 14.

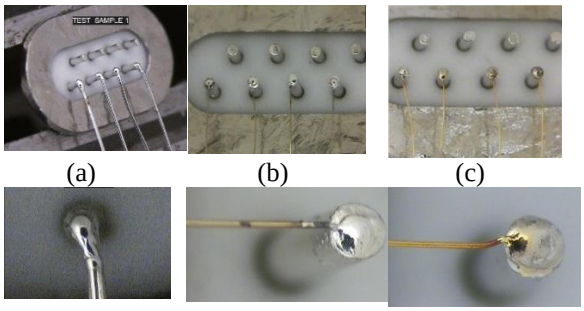


Figure 14: Images of (a) 0.005in Pt/Ir wire, (b) 0.001in Pt wire, and (c) 0.001in Au wire attached to Pt/Ir Pins.

As shown in Figure 11, the external side of the feedthrough plate contains a recess for the wires to be positioned into and attach to the pins. The recess also provides strain relief of the wires after they are encapsulated. Once the wire are encapsulated, a wire cap is then attached to the satellite using epoxy and over-molding in silicone. The anchor points on the cap are used for securing the satellite to skull after it is recessed into the bur hole, as shown previously in Figure 10.

The standardized feedthrough on the satellite enables the system to interface to various electrodes (i.e. microelectrode arrays, ECoG and DBS electrodes) as well as commercial connector blocks, as shown in Figure 15.

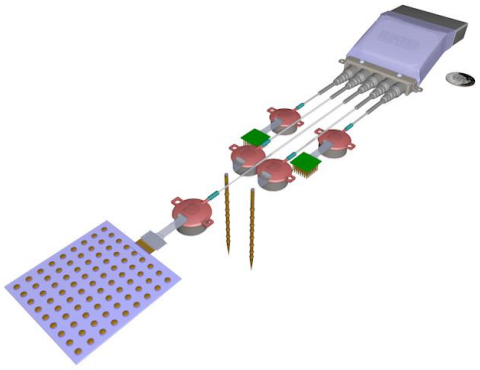


Figure 15: Illustration of a Neural System with a Central Hub Connected to 5 Satellite-Electrode Systems.

V. SUMMARY

An implantable neurological recording and stimulation system with closed loop control has been designed, which utilizes architecture of distributed electronic packages. Design of all major components of the system were done with respect to adhering to guideline provided by the program and clinicians, as well meeting regulatory requirements. Fabrication of the components are near completion and process development efforts for system assembly has begun.

ACKNOWLEDGMENTS

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