

# How CARSS can support your work

*Webinar #2  
May 7, 2024*



**USC Viterbi**  
School of Engineering



**Medipace Inc**

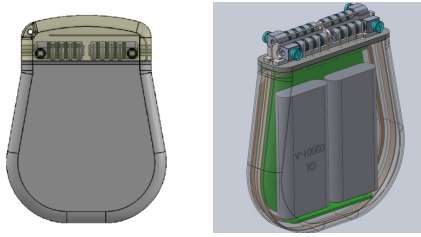


Funded by NIH SPARC (U41-NS129514)

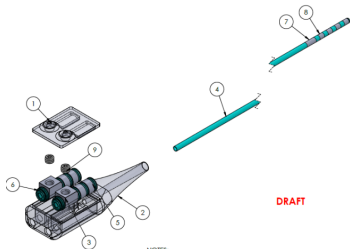


# Summary of our components

## Implantable Pulse Generator

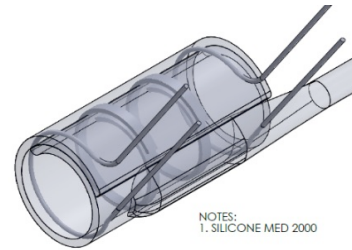


## Splitter

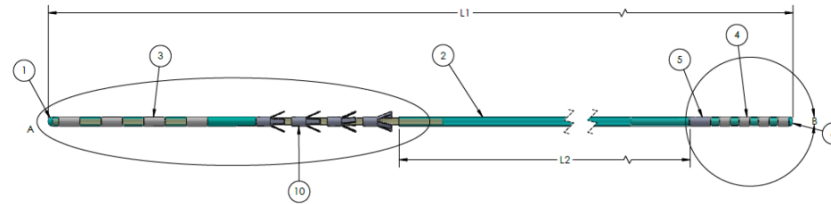


## Stimulation Leads

Clinical: VNS cuff, SNS lead



NOTES:  
1. SILICONE MED 2000

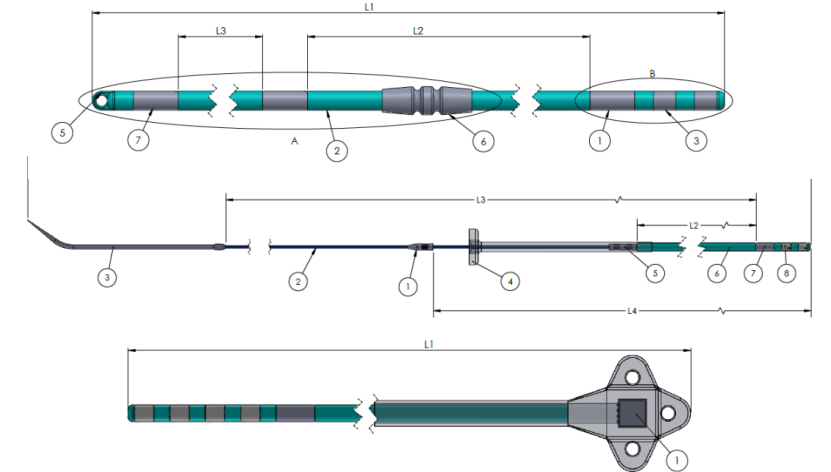


Research: sub-mm nerve cuff

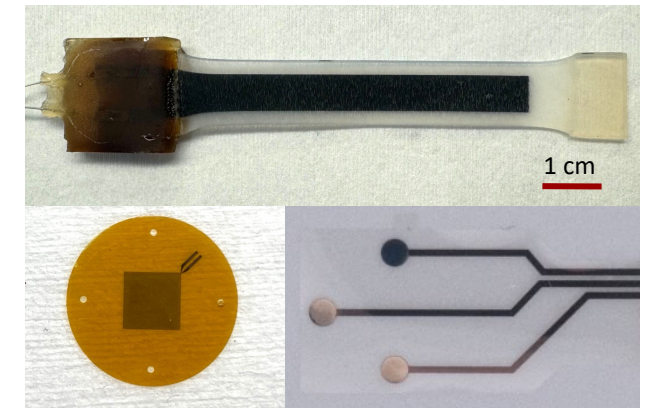


## Sensing Leads

Clinical: ECG lead, EMG lead, motion sensor



Research: strain, temperature, neurotransmitters, pH





# CARSS resources and documents

## Open-Source Data



**GitHub**

**Design files and Documentation**

[github.com/CARSSCenter/  
OpenNerve](https://github.com/CARSSCenter/OpenNerve)



**Benchtop and animal data**

[sparc.science/projects/Z1  
X1or4wcgUy1Jk6BYqBD](https://sparc.science/projects/Z1X1or4wcgUy1Jk6BYqBD)

## Updates and Communication



[www.opennerve.org](http://www.opennerve.org)



[linkedin.com/company/  
hornet-carss/](https://linkedin.com/company/hornet-carss/)



# License

- All design files are under the Creative Commons CC-BY 4.0 open source license
- What this license allows:
  - You can use materials for anything, commercial or academic
  - You can patent or keep proprietary any improvements built on top of OpenNerve
- What this license requires:
  - If you use our resources, you must give us credit (e.g. cite us)
  - If this is an issue, let us know and we can work something out individually

Users are encouraged to contribute changes or improvements back to the project!





# The different parts of CARSS



Center for Autonomic Nerve  
Recording and Stimulation Systems



## About:

- ISO13485 certified manufacturer based in South Carolina
- Experience designing and manufacturing clinical neuromodulation implants
- Experts in enclosures, leads, electrode design, implanted electronics, soft/firmware

## How they can help:

- Manufacture standard IPG and clinical leads
- Design and build custom electrodes
- Connect research leads (including thin films) to lead bodies
- Support groups from research, to first in human, to mass manufacturing

## Medipace Inc

## About:

- Medical device design company based in Los Angeles
- Experts in bioelectronic medicine, implantable electronics, firmware

## How they can help:

- Design and manufacture standard PCBAs for IPGs
- Customize PCBAs, software, and/or firmware for a specific application
- Consulting on commercializing neurotechnology

## USC Viterbi

School of Engineering

## About:

- Three contributing investigators developing novel sensing and stimulation leads
- Coordinate and conduct animal studies
- Create and maintain Github and open-source resources

## How they can help:

- Customize and manufacture thin-film sensing or stimulation leads (bench/animal only)
- Design and conduct preclinical studies using OpenNerve
- Coordinate collaborations and support grant proposals



# How CARSS can help at different stages of research

## Exploratory Research

- Rodent and small animal studies
- Acute experiments
- Percutaneous tests

CARSS can help with:

- Bare PCBAs (purchased or manufactured yourself)
  - Modify and customize firmware, software
  - Electrodes with wires for percutaneous studies
- 

## Developmental Research

- Chronic large animal studies
- Mechanistic investigation
- Exploring stimulation sites or parameters

CARSS can help with:

- Lower-cost options for IPG: PEEK housing, primary cell, electrodes soldered directly to PCB, non-GMP manufacturing
  - Standard or custom electrodes to investigate therapies
- 

## Validation and Clinical Research

- Chronic safety or efficacy studies in animals
- First in human studies

CARSS can help with:

- GMP manufacturing at ISO-13485 certified facility (Med-Ally)
- Hermetic titanium package for long-term implantation
- Documentation to support IDE application



# Why use OpenNerve for early-stage research?

**Exploratory**



- Reduce cost: quickly prototype and test using electronics that can be moved to implants
- Reduce time: no need to build your own system from scratch
- Reduce risk: have the confidence that your therapy can be implemented in OpenNerve

**Development**



- Reduce cost: many tests with development hardware are directly applicable to clinical hardware
- Reduce time: test earlier and faster with the confidence that you can ramp up if needed
- Reduce risk: reduce unexpected effects of developing a new system for the clinic

**Validation/Clinical**



## Lead times and costs

- Bare PCBA development boards – limited availability, can provide for ~\$2.6k each to researchers interested in developing new therapies using OpenNerve
  - Next batch of PCBAs will be available in September – let us know if you're interested!
- Full OpenNerve IPGs: estimated cost of ~\$8k with ~1 month manufacturing time
  - Lead time assumes no issues with material procurement
  - For quotes or to discuss your specific needs please reach out





# What funding sources have our collaborators used?

## **Exploratory Research:**

- NIH R21

## **Development:**

- NIH R18 (BRAIN or HEAL)
- NIH/NSF SBIR or STTR
- NIH Blueprint Medtech Incubator Hubs - Seedling

## **Validation / first in human:**

- NIH Blueprint Medtech Incubator Hubs - Optimizer
- NIH Blueprint Medtech U44 or UG3/UH3

We are also happy to support other funding mechanisms or working with your existing funding



# Story from a collaborator (anonymized)

A professor has a promising idea and excellent results in rodents, and is interested in commercialization

Their needs:

- Devices for large animal testing
- A viable pathway to IDE



They reached out to CARSS to see if we can help

After talking to them in depth about their application, we found that the standard OpenNerve IPG would work but they would require custom electrodes and firmware that could implement their patented therapy

**Medipace Inc**

Firmware customization



Custom electrodes design

For funding, we supported their NIH Blueprint Medtech grant application

**Leveraging OpenNerve can reduce their projected time to IDE by ~1 year**



## How to get in touch

If you're interested in learning more, or you think CARSS might be able to help support your work, please reach out!

My direct email: [abbaldwi@usc.edu](mailto:abbaldwi@usc.edu)

CARSS email: [CARSS@usc.edu](mailto:CARSS@usc.edu)