Introduction

The Cleveland FES Center's Technical Development Laboratory (TDL) designs and fabricates implantable medical devices that are intended for use in human feasibility studies conducted under several Investigational Device Exemptions (IDEs). In 1991, the TDL was established to facilitate the design and development of implantable hardware required for clinical studies conducted within the Cleveland FES Center. The TDL is part of the network of CWRU core centers that provides state-of-the-art services for the multi-disciplinary research institutes outlined in the University's Strategic Plan. To fully realize this vision, TDL will try to meet the needs of researchers in the Biomedical and Electrical Engineering Departments (BME, EECS), and the Case School of Medicine (SOM).

The Technical Development Laboratory (TDL)

Since 1991, the TDL has been a resource core for the local FES community that provided design, development, fabrication, and testing of implantable and external systems, biomedical instrumentation, and software solutions (embedded and applications). The TDL staff consists of seven fulltime employees and includes biomedical engineers, computer engineers, electrical engineers, a physicist, and several technicians. These seven employees have nearly 150 years of combined experience in the design, development and clinical deployment of implantable technologies for human research. The TDL provides a resource core for design, development, fabrication, and testing of implantable and external systems, instrumentation, and software. Technical capabilities include system integration, electronics design, multi-level software design, mechanical design, material science, and project management. The TDL facilities include the cleanroom, micro-fabrication lab, machine shop, electronics lab, embedded systems lab, computer lab, and staff office cubicles. The Technical Development Laboratory (TDL) designs and fabricates all technologies for use in all clinical studies performed within the Center.

Organization and control of human implantable device design

To facilitate the transfer of promising technology from the Technical Development Laboratory (TDL) to the commercial realm, the TDL has implemented Standard Operating Procedures (SOPs) that define and delineate activities related to 21 CFR 820 Subpart C, Design Controls. The ongoing clinical studies within the Cleveland FES Center are conducted under Investigational Device Exemptions (IDEs), which are governed by 21 CFR 812.

Facilities

The TDL is located on the campus of Case Western Reserve University. The facility, which includes several laboratories and some office space, occupies 5500 square feet of space.

The TDL's class 6 *cleanroom* (ISO 14644-1) provides a controlled environment for the assembly, testing and packaging of human-grade implantable hybrid electronic circuits and surgical tools. This 1100 square foot facility includes a CNC Nd/YAG pulsed laser, several spot welders, glove box, two wire bonders, a probing station with curve tracer, oven, fume hood, heat sealer, and computer-controlled wire winder.

The TDL's *micro-fabrication lab* is a materials facility used for prototyping and analysis as well as fabrication of components that don't require the rigors of a cleanroom. The lab includes several types of microscopes that include video and photographic documentation capabilities, circuit board screen printer, a spot welder, soldering/de-soldering workstations, balances, several ovens including a vacuum oven, a surface-mount technology (SMT) flow oven, furnace, fume hoods, and a water bath.

The TDL's *electronics lab* provides workstations for bench top development and testing, GPIB networked instrumentation including oscilloscopes, bench meters, power supplies, a spectrum analyzer, an RF power meter, arbitrary waveform generators, and custom built instrumentation. The electronics lab maintains an extensive inventory for fabricating prototypes as well as specialized SMT rework stations. Within the electronics lab is the *embedded systems lab,* which provides software and hardware tools such as compilers, assemblers, linker/loaders, emulators, background debuggers, and a revision control system. A *computer modeling lab* provides workstations for CAE/CAD/CAM, modeling, rapid prototyping, and simulation.

Finally, TDL has a *machine shop* that includes a three-axis CNC milling machine, circuit board prototyping system, bead blaster, diamond dicing saw, lathes, a conventional milling machine, a band saw, a surface grinder, a jeweler's lathe, drill presses, and a belt/disk sander.

The staff of the TDL includes 7 full-time employees with a combined experience of 150 man-years with backgrounds in biomedical, electrical and computer engineering, physics, and electronic and engineering technology.

Expertise/Core Competencies

Over the past 25 years, our effective use of the core competencies has enabled the TDL to develop, implement, and transfer to industry numerous implanted hardware components, external hardware components, and integrated software solutions

focused on implantable pulse generators for restoration of function in individuals paralyzed by stroke or SCI.

Among the seven full time TDL staff, there are five core areas of expertise:

I. External hardware design and development

- Circuit design
- Circuit layout (Orcad, Eagle)
- Circuit board fabrication
- Circuit board assembly (including surface-mount rework capabilities)
- Circuit board testing and debugging
- Cabling and wiring systems
- CNC machining
- Solidworks 3D CAD design
- Injection molding (small scale)
- 3D printing (small scale)
- Wireless LI-iON battery charging
- Low-power systems design
- Embedded system development (TI MSP430, Freescale, PIC, Arduino)
- Radio enabled devices (MedRadio, 900Mhz, BlueTooth, TI CC1101)
- External hardware corrective maintenance/repair
- Surface mount rework
- Electrical Safety Testing (UL 60601-1)

II. Implanted hardware design and development

- uCircuit design
- uCircuit layout
- uCircuit board fabrication
- uCircuit board assembly
- uCircuit board testing and debugging (with probing station)
- Electrode design and development
- Electrode fabrication
- Wire bonding (ball and wedge-type)
- Spot welding
- Laser welding
- Hermeticity packaging
- Hermeticity testing
- Biocompatibility of implantable materials
- Sterilization validation

III. Quality Systems management

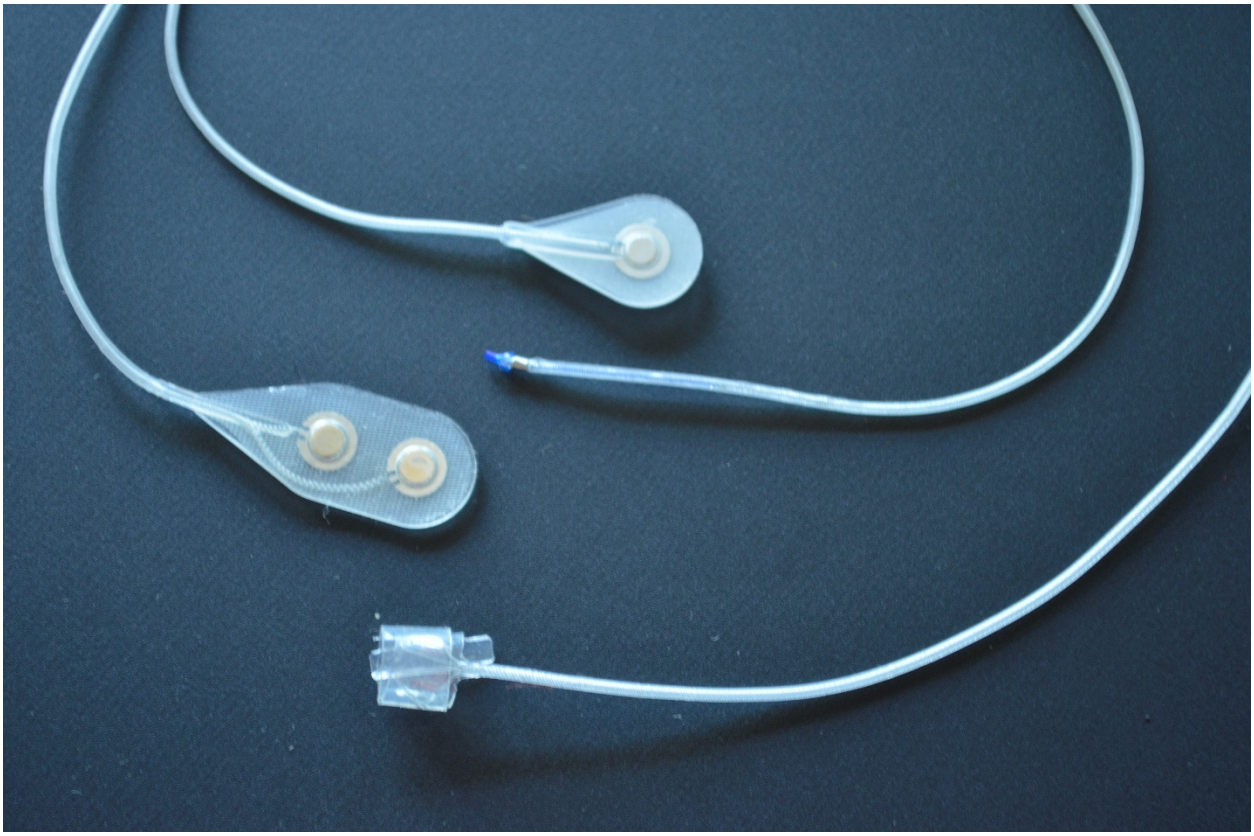
- Extensive knowledge of FDA Quality System Regulation (21 CFR 820 and ISO 13485)
- Extensive knowledge of FDA Investigational Device Exemption Regulation (21 CFR 812)
- Extensive knowledge of Medical Device Risk Management (ISO 14971)
- Extensive knowledge of Medical Device Sterilization Validation (ISO 11135)

IV. Project management/product development

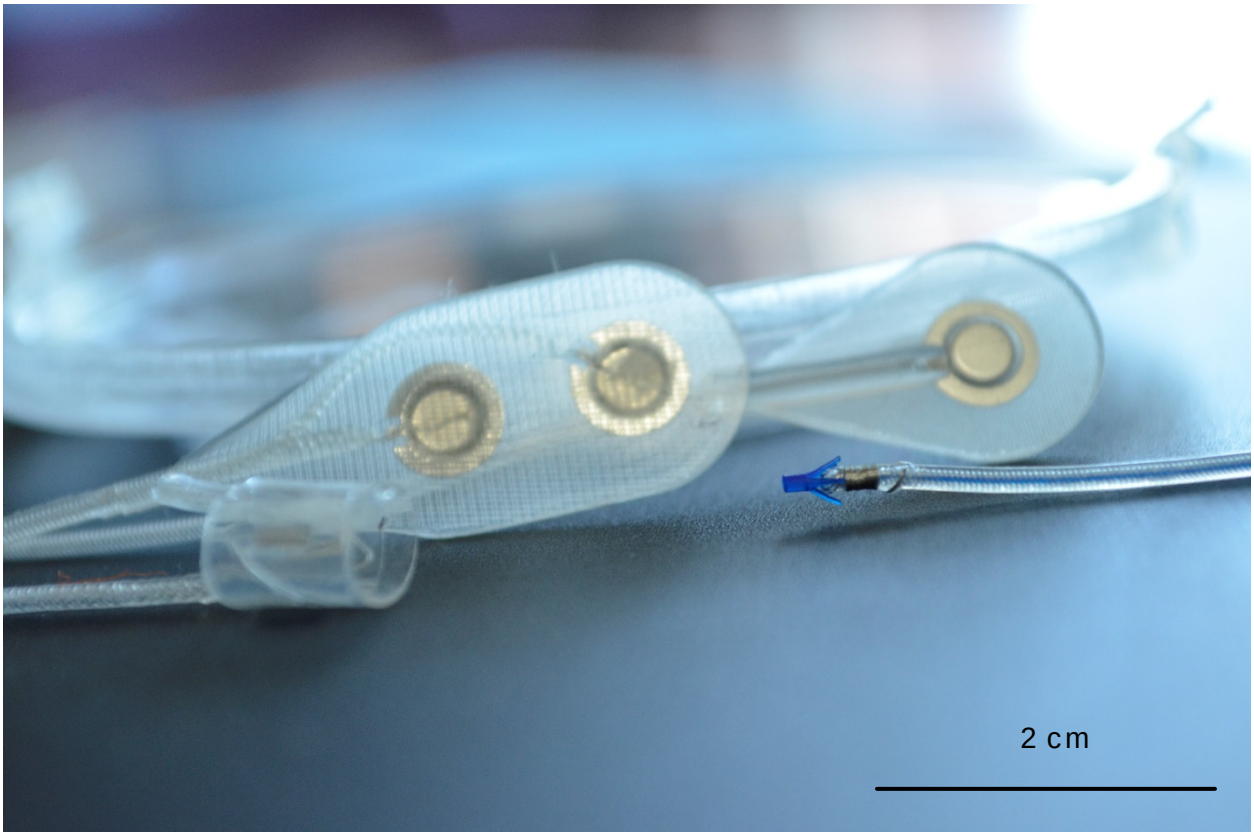
- Extensive knowledge of product development from the concept phase through the rapid-prototyping and production-prototyping stages.
- Extensive knowledge of the budgeting/costing (time *and* $$) requirements for product development efforts.
- Fluent in Atlassian Confluence, Microsoft Project and all other MS Office tools for project management.

V. Technology Transfer

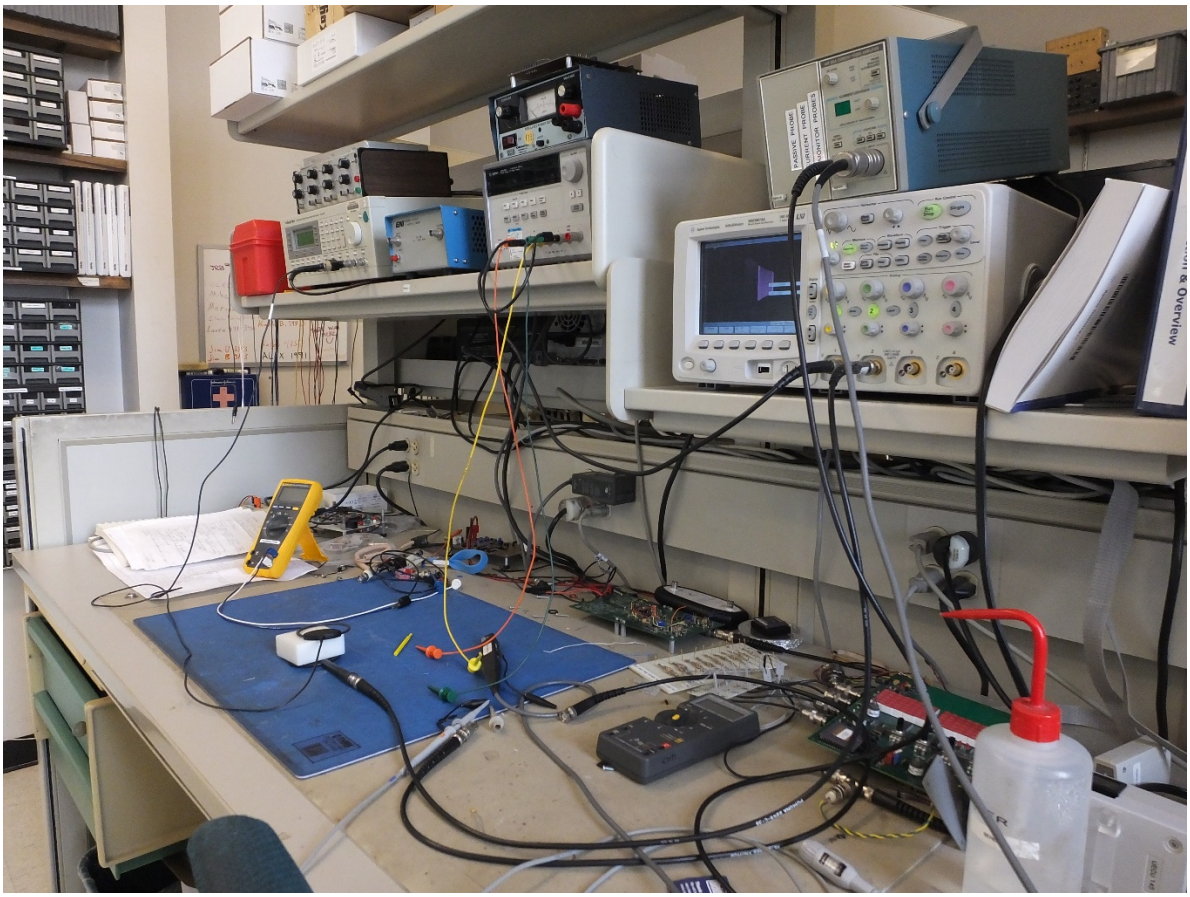
- Extensive knowledge of technology transfer processes, from identifying appropriate partners to re-establishing fabrication and testing protocols within the external subcontracting facilities.
- Working knowledge of the licensing of technologies to 3rd-party vendors/suppliers.



Four types of human-quality implantable electrodes (from top: epimysial stimulating electrode, intramuscular stimulating electrode, epimysial recording (bipolar) electrode, spiral nerve cuff electrode). All electrodes were designed, developed and fabricated within our facility. Depending on the application, electrodes can be fabricated for mono-polar or bi-polar use.

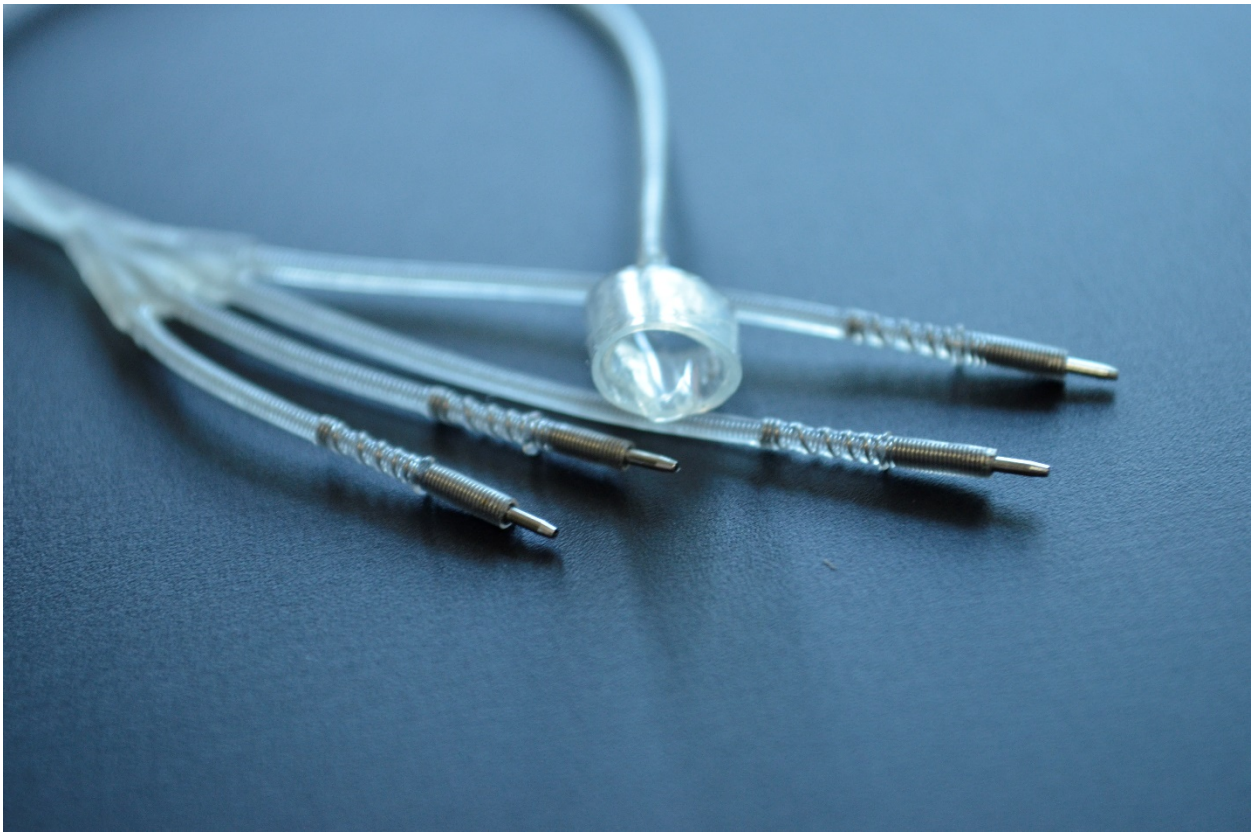


Four types of human-quality implantable electrodes (from left: spiral nerve cuff electrode, epimysial recording (bipolar) electrode, epimysial stimulating electrode, intramuscular stimulating electrode). All electrodes were designed, developed and fabricated within our facility. Depending on the application, electrodes can be fabricated for mono-polar or bi-polar use.

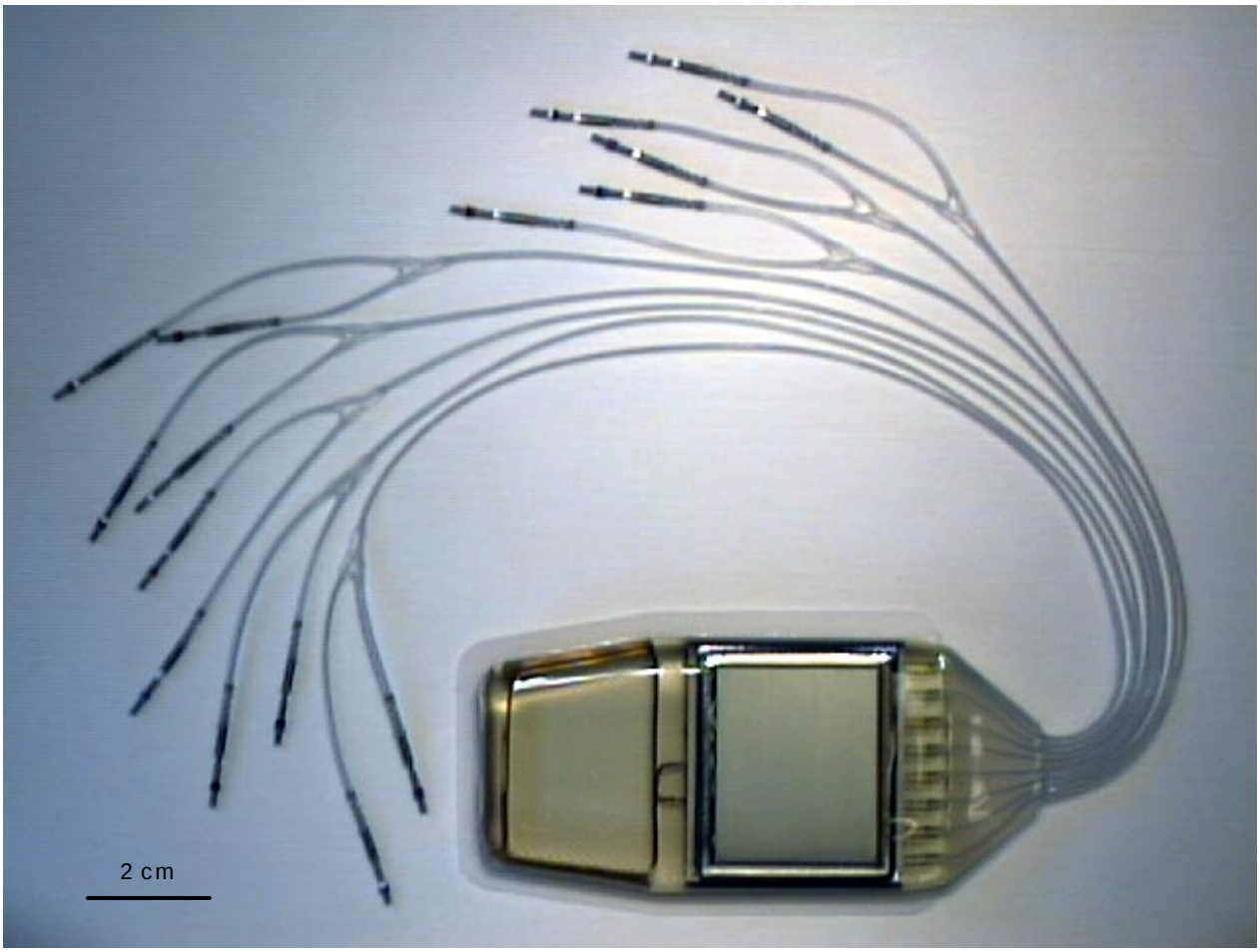


Instrumentation for design, development, fabrication, verification testing and maintenance of our internally-developed medical devices.

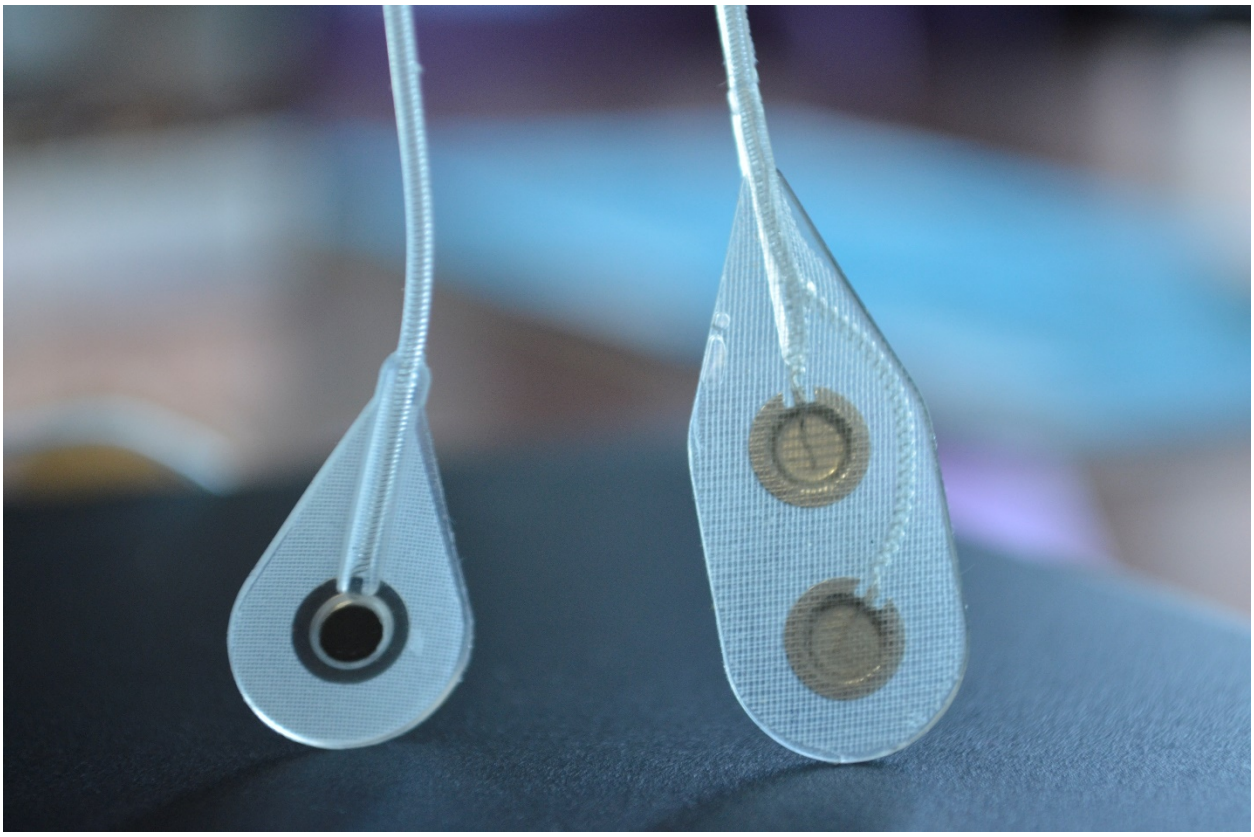
Our staff has nearly 150 man-years of combined experience in the design, development and clinical deployment of implantable technologies for human research.



Spiral nerve cuff electrode in four-contact/quad lead configuration. This electrode is self-sizing and wraps around the epineurium to activate the target nerve entirely or to activate individual fascicles within the nerve bundle. This electrode was designed, developed and fabricated within our facility. Depending on the application, these electrodes can be fabricated for mono-polar or multiplexed use.

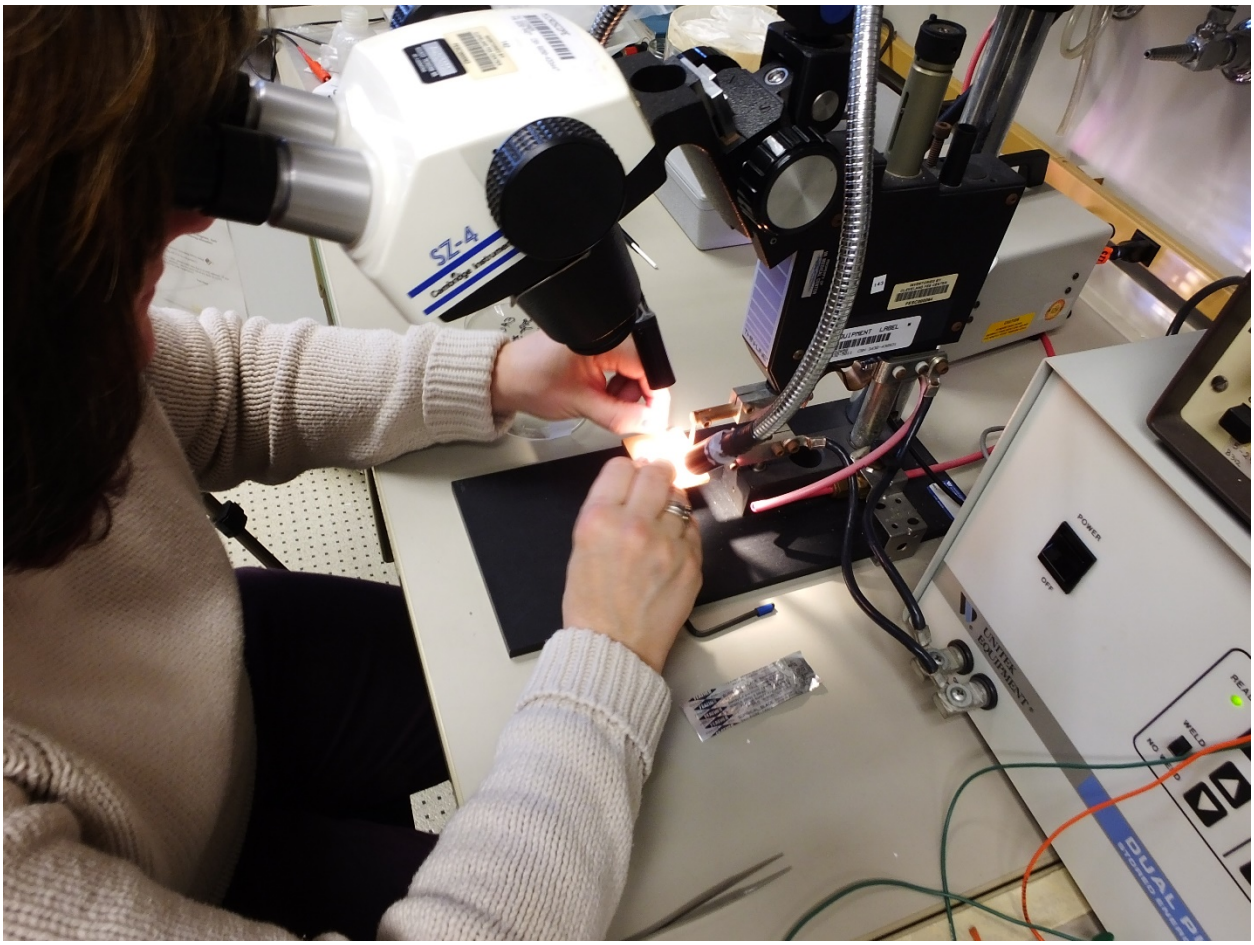


Implantable Stimulator Telemeter (IST). This device is used as a 10, 12, or 16 channel implantable pulse generator (IPG). It is inductively powered and controlled via an external coil which is placed on the skin over the coil (left side of the device). Communication is bidirectional and can accommodate up to 2 bipolar EMG signals.



From left, epimysial stimulating electrode (monopolar), and epimysial recording (bipolar) electrode. This electrode is sutured to the muscle epimysium near the target motor point (for stimulation) or near the best electromyogram (EMG) site (for recording). These electrodes were designed, developed and fabricated within our facility.

We have the facilities and capabilities to take your idea from concept to reality. We can help you demonstrate feasibility or to build devices which will enable clinical data collection for study validation.



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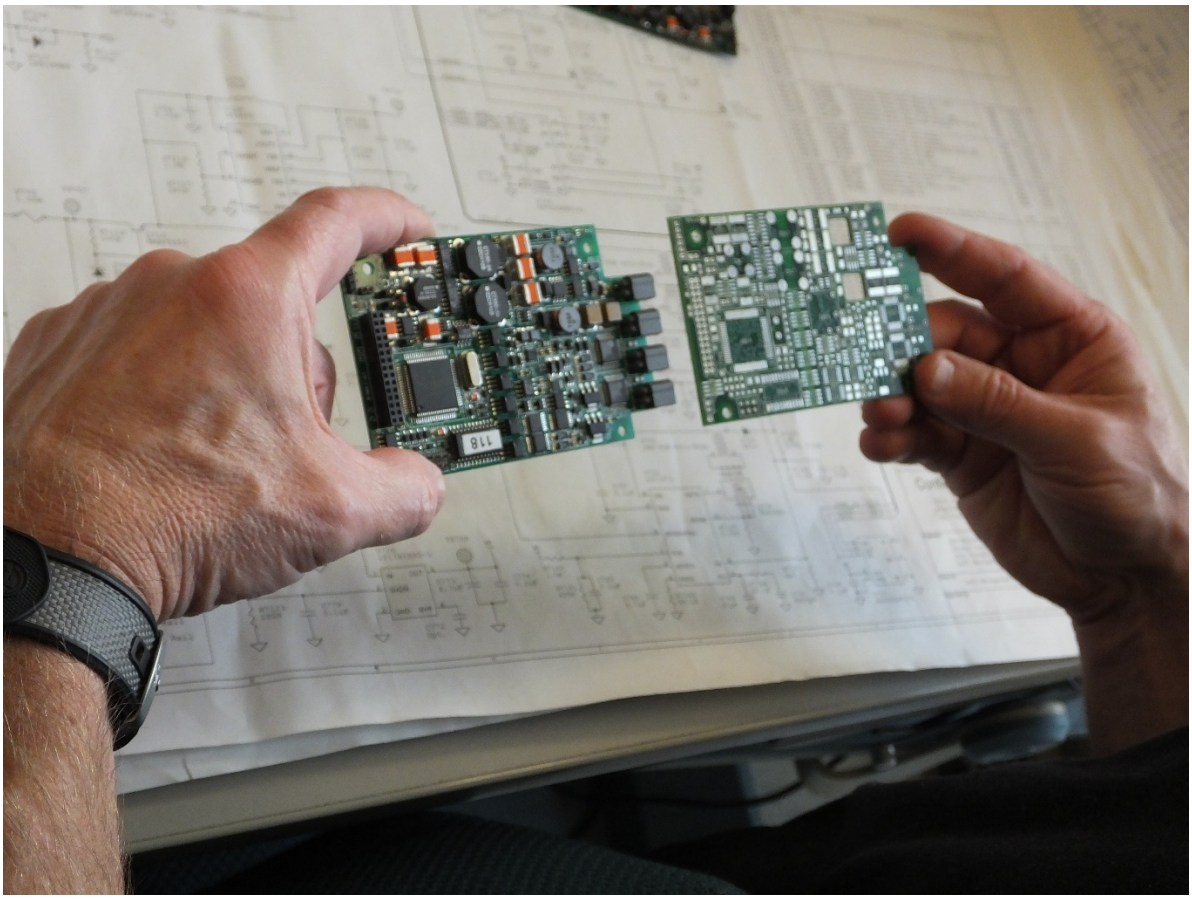

One of our core competencies is in the design, layout, fabrication, assembly and design verification of circuit boards and/or electronic hardware for your idea.

Universal External Control Unit (UECU). This portable, modular, externally worn controller is FDA approved (IDE) for use in the clinical research laboratory and home use. It utilizes a rapid-prototyping approach to application development through the use of Mathworks software (RealTime Workshop, Simulink, XPc Target). This allows the PI to arrive at clinically relevant hardware solutions (both stimulating and recording) more efficiently. These devices were designed, developed, and fabricated within our facility, and can accommodate any combination of implanted stimulation (IRS or IST), surface stimulation, percutaneous stimulation, analog sensor recording.

ISO Class 6 cleanroom facility for the fabrication of implantable medical devices for research under IDE regulations.