Neural Interfaces: Ensuring the Long-Term Reliability of Brain-Computer Interfaces to Control Robotic Devices for Paralyzed Patients

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CDRH/Office of Science and Engineering Labs

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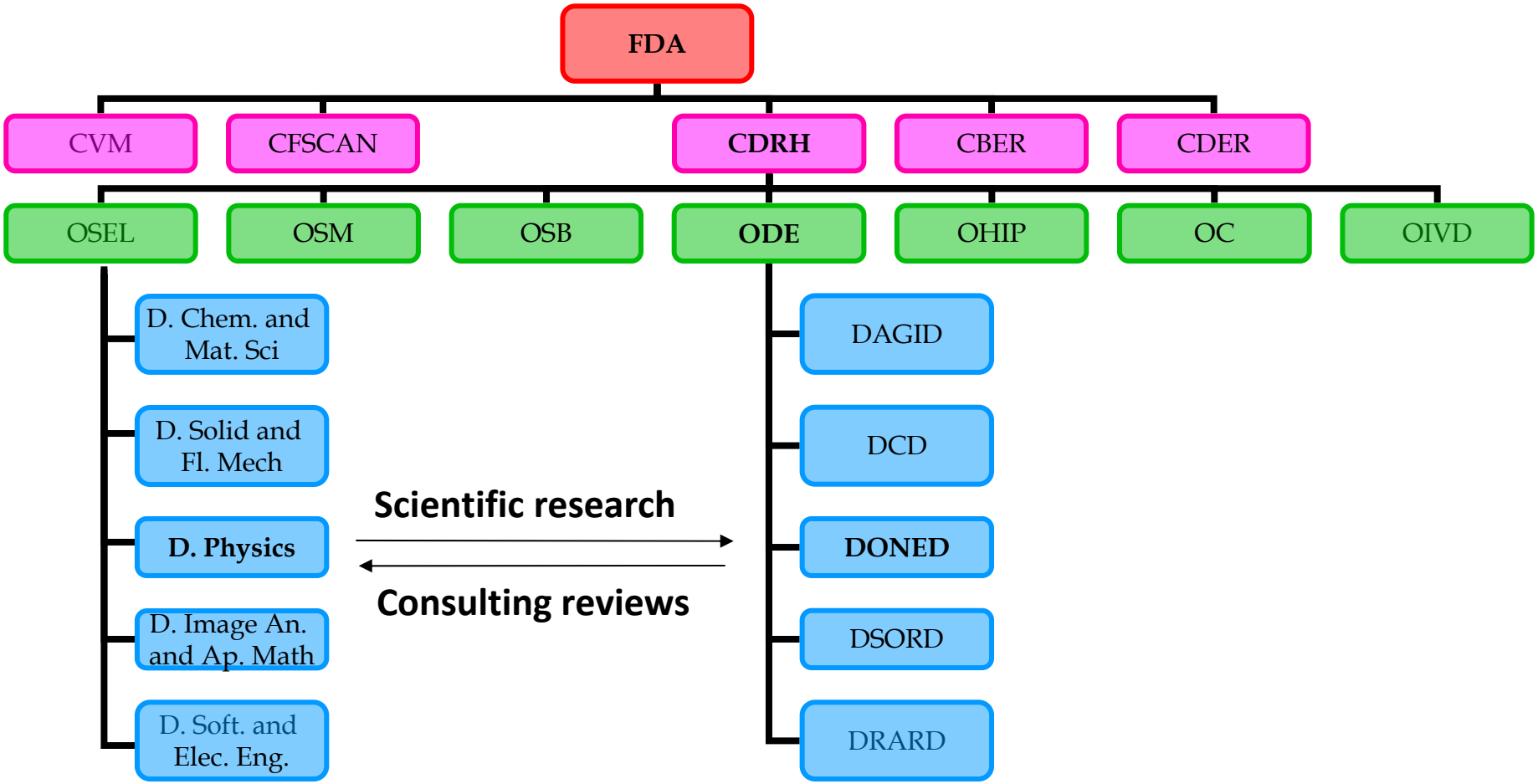
Center for Devices and Radiological Health (CDRH)

We protect and promote the public health by:

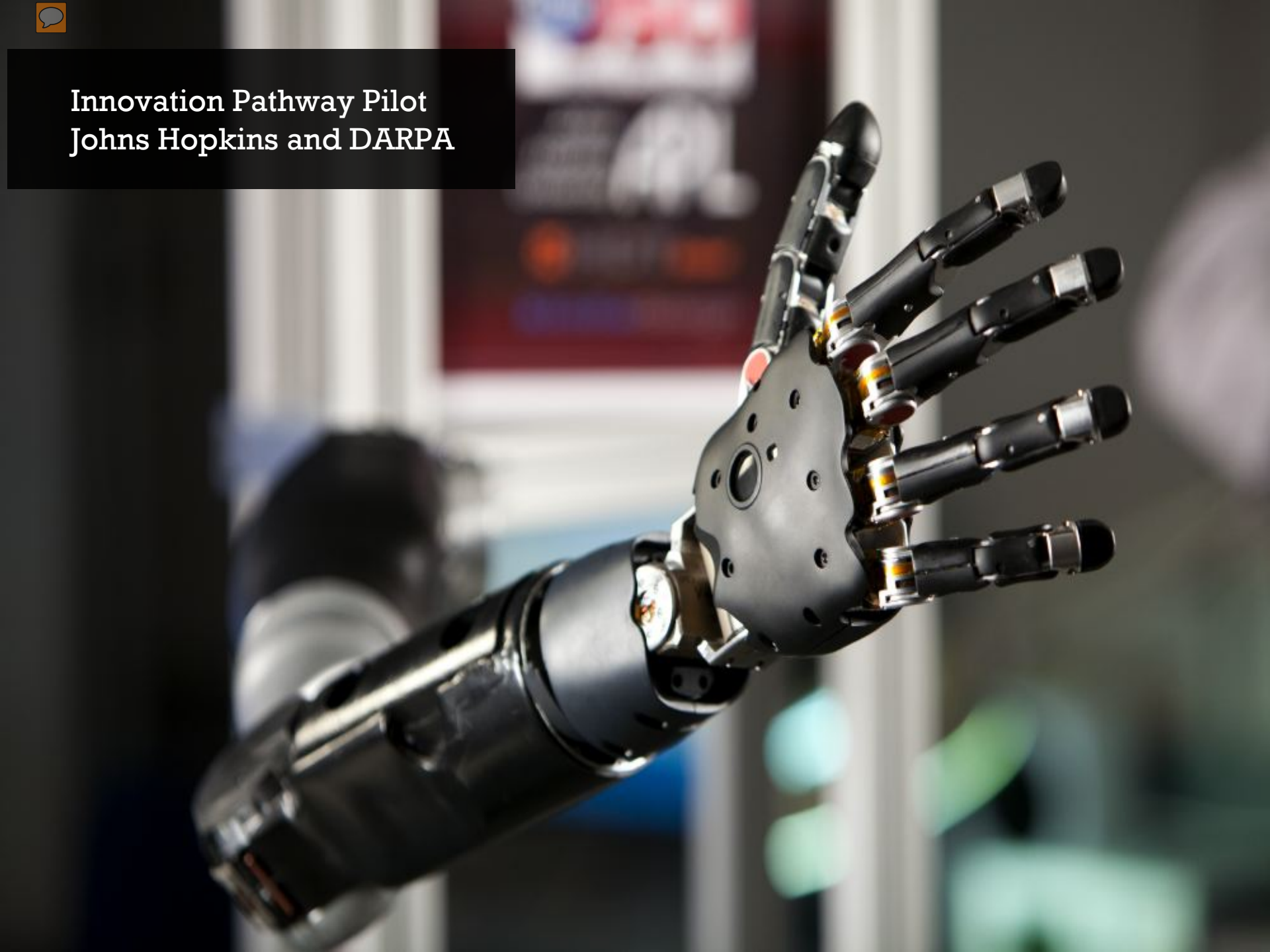
- Assuring the safety and effectiveness of medical devices,
- Assuring the safety of radiation-emitting products
- Fostering innovation throughout the total product life cycle

The products we regulate…

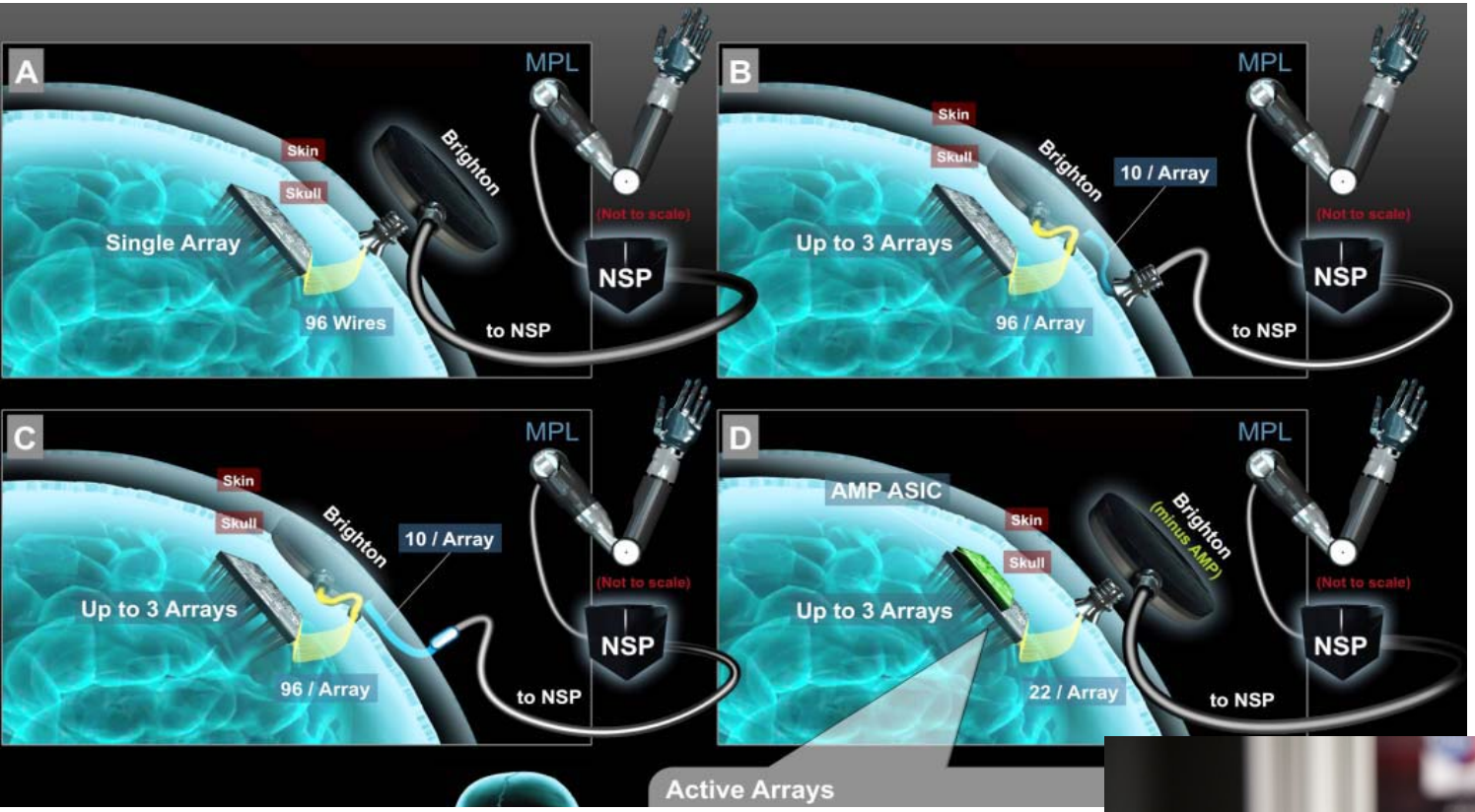


Neuroprosthetic systems

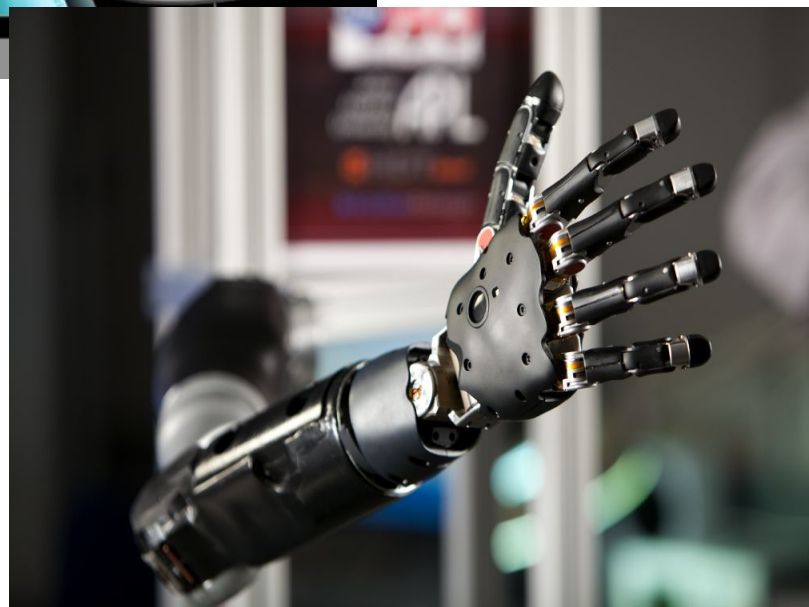
Innovation Pathway Pilot
Johns Hopkins and DARPA



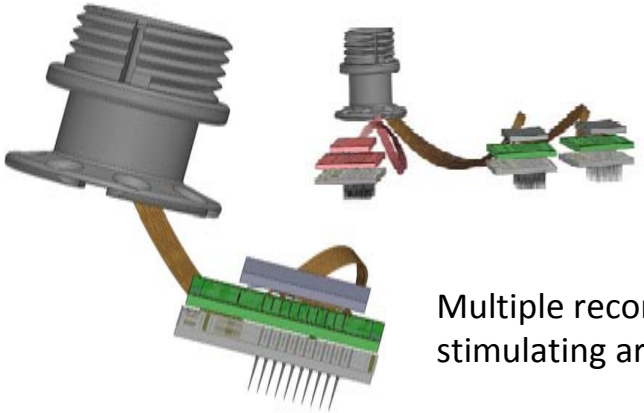
Two Distinct Devices Comprise the System



2. Prosthetic / Robotic Arm



1. Cortical Controller w/ Arrays



Multiple recording and stimulating arrays

Value of Innovation Pathway

Extra attention and early engagement carried challenges for interactions but appeared to better serve the needs of applicant.

"The ability to discern the FDA's concerns earlier in the program enabled us to better focus resources and ultimately will reduce risk and enable more effective use of the Governments funds."
--JHU-APL

Value in using the visibility of the project to address internal FDA hurdles.

Integrated CDRH regulatory and research units to provide scientific expertise to review process and to guide research on brain-computer interfaces in pre-IDE process

Contributed to the ongoing development of research platform to test long-term safety, reliability and effectiveness of neural interfaces

Neuroprosthetics systems in paralyzed patients restore interaction with environment

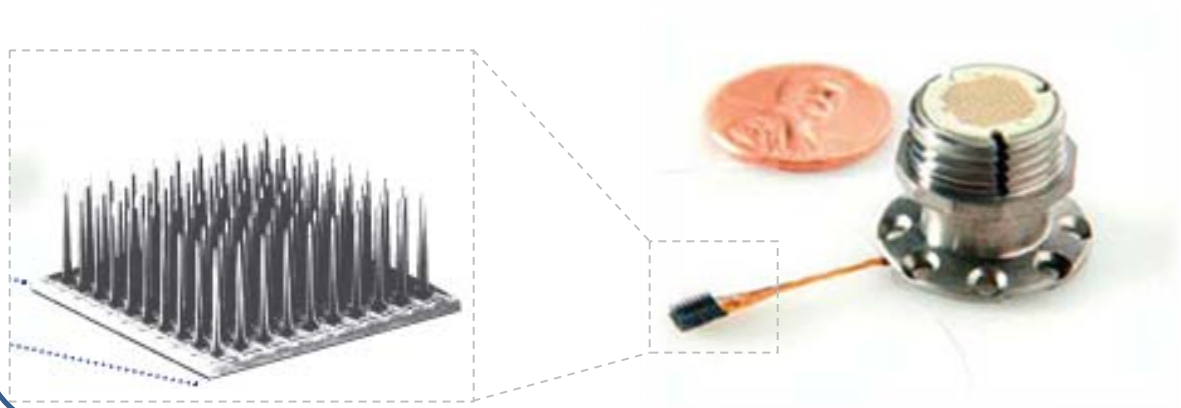
Reach and grasp by people with tetraplegia using a neurally controlled robotic arm

Nature 2012

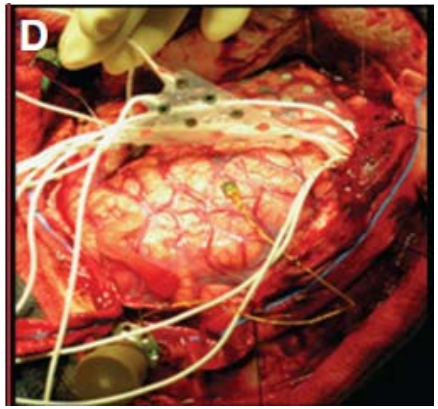
Innovation 1.0

Leigh R. Hochberg[1,2,3,4], Daniel Bacher[2*], Beata Jarosiewicz[1,5*], Nicolas Y. Masse[5*], John D. Simeral[1,2,3*], Joern Vogel[6*], Sami Haddadin[6], Jie Liu[1,2], Sydney S. Cash[3,4], Patrick van der Smagt[6] & John P. Donoghue[1,2,5]

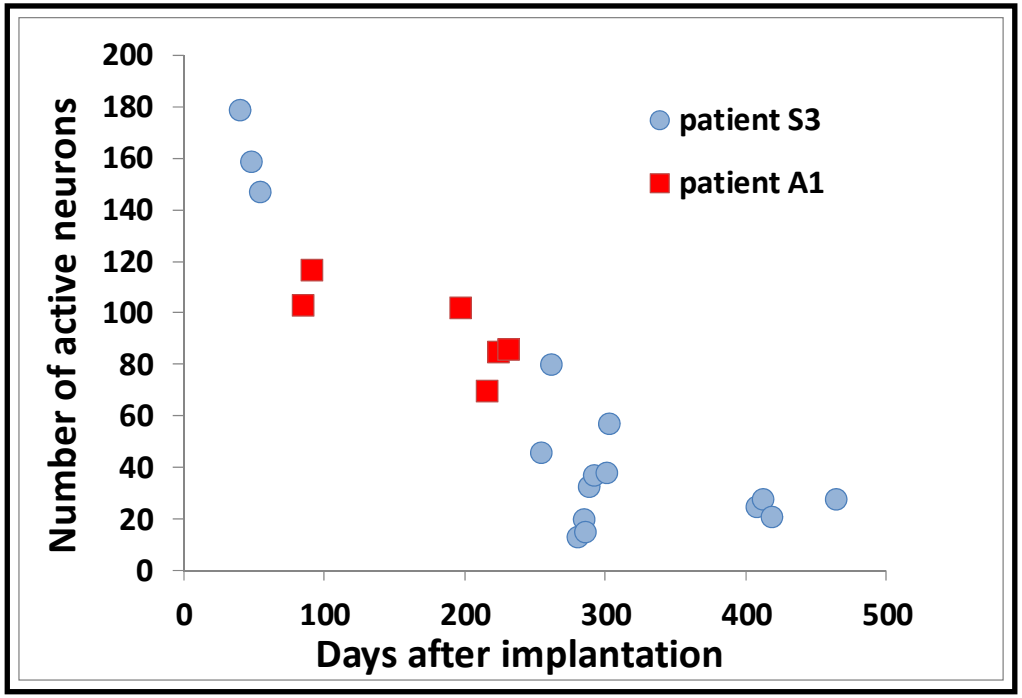
Multi-electrode array (100 electrodes)



Array surgically inserted in to motor cortex



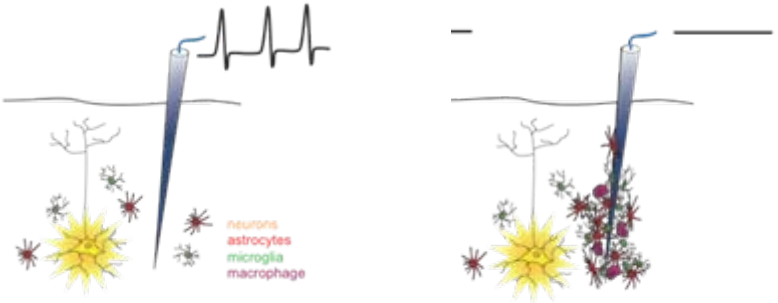
Why do neural signals decline over time?



Two human patients

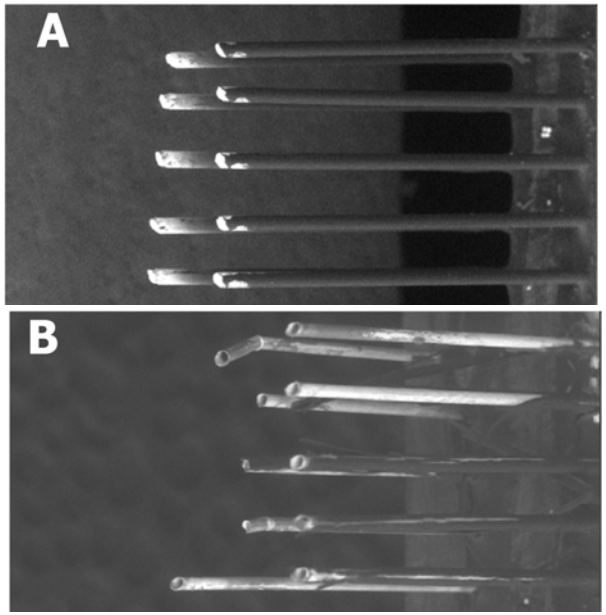
Kim et al 2008; Simeral et al 2011

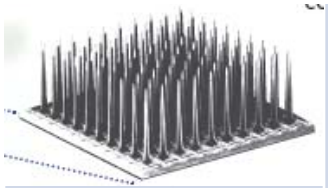
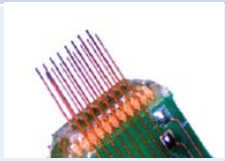
Tissue response



Or…

Biomaterials failure

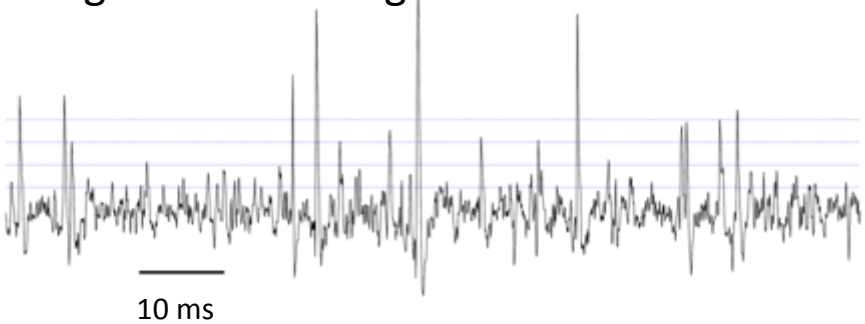


Electrode	Manufacturer	Materials	
	Blackrock Microsystems	Silicon, platinum, parylene	
	Neuronexus Technology	Silicon, platinum/ iridium, silicon nitride	
	Microprobes for Life Science	Platinum/ iridium, ceramic, parylene	
	Tucker-Davis Technology	Tungsten, polyamide	

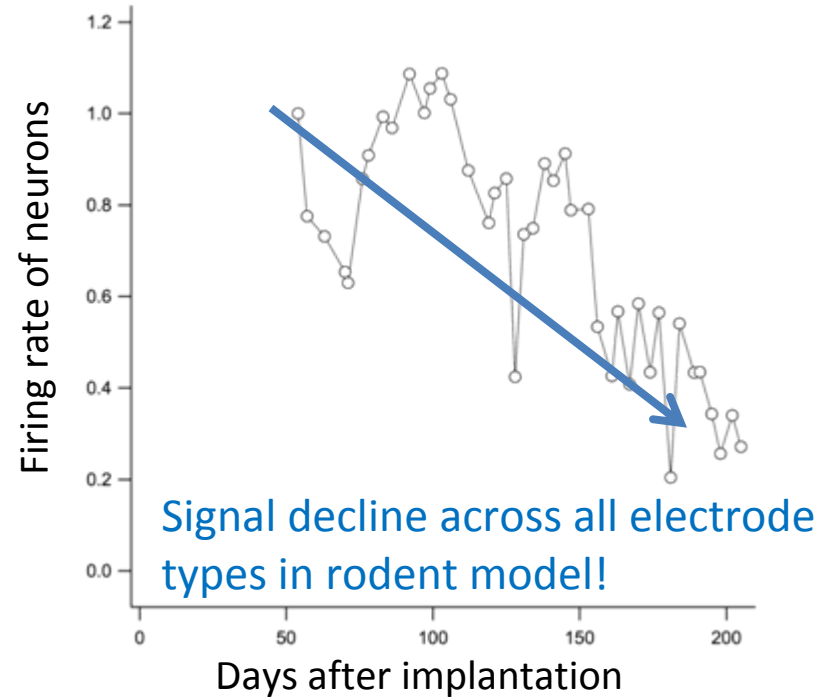
Electrodes implanted in motor cortex of mouse ->
Electrophysiological recordings performed from awake, behaving animal

Understanding tissue response: Electrodes implanted in rodent animal model

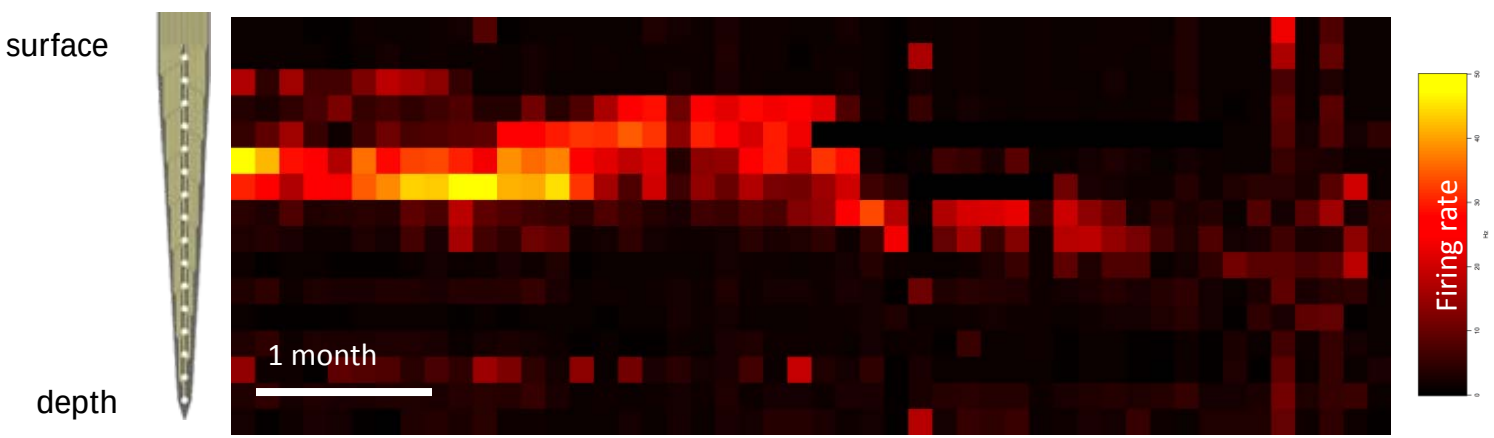
Single neuron firing



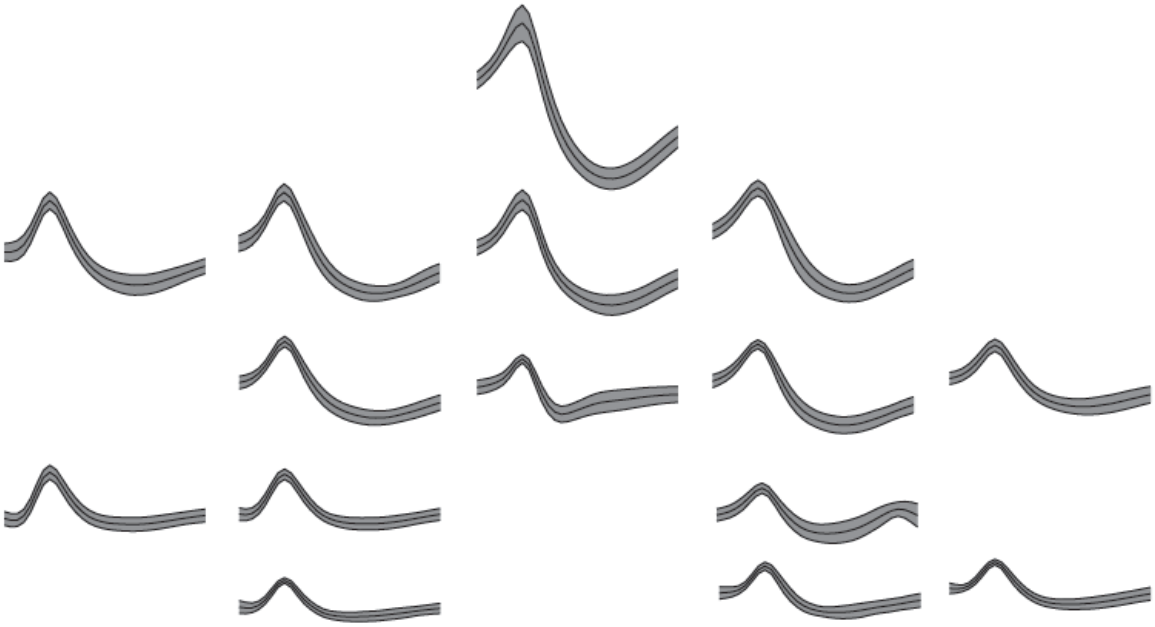
In summary….



Many neurons on 16 electrodes over time



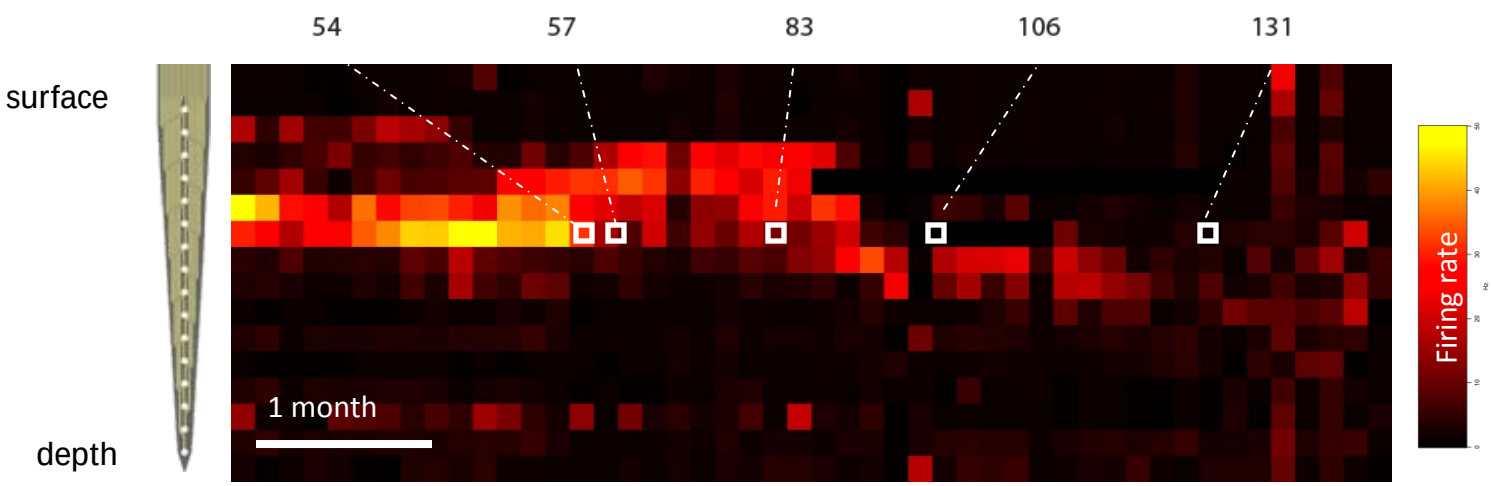
Understanding tissue response: Single unit action potentials over time



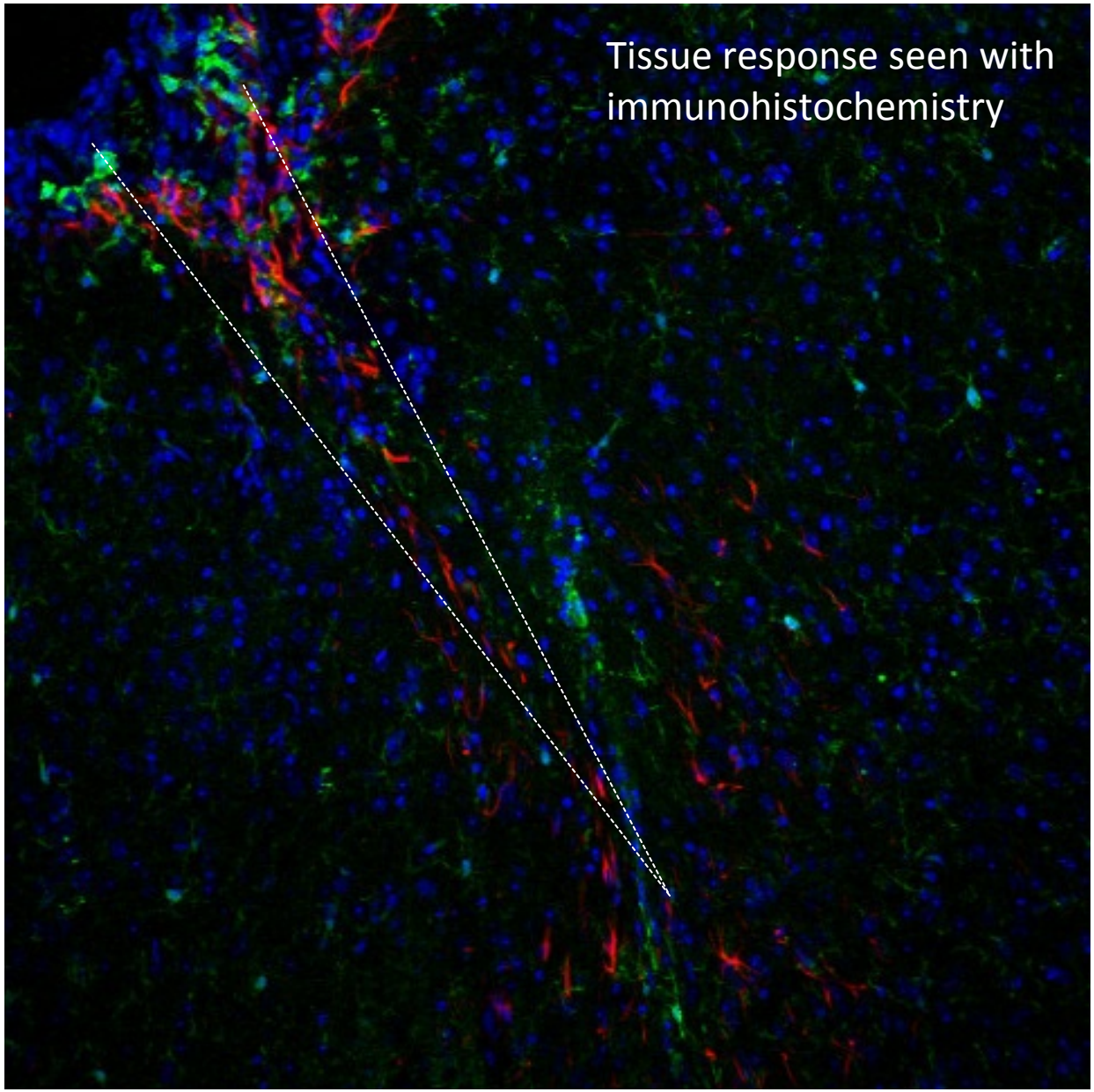
Over time…

Number of single neurons

Amplitude of the action potential



Understanding tissue response: Electrodes implanted in rodent animal model

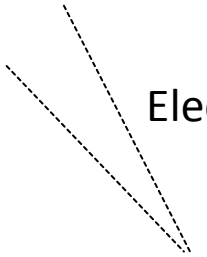


Color codes

Blue - Cell soma

Green - Microglia

Red - Astrocytes

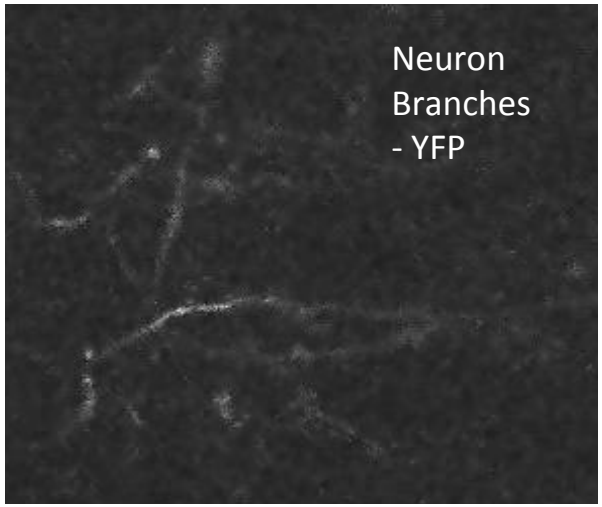


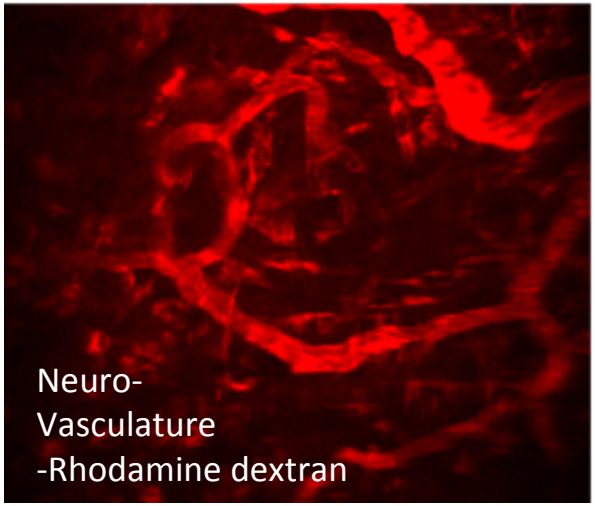
Electrode track

Neurons don't die, but electrode track is surrounded by the brain's immune response

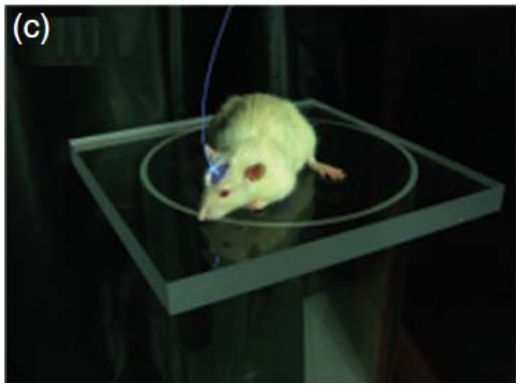
Understanding tissue response: Electrodes implanted in rodent animal model

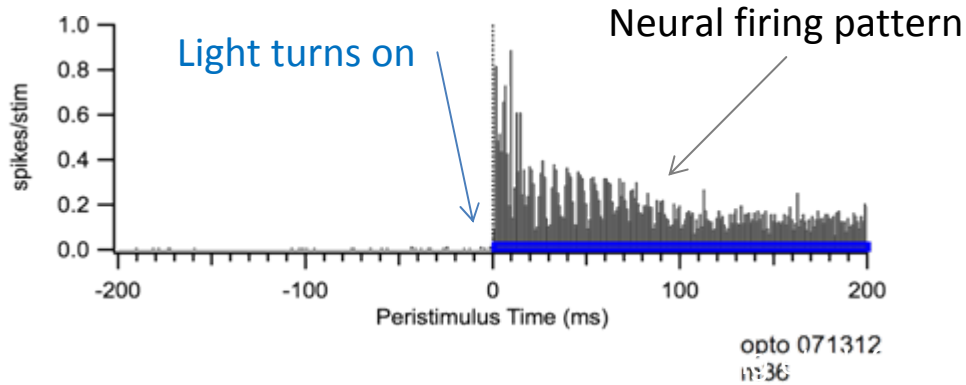
Imaging of cortical neurons and vasculature in alive animals



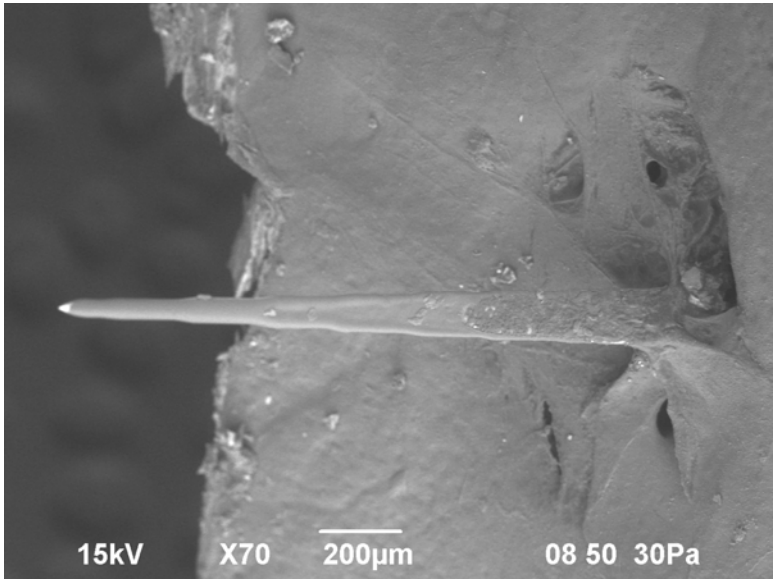


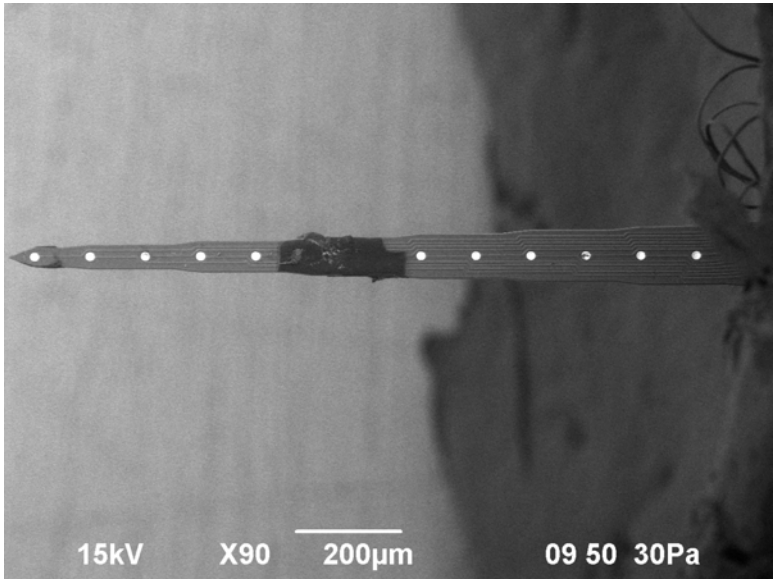
Light-controlled neural firing (optogenetics) in awake, behaving animals





Understanding electrode biomaterials: Explanted array characteristics

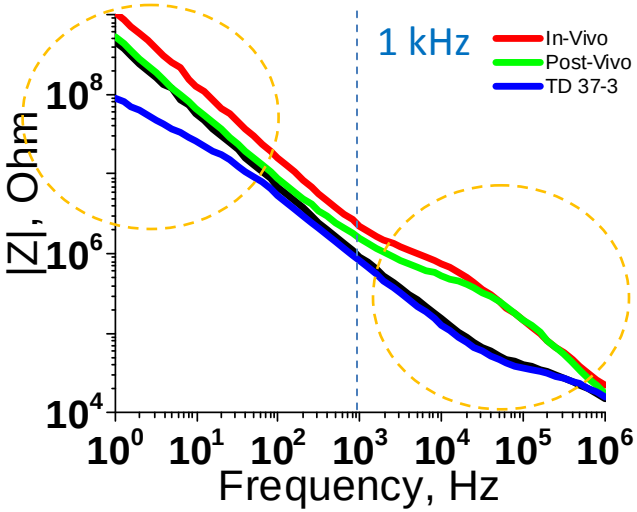




High frequencies unchanged by implantation

Low frequencies show difference

… Best to characterize entire frequency spectrum



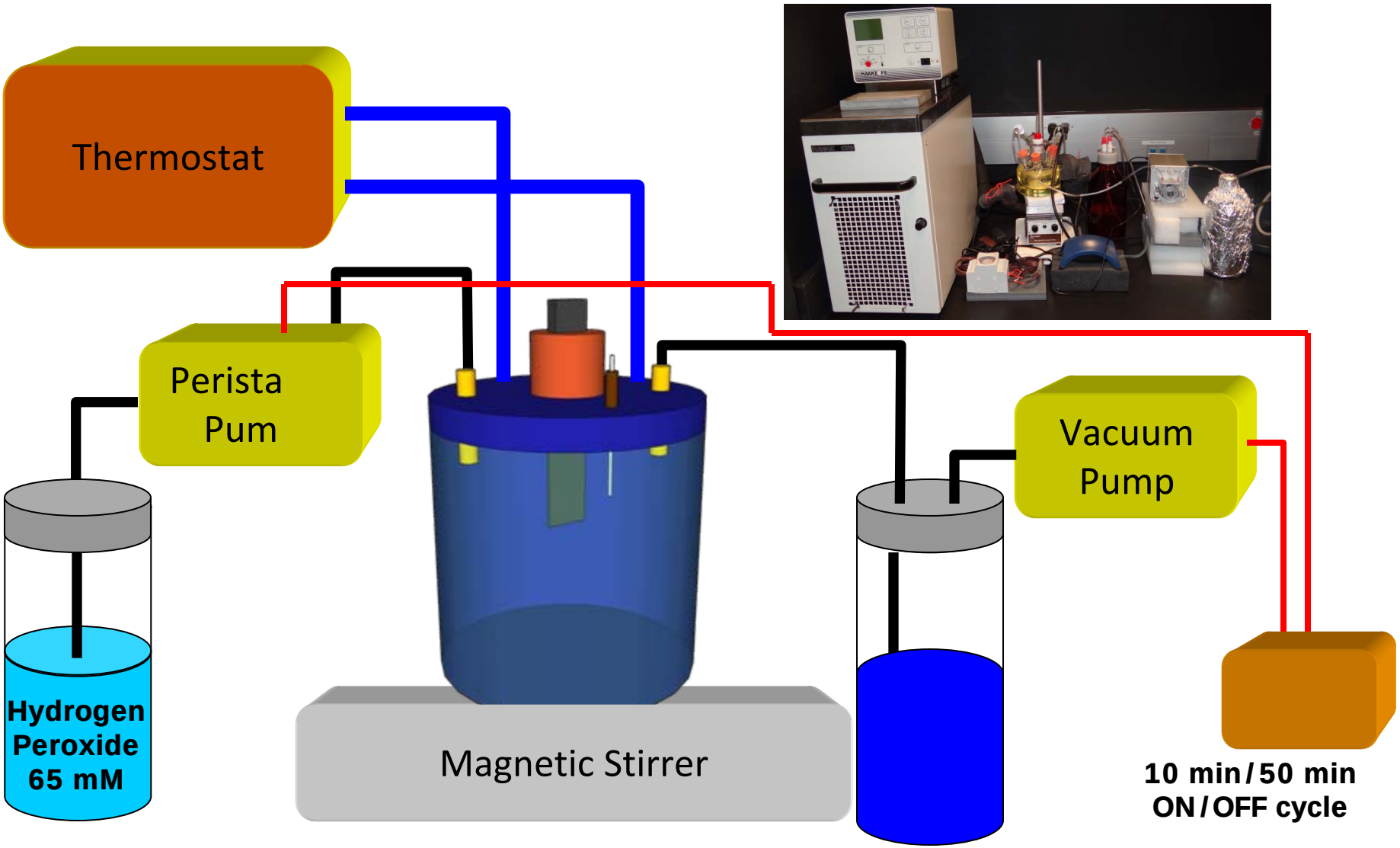
New, from manufacturer

In animal

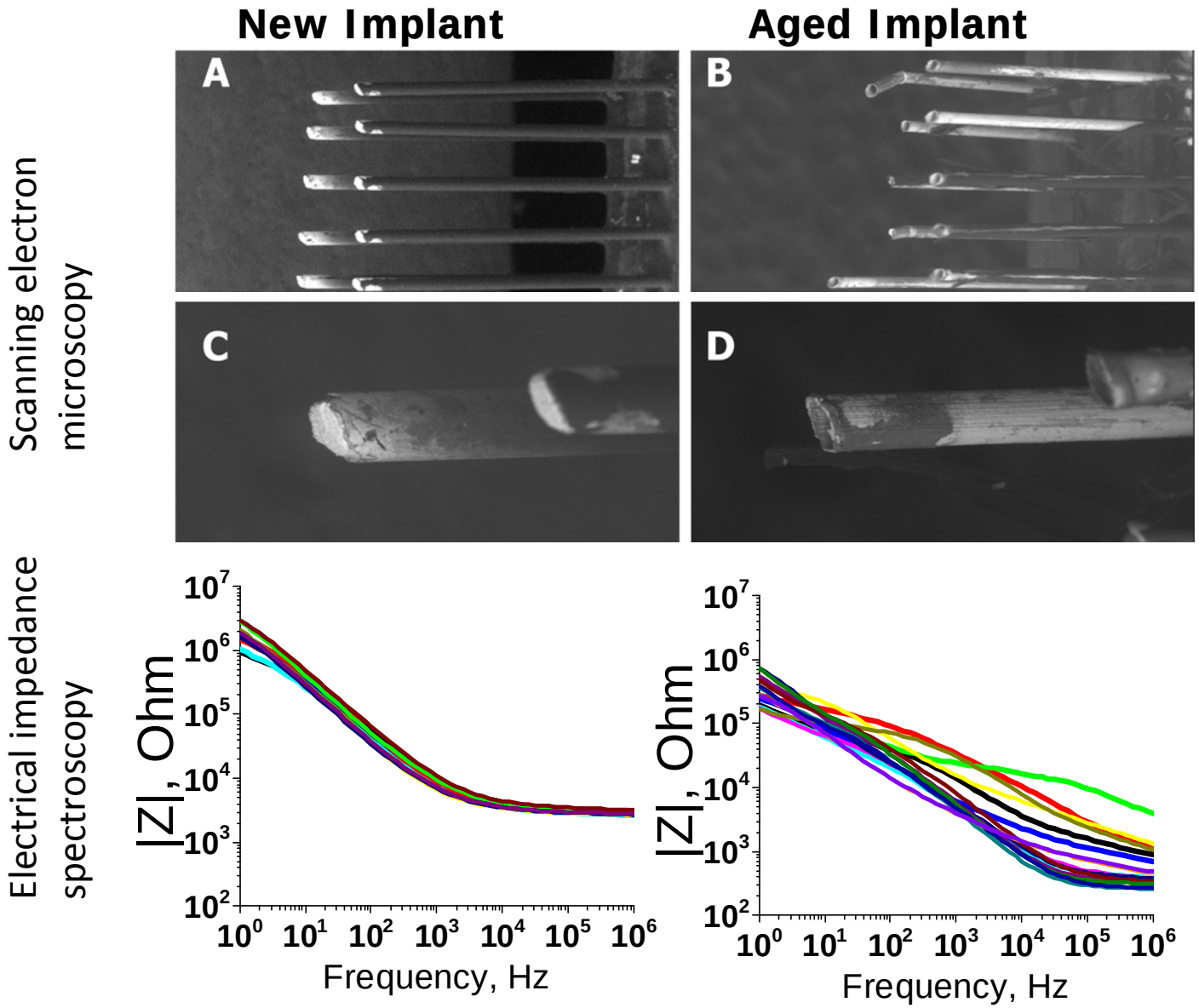
Immediately after explant

After cleaning

Understanding electrode biomaterials: Accelerated aging in “Artificial Brain”



Understanding biomaterial failure : “Artificial brain” for accelerated aging of neural implants



In summary…

Signal decline from cortical implants is independent of electrode array style or form factor

Electrodes evoke a strong immune response in the brain

Electrical impedance spectroscopy hints that changes in the electrode materials may also contribute

Certain materials may be more susceptible to aging processes

…. Success in long-lasting electrode arrays likely involves strategies to mitigate both biological and material failure mechanisms

Thank you!

Neural Implant Lab:

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