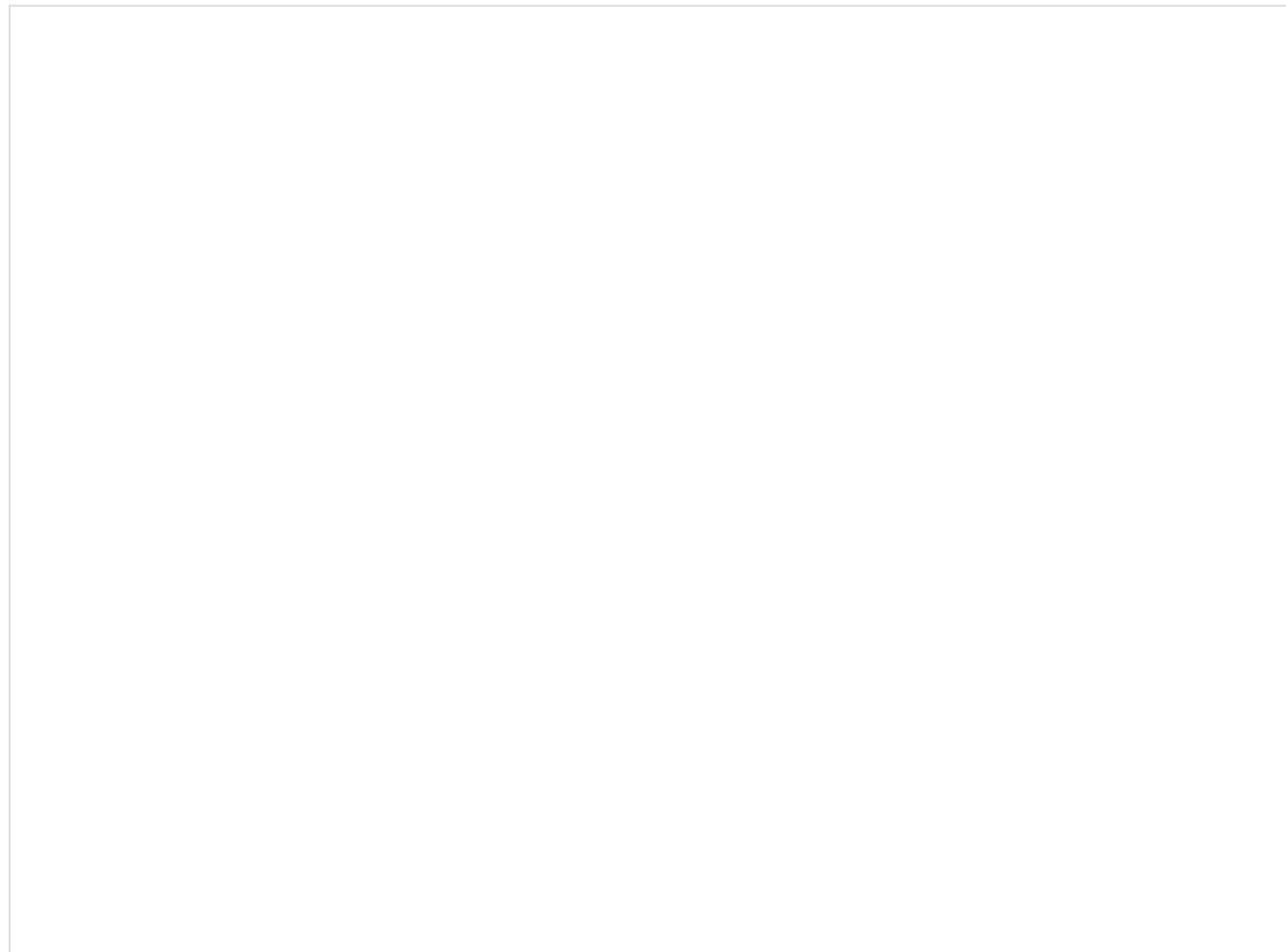


synchron

## **Synchron Announces First Human U.S. Brain-Computer Interface Implant**

*- First U.S. Human Procedure Performed at Mount Sinai Health System in New York City*



Stentrode™ is implanted within the motor cortex of the brain via the jugular vein in an endovascular procedure.

July 19, 2022 08:00 AM Eastern Daylight Time

NEW YORK--(BUSINESS WIRE)--Synchron, an endovascular brain-computer interface (BCI) company, today announced the first human BCI implant in the United States. This procedure represents a significant technological milestone for scalable BCI devices and is the first to occur in the U.S. using an endovascular BCI approach, which does not require invasive open-brain surgery.

The procedure was performed at Mount Sinai West in New York, led by clinical investigator Shahram Majidi, MD, assistant professor of neurosurgery, neurology and radiology at the Icahn School of Medicine at Mount Sinai. The procedure was performed in the angiography suite with a minimally invasive, endovascular approach. Mount Sinai's Department of Rehabilitation and Human Performance helped coordinate the procedure.

The procedure marks the first U.S. patient implant in Synchron's COMMAND trial, which is being conducted under the first investigational device exemption (IDE) awarded by the FDA to a company assessing a permanently implanted BCI. The U.S.-based trial is being conducted with support from the NIH Neural Interfaces Program.

The COMMAND study will assess the safety and efficacy of the company's motor BCI technology platform, including the Stentrode™, in patients with severe paralysis with the goal of enabling the patient to control digital devices hands-free. Study outcomes include the use of brain data to control digital devices and achieve improvements in functional independence.

"This is an incredibly exciting milestone for the field, because of its implications and huge potential," said Shahram Majidi, MD, the neurointerventional surgeon who performed the procedure, and assistant professor of neurosurgery, neurology and radiology at the Icahn School of Medicine at Mount Sinai. "The implantation procedure went extremely well, and the patient was able to go home 48 hours after the surgery."

"We are beyond excited to get to work with our patient, guiding them through the training process as they learn to use this device to live more independently and, most importantly, communicate with their family and friends," said David Putrino, PhD, PT, Director of Rehabilitation Innovation for the Mount Sinai Health System and a Principal Investigator of the COMMAND study.

"The first-in-human implant of an endovascular BCI in the U.S. is a major clinical milestone that opens up new possibilities for patients with paralysis," said Tom Oxley, MD, PhD, CEO & Founder, Synchron. "Our technology is for the millions of people who have lost the ability to use their hands to control digital devices. We're excited to advance a scalable BCI solution to market, one that has the potential to transform so many lives."

The Stentrode is implanted within the motor cortex of the brain via the jugular vein in a minimally-invasive endovascular procedure. Once implanted, it detects and wirelessly transmits motor intent using a proprietary digital language to allow severely paralyzed patients to control personal devices with hands-free point-and-click. The trial will assess the impact of everyday tasks such as texting, emailing, online shopping and accessing telehealth services, and the ability to live independently. The FDA granted Breakthrough Device designation to Synchron in August 2020.

Synchron will continue to advance enrollment in its COMMAND trial as the industry-first FDA-approved clinical trial for a permanently implanted BCI in the U.S. Recently reported [long-term safety results](#) have demonstrated this technology to be safe in four patients out to 12 months in Synchron's SWITCH trial in Australia, as reported at the 2022 American Academy of Neurology Conference.

#### **About the Stentrode™**

Synchron's flagship technology, the Stentrode, is an endovascular brain implant designed to enable patients to wirelessly control digital devices through thought and improve functional independence. Synchron's foundational technology, a motor neuroprosthesis (MNP), or motor BCI, is implanted via the jugular vein using neurointerventional techniques commonly used to treat stroke, and does not require drilling into the skull or open-brain surgery. The system is designed for patients suffering from paralysis as a result of a range of conditions. It is designed to be user friendly and dependable for patients to use autonomously.

#### **About Synchron, Inc.**

Synchron, an endovascular brain interface company, is a leader in implantable neural interface technology. The clinical-stage company is developing a neuroprosthesis for the treatment of paralysis and the first endovascular implantable neuromodulation therapy. Future applications include the potential to diagnose and treat conditions of the nervous system, including Parkinson's disease, epilepsy, depression, and hypertension. Synchron is headquartered in New York City, with R&D facilities in Melbourne, Australia. For more information, visit [www.synchron.com](http://www.synchron.com). Follow us on Twitter [@synchroninc](#).

## **Contacts**

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## Social Media Profiles

Synchron on Twitter

Synchron on LinkedIn

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THE SCIENCE

# Introducing Neuro EP

A new frontier in the treatment  
of neurological disorders.

## The brain is complex.

synchron



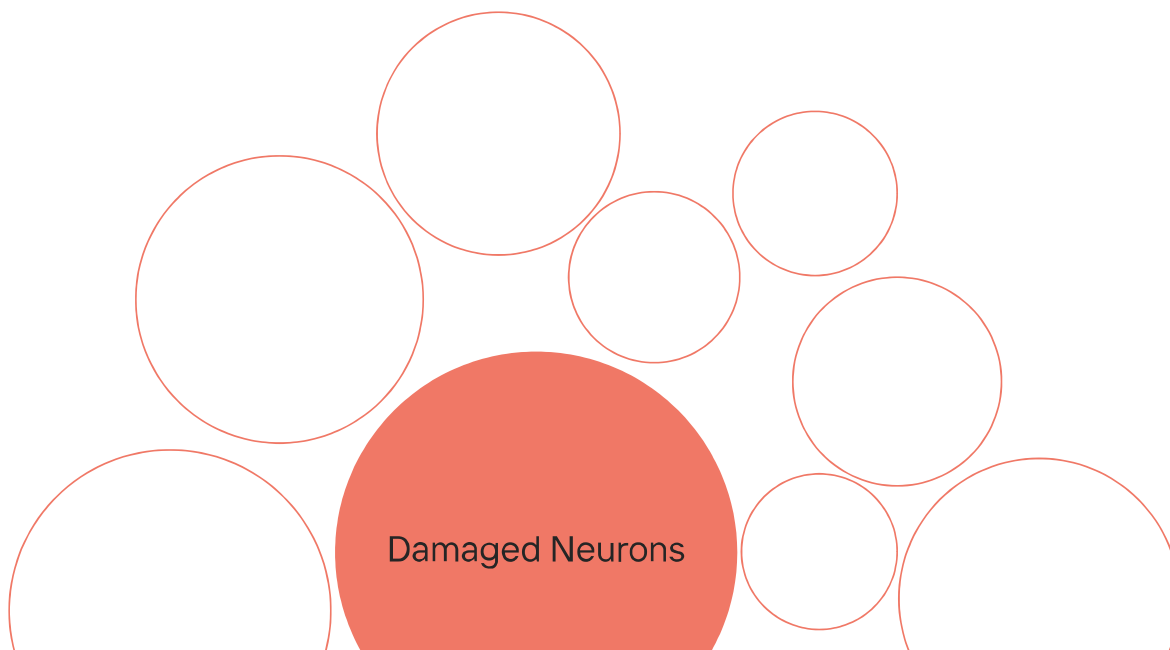
of neurological disorders.

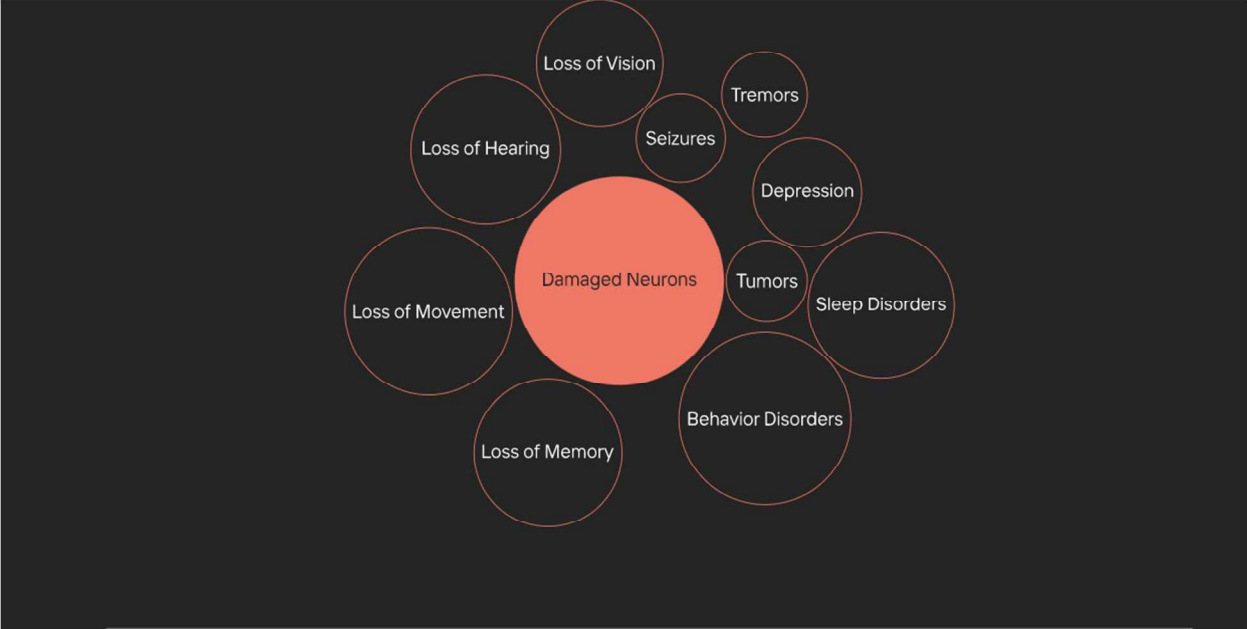
# The brain is complex.

There are billions of inaccessible neurons and over 400 miles of blood vessels that navigate every part of the brain.

# The Challenge

Damaged neurons can wreak havoc on our bodies and lives.



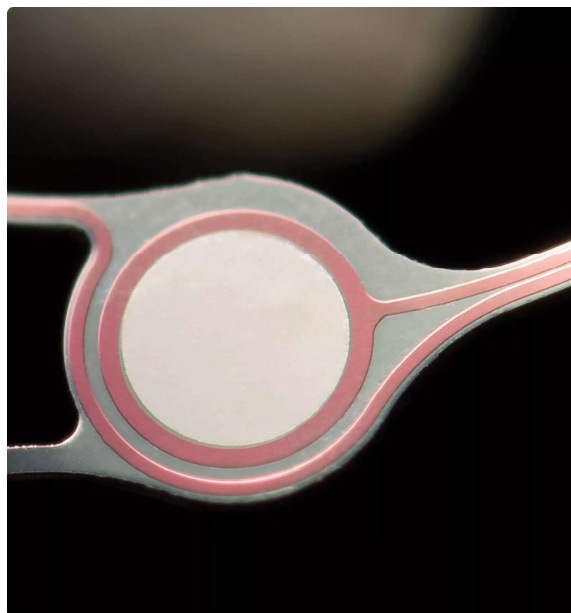




# The Endovascular Solution

Our team has collectively spent decades studying these pathways and the

application of our technology with an endovascular surgical procedure. We have solved how to deliver electronics into the wall of the blood vessel, giving us access to an unprecedented amount of data from untouched areas of the brain. Applications of Neuro EP will fundamentally change how we study, diagnose, and treat the brain.



## Neuro EP

The science of restoring, treating, and mapping the

## Neuroprosthetics

The restoration of a lost brain function, e.g loss of movement or vision.

# Neuro EP

The science of restoring, treating, and mapping the electrical activities of the brain.

Neurointerventional Electrophysiology (Neuro EP) is a new field of medical science that combines and elevates three existing areas of research: neuroprosthetics, neuromodulation, and neurodiagnostics.

Neuroprosthetics

Neuromodulation

Neurodiagnostics

180,000,000<sup>1</sup>

People with severe disabilities

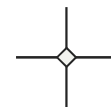
1. World Health Organization Fact Sheets

ABOUT US

# Radically outpacing traditional BCI.

Our mission is to create an  
endovascular implant that can  
transfer information from every  
corner of the brain at scale.

In the News



OUR STORY

# Innovating an Industry

Since 2012, we have been developing a solution that avoids the need for open brain surgery by using a minimally-invasive procedure.



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# Quick facts about us

# Quick facts about us

## 01

The device, the stentrode™, is 8mm in diameter and made from a flexible alloy called nitinol. It is inserted into Superior Sagittal Sinus in the brain via the jugular vein.

## 02

Initial grant funding was provided to a lab in the University of Melbourne by the U.S. Defense Advanced Research Projects Agency (DARPA) and Department of Defense (DoD).

## 03

In 2020, FDA awarded the stentrode™ the Breakthrough Device Designation. In 2021, Synchron became the first company to receive an FDA IDE to conduct trials of a permanently implantable BCI.

## 04

Series B funding was led by Khosla Ventures, with total capital raised now of \$70M, including support from the

## 05

Synchron is headquartered in Brooklyn, New York, and has an office in Melbourne, Australia.



Amanda Zwarenstein  
Director,  
Product



Chloe Brown  
Director,  
Strategic  
Marketing



Kimberly Ha  
Communications  
Lead

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# Awards



The Best Inventions of 2021  
Time Magazine 2021

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# Partners



Next Big Things in Tech  
Fast Company 2021

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# Board



## Awards



The Best Inventions of 2021  
Time Magazine 2021

## Partners



Next Big Things in Tech  
Fast Company 2021

## Board

## Advisors



Most Disruptive Innovator  
Award  
Newsweek 2021



Innovation Award  
Society of Vascular and  
Neurointerventional  
Neurology 2021



BCI Award  
BCI Award  
Foundation 2021