

# Longeviti Launches the Customizable ClearFit™ Implant to Restore Cranial Voids and Correct Skull Deformities

The ClearFit allows surgeons to reconstruct the cranium while simultaneously observing neurological anatomy and critical components

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**Longeviti Neuro Solutions →**

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HUNT VALLEY, Md., Sept. 4, 2018 /PRNewswire/ -- Longeviti Neuro Solutions (Longeviti) today announced the U.S. commercial launch of its novel ClearFit™ implant solution to correct and/or restore bony voids or defects of the cranium. This unique, clear, patient specific implant enables neurosurgeons to see neuroanatomy and critical functional components beneath the ClearFit once it is implanted.

"The real advantage to this system is the ability to see what's underneath the cranioplasty," said Dr. Justin Caplan, Assistant Professor of Neurosurgery with Johns Hopkins School of Medicine. "Now instead of having to worry if there is blood accumulating putting pressure on the brain, the surgeon can see this directly right up until the wound is closed. Here the advantage is *clear!*"

The Longeviti Neuro Solutions ClearFit Implant, which received a 510(k) clearance from the U.S. Food and Drug Administration in March 2018, is made of polymethyl-methacrylate (PMMA), a biocompatible material with over 40 years of proven clinical performance. The ClearFit uses a patient's CT scans and a novel 3D-printing process to ensure a precise fit and restorative

contour. The clear, radiopaque, and sonolucent ClearFit enables surgeons the newfound ability to see important neuroanatomy through the implant, providing increased ultrasound visibility for post-operative monitoring.

"The implants were great to work with and easy to customize on the table," said Dr. Gabriel F. Santiago, Neuroplastic Surgeon and Lieutenant Commander of the U.S. Navy. "The ability to see through the clear implant at the anatomy underneath is a game-changer with regards to ensuring an epidural bleed is not occurring at the time of scalp closure."

The launch is Longeviti's second national product launch in two months following the launch of the InvisiShunt® at the at the 15th National Conference on Hydrocephalus: HA CONNECT.

"For patients who require a cranioplasty as a result of trauma and/or restorative surgery, there is no one-size-fits-all treatment option," said Jesse Christopher, Co-Founder and CEO of Longeviti. "Building on the recent launch of the InvisiShunt and our 'first-in-human' experiences published in several journals such as Operative Neurosurgery, Longeviti is proud to be able to offer patients innovative, customizable solutions for various neurological procedures."

The ClearFit implant is available in three different designs:

- Standard ClearFit
- Complex ClearFit
- Single-Stage ClearFit

Neurosurgeons can order a ClearFit by uploading a CT scan to Longeviti's Secure File Exchange where a customizable design is proposed to the neurosurgeon and finalized. With a proprietary process consisting of 3D-printing, CT scans conversion to Cad/Cam, and an expert design team, Longeviti is able to deliver a personalized implant for the patient.

Cranioplasty procedures are indicated for correcting skull defects as well as providing enhanced cerebral protection, improving one's appearance with reconstructive symmetry, and reversing the under-diagnosed "sunken flap or Trephined syndrome". Historically, larger size-

craniotomy and craniectomy patients are at increased risk for bone flap-related complications including infectious osteomyelitis, sterile resorption, and/or visual deformities.

### **About ClearFit™**

Longeviti's ClearFit is patient-specific, implantable prosthetic plates intended to correct and/or restore bony voids and/or defects of the cranium. These cranial implants are clear in color unlike many existing products on the market, and at the same time, provide the time-tested safety and dependability of PMMA. ClearFit implants are designed using the patient's CT scan data. The devices are provided sterile to the surgeon and are fixated to the surrounding bone using commercially-available fasteners.

### **About Longeviti**

Longeviti is a neuro-innovation company creating platforms for novel medical devices by utilizing the latest in advanced technology. Longeviti was founded by leading medical device industry executives, biomedical engineers, and multidisciplinary surgeons. Our team collaborates closely with industry and academia to bring promising neuro-therapies expeditiously from the lab to the commercial market. For more information, visit [Longeviti.com](http://Longeviti.com), and connect with us on Facebook and LinkedIn.

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