longeviti

CLEARFIT

IMAGING WORKFLOW

Visit Our Website
www.longeviti.com

Longeviti Neuro Solutions

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Disclaimers:

FOR HEALTHCARE PROFESSIONALS ONLY

Transcranial imaging using the device should only aid in the clinical workflow and not replace any part of the current routine care. Transcranial stimulation should not be applied. Please see product IFU for additional warnings and considerations.

GETTING STARTED

Personnel	Role
SURGEON/ RESIDENT	triage for a quick look with a handheld or POC ultrasound to make clinical decisions in hospital or clinic
NEUROINTENSIVIST	triage or full diagnostic exam for clinical decision making in hospital
PA/NP or RN	triage or routine scan for surveillance, follow up of complication, or measurements
SONOGRAPHER	diagnostic scan with high resolution ultrasound for any clinical indication

CLEARFIT IMPLANTED

Once ClearFit is implanted, ClearFit should be noted in the electronic charting system.

Dictation: An Ultrasound Penetrable replacement cranial plate was implanted over/in the cranial defect (ICD-10 PCS Code: XNR80D9).

This could be in a pre-operative or operative note. **Identify who will be imaging during inpatient stay AND clinic. Longeviti will provide training to these individuals.**

A member from the surgical team (i.e. resident or APP) should follow the patient from the OR to the floor, communicate patient status, and that a ClearFit has been implanted, allowing for post-operative imaging using ultrasound.

INPATIENT STAY

Nurse

- ClearFit patients are unique because their cranial implant enables bedside ultrasound imaging, no transport needed.
- Ultrasound is a quick diagnostic tool to assess ClearFit patients presenting with new symptoms.
- Follow protocols for appropriate sterile precautions (sterile probe cover, sterile gel, Bacitracin, etc.).
- Develop a process to inform care team that patient has a ClearFit (ultrasound penetrable) implant.

INPATIENT **STAY**

Neurosurgical Care Team

- Monitor for complications such as pseudomeningocele formation, new hemorrhage, midline shift, ventricular size enlargement, and bypass patency scanning as appropriate.
- Consideration: The first post-op ultrasound should be performed 24-48 hours after surgery to allow for resorption of air and epithelialization of the surgical wound. Use a proper sterile probe cover when appropriate.
- Pathology considerations:
  - **Hydrocephalus**: Q daily neurosonography with ventricle measurements for a baseline. This allows for serial monitoring of over/under drainage. If a change is seen, consider CT scan, adjustment of shunt, further intervention, etc.
  - **Tumor**: Q daily neurosonography to monitor for complications such as hydrocephalus, bleeding, or edema. If seen, consider sending patient for CT scan and/or further intervention.
  - **Bypass:** Q daily neurosonography to monitor for graft patency, velocity, and/or volume flow changes. Abnormal results should be reviewed for additional testing to determine if intervention is necessary.
  - **Craniotomy/TBI**: Q daily neurosonography for any open procedure to monitor for complications such as bleeding, midline shift, and CSF disruption (ventricle size). If complications are seen, consider additional testing or intervention as necessary.
  - **Chiari**: Q daily neurosonography to assess compressed craniocervical junction and pulsatility to confirm flow.

CLINIC **VISIT**

1. Longeviti representative brings ClearFit case log to clinician
2. Clinician team may schedule the patient 91-days out for ultrasound imaging
3. Clinician performs ultrasound as part of patient assessment, patient gets live haptic feedback from clinician
4. Imaging report and billing codes submitted for reimbursement
5. Exam and report is saved in PACS/EMR (or other).

CPT GLOSSARY

CPT DESCRIPTION	CPT CODE
US limited scanning of head and neck blood flow (inside the brain)	**93888**
US scanning of head and neck vessel blood flow (inside the brain)	**93886**
US scanning of blood flow (outside of brain) on one side of head and neck or limited	**93882**
Ultrasound scanning of blood flow (outside the brain) on both sides of head and neck	**93880**
US of head and neck	**76536**
US of brain	**76506**

NEUROSONOGRAPHY REPORTING

Imaging requirements for neuroanatomy ultrasound (CPT 76506)

Minimum Images (3):	1 x surgical site + 2 x medial/lateral sweep
Report:	see Longeviti sample report for guidance
Common Pathologies:	Hydrocephalus, ETV, decompression, tumor, bleeds, etc

Imaging requirements for EC-IC Bypass (CPT 93886 or 93888)

Minimum Images (4):	2 x color with PW and 2 x greyscale of MCA + STA
Report:	see Longeviti sample report for guidance
Note:	Volume flow assessment may provide additional clinical value

Imaging requirements for Transcranial Doppler (TCD) (CPT 93886 or 93888)

Minimum Images (4):	2 x color and 2 x PW of bilateral (complete) or unilateral (limited) MCA
Report:	see Longeviti sample report for guidance
Note:	Volume flow assessment may provide additional clinical value

Imaging Summary

Nurse

- ClearFit patients are unique because their cranial implant enables bedside ultrasound imaging, no transport is needed.
- Ultrasound is a quick diagnostic tool to assess ClearFit patients presenting with new symptoms.
- Follow protocols for appropriate sterile precautions (sterile probe cover, sterile gel, Bacitracin, etc.).
- Develop a process to inform care team that patient has a ClearFit (ultrasound penetrable) implant.

Neurosurgical Care

- Surgical considerations that may interfere with ultrasound include:
  - Air: the first post-op ultrasound should wait 24+ hours to allow air to reabsorb.
  - Ultrasound interference: early research suggests topical hemostatic agents (ie GelFoam), collagen-based overlays (ie Tachosil®), and some dural substitutes (ie DuraMatrix®) may interfere with ultrasound penetration.
  - Skin contact: incision may be difficult to scan over. Extra gel creates a standoff that may help overcome this challenge.
- Imaging considerations
  - Implant size: ultrasound does not penetrate through bone so aligning the probe over the implant is critical and size matters.
  - Artifact: shadows help identify when the probe is over bone vs implant. Use this to help optimize probe position.
  - Ultrasound options: POC systems including handheld can evaluate for complications. Consider radiology consoles when higher image quality is needed.
- Also see pathology considerations on page 3.

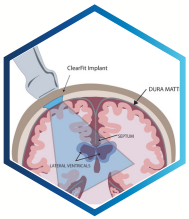
CCM

- Imaging field of view is dependent on Implant size and footprint of the probe. Careful attention is needed to create an optimal line of sight for visualizing the region of interest (surgical site) when evaluating neurosurgical patients.
- Ultrasound presets are necessary to create the optimal image quality.
- The sector (phased array) probe is best for imaging anatomy and vascular structures (is TCD) that are 3-16cm deep.
  - Neuroanatomy and neurovascular (TCD) exams: use the sector probe with “Abdominal” preset and consider “TCD” as needed.
- A low frequency linear probe (i.e. 9 MHz) is best for visualizing superficial anatomy in the 1-3cm range and shallow EC-IC bypass scans.
  - The “Carotid” preset is best for shallow neurovascular (bypass) imaging while “MSK” for soft tissue neuroanatomy imaging.
- Bedside neurosonography can provide immediate results when patient symptoms change or for routine surveillance/screening. Higher resolution ultrasound systems such as radiology consoles should be considered when appropriate.

MEDICAL EDUCATION
OPPORTUNITIES

Phantom Training

The Longeviti ClearFit Phantom is expertly designed to simulate the visualization of tumor and ventricles while using transcranial ultrasound



Neurosonography Courses

Hosted by Longeviti, these medical education courses cover the foundations for imaging through ClearFit. Attendees will take part in seminars and get hands on experience with ClearFit patients.

SONOSIM

Virtually accessible courses ranging from fundamentals to specific neurological pathologies in TCUS

Site visits available to the Centers of Excellence!

Longeviti ClearFit Cranial Implant Class II

Longeviti ClearFit OTS Cranial Implant Class II

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