

CRANIAL Loop™



THE IDEAL CRANIAL
FIXATION SYSTEM FOR
PEDIATRIC PATIENTS.



Cranial LOOP is a cranial fixation system made of PEEK polymer, designed to ensure secure and stable bone flap fixation, while supporting natural cranial growth and appropriate skull healing.

WHY CRANIAL LOOP FOR PEDIATRIC PATIENTS?

IDEAL FOR GROWING CRANIAL STRUCTURES

- ✔ Unlike metal fixation systems, **PEEK material does not interfere** with skull development, making it ideal for young patients.

ADAPTABILITY TO COMPLEX ANATOMY

- ✔ The flexible, **contour-adaptive design** ensures a precise and secure fit—ideal for challenging locations.

SAFE AND EFFECTIVE FIXATION

- ✔ Ensures **proper bone flap stability and alignment** without complications.



CHALLENGES OF CRANIAL FIXATION IN THE PEDIATRIC POPULATION

Selecting the appropriate cranial fixation method in children remains a challenge due to ongoing skull growth. The table below outlines the key challenges associated with titanium and biodegradable fixation systems in pediatric neurosurgery.

FIXATION METHOD

KEY CHALLENGES & RISKS



TITANIUM PLATES & SCREWS

- ✗ Interferes with natural skull growth¹⁻³.
- ✗ Risk of transcranial migration and misalignment¹⁻³.



BIODEGRADABLE FIXATION

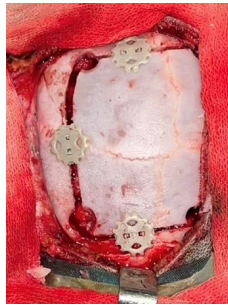
- ✗ Non-stable bone resorption rates^{4,5}.
- ✗ Cases of inflammation, granuloma and infections reported^{4,5,6,7}.
- ✗ Resorbable screws often fail to provide mechanical stability (as reported in the MAUDE database)⁸.

RETROSPECTIVE STUDY

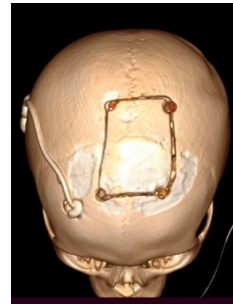
Cranial LOOP is a safe and effective bone flap fixation that allows bone growth and fusion in pediatric patients. N=60, with a maximum follow-up period up to seven years.

KEY CLINICAL FINDINGS & BENEFITS

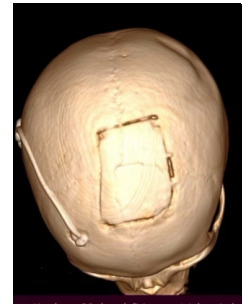
- ✓ **Bone fusion was achieved in 90.5%** of patients over the course of the follow-up period.



During surgery

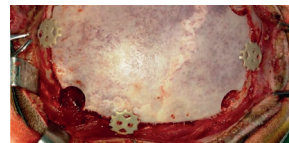
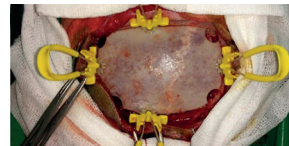


Day after surgery



3 months after surgery

- ✓ **Stable bone flap fixation & alignment:** ensures secure and precise bone flap positioning.



- ✓ **Facilitates natural skull growth,** with follow-up extending up to **5–7 years.**
- ✓ **Adaptive low-profile design:** adapts precisely to all cranial regions, including challenging areas with irregular bone contours.
- ✓ **No implant-related complications reported,** including migration, misalignment, or loss of tensile strength.
- ✓ **Biocompatible & radiolucent:** ensures **clear CT/MRI scans** for accurate post-op monitoring.



"In my experience, Cranial LOOP reduces operating time compared to other fixation systems, minimizing surgical time, bleeding, and anesthesia exposure"
"We see excellent bone fusion results, higher adaptability to irregular anatomies and superior efficiency compared to other fixation methods".

DR. DANIEL DEMARCHI

"Cranial LOOP has been implanted in pediatric patients with good follow-up results and no reported complications."

DR. CARLOS ASENCIO





SET A NEW STANDARD IN PEDIATRIC CRANIAL FIXATION

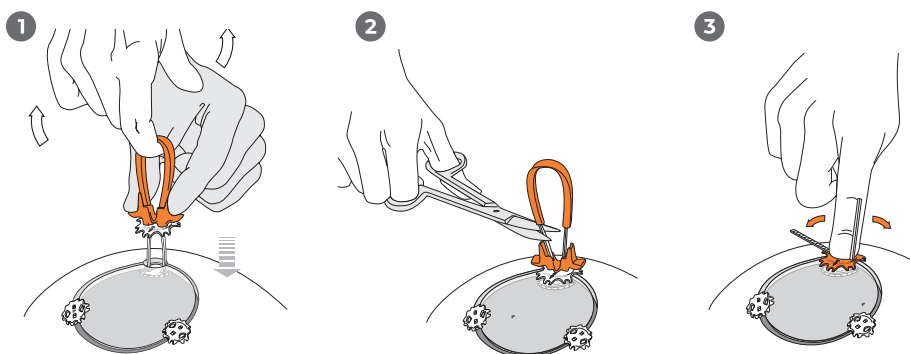
- Enables natural cranial growth with gentle fixation.
- Maintains accurate bone flap alignment from surgery through follow-up evaluations.
- Designed for safety, precision, and ease of use in growing patients.

PROVEN PERFORMANCE

- The most clinically studied cranial fixation system in neurosurgery.
- Trusted by surgeons worldwide for over 10 years.
- Long-term safety and performance proven in both pediatric and adult populations.

FAST & EASY INSTRUMENT-FREE

A simple pull & tighten action allows a **fast & easy application, in less than 1 minute.**



Visit our website for additional information and resources.

Before using the device, the physician must consult the Instructions for Use (IFU) and be familiar with the method of application, intended use, and contraindications.

1. Duke BJ, Mouchantat RA, Ketch LL, Winston KR. Transcranial Migration of Microfixation Plates and Screws. *Pediatr Neurosurg.* 1996;25(1):31-35. doi:10.1159/000121093 / 2. Fearon JA, Munro IR, Bruce DA. Observations on the use of rigid fixation for craniofacial deformities in infants and young children. *Plast Reconstr Surg.* 1995;95(4):634-637. / 3. Goldberg DS, Bartlett S, Yu JC, Hunter J V, Whitaker LA. Critical review of microfixation in pediatric craniofacial surgery. *J Craniofac Surg.* 1995;6(4):301-307. doi:10.1097/00001665-199507000-00008 / 4. Bergsma JE, de Bruijn WC, Rozema FR, Bos RR, Boering G. Late degradation tissue response to poly(L-lactide) bone plates and screws. *Biomaterials.* 1995;16(1):25-31. doi:10.1016/0142-9612(95)91092-d / 5. Kumar CR, Sood S, Ham S. Complications of bioresorbable fixation systems in pediatric neurosurgery. *Childs Nerv Syst.* 2005;21(3):205-210. doi:10.1007/s00381-004-0997-0 / 6. Rocque BG, Agee BS, Thompson EM, et al. Complications following pediatric cranioplasty after decompressive craniectomy: a multicenter retrospective study. *J Neurosurg Pediatr.* 2018;22(3):225-232. doi:10.3171/2018.3.PEDS17234 / 7. Van de Vijfeijken SECM, Munker TJAG, Spijker R, et al. Autologous Bone Is Inferior to Alloplastic Cranioplasties: Safety of Autograft and Allograft Materials for Cranioplasties, a Systematic Review. *World Neurosurg.* 2018;117:443-452.e8. doi:10.1016/j.wneu.2018.05.193 / 8. MAUDE database (Manufacturer and User Facility Device Experience).