

CRANIAL Loop™



REINVENTING CRANIAL FIXATION

INSTRUMENT-FREE | FAST & EASY | RELIABLE FIXATION

The Cranial LOOP Family
offers three different sizes,
two for the craniotomy line
and one for burr holes.

CRANIAL
Loop™

12 mm

CRANIAL
Loop (L)™

16 mm

CRANIAL
Loop (XL)™
BURR HOLE

22 mm

The Cranial LOOP family of cranial fixation devices are a smart system for securing bone flaps resulting from craniotomies.

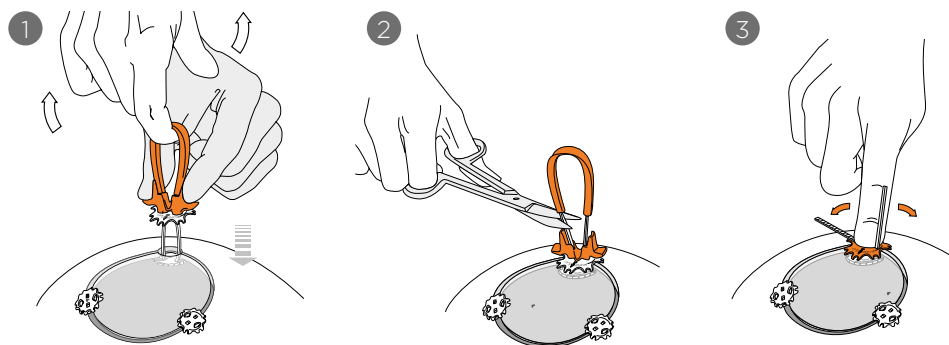
Engineered from PEEK-OPTIMA™ polymer for excellent mechanical strength and resistance.

Artifact-free in X-Ray, CT scan and MRI.



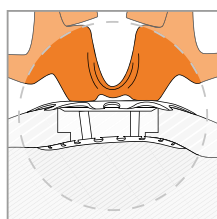
FAST & EASY INSTRUMENT-FREE

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



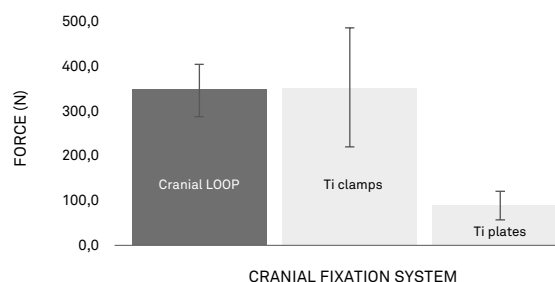
RELIABLE FIXATION

The **Cranial LOOP family** produces equivalent fixation strengths to those of other standard metallic fixation devices. The high strength of PEEK polymer material and the products' design provide a secure fixation and high adaptability to the skull.



FORCE REQUIRED TO SINK THE BONE FLAP 2 mm

NEOS Surgery's data, based on the testing methodology by Dr. Lerch (Neurosurgery. 1999; 44 (4): 902-5)



CLINICAL EVIDENCE

Cranial LOOP long-term safety and performance. Used for more than 10 years.^{1,2}

- Optimal bone flap alignment after surgery and at follow-up.
- High surgeon satisfaction rate.
- Safety demonstrated during a mean follow-up of 12 months.
- Patients with a maximum follow-up of 5 years.

¹ Asencio, C. et al. "Long-Term Safety and Performance of a Polymeric Clamp-Like Cranial Fixation System". World Neurosurg 2019; 126: e758-e764. ² Van Loock, K. et al. "Cranial Bone Flap fixation using a New Device (Cranial Loop™)". Minim Invas Neurosurg 2011; 54:119-124.

GENERAL INFORMATION

- Supplied ready to use: sterile, no instrument tray needed.
- Reduced risk of soft tissue damage due to the smart design and less aggressive material: PEEK-OPTIMA™.
- Can be used for bone thicknesses between 1.5 and 24 mm.
- Easy to remove using standard Neurosurgery forceps or rongeurs.
- PEEK-OPTIMA™ polymer has a track record of more than 20 years for safety, biocompatibility and biostability.
- CE-mark and FDA clearance.
- Cranial LOOP is patented.

HIGH STRENGTH & SAFETY

Double locking mechanism

INSTRUMENT-FREE

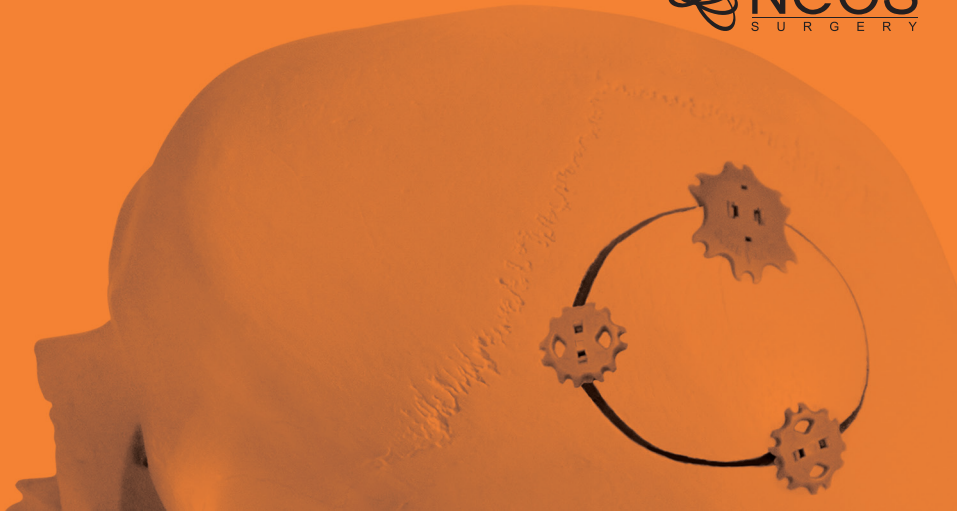
Fast & Easy implantation

CT/MRI ARTIFACT-FREE

100% PEEK-OPTIMA™

MINIMAL PROFILE

Guaranteed by 3D adaptation



CRANIAL Loop (XL) BURR HOLE



REF: FC050200

- Burr hole device
- 22 mm diameter
- Profile: 0.9 mm

CRANIAL Loop (L)



REF: FC050100

- Osteotomy line device
- 16 mm diameter
- Profile: 1 mm

CRANIAL Loop



REF: FC050000

- Osteotomy line device
- 12 mm diameter
- Profile: 1 mm



**MEDICAL
DESIGN
EXCELLENCE
AWARDS®
2011 WINNER**

Cranial LOOP was awarded the
MDEA Gold distinction (NYC-USA)

CLINICAL AND FUNCTIONAL STUDIES

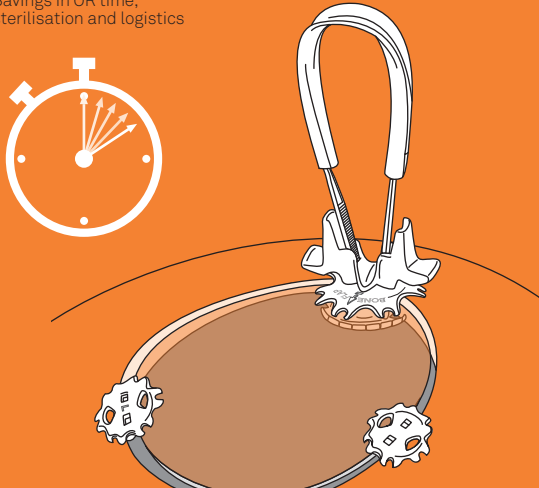
Asencio, C. *et al.* Long-Term Safety and Performance of a Polymeric Clamp-Like Cranial Fixation System. *World Neurosurg* 2019; 126: e758-e764

Van Loock, K. *et al.* "Cranial Bone Flap fixation using a New Device (Cranial Loop)", *Minim Invas Neurosurg* 2011; 54:119-124

Vilana, X. *et al.* "Comparison between PEEK and Titanium cranial fixation devices", *Proceedings of the 24th European Conference on Biomaterials* (September 2011, Dublin, Ireland).

INSTRUMENT-FREE

Savings in OR time,
sterilisation and logistics

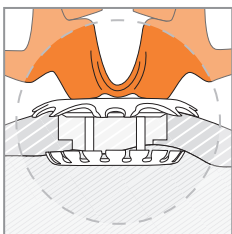


GENERAL INFORMATION

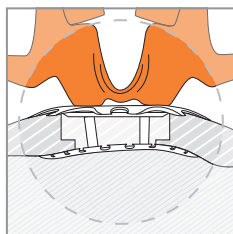
- Supplied ready to use: sterile, no instrument tray needed.
- Artifact-free in X-Ray, CT scan and MRI.
- Reduced risk of soft tissue damage due to the smart design and less aggressive material: PEEK-OPTIMA™.
- Can be used for bone thicknesses between 1.5 and 24 mm.
- Easy to remove using standard Neurosurgery forceps or rongeurs.
- PEEK-OPTIMA™ polymer is certified for implantation under ISO 10993 standards and US FDA Drug & DMF.
- CE-mark and FDA clearance.

NEOS SURGERY and Cranial LOOP are trademarks of NEOS SURGERY S.L.
PEEK OPTIMA™ is a trademark of Invibio Ltd.
Cranial LOOP is patented.

MINIMAL PROFILE



Before tightening



After tightening

CT/MRI ARTIFACT-FREE



Artifacts due to titanium device



Cranial LOOP artifact-free image

REINVENTING CRANIAL FIXATIONS

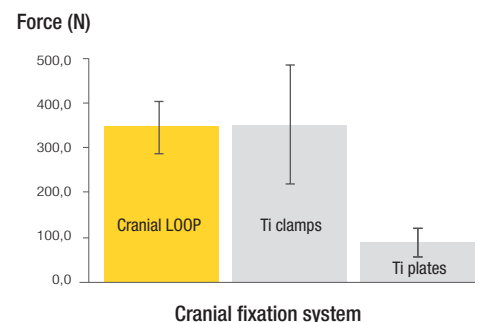
The **Cranial LOOP** family of cranial fixation devices are a smart system for securely fixing bone flaps resulting from **craniotomies**.

A **fast and easy** 'Pull and tighten' action allows the **surgeon to control and feel the fixation**. A standard bone flap with **three Cranial LOOP devices** can be fixed in **less than a minute**.

The different members of the **Cranial LOOP** family produce **equivalent fixation strengths** to those of other standard metallic NON-instrument-free fixation devices.

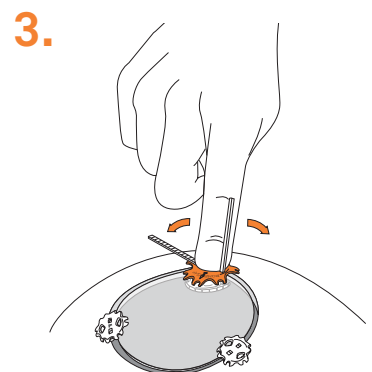
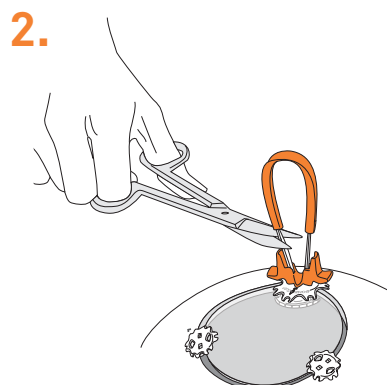
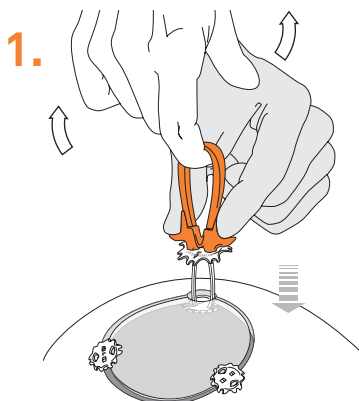
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The Cranial LOOP family offers the safety of microplates and screws concerning brain tissue damage, combined with the ease of use and strength of clamping systems.

FAST & EASY



Distributed by:

Manufactured by:



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