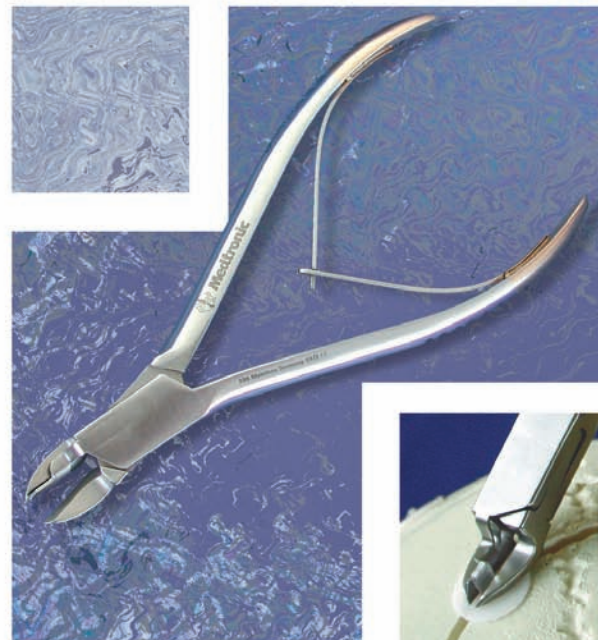


INVIS^x® CRANIAL FIXATION SYSTEM

An easier way to close a flap

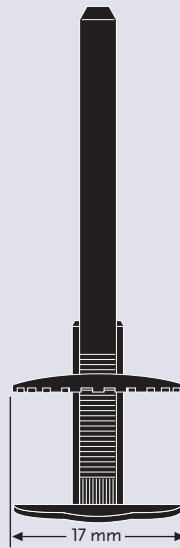


The **INVISx**[®] Cranial Fixation System is designed to assure the structural stability of the replaced skull flap following a craniotomy procedure. It is a unique screwless fixation system that reduces surgical time while maintaining flap closure strength.

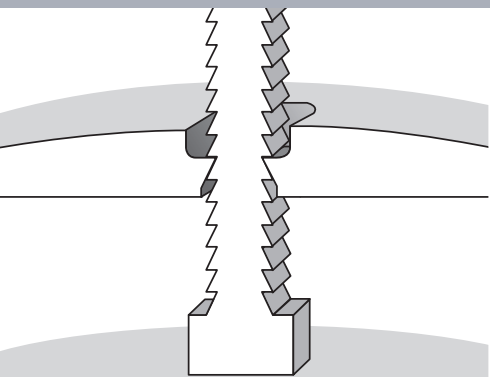
Features & Benefits

- Radiolucent – Permanent locks provide CT and MR compatibility, resulting in enhanced image clarity
- Adaptable – Polymer material and design combine to augment ability of locks to contour to the anatomy
- Fast – Four simple steps required to fixate a cranial flap
- Easy to Use – Intuitive ergonomic instrumentation facilitates handling
- Cost Effective System – Time saved in the operating room results in cost savings per procedure

INVISx Lock

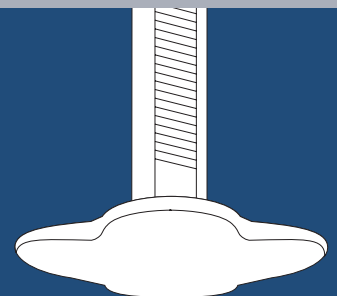


- Superior cap interfaces with stem teeth to provide stable, strong fixation
- Designed to fit in osteotomy gap (i. . kerf)



Lock Assembly

- Superior cap interface with stem teeth provides strong fixation.
- Clover design of inferior cap enhances adaptability to anatomy
- Implanted permanently



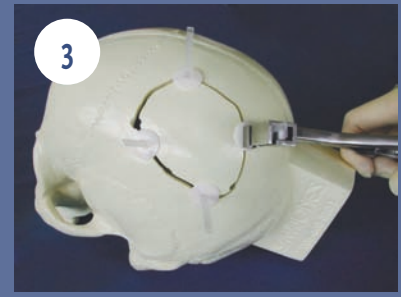


With the flap removed, position the INVISx Locks equidistantly around the opening. The Stem base should lie between dura and skull.

NOTE: Care should be taken to avoid placing dural packup suture where an INVISx Lock will be positioned for closing.



Replace the flap, ensuring that the Stems remain vertical within the kerf.



Place Tensioning instrument on Stem and tighten until the Cap just touches the skull. Repeat the procedure in a diagonal sequence. Complete the tensioning procedure by tightening each cap until the Stem safety tab breaks off.

NOTE: The safety tab breaks off when the lock has reached the optimum degree of tension needed for cranial flap fixation.

Application Procedure: 4 Simple Steps



Using the Trimming instrument, cut each Stem flush with the top of the Cap.



Lock Removal. Use Trimming instrument or surgical clamp to pry Cap off of Stem.



Cranial flap fixated using four INVISx locks.
Photo courtesy of Scott Gingold, M.D., Department of Neurosurgery, Crouse Irving Hospital, Syracuse, NY.

Tensioning Instrument

- Intuitive stainless steel instrument designed to advance cap down to the skull
- Ergonomic design
- Easy to clean and sterilize (no disassembly required)

Trimming Instrument

- Stainless steel trimming instrument designed to trim stem flush with the top of the superior cap
- Retention clip designed to retain stem remnant
- Instrument can be used to remove cap from stem for site revisits



REF NO.	Product Description	
60100	INVISx Locks (2/box)	
60101	INVISx Lock (1/box)	
60110	INVISx Locks Shelf Pack (10 boxes of REF 60100)	
60700	INVISx Cranial Fixation System Instrument Set (includes REF 60710, 60720, 60730)	
60710	INVISx Tensioning Instrument, reusable	
60720	INVISx Trimming Instrument, reusable	
60730	INVISx Instrument Tray	



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For more information, please contact your Neurologic Technologies representative, or refer to www.medtronic.com.

Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. Refer to product package insert for instructions, warnings, precautions and complications.