

Pro-Close™ 1.5mm Cranial Fixation System

Product Ordering Information

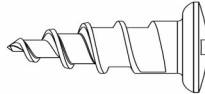
1.5mm Cranial Fixation System

- 200.400 - Pro-Close Instrument Tray
- 410.076 - 76mm Cruciform Driver Blade
- 404.100 - Screwdriver Handle
- 430.045 - Mesh Cutter

Titanium Implants

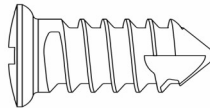
1.5mm Cranial Screws, Self-Drilling

- 800.15.03 - 3mm length, packs of 3, 6 or 10
- 800.15.04 - 4mm length, packs of 3, 6 or 10
- 800.15.05 - 5mm length, packs of 3, 6 or 10



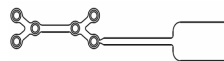
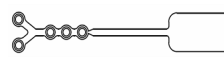
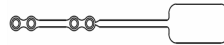
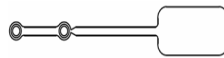
1.8mm Emergency Screws, Self-Tapping

- 812.18.03 - 3mm length, 1 ea.
- 812.18.04 - 4mm length, 1 ea.
- 812.18.05 - 5mm length, 1 ea.



1.5mm Titanium Plates, 0.4mm

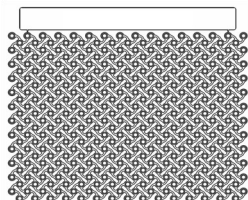
- 401.04.01 - Straight Plate, 2 hole, 9mm, 1 ea.
- 401.04.02 - Straight Plate, 2 hole, 12mm, 1 ea.
- 401.04.03 - Straight Plate, 4 hole, 20mm, 1 ea.
- 401.04.04 - X-Plate, 4 hole, 8mm x 8mm, 1 ea.
- 401.04.05 - Box Plate, 4 hole, 10mm x 10mm, 1 ea.
- 401.04.09 - Y-Plate, 5 hole, 16mm, 1 ea.
- 401.04.11 - Double Y-Plate, 6 hole, 21mm, 1 ea.
- 403.04.02 - Burr Hole Cover, 15mm, 1 ea.
- 403.04.03 - Burr Hole Cover, 17mm, 1 ea.



Malleable Mesh

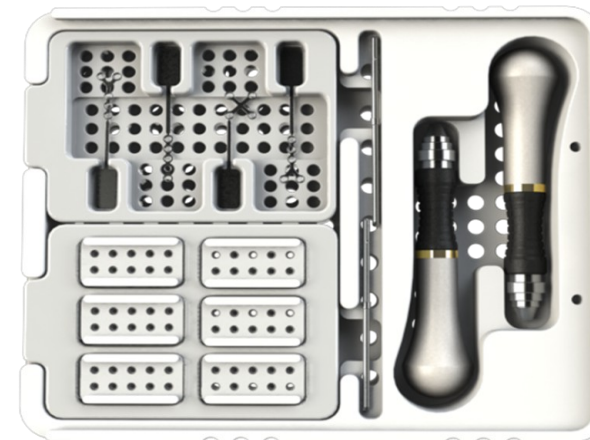
1.5mm Mesh

- 915.45.13 - 0.45mm x 90mm x 120mm, 1 ea.
- 915.60.13 - 0.6mm x 90mm x 120mm, 1 ea.



Neuro Closure System

1.5mm Cranial Fixation System



Pyrogen-Free

Compact Design

Unique Snap-In
Screw Cartridge
System

Low Profile
Plate/Screw
Interface



Pro-Close™ 1.5mm Cranial Fixation System

Advantages

Pyrogen Free

- Each lot of cranial plates and screws is tested for endotoxins and ensured to meet the latest most rigorous FDA pyrogen-free requirements
- Each lot of cranial plates and screws are supplied sterile as opposed to non-sterile to meet FDA requirements which do not consider autoclaved devices as pyrogen-free **unless the hospital can verify that each autoclave run is pyrogen-free**
- Detection of bacterial endotoxin contamination is essential to insure the safety of medical devices. Any product labeled pyrogen-free must be tested to verify that claim.

FDA Requirements

- According to the FDA guideline document for pyrogens¹, the allowable amounts of endotoxin units (EU) for medical devices are:

"The new limit for medical devices is 0.5 EU/ml except for devices in contact with cerebrospinal fluid for which the limit is 0.06 EU/ml."

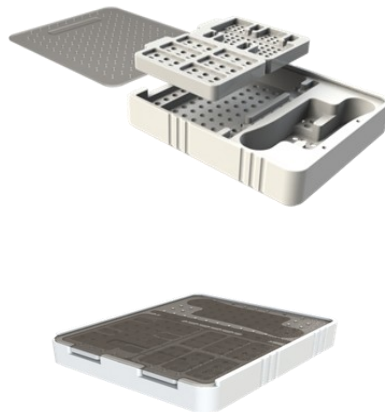
- These are the limits in terms of the endotoxin test results. In terms of EU amounts per device, the limits are 20 EU for medical devices and 2.15 EU for devices in contact with cerebrospinal fluid. This guideline is issued under section 10.90(b) (21 CFR 10.90(b)) of the FDA regulations.

1. FDA Guideline on validation of the Limulus amoebocyte lysate test as an end-product endotoxin test for human and animal parenteral drugs, biological products and medical devices (1987).

Features

Instrument Tray

- Extensive plate and screw selection compartments, two screwdriver handles, screwdriver blades and mesh cutters
- Compact design fits into smaller autoclave
- Unique snap-in, sterilized screw cartridge



Features

Ergonomically Designed Driver Handle

- Allow clear visualization of screw placement
- Quick connect simple and effective 3-finger technique



Driver Blade

- Manufactured from high strength stainless steel
- Heat treated to guarantee strength and increased durability
- Cruciform head designed for easy screw pick up



Self-Drilling Screws

- Cranial screws are self-drilling for easy one-step insertion
- Manufactured from titanium alloy (Ti-6Al-7Nb) for strength and biocompatibility
- Cruciform Drive Recess
 - Provides high-torque capacity
 - Minimizes stripping
- Emergency screw anodized blue for easy identification

