Universa Neuro" III

1.5mm Cranial fixation system



Universal Neuro III



The Universal Neuro III module neatly contains a comprehensive selection of screws, low profile plates, skull base plates, dynamic mesh, and instrumentation.

Unique Features:

Low profile

Low profile height (0.4mm) with deeper countersinks, broader bars, and a smoother geometry.

AXS screw

Optimized self-drilling AXS (axial stability) screws help with off-axis loading and insertion.

Specialized plates

Specialized plates to reconstruct difficult skull base approaches with minimal plate modification.

Color coding

Color coding of the modules and associated instrumentation provides ease of use for surgeon and staff.

You specialize in your patients. We specialize in you.

Module

Universal Neuro III module

The Universal Neuro III module neatly contains a comprehensive selection of skull base plates, low-profile plates, dynamic mesh, screws, and the instrumentation needed to fixate cranial bone flaps.

Unique features:

- Addition of specialized plates to reconstruct difficult skull base approaches with minimal plate modification
- Optimized self-drilling screws with addition of 3mm option
- Unique burr hole cover design with added fixation hole and dynamic bar for ease of contouring
- 20% thinner plates* with deeper countersink, broader bars, smoother geometry, and same stability
- Addition of ergonomic screwdriver handle
- Redesigned module with designated pockets for decreased plate stacking and ease of identification
- Customizable screw disc with screws of different lengths



Storage options

Universal Neuro III system: Storage and sterilization containers

The Universal Neuro III System features Half (not shown), Combined and Quarter size sterilization containers to accommodate a wide variety of options for your specific neurosurgical needs. In addition, there are 2D and 3D mesh storage options.



Technology and innovations

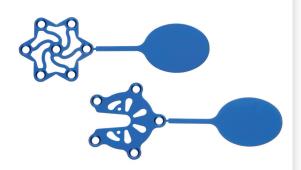
Instrumentation

• Ergonomically shaped screwdriver handle and newly designed screwdriver blade for improved handling, allowing optimal blade-to-screw interface/retention and easier screw insertion



Burr hole covers

• Unique burr hole covers with added fixation hole and dynamic bar design for ease of contouring; in addition to two new shunt plate options



Lower profile plates

- 0.4mm profile height allows for rigid fixation of cranial flaps with decreased palpability
- Deeper countersink* for a more flush plate/screw construct
- Select plates feature break-off tabs for easy handling and identification
- Comprehensive selection of implants including shunt, "dog-bone," gap, and box plates along with 5 sizes of burr hole covers offer numerous fixation options



VariSpeed - battery powered screwdriver

- Touch sensors for continuous, variable speed control
- Forward and reverse capabilities
- Ergonomically balanced for both left and right hand use
- Acoustic Feedback to help ensure battery is attached and device is working properly
- Standby Mode to minimize power consumption and improve battery life
- Improved electrical components to protect against rigorous sterilization parameters and excessive heat

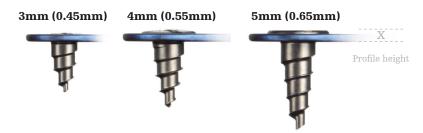


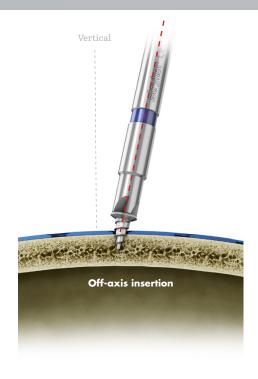
AXS - Axial stability screw

The latest iteration of the Universal Neuro screw continues to advance neurotechnology. A brand new head design provides surgeons with ease-of-use and performance.

Unique features:

- Enhanced pick-up designed to minimize complications in loaded screwdriver hand-off from tech to surgeon, with optimized self-retention to allow reliable transport into OR field
- Self-centering feature facilitates off-axis insertion
- Low profile heights:
 - 4mm SD screw with blue plate 0.55mm
 - 4mm SD screw with gold plate 0.6mm





Optimized selfdrilling (SD) screws

- Addition of 3mm self-drilling screw provides lowest plate-to-screw profile option in UNIII system for minimal palpability
- Newly designed self-drilling screws require 25% less turns to fully insert*
- 23% lower construct for decreased palpability*
- 40% greater initial bite into bone for quicker insertion*



Customizable screw disc delivery system

 Customizable screw disc allows placement of 3, 4, and 5mm SD screws and/or 4, 5, 6mm ST screws in a single screw disc



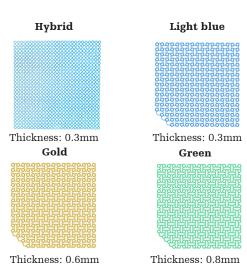
Dynamic mesh

Dynamic mesh has optimized properties to facilitate controlled, three-dimensional contouring while maintaining adequate rigidity for bone defects of varied size and location. Dynamic mesh can be shaped to fit most three-dimensional bone surfaces without unwanted wrinkled or overlapped areas.

Unique features:

- Standard
 (Gold 0.60mm profile height) and Malleable Low Profile
 (Blue 0.30mm profile height) designs
- Dedicated screw holes for many options in screw placement
- Easy to cut and accurately contour to anatomical structures
- Instrumentation for cutting





2D mesh

Unique features:

- Countersink designed to reduce palpability
- Smooth edge aids insertion
- MR conditional allows diagnostics after implantation
- · Variety of mesh types strength vs malleability
- New 0.3mm Hybrid mesh 3x stronger than 0.3mm Dynamic mesh¹

3D mesh

Unique features:

- Countersink designed to reduce palpability
- Has stiffness equivalent to golden 2D mesh²
- Used for open defects up to 70mm and muscle attachment
- Pre-formed minimizes bending effort to fit patient



Unique features:

- Countersink designed to reduce palpability
- Increased stiffness, for increased patient protection, compared to 2D mesh²
- Used for open defects up to the size of the mesh and muscle attachment³
- · Anatomically pre-formed minimizes bending

Sliver

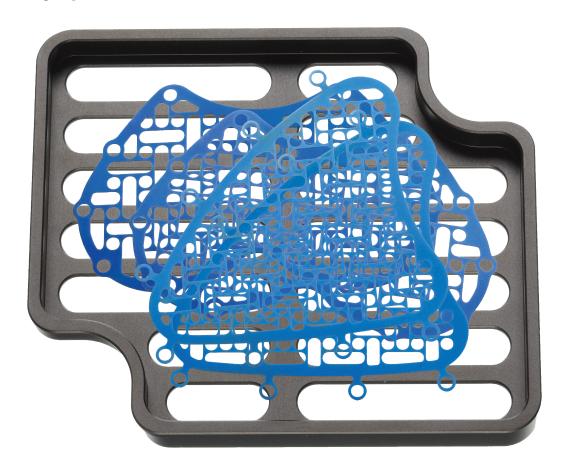


Skull base plates

The addition of dedicated skull base plates may make reconstruction of unique cranial approaches quicker and more efficient through minimal plate modification.

Unique features:

- Low profile 0.3mm construct for minimal implant palpability
- Multiple thickness and size options to match unique patient needs
- Closed outer frame design offers enhanced stability
- Multiple fixation holes, including long holes within center of plates, for added rigidity











Translabyrinthine

Temporal

Suboccipital

QuikFlap[®]

OuikFlap offers an easy, cost effective solution for cranial flap fixation. Provided sterile, the procedure packs can limit processing risks for the hospital while decreasing inventory and the cost of backstock.

Unique features:

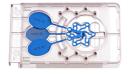
- Space conservation
- Sterilization by manufacturer specifications
- Cost efficiency
- Comprehensive product offering
- · Now offered with the AXS screw

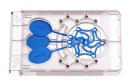
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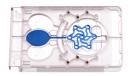












12-015405 - 2-hole plate set with self-drilling screw Contains:

UNIII 0.6mm 2-hole rigid plate (x3) UNIII screw AXS self-drilling 1.5x4mm (x6)

12-015415 - 2-hole plate set, self-tapping screw Contains:

UNIII 0.6mm 2-hole rigid plate (x3) UNIII screw AXS self-tapping 1.5x4mm (x6)

12-015425 - 2-hole plate set, low profile with tab Contains:

UNIII 0.4mm 2-hole plate with tab (x3) UNIII screw AXS self-drilling 1.5x4mm (x6)

12-015445 - 2-hole plate burr hole cover 14mm set Contains:

UNIII 0.4mm 2-hole plate with tab (x2) UNIII 0.4mm 14mm burr hole cover (x1) UNIII screw AXS self-drilling 1.5x4mm (x10)

12-015465 - 2-hole plate burr hole cover 20mm set Contains:

UNIII 0.4mm 2-hole plate with tab (x2) UNIII 0.4mm 20mm burr hole cover (x1) UNIII screw AXS self-drilling 1.5x4mm (x10)

12-015485 - 2-hole plate burr hole cover 14mm set Contains:

UNIII 0.4mm 14mm burr hole cover (x1) UNIII screw AXS self-drilling 1.5x4mm (x6)

Ordering information

1.5mm Neuro plates/mesh product number description

Low bi	'0fi	le p	lates

(Order quantity: package of 1) 53-34804 Straight plate, 8-hole 53-34164 Straight plate, 16-hole 53-34406 Straight plate, 4-hole w/bar 53-36212 Dog-bone plate, 2-hole rigid (0.6mm), 12mm bar 53-34212 Dog-bone plate, 2-hole, 12mm bar, w/ tab 53-34216 Dog-bone plate, 2-hole, 16mm bar 53-34228 Box plate, 2 x 2 hole, small 53-34300 Rectangle plate, 2 x 2 hole 53-34608 Double-Y plate, 6-hole, w/bar 53-34612 Gap plate, 6-hole, small 53-34622 Gap plate, 6-hole, large 53-34240 Box plate, 2x2 hole, large 53-34230 Box plate, 2x2 hole, large, w/ tab 53-34630 X plate, 4-hole

Skull base plates

(Order quantity: package of 1) 53-00362 Round malleable (0.3mm), small 53-00364 Round malleable (0.3mm), medium 53-00466 Round rigid (0.4mm), large 53-00342 Translabyrinthine malleable (0.3mm), small 53-00346 Translabyrinthine malleable (0.3mm), large 53-00324 Temporal malleable (0.3mm) 53-00382 Suboccipital malleable (0.3mm), small 53-00486 Suboccipital rigid (0.4mm), large

with tab

Low profile burr hole covers (Order quantity: package of 1) 53-34507 Burr hole cover, 7mm, with 53-34510 Burr hole cover, 10mm, with 53-34514 Burr hole cover, 14mm, with 53-34520 Burr hole cover, 20mm, with 53-34524 Burr hole cover, 24mm, with 53-34614 Shunt burr hole cover, 14mm, with tab Shunt burr hole cover, 20mm, 53-34620

2D mesh

(Order quantity: package of 1) 56-90312 Dynamic mesh 40x40x0.3mm 56-90314 Dynamic mesh 90x90x0.3mm 56-90316 Dynamic mesh 120x120x0.3mm 56-90612 Dynamic mesh 40x40x0.6mm 56-90614 Dynamic mesh 90x90x0.6mm 56-90616 Dynamic mesh 120x120x0.6mm 56-90618 Dynamic mesh 200x200x0.6mm 56-90814 Dynamic mesh 90x90x0.8mm 56-90816 Dynamic mesh 120x120x0.8mm 56-90818 Dynamic mesh 200x200x0.8mm 56-90342 Hybrid mesh 60x60x0.3mm 56-90344 Hybrid mesh 90x90x0.3mm 56-90346 Hybrid mesh 120x120x0.3mm 3D mesh

(Order quantity: package of 1)

56-90654 Pre-form mesh, 90x90x0.6mm 56-90656 Pre-form mesh, 120x120x0.6mm 56-90658 Pre-form mesh, 190x190x0.6mm 56-91062 Pre-form mesh, right, 17.5x12,8cm; T:1mm

56-91064 Pre-form mesh, left, 17.5x12,8cm; T:1mm

Neuro containers product number description

Sterilization containers

29-15330 Module with lid 29-15331 Plate inlay 29-15335 Mesh inlay 29-15336 Screw disc inlay 29-15332 Instrument inlay 29-15012 Half-size container 29-15013 Half-size lid 29-15023 Lid for combined tray 29-15026 Combined container Mat for combined tray 29-15027 29-15028 Instrument inlay for combined 29-15031 Quarter-size container 29-15032 Quarter-size lid 29-15036 Accessory tray 29-15037 Silicon mat

Mesh storage and instrumentation

01-01036 Mesh cutter coarse, 190x55x20mm 01-01038 Mesh clipper, 135x60x20mm 29-92001 2D mesh storage rack with lid 29-92002 2D mesh storage tray with lid 29-92003 2D silicon mat, small 29-92004 2D silicon mat, large 29-91002 Storage tray for mesh instruments 29-93001 3D mesh storage rack with lid 29-93002 3D mesh storage rack with lid

29-93003 3D silicon mat

1.5mm AXS neuro screws product number description

Screw disc - pre-loaded

(Order Oty: Pkg of 1) 29-56933 Screw disc, 1.5x3mm, SD, 80/p 29-56934 Screw disc, 1.5x4mm, SD, 80/p 29-56935 Screw disc, 1.5x5mm, SD, 80/p 29-56034 Screw disc, 1.5x4mm, ST, 80/p

29-56035 Screw disc, 1.5x5mm, ST, 80/p Screw disc - empty

(Order Oty: Pkg of 1)

29-15091 Screw disc, 1.5mm, empty

AXS screws

60-15035 Screwdriver blade long 60-15036 Screwdriver blade short 56-15034 Self-tapping screw, 1.5x4mm 56-15035 Self-tapping screw, 1.5x5mm 56-15036 Self-tapping screw, 1.5x6mm 56-15933 Self-drilling screw, 1.5x3mm 56-15934 Self-drilling screw, 1.5x4mm 56-15935 Self-drilling screw, 1.5x5mm 56-17334 Emergency screw, 1.7x4mm

Twist drills (Single use only)

(Order quantity: package of 1)

60-12594 1.2mm drill bit, 4mm stop, J-latch end

60-12596 1.2mm drill bit, 6mm stop, J-latch end 60-12394 1.2mm drill bit, 4mm stop,

TPS end

60-12396 1.2mm drill bit, 6mm stop, TPS end

Neuro instrumentation product number description

Instrumentation

62-18110 Plate forcep

62-18330 In-situ cutter 62-15001 Screwdriver handle, small 62-15002 Screwdriver handle, medium 62-15035 UNIII AXS screwdriver blade,

62-15036 UNIII AXS screwdriver blade,

36-00726 Plate bending plier 64-00132 Mesh bending plier

37-10930 Plate/mesh scissors

60-12294 Drill w/ dental interface 60-12296 Drill w/ dental interface

Markers

52-00003 Screw marker 3mm 52-00004 Screw marker 4mm 52-00005 Screw marker 5mm 52-00006 Screw marker 6mm

Complementary products

DirectInject

DirectInject is the first and only on-demand HA cement, redefining ease-of-use in cranial closure. It's intended to repair neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects.

DuraMatrix-Onlay PLUS

DuraMatrix-Onlay PLUS is derived from purified, bovine Achilles tendon. It is intended for use as a dura substitute for the repair of dura mater.

DuraMatrix Suturable

DuraMatrix Suturable is a collagen dura membrane from purified intact bovine dermis tissue. It is intended for use as a dura substitute for the repair of dura mater.

Cranial iD - patient specific implants

Cranial iD implants allow you to address your patients desire for complete restoration and aesthetic results. These are available in the material of your choice including MEDPOR, PEEK and PMMA.

MEDPOR neuro implants

MEDPOR porous polyethylene implants provide surgeons with an expanding range of options for reconstruction and augmentation. MEDPOR is a biocompatible, porous polyethylene material. The interconnecting, omnidirectional pore structure may allow for fibrovascular in-growth and integration of the patient's tissue. More than 650,000 procedures have been performed with MEDPOR biomaterial, with more than 350 published clinical reports in cranial, reconstructive, oculoplastic and cosmetic applications.

Delta system

Delta System resorbable implant technology merges science and simplicity. The system consists of resorbable bone plates and screws fabricated from a unique tripolymer. The Delta system tripolymer is a composition of poly L-Lactide/D-Lactide/Glycolide having a molecular ratio of 85/5/10. The resulting tripolymer is an extraordinary combination of strength, contourability and absorption, well suited for craniomaxillofacial surgery.

Colorado needle

The Colorado microdissection needle has an ultra-sharp tip for clean, precise soft tissue dissection. The heat resistant tungsten alloy maintains tip sharpness, and is highly polished for easy cleaning. We offer a wide selection of needle electrodes and standard shaft sizes for use in standard handpieces.

Applications

- Ready for implantation immediately upon request
- A second mixer-cannula allows for dual interval implantation
- Requires no manual mixer or preparation
- Maintains consistent viscosity with negligible displacement of cement

Features

- Leak resistant, providing durability and additional protection against CSF leaks^{4,5,6}
- Resorption time of approximately 8 weeks that occurs at a balanced rate^{5,6}
- Sponge-like product that conforms to the natural contours of the defect site

Features

- Highest suture pull out strength in DuraMatrix portfolio4
- Demonstrates effective protection against CSF leakage^{5,6}
- 38-40 weeks resporption that occurs at a balanced rate^{5,6}

Features

- PMMA is validated to fit within 2mm
- Pterional PLUS implants are available in both MEDPOR and PEEK materials
- PEEK is designed with exacting parameters to optimize the bone-to-implant interface
- MEDPOR's biocompatible material makes it easy to modify

Applications

- Craniofacial reconstruction and repair of craniofacial
 trauma
- $\bullet\,$ Implants intended for reconstruction of the cranium
- Implants with Titanium mesh embedded in the MEDPOR biomaterial are designed to help the implant retain its shape when bent and contoured to meet a specific patient defect
- May be trimmed and cut with surgical scissors.
- Easily fixated with plates/screws designed to stay in place

Applications

- Adult and pediatric craniomaxillofacial applications
- Fixation of bones affected by trauma or for reconstruction
- Cranial flap fixation
- Comminuted fractures
- $\bullet\,$ Reconstructive procedures of the midface

Applications

• Precise electro-cutting and electro-coagulation during electrosurgery

Craniomaxillofacial

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DuraMatrix and DuraMatrix-Onlay are trademarks of Collagen Matrix, Inc. and manufactured by Collagen Matrix, Inc.

References:

- 1. Internal testing TI4282
- TI4579 Mesh Upgrade 3D Mesh Impression Test with Maximum Defect
- 3. TI4580 Mesh Upgrade 3D Mesh Impression Test with 70mm Defect 4. In vitro data on file at Collagen Matrix, Inc.
- 5. Rabbit duraplasty study. Data on file at Collagen Matrix inc.
- 6. The results of preclinical in vitro studies may not be indicative of human clinical outcomes In vivo evaluation of resorption in a rabbit duraplasty model. Data on file.
- 7: Liu JK, Gotfried ON, Cole CD, Dougherty, WR, Couldwell WT, "MEDPOR Porous Polyethylene implant for Cranioplasty and Skull Base Reconstruction"Neurosurgery [April 2004].
- * When compared to Stryker Universal Neuro II System Implants 1 Stryker Test Reports TI2269 and TI3137
- 2 Stryker Test Reports TI2441 and TI2446

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