

Cranial Restoration portfolio

Titanium fixation

Universal Neuro III

The Universal Neuro III neatly contains a comprehensive selection of low-profile plates, skull base plates, screws, dynamic mesh, pre-formed mesh, and the instrumentation (including the ergonomic screwdriver handle) needed to fixate cranial reconstruction.

Lower profile plates

- 0.4mm profile height allows for rigid fixation with decreased palpability
- + 25% deeper countersink $^{\scriptscriptstyle 1}$ for a more flush plate/screw construct
- Select plates feature break-off tabs for easy handling and identification
- Comprehensive selection of plates including "dog-bone," gap, and box plates along with various sizes of burr hole covers and shunt options





Skull base plates

- 20% thinner plates¹ with deeper countersink, broader bars, and smoother geometry
- The addition of dedicated skull base plates may make reconstructio of unique cranial approach quicker and more efficient through minimal plate modification

AXS - Axial stability screw

- Enhanced pick-up minimizes complications in loaded screwdriver hand-off from tech to surgeon, with optimized self-retention for reliable transport into OR field²
- Self-centering feature facilitates off-axis insertion²
- Optimized self-drilling screws²
- Low profile heights of plate (0.4mm) and screw together: .45mm (3mm), .55mm (4mm), and .65mm (5mm)



Bone cements

DirectInject

DirectInject is the first and only on-demand, self-setting, HA cement. It is intended to repair neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects not intrinsic to the stability of the bony structure.

Unique Features:

- No manual mixing
- Dual interval implantation due to second mixing cannula
- Consistent viscosity
- Fast setting³
- Isothermic³
- Osteoconductive³
- Excellent wet field characteristics^{4,5}

HydroSet

The Universal HydroSet is a self-setting, HA cement intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton.

Unique Features:

- Fast-setting³
- Osteoconductive³
- Isothermic³
- Injectable or manual implantation⁶
- Excellent wet field characteristics $^{\!\!\!\!\!^{4,5}}$



Cranial D[®] Individually designed. Personalized care.

We offer a comprehensive portfolio for your cranial reconstruction needs: PEEK and MEDPOR

PEEK

PEEK customized implants offer a strong alloplastic material with multiple options to accommodate the needs of both you and your patient. A PEEK CCI comes in two different kit configurations, Complex or Priority, based on both customer preference and complexity of implant design. A PEEK Complex kit comes with one non-sterile PEEK implant, a nonsterile Host Bone Model to represent the patient's defect, and the design proposal with imbedded 3D views of the implant. A PEEK Priority kit includes both one non-sterile implant and the design proposal however omits the Host Bone Model.

Unique features:

- Precise fit: Designed and manufactured to produce a "drop-in fit"*
- Customizable suture/drainage hole design with option for 1-6 pairs or full pattern suture hole implant
- Thickness: Implant wall thickness provided in either 3.3, 4, 5, or 6mm to cater to patient-specific needs
- Implant material and strength: Alloplastic material with the strongest yield strength within the CCI product portfolio¹¹

PEEK Priority

PEEK Priority implants are to be designed, manufactured and shipped to your facility within 5 standard business days. Implants can be ordered under this option depending on complexity and/or the patient's defect.

Pterional PLUS

Traditional methods for cranial reconstruction do not account for post surgical hard and soft tissue atrophy that occurs over time, leading to persistent temporal hollowing (PTH). PTH causes drastically altered appearances and could possibly cause patients to seek revision surgery for an improved quality of life.

MEDPOR

MEDPOR is a biocompatible, porous polyethylene material indicated for augmentation and/or restoration of bony and/or soft tissue deformities. The interconnecting, omni-directional pore structure may allow for fibrovascular ingrowth and integration of the patient's soft tissue.¹¹ The MEDPOR kit comes with 2 sterile MEDPOR implants, a sterile host bone model to represent the patient's defect, and the design proposal with imbedded 3D views of the implant.

Unique features:

- Precise fit into voids by either a flange, inlay, or multi-piece design
 - Flanged designs allow for fixation directly into the flange, while inlays require plates and screws.
- Onlay indication to allow for enhanced functional and cosmetic outcomes for partial bone defects
- Easy intraoperative modification with scalpel

PEEK and MEDPOR Single Stage

- Patient needs are addressed in one surgery
- A predictive/virtual craniotomy is made with correspondence from the surgeon to the design engineer in a "design session"
- The CCI is designed to that virtual resection, with additional views and warnings included in the design proposal
- PEEK Single stage is compatible with 3D Systems guides, along with STL and DICOM files compatible with a Navigation system



DuraMatrix® and Adherus®

DuraMatrix

DuraMatrix-Onlay Plus

DuraMatrix-Onlay Plus is derived from purified Type 1, bovine Achilles tendon. It is intended for use as a dura substitute for the repair of dura mater. Exclusive non-porous layer provides additional leakage resistance.

DuraMatrix Suturable

DuraMatrix Suturable is a collagen dura membrane from purified Type 1 intact bovine dermis tissue.

DuraMatrix-Onlay

DuraMatrix-Onlay is a purified, Type 1 collagen membrane derived from bovine Achilles tendon DuraMatrix-Onlay has a thickness of 0.6mm, similar to that of the native dura.

74.8%

greater suture pullout strength than Durepair

50x^{8,9,10}

lower liquid permeability rate than DuraGen Plus

Adherus AutoSpray and AutoSpray ET Dural Sealant

Adherus AutoSpray and Adherus AutoSpray ET Dural Sealant are indicated for use in patients who are 13 years of age and older, as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure during cranial procedures.

- Maintains burst pressure strength above physiological intracranial pressure in an in vitro model^{16}
- Absorbs over approximately 90 days¹⁷
- Pre-assembled applicator
- Delivery through a tight spray pattern
- Zero device related infections during the Pivotal Randomized Clinical Trial¹⁸

Product code	Description	Qty
NUS-106	Adherus AutoSpray Dural Sealant	5 units
NUS-109	Adherus AutoSpray ET Dural Sealant	5 units

MEDPOR[®] stock implants

MEDPOR

MEDPOR biocompatible high-density porous polyethylene implants provide surgeons with an expansive range of options for reconstruction and augmentation. The interconnecting, omni-directional pore structure may allow for fibrovascular in-growth and integration of the patient's tissue.¹¹

MEDPOR is easy to work with. The material can be trimmed with a blade in the sterile field, carved and feathered intra-operatively for an excellent final fit.

Cranial hemisphere

The MEDPOR cranial hemisphere for large cranial defects provides surgeons with an off-the-shelf alternative to customized implants, complex grafts, and other implant materials. The implant shape approximates the contour of the half cranium..





TSI

The MEDPOR TSI is designed to repair the sellar floor.

TITAN implants

Combines high-density polyethylene and titanium mesh in a single implant for increased flexibility, shape retention, radiographic visualization and strength.¹¹





Pterional

The MEDPOR pterional implant is designed to correct temporal hollowing.

Mesh

Universal mesh

2D mesh

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

Unique features:

- Standard
 - Gold 0.6mm profile height
 - Blue 0.3mm profile height
 - Green 0.8mm profile height
- Dedicated screw holes for many options in screw place
- Countersink capabilities allow for lower screw-to-mesh profile height
- MR conditional allows diagnostics after implantation



Hybrid mesh

Unique features:

- New 0.3mm Hybrid mesh 3x stronger than 0.3mm Dynamic mesh¹²
- MR conditional allows diagnostics after implantation¹²

Thickness: 0.3mm

3D mesh

Unique features:

- Countersink designed to reduce palpability
- Increased stiffness, for increased patient protection, compared to 2D mesh $^{\rm 13}$
- Used for open defects up to 70mm and muscle attachment (the 1.0mm can cover a max opening of approximately 114mm x 164mm)¹⁴
- Pre-formed can minimize bending to fit patient
- MR conditional allows diagnostics after implantation



Craniomaxillofacial

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets.

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DuraGen is a registered trademark of Integra Lifesciences Corporation.

Durepair is a registered trademark of TEI Biosciences Inc. DuraMatrix, DuraMatrix-Onlay and DuraMatrix-Onlay PLUS are manufactured by Collagen Matrix, Inc., Oakland, New Jersey USA.

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Contraindications: Adherus AutoSpray & Adherus AutoSpray ET Dural Sealant should not be used in confined anatomical spaces where nerve compression is of concern. The hydrogel may swell by up to 13% of its size in any dimension or 46% by volume after application.

Pivotal Trial Results: A prospective, randomized, controlled, multicenter pivotal trial was conducted to evaluate the safety and effectiveness of Adherus AutoSpray Dural Sealant. The primary endpoint of this study was a composite evaluation of the safety and effectiveness of Adherus AutoSpray Dural Sealant (n=124 subjects) when compared to an active control (n=126 subjects). The endpoint results were based on the number of subjects who were free from intra-operative CSF leakage from dural repair after up to two applications of sealant during the Valsalva maneuver, CSF leak/pseudomeningocele during the 120-day follow-up period and unplanned retreatment of the original surgical site within 120 days post-surgery. The overall success rate for the complete case analysis was 91.2% in the Adherus group compared to 90.6% in the control group. Adherus was found to be non-inferior to the control with the non-inferiority margin of 10% (p = 0.005). In the early post-surgical period when the sealants are expected to function, the overall success rate at the 14-day follow-up on subjects who completed the visit was 99.1% in the Adherus group compared to 95.0% in the control group. In addition, the overall success rate at the 45-day follow-up on subjects who completed the visit was 96.6% in the Adherus group compared to 91.9% in the control group. There were no unanticipated adverse device effects. Among the subjects treated with Adherus AutoSpray Dural Sealant, there were no device related deep wound infections and no cases of meningitis. The type and rate of adverse events observed in this study are consistent with the complexity of the surgical procedure and the co-morbid condition of the treated subjects.

Please see Adherus AutoSpray and Adherus AutoSpray ET Dural Sealant instructions for use for more information

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