Duraplasty and Cranioplasty
solutions for all surgical approaches

Codman's got you covered.

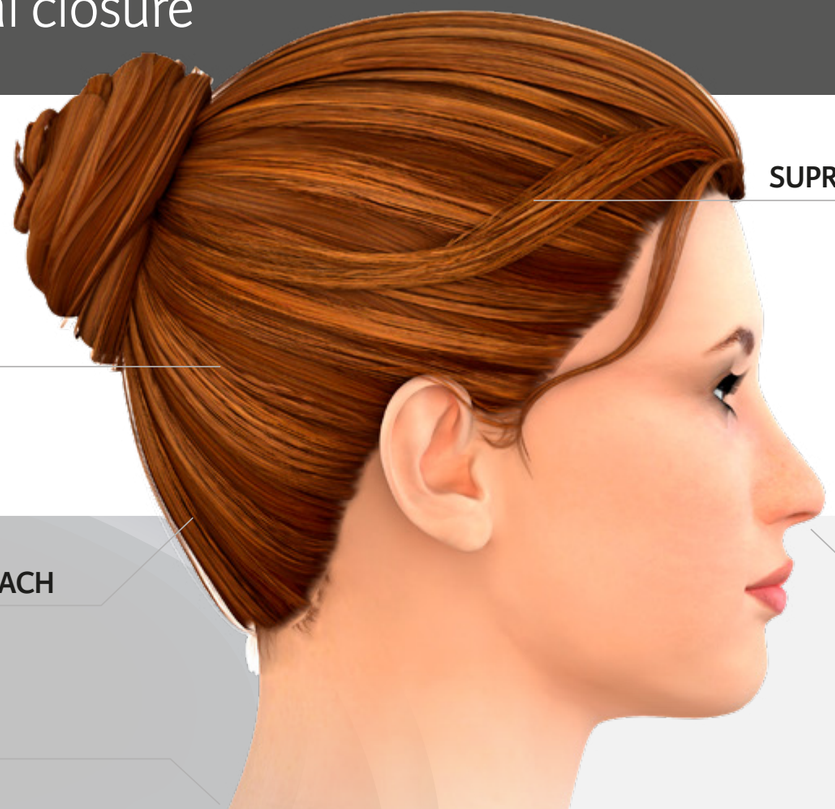
The global leader in neurosurgery.
Your one-stop, comprehensive source
for proven, market-leading solutions.

A DIVISION OF INTEGRA LIFESCIENCES COMPANY

Codman®
SPECIALTY SURGICAL

A complete line of options for dural repair and cranial closure

Codman® SPECIALTY SURGICAL



SUPRATENTORIAL APPROACH / CRANIECTOMY

HEMICRANIECTOMY

The use of DuraGen® in decompressive hemicraniectomy reduces by 1 hour the dural separation time compared to traditional treatment without graft.[1]

Largest size available: 12,5 x 17,5 cm

SKULL-BASE APPROACH

POSTERIOR FOSSA APPROACH

TRANSSPHENOIDAL / ENDONASAL APPROACH

SPINAL APPROACH*

* DuraSeal® Xact Sealant System is indicated for use during spine procedures.

Duraplasty:
DuraGen® family

DuraGen® Plus
Adhesion Barrier Matrix

Versatility and performance: Immediate closure without the use of sutures, facilitated handling and adhesion prevention

Suturable DuraGen®
Dural Regeneration Matrix

Reinforced design to allow mechanical anchoring of the graft

DuraGen® Secure
Dural Regeneration Matrix

CSF prevention in challenging patients thanks to enhanced contact assurance

Sealing:
DuraSeal® Dural Sealant System
DuraSeal® Xact Sealant System

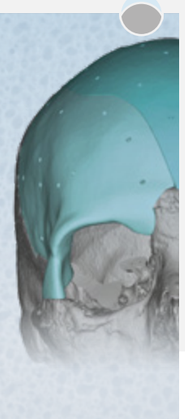
Need an additional layer of security?

The DuraSeal Family of sealants has been specifically designed to augment your sutures and create an immediate and long-lasting watertight closure.

Cranioplasty:
CustomBone Service™

CustomBone Service™ is made of a **bio-mimetic** material resembling the mineral component of **human bone**. This material, combined with an elevated interconnected **porosity**, is suitable for housing cells responsible for bone regeneration thus playing an important role in the process of perimetral **osteointegration** of the implant.

CustomBone Service™ is indicated for reconstructing cranial defects, which may be associated with cranial decompression.



Suturable Duragen® Indications: Suturable DuraGen is indicated as a dural substitute for the repair and restoration of dural defects in cranial and spinal surgical procedures. Suturable DuraGen readily conforms to the surface of the brain and overlying tissues. Suturable DuraGen may be used to close dural defects following traumatic injury, excision, retraction or shrinkage. Suturable DuraGen may be used to supplement primary closure. Suturable Duragen™ Contraindications: Suturable DuraGen is not designed, sold or intended for use except as described in the indications for use and is contraindicated in the following situations: • For patients with a known history of hypersensitivity to bovine derived materials. • Should be used with caution in infected regions.
DuraGen Plus® Indications: DuraGen Plus Adhesion Barrier Matrix is indicated as an onlay graft for the repair and restoration of dural defects in cranial and spinal surgical procedures. DuraGen Plus matrix is also indicated as an adhesion barrier for the inhibition of post-surgical peridural fibrosis. DuraGen Plus matrix readily conforms to the surface of the brain, spinal cord and overlying tissues. DuraGen Plus matrix may be used to close dural defects following traumatic injury, excision, retraction or shrinkage. DuraGen Plus matrix may be used to supplement primary closure. DuraGen Plus™ Contraindications: DuraGen Plus matrix is not designed, sold or intended for use except as described in the indications for use and is contraindicated in the following situations: • For patients with a known history of hypersensitivity to bovine – derived materials. • For primary repair of spinal neural tube defects; anterior spinal surgery with dural resection (e.g., transoral surgery). • Should be used with caution in infected regions. • Not recommended to cover dural defects involving mastoid air cells. • Not recommended for large defects at the skull base following surgery.
Duragen® Secure Indications: DuraGen® Secure Dural Regeneration Matrix is indicated as an onlay graft for the repair and restoration of dural defects in cranial and spinal surgical procedures. DuraGen® Secure Dural Regeneration Matrix readily conforms to the surface of the brain, spinal cord and overlying tissues. DuraGen® Secure Dural Regeneration Matrix may be used to close dural defects following traumatic injury, excision, retraction or shrinkage. DuraGen® Secure Dural Regeneration Matrix may be used to supplement primary closure. DuraGen® Secure matrix may be used in the following procedures:
Cranial Convexity: may be used to cover large defects following surgery, especially for dural loss from excision, contraction, retraction and/or shrinkage; Brain Swelling: intra-operative brain swelling or anticipated postoperative swelling; Posterior Fossa Surgery: 1) General use as a dural graft, 2) decompression craniectomy and dural release for infarcts, i.e., Posterior Inferior Cerebellar Artery (PICA) infarcts, 3) anticipated swelling after trauma, and 4) may be used in Chiari decompression procedures;
Spinal Surgery: 1) General use as a spinal onlay dural graft, especially useful for defects arising from pinhole tears, disc surgery, and spinal stenosis decompression, 2) after resection of intradural tumors, 3) onlay graft after dural approximation with sutures, 4) as a separation layer between the dura and overlying tissues. Duragen® Secure Contraindications: DuraGen® Secure Dural Regeneration Matrix is not designed, sold or intended for use except as described in the Indications for Use and is contraindicated in the following situations: For patients with a known history of hypersensitivity to bovine derived materials. For repair of spinal neural tube defects or anterior spinal surgery with dural resection. Should be used with caution in infected regions. Not recommended to cover dural defects involving mastoid air cells. Not recommended for large defects at the skull base following surgery.

Indications: The DuraSeal® dural sealant system is intended for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure. The DuraSeal® Xact system is indicated for use during spine procedures as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure. Contraindications: Do not apply the DuraSeal® Dural Sealant in abdominopelvic surgical procedures for use as a sealant or adhesion barrier. Do not apply the DuraSeal® Xact hydrogel in abdominopelvic surgical procedures for use as a sealant or adhesion barrier. Do not use Extended Tip Applicator, MicroMyst® Applicator and Flow Regulator for other indications than the ones mentioned in the instructions for use.

CustomBone Service Intended Use: CustomBone Service is intended to replace bony voids in the cranial and/or craniofacial skeleton. This device may be used both for adult and paediatric patients (for children above 2 years of age). "CustomBone" custom-made implants are suitable for reconstructing cranial defects resulting from: trauma and vascular pathologies, either associated or non-associated to cranial decompression; removal of tumours; reabsorption of autologous bone; rejection of other prosthetic materials; congenital
malformations.
Contraindications: Use of "CustomBone" prostheses should be avoided in the presence of inflammatory conditions and manifest infections of the surgical area to be treated, as well as in insufficiently vascularized sites. The "CustomBone" prostheses should not be implanted if duramater lacerations are present. In addition, they should not be used in
patients suffering from a proven hypersensitivity to calcium phosphates or serious forms of demineralization diseases, chronic hypertension, hemocoagulation disorders, in the event of infections resulting from previous surgery or in patients treated with steroid or anti-coagulation therapies. No side effects have been noted in the use of "CustomBone" where tumours have been present. Nonetheless, patients that undergo treatment with "CustomBone" following the removal of a neoplasm should be monitored. The product must not be implanted in areas in which skin tissue is not sufficient to cover the implant entirely.

Duraplasty and Cranioplasty solutions for all surgical approaches

DuraGen® Plus matrix

Reference	Size	Units
DP1011I	1 in x 1 in (2.5 cm x 2.5 cm)	1
DP5011I	1 in x 1 in (2.5 cm x 2.5 cm)	5
DP1013I	1 in x 3 in (2.5 cm x 7.5 cm)	1
DP5013I	1 in x 3 in (2.5 cm x 7.5 cm)	5
DP1022I	2 in x 2 in (5 cm x 5 cm)	1
DP5022I	2 in x 2 in (5 cm x 5 cm)	5
DP1033I	3 in x 3 in (7.5 cm x 7.5 cm)	1
DP5033I	3 in x 3 in (7.5 cm x 7.5 cm)	5
DP1045I	4 in x 5 in (10 cm x 12.5 cm)	1
DP1057I	5 in x 7 in (12.5 cm x 17.5 cm)	1

Suturable DuraGen® matrix

Reference	Size	Units
DURS1391ITL	1 in x 3 in (2.5 cm x 7.5 cm)	1
DURS1395ITL	1 in x 3 in (2.5 cm x 7.5 cm)	5
DURS2291ITL	2 in x 2 in (5 cm x 5 cm)	1
DURS2295ITL	2 in x 2 in (5 cm x 5 cm)	5
DURS3391ITL	3 in x 3 in (7.5 cm x 7.5 cm)	1
DURS3395ITL	3 in x 3 in (7.5 cm x 7.5 cm)	5
DURS4591ITL	4 in x 5 in (10 cm x 12.5 cm)	1

DuraGen® Secure matrix

Reference	Size	Units
DRM1011I	1 in x 1 in (2.5 cm x 2.5 cm)	1
DRM1013I	1 in x 3 in (2.5 cm x 7.5 cm)	1
DRM1022I	2 in x 2 in (5 cm x 5 cm)	1
DRM1033I	3 in x 3 in (7.5 cm x 7.5 cm)	1

DuraSeal® Dural Sealant

Reference	Size	Units
DSD5001	DuraSeal® dural sealant system - 5mL	1kit/box
DSD5005	DuraSeal® dural sealant system - 5mL	5 kits/box
203001	DuraSeal® Xact - spinal sealant system - 3mL	1kit/box
204003	DuraSeal® Xact - spinal sealant system - 3mL	5kits/box
205108	Extended Tip Applicator - 8cm length	5kits/box
205115	Extended Tip Applicator - 15cm length	5kits/box
205000DS**	MicroMyst® Applicator - 14cm length	5kits/box
FR6065	Flow Regulator	1 unit/box

** MicroMyst® Applicator requires an air source to operate – used in conjunction with the Flow Regulator.

CustomBone Service™

82-6650	Single implant
82-6650CX	Double implant

1. Horaczek JA, et al
Collagen matrix in decompressive hemicraniectomy.
Neurosurgery 63 (1 suppl.1) : ONS 176-ONS 181, 2008

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Please read carefully the instructions for use.
- Non contractual document. Integra reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

Products mentioned in this document are CE class IIa (applicators) and III devices. Please contact Integra customer service should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE MARKED".

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