

Integra®

Dural Repair Catalogue
Grafts & Sealants

Limit the uncertainties at the closure stage with DuraGen® and DuraSeal®, the complete solution to achieve an effective dural watertightness in cranial and spinal procedures



INTEGRA®
LIMIT UNCERTAINTY

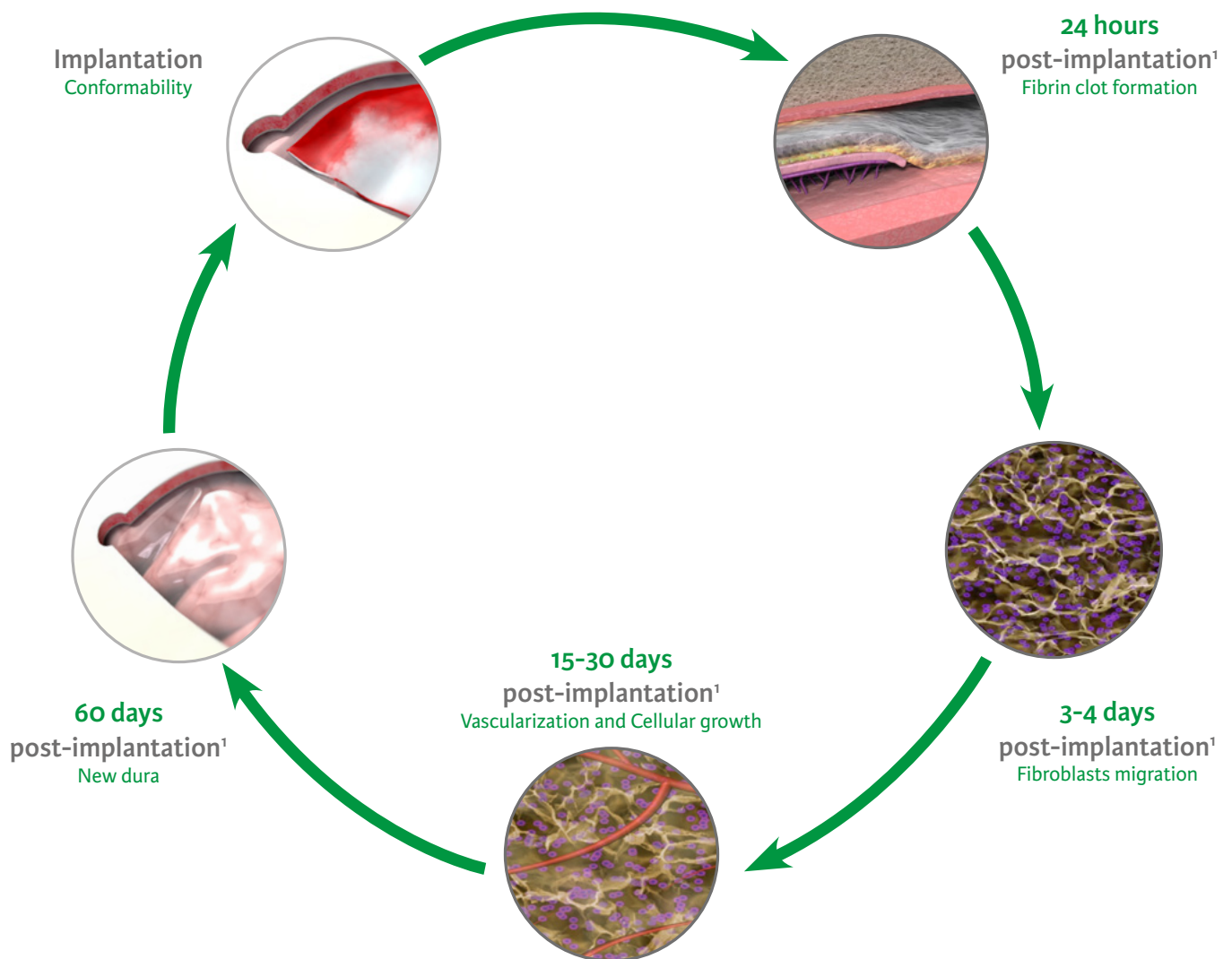
1. The DuraGen® Family

1.1. The Ultra Pure Collagen™ Technology

The DuraGen® Family of dural regeneration matrices has been specifically designed for restoration and repair of the dura mater. The DuraGen® Family is manufactured from a controlled collagen source, and treated using a process intended to eliminate antigenic components: the Ultra Pure Collagen™ Technology.

1.2. Mode of action of the Integra dural regenerative matrices

The histological post-implantation evaluation from 100 patients¹ has shown that fibroblasts migrate into the collagen matrix and proliferate. The porous structure of the collagen matrix supports the fibroblasts growth into the graft. Fibroblasts have been observed using the collagen fibers of the matrix as a scaffold for the new layer of collagen formed.



1. NAROTAM PK, et al. A clinicopathological study of collagen sponge as a dural graft in neurosurgery. J Neurosurg 82:406–412, 1995

DuraGen® Plus matrix

Designed for the repair and restoration of dural defects in cranial and spinal procedures, and as an adhesion barrier for the reduction of peridural fibrosis.



Performance

DuraGen® Plus matrix

Reference	Size	Unit(s)
DP1011l	1 in x 1 in (2.5 cm x 2.5 cm)	1
DP5011l	1 in x 1 in (2.5 cm x 2.5 cm)	5
DP1013l	1 in x 3 in (2.5 cm x 7.5 cm)	1
DP5013l	1 in x 3 in (2.5 cm x 7.5 cm)	5
DP1022l	2 in x 2 in (5 cm x 5 cm)	1
DP5022l	2 in x 2 in (5 cm x 5 cm)	5
DP1033l	3 in x 3 in (7.5 cm x 7.5 cm)	1
DP5033l	3 in x 3 in (7.5 cm x 7.5 cm)	5
DP1045l	4 in x 5 in (10 cm x 12.5 cm)	1
DP1057l	5 in x 7 in (12.5 cm x 17.5 cm)	1

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 may be used for 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; -Adhesion Barrier: To inhibit post-surgical peridural fibrosis in laminectomy, laminotomy or discectomy procedures where nerve roots are exposed.

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 hyper sensitivity to bovine derived materials; for repair of spinal neural tube defects; anterior spinal surgery with dural resection (e.G., Trans oral 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.

*Compared with DuraGen® matrix, the 1st generation of Integra dural grafts.

**Decompressive Hemicraniectomy.

Suturable DuraGen® matrix

Designed for the repair and restoration of dural defects in cranial and spinal procedures.



Adaptability

Suturable DuraGen® matrix

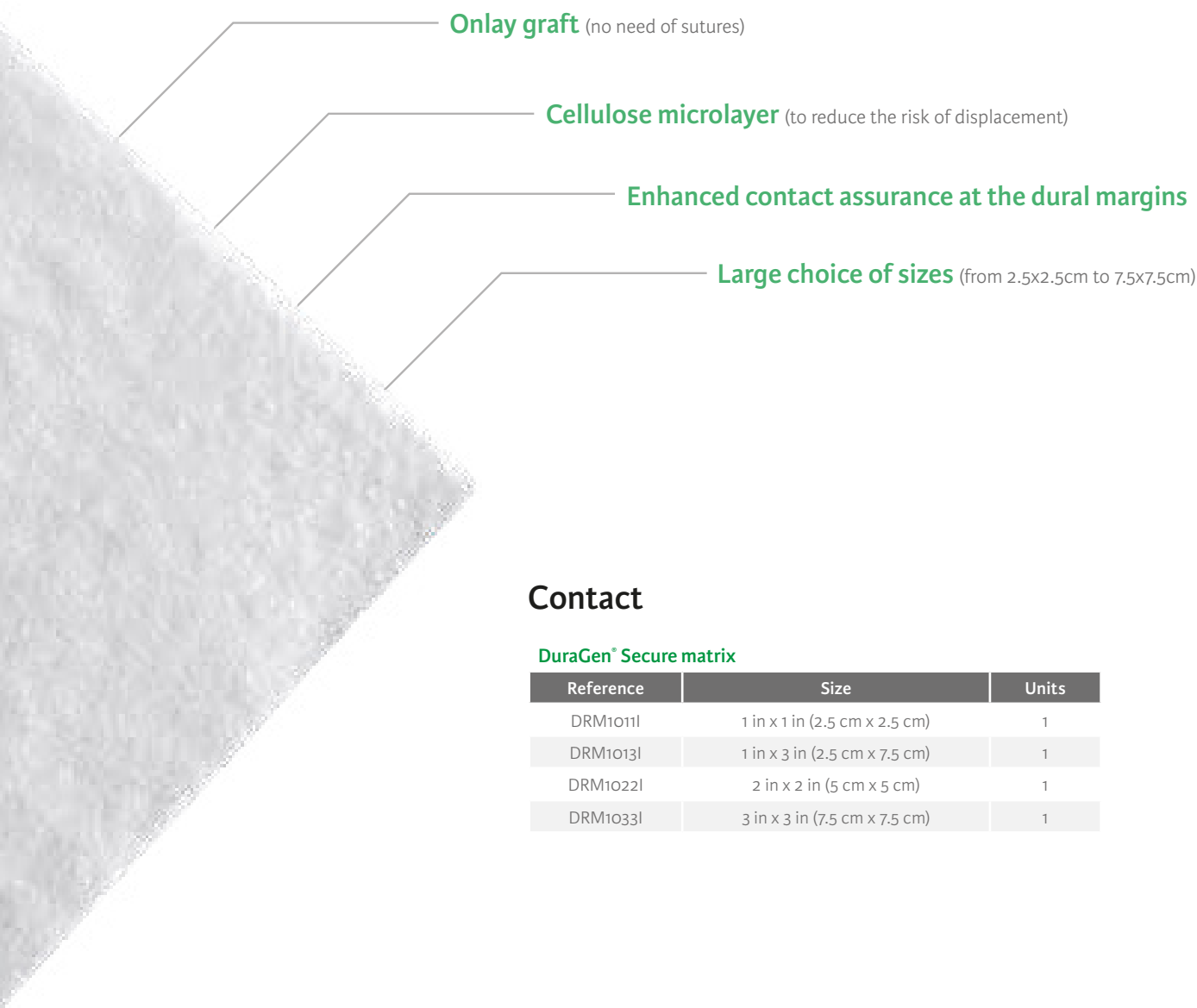
Reference	Size	Unit(s)
DURS1391ITL	1 in x 3 in (2.5 cm x 7.5 cm)	1
DURS1395ITL	1 in x 3 in (2.5 cm x 7.5 cm)	5
DURS2291ITL	2 in x 2 in (5 cm x 5 cm)	1
DURS2295ITL	2 in x 2 in (5 cm x 5 cm)	5
DURS3391ITL	3 in x 3 in (7.5 cm x 7.5 cm)	1
DURS3395ITL	3 in x 3 in (7.5 cm x 7.5 cm)	5
DURS4591ITL	4 in x 5 in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

Suturable DuraGen® matrix readily conforms to the surface of the brain and overlying tissues. Suturable DuraGen® matrix may be used to close dural defects following traumatic injury, excision, retraction or shrinkage. Suturable DuraGen® matrix may be used to supplement primary closure. Suturable DuraGen® 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 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, and 4) as a separation layer between the dura and overlying tissues.

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® Secure matrix

Designed for the repair and restoration of dural defects in cranial and spinal procedures.



Contact

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

DuraGen® Secure matrix readily conforms to the surface of the brain, spinal cord and overlying tissues. DuraGen® Secure matrix may be used to close dural defects following traumatic injury, excision, retraction or shrinkage. DuraGen® Secure 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 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.

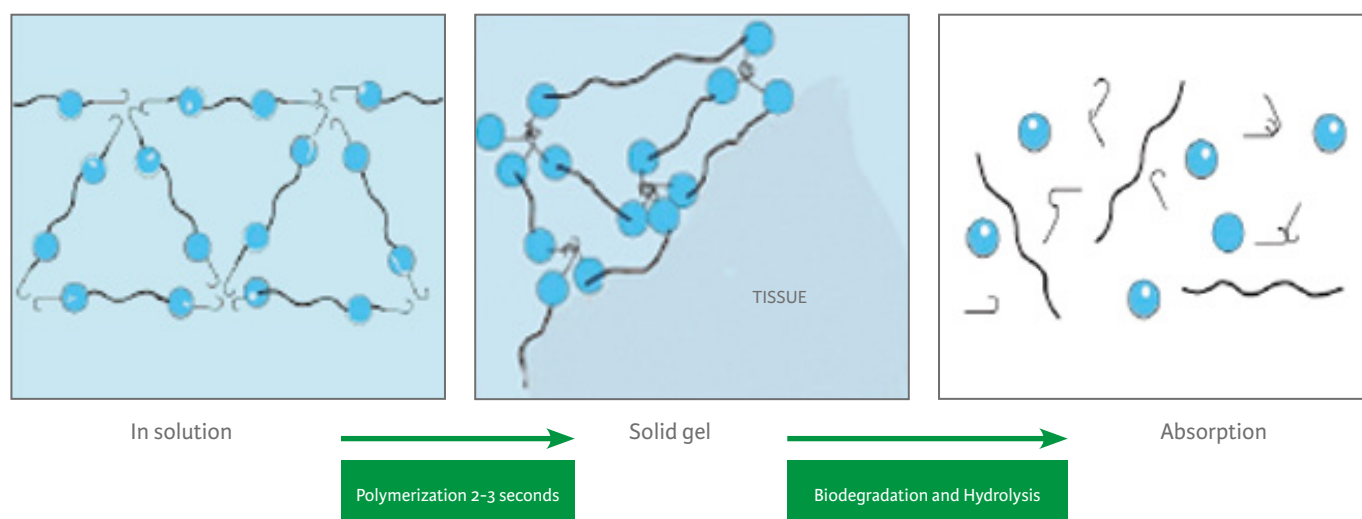
2. The DuraSeal® Family

2.1. The PEG Hydrogel Technology

The DuraSeal® Family of sealants has been specifically designed for use as adjuncts to standard methods of dural repair, such as sutures, to provide watertight closure intraoperatively and through the critical healing period. The DuraSeal® Family is manufactured with a specific polymer technology, combining a PEG ester (Polyethylene Glycol) and Trilysine amine, and resulting in a flexible and biocompatible hydrogel.

2.2. Mode of action of the Integra dural sealants

The polymerization is the mechanics behind the formation of the hydrogel. The resulting surgical sealant hydrogels contain more than 90% water. When the 2 precursors mix, the trilysine amine locate on the terminations of the PEG molecules and allow crosslinking to occur. Hydrolysis releases the soluble PEG molecules and trilysine molecules into the water.



DuraSeal® Cranial Sealant

Designed for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure during cranial procedures.



Cranial

DuraSeal® Sealant System

Product Code	Size	Unit(s)
DSD5001	Cranial Sealant - 5mL	1
DSD5005	Cranial Sealant - 5mL	5

The DuraSeal® cranial sealant system is intended for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure. Do not apply the DuraSeal® Cranial Sealant in abdominopelvic surgical procedures for use as a sealant or adhesion barrier.

1. Campbell PK. et al. Evaluation of Absorbable Surgical Sealants. In vitro Testing LT-6000-016 Rev. Confluent Surgical, Inc., Waltham, MA 02451, 2005.

2. DuraSeal® Tender Package ref. 0274115, page 3.

DuraSeal® Xact Spinal Sealant

Designed for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure during spinal procedures.



Spinal

DuraSeal® Xact Sealant System

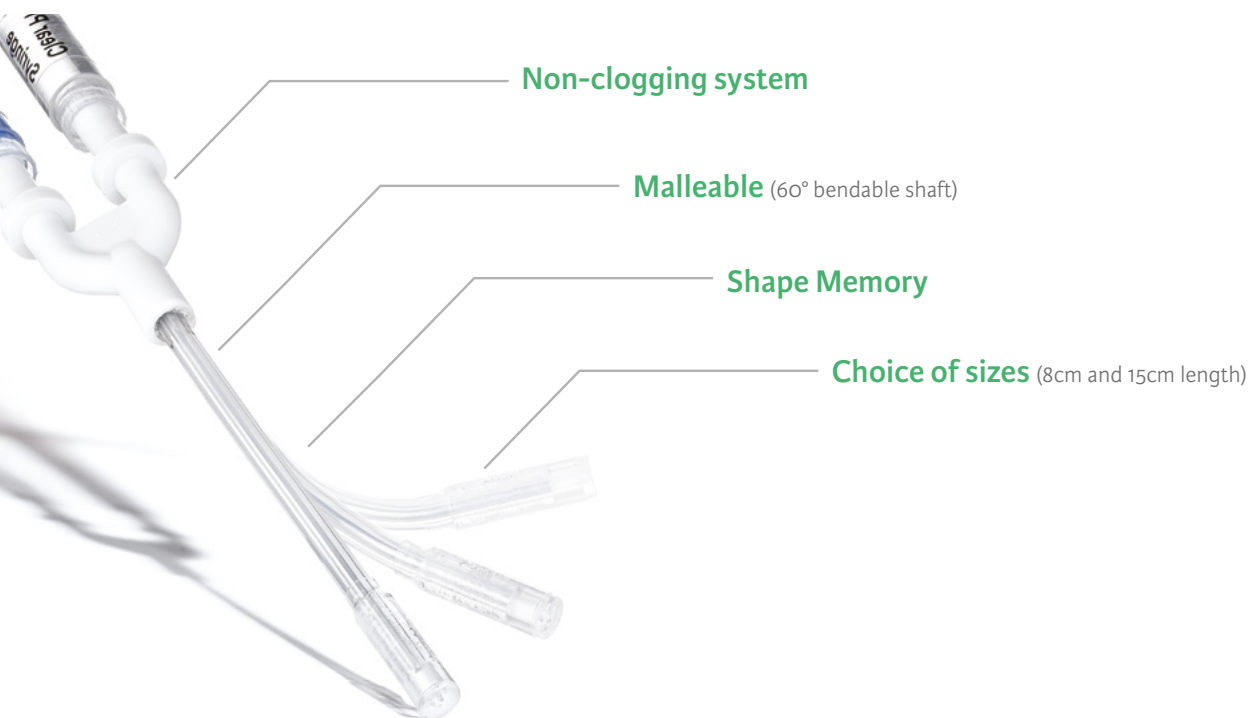
Product Code	Size	Unit(s)
203001	Spinal Sealant - 3mL	1
204003	Spinal Sealant - 3mL	5

The DuraSeal® Xact Sealant System is indicated for use during spine procedures as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure. Do not apply the DuraSeal® Xact Spinal Sealants in abdominopelvic surgical procedures for use as a sealant or adhesion barrier.

1. Campbell PK. et al. Evaluation of Absorbable Surgical Sealants. In vitro Testing LT-6000-016 Rev. Confluent Surgical, Inc., Waltham, MA 02451, 2005.

Extended Tip Applicators

Designed for use in the simultaneous delivery of two nonhomogeneous solutions onto a surgical site.



Tight Spaces



Extended Tip Applicators

Product Code	Size	Unit(s)
205108	8cm length	5
205115	15 cm length	5

The Extended Tip Applicator is intended for use in the simultaneous delivery of two non homogenous solutions onto a surgical site. Do not use Extended Tip Applicator for other indications than ones provided in the instructions for use.

The DuraGen® Clinical Evidence:

- **DuraGen® has more clinical data than any other collagen-based dural grafts¹⁻¹⁰:**
 - ✓ More than 1400 patients studied*
 - ✓ 0% Foreign Body Response*
 - ✓ CSF leaks: 1.9% in average (0%-7.1%)*
 - ✓ Infection: 2.1% in average (0%-5.6%)*
- **DuraGen® has shown significant outcomes in terms of:**
 - ✓ Operative time reduction^{1,3}
 - ✓ Ease of use⁸
 - ✓ Regeneration and resorption capability⁵

The DuraSeal® Clinical Evidence:

- **DuraSeal® is more effective at preventing CSF leaks than fibrin glue¹¹:**
 - ✓ Significantly less incisional CSF leaks (P=0.03**)
 - ✓ Length of hospital stay: shorter by more than a day, on average (P=0.02**)
 - ✓ Longer mean time to leak (P=0.005**)
- **DuraSeal® Xact helps surgeons achieve watertight dural closure better than the Standard of Care¹²:**
 - ✓ Clinically proven to prevent intra-operative CSF leaks: 100% success rate (P<0.001**)
 - ✓ Fewer applications achieve watertight closure, saving surgeon's time

(*) Summary outcome statistics derived from the following clinical studies:

1. Danish SF, et al: Experience with acellular human dura and bovine collagen matrix for duraplasty after posterior fossa decompression for Chiari malformations. J Neurosurg Pediatrics 104:16-20, 2006
2. Harvey RJ, et al: Closure of large skull base defects after endoscopic transnasal craniotomy. J Neurosurg 111 (2) : 371-379, 2009
3. Horaczek JA, et al: Collagen matrix in decompressive hemicraniectomy. Neurosurgery 63 (1 suppl.1) : ONS 176-ONS 181, 2008
4. Lee JH, et al: Dural reconstruction in meningioma surgery in, Lee JH (ed): Meningiomas: Diagnosis, Treatment and Outcome. London: Springer, 2009, pp 619-624
5. Narotam PK, et al: A clinicopathological study of collagen sponge as a dural graft in neurosurgery. J Neurosurg 82:406-412, 1995.
6. Narotam PK, et al: Collagen matrix (DuraGen) in dural repair: analysis of a new modified technique. Spine 29 (24) :2861-2867, 2004
7. Narotam PK, et al: Collagen matrix duraplasty for cranial and spinal surgery: a clinical and imaging study. J Neurosurg 106 (1) :45-51, 2007
8. Narotam PK, et al: Collagen matrix duraplasty for posterior fossa surgery: evaluation of surgical technique in 52 adult patients. J Neurosurg 111 (2) :380-386, 2009
9. Sade B, et al: Non-watertight dural reconstruction in meningioma surgery: results in 439 consecutive patients and a review of the literature. Clinical article. J Neurosurg 114 (3) :714-718, 2011.
10. Stendel R, et al: Efficacy and safety of a collagen matrix for cranial and spinal dural reconstruction using different fixation techniques. J Neurosurg 109 (2) :215-221, 2008

(**) Statistically significant, P<0.05.

11. Than KD, et al: Polyethylene glycol hydrogel dural sealant may reduce incisional cerebrospinal fluid leak after posterior fossa surgery. Neurosurgery 2008;63(suppl 1):ONS182-ONS186.
12. Kim KD, et al: Polyethylene glycol hydrogel spinal sealant (DuraSeal Spinal Sealant) as an adjunct to sutured dural repair in the spine. Spine 2011; 36(Number 23):1906-1912.

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.

- Non contractual document. The manufacturer 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.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

Products mentioned in this document are CE class IIa (Extended Tip 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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