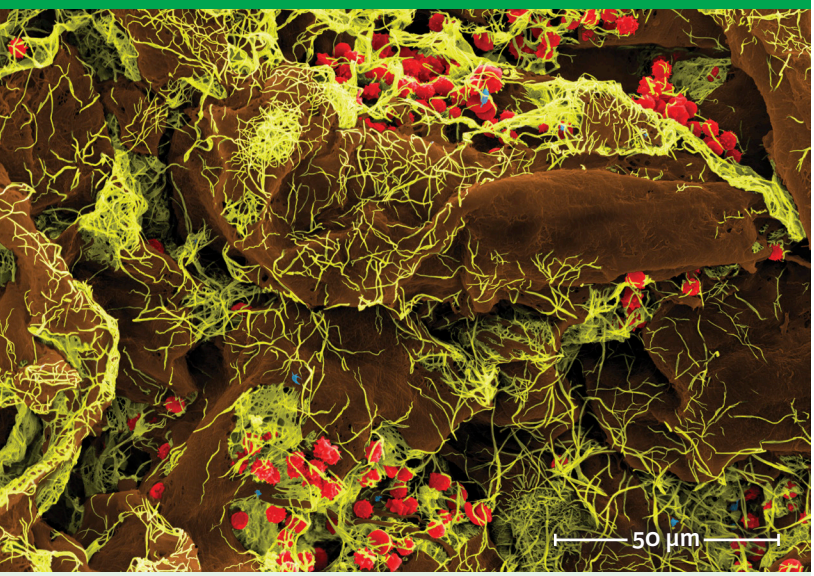
# DuraGen® Plus Dural Regeneration Matrix: Any side is the right side

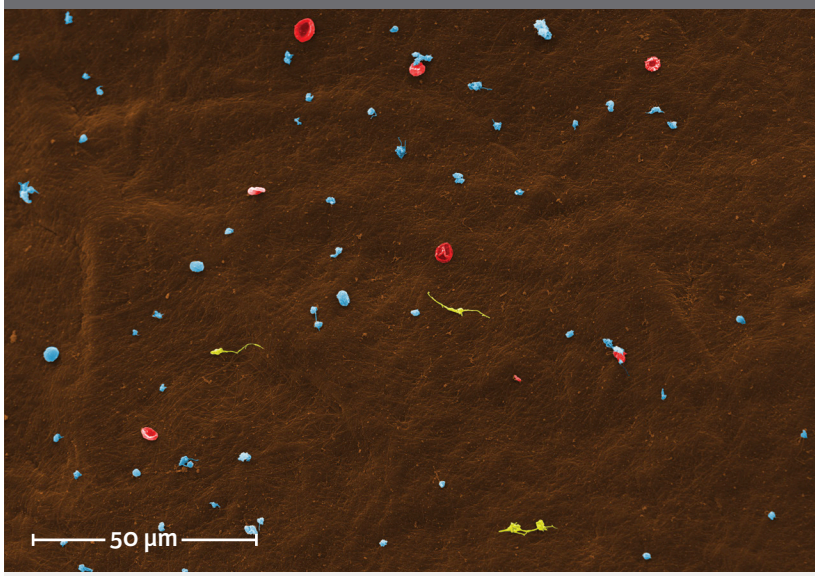
Safely apply either side down, with no need to prehydrate

## DuraGen® Plus Dural Regeneration Matrix (top side)




**After 10-minute laboratory tests, the open-pore structure of DuraGen Plus' top side** promotes rapid platelet aggregation, and an extensive fibrin network forms to provide a watertight seal.[1†]

## DuraMatrix-Onlay® Plus matrix (top, smooth, side)*




**After 10-minute laboratory tests, the impermeable top, smooth, side of DuraMatrix Onlay Plus** shows sparse infiltration of red blood cells and little platelet aggregation; only a few fibrin strands can be seen and fibrin networks are absent.[1†‡]

KEY Collagen matrix | Platelet | Fibrin | Red blood cell

## Always the right choice

DuraGen® Plus promotes rapid platelet aggregation and degranulation, helping to form a stable fibrin clot for CSF leak prevention.

CSF=cerebral spinal fluid.

*IFU indicates DuraMatrix-Onlay® Plus to be applied prehydrated over the defect site, with the smooth side up and the sponge side down (toward the brain).

†Image is representative of study data on file.[1]

‡Please refer to IFU for directions for use.

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# DuraGen® Plus Dural Regeneration Matrix

- **DuraGen® Clinical Data:** 10 peer-reviewed, published studies with more than 1,400 patients[2-11]
- **Trusted By Neurosurgeons:** Implanted in more than 2 million patients and counting[12]
- **Precisely Engineered Porosity:** Ultra Pure Collagen™ matrix rapidly initiates fibrin clot[12]

## Ordering Information

| Reference | Size | Units/Case |
|---|---|---|
| DP1011-I | 1 in x 1 in (2.5 cm x 2.5 cm) | 1 |
| DP5011-I | 1 in x 1 in (2.5 cm x 2.5 cm) | 5 |
| DP1013-I | 1 in x 3 in (2.5 cm x 7.5 cm) | 1 |
| DP5013-I | 1 in x 3 in (2.5 cm x 7.5 cm) | 5 |
| DP1022-I | 2 in x 2 in (5 cm x 5 cm) | 1 |
| DP5022-I | 2 in x 2 in (5 cm x 5 cm) | 5 |
| DP1033-I | 3 in x 3 in (7.5 cm x 7.5 cm) | 1 |
| DP5033-I | 3 in x 3 in (7.5 cm x 7.5 cm) | 5 |
| DP1045-I | 4 in x 5 in (10 cm x 12.5 cm) | 1 |
| DP1057-I | 5 in x 7 in (12.5 cm x 17.5 cm) | 1 |

**For more information or to place an order, please contact:**

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**References: 1.** Data on file. Platelet Aggregation Test. October 2018. **2.** Narotam PK, Jose S, Nathoo N, Taylon C, Vora Y. Collagen matrix (DuraGen) in dural repair: analysis of a new modified technique. *Spine.* 2004;29(24):2861-2867. **3.** Danish SF, Samdani A, Hanna A, Storm P, Sutton L. Experience with acellular human dura and bovine collagen matrix for duraplasty after posterior fossa decompression for Chiari malformations. *J Neurosurg.* 2006;104(suppl 1):16-20. **4.** Narotam PK, Reddy K, Fewer D, Qiao F, Nathoo N. Collagen matrix duraplasty for cranial and spinal surgery: a clinical and imaging study. *J Neurosurg.* 2007;106(1):45-51. **5.** Horaczek JA, Zierski J, Graewe A. Collagen matrix in decompressive hemicraniectomy. *Neurosurgery.* 2008;63(1)(suppl 1):ONS176-181. **6.** Stendel R, Danne M, Fiss I, et al. Efficacy and safety of a collagen matrix for cranial and spinal dural reconstruction using different fixation techniques. *J Neurosurg.* 2008;109(2):215-221. **7.** Harvey RJ, Nogueira JF, Schlosser RJ, Patel SJ, Vellutini E, Stamm AC. Closure of large skull base defects after endoscopic transnasal craniotomy. Clinical article. *J Neurosurg.* 2009;111(2):371-379. **8.** Narotam PK, Qiao F, Nathoo N. Collagen matrix duraplasty for posterior fossa surgery: evaluation of surgical technique in 52 adult patients. Clinical article. *J Neurosurg.* 2009;111(2):380-386. **9.** Lee JH, Sade B. Dural reconstruction in meningioma surgery. In: Lee JH, ed. *Meningiomas: Diagnosis, Treatment and Outcome.* 1st ed. London, UK: Springer-Verlag London Ltd; 2009:619-624. **10.** Litvack ZN, West GA, Delashaw JB, Burchiel KJ, Anderson VC. Dural augmentation: part I: evaluation of collagen matrix allografts for dural defect after craniotomy. *Neurosurgery.* 2009;65(5):890-897. **11.** Sade B, Oya S, Lee JH. Non-watertight dural reconstruction in meningioma surgery: results in 439 consecutive patients and a review of the literature. Clinical article. *J Neurosurg.* 2011;114(3):714-718. **12.** Data on file. Integra LifeSciences Corporation, October 2018.

**Disclaimer: In vitro studies are not indicative of clinical outcomes.**

**INDICATIONS FOR USE.** 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. In clinical evaluations, DuraGen Plus matrix has been demonstrated to be an effective dural graft matrix 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.

**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.



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