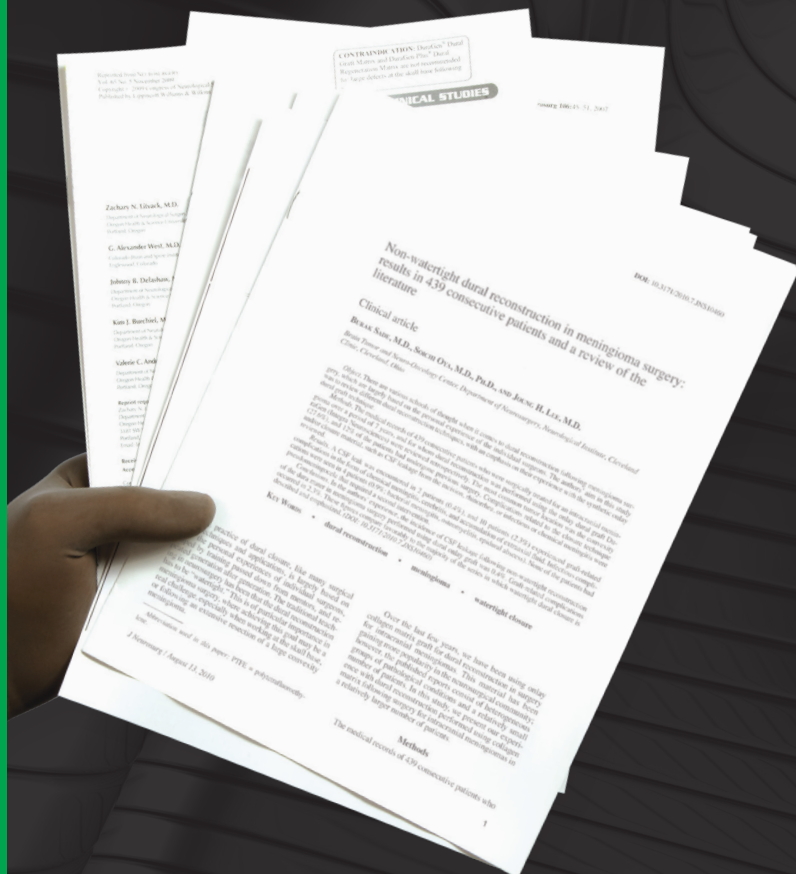


# Integra® DuraGen®

Dural Regeneration Matrix

Limit uncertainty with the most studied and proven collagen-based dural grafts



# Integra® DuraGen® Matrix

Unsurpassed Clinical Data



## What is DuraGen® Matrix

**DuraGen matrix is one of the safest and most effective onlay grafts for the restoration and repair of dura mater.**

It is conformable and contours instantly and effectively to the complex, moist surfaces of the brain and spinal cord, rapidly supporting the formation of a biological seal to protect against CSF leakage.

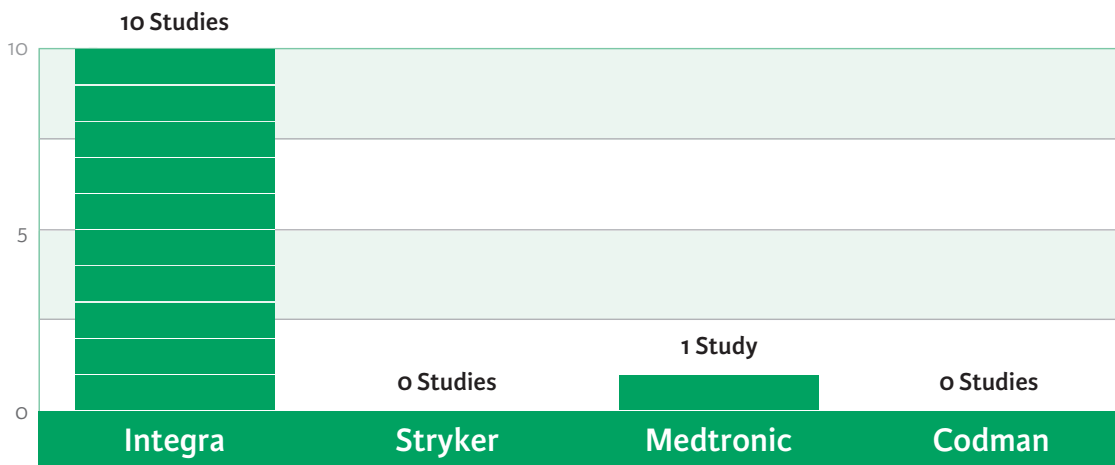
## The DuraGen Matrix Difference

“**The Fibroblasts Use the Pores** on the Matrix to **Lay Down Endogenous Collagen**. By 6-8 Weeks, the Collagen Matrix (DuraGen Matrix) is **Resorbed and is Integrated** to the Endogenous Dura Mater. The Compact Structure of the **(Other) Xenogenic Materials** May **Limit the Fibroblast Migration** to the Edges or to the Suture Holes. These Processes **do not Constitute an Ideal Situation** with Regards to the **Sealing Quality** of the Material.”

- Sade et al<sup>9</sup>

## An Investment in Data

Patient outcomes are very important to you and your patients—DuraGen Matrix has more published clinical data than any other collagen-based dural graft.



Date: As of January 1, 2012

## The DuraGen Matrix Studies

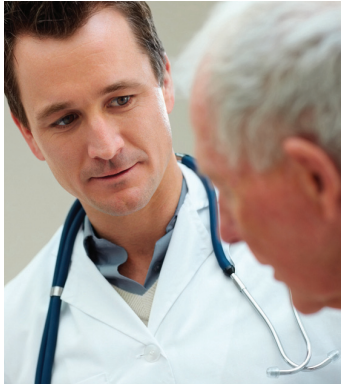
**Over 1,400 Patients  
in 10 Published  
Clinical Studies**

- 0% Foreign body response
- 1.9% Infection rate
- 2.1% Leakage rate

Author	Study Name	DuraGen Patients Studied	Procedure Type
Danish et al <sup>1</sup>	Experience with acellular human dura and bovine collagen matrix for duraplasty after posterior fossa decompression for Chiari malformations	56	Posterior Fossa Decompression
Harvey et al <sup>2</sup>	Closure of large skull base defects after endoscopic transnasal craniotomy	30	Endoscopic Transnasal Craniotomy
Horaczek et al <sup>3</sup>	Collagen matrix in decompressive hemicraniectomy	18	Decompressive Hemicraniectomy, Cranioplasty
Lee et al <sup>4</sup>	Dural reconstruction in meningioma surgery	237	Intracranial Meningioma Resection
Litvack et al <sup>5</sup>	Dural augmentation: Part I – Evaluation of collagen matrix allografts for dural defect after craniotomy	320	Frontal Craniotomy, Suboccipital/Retrosigmoid Craniotomy, Temporal Craniotomy
Narotam et al <sup>6</sup>	Collagen matrix (DuraGen) in dural repair: analysis of a new modified technique	110	Spinal Surgery
Narotam et al <sup>7</sup>	Collagen matrix duraplasty for cranial and spinal surgery: a clinical and imaging study	79	Posterior Fossa Craniectomy, Lumbar Laminectomy, Supratentorial Craniotomy
Narotam et al <sup>8</sup>	Collagen matrix duraplasty for posterior fossa surgery: evaluation of surgical technique in 52 adult patients	52	Posterior Fossa Surgery
Sade et al <sup>9</sup>	Non-watertight dural reconstruction in meningioma surgery results in 439 consecutive patients and a review of the literature	439	Intracranial Meningioma Resection
Stendel et al <sup>10</sup>	Efficacy and safety of a collagen matrix for cranial and spinal dural reconstruction using different fixation techniques	112	Cranial and Spinal Procedures

**TOTAL: 1,453**

These studies represent the use of DuraGen matrix without the use of dural sealants.



## 1 Million Dural Grafts and Counting

Only Integra DuraGen graft provides the confidence of utilizing a dural matrix which has been implanted over one million times.

## 10 Million Collagen Implants and Counting

Our leading technology collagen products have been implanted over 10 million times in a variety of procedures throughout the world.

### DuraGen Dural Regenerative Matrix

- Made from Ultra Pure Collagen™
- Precisely engineered porosity for complete and natural repair
- Superior conformability

### Summary outcome statistics derived from the following 10 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*. 2006;104:16-20.
2. Harvey RJ, et al. Closure of large skull base defects after endoscopic transnasal craniotomy. *J Neurosurg*. 2009;111: 271-329.
3. Horaczek JA, et al. Collagen matrix in decompressive hemicraniectomy. *Operative Neurosurgery*. 2008;63:ONS176-81.
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. Litvack ZN, et al. Dural augmentation: Part I: evaluation of collagen matrix allografts for dural defect after craniotomy. *Neurosurgery*. 2009;65:890-897.
6. Narotam PK, et al. Collagen matrix (DuraGen) in dural repair: analysis of a new modified technique. *SPINE*. 2004;292:861-2867.
7. Narotam PK, et al. Collagen matrix duraplasty for cranial and spinal surgery: a clinical and imaging study. *J Neurosurg*. 2007;106:45-51.
8. Narotam PK, et al. Collagen matrix duraplasty for posterior fossa surgery: evaluation of surgical technique in 52 adult patients. *J Neurosurg*. 2009;111:380-386.
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*. [epub ahead of print August 13, 2010. DOI: 10.3171/2010.7.JNS10460]
10. Stendel R, et al. Efficacy and safety of a collagen matrix for cranial and spinal dural reconstruction using different fixation techniques. *J Neurosurg*. 2008;109:215-221.

Medtronic Study: Parker, et al: Complications following decompression of Chiari malformation Type I in children: dural graft or sealant? *J Neurosurg. Pediatrics* 2011;8:177-183.

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