Integra

DuraGen® Family
Dural Regeneration Matrices

Limit uncertainty with proven solutions for CSF leak prevention and natural dural repair.
A Pioneer in Collagen Regeneration Matrices

For almost forty years, Integra and its predecessors have been leading the development and manufacturing of collagen implants and advanced regenerative technologies. In the early 1970’s the first collagen matrix to improve skin restoration of severely burned patients was developed. This advanced matrix led to a revolution in understanding the science behind the biological response and role of extracellular matrices in tissue regeneration. This science along with expertise in collagen processing and manufacturing resulted in DuraGen® dural regeneration matrix.

- Integra pioneered regenerative medicine.
- Over 10 million collagen implants.
- 1 million implants and counting.
- Integra created the onlay dural graft paradigm.

What is DuraGen® Matrix?

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

- DuraGen® matrix is made from a controlled collagen source and is treated with a proprietary process designed to remove antigenic components, yielding our Ultra Pure Collagen™ Technology.

- It is conformable and contours instantly and effectively to the complex surfaces of the brain and spinal cord, rapidly forming a biological seal to protect against cerebrospinal fluid (CSF) leakage: 1 day post-implantation, a fibrin clot has formed within the matrix creating a watertight barrier.

How does the Duragen® matrix work?

The onlay nature of DuraGen® matrix revolutionized duraplasty.

- The highly porous collagen scaffold promotes rapid fibrin clot formation.
- DuraGen® matrix rapidly provides watertight closure to prevent CSF leakage while promoting natural dural growth.
THE DURAGEN® MATRIX WAS ENGINEERED WITH THE IDEAL BALANCE OF STRENGTH AND FLEXIBILITY TO ENSURE OPTIMAL HANDLING, SEALING, AND RESORPTION—LEAVING THE PATIENT WITH A NATURAL DURAL REPAIR.

It Starts with Ultra Pure Collagen™ Technology

- Harvested, processed, and purified to limit the risk of infection, immunological response, and foreign body reaction, thereby reducing the chance of fibrotic encapsulation.
- In almost 40 years of Ultra Pure Collagen™ Technology use, there have been no confirmed reports of foreign-body reactions or rejections.
- Integra’s Ultra Pure Collagen™ Technology is the foundation of DuraGen® matrix.

Precisely Engineered Porosity

- Platelets infiltrate the matrix and initiate fibrin clot formation, forming an effective layer that prevents CSF leakage and initiates the dural repair process.
- The pore size is optimized to allow fibroblasts to rapidly enter the matrix and lay down natural collagen fibers.
- The optimized 99% porosity, even distribution, and pore interconnectivity promote uniform tissue regeneration throughout the matrix.

Excellent Conformability and Handling

- Offers optimal conformability and ease of handling.
- DuraGen® matrix is quickly and easily hydrated prior to implantation or in situ.
- Upon hydration, DuraGen® matrix becomes a pliable membrane that conforms to the existing dura and remains in place through surface tension and fibrin clot formation, eliminating the need for sutures.

Integra’s Dural Regeneration Matrices are specially designed to meet your cranial and spinal needs.

Safety Profile

- Better safety profile than synthetic dural substitute\(^1\)–\(^6\) — minimization of postoperative complications.
- Infection rate comparable to other methods of dural closure.\(^1\)–\(^5\)
- Effectiveness proved against CSF leakage.\(^1\)–\(^3\),\(^4\),\(^6\)
- Inhibition of fibrosis and prevention of adhesion.\(^8\)

![Incidence of infection](chart.png)

- Hoeser et al.\(^2\)
- Messing-Jünger et al.\(^5\)
- von Wild\(^3\)
- Raul et al.\(^4\)
- Malliti et al.\(^6\)

0 1 2 3 4 5 Percentage of patients

- Heuer et al.\(^2\)
- Reyes-Moreno et al.\(^7\)
- Messing-Jünger et al.\(^5\)
- Raul et al.\(^4\)

0 3 6 9 12 15 Percentage of patients

- Integra Dural Regeneration Matrix
- Synthetic substitute
- Autograft

Integra®
DuraGen® Matrix
The Science that Seals
**Scientific Superiority**

1. **Excellent Conformability and Adherence**
   - The hydrated graft conforms closely to the complex surfaces of the exposed brain or spinal cord.
   - Matrix rapidly fills with the patient’s blood and plasma exudate.

2. **Rapid CSF Leak Prevention**
   - Type 1 collagen matrix rapidly initiates platelet aggregation.
   - Upon contact with the collagen matrix, platelets degranulate and release clotting factors that initiate fibrin clot formation.
   - The fibrin clot creates a watertight barrier and binds the implanted matrix to the patient’s dura.

**In Vivo Dural Repair Continuum**

**By 60-days post-implantation, new dural tissue has formed.**

1 Day Post Implantation
- Fibrin clot formed within matrix creating watertight barrier

3 Days Post Implantation
- Fibroblasts infiltrate and attach to graft matrix to lay down new collagen
Rapid Fibroblast Infiltration

- Ultra Pure Collagen™ Technology, in combination with the open pore structures, promotes fibroblast activity and acts as a scaffold for cells to deposit new collagen.
- The graft structure features pores of 50 to 150 microns, within the optimal size for rapid fibroblast infiltration.
- Fibroblasts begin to migrate into the matrix 2 to 3 days after implantation and start the process of laying down new collagen.

Uniform Tissue Formation

- Within two weeks of implantation, a neodural membrane has formed between the dural margins to permanently close the dural defect.
- After 6-8 weeks, the implant is resorbed and replaced by dura.
- After 1 year, the neodura has developed into mature dura.

Limit uncertainty with one of the most innovative line of products for optimal dural repair:

**PLUS: Reliability**

DuraGen Plus™ matrix has an excellent safety record and provides industry-leading conformability and resorption. The improved consistency of DuraGen Plus™ matrix* offers increased tensile strength for optimized handling during challenging neurosurgery cases. Clinically proven to limit CSF leakage, DuraGen Plus™ matrix is also indicated to be used as an adhesion barrier in spinal procedures.

*compared with DuraGen® matrix, the 1st generation of Integra Dural Regeneration Matrices.

**SUTURABLE: Adaptability**

Suturable DuraGen™ matrix provides the benefits of DuraGen Plus™ matrix with the added versatility of accommodating both suture and onlay techniques. Suturable DuraGen™ matrix is a bilayer collagen graft with enhanced strength and support, providing the ability to suture without losing the conformability and resorption you demand from a dural graft.

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**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.

**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® Matrix
### Product Sizes to Meet Your Surgical Needs

### Duragen Plus™ Dural Regeneration Matrix

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### Suturable Duragen™ Dural Regeneration Matrix

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### References

Integra’s DuraGen® products have more published human clinical data than any other collagen-based dural graft. Clinical studies have shown effective protection against CSF leakage with sutureless closure and no reports of foreign body reactions or graft rejections.

Summary outcome statistics derived from the following 10 clinical studies:


DuraGen® Family Regenerative Matrices

- Made from Ultra Pure Collagen™ Technology.
- Precisely engineered porosity for complete and natural repair.
- Excellent conformability & handling.

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

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. Images refer to the appropriate instructions for use for complete clinical instructions. 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. DuraGen, Integra and the Integra logo are registered trademarks of Integra Lifesciences Corporation in the United States and/or other countries. DuraGen Plus, Suturable DuraGen and Ultra Pure Collagen are trademarks of Integra Lifesciences Corporation. All the references numbers 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.”