Integra®
DuraGen®
Dural Regeneration Matrix

Limit uncertainty with complete conformability and optimal strength for proven CSF leak prevention.
The DuraGen family of products was engineered with the ideal balance of strength and conformability to ensure optimal porosity, sealing, and resorption - leaving the patient with a natural dural repair.

**Conformability**

Conformability is critical in the prevention of CSF leakage when using an onlay graft. The DuraGen® graft conforms intimately when hydrated to the complex surfaces of the exposed brain or spinal cord, rapidly forming a biological clot that seals to protect against CSF leakage.¹

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**Clinically Demonstrated CSF Leak Prevention**

Onlay grafts require the graft to intimately conform to and touch the dural margins to close off pathways that could allow CSF flow.

DuraGen graft has a high level of conformability verses DuraMatrix-Onlay membrane, allowing for intimate dural contact without suture. In 1,400 patients within 10 published clinical studies, a CSF leakage rate of 2.1% was observed for DuraGen graft.

DuraMatrix-Onlay™ membrane has 20% less conformability than DuraGen grafts. This decreases dural contact and may require suture to achieve direct dural apposition. No clinical data examining CSF leakage rate was found for DuraMatrix-Onlay.**

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*3 lots and 3 products/lot (n=3 replicates per product) were tested for each product group except DuraMatrix-Onlay membrane. For DuraMatrix-Onlay membrane 3 lots were tested but due to material availability while 9 products were tested from first lot, only one product each was tested from the second lot and the third lot (n=3 replicates/each product).

** Data as of January 1, 2012.

The DuraGen Graft Difference

“The Fibroblasts Use the Pores on the Matrix to Lay Down Endogenous Collagen. By 6-8 Weeks, the Collagen Matrix (DuraGen graft) 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 B, et al9

Porosity

Porosity supports two critical functions within the dural repair process. First, open pore structure aids in the immediate formation of a biological seal to protect against CSF leakage. Next, a highly porous collagen scaffold promotes rapid cellular infiltration that allows the neodura to develop within just two weeks.

DuraGen graft offers compressable thickness1 that provides the optimal porosity (50-150µm) for fibrin clot formation and cell infiltration to achieve natural dural repair.

DuraMatrix-Onlay membrane is a highly compressed matrix with low porosity (10µm)2 that tends to impede tissue healing and regeneration and increases the likelihood of graft encapsulation.

DuraGen Grafts Offer Rapid Resorption and Proven Dural Repair With No Reports of Foreign Body Reaction, Graft Encapsulation, or Rejection.

<table>
<thead>
<tr>
<th>DuraGen Graft</th>
<th>DuraMatrix-Onlay Membrane</th>
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<tbody>
<tr>
<td>Fibroblasts begin to migrate into the matrix 2-3 days after implantation and start the process of laying down new collagen.</td>
<td>Fibroblasts invade the implant and produce new collagen at 12 weeks post implantation.2</td>
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<tr>
<td>Within two weeks of implantation, a neodural membrane has formed between the dural margins to permanently close the dural defect.</td>
<td>The implant does not fully resorb for at least 6-9 months: leaving the patient at risk for foreign body reaction, inflammatory responses, and potential graft encapsulation.</td>
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<td>After 6-8 weeks, the implant is resorbed and replaced by neodura.</td>
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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.

12 Million Collagen Implants and Counting
Our leading technology collagen products have been implanted over 12 million times in a variety of procedures throughout the world.

An Investment in Data

Over 1,400 Patients in 10 Published Clinical Studies
- 0% Foreign Body Response.
- 1.9% Infection Rate.
- 2.1% Leakage Rate.

Summary outcome statistics derived from the following 10 clinical studies:

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