DuraMatrix™
Collagen Dura Substitute Membrane

Manufactured by:
Collagen Matrix, Inc., Franklin Lakes, New Jersey
What is DuraMatrix?

- Onlay or Sutured Implantation
- Balanced Implant Resorption vs. Host Tissue Regeneration
- Pure Type I Collagen
- Well-accepted Biocompatible Material
- Water-tight Closure
- Excellent Handling Characteristics; Strong
- Primary and/or Secondary Closure
- Keeps Shape Over Defect Site
- Neutral pH
- Cut in Dry or Hydrated State
What is DuraGen (DuraForm)?

- Type I Collagen
- Highly porous sponge (99% air space, 1% collagen)
- Originally designed as non-implantable sponge for protecting brain from surgical instrument damage during brain surgery (Bicol)
- Minimal mechanical strength (cannot be sutured)
- Not water-tight (potential intracranial leakage)
- Premature resorption (no repair)
What is Durepair?

- Bovine Fetal Skin (unborn calf skin)
- Mixed Composition (various types of collagen, glycoproteins, proteoglycans, lipids, etc.)-potentially immunogenic
- Resorbable
- Limited History of Material Use in Medical Devices (Long Term Effect is Unknown)
- Claimed to be Onlay and Suturable
What is Dura-Guard/Endura?

- Bovine Pericardium
- Fixed (crosslinked) as Permanent Implant – Non resorbable (encapsulation in vivo)
- Originally designed as pericardial patch
- Mechanically strong – suturable
- Potentially more adherent to cortex
Balanced Implant Resorption and Host Tissue Regeneration

- 64 rabbits
- Duraplasty
- Test groups
  - DuraMatrix onlay
  - DuraMatrix sutured
  - DuraGen (Integra NeuroSciences)
  - DuraGuard (Synovis)
- 2, 7, and 12 weeks follow-up
Animal Study: Data Collection

- Gross observations
- Histology – Resorption and Replacement
- Adhesion test
Gross Observation: 12 weeks

- DuraMatrix integrated with host
- DuraGen resorbed with no replacement
- DuraGuard not integrated with host
Histology: 12 weeks

- No implant remaining in 4 of 4 defects implanted with DuraGen
- DuraMatrix
- DuraGuard
Histology

In Vivo Resorption and Replacement
Rabbit Dural Repair Study

Weeks
0 5 10 15 20 25 30

% Implant remaining
0 20 40 60 80 100

% Implant replacement
0 20 40 60 80 100

- DuraMatrix resorption
- DuraMatrix replacement
- DuraGen resorption
- DuraGen replacement
- DuraGuard

Data on file
Adhesion Test

12 weeks post-implantation

- **DuraMatrix**: Negligible adhesion

- **DuraGuard**: Generally more adherent to the brain cortex as compared with DuraMatrix

- **DuraGen**: No implants remaining, and no formation of new tissue. Adhesion test could not be performed.
Clinical Experience

- Product being used in the U.S., Turkey, Middle East, parts of Europe

- Clinical Studies
  - European Study, The Netherlands
  - Post-market U.S. Study, Grady Health System, Emory University
European Clinical Study  
Dr. J.A. Grotenhuis

Professor and Chairman  
Neurosurgical Center Nijmegen  
Department of Neurosurgery  
University Medical Center St. Radboud, Nijmegen, The Netherlands

<table>
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MT = malignant brain tumor  
BT = benign brain tumor
EU Clinical Study Summary

- No device-related adverse effects
- No CSF leakage
- No infections
- Good to excellent handling characteristics during implantation
## Comparative Analysis

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<th>Product</th>
<th>Onlay</th>
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<th>Balanced Resorption &amp; Replacement</th>
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1^Data on file. To be published; DuraMatrix, a novel collagen dura substitute: Comparison with DuraGen and Dura-Guard, Transactions of Society for Biomaterials, May 2005.

2^Abstract; Zerris, VA et al., Repair of the dura mater with processed collagen devices, Congress of Neurological Surgeons, October, 2004.

3^Data on file.
DuraMatrix vs. DuraGen

- DuraGen resorbs prematurely resulting in no repair (safe and effective?)

- DuraMatrix balances resorption with regeneration
DuraMatrix vs. Durepair

- Durepair has the potential for Implant Rejection due to presence of potential immunogens (safe?)

- Limited history of using bovine fetal skin as implantable medical devices – long term effects unknown

- DuraMatrix is type I collagen – long term history for manufacturing of implantable medical devices
DuraMarix vs. Dura-Guard/Endura

- Dura-Guard/Endura can cause chronic foreign body reaction
- Potentially more adherent to the cortex
- DuraMatrix supports host tissue regeneration with minimal adherence and foreign body reaction
Introductory Offer

- Buy 2 boxes of any size, get Variety Pack FREE.
  - Pricing of 2 boxes should be based on pricing tier recommendations
  - Variety Pack includes:
    - 2 ea CDSM11
    - 1 ea CDSM13
    - 1 ea CDSM22
    - 1 ea CDSM33
  - $1,890 Value