DuraGen™

Dural Graft Matrix

The revolutionary advance in cranial and spinal duraplasty

Scan of actual patient 12 months postsurgery

Scanning electron image of DuraGen™ matrix

Scan of actual patient 3 months postsurgery

INTEGRA NEUROSCIENCES™
DuraGen™ is a matrix for repair of the dura mater.

- DuraGen is an innovative **collagen matrix** for primary dural closure.
- DuraGen is a remarkable **onlay graft** for the repair of dural defects.\(^1,2\)
- DuraGen is **fully resorbed** following complete tissue closure of the dural defect.\(^2\)
- DuraGen is **not encapsulated** following neurosurgical implantation.\(^2,3\)
- DuraGen **easily conforms** to complex surfaces.\(^1,3\)

DuraGen handles and conforms similar to normal soft tissue.\(^3\)

- DuraGen is soft, pliable and molds instantly to the brain surface.\(^1\)
- Suturing is not required, but tensionless stay sutures may be used if desired.\(^1\)
- DuraGen can be easily cut to fit dural defects of any shape or size.\(^1\)
*The collagen used to manufacture DuraGen is currently used in the manufacture of artificial skin, absorbable hemostatic sponges and absorbable wound dressings. The manufacturing process for DuraGen meets US and European standards for animal tissue sourcing, handling and inactivation of spongiform encephalopathy (SE) pathogens. This process involves a treatment with sodium hydroxide that is a recognized method of inactivation of SE pathogens.1,3

† Patients in whom the dura was left open or sutured.
Repair of Spinal Dura Following Tumor Resection

DuraGen™ Spinal Application

Repair of Spinal Dura Following Tumor Resection

Laminectomy: For removal of spinal Schwannoma.

BEFORE: Sagittal MRI scan of patient with an intra-spinal Schwannoma.

AFTER: Gd+ MRI scan at 3 months show no enhancement of the dura/DuraGen.

DuraGen is applied as an onlay graft after loosely re-approximating the dural edges. Fibrin clot formation within the DuraGen matrix creates a rapid mechanical barrier against CSF leakage.

Closed suction drainage is recommended (48-72 hours) in spinal procedures to remove fluid collections, obliterate dead space and approximate overlying tissues. This prevents CSF leakage and pseudo-meningocele formation.
DuraGen™ Clinical Study

A clinical study involving over 1,000 patients has shown...

In this three-part study, one portion focused on neurosurgical wound infection, determined prospectively in patients undergoing craniotomy procedures (n=1,096). Secondly, biopsies or post-mortem materials were examined histologically from 100 craniotomy patients. A third portion was a retrospective assessment of CSF leakage following collagen matrix graft repair of the dura in three locations: spinal (n=80), posterior fossa (n=67) and anterior cranial fossa base (n=9).2,3

The study reflects one of the most extensive clinical evaluations of a dural replacement graft to date.

Infection rate comparable to other methods of dural closure.†

There was no significant difference in the wound infection rate in patients who received collagen matrix implants (6.1%, 28/459) versus other methods of dural closure (5.5%, 35/637) (P=0.67) over a 2½-year period.2,3

No reports of graft encapsulation.

In the pathological study involving 100 neurosurgery patients, graft encapsulations or foreign body reactions were not found over a period of 5 years postsurgery. The DuraGen collagen matrix is completely replaced with endogenous tissue within 8-12 months of implantation.2,3

Extremely low incidence of CSF leakage with sutureless closure.

Following the use of the collagen matrix for dural reconstruction, CSF leaks were reported in only 4 of 459 craniotomy procedures, in none of 80 spinal procedures, in 3 of 67 procedures involving intradural posterior fossa surgery, and in 2 of 9 procedures for the repair of anterior skull base CSF fistulae.2,3

Cross section of dry DuraGen showing the thin eosinophilic trabeculae (X125).3

After rehydration and implantation, the collagen fibers are thickened. Blood from the surgical field fills the trabeculae. (X125).3

Twelve days postimplantation, fibroblasts migrate into the DuraGen matrix (X250).3

Two months postimplantation, fibroblastic infiltration and proliferation are evident. The interstices of the trabecular framework have become filled with endogenous collagen (X250).3
### DuraGen™ Ordering Information

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**References:**


**Make DuraGen™ your first choice for primary dural closure.**


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