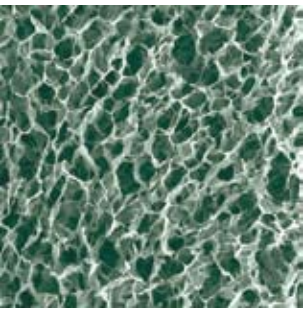
DuraGen®

DURAL GRAFT MATRIX



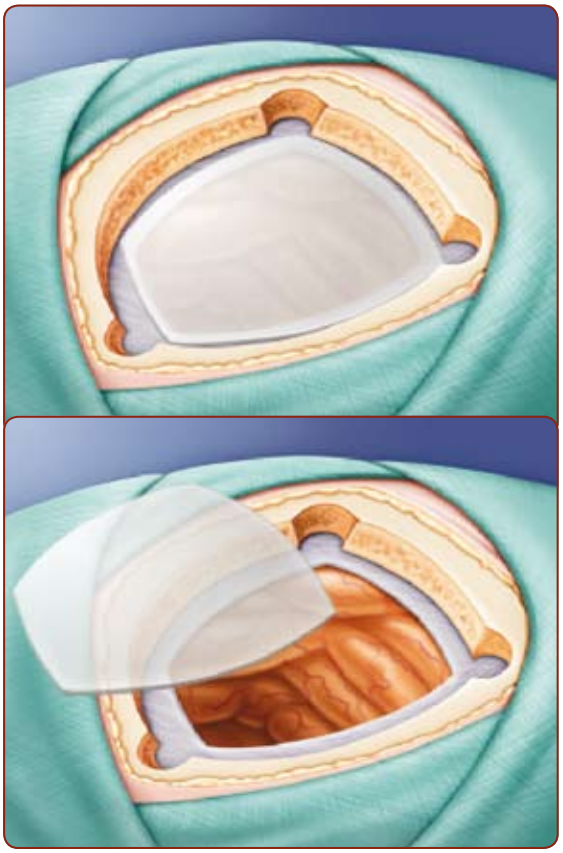
Restoration…
not just repair

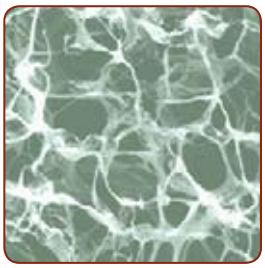
REGENERATIVE
TECHNOLOGY

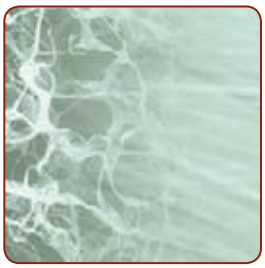
INTEGRA
NEUROSCIENCES™

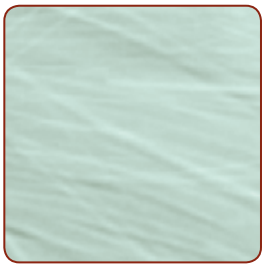
DuraGen®
DURAL GRAFT MATRIX

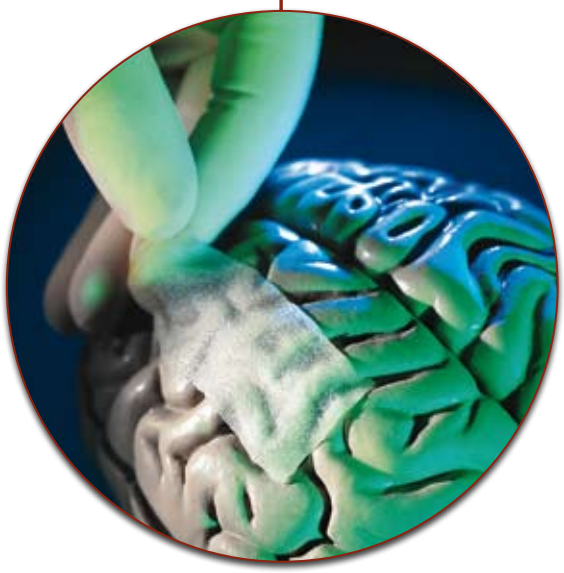
More than a graft...











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]

DuraGen® is simple, safe and easy to use.

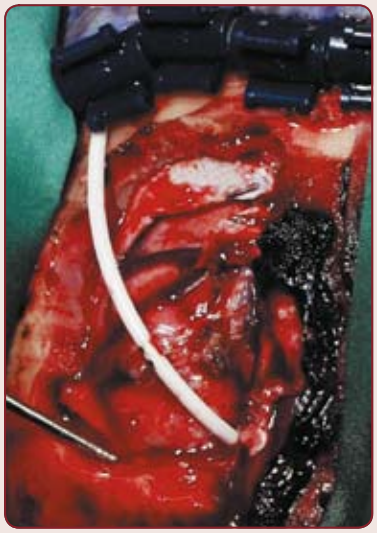
DuraGen® has an excellent safety profile**

- Minimal adhesion formation only following significant disruption of pia-arachnoid.[2,3]
- Effective protection against cerebro-spinal fluid (CSF) leakage with sutureless closure.[2,3]
- Infection rate comparable to other methods of dural closure.†,[2]
- Immunologically well tolerated — no foreign body reactions reported in all clinical trials.[2,3]

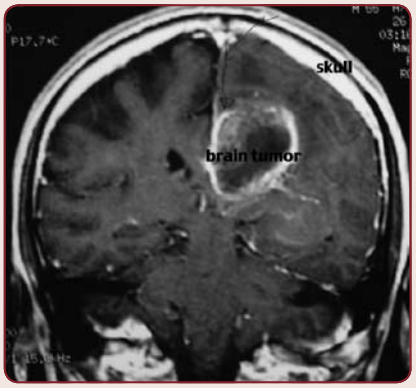
Adverse Events

Possible complications can occur with any neurosurgical procedure and include cerebrospinal fluid leaks, infection, delayed hemorrhage and adhesion formation. In clinical evaluations involving 1,096 patients, postoperative wound infection rates for DuraGen® were reported at approximately the same rate as the control group. Postoperative cerebrospinal fluid leaks were reported in 3 of 67 patients who underwent intradural posterior fossa procedures. Macroscopic evaluations revealed minimal adhesion formation only when there was significant disruption of the pia-arachnoid. There were no reports of graft encapsulation, neomembrane formation or foreign body reactions. There were no reports of graft rejection at histology.[1]

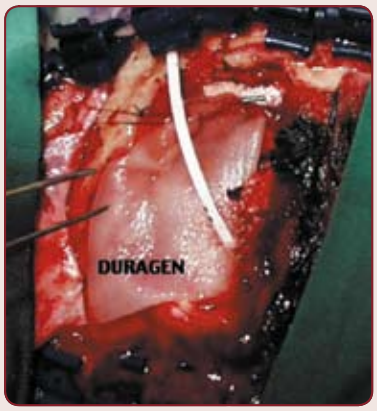
DuraGen® Cranial Application[4] Resection of Brain Tumor



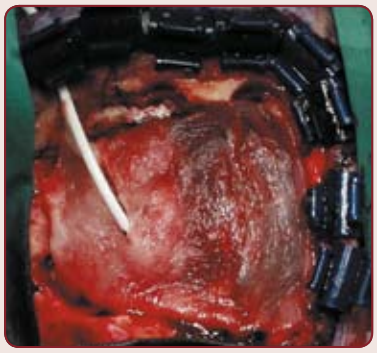
Para-sagittal Craniotomy: Dural defect further enlarged due to coagulation & shrinkage of the dura.



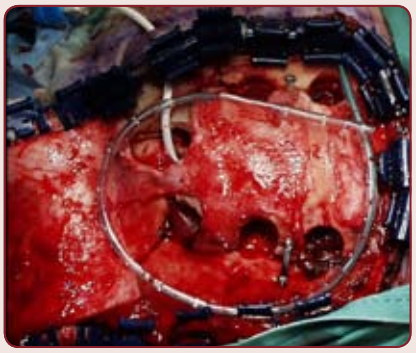
Coronal MRI scan of a patient with malignant glioma.



DuraGen® is applied as an onlay graft and moistened in-situ. Suturing is not required.



DuraGen® absorbs plasma and blood from the surgical field. Fibrin clot formation within the DuraGen® matrix creates a rapid mechanical barrier against CSF leakage.

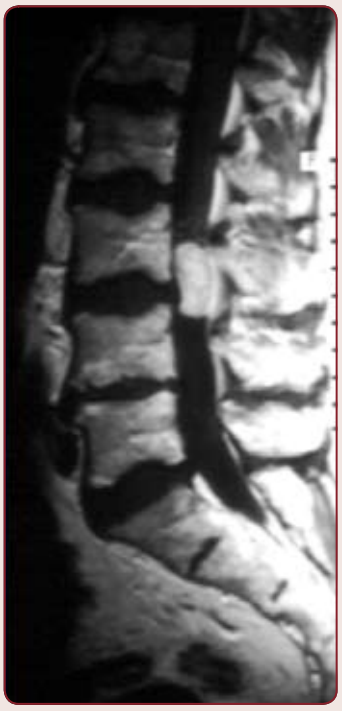


Placement of closed suction drainage over cranial flap as recommended in instructions for use.

* 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.[13]

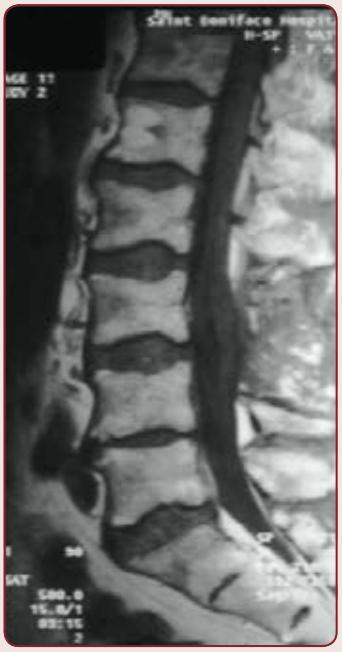
† Patients in whom the dura was left open or sutured.

DuraGen® Spinal Application[4]
Repair of Spinal Dura Following Tumor Resection



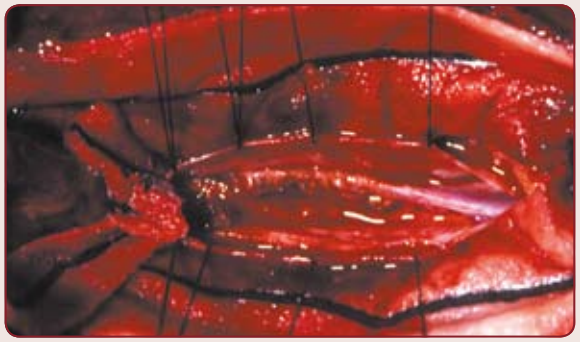
BEFORE

Sagittal MRI scan of patient with an intraspinal Schwannoma.

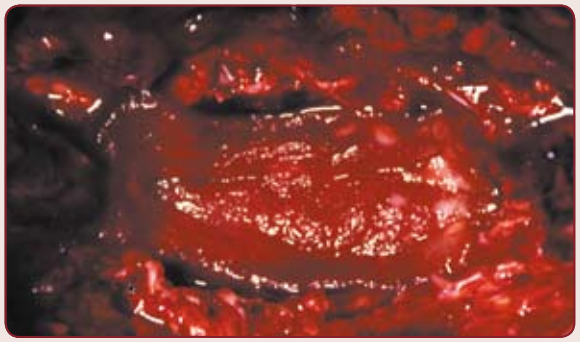


AFTER

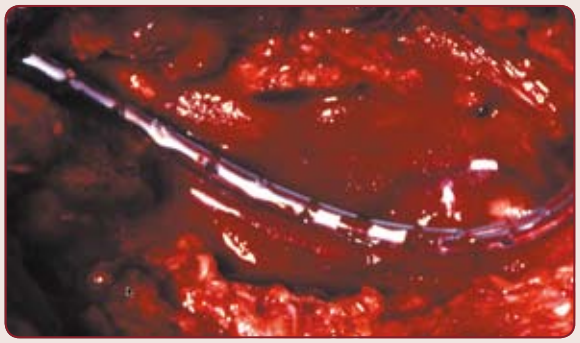
Gd+ MRI scan at 3 months show no enhancement of the dura/DuraGen®.



Laminectomy: For removal of spinal Schwannoma.



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.†

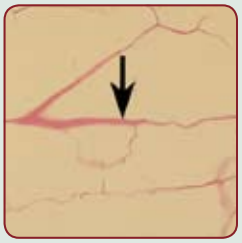
There was no significant difference in the wound infection rate in patients who received collagen matrix implants (6.1%, 28/459) versus other methods of dural closure (5.5%, 35/637) (P=0.67) over a 21/2-year period.[2,3]

No reports of graft encapsulation.

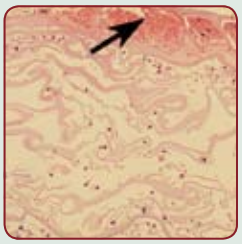
In the pathological study involving 100 neurosurgery patients, graft encapsulations or foreign body reactions were not found over a period of 5 years postsurgery. The DuraGen® collagen matrix is completely replaced with endogenous tissue within 8-12 months of implantation.[2,3]

Extremely low incidence of CSF leakage with sutureless closure.

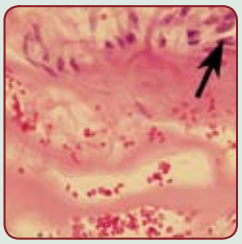
Following the use of the collagen matrix for dural reconstruction, CSF leaks were reported in only 4 of 459 craniotomy procedures, in none of 80 spinal procedures, in 3 of 67 procedures involving intradural posterior fossa surgery, and in 2 of 9 procedures for the repair of anterior skull base CSF fistulae.[2,3]



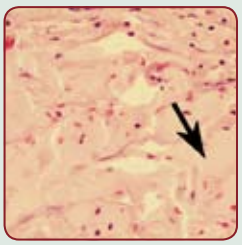
Cross section of dry DuraGen® showing the thin eosinophilic trabeculae (x125).[3]



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]



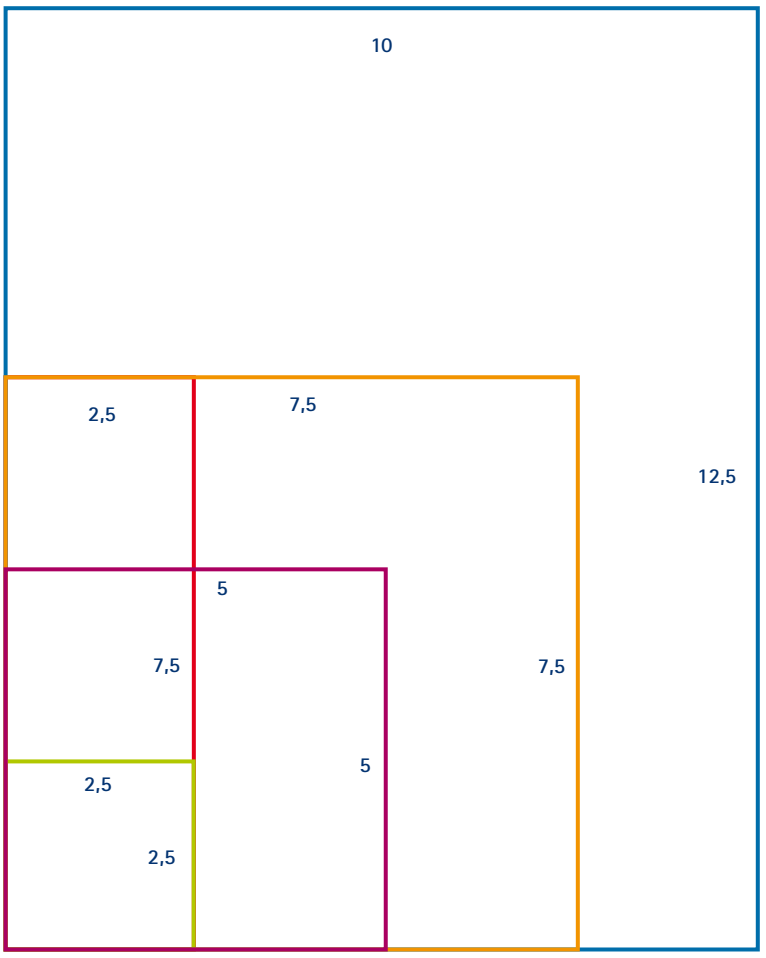
Two months postimplantation, fibroblastic infiltration and proliferation are evident. The interstices of the trabecular framework have become filled with endogenous collagen (x250).[3]

DuraGen®
DURAL GRAFT MATRIX

Make DuraGen® your first choice for primary dural closure.

DuraGen® Ordering Information

Catalog #	Size	Unit / case
ID-1101-I	2,5 cm x 2,5 cm	1
ID-1105-I	2,5 cm x 2,5 cm	5
ID-1301-I	2,5 cm x 7,5 cm	1
ID-1305-I	2,5 cm x 7,5 cm	5
ID-2201-I	5 cm x 5 cm	1
ID-2205-I	5 cm x 5 cm	5
ID-3301-I	7,5 cm x 7,5 cm	1
ID-3305-I	7,5 cm x 7,5 cm	5
ID-4501-I	10 cm x 12,5 cm	1



DuraGen sizes – scale 1-1.

References

1. **DuraGen® Gebrauchsanleitung,**
Integra LifeSciences Corporation; 1999.

2. **P. K. Narotam, J. R. van Dellen, K. D. Bhoola;**
A clinipathological study of collagen sponge as a dural graft in neurosurgery [eine klinisch-pathologische Untersuchung von Kollagenschwamm als Dura-Graft in der Neurochirurgie];
J. Neurosurg. 1995; 82:406-412.

3. Daten liegen der Integra LifeSciences Corporation vor.

4. **P. Narotam, A. Gousseau, G. McGinn;**
Collagen Matrix (DuraGen) for duraplasty following cranial and spinal surgery [Kollagen-Matrix (DuraGen) zur Duraplastik nach der Kranial- bzw. Spinaloperation];
35th Canadian Congress of Neurological Sciences, Ottawa, Kanada; Juni 2000.

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PRODUCTS FOR SALE IN EUROPE, MIDDLE-EAST and AFRICA ONLY.

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