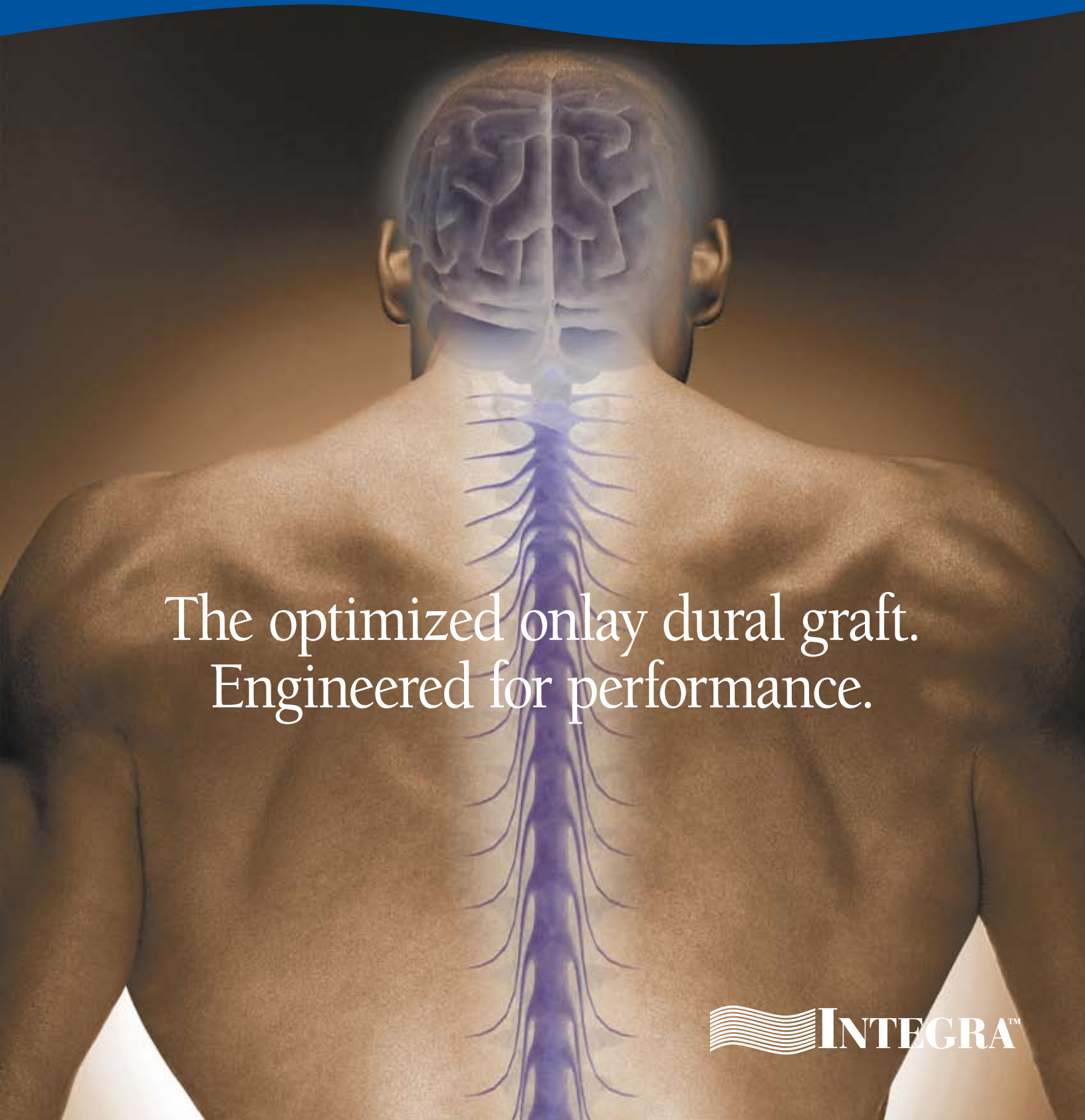
DuraGen Plus®

DURAL REGENERATION MATRIX

Duraplasty solutions from the leader in regenerative technology



The optimized onlay dural graft. Engineered for performance.

INTEGRA™

DuraGen Plus®

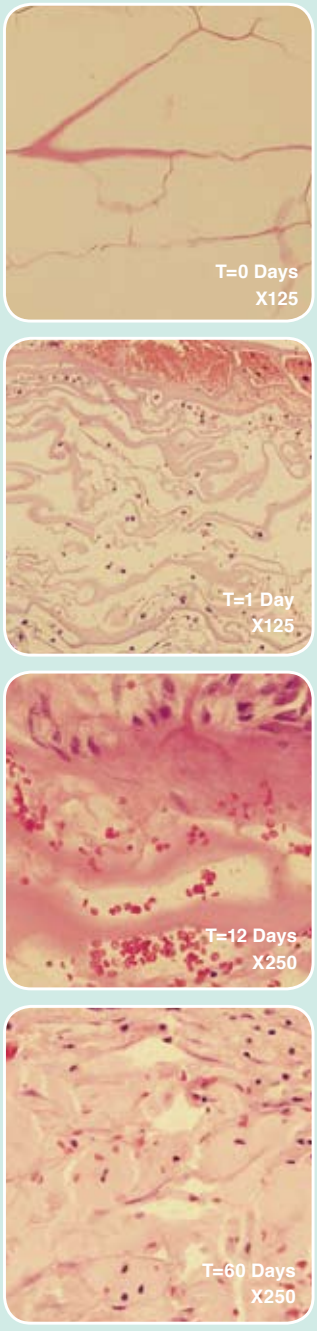
DURAL REGENERATION MATRIX

The most *advanced* Dural Regeneration Matrix

DuraGen Plus® meets the requirements of an onlay and delivers superior results

Requirements	Function
Ultra Pure Collagen™	No reported foreign body reaction, fibrin clot formation for biological seal
Excellent Conformability	Ensures graft approximation at the dural margin
Optimized Resorption	Matrix resorbs at the same rate as new tissue forms
Engineered Porosity	Facilitates tissue integration, no reported encapsulation

THE DURAL REGENERATION MATRIX RESORPTION RATE MATCHES THE GROWTH RATE OF NEW TISSUE



The Dural Regeneration Matrix is immediately infiltrated by fibroblasts and is completely replaced with endogenous tissue within 8 to 12 months

Integra Advanced Biomaterials Innovation Timeline

- **1970–1980's** — Collagen Matrix Development
- **1985** — ORAL SURGERY: CollaCote,® CollaPlug,® CollaTape® absorbable dental implants
- **1994** — ORTHOPEDIC SURGERY: Absorbable Collagen Sponge with Bone Growth Factor
- **1995** — ORAL SURGERY: BioMend,® guided tissue regeneration

DuraGen Plus, safe and effective in over 450,000 patients

- Minimal adhesion formation only following significant disruption of pia-arachnoid[1]
- Effective protection against CSF leakage with sutureless closure[1]
- No foreign body reactions or immune rejection reported[3-5]

Integra's Dural Regeneration Matrix – 30 years of science, innovation, and application

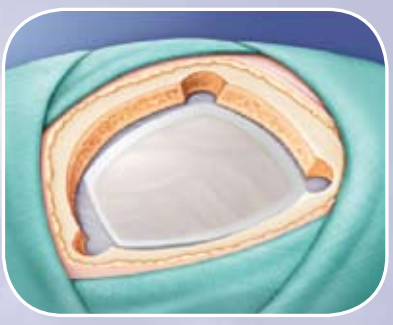
- Integra's Ultra Pure Collagen technology is the basis of products used by neuro, orthopedic, plastic & reconstructive, and oral surgeons[2]
- Integra's Ultra Pure Collagen has been used in over 10 million procedures[2]
- Integra's Ultra Pure Collagen is used to manufacture product for some of the world's largest medical device companies[2]
- Integra offers a complete set of neurosurgical solutions for the repair of dura mater (DuraGen Plus, Suturable DuraGen, and Endura)

Integra...

Driven by science.

Delivering innovation.

DURAGEN PLUS, THE VERSATILE ONLAY GRAFT



Cranial applications

Spinal applications

1996
- BURN SURGERY: INTEGRA® Dermal Regeneration Template

1999
- NEUROSURGERY: DuraGen® Dural Graft Matrix
- ORAL SURGERY: BioMend Extend™

2001
- NEUROSURGERY: NeuraGen® Nerve Guide

2002
- PLASTIC and RECONSTRUCTIVE: Integra™ Bilayer Matrix Wound Dressing

2003
- NEUROSURGERY: DuraGen Plus®
- NEUROSURGERY: Endura™ No-React® Dural Substitute

2004
- NEUROSURGERY: NeuraWrap™ Nerve Protector
- PLASTIC and RECONSTRUCTIVE: Integra™ Matrix Wound Dressing

2005
- NEUROSURGERY: Suturable DuraGen™

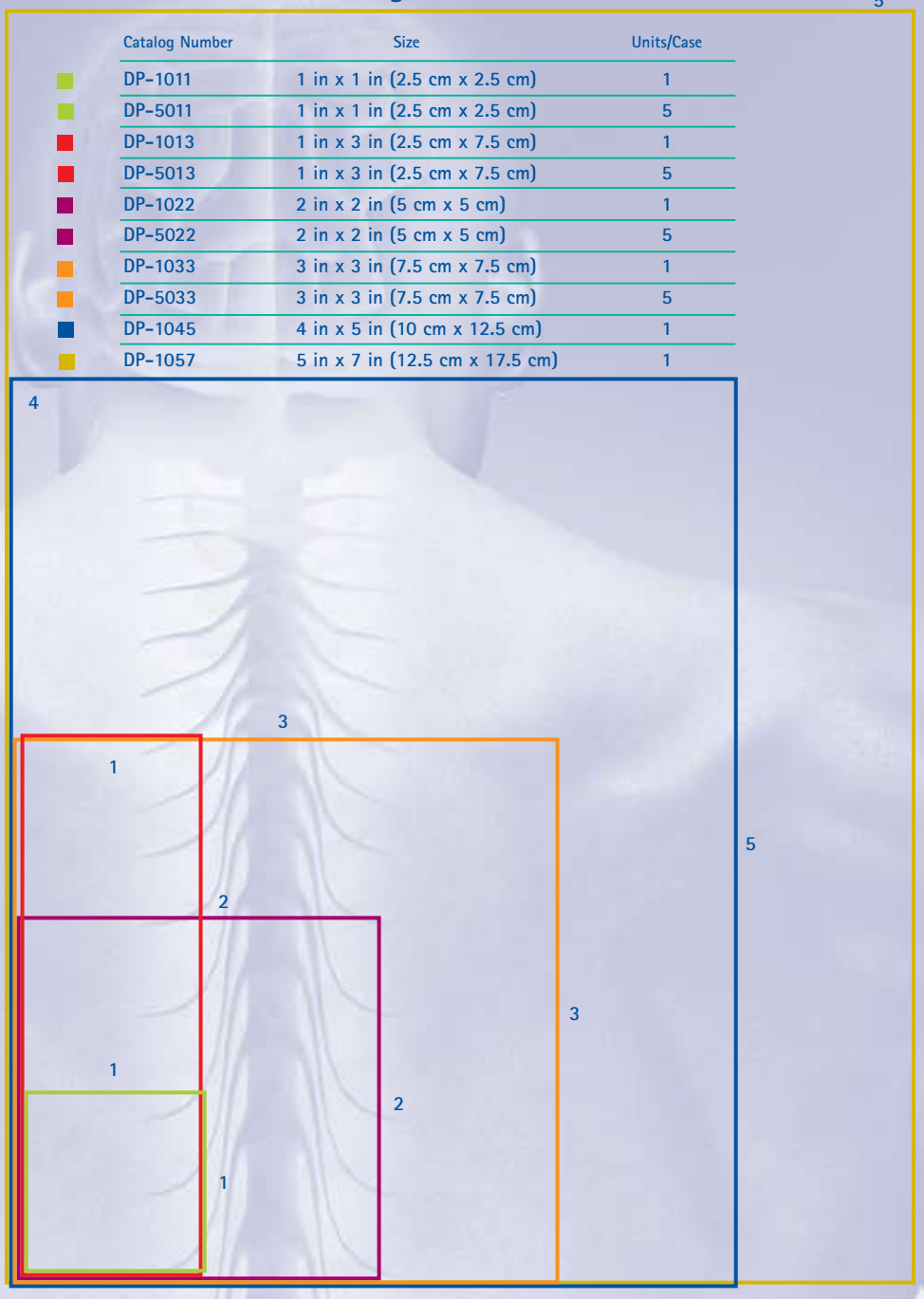
DuraGen Plus®

DURAL REGENERATION MATRIX

Duraplasty solutions from the leader in regenerative technology

DuraGen Plus Ordering Information

Catalog Number	Size	Units/Case
DP-1011	1 in x 1 in (2.5 cm x 2.5 cm)	1
DP-5011	1 in x 1 in (2.5 cm x 2.5 cm)	5
DP-1013	1 in x 3 in (2.5 cm x 7.5 cm)	1
DP-5013	1 in x 3 in (2.5 cm x 7.5 cm)	5
DP-1022	2 in x 2 in (5 cm x 5 cm)	1
DP-5022	2 in x 2 in (5 cm x 5 cm)	5
DP-1033	3 in x 3 in (7.5 cm x 7.5 cm)	1
DP-5033	3 in x 3 in (7.5 cm x 7.5 cm)	5
DP-1045	4 in x 5 in (10 cm x 12.5 cm)	1
DP-1057	5 in x 7 in (12.5 cm x 17.5 cm)	1



Sizes shown in inches at actual size.

INTEGRA™

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800-654-2873 (USA and Canada)

609-275-0500 (Outside USA)
609-275-5363 (Fax)

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 Integra's collagen matrix 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]

* The collagen used to manufacture DuraGen Plus is currently used in the manufacture of artificial skin, absorbable hemostatic sponges and absorbable wound dressings. The manufacturing process for DuraGen Plus 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.[1,2]

References:
1. DuraGen Plus Instructions for Use, Integra LifeSciences Corporation; 2003.
2. Data on file, Integra LifeSciences Corporation.
3. P. Narotam, A. Gousseau, G. McGinn. Collagen Matrix (DuraGen) for duraplasty following cranial and spinal surgery. 35th Canadian Congress of Neurological Sciences, Ottawa, Canada, June 2000.
4. P. Narotam, S. Jose', N. Nathoo, C. Taylor, Y. Vora. Collagen Matrix (DuraGen) in Spinal Durotomy: Technique Appraisal and Clinical Results. 18th Annual Meeting of the North American Spine Society, San Diego, California, October 2003.
5. G. Heuer, M. Stiefel, E. Maloney-Wilensky, S. Danish, C. Dolinskas, P. LeRoux. DuraGen is an Effective Dural Substitute: Clinical Experience with 100 Cases. American Association of Neurological Surgeons Annual Meeting, April 2003.
6. P. Narotam, S. José, N. Nathoo, C. Taylor, Y. Vora. Collagen Matrix (DuraGen) in Dural Repair: Analysis of a New Modified Technique. SPINE 29:2861-2867, December 2004.

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