

DuraSeal® Xact

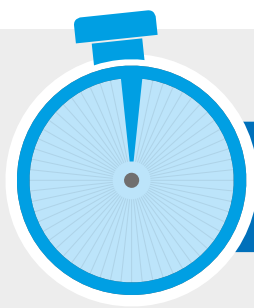
Spinal Sealant System



Every Masterpiece deserves a final touch.

DuraSeal® Hydrogel Technology: Choose the right final touch

We have your back,
whether you planned it or not



Convenience

Prepared in 1 minute.¹
Seal formation < 2 seconds.¹

When applied, the seal forms in **less than 2 seconds**.¹
This **immediate polymerization** provides strong tissue adherence and the **distinctive blue colorant** provides **visualization** of application to assess coverage and thickness.

Ready when you need it:

- Can be used on the spot as it is stored at room temperature.
- Prepared in about 1 minute.¹

Extended Tip Applicator

Improve access to the surgical site with Extended Tip Applicators.

The Extended Tip Applicators give DuraSeal® Xact users the versatility of a manual applicator with **extended reach** and **visibility to the surgical site**.

Features

- Non-clogging system
- Malleable (60° bendable shaft)
- Shape Memory
- Choice of sizes: 8cm and 15cm long

The right tool for the right job

DuraSeal® Xact

Spinal Sealant System*

* Limited swelling formula mitigates concern of expansion in confined spaces.²

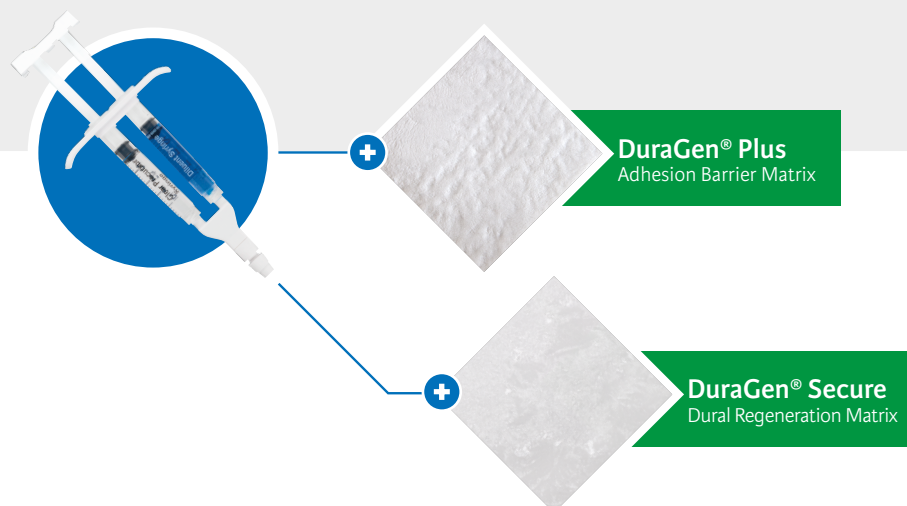
Efficacy

Designed to augment your sutures and create a long-lasting watertight closure: DuraSeal® Xact remains throughout the healing period of the dura.³

100% watertightness achieved with maximum 2 applications.²

Versatility with other products

Can be used in combination with DuraGen® product family:
DuraGen® Plus and DuraGen® Secure only grafts recommended.



Ordering Information

DuraSeal® Xact Spinal Sealant System

Reference	Description	Quantity
203001	DuraSeal® Xact - spinal sealant system - 3mL	1kit/box
204003	DuraSeal® Xact - spinal sealant system - 3mL	5kits/box
205108	Extended Tip Applicator - 8cm length	5kits/box
205115	Extended Tip Applicator - 15cm length	5kits/box

DuraGen® Secure matrix

Reference	Description	Quantity
DRM1011I	2,5 cm x 2,5 cm (1 in x 1 in)	1
DRM1013I	2,5 cm x 7,5 cm (1 in x 3 in)	1
DRM1022I	5 cm x 5 cm (2 in x 2 in)	1
DRM1033I	7,5 cm x 7,5 cm (3 in x 3 in)	1

DuraGen® Plus matrix

Reference	Description	Quantity
DP-1011-I	2,5 cm x 2,5 cm (1 in x 1 in)	1
DP-5011-I	2,5 cm x 2,5 cm (1 in x 1 in)	5
DP-1013-I	2,5 cm x 7,5 cm (1 in x 3 in)	1
DP-5013-I	2,5 cm x 7,5 cm (1 in x 3 in)	5
DP-1022-I	5 cm x 5 cm (2 in x 2 in)	1
DP-5022-I	5 cm x 5 cm (2 in x 2 in)	5
DP-1033-I	7,5 cm x 7,5 cm (3 in x 3 in)	1
DP-5033-I	7,5 cm x 7,5 cm (3 in x 3 in)	5
DP-1045-I	10 cm x 12,5 cm (4 in x 5 in)	1
DP-1057-I	12,5 cm x 17,5 cm (5 in x 7 in)	1

DuraSeal® Xact Spinal Sealant System

Indications: The DuraSeal® Xact system is indicated for use during spine procedures as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure. The Extended Tip Applicator is intended for use in the simultaneous delivery of two non-homogenous solutions onto a surgical site.

Contraindications: Do not apply the DuraSeal® Xact hydrogel in abdominopelvic surgical procedures for use as a sealant or adhesion barrier. Do not use Extended Tip Applicator, MicroMyst® Applicator and Flow Regulator for other indications than the ones mentioned in the instructions for use.

DuraGen® Secure matrix

Indications: DuraGen® Secure matrix is indicated as an onlay graft for the repair and restoration of dural defects in cranial and spinal surgical procedures. DuraGen® Secure matrix readily conforms to the surface of the brain, spinal cord and overlying tissues. DuraGen® Secure matrix may be used to close dural defects following traumatic injury, excision, retraction or shrinkage. DuraGen® Secure matrix may be used to supplement primary closure.

Contraindications: DuraGen® Secure matrix is not designed, sold or intended for use except as described in the Indications for Use and is contraindicated in the following situations: For patients with a known history of hypersensitivity to bovine derived materials; For repair of spinal neural tube defects or anterior spinal surgery with dural resection; Should be used with caution in infected regions; Not recommended to cover dural defects involving mastoid air cells; Not recommended for large defects at the skull base following surgery.

DuraGen® Plus matrix

Indications: DuraGen® Plus matrix is designed for the repair and restoration of dural defects and as an adhesion barrier for the reduction of peridural fibrosis. DuraGen® Plus matrix is indicated as an onlay graft for the repair and restoration of dural defects in cranial and spinal surgical procedures. DuraGen® Plus matrix is also indicated as an adhesion barrier for the inhibition of post-surgical peridural fibrosis. DuraGen® Plus matrix readily conforms to the surface of the brain, spinal cord and overlying tissues. DuraGen® Plus matrix may be used to close dural defects following traumatic injury, excision, retraction or shrinkage. DuraGen® Plus matrix may be used to supplement primary closure.

Contraindications: DuraGen® Plus matrix is not designed, sold or intended for use except as described in the indications for use and is contraindicated in the following situations:

- For patients with a known history of hypersensitivity to bovine - derived materials.
- For primary repair of spinal neural tube defects; anterior spinal surgery with dural resection (e.g., transoral surgery).
- Should be used with caution in infected regions.
- Not recommended to cover dural defects involving mastoid air cells.
- Not recommended for large defects at the skull base following surgery.

1. Campbell PK, et al. Evaluation of Absorbable Surgical Sealants. In vitro Testing LT-6000-016 Rev. Confluent Surgical, Inc., Waltham, MA 02451, 2005. Page 2, Figure 2 and Figure 1.
2. Wright N M., et al. Spinal Sealant System Provides Better Intraoperative Watertight Closure Than Standard of Care During Spinal Surgery. Spine 2015;40:505-513.
3. In-vitro Product Comparison Study of Wound Healing Sealants. Report no: R090417B (Cyanta Report).

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Please read carefully the instructions for use.
- Non contractual document. Integra reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

Products mentioned in this document are CE class IIa (applicators) and III devices. Please contact Integra customer service should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked in accordance with the applicable European laws, unless specifically identified as "NOT CE MARKED".

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