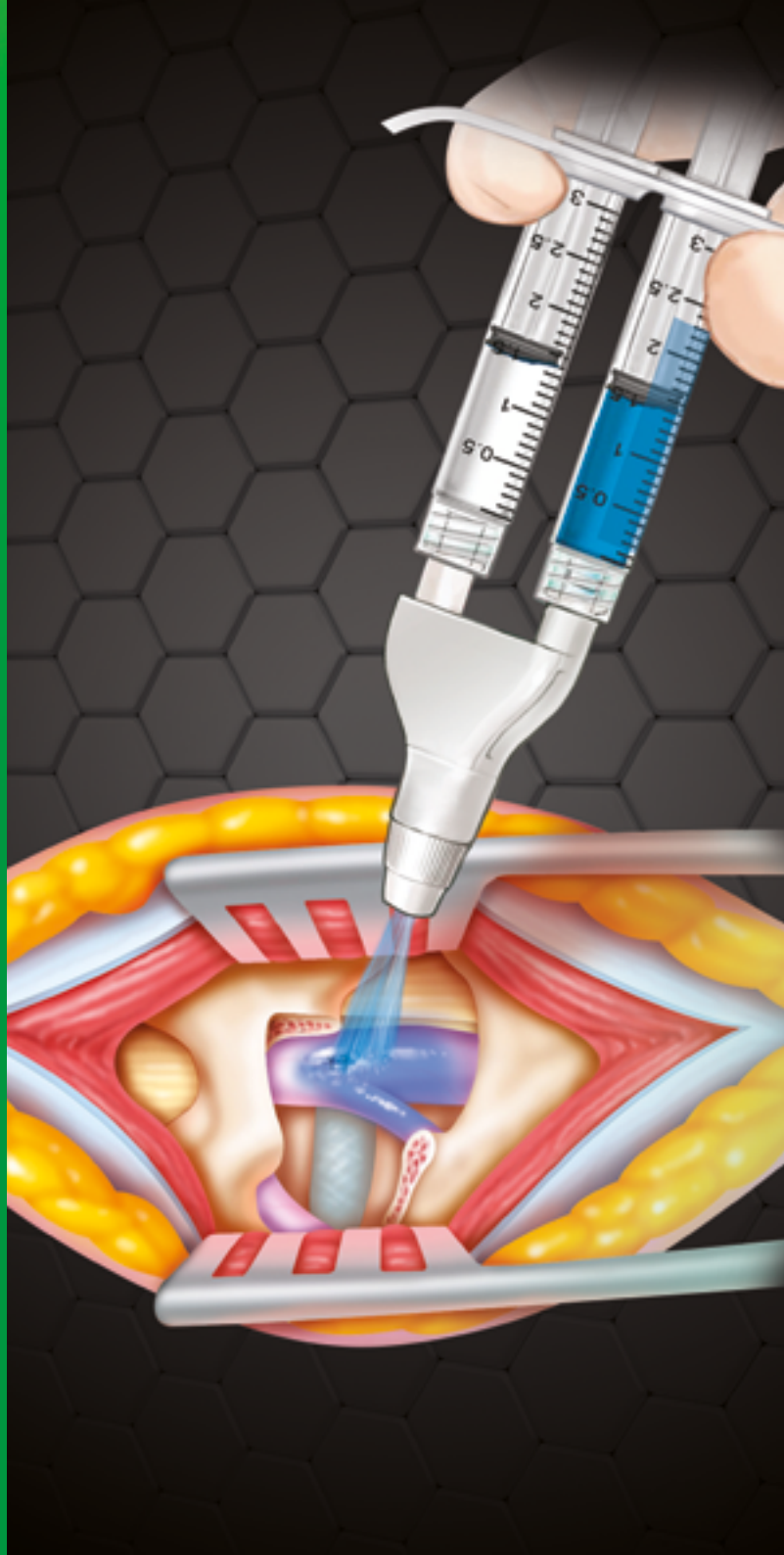


Integra®

DuraSeal® Xact Adhesion Barrier
and Sealant System for Spinal Surgery

Limit uncertainty
by using DuraSeal® Xact
adhesion barrier
and sealant system
to ensure a watertight closure.



INTEGRA®
LIMIT UNCERTAINTY

DuraSeal® Xact adhesion barrier and sealant system for an optimal watertight dural closure

During spinal surgery procedures, it is essential to prevent the leakage of cerebrospinal fluid (CSF) in order to reduce potential adverse events and ensure positive patient outcome. DuraSeal® Xact adhesion barrier and sealant system provides surgeons with an optimal polymer technology that provides a watertight seal quickly and effectively, intraoperatively and through the critical healing period.



STRENGTH¹

Tissue adherence and cohesive strength to withstand critical pressures.

BIOCOMPATIBILITY^{2,3,4}

Biocompatible PEG (Polyethylene glycol) hydrogel.

VISIBILITY

Distinctive blue colorant provides visualization to assess sealant coverage and thickness.

SPEED

Prepared in less than two minutes.
When applied, forms a watertight seal in seconds.

FEATURE^{2,3,4}

Limited swelling formula mitigates concern of expansion in confined spaces.
Fully synthetic and absorbable in 9-12 weeks for normal healing while maintaining a barrier against adhesions.

CONVENIENCE

Single kit, stored at room temperature.



THE HYDROGEL ADHERES TO THE TISSUE SURFACE AND PROVIDES A WATERTIGHT SEAL.

1 WEEK POST-SURGERY

AFTER APPLICATION OF DURASEAL® XACT ADHESION BARRIER AND SEALANT SYSTEM, THE BODY'S NORMAL HEALING PROCESS CAN CONTINUE.

1-4 WEEKS POST-SURGERY

THE PRESENCE OF DURASEAL® XACT ADHESION BARRIER AND SEALANT SYSTEM PREVENTS CLOT ATTACHMENT TO THE DURA.

4-12 WEEKS POST-SURGERY

THE PERSISTENCE OF DURASEAL® XACT ADHESION BARRIER AND SEALANT SYSTEM CONTINUES TO PROTECT THE DURA AND EVENTUALLY LIQUIFIES WITHIN 9-12 WEEKS AND IS ABSORBED.

Clinical Results

During spinal surgery procedures, it is essential to prevent the leakage of cerebrospinal fluid (CSF) in order to reduce potential adverse events and ensure positive patient outcomes. DuraSeal® Xact adhesion barrier and sealant system provides surgeons with an optimal polymer technology that provides a watertight seal quickly and effectively, intraoperatively and through the critical healing period.

Fibrosis Prevention^{2,4}

Although this study is too small to have conclusions of efficacy and will need confirmation by larger trials, treatment of a microdiscectomy site with DuraSeal® Xact Adhesion Barrier and Sealant System for fibrosis prevention shows promising results in terms of safety, reduction of postoperative pain and functional results when compared to control with the additional advantage of being suitable for use in the presence of a dural tear.

Dural Watertight Closure³

Patients treated with the PEG* hydrogel spinal sealant had a significantly higher rate of watertight closure than the control (100% vs. 64.3%, $P < 0.001$).

1. *In-vitro Product Comparison Study of Wound Healing Sealants*. Report no: RO90417B (Cyanta Report)

2. Fransen P. Reduction of postoperative pain after lumbar microdiscectomy with DuraSeal® Xact Adhesion Barrier and Sealant System. *Spine J*. 2010 Sep;10(9):751-761.

3. Kim KD., Wright NM., Polyethylene glycol hydrogel spinal sealant (DuraSeal® Spinal Sealant) as an adjunct to sutured dural repair in the spine: results of a prospective, multicenter, randomized controlled study. *Spine (Phila Pa 1976)*. 2011 Nov 1;36(23):1906-1912.

4. Webster R, Didier E, Harris P, Siegel N, Stadler J, Tilbury L, Smith D., *PEGylated Proteins: Evaluation of Their Safety in the Absence of Definitive Metabolism Studies Drug Metab Dispos*. 2007 Jan;35(1):9-16.

* Polyethylene Glycol

Applicators

The DuraSeal® Xact adhesion barrier and sealant system applicators provide extended reach and visibility to the surgical site.

Extended Tip Applicator

The Extended Tip Applicators give DuraSeal® Xact adhesion barrier and sealant system users the versatility of a malleable manual applicator with extended reach and added visibility. Available in 8 cm and 15 cm length.



MicroMyst® Applicator

The flexible air-assisted MicroMyst® applicator delivers precise application through a fine mist spray (14 cm length). Used with the Flow Regulator for the controlled application of two liquids.



The Flow Regulator provides air flow to facilitate a consistent and even spray. Only use the MicroMyst® Applicator with the Flow Regulator.

NOTE: Supplied pressure from N2 or compressed air source should be set between 50-200 psi (3.45 - 13.8 Bar).

Application Tip

1. Do not prime any Applicator prior to use as plugging may result.
2. Prepare application site by removing all blood clots and fluid.
3. While in the surgical field, spray on gauze briefly prior to moving to the target site.
4. All Applicator tips should be positioned approximately 2cm from the target site. When using the MicroMyst® Applicator move tip back and forth during application to improve mixing of solutions.

Extended Tip Applicator:

When attaching a spray tip to the Extended Tip Applicator, gently twist the spray tip onto the applicator so that the treads engage cleanly. Use strong even pressure with non air-assisted applicators.

MicroMyst® Applicator:

When using the MicroMyst® Applicator move tip back and forth during application to improve mixing of solutions.

Ordering Information

Reference	Description	Quantity
203001	DuraSeal® Xact - adhesion barrier and sealant system - 3mL	1kit/box
20-4003	DuraSeal® Xact - adhesion barrier and sealant system - 3mL	5kits/box
205108	Extended Tip Applicator - 8cm length	5kits/box
205115	Extended Tip Applicator - 15cm length	5kits/box
20-5000*	MicroMyst® Applicator - 14cm	5kits/box
FR-6065	Flow Regulator	1 unit/box

* MicroMyst® Applicator requires an air source to operate – used in conjunction with the Flow Regulator.

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, and as an adhesion barrier for the inhibition of post-surgical peridural fibrosis.

The MicroMyst® Applicator is intended for use in the delivery of two non-homogenous solutions onto a surgical site. The Flow Regulator is intended to provide pressurized gas (air or nitrogen) to gas-assisted applicators.

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.

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