DuraSeal®

Dural Sealant System

Every Masterpiece deserves a final touch.

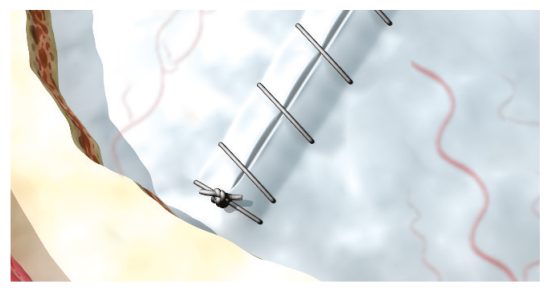
A DIVISION OF INTEGRA LIFESCIENCES COMPANY

Codman® SPECIALTY SURGICAL

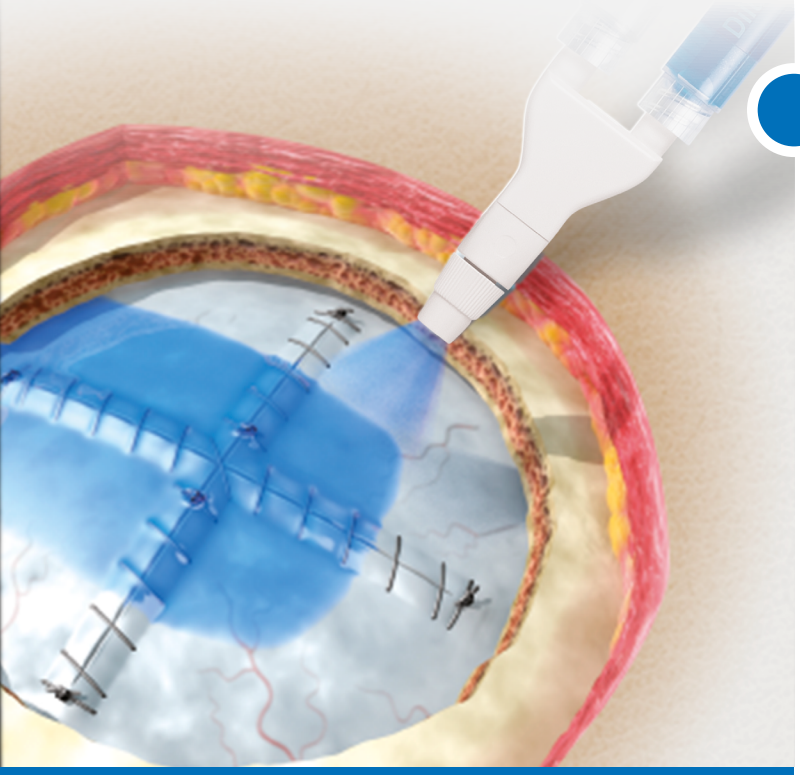
The steps of dural closure: the right tool for the right job

Hemostasis (mechanical, chemical, electrical)

While some hemostats are often used to seal[3], they are intended to coagulate blood.



Primary Closure (suture, graft, etc.)



Watertight Sealing

Immediate

DuraSeal® showed 100% water tightness after intraoperative Valsalva maneuver.[4, 5]

Long-term

DuraSeal® is more effective at preventing CSF leaks than fibrin glue after posterior fossa surgery (2% vs. 10%; p=0,03*).[6]

To SEAL until it HEALS.

DuraSeal® Hydrogel Technology: Choose the right final touch

The DuraSeal Family of sealants has been specifically designed to **second your sutures** and create an immediate and long-lasting **watertight closure.**

The DuraSeal technology combines Polyethylene Glycol (PEG) and Trilysine Amine.
The polymerisation results in a flexible hydrogel which degrades by hydrolysis.

DuraSeal®

Sets where you want it

When applied, the seal forms in **less than 2 seconds**.[1]

Stays where you want it

Adherence to underlying tissue and **cohesive strength** to withstand critical pressures[2] up to 30 mmHg at day 1.[1]

Remains long enough

Until the healing period of the dura (absorbed in 4-8 weeks for cranial version, 9-12 weeks for spinal version).[2]

Provides convenience

- **See** where you put it (distinctive blue colorant provides visualization of application to assess coverage and thickness).
- **Ready** when you need it:
  - Prepared in about 1 minute.[1]
  - Can be used on the spot as it is stored at room temperature.

What should a sealant do?

We've got you covered in all neurosurgical procedures

DuraSeal Family consists in 2 distinct product versions for your cranial and spinal surgeries.

DuraSeal® Cranial Sealant System

Contains 5mL

DuraSeal® Xact Sealant System

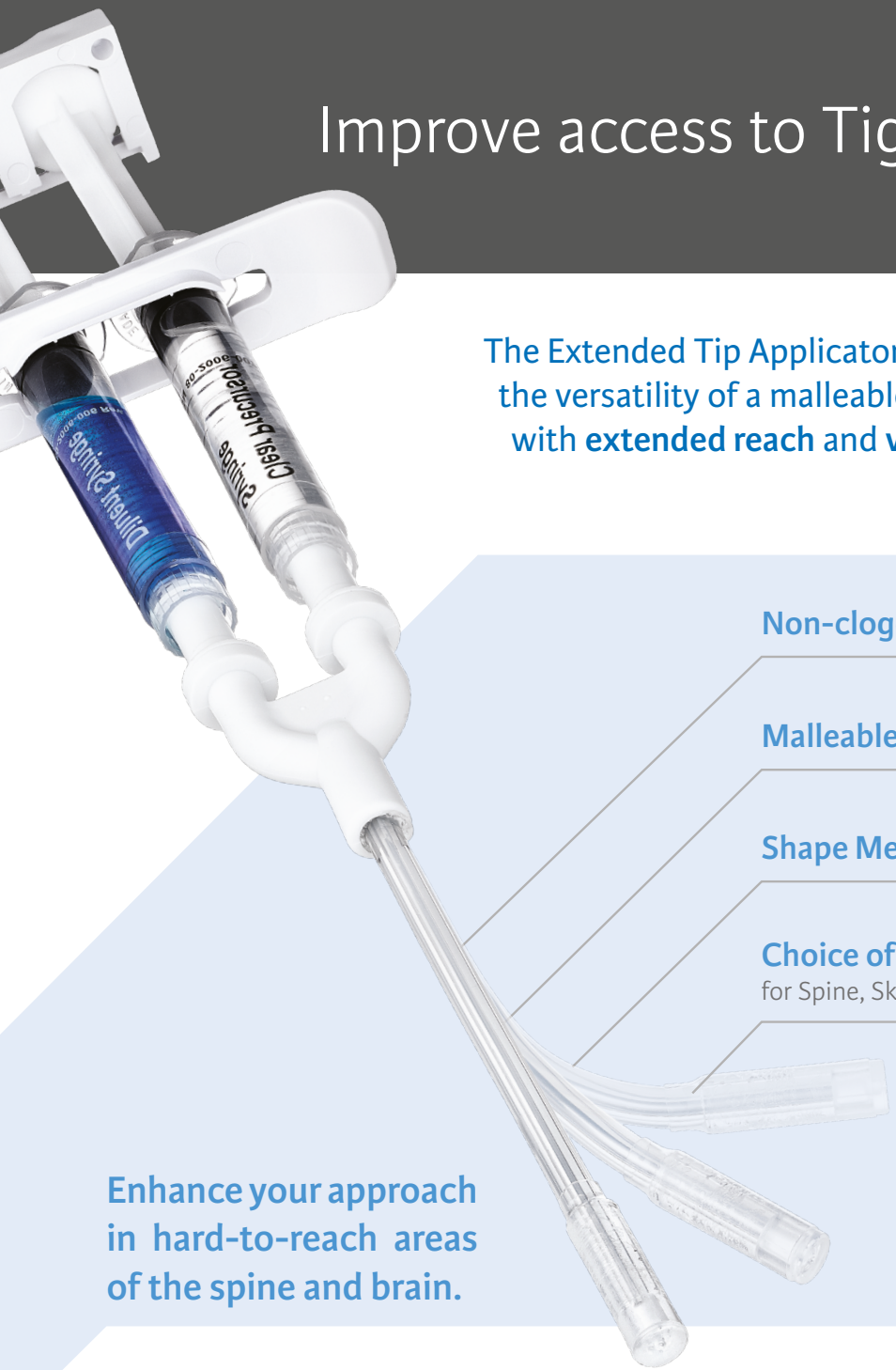
Limited swelling formula mitigates concern of expansion in confined spaces[7].

Contains 3mL

Be reliable and be effective.[8,9]

Improve access to Tight Spaces

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



Non-clogging system

Malleable (60° bendable shaft)

Shape Memory

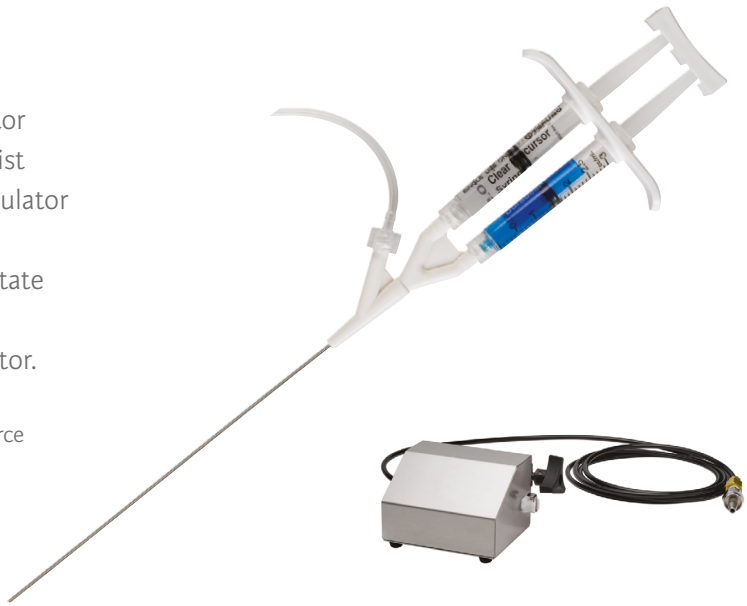
Choice of sizes (8cm and 15cm length for Spine, Skull-base and Endonasal access)

Enhance your approach in hard-to-reach areas of the spine and brain.

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).



DuraSeal®
Dural Sealant System

Ordering Information

Reference	Description	Quantity
DSD5001	DuraSeal® dural sealant system - 5mL	1kit/box
DSD5005	DuraSeal® dural sealant system - 5mL	5 kits/box
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
205000DS**	MicroMyst® Applicator - 14cm length	5kits/box
FR6065	Flow Regulator	1 unit/box

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. In-vitro Product Comparison Study of Wound Healing Sealants. Report no: R090417B (Cyanta Report)
3. Esposito F, Angileri FF, Kruse P, Cavallo LM, Solari D, Esposito V, et al. (2016) Fibrin Sealants in Dura Sealing: A Systematic Literature Review. PLoS ONE 11(4): e0151533. doi:10.1371/journal.pone.0151533
4. Cosgrove GR et al. "Safety and efficacy of a novel polyethylene glycol hydrogel sealant for watertight dural repair". J Neurosurg 106: 52-58, 2007 page 3
5. Boogaarts JD et al. "Use of a novel absorbable hydrogel for augmentation of dural repair: results of a preliminary clinical study".Neurosurgery. 57:146-151, 2005 page 2.
6. Than KD, Baird CJ, Olivi A. Polyethylene glycol hydrogel dural sealant may reduce incisional cerebrospinal fluid leak after posterior fossa surgery. Neurosurgery 2008;63(suppl 1):ONS182-ONS186.
7. 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.
8. Preul, M. et al., Application of a hydrogel sealant improves watertight closures of duraplasty only grafts in a canine craniotomy model. Journal of NeuroSurgery. September 2007. Volume 107(3)642-650
9. Weinstein, J. et al., The safety and effectiveness of a dural sealant system for use with nonautologous duraplasty materials. Journal of Neurosurgery. July 2010;112(2):428-433.

*Statistically significant, p<0.05 ** MicroMyst® Applicator requires an air source to operate – used in conjunction with the Flow Regulator.

Indications:
The DuraSeal® dural sealant system is intended for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure.
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.
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® Dural Sealant** in abdominopelvic surgical procedures for use as a sealant or adhesion barrier.
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.

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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