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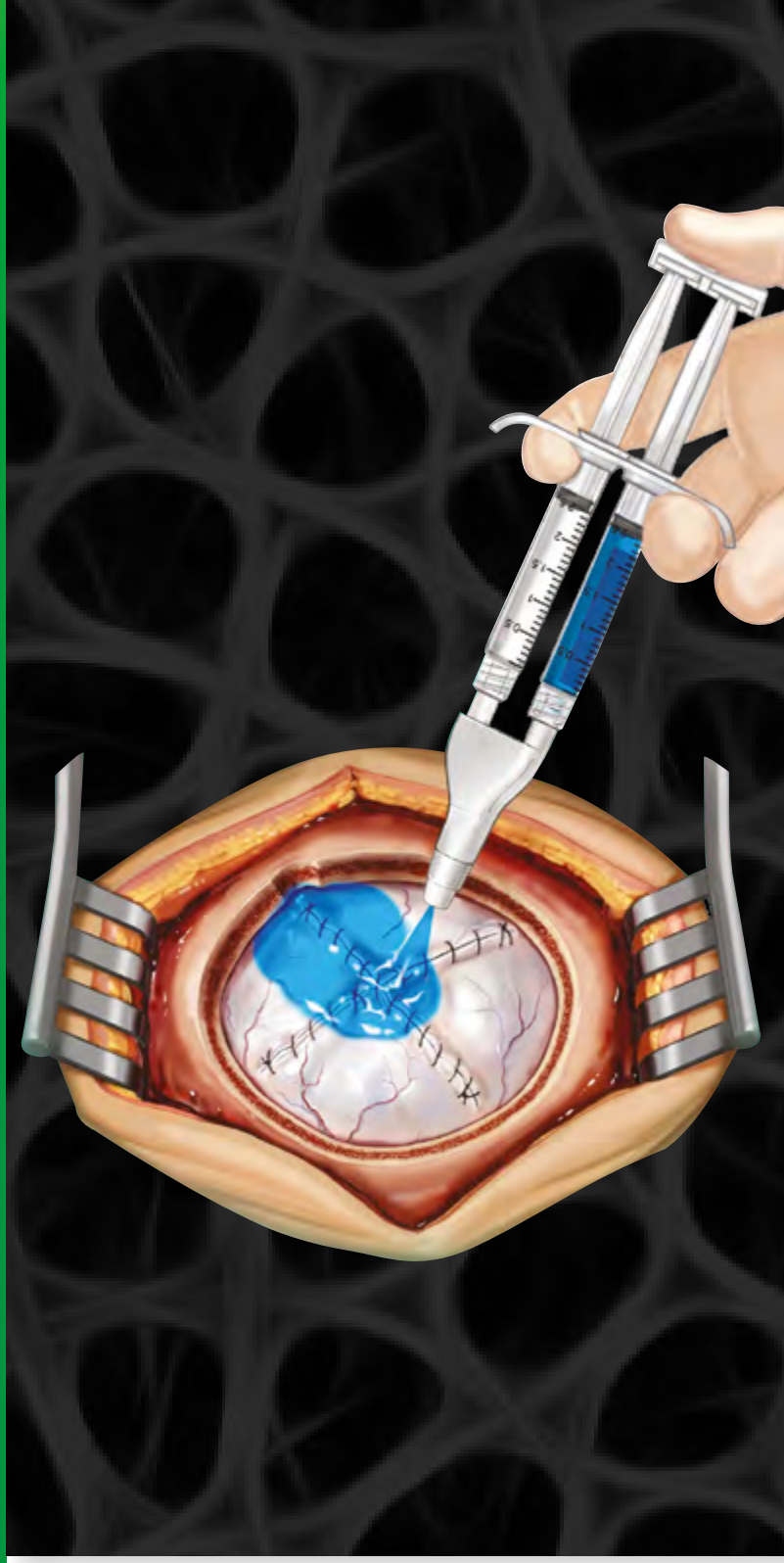
Integra®

DuraSeal® Dural Sealant System
for Cranial Surgery

Limit uncertainty with DuraSeal® dural sealant system, hydrogel technology for watertight closure during cranial neurosurgery procedures.

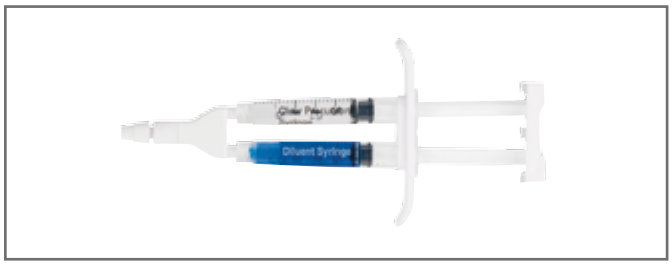


INTEGRA LIMIT UNCERTAINTY

Integra®
DuraSeal® Dural Sealant System for cranial surgery

DuraSeal® Dural Sealant System

During neurosurgical 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® dural sealant system, hydrogel made with a specific polymer technology, provides a quick and effective watertight seal intraoperatively and through the critical healing period.



STRENGTH[2]
Tissue adherence and cohesive strength to withstand critical pressures.

BIOCOMPATIBILITY[1,3]
Biocompatible PEG (polyethylene glycol) hydrogel.

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

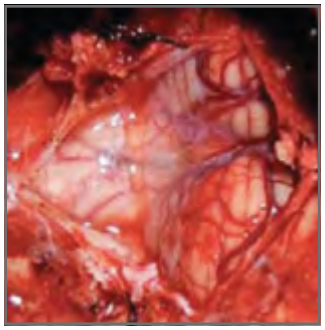
SPEED[1,4]
Prepared in less than two minutes. When applied, forms a watertight seal in seconds.

CONVENIENCE
Single kit, stored at room temperature.

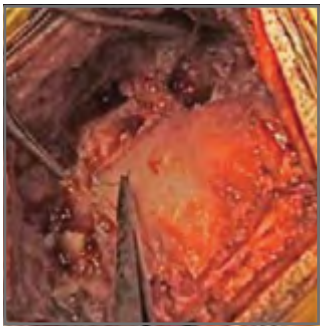
Clinical results

DuraSeal® dural sealant system has been studied in two separate, prospective, non-randomized clinical investigations.[1,5]

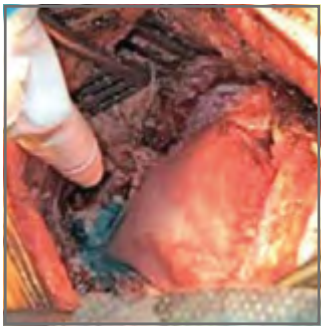
In 111 patients treated, the dural sealant demonstrated a total of 100%[1] intraoperative success rate in holding a watertight seal with no overt CSF leakage upon a subsequent Valsalva maneuver.



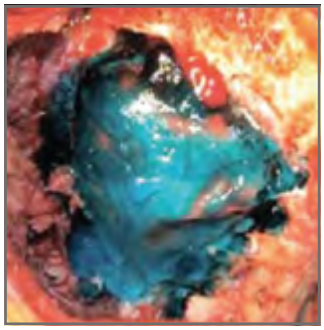
Midline suboccipital craniectomy with dural opening for Chiari Malformation. Cerebellar tonsils below foramen magnum.



Dura closed with bovine pericardial graft using 6-O Prolene™* suture for duroplasty for treatment of symptomatic Chiari malformation.



Application of DuraSeal® sealant to augment dural closure.



Completion of Duraseal® dural sealant application of duraplasty for decompression of Chiari malformation.

Watertight closure success rate

	Patients	Follow-up	Rate of success (no overt CSF leak)
Cosgrove[1]	111	3 months	100%
Boogaarts[5]	47	1 month	95,3%

Images: **Delashaw J, Coppa N.** *"Closure Techniques for Common Craniotomies in the Posterior Fossa"* (White Paper)
1. **Cosgrove GR et al.** *"Safety and efficacy of a novel polytheylene glycol hydrogel sealant for watertight dural repair"*. J Neurosurg 106: 52-58, 2007
2. **In-vitro Product Comparison Study of Wound Healing Sealants.** Report no: R090417B (Cyanta Report)
3. **Safety Testing** for 4a20kSG-trilysine sealant with BHT. Report no: ER1105, page 2-9
4. **Delashaw JB et al.** *"Reconstruction After Posterior Cranial Fossa Surgery: Application of a Synthetic Tissue Sealant to Augment Dural Closure."* Case Report 2009
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

Applicators

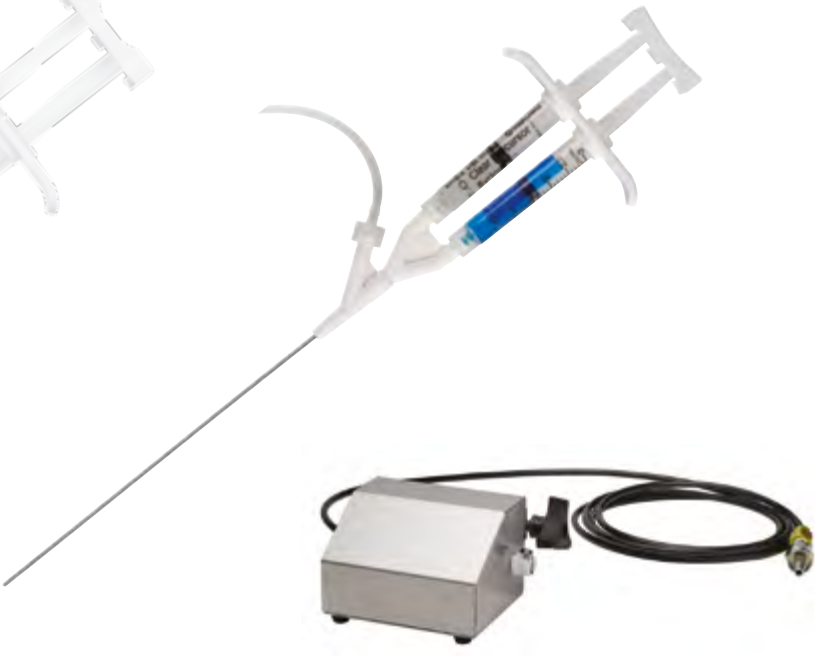
The DuraSeal® dural sealant system applicators provide extended reach and visibility to the surgical site.

Extended Tip Applicator

The Extended Tip Applicators give DuraSeal® dural 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 2-4cm 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.

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DuraSeal® Dural Sealant System for cranial surgery

Ordering Information

For EUROPE, MIDDLE-EAST and AFRICA

Reference	Description	Quantity	Availability
DSD5001	DuraSeal® dural sealant system - 5mL	1kit/box	All EUROPE, MIDDLE-EAST and AFRICA countries
DS-D-5005	DuraSeal® dural sealant system - 5mL	5kits/box	
205108	Extended Tip Applicator - 8cm length	5kits/box	
205115	Extended Tip Applicator - 15cm length	5kits/box	
20-5000**	MicroMyst® Applicator - 14cm length	5kits/box	
FR-6065	Flow Regulator	1 unit/box	

For LATIN AMERICA, ASIA PACIFIC and CANADA

Reference	Description	Quantity	Availability
DSD5001	DuraSeal® dural sealant system - 5mL	1kit/box	LATIN AMERICA and ASIA PACIFIC countries*
DS-D-5005	DuraSeal® dural sealant system - 5mL	5kits/box	LATIN AMERICA and ASIA PACIFIC countries*
20-2010	DuraSeal® dural sealant system - 5mL - NOT CE MARKED	1kit/box	LATIN AMERICA and ASIA PACIFIC countries*
20-2050	DuraSeal® dural sealant system - 5mL - NOT CE MARKED	5kits/box	LATIN AMERICA and ASIA PACIFIC countries*
209001	DuraSeal® dural sealant system - 5mL - NOT CE MARKED	1kit/box	Canada ONLY
20-9005	DuraSeal® dural sealant system - 5mL - NOT CE MARKED	5kits/box	Canada ONLY
JDSD5001	DuraSeal® dural sealant system - 5mL - NOT CE MARKED	1kit/box	Japan ONLY
JDSD5001	DuraSeal® dural sealant system - 5mL - NOT CE MARKED	5kits/box	Japan ONLY
205108	Extended Tip Applicator - 8cm length	5kits/box	LATIN AMERICA, ASIA PACIFIC countries* and CANADA
205115	Extended Tip Applicator - 15cm length	5kits/box	LATIN AMERICA, ASIA PACIFIC countries* and CANADA
20-5000**	MicroMyst® Applicator - 14cm length	5kits/box	LATIN AMERICA, ASIA PACIFIC countries* and CANADA
FR-6065	Flow Regulator	1 unit/box	LATIN AMERICA, ASIA PACIFIC countries* and CANADA

* Not all products are available in all regions. Please check the specific reorder number to determine which product is available in your region.
For all the medical devices specially identified as "NOT CE MARKED", please refer to the appropriate Instruction for use: the indications and contraindications of the product may be different as the ones mentioned on this document for CE MARKED medical devices.

** 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 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 use **Extended Tip Applicator, MicroMyst® Applicator** and **Flow Regulator** for other indications than ones provided in the instructions for use.

Integra Contact - Sales & Marketing
EUROPE, MIDDLE-EAST and AFRICA
Integra LifeSciences Services (France) SAS
Immeuble Séquoia 2 97 allée Alexandre Borodine
Parc technologique de la Porte des Alpes
69800 Saint Priest FRANCE
Phone +33 (0)4 37 47 59 00
Fax +33 (0)4 37 47 59 99
emea.info@integralife.com

LATIN AMERICA, ASIA PACIFIC and CANADA
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536 USA
Phone +1 609 936 5400 ▪ +1 609 750 4259 (fax)
lapac_cs@integralife.com

Integra Contact - Questions & Information
Europe, Middle East and Africa: +33 (0)4 37 47 59 50 ▪ +33 (0)4 37 47 59 25 (fax) ▪ csemea@integralife.com
Benelux: +32 (0)2 257 4130 ▪ +32 (0)2 253 2466 (fax) ▪ custsvcbenelux@integralife.com
United Kingdom: +44 (0)1 264 345 780 ▪ +44 (0)1 264 363 782 (fax) ▪ custsvcs.uk@integralife.com
Switzerland: +41 (0)2 27 21 23 30 ▪ +41 (0)2 27 21 23 99 (fax) ▪ custsvcsuisse@integralife.com
Germany: +49 (0)2102 5535 6200 ▪ +49 (0)2 102 5536 636 (fax) ▪ custsvcgermany@integralife.com
Australia: +61 (0) 3 8540 0400 ▪ +61 (0) 3 9540 0004 (fax) ▪ orders@integra-LS.com.au
Latin America: +1 609 936 5400 ▪ +1 609 750 4259 (fax) ▪ lapac_cs@integralife.com
Asia Pacific: +1 609 936 5400 ▪ +1 609 750 4259 (fax) ▪ lapac_cs@integralife.com
New Zealand: +64 (0) 9 447 3460 ▪ +64 (0) 9 447 3440 (fax) ▪ customerservice@integra-LS.com.au
Canada: +1 800 263 6693 or + 1 905 632 788 ▪ +1 905 632 7938 (fax) ▪ custserv.canada@integralife.com
integralife.eu - integralife.com

Contact - Product Ordering
integralife.eu/duraseal-order/

Covidien LLC
15 Hampshire Street
Mansfield, MA 02048 ▪ USA

EC REP Covidien Ireland Limited
IDA Business and Technology Park
Tullamore ▪ Ireland

CE 0123 TÜV

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