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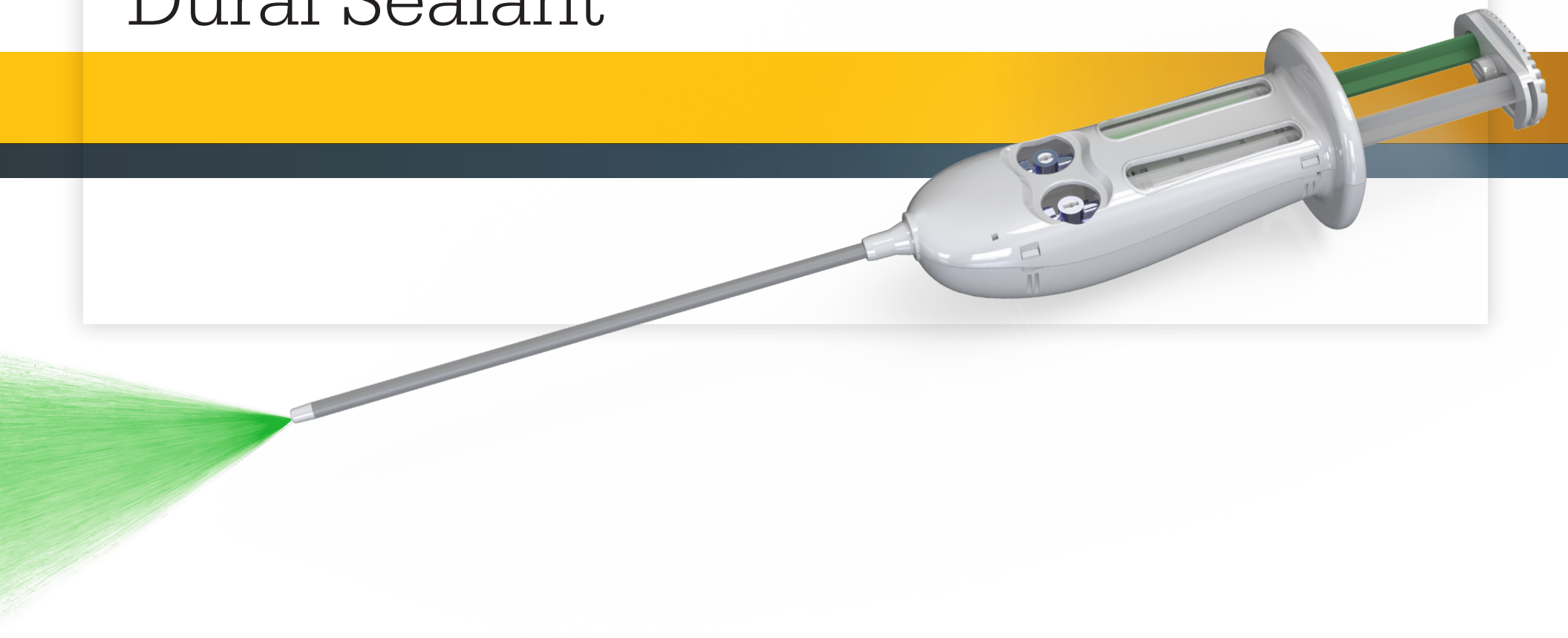
Adherus®

AutoSpray ET Dural Sealant



Adherus® AutoSpray ET Dural Sealant

Demonstrated to be 99.1% effective at preventing CSF leaks through 14 days of post-operative follow-up.[3]

- Maintains burst pressure strength above physiological intracranial pressure in an in vitro model[1]
- Absorbs over approximately 90 days[2]
- Extended tip applicator

Product code	Description	Qty
NUS-109	Adherus AutoSpray ET Dural Sealant	5 units

Craniomaxillofacial

Adherus AutoSpray ET Dural Sealant is indicated for use in patients who are 13 years of age and older, as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure during cranial procedures.

1 Second set time
The Adherus hydrogel sets in approximately one second. It remains where it is applied.[2]

1 Minute setup
Easy setup. Ready to use in one minute.

Two hour window
Once setup, Adherus AutoSpray ET Dural Sealant gives you a two hour window of use.

Go. Stop. Go.
The Adherus AutoSpray ET Dural Sealant applicator allows the surgeon to start and stop as often as required to give complete control of the application.

17
The crosslinker with Adherus AutoSpray ET Dural Sealant has been designed with an average of 17 crosslinking endpoints to help increase strength and minimize swelling.

0 Infections
Among the subjects treated with Adherus AutoSpray Dural Sealant in a Pivotal Randomized Controlled Trial, there were no device related infections and no cases of meningitis.[3]

Adherus and Adherus ET are the only FDA-approved hydrogel dural sealant with a patent pending AutoSpray applicator with internal air pump.

References:
1: van Doormaal T, Kinaci A, van Thoor S, et al. Usefulness of Sealants for Dural Closure: Evaluation in an In Vitro Model. Operative Neurosurgery. 15(4): 425-432; 2018.
2: Data on file with Stryker.
3: Tew, Jr JM, Strong MJ, West GA, Woo H, Couture DE, Wilson JA, Munoz LF, Rosen CL, Greenlee JD, van Loveren HR, Iantosca M, Baird CJ, Smith M, McGirt M, Parish J, Asher AL. A Pivotal Randomized Clinical Trial Evaluating the Safety and Effectiveness of a Novel Hydrogel Dural Sealant as an Adjunct to Dural Repair.Oper Neurosurg13:204-212, 2017.

Manufactured by:
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Contraindications: Adherus AutoSpray ET Dural Sealant should not be used in confined anatomical spaces where nerve compression is of concern. The hydrogel may swell by up to 13% of its size in any dimension of 46% by volume after application.

Pivotal Trial Results: A prospective, randomized, controlled, multicenter pivotal trial was conducted to evaluate the safety and effectiveness of Adherus AutoSpray Dural Sealant. The primary endpoint of this study was a composite evaluation of the safety and effectiveness of Adherus AutoSpray Dural Sealant (n=124 subjects) when compared to an active control (n=126 subjects). The endpoint results were based on the number of subjects who were free from intra-operative CSF leakage from dural repair after up to two applications of sealant during the Valsalva maneuver, CSF leak/pseudomeningocele during the 120-day follow-up period and unplanned retreatment of the original surgical site within 120 days post-surgery. The overall success rate for the complete case analysis was 91.2% in the Adherus group compared to 90.6% in the control group. Adherus was found to be non-inferior to the control with the non-inferiority margin of 10% ($p = 0.005$). In the early post-surgical period when the sealants are expected to function, the overall success rate at the 14-day follow-up on subjects who completed the visit was 99.1% in the Adherus group compared to 95.0% in the control group. In addition, the overall success rate at the 45-day follow-up on subjects who completed the visit was 96.6% in the Adherus group compared to 91.9% in the control group. There were no unanticipated adverse device effects. Among the subjects treated with Adherus AutoSpray Dural Sealant, there were no device related deep wound infections and no cases of meningitis. The type and rate of adverse events observed in this study are consistent with the complexity of the surgical procedure and the co-morbid condition of the treated subjects. [3]
Please see Adherus AutoSpray ET Dural Sealant instructions for use for more information.