stryker

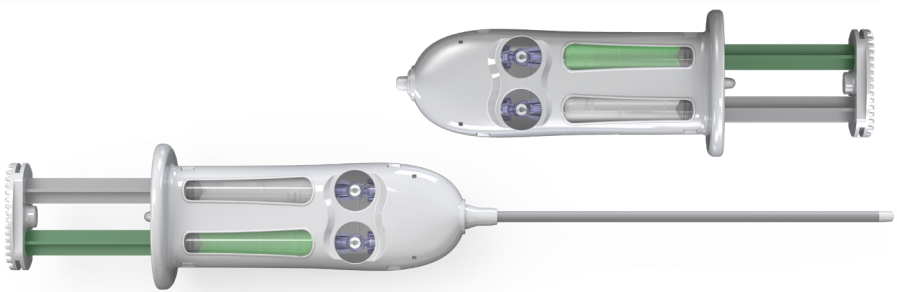
# Adherus®

## AutoSpray and AutoSpray ET Dural Sealant

**Adherus AutoSpray and Adherus AutoSpray ET Dural Sealant are 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.**

- Maintains burst pressure strength above physiological intracranial pressure in an in vitro model[1]
- Absorbs over approximately 90 days[2]
- Pre-assembled applicator
- Delivery through a tight spray pattern
- Zero device related infections during the Pivotal Randomized Clinical Trial[3]

| Product code | Description | Qty |
|---|---|---|
| NUS-106 | Adherus AutoSpray Dural Sealant | 5 units |
| NUS-109 | Adherus AutoSpray ET Dural Sealant | 5 units |



# Craniomaxillofacial

This document is intended solely for the use of healthcare professionals.
A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area. Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: Adherus, Stryker. All other trademarks are trademarks of their respective owners or holders.

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.

**Contraindications:** Adherus AutoSpray & 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 or 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 and Adherus AutoSpray ET Dural Sealant instructions for use for more information.

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HyperBranch Medical Technology, Inc., a subsidiary of Stryker, located in Durham, North Carolina USA.

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