



# Adherus<sup>®</sup>

AUTOSPRAY  
DURAL SEALANT

**REF** NUS-106

## Instructions for Use



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**Rx**  
ONLY

## Explanation of Symbols

The following table shows symbols used in this manual, on system components and on packaging labels. The table gives the corresponding meaning of each symbol. Pay attention to these symbols as they may relate to important safety precautions and warnings.

Symbol	Meaning
	Federal (US) law restricts this device to sale by or on the order of a physician.
	Consult Instructions For Use for additional information
	Single use only; Do not reuse
	Do not re-sterilize
	Sterilized using irradiation
	Use by date; Expiration date – year and last day of month
	Do not use if package is damaged
	Keep away from sunlight
	Not for general waste
	Lot number
	Catalog Number
	Quantity
	Manufacturer
	Type BF equipment (Non-cardiac Floating—Applied Part)
	Direct Current
	Temperature Limitations (store below)
	Biohazard
	“On”/“Off” (push-push)

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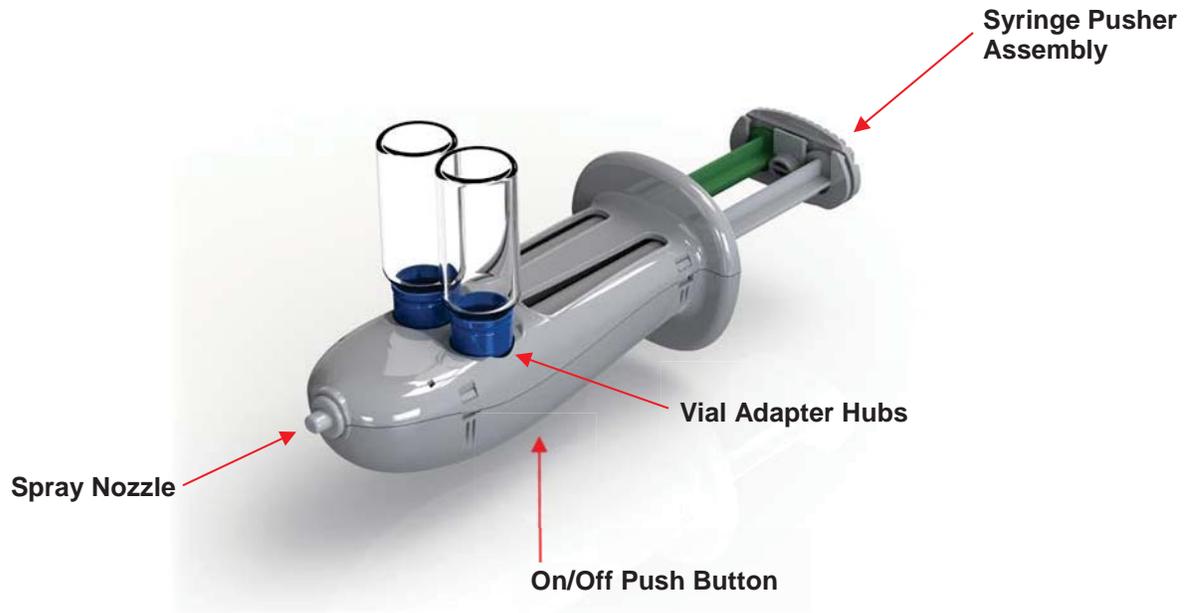
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## Device Description

Adherus AutoSpray Dural Sealant is a sterile, single-use, electromechanical, battery operated, device with internal system components that provide air flow to aid in the delivery of a synthetic, absorbable, two-component hydrogel sealant system and allow delivery to be interrupted without clogging.

The device is supplied as a pre-assembled applicator and two separate glass vials, one of which is packaged within a foil pouch. The two glass vials contain either an activated polyethylene glycol (PEG) ester powder or a polyethyleneimine (PEI) dissolved in sterile water. The crosslinking components are reconstituted prior to use by their respective reconstitution buffers which are housed within the applicator. The resulting solutions mix within the applicator and quickly crosslink to form the hydrogel sealant soon after exiting the applicator tip. The delivered solution immediately crosslinks to form a hydrogel sealant which is absorbed over approximately 90 days, sufficient time to allow for healing.

The Adherus AutoSpray Dural Sealant device is comprised of the following primary components:



### Spray Nozzle

The spray nozzle thoroughly mixes the two sealant solutions and delivers the mixed solution to the target site through a tight spray pattern. The spray nozzle is integral to the system and is not removable.

### Vial Adapter Hubs

The vial adapter hubs accept the vials containing the crosslinking components. During the reconstitution phase, the vials are attached to the vial adapter hubs. After reconstitution is completed, the hubs are removed from the Adherus AutoSpray Dural Sealant device by rotating them counterclockwise. Removing the hubs opens the pathways for the solutions to flow through the nozzle.

### On/Off Push Button Switch

The On/Off switch turns the battery powered air pump on and off. The device is shipped with the switch in the off position which isolates the air pump from the battery power source. Before removing the vial adapter hubs, push the On/Off switch to On and the air pump will be engaged.

### Battery Door

A door on the underside of the housing allows the operating room (OR) staff to remove the batteries for appropriate disposal at the end of the device use. The battery door is glued shut. Use a flat instrument to pry the battery door open and remove the batteries for disposal.

### Syringe Pusher Assembly

The syringe pusher assembly mechanically locks the two syringe plungers such that advancement of both syringe plungers occurs simultaneously.

## Indication

Adherus AutoSpray 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.

## Contraindications

- Adherus AutoSpray 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.

## Warnings

- Adherus AutoSpray Dural Sealant has not been studied in:
  - Subjects who require a procedure involving a translabyrinthine, transsphenoidal, or transoral approach, or any procedure that penetrates the air sinus or mastoid air cells;
  - Subjects whose dural edge gaps are larger than 2 mm;
  - Subjects with severely altered renal or hepatic function;
  - Subjects with an active infection present at the surgical site;
  - Subjects who have treated or untreated hydrocephalus (e.g., those with devices designed to evacuate cerebrospinal fluid (CSF) or altered CSF dynamics);
  - Subjects who have an underlying medical co-morbidity or are on a medication known to interfere with wound healing (e.g., those with previous intracranial neurosurgical procedure in the same anatomical location, radiation and chemotherapy treatment, known malignancy, diabetes, steroid toxicity and chronic corticosteroid use, compromised immune system, or on an anticoagulant agent, aspirin or non-steroid anti-inflammatory agent);
  - Subjects with a known allergy to FD&C Blue #1 Dye or FD&C Yellow #5 Dye; or
  - Subjects who are pregnant or lactating.
- Adherus AutoSpray Dural Sealant is intended for use as an adjunct to standard methods of dural repair. The effectiveness of Adherus AutoSpray Dural Sealant on other tissue types has not been studied.

## Precautions

- The Adherus AutoSpray Dural Sealant pouch is packaged sterile. Do not use if the pouch has been damaged or opened. Do not re-sterilize.
- The Adherus AutoSpray Dural Sealant package is intended for single patient use only. Discard all unused and / or opened product. Reuse of the device may result in cross contamination which may lead to injury, illness or death of the patient.
- Keep away from sunlight. Do not use if the PEG ester powder is not free flowing.
- Use Adherus AutoSpray Dural Sealant within 2 hours of reconstituting the crosslinking components. When tested 8 hours after reconstitution, the resulting sealant swelled a small but statistically significant amount more when compared to samples reconstituted for 1, 2, or 4 hours.
- The applicator system has a battery life of approximately 2 hours of continuous use.
- Prior to application of the Adherus hydrogel, ensure that fluid (cerebrospinal fluid, blood etc.) outflow has been suspended.
- Do not use the Adherus AutoSpray Dural Sealant in the presence of flammable anesthetics or flammable anesthetics with oxidants.
- Keep the Adherus AutoSpray Dural Sealant device away from strong magnetic fields to avoid possible interference of RF communication. Magnetic resonance equipment may generate interference with pump operations.
- Do not remove system covers other than the battery door.

## Training

The neurosurgeon should have “hands-on” experience with simulated use of the Adherus sealant in a bench top model prior to patient use. The training should also review the device, its Instructions for Use, and precautions, as well as the details of the clinical study. A representative of the manufacturer should be available on site to answer assembly questions during the initial use of the device in actual procedures, as part of the training, to ensure the safe use of the device.

## Adverse Events

Adherus AutoSpray Dural Sealant was evaluated in 124 investigational patients in a prospective, controlled, multicenter pivotal clinical study. The incidence and nature of adverse events observed in this patient population

was consistent with the type and complexity of the neurosurgical procedures performed and the co-morbid state of the treated patients. There were 4 patient deaths among Adherus AutoSpray Dural Sealant subjects and five deaths among control subjects. The deaths were attributed to the subjects' prior condition. The adverse events occurring at a rate of 1% or higher among the adverse events reported for the subjects treated with Adherus AutoSpray Dural Sealant are summarized in the table below. There were no unanticipated adverse device effects.

Table 1. Summary of Adherus AutoSpray Dural Sealant Adverse Events

<b>Adverse Event</b>	<b>Patients (n (%)) N=124</b>
Anaemia	3 (2.4)
Leukocytosis	2 (1.6)
Deafness Unilateral	2 (1.6)
Tinnitus	4 (3.2)
Diplopia	5 (4.0)
Eyelid Ptosis	2 (1.6)
Periorbital Oedema	6 (4.8)
Vision Blurred	7 (5.6)
Dysphagia	4 (3.2)
Nausea	2 (1.6)
Adverse Reaction	6 (4.8)
Chest Pain	3 (2.4)
Disease Progression	3 (2.4)
Fatigue	2 (1.6)
Pneumonia	2 (1.6)
Urinary Tract Infection	2 (1.6)
Wound Infection	2 (1.6)
Incision Site Hypoaesthesia	3 (2.4)
Incision Site Pain	4 (3.2)
Periorbital Haemorrhage	3 (2.4)
Post Procedural Oedema	2 (1.6)
Pseudomeningocele	9 (7.3)
Seroma	3 (2.4)
Subdural Haematoma	3 (2.4)
Wound Dehiscence	2 (1.6)
Muscular Weakness	2 (1.6)
Aphasia	4 (3.2)
Balance Disorder	2 (1.6)
Convulsion	5 (4.0)
Cranial Nerve Palsies Multiple	2 (1.6)
Dizziness	7 (5.6)
Embolic Stroke	2 (1.6)
Headache	14 (11.3)
Hemiparesis	2 (1.6)
Hypoaesthesia	4 (3.2)
Hypoglossal Nerve Paralysis	2 (1.6)
Memory Impairment	2 (1.6)
Nystagmus	3 (2.4)
Paraesthesia	5 (4.0)
Sensory Loss	3 (2.4)
Tremor	2 (1.6)
VIIIth Nerve Paralysis	3 (2.4)
Vocal Cord Paralysis	2 (1.6)
Atelectasis	2 (1.6)
Respiratory Failure	2 (1.6)
Alopecia	2 (1.6)
Rash	2 (1.6)
Swelling Face	4 (3.2)

## Clinical Information

A prospective, randomized, controlled, multicenter pivotal trial has been conducted to evaluate the use of Adherus AutoSpray Dural Sealant as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure during cranial surgery. 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. The freedom from primary endpoint failure analysis also showed that the primary endpoint failures in the control group tended to occur early in the follow-up period while a majority of Adherus endpoint failures were identified through protocol-required radiographic imaging at the 120-day follow-up visit.

Safety was assessed based on evaluation of wound healing, surgical site infections, meningitis, worsening Modified Rankin Score, surgical site swelling and adverse events through the 120 day follow-up period. One hundred (80.6%) subjects in the Adherus group and 98 (77.8%) subjects in the control group experienced at least one adverse event within the 120 day follow-up period. 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.

Key Inclusion/Exclusion criteria for the study included the following:

### Pre-Operative Inclusion Criteria:

- Subject was  $\geq 18$  and  $\leq 75$  years of age.
- Subject was scheduled for an elective cranial procedure involving a dural incision using any of the following surgical locations / approaches (or combination): frontal, temporal, occipital and parietal (i.e. supratentorial), and/or midline or lateral suboccipital (i.e. infratentorial).
- Subject required a procedure involving a Class I/clean wound (uninfected surgical wound in which no inflammation was encountered).

### Pre-Operative Exclusion Criteria:

- Subject required a procedure involving a translabrynthine, transsphenoidal, transoral approach, or any procedure that penetrates the air sinus or mastoid air cells. Note: Superficial penetration of mastoid air cells was not an exclusion if cells were appropriately sealed (e.g. bone wax).
- Subject had a CSF shunt such as; ventriculo-peritoneal, ventriculo-pleural, ventriculo-atrial or lumbo-peritoneal shunts.
- Subject had an external ventricular or lumbar CSF drain that must be left in place after surgery.
- Subject had clinically significant hydrocephalus or clinical evidence of altered CSF dynamics.
- Subject had undergone a previous intracranial neurosurgical procedure in the same anatomical location. (Note: stereotactic biopsy was not exclusionary).
- Subject experienced previous CSF leak (secondary to trauma, neoplasm, surgery or other etiology).
- Subject had radiation treatment to the surgical site, or standard fractionated radiation therapy was planned within ten days post index-procedure. (Note: stereotactic radiosurgery prior to the planned index procedure was not an exclusion criterion).
- Subject had experienced a traumatic injury to the head within 30 days prior to the planned index procedure resulting in basilar skull fracture or fractures involving the paranasal sinuses.
- Subject had a known malignancy or another condition with anticipated survival shorter than six months.
- Subject had undergone chemotherapy treatment, excluding hormonal therapy, within three weeks prior to the planned index procedure, or use of intracavitary chemotherapy wafer (BCNU) was planned, or chemotherapy treatment was planned within two weeks after the index procedure was performed.
- Standard use of peri-operative steroids (i.e., corticosteroids) was permitted. Chronic steroid use (defined as daily use of corticosteroids for  $\geq 8$  weeks) for the purposes of reducing the side effects of chemotherapy and/or radiation therapy for cancer was not exclusionary unless the patient was deemed by the investigator to be suffering from steroid toxicity. Use of corticosteroids on a chronic basis (as defined previously) for purposes other than decreasing the symptoms of systemic chemotherapy was exclusionary unless those steroids were discontinued 4 weeks prior to the planned index procedure.

- Subject received warfarin, heparin, other anticoagulant agents, aspirin or non-steroid anti-inflammatory agents on a daily basis and pre-surgical, standard of care drug wash-out did not occur.
- Subject had a documented clinically significant coagulopathy with a PTT > 37 seconds, or INR > 1.3 INR units.
- Subject had a compromised immune system or autoimmune disease, or was on chronic immunosuppressant agents at baseline.
- Subject had a systemic infection or evidence of any infection near planned operative site.
- Subject had a serum creatinine level > 2.0 mg/dL.
- Subject had a serum total bilirubin > 2.5 mg/dL at baseline.
- Subject had uncontrolled diabetes as evidenced by the Institution's standard of care (HbA1c >7%, blood glucose, etc) at baseline.

**Intra-Operative Inclusion Criteria:**

- Subject's linear extent of durotomy was  $\geq$  2 cm.
- Subject's dural margins from the edges of bony defect were  $\geq$  3 mm throughout.
- Subject's CSF leak was present intra-operatively following completion of primary dural closure (with or without non-autologous duraplasty or autologous tissue), either spontaneously or upon Valsalva maneuver, at up to 20 cm H<sub>2</sub>O for up to five (5) seconds.

**Intra-Operative Exclusion Criteria:**

- Subject had an Incidental finding that met any pre-operative exclusion criterion listed above.
- Subject required the intra-operative placement of a CSF diversion device (e.g. ventricular catheter, subdural catheter, lumbar drain, or other device designed to externally evacuate CSF) that was left in place after the procedure. Note: Subgaleal drains used for acute post-operative management of the incision site were permitted.
- Subject had a gap > 2 mm present between dural edges, or between the edge of dura and duraplasty material, based on visual estimate by surgeon before application of the surgical sealant.

Table 2 Summary of Demographic Information for Study Patients

Characteristics	Adherus AutoSpray Dural Sealant	
	Population	Control Population
Number of Subjects	124	126
Men/Women	41/83	40/86
Median Age (years)	54.2	51.1
Subject ASA score (N (%))		
I	2 (1.6)	8 (6.3)
II	47 (37.9)	50 (39.7)
III	69 (55.6)	62 (49.2)
IV	6 (4.8)	6 (4.8)
V	0 (0.0)	0 (0.0)
Primary indication for surgery (N (%))		
Tumor	56 (45.2)	53 (42.1)
Epilepsy	1 (0.8)	1 (0.8)
Nerve decompression	17 (13.7)	21 (16.7)
AVM	3 (2.4)	5 (4.0)
Aneurysm	28 (22.6)	26 (21.3)
Chiari malformation	17 (13.7)	18 (14.3)
Cyst	2 (1.6)	1 (0.8)
Other	0 (0.0)	1 (0.8)
Approach (N (%))		
Infratentorial	53 (42.7)	52 (41.3)
Supratentorial	71 (57.3)	74 (58.7)
Primary technique for dural closure (N (%))		
Suture	48 (38.7)	48 (38.1)
Suture + autologous dural material	29 (23.4)	34 (27.0)
Suture + non-autologous dural material	45 (36.3)	39 (31.0)

AEs reports at a rate of great than 1% in the intent to treat (ITT) subject population are summarized in Table 1, above.

## Adherus AutoSpray Dural Sealant Sterilization Method and Device Disposal

The following table details the method of sterilization and disposal of the Adherus AutoSpray Dural Sealant device.

Description	Part Number	Sterilization Method	Frequency of Use	Method of Disposal
Adherus AutoSpray Dural Sealant	<div style="border: 1px solid black; padding: 2px; display: inline-block;">REF</div> NUS-106	Radiation <div style="border: 1px solid black; padding: 2px; display: inline-block;">STERILE R</div>	Single Use Only 	Dispose of the Adherus AutoSpray Dural Sealant device in a hospital approved biohazard container. <b>Do not place in the trash!</b> 

### Environmental Operating Conditions

<b>Storage Temperature</b>	Store below 30°C
<b>Operating Temperature</b>	5°C to 35°C
<b>Noise Level</b>	≤60 db

### How Supplied

The components of the Adherus AutoSpray Dural Sealant package are:

- Adherus AutoSpray Dural Sealant kit tray (1)
  - ◆ Pre-Assembled applicator (1)
  - ◆ Foil pouch containing glass vial (1)
    - Activated PEG powder in green capped vial (1)
  - ◆ PEI solution in silver capped vial (1)
  - ◆ Oxygen absorber (Do not remove the oxygen absorber from the tray)

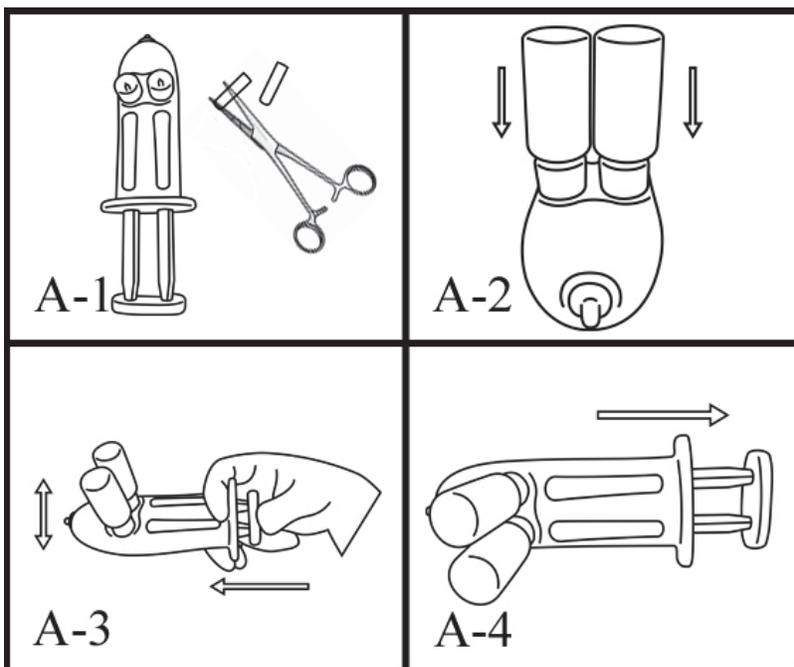
### Adherus AutoSpray Dural Sealant Operations

The following sections give instructions for preparing and powering Adherus AutoSpray Dural Sealant.

#### Reconstituting the Crosslinking Components

- 1) Using aseptic technique, introduce the contents of the large foil tear pouch labeled Adherus AutoSpray Dural Sealant into the sterile field.
- 2) Remove the lid from the Adherus AutoSpray Dural Sealant kit tray.
- 3) Remove the pre-assembled Adherus AutoSpray Dural Sealant applicator and the adjacent vial containing the clear liquid from the tray.
- 4) With the device oriented such that the spray nozzle is pointing up, remove and discard the red caps covering the spikes on the blue vial adapter hubs on the applicator (Fig. A-1).  
**Note:** It may be necessary to use hemostats or a similar tool to remove the caps. A twisting motion while removing the cap is also recommended.
- 5) Seat the vial containing PEI solution (**silver** capped vial) into the blue vial adapter hub of the applicator corresponding to the **white** syringe plunger by grasping the applicator and fully depressing the vial so that the spike penetrates the septa and the silver aluminum seal bottoms out in the vial adapter hub (Fig. A-2).
- 6) Remove the foil pouch containing the PEG ester powder from the tray and remove the vial containing the PEG ester powder (green capped vial).
- 7) Seat the vial containing the PEG ester powder into the blue vial adapter hub of the applicator corresponding to the **green** syringe plunger by grasping the applicator and fully depressing the vial so that the spike penetrates the septa and the green aluminum seal bottoms out in the vial adapter hub (Fig. A-2).
- 8) With the vials oriented upward, depress the syringe pusher assembly to transfer the liquids into the vials. Continue to depress the syringe pusher assembly (Fig. A-3).  
**Note:** Use two hands to depress the syringe pusher assembly if necessary.
- 9) With the syringe pusher assembly still depressed, gently shake the device intermittently until the powder is completely dissolved (Fig. A-3).  
**Note:** The PEG ester powder will continue to dissolve in between periods of gentle shaking; overly aggressive shaking can cause excessive entrapped air bubbles.

- 10) Release the syringe pusher assembly to allow it to rebound backwards and depress a second time to ensure both solutions are homogeneous.
- 11) Allow the syringe pusher assembly to rebound backwards again and pull the syringe pusher assembly backwards until all of the reconstituted ingredients are transferred from the vials (overhead view in Fig. A-4).  
**Note:** If the On/Off Push Button is accidentally engaged during the reconstitution phase, the device may be turned off with no detrimental effects. Use must be completed within two hours of reconstitution for optimal results.



### Turning the Adherus AutoSpray Dural Sealant Device On

- 12) Push the On/Off button on the bottom of the device to “activate” the system prior to hydrogel spray application (Fig. B-1).  
**Note:** The Adherus AutoSpray Dural Sealant applicator should be activated prior to removal of the vial adapter hubs, just prior to spray application, to avoid inadvertently clogging the nozzle.

### Device and Treatment Site Preparation

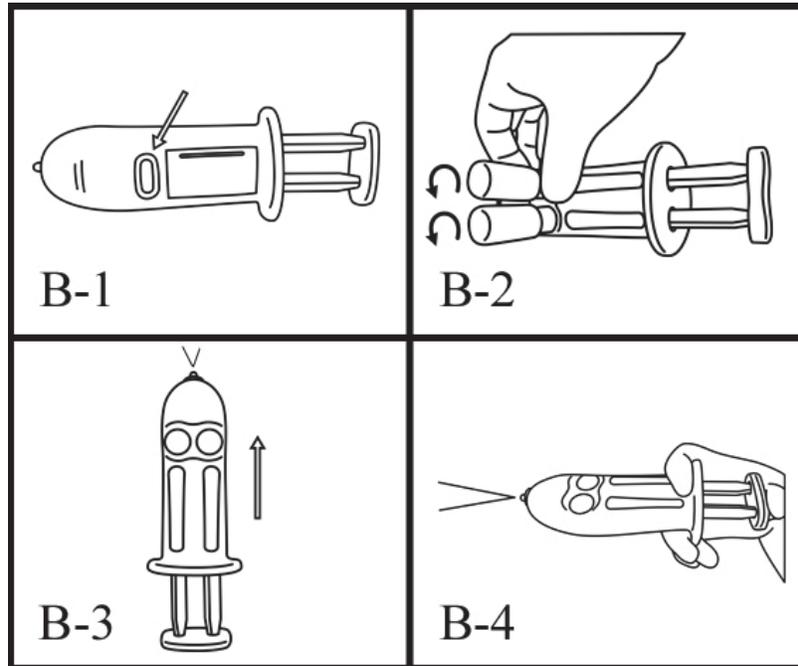
- 13) If not already on, push the On/Off button to turn on the Adherus AutoSpray Dural Sealant applicator (Fig. B-1).  
**Note:** The internal air pump is activated by pushing the On/Off button, providing an audible sound that the system has been activated. If the audible sound from the pump is not present, discontinue use of the current Adherus AutoSpray Dural Sealant unit and follow instructions in the Troubleshooting section.
- 14) Prior to treatment delivery, orient the device so that the vials are pointed upwards and remove and discard both vial adapter hubs by rotating the blue hubs counterclockwise until the hubs are ejected from the device (overhead view in Fig. B-2).
- 15) For optimal tissue adherence at the treatment site, ensure that 2 to 3 millimeter margins around the defect are clear of blood, hemostatic agents or other loose tissues and that cerebrospinal fluid outflow is minimized.

### Treatment Delivery

- 16) To apply the prepared product, if not already on, push the On/Off button in to turn on the device.
- 17) Orient the device such that the spray nozzle is pointed up and hold a piece of gauze approximately 5 to 10 centimeters above the nozzle (Fig. B-3).
- 18) Apply firm even pressure to the center of the syringe pusher assembly until product begins to spray out of the nozzle (Fig. B-3).
- 19) Once a green sealant begins to form on the piece of gauze, stop depressing the syringe pusher assembly. Adherus AutoSpray Dural Sealant is now ready for the treatment delivery.
- 20) While aiming at the treatment site and holding the device nozzle approximately 2 to 4 centimeters away, apply firm even pressure to the center of the syringe pusher assembly to dispense the mixed solution (Fig. B-4).
- 21) Continue applying the Adherus sealant system until a thin coating (**approximately 1 – 2 mm**) is formed.  
**Note:** Gauging Thickness:

**Sutured dural closure:** Ensure that all suture knots are completely covered with hydrogel sealant. Typically, size 4-0, size 3-0 and size 2-0 sutures are used for dural closure. The smallest of these is size 4-0 which has a diameter of 0.15 mm to 0.2 mm. A knot of size 4-0 suture will have at least four widths of suture or approximately 0.6 to 0.8 mm of thickness. Complete knot coverage ensures that the minimum thickness of application is achieved.

**Onlay duraplasty closure:** Ensure that enough hydrogel sealant is applied to cover the duraplasty onlay and at least 3-4 mm of surrounding native dura with 1-2 mm of hydrogel using the height of the onlay material as a depth reference. Note that when moistened with saline, two common onlay duraplasty materials, DuraGen<sup>®</sup> Dural Graft Matrix and Durepair<sup>®</sup> Dura Regeneration Matrix are approximately 3 mm and 1 mm thick respectively.



### Stopping a Spray Application

22) The application may be interrupted at any time during a treatment by halting the pressure applied to the pusher assembly. However, to prevent clogging, do not turn off the pump until the final sealant application has been completed.

**Note:** If excess hydrogel forms on the spray nozzle during an application, it may be removed by gently wiping with a piece of gauze.

### Finishing a Delivery

23) If necessary, excess sealant beyond the edges of the dural margin may be removed with a Penfield probe, scissors or mechanical disruption.

## Adherus AutoSpray Dural Sealant Disposal

When the final spray application is complete, turn off the device, open the battery door to break the internal seal and remove the batteries for appropriate disposal. The following table relays important information regarding disposal of the Adherus AutoSpray Dural Sealant components.

Device	Disposal Instructions
Adherus AutoSpray Dural Sealant	<p>Adherus AutoSpray Dural Sealant consists of a plastic enclosure and electrical components. This device must be taken to separate collection at the product end of life. Do not dispose of this product as unsorted municipal waste.</p> 

## Troubleshooting Adherus AutoSpray Dural Sealant

The following potential failure modes for Adherus AutoSpray Dural Sealant have been identified. Each of the failure modes includes a safeguard (as listed below) to control for the results of such malfunctions.

Potential Failure Modes	Safeguard
1. Air-pump not activated	1. On/Off switch not depressed
2. Spray nozzle blocked	2. Do not remove vial adapter hubs prior to turning on air pump, wipe off nozzle after use.

To avoid complications, follow exactly the Adherus AutoSpray Dural Sealant Troubleshooting Flow Chart in the above table. During a procedure, the user's efforts to troubleshoot Adherus AutoSpray Dural Sealant should be strictly limited to the steps described above. If troubleshooting is not successful, discontinue use of the current Adherus AutoSpray Dural Sealant unit **immediately** and open a new Adherus AutoSpray Dural Sealant unit.

## Adherus AutoSpray Dural Sealant Electrical Specifications

The Adherus AutoSpray Dural Sealant meets the following standards:

- IEC 60601-1 3<sup>rd</sup> edition Electrical safety standard requirements
- IEC 60601-1-2 3<sup>rd</sup> edition Immunity requirements

## Guidance & Manufacturer's Declaration – Electromagnetic Emissions

Adherus AutoSpray Dural Sealant is intended for use in the electromagnetic environment specified below. The customer or user of Adherus AutoSpray Dural Sealant should assure that it is only used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	Adherus AutoSpray Dural Sealant uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Adherus AutoSpray Dural Sealant is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 6100-3-2	Not applicable	
Voltage fluctuations /Flicker emissions IEC 6100-3-3	Not applicable	

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity for all Equipment and Systems

Adherus AutoSpray Dural Sealant is a battery operated system and is intended for use in the electromagnetic environment specified below. The customer or user of Adherus AutoSpray Dural Sealant should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Not Applicable Battery Operated System with no Digital Circuitry	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable Battery Operated System	Main power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable Battery Operated System	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70% $U_T$ (30% dip in $U_T$ ) for 25 cycles  <5% $U_T$ (>95 % dip in $U_T$ ) for 5 sec	Not Applicable Battery Operated System	Main power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power main interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not Applicable Battery Operated System with no Magnetically Sensitive Components	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

\*NOTE:  $U_T$  is the a.c. main voltage prior to application of the test level.

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Adherus AutoSpray Dural Sealant is intended for use in the electromagnetic environment specified below. The customer or user of Adherus AutoSpray Dural Sealant should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80MHz to 2.5GHz</p>	<p>Not Applicable Battery Operated System with no Digital Circuitry</p> <p>Not Applicable Battery Operated System with no Digital Circuitry</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of Adherus AutoSpray Dural Sealant, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d = 1.2\sqrt{P}$ <p><math>d = 1.2\sqrt{P}</math> 80MHz to 800MHz <math>d = 2.3\sqrt{P}</math> 800MHz to 2.5GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1 At 80 MHz and 800 MHz, the higher frequency range applies. Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Adherus AutoSpray Dural Sealant is used exceeds the applicable RF compliance level above, the Adherus AutoSpray Dural Sealant device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Adherus AutoSpray Dural Sealant device.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less the 3V/m</p>			

## Recommended Separation Distances Between Portable and Mobile RF Communications and Adherus AutoSpray Dural Sealant

Adherus AutoSpray Dural Sealant is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Adherus AutoSpray Dural Sealant device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Adherus AutoSpray Dural Sealant device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter <b>W</b>	Separation distance according to frequency of transmitter <b>m</b>		
	150 kHz to 80 MHz  $d = 1.2\sqrt{P}$	80 MHz to 800 MHz  $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz  $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.