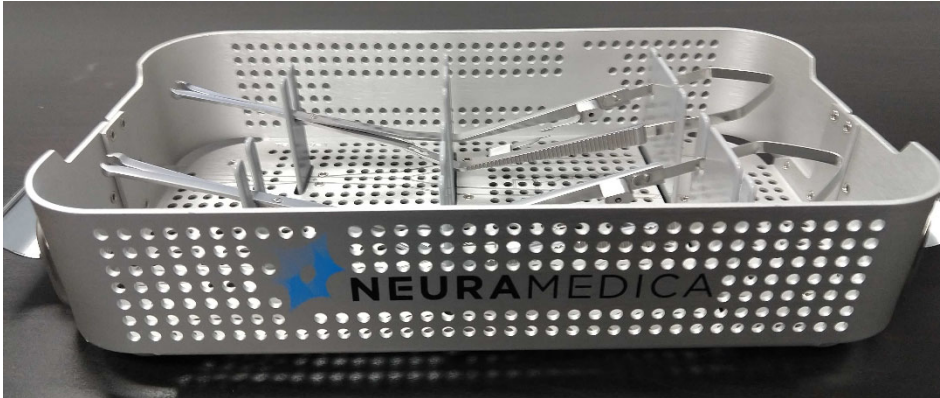
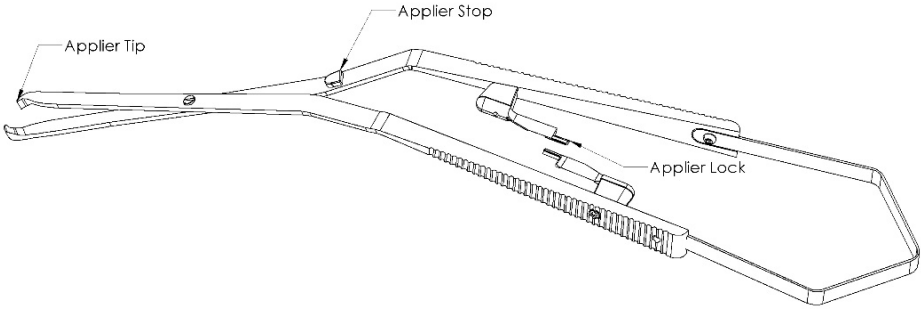
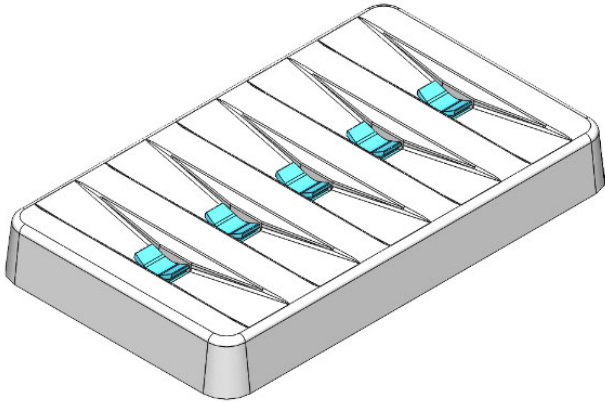


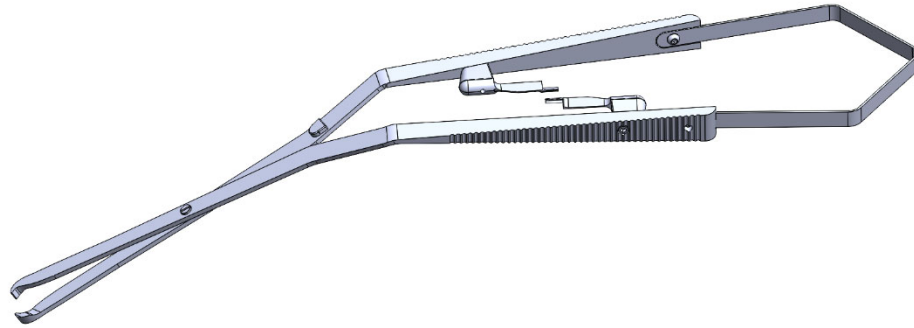
NeuraMedica DuraFuse Clip Applier and Tray Instructions for Use (IFU)

Description	<p>DuraFuse Clip instruments are designed to aid in the installation of DuraFuse Clips during open and tubular retractor procedures of the spine for approximation/attachment and/or closure of the dura mater in neurosurgical and orthopedic spine procedures.</p>
Material	<p>The applier is made from surgical grade stainless steel. The instrumentation tray is made from Aluminum, Stainless Steel, and Nylon.</p>
Indications	<p>DuraFuse Clips are indicated for open and tubular retractor procedures of the spine in the prone position for approximation/attachment and/or closure of the dura mater in neurosurgical and orthopedic spine procedures.</p>
How Supplied	<p>The DuraFuse Clip Applier is supplied non-sterile. Appliers are provided in a sterilization tray (shown below). Each tray has two identical Appliers. Sterilize prior to use using the sterilization method described in this document.</p> <div data-bbox="483 1119 1417 1514" data-label="Image">  </div>

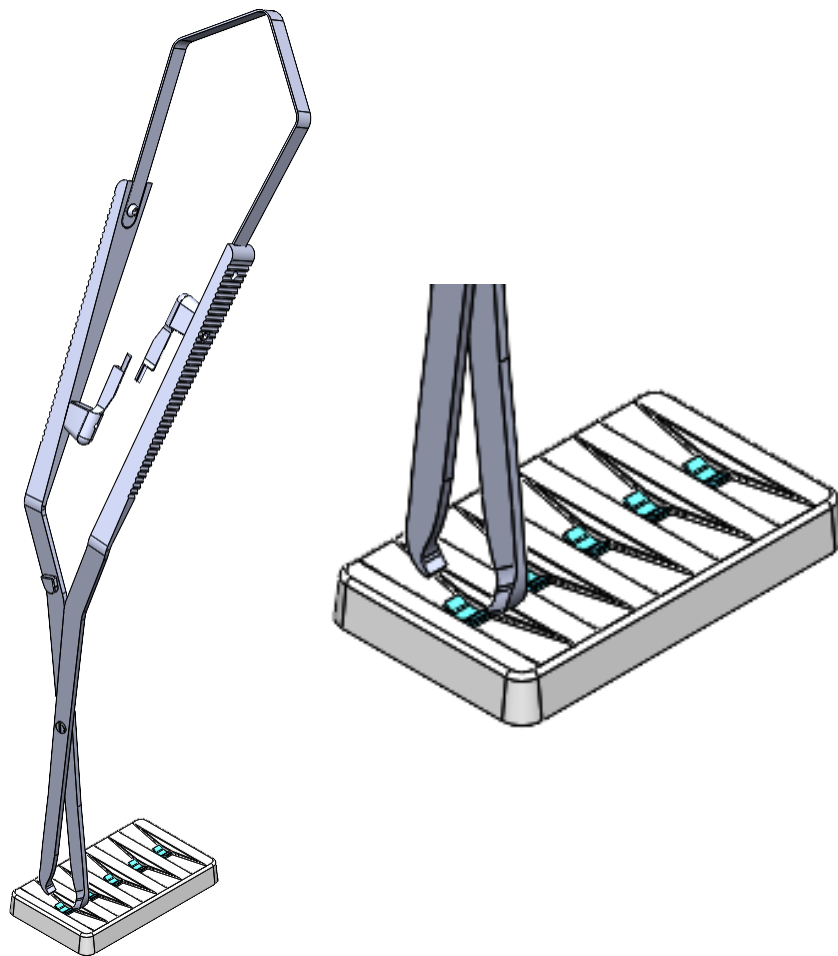
Caution: Federal Law (USA) restricts this product sale by or on the order of a physician or hospital.

Schematic View with Nomenclature	
Contraindications	<p>DuraFuse Clips are contraindicated in the following situations:</p> <ul style="list-style-type: none"> • For patients with a known sensitivity to bioabsorbable polymers such as bioabsorbable suture • For repair of cranial dural tissue around the skull • Dural tissue cannot be properly everted due to anatomical limitations • Dural tissue is too friable for the use of sutures • Do not use DuraFuse Clips in sites with acute or chronic infections
Notification Key	<ul style="list-style-type: none"> • WARNING: Indicates critical information about a potential serious outcome to the patient or user. • CAUTION: Indicates instructions that must be followed to ensure the proper use of the device. • NOTE: Indicates information requiring special attention.
Instructions For Use	<p>CAUTION: The locking mechanism of the Applier can become misaligned during reprocessing. Make sure the locking mechanism is working properly prior to use.</p> <ol style="list-style-type: none"> 1. Remove DuraFuse Clip Cartridge holding five (5) sterile Clips from foil pouch. 

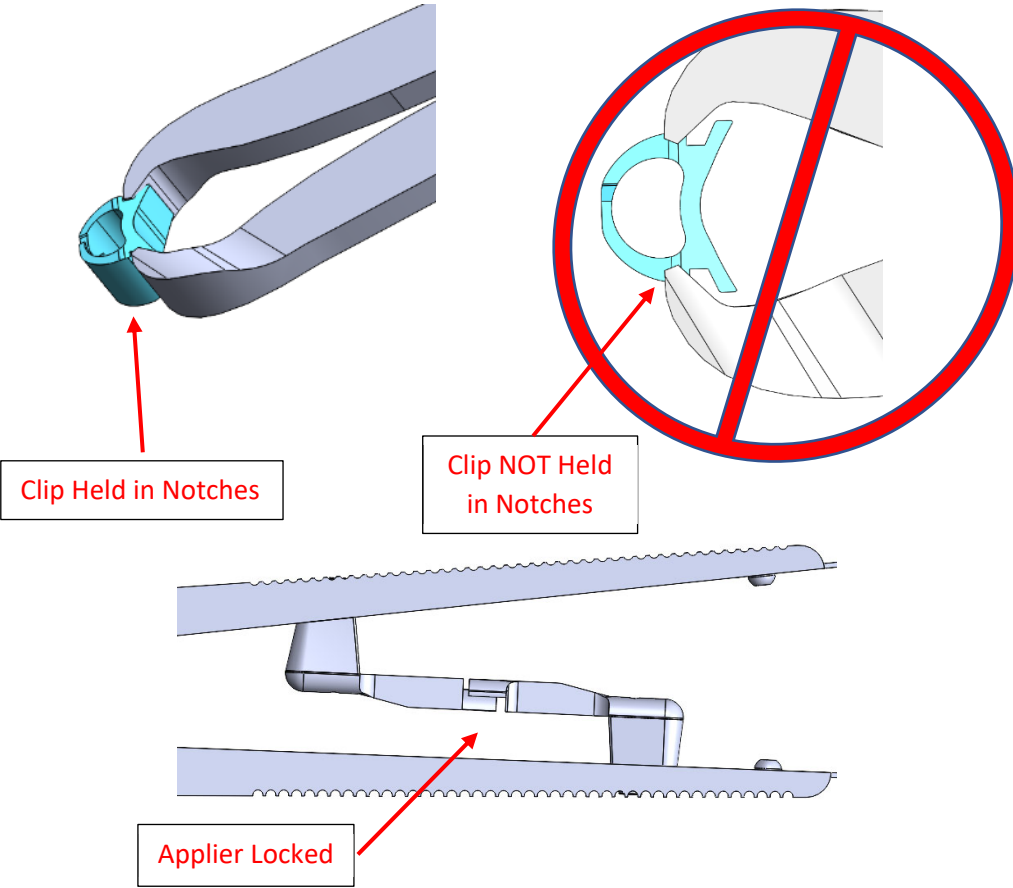
2. Remove one custom Applier from surgical tray (tray holds two identical Appliers).



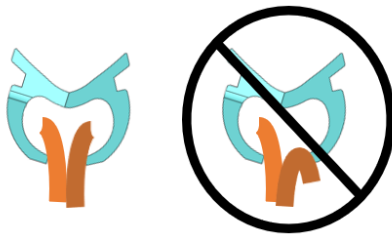
3. Use Applier to grasp a Clip. The lock should engage and hold Clip securely. Clip will be held in the closed position, and Applier may be set aside until Clip is ready to be applied.



CAUTION: Applier should be holding Clip in the notches. If Applier is misaligned, then manually align Clip before use.



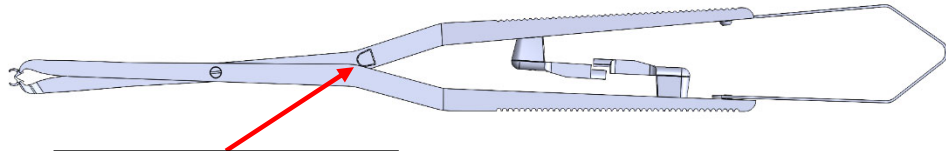
4. If using a surgical dilation tube, adjust the position of the tube to allow appropriate visualization of the dural defect.
5. Examine the size of the defect and if longer than 1 cm, more than one package of DuraFuse Clips may be needed.
6. Use forceps to close the dural defect by approximating the dural ends. Ensure all tissue edges are symmetrically everted prior to applying Clip.
WARNING: Failure to appropriately evert the dural ends can result in improper closure, which can cause possible cerebrospinal fluid (CSF) leakage and/or neural tissue adhesions.



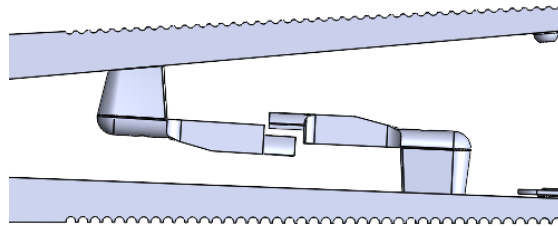
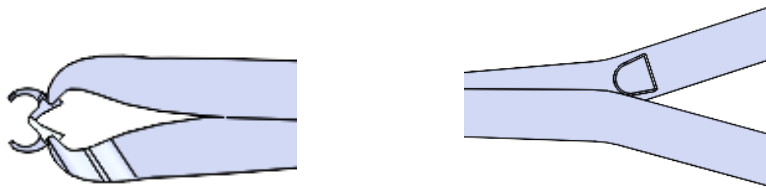
Caution: Federal Law (USA) restricts this product sale by or on the order of a physician or hospital.

7. When ready to apply Clip, squeeze Applier handles until physical stop is reached and Clip is fully opened. Do not release handle until Clip is positioned over dural ends.

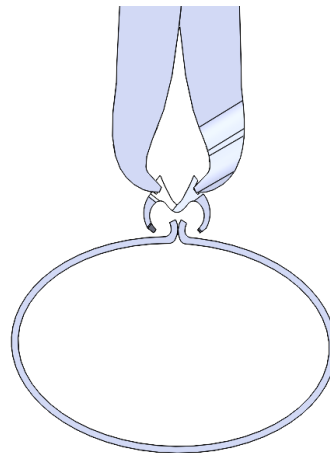
NOTE: Applier has a built-in stop that prevents over-opening of Clip.



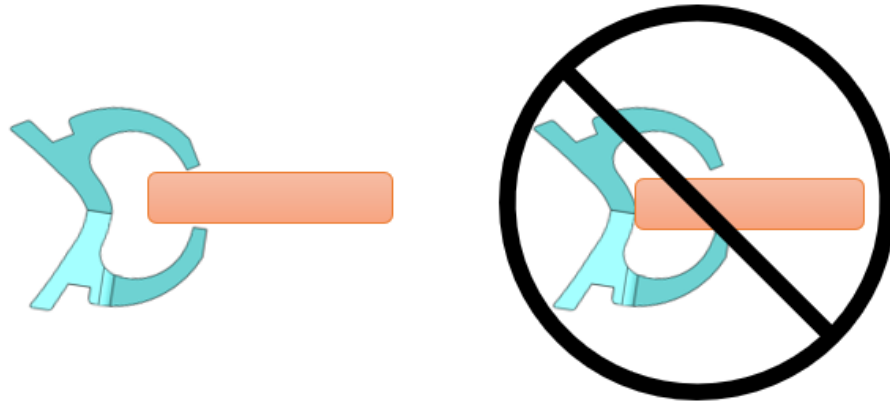
Applier Stop, Clip is OPEN



8. Use Applier to position Clip above the everted dural ends, making certain that both dural ends are within Clip. Position OPEN Clip over the dural ends. Then release pressure on Applier handle to APPLY Clip.



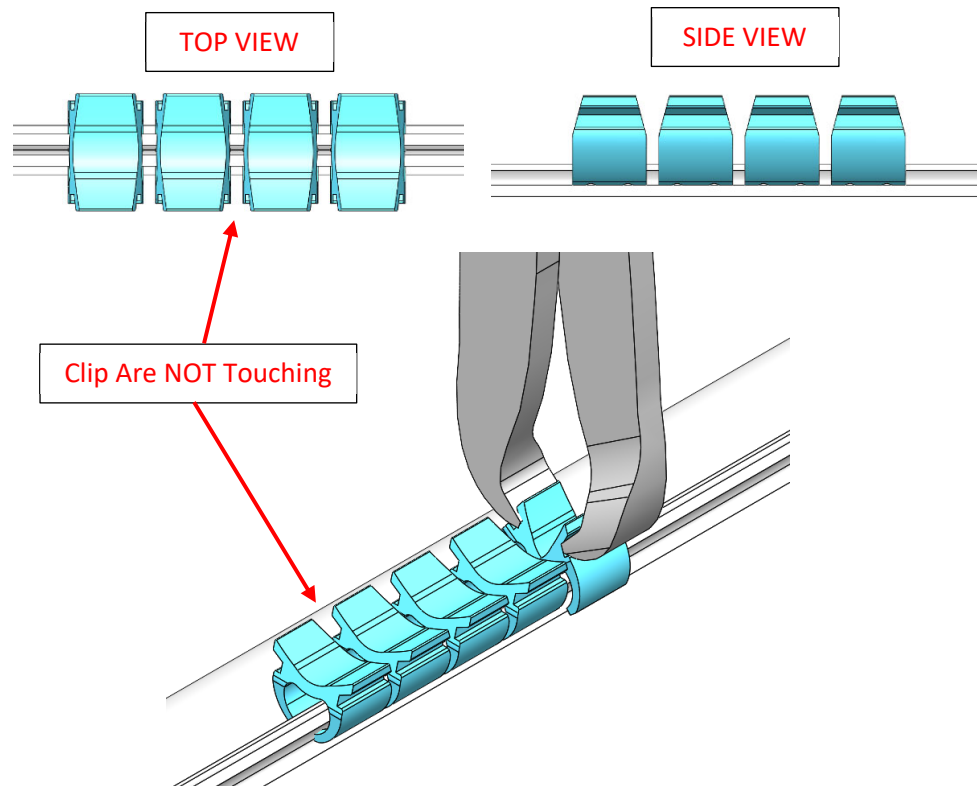
WARNING: DO NOT over-apply Clips or they may not form a seal. Too much dural tissue inserted into Clip opening can interrupt formation of a seal, allowing CSF to leak out of the closure site.



CAUTION: Clips may be repositioned several times during application using Applier. If Clip is opened excessively, discard and use new Clip.

9. Apply additional Clips as needed, spacing them approximately 0.5 mm apart.

WARNING: Clips may be placed together closely, a gap of approximately 0.5 mm is acceptable.



	<p>10. After application of Clips, thoroughly inspect the closure. A Valsalva maneuver may be used to identify areas of persistent leakage. If inadequate closure is identified, readjustment of Clips may be necessary to obtain a watertight closure.</p> <p>11. After a satisfactory closure of the dural defect is obtained, a multilayered tissue closure of the fascia and soft tissues should be performed.</p> <p>12. Following tissue closure, the patient may be kept in a supine bed rest position post-operatively following appropriate protocol for dural repair procedures.</p>
WARNINGS	<ul style="list-style-type: none"> • Instrument breakage or damage, as well as tissue damage, may occur when an instrument is subjected to excessive loads, improper use, or unintended use. • Improper insertion of the device can lead to soft tissue complications. • The instruments are intended only for professional use by a licensed physician.
CAUTIONS	<ul style="list-style-type: none"> • Any device contaminated with blood, tissue, or other bodily fluids should be handled according to hospital protocol. • Do not use metal brushes or scouring pads during manual cleaning. • The use of neutral pH enzymatic and cleaning agents is recommended.
Adverse Effects	<ul style="list-style-type: none"> • Infection • Pain/swelling • Tissue damage • Blood leakage • Hemorrhage • Stenosis • Thrombosis/occlusion • Dehiscence • Necrosis • Seroma • Nerve injury • Steal phenomenon • CSF leak • Pseudomeningocele • Neuropathic pain • Spinal infarction
Limitations on Reprocessing	<ul style="list-style-type: none"> • The instruments are designed to withstand typical cleaning and steam sterilization cycles. • Instruments should be inspected after cleaning for damage, wear, and/or misalignment of the locking mechanism. Instrument life is normally determined by damage and wear. • Damaged instruments should be returned to NeuraMedica for replacement.



Caution: Federal Law (USA) restricts this product sale by or on the order of a physician or hospital.












Point of Use	<ul style="list-style-type: none"> Remove biological material from the instruments with a lint-free disposable wipe. It is recommended that instruments are decontaminated as soon as possible following use. Transport the instruments in the tray provided.
Preparation for Decontamination	<ul style="list-style-type: none"> Applier should not be disassembled.
Manual Cleaning of the Applier	<p>Step 1: Rinse Applier to remove any gross soil.</p> <p>Step 2: Prepare a Neutral pH (<.8.5) enzymatic detergent solution according to the manufacturer's instructions.</p> <p>Step 3: Completely submerge Applier in the enzyme detergent solution and gently shake to remove trapped bubbles. Actuate Applier hinge to ensure contact of the solution with all surfaces.</p> <p>Step 4: Soak Applier for a minimum of three (3) minutes. While soaking, scrub surfaces using a soft, nylon-bristled brush until all visible soil has been removed; however, do not apply excessive pressures onto locking mechanism. Actuate Applier handle. Particular attention should be given to crevices and the hinged joint. Note: All scrubbing should be performed below the surface of the solution to minimize the potential of aerosolizing contaminated solution.</p> <p>Step 5: Remove Applier from the solution and rinse in tap water for a minimum of one (1) minute. Actuate Applier handle while rinsing.</p> <p>Step 6: Prepare an ultrasonic cleaning bath with detergent according to the manufacturer's recommendations. Completely submerge Applier in the cleaning solution and gently shake to remove any trapped bubbles. Sonically clean Applier at the time, temperature, and frequency recommended by the equipment manufacturer and optimal for the detergent used. A minimum of ten (10) minutes is recommended.</p> <p>Step 7: Remove Applier from the ultrasonic bath and rinse in purified water for a minimum of one (1) minute or until there is no sign of residue detergent or biologic soil. Actuate Applier handle while rinsing.</p>
Drying	<ul style="list-style-type: none"> Dry Applier with a clean, absorbent, non-shedding, lint-free cloth. Applier is made from stainless steel and can corrode if not dried.
Maintenance, Inspection, and Testing	<ul style="list-style-type: none"> Inspect Applier under normal lighting to ensure soil has been removed. Repeat the cleaning process if any soil is visible. Inspect the Applier after cleaning/sterilization to ensure that the locking mechanism is still functioning correctly. <ul style="list-style-type: none"> Gently squeeze handles (partially) until you hear a click, release handles, the locking mechanism should be engaged. Next, squeeze handles fully closed, then release, the locking mechanism should not engage, and appliers should open all the way. If needed, slightly bend one of the locking teeth up or down for proper functioning.

Caution: Federal Law (USA) restricts this product sale by or on the order of a physician or hospital.

Packaging	<ul style="list-style-type: none"> • Applier should be placed in the appropriate place in the supplied tray. • Wrap the tray in two layers of 1 ply polypropylene wrap and place in a steam sterilizer. 										
Sterilization	<ul style="list-style-type: none"> • Applier is provided non-sterile. The steam sterilization method identified below has been validated to the requirements of ISO 17665. <p style="text-align: center;">Sterilize Applier in the surgical tray using the guidelines below:</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="2" style="text-align: center;">Pre-Vacuum Steam Sterilization</th> </tr> <tr> <th style="text-align: center;">Condition</th> <th style="text-align: center;">Wrapped</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Exposure Temperature</td> <td style="text-align: center;">270°F (132° C)</td> </tr> <tr> <td style="text-align: center;">Exposure Time</td> <td style="text-align: center;">4 Minutes</td> </tr> <tr> <td style="text-align: center;">Dry Time</td> <td style="text-align: center;">45 Minutes</td> </tr> </tbody> </table>	Pre-Vacuum Steam Sterilization		Condition	Wrapped	Exposure Temperature	270°F (132° C)	Exposure Time	4 Minutes	Dry Time	45 Minutes
Pre-Vacuum Steam Sterilization											
Condition	Wrapped										
Exposure Temperature	270°F (132° C)										
Exposure Time	4 Minutes										
Dry Time	45 Minutes										
Storage	<ul style="list-style-type: none"> • Following drying, allow the surgical tray to cool before touching with unprotected hands. • Remove surgical tray from the autoclave and store at ambient temperature and humidity. • Prior to use, inspect the tray and Applier for wear, damage, or tampering. 										
MR Unsafe	<ul style="list-style-type: none"> • The Applier and Tray are MR Unsafe. 										
Product Warranty	<ul style="list-style-type: none"> • NeuraMedica Inc. warrants that reasonable care has been used in the manufacture of this device. NeuraMedica Inc. makes no representation regarding the suitability for any treatment in which this device is used, which determination is the sole responsibility of the purchaser. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to safely store, this device by the purchaser or any third party. • DuraFuse Clip Applier is warranted for one year from the date of shipment from NeuraMedica. Please contact NeuraMedica to arrange return/replacement of Applier. 										

Caution: Federal Law (USA) restricts this product sale by or on the order of a physician or hospital.

Manufacturer Contact	 NEURAMEDICA NeuraMedica Inc. 1515 7 th St, STE A Oregon City, OR 503.914.0723 www.neuramedica.com 	<p>Products may not be approved for use in all countries. Nothing in these materials should be construed as a representation or warranty as to the efficacy or quality of this product, nor the appropriateness of this product to treat any condition. Physicians may direct questions about the availability and use of this product described in these materials to their authorized NeuraMedica representative. Specific questions patients may have about the use of the product described in these materials or the appropriateness for their own conditions should be directed to their own physician.</p>
-----------------------------	--	---

	Manufacturer		Date of Manufacture
	Lot Number		Part Number
	Do not use if package is damaged		Non-Sterile
	Medical Device		Consult Instructions for use
R_x Only	Prescription Use Only		Manufactured in the USA
	MRI Unsafe		Unique Device Identifier

Caution: Federal Law (USA) restricts this product sale by or on the order of a physician or hospital.