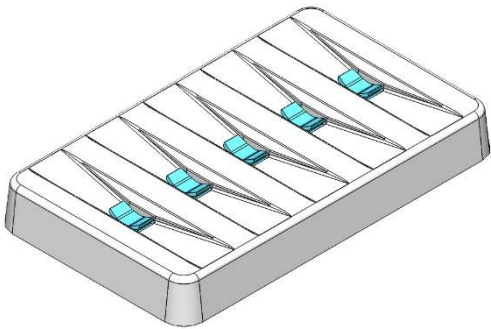
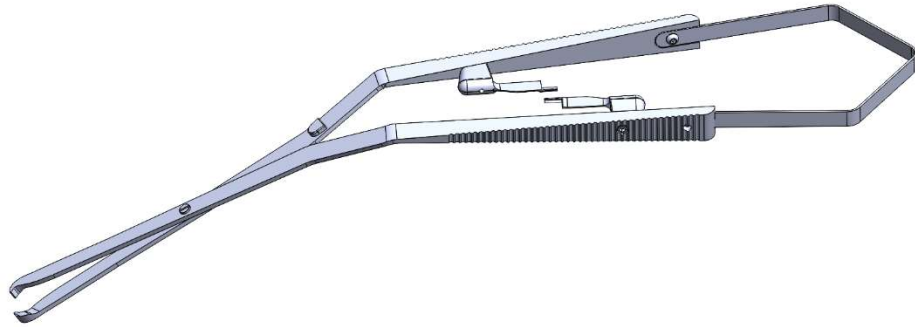


DuraFuse™ Clip Instructions for Use (IFU)

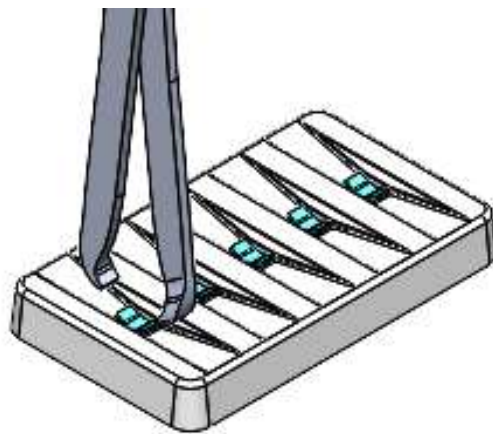
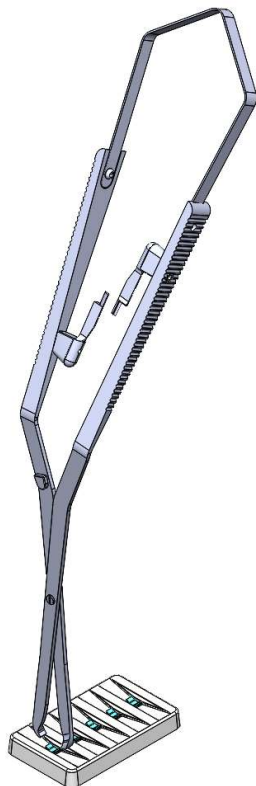
Description	DuraFuse Clips are bioabsorbable surgical clips designed to aid in closure of the dura mater in neurosurgical and orthopedic spine procedures. DuraFuse Clips are 3 mm wide by 4.6 mm long. They are applied using a reusable stainless-steel applier. The Applier is a separately-supplied reusable instrument.
Material	The DuraFuse Clips are injection molded out of a bioabsorbable polymer.
Indications	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.
How Supplied	DuraFuse Clips are provided in non-pyrogenic, sterile, single-use cartridges containing 2, 3, or 5 clips. The sterility of the device is assured if the packaging is not opened or damaged.
Contraindications	<p>The DuraFuse Clips are contraindicated in the following situations:</p> <ul style="list-style-type: none"> • For patients with a known sensitivity to bioresorbable polymers such as resorbable sutures • 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 the sterile Clips from foil pouch. The image below and throughout this IFU shows the 5-clip configuration. 

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

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

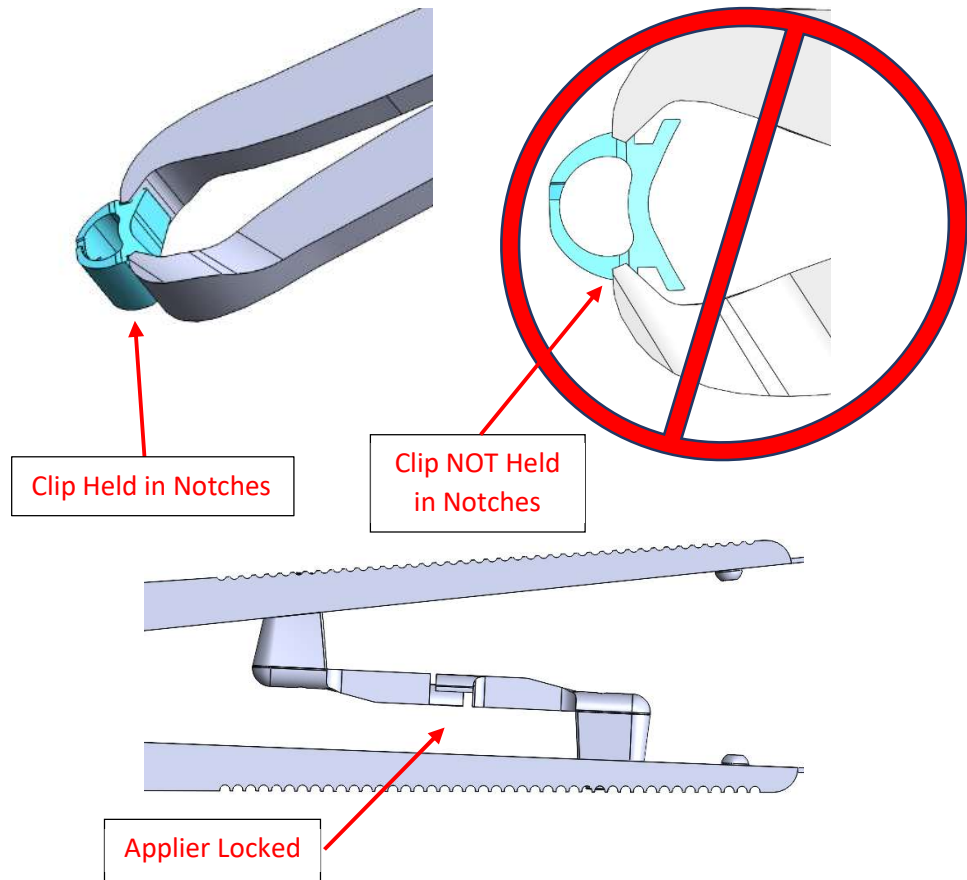


3. Use Applier to grasp a Clip. The lock should engage and hold Clip securely. Clip will be held in the closed position, and Applier may be set aside until Clip is ready to be applied. You may also manually load/adjust clips in the Applier as needed.



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



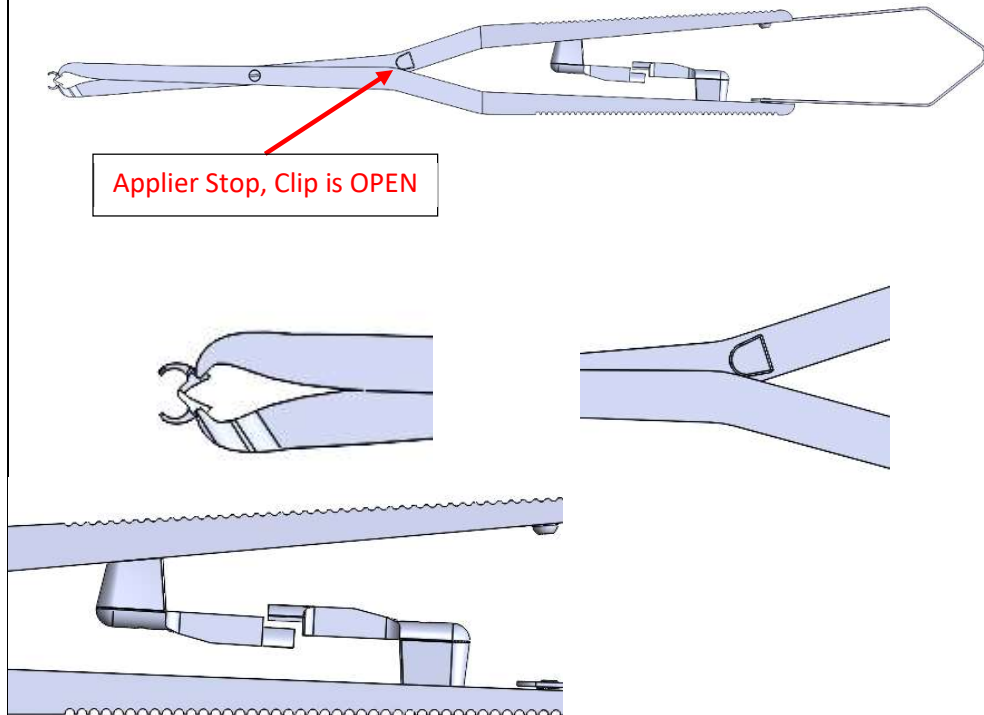
4. If using a surgical dilation tube, adjust the position of the tube to allow appropriate visualization of the dural defect.
5. Examine the size of the defect and if longer than 1 cm, more than one package of DuraFuse Clips may be needed.
6. Use forceps to close the dural defect by approximating the 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.



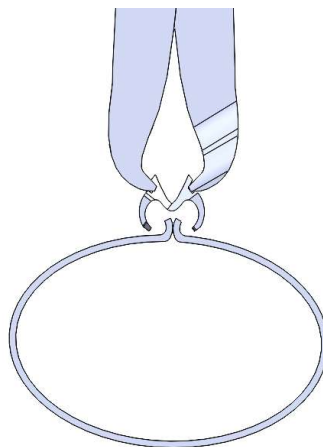
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7. When ready to apply Clip, squeeze Applier handles until physical stop is reached and Clip is fully opened. Do not release handle until Clip is positioned over dural ends.

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

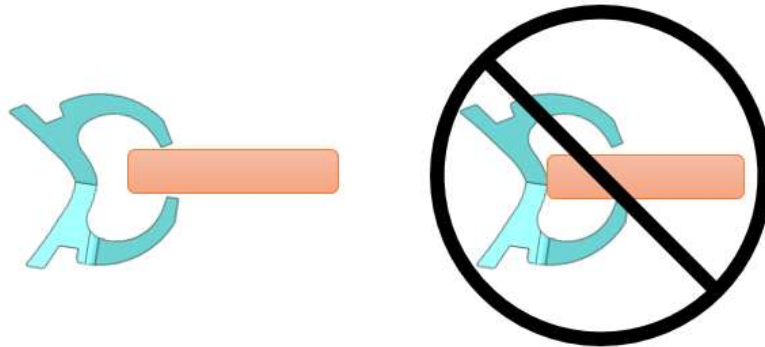


8. Use Applier to position Clip above the everted dural ends, making certain that dural ends are within Clip. Position OPEN Clip over the dural ends. Then release pressure on Applier handle to APPLY Clip.



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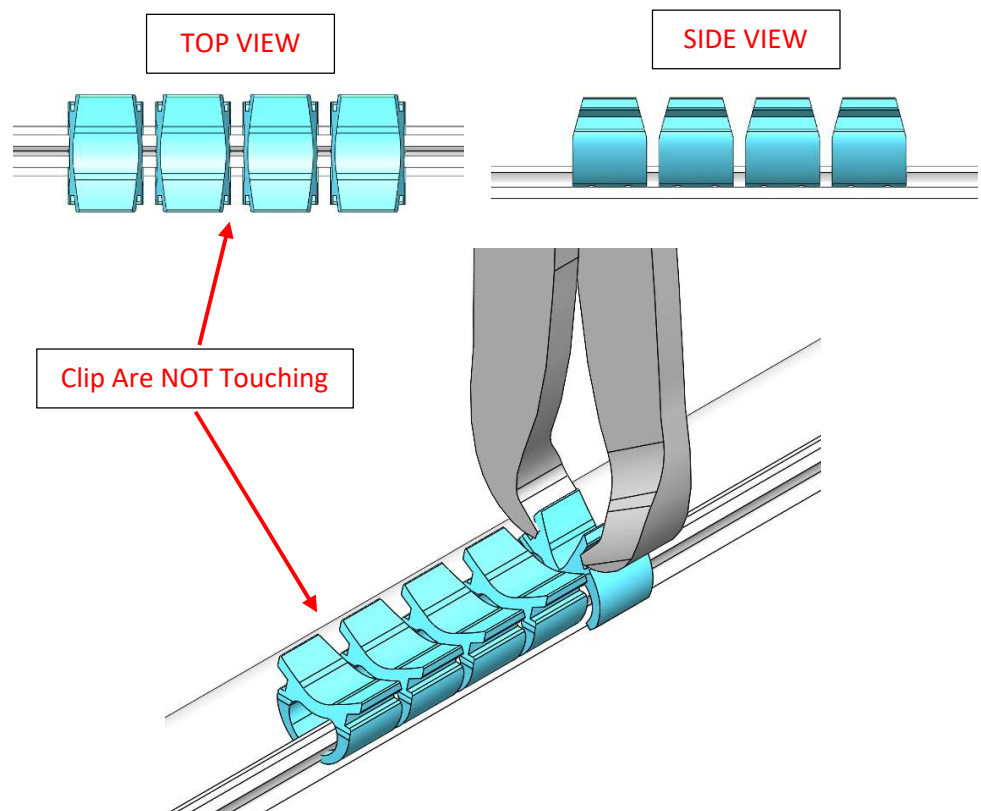
WARNING: DO NOT over-apply Clips or they may not form a seal. Too much dural tissue inserted into Clip opening can interrupt formation of a seal, allowing CSF to leak out of the closure site.





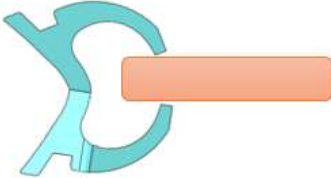

CAUTION: Clips may be repositioned several times during application using Applier. If Clip is opened excessively, discard and use new Clip.

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

WARNING: Clips should be placed together closely, but not directly touching. A gap of approximately 0.5 mm is acceptable.





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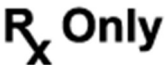



	<p>10. After application of Clips, thoroughly inspect the closure. A Valsalva maneuver may be used to identify areas of persistent leakage. If inadequate closure is identified, readjustment of Clips may be necessary to obtain a watertight closure.</p> <p>11. After a satisfactory closure of the dural 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"> Failure to appropriately evert the dural ends can result in improper closure, which can cause possible CSF leakage and/or neural tissue adhesions.   <ul style="list-style-type: none"> 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.   <ul style="list-style-type: none"> Clips should be placed closely together, but not directly touching. A gap of <i>approximately</i> 0.5 mm is acceptable. DO NOT re-sterilize Clips. DO NOT use if any of the packaging or sterile barriers are damaged.

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CAUTIONS	<ul style="list-style-type: none"> • Applier should be holding Clip in the notches. If Applier is misaligned, then manually align Clip before use. • Clips may be repositioned several times during application using Applier. If Clip is opened excessively, discard and use new Clip. • Variations in patient anatomy, such as unusually thin dural tissue, health comorbidities, vascularity, and other factors should be considered by the physician before using DuraFuse Clips. • Do not open and close Clips multiple times, as this may weaken their effectiveness.
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
Re-Sterilization/ Reuse	DuraFuse Clips are single-use only. Do not reuse, reprocess, or re-sterilize. The cleanliness and sterility of the reprocessed device cannot be assured. Reuse of the device may lead to cross-contamination, infection, or patient death. The performance characteristics of the device may be compromised due to reprocessing or re-sterilization since the device was only designed and tested for single-use. The shelf life of the device is based on single-use only.
MR Safe	DuraFuse Clips are MR safe.
Storage Instructions	Store DuraFuse Clips at ambient temperature in a dry place and keep away from direct sunlight. Prior to use, inspect packaging for signs of tampering, damage, or water contamination. Check the expiration date on the box to ensure the shelf life of the product has not been exceeded. Use the oldest unexpired lots first, because the bioabsorbable material has a finite shelf life.
Product Warranty	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.

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Manufacturer Contact	 NEURAMEDICA NeuraMedica Inc. 1515 7 th St, STE A Oregon City, OR 503.914.0723 www.neuramedica.com 	Products may not be approved for use in all countries. Nothing in these materials should be construed as a representation of 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.
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	Manufacturer		Use by Date		Fragile Handle with care
	Lot Number		Part Number		Unique Device Identifier
 55°C	Upper limit of Temperature		Do Not Reuse		DO not use if package is damaged
	Consult Instructions for use		Magnetic Resonance (MR) safe		Date of Manufacture
	Prescription Use Only		Manufactured in the USA		Medical Device
	Two Sterile barrier system, sterilized using irradiation				

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