Nurami

medical nanofiber technology

ArtiFascia® Instructions for Use

Do not use this device without reading and understanding the instructions enclosed herein thoroughly.

ArtiFascia® – Instructions For Use

℞Only

Caution: Federal (U.S.A) law restricts this device to sale by or on order of a physician

DEVICE DESCRIPTION

ArtiFascia® is a resorbable dural repair implant. ArtiFascia® is a flexible, white, non-friable soft matrix composed of synthetic non-woven fibers and a non-porous barrier film. ArtiFascia® is available in a variety of sizes and is packaged in a sterile single-use peelable blister enclosed within an aluminum pouch. ArtiFascia is provided sterile and is non-pyrogenic. ArtiFascia® is applied to the dural defect by using sutures.

INTENDED USE / INDICATIONS FOR USE

ArtiFascia® is indicated as a dura substitute for the repair of dura mater. ArtiFascia® is indicated for defects of 25cm^2 (3.87 in^2) or less in area. For example, 6 cm X 4 cm (24 cm^2) would be an acceptable defect size.

CONTRAINDICATIONS

ArtiFascia® is not designed, sold or intended for use except as described in the indications for use and is contraindicated in the following situations:

- Patients with a known history of sensitivity to synthetic polymeric implants.
- Patient with an active infection.
- To stop bleeding and should be used in areas where hemostasis was achieved.
- For repair of spinal neural tube defects; anterior spinal surgery resection (e.g., transoral surgery).
- To cover dura defects involving mastoid air cells.

WARNINGS AND PRECAUTIONS.

- Do not use the device if the “Use by” date indicated on the package label has passed.
- During storage, ArtiFascia® should not be exposed to temperatures above 30 degrees Celsius. Store in a cool, dry place.
- Inspect the ArtiFascia® package and content to verify that no damage has occurred as a result of shipping, handling and / or storage. If damage to the sterile barrier or the device is noted, DO NOT USE the device. Retain the package with the contents and notify your Nurami Medical Ltd., representative.
- For single use only. DO NOT reuse, reprocess, or re-sterilize. Reuse, reprocessing or re-sterilization may create a risk of contamination of the device and / or cause patient infection or cross-infection, including, but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
- Do not use if the pouch and / or the internal blister do not include product labels or product information is missing.
- Surgical gloves shall be rinsed to remove any glove powder prior to handling ArtiFascia®.
- ArtiFascia® should be cut to size ensuring an overlap to cover the missing dura.
- Do not use ArtiFascia® on defects that may not be completely covered by the device.
- No clinical data exist to support safety and effectiveness of ArtiFascia in preventing cerebrospinal fluid (CSF) leakage in spine surgeries.

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HOW SUPPLIED

ArtiFascia® is packaged in a Tyvek-lidded blister wrapped in an aluminum pouch. ArtiFascia® is supplied STERILE, is sterilized using irradiation, is non-pyrogenic, and is for single use only. Sterility is maintained as long as the package is closed and undamaged.

SHIPPING AND STORAGE

ArtiFascia® should be stored at any temperature between 2 °C – 25 °C (refrigerate or store at a controlled room temperature). Avoid excessive heat (> 30 °C) or humidity.

INSTRUCTIONS FOR USE

1. Open the outer aluminum pouch. The inner blister pack is sterile and may be placed on the sterile field.
2. If necessary, rinse surgical gloves to remove any glove powder prior to handling ArtiFascia®.
3. Open the blister pack and remove ArtiFascia® from within using standard aseptic techniques.
4. Under aseptic conditions, cut ArtiFascia® to the desired shape either wet or dry. There is no preference to side of application.
5. When suturing the implant, there is no need to hydrate ArtiFascia®, the implant can be sutured wet as well.

   Suture and needle selection should be determined by clinical need and surgeon's preference. A standard suturing technique can be used. Suture bites should be taken 2-3 millimeters from the edges of the implant. Either a running suture or interrupted stitching technique may be used, upon physician discretion.
6. ArtiFascia was not clinically tested in combination with a liquid sealant.
7. Suture retention of ArtiFascia was non-clinically tested with Premilene™, 4/0.

ADDITIONAL INSTRUCTIONS

Dispose of any unused pieces of the product in accordance with administrative and / or local, state and federal laws and regulations.

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RESORPTION

Animal study histology shows that 12 months after implantation, ArtiFascia is mostly degraded, but remnants of the implanted material were identified in all animals of the 12-month cohort (n=4). Although minor inflammation was observed at 12 months at the ArtiFascia implantation site, consistent with the longer resorption period, overall, the nature and severity of the biological response was comparable to that of the control which was fully degraded and without an associated inflammatory response by 6 months. It should be noted that the macrophage reaction was not accompanied with any other type of inflammation, or necrosis, and therefore it was judged to reflect expected absorptive reaction of well tolerated biodegradable materials.

POTENTIAL ADVERSE EVENTS

Possible complications can occur with any neurosurgical procedure and include cerebrospinal fluid leaks, infection, delayed hemorrhage, pseudomeningocele, inflammation, and tissue adhesions.

CLINICAL STUDY SUMMARY

ArtiFascia® was investigated in an outside of the United States (OUS), prospective, randomized, controlled, multi-center, single-blinded, parallel group clinical study, to evaluate the safety and effectiveness of ArtiFascia in comparison with commercially available dural substitutes in subjects requiring dural repair following elective neurosurgery. The study hypothesis was that ArtiFascia is non-inferior to other FDA-cleared commercially available dural repair devices. A total of 85 patients were enrolled and randomized of which 78 received ArtiFascia® or an FDA-cleared control device (58 patients treated with ArtiFascia, 20 patients treated with control devices) at 7 clinical OUS sites. ArtiFascia was not clinically tested in pediatric patients less than 18 years of age or pregnant patients. The study included patients between the ages of 18-75 years old, that had undergone imaging, such as, magnetic resonance imaging (MRI) in the past 6 months, prior to being scheduled for an elective cranial surgery with a dural damage that can be completely repaired where the surgical wound is expected to be Class I/clean.

The primary outcome of the study was assessed by evaluating the absence of cerebrospinal fluid (CSF) fistula (drainage from wound or sinus) and pseudo-meningocele post-operative as evaluated by physical examination and MRI at 6 months post-operative. Additionally, neurological outcomes, adverse events rate, adverse device effects and device deficiencies were assessed from the baseline visit through 6 months post-operative. Patients were enrolled according to the following inclusion and exclusion criteria:

<u>Inclusion Criteria:</u>

1. Subject between the ages of 18-75.
2. Subject is scheduled for an elective cranial surgery with a dural damage that can be completely repaired/closed by a suturable dural substitute (ArtiFascia® device or other commercially available dural substitutes).
3. Subject has undergone imaging, such as MRI, in the past 6 months before enrollment.
4. Surgical wound is expected to be Class I/clean.
5. Subject understands the study requirements and the treatment procedures and provides written informed consent before any study-specific tests or procedures are performed.

6. Subject is able and willing to adhere to the required follow-up visits and testing.

Exclusion Criteria:

1. Pregnant women or interest in becoming pregnant during the duration of the study.
2. Subject has known hydrocephalus.
3. Subject is unable to undergo MRI after the surgery.
4. Subject's life expectancy is less than 12 months.
5. Subject has a local or systemic infection (e.g., urinary tract infection (UTI), active pneumonia) or evidence of any surgical site infection, fever > 38.3 °C, positive blood culture, and/or a positive chest x-ray for acute infectious process.
6. Subject will require use of dural adhesive or sealant.
7. Subject is intended to undergo craniectomy where the bone flap will not be returned.
8. Subject with suspected low success in wound healing due to past treatments (e.g., chemotherapy, radiation therapy, severe diabetes) or other conditions (e.g., severe peripheral vascular disease, long standing steroids treatment).
9. Subject has been clinically diagnosed with malignancy (other than basal cell carcinoma or low-grade glioma), uncontrolled diabetes (A1C > 6.5%), sepsis, systemic collagen disease.
10. Subject had chemotherapy and/or radiotherapy in the past 12 weeks before surgery or is planned to have chemotherapy or radiotherapy less than 12 weeks after surgery.
11. Subject is an acute cranial trauma surgical case.
12. Subjects with a concurrent disease that would place the patient in excessive risk to the planned surgery.
13. Subject had a previous neurosurgery in the same anatomical site.
14. Subject with other undesirable symptoms defined by the principal investigator.
15. Patient has clinically significant coagulopathy as determined by the surgeon.
16. Subject is participating in another clinical study using similar investigational devices/drugs.

There were no reported cases of CSF fistula in either ArtiFascia or control group patients during the entire 6-month follow-up period. There was only a single case of CSF pseudomeningocele in the control group at the 6-month visit. There were no cases of CSF pseudomeningocele in ArtiFascia patients during the entire follow-up period, so that at 6 months, 100% of patients implanted with ArtiFascia did not have CSF fistula or pseudomeningocele.

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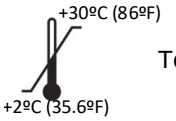
SYMBOLS USED AS PART OF THE ARTIFASCIA® LABELING

	Consult Instructions For Use		Medical Device
	Catalogue Number		Caution
	Batch Code		Do Not Reuse
	Use by Date		Do Not Resterilize
	Temperature Limits		Do Not Use if Package is Damaged
	Keep Away from Sunlight		Single Sterile Barrier system with Protective Packaging Inside
	Keep Dry		Quantity Per Box Any number can be presented in the box.
	Non-Pyrogenic		Unique Device Identifier
	Date of Manufacture		EU Authorized Representative:
	Legal Manufacturer		CE Mark
	MR Safe		Not made with natural rubber latex
	Prescription Only. U.S. Federal Law Restricts This Device to Sale by or on the Order of a Physician or Properly Licensed Practitioner		

DISCLAIMER OF WARRANTY

Note: Although ArtiFascia® has been manufactured under carefully controlled conditions, Nurami Medical has no control over conditions under which this product is used. Nurami Medical, therefore ,disclaims all warranties and representations, both expressed and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Nurami Medical shall not be liable to any person or entity to any, incidental or consequential damages including without limitation, for any medical expenses in connection to the product, caused by any use, defect, failure satisfactory quality, correspondence with description, non-infringement and / or any malfunction of the product, whether a claim for such damages is based upon representation, warranty, contract, tort, operation of law, statutory or otherwise and / or otherwise. No person has any authority to bind Nurami Medical to any representation or warranty with respect to the product.

The exclusions and limitations set out above are not intended to and should not be construed to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected.

Legal Manufacturer:
Nurami Medical Ltd.

Phone: +972 74 7408822
E-Mail: info@nurami-medical.com

EC REP EU Authorized Representative:

Phone:
E-mail:

U.S Agent TBD

Phone:
E-Mail: