DYNAVISC®

Adhesion Barrier Gel for Tendon and Peripheral Nerve Surgery

Manufactured by:

FzioMed

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DESCRIPTION

DYNAVISC® is an absorbable, clear, viscoelastic gel that is applied during tendon and/or peripheral nerve surgery. DYNAVISC is easily placed around tendon and peripheral nerve tissues and remains at the site of application for a period of time, providing a temporary mechanical barrier separating opposing tissue surfaces during the healing process. It is non-pyrogenic and contains no animal or bacterial components. No color additives are used in the gel. DYNAVISC is absorbed and does not require a second operation for removal. A sterile, soft, flexible plastic applicator is provided for attachment to the syringe for ease of administration of the gel into the surgical site.

INTENDED USE/INDICATION FOR USE

DYNAVISC is intended to reduce fibrosis and formation of adhesions following tendon and/or peripheral nerve surgery.

CONTRAINDICATIONS

DYNAVISC is contraindicated for use in the presence of frank infection.

WARNINGS

Do not inject DYNAVISC into blood vessels or allow it to enter blood vessels.

PRECAUTIONS

DYNAVISC is supplied sterile. Do not use beyond the expiry date. Safety and efficacy of DYNAVISC have not been studied under conditions of reuse of the device and/or applicator. Reuse may lead to immunological response and/or infection due to cross contamination, improper storage and/or handling. The use of DYNAVISC in combination with other medical devices, drugs or biologics has not been evaluated. DYNAVISC has not been evaluated in the presence of malignancy. The use of DYNAVISC has not been evaluated in children, or during pregnancy.As with any surgical adjuvant, foreign body reactions may occur.

STORAGE AND HANDLING

Store at room temperature (2 - 25°C). The product does not require refrigeration but should never be exposed to temperatures greater than 39°C.

INSTRUCTIONS FOR USE

PRE-PROCEDURE

Risk is inherent in the use of all medical devices. To minimize risk associated with the use of this device, it is recommended that the information for use be read by the physician and discussed with the patient prior to use of the device. Patients known to have a history of hypersensitivity to DYNAVISC or its components should not be treated with DYNAVISC.

DEVICE PREPARATION

- Remove packaging containing the DYNAVISC filled syringe and applicator from box.
- Inspect packaging for any damage. Do not use if damaged or open. The exterior of the package is not sterile.
- DYNAVISC is for single use only. Do not reuse/re-sterilize.
- Using sterile technique, introduce syringes and applicator into the sterile operating field.
- Remove cap from luer lock end of syringe and connect the gel applicator to the luer lock end of the syringe; rotate until firmly attached.
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DEVICE PLACEMENT

IMPORTANT: DYNAVISC is to be used by physicians only. Use DYNAVISC according to the instructions for use.

Following tendon and peripheral nerve repair and prior to closure of the access site incision:

1. Achieve hemostasis.
2. Apply the gel between the tendon and sheath and along the surface of the tendons and nerves and surrounding tissues by depressing the syringe plunger, covering the tissue surfaces completely.
3. Do not irrigate the surgical field after application of the gel in order to prevent dilution/removal of the product.
4. If closed suction drainage is to be used post-operatively, do not place the suction tube close to the gel as the holes in the suction tube may become occluded by the gel.
5. Place the suction tube away from the treated area where fluids are most likely to pool (i.e. proximal to the wound closure site).
6. The surgical procedure is concluded according to the standard technique of the surgeon.

7. Discard syringes, any remaining gel and applicator. The used DYNAVISC device may be a biohazard. Follow national, local or institutional guidelines for disposal of biohazard material.

ADVERSE REACTIONS

Adverse events typically related to surgery include: fever (within 36 hours postop), chills, and pain, redness, swelling, itching, bruising/hematoma, seroma, hemorrhage, wound drainage, cellulitis, limited range of motion (several months), weakness, stiffness, spasms, and tightness at the surgical site.

Adverse events related to tendon and peripheral nerve surgery (without the use of DYNAVISC) include: infection, wound dehiscence, thrombosis, embolism, formation of scar tissue, nerve damage, abnormal motor function, sensory loss, sensory decrease, partial loss of function in a particular joint, permanent range of motion loss, joint contractures, amputation, and rupture at the repair site.

Adverse events reported but not necessarily attributable to the use of DYNAVISC include wound rupture.

Contents: 1 - Syringe 1mL (luer lock)
1 - Applicator tip (luer lock)
1 - Instructions for use with product