For reference only. Please see current version of the Instructions for Use for complete information.

Description

DYNAVISC is an absorbable, clear, viscoelastic gel that is applied during tendon and/or peripheral nerve surgery such as shoulder and hand surgery. DYNAVISC is easily placed around tendon and peripheral nerve tissues by the orthopedic surgeon or hand surgeon 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

For professional/prescription use only. Use DYNAVISC according to the instructions for use. DYNAVISC is supplied sterile and is for single use only. Do not use if the package is damaged or opened. Do not resterilize. Discard any opened or unused product. The safety and efficacy of DYNAVISC have not been studied under conditions of reuse of the device. Reuse may lead to infection and/or immunological response 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. After use, DYNAVISC may be a potential biohazard. Handle and dispose of DYNAVISC in accordance with accepted medical practice and applicable national, local and institutional requirements.

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

Opening the Package

The exterior of the package is not sterile. To maintain sterility, peel open the packaging and place contents onto the sterile field. Twist off the syringe cap and secure the applicator tip to the syringe.

Device Placement

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). The surgical procedure is concluded according to the standard technique of the surgeon.
6. The surgical procedure is concluded according to the standard technique of the surgeon.

Side Effects

There are no known side effects associated with the use of DYNAVISC in humans.

Adverse Reactions

Adverse event rates for DYNAVISC have not been established; however, postmarket surveillance of approximately 250,000 distributed devices consisting of the same gel with a different intended use (temporary mechanical barrier to adhesion formation for use in the spine) has resulted in no reports of adverse events that were attributable to the device. 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.

Contents:

1 - Syringe 1mL (luer lock)

1 - Applicator tip (luer lock)

1 - Instructions for use with product tracking labels

DYNAVISC® is currently only available in the European Union. FzioMed's products are not currently available for distribution in the United States.

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