# Gelfilm®

absorbable gelatin film, USP

## DESCRIPTION

GELFILM Sterile Film and GELFILM Sterile Ophthalmic Film are absorbable gelatin film approximately 0.075 mm in thickness, designed for use as an absorbable gelatin implant in neurosurgery and thoracic and ocular surgery. In the dry state absorbable gelatin film has the appearance and texture of cellophane of equivalent thickness; when moistened, it assumes a rubbery consistency and can be cut to desired size and shape and fitted to rounded or irregular surfaces.

## ACTIONS

Rate of absorption of GELFILM Sterile Film and GELFILM Sterile Ophthalmic Film after implantation ranges from one to six months depending on size of the implant and site of implantation. Pleural and muscle implants have been reported to be completely absorbed in eight to 14 days, whereas dural and ocular implants usually require at least two to five months for absorption. Absence of undue tissue reaction incident to implantation and absorption of absorbable gelatin film, with consequent decreased likelihood of developing adhesions, has been found to be of particular value in dural and ocular implants.

## INDICATIONS AND USAGE

**Neurosurgery:** Nonconducive to undue inflammatory reaction and absorbable at a rate sufficiently slow to permit dural regeneration and healing of the arachnoid layer, GELFILM Sterile Film favorably meets requisites for a dural substitute. Use in patients undergoing craniotomies has been reported to prevent development of meningocerebral adhesions and thereby reduce risk of postoperative sequelae.

**Thoracic Surgery:** In repair of pleural defects in connection with thoracotomies, thoracoplasties, and extrapleural procedures, implantation of GELFILM Sterile Film has been observed to be followed by minimal tissue reaction and closure of the defect by ingrowth of regenerating pleural and fibrous tissue across the gradually resorbed GELFILM implant.

**Ocular Surgery:** Various ocular surgical procedures in which GELFILM Sterile Ophthalmic Film has been used include glaucoma filtration operations (i.e., trephination), extraocular muscle surgery, and diathermy or scleral "buckling" operations for retinal detachment. Experimental studies in rabbits and clinical trials in patients have shown a remarkable lack of cellular reaction to GELFILM implanted subconjunctivally or used as a seton into the anterior chamber. Objective evidence that GELFILM implants aid in preventing formation of adhesions between contiguous ocular structures has been reported in extraocular muscle surgery and operations for retinal detachment, where insertion of GELFILM implants between contiguous tissue layers was found to enhance the ease of secondary operations.

**Directions for Use:** To prepare for use, immerse absorbable gelatin film in sterile saline solution and allow it to soak until it becomes quite pliable; it may then be cut to desired size and shape without difficulty and applied as follows:

*For covering dural defects*, GELFILM Sterile Film is placed over the surface of the brain, the edges of the implant tucked beneath the dura and the wound then closed in the usual manner. If desired, the GELFILM can be sutured loosely to the dura. Care must be exercised, however, because moist film tears easily. For covering pleural defects, GELFILM Sterile Film is placed over the defect and anchored in place by small interrupted sutures.

*In diathermy or scleral "buckling" operations*, GELFILM Sterile Ophthalmic Film may be placed over the sclera, the muscle and the conjunctiva then sutured over the underlying GELFILM.

*In extraocular muscle surgery*, GELFILM Sterile Ophthalmic Film may be placed over and beneath the muscle before Tenon's capsule and the conjunctiva are closed in layers.

**CONTRAINDICATIONS**
Do not use GELFILM Sterile Film and GELFILM Sterile Ophthalmic Film in patients with known allergies to porcine collagen (see **WARNINGS**).

**WARNINGS**
Life-threatening anaphylactic reactions, including death, have been reported after exposure to absorbable gelatin. Patients with history of allergies to porcine products may be at risk of serious acute hypersensitivity reactions, including anaphylaxis (see **CONTRAINDICATIONS**). If an anaphylactic reaction is observed, absorbable gelatin administration should be immediately discontinued and any applied product removed.

**PRECAUTIONS**
Because the rate of absorption of GELFILM Sterile Film and GELFILM Sterile Ophthalmic Film is likely to be increased in presence of purulent exudation, it is recommended that absorbable gelatin film not be implanted in grossly contaminated or infected surgical wounds.

**ADVERSE REACTIONS**
Life-threatening anaphylactic reactions, including death, have been reported after exposure to absorbable gelatin (see **WARNINGS**).

**HOW SUPPLIED**
GELFILM Sterile Film and GELFILM Sterile Ophthalmic Film are supplied in the following packages:
GELFILM Sterile Film, for use in neurosurgery and thoracic surgery, sterile envelopes, one per carton, GTIN 00300090283018 (0009-0283-01).
GELFILM Sterile Ophthalmic Film, for use in ocular surgery, sterile envelopes, six per carton, GTIN 00300090297039 (0009-0297-03).

**STORAGE AND HANDLING**
GELFILM Sterile Film and GELFILM Sterile Ophthalmic Film should be stored at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Once the envelopes have been opened, contents are subject to

contamination. To insure sterility, it is recommended that absorbable gelatin film be used immediately after withdrawal from the envelope.

This product is prepackaged sterile and intended only for single use. Reuse can result in transmission of bloodborne pathogens (including HIV and hepatitis), potentially endangering patients and health care providers. Adherence to the principles of aseptic technique when using this product is essential.

Warning: To prevent contamination, employ aseptic procedure in opening envelope and withdrawing GELFILM Sterile Film and GELFILM Sterile Ophthalmic Film. If the envelope is torn or punctured, the contained GELFILM Sterile Film and GELFILM Sterile Ophthalmic Film should not be used.

**Caution:** Federal law restricts this device to sale by or on the order of a physician.

This product's label may have been updated. For current full prescribing information, please visit www.pfizer.com.

DO NOT RE-USE


Method of sterilization using steam or dry heat

Attention, see instructions for use

CONSULT Instructions for Use

DO NOT RESTERILIZE

DO NOT USE IF PACKAGE IS DAMAGED

Manufactured by:
Pharmacia and Upjohn Company
7000 Portage Road
Kalamazoo, Michigan 49001
USA
1-800-253-8600

Pfizer Injectables

Distributed by
Pharmacia & Upjohn Co
Division of Pfizer Inc
New York, NY 10017

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