Providing options for
NEUROSURGEONS
for more than 60 years.\textsuperscript{1,2}

Clinical Applications

Please note that the Indication and Important Safety Information for Gelfilm Sterile Film are available on the following pages.

Please see accompanying full Prescribing Information for Gelfilm Sterile Film beginning on page 6.
Gelfilm Sterile Film is an implantable and absorbable gelatin film used as a Dural Substitute That Prevents Adhesions in craniotomy procedures.¹

**Gelfilm Functions and Benefits**

- Gelfilm is an absorbable gelatin implant used to cover dural defects in indicated neurosurgery procedures.¹
- Gelfilm is absorbable at a rate sufficiently slow to permit dural regeneration and healing of the arachnoid layer. Resorption usually occurs in 2 to 5 months or longer.¹,³
- Gelfilm favorably meets the requisites for a dural substitute.¹
- Absence of undue tissue reaction incident to implantation and absorption of Gelfilm, with consequent decreased likelihood of developing adhesions, has been found to be of particular value in dural implants; during craniotomies, Gelfilm reduces the risk of postoperative sequelae.¹

**Indication for Neurosurgery**

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.

**Important Safety Information**

Do not use GELFILM Sterile Film in patients with known allergies to porcine collagen.

To prevent contamination, employ aseptic procedure in opening envelope and withdrawing GELFILM Sterile Film. If the envelope...
Step-by-Step Application of Gelfilm Sterile Film in a Craniotomy

1. The dura is opened in a stellate fashion during a craniotomy.

2. Gelfilm 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.¹

3. Following reapproximation of the dura, Gelfilm is held in place by interrupted tacking sutures.¹

4. The bone flap is replaced and secured using the preferred fixation method.

¹ Or using the surgeon’s preferred dural incision method (see next page).

is torn or punctured, the contained GELFILM Sterile Film should not be used.

Because the rate of absorption of GELFILM Sterile 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.

Please see accompanying full Prescribing Information for Gelfilm Sterile Film beginning on page 6.
In a stellate opening, the dural folds are reapproximated following the application of Gelfilm in a craniotomy procedure.

**Indication for Neurosurgery**
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.

**Important Safety Information**
Do not use GELFILM Sterile Film in patients with known allergies to porcine collagen.

To prevent contamination, employ aseptic procedure in opening envelope and withdrawing GELFILM Sterile Film. If the envelope
In a U-shaped opening, the dural fold is reapproximated following the application of Gelfilm in a craniotomy procedure.

Gelfilm can be applied beneath several types of dural incisions, based on the physician’s surgical preference (see the examples below).

Gelfilm Application (not to scale)

In a U-shaped opening, the dural fold is reapproximated following the application of Gelfilm in a craniotomy procedure.

is torn or punctured, the contained GELFILM Sterile Film should not be used.

Because the rate of absorption of GELFILM Sterile 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.

Please see accompanying full Prescribing Information for Gelfilm Sterile Film beginning on page 6.
1. Remove Gelfilm Sterile Film from inner envelope packaging.

2. Immerse in sterile saline solution and allow to soak until it becomes quite pliable.

**Indication for Neurosurgery**
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.

**Important Safety Information**
Do not use GELFILM Sterile Film in patients with known allergies to porcine collagen.

To prevent contamination, employ aseptic procedure in opening envelope and withdrawing GELFILM Sterile Film. If the envelope
3 Remove from sterile solution. Gelfilm can then be cut to desired shape and size.

4 Use Gelfilm for covering dural defects in craniotomy procedures.

is torn or punctured, the contained GELFILM Sterile Film should not be used.

Because the rate of absorption of GELFILM Sterile 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.

Please see accompanying full Prescribing Information for Gelfilm Sterile Film beginning on page 6.
Consider using Gelfilm Sterile Film as an absorbable implant in craniotomy procedures.¹

Gelfilm Sterile Film
- 1 per carton
- 10 x 12.5 cm
- 0.075-mm thickness
NDC 00009-00283-01

Indication for Neurosurgery
GELFILM Sterile Film favorably meets requisites for a dural substitute. Use in patients undergoing craniotomies has been reported to prevent development of meningoencephaladhesions and thereby reduce risk of postoperative sequelae.

Important Safety Information
Do not use GELFILM Sterile Film in patients with known allergies to porcine collagen.
To prevent contamination, employ aseptic procedure in opening envelope and withdrawing GELFILM Sterile Film. If the envelope is torn or punctured, the contained GELFILM Sterile Film should not be used.
Because the rate of absorption of GELFILM Sterile 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.

References

Gelfilm® is a registered trademark of Pharmacia & Upjohn Company, LLC, a Pfizer company.

Working to be your partner of choice.
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 meningoencebral 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., iridencleisis and 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 as follows: in iridencleisis in which GELFILM was employed as a seton, the resultant filtrating areas were large and there was no postoperative rise in intracocular tension; in extraocular muscle surgery and operations for retinal detachment, 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.
For use as a seton in iridencleisis, a small piece of GELFILM Sterile Ophthalmic Film (approximately 4 x 10 mm) is placed over the prolapsed iris pillar parallel to the limbus; Tenon’s capsule and the conjunctiva are then closed with continuous absorbable sutures spaced to insure tight closure.
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.

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.

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.