

ABSORBABLE POLYGLYCOLIC ACID FELT

NEOVEIL

SHEET TYPE

CE 0123



GUNZE

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SHEET TYPE

Characteristics

NEOVEIL is an absorbable reinforcement material made from PGA, and has the following characteristics.

1. NEOVEIL is a soft non woven fabric with elasticity through a special process.
2. NEOVEIL is absorbed for about 15 weeks like an absorbable PGA suture material. So its advantages are for use to regions which do not take a long time to heal.
3. NEOVEIL has good biocompatibility since it is made from PGA that is used in many clinical cases as a suture.
4. NEOVEIL is colored with green dyestuff, therefore it is easy to distinguish between NEOVEIL and tissues in clinical use.

Component

polyglycolic acid (PGA)
solvent green 3 (a very little quantity)



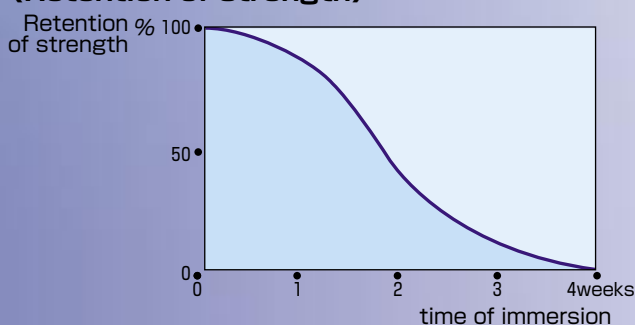
Action

In the human body, the strength of this product is decreased gradually by hydrolysis, then this product is absorbed and finally metabolized. In the absorption process, at first, the strength is decreased, next, the mass is gradually decreased, and this product is absorbed completely in about 15 weeks.

The following table shows the change of tensile strength of this product after immersion in saline at 37°C.

Days after immersion	Retention of strength
10days	50%
20days	20%
30days	0%

<Retention of strength>



This figure shows retention of the tensile strength of NEOVEIL after immersion in saline at 37°C. The strength is decreased 50% after about 10 days.

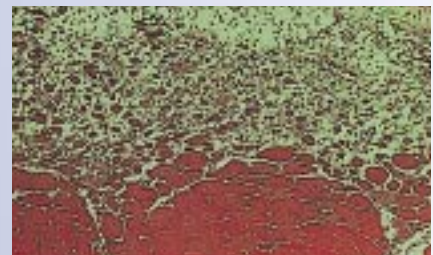
Indications

NEOVEIL is the product for reinforcing to the suturing part (especially, preventing air leakage from lung), and is applied to the following cases.

1. Reinforcement in regions which do not take a long time to heal
2. Reinforcement in sutured region of weak organs like lung, bronchi, liver, and digestive tract
3. Reduction and prevention of air leakage from the lung which are hard to perform by only using suture or surgical stapler, and reinforcement in wide defect

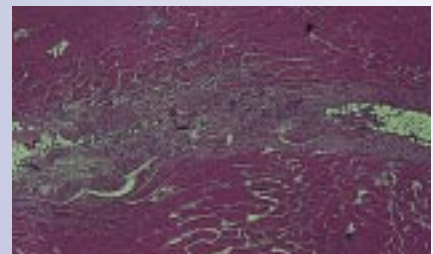
Tissue reaction

Tissue reactions for NOVEIL in the muscle on rabbit's back.



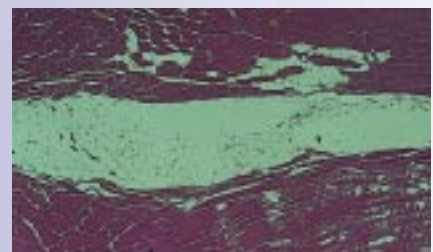
1 week after implantation

Infiltration of fibroblast and leukocyte family cells was observed around the PGA filaments. The tissue reaction was minimal.



11 weeks after implantation

Most of the PGA filaments were degraded and absorbed.



15 weeks after implantation

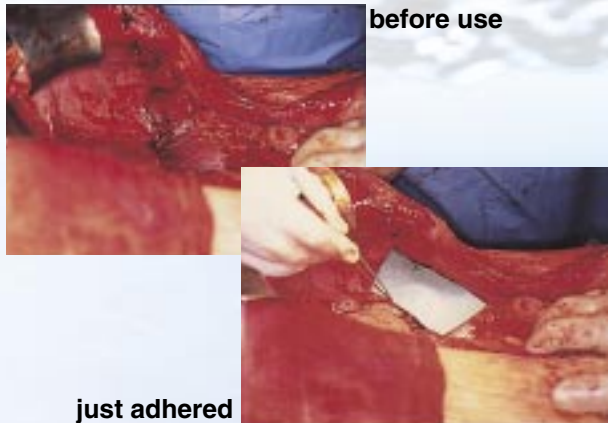
PGA filaments had been completely absorbed after 15 weeks.

NEOVEIL is an absorbable reinforcement material that is applied to regions which do not take a long time to heal, and its advantages have been confirmed in many clinical uses.

Examples of usage



NEOVEIL was used with fibrin glue to prevent air leakage at the interlobar surface of lung without suturing. (It is possible to avoid decreasing the functions of the lung.)



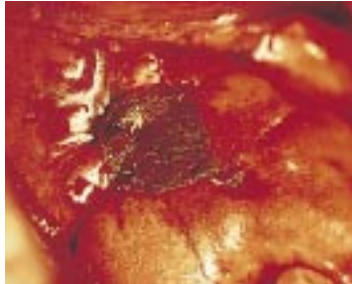
Its advantage is that NEOVEIL adheres to the wide defect for reinforcement in a large serious tunic on diaphragm or peritoneum.

Usage

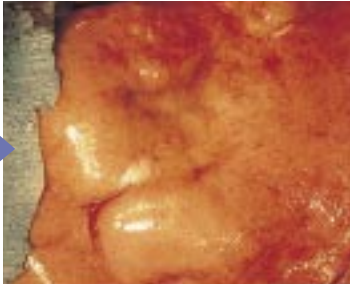
- 1. Operation method and usage**
Apply NEOVEIL on sutured regions of weak organs which do not take a long time to heal. Do not use this product with folded. This product is sterilized by ethylene oxide gas (EOG). Use under aseptic condition after opening and do not reuse.
- 2. Concrete usage**
 - (1) Confirm the region that needs to be reinforced or where air leakage needs to be prevented.
 - (2) Cut this product to proper size and shape before use, if necessary.

- (3) Use fibrin glue together in application of NEOVEIL to regions where it is difficult to suture.
- 3. Care for usage related operation method**
 - (1) User should be familiar with surgical procedures and techniques involving suture-reinforcing materials before employing this product.
 - (2) This product is sterilized by EOG. Use under aseptic condition as soon as possible after opening.
 - (3) Consider the possibility of late absorption in the tissue where little volume of blood stream exists.


A thoracotomy was executed on an adult dog. Defects were made on the lung surface at first. NEOVEIL was used for covering the defect, and four corners of this product were fixed by absorbable sutures. NEOVEIL had been absorbed after three months, then a new thin layer grew on the lung surface.



after the operation



after three months



comparison with the other materials after three months

NEOVEIL



[Warning]

- (1) Do not apply nor use in conditions where excessive tension and load act upon NEOVEIL ; nor should it be used in cases where it presses the region by its own weight when used for reinforcement. (There are cases where NEOVEIL is torn or damaged)
- (2) Do not apply to infected regions.

[Contraindication]

- (1) Do not use NEOVEIL in patients with systemic complications.

[Prohibited]

- (1) Do not reuse.
- (2) Do not use in regions which take a long time to heal. Moreover, do not use NEOVEIL for the eternal purpose. (It might be unable to keep adequate fixation because of the characteristic of this product)
- (3) Do not use on nerve system and cardiac vessels, since the safety and efficiency for these applications are not confirmed yet.
- (4) Do not use to make up an epidural deficiency area.



[Care for usage]

Read contraindication, warning and the following lines before usage.

1. Usage note

- (1) The use of NEOVEIL for the patients who have allergic should be considered from the characteristic of this product.
- (2) Consider the possibility of using this product to weak patients and those wounds take a long time to heal.

2. Important basic cares

In case of postoperative infection, treat with debridemet after removing this product.

3. Disadvantages and adverse reaction

No NEOVEIL related disadvantages or adverse reaction were reported. However, the following disadvantages may occur with the characteristic of this product.

As with any foreign body, prolonged cotact of this product with the ureter or the biliary might result in calculus formation. Failure to support the region due to excessive tension Failure to support the region of elderly patients, weak patients or those whose wounds take a long period to heal

Minimum acute tissue inflammation

In case of use in little blood stream regions or regions near the skin

*Inflammation or partial extrusion of material with late absorption or mechanical irritation

*Local pH decrease by accumulation of this dissolved unmetabolized material, and inflammation caused from pH decrease

4. Application of the elderly patients

The use of NEOVEIL for the elderly patients should be considered from the characteristic of this product.

5. Application of the pregnancy or the lactation

The use of NEOVEIL for pregnant women, lactated women or women suspected of being pregnant should be considered from the characteristic of this product.

6. Application of the child patients

Sufficient knowledge about using this product for child patients has not been obtained. Therefore the use of NEOVEIL for the child should be considered from the characteristic of this product.

[Result of clinical trial]

134 cases of clinical trials for reinforcing and preventing air leakage of the suturng part and hemostasis were conducted surgical procedure of respiratory organ and digestive organ from October 1989 to September1990.

Fibrin glue was used for hemostasis at the same time.

In general evaluation which based on the working easiness, the clinical efficacy and the side effect was that 68 cases were "very useful", 62cases were "useful" and 4 cases were "not deemed useful".

602 case of PMS studied from March 1992 to April 2000. In any case, side effect, disadvantage and adverse reaction which caused by this product were not existent.

[Storage]

1. The available period is 3years from a manufacture day. The expiration time is defined on each package. Do not use the product past the term.
2. Handle and store carefully to avoid damaging the package.
3. Store this product in a clean place, and avoid high temperatures (over 40°C), direct rays of the sun and moisture.
4. Please use the product immediately after opened an aluminum bag. If the product exposed to the air, it may degrade due to moisture contained in the air.
5. When this product store, use in order of production days.

[Product Variation (sterilized by EOG)]

Code	Size and Color	Package
NV-LL-015G	150×150×0.15mm green	1 sheet / box
NV-L-05G	100×100×0.5mm green	
NV-L-04G	100×100×0.4mm green	
NV-L-03G	100×100×0.3mm green	
NV-L-015G	100×100×0.15mm green	
NV-M-05G	100× 50×0.5mm green	
NV-M-04G	100× 50×0.4mm green	
NV-M-03G	100× 50×0.3mm green	
NV-M-015G	100× 50×0.15mm green	
NV-S-05G	50× 50×0.5mm green	
NV-S-04G	50× 50×0.4mm green	
NV-S-03G	50× 50×0.3mm green	



Manufacturer

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