ABSORBABLE POLYGLYCOLIC ACID FELT

NEOVEIL™

TUBE TYPE

The types for surgical staplers (Open•Endoscopic surgery)

GUNZE
NEOVEIL is the product for reinforcing the stapled region (especially, preventing air leakage from lung), and is applied to the following cases:
1. Reinforcement in regions which does not require long time healing.
2. Reinforcement in stapled region of weak organs like lung, bronchi, liver, 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.

Action

In the human body, the strength of this PGA sheet is decreased gradually by hydrolysis, then eventually absorbed and metabolized. In the absorption process, first, the strength decreases, next, the mass of this product gradually decreases, and eventually this product is absorbed in 40~70days. The following table shows the change of tensile strength after immersion in saline at 37℃.

<table>
<thead>
<tr>
<th>Days after immersion</th>
<th>Strength retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 0 days</td>
<td>50 %</td>
</tr>
<tr>
<td>2 0 days</td>
<td>20 %</td>
</tr>
<tr>
<td>3 0 days</td>
<td>0 %</td>
</tr>
</tbody>
</table>

(Strength retention)
Measuring the strength retention of a narrow striped PGA sheet immersed in saline at 37℃ with time. The strength decreases 50% after about 10days.

The TUBE TYPES for surgical stapler for open surgery

Product Variation

<table>
<thead>
<tr>
<th>Product code</th>
<th>Supported stapler models</th>
<th>Package</th>
</tr>
</thead>
<tbody>
<tr>
<td>NV-T-M60-R</td>
<td>[Ethicon Endo-Surgery] PROXIMATE 55mm Linear Cutter [COVIDIEN] MULTIFIRE GIA 60 Stapler GIA 60 Stapler</td>
<td>1set / bag</td>
</tr>
<tr>
<td>NV-T-M80-R</td>
<td>[Ethicon Endo-Surgery] PROXIMATE 75mm Linear Cutter [COVIDIEN] MULTIFIRE GIA 80 Stapler GIA 80 Stapler</td>
<td></td>
</tr>
</tbody>
</table>
NEOVEIL is an absorbable reinforcement material that is applied to regions which does not require long time healing, and its advantages have been confirmed in many clinical cases.

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<tr>
<td>NV-ET-M45E-2</td>
<td>[Ethicon Endo-Surgery] Echelon 45mm Endocutter (Blue, Green) Echelon Flex 45mm Endocutter (Blue, Green)</td>
<td>[COVIDIEN] ENDO GIA II45 Cartridge (Green) ENDO GIA Roticator 45 Cartridge (Green) ENDO GIA 45mm Articulating Extra-Thick Reload with Tri-Staple Technology (Black)</td>
</tr>
<tr>
<td>NV-ET-M60E-2</td>
<td>[Ethicon Endo-Surgery] Echelon 60mm Endocutter (Blue, Green) Echelon Flex 60mm Endocutter (Blue, Green)</td>
<td>[COVIDIEN] ENDO GIA II60 Cartridge (Green) ENDO GIA Roticator 60 Cartridge (Green) ENDO GIA 60mm Articulating Extra-Thick Reload with Tri-Staple Technology (Black)</td>
</tr>
<tr>
<td>NV-ET-M45A-2</td>
<td>[Ethicon Endo-Surgery] ENDO GIA II45 Cartridge (Blue) ENDO GIA Roticator 45 Cartridge (Blue) ENDO GIA 45mm Articulating Medium/Thick Reload with Tri-Staple Technology (Purple)</td>
<td>[COVIDIEN] ENDO GIA II60 Cartridge (Blue) ENDO GIA Roticator 60 Cartridge (Blue) ENDO GIA 60mm Articulating Medium/Thick Reload with Tri-Staple Technology (Purple)</td>
</tr>
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<td>[Ethicon Endo-Surgery] ENDO GIA II60 Cartridge (Blue) ENDO GIA Roticator 60 Cartridge (Blue) ENDO GIA 60mm Articulating Medium/Thick Reload with Tri-Staple Technology (Purple)</td>
<td>[Ethicon Endo-Surgery] EZ 45mm Endocutter (Blue, Green)</td>
</tr>
</tbody>
</table>

### Usage

When you attach NEOVEIL to the surgical stapler, please be aware that the thickness will increase.

1. Mount the larger part of the product to the cartridge jaw of the stapler and the smaller one to the anvil jaw, both green sheets of which have to be face to face to each other. Do not set the elastic knit or the seam on the inside.

2. Insert the head of the stapler into the patient’s body, paying sufficient attention not to entangle the tacking suture when using in an endoscopic surgery.

3. Hold the organ properly with the stapler. Adjust the sheet to be properly mounted on the stapler since the sheet may get loosened or may rotate. Take care not to hold the suture by the stapler.

4. Execute normal operation (stapling and cutting) of the stapler. Before removing the tacking sutures, please ensure that no organ tissue from the treated area is attached to the tacking suture.

5. Pull out the tacking sutures followed by separation of PGA sheet and elastic knit, and gently remove the stapler. Dispose the tacking sutures and the elastic knit outside of the body. Do not fail to carry out the same process at the anvil jaw as at the cartridge jaw. Make sure that nothing except green sheet remains in the body.

6. Cut apart the end of the sheet by scissors or the like, if necessary.
NEOVEIL™
Absorbable PGA reinforcement material.
TUBE TYPE for open and endoscopic surgical staplers.

1. DESCRIPTION
- As packaged, NEOVEIL is the reinforcement absorbable PGA (polyglycolic acid) nonwoven. NEOVEIL Tube type constitutes preformed porous bio-absorbable nonwoven sheets provided in the form of sleeves (one set consists of one cartridge and one anvil).
- After deployment of the stapler/reinforcement material combination, the excess material is removed and discarded.
- The implanted NEOVEIL sheet is a porous fibrous structure 100% PGA with a very small quantity of Solvent Green 3 (D&C Green No. 6) for colouring.
- Degraded via a combination of hydrolytic and enzymatic pathways, the PGA has been found to be biocompatible and non-antigenic, with a history of use as bio-absorbable sutures and other implantable devices.
- In vivo studies with this PGA indicate the bio-absorption process should be complete after 15 weeks.
- This device is designed for single use.
- NEOVEIL has been sterilised by ethylene oxide gas. Provided the package is stored at room temperature (less than 30°C) and is not compromised in any way, it will serve as an effective barrier until the “use by” (expiration) date printed on the label.

2. INTENDED/INDICATIONS FOR USE
- NEOVEIL tube type is intended for reinforcing and preventing air leakage of the stapling region.

3. CONTRAINDICATIONS
- Not for the patch reconstruction of cardiovascular defects such as cardiac, great vessel and peripheral vascular arteries or veins. Do not use on nerve system or epidural for reconstruction.
- Do not use on nervous system or epidural for reconstruction.
- Do not use. Do not re-stereilise. (If re-stereilised and reused, NEOVEIL might be degraded and its performance and safety might be ruined.)
- Do not use in regions which take a long time to heal.

4. WARNINGS
- Use under aseptic condition after opening the package.
- Use of this product in applications other than those indicated has the potential for serious complications. Potential complications include:
  - inadequate reinforcement strength, staple pullout, infection, abrasion, migration and erosion.
- If NEOVEIL moves while positioning the stapler, it is recommended to reposition the reinforcement to the correct location on the stapler jaws. Any rotation, sliding, or bunching of NEOVEIL could affect the total thickness of the material being stapled or impact the ease of removing the excess material after firing the stapler. Direct visualisation of NEOVEIL prior to firing the stapler is strongly recommended in open surgery.
- Use of this product with stapler models other than those listed on this instruction is not recommended.

5. PRECAUTIONS
- To avoid damage or contamination, always use clean gloves and traumatic instruments when handling the NEOVEIL. Always protect the NEOVEIL from damage by heavy or sharp objects.
- Use the suitable type of NEOVEIL according to the surgical stapler used.
- Reuse or re-sterilising may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death.
- The NEOVEIL will increase the thickness of the area to be stapled by a maximum of 0.5 mm. Selection of staple size should reflect the thickness of the NEOVEIL such that the total thickness of material to be stapled falls within the recommended range for the stapler (see stapler Instructions for Use). Use of staples with insufficient length for the procedure performed may lead to disruption of the staple line due to inadequate staple closure.
- Do not use in regions which take a long time to heal. (It might be impossible to keep performance because of the characteristics of NEOVEIL.)
- The use of NEOVEIL for patients who have allergies should be considered based on the characteristics of NEOVEIL.
- Consider the advantages and disadvantages of using NEOVEIL on weak patients, elderly patients, child patients, the pregnant or the lactation patients and those whose wounds take a long time to heal.
- In case of postoperative infection, treat with debridement after removing NEOVEIL.
- The following disadvantages may occur based on the characteristics of NEOVEIL.
  a. Calculus formation resulting from prolonged contact of NEOVEIL with the ureter or the biliary.
  b. Failure to support the region due to excessive tension.
  c. Failure to support the region of elderly patients, weak patients or those whose wounds take a long time to heal.
  d. Slight acute tissue inflammation.
  e. Inflammation or partial extrusion of material with late absorption or mechanical irritation in cases when used in regions with limited blood supply or regions near the skin.
  f. Local pH decrease by accumulation of this dissolved unmetabolised material, and inflammation caused from pH decrease in cases when used in regions with limited blood supply or regions near the skin.
  g. The surgical stapler-abnormalities due to use in unsuitable regions.
  h. Tissue injury caused by the edges of NEOVEIL.

6. ACTION
In the human body, the strength of NEOVEIL is decreased gradually by hydrolysis, and then NEOVEIL is absorbed and finally metabolised. In the absorption process, at first, the strength is decreased, next, the mass is gradually decreased, and NEOVEIL is absorbed for about 15 weeks. Tensile strength retentions for NEOVEIL are approximately 50% at 10 days, approximately 20% at 20 days and approximately 0% at 30 days in saline at 37°C.

7. STORAGE
a. The usable period is 3 years from the date of manufacture. The expiration time is defined on each package. Do not use the product past the term.
b. Handle and store carefully to avoid damaging the package.
c. Store NEOVEIL in a clean place, and avoid high temperatures (over 30°C), direct rays of the sun and moisture.

8. QUANTITY
1 set/bag

Before using this product be sure to read the IFU.

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