INSTRUCTIONS FOR USE
FRANKENMAN SINGLE USE PURSE STRING FORCEPS

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT! This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION
The FRANKENMAN PSF35 and PSF55 are single use instruments and place a circumferential strand of 2-0 Synthetic fibre suture, to the structure or organ where a purse-string is desired.

INDICATIONS
The FRANKENMAN PSF35 and PSF55 are single use instruments have application in intestinal, colorectal, esophageal, gastric and cardiac surgery for temporary and permanent purse-string placement.

CONTRAINDICATIONS
1. Use of the single use instruments on friable tissue may be contraindicated.
2. Do not use the instruments on tissue with severe edema.
3. Do not use the instruments on tissue that is wider than the head of the device.
4. Do not use the instruments on unhealthy tissue.

WARNINGS AND PRECAUTIONS
1. Prior to placing the instrument, make sure fat and mesentery are cleaned from the tissue structure at the level where the purse-string is to be placed.
2. Center the tissue structure within the jaws of the instrument. Placing the tissue structure at either end of the jaws may result in a gap in the suture line, necessitating replacement of the suture line.
3. When closing the instrument jaws, the ring handles must be squeezed until they lock together. Failure to lock the handles may result in improperly formed suture lines.
4. After removing the instrument, inspect the lumen of the tissue structure for any possible gaps.
5. Use one suture throw to tighten the purse-string.
6. For atrial appendage application (FRANKENMAN PSF 35 only), inspect the tissue before and after tying the suture securely. If tissue tears are noted, excise the purse-string closure and replace it.
7. The instruments are provided STERILE and are intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RE-STERILISE.

SCHEMATIC VIEW

| 1) PURSE-STRING FORCEPS | 2) SUTURE NEEDLES AND SUTURE THREAD | 3) LOCKING JAWS | 4) LOCKING RING HANDLES | 5) SUTURE HOLES |

**Table 1: Basic Size**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Matched Suture</th>
<th>L</th>
<th>H</th>
<th>Needle Thread Length</th>
<th>Suture thread Diameter</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSF 35</td>
<td>PSF 45</td>
<td>268</td>
<td>35</td>
<td>45</td>
<td>1.0</td>
<td>2.0 Synthetic fibre</td>
</tr>
<tr>
<td>PSF 55</td>
<td>PSF 65</td>
<td>275</td>
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**Instructions**
The device is only used by surgeons equipped with related professional knowledge and adequate training and/or instruction by experienced operator.

1. Before use, check for the integrity of the inner package and make sure there is no damage to the device or packaging. Do not use the instrument if any damage or suspected damage is noted, and please contact the representatives of Frankenman directly for further information.
2. Open the package, place the tissue to be sutured between the opening of the jaw (the tissue must be free from traction and any other tensile force when being placed to the jaw), lock the ring to the end of the locker as far as possible, and the surgeon hears a “Crack” when it is locked.
3. Open the suture string with needles.
4. Use suitable needle holders to grip the needle at the first third of the needle tip.
5. Aim the needle point at either of the suture holes (top or bottom) and then enter the needle into the appropriate hole.
6. Release the needle holder and re-grasp the needle at the posterior 1/3 of the suture needle and continue to pass the needle through the hole. Then release the needle holder, grip the end of needle and send it through the device head until the suture point appears at the other side.
7. Grip the needle point with forces and pull it out. If the space within the body habitus is too small to pull it out, without damaging surrounding tissue and organs, grip the needle point with a needle holder and rotate the forces; at the same time, apply a force that is in line to the needle hole direction and rotate the needle around the needle holder jaws until the needle is completely extracted.
8. Use the needle holder to grip the first 1/3 of the other needle and repeat the process as outlined about making sure the needle is not positioned in the hole which is already occupied.
9. Prior to removal, the instrument edge may be used as a cutting guide to transect tissue with a scalpel or electrical knife. This will ensure cutting at a proper distance from the purse-string.
10. To release the instrument, open the jaws by releasing the handle lock, or keep the device closed working as a locking clamp.
11. Open and remove the instrument slowly and check the suture line placed by the device and that the tissue is correctly sutured.

**Precautions**
1. This product is sterilized by ethylene oxide (EO) before being supplied. If the isolation layer is damaged, the product should not be used. Do not use the product if package is damaged. If anything contained is broken, contact the representatives of our company.
2. This device is for single use only. DO NOT REUSE OR RE-STERILIZE. Reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, or infection. Also, reuse may create a risk of contamination and/or cause patient infection or cross-infection.
3. Check the product codes, specification, expiration date and the integrity of the package before using the product.
4. The device shall lock the tissue completely to make sure that the tissue is fully enclosed in the grooves of the Purse String Forceps so as to achieve full layer suture.
5. Two needles should never enter into the same hole otherwise it will lead to failure in creating a purse-string suture.
6. If any damage or suspected damage happens, such dropping or other inappropriate handlings, the device shall not be used clinically.

**Package and storage**
The shelf life is two years if the sterile isolation layer is not opened or broken. Use the product before expiry date marked on the package. The product should be kept in dry and shady room with good ventilation and without caustic gases; the comparative humidity should be lower than 80%.

**Product Package Markings**
- Ethylene Oxide Sterilization
- Single Use
- Caution: please refer to attached IFU.
- Do not re-sterilization.
- DO NOT USE the product if package is damaged
- Expiry Date
- Manufacture Date
- Lot No.

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