

PremiPatch® PTFE Pledgets Instructions for Use

Caution: Federal (USA) law restricts this device to sale or use by or on the order of a physician.

Description

PremiPatch® PTFE pledgets are pre-cut sections of nonabsorbable, undyed PTFE (polytetrafluoroethylene), available in various sizes and two modes of application (firm, soft). PremiPatch® PTFE pledgets are used as a suture buttress for non-absorbable sutures.

Indications

PremiPatch PTFE Pledgets are indicated for use in cardiovascular tissue. Pledgets are used to mechanically secure and support sutures in fragile tissue and organ parenchymas, when a non-absorbable suture is indicated. Pledgets are also used to aid in suture buttressing.

Mode of application

According to the surgical requirements, as a suture buttress when non-absorbable sutures are used. PremiPatch® PTFE pledgets can also be used in the blood stream.

Mode of action

PremiPatch® PTFE pledgets act exclusively mechanically as a suture buttress. Like many non-absorbable materials, PremiPatch® PTFE pledgets initially cause a mild foreign body reaction in the body and become encapsulated in connective tissue over time.

Contraindications

PremiPatch® PTFE pledgets may not be used on patients who are known to react sensitively or to be allergic to the materials components of the PremiPatch® PTFE pledgets.

Precautionary measures on application

PremiPatch® PTFE pledgets must not be resterilized. Opened or damaged packages must not be used. Do not reuse the product: Infection hazard for patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product. No special storage conditions are required.

When using PremiPatch® PTFE pledgets, extreme care must be taken in handling traumatizing surgical instruments (forceps, needleholders).

Side effects

Infections, erosions and fistula formations on the PremiPatch® PTFE pledgets can arise in rare cases when PremiPatch® PTFE pledgets are used. Detaching of suture materials, embolisation and perforation cannot be excluded under all circumstances when PremiPatch® PTFE pledgets are used. The occasional occurrence of incompatibility reactions to PTFE materials cannot be excluded. As with all other suture materials long contact with salt solutions, such as urine and bile, can lead to lithiasis.

Sterilization

PremiPatch® PTFE pledgets are sterilized with ETO gas.

CUSTOMER SERVICE

For further information regarding PremiPatch® PTFE pledgets Suture please contact Tissue Seal, LLC's Customer Service at 1-877-754-6458 or customerservice@tissue seal.com

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