IMPLANT INFORMATION BROCHURE FOR PATIENTS

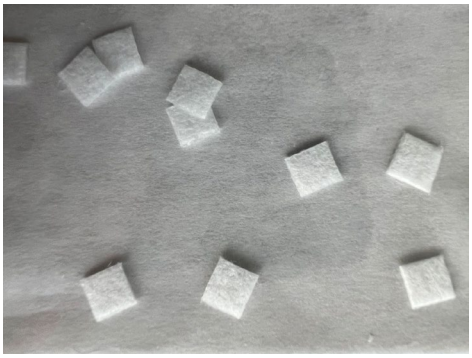
PTFE FELT – FELT STRIP – FELT PLEDGET

This patient information brochure has been prepared to help you better understand GEMED™ PTFE Felt, Felt Strip, and Felt Pledget. While this brochure answers some questions that patients frequently ask, it is not intended to replace the medical advice of your healthcare provider. If you have any questions while reading this brochure, please make a note of them and discuss them with your healthcare provider. It is important to remember that every patient is different. Only your healthcare provider can provide you with details about your specific treatment. Please read this brochure carefully and keep it for future reference.

What is this implant, and what is it made of?

The implant placed in you is a medical device called PTFE (Polytetrafluoroethylene) Felt, Strip, or Pledget. This implant is used by surgeons—particularly in cardiac and vascular surgery—to support the suture line. The implant's function is to provide mechanical support to the suture line created during surgery, help prevent tissue tearing or the suture from cutting into the tissue, and support the safety of the surgical repair. The product contains no drugs and has no pharmacological, immunological, or metabolic effects; it exerts its effect solely by providing physical (mechanical) support. GEMED™ PTFE Felt, Felt Strip, and Felt Pledget are manufactured from %100 polytetrafluoroethylene (PTFE).. This material is inert and is not known to cause any allergic reactions.

Product Image

PTFE FELT	PTFE FELT PLEDGET	PTFE FELT STRIP
		

Why was the implant used?

Your surgeon used this implant during cardiovascular surgery to reinforce the suture line, help prevent tissue tearing, and support the safety of the surgical repair. If you would like more information about the location or use of your device, please contact your healthcare provider.

How does the implant work in my body?

The implant provides mechanical support to the suture line in the area where it is placed. It does not release any medication, does not produce an electrical effect in the body, and is not an active device.

When should I not use my implant (Contraindications for Use)?

There is no known reason that would prevent you from using these devices. Your healthcare provider will determine whether these devices are appropriate for you.

Why should you keep your implant card?

The implant card provided to you has been prepared to identify the implant used, to enable quick verification of product information when necessary, and to ensure that healthcare professionals have access to the correct information during any future medical procedures. Please keep your implant card in a safe place and bring it with you when you visit a healthcare facility.

If you have another surgery or treatment in the future

Show your doctor or other healthcare professionals that you have this implant, and present your implant card and this brochure. This information is important for any future medical procedures.

Magnetic Resonance Imaging (MRI)

This product is PTFE-based and contains no metallic components. Therefore, it contains no metallic structures that could interact with a magnetic field. Please inform medical staff that you have an implant before undergoing an MRI or other imaging procedures.

Medical follow-up regarding your implant

Please continue your postoperative follow-up visits as recommended by your doctor. If you have any questions about your implant or if you need an evaluation of your health, please consult your doctor.

Important Points You Should Know

This implant is to be used only by a surgeon. The implant is for single use only. It cannot be reused or re-sterilized.

Who is it not suitable for?

This implant should not be used in individuals with a known allergy to PTFE. This assessment is performed by your surgeon prior to surgery.

Life After a Medical Procedure

What should you expect during the recovery process?

The exact duration of the recovery period varies depending on factors such as your age and overall health. These implants do not affect your recovery period and do not require any special monitoring or follow-up beyond what is necessary for your procedure. Please contact your healthcare provider for specific recovery expectations regarding your procedure.

What is the functional lifespan of the GEMED™ PTFE Felt, Felt Strip, and Felt Pledget products in your body?

This product's functional lifespan for healing and supporting your tissues after surgery is 2 to 4 weeks (approximately 1 month). During this time, your body's natural healing process in that area is completed, your tissues fully integrate, and the repaired area becomes capable of bearing its own weight without external support.

How long does the product remain in your body, and does it degrade?

The special material called PTFE used in the product's manufacture is completely durable inside the body. It does not react with bodily fluids; it does not melt, decompose, or degrade in any way. Clinical data show that this product remains completely safe and biocompatible in your body for life, without suffering any wear or tear.

Living with My Implant

Please consult your healthcare provider about any restrictions, limitations, or daily activities you should avoid following your procedure.

Can my implant be removed?

GEMED™ PTFE Felt, Felt Strip, and Felt Pledget are designed as permanent implants. They are intended to remain in the body after being placed during surgery and, under normal conditions, are designed to remain in your body for life. Even after the product has fulfilled its functional role during the surgical healing process, it remains safely in place. Therefore, routine removal is not planned, and its removal may be considered only during a subsequent surgical procedure if medically necessary.

More Information About the Implant

If you have any questions about your implant, please consult your doctor.

If you would like to contact the manufacturer

GEMED Sağlık Ürünleri Sanayi ve Ticaret Ltd. Şti.

Phone: +90 (216) 452 35 25

Email: info@gemed.com.tr

Web: www.gemed.com.tr

Important Reminder

✓ Do not lose your implant card.

✓ Show your implant card when you visit a healthcare facility.

✓ Keep this brochure for future reference.

This brochure has been prepared to inform patients who have received an implant, in accordance with Article 18 of the European Union Medical Device Regulation (MDR) 2017/745. This brochure is not a substitute for your doctor's recommendations and does not constitute medical advice. Decisions regarding your treatment and follow-up care will be made by your doctor.