

EsophyX[®] Z+

with SerosaFuse[®] Implantable Fasteners

PATIENT INFORMATION LEAFLET

PLEASE PROVIDE TO THE PATIENT

The TIF 2.0 procedure uses the EsophyX Z+ device with the SerosaFuse Fasteners to help stop stomach acid from entering the esophagus. The procedure also helps stop the issues caused by acid reflux that can be harmful over time. Doctors do this by inserting a thin tube with a camera on it through the mouth to visualize the stomach and esophagus to perform procedure.

WHAT IS IT USED FOR?

The EsophyX Z+ System is for use in patients who experience long term acid reflux.

WHAT IS THE PURPOSE?

The device is placed through the mouth to form a new valve between the esophagus and stomach using small connectors to hold it in place long term.

POTENTIAL COMPLICATIONS

- Bleeding or hematoma
- Popping, crackling, grating, or crunching sensation
- Swelling
- Fastener site irritation and/or bleeding
- Injury to the stomach and/or esophagus
- Feeling like there is a lump in your throat
- Raspy or strained voice
- Infection, Abscess
- Inflammation
- Chest injury
- Nausea and/or vomiting
- Nerve injury
- Pain
- Fluid buildup in the space between the lungs and chest wall
- Air or gas in the abdominal cavity
- Air in the space between the lung and the chest wall
- Difficulty swallowing
- Damage to blood vessels

In the European Union, if any serious events happen because of the device, tell the company who made the device right away.

MRI INFORMATION

- The EsophyX Z+ Fastener Delivery Device is not safe to use if you have an MRI.
- The SerosaFuse Implantable Fasteners are safe if you have an MRI.

HOW LONG DOES THE DEVICE LAST?

- The EsophyX Z+ System includes the delivery device and the fasteners. The EsophyX Z+ device is used once and for an hour or less. The SerosaFuse fasteners are used once and stay in your body long term. It takes about 12 weeks for your body to make a seal where the new flap is. The goal of the procedure is for this seal to become your new valve.

THIS PART OF THE INFORMATION TELLS YOU ABOUT THE MATERIALS THE PATIENTS MIGHT COME INTO CONTACT WITH DURING THE PROCEDURE, AND HOW MUCH AND FOR HOW LONG THEY MIGHT BE IN CONTACT.

Material	Duration of Exposure	WORST CASE LEVEL OF PATIENT EXPOSURE (MILLIGRAMS)
Polypropylene	≥30 days	399.4
Phthalo Blue Colorant	≥30 days	0.8

ALWAYS FOLLOW THE ADVICE OF YOUR DOCTOR AND TELL THEM RIGHT AWAY IF YOU HAVE PAIN OR SIDE EFFECTS.

For more procedure and patient information please visit www.merit.com/product/esophyx-z-device/ and gerdhelp.com.



Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

The information presented here should not be construed as specific medical advice, diagnosis, treatment or recommendation. This material is not a substitute for a consultation or physical examination by a physician. Always seek the advice of a qualified physician regarding any medical questions or conditions. Merit Medical assumes no responsibility for a patient's success as results may vary.

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