

## WARNINGS AND PRECAUTIONS FOR THE USE OF JACE MEDICAL TITAN™ DOUBLE WIRE

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

### Description

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The Titan™ Double Wire is sterile, non-absorbable, stainless steel suture used in sternal closure, abdominal wound closure, and hernia repair. The monofilament suture is attached to a blunt or sharp stainless steel needle to facilitate placement through tissue or around bones.

The Titan™ Double Wire Twister is a non-sternal instrument designed for tightening and securing Titan™ Double Wire.

### Implant Materials

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Titan™ Double Wire is manufactured from 316LVM stainless steel.

### Intended Use

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Titan™ Double Wire is indicated for use in sternal closure, abdominal wound closure, and hernia repair.

### Contraindications

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Material sensitivity- if metal sensitivity is suspected, tests should be completed prior to implantation.

### Warnings

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- Users should be familiar with surgical procedures and techniques involving stainless steel sutures and suture needles prior to use.
- The Titan™ Double Wire is a single use device – do not reuse the Titan™ Double Wire under any circumstances. While the Titan™ Double Wire may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with Titan™ Double Wire that have been even momentarily placed in a different patient.
- Do not use if sterile packaging is opened or if the expiration date has passed. Do not use if Titan™ Double Wire and/or Titan™ Double Wire's packaging is damaged.
- The Titan™ Double Wire Twister is supplied non-sterile. Follow the cleaning and sterilization instructions provided in this document prior to use.

### Precautions

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- Instruments are available for the implant system to aid in the accurate implantation of the devices. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. It is recommended that all instruments be regularly inspected for wear and disfigurement.
- Surgical instruments must be used only for the device systems for which they are designed. Use of other manufacturer instruments can involve incalculable risks for the implant and instrument, thereby potentially endangering the patient, user, or third party.

## MRI Safety Information

	
MRI Safety Information	
The JACE Medical Titan™ Stainless Steel Sutures are made from non-magnetic stainless Steel 316LVM alloy. Non-clinical testing and analysis has demonstrated that the Titan stainless steel sutures are MR Conditional. A patient with the sutures can be safely scanned under the following conditions:	
Name/Identification of Device	Titan™ Double Wire
Nominal Value(s) of Static Magnetic Field [T]	Static magnetic field of 3.0 tesla or less
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3,000 gauss/cm)
Maximum Whole Body SAR [W/kg]	<2 W/kg
Head SAR [W/kg]	3.2 W/kg or less
MR Image Artifact	The presence of this implant may produce an image artifact.
Normal mode operation of the MR system for SAR	
Normal mode operation of the MR system for gradients	
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

The health state of the patient or the presence of other implants may require reduction of the MR limits.

## Possible Adverse Effects

- Wound dehiscence.
- Fracture or loosening of the implant.
- Metal sensitivity or allergic reaction to a foreign body.
- Pain, discomfort, abnormal sensation or palpability due to the presence of the device.
- Increased fibrous tissue response around the fracture site and/or the implant.
- Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

Apart from these adverse effects, there are always possible complications of any surgical procedure such as, but not limited to infection, nerve damage, and pain which may not be related to the implant.

## Cleaning and Sterilization

The Titan™ Double Wire is provided sterile. These implants must not be reused.

The Titan™ Double Wire Twister is provided non-sterile and must be sterilized prior to surgical use. Steam autoclaving is performed after removal of the protective packaging.

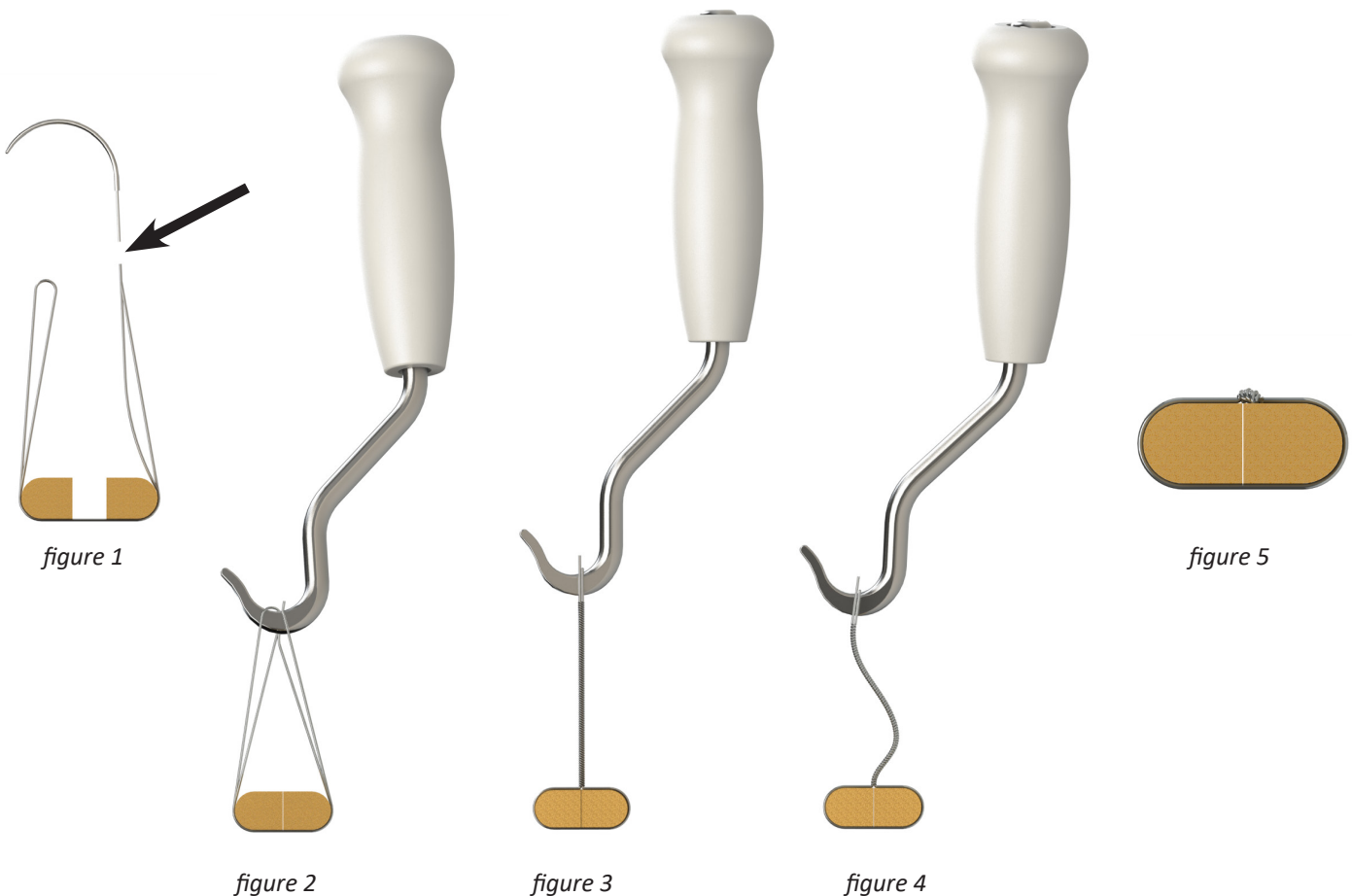
After use in the operative site, all instruments must be carefully cleaned and inspected prior to sterilization. Cleaning should be performed by trained medical personnel.

The **JACE Medical Product Care, Cleaning and Sterilization** instructions are available on the JACE Medical website ([www.JaceMed.com](http://www.JaceMed.com)) or by calling customer service at (574) 306-0355.

## Instructions For Use














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1. Using the curved needle, pass the Titan™ Double Wire around the sternal halves so equal lengths of wire are exposed above the sternal halves.
2. Remove the needle with a wire cutter. Only cut the single wire portion between the needle and double wire joint (figure 1).
3. Insert the wire twister hook through each loop of the double wire (figure 2).
4. Apply upward tension while gently rocking the wire twister mediolaterally to make the loops even on both sides of the sternum.
5. Continue to apply upward tension while rotating the wire twister to draw the sternal halves together (figure 3).  
Twisting is best achieved by keeping the elbow still while twisting with the wrist. The appropriate amount of tension is achieved once double cabling is achieved (figure 4).
6. Cut the wires with a wire cutter leaving approximately 7 to 10mm.
7. Using a needle holder, turn down the cut portion of the wire in the direction of the twist. The twist can be flattened onto the anterior sternum using a needle holder (figure 5).



## Symbols

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	Catalogue number
	Batch code
	Use-by-date
	Sterilized using ethylene oxide
	Manufacturer
	Do not use if package is damaged
	Do not re-use
	Do not re-sterilize
	MR conditional
	Consult instructions for use
	Federal Law (USA) restricts this device to sale by or on the order of a physician, dentist or properly licensed practitioner
	Unique device identifier
	Single sterile barrier system with protective packaging inside

**Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities which they are involved in the handling and use of this product.**

 **MANUFACTURER:**

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