Grandus® VersaFix Instructions for Use

Grandus® VersaFix Meniscus Repair Device

1.1 susideda iš dviejų "T" formos inkarų su #2 storio siūlu polietileno pluošto pagrindu (UHMWPE - ypač didelės mokelulinės masės polietilenas) ir vienkartinio pravedėjo.

DESCRIPTION

✓ The Grandus® VersaFix Meniscus Repair Device is comprised of an implant-suture construct incorporating #2-0 nonabsorbable UHMWPE suture having a pre-tied one-way sliding knot between two non-absorbable PEEK implants. The needle delivery inserter is offered in three device configurations of straight, curved and reverse curved, whose needle can be bent by the end user.

1.4.Turi iš anksto paruoštą slystantį mazgą.

1.2."T" formos inkarų cheminė sudėtis - polimeras "peek " (polietereterketonas).

1.6.Įvedimo adata tiesi, lenkta arba reversinė (yra pasirinkimas visų rūšių).

INTENDED USE

The Grandus® VersaFix Meniscus Repair Device is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as meniscal repairs and allograft transplant procedures.

CONTRAINDICATIONS

- Pathological conditions that will prevent the suture-safe fixation.
- Unsuitable meniscal lacerations for repair due to the extent of damage to the meniscus body.
- Oversensitivity known to any of the implant materials.

WARNINGS

• Contents sterile unless package is opened or damaged.
• The device is intended for single use only. DO NOT RESTERILIZE. This may result in impaired performance and could cause patient injury.
• Discard open unused product.
• Do not use past expiration date.
• Read the instructions for use completely prior to using the device.
• Suture anchor delivery mechanism is required for deployment of the suture anchors for optimal surgical result.
• Over penetration of the meniscus/capsule by the needle and/or suture anchors may result in damage to neurovascular structures.
• Excessive bending of the delivery needle may render the device unusable. Do not kink the delivery needle.
• Do not push deployment trigger/slider until the needle tip is positioned through the meniscus as this could lead to premature deployment of the first anchor.

PRECAUTIONS

- Review Usage Instructions before using.
- ✓The contents are STERILE unless sterile packaging is damaged or opened. Do not use if any damage is seen on the sterile package.

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- Care should be paid to asepsis and avoidance of anatomic hazards.

- After use, the practitioner can pose a potential biohazard/incendiary tool hazard and must be processed in accordance with the accepted medical practices and the local and national requirements.
- Be careful when you apply tension to the suture. Excessive strain can cause tissue damage and/or break the suture.

ADVERSE EFFECTS

Adverse reactions caused by implantation of foreign materials include mild inflammatory reactions and foreign body reactions.

INTENDED USER

Orthopedic and/or sporting surgical specialist in an operating room environment.

USAGE INSTRUCTIONS

1. Press and slide depth limiter button on device to distal stop until needle tip is fully covered in plastic sheath. Thus, a slotted cannula use won't be necessary
2. Introduce the device into the joint.
3. Adjust the depth limiter to the preferred setting by pressing the depth limiter button. The laser marks on the tip of the needle can also be used as a reference.
4. For a horizontal or vertical repair, place the needle tip in the desired location for first anchor and puncture the meniscus across the repair site to the preset depth.
   For allograft transplantation using a horizontal or vertical technique place first anchor in the desired location and puncture the needle into the outer meniscal fragment to the preset depth.
5. Leave the needle in position and push the deployment slider forward until a click is heard to deploy the first anchor.
6. Slowly retract the needle out of the meniscus, keeping the needle within arthroscopic view.
   For allograft transplantation insert the needle approximately 4–5mm from first anchor and puncture the needle into the outer meniscal fragment to the preset depth.
7. Push the slider all the way forward until a click is heard to deploy the second anchor.
8. Gently pull on the free end of the suture to achieve adequate tension to reduce the tear. The knot will slide towards the first deployed anchor. Too much tension may result in tissue damage. A knot pusher should be used to fully tension the suture and countersink the knot.

STORAGE

Store at room temperature.

STERILIZATION

This product is sterilized by exposure to ethylene oxide gas.

SHELF LIFE

Shelf life is set to 24 months and expiration dates are on the label.

THE MEANINGS OF THE SYMBOLS USED IN THE LABEL

	MANUFACTURER
	DO NOT RE-USE
	STERILIZED BY EXPOSURE TO ETHYLENE OXIDE GAS
	USE-BY DATE
	DO NOT USE IF PACKAGE IS DAMAGED
	BATCH CODE
	CATALOGUE NUMBER
	DO NOT RESTERILIZE
	CAUTION
	CONSULT INSTRUCTIONS FOR USE
	DATE OF MANUFACTURE
	CE MARK

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