

GENERAL DESCRIPTION OF INTENDED USE

The Portal SportsMed MeniPass is intended for use as a suture passing device to facilitate percutaneous or endoscopic soft tissue procedures.

All Portal SportsMed instruments labelled as 'sterile' or 'single-use' are not intended to be reused.

All Portal SportsMed instruments labelled as 'non-sterile' must be sterilised by the user per the instructions noted under the resterilisation section below.

Portal SportsMed MeniPass

CLINICAL BENEFITS

The clinical benefits for all Portal SportsMed instrumentation depends on the specific indications and applicable intended use of the related implants.

DEFINITION OF SYMBOLS

	Manufacturer		Sterilised using irradiation		Consult IFU or electronic IFU
	Authorised representative in the European Community		Catalogue number		Caution
	Date of manufacture		Do not use if package is damaged, consult IFU		Medical device
	Use-by date		Do not re-use		Unique device identifier
	Batch code		Do not resterilise		Double <i>sterile</i> barrier system

INDICATIONS AND CONTRAINDICATIONS

Indications

The MeniPass Soft Tissue Repair System is intended for use as a suture passing device to facilitate the repair of Meniscus, Tendon, Ligament structures in percutaneous and arthroscopic procedures.

Contraindications

- Surgical procedures other than those listed in the indications.
- Physical conditions that eliminate or tend to eliminate adequate support or retard healing.
- Pathological changes in the soft tissue to which the MeniPass needle is being passed that would prevent secure fixation of the suture are contraindicated.
- Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively. Certain patient conditions and/or predispositions should be avoided.
- Previous or active infections.
- Conditions that tend to affect the patient's ability or willingness to restrict activities during the healing period.

Warnings

- Do not use if package is damaged.
- Do not use if the product sterilization barrier or its packaging is compromised.
- Care should be taken removing the needle device from the package to avoid sharps injury to the user or the patient.
- Prior to use, inspect the product package for structural integrity. If the seal of the outer sterile barrier is broken, or if the sterile barriers are otherwise damaged, the product should be considered non-sterile and not be used.
- Contents are sterile unless package is opened or damaged.
- Do not resterilise instruments that are provided sterile. These are for single use only.
- Discard any open, unused product.
- Do not use after the expiration date.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read these instructions and surgical technique completely prior to use.
- Care should be taken when using this device to avoid any neurovascular structures in close approximation to the intended repaired area.
- Delivery instrumentation is required for proper placement of the needle for optimal surgical result.
- Do not bend delivery needle or cannulated tube.
- If the needle is bent or damaged with normal use discard immediately and open a new device.

Precautions

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Hazards associated with reuse of this device include, but are not limited to, patient infection and/or device malfunction.
- Prior to use, inspect the device to ensure it is not damaged.
- Do not use a damaged device.
- Careful attention should be paid to asepsis and avoidance of anatomical hazards.

- After use, this device may be a potential biohazard/sharps hazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

POSSIBLE COMPLICATIONS

1. Loss of anatomic position with compromised healing, non-union or malunion with rotation or angulation.
2. Infections, both deep and superficial.
3. Fat embolism syndrome.
4. Allergies and other reactions to device materials.
5. Irritation of soft tissues, including impingement syndrome.
6. Damage to surrounding tissues or neurovascular structures.

In the event of a serious incident involving a Portal SportsMed product, users must contact the manufacturer and the Competent Authority of the relevant Member State.

WARNINGS AND PRECAUTIONS**Preoperative**

1. Patient conditions and/or predispositions, such as those addressed in Contraindications above, should be avoided.
2. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out pre-operatively.
3. Before the initial use of these implants, we recommend that the surgeon acquaint themselves with them and attend a technique seminar. Surgical Technique brochures are available upon request at no charge and should be reviewed by the surgeon prior to initial surgery.

Instructions for use

1. Contact Portal SportsMed for Surgical Technique

Postoperative

1. Postoperative directions and warnings to patients by physicians, and appropriate nursing care, are extremely important, particularly those admonitions that concern early weight-bearing or active use of the extremities. These activities substantially increase the stress on implants that can lead to complications.
2. Reusable devices should be continually inspected and maintained between each use. In the event of breakage or significant degradation, return device to manufacturer or dispose in accordance with local laws.

PACKAGING AND LABELLING

Instruments labelled 'Sterile' have been sterilised by a minimum of 25 kiloGrays of gamma irradiation. Inspect packaging for punctures or other damage prior to surgery. All devices provided sterile should be accepted only if the factory packaging and labelling arrive intact. If the sterile barrier has been broken, refer to the Resterilisation section below for additional instructions.

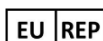
RESTERILISATION

Products labelled "do not resterilise" or "do not reuse" or "Single Use" must not be re-sterilised or reused, as these may affect the integrity of the device, which can lead to device failure, patient injury, illness or death. Reuse or reprocessing of single-use devices may create a risk of contamination, which could result in injury or death.

Procedures kits intended to be reused may be resterilised, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all of the original packaging. The following process parameters are recommended for these devices: Ultra sonic solution:Sonic 1, Enzyme cleaners:Medizyne – Neutral pH Enzyme Cleaner (manual clean), Disinfectant:Aidal-Plus (manual disinfect), Pre-vacuum cycle, 4 minutes at 134 C, followed by 20 minutes of drying time.



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