The instrument must not be used for any procedure use in patients undergoing repair of lacerated flexor the repair of a lacerated digital flexor tendon(s) in the the retrieval of the proximal tendon stump(s) during

The FlexPasser Tendon Retrieval Kit is intended for use

The device is manufactured from Stainless Steel, Low-Density Polyethylene (LDPE) and Fluorinated

An integrated probe and needle carrier

Low-Density Polyethylene (LDPE) and Fluorinated

The device should not be used in patients with a known sensitivity to Stainless Steel, LDPE or FEP. If the patient is suspected of having any foreign body sensitivity, appropriate tests should be made prior to use.

Packaging

Avoid damage when handling the FlexPasser Tendon Retrieval Kit. Avoid crushing or crimping when using surgical instruments such as forceps or needle holders.

Use only needles between 15 and 26 mm in length, needles outside this range have not been approved for use with this product. Some needle sizes may be too large for the patient.

We recommend a needle with a 3/8 circumference, although a small needle with 4/8 circumference may still pass.

Use sterile technique throughout the procedure.

• The instruments are supplied sterilised by gamma irradiation in a double pouch.

• Packages should be intact upon receipt and once opened, should be used immediately. The instruments, packaging and label should not be viewed for use with this product.

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• Use sterile technique throughout the procedure.

The FlexPasser Tendon Retrieval Kit consists of two components:

- The integrated probe and needle carrier consists of a flexible elongated device with a smooth, semi-rigid, rounded end. At the other end there is a more flexible section to allow for use as a needle and needle holder to be threaded through the sheath. There is a wire loop at this end to which is attached the plastic sleeve. This sleeve allows the probe and needle carrier, and then the tendon to be passed through the tendon sheath from proximal to distal in a single stage.

Material Specification

The device is manufactured from Stainless Steel, Low-Density Polyethylene (LDPE) and Fluorinated Ethylene Propylene (FEP)

Indications for use

The FlexPasser Tendon Retrieval Kit is intended for use in the retrieval of the proximal tendon stump(s) during the repair of a lacerated digital flexor tendon(s) in the hand.

Indications for use

The FlexPasser Tendon Retrieval Kit is intended for use in patients undergoing repair of lacerated flexor tendons in the hand.

Contraindications

• The device must not be used for any procedure other than the intended use.

Potential Adverse Effects

Below is a list of possible adverse effects [eg. complications] associated with the use of the device: 1. Infections associated with any surgical procedure: 2. Infections associated with the FlexPasser device.

Potential Adverse Effects

• The instrument must not be used for any procedure

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The FlexPasser Tendon Retrieval Kit is intended for use in the retrieval of the proximal tendon stump(s) during the repair of a lacerated digital flexor tendon(s) in the hand.

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