

Capio™ SLIM Suture Capturing Device

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

The Capio SLIM Suture Capturing Device is intended for use in general suturing applications during open surgery to assist in the placement of suture material in tissues at the operative site. The Capio SLIM Suture Capturing Device is to be used with sensory and/or direct visual control. The Capio SLIM Suture Capturing Device is also intended for use as an aid in the insertion, placement, fixation or anchoring of surgical mesh during urogynecologic procedures.

Contraindications

The use of the Capio SLIM Suture Capturing Device is contraindicated as follows:

- For placing sutures into or through bone.

Warnings

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during placement and may require surgical repair.
- Once the suturing action has begun, do not turn, rotate or torque the Capio SLIM Device. To do so, may result in injury.
- For single use only. Do not reuse, reprocess or resterilize.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Adverse Events

Potential complications associated with the Capio SLIM Device include, but are not limited to:

- bleeding
- dyspareunia
- infection
- inflammatory reaction
- injury to internal organs/tissue including perforation and occlusion
- injury to vessels and nerves
- pain

Precautions

- Use only size 0 Capio Sutures with the Capio SLIM Suture Capturing Device
- The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- The Capio SLIM Suture Capturing Device is not intended to be used to manipulate tissue, organ or bone.
- Do not bend or alter the device as this may result in mechanical damage to the device.

Cautions

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician

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