

Colpassist™ Vaginal Positioning Device

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

The Vaginal Positioning Device is intended for use in general gynecological surgery to assist in the positioning and manipulation of the vagina during the procedure. It may also be used as support/back-stop for potential vaginal attachment during sacrocolposuspension/sacrocolpopexy. The device can be used with tactile feedback and/or direct visualization.

Contraindications

- None known.

Warnings

- Do not use excessive force during the insertion and movement of the device within the vagina.
- 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

- Tissue Damage
- Perforation

Cautions

- Aseptic technique must be adhered to throughout procedure.

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

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