

UroCure

ArcTV™

TRANSVAGINAL SLING SYSTEM

Taken from: DMR-1001-001 Rev E | May 2020

INSTRUCTIONS FOR USE

For the most up-to-date information, see section 2.3 in the current IFU found at www.urocure.com/IFU.

2.3 ADVERSE EVENTS

The following adverse events have been reported due to polypropylene mid-urethral sling placement, but are not limited to:

- Complete failure of the procedure, including worsening of incontinence
- Partial failure resulting in mild to moderate incontinence
- Denovo, persistent or worsening overactive bladder, with or without incontinence
- Perforation or laceration of vessels, nerves, bladder, urethra or bowel
- Pain (local or regional discomfort that may be transient or persistent)
- Pain, ongoing pain (pelvic, bladder, vaginal, groin, thigh, suprapubic, dyspareunia)
- Loss of sexual function
- Severe chronic pain
- Bleeding (routine surgical, hematoma, hemorrhage)
- Bruising, bleeding (vaginal, hematoma formation)
- Tissue responses to the sling implant include:
 - erosion / exposure / extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue and/or other organs
 - scarring / scar contracture / tissue contraction of vagina or surrounding tissues
 - device migration
 - fistula formation and inflammation
- Temporary or permanent lower urinary tract obstruction and retention
- Like all foreign bodies, the polypropylene sling may potentiate an existing infection
- A foreign body inflammatory response or infection, which may result in systemic symptoms, pain, damage to adjacent structures, scarring and adhesions.
- Infection (superficial, abscess, systemic sepsis)
- Local irritation at the wound site and/or a foreign body response may occur.
- Edema and erythema at the wound site
- Dehiscence of vaginal incision
- Vaginal discharge
- Allergic reaction to the polypropylene sling

The occurrence of adverse events from this procedure may require additional surgical interventions, including removal of the entire sling. Removal of sling and/or attempts to correct the sling or procedure related adverse events may involve multiple surgeries. Complete removal of sling may not be possible and additional surgeries may not always fully correct the adverse events and/or associated symptoms. These additional surgeries are associated with their own unique adverse events.