



Desara[®] One
SINGLE INCISION SLING

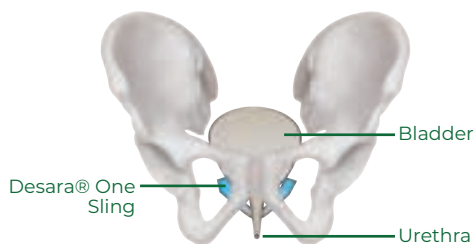
 **CALDERA**
MEDICAL

Desara® One

The Single Incision Sling System



Desara® One is the choice for single incision slings, allowing for a minimally invasive, outpatient procedure. Desara® One, placed under the urethra, helps to rebuild support to prevent urine leakage due to stress urinary incontinence.



THE PROCEDURE

- Minimally invasive
- Outpatient surgery
- Typically 30 minute procedure or less
- No external skin incisions



RECOVERY PERIOD

4-6 WEEKS

- Normal activities such as getting dressed and low impact exercise are ok
- Avoid high-impact exercise and activities
- Do not have intercourse or place anything in the vagina



RESULTS

- Typically experience immediate results
- Return to daily activities within several days
- Effective procedure¹⁻³ with patient satisfaction³

+ For a detailed list of risk associated with this device, contact Caldera Medical.
10-470 Rev A

Risks

Surgery carries some risks. If you experience vaginal discharge, redness or pain at the incision sites, pain that is severe or lasts longer than expected, slow urination flow, or the inability to urinate, it may be a sign of complications. Contact your physician immediately. You should discuss with your physician your recovery process, expected results, and the potential complications associated with having a Desara® procedure.

Warnings & Precautions

Potential adverse reactions are those associated with surgery using implantable mesh materials of this type, including mesh hematoma, urinary incontinence, urinary retention/obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, inflammation, fistula formation, and mesh exposure, erosion, or extrusion*. Punctures or laceration of vessels, nerves, bladder, urethra or bowel may occur during mesh placement and may require surgical repair.

*Extrusion of the mesh into the vagina is one of the most common adverse events⁴. You may be able to be treated in your doctor's office. In some cases, treatment may occur in the operating room. Be sure to discuss all treatment options with your physician. If mesh is exposed on the surface of the vagina, sexual intercourse may be painful for both you and your partner.

Sling procedures should not be performed on:

- Patients who are pregnant or planning future pregnancies.
- Patients with a urinary tract infection or with an infection in the operative field.
- Infants, children, or any patient with future growth potential.

1. Ogah, J., J.D. Cody, and L. Rogerson, Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev*, 2009(4): p. CD006375.
2. Novara, G., et al. Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings and midurethral tapes in the surgical treatment of female stress urinary incontinence. *Eur Urol*, 2010. 58(2): p. 218-38.
3. Richter, H.E., et al. Retropubic versus transobturator midurethral slings for stress incontinence. *N Engl J Med*, 2010. 362(22): p. 2066-76.
4. FDA's Urogynecologic Surgical Mesh Implants website: <https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-mesh-sui>