



PRODUCT REFERENCE

ORDER NUMBER	DESCRIPTION	QUANTITY
CAL-DS2113	Desara [®] One Single Incision Sling System for Female Stress Urinary Incontinence	Box of 3

This surgical guide is intended as an overview of the procedure only and does not replace proper surgical technique. Before utilizing this product, the surgeon must be familiar with the surgical procedures and techniques involving bladder slings and suspensions using non-absorbable meshes. Training on the use of Desara[®] One is recommended and available. Contact your company sales representative to arrange for this training. Federal Law restricts the use of this device to physicians trained in performing suburethral sling procedures for treating stress urinary incontinence. Please refer to the Instructions for Use included with this device.



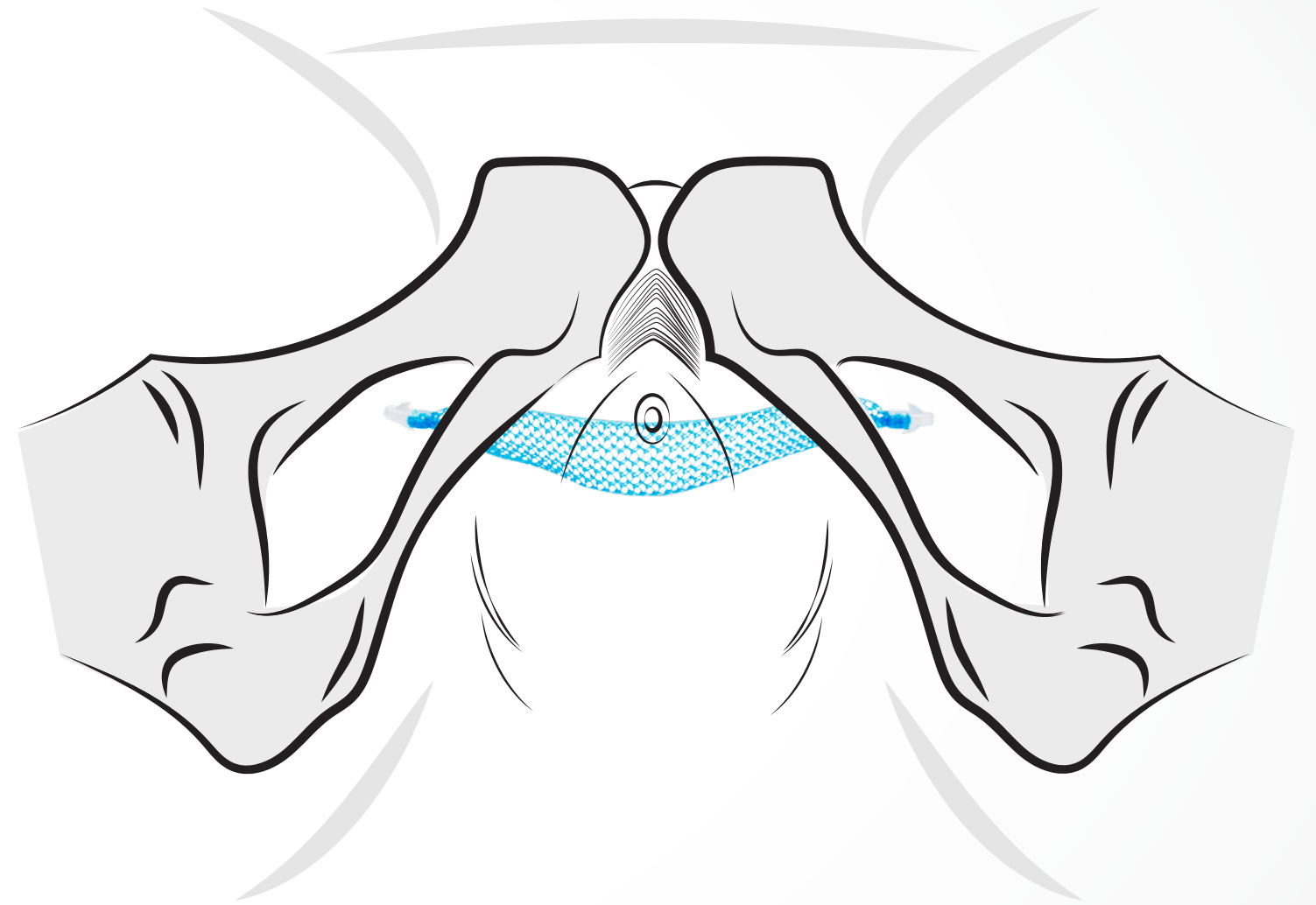
For product evaluation, call your Caldera Sales Representative today at (866) 4-CALDERA



For more information visit: www.calderamedical.com

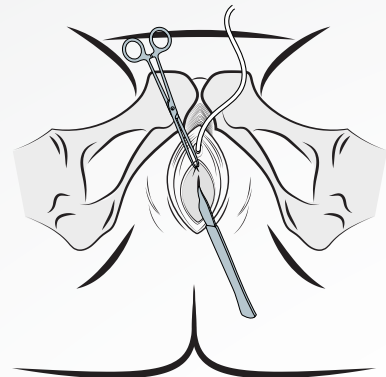


Contact us at:
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PROCEDURE GUIDE

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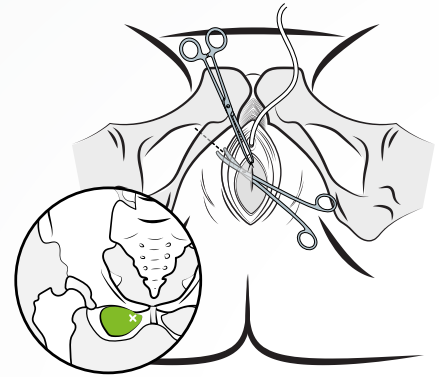


STEP 1 - INCISION

- Perform a full thickness vertical incision at the level of the mid urethra wide enough to accommodate at least the width of the sling.

It is recommended to hold the vaginal epithelium taut during placement. Local anesthetic may be used to anesthetize and hydrodissect the surgical site.

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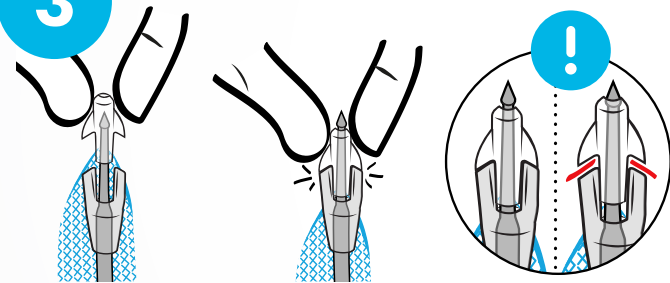


STEP 2 - DISSECTION

- Perform a full thickness paraurethral dissection towards the ischiopubic ramus from midline bilaterally.
- Dissect laterally toward the obturator internus muscle until under the ipsilateral ischiopubic ramus creating a peri-urethral space for the sling.

Dissecting to the obturator internus muscle improves ease and proper anchor placement.

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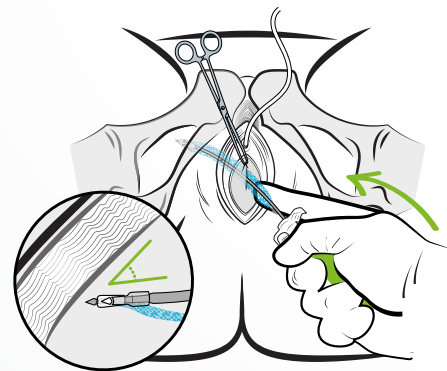


STEP 3 - TIP ATTACHMENT

- Load Desara® One onto the introducer, ensuring that the mesh wraps along the outside of the introducer.
- Press the implant's anchor onto the introducer tip until it is securely affixed to the introducer. A "click" should be felt.

Make sure anchor is totally engaged with no significant gap between the anchor and the disengagement wings.

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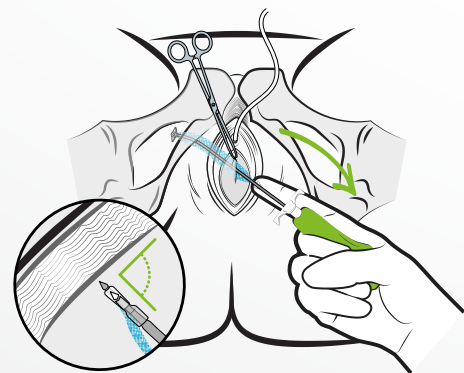


STEP 4 - TIP APPROACH

- Advance the introducer through the previous dissection aiming for the medial edge of the obturator foramen.

An index finger may help guide the introducer during placement.

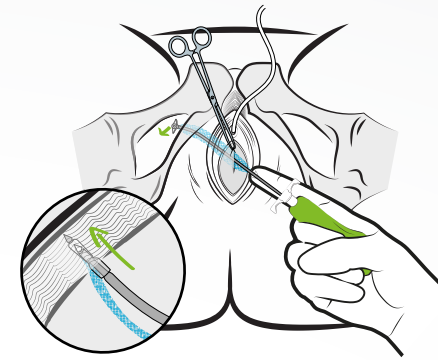
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STEP 5 - TIP ORIENTATION

- Once beyond the ischiopubic ramus, orientate the tip so the anchor is advancing into the obturator internus muscle at a perpendicular angle.

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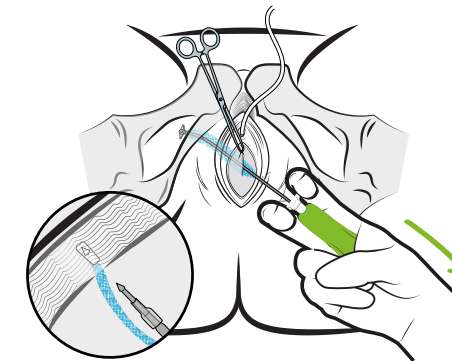


STEP 6 - TIP INSERTION

- Insert the tip perpendicularly into the obturator internus muscle until the introducer's mid-line mark is aligned with the midline of the urethra.

Avoid pulling back on the release buttons during anchor insertion.

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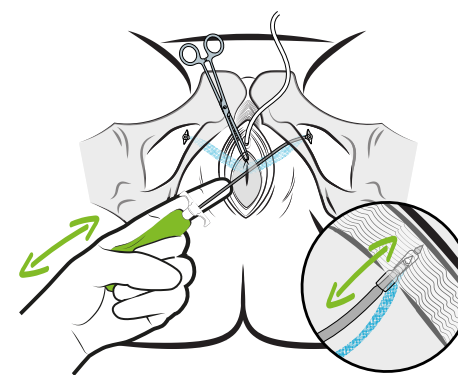


STEP 7 - ANCHOR RELEASE

- Once satisfied with the location of the tip, deploy the first anchor by pressing down on the introducer release buttons.

Keep the release buttons depressed while removing the introducer.

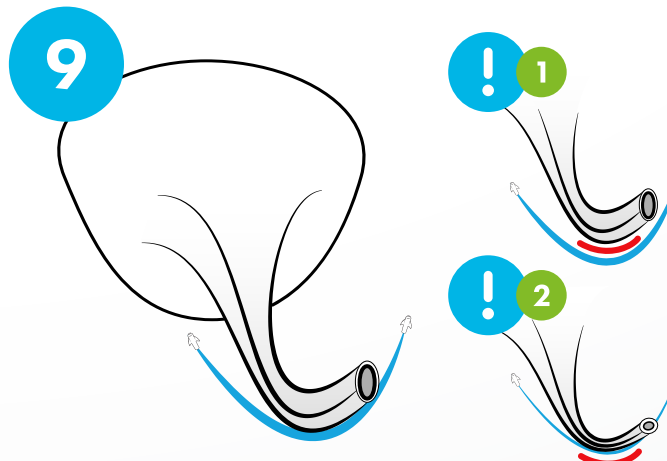
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STEP 8 - SECOND TIP PLACEMENT

- Load the contralateral anchor ensuring that the mesh is not twisted.
- Use the previous steps to place the second anchor.
- Adjust the tension if needed. Do not release the anchor until the correct tensioning is achieved.

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STEP 9 - ADJUSTING TENSION

- Anchor location is adjustable bidirectionally until deployment.
- Tension such that the mesh lies directly up and flat against the urethra.

1. There should be no space between the mesh and the urethra.
2. Avoid excessive tension that visually depresses the urethra or significantly narrows the mesh under the urethra.

Cystoscopy may be performed to rule out any bladder or urethral perforations.