Summary of Warnings, Precautions and Contraindications for the MiniArc® Precise Sling System

As with any surgical procedure, inherent risks are present. Although rare, some of the most severe risks with sling procedures include infection, erosion, and vessel or urethra perforation. Some of the most common risks include urinary tract infections, urine symptoms and urinary retention. Sling procedures should not be performed on pregnant patients.

For a complete list of indications, contraindications, warnings and precautions, refer to the product Instructions for Use or contact your AMS representative. This document is written for professional medical audiences. Contact AMS for lay publications. AMS periodically updates product literature. If you have questions regarding the currency of this information please contact AMS.

©2011 American Medical Systems, Inc. All rights reserved. 60118-01B (03/11)
MiniArc® Precise Sling System is the next generation in the MiniArc family of products. Built on the success of the original MiniArc sling and supported by more than 75,000 implants, the MiniArc Precise sling provides even greater control and delivery. Featuring a fixed needle to sling connection, an improved ability to tension, MiniArc Precise sling further simplifies the ease of use.

**Features and Benefits:**

**PATIENT:**
- Minimizes tissue injury
- Reduces potential for blood loss
- Provides significant holding force with minimal pain for the patient
- Reduces potential for mesh movement after placement
- Minimally invasive
- Potential for less post-operative pain
- Can be used with local anesthesia

**PHYSICIAN:**
- Designed to minimize dissection and lessen tissue disruption
- Low insertion force which may provide more control with needle advancement
- Fixed needle to sling tip connection further simplifies procedure
- Needle to mesh connection doesn’t rotate on needle, minimizing potential for mesh twisting
- Provides immediate fixation and helps prevent migration during initial tissue fixation and ingrowth
- The pull-out force required to remove the mesh is 4 times the pull-out force applied to a typical pelvic floor event
- Minimizes concern over mesh movement during intra-operative needle disengagement

**MINIARC PRECISE SLING SYSTEM**

- Single, 1.5 cm vaginal incision
- Proven efficacy

**Pull-Out Force (lbf)**

- Typical Pelvic Floor Event (1.3 lbf)
- MiniArc Precise Sling (5.75 lbf)

**MiniArc Precise Sling Utilizes**

- AMS proven knitted Type I polypropylene mesh with a midline centering mark that promotes accurate placement under the urethra. AMS mesh facilitates healing and promotes tissue integration. This is the same mesh used in more than 750,000 MiniArc®, Monarc®, and SPARC® implants.

- Minimizes concern over mesh movement during intra-operative needle disengagement.

- The pull-out force required to remove the mesh is 4 times the pull-out force applied to a typical pelvic floor event.

- Provides immediate fixation and helps prevent migration during initial tissue fixation and ingrowth.

- The pull-out force required to remove the mesh is 4 times the pull-out force applied to a typical pelvic floor event.

- Minimizes concern over mesh movement during intra-operative needle disengagement.

**OLLER TEXT END**
MiniArc’s Precise Sling System is the next generation in the MiniArc family of products. Built on the success of the original MiniArc sling and supported by more than 75,000 implants, the MiniArc Precise sling provides even greater control and delivery. Featuring a fixed needle to sling connection, an improved ability to tension, MiniArc Precise sling further simplifies the ease of use.

**Features and Benefits**: MiniArc Precise sling utilizes the AMS proven knitted Type I polypropylene mesh with a midline centering mark that promotes accurate placement under the urethra. AMS mesh facilitates healing and promotes tissue integration. This is the same mesh used in more than 750,000 MiniArc®, Monarc®, and SPARC® implants.

- Provides significant holding force with minimal pain for the patient
- Designed to promote proper tensioning to achieve continence
- Provides immediate fixation and helps prevent migration during initial tissue fixation and ingrowth
- The pull-out force required to remove the mesh is 4 times the pull-out force applied to a typical pelvic floor event
- Minimizes concern over mesh movement during intra-operative needle disengagement
- Designed to minimize dissection
- May reduce risk of bladder, bowel and major vessel perforation
- Minimally invasive
- Potential for less post-operative pain
- Can be used with local anesthesia
- Single, 1.3 cm vaginal incision
- Minimal steps for potentially reduced procedure time and the amount of anesthesia required.

**PATIENT:**
- Minimizes tissue injury
- Reduces potential for blood loss
- Provides immediate fixation and helps prevent migration during initial tissue fixation and ingrowth
- Pull-out force required to remove the mesh is 4 times the pull-out force applied to a typical pelvic floor event
- Minimizes concern over mesh movement during intra-operative needle disengagement

**PHYSICIAN:**
- Designed to minimize tissue disruption and lessen tissue disruption
- Low insertion force which may provide more control with needle advancement
- Needle retract’s into body so there is no additional advancement; where you place it is where it stays
- Physicians report it is easy to use
- Provides immediate fixation and helps prevent migration during initial tissue fixation and ingrowth
- Designed to minimize dissection

**Pull-Out Force (lbf):**

<table>
<thead>
<tr>
<th>Event</th>
<th>Pull-Out Force</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typical Pelvic Floor</td>
<td>1.3 lbf</td>
</tr>
<tr>
<td>MiniArc Precise Sling</td>
<td>5.75 lbf</td>
</tr>
</tbody>
</table>

**Proven efficacy:**
- MiniArc Precise sling system is part of the proven MiniArc family sling system which has been used in more than 75,000 implants
- Simplifies procedure
- Designed to promote proper tensioning to achieve continence
- Smooth and easy disengagement of mesh
- Needle retracts into body so there is no additional advancement; where you place it is where it stays
- Physicians report it is easy to use
- Provides immediate fixation and helps prevent migration during initial tissue fixation and ingrowth
- Designed to minimize dissection
- May reduce risk of bladder, bowel and major vessel perforation
- Minimally invasive
- Potential for less post-operative pain
- Can be used with local anesthesia
- Single, 1.3 cm vaginal incision
- Minimal steps for potentially reduced procedure time and the amount of anesthesia required.
The Next Generation in the MiniArc® Sling Family System

This is a summary of the warnings, precautions, and contraindications for the MiniArc® Precise Sling System. It includes information on the inherent risks associated with surgical procedures, such as infection, erosion, vessel or urethra perforation, urinary tract infections, urge symptoms, and retention. It also states that sling procedures should not be performed on pregnant patients.

For a complete list of indications, contraindications, warnings, and precautions, refer to the product instructions for use or contact your AMS representative. This document is written for professional medical audiences. Contact AMS for lay publications. AMS periodically updates product literature. If you have questions regarding the currency of this information please contact AMS.

References:

ORDERING INFORMATION

<table>
<thead>
<tr>
<th>Description</th>
<th>Order Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>MiniArc® Precise Single-Incision Sling System</td>
<td>720191-01</td>
</tr>
</tbody>
</table>