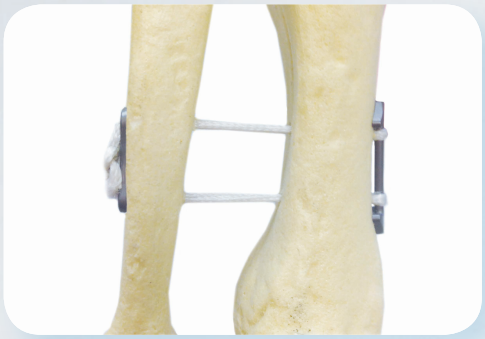
arthrosurface®

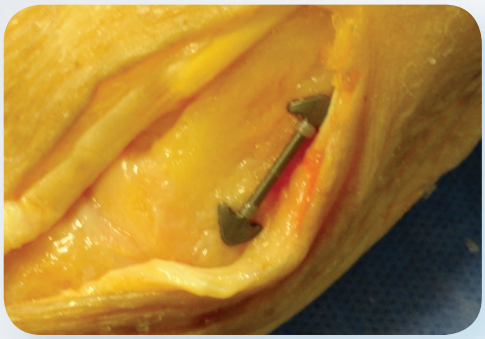
Technique Guide

KISSloc® Suture System

KISSLOC®

The KISSloc® Suture System consists of a strong self-cinching suture assembly, a unique load-dispersing Arrow Plate and procedure specific instrumentation.





- ☑ Simple, strong & fast fixation
- ☑ Locks motion in the coronal plane while still allowing sagittal motion
- ☑ Significantly reduces metatarsal stresses
- ☑ Strong #5 self-cinching suture
- ☑ Small tunnels (Ø 1.2mm) minimize risk of stress fractures
- ☑ All-inclusive single use, disposable instrument kit

Description

The Arthrosurface® KISSloc® Suture System consists of a small pre-tied suture assembly, an arrow plate and a set of instruments used for site preparation and implant delivery.

Materials

Suture Plate & Arrow Plate:	Ti-6AL-4V ELI Titanium Alloy
Suture Construct:	#5 UHMWPE Braided Fiber

Indications

Intended for use in reconstruction (correction) of a hallux valgus deformity by providing for the reduction of 1st metatarsal-2nd metatarsal (IM) angle.

Patient Population

Patient Selection Factors to be Considered Include:

- Failure of previous conservative treatment options in correcting and achieving pain relief.
- Adequacy of bone stock to support implant components.
- Patient's age indicative of skeletal maturity.
- Functionality and/or stability of patient's musculotendinous system.
- Patient's overall well-being, including the ability and willingness to follow pre and post-operative treatment regimen.

Contraindications

- Previous or current infection at or near the implantation site.
- Insufficient bone quantity and quality
- Pre-existing conditions such as limited blood supply that may significantly affect the healing response.
- Patients with known allergies or hypersensitivity to titanium alloys typically used in prosthetic devices.
- Conditions which lend to limit the patient's ability to follow pre and post-operative treatment regimen.

Sterility

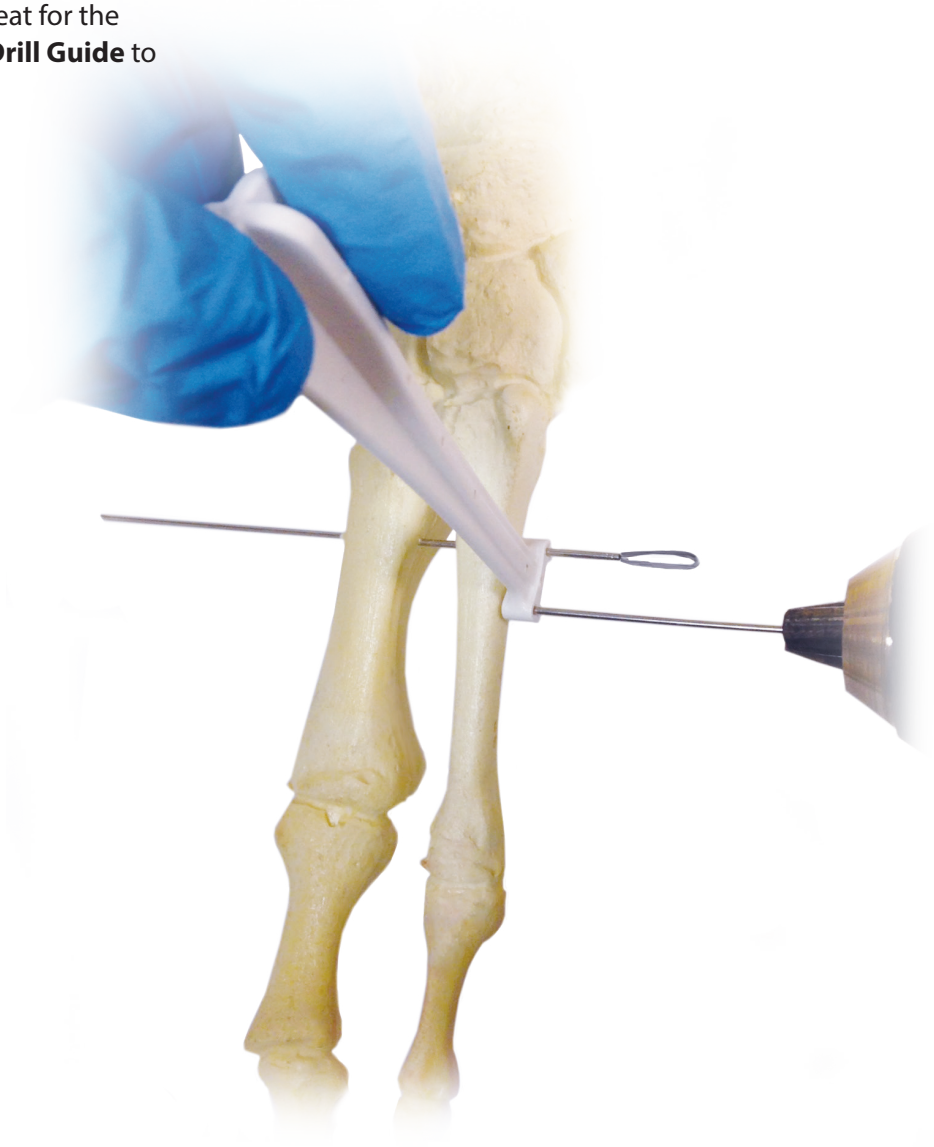
The KISSloc® implants and associated instrumentation are provided STERILE. The suture construct assembly is sterilized by exposure to Ethylene Oxide. The Arrow Plate & Instrumentation Package is sterilized by exposure to gamma irradiation. Do not re-sterilize. Do not use if packaging is opened or damaged. Do not use if beyond expiration date. For Single Use Only.

Surgical Technique

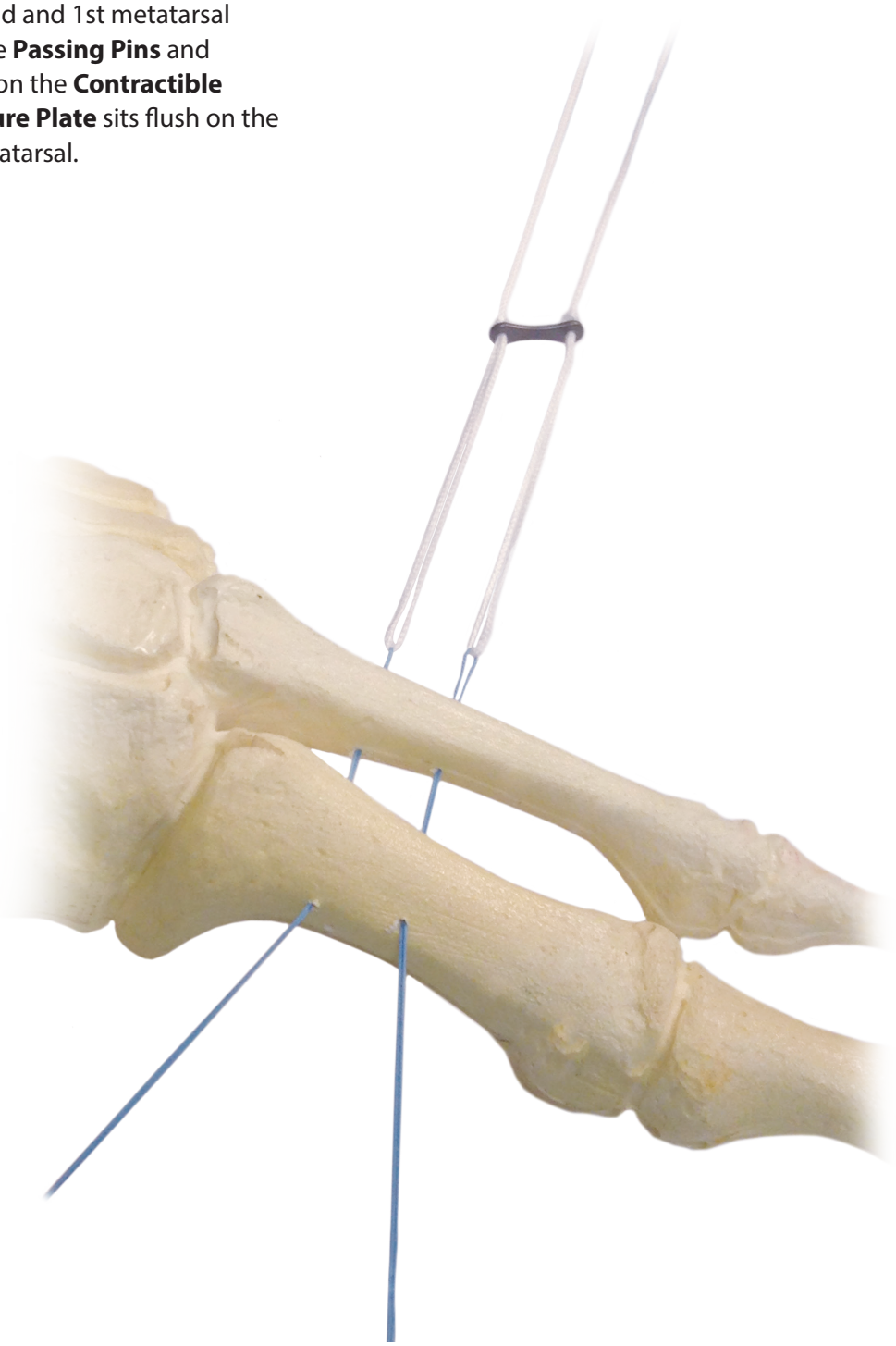
The KISSloc®Suture System will be placed such that the Suture Construct, supported between a Suture Plate and an Arrow Plate, reduces bones or bone segments to the desired levels and maintains correction and normal alignment.

1. Create adequate surgical incisions to expose the bones to be reduced.

2. Reduce and hold the IM angle in the desired final position. Using the **Drill Guide**, insert a **Passing Pin** through both cortices of the 2nd metatarsal. Confirm position of the 1st metatarsal prior to inserting the **Passing Pin** through the 1st metatarsal. Repeat for the second **Passing Pin**, using the **Drill Guide** to offset 10 mm.

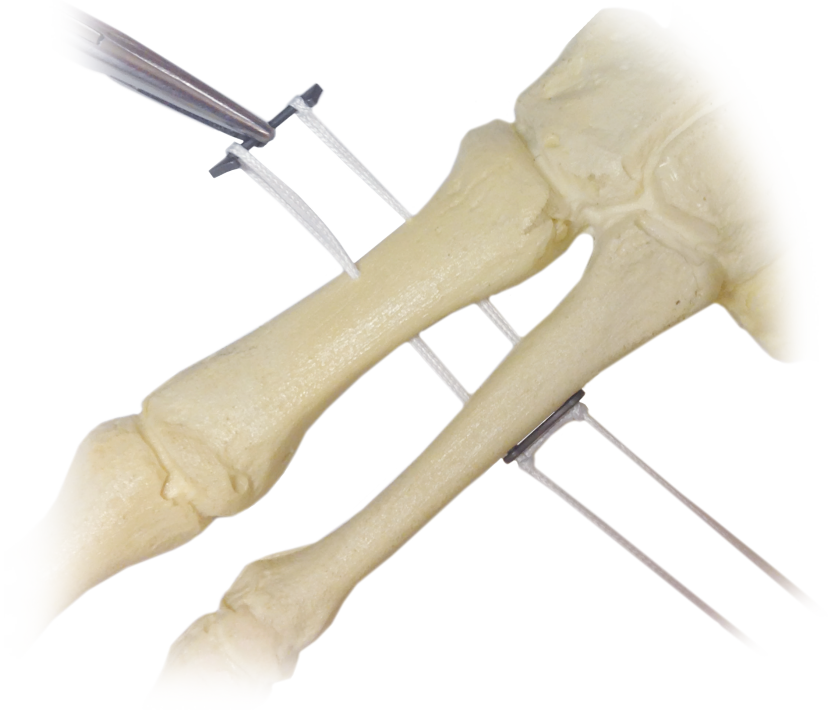


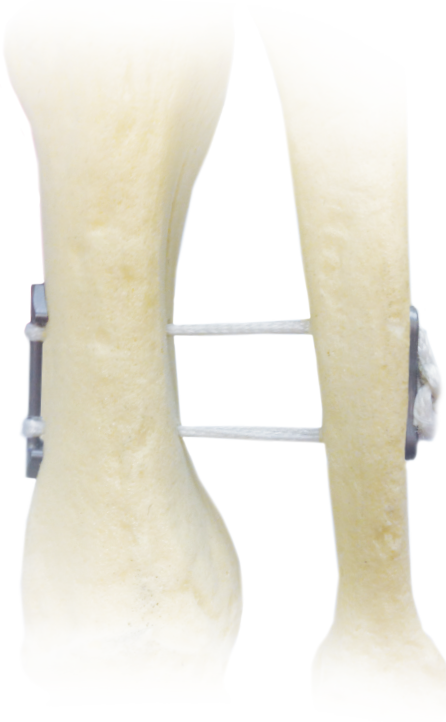
3. Pass the **Contractible Loops** of the **KISSloc® Suture** through the 2nd and 1st metatarsal using the eyelets of the **Passing Pins** and shuttle suture(s). Tension the **Contractible Loops** so that the **Suture Plate** sits flush on the surface of the 2nd metatarsal.



4. Hook the exposed ends of the **Contractible Loops** over the **Arrow Plate** such that each loop is captured by the adjacent arrow head. Hold the **Arrow Plate** off the bone while reducing the **KISSloc® Suture**. Reduce the **KISSloc® Suture** by pulling the **Locking Limbs** away from the **Suture Plate**. Tighten the system until the **Arrow Plate** is seated flush on the outer face of the 1st metatarsal.

5. Manually reduce the two bones to the desired final position.



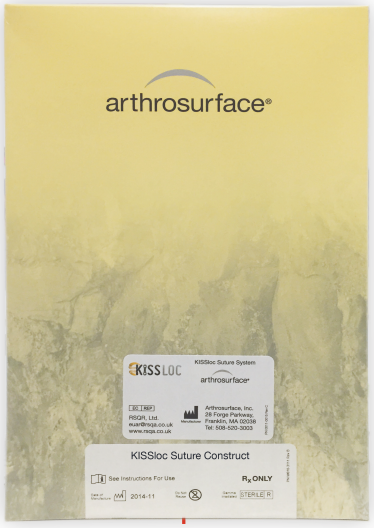


6. While maintaining desired position, complete placement of the **KISSloc® Suture** by pulling the **Locking Limbs** so desired tension is maintained in the system. **Caution: when correcting IM angles greater than 14°, use the KISSloc® Suture System as an adjunct device.** Confirm that the **Contractible Loops** are held captive by the **Arrow Plate**, and that the **Arrow Plate** and **Suture Plate** are in desired position.

7. With the two **Locking Limbs**, complete the implant placement by tying a square knot as close to the **Suture Plate** as possible. Trim excess suture.

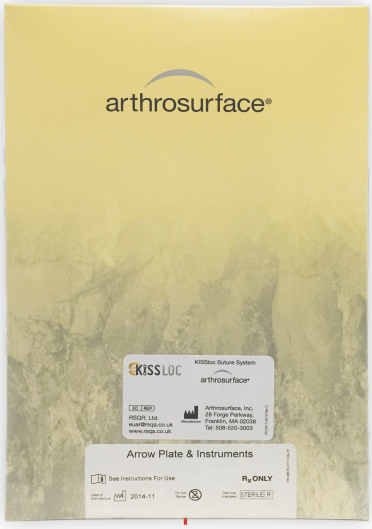
Instruments & Implants

KISSloc® Suture Component Package



KISSLOC® SUTURE CONSTRUCT

Arrow Plate & Instrument Package



ARROW PLATE

DRILL GUIDE

PASSING PINS (2)

System Catalog

KISSloc® Suture Component Package

9V00-0100	KISSloc® Suture Construct

Arrow Plate & Instrument Package

9V00-0200	Arrow Plate Drill Guide Passing Pins (2)

Warnings & Precautions

The KISSloc® Suture System (KSS) is not intended to be used as a ligament replacement device.

- To achieve desired outcomes with Arthrosurface Inc's KSS, pre-operative patient evaluation is extremely important. Patient's weight occupation, activity level, metal condition, foreign body sensitivity and any degenerative diseases are important factors to consider. Based on these the surgeon must decide whether or not the implant components are viable for the individual patient.
- Pre-operative and operative procedures, including knowledge of surgical technique, proper selection and placement of implant components are important considerations in the successful utilization of this system.
- Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quantity and quality must be assessed at the time of surgery. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
- Bone must be of sufficient quality to support two tunnels spaced 10 mm apart.
- KISSloc® Suture System components should only be used as a system. Other available sutures or substitute components have not been evaluated for adequate performance as part of the KSS.
- Use of instruments from other systems may result in improper implant selection, placement and fixation, which could result in implant failure, poor clinical outcome or compromise patient safety.
- Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
- Correct implant handling is extremely important for successful outcomes. Implant components should not be bent, notched, scratched or manipulated in such a way that the suture construct cannot function as intended. All of these operations can produce defects which may lead to the eventual failure of the implant system.
- Implant removal is at the sole discretion of the surgeon. Great care must be taken while removing the implant components. Adequate and appropriate postoperative care should be employed to stabilize the joint and avoid fracture or refracture.
- The KSS implants and associated instrumentation are provided sterile. Do not re-sterilize. DO NOT USE if there is a loss of sterility of the device. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened or un damaged containers.
- DO NOT RE-USE. Although it may appear undamaged, the used implant component may have small defects and internal stress patterns that may lead to failure. KSS implant components are Single Use devices that have not been designed to undergo or withstand any form of alterations, such as disassembly, cleaning or re-sterilization, after single patient use. Reuse can eventually compromise implant performance and patient safety.
- Once open, discard any unused suture.
- The KSS metallic components have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.

Possible Adverse Effects

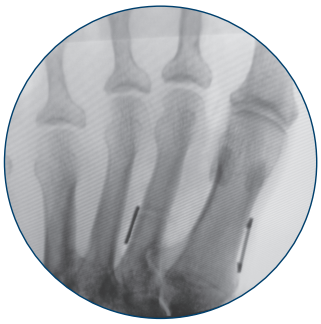
1) Bending or fracture of the implant including breakage of the suture.
2) Loosening or migration of the implant.
3) Metal sensitivity or allergic reaction to a foreign body.
4) Infection, both deep or superficial.
5) Pain, discomfort, or abnormal sensation due to the presence of the device.
6) Nerve damage due to surgical trauma.
7) Necrosis of bone or tissue.
8) Inadequate healing.
9) Intraoperative or postoperative bone fracture and/or postoperative pain.

Caution

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

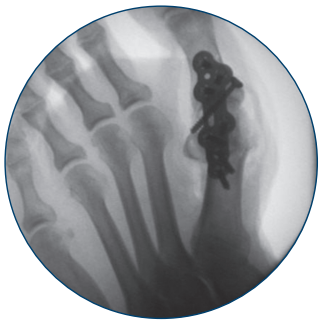
KISSLOC®

Arthrosurface® currently provides the following trauma & osteotomy products:



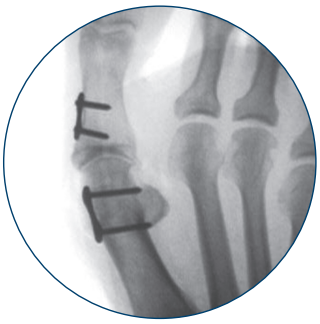
KISSLOC®

Suture System



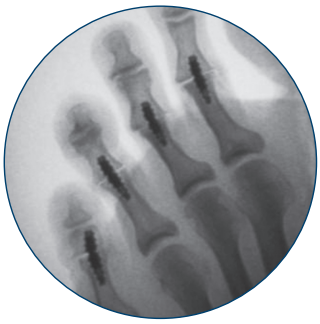
CheckMATE

Fusion Plate



pinit Plate

Small Bone Fusion



ToeMATE

Hammertoe Correction

arthrosurface®

For more information, visit our website:
www.arthrosurface.com

28 Forge Parkway • Franklin, MA 02038
1 508 520 3003
fax: 1 508 528 3785

This pamphlet and information is intended for markets where regulatory approval has been granted.