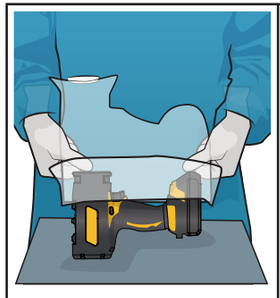
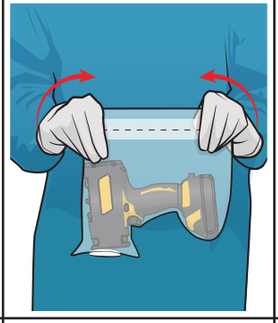
TRAKPAK® SKELETAL TRACTION KIT

ARBUTUS MEDICAL

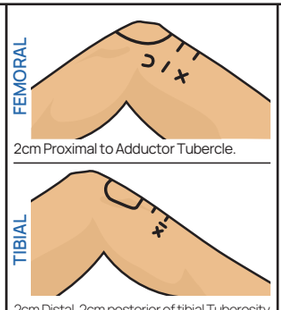
1. LOAD



2. UNFOLD AND SEAL



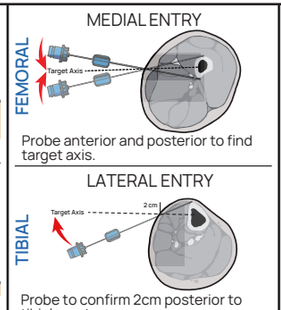
3. BUMP LEG & LANDMARK



2cm Proximal to Adductor Tubercle.

2cm Distal, 2cm posterior of tibial Tuberosity.

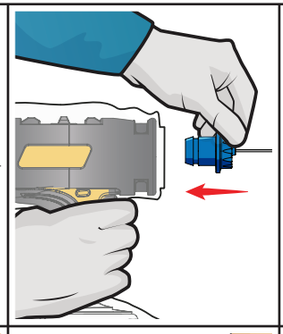
4. CONFIRM CENTER



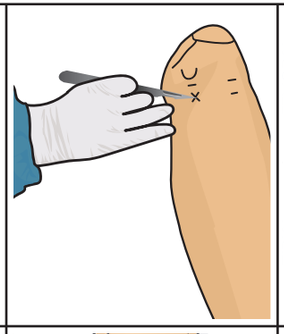
Probe anterior and posterior to find target axis.

Probe to confirm 2cm posterior to tibial crest.

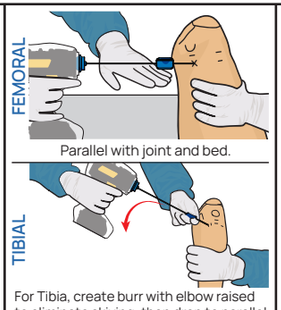
5. INSERT



6. SKIN NICK



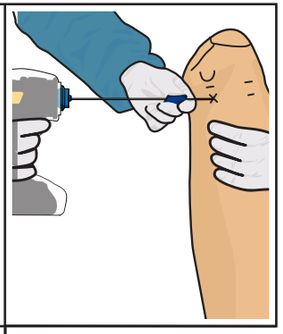
7. CHECK DRILL AXIS



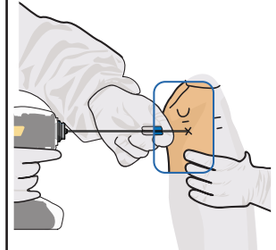
Parallel with joint and bed.

For Tibia, create burr with elbow raised to eliminate skiving, then drop to parallel.

8. APPLY COUNTER PRESSURE

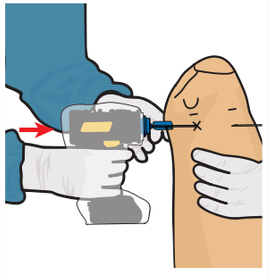


9. EXPECT BENDING



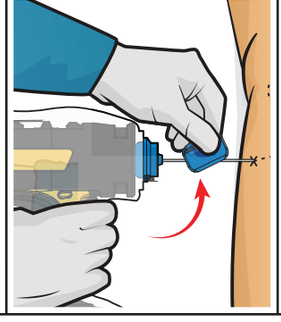
Bending is expected, focus on keeping the pin straight on the patient side of the guide.

10. DRILL

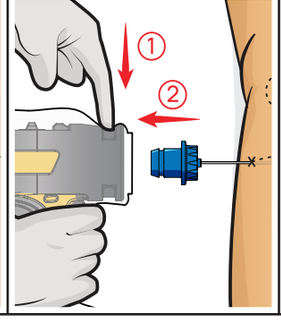


Confidence: Push hard and progress quickly to reduce heat.

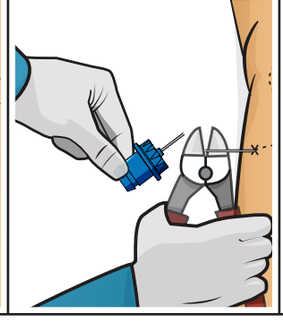
11. REMOVE



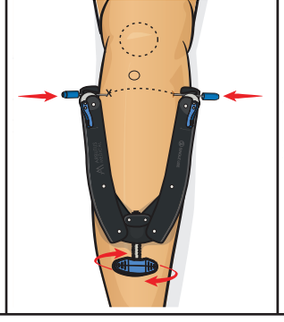
12. RELEASE



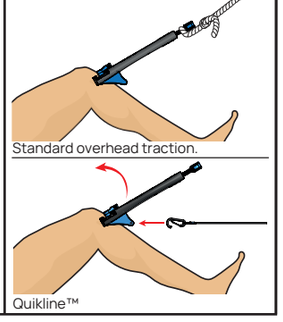
13. CUT



14. TENSION QUIKBOW® AND CAP



15. HANG WEIGHT



Standard overhead traction.

Quikline™

Tibial Placement Training Video

Femoral Placement Training Video

Arbutus Medical Inc | www.arbutusmedical.com | 2520 Columbia St. | Vancouver | British Columbia | Canada | V5Y 3E9

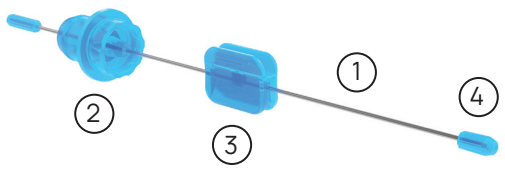
TrakPak®, SteriTrak® & QuikBow®
Instructions for Use

ARBUTUS MEDICAL

Description
The TrakPak® is a surgical kit for skeletal traction. The SteriTrak® System is an orthopedic drilling system. The SteriTrak® System is designed to be used exclusively with the SteriTrak® Drill. The QuikBow® is a pin tensioner for skeletal traction.

Indications for Use
TrakPak® is indicated for skeletal traction. SteriTrak® is indicated for implantation through the skin and bone so that traction may be applied to the skeletal system.

The SteriTrak® is comprised of
1. an implantable k-wire,
2. an adapter to fit into the SteriTrak® Drill,
3. a guide for the user to hold while drilling,
4. 2 pin tip covers to guard the sharp ends of the pin,
5. and a SteriGo® power tool drape (not pictured)



Warnings, SteriTrak®
1. In the procedure described in these instructions for use, the SteriTrak® drill is nonsterile. Take care not to contaminate sterile surfaces on the SteriTrak® drill.
2. The SteriTrak® System is for use as an anchor for skeletal traction only and is not for use in general orthopedic fracture fixation.
3. Single use only. Do not reuse.
4. Do not cut the wire before confirming the desired placement. If the wire is cut prematurely, restart the procedure with a new SteriTrak®.
5. The SteriTrak® should be unpackaged and deployed using sterile technique, product is sterile if packaging is undamaged and unopened.
6. The SteriTrak® system is intended to remain in the body for less than 30 days.
7. Contraindications: Patients not indicated for skeletal traction or patients under 12 years of age.

Warnings, QuikBow®
1. Apply and confirm pin tension before weight is hung from the bow.
2. QuikBow® is single use only, do not reprocess.
3. For prolonged traction, periodically confirm pin tension. More tension can be applied by tightening the tension screw.
4. Ensure the QuikBow® does not rest on the patient's tibia.

Maintaining Device Effectiveness
1. The surgeon should have specific training, experience, and familiarity with the use of K-wire placement for skeletal traction.

Instructions for Use, TrakPak®
1. Position the leg and mark the operation site with the skin marking pen.
2. Use Chloraprep to sterilize the leg's medial and lateral aspects based on the planned pin trajectory.
3. Draw up 20 mL of anesthetic (e.g. lidocaine) in the syringe using the 18-gauge needle. Switch to the 22-gauge needle prior to injection.
4. Inject 10ml of anesthetic in each side of the leg. On the medial side inject from the skin down to the level of the periosteum of the medial femur. Similarly, the lateral side of the femur should be anesthetized with 10mL of lidocaine to the level of the lateral femoral periosteum.
5. Using Chloraprep, resterilize the areas of the thigh that were just anesthetized.
6. Drape the site with the sterile towels or drapes
7. Use the scalpel to make an incision at the pin entry and exit site
8. While maintaining sterility, assemble and use the SteriTrak® to insert the traction pin.

Instructions for Use, SteriTrak®
1. Load the powertool into the sterile cover.
2. Unfold the cuff and seal the cover.
3. Insert the SteriTrak® pin into the powertool.
4. Partially drive the pin until it contacts bone using the guide to provide stability. Confirm the anatomical location is correct by probing the surrounding anatomy with the pin.
5. Drive the pin through the bone using the guide to provide stability.
6. Confirm that the pin is placed in the desired location.
7. Remove the guide.
8. Release the powertool.
9. Apply the QuikBow® pin tensioner
10. Cut the pin to size.
11. Cap the pin with the provided pin caps.
12. Kerlix can be used to wrap around the pin for pin care. Xeroform can be used at the pin entry and exit site.

Instructions for Use, QuikBow®
1. Turn the tension screw to set the desired span, up to 9.5"
2. Compress thumb levers and apply to the pin.
3. Tighten the tension screw to apply desired tension to the pin. Turn until tight.
4. Loop traction rope around the tension screw handle to hang desired traction weight, up to 30 lbs. Direct the rope over a traction frame.
5. If QuikLine™, clip provided ropes to bow adapters, as shown. Hang directly off the bed.

Sterile Product & TrakPak®
SteriTrak® & TrakPak® System is supplied sterile. Prior to use, inspect the package for damage, which may compromise sterility. If damaged, the product must be assumed to be non-sterile.

DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.

MRI Safety Information
The SteriTrak® device is nonmagnetic and conditionally safe for MRI. No unsafe displacement or heating has been observed in worst case scenario testing with 1.5T MRI. No patient risk is expected. There is no limitation to scan parameters recommended, however, the device has not been tested with 3T or 7T MRI, therefore, reasonable precautions should be taken.
The QuikBow® is designated MR Unsafe and is not acceptable for MRI.

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

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LBL-202(02)

Symbols Glossary

Symbols	Description
REF	Reference Number
LOT	Batch Code
	Do not use if package is damaged
	Do not reuse
Rx only	Device only to be sold on or by the order of a physician.
	Manufacturer
	Caution
	Consult Instructions for Use
MR	MRI Conditional