Akilink®

MINI INVASIVE ACHILLES TENDON REPAIR SYSTEM

Single use system

•

90° handle to ease introduction and positioning

•

Multidirectionnal sutures targeting jig

In2Bones

A GLOBAL EXTREMITY COMPANY

ST-DIG-Akilink-EN-052019

Indications

INDICATIONS

The Akilink® system is indicated for the mini invasive repair of acute (less than 10 days) closed ruptures of the Achilles tendon, located between 2 cm and 8 cm above the tuberosity of the calcaneum.

Note
2 cm is the lowest limit, in this case, please choose an oblique suture on the calcaneus side.

CONTRA-INDICATIONS

The device should not be used in a patient who has currently, or who has history of:

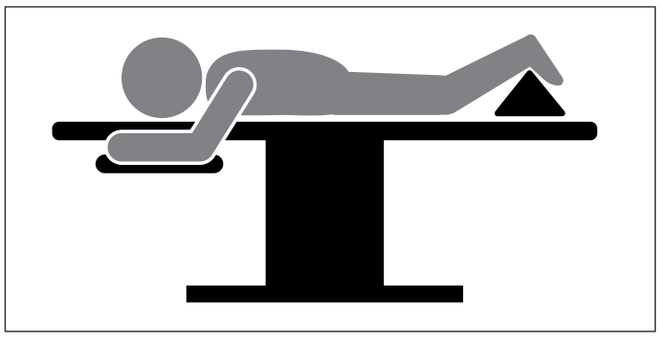
- Acute or chronic, systemic inflammations,
- Active infections,
- Chronic rupture,
- Open rupture,
- Complex open rupture with skin defect,
- Rupture located between 0 and 2 cm above the tuberosity of the calcaneum or higher than 8 cm above the tuberosity of the calcaneum,
- Previous local surgery,
- Sensitivity/allergies to the medical device materials,
- Patient under steroid, quinolones,
- Diabetic patient.

In2Bones® as the manufacturer of this device, does not practice medicine.

The surgeon who performs any implant procedure is responsible for determining and using the appropriate surgical techniques for implanting the device in each patient.

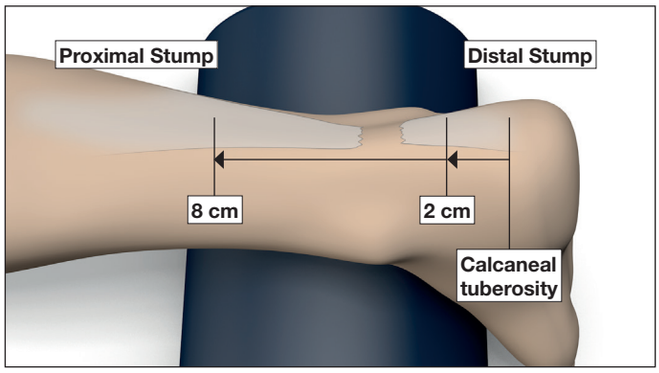
This Surgical Technique Manual is furnished for information purposes, as an aid to use properly the device and its dedicated instruments.

Surgical technique



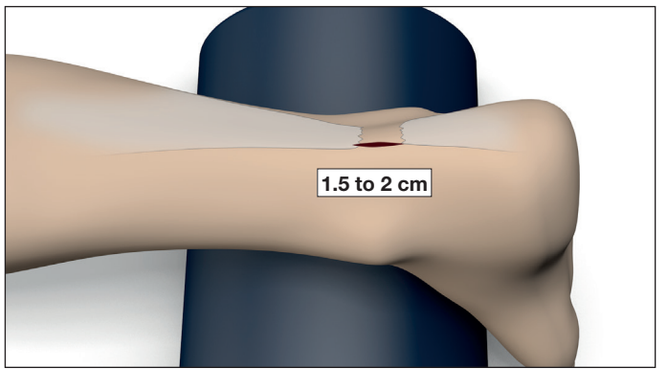
The patient is placed prone on the surgical table with standard protection on the various pressure points.

Both ankles are elevated and a tourniquet is applied (except if contraindicated).



Accurately feel the gap (soft spot) corresponding to the rupture site.

> In more than 90% of cases, rupture is located 4 cm above calcaneal tuberosity.
> The Akilink® is intended to be used for ruptures occurring between 2 and 8 cm proximal to the calcaneal tuberosity.

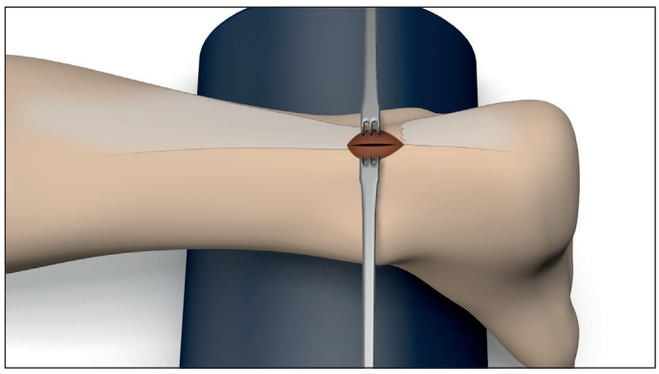


Incision

Vertical and medial to the tendon.

1.5 to 2 cm in length, proximally from the soft spot.

With scalpel blade N°15 (smallest size), delicately dissect the thin subcutaneous tissue.

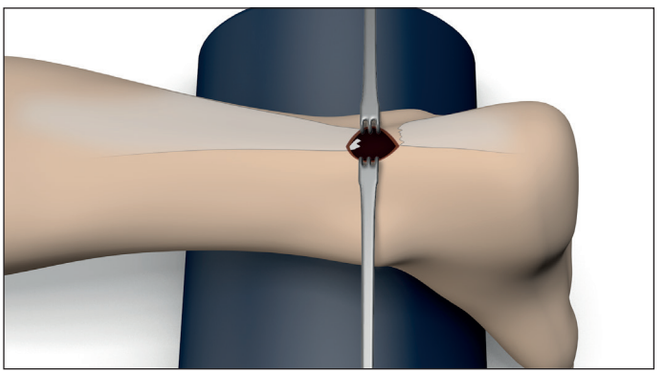


Retract the skin layer with 2 small hook retractors (Guillis type).

Carefully identify the Paratenon.

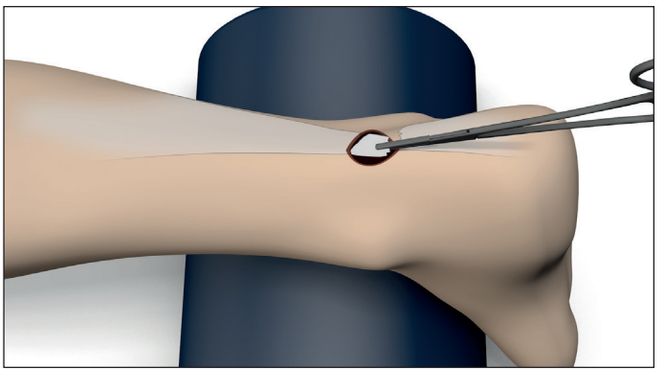
Make a 2 cm vertical incision in the paratenon.

Be careful to avoid the sural nerve. The incision is slightly medial in order to avoid any friction and limit sural nerve lesions postoperatively



Place a stay suture in each edge of the paratenon.

The space under the paratenon has to be cleared proximally and distally in order to vizualize its “tunnel shape”.

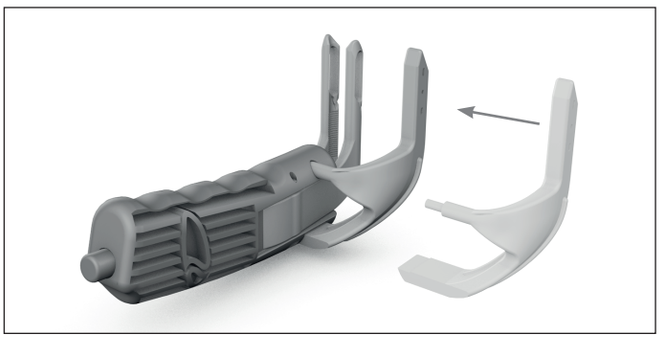


Grap the proximal part of the tendon with a clamp

It is recommended to carefully release the tendon’s sheath at this time to ease the insertion of the device.

On the medial side, the plantaris tendon may be visualized.

In most cases the tendon stumps have become frayed.
If the rupture spot is particularly difficult to locate, the skin incision can easily be extended proximally or distally.



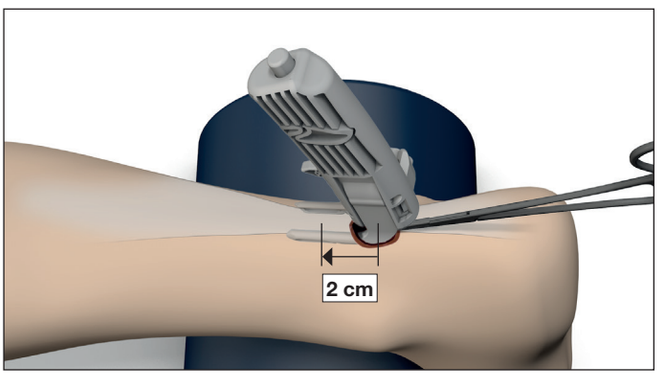
Insert the targeting lateral extension on the system

Push to open arms.

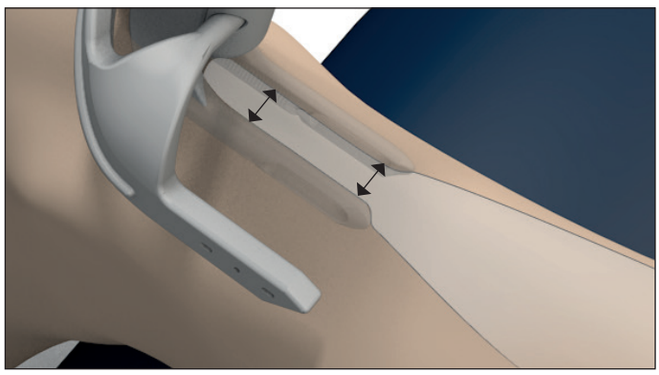
Introduce within the tendon sheath both arms of the instruments on each side of the tendon while maintaining the tendon with the clamp.

Introduce both arms to recover the tendon, the distal suture must be located at least at 2cm from the rupture site.

If necessary, gradually spread the arms during introduction by pushing the top button.

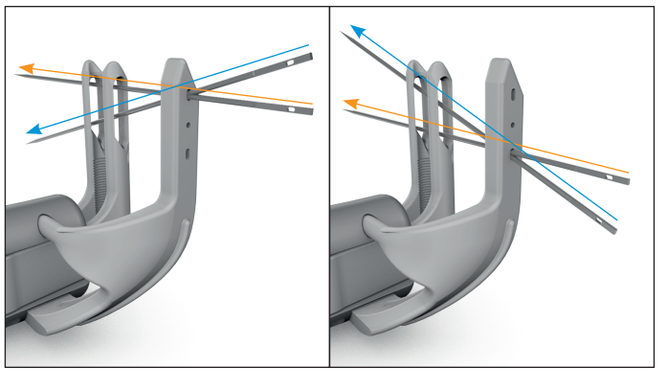


Take care not to damage the sheath while inserting the device. Caution will be taken to have sufficient space between the tendon and the sheath to achieve a smooth introduction of the system.
It might be useful to insert first the tip of one arm, then the other one.



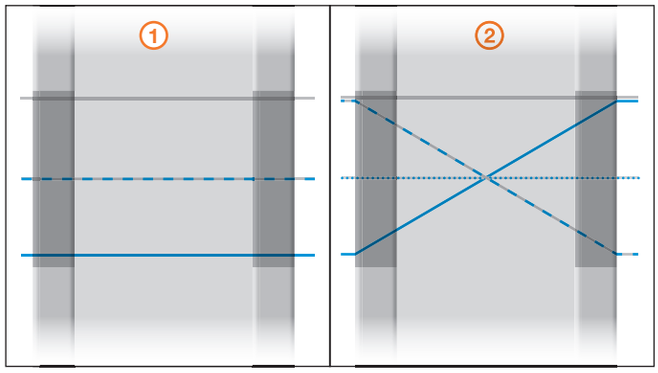
Before introducing the sutures, the appropriate position and angulation of the Akilink® is confirmed by external digital palpation.

The tendon should fall between the two central branches of the device.



Proximal and distal sutures can be inserted in different planes per surgeons' preference.

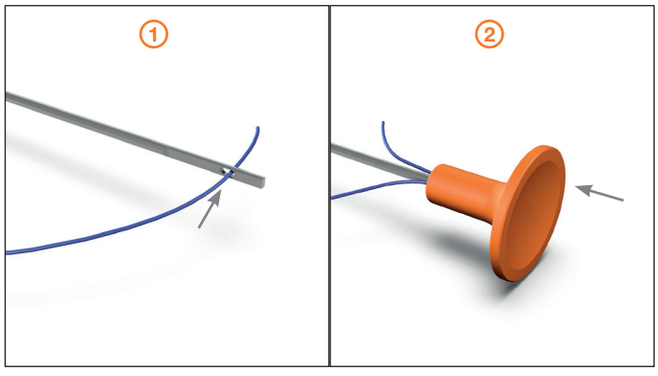
The use of a suture USP 0 to 2 / metric 3.5 to 5 is advised, as per surgeon's preference.



A minimum of 3 parallel sutures is required. ①

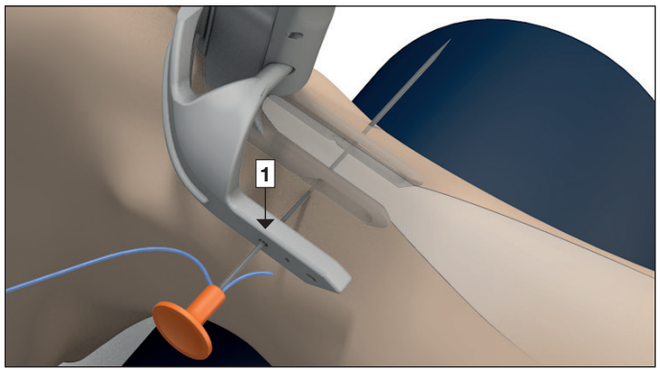
An assembly with 4 sutures with 2 cross sutures can be realized by introducing the sutures in the extreme holes with a convergent axis. In this case, remove one from the lateral. ②

3 different colors of sutures shall be used in order to have a better visualization of the sutures to tie together



Pass the suture in the eye of the provided needle. ①

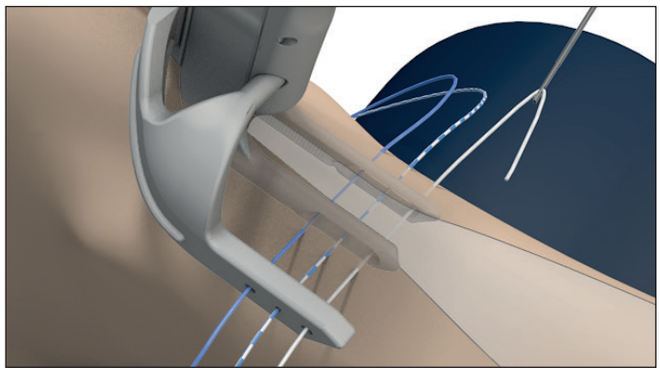
Insert the needle pusher. ②



Using the needle pusher, insert the needle with the suture within the **distal hole** through the leg.

With the thumb, apply a slight pressure on the tendon to ensure that the tendon is properly positioned between the arms while inserting the needle.

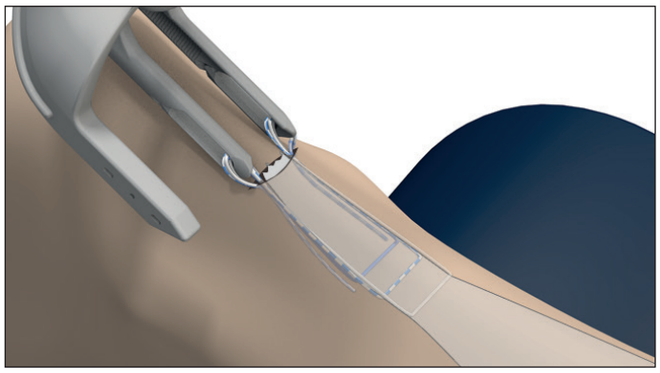
Ensure the handle is stable during this phase.



Note: Leave the sutures outside on each side of the leg, and ensure to fully insert the needle into the pusher

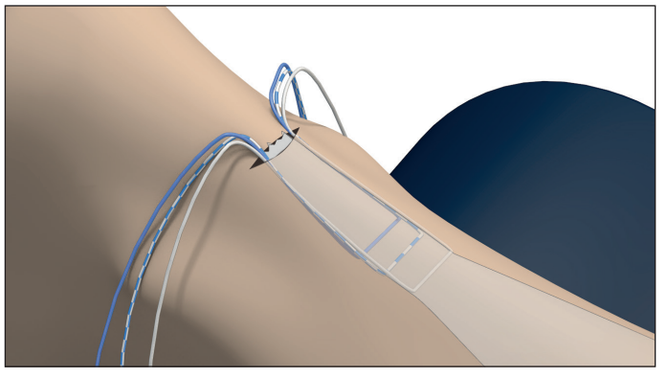
Note: Push on the skin at the sural nerve area in order to lower it and avoid any conflict during the needle introduction.

Accurately feel the gap (soft spot) corresponding to the rupture site.



The Akilink® is withdrawn gently in order to prevent any suture or soft tissue damage.

When the arms are outside of the leg, remove the sutures from the lateral extension.

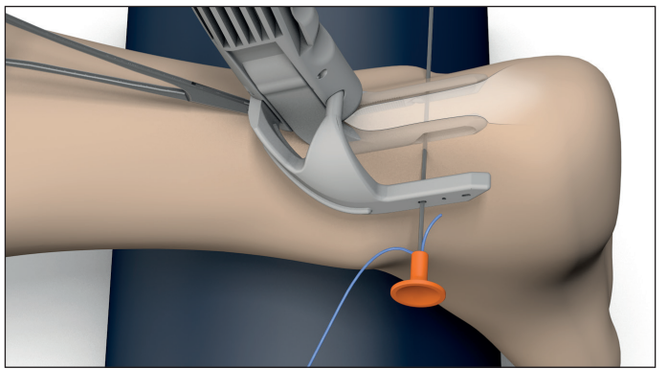


Continue to gently pull the system until all sutures are outside the incision site

Identify and isolate each suture on a separate clamp before starting the distal sutures insertion.

Each clamp must remain on its respective side. In this way sutures will not cross the midline.

Caution will be taken not to damage the tendon sheath while introducing the system. Space between the tendon and the sheath must be checked in order to have an easier introduction of the device.



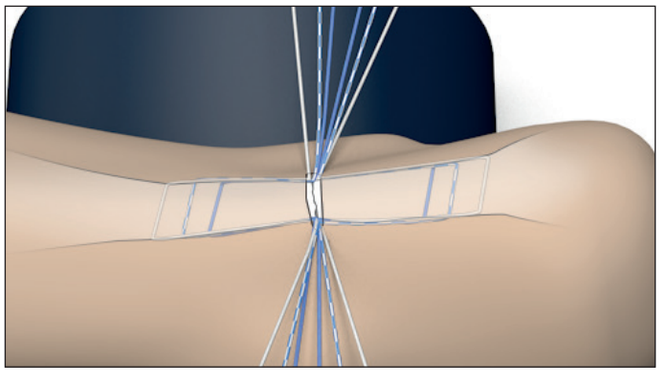
The same sequence is performed on the distal stump.

Place the foot in equinus position to facilitate the tendon distal part catch.

The Akilink® is introduced under the paratenon and pushed until it touches the calcaneum.

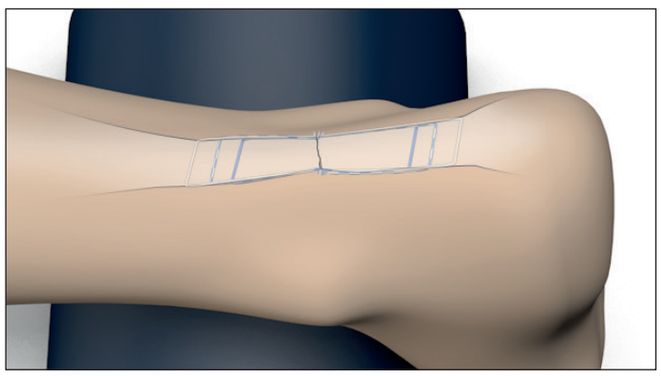
It is recommended to carefully release the tendon's sheath before to ease the insertion of the device.

Again 3 sutures are placed starting with the proximal suture.



Remove the Akilink® paying attention not to damage the soft tissue.

Release the suture from the lateral arm when the arms are removed.



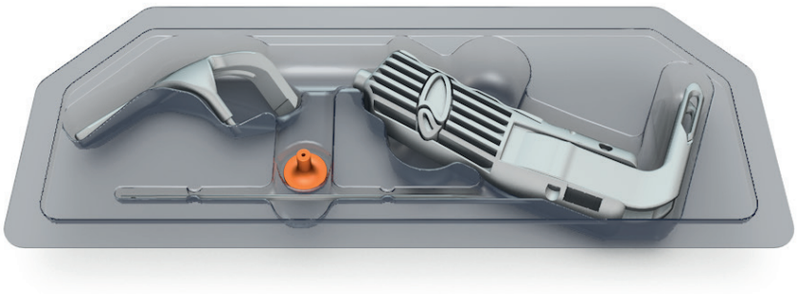
Sutures are then tied by corresponding pairs in order to realize 3 or 4 peritendinous settings while maintaining the foot in physiological equinus position.

Check the good tendon to tendon contact, without any overlapping

Legal informations

LIST OF PRODUCTS

G03 10001 :
Akilink® MINI INVASIVE ACHILLES TENDON REPAIR SYSTEM



RECOMMANDATION

It is recommended to carefully read the instructions for use available in the package insert.

DEVICES

Instruments: Single Use Instruments: Class IIa - CE2797

REIMBURSEMENT

Reimbursement may vary from countries to countries. Check with local authorities.

MANUFACTURER

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DOCUMENT

Reference : ST-DIG-Akilink-EN-052019

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