EN

Integra®

Achillon® Achilles Tendon Suture System

SURGICAL TECHNIQUE

INTEGRA®
LIMIT UNCERTAINTY

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Description

The Integra Achillon® System is a minimally invasive method to treat acute Achilles tendon ruptures. It is a procedure that allows direct visual control of the repair, as well as percutaneous introduction of the sutures. The surrounding soft tissues and tendon itself are treated with the care to avoid any local trauma.

Indications

- Acute (less than 10 days) closed ruptures of the Achilles tendon.
- Open ruptures (less than 6 hours) without skin defect.
- Rupture located between 2 cm and 8 cm above the tuberosity of the calcaneum.

Contraindications

The instrument should not be used in a patient :

- Who has currently, or who has history of :
  - › Chronic rupture.
  - › Previous local surgery.
  - › Patient under steroids.
  - › Open ruptures (more than 6 hours).
  - › Complex open ruptures with skin defect.
  - › Pediatric age.
  - › Rupture located between 0 and 2 cm above the tuberosity of the calcaneum and higher then 8 cm above the tuberosity of the calcaneum.
  - › Non collaborating patient.
  - › Patient unable to walk with crutches.
- Each patient must be evaluated by the surgeon to determine the specific risk/ benefit relationship in light of the patient's condition and the surgeon's practice, training, experience, and knowledge of the related medical literature
- Complications with the use of similar surgical technic have been reported in the medical literature. Any patient undergoing a surgical procedure is subject to intra-operative and post operative complications. Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different.
- Possible risks, adverse reactions, and complications associated with surgery and the use of this surgical technique should be discussed with and understood by the patient prior to surgery. The patient should not be led to unrealistic expectations as to the performance or results that the surgery can provide. The patient should be informed that successful results cannot be guaranteed.
- It is the responsibility of the surgeon to provide the patient with information prior to surgery
- Complications may include but are not limited to:
  - › Pain, discomfort, or abnormal sensations;
  - › Risk of additionnal injury from post-operative trauma
- Side effects may include but are not limited to :
  - › Infections
  - › Hematoma
  - › Allergy
  - › Skin necrosis
  - › Venous Thrombosis
- Adverse effects may necessitate re-operation.

Details

Precise order and direction for introduction of the sutures

Needle driver
Sutures size: USP (3.5 metric).

4° Angle to conform to the anatomy

Material:
Stainless steel

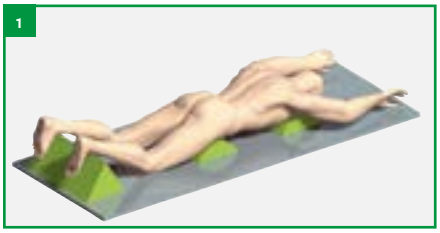
Adjustment screw provides for appropriate adaptation to the tendon stump

As the manufacturer of this device, Newdeal does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate techniques for utilizing the device with each patient.

Surgical Technique

Step 1 • Patient Positioning

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).



Step 2 • Preparation of surfaces

- Antibiotic prophylaxis pre-op.
- Do not use plastic drape (percutaneous technique).
- Inflate tourniquet.

Step 3 • Rupture site

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

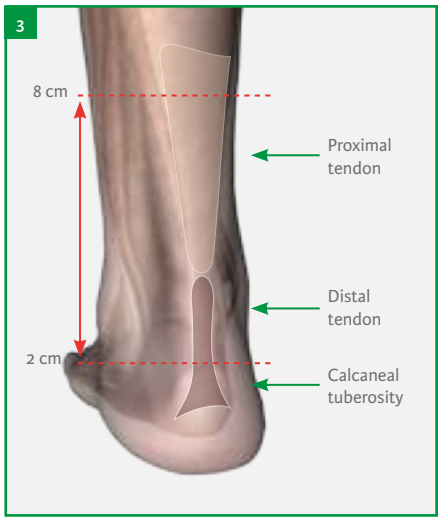
Note
In more than 90% of cases it is located 4 cm above calcaneal tuberosity). The indication for use of the Achillon® System is for ruptures occurring between 2 and 8 cm proximal to the calcaneal tuberosity.

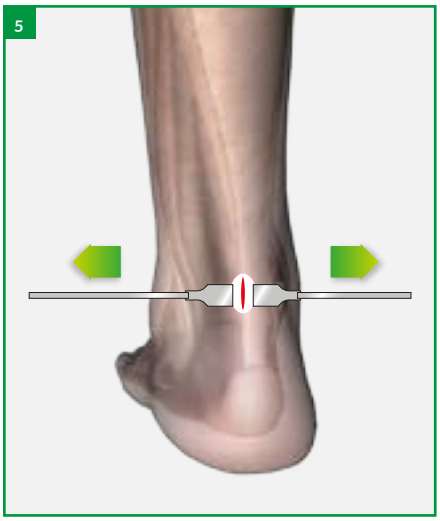
Step 4 • First incision

- 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.

Step 5 • Paratenon incision

- Retract the skin layer with 2 small hook retractors (Guillis type).
- Carefully identify the paratenon.
- Make a 2 cm vertical incision in the paratenon.





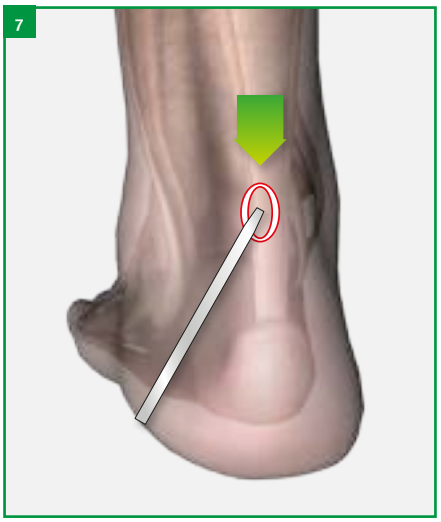
Step 6 • Stay suture

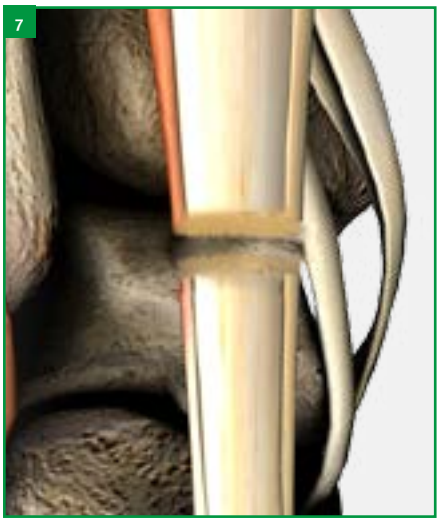
- Place a stay suture in each edge of the paratenon.
- The space under the paratenon has to be cleared proximally and distally in order to visualize its “tunnel shape”.

Note
This maneuver will facilitate the introduction of the Achillon®.

Step 7 • Stumps identification

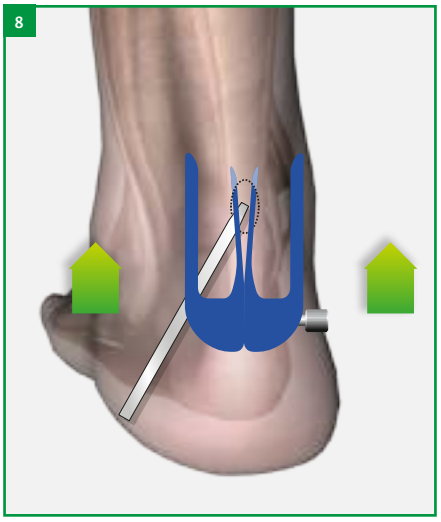
- Identify both proximal and distal tendon stumps.
- On the medial side, the plantaris tendon may be visualized.

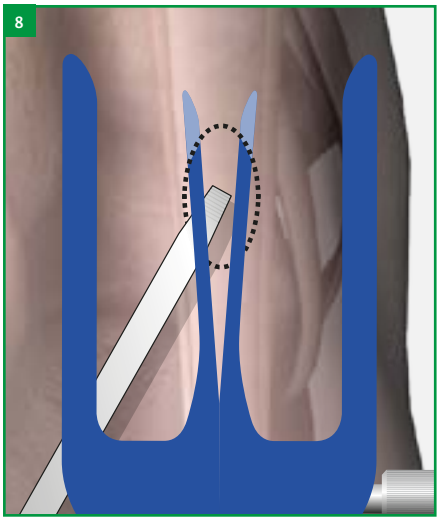




Step 8 • Introduction

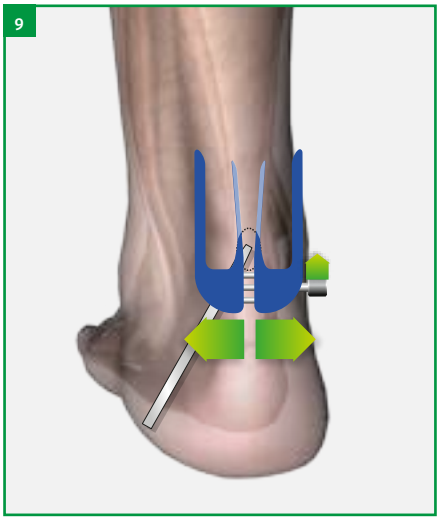
- Introduce the Achillon® in the closed position (minimal width) under the paratenon proximally.
- The tendon stump comes in between the two internal branches.





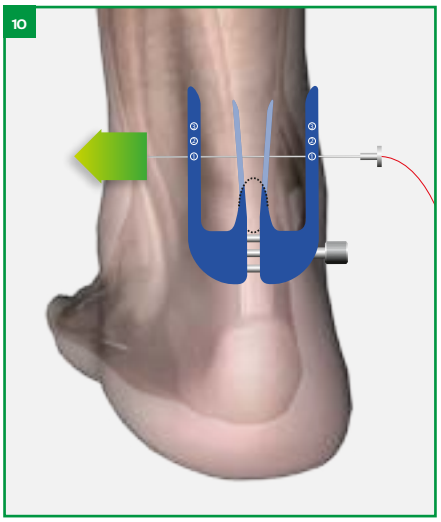
Step 9 • Widening

- As soon as the Achillon® is introduced, it is progressively widened.
- The tendon stump is held with fine forceps or a clamp passed under the Achillon (Kocher or Mosquito).



Step 10 • Positioning

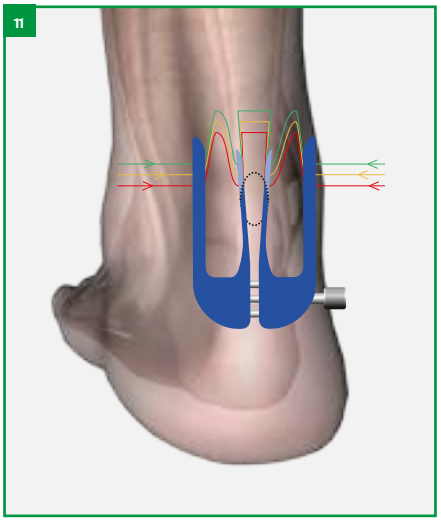
- Before introducing the sutures, the appropriate position and angulation of the Achillon® is confirmed by external digital palpation.
- The tendon should fall between the two central branches of the instrument.
- Using the needle driver, the first needle is introduced according to arrows and numbers printed on the instrument.

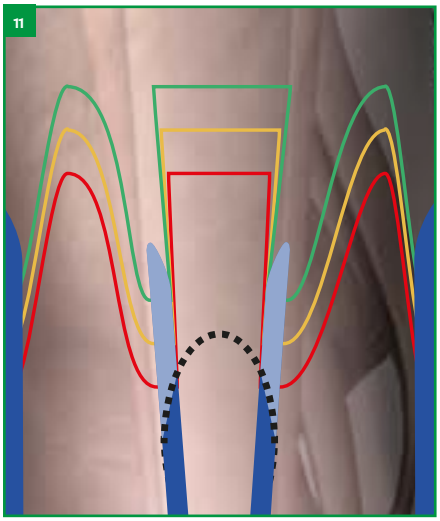


Note
Suture size 0 USP (3,5 metric).

Step 11 • Sutures

- Three sutures are passed and left outside.

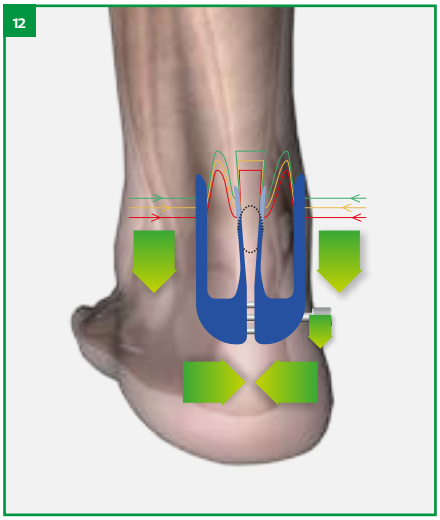


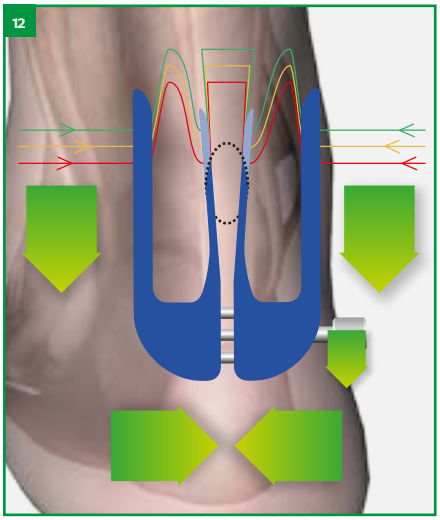


Step 12 • Achillon® system removal

- The Achillon® is withdrawn gently in order to prevent any suture or soft tissue damage.
- As it is being withdrawn, the Achillon® is progressively closed.

Note
From an extracutaneous position, the sutures become subperitendinous. Thus, the tendon itself becomes the only site of tissue attachment for the suture.

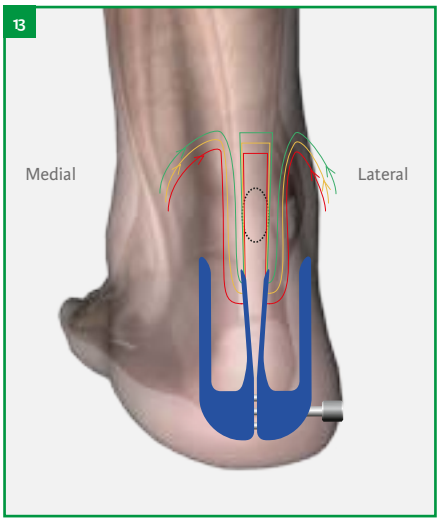


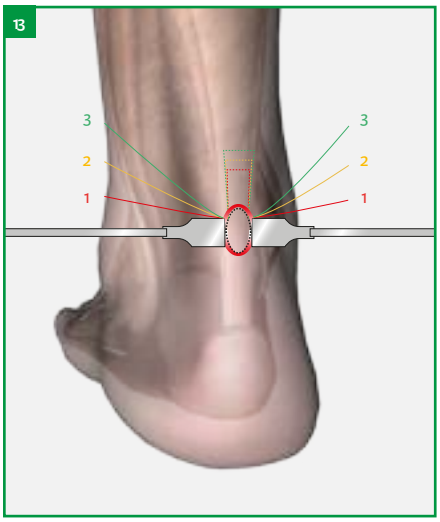


Step 13 • Clamp

- A clamp is placed on the 3 sutures coming out laterally and another clamp is placed on the 3 sutures coming out medially.
- Each clamp must remain on its respective side. In this way sutures will not cross the midline.

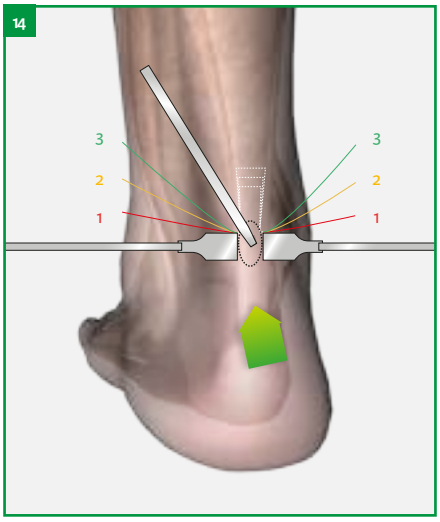
Note
If any suture fails, it has to be replaced by repeating the previous technique.

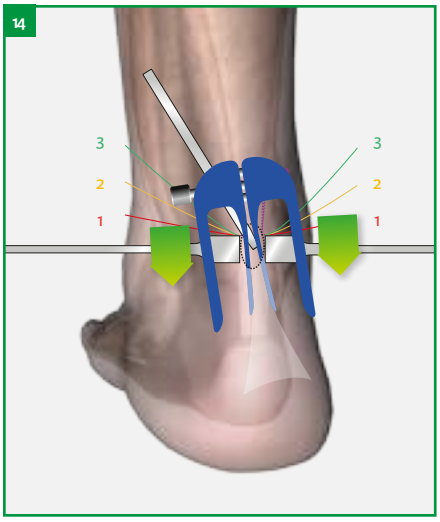




Step 14 • Distal tendon

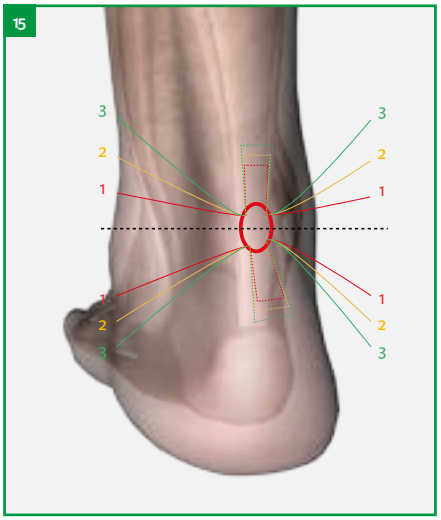
- The same sequence is performed on the distal stump.
- The Achillon® is introduced under the paratenon and pushed until it touches the calcaneum.
- Again 3 sutures are placed.
- Then, Achillon® system is delicately removed in order to preserve the sutures and the soft tissues.





Step 15 • Organization

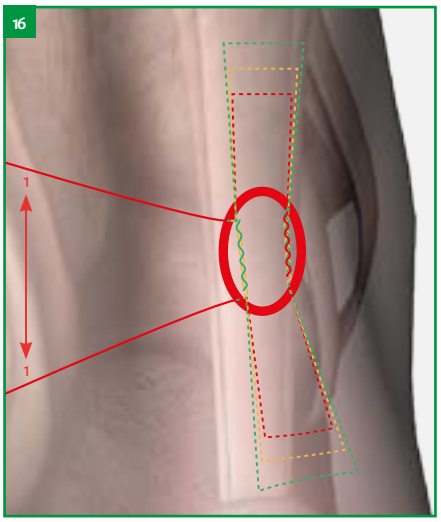
Correctly organize the suture pairs. They must not cross the midline: the sutures coming out on the lateral side have to remain lateral and those on the medial side have to remain medial.



Step 16 • Tendon suture

The sutures are tied by corresponding pairs.

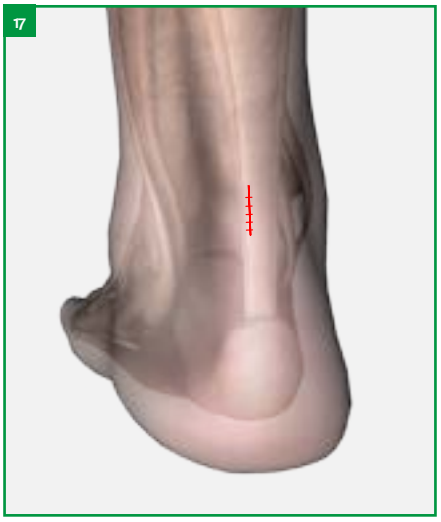
Note
If the tendon is frayed and prevents any landmark for control of length, then the tendon tension should be compared to the opposite leg.



Step 17 • Closure

Careful closure of paratenon and skin.

Post-operative cares
The ankle is maintained in 30° of plantarflexion with a splint, during the first three weeks. It is then progressively brought to the neutral position over the following five weeks. Always be sure of patient compliance.



Instrumentation

Achillon®

Reference	Description
119 700	One Achillon® instrument
	One needle drive
	Two surgical needles of 1.6mm diameter

Notes

Integra®

Achillon® - Minimal invasive Achilles tendon suture system

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Please read carefully the instructions for use.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- WARNING: Applicable laws restrict these products to sale by or on the order of a physician.

All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE MARKED". Products mentioned in this document are CE class IIa. Please contact Integra customer service should you need any additional information on devices classification.

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