

SINGLE USE KIT

STERILE R



NEWCLIP
TECHNICS



INITIAL SiTa



With a non sterile standard kit



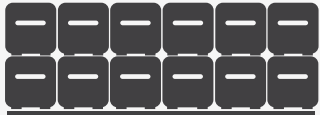
Calling on medical staff

Constraints > Complex traceability + Contracted out sterilization + Suppliers' deadline

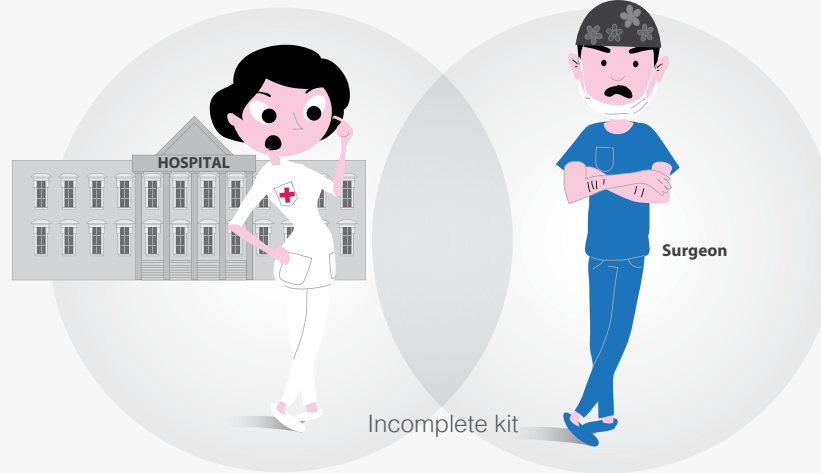
High costs



- \$ Stocks
- \$ Control
- \$ Cleaning
- \$ Decontamination
- \$ Sterilization



Bulky storage



Complex process



Prevents an effective solution & a quick response



Defective sterilization



Incomplete kit



Damaged instrumentation



INCREASED RISKS
NON OPTIMAL surgery



URGENT SURGICAL CASES COMPROMISED

Safety



TRACEABILITY
100%



STERILE R
SINGLE USE KIT



Always
NEW



Risk
of contamination

Cost efficiency



Controlled stocks
Simplified control

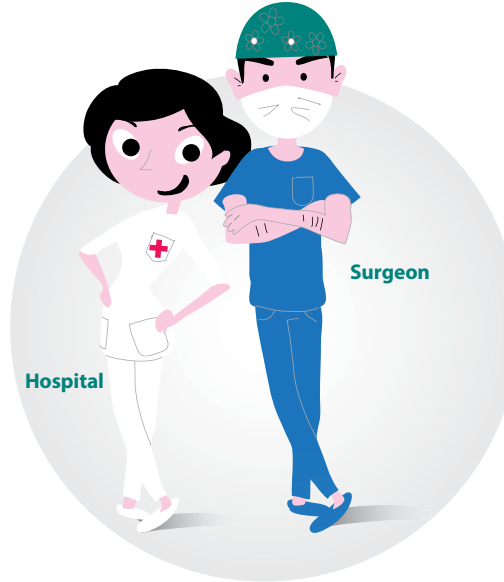
- 0 Cleaning
- 0 Decontamination
- 0 Sterilization



Sundry
expenses



Optimized storage



Hospital

Surgeon



STERILE R SINGLE USE KIT

with state-of-the-art implants

Efficiency



- 1 Delivery
- 2 Storage
- 3 Surgery



An effective
solution &
a quick response



Available when
needed



READY-TO-USE FOR
SURGERY

+ Optimized handling of
URGENT SURGICAL CASES

Ready
when you are!



Safety:

The Initial F™ SiTa kit is fully traceable and has a shelf life of 5 years. The instrumentation is always new and has never been opened or used before.



Available when needed:

The Initial F™ SiTa kit comes pre-sterilized and ready to use, ideal for use in urgent surgical cases.



Storage:

Initial F™ SiTa can be easily stored in the operating room because of its small size.



Costs:

Initial F™ SiTa is a cost-effective solution. The additional costs including cleaning, decontamination, sterilization of kits are cancelled.



Contamination:

Sterile single-use instrumentation minimizes contamination risks.



Buying procedure:

Initial F™ SiTa facilitates buying procedures: restocking and orders are simplified, stock management is optimized.

Kit content



> Intended purpose

The subtalar screws of the SiTa range are intended for hyperpronated foot surgery.

The Initial F™ SiTa kits consist of sets of instruments to be used only in orthopaedic surgery, when Newclip Technics subtalar screws are implanted or explanted.

> Contraindications

- Pregnancy.
- Acute or chronic local or systemic infections.
- Allergy to one of the materials used or sensitivity to foreign bodies.



Reading gauge incorporated in the blister to verify the templates' size

Kit features

> Screwdriver

The Initial F™ SiTa screwdriver is compatible with the dilator and the 5 templates from the single use kit as well as the 5 associated implants.

The screwdriver is composed of:

• Handle (a)



• Cannulated threaded rod (b)



The cannulated rod is inserted through the handle.



This assembly guarantees a secured lock between the screwdriver and the desired device (dilator, template or implant). This is achieved by turning the rod clockwise once the device has been connected to the screwdriver. To release, turn the rod anticlockwise.



> Templates

The Initial F™ SiTa kit includes 5 different size templates in a radiopaque plastic. They correspond to 5 associated subtalar arthroereisis screws. The template allows to select the appropriate size of implant for the desired correction.



⚠ CAUTION: Do not use template to widen the sinus tarsi.

Implant features

> Design features of the subtalar arthroereisis screws

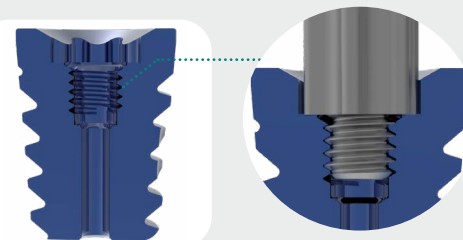
Subtalar arthroereisis screws available separately in a sterile version (S-box) (see page 10).



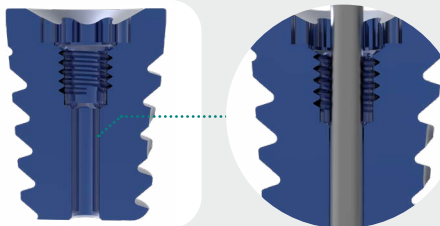
Implant manufactured from titanium alloy for mechanical strength and biocompatibility.



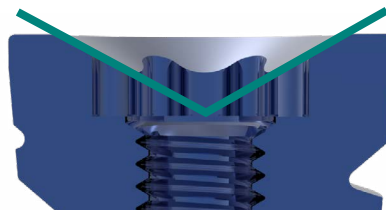
Range of 5 implants from Ø8.0 mm to Ø12.0 mm (1 mm incrementation).



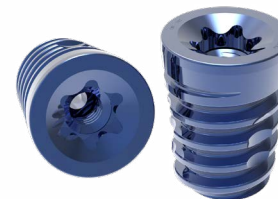
Monobloc connection between the device and the screwdriver allowing anchorage testing of the template before the final selection of the implant.



Optimized cannula for Ø2.0 mm pins allowing insertion in the sinus tarsi canal.



Screw head designed to ease insertion of the screwdriver in the stamp.



Standard T40 stamp minimizing stripping and improving driving force.

Surgical technique

Example: surgical technique using a $\varnothing 9.0$ mm L14 mm subtalar arthroereisis screw (H2.1YT9.0L14D-ST)

(Same technique for all screw sizes)

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HOW TO USE THE SCREWDRIVER



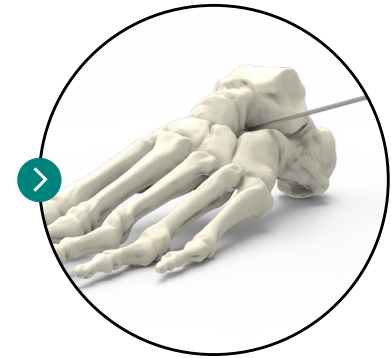
1. Insert the rod through the handle.



2. Place the device on the screwdriver.



3. Turn the rod clockwise to lock the device to the screwdriver. To release, turn the rod anticlockwise.

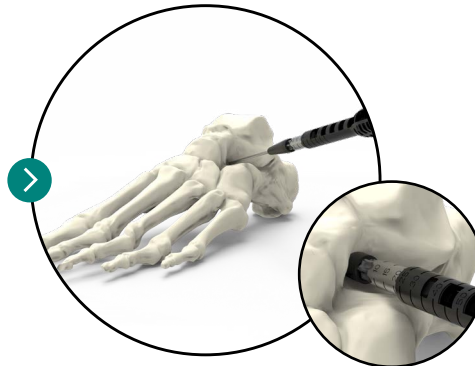


1. Make an incision proximal to the anterior process of the calcaneus and along the course of the intermediate dorsal superficial peroneal nerve.

Dissect the subcutaneous tissue on the sinus tarsi canal to prepare the insertion of the pin.

2. Insert the $\varnothing 2.0$ mm pin through the sinus tarsi canal. The pin must touch the skin on the medial side.

N.B.: A small incision can be made to hold the pin in position on the medial side of the foot.



3. Lock the dilator to the screwdriver (see "how to use the screwdriver").

Then, insert the whole assembly along the pin to widen the sinus tarsi canal prior to the insertion of the templates and the implant.

After widening, remove the construct, leaving only the pin in place.

4. Lock the smallest template ($\varnothing 8.0$ mm) to the screwdriver (see "how to use the screwdriver").

Insert the assembly along the pin and check the eversion of the calcaneus. Increase the size of the template until finding the desired correction.

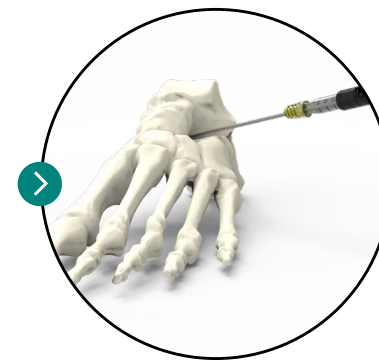
N.B.: Evaluate the positioning via X-ray (anterior, posterior and lateral). The template and implant should not be medial to the midline of the talar neck.

Surgical technique

Example: surgical technique using a $\varnothing 9.0$ mm L14 mm subtalar arthroereisis screw (H2.1YT9.0L14D-ST)

(Same technique for all screw sizes)

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5. When the desired correction is reached with the template, note the depth of the screwdriver at the skin level. Select the corresponding sterile screw (see "corresponding table").

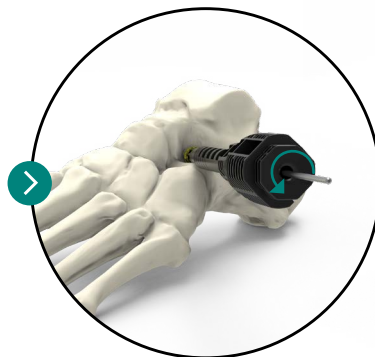
Remove the whole construct, leaving only the pin in place.

6. Lock the corresponding sterile implant to the screwdriver (see "how to use the screwdriver") and insert the assembly along the pin.

Position the subtalar arthroereisis screw and ensure the depth of the insertion is identical to the one on step 5.

CORRESPONDING TABLE

| TEMPLATES | | IMPLANTS |
|---|---|--|
|  |  |  H2.1YT8.0L14D-ST |
|  |  |  H2.1YT9.0L14D-ST |
|  |  |  H2.1YT10.0L14D-ST |
|  |  |  H2.1YT11.0L16D-ST |
|  |  |  H2.1YT12.0L16D-ST |



7. Disconnect the instrument from the implant (see "how to use the screwdriver").

Remove the screwdriver, and the pin.



FINAL RESULT

Initial F™ SiTa kit

INITIAL F™ SITA KIT - INSTRUMENTATION CONTENT

| Ref. | Description | Content | Qty | Colour |
|---------|---|--|-----|--------|
| KIT-SCY | Instrumentation kit for subtalar arthroereisis screws | Dilator for subtalar arthroereisis screw | 1 | - |
| | | Screwdriver for subtalar arthroereisis screw | 1 | - |
| | | Template for subtalar arthroereisis screw H2.1YT8.0L14D | 1 | ● |
| | | Template for subtalar arthroereisis screw H2.1YT9.0L14D | 1 | ● |
| | | Template for subtalar arthroereisis screw H2.1YT10.0L14D | 1 | ● |
| | | Template for subtalar arthroereisis screw H2.1YT11.0L16D | 1 | ● |
| | | Template for subtalar arthroereisis screw H2.1YT12.0L16D | 1 | ● |
| | | Pin Ø2.0 mm L250 mm | 2 | - |



Implants

Subtalar arthroereisis screws available separately in a sterile version (S-box).

STERILE IMPLANTS

| Ref. | Description | Anodized screw colour |
|-------------------|---|-----------------------|
| H2.1YT8.0L14D-ST | Ø8.0 mm subtalar arthroereisis screw - cannula Ø2.1 - L14 mm - STERILE | ● |
| H2.1YT9.0L14D-ST | Ø9.0 mm subtalar arthroereisis screw - cannula Ø2.1 - L14 mm - STERILE | ● |
| H2.1YT10.0L14D-ST | Ø10.0 mm subtalar arthroereisis screw - cannula Ø2.1 - L14 mm - STERILE | ● |
| H2.1YT11.0L16D-ST | Ø11.0 mm subtalar arthroereisis screw - cannula Ø2.1 - L16 mm - STERILE | ● |
| H2.1YT12.0L16D-ST | Ø12.0 mm subtalar arthroereisis screw - cannula Ø2.1 - L16 mm - STERILE | ● |



References

Removal kit

Sterile instruments available separately.

| REMOVAL KIT | | | |
|--------------|--|---|--------|
| Ref. | Description | Content | Qty |
| KIT-REMOVE-7 | Removal kit for subtalar arthroereisis screw | - Screwdriver for subtalar arthroereisis screw - Pin Ø2.0 mm L250 mm | 1 1 |



Ready
when you are!

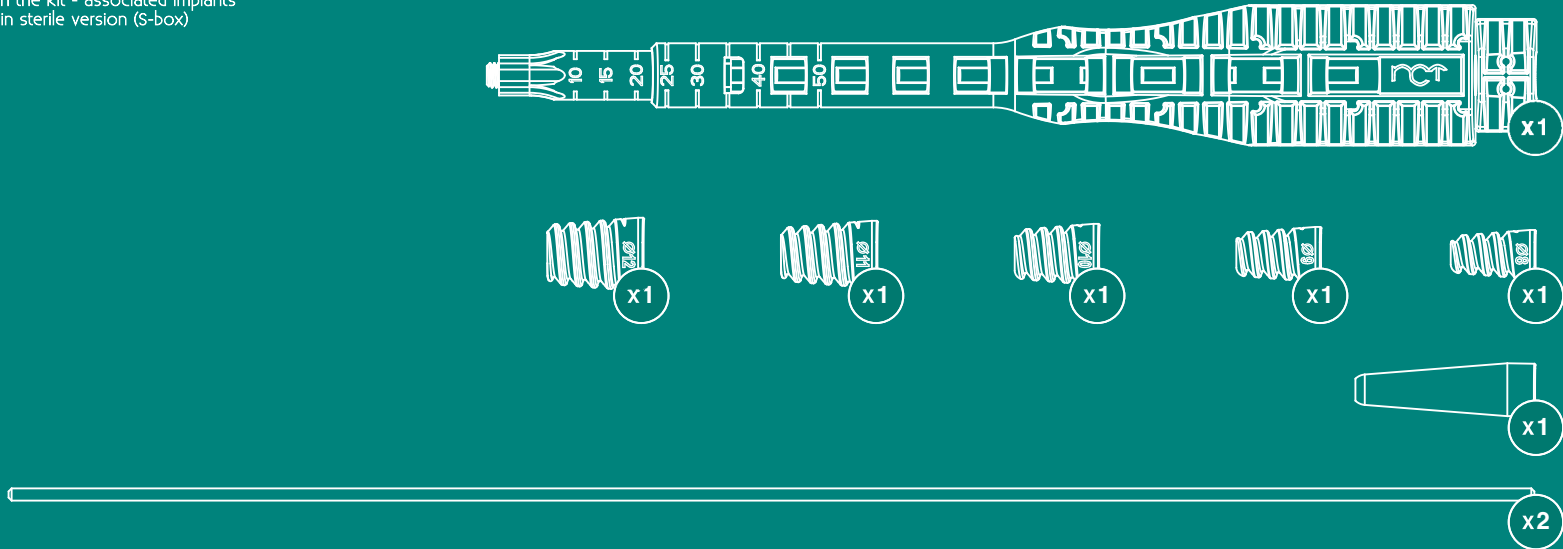
This information is intended to demonstrate the Newclip Technics portfolio of medical devices. Always refer to the package insert, product label and/or user instructions before using any Newclip Technics product. These products must be handled and/or implanted by trained and qualified staff who have read the instructions before use. A surgeon must always rely on her or his own professional clinical judgement when deciding whether to use a particular product when treating a particular patient. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Newclip Technics representative if you have questions about the availability of Newclip Technics products in your area.

KIT- SCY

Instrumentation for subtalar arthroereisis screws*

*Templates included in the kit - associated implants available separately in sterile version (S-box)

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