

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

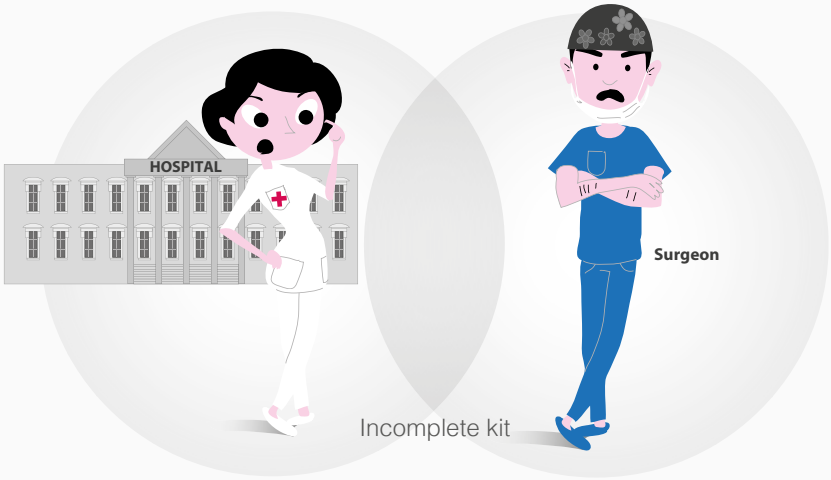
High costs



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



Bulky storage



Complex process



- | | | | |
|---------------------------|----------------------------|---------------------|-----------------------|
| 1
Delivery | 2
Storage | 3
Unpacking | 4
Control |
| 5
Decontamination | 6
Cleaning | 7
Drying | 8
Control |
| 9
Packaging of the kit | 10
Sterilization | 11
Surgery | 12
Decontamination |
| 13
Cleaning | 14
Drying | 15
Control | 16
Traceability |
| 17
Restocking | 18
Packaging of the kit | 19
Sterilization | 20
Storage |

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%



Risk
of contamination

Cost efficiency



Controlled stocks
Simplified control

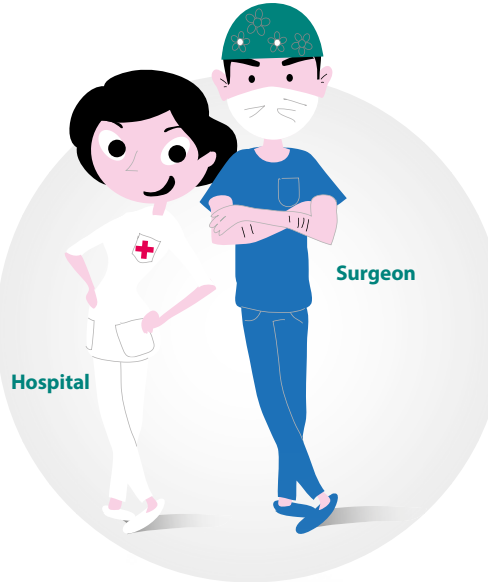
- 0 Cleaning
- 0 Decontamination
- 0 Sterilization



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!



TRACEABILITY:

- Easiest traceability with detailed label sheets.
- Easy inventory management.
- Streamlining of logistic monitoring for nurses and pharmacists.



RESPONSIBILITY:

- External packaging in recyclable cardboard.
- Dematerialized instructions for use.
- Less CO2 emissions during manufacture and use than a reusable kit⁽⁶⁾.



PRACTICALITY:

- Immediate identification and intuitive use.
- Ergonomic format for gears.
- Simplified orderings.



AVAILABILITY:

- Equipment availability: no restocking and waiting time.
- Shorter and easiest process⁽⁵⁾.
- Full range of latest-generation implants in sterile format.
- No interruption of preoperative flow⁽³⁾.



EFFICIENCY:

- Less transportation costs.
- No sterilization costs for hospitals.
- Reduced operative costs⁽³⁾.
- Reduced perioperative time⁽⁴⁾.
- Reduced receiving and handling costs.
- Increased turnover in the OR⁽⁴⁾.



SAFETY:

- Reduced risk of contamination⁽¹⁾.
- Reduced risk of a bacterial biofilm formation⁽²⁾.
- New instruments for each surgery.

(1) Mont et al. Single-use instrumentation, cutting blocks, and trials decrease contamination during total knee arthroplasty: a prospective comparison of navigated and nonnavigated cases. J Knee Surg. 2013;26(4):285–290. - (2) Costa D de M, Lopes LK de O, Tipple AFV, Johani K, Hu H, Deva AK, et al. Evaluation of stainless-steel surgical instruments subjected to multiple use/processing. Infect Dis Heal. 2018;23(1):3–9. - (3) Shippert RD. A Study of Time-Dependent Operating Room Fees and How to save \$100,000 by Using Time-Saving Products. Am J Cosmet Surg. 2005;22(1):25–34. - (4) Siegel GW et al., Cost Analysis and Surgical Site Infection Rates in Total Knee Arthroplasty Comparing Traditional vs. Single-Use Instrumentation. J Arthroplasty. 2015;30(12):2271–4. - (5) Matron P, Etude comparative économique et pratique de plaques d'ostéosynthèse de l'extrémité distale du radius présentées individuellement et en kit stérile "tout en un" dans un établissement de santé privé, 2016, 1–21. - (6) "Empreinte carbone comparée de deux dispositifs médicaux implantables" - Etude Carbon 4.

Kit content

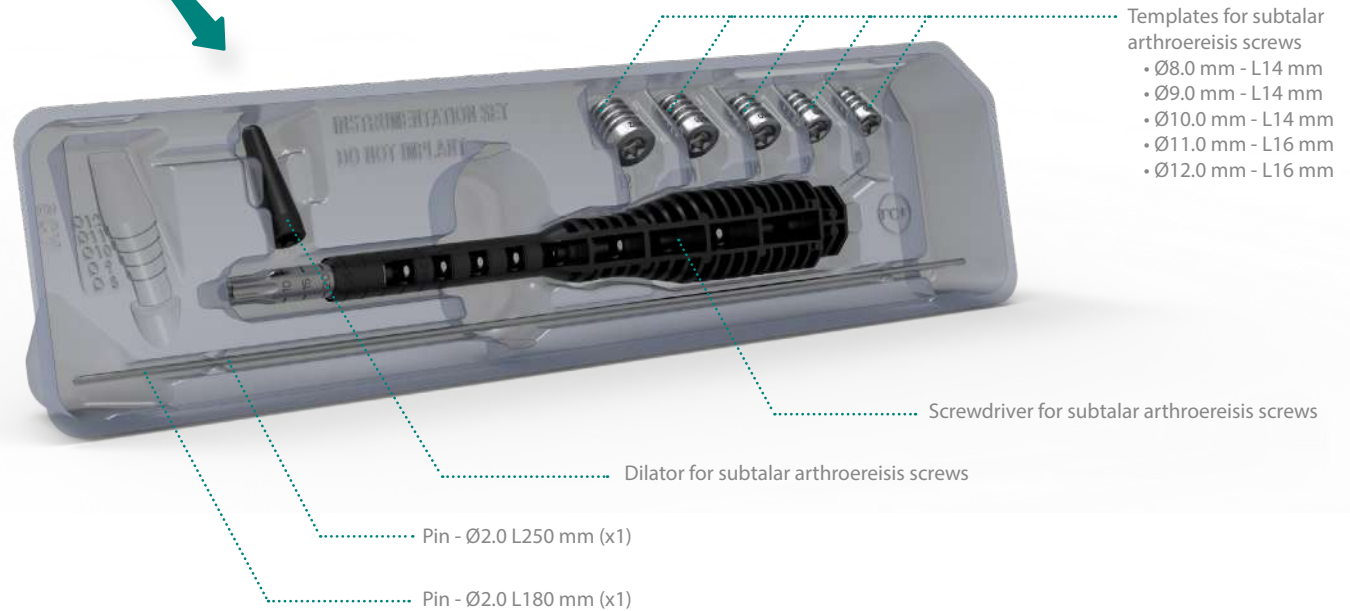
> Intended purpose

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.



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 permit to lock and remove implants, templates and dilator from the screwdriver. 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 five template sizes, each associated with a specific subtalar arthroereisis screw. The template allows to select the appropriate implant size according to the desired correction and must not be used to widen the sinus tarsi.

TEMPLATES		IMPLANTS
	 Ø8.0 mm - L14 mm	 H2.1YT8.0L14D-ST
	 Ø9.0 mm - L14 mm	 H2.1YT9.0L14D-ST
	 Ø10.0 mm - L14 mm	 H2.1YT10.0L14D-ST
	 Ø11.0 mm - L16 mm	 H2.1YT11.0L16D-ST
	 Ø12.0 mm - L16 mm	 H2.1YT12.0L16D-ST
 CAUTION: Do not implant the templates.		

Implant features

> Design features of the subtalar arthroereisis screws

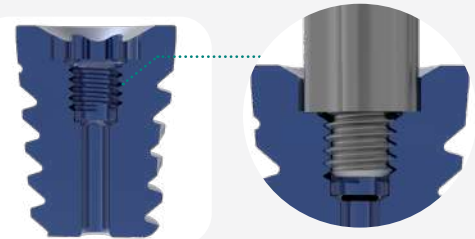
Subtalar arthroereisis screws available separately in a sterile version (*see page 10*).



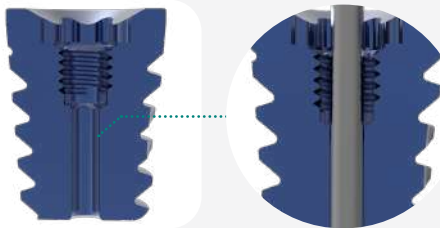
Implant manufactured from titanium alloy for mechanical strength and biocompatibility.



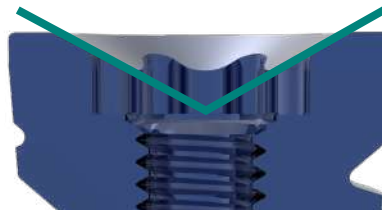
Range of 5 implants from Ø8.0 mm to Ø12.0 mm (1 mm incrementation).



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



Cannula for Ø2.0 mm pins designed to guide the implant within the sinus tarsi canal.



Screw head designed to facilitate screwdriver insertion into the recess.



Standard T40 hexalobe recess

Surgical technique

Example: surgical technique using a Ø9.0 mm L14 mm subtalar arthroereisis screw (H2.1YT9.0L14D-ST)

(Same technique for all screw sizes)

Page 1/2

HOW TO USE THE SCREWDRIVER



Handle



Cannulated threaded rod

1. Place the device on the screwdriver.

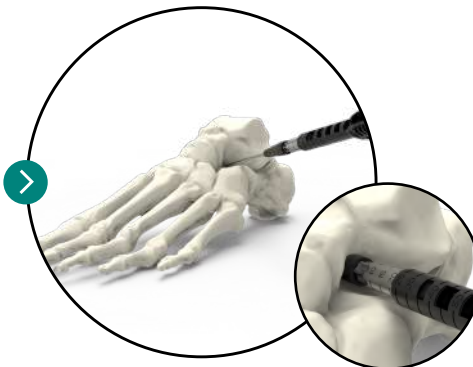


2. Turn the rod clockwise to lock the device to the screwdriver. To release, turn the rod anticlockwise.



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

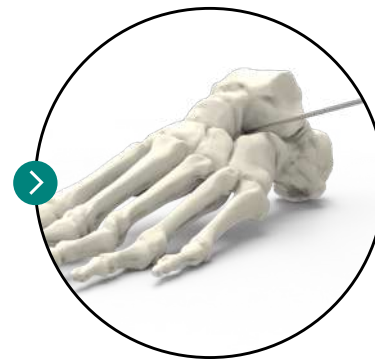
Dissect the subcutaneous tissue on the sinus tarsi canal to prepare the insertion of the pin.



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

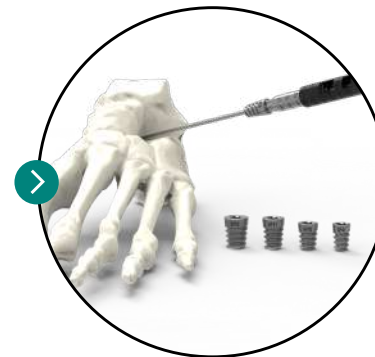
Then, insert the whole assembly along the pin to widen the sinus tarsi canal prior to the insertion of the templates and the implant.

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



2. Insert the Ø2.0 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.



4. Lock the smallest template (Ø8.0 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.

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

Surgical technique

Example: surgical technique using a Ø9.0 mm L14 mm subtalar arthroereisis screw (H2.1YT9.0L14D-ST)

(Same technique for all screw sizes)

Page 2/2

CORRESPONDING TABLE

TEMPLATES

IMPLANTS



H2.1YT8.0L14D-ST



H2.1YT9.0L14D-ST



H2.1YT10.0L14D-ST



H2.1YT11.0L16D-ST



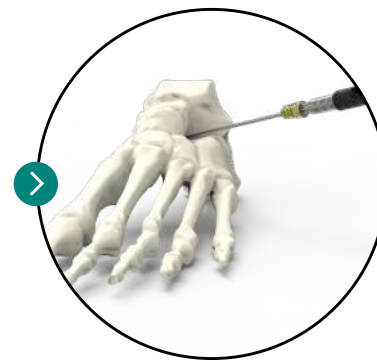
H2.1YT12.0L16D-ST



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”).

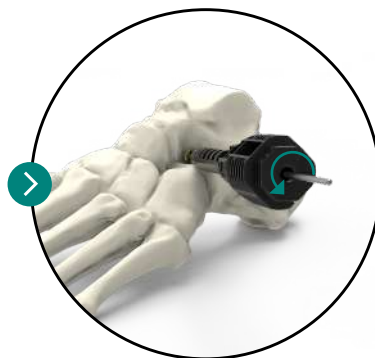
Remove the whole construct, leaving only the pin in place.

Warning: Do not use template to widen the sinus tarsi.



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.



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

Remove the screwdriver, and the pin.



FINAL RESULT

References

Initial F SiTa kit

INITIAL F SITA KIT - INSTRUMENTATION CONTENT

Ref.	Description	Content	Qty
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	1
		Pin Ø2.0 mm L180 mm	1



Implants

Subtalar arthroereisis screws available separately in a sterile version.

STERILE IMPLANTS

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



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

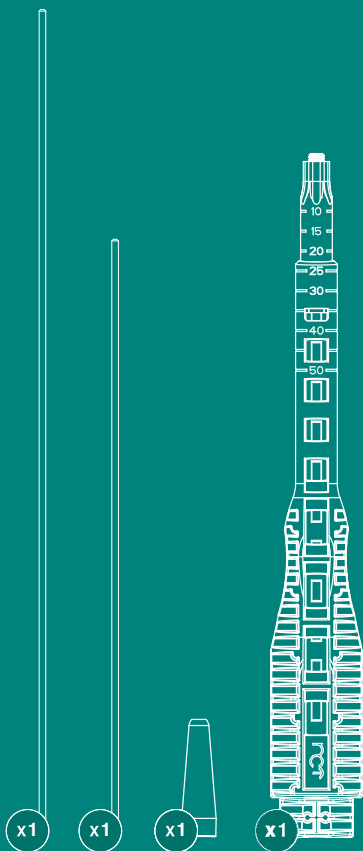


Ready
when you are!

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



Do not implant the templates.
Screws are available separately.



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F
INITIAL
SiTa



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