ST SURGICAL TECHNIQUE

enovis™

# AIRLOCK®

ANKLE PLATING SYSTEM

PLATING SYSTEM

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Novastep® S.A.S is a manufacturer of orthopedic implants and does not practice medicine. This surgical technique was prepared in conjunction with licensed health care professionals. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

See package insert for complete list of potential adverse effects, contraindications, warnings and precautions.

A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions, if applicable. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient.

Some implants / instruments are not available in all territories. For more information, please contact your local sales representative.

# INDICATIONS & CONTRAINDICATIONS



## INDICATIONS

The osteosynthesis screw-plate systems are indicated for arthritis (Hallux Rigidus, Osteoarthritis), Hallux valgus and other bone alignment defaults (Hallux Varus, Flatfoot, Cavus foot).

## EXAMPLE OF USE

Tibio-talar arthrodesis

NOTE: Detailed information on each medical device is provided in the instructions for use. Refer to the instructions for use for a complete list of side effects, warnings, precautions, and directions for use.

## CONTRAINDICATIONS

- Severe muscular, neurological or vascular deficiency in the extremity concerned.
- Bone destruction or poor bone quality likely to impair implant stability.
- Hypersensitivity to vanadium and/or aluminium.

# DESIGN FEATURES



Airlock® anterior ankle arthrodesis plates, made of titanium alloy, allow fusion of the tibio-talar joint.
Available in mini and medium versions, as right and left options, with a design optimized to minimize the initial tibial incision and preserve soft tissue.

## AIRLOCK® ANKLE PLATES

### 1 MINI ANTERIOR PLATE

MINI plate thanks to reduced tibial part
MINI incision for mini invasive approach
MINImized design to limit subcutaneous discomfort

### 2 MEDIUM ANTERIOR PLATE

Anatomical helitorsion: proximal part designed to adapt to the tibia curvature

### LOW PROFILE PLATE

. 2mm proximal thickness
. Optimized to limit subcutaneous discomfort

### ORIENTATION MARKS:

**Tibial axis**
Precise positioning of the plate in relation to the tibial axis

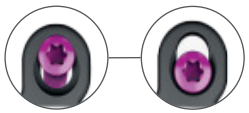
**Compressive screw**
Indicated positioning of the compressive screw in relation to the plate

### SHORT TALAR NECK

. Minimized incision
. Wider anatomical adaptation
. Talar anchorage maximized by various defined directions of the 3 locking screws


### STANDARD COMPRESSION HOLE

. Accomodates with Ø4 and Ø4.7 non-locking screws
. Delivers up to 3 mm of additional compression



### UNIVERSAL HOLES

. Threaded holes for Ø4 and Ø4.7 locking or non-locking screws
. Optimized design for complete burial of screw heads

## AIRLOCK® ANKLE PLATES & SCREWS


**Anterior mini plates**
. Length: 50 mm
. Width: 26 mm
. Thickness: 2 mm (proximal) & 4 mm (distal)


**Anterior medium plates**
. Length: 86 mm
. Width: 28 mm
. Thickness: 2 mm (proximal) & 4 mm (distal)

### Ø4 AND Ø4.7 LOCKING AND NON-LOCKING SCREWS


**SCREW HEAD:**
. Smooth edge: protects soft tissue
. Conical head
. T15 retentive recess

**SCREW TIP:**
. Self-tapping

**POLYAXIAL LOCKING:**
. Angulation cone possible up to 20° on tibial part
. Double thread: ensures a stable & strong locking system
. Straight flute: locks the screw into the hole

## CUTTING GUIDE

The cutting guide enables quick parallel cuts of the tibio-talar articular surfaces.

① **GUIDED POSITIONING**
on the joint thanks to the centering device and orientation marker

② **CHOICE OF CORRECTION**
in all spatial planes before stabilizing the guide with the positioning pins

③ **PRECISE BONE CUTS**
through the tibio-talar cutting window

**NOTE:** The saw blade should be :
Cutting Thickness : 1.27 mm
Width : 17 mm or between 15-19 mm
Length : 100 mm or between 90-110 mm

## TIBIO-TALAR QUICK-DRILL GUIDE

Adapted to mini and medium anterior plates, the tibio-talar quick-drill guide simplifies the steps required to **prepare** the holes, **insert** the talar screws and **guide** the compression screw insertion.


① **RAPIDITY**
Simultaneous drilling and screw insertion on talar part

② **GUIDED PLACEMENT**
Of the tibio-talar compression screw to avoid conflict with the trajectory of the plate's screws

## 1. TIBIO-TALAR ARTHRODESIS

### 1.1 INCISION & EXPOSURE

Perform a longitudinal incision on the medial line at the anterior ankle. The size of the incision must be adapted to the desired plate size (FIGURE 1).

FIGURE 1

### 1.2 ARTICULAR SURFACES PREPARATION WITH CUTTING GUIDE

If necessary, resect the anterior tibial margin using an oscillating saw.

**Cutting guide positioning:** Using a centering device, locate the tibial ceiling and insert the centering device into the tibiotalar joint (FIGURE 2).

FIGURE 2

Once the centering device is positioned, place the cutting guide through the centering window attached to the cutting guide.

NOTE: Assembly of centering window to cutting guide :

1 - Push the centering window upwards

2 - Release and screw the dial to fix the assembly


Orient the cutting guide in the axis of the tibial crest and parallel to the tibia (FIGURE 3 A & B). Insert the first two positioning pins into proximal holes on the tibia to stabilize the position (FIGURE 4).

Once the guide is stabilized, the centering device and the centering window can be removed.

Manipulate the foot in the different planes of space to find the desired correction (FIGURE 5).

Stabilize the montage by inserting two positioning pins into distal holes on the talus.

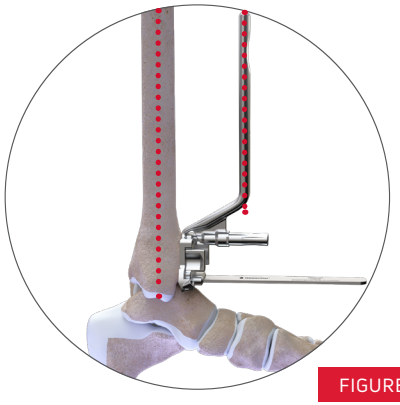


FIGURE 3A

FIGURE 3B

FIGURE 4

FIGURE 5

**Bone cuts:** Position the tibio-talar cutting window on the central part of the cutting guide frame. (FIGURE 6).

Unscrew the dial to clear the passage and push the cutting window up. Once the window is correctly positioned, push the dial and screw to secure the assembly.

NOTE: Use the A0 T15 screwdriver tip, compatible with the dial footprint, to lock the window in place on the cutting guide.

Perform the cuts of the articular surface of the tibia and the base of the talus with the saw blade through the cutting windows (FIGURE 7).

NOTE: Articular surfaces can also be prepared without the cutting guide, using a distractor and a saw blade or osteotome or rongeur.

Remove positioning pins and cutting guide. Remove all residual bone fragments and check that the bone surfaces have been properly prepared. If necessary, perform a transverse osteotomy or a shortening osteotomy of the fibula (FIGURE 8).

A K-wire can be placed across the tibio-talar joint to stabilize bone fragments.

FIGURE 6

FIGURE 7

FIGURE 8

## 1.3 PLATE POSITIONING

**Trial plate positioning:** Trial anterior plates are available to select the most adapted plate size according to the anatomy of the joint. The trial plates are equipped with a grip bar for easy handling (FIGURE 9).

NOTE: Preparation of the tibial metaphysis and neck of the talus may be necessary to improve congruence between the plate and the bone surface.


FIGURE 9

Optional use of plate benders for medium plates (FIGURE 10):

NOTE: Depending on the patient's anatomical specificities, our plate benders may be used. Over-bending of the medium plate must be strictly avoided. Only minimal, unidirectional contouring is permitted in order to prevent the formation of stress concentration areas.

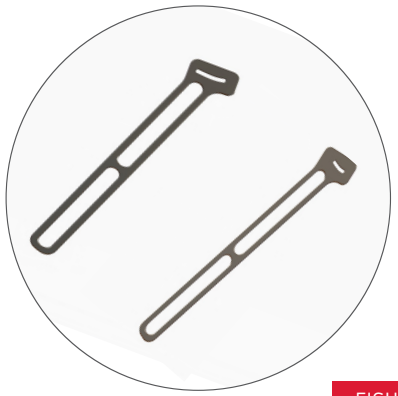


FIGURE 10


FIGURE 11

First, insert the distal plate bender (wide slot) (FIGURE 11) onto the medium plate, then insert the proximal plate bender (small slot) (FIGURE 12) onto the proximal zone of the plate to be slightly contoured (FIGURE 13).


FIGURE 12


FIGURE 13

NOTE: Following steps can also be done without the tibio-talar quick drill guide. Use spheric positioning pins to stabilize the plate.

Plate positioning:

Before positioning the chosen plate on bones, place the tibio-talar quick drill guide on the talar part of the plate. Stabilize the assembly by screwing the central locking dial (FIGURE 14). Then, screw 2 drill guides onto the remaining holes.

Position the plate/tibio-talar quick-drill guide/drill guide assembly and check its position in relation to the joint.

Insert and let in place a drill bit Ø2.8 in the central locking dial to stabilize the plate (FIGURE 15).

Talar screws insertion:

Prepare the medial and lateral screw holes using the drill bit Ø2.8. Determine the appropriate screw length by directly reading through the open part of the drill guide and of the quick-drill block.
Remove the drill guide and then insert the locking polyaxial screw Ø4 using the AO T15 screwdriver tip (FIGURE 16).

NOTE:

Using the drill bit through the drill guide enables drilling to a depth of up to 25 mm, where resistance is encountered.

The screw length can also be determined using a depth gauge through the quick-drill block after removing the drill guide.

FIGURE 14

FIGURE 15

FIGURE 16

## 1.4 COMPRESSION AND PLATE FIXATION

**NOTE:** Compression is applied in three steps:

1- Pre-positioning the screw in the compression hole

2- Inserting the Nexis® Ø7 compressive screw

3- Finalizing screw insertion into the compression hole

Pre-positioning of screw in compression hole :

To stabilize and maintain correct alignment of the ankle, pre-position a non-locking Ø4 or Ø4.7 screw in the standard compression hole by following the steps below.

Use the oblong drill guide to prepare the screw hole using the drill bit Ø2.8 or Ø3.6.

Determine the appropriate screw length by direct reading or using the depth gauge, after removing the drill guide (FIGURE 17).

Position the chosen non-locking screw Ø4 or Ø4.7 in the oblong hole using the AO T15 screwdriver tip (FIGURE 18).

Stop the screw insertion before complete contact with the plate (FIGURE 19).

FIGURE 17

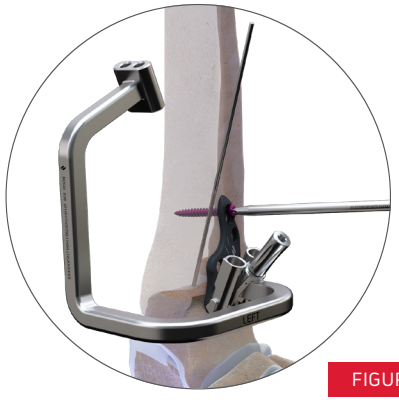


FIGURE 18

FIGURE 19

Nexis® Ø7 compression screw insertion:

Position the K-wire sleeve - Nexis® Ø7 screw in the anterior or posterior hole in the upper part of the tibio-talar quick drill guide, according to the patient's anatomy. Then perform an incision above the medial malleolus.

Through the K-wire sleeve, insert a K-wire Ø2.2 lg200 from the tibia to the talus, following the laser marking on the plate (FIGURE 20).

Unscrew the central locking dial and remove the stabilization K-wire and the tibio-talar quick drill guide.

Determine the appropriate screw length using the ruler lg 180/200. A Nexis® Ø7 screw is chosen that is 5-10 mm shorter than the indicated length to ensure that the implant is fully recessed after insertion.

OPTION 1 :

Use the T25 AO screwdriver tip to insert the Nexis® compressive screw Ø7 manually or with a power tool.

OPTION 2 :

Prepare the bone housing using the dedicated drill bit Ø4.8 and the countersink reamer Ø6. Insert the Nexis® compressive screw Ø7 with the T25 AO screwdriver tip.

FIGURE 20

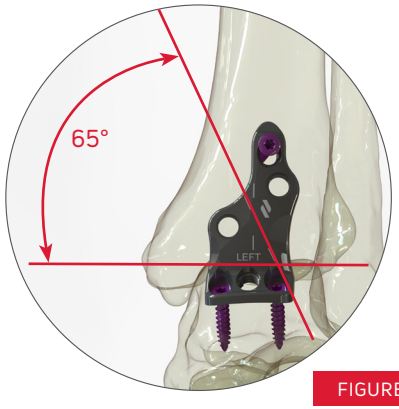



FIGURE 21

NOTE: The ideal angulation of the tibio-talar screw according to the radiographic analysis is 65°* (FIGURE 21).

** Based on internal radiographic analysis*

**Finalizing insertion into compression hole:** Once the Nexis® Ø7 has been inserted, finalize the non-locking screw Ø4 or Ø4.7 insertion in the standard compression hole to provide additional compression. (FIGURE 22).

**Talar screws insertion:** Finalize the talar stabilization by inserting the central talar screw.

**Tibial screws insertion:** Finalize the positioning of the plate by inserting the tibial screws.

According to the type of screw required, position the polyaxial (FIGURE 23) or the locking drill guide on one of the slot, at the tibial part of the plate.

Prepare the screw hole using the drill bit Ø2.8 or Ø3.6. Determine the appropriate screw length by direct reading or using the depth gauge (after removing the drill guide) then insert the locking polyaxial or non-locking screw Ø4 or Ø4.7 using the AO T15 screwdriver tip.

Repeat these steps for the remaining holes (FIGURE 24).

Check the construct stability and confirm placement using fluoroscopy.

FIGURE 22


FIGURE 23


FIGURE 24

# ORDERING INFORMATION



## ANTERIOR MINI PLATE

| PART NO. | DESCRIPTION |
|---|---|
| PL090110 | ANTERIOR MINI PLATE RIGHT |
| PL090210 | ANTERIOR MINI PLATE LEFT |

## ANTERIOR MEDIUM PLATE

| PART NO. | DESCRIPTION |
|---|---|
| PL090140 | ANTERIOR MEDIUM PLATE RIGHT |
| PL090240 | ANTERIOR MEDIUM PLATE LEFT |

## LOCKING POLYAXIAL SCREWS

| PART NO. | DESCRIPTION |
|---|---|
| SP0140XX | Ø 4 mm |
| SP0147XX | Ø 4.7 mm |

*With XX from 16 to 60 in 2 mm increments up to 50 and 5 mm increments up to 60.*

## NON LOCKING SCREWS

| PART NO. | DESCRIPTION |
|---|---|
| SP0440XX | Ø 4 mm |
| SP0247XX | Ø 4.7 mm |

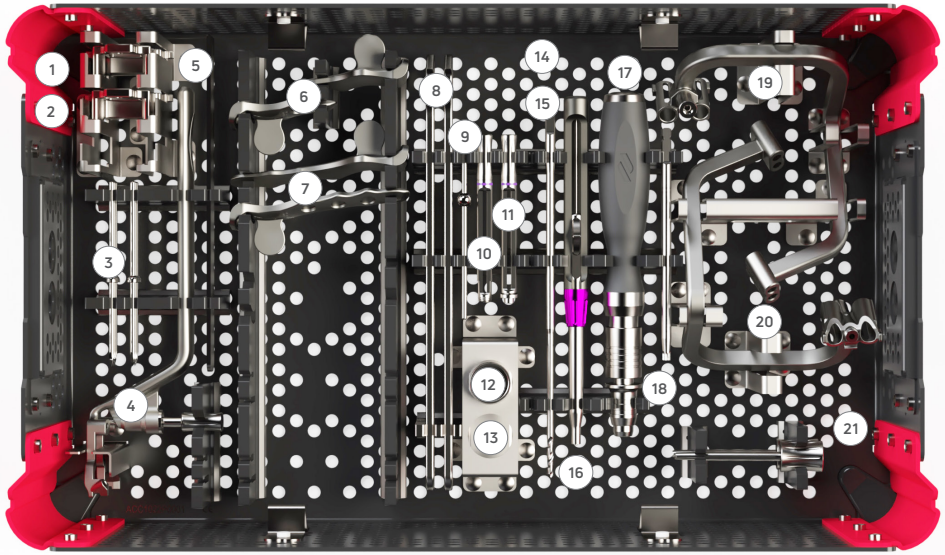
*With XX from 16 to 60 in 2 mm increments up to 50 and 5 mm increments up to 60.*

## NEXIS® Ø7MM COMPRESSIVE SCREWS

| LENGTH (mm) | Ø7mm SHORT THREAD | Ø7mm LONG THREAD |
|---|---|---|
| 40 | SC070040 | SC080040 |
| 45 | SC070045 | SC080045 |
| 50 | SC070050 | SC080050 |
| 55 | SC070055 | SC080055 |
| 60 | SC070060 | SC080060 |
| 65 | SC070065 | SC080065 |
| 70 | SC070070 | SC080070 |
| 75 | SC070075 | SC080075 |
| 80 | SC070080 | SC080080 |
| 85 | SC070085 | SC080085 |
| 90 | SC070090 | SC080090 |
| 95 | SC070095 | SC080095 |
| 100 | SC070100 | SC080100 |
| 105 | SC070105 | SC080105 |
| 110 | SC070110 | SC080110 |
| 115 | SC070115 | SC080115 |
| 120 | SC070120 | SC080120 |

# ORDERING INFORMATION






## AIRLOCK® ANKLE INSTRUMENTATION

| # | DESCRIPTION | PART NO. | QTY |
|---|---|---|---|
| - | TRAY | ACC1022P0001 | 1 |
| - | LID | ACC1022P0003 | 1 |
| 1 | CENTERING WINDOW | XMS01043 | 1 |
| 2 | TIBIO-TALAR CUTTING WINDOW | XMS01044-3 | 1 |
| 3 | POSITIONING PIN - CUTTING GUIDE - STERILE [1] | SKW09001 | 6 |
| 4 | CUTTING GUIDE FRAME | XMS01042 | 1 |
| 5 | CENTERING DEVICE | XMS01045 | 1 |
| 6 | ANTERIOR MINI TRIAL PLATE RIGHT | XTI09110 | 1 |
| 6 | ANTERIOR MINI TRIAL PLATE LEFT | XTI09210 | 1 |

*[1]Supplied separately.*

| # | DESCRIPTION | PART NO. | QTY |
|---|---|---|---|
| 7 | ANTERIOR MEDIUM TRIAL PLATE RIGHT | XTI09140 | 1 |
| 7 | ANTERIOR MEDIUM TRIAL PLATE LEFT | XTI09240 | 1 |
| 8 | PROXIMAL PLATE BENDER | XMS01048 | 1 |
| 8 | DISTAL PLATE BENDER | XMS01049 | 1 |
| 9 | SPHERIC POSITIONING PIN | XPP01006 | 2 |
| 10 | LOCKING DRILL GUIDE FOR SCREW Ø 4 AND Ø 4.7 | XDG01025 | 3 |
| 11 | OBLONG DRILL GUIDE FOR SCREW Ø 4 AND Ø 4.7 | XDG01026 | 1 |
| 12 | POLYAXIAL DRILL GUIDE FOR SCREW Ø 4 | XDG01031 | 1 |
| 13 | POLYAXIAL DRILL GUIDE FOR SCREW Ø 4.7 | XDG01032 | 1 |
| 14 | DRILL BIT Ø 2.8 | XDB01026 | 3 |
| 15 | DRILL BIT Ø 3.6 | XDB01027 | 3 |
| 16 | DEPTH GAUGE | XGA01012 | 1 |
| 17 | AO RATCHET HANDLE | XHA01002 | 1 |
| 18 | T15 AO SCREWDRIVER TIP | XSD08001 | 2 |
| 19 | TIBIO-TALAR QUICK DRILL - RIGHT | XDG01038 | 1 |
| 20 | TIBIO-TALAR QUICK DRILL - LEFT | XDG01039 | 1 |
| 21 | K-WIRE SLEEVE - NEXIS® Ø 7 | XMS01022-4 | 1 |

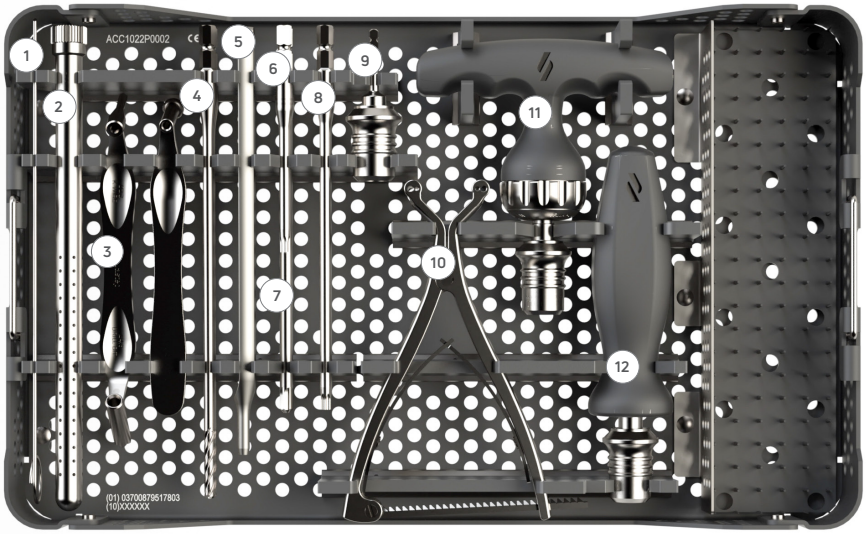
## SAW BLADES

| # | DESCRIPTION | PART NO. | QTY |
|---|---|---|---|
| - | STERILE SAW BLADE 100 x 17 x1.27<br>STRYKER CONNECTOR | 71.34.0751[2] | 2 |
| - | STERILE SAW BLADE 100 x 17 x1.27<br>SYNTHES CONNECTOR | 71.34.0095[2] | 2 |

*[2]Supplied separately.*

# ORDERING INFORMATION






## NEXIS® Ø 7 INSTRUMENTATION

| # | DESCRIPTION | PART NO. | QTY |
|---|---|---|---|
| - | UPPER TRAY | ACC1022P0002 | 1 |
| 1 | CLEANING PIN Ø 1.6 | XKW01003 | 1 |
| 2 | LONG K-WIRE TUBE | ACC1000P0003 | 1 |
| - | K-WIRE Ø 2.2 LG 200 TR/RD[1] - NON STERILE | - | 5 |
| - | K-WIRE Ø 2.5 LG 140 TR/RD[2] - STERILE | SKW05004 | 3 |
| 3 | DOUBLE DRILL GUIDE FOR SCREW Ø 7 | XDG01016 | 1 |
| 4 | CANNULATED DRILL GUIDE Ø 4.8 | XDB01010 | 1 |
| 5 | RULER LG 180/200 | XGA01007 | 1 |
| 6 | T25 LARGE AO SCREWDRIVER TIP | XSD06003 | 1 |
| 7 | COUNTERSINK Ø 6 | XRE01009 | 1 |
| 8 | SOLID T25 LARGE AO SCREWDRIVER TIP | XSD06002 | 1 |
| 9 | ADAPTATOR AO - 1/4 HEX | XHA01006 | 1 |
| 10 | OPEN ARMS DISTRACTOR | XFP01008 | 1 |
| 11 | LARGE AO T HANDLE RATCHET | XHA01004 | 1 |
| 12 | LARGE AO STRAIGHT HANDLE | XHA01003 | 1 |

*[1]K-wire supplied separately - Medetechnik® K-wire (33-T10-R-22-200) or Novastep® K-wire (CKW01011) are available depending on your market.*

*[2]K-wire supplied separately*

# NOTES

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*Carefully read the enclosed Instructions For Use (IFU) and all packaging label information. Devices: Implants: Class IIb-CE1639 / Instruments: Class I / Class Ir-CE1639 / Class IIa-CE1639.*

REFERENCE: AIR-ANK-ST-ED2-05-26-EN