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 avail able 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 osteosynthesis screw/plate system, 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
MINI 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
Guided positioning of the compressive screw in relation to the plate

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

SHORT TALAR NECK

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

AIRLOCK® ANKLE PLATES & SCREWS

Anterior mini plates
. Length: 50 mm
. Width: 32 mm
. Thickness: 2 mm (proximal) & 4 mm (distal)

Anterior medium plates
. Length: 86 mm
. Width: 32 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
. Helical 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

QUICK-DRILL BLOCK

Adapted to mini and medium anterior plates, the quick-drill block simplifies the steps required to prepare the holes and insert the talar screws.

① **OPTIMIZATION**
Positioning the quick-drill block on the plate upstream

② **RAPIDITY**
Simultaneous drilling and screw insertion

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

Resect the anterior tibial margin using an oscillating saw.

NOTE: Assembly of centering window to cutting guide :

1- Push the centering window upwards

2- Push and screw the dial to fix the assembly

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 over it via the centering window attached to the cutting guide.

Orient the cutting guide in the axis of the tibial crest and parallel to the tibia (FIGURES 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. Stabilize the construct by inserting two positioning pins into distal holes on the talus.

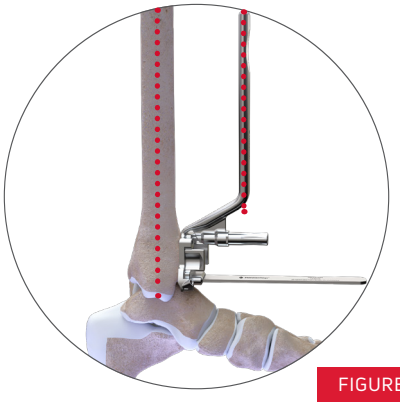


FIGURE 3A

FIGURE 3B

FIGURE 4

Bone cuts: Position the tibio-talar cutting window on the central part of the cutting guide frame. (FIGURE 5).

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.

FIGURE 5

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 6).

NOTE: Articular surfaces can also be prepared witout the cutting guide, using a distractor and a saw blade or osteotome or rongeur.

FIGURE 6

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.

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

1.3 PLATE POSITIONING

Trial plate positioning: Trial anterior plates are available to select the most adapted plate shape and size according to the anatomy of the joint. The trial plates are equipped with a grip bar for easy handling (FIGURE 7).

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

FIGURE 7

Plate positioning:

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

Before positioning the chosen plate on bones, place the quick-drill block on the talar part of the plate. Stabilize the assembly by screwing one of the three drill guides into the threaded holes through the quick-drill block. Then, screw the other two drill guides onto the remaining remaining holes (FIGURE 8).

FIGURE 8

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

Insert and let in place a drill bit Ø2.8 on the central distal talar hole to stabilize the plate (FIGURE 9).

Talar screws insertion: Prepare the medial and lateral screw holes using the drill bit Ø2.8. Determine the appropriate screw length by direct reading through the open part of the drill guide and of the quick-drill block.Then insert the locking polyaxial screw Ø4 using the AO T15 screwdriver tip (FIGURE 10). Repeat this steps for the central hole.

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

FIGURE 9

FIGURE 10

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 the 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 11).

Position the chosen non-locking screw Ø4 or Ø4.7 in the oblong hole using the AO T15 screwdriver tip (FIGURE 12).

Stop screwing before applying compression.

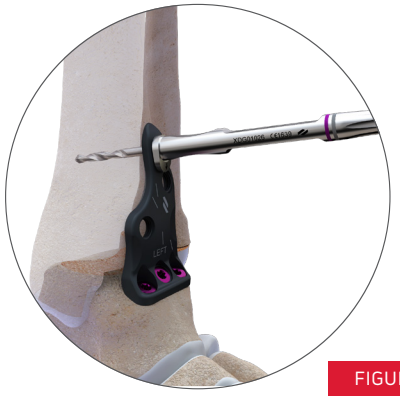


FIGURE 11

FIGURE 12

Nexis 7 compression screw insertion:

Remove stabilization k-wire and perform an incision above the medial malleolus.

Insert a k-wire Ø2.2 lg200 from the tibia to the talus, following the laser marking on the plate (FIGURE 13). Then 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.

NOTE: The ideal angulation of the tibio-talar screw according to the radiographic study is 65°* (FIGURE 14).

FIGURE 13

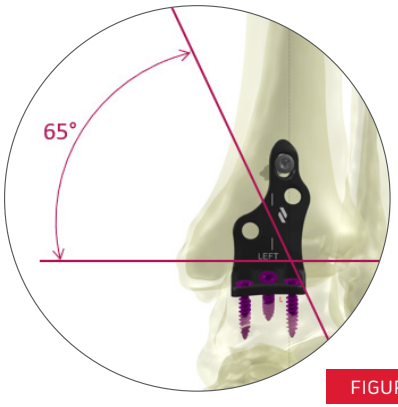


FIGURE 14

** 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 15).

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

According to the type of screw required, position the polyaxial 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 16).

Check the construct stability and confirm placement using fluoroscopy.

FIGURE 15

FIGURE 16

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

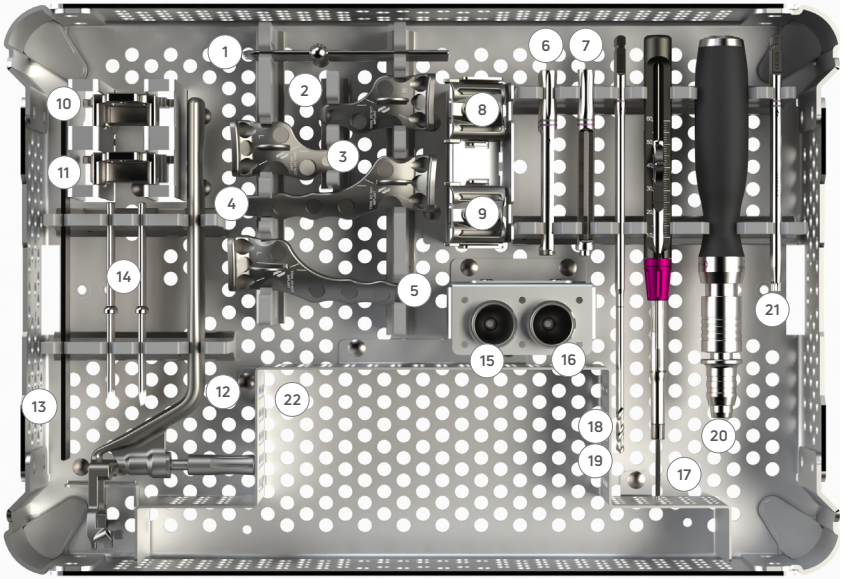
With XX from 14 to 60 in 2 mm increments up to 50 and 5 mm increments up to 60.

NON LOCKING SCREWS

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

With XX from 14 to 60 in 2 mm increments up to 50 and 5 mm increments up to 60.

ORDERING INFORMATION



AIRLOCK® ANKLE INSTRUMENTATION

#	DESCRIPTION	PART NO.	QTY
-	TRAY	acc1021P0001	1
-	LID	acc1021P0002	1
1	SPHERIC POSITIONING PIN	XPP01006	4
2	ANTERIOR MINI TRIAL PLATE RIGHT	XTI09110	1
3	ANTERIOR MINI TRIAL PLATE LEFT	XT09210	1
4	ANTERIOR MEDIUM TRIAL PLATE RIGHT	XTI09140	1
5	ANTERIOR MEDIUM TRIAL PLATE LEFT	XTI09240	1
6	LOCKING DRILL GUIDE FOR SCREW Ø 4 AND Ø 4.7	XDG01025	3
7	OBLONG DRILL GUIDE FOR SCREW Ø 4 AND Ø 4.7	XDG01026	1
8	QUICK-DRILL BLOCK - RIGHT	XMS01047-1	1
9	QUICK-DRILL BLOCK - LEFT	XMS01047-2	1
10	CENTERING WINDOW	XMS01043	1
11	TIBIO-TALAR CUTTING WINDOW	XMS01044-3	1
12	CUTTING GUIDE FRAME	XMS01042	1
13	CENTERING DEVICE	XMS01045	1
14	POSITIONING PIN - CUTTING GUIDE - STERILE	SKW09001	6
15	POLYAXIAL DRILL GUIDE FOR SCREW Ø 4	XDG01031	1
16	POLYAXIAL DRILL GUIDE FOR SCREW Ø 4.7	XDG01032	1
17	DEPTH GAUGE	XGA01012	1
18	DRILL BIT Ø 2.8	XDB01026	3
19	DRILL BIT Ø 3.6	XDB01027	3
20	AO RATCHET HANDLE	XHA01002	1
21	T15 AO SCREWDRIVER TIP	XSD08001	2

NEXIS® Ø7 INSTRUMENTATION - OPTIONAL

#	DESCRIPTION	PART NO.	QTY
22	T25 LARGE AO SCREWDRIVER TIP	XSD06003	1
22	CANNULATED DRILL BIT Ø 4.8	XDB01010	1
22	COUNTERSINK Ø 6	XRE01009	1
22	LARGE AO STRAIGHT HANDLE	XHA01003	1
22	RULER LG 180/200	XGA01007	1
22	K-WIRE Ø 2.2 LG 200 TR/RD[1]	-	5

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

SAW BLADES

#	DESCRIPTION	PART NO.	QTY
-	STERILE SAW BLADE 100 X 17 X1.27 STRYKER CONNECTOR	71.34.0751[2]	1
-	STERILE SAW BLADE 100 X 17 X1.27 SYNTHES CONNECTOR	71.34.0095[2]	1

[2]Supplied separately - Saw blades KMS1713.L62 STE are available depending on your market.

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-ED0-05-25-EN