



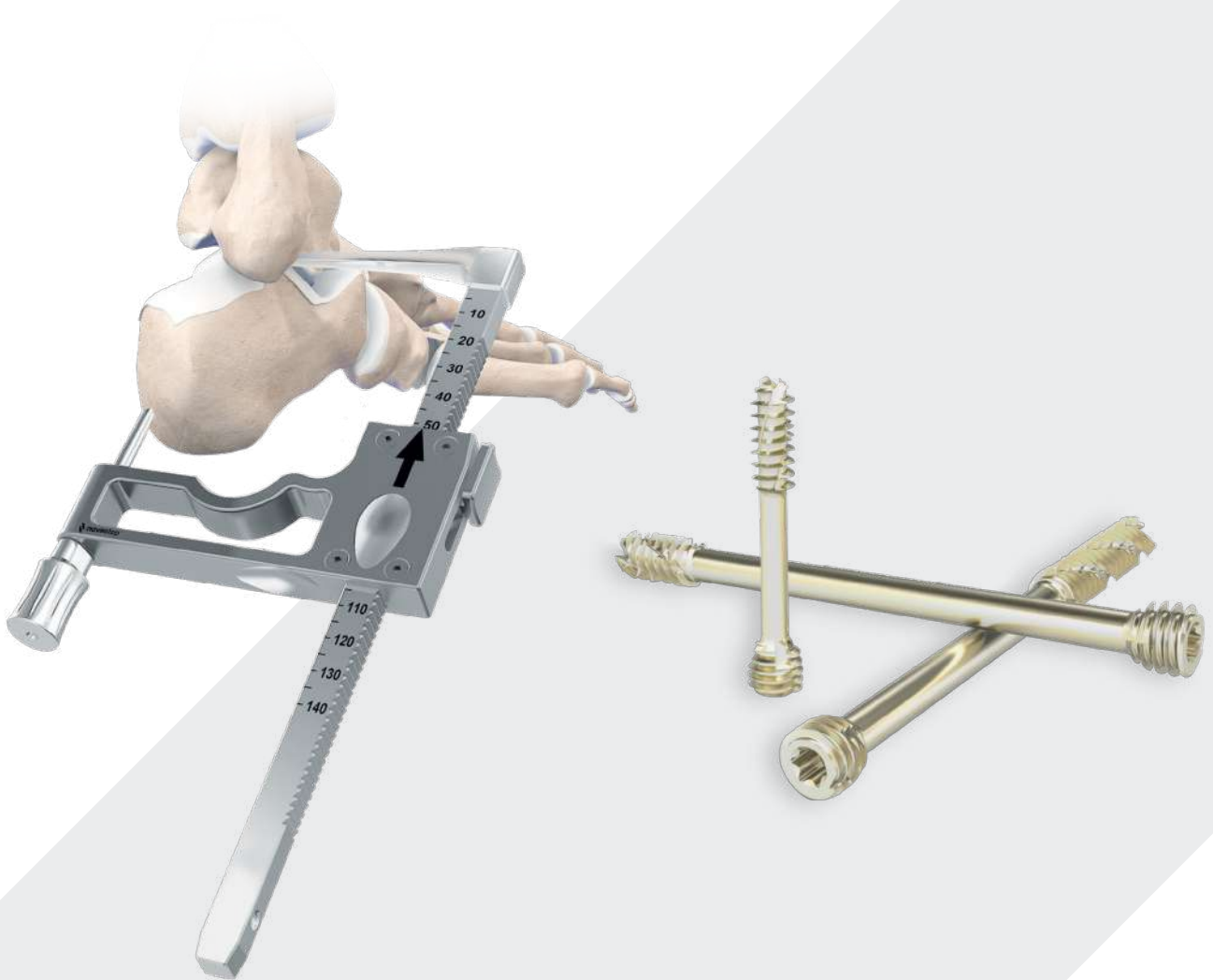
Rearfoot

nexis[®]

Cannulated Screws

Operative Technique

Large Compression Screws
with Hindfoot Targeter





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Nexis® 5.0 & 7.0: Implants & Instruments

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Operative Technique

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Introduction

The Nexis® 5.0 and 7.0 mm cannulated compression screws, made of Titanium alloy, are designed to address midfoot and rearfoot indications.

Designed in partnership with an international panel of foot and ankle specialists, the Nexis® range offers stable fixation, a substantial range of lengths, and rapid insertion features. It is available with a targeting guide which allows for accurate and reliable K-wires placement.

Indications

The Nexis® osteosynthesis compressive screws are single use devices indicated for the fixation, correction and stabilization of bones in the foot (phalanx, metatarsal and tarsal bones) and ankle.

Examples of use:

Ø 5.0 mm:

- Partial or complete Lisfranc arthrodesis.
- Talo-navicular fusion.
- Calcaneo-cuboid fusion.
- Lapidus procedure.

Ø 7.0 mm:

- Tibio-talar fusion.
- Subtalar fusion.
- Calcaneal osteotomy.

Contraindications

The Nexis® 5.0 and 7.0 mm should not be used in case of any of the following:

- Severe muscular or vascular deficiency in the extremity concerned.
- Bone destruction or poor bone quality, likely to impair implant stability.
- Surgical procedure other than those listed in the « Indications » section.
- Known or suspected allergy to any of the device components.
- Use of this implant in combination with implants of another origin not recommended by Novastep.

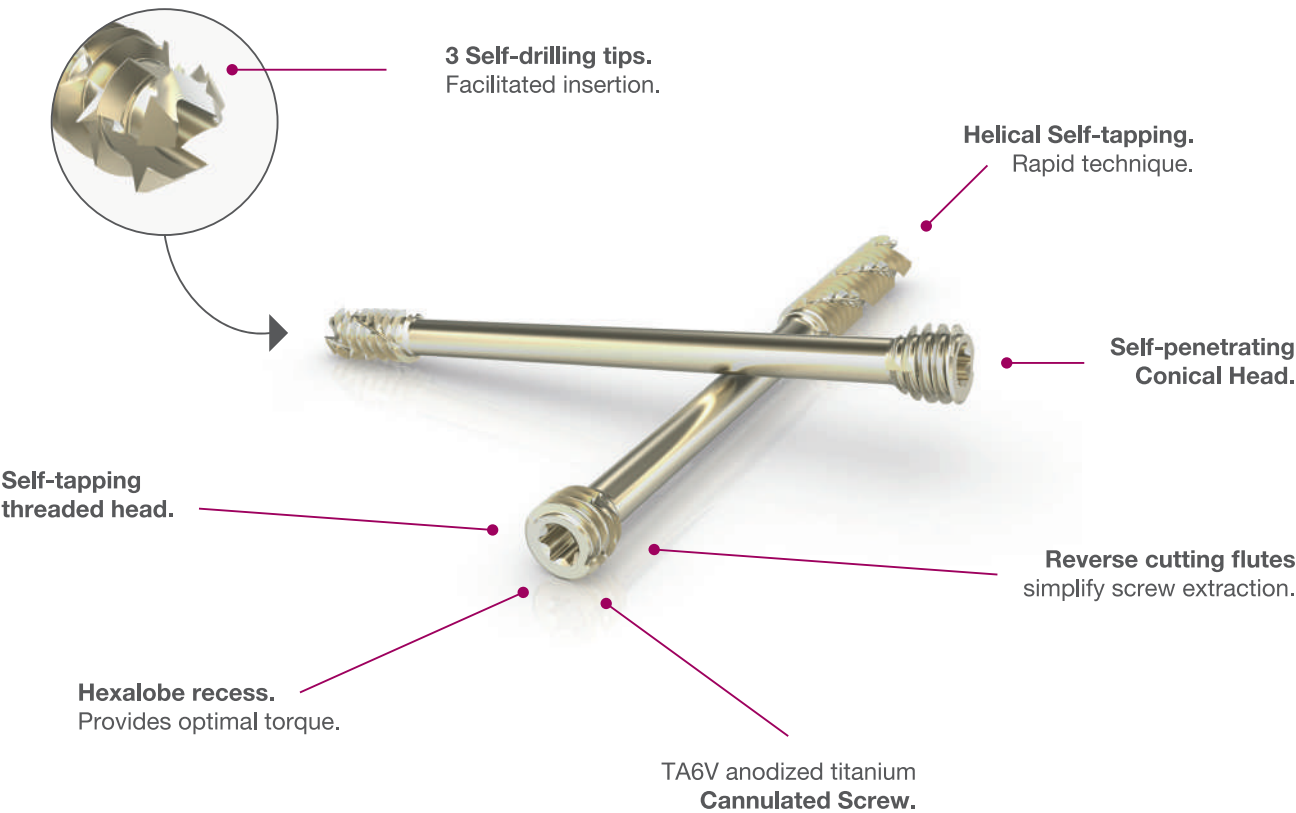
Note: See package insert for a complete list of potential adverse effects, warnings, precautions, contraindications and instructions for use.



Nexis® 5.0 / 7.0: Implants & Instruments

1 - Technical Features

The **Nexis® 5.0 / 7.0 screw system** is composed of anodized titanium screws designed for procedures that require fixation in the rearfoot. The **cannulated** Ø 5.0 mm and Ø 7.0 mm short and Ø 7.0 mm long threaded implants are **self-drilling** and **self-tapping**, and the **reverse cutting flutes** aid the surgeon in simplified extraction. **Self-penetrating conical compression cone** facilitates atraumatic penetration while **hexalobe recess** protects the screw interface and provides optimal torque.



2 - Nexis® Screw Range

	<div>Ø5 nexis</div>	<div>Ø7 nexis</div>
Screwdriver Tip	T20	T25
Distal Thread Diameter	Ø 5.0 mm	Ø 7.0 mm
Distal Thread Length	1/4 of the overall lenght	16 mm or 32 mm
Length	30 - 100 mm*	40 - 120 mm**
K-wire	Ø 1.6 x 180 mm	Ø 2.2 x 200 mm

* 2 mm increments up to 50 mm, then 5 mm increments.
** 5 mm increments.

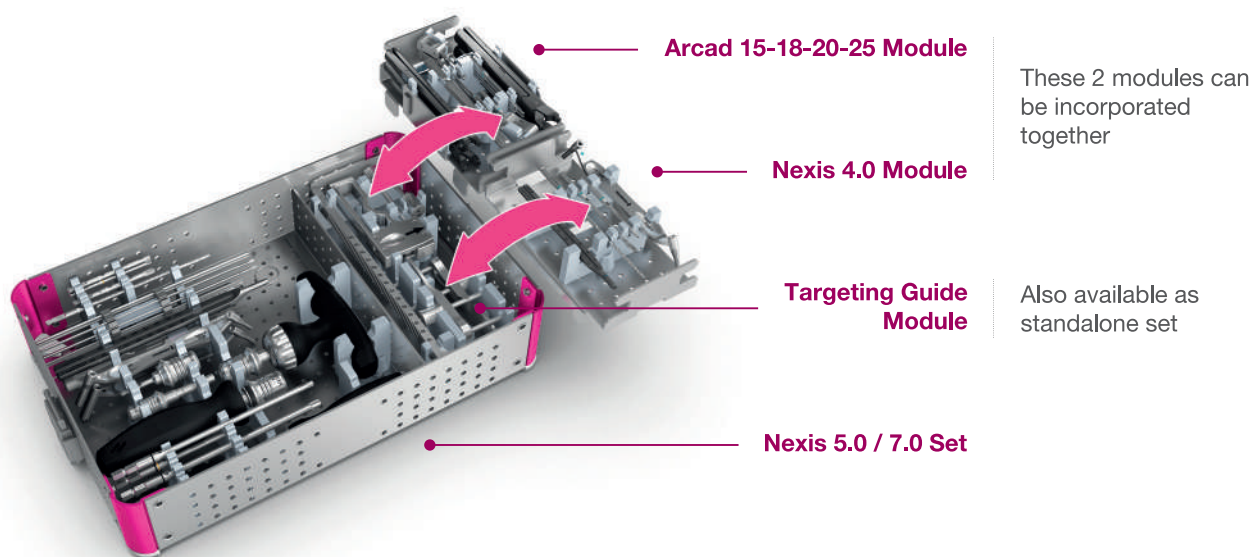
Nexis® 5.0 / 7.0: Implants & Instruments

3 - Instrumentation

3.1 - Set Nexis® 5.0 / 7.0: Modular and All-inclusive Solution

The instrumentation set is fully modular and customizable to meet individual surgeon requirements. Several modules are available and can be incorporated to the 5.0 / 7.0 Nexis® screws set:

- **Targeting guide** module.
- **Nexis® 4.0** module.
- Compressive staples **ARCAD 15-18-20-25** module.



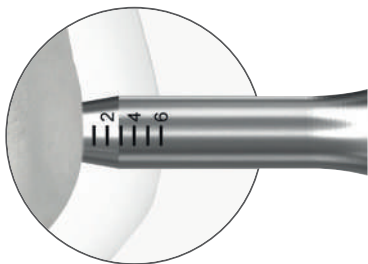
Ergonomic Instrumentation

The Nexis® screws can be used with two types of handle: a straight AO handle or a T-handle for optimum transmission of forces and with ratchet for fast screw insertion.



Nexis[®] 5.0 / 7.0: Implants & Instruments

Additional graduations on the tip of the ruler and of the cannulated screwdrivers T20 and T25-S facilitate measurement of soft tissue depth, especially in MIS procedures. Insert the ruler on the bone for K-wire measurement. In addition, read the depth in soft tissue. This value can be reported on the screwdriver graduated tip to make sure the screw head extremity is flush or lower than the bone cortex.

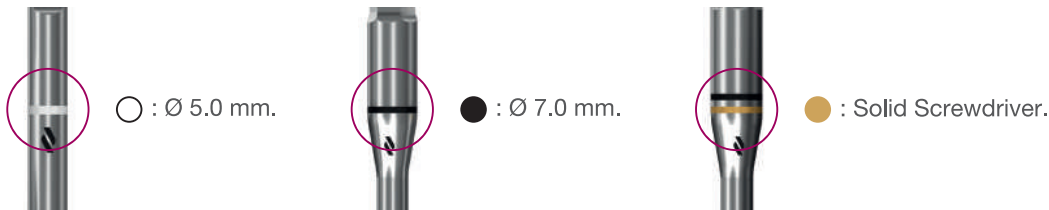


Graduated Ruler Tip



Graduated Screwdriver Tip

Color Code Identification



Nexis® 5.0 / 7.0: Implants & Instruments

3.2 - Hindfoot Targeting Guide for Nexis® 5.0 / 7.0

Specifically designed for rearfoot indications, the Hindfoot targeting guide acts as a clamp to allow for accurate K-wire placement.

Features and Advantages

Hindfoot Targeting Guide:

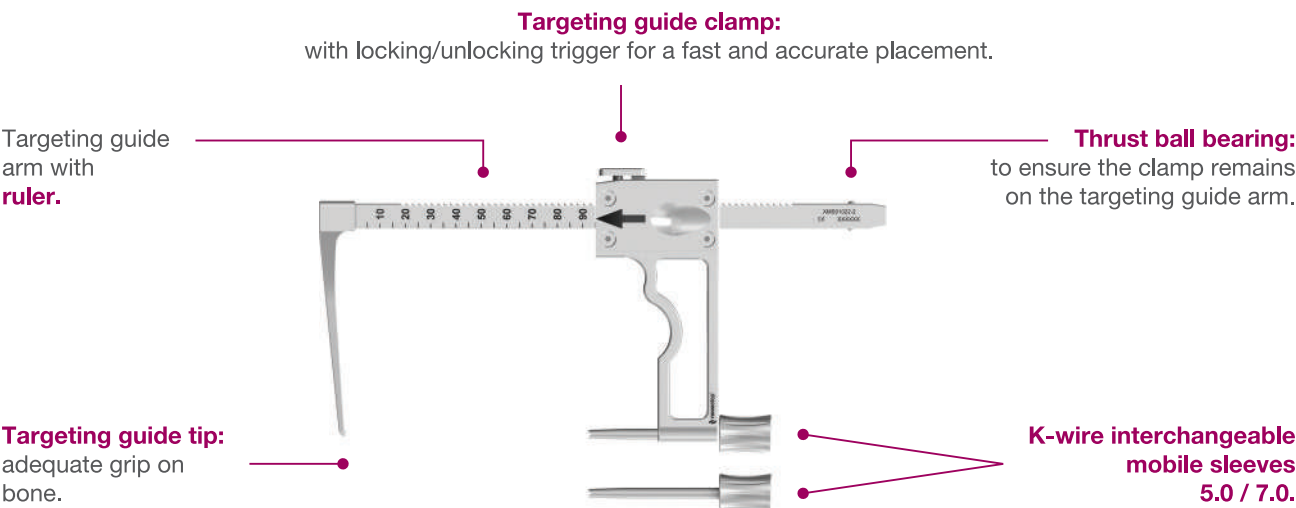
- Accurate K-wire placement, positioning entry and exit points.
- Increased accuracy when used in arthroscopic surgery.
- Optimized design with smoothed outer surface of the tip to preserve soft tissue.
- One handed adjustable instrument with trigger rack and pinion design.
- Toothed K-wire sleeve, provides adequate grip on the bone for good stability.
- Accurate screw lengths can be measured off the targeting guide arm.

Parallel Wire Guide:

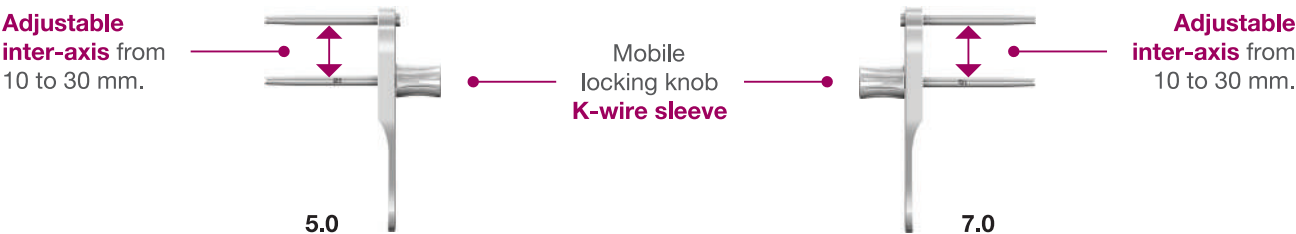
- Avoids any potential risk of conflict between two Nexis® 5.0 / 7.0 screws with a minimum inter-axis of 10 mm.
- Positioning of 2 parallel screws with an inter-axis from 10 to 30 mm.
- Adjustable position of the K-wire sleeve secured with a locking knob.

Instruments in Détail

Targeting Guide for Nexis® 5.0 / 7.0 screws:



Parallel Wire Guide:



Nexis® 5.0 / 7.0: Implants & Instruments

4 - Nexis® 5.0 / 7.0 Instructions for Use

1 - K-wire Insertion

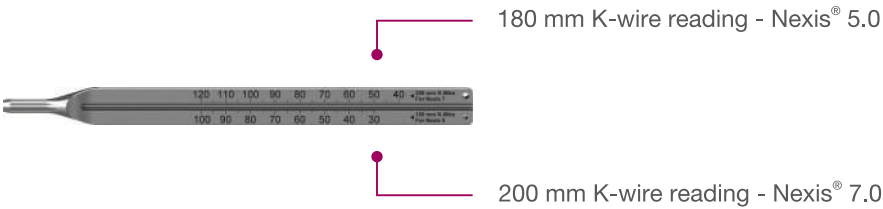
The **K-wire** can be inserted either with the Targeting guide or directly.

Tissue protector Nexis® 5 or Nexis® 7 can be used before K-wire insertion.



2 - Screw Length Assessment

A Nexis® ruler can be slid on the K-wire to assess appropriate screw length. If the targeting guide has been used to position the K-wire, a direct reading of the measurement is possible on the graduated arm of the targeting guide, depending on the indications. A screw length is typically 5mm shorter than measurement on the depth gauge.

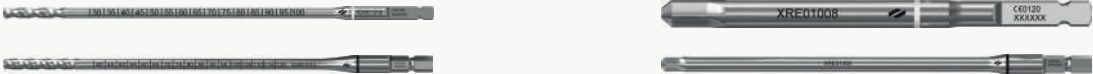


3 - Screw Insertion

Optional - Screw insertion preparation: The self-drilling and self-tapping Nexis® screws are efficient in cancellous bone. In dense cortical bone, pre-drilling and/or countersink is recommended.

1 : Pre-drilling - A graduated cannulated drill-bit can be used over the K-wire to drill. Direct reading of appropriate screw length is possible.

2 : Screw head preparation - A cannulated counter-sink can be used either manually or preferably attached to the power driver.



Nexis® 5.0 / 7.0: Implants & Instruments

The screw is inserted over the K-wire and screwed with the cannulated screwdriver either manually or attached to the power driver, depending on surgeon’s preferences. After correct screw placement, remove the guide wire.



Optional - Screw removal: Each screw has reversed cutting flutes easing the screw extraction. To remove an implanted screw, after cleaning out the screw head:

Option 1: Insert the adequate K-wire in the cannula of the screw and use the adequate cannulated screwdriver.



Option 2: Use the adequate solid screwdriver.



Remark: Instruments can be connected to power or used manually attached to straight handle or T-handle. Adaptors are available in the Nexis® set to suit the power tools type available in the OR:

Nexis® 5.0 Instrument:



Adaptator 1/4'' Hex - AO

T20

Nexis® 7.0 Instrument:



Adaptator AO 1/4'' Hex (Nexis® 7)

T25S

Nexis® 5.0 / 7.0: Implants & Instruments

5 - Targeting Guide and Parallel Wire Guide Instructions for Use

Instruction for use:
Unlock the clamp by pressing the button to move it forward or backward.

Insert the clamp on the targeting guide arm. The anti-return rack and pinion system enable to hold the chosen position.

1

2

Insert the Nexis® K-wire sleeve

5.0

7.0

Option:
Depending on the indicated use, direct reading of the needed screw length is possible.

Determine the Entry and Exit point to position the targeting guide which acts as a clamp. Insert the K-wire until it stops at the desired position.

3

K-wire Exit point

K-wire Entry point

3

4

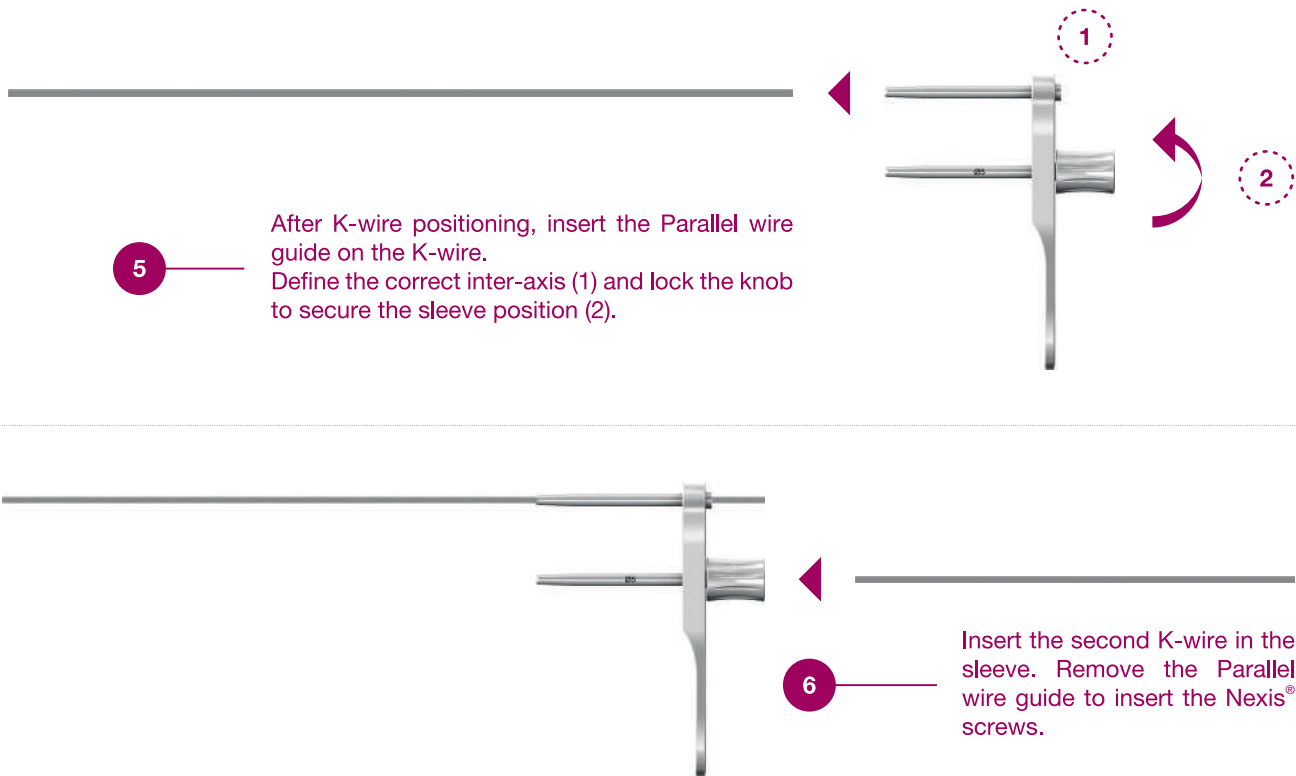
2

1

Keep the K-wire in place and remove the Nexis® K-wire sleeve (1), the clamp (2) and the targeting guide arm (3).

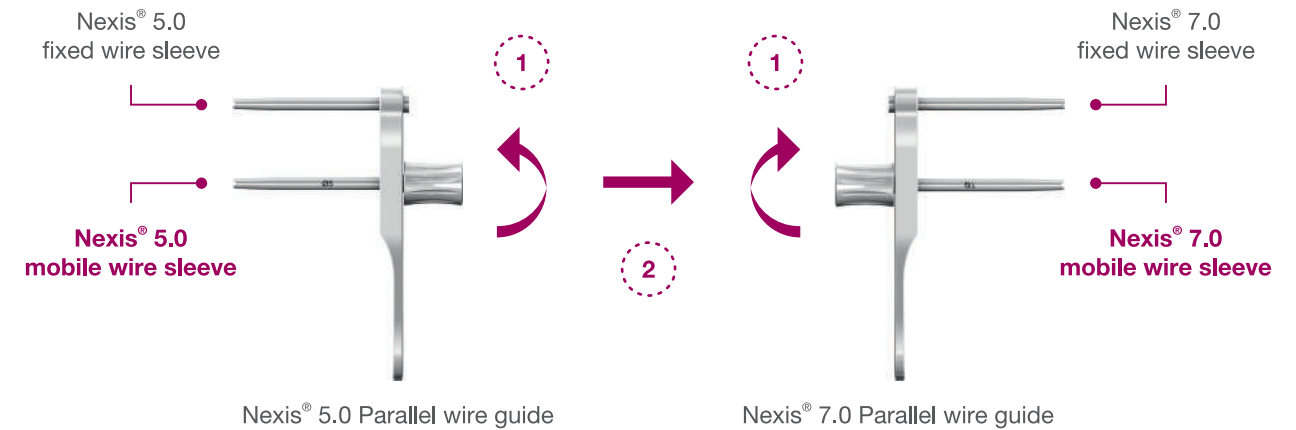
Nexis® 5.0 / 7.0: Implants & Instruments

Option - Two screws implantation with the Parallel wire guide



Remark: Depending on the indications, the Parallel Wire Guide can be used as standalone, without prior use of the targeting guide.

Trick:
Insertion of 2 screws with different diameters.
Nexis® 5.0 Parallel Wire Guide can be used over Ø 1.6 K-wire. Nexis® 7.0 Parallel Wire Guide can be used over Ø 2.2 K-wire.
If needed, it is possible to swap the mobile wire sleeves by unscrewing them off the parallel wire guide.



Nexis[®] 5.0 / 7.0: Implants & Instruments

After K-wire positioning, follow the Instructions for use of Nexis[®] screws (cf part 4).

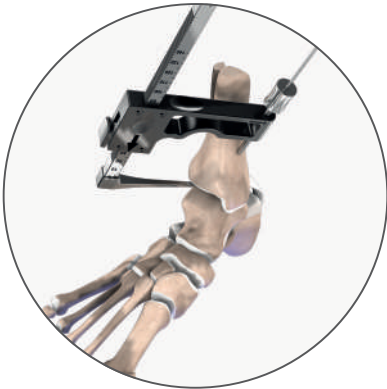
Cleaning / Sterilization recommendation: For appropriate cleaning of the instruments, disassemble all pieces. Remove the K-wire sleeve from the clamp and the clamp from the targeting guide arm. Unscrew the K-wire sleeve and remove it from the Parallel guide.

Indications

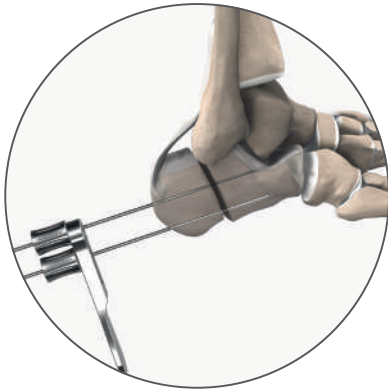
The hindfoot targeting guide aides in the following procedures:



**Subtalar Joint
Fusions**



**Tibiotalar Fusions /
Ankle Fusions**



**Calcaneal
Slides**



**Talo-navicular
Fusion**



**Calcaneal-cuboid
Fusions**

Operative Technique

Novastep does not practice medicine and does not recommend this or any other surgical technique. Each surgeon must consider the specific needs of each patient and is responsible for making applicable adjustment and determining and using the appropriate techniques for implanting the device in each cases.

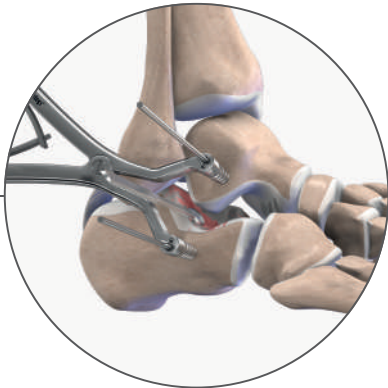
1 - Example of Use: Subtalar Arthrodesis

Subtalar fusion surgical technique with two Nexis® 7.0 screws implanted with the help of the Targeting guide and Parallel wire guide.

1 - Incision and Exposure

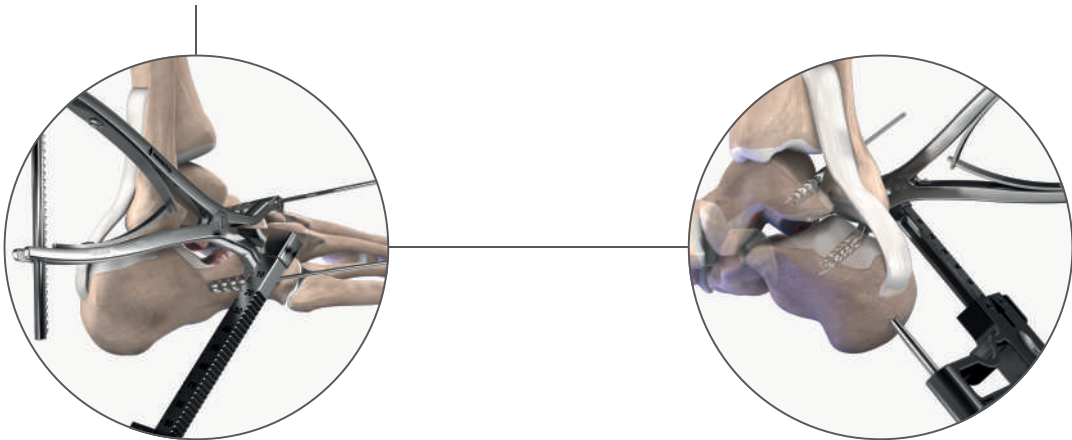
Make a cut on the lateral aspect of the ankle and expose the subtalar joint. Position an outspread arms bone distractor between the calcaneus and the talus. Sterile threaded wires are available for use with the distractor. Threaded Kwire tips provide adequate grip when compared to smooth wires which avoid retractor migration when distracting the joint.

Distract the joint to prepare the joint surfaces for fusion by removing the cartilage on superior aspect of the calcaneus and inferior aspect of the talus with an osteotome or a curette until arriving in the presence of bleeding subchondral bone.



2 - Targeting Guide Set Up

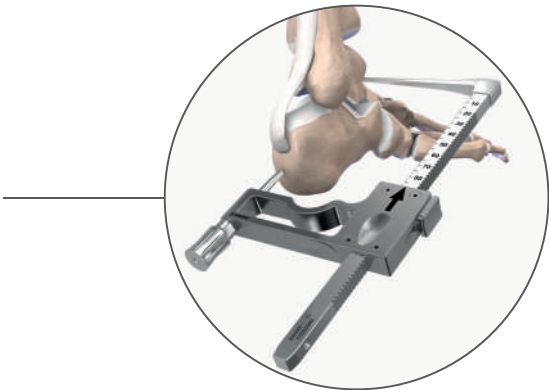
Assemble the targeting guide. Make a cut on the posterior aspect of the calcaneum, at the entry point level of the first K-wire. Position the tip of the targeting guide in the subtalar joint, at the desired exit point of the first K-wire. Slide the clamp on the targeting guide arm to position the Nexis® 7.0 K-wire sleeve in the incision. The no-return ratcheted system and pinion system maintains the clamp in place.



Operative Technique

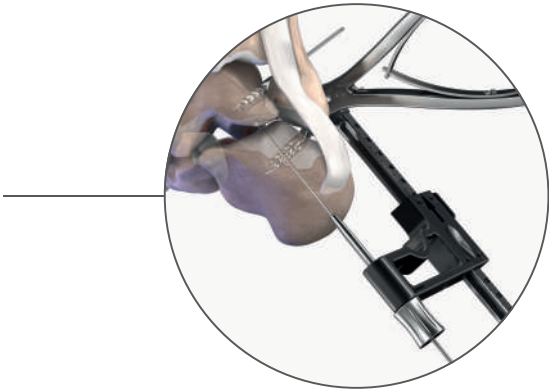
Other targeting guide positioning example:

When the subtalar joint surface is prepared, remove the distractor. Assemble the targeting guide. Position the tip of the targeting guide on the tarsal sinus. Slide the clamp on the targeting guide arm to position the Nexis® 7.0 K-wire sleeve on the posterior aspect of the calcaneum, at the entry point level of the first K-wire.

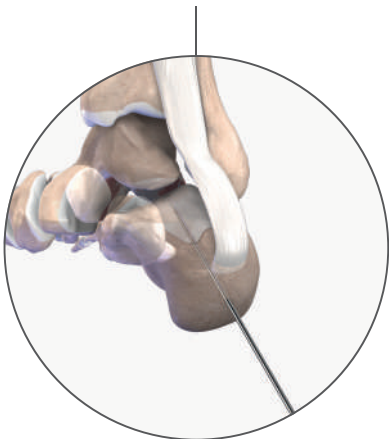


3 - K-wires Positioning with Targeting Guide and Parallel Wire Guide

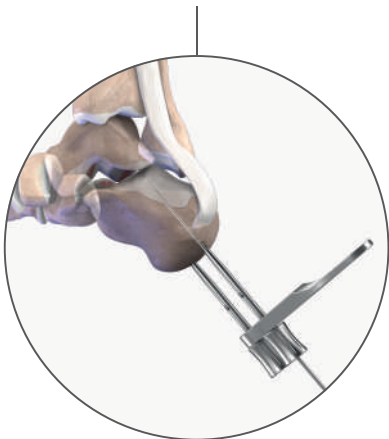
3.1 - Insert a Ø 2.2 lg 200 K-wire in the Nexis® 7.0 K-wire sleeve through the calcaneus until it reaches the tip of the targeting guide.



3.2 - Keep the K-wire in place and remove the Nexis® K-wire sleeve with the clamp, and the targeting guide arm.

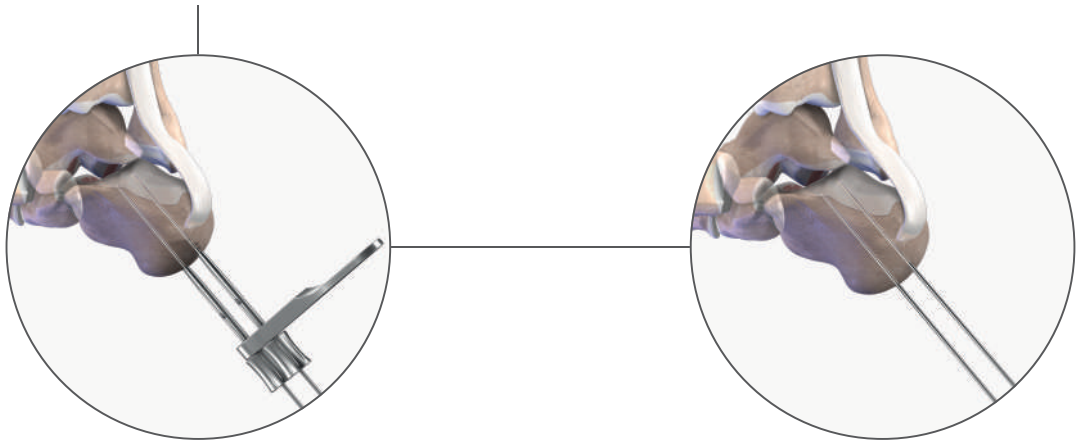


3.3 - Insert the Nexis® 7.0 Parallel wire guide on the K-wire.



Operative Technique

3.4 - Insert the second Ø 2.2 Ig 200 K-wire in the Nexis® 7.0 K-wire sleeve. Remove the parallel wire guide, letting the two K-wires in position.



Remove the outspread arms bone distractor to reduce the subtalar joint. Insert both K-wires deeper into the talus until the appropriate depth with fluoroscopic guidance.

4 - Screws Insertion

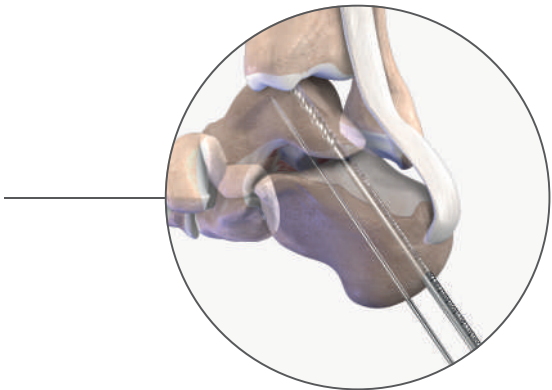
Optional: A tissue protector can be positioned over the K-wire.



Option 1: Pre-drill

Pre-drilling is recommended in the presence of dense cortical bone.

Nexis® Ø 4.8 cannulated drill-bit is used to prepare the insertion of the screw. Use the drill-bit over the K-wire until the appropriate depth. Screw measurement can be read directly off of the graduated drill-bit.

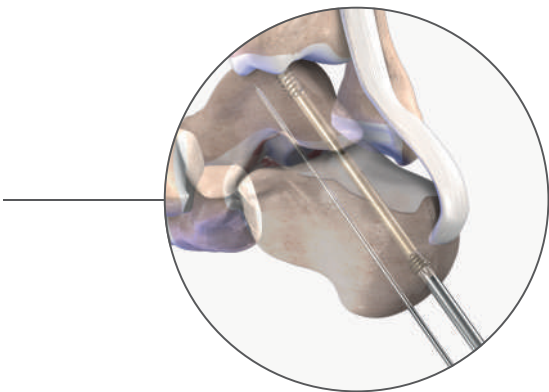


Optional: Nexis® Ø 6.0 countersink can be used to prepare the location of the screw head.



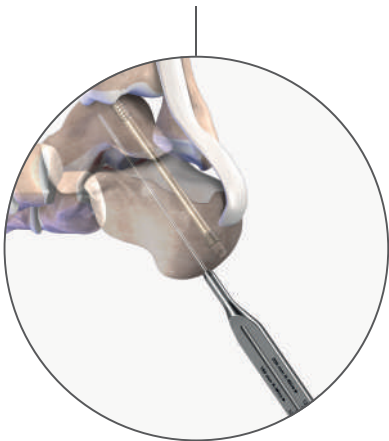
Operative Technique

Use the Nexis® T25-S cannulated screwdriver tip over the K-wire to insert Nexis® 7.0 screw manually or connected to the power driver that can be connected to our adaptor.

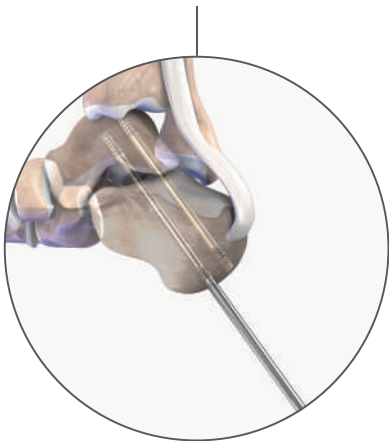


Option 2: Screw Insertion without Pre-drilling

Assess the appropriate screw length with the graduated Nexis® ruler.



Use the Nexis® T25-S cannulated screwdriver tip over the K-wire to insert Nexis® 7.0 screw manually or connected to the power driver.



Confirm the placement and length of the screws under fluoroscopy and stability of the construct. Remove the K-wires before closing and dressing.



References - Nexis® Screws 5.0 / 7.0 mm

Implants

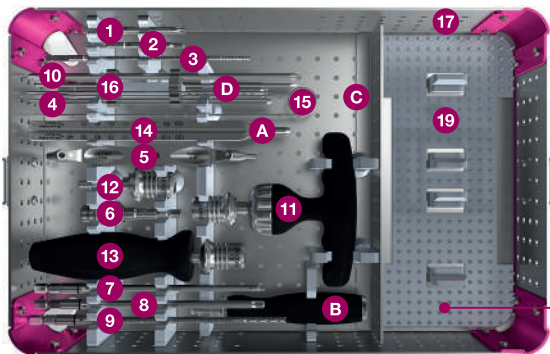
Nexis® screws 5.0 / 7.0



Length	Ø 5.0	Ø 7.0 Short Thread (16 mm)	Ø 7.0 Long Thread (32 mm)
30	SC060030	-	-
32	SC060032	-	-
34	SC060034	-	-
36	SC060036	-	-
38	SC060038	-	-
40	SC060040	SC070040	SC080040
42	SC060042	-	-
44	SC060044	-	-
45	-	SC070045	SC080045
46	SC060046	-	-
48	SC060048	-	-
50	SC060050	SC070050	SC080050
55	SC060055	SC070055	SC080055
60	SC060060	SC070060	SC080060
65	SC060065	SC070065	SC080065
70	SC060070	SC070070	SC080070
75	SC060075	SC070075	SC080075
80	SC060080	SC070080	SC080080
85	SC060085	SC070085	SC080085
90	SC060090	SC070090	SC080090
95	SC060095	SC070095	SC080095
100	SC060100	SC070100	SC080100
105	-	SC070105	SC080105
110	-	SC070110	SC080110
115	-	SC070115	SC080115
120	-	SC070120	SC080120

Instruments

Nexis® 5.0 / 7.0 Set










Optional Modules p.20, 21 & 22.





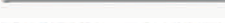




References - Nexis® Screws 5.0 / 7.0 mm






Nexis® 5.0 mm Instrumentation

Number	Ref	Description	
1	XSD05001	Nexis® AO T20 Cannulated Screwdriver tip	
1	XSD05002	Nexis® AO T20 Solid Screwdriver tip	
2	XRE01008	Nexis® Ø 4.9 Countersink	
3	XDB01009	Nexis® Ø 3.2 Cannulated Drill bit	
4	33-0216-180	Guide Wire Ø 1.6 lg 180 TR / RD	
5	XDG01015	Nexis® Ø 5 Tissue Protector	
6	XHA01005	Adaptator 1/4" Hex-AO	


Nexis® 7.0 mm Instrumentation

Number	Ref	Description	
7	XSD06003	Nexis® T25-S Cannulated Screwdriver tip	
7	XSD06002	Nexis® T25 Solid Screwdriver tip	
8	XRE01009	Nexis® Ø 6 Countersink	
9	XDB01010	Nexis® Ø 4.8 Cannulated Drill bit	
10	33-0222-200	Guide Wires Ø 2.2 lg 200 TR / RD	
5	XDG01016	Nexis® Ø 7 Tissue Protector	
12	XHA01007	Cannulated Adaptator Jacob - 1/4" Hex-AO - Optional	

Universal Instruments

Number	Ref	Description	
11	XHA01004	T Handle 1/4" Hex Ratchet	
13	XHA01003	Handle Straight 1/4" Hex	
14	XGA01007	Nexis® Ø 5 - Ø 7 Graduated Ruler	
15	XKW01003	Cleaning Pin Ø 1,6	
16	ACC1008P0004	Nexis® Ø 5 - Ø 7 Tray K-Wires Holder	
17	ACC1008P0001	Nexis® Midfoot & Rearfoot Tray System	
18	ACC1008P0002	Nexis® Midfoot & Rearfoot Tray System lid	
19	ACC1008P0003	Nexis® Ø 5 - Ø 7 Tray Silicone	

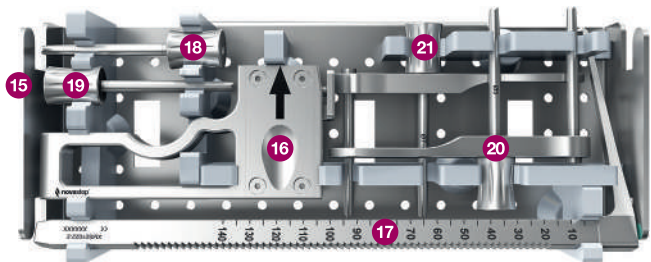
Optional Instruments

Ref	Description	
XFP01008	Outspread Arms Bone Distractor	
348-150S	Threaded K-wire Ø 1.6 lg 150 TR-RD Sterile	
353-200S	Threaded K-wire Ø 2.5 lg 200 TR-RD Sterile	

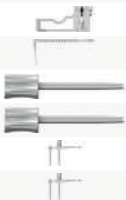
References - Hindfoot Targeting Guide

The Nexis® Hindfoot targeting guide is available either as a module or as a standalone in a set.

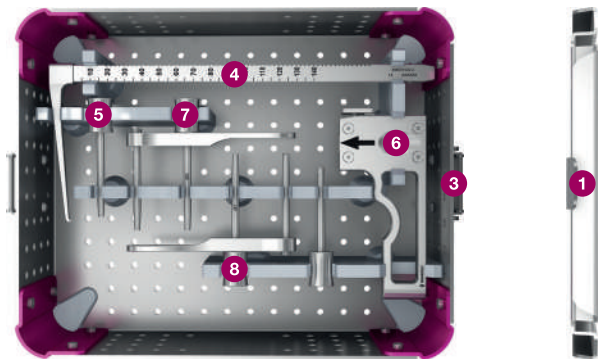
Nexis® 5.0 / 7.0 Targeting Guide Module



Number	Ref	Description
15	ACC1012P1003	Nexis® Targeting Guide Tray
16	XMS01022-1	Targeting Guide Clamp
17	XMS01022-2	Targeting Guide Arm
18	XMS01022-3	Nexis® 5.0 K-wire Sleeve
19	XMS01022-4	Nexis® 7.0 K-wire Sleeve
20	XMS01023	Nexis® 5.0 Parallel Wire Guide
21	XMS01024	Nexis® 7.0 Parallel Wire Guide



Nexis® 5.0 / 7.0 Targeting Guide Set



Number	Ref	Description
1	ACC1012P0001	Nexis® Targeting Guide Tray
2	ACC1012P0002	Nexis® Targeting Guide Tray Lid
3	XMS01022-1	Targeting Guide Arm
4	XMS01022-2	Targeting Guide Clamp
5	XMS01022-3	Nexis® 5.0 K-wire Sleeve
6	XMS01022-4	Nexis® 5.0 Parallel Wire Guide
7	XMS01023	Nexis® 7.0 K-wire Sleeve
8	XMS01024	Nexis® 7.0 Parallel Wire Guide

The Nexis® 5.0 / 7.0 set can be completed with a **Nexis® 4.0 module** and/or **15-18-20-25 ARCAD Compressive staples module**.

References - Nexis® Screw 4.0 mm

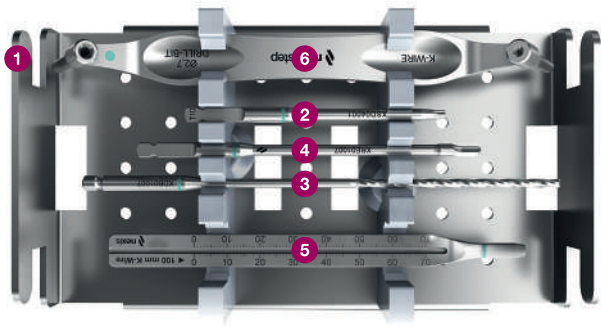
Implants

Nexis® Screw 4.0 mm

Length	Ø 4.0
18	SC050018
20	SC050020
22	SC050022
24	SC050024
26	SC050026
28	SC050028
30	SC050030
32	SC050032
34	SC050034
36	SC050036
38	SC050038
40	SC050040
42	SC050042
44	SC050044
46	SC050046
48	SC050048
50	SC050050
55	SC050055
60	SC050060

Instruments

Nexis® 4.0 Module



Number	Ref	Description	
1	ACC1002P0004	Nexis® Ø 4 Tray	
2	XSD04001	Nexis® AO T10 Screwdriver tip	
3	XDB01007	Nexis® Ø 2.7 Cannulated Drill bit	
4	XRE01007	Nexis® Ø 3.7 Countersink	
5	XGA01004	Nexis® Ø 4 Ruler	
6	XDG01009	Nexis® Double Drill Guide	
C	XKW01002*	Cleaning Wire Ø 1.4	
D	XMS01001*	Guide Wire Tube	
D	33-0214-100*	Guide Wire Ø 1.4 lg 100 TR / RD	
A	XGA01002*	Gauge	
B	XHA01001*	AO Handle	

* Instruments included in Nexis® 5.0 / 7.0 set.

References - Arcad[®] Compressive Staples

Implants

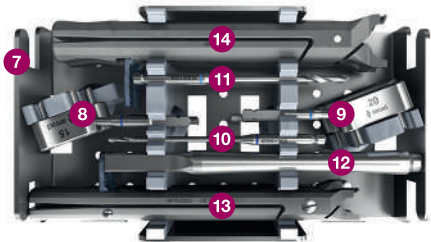







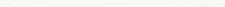









Arcad[®] Compressive Staples 15-18-20-25

Ref	Description	Bridge Width	Leg Length	Wire Dimensions
CS031212	Arcad [®] Compressive Staples 15-12-12	15 mm	12-12 mm	1,3 x 1,8 mm
CS031414	Arcad [®] Compressive Staples 15-14-14	15 mm	14-14 mm	1,3 x 1,8 mm
CS041212	Arcad [®] Compressive Staples 18-12-12	18 mm	12-12 mm	1,3 x 1,8 mm
CS041414	Arcad [®] Compressive Staples 18-14-14	18 mm	14-14 mm	1,3 x 1,8 mm
CS041416	Arcad [®] Compressive Staples 18-14-16	18 mm	14-16 mm	1,3 x 1,8 mm
CS041618	Arcad [®] Compressive Staples 18-16-18	18 mm	16-18 mm	1,3 x 1,8 mm
CS041818	Arcad [®] Compressive Staples 18-18-18	18 mm	18-18 mm	1,3 x 1,8 mm
CS051818	Arcad [®] Compressive Staples 20-18-18	20 mm	18-18 mm	2,5 x 1,6 mm
CS062020	Arcad [®] Compressive Staples 25-20-20	25 mm	20-20 mm	2,5 x 1,6 mm

Instruments

Module Arcad[®] 15-18-20-25



Number	Ref	Description	
7	ACC1005P0007	Arcad [®] 15-18-20-25 Tray	
8	XDG01003	Arcad [®] 15 Drill Guide	
8	XDG01004	Arcad [®] 18 Drill Guide	
9	XDG01005	Arcad [®] 20 Drill Guide	
9	XDG01006	Arcad [®] 25 Drill Guide	
10	XPP01001	Arcad [®] Positioning Pin Ø 2	
11	XPP01002	Arcad [®] Positioning Pin Ø 3	
12	XMS01002	Arcad [®] Staple Impactor	
10	XDB01008	Arcad [®] Ø 2 Drill bit	
11	XDB01004	Arcad [®] Ø 3 Drill bit	
13	XFP03003	Arcad [®] 15 Forceps	
13	XFP03004	Arcad [®] 18 Forceps	
14	XFP03005	Arcad [®] 20 Forceps	
14	XFP03006	Arcad [®] 25 Forceps	
A	XGA01002*	Gauge	
B	XHA01001*	AO Handle	

* Instruments included in Nexis[®] 5.0 / 7.0 set.

Notes

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

This document is intended solely for the use of healthcare professionals. This technique was developed in conjunction with healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Novastep does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate a Novastep product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for Cleaning and Sterilization (if applicable), before using any Novastep product.

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