

about us

Auxein Medical is an integrated, research based, orthopaedic Implants & instruments manufacturing company, producing a wide range of quality, affordable generic implants, trusted by healthcare professionals and patients across geographies. It is the Company's constant endeavor to provide a wide basket of generic and our innovator products that exceed the highest expectations of customers in term of quality and safety. The company has world-class manufacturing unit established in india and serves customers in over 75 countries worldwide.

Guidelines

This publication sets forth detailed recommended procedures for using Auxein Medical devices and instruments.

It offers guidance that needs to be heeded. However, with any such technical guide, each surgeon must consider the unique needs of each patient and make appropriate adjustments when and as required.

A workshop training under DAIS Academy by Auxein will provide assistance prior to first surgery. It is vital to know that all non-sterile devices must be cleaned and sterilized before use.

Moreover, multi-component instruments must be disassembled for cleaning. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Please NOTE that all the bone screws referenced in this document here are not approved for screw attachment or fixation in the areas not mentioned in this publication.

Warning:

This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.







AV-WISELOCKTM

2.4mm AV-Wiselock Endosteal Plate

INTRODUCTION

Endosteal plates are used for the first metatarsal bone correction. The plates are a part of the 2.4mm AV-Wiselock plates system developed by Auxein. The presented range of implants is made of Titanium Alloy.

 $Compliance\ with\ the\ requirements\ of\ quality\ management\ systems\ and\ the\ requirements\ of\ Directive.$



2 holes for 2.4mm AV-Wiselock screws locked angularly



Plate shape allowing its stable fixation in the medullary canal



Plate profile that increases the stiffness of the implant



The edge of the plate facilitating plate insertion into the intramedullary canal



Titanium as per ISO 5832-3



PATIENT'S POSITIONING

The patient is position in supine position with a roller under the calf to level up the foot.



SURGICAL APPROACH

Medial approach is recommended. Perform a short arched incision above theme tatarsophalangeal joint. The cutting shall be slightly dorsal.

There are two different approaches for implantation of Endosteal plate:-

- 1. Standard technique which helps in stable fixation of screw corresponding to direction of locking holes in the distal part of the bone.
- 2. Technique using VA Locking Screw:
 In this the plate is implant more deeply into the canal.

In the surgical steps below we have chosen the approach 2.





PLATE AND TARGETER ASSEMBLY

At beneath surface of targeter there is a cavity that exactly matches the curvature or foam of the plate. Once the plate sits nicely into the cavity then use the T8 star driver to lock the cannulated sleeve with the plate. Make sure the cannulated sleeve flushes well with the top surface of the targeter.

Instruments:

7-155-09 Targeter for Endosteal Plate, Left



1312-18 Star Screwdriver Shaft, T8

7-155-09-A Cannulated Threaded guide Sleeve, Ø1.8.



Note: 7-155-09-A is a child part of 7-155-09 having star recess. The threaded distal end holds the plate in place via targeter and complete the plate assembly.





BONE PREPERATION

Bone correction

If need be, prior to osteotomy, remove a part of the head of the first metatarsal bone.



Osteotomy

Perform osteotomy at the site of endosteal plate implantation. The cutting should be performed at the base of the metatarsal head.





MEDULLARY CANAL PREPARATION

Use the rasp to replicate the plate shape into the medullary canal for plate insertion. If required light hammer the rasp. Even guided hammer can be use by unscrewing the top screw and screwing the extraction rod for guide hammering.

Instruments:

7-155-08 Raspatony for Endosteal Plate



7-155-06 Mallet for Endosteal Plate



Prepare the medullary canal for plate insertion using raspatory (7-155-08).

NOTE: Use mallet (7-155-06) if required.



PLATE INSERTION

Introduce the plate assembly into the reamed cavity of medullary canal. Light hammer the targeter screw as shown in the image.

Instruments:

7-155-09 Targeter for Endosteal Plate, Left



7-155-06 Mallet for Endosteal Plate



7-155-01 Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate



Insert the plate into the prepared canal.

NOTE: Use mallet (7-155-06) if required.





INSERTION OF THE FIRST LOCKING SCREW

Approach preparation

Using drill 4.0 (**7-155-11** Drill Bit with Quick Coupling End, Ø4.0mm) to the full depth, directly through the oblique targeter hole (**7-155-09** Targeter for Endosteal Plate, Left)/(**7-155-10** Targeter for Endosteal Plate, Right) and thus remove the part of the bone that covers proximal locking hole.

The step in the distal end of the drill has a step which prevent the drill from collision from targeter.

Instruments:

7-155-09 Targeter for Endosteal Plate, Left



7-155-11 Drill Bit with Quick Coupling End, Ø4.0mm

NOTE: The drill is equipped with a limiter that prevents from instrument-implant collision.

GUIDE INSERTION

Insert the (Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate **7-155-01** into the oblique hole of the targeter until it reaches the plate.

Instruments:

7-155-01 Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate



NOTE: Do not screw in the guide.

The holes in the guide and in the implant do not correspond with each other in this position. There is a risk of threads damage.



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DRILLING

Screw the cannullated drill sleeve on the locking hole passing through the targeter. Pase the 1.8 mm (Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate **7-155-01**) drill bit through the sleeve into the bone. Carefully observe the drill depth under fluoroscopy.

Instruments:

7-155-01 Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate



1312-04-1.8 Drill Bit with Quick Coupling End, Ø1.8mm x Length 140mm



DRILLING AND SCREW LENGTH MEASUREMENT

Use locking screw length measure (**7-155-03**). to measure the hole depth.

Keep the bit in place and slide the depth gauge(**7-155-03**) over the drill bit and observe the distal end carefully aligning with the marking on the scale.

Instruments:

7-155-03 Length Measuring Device for Locking Screw







THREADED GUIDE REMOVAL

Remove Drill Bit with Quick Coupling End, Ø1.8mm x Length 140mm **1312-04-1.8**) and Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate **7-155-01**).

Once the hole is drilled pull back the drill bit and disengage the cannulated sleeve from the plate hole and targeter.

Instruments:

7-155-01 Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate



1312-04-1.8 Drill Bit with Quick Coupling End, Ø1.8mm x Length 140mm



1312-18 Star Screwdriver Shaft, T8



Use Torque Limiting Attachment, 0.8Nm (1312-21) and Star Screwdriver Shaft, T8 (1312-18) to insert desirable length screw.

For screw fixation:-

Unmount the cannulated drill sleeve.

Mount the star drive recess driver shaft (1312-18) over the torque limiting attachment (1312-21) and finally this assemby with Quick coupling handle (7-019-03).

Hold the screw into the driver recess and pass this assembly through the targeter hole

Tightnen the screw until a audible click is heard. This click will ensure that the screw is

lock upto its maximum limit.

Instruments:

1312-21 Torque Limiting Attachment, 0.8Nm

1312-18 Star Screwdriver Shaft, T8











INSERTION OF THE OTHER LOCKING SCREW

DRILLING

Using Drill Bit with Quick Coupling End, Ø1.8mm x Length 140mm (**1312-04-1.8**) VA cannulated fixing screw of the targeter until the desired depth is reached.

Pass the 1.8 mm drill bit through the canualated sleeve mounted on the targeter. Observe the drill length under fluroscopy images.

Instruments:

1312-04-1.8 Drill Bit with Quick Coupling End, Ø1.8mm x Length 140mm

W.8.

OPTIONAL: If the surgeon is willing to fix the second screw free handedly with variation in screw axis. The suregon can remove the targeter and use the universal drill guide to drill hole is desired direction.



7-155-02 1.8 mm Variable Angle Locking Drill Guide, Conical

TARGETER REMOVAL

Loosen the fixing screw using Star Screwdriver Shaft, T8 (1312-18) and remove the Targeter for Endosteal Plate, Left (7-155-09)

Once the plate is stabilize loosen the cannulated sleeve using star driver(1312-18) and remove the targeter.

Instruments:

7-155-09 Targeter for Endosteal Plate, Left



1312-18 Star Screwdriver Shaft, T8









DEPTH MEASURE

Use depth measure (1312-17) to measure the hole depth.

Place the distal knob of depth gauge (1312-17) and slide the measuring pin until the knob touches the end of the drill hole. Observe the reading on the scale.

Instruments:

1312-17 Depth Gauge with Protector measuring upto 50mm



NOTE: Do not measure the other hole depth using locking screw length measure (**7-155-03**) via the cannulated screw that secures the targeter (**7-155-09**). Measurement with the use of locking screw length measure (**7-155-03**) is possible only via Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate(**7-155-01**)



SCREW INSERTION

Use Torque Limiting Attachment, 0.8Nm (1312-21) & Star Screwdriver Shaft, T8 (1312-18) to insert desirable length screw.

Instruments:

1312-21 Torque Limiting Attachment, 0.8Nm

1312-18 Star Screwdriver Shaft, T8

7-019-03 Handle for Torque Limiting Attachment







IMPLANT REMOVAL

Based on the doctor descision the implant can be removed as shown in the steps below

- Perform an incision above the metatarsophalangeal joint above distal part of the plate.
- 2. Unlock and remove all the screw form the plate.
- 3. Facilitate the targerter (**7-155-09**) into the incision and lock into the plate through cannulated sleeve (**7-155-01**).
- 4. Attach the extraction rod at the distal end of the targeter and hammer the guide rod to extract the plate.

Instruments:

7-155-07 Extractor Rode for Endosteal PLate



7-155-09 Targeter for Endosteal Plate, Left



7-155-06 Mallet for Endosteal Plate



7-155-01 Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate





Endosteal Plate

2.4mm AV-Wiselock Endosteal Plate, Standard







Length	Direction	Titanium
40mm	Left	11-091-40LTI
40mm	Right	11-091-40RTI
45mm	Left	11-091-45LTI
45mm	Right	11-091-45RTI
50mm	Left	11-091-50LTI
50mm	Right	11-091-50RTI

STERILE

Length	Direction	Titanium
40mm	Left	11-091-40LTI-S
40mm	Right	11-091-40RTI-S
45mm	Left	11-091-45LTI-S
45mm	Right	11-091-45RTI-S
50mm	Left	11-091-50LTI-S
50mm	Right	11-091-50RTI-S



Endosteal Plate

2.4mm AV-Wiselock Endosteal Plate, Curved







Length	Direction	Titanium
40mm	Left	11-092-40LTI
40mm	Right	11-092-40RTI
45mm	Left	11-092-45LTI
45mm	Right	11-092-45RTI
50mm	Left	11-092-50LTI
50mm	Right	11-092-50RTI

STERILE

Length	Direction	Titanium
40mm	Left	11-092-40LTI-S
40mm	Right	11-092-40RTI-S
45mm	Left	11-092-45LTI-S
45mm	Right	11-092-45RTI-S
50mm	Left	11-092-50LTI-S
50mm	Right	11-092-50RTI-S



Endosteal Plate-Screw

2.4mm Variable Angle Screw, Self-Tapping, (Star Head)



Dia	Length	Titanium
Ø2.4	8mm	TI-549.008
Ø2.4	10mm	TI-549.010
Ø2.4	12mm	TI-549.012
Ø2.4	14mm	TI-549.014
Ø2.4	16mm	TI-549.016
Ø2.4	18mm	TI-549.018
Ø2.4	20mm	TI-549.020
Ø2.4	22mm	TI-549.022
Ø2.4	24mm	TI-549.024
Ø2.4	26mm	TI-549.026
Ø2.4	28mm	TI-549.028
Ø2.4	30mm	TI-549.030
Ø2.4	32mm	TI-549.032
Ø2.4	34mm	TI-549.034

STERILE

Dia	Length	Titanium
Ø2.4	8mm	TI-549.008-S
Ø2.4	10mm	TI-549.010-S
Ø2.4	12mm	TI-549.012-S
Ø2.4	14mm	TI-549.014-S
Ø2.4	16mm	TI-549.016-S
Ø2.4	18mm	TI-549.018-S
Ø2.4	20mm	TI-549.020-S
Ø2.4	22mm	TI-549.022-S
Ø2.4	24mm	TI-549.024-S
Ø2.4	26mm	TI-549.026-S
Ø2.4	28mm	TI-549.028-S
Ø2.4	30mm	TI-549.030-S
Ø2.4	32mm	TI-549.032-S
Ø2.4	34mm	TI-549.034-S







Endosteal Plate Instruments

7-155-01 Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate



7-155-02 1.8 mm Variable Angle Locking Drill Guide, Conical



1312-04-1.8 Drill Bit with Quick Coupling End, Ø1.8mm x Length 140mm



1312-18 Star Screwdriver Shaft, T8



1312-30-2.4 Screw Holding Sleeve for 2.4mm Wise-Lock Screw



1312-17 Depth Gauge with Protector measuring upto 50mm





Endosteal Plate Instruments

7-155-03 Length Measuring Device for Locking Screw



1312-21 Torque Limiting Attachment, 0.8Nm



7-019-03 Handle for Torque Limiting Attachment



7-155-04 Hohmann Retractor, 6mm



7-155-05 Hohmann Retractor, 8.5mm



7-155-06 Mallet for Endosteal Plate





Endosteal Plate Instruments

7-155-07 Extractor Rode for Endosteal PLate



7-155-08 Raspatony for Endosteal Plate



7-155-09 Targeter for Endosteal Plate, Left



7-155-10 Targeter for Endosteal Plate, Right



7-155-11 Drill Bit with Quick Coupling End, Ø4.0mm





7-155-16 Container for Endosteal Plate Instrument Set



7-155-17 Lid for Endosteal plate Instrument Set





Endosteal Plate Instruments

7-155 Instruments Set for AV- WiseLock Endosteal Plate

Code	Set Consisting of	Units
7-155-01	Threaded guide Sleeve, Ø1.8/2.4mm for Endosteal Plate	2
7-155-02	1.8mm Variable Angle Locking Drill Guide, Conical	1
1312-04-1.8	Drill Bit with Quick Coupling End, Ø1.8mm x Length 140mm	1
1312-18	Star Screwdriver Shaft, T8	1
1312-30-2.4	Screw Holding Sleeve for 2.4mm Wise-Lock Screw	1
1312-17	Depth Gauge with Protector measuring upto 50mm	1
7-155-03	Length Measuring Device for Locking Screw	1
1312-21	Torque Limiting Attachment, 0.8Nm	1
7-019-03	Handle for Torque Limiting Attachment	1
7-155-04	Hohmann Retractor, 6 mm	1
7-155-05	Hohmann Retractor, 8.5mm	1
7-155-06	Mallet for Endosteal PLate	1
7-155-07	Extractor Rod for Endosteal Plate	1
7-155-08	Raspatony for Endosteal Plate	1
7-155-09	Targeter for Endosteal Plate, Left	1
7-155-10	Targeter for Endosteal Plate, Right	1
7-155-11	Drill Bit with Quick Coupling End, Ø4.0mm	1
7-155-16	Container for Endosteal Plate Instrument Set	1
7-155-17	Lid for Endosteal plate Instrument Set	1



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