

Variable Angle LCP Mesh Plate

2.4/2.7. Part of the Variable Angle LCP Forefoot/Midfoot System 2.4/2.7.

Surgical Technique



This publication is not intended for distribution in the USA.

Instruments and implants approved by the AO Foundation.



DePuy Synthes

COMPANIES OF *Johnson & Johnson*

Table of Contents

| | | |
|----------------------------|---------------------------------------|----|
| Introduction | Variable Angle LCP Mesh Plate 2.4/2.7 | 2 |
| | AO Principles | 3 |
| | Indications | 4 |
| Surgical Technique | Screw Insertion Techniques | 5 |
| | Implantation | 6 |
| | Implant Removal | 19 |
| Product Information | Screws | 20 |
| | Plate | 22 |
| | Instruments | 23 |
| MRI Information | | 27 |

 Image intensifier control

Warning

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

<http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance>

Variable Angle LCP Mesh Plate

2.4/2.7. Part of the Variable Angle LCP Forefoot/Midfoot System 2.4/2.7.

Features and Benefits

Mesh plate

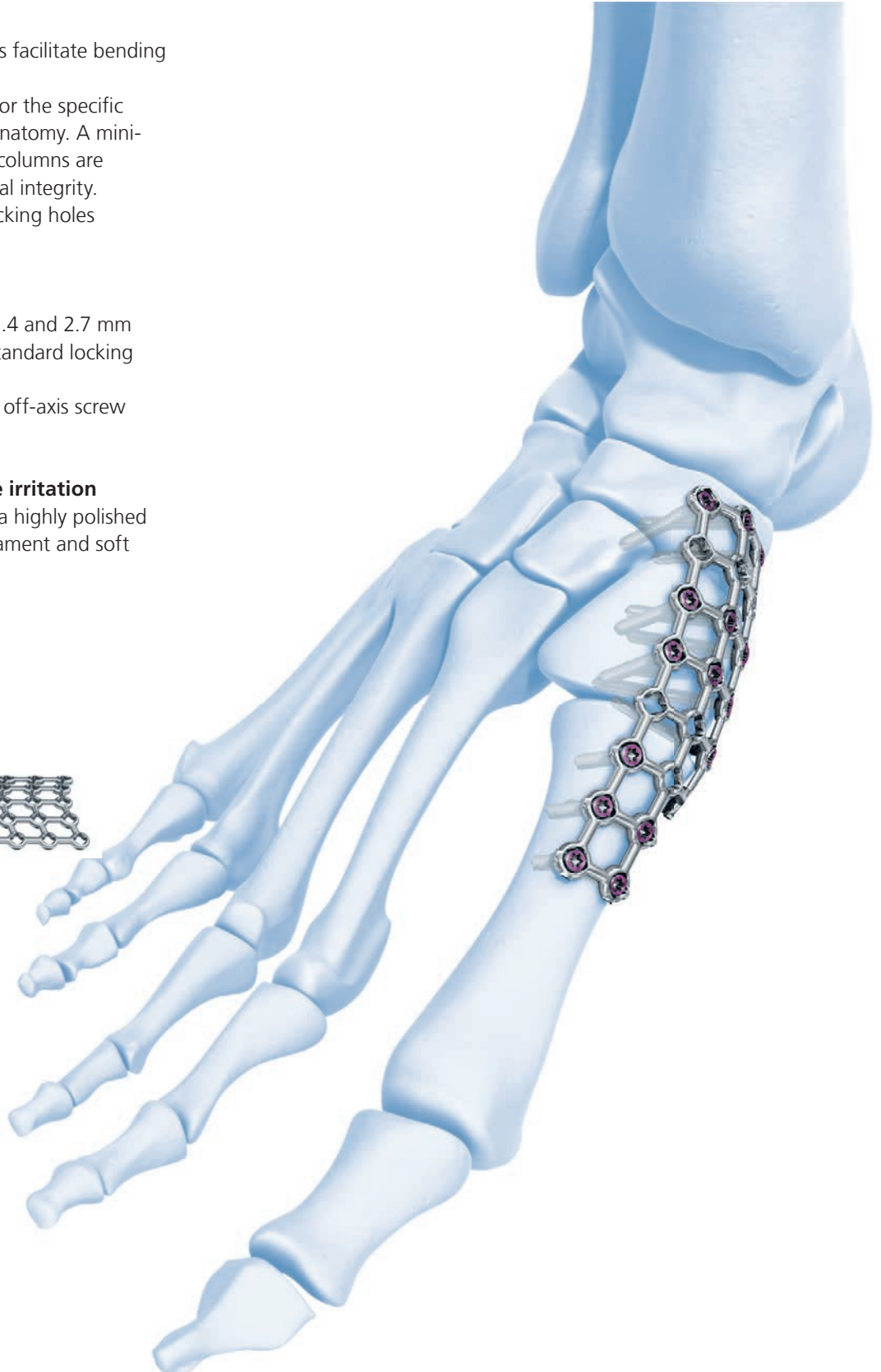
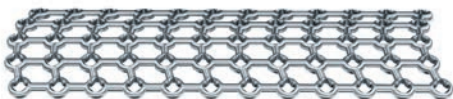
- Ribs between the plate holes facilitate bending and contouring
- Plates can be cut to length for the specific fracture pattern or patient anatomy. A minimum of two rows and two columns are necessary to ensure structural integrity.
- 5×12 variable angle (VA) locking holes
- One size

Variable angle locking

- VA locking holes accept Ø 2.4 and 2.7 mm (head 2.4) VA locking and standard locking screws
- Screw holes allow up to 15° off-axis screw angulation in all directions

Decreased risk of soft tissue irritation

Plate with rounded edges and a highly polished surface decrease the risk of ligament and soft tissue irritation



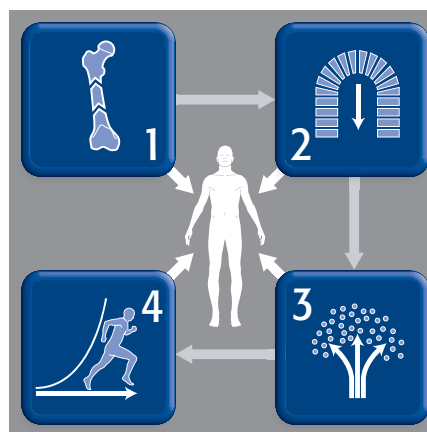
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.^{1,2}

Anatomic reduction

Fracture reduction and fixation to restore anatomical relationships.

Early, active mobilization

Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.



Copyright © 2007 by AO Foundation

Stable fixation

Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

Preservation of blood supply

Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

¹ Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991.

² Rüedi TP, Buckley RE, Moran CG. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007.

Indications

The Mesh Plate, part of the Variable Angle LCP Forefoot/Midfoot System 2.4/2.7, is indicated for fractures, deformations, severe osteoarthritis and non- and mal-unions in the forefoot and midfoot, particularly in osteopenic bone.

Screw Insertion Techniques

Variable angle (VA) locking holes 2.4/2.7 accept \varnothing 2.4 mm and 2.7 mm variable angle (VA) locking screws.

Screws can be inserted using two different techniques:

- Variable angle technique
- Predefined nominal angle technique

Variable angle technique

To drill variable angle holes at $\pm 15^\circ$ deviation from the nominal trajectory of the locking hole, insert the tip of the VA-LCP drill sleeve (03.211.003/03.110.023) and key into the cloverleaf-designed VA locking hole.

Precaution: It is important not to angulate more than 15° from the central axis of the screw hole. Overangulation may complicate screw locking and ultimately lead to inadequate screw locking.

Predefined nominal angle technique

The fixed-angle VA-LCP drill sleeve (03.211.004/03.110.024) only allows the drill bit to follow the nominal trajectory of the locking hole.



VA-LCP Drill Sleeve, conical, for Drill Bits (03.211.003/03.110.023)



Use of funnel-shaped VA-LCP Drill Sleeve



VA-LCP Drill Sleeve, coaxial, for Drill Bits (03.211.004/03.110.024)



Implantation

1a

Prepare joint surface

Remove the cartilage and prepare the joint surface for arthrodesis. The surface of the joint can be manipulated to achieve the desired correction.


1b

Osteotomy

Create an osteotomy starting from one side. Do not cut through the bone, being sure to leave the other cortex intact.

1c

Reduce fracture

-  Reduce the fracture under image intensifier control and, if necessary, fix with Kirschner wires or reduction forceps. The reduction method will be fracture specific.

2

Cut plate

Instruments

| | |
|------------|----------------------------------|
| 03.211.007 | Cutting Pliers for Mesh Plate |
| 391.940 | Wire Cutter, long, length 230 mm |

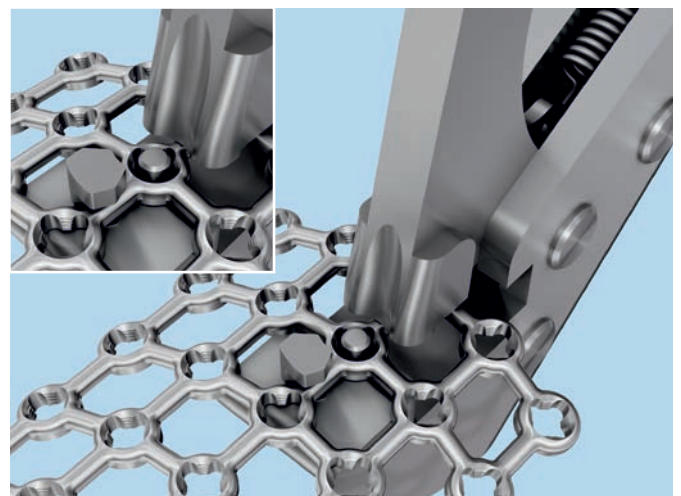
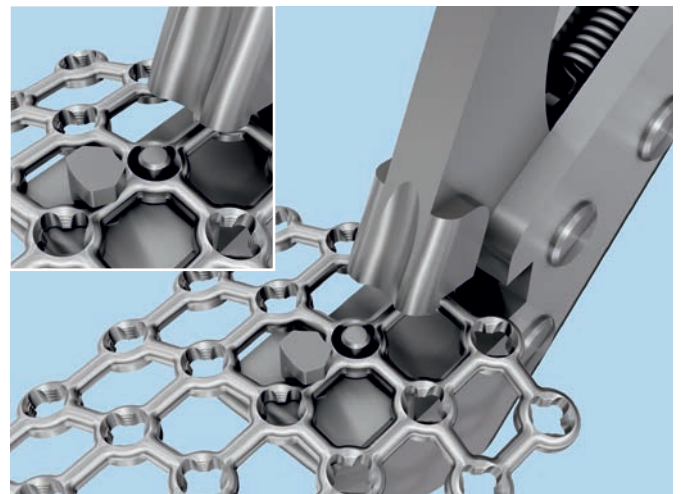
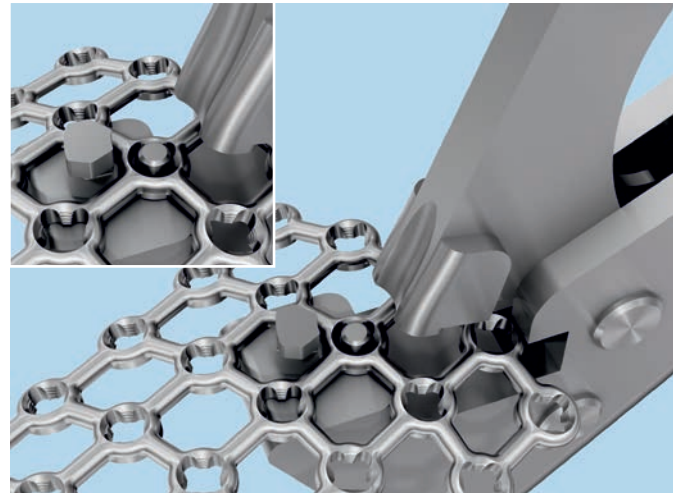
The plate can be cut to fit the patient anatomy. To cut multiple rows, use the wire cutter.

Precaution: A minimum of two rows and two columns are necessary to ensure structural integrity.

The cutting pliers for mesh plate can be used for finer cuts around the screw holes. To prevent sharp edges from causing soft tissue irritation, place the plate into the jaws of the cutter as shown.

- 1) Position the plate on the seating pin.
- 2) Position the plate under the notched pin.
- 3) Cut.

Warning: To prevent sharp edges from causing soft tissue irritation, place the plate into the jaws of the cutter as described. The hole or edge to be removed should be inside the jaws as depicted. To aid in alignment, the adjacent plate hole should be positioned on the seating pin and under the notched pin.



3

Contour plate

Instrument

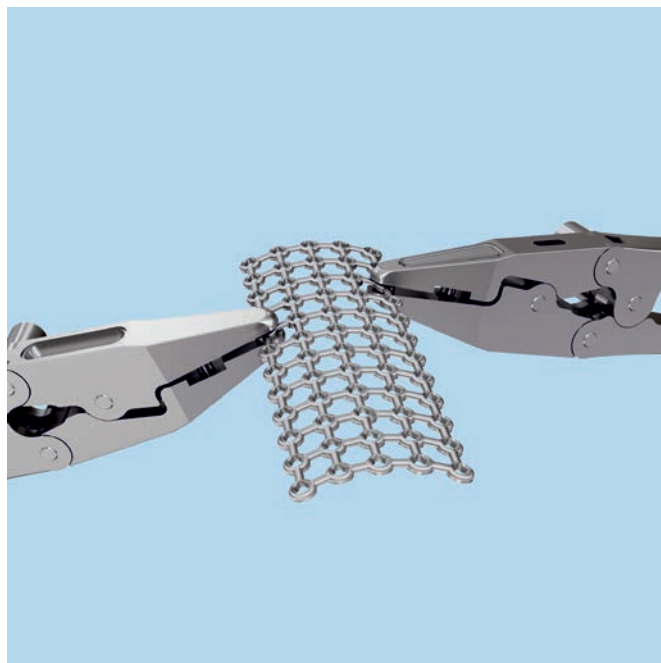
03.211.005 Bending Pliers for VA Locking Plates

The plate can be contoured to fit the specific anatomy and fixation options.

The bending pliers are designed to protect the VA locking holes during contouring. The feature on the pliers lines up with the cloverleaf design of the plate hole. Use two pliers to contour the plate.

Precaution:

- If possible, bend the plate between the VA locking holes. Do not deform the threaded part of the holes or over-bend the plates during bending as this may adversely affect insertion of VA locking screws.
- Do not repeatedly bend the plates back and forth as this may weaken the plate.



4

Drill and insert cortex screws

Instruments for use with cortex screws Ø 2.7 mm

| | |
|------------|---|
| 310.534 | Drill Bit Ø 2.0 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling |
| 310.260 | Drill Bit Ø 2.7 mm, length 100/75 mm, 2-flute, for Quick Coupling |
| 323.260 | Universal Drill Guide 2.7 |
| 03.111.005 | Depth Gauge for Screws Ø 2.0 to 2.7 mm, measuring range up to 40 mm |
| 03.111.038 | Handle with Quick Coupling |
| 314.467 | Screwdriver Shaft, Stardrive, T8, self-holding |

Instruments for use with cortex screws Ø 2.4 mm

| | |
|------------|---|
| 310.509 | Drill Bit Ø 1.8 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling |
| 310.530 | Drill Bit Ø 2.4 mm, length 100/75 mm, 2-flute, for Quick Coupling |
| 323.202 | Universal Drill Guide 2.4 |
| 03.111.005 | Depth Gauge for Screws Ø 2.0 to 2.7 mm, measuring range up to 40 mm |
| 03.111.038 | Handle with Quick Coupling |
| 314.467 | Screwdriver Shaft, Stardrive, T8, self-holding |

Insert independent cortex screws according to the corresponding indication and situation. Use the lag screw technique to achieve additional compression.

For \varnothing 2.4 mm cortex screws, use the 2.4 universal drill guide and predrill the screw hole with the \varnothing 1.8 mm drill bit. For \varnothing 2.7 mm cortex screws, use the 2.7 universal drill guide and predrill the screw hole with the \varnothing 2.0 mm drill bit.

To drill a gliding hole for compression, use the \varnothing 2.7 mm drill bit (for \varnothing 2.7 mm cortex screws) or the \varnothing 2.4 mm drill bit (for \varnothing 2.4 mm cortex screws) with the double drill guide.

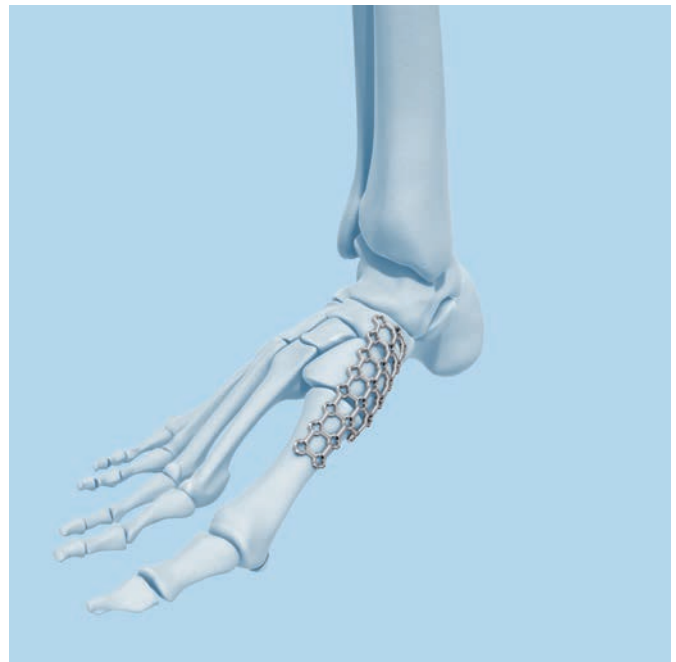
Determine the screw length with the depth gauge and insert the cortex screws manually.

5

Position plate

Position the plate over the osteotomy, the joint or the fracture gap. If necessary, fix provisionally with Kirschner wires or reduction forceps.

Place the plate on the bone, ensuring appropriate placement according to the specific procedure.



6

Predrill for VA locking screws

Instruments for use with VA locking screws \varnothing 2.7 mm

| | |
|------------|---|
| 310.534 | Drill Bit \varnothing 2.0 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling |
| 03.211.003 | VA-LCP Drill Sleeve 2.7, conical, for Drill Bits \varnothing 2.0 mm |
| 03.211.004 | VA-LCP Drill Sleeve 2.7, coaxial, for Drill Bits \varnothing 2.0 mm |
| 03.111.005 | Depth Gauge for Screws \varnothing 2.0 to 2.7 mm, measuring range up to 40 mm |



Instruments for use with VA locking screws \varnothing 2.4 mm

| | |
|-------------|---|
| 310.509 | Drill Bit \varnothing 1.8 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling |
| 03.110.023 | VA-LCP Drill Sleeve 2.4, conical, for Drill Bits \varnothing 1.8 mm |
| 03. 110.024 | VA-LCP Drill Sleeve 2.4, coaxial, for Drill Bits \varnothing 1.8 mm |
| 03.111.005 | Depth Gauge for Screws \varnothing 2.0 to 2.7 mm, measuring range up to 40 mm |



Determine the size of the VA locking screws (\varnothing 2.4 or 2.7 mm) and the insertion technique: variable angle (6a) or predefined nominal angle (6b).

6a

Predrill using variable angle technique

Instruments for use with VA locking screws Ø 2.7 mm

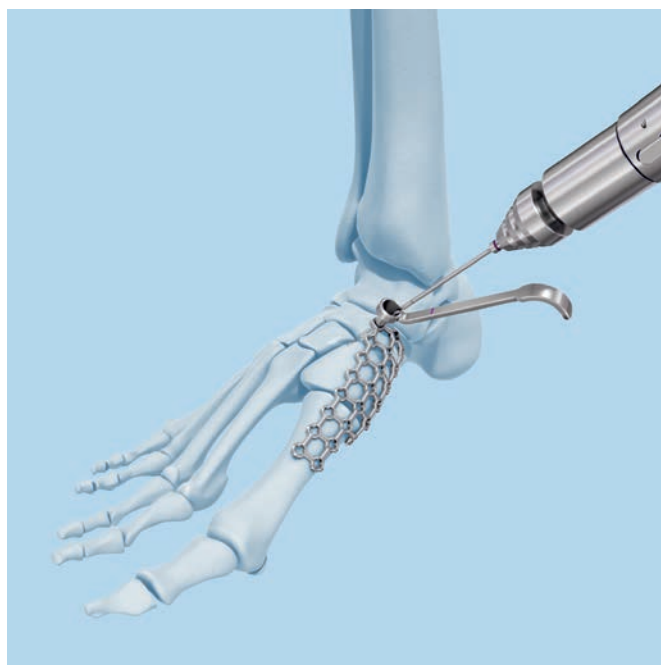
| | |
|------------|---|
| 310.534 | Drill Bit Ø 2.0 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling |
| 03.211.003 | VA-LCP Drill Sleeve 2.7, conical, for Drill Bits Ø 2.0 mm |
| 03.111.005 | Depth Gauge for Screws Ø 2.0 to 2.7 mm, measuring range up to 40 mm |

Instruments for use with VA locking screws Ø 2.4 mm

| | |
|------------|---|
| 310.509 | Drill Bit Ø 1.8 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling |
| 03.110.023 | VA-LCP Drill Sleeve 2.4, conical, for Drill Bits Ø 1.8 mm |
| 03.111.005 | Depth Gauge for Screws Ø 2.0 to 2.7 mm, measuring range up to 40 mm |

VA locking screws allow manipulation around the independent lag screw or existing implants.

Insert and lock the tip of the VA-LCP drill sleeve into the cloverleaf-designed VA locking hole. The cone will self-retain in the hole.



Use the Ø 2.0 drill bit (for Ø 2.7 mm VA locking screws) or the Ø 1.8 mm drill bit (for Ø 2.4 mm VA locking screws) to drill at the desired angle and to the desired depth.

The funnel of the drill sleeve allows the drill bit up to 15° angulation around the central axis of the locking hole.

Precaution: To ensure that the drill sleeve is locked correctly, do not angle the drill bit in excess of +/- 15° from the nominal trajectory of the hole.

- Verify the drill bit angle and depth under image intensifier control. If incorrect, drill at a different angle and verify again.

Use the corresponding depth gauge to measure the correct screw length.



6b

Predrill using predefined nominal angle technique

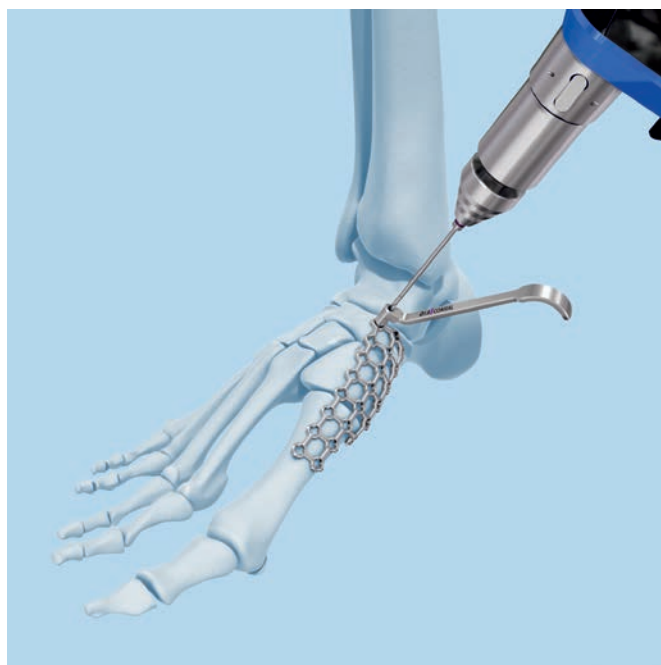
Instruments for use with VA locking screws Ø 2.7 mm

| | |
|------------|---|
| 310.534 | Drill Bit Ø 2.0 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling |
| 03.211.004 | VA-LCP Drill Sleeve 2.7, coaxial, for Drill Bits Ø 2.0 mm |
| 03.111.005 | Depth Gauge for Screws Ø 2.0 to 2.7 mm, measuring range up to 40 mm |

Instruments for use with VA locking screws Ø 2.4 mm

| | |
|------------|---|
| 310.509 | Drill Bit Ø 1.8 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling |
| 03.110.024 | VA-LCP Drill Sleeve 2.4, coaxial, for Drill Bits Ø 1.8 mm |
| 03.111.005 | Depth Gauge for Screws Ø 2.0 to 2.7 mm, measuring range up to 40 mm |

VA locking screws and standard locking screws can be inserted into the plate at the predefined hole angle.



Insert and lock the tip of the VA-LCP drill sleeve into the cloverleaf-designed VA locking hole. The coaxial drill sleeve will self-retain in the hole.

Use the \varnothing 2.0 drill bit (for \varnothing 2.7 mm VA locking screws and standard locking screws) or the \varnothing 1.8 mm drill bit (for \varnothing 2.4 mm VA locking screws and standard locking screws) to drill to the desired depth.

- Verify the drill bit depth under image intensifier control.

Use the corresponding depth gauge to measure the correct screw length.



7

Insert VA locking screws

Instruments

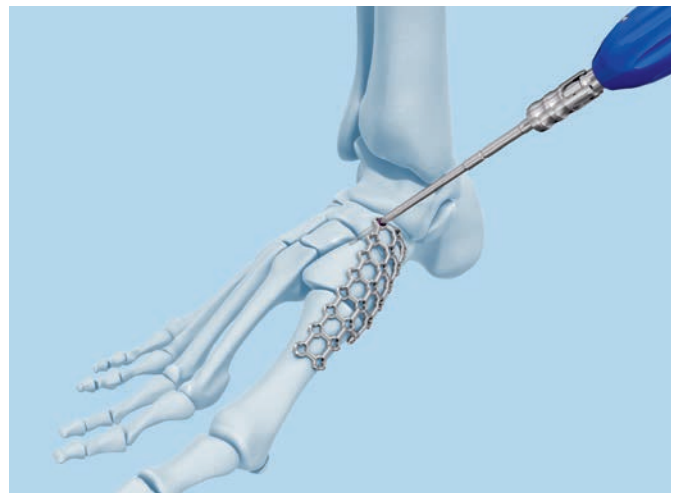
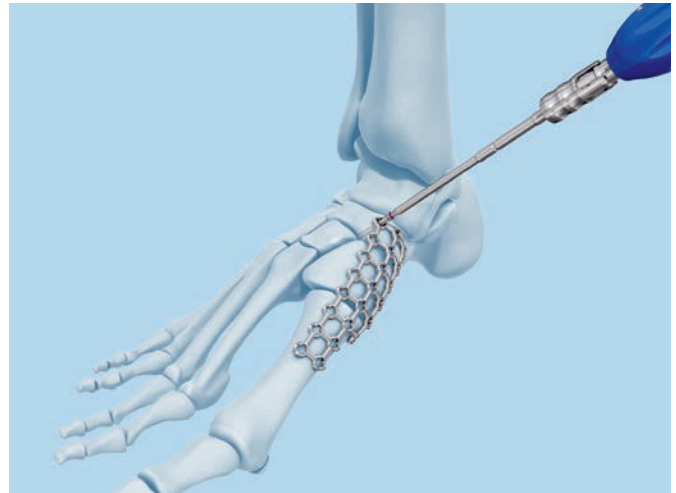
| | |
|------------|--|
| 314.467 | Screwdriver Shaft, Stardrive, T8, self-holding |
| 03.111.038 | Handle with Quick Coupling |

Insert the correct length VA locking screw manually using the screwdriver shaft and handle with quick coupling. Insert the screw until the screw head is seated (with limited force) in the VA locking hole.

Precaution: Do not over-tighten screws. This allows for the screws to be easily removed should they not be in the desired position.

Insert additional screws as needed.

Confirm proper reconstruction, screw placement and screw length under image intensifier control.



8

Final tighten VA locking screws

Instruments

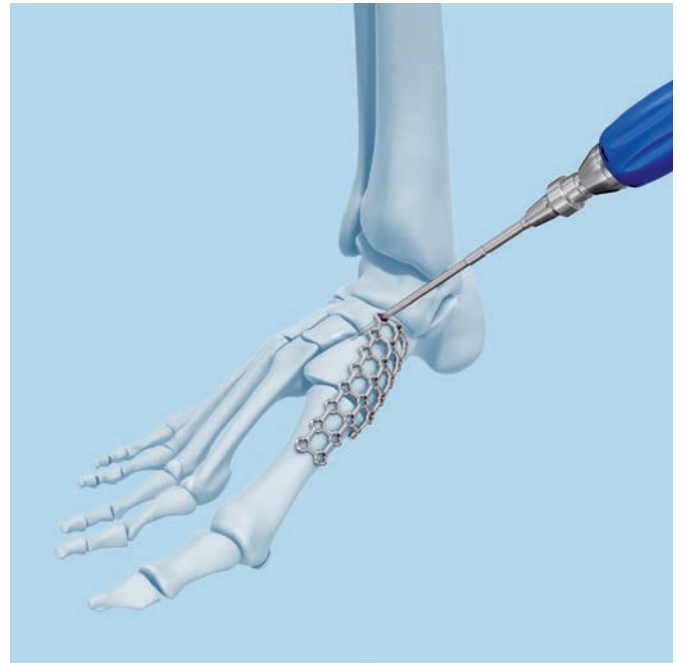
| | |
|------------|---|
| 314.467 | Screwdriver Shaft, Stardrive, T8, self-holding |
| 03.110.002 | Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling |
| 03.110.005 | Handle for Torque Limiters 0.4/0.8/1.2 Nm |

Use the 1.2 Nm torque limiter to final tighten the VA locking screws. The torque limiter attaches to the T8 Stardrive screwdriver shaft and the blue handle of the torque limiter.

Use of the torque limiter is mandatory for VA locking holes to ensure the correct amount of torque is applied when final tightening the screws.

After final tightening, the screws are securely locked in the plate to achieve maximum strength of the plate-screw interface.

Note: For final locking, the 1.2 Nm TLA torque limiting attachment is required.



9

Ensure proper reconstruction

Ensure proper joint reconstruction, screw placement and screw length under image intensifier control. Verify that the screws are not in the joint or the soft tissue.



Implant Removal

Instruments

| | |
|---------|--|
| 314.467 | Screwdriver Shaft, Stardrive, T8, self-holding |
|---------|--|

| | |
|------------|----------------------------|
| 03.111.038 | Handle with Quick Coupling |
|------------|----------------------------|

To remove locking screws, first unlock all locking screws before removing them completely, otherwise the plate may rotate and damage the soft tissue.



Screws

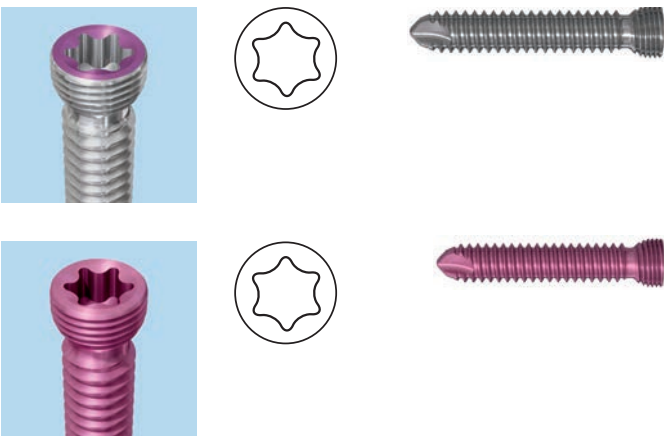
Variable Angle Locking Screws Ø 2.7 mm

| | |
|-----------------------------|--|
| 0X.211.010– 0X.211.040* | VA Locking Screw Stardrive Ø 2.7 mm (head 2.4), self-tapping, length 10–40 mm |
| 0X.211.042S– 0X.211.060S | VA Locking Screw Stardrive Ø 2.7 mm (head 2.4), self-tapping, length 42–60 mm, sterile |

Threaded, rounded head locks securely into the threaded VA locking holes to provide angular stability at angles determined by the surgeon.

Also securely locks into standard locking holes of the plate at the predefined angle.

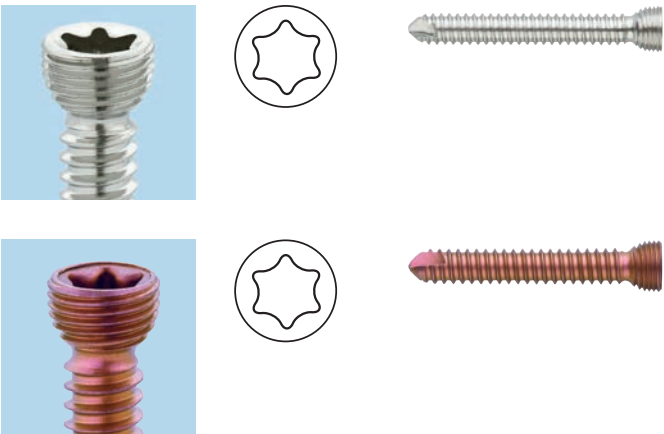
Note: For final locking, the 1.2 Nm TLA torque limiting attachment is required.



Optional

Variable Angle Locking Screws Ø 2.4 mm

| | |
|-----------------------------|--|
| 0X.210.106– 0X.210.140* | VA Locking Screw Stardrive Ø 2.4 mm, self-tapping, length 6–40 mm |
| 0X.210.142S– 0X.210.160S | VA Locking Screw Stardrive Ø 2.4 mm, self-tapping, length 42–60 mm, sterile |



X = 2: Stainless steel
X = 4: TAN

*Are available nonsterile and sterile packed. To order sterile packed screws, add suffix “S” to article number.

Optional

Cortex Screws Ø 2.7 mm

| | |
|-----------------------|--|
| X02.870– X02.900* | Cortex Screw Stardrive Ø 2.7 mm, self-tapping, length 10–40 mm |
| X02.962S– X02.960S | Cortex Screw Stardrive Ø 2.7 mm, self-tapping, length 42–60 mm, sterile |



Optional

Cortex Screws Ø 2.4 mm

| | |
|-----------------------------|--|
| X01.756– X01.790* | Cortex Screw Stardrive Ø 2.4 mm, self-tapping, length 6–40 mm |
| OX.210.942S– OX.210.960S | Cortex Screw Stardrive Ø 2.4 mm, self-tapping, length 42–60 mm, sterile |



Optional

Locking Screws Ø 2.4/2.7 mm

| | |
|----------------------|---|
| X12.806– X12.830* | Locking Screw Stardrive Ø 2.4 mm, self-tapping, length 6 – 30 mm |
| X02.206– X02.260* | Locking Screw Stardrive Ø 2.7 mm (head LCP 2.4), self-tapping, length 6–60 mm |

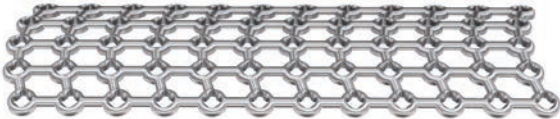


X = 2: Stainless steel
X = 4: TAN

*Are available nonsterile and sterile packed. To order sterile packed screws, add suffix "S" to article number.

Mesh Plate 2.4/2.7, VA locking

| Art. No. | Holes | Length (mm) | Width (mm) |
|-------------|-------|-------------|------------|
| 0X.211.224S | 5×12 | 113 | 39 |



X = 2: Stainless steel
X = 4: TAN

Plates are only available sterile packed.

Instruments

314.467 Screwdriver Shaft, Stardrive, T8, self-holding



03.110.002 Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling



03.110.005 Handle for Torque Limiters 0.4/0.8/1.2 Nm



03.111.005 Depth Gauge for Screws \varnothing 2.0 to 2.7 mm, measuring range up to 40 mm



03.111.038 Handle with Quick Coupling



03.211.001 Holding Pin for VA Locking Plates 2.4/2.7



Instruments for mesh plate

391.940 Wire Cutter, long, length 230 mm



03.211.005 Bending Pliers for VA Locking Plates



03.211.007 Cutting Pliers for Mesh Plate



Instruments for insertion of Ø 2.7 mm screws

| | |
|---------|---|
| 310.260 | Drill Bit Ø 2.7 mm, length 100/75 mm, 2-flute, for Quick Coupling |
|---------|---|



| | |
|---------|---|
| 310.534 | Drill Bit Ø 2.0 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling |
|---------|---|



| | |
|---------|---------------------------|
| 323.260 | Universal Drill Guide 2.7 |
|---------|---------------------------|



| | |
|------------|---|
| 03.211.003 | VA-LCP Drill Sleeve 2.7, conical, for Drill Bits Ø 2.0 mm |
|------------|---|



| | |
|------------|---|
| 03.211.004 | VA-LCP Drill Sleeve 2.7, coaxial, for Drill Bits Ø 2.0 mm |
|------------|---|



Instruments for insertion of Ø 2.4 mm screws

310.509 Drill Bit Ø 1.8 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling



310.530 Drill Bit Ø 2.4 mm, length 100/75 mm, 2-flute, for Quick Coupling



323.202 Universal Drill Guide 2.4



03.110.023 VA-LCP Drill Sleeve 2.4, conical, for Drill Bits Ø 1.8 mm



03.110.024 VA-LCP Drill Sleeve 2.4, coaxial, for Drill Bits Ø 1.8 mm



Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils [whole body averaged specific absorption rate (SAR) of 2 W/kg for 6 minutes (1.5 T) and for 15 minutes (3 T)].

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
 - Patients with impaired thermo regulation or temperature sensation should be excluded from MR scanning procedures.
 - Generally it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
 - Using the ventilation system may further contribute to reduce temperature increase in the body.
-

