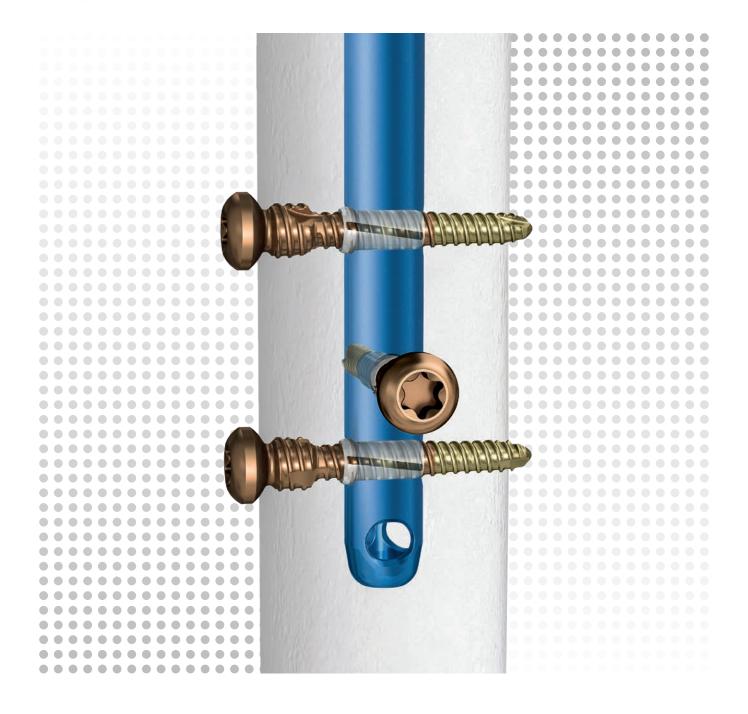
Angular Stable Locking System (ASLS)

For Angular Stable Locking of Intra-medullary Tibial Nails

Surgical Technique









(Image intensifier control

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

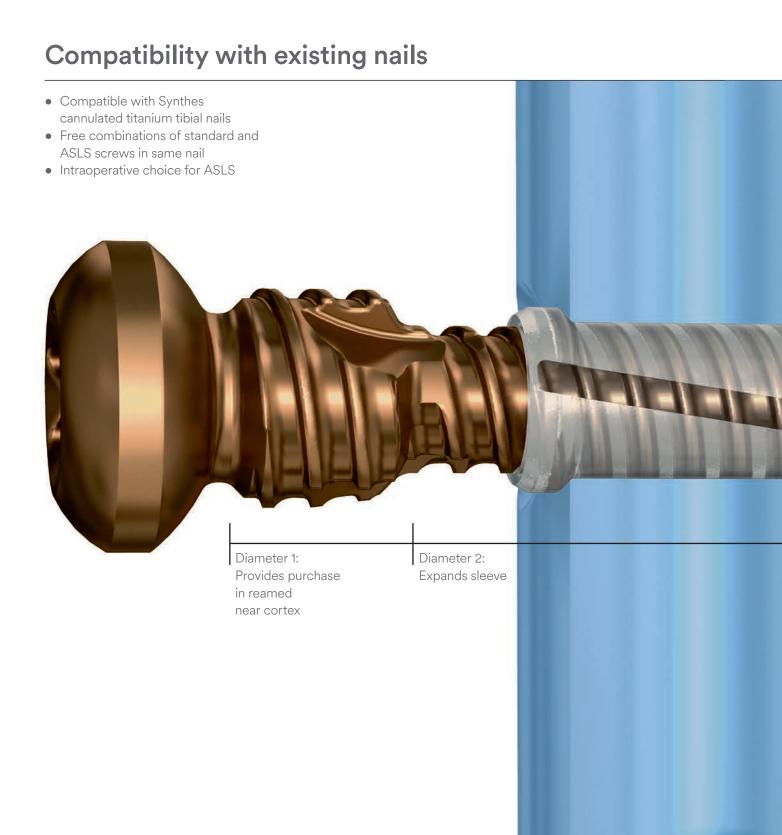
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

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

Table of Contents

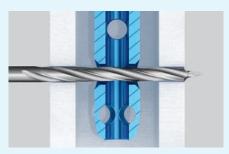
Introduction	Angular Stable Locking System (ASLS)	2
	The AO Principles of Fracture Management	4
Surgical Technique	Preparation	6
	Targeted Locking	8
	Freehand Locking	14
	Screw Insertion	21
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	ASLS Compatibility with Tibial Nails	30
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Angular Stable Locking System (ASLS)





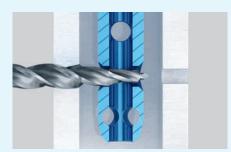
Bioresorbable sleeve 70:30 poly (L-lactide-co-D,L-Lactide)



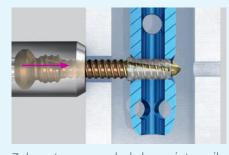
1. Drill both cortices



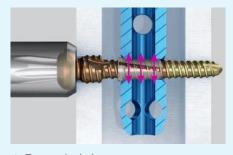
Diameter 3:
Holds unexpanded sleeve for screw insertion



2. Ream near cortex



3. Insert unexpanded sleeve into nail



4. Expanded sleeve

The AO Principles of Fracture Management

Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles^{1,2}

1.



Fracture reduction and fixation to restore anatomical relationships.

2.



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

3.



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling. 4.



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

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

² Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

Intended Use, Indications, and Contraindications can be found in the corresponding system Instructions for Use.

▲ Precaution:

Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding Instructions for Use, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.

Preparation

The following pages depict different techniques for locking with ASLS. All images use illustrations of the Expert Tibial Nail as an example.

1. Preoperative Planning

Complete the preoperative radiographic assessment and prepare the preoperative plan.

■ Note:

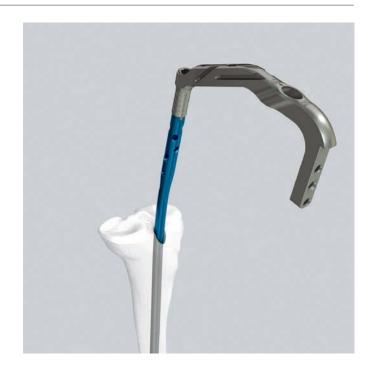
When selecting the nail size, consider canal diameter, fracture pattern, patient anatomy and post-operative protocol.

2. Reduce fracture and insert nail

Reduce the fracture and insert the nail. Use a compatible Synthes cannulated titanium intramedullary nailing system according to the respective technique guide.

■ Note:

The ASLS is only compatible with cannulated tibial nails.



3. Choose appropriate locking screws

For each locking hole, pre-select the appropriate locking implant that will stabilize the fracture. If using an ASLS screw, the diameter of the ASLS screw and instruments will match the diameter of the standard screw/bolt for the respective nail.

■ Note:

A combination of standard locking screws/bolts and ASLS screws can be used in the same nail.

▲ Precaution:

Do not exchange a standard locking screw/bolt for an ASLS screw or vice versa as this may reduce screw-to-bone interface stability.



Targeted Locking

1. Mount aiming arm and insert trocar combination

Instruments	
03.010.063	Protection Sleeve 12.0/8.0, length 188 mm (for Expert nails)
03.025.040	Protection Sleeve 11.0/8.0, length 188 mm (for other nail systems)
ASLS4:	
03.010.064	Drill Sleeve 8.0/3.2, for No. 03.010.063
03.010.069	Trocar Ø 3.2 mm, for No. 03.010.064
ASLS5:	
03.010.065	Drill Sleeve 8.0/4.2, for No. 03.010.063
03.010.070	Trocar Ø 4.2 mm, for No. 03.010.065



Select the appropriate protection sleeve.

Insert the appropriate three-part trocar combination (protection sleeve, drill sleeve and trocar) through the desired hole in the aiming arm. Make a skin incision and insert the trocar to the bone. Remove the trocar.

■ Note:

Ensure that the drill sleeve is pressed firmly to the near cortex.



2. Drill through both cortices

Instruments	
ASLS4:	
03.025.104	Drill Bit ASLS4, calibrated, length 331mm, 3-flute, for Quick Coupling, for No. 03.010.064
ASLS5:	
03.025.105	Drill Bit ASLS5, calibrated, length 331mm, 3-flute, for Quick Coupling, for No. 03.010.065

Using the appropriate drill bit, drill through both cortices until the tip of the drill bit penetrates the far cortex.

(1) If necessary, use image intensification to control the position of the drill bit.

▲ Precaution:

Follow all recommended techniques for screw/bolt insertion for the respective nail system. When using monocortical locking screws, stop drilling immediately after penetrating the near cortex.



3. Determine locking screw length

Read the measurement from the calibrated drill bit at the back of the drill sleeve. Select the length of the ASLS screw accordingly. Remove the drill bit and drill sleeve.

Follow all recommended techniques for screw/bolt measurement for the respective nail system.



Alternative technique

Instrument

03.025.052 Depth Gauge for ASLS

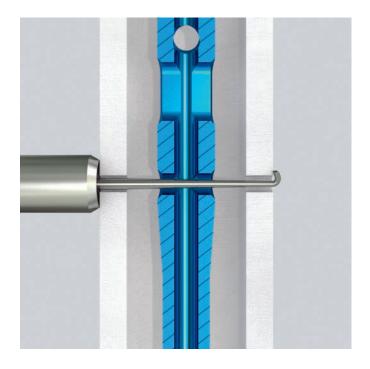
Remove the drill bit and the drill sleeve. Disassemble the depth gauge, separating the outer sleeve from the measuring device with hook. Insert the measuring device with hook into the protection sleeve.

Read the measurement from the back of the protection sleeve and select the length of the ASLS screw accordingly.



■ Note:

Ensure that the hook grasps the far cortex and that the protection sleeve is pressed firmly to the bone.



4. Ream near cortex

Instruments	
ASLS4:	
03.025.030	Hand Reamer ASLS4, length 270 mm, for near cortex
ASLS5:	
03.025.031	Hand Reamer ASLS5, length 270 mm, for near cortex

Align the hand reamer with the locking hole axis. Ream the near cortex and clear the passage down to the nail. Remove the hand reamer.

(1) If necessary, use image intensification to control the position of the hand reamer.

■ Note:

To correctly insert the ASLS sleeve, ensure:

- the near cortex is completely reamed.
- the passage from near cortex to nail locking hole is cleared.
- the drilled/reamed hole is in line with the nail locking hole.



Alternative technique

Instruments	
ASLS4:	
03.025.134	Reamer ASLS4, length 268 mm, for near cortex, for Quick Coupling
ASLS5:	
03.025.135	Reamer ASLS5, length 288 mm, for near cortex, for Quick Coupling

Use a power driven reamer to open the near cortex.

Align the reamer with the locking hole axis and ream the near cortex. Once the large diameter of the reamer passes through the near cortex, stop reaming immediately. Remove the reamer.

If necessary, clear the passage down to the nail with the hand reamer.

(1) If necessary, use image intensification to control the position of the reamer.

▲ Precaution:

Ensure that the reamer does not damage the nail.

Continue with chapter "Screw insertion".



Freehand Locking

1. Align image

The techniques for distal locking apply. Align the image intensifier with the desired locking hole until a perfect circle is visible in the center of the screen.

■ Note:

Ensure that the image displayed on the image intensifier mirrors the actual image in all axes.



2. Make incision

Using image intensification, place a long K-wire or alternative long instrument on the skin over the center of the hole to mark the incision point.

Make a skin incision with a scalpel blade at this location.

■ Note:

Check the reduction, correct alignment of the fragments, and leg length before locking.



3. Drill through both cortices

Instruments	Instruments	
511.300	Radiolucent Drive	
ASLS4:		
03.025.124	Drill Bit ASLS4, length 145 mm, 3-flute, for RDL	
ASLS5:		
03.025.125	Drill Bit ASLS5, length 145 mm, 3-flute, for RDL	

- Attach the appropriate drill bit to the radiolucent drive. Using image intensification, insert the tip of the drill bit through the incision and to the bone.
- Incline the drive to center the tip of the drill bit over the locking hole. The drill bit should nearly fill the circle of the locking hole. Hold the drill bit in this position and drill through both cortices. Stop drilling immediately after the tip of the drill penetrates the far cortex. Remove the drill bit.

▲ Precaution:

Follow all recommended techniques for screw/bolt insertion for the respective nail system. When using monocortical locking screws, stop drilling immediately after penetrating the near cortex.





Alternative technique

Instruments	
ASLS4:	
03.025.082	Drill Bit ASLS4, length 150 mm, 3-flute, for Quick Coupling
ASLS5:	
03.025.083	Drill Bit ASLS5, length 150 mm, 3-flute, for Quick Coupling

Standard freehand locking technique can be performed without the radiolucent drive. Use the appropriate drill bit shown in the table above.

4. Determine locking screw length

Instrument

03.025.052 Depth Gauge for ASLS

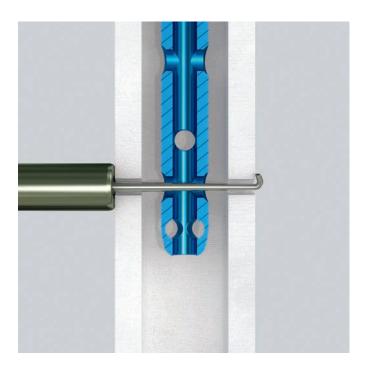
Insert the depth gauge into the drilled hole. Read the measurement from the outer sleeve of the depth gauge and then select the length of the ASLS screw accordingly.

Follow all recommended techniques for screw/bolt measurement for the respective nail system.



■ Note:

Ensure that the hook grasps the far cortex and that the protection sleeve is pressed firmly to the bone.



Alternative technique

Instrument	
03.010.106	Direct Measuring Device for Drill Bits of length 145 mm, for Nos. 03.010.100 to 03.010.105

Use the direct measuring device for radiolucent drill bits according to the technique described in the respective Expert Nail technique guide.



5. Ream near cortex

Instruments	
ASLS4:	
03.025.030	Hand Reamer ASLS4, length 270 mm, for near cortex
ASLS5:	
03.025.031	Hand Reamer ASLS5, length 270 mm, for near cortex

Align the hand reamer with the locking hole axis. Ream the near cortex and clear the passage down to the nail. Remove the hand reamer.

If necessary, use image intensification to control the position of the hand reamer.

■ Note:

To correctly insert the ASLS sleeve, ensure:

- the near cortex is completely reamed.
- the passage from near cortex to nail locking hole is cleared.
- the drilled/reamed hole is in line with the nail locking hole.



Alternative technique

Instruments ASLS4: 03.025.027 Reamer ASLS4, length 145 mm, for near cortex, for Quick Coupling ASLS5: 03.025.028 Reamer ASLS5, length 145 mm, for near cortex, for Quick Coupling

Use a power driven reamer to open the near cortex. Align the reamer with the locking hole axis and ream the near cortex. Once the large diameter of the reamer passes through the near cortex, stop reaming immediately. Remove the reamer.

If necessary, clear the passage down to the nail with the hand reamer.



▲ Precaution:

Ensure that the reamer does not damage the nail.



Screw Insertion

1. Mount sleeve

Instruments

ASLS4:

08.025.032.01S Sleeve for ASLS, resorbable, sterile

ASLS5:

08.025.044.01S Sleeve for ASLS, resorbable, sterile

Select the appropriate sleeve.

Insert the sleeve so that the sleeve lip is facing the screw head. Thread the ASLS sleeve onto the ASLS screw. The screw tip will protrude approximately 2 mm beyond the sleeve.

■ Note:

The sleeve is positioned correctly when gold is visible on either side of the sleeve and the screw tip protrudes 1–2 mm beyond the sleeve.

▲ Precautions:

Do not use ASLS screws without sleeves.

 When mounting the sleeve, stop threading the sleeve once resistance increases. Resistance occurs when the sleeve expands as it moves onto the larger diameter of the screw. An expanded sleeve will prevent screw/ sleeve insertion into a locking hole.

▲ WARNINGS:

- Only use ASLS Sleeves together with the specially developed Synthes ASLS screws.
- Do not use ASLS with solid nails.
- Do not use ASLS with Stainless Steel nails.
- Do not use ASLS with any other than Synthes nails.
- The use of ASLS with antibiotic-coated nails may require increased force for the insertion of the ASLS sleeve.



Alternative technique

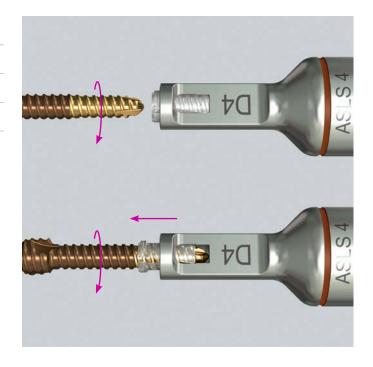
Instruments

ASLS4/5:

03.025.067 Sleeve Positioner ASLS4/ SLS5

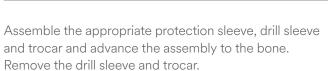
Place the sleeve into the appropriate side of the sleeve positioner.

Insert the screw into the sleeve until the sleeve is pushed out of the sleeve positioner.



2. Push screw/sleeve assembly into locking hole

Instruments	
03.010.063	Protection Sleeve 12.0/8.0, length 188 mm (for Expert nails)
03.025.040	Protection Sleeve 11.0/8.0, length 188 mm (for other nail systems)
03.010.107	Screwdriver Stardrive, SD25, length 330 mm
ASLS4:	
03.010.064	Drill Sleeve 8.0/3.2, for No. 03.010.063
03.010.069	Trocar ∅ 3.2 mm, for No. 03.010.064
ASLS5:	
03.010.065	Drill Sleeve 8.0/4.2, for No. 03.010.063
03.010.070	Trocar ∅ 4.2 mm, for No. 03.010.065



Mount the ASLS screw/sleeve assembly onto the screw-driver.



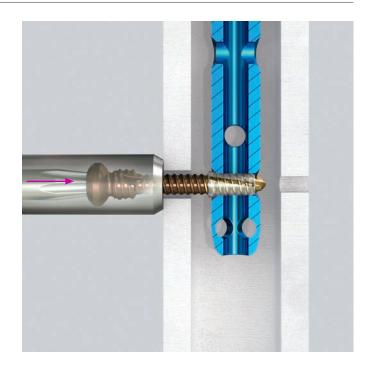
Push the ASLS screw/sleeve assembly through the protection sleeve, near cortex, and into the nail locking hole. If necessary, lightly tap the screwdriver to insert the screw/sleeve into the locking hole.

▲ Precaution:

Do not rotate the screwdriver until the sleeve is seated in the locking hole.

■ Note:

If the screw/sleeve assembly cannot be pushed to the nail stop, use the appropriate reamer to completely open the near cortex. (see step "Ream near cortex")



Optional technique

Instrument

399.500 Hammer 100 g

If necessary, lightly hammer to insert the screw into the nail locking hole.

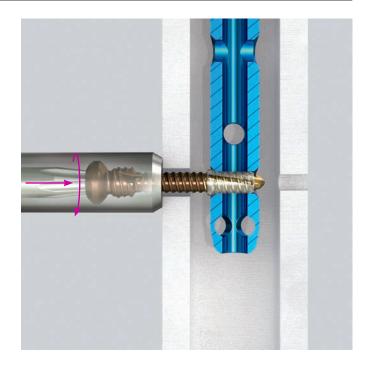


3. Screw into far cortex

Push the screwdriver to get the screw started. Rotate the screwdriver to advance the screw and engage the screw threads in the far cortex.

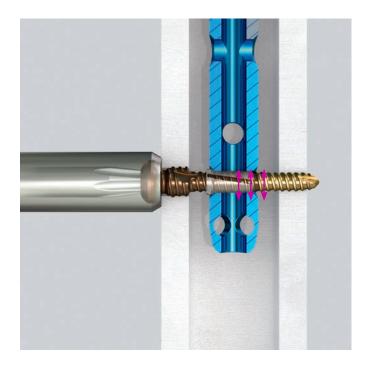
■ Note:

The larger diameter core expands the sleeve in the nail.



■ Note:

In the final screw position, the largest diameter screw threads will engage the near cortex and the screw tip will protrude beyond the far cortex.

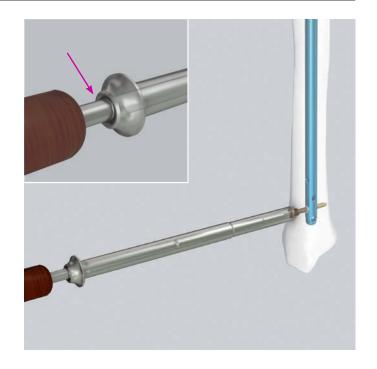


■ Note:

To prevent over-insertion of the ASLS screw, use a protection sleeve during screw insertion.

Ensure that the protection sleeve is pressed to the bone. Advance the screw until the engraved line on the screw-driver shaft meets the edge of the protection sleeve.

After insertion of all screws, use image intensification to ensure that reduction is maintained that the screw heads are down the bone and the screws are not over inserted.



4. Intraoperative screw exchange

Instruments	
03.010.107	Screwdriver Stardrive, T25, length 330 mm
03.010.112	Holding Sleeve, with Locking Device

Using standard technique, remove the ASLS screw with the screwdriver and if necessary, by pulling with the holding sleeve.

■ Note:

Since the sleeve remains in the nail, it does not need to be removed and exchanged.



Implant Removal

1. Remove screws

Instruments	
03.010.107	Screwdriver Stardrive, T25, length 330 mm
03.010.112	Holding Sleeve, with Locking Device

Using standard technique, remove ASLS screws with the screwdriver and if necessary, the holding sleeve.



2. Remove nail

Remove the nail using standard technique for the respective nail system.

■ Note:

The sleeves remain in the nail if not fully resorbed and can be removed with the nail during nail removal.



Implants

	ASLS4	ASLS5
Length	Ø4mm	Ø 5 mm
26 mm	04.025.416\$	
28 mm	04.025.4185	
30 mm	04.025.420\$	04.025.520\$
32 mm	04.025.4225	04.025.5225
34 mm	04.025.4245	04.025.524\$
36 mm	04.025.4265	04.025.526\$
38 mm	04.025.4285	04.025.528\$
40 mm	04.025.430\$	04.025.530\$
42 mm	04.025.4325	04.025.5325
44 mm	04.025.434\$	04.025.534\$
46 mm	04.025.436\$	04.025.536\$
48 mm	04.025.438\$	04.025.538\$
50 mm	04.025.440\$	04.025.540\$
52 mm	04.025.4425	04.025.5425
54 mm	04.025.444\$	04.025.544\$
56 mm	04.025.4465	04.025.546\$
58 mm	04.025.448\$	04.025.548\$
60 mm	04.025.450\$	04.025.550\$
62 mm	04.025.4525	04.025.5525
64 mm	04.025.454\$	04.025.554\$
66 mm	04.025.456\$	04.025.556\$
68 mm	04.025.458\$	04.025.558\$
70 mm	04.025.460\$	04.025.560\$
72 mm	04.025.462\$	04.025.5625
74 mm	04.025.4645	04.025.564\$
76 mm	04.025.466\$	04.025.566\$
78 mm	04.025.4685	04.025.568\$
80 mm	04.025.470\$	04.025.570\$
85 mm		04.025.575\$
90 mm		04.025.580\$
95 mm		04.025.585\$
100 mm		04.025.590\$



ASLS Screws

- Titanium-6% aluminium-7% niobium alloy (TAN)
- Fully threaded shaft with 3 diameters
- Self-tapping, blunt tip
- Stardrive SD25 recess
- Available in diameters of 4.0 mm (ASLS4) and 5.0 mm (ASLS5)
- Sterile-packed

ASLS sleeves

- 70:30 poly (L-lactide-co-D, L-lactide)
- Inner thread for fit to screw
- Expands in nail locking hole
- Available in diameters of 4 mm (ASLS4) and 5 mm (ASLS5)
- Sterile-packed

	ASLS4	ASLS5
Diameter	Ø4mm	Ø5mm
	08.025.032.01S	08.025.044.01S



ASLS Compatibility with Tibial Nails

The Angular Stable Locking System is compatible with tibial nailing system fulfilling following criteria:

- Made of Titanium
- Cannulated

	Nailing System	⊘ Nail (mm)	ASLS4 ∅ 4 mm (brown)	ASLS5 ∅ 5 mm (light blue)
Tibia	Expert Tibial Nail (ETN)	8-9	•	
		10 –13		•

Instruments

General in	nstruments	
03.010.063	Protection Sleeve 12.0/8.0, length 188 mm (For Expert nails)	
03.025.040	Protection Sleeve 11.0/8.0, length 188 mm (For other nail systems)	
03.010.107	Screwdriver StarDrive, T25, length 330 mm	
03.010.112	Holding Sleeve, with Locking Device	
03.025.052	Depth Gauge for ASLS	
03.025.067	Sleeve Positioner ASLS4/5	₩ 10
399.500	Hammer 100 g	

Instruments	for tare	aeted l	ockina
iliati diliciita	ioi taiş	gotour	OCKIIIG

03.010.064	Drill Sleeve 8.0/3.2, for No. 03.010.063
03.010.065	Drill Sleeve 8.0/4.2, for No. 03.010.063



03.010.069	Trocar Ø 3.2 mm, f	or No.	03.010.064
03.010.070	Trocar Ø 4.2 mm, f	or No.	03.010.065



03.025.104	Drill	Bi	t ASLS4	, C	alib	rated,
				_	CI	

length 331mm, 3-flute, for Quick Coupling, for No. 03.010.064

03.025.105 Drill Bit ASLS5, calibrated,

length 331mm,

3-flute, for Quick Coupling,

for No.03.010.065

	_	
it ASLS4, calibrated,		 144444444
n 331mm. 3-flute.		

03.025.134 Reamer ASLS4, length 268 mm,

for near cortex, for Quick Coupling

03.025.135 Reamer ASLS5, length 288 mm, for near cortex, for Quick Coupling



03.025.030 Hand Reamer ASLS4, length 270 mm,

for near cortex

03.025.031 Hand Reamer ASLS5, length 270 mm,

for near cortex



Instruments for freehand locking

03.025.027	Reamer ASLS4, length 145 mm,
	for near cortex, for Quick Coupling
03.025.028	Reamer ASLS5, length 145 mm,
	for near cortex, for Quick Coupling



03.025.030	Hand Reamer ASLS4, length 270 mm,
	for near cortex
03.025.031	Hand Reamer ASLS5, length 270 mm,
	for near cortex



03.025.124	Drill Bit ASLS4, length 145 mm,
	3-flute, for RDL
03.025.125	Drill Bit ASLS5, length 145 mm,
	3-flute, for RDL



03.025.082	Drill Bit ASLS4, length 150 mm, 3-flute,
	for Quick Coupling
03.025.083	Drill Bit ASLS5, length 150 mm, 3-flute,
	for Quick Coupling



Vario Case

68.025.001	Vario Case for ASLS Instruments, size 1/1, without Contents
689.507	Lid (Stainless Steel), size 1/1, for Vario Case

Power Tools

Compact Air Drive II

511.701	Compact Air Drive II
511.300	Radiolucent Drive
511.730	Chuck with Key, for Compact Air Drive and Power Drive
511.750	AO/ASIF Quick Coupling, for Compact Air Drive and Power Drive

Sets

68.025.001	Vario Case for ASLS Instruments, size 1/1, without Contents
689.507	Lid (Stainless Steel), size 1/1, for Vario Case

General instruments

03.010.112	Holding Sleeve, with Locking Device
399.500	Hammer, 100 g
03.010.063	Protection Sleeve 12.0/8.0, length 188 mm
03.010.107	Screwdriver Stardrive, T25, length 330 mm
03.025.040	Protection Sleeve 11.0/8.0, length 188 mm
03.025.052	Depth Gauge for ASLS
03.025.067	Sleeve Positioner ASLS4/5

ASLS4	
03.010.064	Drill Sleeve 8.0/3.2, for No. 03.010.063
03.010.069	Trocar Ø 3.2 mm, for No. 03.010.064
03.025.027	Reamer ASLS4, length 145 mm, for near cortex, for Quick Coupling
03.025.082	Drill Bit ASLS4, length 150 mm, 3-flute, for Quick Coupling
03.025.104	Drill Bit ASLS4, calibrated, length 331mm, 3-flute, for Quick Coupling, for No. 03.010.064
03.025.124	Drill Bit ASLS4, length 145 mm, 3-flute, for RDL
03.025.134	Reamer ASLS4, length 268 mm, for near cortex, for Quick Coupling
03.025.030	Hand Reamer ASLS4, length 270 mm, for near cortex

ASLS5

03.010.065	Drill Sleeve 8.0/4.2, for No. 03.010.063
03.010.070	Trocar Ø 4.2 mm, for No. 03.010.065
03.025.028	Reamer ASLS5, length 145 mm, for near cortex, for Quick Coupling
03.025.083	Drill Bit ASLS5, length 150 mm, 3-flute, for Quick Coupling
03.025.105	Drill Bit ASLS5, calibrated, length 331mm, 3-flute, for Quick Coupling, for No. 03.010.065
03.025.125	Drill Bit ASLS5, length 145 mm, 3-flute, for RDL
03.025.135	Reamer ASLS5, length 288 mm, for near cortex, for Quick Coupling
03.025.031	Hand Reamer ASLS5, length 270 mm, for near cortex

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-014 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 thermoregulation 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.

Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

Intended use, Indications and Contraindications can be found in the corresponding system Instructions for Use.

All Surgical Techniques are available as PDF files at www.depuysynthes.com/ifu





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