

Locking Blade Nail Proximal Humeral Nail

Clinical Advisor

Professor Dr. med. Dr. h. c. Edgar Mayr Chefarzt, Klinik für Unfall-, Hand- und Wiederherstellungschirurgie Klinikum Augsburg

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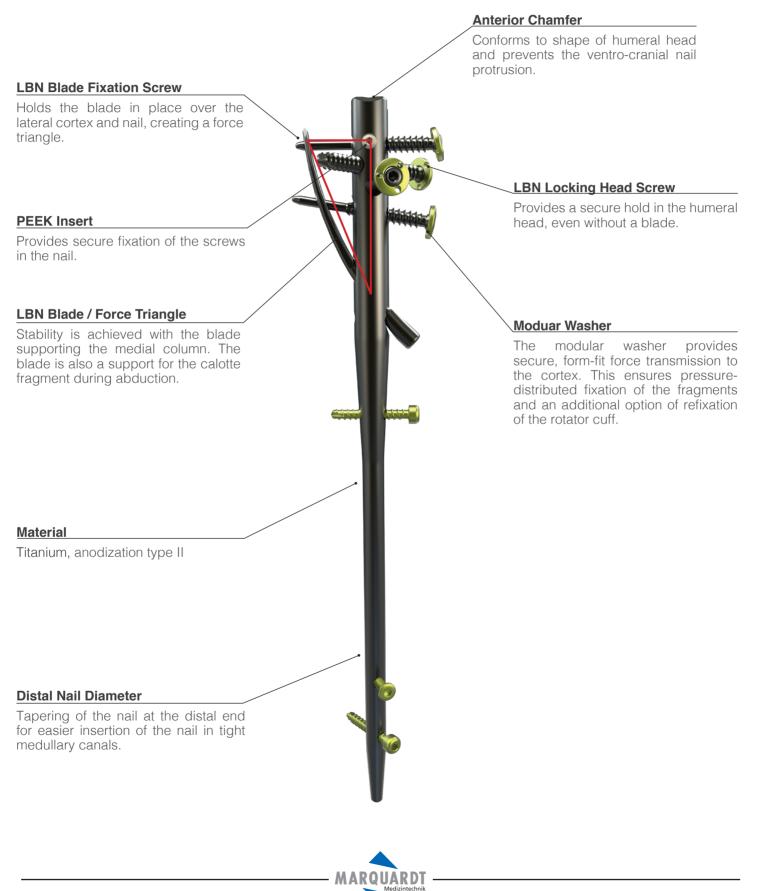
Note:

The surgical technique outlined below reflect the surgical procedure usually chosen by the clinical advisor. However, each surgeon must decide which surgical method and which approach is the most successful for his patient.



Introduction

Locking Blade Nail



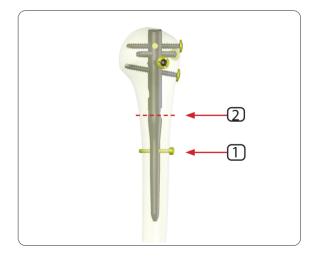
Treatment Options

• The recommended configuration, giving optimal fixation of osteoporotic bone, is with the long blade, four screws in the humeral head, and a distal locking screw.

• As an option, the short blade can be used, with a single blade locking screw, and three head locking screws.



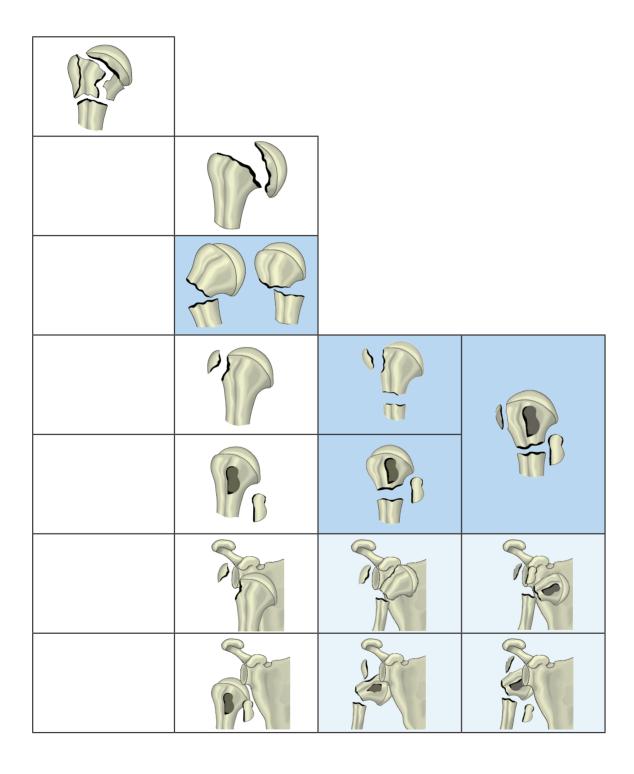
• In younger patients with good bone quality, the blade can be omitted, allowing the use of four head locking screws, and a second distal locking screw.





Indication

- Subcapital humeral fractures (2-part fractures)
- Slightly displaced 3- and 4-part fractures





Case study 1

3-part fracture44 years female, treated with

- LBN Proximal Humerus Nail, short
- LBN Blade (long) with two LBN Blade Fixation Screws
- two LBN Locking Head Screws
- one LBN Distal Locking Screw



preoperative image, A-P view



postoperative image, A-P view



preoperative image, Y view



postoperative image, Y view

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Case study 2

4-part fracture63 years male, treated with

- LBN Proximal Humerus Nail, short
- LBN Blade for Humerus Nail (short) with one LBN Blade Fixation Screw
- three LBN Locking Head Screws
- one LBN Distal Locking Screw



preoperative image, A-P view



postoperative image, A-P view



preoperative image, Y view



postoperative image, Y view



Case study 3

4-part fracture91 years female, treated with

- LBN Proximal Humerus Nail, short
- LBN Blade (long) with two LBN Blade Fixation Screws
- two LBN Locking Head Screws
- one LBN Distal Locking Screw



preoperative image, A-P view



postoperative image, A-P view



preoperative image, Y view



postoperative image, Y view

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Patient Positioning

• The beach chair position is recommended.

Image Intensifier Positioning

- The intensifier is positioned at the head of the table to allow antero-posterior and axillary views, ensuring that the whole length of the nail will be visualized.
- A closed reduction can then be performed before preparing and draping the surgical field.



Assembling Targeting Jig

Instruments

REF 14.30060.010	LBN Coupling Device
REF 14.30060.015	LBN Targeting Arm
REF 14.30060.030	LBN Coupling Screw
REF 14.30060.035	Assembling Screw

- The correct side nail is selected and opened.
- The Targeting Arm is attached to the Coupling Device and held with the supplied Assembling Screw.
- The nail is then attached to the Coupling Device with the long Coupling Screw.
- The nail can only be mounted in one position.

Note:

Initial tightening of the screw is carried out by hand, ensuring that the screw engages and that the nail locks into the Coupling Device. Final tightening is achieved with the Allen key.

Instruments

REF 14.30060.020/025LBN Targeting Module, left/rightREF 14.30060.035Assembling Screw

• The correct side curved Targeting Module left/right for the tuberosity screws is selected, slotted on to the Targeting Arm, and secured with another Assebling Screw.

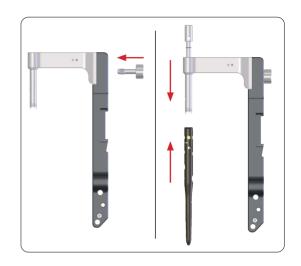
Note:

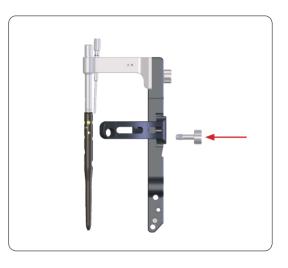
Alternatively this can be attached after the nail has been inserted, but it is wise to check correct alignment of the holes at this stage.

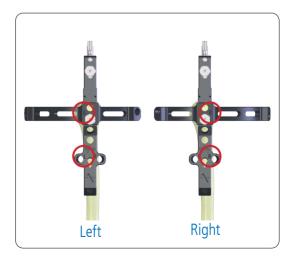
Instruments

REF 14.30060.045 LBN Height Determination Device

- The Height Determination Device is inserted through the side arm hole, lateral to the nail.
- Initially the nail depth can be set at zero by screwing the stop into the jig.
- Trial insertion of the correct drill sleeves and drills is carried out, inserting them into the holes in the jig, ensuring that they line up correctly with the holes in the implant.
- The tightness of all the attachment screws is checked.







Surgical Technique

Surgical Approach

- A deltoid split is recommended which can be extended as an antero-superior approach as required.
- The incision starts on the anterior acromion and extends over the middle fibres of the deltoid.
- The deltoid is then split in the line of its fibres for a distance of up to 5 cm from the lateral edge of the acromion, taking account of the position of the axillary nerve.
- The subacromial bursa is then opened.
- The deltoid can then be reflected from the front of the acromion in continuity with the coraco-acromial ligament (this facilitates later repair of the deltoid) to gain further exposure if reduction of the tuberosties is needed.

Reduction of the Fracture

- Further reduction of the fracture is carried out as necessary.
- This can be aided by inserting traction sutures into the supraspinatus tendon.
- Provisional fixation of the tuberosities with Kirschner wires can help, provided care is taken not to interfere with later positioning of the implant.



Insertion Point Preparation

Instruments

 REF 14.30060.150/151
 LBN Guide Pin with Stop, long/short

 REF 14.30060.155
 LBN Hollow Reamer Ø 11.5 mm

- In the reduced position, the correct nail entry is identified.
- It is located 1 to 2 mm lateral to the apex (highest point) of the head calotte.
- In both the axial and a. p. planes, the entry point projects to the center of the medullary canal of the humeral shaft.
- At this point, the corresponding plate wire is inserted into the humeral head in extension of the shaft axis until the plate of the pin rests on the calotte.
- After fluoroscopic control, the corresponding guide pin is overdrilled with the 11.5 mm hollow reamer.
- The bone core removed in the process is taken out of the crown reamer.



Nail Insertion

Instruments

REF 14.30060.045 LBN Height Determination Device

- The nail is then inserted through the prepared hole into the humeral canal under image intensifier control.
- The nail usually passes with a gentle twisting motion without the need to ream.
- No force should be used and on no account should a hammer be used on the jig as this could cause damage to the jig and further fracture of the bone.
- The nail is inserted until the Height Determination Device contacts the head lateral to the insertion point.
- The depth is usually then adjusted by rotating the Height Determination Device so that the nail sinks in by 2 mm.
- The top of the nail is easily visualized on image intensification, as the diameter is larger than the jig.
- Care is taken to ensure correct rotation of the nail.

Temporary Nail Fixation

Instruments

REF 11.90025.200S Kirschner Wire Ø 2.5 mm

- The nail can be temporarily fixed in position with one or two K-Wires inserted through holes at the proximal end of the jig.
- It is important to take account of the position of the lesser tuberosity screw, which can be referenced by inserting the drill sleeve through the anterior hole.
- This screw should be medial to the bicipital groove.

Insertion of the Tuberosity Screws

Instruments

REF 14.30060.055	LBN Tissue Protection Sleeve
	10.0/11.5 mm
REF 14.30060.061	LBN Trocar Ø 10 mm

- It is recommended that the tuberosity screws are inserted first.
- Depending on the fracture pattern, one or two screws are inserted.
- The lesser tuberosity screw is inserted first.
- The Tissue Protection Sleeve and Trocar are inserted into the correct hole, and a skin incision is made.
- The tissues may be spread with a haemostat before passing the Trocar down to the bone.
- The Tissue Protections Sleeve should be brought flush with the bone.









Insertion of the Drill Sleeve 3.5 mm

Instruments

REF 14.30060.060

LBN Drill Sleeve 10/6.5/3.5 mm

• The Drill Sleeve is now inserted through the Tissue Protection Sleeve.

Drilling of the hole for the tuberosity screws

Instruments

REF 14.30060.090

LBN Drill Bit Ø 3.5 mm

- The near cortex is drilled with the 3.5 mm Drill Bit taking care not to penetrate the articular surface.
- It may only be necessary to open the cortex with the drill and then use the depth measuring device (see below).



Determine the length of the screw:

Instruments

REF 14.30060.091 REF 14.30060.125 LBN Length Determination Instrument LBN Length Determination Instrument

- If the bone is soft, the blunt Lenght Determination Instrment can be used to prepare the rest of the drill hole, resistance being felt as it touches the far cortex.
- The length is read directly off the Lenght Determination Instrment, but it is recommended that 2 mm is subtracted to prevent the screw penetrating of the far cortex.
- Alternatively a conventional Depth Gauge is used.



Insertion of the Head Fixation Screw

Instruments

REF 14.30060.120 LBN Screwdriver, hex 2.5 mm

- Remove the Drill Guide.
- Next, The correct screw length is inserted with the Screwdriver.
- If required the screw can be held to the Screwdriver with a suture passed through a washer hole, brought along the groove in the Screwdriver and tightened around the screw at the end of the handle.
- As the screw is tightened, firm resistance is felt as the washer seats against the tuberosity.



• The Sleeve is then removed and the greater tuberosity screw is inserted in the same manner.



Retroversion of the Humeral Head

Instruments

REF 14.30060.050 LBN Alignment Rod

• If required, an Alignment Rod passed through the hole in the Coupling Device can be aligned with the forearm as a check on retroversion.







Insertion of the Blade

Positioning of the Oblique Drill Guide

Instruments

REF 14.30060.040	Eccentric Fixation Bolt
REF 14.30060.056	LBN Drill Sleeve 10.0/7.0
REF 14.30060.057	LBN Trocar Ø 7.0 mm

- The oblique Drill Sleeve and Trocar are inserted through the distal hole in the Targeting Module.
- The Sleeve will only fit through the jig one way, the flange on the Sleeve engaging with a slot in the hole.
- The Sleeve may need rotating to ensure correct alignment.
- A further suitable stab incision is made.

Note:

If the skin is pulled down to make the incision slightly proximal, this enables the same incision to be used for the next step, as well as the distal cortical screw, without further enlarging the hole.

The Sleeve is pushed down to the bone, and note is made of the depth marking on the sleeve. The Sleeve is attached firmly to the arm using the supplied bolt inserted into the hole.



Determine the Drill Depth

• The drill stop depth is read from the calibrations on the Drill Sleeve against the jig.

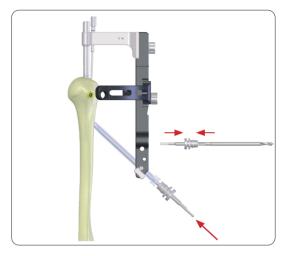


Drilling of the Lateral Cortex for the Blade Insertion

Instruments

REF 14.30060.100LBN Drill Bit for Blade entry Ø 7.0mmREF 14.30060.185LBN Stop for Drill Bit

- The 7.0 mm Drill Bit is selected and the Stop for Drill Bit moved to the same depth marking as read previously from the Sleeve, and locked into position.
- The outer cortex is then opened with the drill.
- The Stop for Drill Bit prevents the drill from damaging the nail.
- The Fixation Bolt is then removed before pulling out the Sleeve.



Preparation of the Blade Channel

Instruments

REF 14.30060.040	Eccentric Fixation Bolt
REF 14.30060.065	LBN Guide Sleeve for Blade
REF 14.30060.070	LBN Trocar
REF 14.30060.160	LBN Blade Postitioning Instrument
REF 14.30060.161	LBN Fixation Bolt

- The curved Guide Sleeve with Trocar is inserted through the keyhole shaped aperture in the jig, then through the previous incision to the bone.
- The Blade Positioning Instrument is attached with the Locking Bolt to the appropriate hole in the jig.
- The Sleeve is then locked to the jig with the Fixation Bolt.
- The Trocar is then removed.

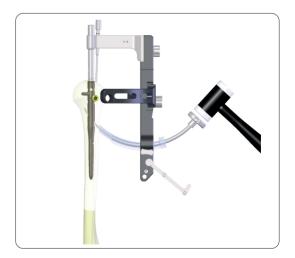
Insertion of Curved Chisel

Instruments

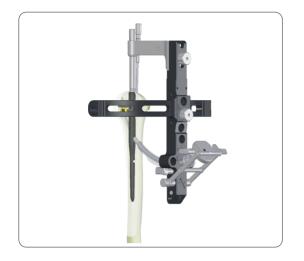
REF 14.30060.073/074 LBN Blade Awl short/long REF 14.30060.170 Mallet

- Next the curved Blade Awl, usually the long Blade Awl, though the short Blade Awl should be selected if the short blade is to be used, is passed through the Sleeve, and pushed through the bone under image intensifier control.
- The Blade Awl should remain within the head, supporting the medial cortex, without causing displacement of the fracture.







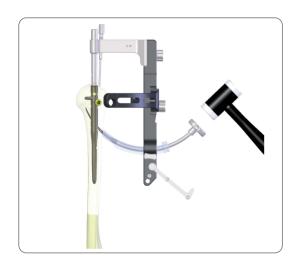


Control of Depth of Chisel Insertion

Instruments

REF 14.30060.145 REF 14.30060.146 LBN Extractor for Nail Slide Hammer for Extractor

- The Blade Awl is advanced with gentle hammer taps, until the Blade Positioning Instrument can be flipped over the end.
- If indicated the short Blade Awl may be used.
- The Blade Awl is then removed using the Extractor (screwed onto the Blade Awl) and the Slide Hammer.



Insertion of Blade

Instruments

REF 14.30060.075

LBN Blade Inserter

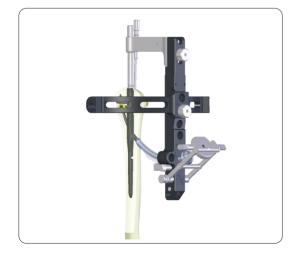
- Choose either the long or short blade and place sharp tip into the curved Guide Sleeve.
- The curved Blade Inserter is then used to push the blade into the prepared channel using gentle taps with the Hammer until it seats home.

Note:

If the blade is not used, head locking screws can be inserted instead into the blade fixation screw holes, with a distal locking screw into the blade hole itself.

Insertion Depth of the Blade

- The Blade Positioning Instrument is clipped over the end of the punch to ensure that the blade is fully inserted.
- This is left in place for stability and to hold the blade in position.





Insertion of Distal Blade Fixation Screw

Instruments

REF 14.30060.055	LBN Tissue Protection Sleeve 10.0/11.5 mm
REF 14.30060.061	LBN Trocar Ø 10 mm

- Insertion of the distal most blade fixation screw next confers stability before the proximal screw is inserted.
- The initial Tissue Protection Sleeve and Trocar are then inserted through the appropriate hole (second from top), and a further incision made.
- When the Sleeve contacts the bone, a note is made of the graduation mark against the jig.

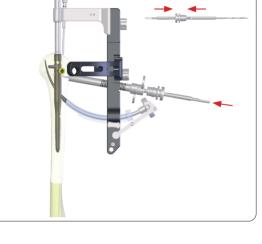


Drilling of the Lateral Cortex

Instruments

REF 14.30060.060 REF 14.30060.090 REF 14.30060.185 LBN Drill Sleeve 10.0/6.5/3.5 LBN Drill Bit Ø 3.5 mm LBN Stop for Drill Bit

- This reading is used when assembling the Stop for Drill Bit to the 3.5 mm Drill Bit.
- The Drill Sleeve is inserted and the bone is then drilled to the stop.



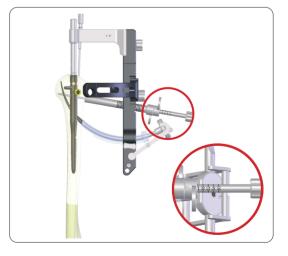
Measuring the Appropriate Screw Length

Instruments

REF 14.30060.091	
REF 14.30060.125	

LBN Length Determination Instrument LBN Length Determination Instrument

- The blunt LBN Length Determination Instrument is used to prepare the rest of the drill hole, resistance being felt as it touches the far cortex.
- The length is read directly off the LBN Length Determination Instrument, but it is recommended that 2-3 mm is subtracted to prevent the screw penetrating the far cortex.
- Alternatively a conventional Depth Gauge is used.







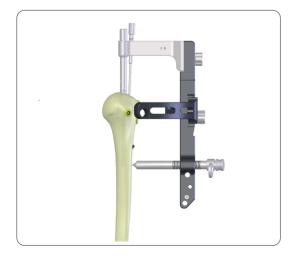
Insertion of the Appropriate Blade Fixation Screw

Instruments

REF 14.30060.120

LBN Screwdriver, hex 2.5 mm

• The correct length blade fixation screw is inserted with the Screwdriver, ensuring that the leading edge of the screw passes through the nail and the blade.



Insertion of Proximal Blade Fixation Screw

Instruments

REF 14.30060.180 Suture Retriever

- This is inserted through the top hole of the jig in the same manner as the first.
- The Stop for Drill Bit can be left on the 3.5 mm Drill Bit at the same depth as for the first screw.
- It may be useful to pass a suture through one of the washer holes for later repair of the rotator cuff.
- The Suture Retriever can be used to pull the suture into the proximal wound.

Distal Locking Screw

Instruments

REF 14.30060.055

REF 14.30060.061

LBN Tissue Protection Sleeve 10.0/11.5 mm LBN Trocar Ø 10 mm

- The Tissue Protection Sleeve and Trocar are inserted through the marked hole in the jig.
- Note that the correct hole is marked left or right, and sits on the anterior aspect of the jig.
- The Sleeve will pass through the distal puncture wound.

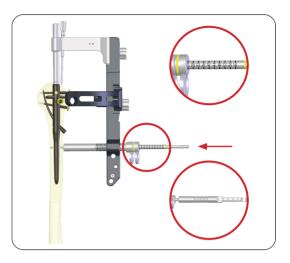


Drilling of the Distal Locking Hole

Instruments

REF 14.30060.062 REF 14.30060.085 LBN Drill Sleeve 10/6.5/2.9 Drill Bit Ø 2.9 mm

- The distal Drill Sleeve is inserted and the 2.9 mm distal Drill Bit used to drill through the near and far cortex.
- The correct length of screw may be read off the calibrations of the drill, or the conventional Depth Gauge may be used.



Insertion of the Appropriate Distal Locking Screw

Instruments

REF 14.30060.120 LBN Screwdriver, hex 2.5 mm

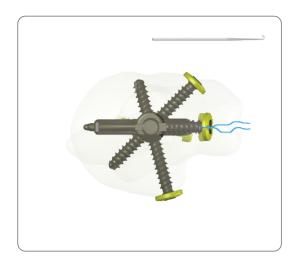
• The correct length 3.5 mm distal locking screw is inserted with the Screwdriver through the Tissue Protection Sleeve after removing the Drill Sleeve.











Rotator Cuff Repair and Closure

Instruments

REF 14.30060.180

Suture Retriever

- The jig is removed.
- The final position of the implants is checked by screening under image intensifier control, rotating the arm to ensure that screws have not penetrated the articular cartilage.
- The rotator cuff is carefully closed.
- If necessary the suture already passed through the screw washer may be used to reinforce the repair.
- Closure is carried out according to surgeon preference, paying careful attention to the reattachment of the deltoid to the acromion.

Insertion of the Cap Screw

Instruments

REF 14.30060.190	Handle with
REF 14.30060.192	Screwdriver

h AO Coupling er Shaft, hex 2.5 mm

- If desired the end of the nail can be closed with an end cap, or lengthened with a 2 mm end cap.
- The screw is inserted with the Screwdriver Shaft on the Handle.



Long Locking Blade Nail

- The long nail is available for fractures extending down the shaft.
- Insertion follows the same steps as the short nail, using the same instrumentation.
- As with the short nail, there is a choice of three different configurations.
- The nail may be used with a long blade, a short blade, or just screws - see page 3.
- The shaft may require reaming.
- The nail is solid, so cannot be inserted over a Guide Wire.



Distal Locking

Instruments

REF 14.30060.082 REF 14.30060.200 LBN Drill Bit Ø 2.9 mm LBN Drill Guide 2.9

- There are two distal locking screw holes, running in an anteroposterior direction, but angled relative to each other.
- The screw holes are drilled freehand using standard techniques.
- The nail holes are located under image intensifier control, the beam being adjusted so that the hole is seen as a perfect circle.
- A longitudinal incision is made over the hole and the muscle is split.
- The short 2.9 mm Drill Bit is used, the centre of the nail hole located with the image intensifier, and the hole drilled, aligning the drill with the image intensifier.
- The length of the screw is determined with the Depth Gauge.

Insertion of distal locking screw

Instruments

Implant Removal

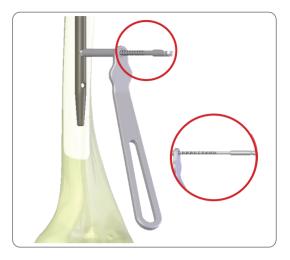
• The top of the nail is exposed.

• If an end cap has been used, this is removed.

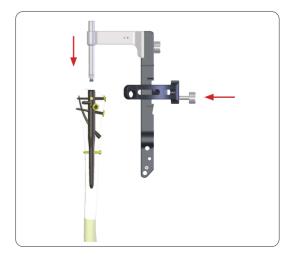
• The targeting jig is assembled and attached to the nail.

REF 14.30060.190	Handle with AO Coupling
REF 14.30060.192	Screwdriver Shaft, hex 2.5 mm

• The correct length 3.5 mm distal locking screw is inserted with the Screwdriver Shaft on the Handle.











Removal of Screws

Instruments

REF 14.30060.055

REF 14.30060.190 Handle REF 14.30060.192 Screwc

LBN Tissue Protection Sleeve 10.0/11.5 mm Handle with AO Coupling Screwdriver Shaft, hex 2.5 mm

- The screw heads are located using the Tissue Protection Sleeve inserted through the appropriate hole in the jig.
- The Screwdriver Shaft on the Handle is used to remove the screws.

Locating the Blade

Instruments

REF 14.30060.056 REF 14.30060.140 LBN Drill Sleeve 10.0/7.0 LBN Extractor for Blade

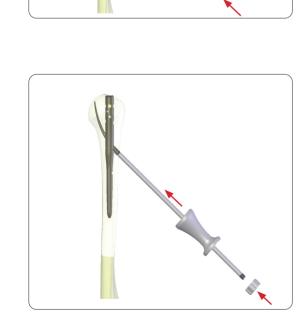
- Having removed the screws, the blade is located with the aid of the oblique Drill Sleeve inserted through the lowermost hole on the jig.
- An incision is made and the Sleeve pushed down to the bone.
- The Extractor for Blade can then be threaded onto the end of the blade without the end nut.
- It is then possible to disassemble the jig leaving the Extractor in situ.

Assembling the Blade Extraction Tool

Instruments

REF 14.30060.141 REF 14.30060.146 Nut for REF 14.30060.140 Slide Hammer for Extractor

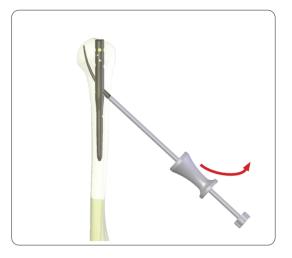
• The Slide Hammer is slid over the Extractor, and the Nut screwed to the end to act as a stop.





Removal of the Blade

- The blade can then be removed with the Slide Hammer.
- The instrument should be pulled proximally, allowing the curved nail to slide out of the bone.



Removal of the nail

Instruments

REF 14.30060.145 REF 14.30060.146 LBN Extraktor for Nail Slide Hammer for Extractor

• The nail can now be removed by screwing the Extractor for Nail and Slide Hammer to the nail, and tapping it out.





Implants

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Dimensions short nail			
• Length:	150 mm		
 Proximal diameter: 	11 mm		
• Distal diameter:	8.0 mm		
 Material: 	Ti6Al4V		

Article Number	Length	Orientation	Diameter
14.31008.150S	150 mm	Left	11 / 8.0 mm
14.31108.150S	150 mm	Right	11 / 8.0 mm

Dimensions long na	ail	Article Number	Length	Orientation	Diameter
		14.31008.230S	230 mm	Left	11 / 7.0 mm
	230 mm 250 mm	14.31008.250S	250 mm	Left	11 / 7.0 mm
	270 mm	14.31008.270S	270 mm	Left	11 / 7.0 mm
	290 mm	14.31008.290S	290 mm	Left	11 / 7.0 mm
 Proximal diameter: 	11 mm	14.31108.230S	230 mm	Right	11 / 7.0 mm
 Distal diameter: 	7 mm	14.31108.250S	250 mm	Right	11 / 7.0 mm
• Material:	Ti6Al4V	14.31108.270S	270 mm	Right	11 / 7.0 mm
		14.31108.290S	290 mm	Right	11 / 7.0 mm



Dimensions LBN Blade for Humerus Nail

Length short blade:Length long blade:

• Material:

61.5 mm 67.2 mm Ti6Al4V

Article Number	Blade Length
14.31356.063S	61.5 mm
14.31356.070S	67.2 mm



Implants

Article Number	Length
14.31635.018S	18 mm
14.31635.020S	20 mm
14.31635.022S	22 mm
14.31635.024S	24 mm
14.31635.026S	26 mm
14.31635.028S	28 mm
14.31635.030S	30 mm
14.31635.032S	32 mm
14.31635.034S	34 mm
14.31635.036S	36 mm
14.31635.038S	38 mm
14.31635.040S	40 mm
14.31635.042S	42 mm
14.31635.044S	44 mm
14.31635.046S	46 mm
14.31635.048S	48 mm
14.31635.050S	50 mm
14.31635.052S	52 mm
14.31635.054S	54 mm
14.31635.056S	56 mm
14.31635.058S	58 mm
14.31635.060S	60 mm

Article Number

14.31550.000S

14.31550.002S

Extension

0 mm

2 mm

Dimensions LBN Distal Locking Screw

• Length:	18 - 60 mm
• External diameter:	3.5 mm
Core diameter:	2.9 mm
Head diameter:	6.0 mm
Thread pitch:	1.75 mm
 Hexagonal socket: 	2.5 mm
Material:	Ti6Al4V

Dimensions LBN Cap Screw

- External diameter:
- Hexagonal socket:
- Material:

6 / 11 mm 2.5 mm Ti6Al4V





Implants



Dimensions LBN Blade Fixation Screw

• Length A:	32 - 60 mm
• Length B:	23.5/25.5/27/29 mm
• Proximal external diameter:	5.0 mm
• Distal outside diameter:	2.8 mm
• Core diameter:	3.5 mm
• Thread pitch:	1.75 mm
• Diameter modular washer:	10.0 mm
• Material:	Ti6Al4V

Article Number	Length A	Length B
14.31555.032S	32 mm	23.5 mm
14.31555.034S	34 mm	23.5 mm
14.31555.036S	36 mm	25.5 mm
14.31555.038S	38 mm	25.5 mm
14.31555.040S	40 mm	25.5 mm
14.31555.042S	42 mm	25.5 mm
14.31555.044S	44 mm	27 mm
14.31555.046S	46 mm	27 mm
14.31555.048S	48 mm	27 mm
14.31555.050S	50 mm	27 mm
14.31555.052S	52 mm	29 mm
14.31555.054S	54 mm	29 mm
14.31555.056S	56 mm	29 mm
14.31555.058S	58 mm	29 mm
14.31555.060S	60 mm	29 mm
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Dimensions LBN Locking Head Screw

• Length:	22 - 60 mm
• External diameter:	5.0 mm
Core diameter:	3.5 mm
• Thread pitch:	1.75 mm
• Diameter modular washer:	10.0 mm
• Material:	Ti6Al4V

Article Number	Length
14.31554.022S	22 mm
14.31554.024S	24 mm
14.31554.026S	26 mm
14.31554.028S	28 mm
14.31554.030S	30 mm
14.31554.032S	32 mm
14.31554.034S	34 mm
14.31554.036S	36 mm
14.31554.038S	38 mm
14.31554.040S	40 mm
14.31554.042S	42 mm
14.31554.044S	44 mm
14.31554.046S	46 mm
14.31554.048S	48 mm
14.31554.050S	50 mm
14.31554.052S	52 mm
14.31554.054S	54 mm
14.31554.056S	56 mm
14.31554.058S	58 mm
14.31554.060S	60 mm

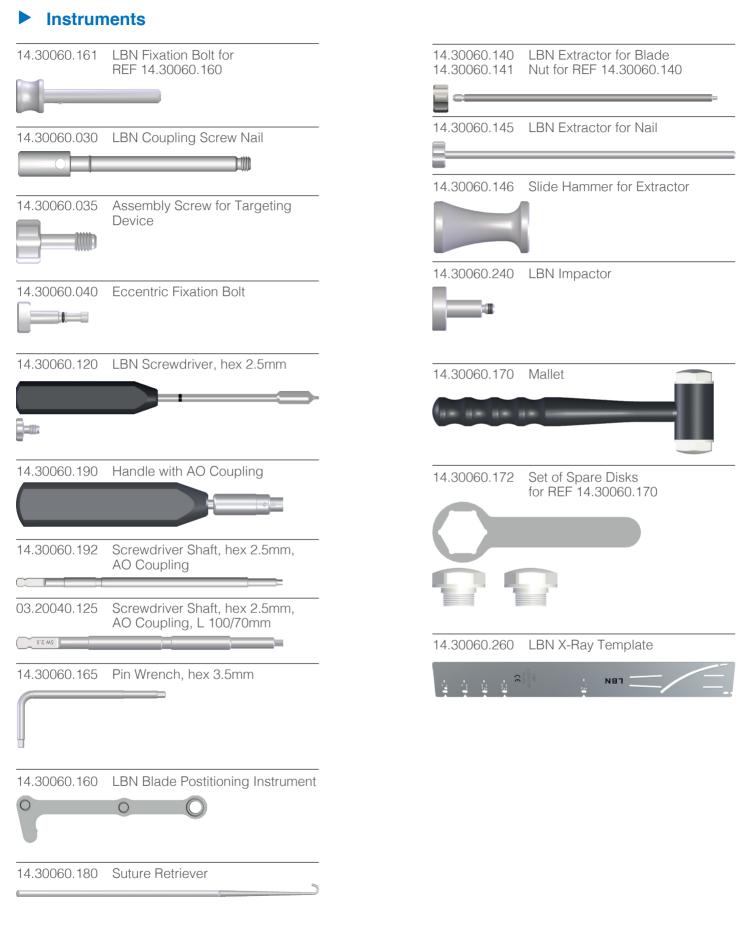


Instruments

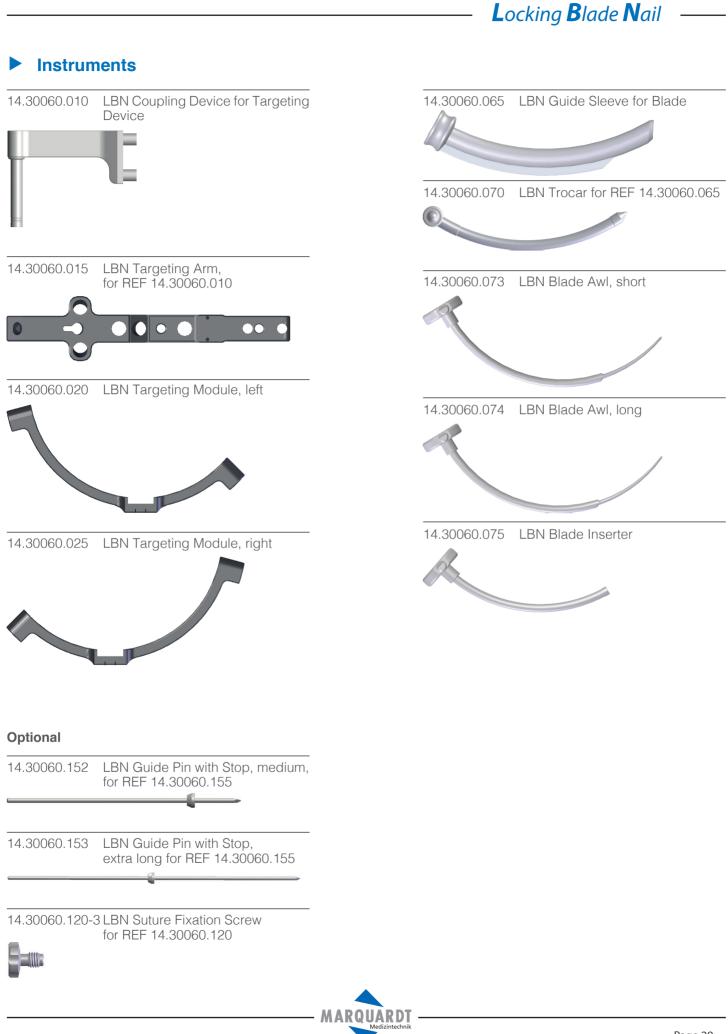
11.90025.200S	Kirschner Wire Ø 2.5 mm, trocar tip, L 200 mm
14.30060.050	LBN Alignment Rod
14.30060.150	LBN Guide Pin with Stop, long, for REF 14.30060.155
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14.30060.151	LBN Guide Pin with Stop, short, for REF 14.30060.155
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14.30060.082	LBN Drill Bit Ø 2.9 mm, scaled, AO Coupling, short
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14.30060.085	LBN Drill Bit Ø 2.9 mm, scaled, AO Coupling, for REF 14.30060.062
14.30060.090	LBN Drill Bit Ø 3.5 mm, scaled AO Coupling
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14.30060.100	LBN Drill Bit for Blade entry Ø 7.0 mm scaled, AO Coupling
14.30060.155	LBN Hollow Reamer Ø 11.5 mm
14.30060.220	LBN Medullary Reamer Ø 11.0mm, short
14.30060.230	LBN Broach for Humeral Nail
	LBN Stop for Drill Bit
14.30060.185	for REF 14.30060.090/100
14.30060.045	for REF 14.30060.090/100 LBN Height Determination Device
	for REF 14.30060.090/100 LBN Height Determination Device
14.30060.045	for REF 14.30060.090/100 LBN Height Determination Device
14.30060.045	for REF 14.30060.090/100 LBN Height Determination Device
14.30060.045	for REF 14.30060.090/100 LBN Height Determination Device



Locking Blade Nail









MRI Safety Information

Non-clinical testing has demonstrated that the Intramedullary Nails range from Marquardt Medizintechnik is MR Conditional in accordance with the ASTM F2503-20 standard definitions. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Cylindrical-bore
- Horizontal magnetic field (B₀)
 - Spatial field gradient lower than or equal to
 - 1.5 T: 23.45 T/m (2345 G/cm)
 - 3.0 T: 11.75 T/m (1175 G/cm)
- Radiofrequency (RF) field exposure:
 - RF excitation: Circularly Polarized (CP)
 - RF transmit coil: whole-body transmit coil
 - RF receive coil type: whole-body receive coil
 - Maximum permitted whole-body averaged specific absorption rate (SAR):
 - Normal Operating Mode, 2 W/kg.
 - Scan duration and wait time:

1.5 T: 2 W/kg whole-body average SAR for **10min and 55s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **10min and 55s** if this limit is reached.

3.0 T: 2 W/kg whole-body average SAR for **7min and 54s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **7min and 54s** if this limit is reached.

- The Intramedullary Nails are expected to produce a maximum temperature rise of 6.2 °C at 1.5 T and 6.5 °C at 3 T both after the scanning periods presented above.
- The presence of this implant may produce an image artifact. Some manipulation
 of scan parameters may be needed to compensate for the artifact. In non-clinical
 testing, the image artifact caused by the device extends approximately 83 mm from
 the device edge when imaged with a spin echo pulse sequence and 65 mm with a
 gradient echo, both at 1.5 T.
- Patients with uncompromised thermoregulation and under uncontrolled conditions or patients with compromised thermoregulation (all persons with impaired systemic or reduced local thermoregulation) and under controlled conditions (a medical doctor or a dedicated trained person can respond instantly to heat induced physiological stress).

Note:

Undergoing an MRI scan, there is a potential risk for patients with a metallic implant. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, or other undesirable effects.





Dieter Marquardt Medizintechnik GmbH

Robert-Bosch-Straße 1 • 78549 Spaichingen, Germany Telefon +49 7424 9581-0 • Telefax +49 7424 501441 info@marquardt-medizintechnik.de • www.marquardt-medizintechnik.de

