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SURGICAL
TECHNIQUE

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SMR

a LimaCorporate family product

LPSI

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Presentation of Materialise

Materialise NV, a company duly organized and existing under the laws of Belgium, based in Leuven (Belgium), Technologielaan n. 15, has developed a specific software (hereinafter only the Software), which may be used by Surgeons as a pre-operative planning tool with the aim to obtain a personalized surgical guide (Medical device) for each patient in connection with Limacorporate S.p.A. products (Medical devices). Materialise NV is the proprietor and – to all effects – the manufacturer of the Software and of the personalized surgical guide. Materialise and the Materialise logo are registered trademarks of Materialise NV.

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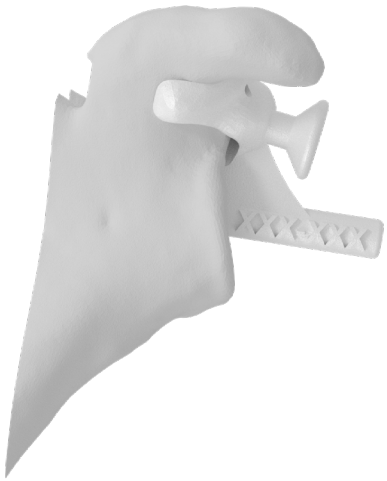
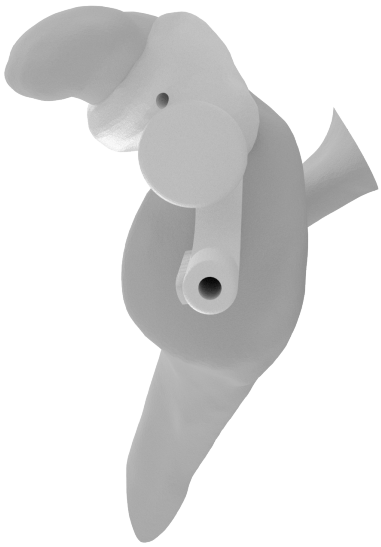
Limacorporate S.p.A., as a manufacturer of medical (prosthetic) devices, dœs not practice medicine. This document – referring to surgical technique – has been developed in consultation with an experienced surgeon team and provides the Surgeon with general guidance when implanting SMR System. Proper surgical procedures and techniques are and remain the total responsibility of the Surgeon. Each surgeon must evaluate the appropriateness of the surgical technique which is about to be used based on personal medical training, experience and clinical evaluation of each individual patient.

Indications





LPSI Shoulder guide is for Total and Reverse Shoulder SMR systems

INTENDED PURPOSE

The Shoulder Guide is intended to be used as a surgical instrument to assist in the intraoperative positioning of glenoid components used with total and reverse shoulder arthroplasty by referencing anatomic landmarks of the shoulder that are identifiable on preoperative CT-imaging scans.

The Shoulder Guide is intended for adult patients. The Shoulder Guide is to be used by a physician trained in the performance of surgery.

The LPSI shoulder guide can be used in conjunction with Lima's following total and reverse shoulder implant systems and their respective compatible components: SMR™ Shoulder System, SMR™ Reverse Shoulder System, SMR™ Modular Glenoid, SMR™3-Pegs Glenoid, SMR™ TT Metal Back Glenoid, SMR™ 40mm Glenosphere, SMR™ TT Augmented 360 Baseplate, SMR™ TT Hybrid Glenoid and PRIMA TT Glenoid.

LPSI is single use only.

MATERIAL: Polyamide

CONTRAINDICATIONS

Patients with conditions or diseases that affect bony landmark recognition.

The SurgiCase Shoulder Planner may restrict use for the LPSI Shoulder guide when placement of the pilot wire is not optimal for implant placement. To ensure safety and effectiveness of the LPSI Shoulder guide, the SurgiCase Shoulder Planner restricts the placement of the pilot wire within the intersection of two cones – a 45° cone from the neutral axis and a 60° cone from the normal of the glenoid face.

Any active infection of the surgical area where the surgery will be performed is a contraindication for LPSI Shoulder guide.

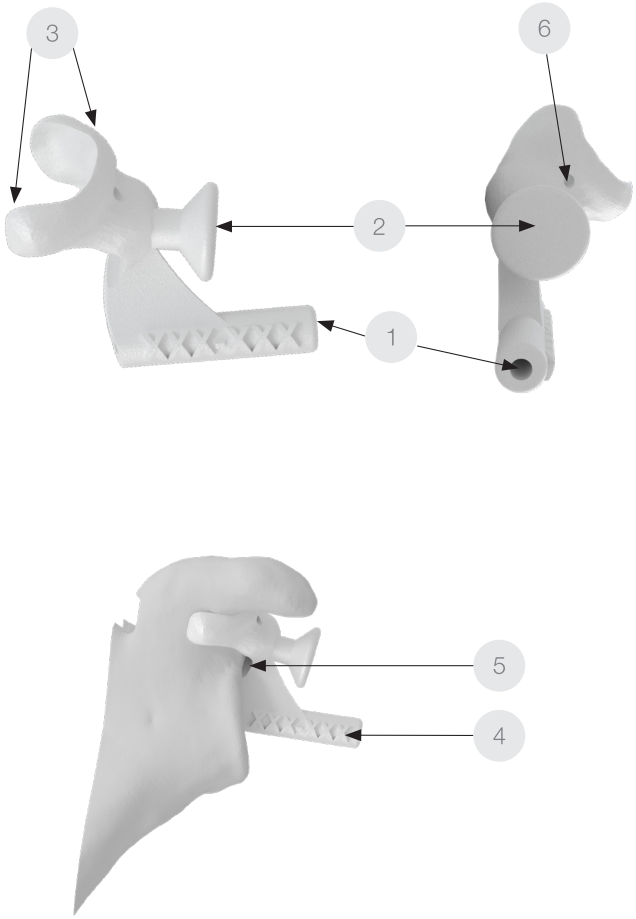


Figure 2

GUIDE AND BONE MODEL

Note: *LPSI Shoulder guides and models are not sterile and must be thoroughly clenead and sterilized prior to use. Please follow the instruction for use enclosed in the product packaging.*

GUIDE

Ergonomically-designed, the glenoid positioning guide is customized to the patient's anatomy that provides accuracy of implant placement to improve alignment and surgical outcome *(Fig. 2)*.

1. *Pilot wire Cylinder:* Facilitates the planned center hole drilling when using the pilot wire
2. *Push or Directional Handle:* Provides haptic or "sensorial touch" feedback and guide seating stability.
3. *Coracoid Clip:* Grips on to the base of coracoid.
4. *Patient Specific Guide Identifier:* Alphanumeric code that links the guide to the patient case.
5. *Labrum Offset:* Bridges between the coracoid clip and the lateral body of the guide to prevent soft tissue interference at the antero-superior border of the glenoid surface.
6. *1.5 mm K-Wire Hole:* Provides the option to pin 1.5 mm k-wire for added guide stability during drilling.

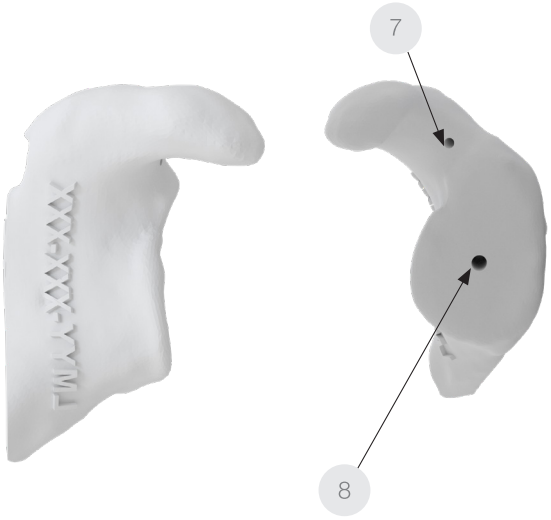


Figure 3

BONE MODEL

Replicate of the patient's glenoid anatomy that is used as a reference for implant placement or in conjunction with the LPSI Shoulder guide *(Fig. 3)*.

7. *1.5 mm K-Wire Entry Hole:* Matches and references the (optional) k-wire fixation and entry point.
8. *Pilot wire Entry Hole:* Matches and references the planned center hole position and pilot wire entry point.

The central pilot wire diameter is 2.5 mm for the SMR system

Follow the appropriate Total or Reverse Shoulder Implant Surgical Technique for patient positioning, surgical approach and exposure techniques, leading up to the exposure of the glenoid.

After following the appropriate surgical technique for exposure, prepare the scapula for the Materialise Glenoid Guide. Each guide is designed to match securely to the patient's neck of the coracoid process. Take care to completely remove all soft tissue from the neck of the coracoid process.

Remove all soft tissue around the lateral face of the coracoid and obtain hemostasis.

Since the guide fits around the coracoid and anterior glenoid face, avoid placing anterior retractors immediately around the coracoid. Place an anterior glenoid retractor at the lower half of the glenoid so as to not interfere with the access to the coracoid.

Perform a 360-degree glenoid release by releasing the glenohumeral ligaments, capsule, and labrum necessary to gain complete visualization of the glenoid.

LPSI Guide Placement And Drilling

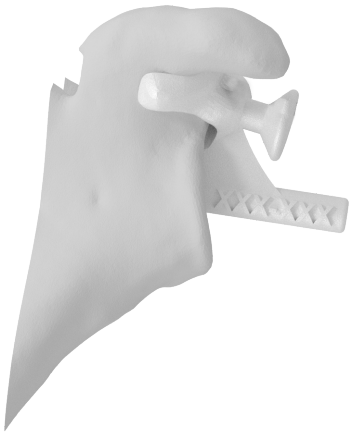


Figure 4a

LPSI GUIDE PLACEMENT AND DRILLING

The glenoid guide is designed to fit the patient's glenoid anatomy. The mating surface of the glenoid face and the coracoid neck should be cleared of soft tissue and dried as much as possible to assure a stable guide fit. Do not remove osteophytes or alter the glenoid bony anatomy before securing the guide. Do not damage the bony surface where the glenoid guide makes contact with the patient's glenoid anatomy.

Compare the fit and position of the glenoid guide on the bone model to the planned fit and position on the patient's glenoid anatomy. The glenoid guide's fit and position on the bone model should match its fit and position on the patient's glenoid anatomy.

Note: *DO NOT USE THE LPSI Guide if it is not possible to place the glenoid guide in a stable position on the patient's glenoid anatomy as the instability can negatively impact the glenoid guide's ability to transfer the pre-operative plan. In the event the LPSI Guide cannot be used, please follow the standard surgical technique.*

Note: *Do not alter the glenoid guide before use. Doing so could generate debris which could contaminate the operating region. In addition, altering the guide could compromise its fit to the patient's glenoid anatomy.*

Make sure the glenoid guide maintains its position on the fitting surface during drilling. Verify that the correct pilot wire diameter is being used which corresponds to the guide's pilot wire cylinder diameter. Do not modify the drill direction by drilling through the pilot wire cylinder's surface (see page 6 for details for positioning and drilling).

Secure the glenoid guide onto the patient's glenoid anatomy by seating the coracoid clip on to the base of coracoid and verify that the base of the pilot wire cylinder is contacting or seated on the glenoid face *(Fig. 4a)*.

LPSI Guide Placement And Drilling

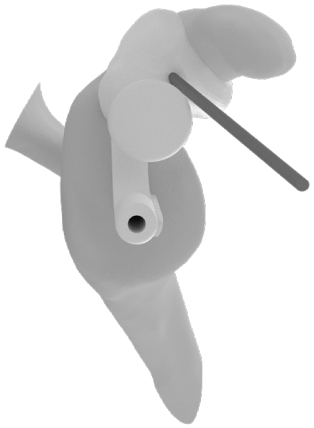


Figure 4b

There is approximately 1 – 2 mm of clearance between the bottom of the labrum offset on the guide and the superior glenoid rim. Avoid excessive downward pushing of the glenoid guide. Make sure critical anatomic structures are not damaged during the guide attachment.

Apply and maintain pressure on the directional/push handle of the glenoid guide to keep contact between the guide and underlying glenoid anatomy during drilling.

Verify full surface contact is achieved between the glenoid guide and the underlying glenoid anatomy with the exception of the 2 mm offset over the superior glenoid ridge. Check for gaps between the guide and the glenoid anatomy to ensure a proper fit.

A 1.5 mm k-wire can be used to affix the guide to the glenoid using the 1.5 mm k-wire hole *(Fig. 4b)*.

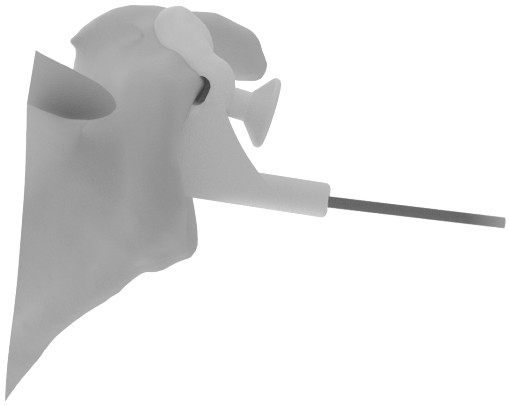


Figure 4c

Once the glenoid guide is seated properly, apply pressure to the directional handle and drill the hole using the appropriate central pilot wire with 2.5 mm diameter *(Fig. 4c)*.

Confirm the glenoid guide fit prior to and after drilling for added measure. During drilling, irrigate to reduce heat and any debris generated.
After 1.5 mm k-wire removal, if used, remove the LPSI Guide. If the guide cannot be removed over the central pilot wire, remove the central pilot wire, then remove the guide and finally reinsert the pilot wire carefully in the bone. Measure the depth of the pilot wire hole using the Depth Gauge.

Follow the appropriate Shoulder Implant Surgical Technique to complete the steps required to finalize the glenoid preparation for the prosthesis.

Note: *Make sure the glenoid guide maintains its position on the fitting surface during drilling. Verify that the correct pilot wire diameter is being used which corresponds to the guide's pilot wire cylinder diameter. Do not modify the pilot wire direction by introducing it through the pilot wire cylinder's surface.*

LPSI Product Codes

LPSI
LIMA PERSONALIZED SURGICAL INSTRUMENTS*

LIMA ITEM ID	DESCRIPTION 1	DESCRIPTION 2	MATERIALISE CODE *(Labels and box package)*
VE.99C13LM01	*LIMA CT RSA GUIDE & BONE MODEL*	*99C13LM010001*	*SHC-LM01-00-01*
	RSA Guide	Guide	SHC-LM01-01-01
	RSA Bone Model	Model	SHC-LM01-02-01
VE.99C13LM02	*LIMA CT TSA GUIDE & BONE MODEL*	*99C13LM020001*	*SHC-LM02-00-01*
	TSA Guide	Guide	SHC-LM02-01-01
	TSA Bone Model	Model	SHC-LM02-02-01

* Materialise is the Legal Manufacturer

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