

Manufacturer



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Surgical technique

Affinis Architec

Patient specific glenoid guide



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Supplement to the relevant Affinis surgical technique

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Remark

Please make yourself familiar with the handling of the instruments, the product-related surgical technique and the warnings, the safety notes and the recommendations of the instruction leaflet before using an implant marketed by Mathys Ltd Bettlach. Make use of the Mathys user training and proceed according to the recommended surgical technique.

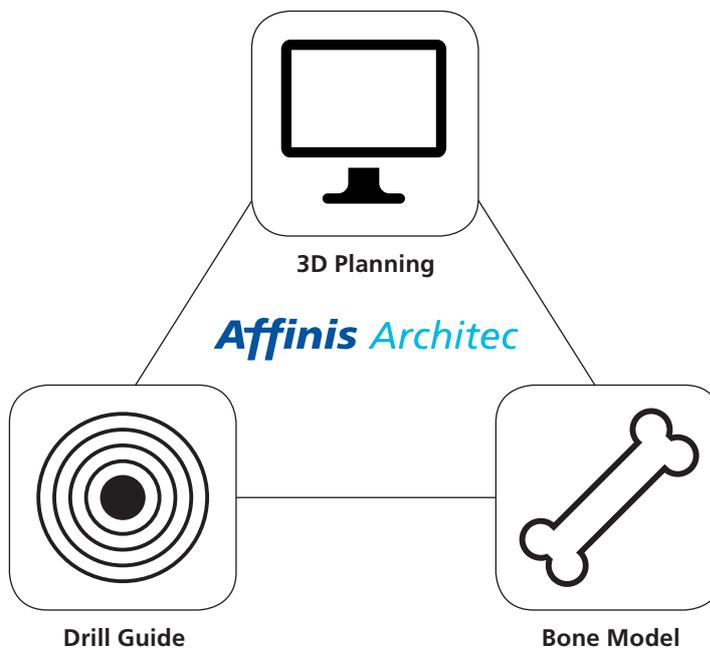
Introduction

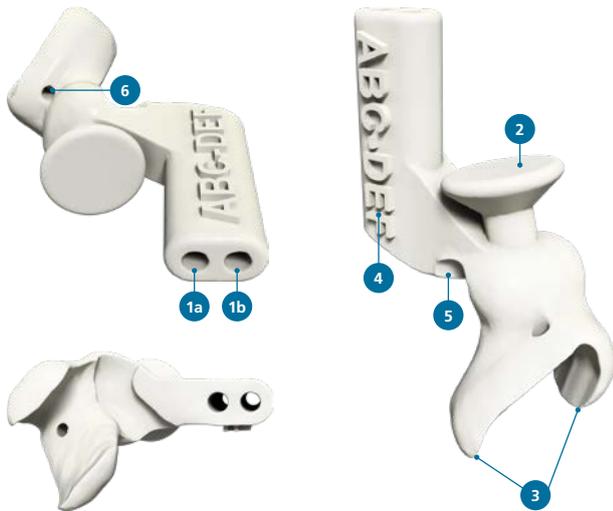
Affinis Architec consists of three components, the SurgiCase Shoulder Planner for 3D planning, glenoid bone model representing the native bone and the Affinis Architec guide itself.

The personalised Affinis Architec guide represents an alternative to the standard instruments for placement of anatomic or reversed glenoid components. When integrated into the conventional surgical technique, this unique, personalised instrument replaces certain surgical steps. With the Affinis Architec guide, placement of the central K-wire is planned in advance and facilitated with a personalised instrument. This obsoletes the need of placing the central K-wire with the standard glenoid or metaglene positioning instruments.

This surgical technique provides guidance for integrating the Affinis Architec guide into the wider Affinis surgical techniques. As the standard instruments are required in the steps preceding and following those where the Affinis Architec guide is used, the surgeon must be familiar with the relevant Affinis surgical technique and the correct use of all the standard instruments in their entirety.

For the surgical steps of a complete implantation of an Affinis system please consult the corresponding Affinis surgical technique.





Affinis Architec Guide

Ergonomically-designed glenoid guide customized to the patient's anatomy that provides accuracy of implant placement to improve alignment and surgical outcome.

1 K-wire Cylinders:

1a Facilitates the planned superior peg hole drilling when using the superior 2.5 mm k-wire

1b Facilitates the planned centre hole drilling when using the central 2.5 mm k-wire

2 Push Handle: Provides haptic or «sensorial touch» feedback and guide seating stability

3 Coracoid Clip: Grabs onto the base of coracoid.

4 Patient Specific Guide Case ID: 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 anterosuperior border of the glenoid surface

6 Fixation K-Wire Hole: Provides the option to pin a 1.2 mm k-wire for added guide stability during drilling

Glenoid Bone Model

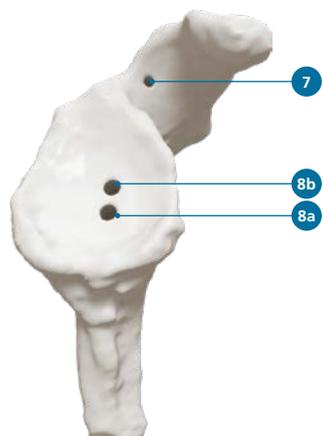
Replicate of the patient's glenoid anatomy that is used as a reference for implant placement or in conjunction with the Affinis Architec guide.

7 Fixation K-Wire Entry Hole: Matches and references the (optional) k-wire fixation and entry point

8 Superior and Central 2.5 mm K-Wire Entry Holes:

8a Matches and references the planned centre hole position and k-wire entry point

8b Matches and references the planned superior peg hole position and k-wire entry point.



1. Indications and contraindications

Indications

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

Affinis Architec system can be used in conjunction with the Affinis Total, Affinis Fracture and Affinis Inverse system and their respective components.

The Affinis Architec guide 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 Affinis Architec system when placement of the central k-wire is not optimal for implant placement. To ensure safety and effectiveness of the Affinis Architec guides, the SurgiCase Shoulder Planner restricts the placement of the central k-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 Affinis Architec guides.

See package insert for a listing of indications, contraindications, warnings and precautions.

2. Preoperative planning

The preoperative planning with the Affinis Architec system is carried out based on computer tomography (CT) images uploaded to the web-based planning software available at <https://surgicaseoos.materialise.com/login>.

To use this password protected 3D planning software, a training is required. Only trained users will be granted access to the software.

The planning and production process of the Affinis Architec guide is defined as followed:

1. Creation of CT images

! One must comply with the imaging protocol. The «CT Scanning Protocol» is available under the help section of the online platform.

2. Creation of a case on the online platform and upload of the CT data

3. CT images are reviewed for quality

4. Performance of 3D reconstruction and anatomical landmarking

5. 3D planning is performed and conclusively the plan accepted by the surgeon

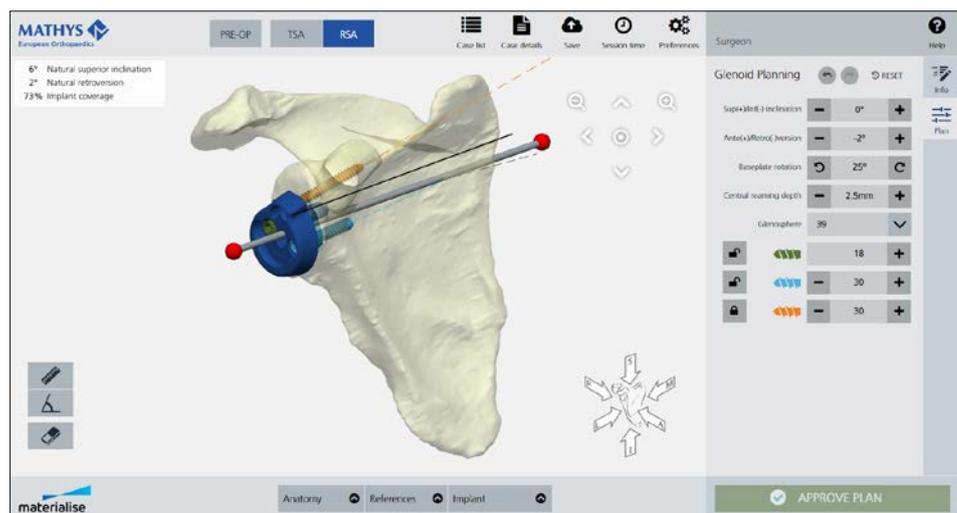
6. Production of the personalised guide and bone model

7. Shipment of the guide and bone model

! The guide and bone model are delivered non-sterile!
For information about reprocessing please consult the IFU.

8. Sterilisation of guide and bone model

9. Surgery



3. Surgical technique

3.1 Glenoid preparation

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. Then prepare the scapula for the Affinis Architec system. Each guide is designed to match uniquely to the patient's glenoid anatomy and the neck of the coracoid process.

Carefully remove all soft tissue from the neck of the coracoid process, around the lateral face of the coracoid and obtain hemostasis. Do not remove cartilage or osteophytes nor alter the glenoid bony anatomy before securing the guide. Do not damage the bony surface where the guide makes contact with the patient's glenoid anatomy.

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 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.



Do not alter the glenoid guide. Doing so could generate debris which could contaminate the operating area. In addition, altering the guide could compromise its fit to the patient's glenoid anatomy.



Fig. 1

3.2 Placement and drilling

Secure the guide onto the patient's glenoid anatomy by seating the coracoid clip onto the base of coracoid and verify that the base of the k-wire cylinders is contacting or seated on the glenoid face.

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

Apply and maintain pressure on the push handle and verify full surface contact to the glenoid anatomy with exception of the 2 mm offset at the superior glenoid rim.



Avoid excessive downward pushing of the guide. Make sure critical anatomic structures are not damaged during the guide attachment.



Do not use the guide if it is not possible to place the guide in a stable position on the patient's glenoid anatomy as the instability can negatively impact the guide's ability to transfer the pre-operative plan. In case the guide cannot be used, please follow the standard surgical technique.



Fig. 2

Optional step

A 1.2 mm k-wire may be used to secure the guide to the glenoid utilising the fixation k-wire hole.



Fig. 3

Apply pressure to the push handle and drill the superior hole using the 2.5 mm k-wire. Drill a k-wire hole that is not bi-cortical yet deep enough to be seen after reaming the glenoid face. During drilling, irrigate to reduce heat and any debris generation. Remove the k-wire from the bone subsequent to drilling.



Make sure the guide maintains its position on the fitting surface during drilling and confirm the guide's fit prior to and after drilling for added measure.



Do not modify the drill direction by drilling through the k-wire cylinder's surface.



Fig. 4

Continue to apply pressure to the push handle. Verify the guide is still in its correct position and drill the central hole using the 2.5 mm k-wire. The central hole is used to position the central k-wire of the reamer. Keep the central k-wire in the bone.



Fig. 5

Remove the guide, by sliding it over the central k-wire. Take care not to alter the direction of the central k-wire while removing the guide.

Should it be difficult to remove the guide over the central k-wire without altering the direction of the central k-wire, (1) remove the central k-wire, (2) then remove the guide and (3) finally reinsert the central k-wire carefully in the pre-drilled inferior hole.



Fig. 6

Proceed with the relevant surgical technique of the corresponding implant to prepare the glenoid face.

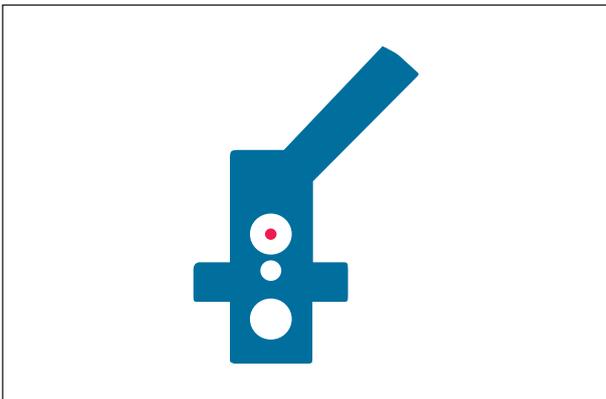


Fig. 7



*To achieve rotational stability with the standard glenoid drill guide check visually or with a wire that the superior k-wire hole is located central in the superior hole.
Then proceed with the drilling of the inferior peg hole. Insert the fixation peg inferiorly before drilling the superior peg hole.*

4. Instruments

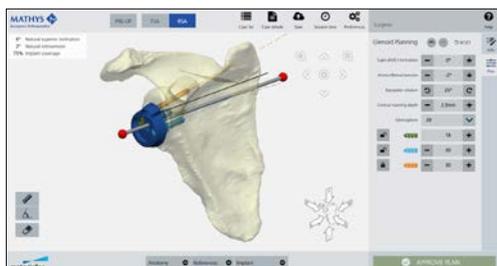


Item no.	Description
292.250	Kirschner wire 2.5/150
not provided by Mathys	Kirschner wire 1.2



3D Planning + PSI guide

Item no.	Description
62.34.0156	RSA Kit (K-Wire Guide and Bone Model)
62.34.0159	TSA Kit (K-Wire Guide and Bone Model)



3D Planning only

Item no.	Description
62.34.0163	3D Planning Shoulder

5. Symbols



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