Manufacturer

materialise

Distributed by

MATHYS
European Orthopaedics

For healthcare professional use only. The illustrated image does not represent a connection between the use of the medical device described, nor its performance.

Surgical technique

Affinis Architec

Patient-specific instrumentation (PSI) for shoulder arthroplasty

Supplement to the relevant Affinis surgical technique

Table of contents

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.

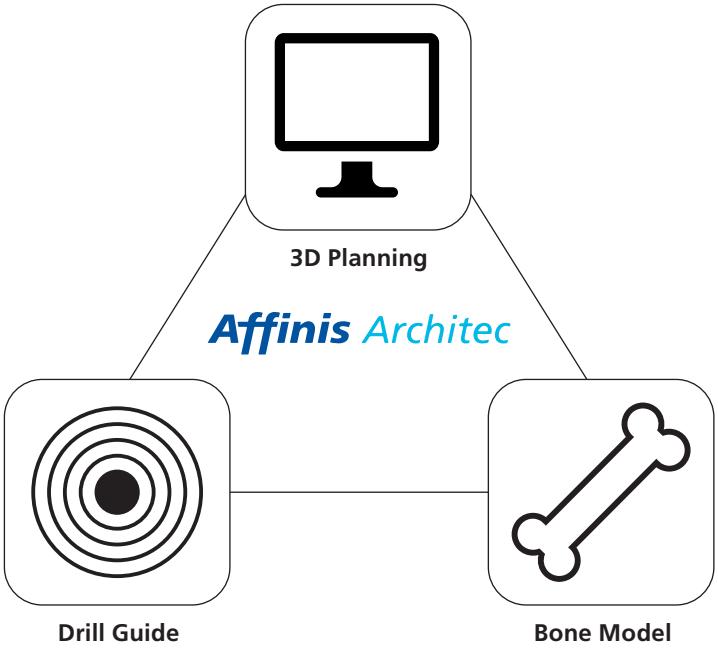
Introduction

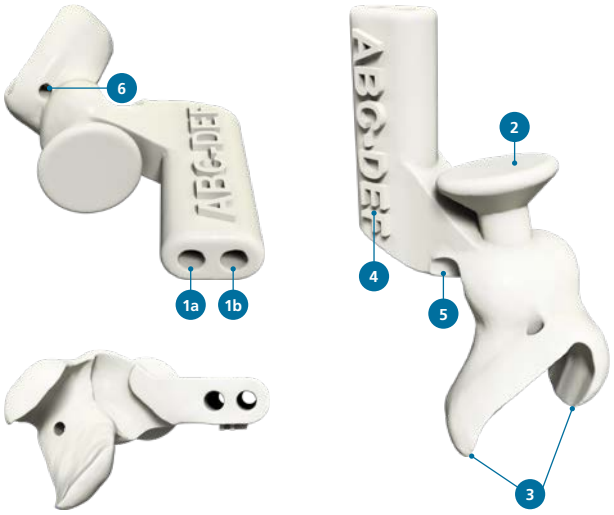
Affinis Architec consists of three components, the SurgiCase Shoulder Planner for 3D planning, glenoid bone model representing the native bone and the Affinis Architec guide itself.

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.

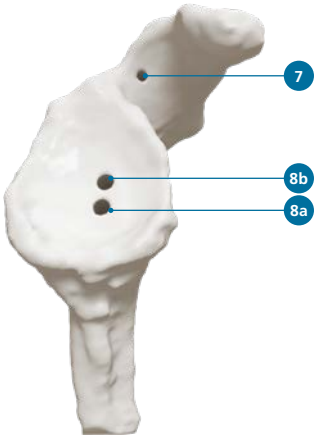




Affinis Architec Guide

Ergonomically-designed glenoid guide patient-specific to the patient's anatomy that aims to provide 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 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 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

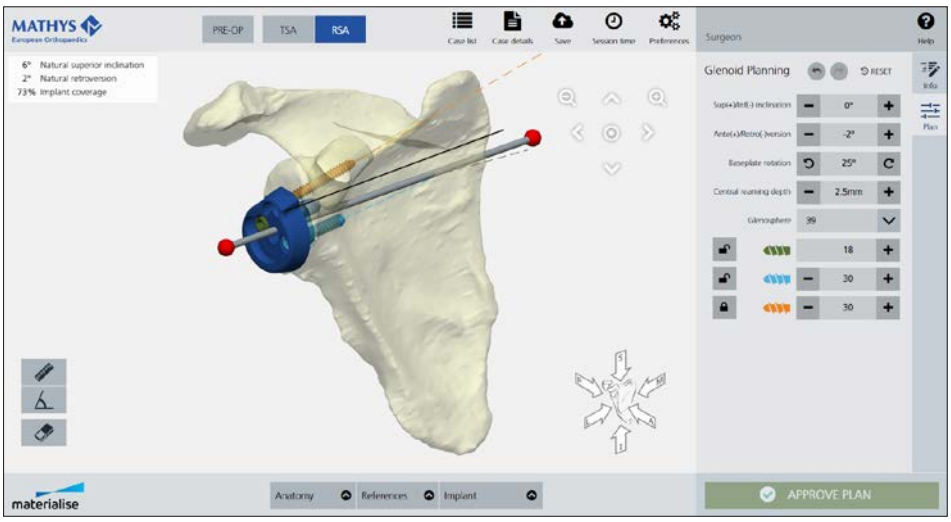
See package insert for a listing of indications, contraindications, warnings and precautions.

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. **Cleaning and sterilization 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.

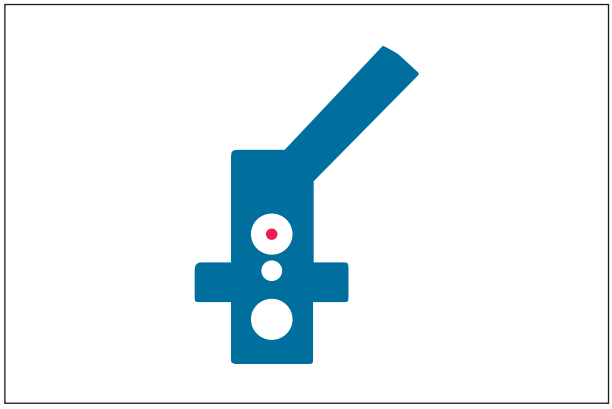


Fig. 7

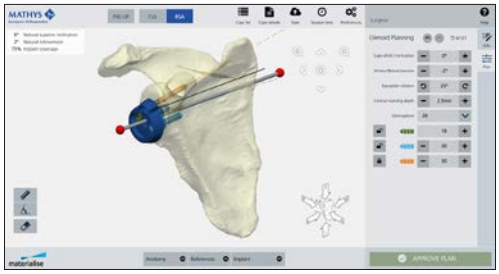
To achieve rotational stability with the standard glenoid drill guide check visually or with a wire that the superior k-wire hole is located central in the superior hole.
Then proceed with the drilling of the inferior peg hole. Insert the fixation peg inferiorly before drilling the superior peg hole.

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


Manufacturer


Caution

Notes

Manufacturer

materialise

Distributed by

MATHYS
European Orthopaedics

Australia
Mathys Orthopaedics Pty Ltd
Artarmon, NSW 2064
Tel: +61 2 9417 9200
info.au@mathysmedical.com

Austria
Mathys Orthopädie GmbH
2351 Wiener Neudorf
Tel: +43 2236 860 999
info.at@mathysmedical.com

Belgium
Mathys Orthopaedics Belux N.V.-S.A.
3001 Leuven
Tel: +32 16 38 81 20
info.be@mathysmedical.com

France
Mathys Orthopédie S.A.S
63360 Gerzat
Tel: +33 4 73 23 95 95
info.fr@mathysmedical.com

Germany
Mathys Orthopädie GmbH
«Centre of Excellence Sales» Bochum
44809 Bochum
Tel: +49 234 588 59 0
sales.de@mathysmedical.com

«Centre of Excellence Ceramics» Mörsdorf
07646 Mörsdorf/Thür.
Tel: +49 364 284 94 0
info.de@mathysmedical.com

«Centre of Excellence Production» Hermsdorf
07629 Hermsdorf
Tel: +49 364 284 94 110
info.de@mathysmedical.com

Italy
Mathys Ortopedia S.r.l.
20141 Milan
Tel: +39 02 4959 8085
info.it@mathysmedical.com

Japan
Mathys KK
Tokyo 108-0075
Tel: +81 3 3474 6900
info.jp@mathysmedical.com

New Zealand
Mathys Ltd.
Auckland
Tel: +64 9 478 39 00
info.nz@mathysmedical.com

Netherlands
Mathys Orthopaedics B.V.
3001 Leuven
Tel: +31 88 1300 500
info.nl@mathysmedical.com

P. R. China
Mathys (Shanghai) Medical Device Trading Co., Ltd
Shanghai, 200041
Tel: +86 21 6170 2655
info.cn@mathysmedical.com

Switzerland
Mathys (Schweiz) GmbH
2544 Bettlach
Tel: +41 32 644 1 458
info@mathysmedical.com

United Kingdom
Mathys Orthopaedics Ltd
Alton, Hampshire GU34 2QL
Tel: +44 8450 580 938
info.uk@mathysmedical.com

Local Marketing Partners in over 30 countries worldwide…

Item no. 336.020.043 02-0621-01 2021-06

Materialise NV • Technologielaan 15 • 3001 Leuven • Belgium
Distributor: Mathys Ltd Bettlach • Robert Mathys Strasse 5 • P. O. Box • 2544 Bettlach • Switzerland