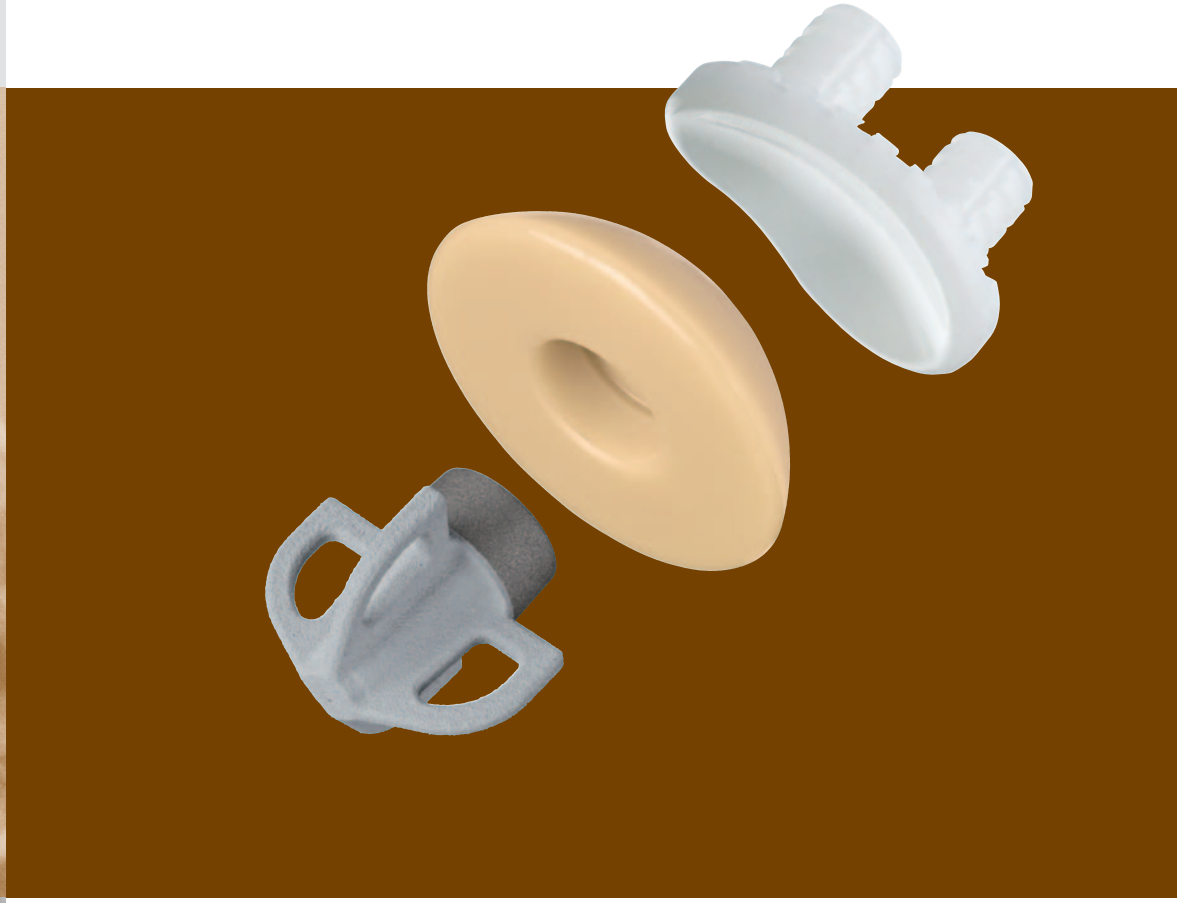
MATHYS
European Orthopaedics

Affinis® Short
Short Stemmed Total Shoulder Prosthesis
Surgical technique



Affinis Short

Contents

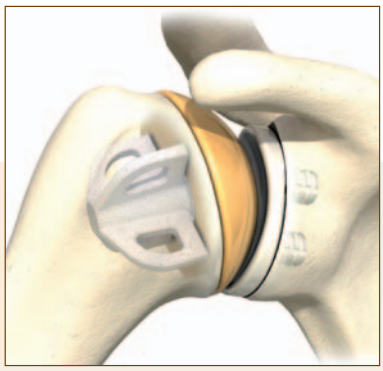
Note
Please make yourself familiar with the handling of the instruments, the product-related surgical technique and the warnings, the safety notes as well as the recommendations of the instruction leaflet before using an implant manufactured by Mathys Ltd Bettlach. Make use of the Mathys user training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

1. Introduction

1.1 Introduction

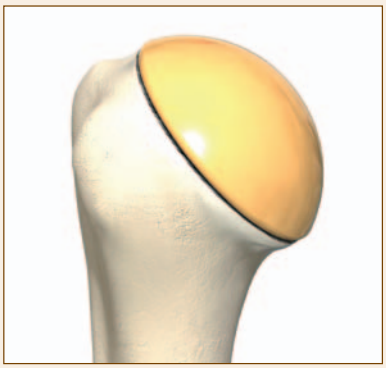
Total shoulder prostheses have proven to be a good solution for patients suffering from arthritis. Thanks to excellent results more and more patients benefit from prosthesis treatment to improve their function in daily life activities, reducing pain and therefore medication costs as well as side effects on general health.

Being less invasive to the bony and soft tissue structures, without the disadvantages of resurfacing, short stemmed prosthesis can help to further improve clinical and functional outcome.



1.2 Features

- 8 ceramic heads
- 6 titanium stems with bioactive calcium phosphate coating (CaP)
- Implant interfaces and instruments harmonised to the whole Affinis® system



1.3 Advantages

- Biologic and anatomic reconstruction of the glenohumeral geometry through guided surgical technique and anatomic ceramic heads
- Metaphyseal anchorage – bone saving and less invasive
- Facilitated approach to the glenoid for a more accurate total prosthesis implantation
- Easy, secure and precise instrumentation

1.4 Implant philosophy

- Hemi or Total Shoulder Prosthesis with less invasive stem anchorage
- Best anatomic 3D-positioning
- Centre of rotation inside bone – safe anchorage
- Utilization of the long lasting articulation pairing: ceramic on PE
- Nickel free implant for the treatment of allergic patients

2. Indications

2.1 Indications

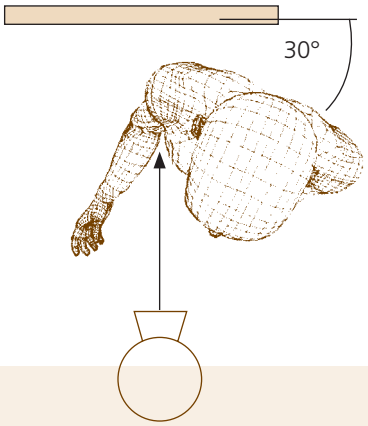
- Primary Osteoarthritis
- Secondary Osteoarthritis
- Rheumatoid Arthritis
- Posttraumatic Osteoarthritis
- Cuff Tear Arthropathy (Hamada grade III or IV) in younger patients
- Metabolic joint destruction (e.g. chondrocalcinosis, haemosiderosis, urate arthropathy)
- Fracture sequelae (malformation healing of humeral head fractures, non union healing/pseudarthrosis, head necrosis, locked dislocations)
- Avascular head necrosis (if sufficient bone stock)

2.2 Contraindications

- Acute or chronic infection, whether local or systemic (or the existence of a corresponding case history)
- Simultaneous paresis of the rotator cuff and of the deltoid muscle
- Any concomitant affection and addictions that could jeopardise the function of the implant
- Bone tumours in the region where the implant is anchored
- Neurogenic joint destruction (syringomyelia, Charcot)
- Defective humeral stem bone substance
- Immaturity of the skeleton

3. Pre-operative planning

Transparent templates of the implants are available in the usual scale of 1.10:1, for pre-operative determination of the dimensional ratios of the shaft, head, and glenoid, if applicable.



The following X-rays of the affected shoulder are recommended:

- a.p. image centred on the joint cavity
- axial image
- CT image to judge status and version of glenoid
- If necessary, MRI to judge status of rotator cuff

4. Instructions for surgery

4.1 Positioning

The ideal position of the patient is in a half-sitting position (beach-chair), with the shoulder that is to be operated upon projecting over the operating table. Make sure that the medial border of the scapula is still supported by the table.

- The arm is wrapped in a sterile manner and can be laid on an arm rail – but must remain freely movable
- The shoulder joint should remain accessible from all sides, including function testing (full adduction and extension) and X-ray checks with the image converter
- The trunk component of the table should be raised by about 35°
- Angle the lower leg component
- Position and secure the head in the head support

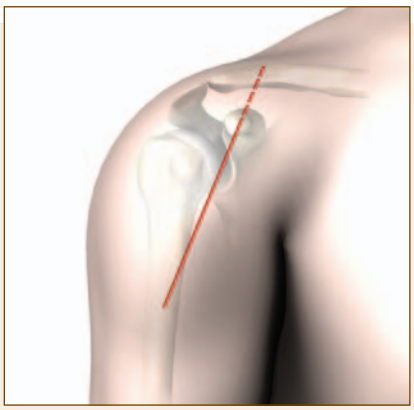


Fig. 1

4.2 Approach

The delto-pectoral skin incision should be made from the tip of the coracoid process, along the anterior edge of the deltoid muscle, to the insertion on the shaft of the humerus. If necessary, the skin incision can be extended to the lateral third of the clavicle (as indicated by the broken line).

Other approaches are possible at the surgeons' discretion.

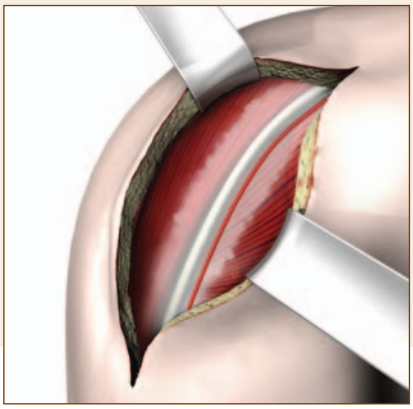


Fig. 2

The lateral skin flap is mobilised and the fascia is incised over the cephalic vein. This vein is usually retracted laterally, together with the deltoid muscle.

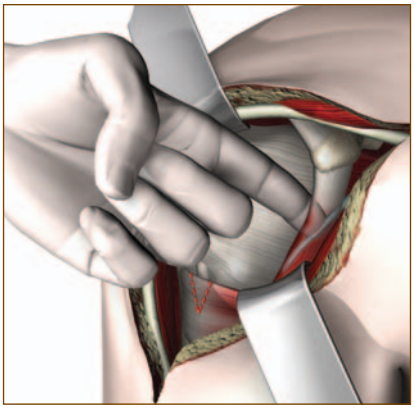


Fig. 3

This is followed by the vertical incision of the clavipectoral fascia.

After mobilisation of the coraco-brachial tendon group in a medial direction, the musculo-cutaneous nerve is palpated postero-medial to the tendons. The nerve should be held to the side with the tendons.

For better exposure, the insertion of the pectoralis major muscle can be notched close to the humerus (approx. 2 cm).

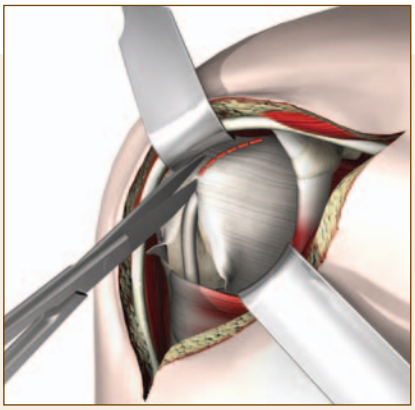


Fig. 4

Split rotator cuff in the interval up to the base of the coracoid process.

The biceps tendon should be tenotomised and tenodesed on the proximal shaft (sulcus area). The intra-articular stump is resected.

After that, the axillary nerve can be palpated at the anterior and lower side of the subscapularis.

Identification can be difficult in the case of revisions, older fractures or adhesions.

The axillary nerve must be protected throughout the entire operation.

Good exposure of the humeral head can be reached through antero-superior dislocation by externally rotating the extended limb.

A tenotomy of the superior part of the subscapularis may be performed when dislocation of the humerus is difficult to achieve.

Make sure that the humerus is displaced cranially during the next step to avoid traction injury of the brachial plexus.

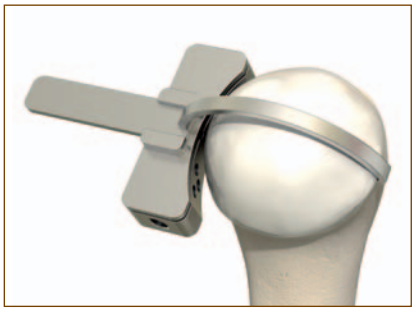


Fig. 5

4.3 Humeral resection
Remove all osteophytes.

Choose the correct size of the Adjustment Arm (S, M, L), slide it onto the Cutting Block and position it on the posterior anatomical neck.

Whilst keeping the posterior contact point at the anatomical neck, bring the slot of the Cutting Block in line with the anterior neck (height and inclination).

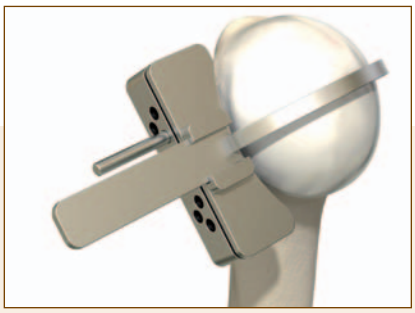


Fig. 6

Predrill a pinhole through one of the holes on the Cutting Block. Insert the first 3.2 mm Pin.

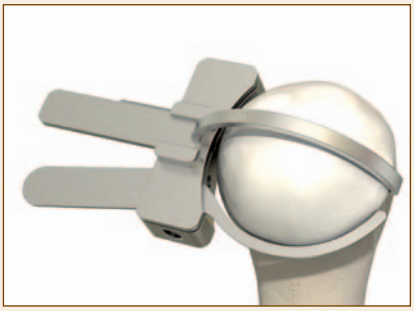


Fig. 7

Having blocked the guide you now can check the correct alignment in more detail and if correct, predrill and insert the 2nd Pin.

Slide back the Cutting Block to remove the Adjustment Arm.

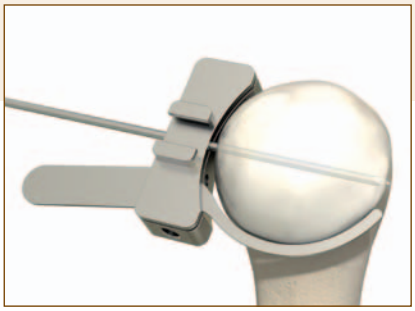


Fig. 8

Option:
Insert a K-Wire (2.5 mm) centrally and aligned to the anatomical neck. When inserted, mount the Cutting Block through the pinhole in the cutting slot.
Use the Stylus to recheck the resection height and the retroversion. Insert two 3.2 mm Pins and remove the K-Wire.

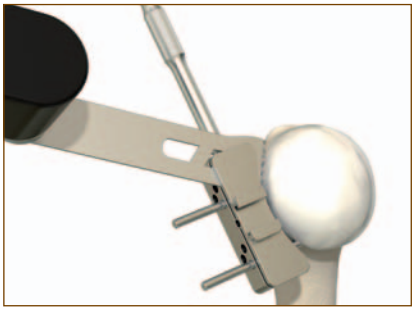


Fig. 9

Resect the humeral head through the saw-blade guide of the Cutting Block. Carefully protect the rotator cuff.

Remove all retractors and check your humeral cut:
Your resection should be in line with the anatomical neck.

If a re-resection is necessary, transfer the Cutting Block onto the Pins in the proximal holes (2 mm re-resection).

Fig. 10

Remove the instruments.

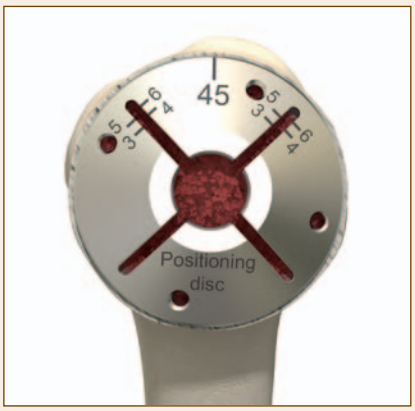


Fig. 11

4.4 Humeral preparation
Centre the Positioning Disc on the resection plane aligned to the outer cortical border.

Alignment can be facilitated by choosing a smaller size of Positioning Disc.

The laser marking with the head size indicator (45) should be positioned laterally in the 12 o'clock position.

The numbers (3, 4, 5, 6) on the slot indicate the Impactor (stem) sizes you can use with each Positioning Disc.

This is the most important step to achieve a centred humeral implant!

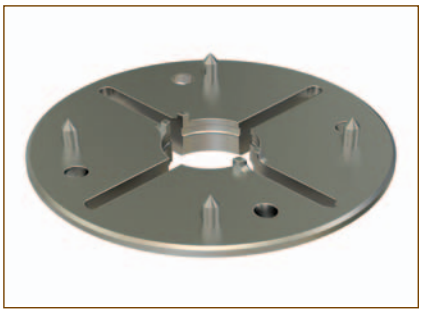


Fig. 12

There are spikes on the backside of the Positioning Disc for pre-fixing the Disc on the resected humerus.

Fig .13

Fix the Disc definitely with additional K-Wires. This prevents the Disc lifting-off which could result in mal-orientation of the stem.

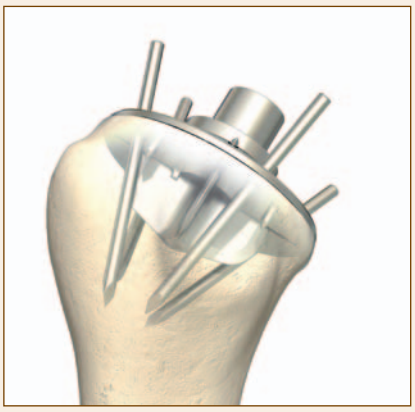


Fig. 14

The K-Wires will not have contact with the Impactor.

Fig. 15

Insert the Pre-Impactor
It is mandatory to hold the Positioner orthogonally to the resection plane!

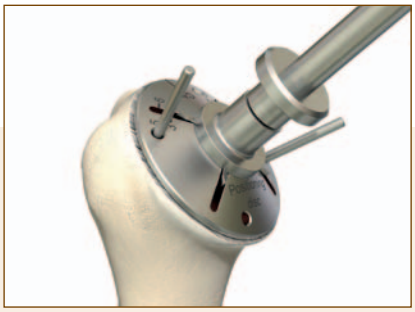


Fig. 16

Insert the Pre-Impactor until the stop is completely flush with the Positioning Disc.

Fig. 17

Extract the Pre-Impactor with light hammer blows on the underside of the Positioning Plate.

Don't "jiggle-out" the Impactor with the Positioner by hand as this would decrease the bone bed quality!

Fig. 18

Choose the appropriate stem size.
The stem should be fixed solely in the spongious bone.

About 5 mm distance to the inner border of the cortex is recommended.

Don't risk fractures of the proximal humerus! In case of doubt, choose a smaller stem.

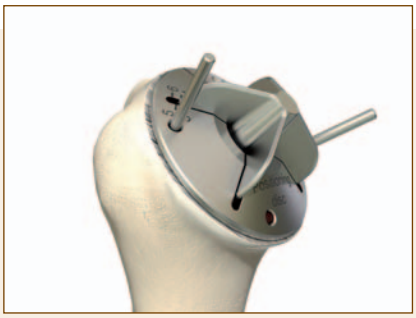


Fig 19

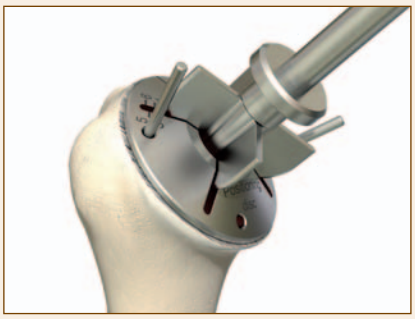


Fig. 20

Impact the chosen Impactor until the stop is fully flush with the Positioning Disc.

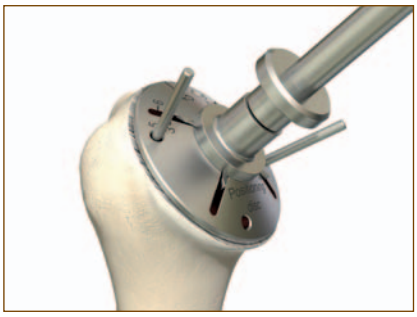


Fig. 21

Unscrew and remove the Positioner, the K-Wires and the Positioning Disc.

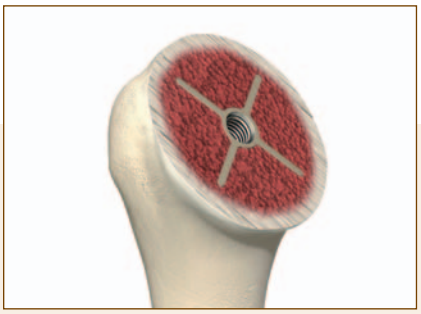


Fig. 22

Leave the Impactor in situ!

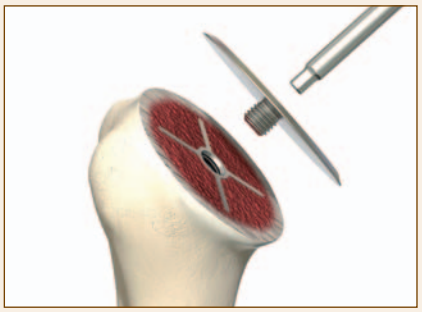


Fig. 23

It is recommended to use the Cover Disc to protect the humeral resection surface.

Fig. 24

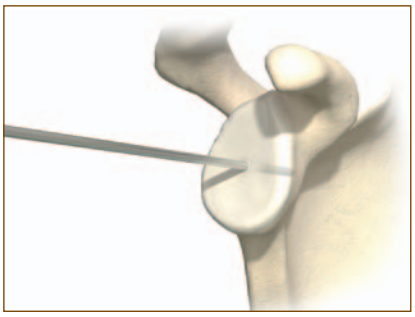


Fig. 25

4.5 Glenoid

Centrally insert a K-Wire as guide for the Glenoid Reamer and the Glenoid Drill Guide.

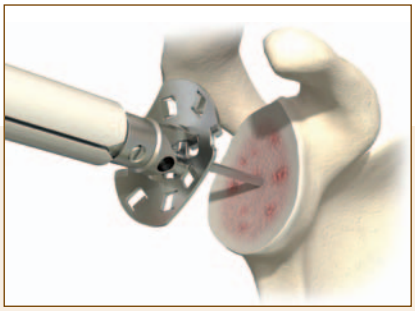


Fig. 26

Use the Glenoid Reamer over the K-Wire (150 mm x 2.5 mm dia.) to ream the glenoid.

Glenoid Reamer Ø	Glenoid Size
32 mm	1
36 mm	2
44 mm	3 + 4

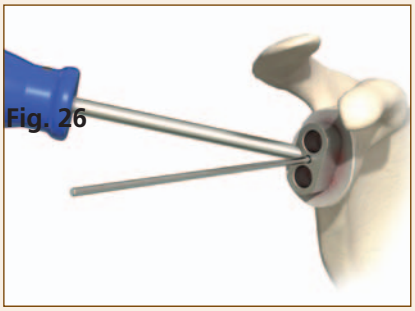


Fig. 26

Fig. 27

Position the Glenoid Drill Guide over the K-Wire and correctly align the guide.

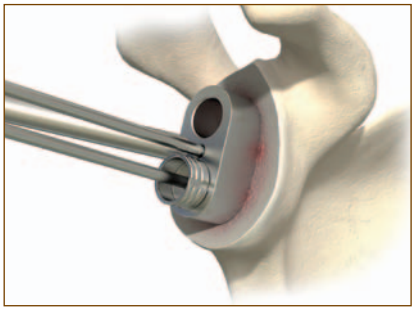


Fig. 28

Insert the 2.5 mm Glenoid Drill Sleeve and a 2.5 mm K-Wire (for rotational stability).

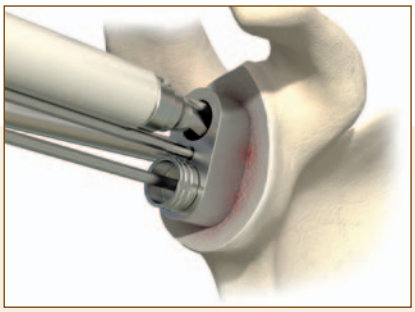


Fig. 29

Use the Glenoid Drill Bit to drill the first anchoring hole.

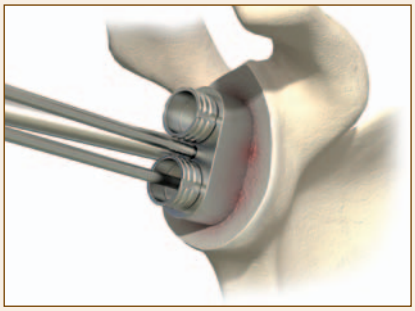


Fig. 30

Remove the Drill Guide and position the Fixation Peg.

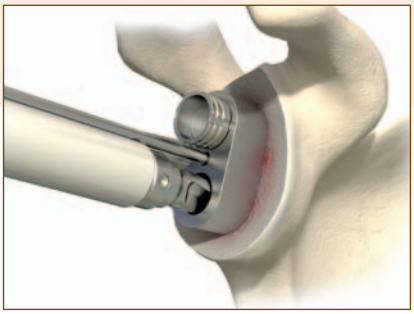


Fig. 31

Remove the 2.5 mm Glenoid Drill Sleeve with the respective K-Wire.

Use the Glenoid Drill Bit to drill the second anchoring hole.

Remove the instruments.

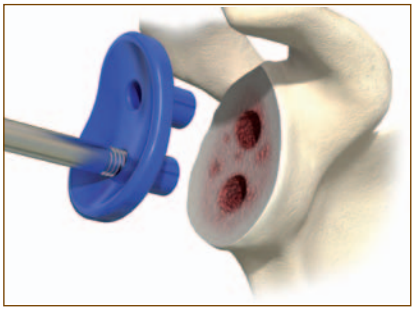


Fig. 32

Select and insert the Trial Glenoid (can be held using the Alignment Rod).

Compatibility of head size and glenoid

Head	Glenoid
Bionit / Head 39/13	1
Bionit / Head 41/14	
Bionit / Head 43/15	2
Bionit / Head 45/16	
Bionit / Head 47/17	3
Bionit / Head 49/18	
Bionit / Head 51/19	4
Bionit / Head 53/20	

Overview of possible combination:

Glenoid	Head							
	39x13	41x14	43x15	45x16	47x17	49x18	51x19	53x20
1								
2								
3								
4								

Colour code: OK congruent forbidden

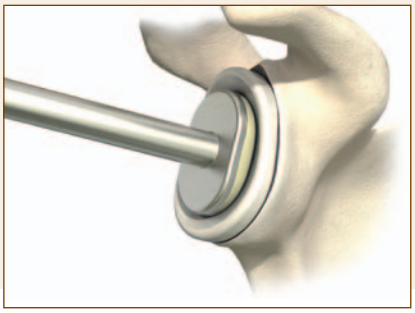


Fig. 33

Fill the drill holes with bone cement. Insert and adapt the glenoid component until it is flush with the spherical rest of the Glenoid Impactor.

Carefully remove the surplus cement. Hold it until the cement compound becomes effective.

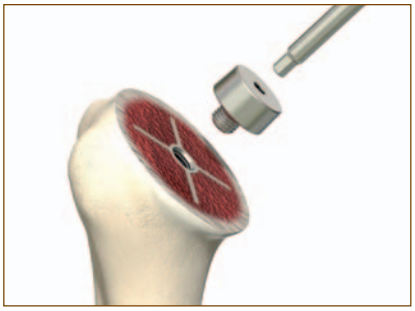


Fig. 34

4.6 Size detection
Screw the Test Cone in the Impactor using the Screwdriver 3.5.

Don’t fasten too tight!

Tip: At this stage sutures for later fixation of the rotator cuff can be inserted.

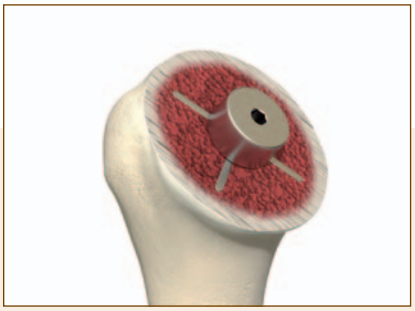


Fig. 35

Fig. 36

Determine the head size by making a comparative measurement of the resected humeral head using the Trial Heads.

Fig. 37

Place the Trial Head onto the Test Cone of the Impactor.
Perform a trial reduction, check the mobility as well as the articular tension, and correct the size of the head if the result is not satisfactory.

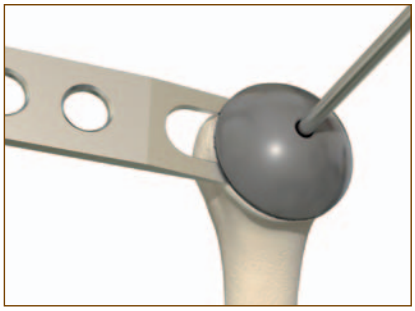


Fig. 38

Trial Head removal. If necessary - use the Head Extractor and the Screwdriver 3.5 as a stabilizer to remove the Trial Head.

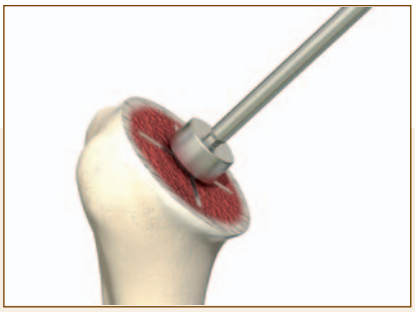


Fig. 39

Remove the Test Cone using the Screwdriver 3.5.

Fig. 40

Extract the Impactor with light hammer blows on the underside of the positioning plate.

Don't "jiggle-out" the Impactor with the Positioner by hand as this would decrease the bone bed quality!

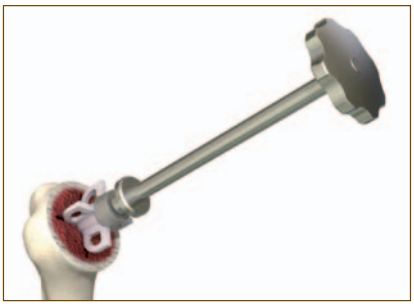


Fig. 41

4.7 Humeral stem/head implantation
Insert the stem with the Positioner orthogonally to the resection plane.

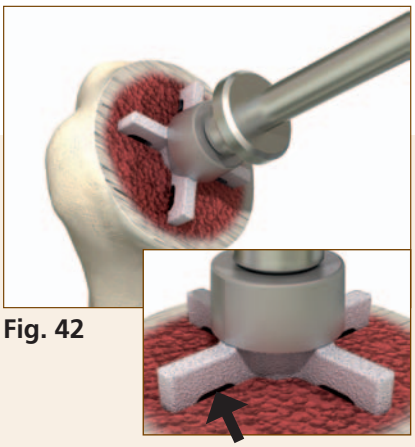


Fig. 42

Stop impacting just before the end of the bone window.

The upper fin surfaces have to be parallel with the resection plane all around.

Carefully unscrew and remove the Positioner.

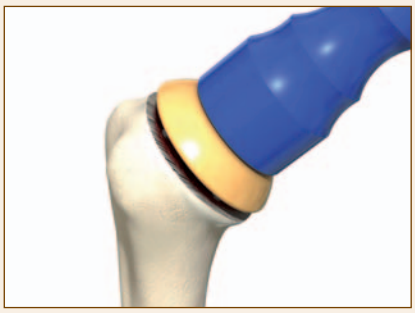


Fig. 43

The cone is then **carefully cleaned and dried.**
The ceramic head must now be mounted with a compressive and rotational movement.

Final impaction of the whole prosthesis with the Head Impactor until the head is sitting flush on the resection plane.

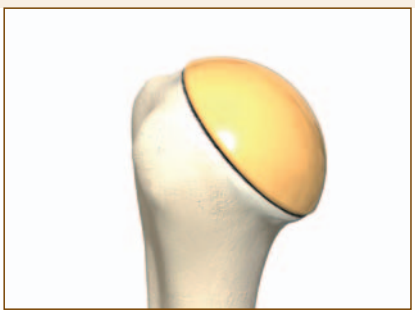


Fig. 44

In dense or sclerotic bone conditions, a remaining gap between head and resection plane of 1 to 2 mm is feasible.

5. Revision

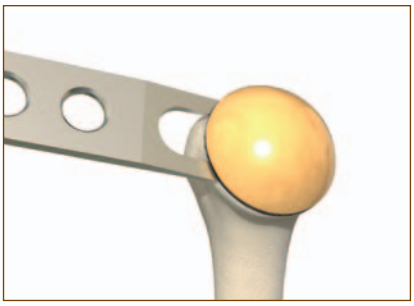


Fig. 45

Use the Head Extractor to remove the prosthesis head.

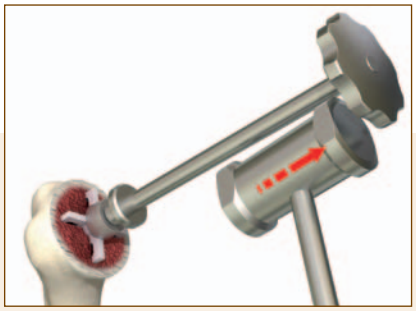


Fig. 46

Extract the stem with the Positioner and the hammer.

Affinis

Affinis *Inverse*

For revision options please ask for the documentation of our total or inverse shoulder prosthesis.

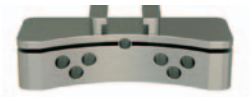
6. Implants

Item no.	Description
102.07.02.31.0	Affinis PE Glenoid 1 cem.
102.07.02.35.0	Affinis PE Glenoid 2 cem.
102.07.02.39.0	Affinis PE Glenoid 3 cem.
102.07.02.43.0	Affinis PE Glenoid 4 cem.

Item no.	Description
62.34.0020	Affinis Short Head 39/13/1
62.34.0021	Affinis Short Head 41/14/1
62.34.0022	Affinis Short Head 43/15/2
62.34.0023	Affinis Short Head 45/16/2
62.34.0024	Affinis Short Head 47/17/3
62.34.0025	Affinis Short Head 49/18/3
62.34.0026	Affinis Short Head 51/19/4
62.34.0027	Affinis Short Head 53/20/4

Item no.	Description
62.34.0010	Affinis Short Stem 1
62.34.0011	Affinis Short Stem 2
62.34.0012	Affinis Short Stem 3
62.34.0013	Affinis Short Stem 4
62.34.0014	Affinis Short Stem 5
62.34.0015	Affinis Short Stem 6

7. Instruments



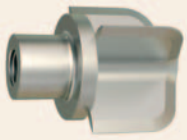
Affinis Short Instrumenation (61.34.0125)

Item no.	Description
61.34.0121	Affinis Short Cutting Block
61.34.0127	Affinis Short Adjustment Arm S
61.34.0128	Affinis Short Adjustment Arm M
61.34.0129	Affinis Short Adjustment Arm L

Item no.	Description
503.08.07.75.0	Affinis Pin 3.2/75

Item no.	Description
61.34.0124	K-Wire 2.5/50

Item no.	Description
61.34.0082	Affinis Short Positioning Disc 39
61.34.0083	Affinis Short Positioning Disc 41
61.34.0084	Affinis Short Positioning Disc 43
61.34.0085	Affinis Short Positioning Disc 45
61.34.0086	Affinis Short Positioning Disc 47
61.34.0087	Affinis Short Positioning Disc 49
61.34.0088	Affinis Short Positioning Disc 51
61.34.0089	Affinis Short Positioning Disc 53



Item no.	Description
61.34.0090	Affinis Short Pre-Impactor

Item no.	Description
61.34.0091	Affinis Short Impactor 1
61.34.0092	Affinis Short Impactor 2
61.34.0093	Affinis Short Impactor 3
61.34.0094	Affinis Short Impactor 4
61.34.0095	Affinis Short Impactor 5
61.34.0096	Affinis Short Impactor 6

Item no.	Description
61.34.0097	Affinis Short Positioner

Item no.	Description
61.34.0099	Affinis Short Cover Disc 41
61.34.0100	Affinis Short Cover Disc 47

Item no.	Description
61.34.0123	Affinis Short Test Cone for Impactor

Item no.	Description
61.34.0101	Affinis Short Trial Head 39/13/1 centric
61.34.0102	Affinis Short Trial Head 41/14/1 centric
61.34.0103	Affinis Short Trial Head 43/15/2 centric
61.34.0104	Affinis Short Trial Head 45/16/2 centric
61.34.0105	Affinis Short Trial Head 47/17/3 centric
61.34.0106	Affinis Short Trial Head 49/18/3 centric
61.34.0107	Affinis Short Trial Head 51/19/4 centric
61.34.0108	Affinis Short Trial Head 53/20/4 centric

Item no.	Description
315.310	AO Drill Bit 3.2/45

Item no.	Description
502.06.16.00.0	Affinis Stylus

Item no.	Description
502.06.03.00.0	Affinis Head Impactor

Item no.	Description
502.06.08.00.0	Affinis Head Extractor

Item no.	Description
60.02.2032	Affinis Inverse Screwdriver 3.5

Item no.	Description
502.06.02.07.0	Affinis Alignment Rod

Item no.	Description
61.34.0061	Affinis Short Tray
61.34.0062	Affinis Short Lid
60.03.0005	Affinis Small-Instrument Case

Affinis Glenoid Instrumentation

Item no.	Description
60.01.0003	Affinis Glenoid Instrumentation

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