

Affinis[®] Inverse
Reverse Shoulder Prosthesis System
Surgical technique



Affinis  *Inverse*

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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



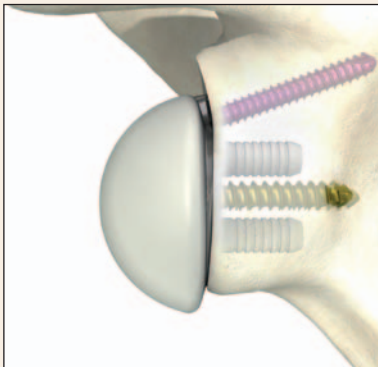
1.1 Introduction

Inverse shoulder prostheses have become widely used in recent years. Although new designs have been developed, the main problems of early notching, loosening and therefore high revision rate, have not yet been solved.

With its new and improved design features as well as reproducible inferior positioning of the metaglene in the surgical technique, the Affinis Inverse does experience less of the failures mentioned above.

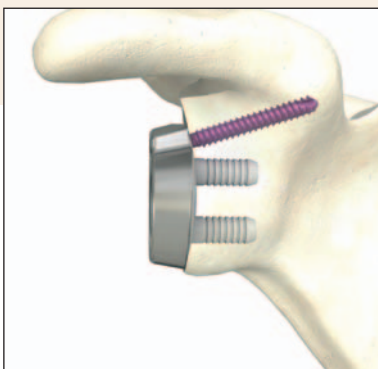
1.2 Features

- CoCr-Inlay
- PE-Glenosphere
- 2-peg metaglene to improve primary and secondary fixation
- Reproducible centric reaming but eccentric positioning of the metaglene
- Special Fracture Inverse implant for intraoperative decision making and revisions



1.3 Advantages

- No (!) implant/implant notching
- Reduced inferior notching
- No screw breakages
- No PE contact to scapula, less PE particles leading to less osteolysis, thus less revisions are expected
- Simple and precise instrumentation



1.4 Implant philosophy

- 2-Peg design
- No inferior screw
- High primary and secondary stability
- Bone preserving

2. Indications

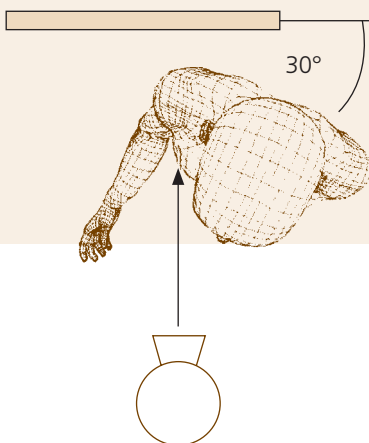
2.1 Indications

- Rotator defect arthropathy (RDA)
- Revision of a failed hemiprosthesis or total prosthesis in patients with rotator cuff defect
- In certain tumour-related modifications of the proximal humerus

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
- Hypersensitivity to the raw materials used, above all to metal (e.g. cobalt, chromium, nickel, etc.).
- 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 or MRI

4. Instructions for surgery

4.1 Positioning

The ideal position of the patient is in a half-sitting position (beach-chair position), 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.

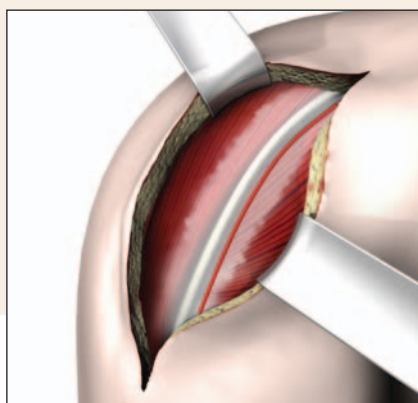


Fig. 2

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.

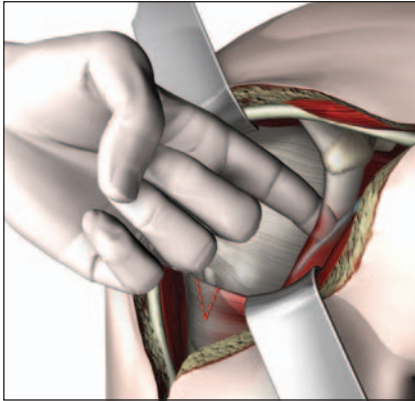


Fig. 3

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

After mobilisation of the coraco-brachial tendon group in a medial direction, the musculo-cutaneous nerve is palpated posteromedial 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).

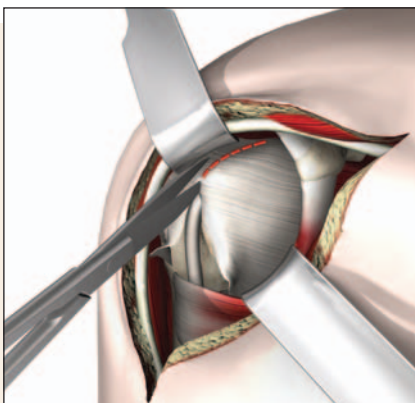


Fig. 4

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 and adducted limb.

A tenotomy of the superior part of the subscapularis may be performed when adequate exposure 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.

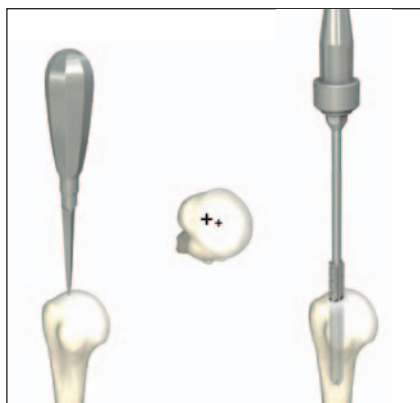


Fig. 5

4.3 Humeral resection

Open the medullary cavity using the awl at the highest point of the humeral head, centred to the shaft axis. Insert the medullary reamer using the handle.

Ream the intramedullary cavity beginning with the 6mm rod and continue with 9 and 12 mm guide rod depending on the diameter of the cavity.

Leave the final rod in place and remove the handle.



Fig. 6

Assemble the resection guide appropriate to the side and the approach used. Place the resection guide on the medullary reamer.

Adjust the desired retroversion by aligning the holding/rotation rod or the k-wire to the forearm.

Use the stylus to finely tune the retroversion and resection height according to the anatomical conditions. The holding/rotation rod locks the resection guide to the medullary reamer.

Predrill the pinholes through at least two distal holes of the resection guide. Insert two 3.2 mm pins.

Loosen the screw of the resection guide and of the bearing rod. Remove the holder, the medullary reamer and the bearing rod.



Fig. 7

Use the stylus to recheck the resection height and the retroversion.

The stylus should be in line with the anatomical neck laterally. Resect the humeral head through the saw-blade guide of the resection guide (155°).

If a re-resection is necessary, transfer the resection guide onto the pins in the proximal holes (2 mm re-resection).



Fig. 8

Optional instruments for the lateral approach:

Assemble the cutting block and the holder marked "lateral" and slide them onto the medullary reamer.

The retrotorsion guide does make retroversion of 0° if aligned with the forearm.

Predrill the pinholes through the holes of the resection guide. Insert two 3.2 mm pins. Loosen the screw of the resection guide and of the bearing rod. Remove the holder, the medullary reamer and the bearing rod.

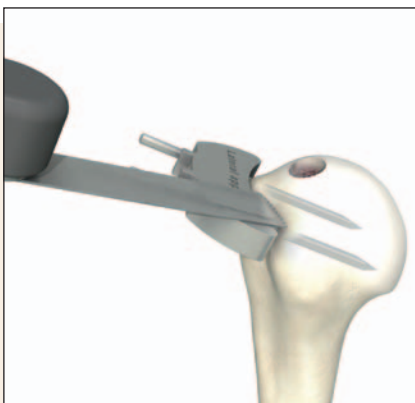


Fig. 9

Resect the humeral head.

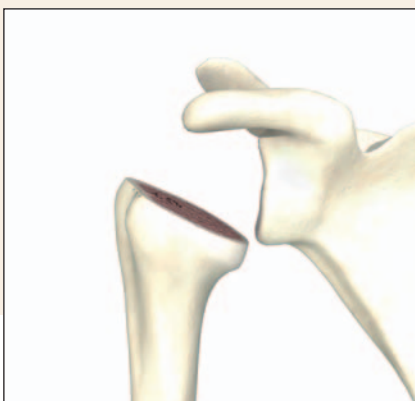


Fig. 10

Remove all instruments and check your humeral cut: Your resection should finish in line with the inferior border of the glenoid.



Fig. 11

Insert the retroversion guide and use the lateral and medial slot to mark the correct alignment of the rasp.

The retroversion guide can also serve as a protection for the humeral resection plane, while preparing the glenoid.

Options

The Affinis Inverse System allows two options to continue with the procedures:

- Perform the glenoid preparation now
- or implant the stem first (chapter 4.5).

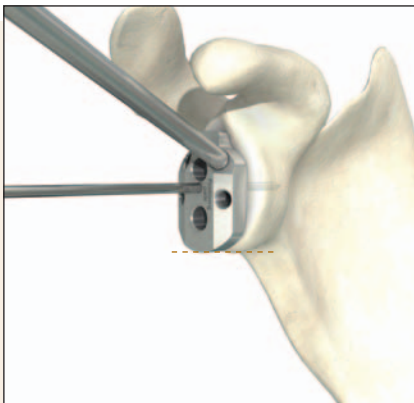


Fig. 12

4.4 Glenoid preparation and metaglene implantation

Mount the holding/rotation rod onto the metaglene drill guide. Use the drill guide to position the central k-wire.

The inferior border of the guide must be flush with the inferior border of the glenoid. This will lead to an implant overhang of at least 3mm to reduce primary notching.

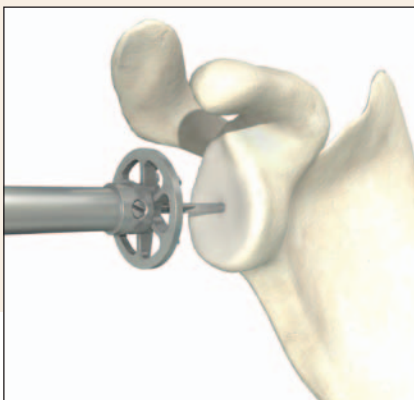


Fig. 13

Use glenoid reamer 28 over the Kirschner wire to ream the glenoid.

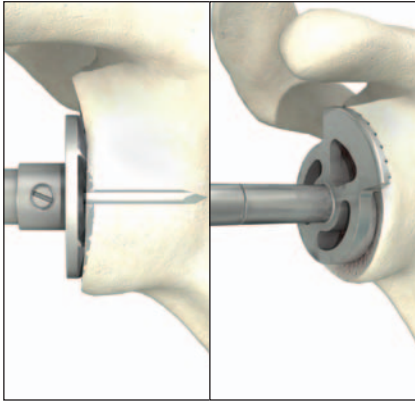


Fig. 14

Stay in the subchondral bone. Never ream into the cancellous bone.

The 42 reamer is required to avoid conflicts between the glenosphere and any distant bone of the glenoid. Make sure that the rim of the glenoid doesn't have any bony prominences that could interfere with the glenosphere.

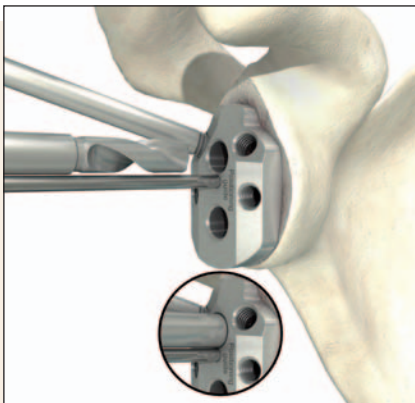


Fig. 15

To prepare the peg holes, slide the glenoid drill guide over the Kirschner wire and correctly align the guide.

Use the glenoid drill bit to drill the superior anchoring hole first.

The drill has an automatic stop.

Remove the drill and position the fixation peg to prevent rotation of the guide.

Use the glenoid drill bit to drill the inferior anchoring hole.

Important When using the revision metaglene with one peg, take care to use the drill bit marked with "revision" to drill the superior hole.

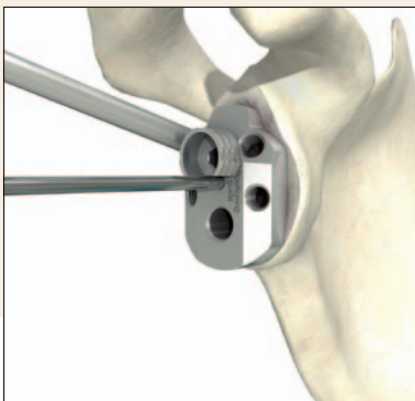
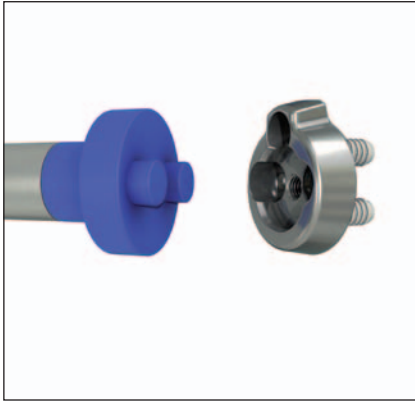


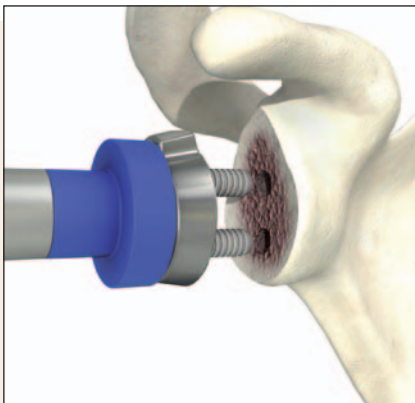
Fig. 16

Remove the instruments.



Slide the metaglene on the impactor.

Fig. 17



Set the metaglene and gently impact it with the impactor. Make sure to be working in the same direction as the drilled peg holes. Don't incline the instrument.

Fig. 18

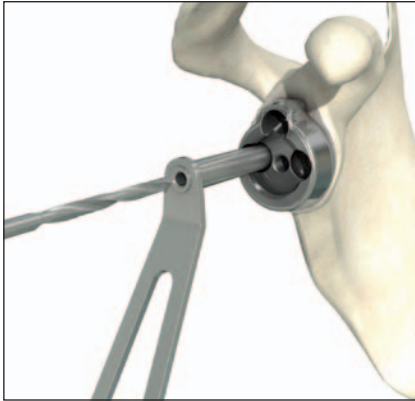


Fig. 19

Hold the lag screw drill guide against the correspondent metaglene hole (anterior and posterior). The lag screws can be directed in an angular freedom of 10° ($\pm 5^{\circ}$). Insert the 3.2 mm drill bit and drill the holes for the lag screws parallel or slightly convergent to the pegs. Fix these two screws first in alternating mode. This will ensure that the metaglene becomes flush on the reamed glenoid.



Fig. 20

The superior screw can be drilled with an angular freedom of $\pm 15^{\circ}$. Using the locking screw drill guide in direction of the base of the coracoid process, drill with the 2.5mm drill bit.



Fig. 21

Block the metaglene with the superior locking screw to secure the fixation.



Fig. 22

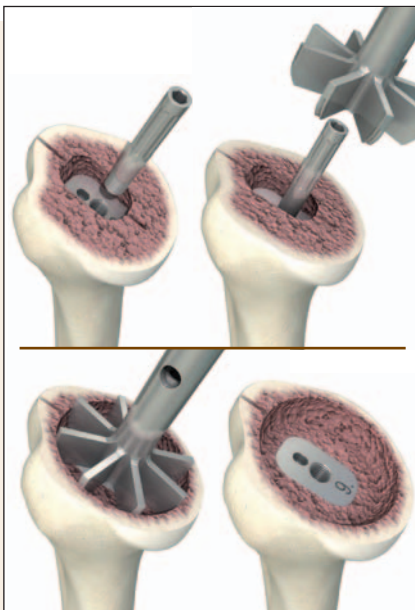


Fig. 23

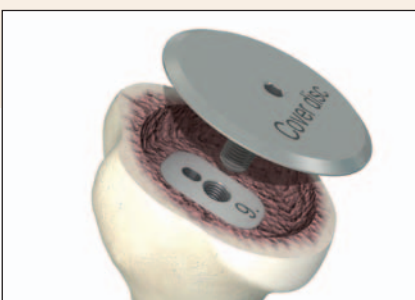


Fig. 24

4.5 Humeral preparation and stem implantation

Ream the medullary cavity step by step (beginning with the smallest size rasp) with a retroversion of 0°–10° in standard cases.

Make sure to place the positioner correctly and to fix it firmly to the rasp during impaction.

Dimensioning of the stems:

Rasp size	Cementless stem	Cemented stem
6.0	6.0 mm	6 mm
7.5	7.5 mm	9 mm
9.0	9.0 mm	12 mm
10.5	10.5 mm	15 mm
12.0	12.0 mm	
13.5	13.5 mm	
15.0	15.0 mm	

When the laser marking is in line with the resection plane, correct depth has been reached.

Remove the setting instrument but leave the rasp in the humerus.

Screw the reamer guiding bolt onto the rasp and ream the metaphyseal cavity. Sufficient reaming is reached when the top of the reamer is in line with resection plane.

It is recommended to use the cover disc inserted into the rasp to protect the humeral resection surface if preparation and implantation of the metaglene and glenosphere is performed at this stage.

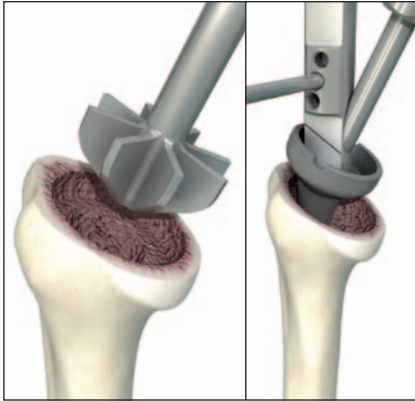


Fig. 25

To finalise humeral preparation, remove the rasp and finish the metaphyseal cavity with humeral reamer no. 2. Stop reaming as soon as the reamer is flush with the resection plane.

Mount the definitive humeral stem on the positioner. Impact the cement-less prosthesis or insert the cemented one with the positioner. The use of a cement plug is recommended!



Fig. 26

If wished the trial glenosphere can be mounted and secured to perform trial reduction.

Perform reduction and verify the function.

Note! If performing a revision from Fracture to Fracture Inverse, please be aware, that only the 39 and 42 glenospheres are available!



Fig. 27

Insert the trial inlay. Bring the markings on stem and inlay in line to reach correct rotation of the inlay.

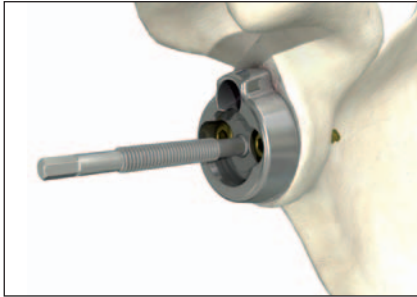


Fig. 28

4.6 Implantation of glensphere and final insert

After having chosen the glensphere and inlay sizes screw the metaglene assembly rod onto the metaglene.

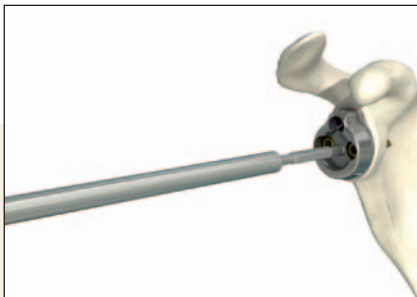


Fig. 29

Secure it with the assembly rod holder ...



Fig. 30

... or with the handle of the pusher.

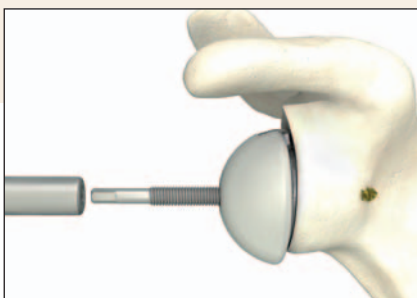


Fig. 31

Slide the glensphere carefully over the assembly rod. Slide, and then screw the glensphere introducer on the rod. This will push the glensphere onto the metaglene.

Stop as soon as you have to push with increased force. Turn back the pusher and check if the glensphere is fully seated on the metaglene. The glensphere will come off easily, if not fully seated.

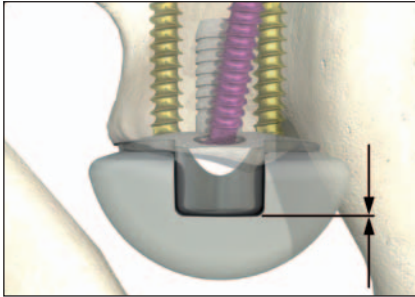


Fig. 32

The full connection between glenosphere and metaglene can additionally be checked through the following parameters:

1. The superior cut out of the Glenosphere needs to be flush with the metal back.

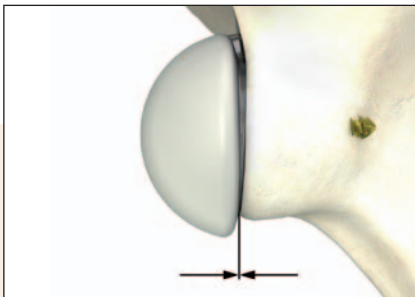


Fig. 33

2. The inferior border of the glenosphere must be flush with the backside of the metaglene

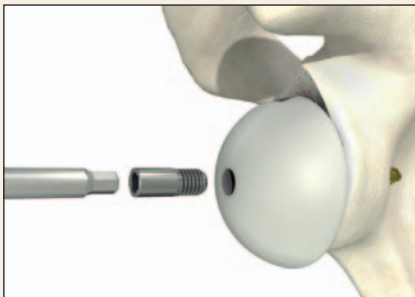


Fig. 34

Finally, screw in the fixation screw to secure the snap-in of glenosphere. If the screw can not be fixed down, the glenosphere may not be fully fixed on the metaglene and the seating has to be checked again.

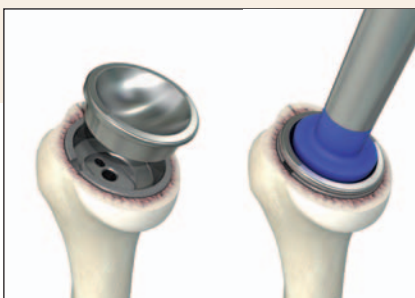


Fig. 35

Insert the appropriate CoCr-Inlay into the stem. Make sure that the lateral laser marking of the inlay is in line with the marking on the stem to assure correct rotation of the inlay.

Impact the inlay.

5. Revision of primary inverse

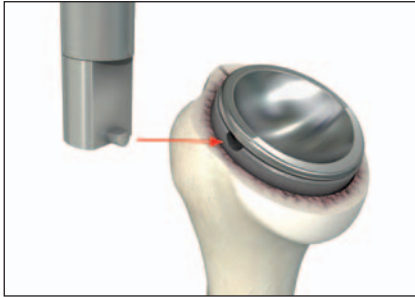


Fig. 36

5.1 Inlay removal

Mount the inlay revision adapter on the impactor. Insert it into one of the lateral sparings of the stem.



Fig. 37

Remove the inlay by pivoting the revision adaptor in the medial-lateral direction.

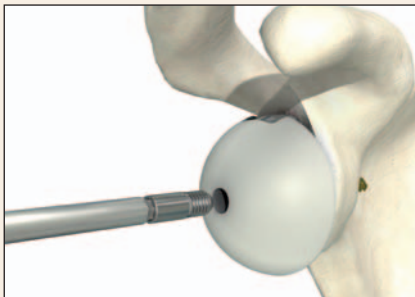


Fig. 38

5.2 Glenosphere removal

Remove the fixation screw of the glenosphere.

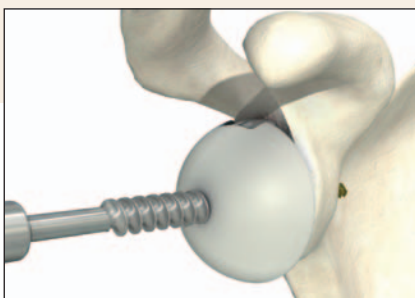


Fig. 39

Screw the glenosphere revision instrument into the glenosphere. The revision device removes the glenosphere from the metaglene.

Providing the stability of the metaglene is secure a new PE-Glenosphere can be implanted. Otherwise the metaglene has to be revised too.



Fig. 40

5.3 Head adaptor and spacer fixation technique

Head Adapter

A head adaptor to convert failed inverse into standard hemi or total shoulder replacement is available.

Spacer

In revision cases the offset of the inverse prosthesis sometimes has to be increased. The Affinis Inverse offers a spacer of 9mm that allows building increased offset up to 24mm (2 spacer + 6mm inlay).

If 2 spacers are used the extra long separately packed fixation screw needs to be used.

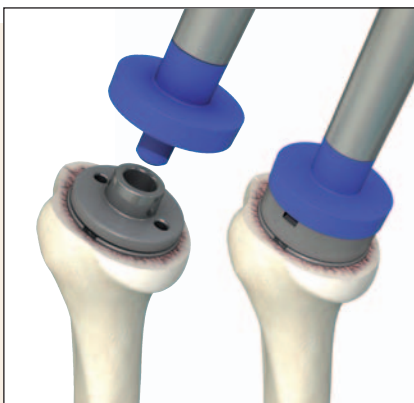


Fig. 41

Both implants need to be secured mandatorily with a fixation screw by the use of the counter adaptor and moment key!

Insert the head adaptor or the spacer and impact it with the special impactor.

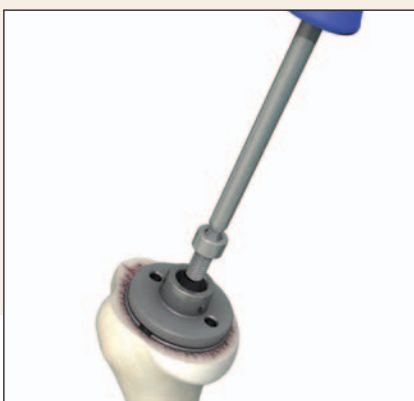


Fig. 42

The preliminary fixation of the screw is performed with the standard hexagonal screw driver.

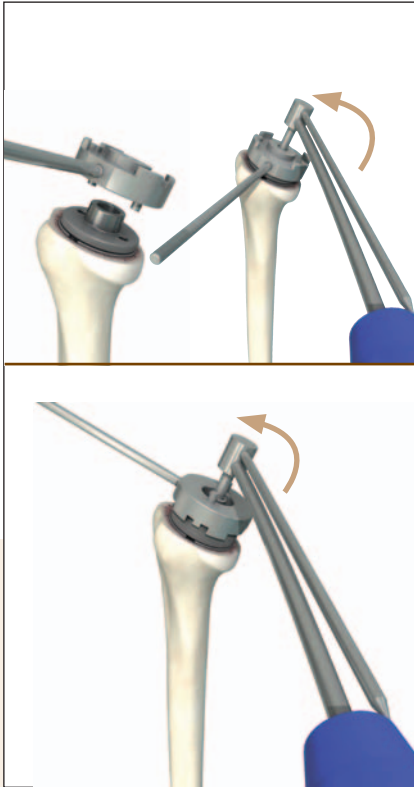


Fig. 43

The countering adaptor is mounted, to secure the implant against rotation, and the torque wrench is inserted.

The use of the counter wrench is mandatory.

The counter wrench and the torque wrench must be used by the same person, as this is the only way to be sure of avoiding stem rotation in the bone or cement socket.

Tensioning takes place by turning the torque wrench clockwise. When the indicator of the torque wrench points away from the wrench handle, permanent bracing has been achieved.

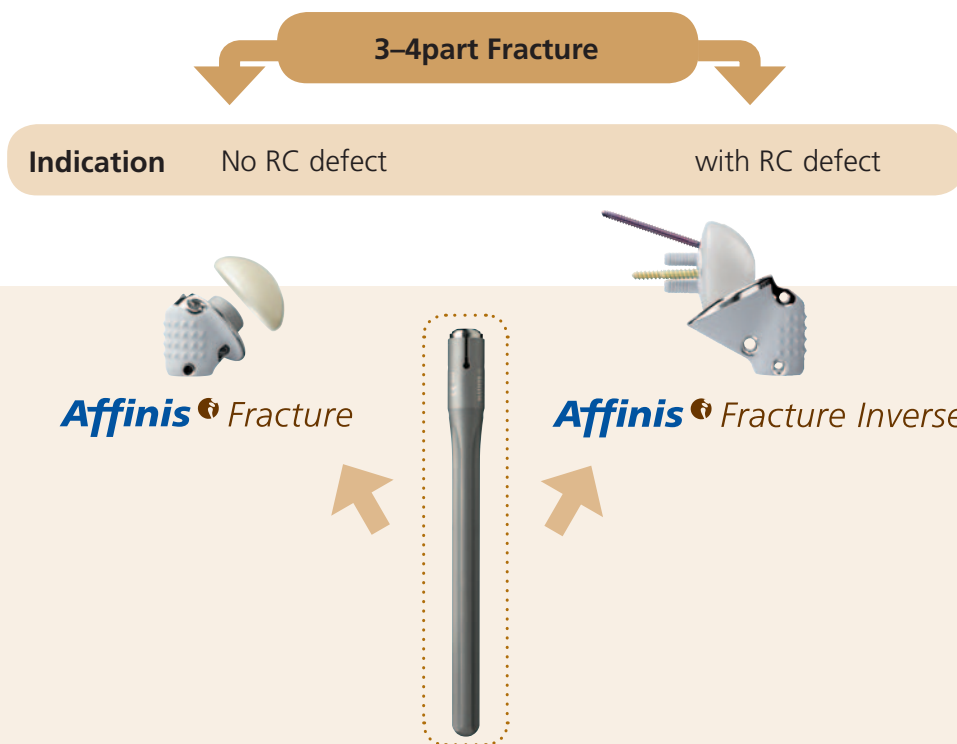
6. Primary Affinis Fracture Inverse

6.1 Intraoperative choice

In rare cases the rotator cuff may be ruptured in fracture situation also.

The Affinis Fracture provides the intraoperative choice of implanting a primary fracture or inverse implant:

You've got the intraoperative choice



6.2 Important notes!

If performing a Fracture Inverse please be aware, that only the 39 and 42 sizes are available!

Please check the surgical technique of the Affinis Fracture as reference for the implantation principle of the fracture system.

Affinis Fracture Inverse

Item no.	Description
60.30.6390	Affinis Fracture Inverse 39+0
60.30.6393	Affinis Fracture Inverse 39+3
60.30.6420	Affinis Fracture Inverse 42+0
60.30.6423	Affinis Fracture Inverse 42+3

Articula Inverse

Item no.	Description
60.30.9390	Articula Inverse 39+0
60.30.9393	Articula Inverse 39+3
60.30.9420	Articula Inverse 42+0
60.30.9423	Articula Inverse 42+3



Fig. 44

6.3 Implantation of Affinis Fracture stem

The humerus shaft is exposed, sparing the periosteum. Coagulations and any bone splinters are carefully removed from the intramedullary canal. The medullary space is now drilled step by step using the medullary reamer, until the desired stem size is reached. The stem size always corresponds to the numbering of the medullary reamer:

Medullary reamer D in mm	Stem size
6	6
9	9
12	12

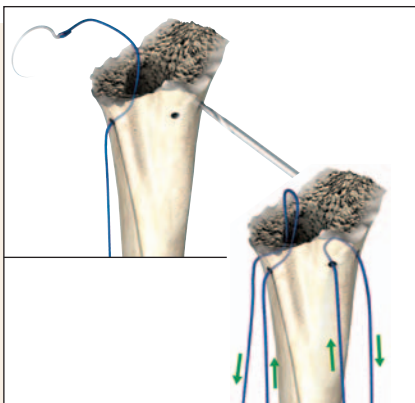


Fig. 45

Four holes are subsequently drilled at the edge of the shaft of the humerus, and two sutures are placed in a U shape. These should be inserted medially and laterally of the sulcus, before the prosthesis stem is cemented in.

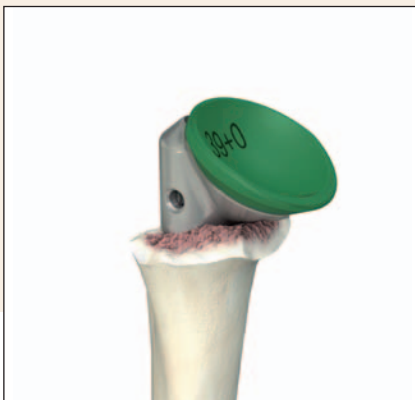


Fig. 46

Before cementing, the Fracture Inverse trial is mounted in a central position onto the stem that is to be implanted. This means that after cementing, it is still possible to displace the central part of the prosthesis 5mm caudally or cranially respectively, for the purposes of exact anatomical positioning.

The adjusting screw is used to fix the central part and stem temporarily. The use of a medullary plug is recommended.



Fig. 47

6.4 Implantation of Inverse central part

Having made the implant choice, the definitive glenosphere (see chapter 4.6) must be mounted and fixed.

The Affinis Fracture Inverse or Artacula Inverse central part is mounted on the shaft and the appropriate height and retroversion is adjusted.

When the correct positioning has been reached, the counter wrench is introduced into the medial hole to secure the central part against rotation, and the torque wrench is inserted.

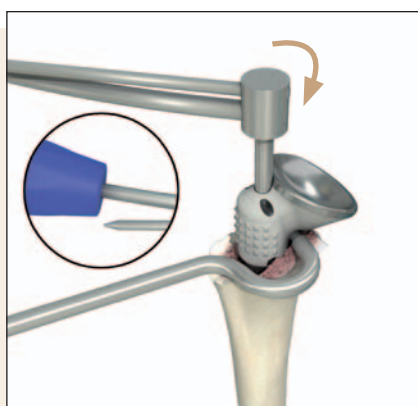


Fig. 48

The use of the counter wrench is mandatory.

The counter wrench and the torque wrench must be used by the same person, as this is the only way to be sure of avoiding stem rotation in the cement socket.

After having secured the central part, it is recommended to re-attach remaining tuberosities and/or rotator cuff tendons to improve rotation and stability of the shoulder joint.

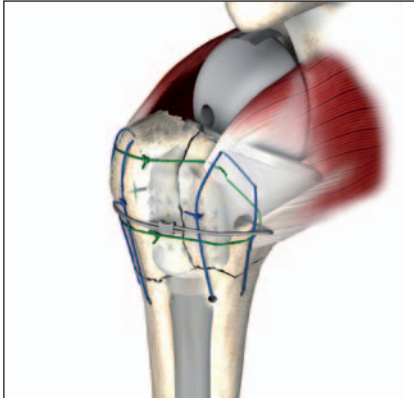


Fig. 49

The following steps lead to a stable refixation:

Positioning and fixation sutures

1. The positioning and fixation of the two tuberosities is carried out in anatomical position relative to one another and to the shaft (green suture).

Fixation or compression sutures

2. Using the sutures placed in the shaft at the outset, the tuberosities are now fixed on the shaft of the humerus. These sutures must be tightened forcefully.

3. The whole package is then compressed onto the bioactively coated central part, by means of encircling suture or cable.

A high degree of primary stability is thereby achieved. The course of the suture runs through the medial drilled hole, through the tendon/bone interval, and is fixed over the two tuberosities.

For the fixation of the tuberosities, cable (encompassing circular suture) and/or non-absorbable sutures should be used.

Additional fragments and cancellous bone are introduced into any remaining cavities and gaps, and are included in the fixation where possible. Secure and anatomically correct fixation of the tuberosity fragments is of greatest importance for the functional outcome of the operation.

Finally, tenodesis of the biceps tendon is carried out in the sulcus area. A functional check, where possible using an image converter with image documentation, and wound closure via Redon drainage, is recommended.

7. Revision of failed primary fracture



Fig. 50

To make revision from primary fracture arthroplasty easier and less invasive, we've developed a unique and dedicated fracture inverse implant. Failed primary fracture implants can now be changed to an inverse arthroplasty whilst leaving the stem in place.

7.1 Removal of the prosthesis implant head

To remove the prosthesis head, perform light blows to the edges of the prosthesis head.

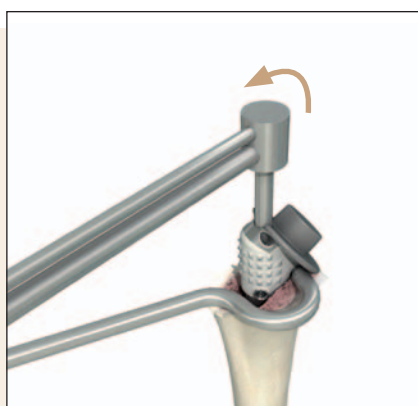


Fig. 51

7.2 Removal of Fracture central part

The counter wrench is mounted, to secure the central part against rotation, and the torque wrench is inserted.

The use of the counter wrench is mandatory.

The counter wrench and the torque wrench must be used by the same person, as this is the only way to be sure of avoiding stem rotation in the cement socket. Disconnection takes place by turning the torque wrench counter-clockwise. Remove the central part and check the stability of the stem. If the stem is still fixed well in the cement mantle, the stem may be left in place. Before continuing with the central part, the implantation of the metaglene has to be performed (see chapter 4.4). When the metaglene is implanted, the appropriate trial glenosphere can be mounted and secured. Afterwards the Inverse trial implants must be mounted. The height (10mm) and retroversion of the central part can now be adjusted as in the Affinis Fracture (see separate surgical technique). By using the different sizes of the central components, the height can additionally be chosen (either 0 or +3 mm). Please check correct implant size with the trials.

The adjustment screw can help to primary fix the central part on the stem.

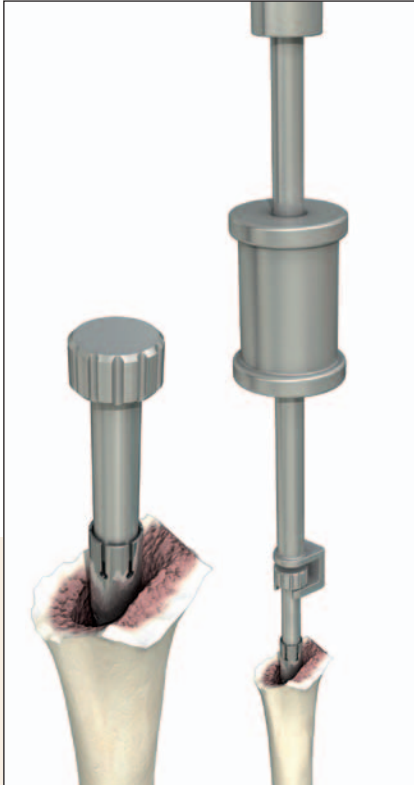


Fig. 52

7.3 Explantation of Fracture stem

In some revision cases the stem may no longer be sufficiently fixed in the shaft. The implant stem must then be removed and replaced by a new implant.

In those cases our extraction instrumentation can be used: Unscrew the fixation screw in the prosthesis stem. Screw the revision adapter into the stem and reject the prosthesis stem with the sledge hammer.

8. Implants



Affinis Inverse metaglène

Item no.
60.30.3150



Affinis Inverse revision metaglène

Item no.
60.30.3151



Affinis Inverse glenosphere

Item no.	Description
60.30.3036	Affinis Inverse glenosphere 36
60.30.3039	Affinis Inverse glenosphere 39
60.30.3042	Affinis Inverse glenosphere 42



Affinis Inverse inlay

Item no.	Description
60.30.2360	Affinis Inverse inlay 36+0
60.30.2363	Affinis Inverse inlay 36+3
60.30.2366	Affinis Inverse inlay 36+6
60.30.2390	Affinis Inverse inlay 39+0
60.30.2393	Affinis Inverse inlay 39+3
60.30.2396	Affinis Inverse inlay 39+6
60.30.2420	Affinis Inverse inlay 42+0
60.30.2423	Affinis Inverse inlay 42+3
60.30.2426	Affinis Inverse inlay 42+6



Affinis Inverse lag screw

Item no.	Description
60.30.4418	Affinis Inverse lag screw 4.5x18
60.30.4422	Affinis Inverse lag screw 4.5x22
60.30.4426	Affinis Inverse lag screw 4.5x26
60.30.4430	Affinis Inverse lag screw 4.5x30
60.30.4434	Affinis Inverse lag screw 4.5x34
60.30.4438	Affinis Inverse lag screw 4.5x38



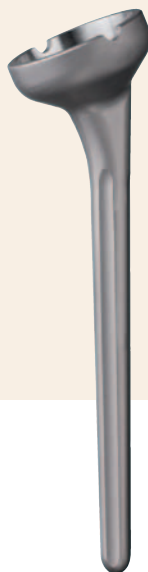
Affinis Inverse locking screw

Item no.	Description
60.30.5424	Affinis Inverse locking screw 4.0x24
60.30.5430	Affinis Inverse locking screw 4.0x30
60.30.5436	Affinis Inverse locking screw 4.0x36
60.30.5442	Affinis Inverse locking screw 4.0x42
60.30.5448	Affinis Inverse locking screw 4.0x48



Affinis Inverse stem

Item no.	Description
60.30.0006	Affinis Inverse stem 6 cem.
60.30.0009	Affinis Inverse stem 9 cem.
60.30.0012	Affinis Inverse stem 12 cem.
60.30.0015	Affinis Inverse stem 15 cem.
60.30.0106	Affinis Inverse stem 6 uncem.
60.30.0107	Affinis Inverse stem 7.5 uncem.
60.30.0109	Affinis Inverse stem 9 uncem.
60.30.0110	Affinis Inverse stem 10.5 uncem.
60.30.0112	Affinis Inverse stem 12 uncem.
60.30.0113	Affinis Inverse stem 13.5 uncem.
60.30.0115	Affinis Inverse stem 15 uncem.



Affinis Inverse revision stem

Item no.	Description
60.30.0186	Affinis Inverse rev. stem 6x180 cem.
60.30.0209	Affinis Inverse rev. stem 9x200 cem.
60.30.0212	Affinis Inverse rev. stem 12x200 cem.
62.34.0001	Affinis Inverse rev. stem 7.5x210 cem.
62.34.0002	Affinis Inverse rev. stem 9x230 cem.
62.34.0003	Affinis Inverse rev. stem 12x230 cem.
60.30.1186	Affinis Inverse rev. stem 6x180 uncem.
60.30.1209	Affinis Inverse rev. stem 9x200 uncem.
60.30.1212	Affinis Inverse rev. stem 12x200 uncem.
62.34.0004	Affinis Inverse rev. stem 7.5x210 uncem.
62.34.0005	Affinis Inverse rev. stem 9x230 uncem.



Affinis Inverse inlay spacer +9

Item no.
60.30.2449



Affinis Inverse head adaptor

Item no.
60.30.7000

All Affinis or Affinis Fracture heads may be implanted.



Affinis fixation screw long

Item no.
60.30.7002

Long fixation screw when both Affinis Inverse inlay spacer +9 and the Affinis Inverse head adaptor are implanted.



Affinis Fracture Inverse

Item no.	Description
60.30.6390	Affinis Fracture Inverse 39+0
60.30.6393	Affinis Fracture Inverse 39+3
60.30.6420	Affinis Fracture Inverse 42+0
60.30.6423	Affinis Fracture Inverse 42+3



Articula Inverse

Item no.	Description
60.30.9390	Articula Inverse 39+0
60.30.9393	Articula Inverse 39+3
60.30.9420	Articula Inverse 42+0
60.30.9423	Articula Inverse 42+3

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