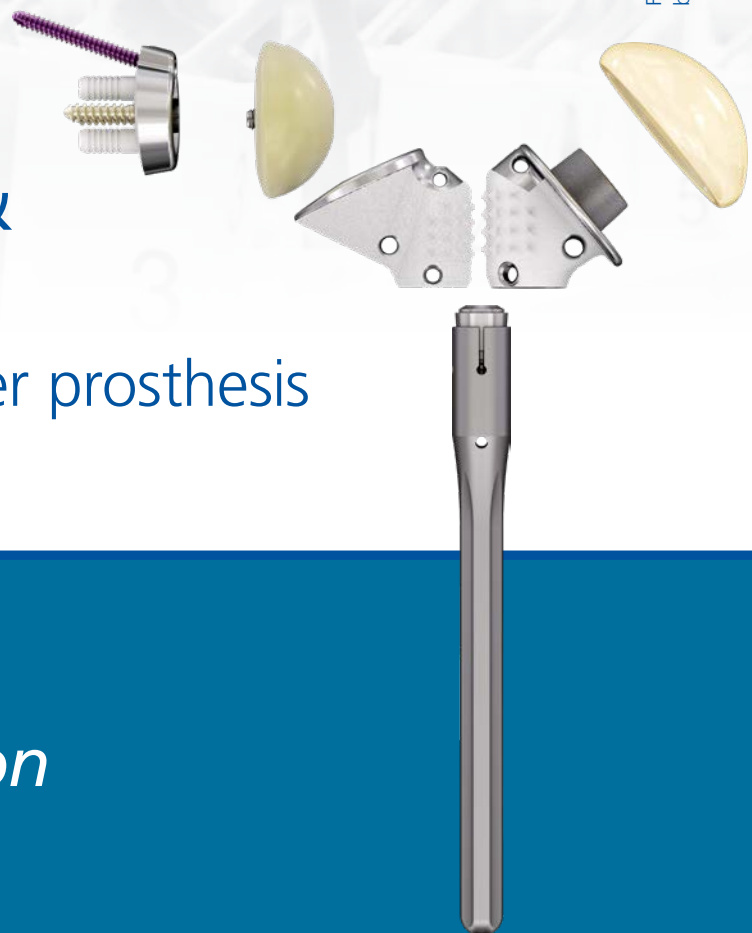


**Surgical technique**

# Affinis Fracture & Fracture Inverse

Modular fracture shoulder prosthesis



***Preservation in motion***

*Building on our heritage  
Moving technology forward  
Step by step with our clinical partners  
Towards a goal of preserving mobility*



## ***Preservation in motion***

*As a Swiss company, Mathys is committed to this guiding principle and pursues a product portfolio with the goal of further developing traditional philosophies with respect to materials or design in order to address existing clinical challenges. This is reflected in our imagery: traditional Swiss activities in conjunction with continuously evolving sporting equipment.*

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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 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.

# Introduction

Treatment with Affinis Fracture or Affinis Fracture Inverse is used when fractures of the humeral head which are difficult to reconstruct. The modular platform system allows intraoperative decision-making and the conversion from a hemiprosthesis to an inverse prosthesis and vice-versa. The Affinis Fracture System is based on a cemented stem and allows conversion after poor healing of a primary implant into an inverse prosthesis. A securely anchored stem can be left in situ. In addition, the modularity allows the surgeon to decide between a hemiprosthesis or an inverse prosthesis during surgery.

A proven spike surface structure, covered with an osteoconductive calcium phosphate coating, supports tuberosity anchoring: The calcium phosphate coating remodels into autologous bone within 6 to 12 weeks after implantation and promotes quick osseointegration.<sup>1</sup>

The middle component on the humeral side of both versions allows continuous height adjustment on the stem up to 10 mm; the retroversion can also be freely adjusted. With these options the patient's individual ligamentous balance can be taken into account.

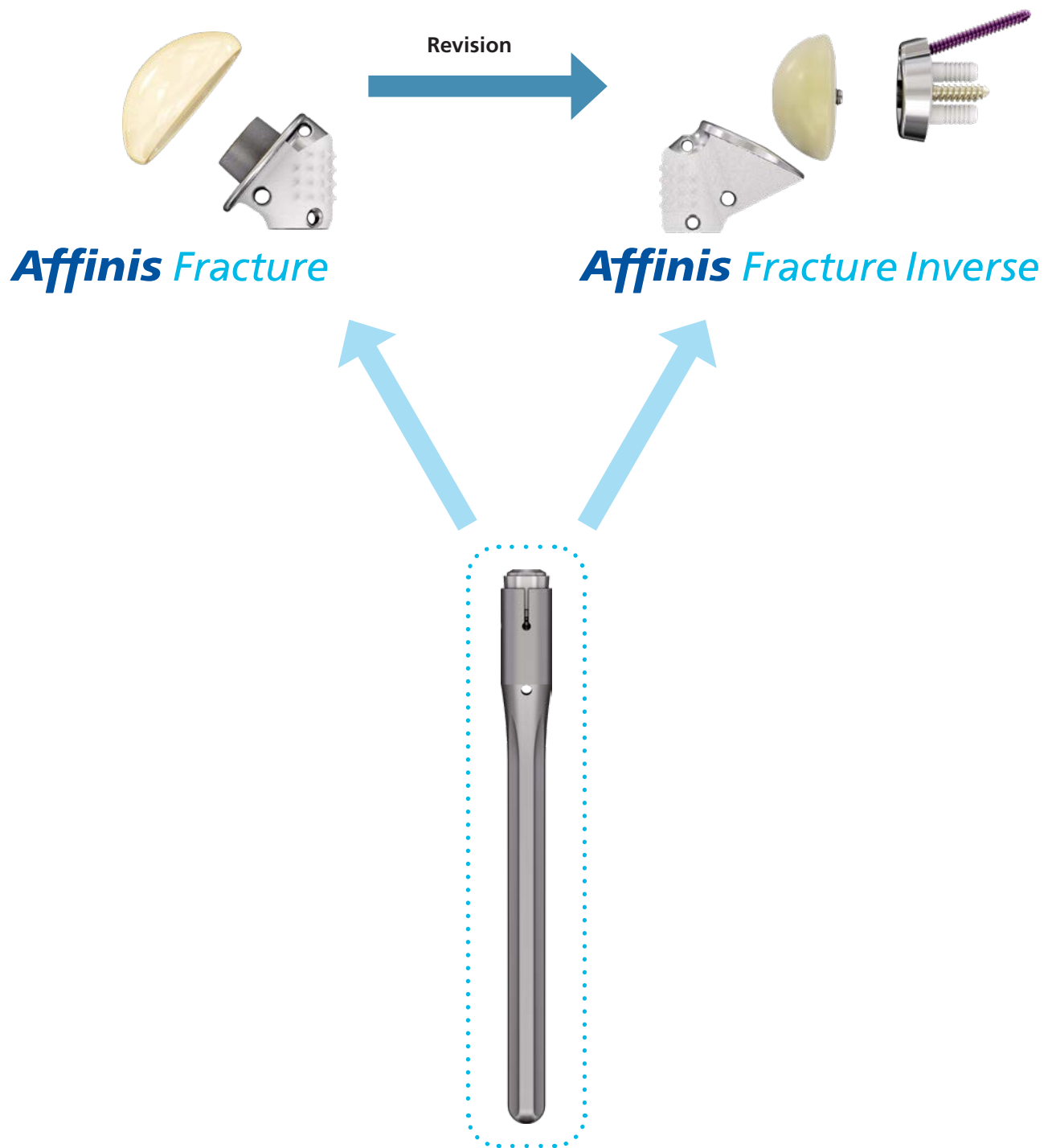
## Advantages

- Continuous height and rotation adjustment
- Modular platform system for less invasive revision surgeries<sup>2</sup>
- Osteoconductive calcium phosphate coating for improved ingrowth of the tuberosities<sup>1</sup>
- Polished drill holes for suture or cable fixation
- Primary stem cementing

<sup>1</sup> Schwarz M.L.K., M.;Rose, S.;Becker, K.;Lenz, T.;Jani, L. Effect of surface roughness, porosity, and a resorbable calcium phosphate coating on osseointegration of titanium in a minipig model. J Biomed Mater Res A, 2009. 89(3): p. 667-78.

<sup>2</sup> Wieser K, Borbas P, Ek ET, Meyer DC, Gerber C. Conversion of stemmed hemi- or total to reverse total shoulder arthroplasty: advantages of a modular stem design. Clin Orthop Relat Res, 2015. 473(2): p. 651-60.

## Modular platform system



# Surgeon design team

The Affinis Fracture and Affinis Fracture Inverse shoulder prostheses and associated surgical technique provide a flexible and modular treatment platform for proximal humerus fractures with a simple instrumentation. <sup>1</sup> This system was developed in cooperation with the following group of European shoulder specialists:

## Affinis Short

### Prosthesis design and surgical technique



Prof. Ulrich Irlenbusch  
Germany



Dr Thierry Joudet  
France



Dr Max Kääh  
Germany



Dr Georges Kohut  
Switzerland



Dr Bernd Mühlhäusler  
Germany



Prof. Stefaan Nijs  
Belgium



Dr Falk Reuther  
Germany



Dr Diethard Wahl  
Germany

<sup>1</sup> Data on file. Mathys Ltd Bettlach

# 1. Indications and contraindications

## **Indications for Affinis Fracture**

- Non-reconstructable fracture with intact rotator cuff and preserved tuberosities that cannot be treated conservatively or with osteosynthesis
- Revision of failed fracture treatment (conservative or surgical) with intact rotator cuff and preserved tuberosities

## **Contraindications for Affinis Fracture**

- Severe soft tissue, nerve or vessel insufficiency that endangers the function and long-term stability of the implant
- Bone loss or insufficient bone substance which cannot provide adequate support or fixation for the implant
- Local, regional or systemic infection
- Hypersensitivity to materials used

## **Indications for Affinis Fracture Inverse**

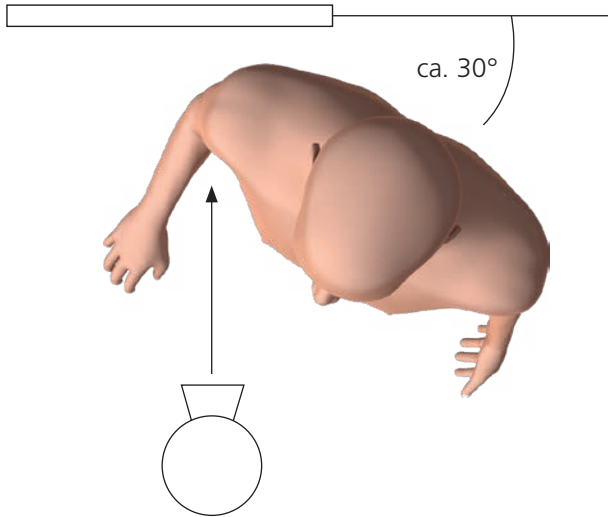
- Non-reconstructable fracture with grossly deficient rotator cuff and/or comminuted tuberosities
- Revision of failed shoulder prosthesis or failed fracture treatment (conservative or surgical) with a grossly deficient rotator cuff and/or comminuted tuberosities

## **Contraindications for Affinis Fracture Inverse**

- Irrecoverable lesion of the axillary nerve; paresis of the deltoid muscle
- Severe soft tissue, nerve or vessel insufficiency that endangers the function and long-term stability of the implant
- Bone loss or insufficient bone substance which cannot provide adequate support or fixation for the implant
- Local, regional or systemic infection
- Hypersensitivity to materials used

**For further information, please refer to the instructions for use or ask your Mathys representative.**

## 2. Preoperative Planning



It is strongly advised to perform preoperative planning to determine the adequate implant sizes and position.

Digital and transparent templates of the implants are available in the usual scale of 1.10:1 for preoperative determination of the implant size (for details see chapter 5).

The following imaging studies of the affected shoulder are recommended:

- Anterior-Posterior (a. p.) X-ray centred on the joint cavity
- Axial X-ray
- CT scan or MRI

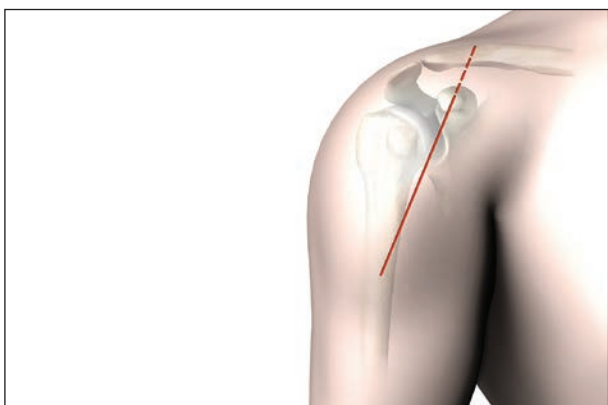
The recommended orientation is the true a. p. view.



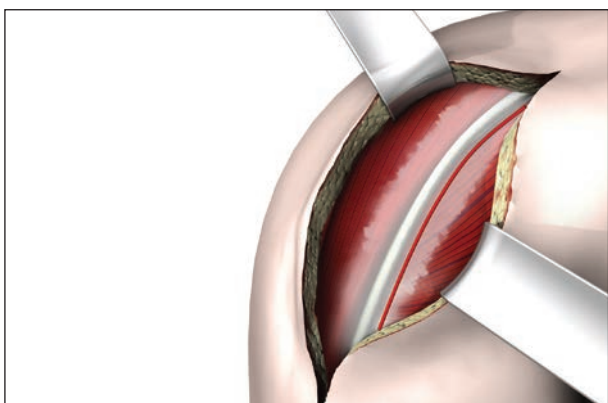
### 3. Surgical technique



**Fig. 1**



**Fig. 2**



**Fig. 3**

#### **3.1 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.

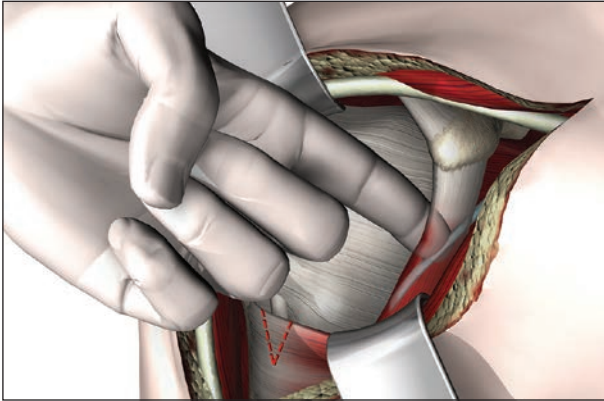
It is important to be able to adduct the arm in extension.

#### **3.2 Approach**

The deltopectoral 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 surgeon's discretion.

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.

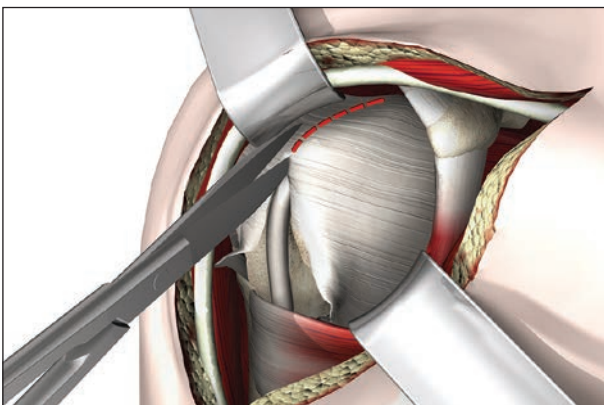


**Fig. 4**

This is followed by the vertical incision of the clavicular 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 incised close to the humerus (for a distance of approx. 2 cm). Marking the most proximal point of its insertion beforehand will facilitate its use as a reference point for later reattachment or repair.



**Fig. 5**

The long biceps tendon serves as a guide for identifying the lesser and greater tuberosity.

The incision over the tendon proceeds in a proximal direction as far as the coracoacromial ligament, which can be partially incised in contracted situations. The rotator cuff is then split in line with the fracture up to the base of the coracoid process. If not possible, the interval between the subscapularis and the supraspinatus should be split.

The biceps tendon may be tenotomised and reinforced with non-absorbable sutures for later tenodesis on the proximal shaft (sulcus area). The intra-articular stump is resected.

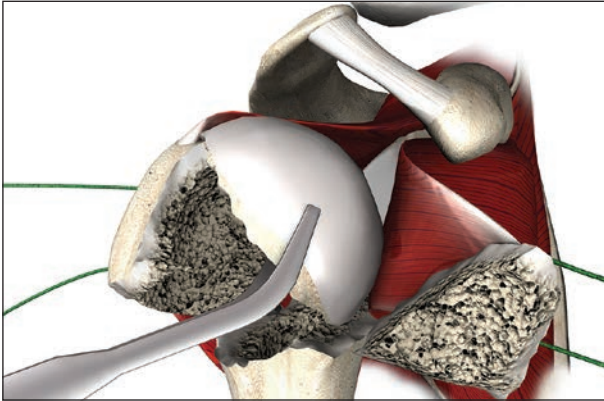


**Fig. 6**

Next, the axillary nerve is palpated at the front and underside of the subscapularis. If the fracture extends into the shaft, the nerve must be exposed and held away.

Identification can be difficult in the case of older fractures and adhesions.

The axillary nerve must be protected throughout the entire operation.



**Fig. 7**



**Fig. 8**

The head fragment, the tuberosities and the attached parts of the rotator cuff are now prepared carefully. It is important here to protect the periosteum on the proximal shaft.

Depending on the shape of the fragments, the initial situations can vary widely. If a fracture has resulted in an isolated greater tuberosity fragment and a lesser tuberosity fragment, these are reinforced with holding sutures. The mostly flat but compact calotte fragment is often tipped in a dorsal or medial direction. It must be extracted carefully, and used for obtaining cancellous bone. The glenoid is now assessed, and can likewise be replaced if necessary. Implantation of a glenoid component is described in the appropriate surgical technique (Affinis/Affinis Short).

There is often a connection between the calotte and the dorsal parts of the greater tuberosity, which is osteotomised close to the head fragment, leaving the tuberosity and rotator cuff fragments.

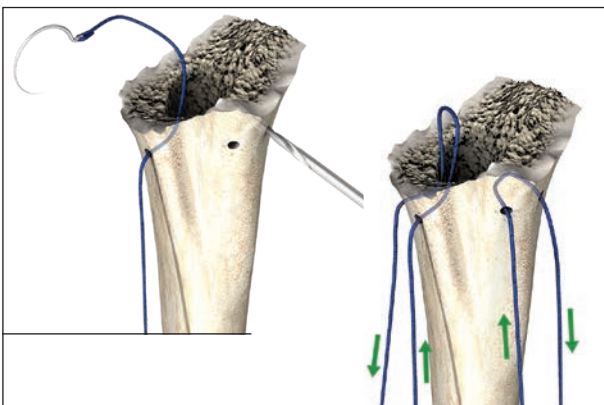
The «4-part fracture» diagnosed pre-operatively is not always found. Often, the tuberosities themselves are also fragmented. In this case, the smaller partial fragments should also be securely reinforced.

Tension-proof reinforcement of the tuberosities is helpful for further manipulation during the implantation of the Affinis Fracture.

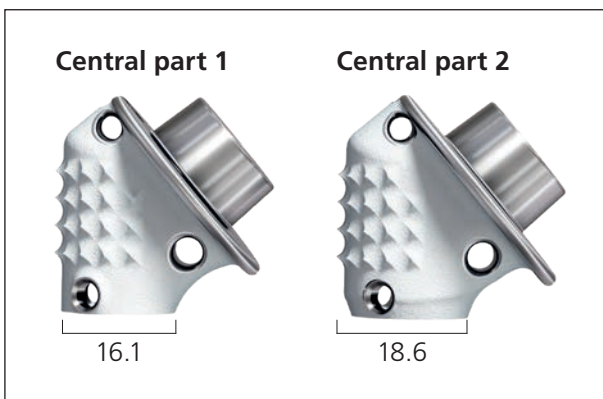
Fixation of the tuberosities should be carried out at the bone/tendon transition, with non-absorbable, polyfil sutures, using the Masen-Allen or modified Kirschmayr technique.



**Fig. 9**



**Fig. 10**



**Fig. 11**

### 3.3 Humerus preparation and Stem implantation

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 Ø in mm	Stem size
6	6
9	9
12	12

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.

### 3.4 Affinis Fracture implantation

#### 3.4.1 Stem implantation

There are two sizes of Affinis Fracture Central part. Select the appropriate size in respect of the dimension of the tubercles.



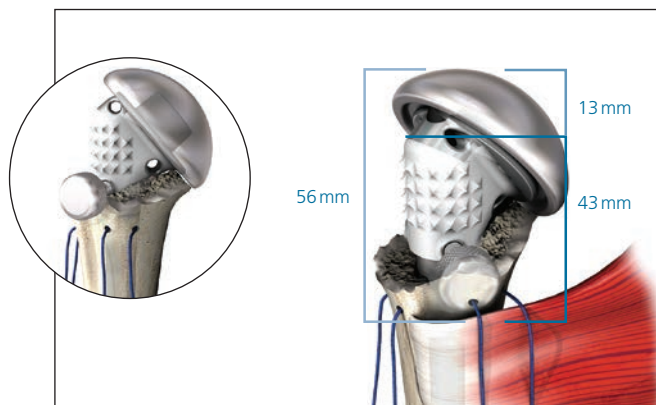
**Fig. 12**

Mount the Central part on the appropriate Affinis Fracture Stem and secure it with the Affinis Fracture Inverse Alignment Rod.



*The Central part is mounted in a superior position on the stem; maximum 5 mm above the laser marking. This will favour a subsequent conversion to a Affinis Fracture Inverse Prosthesis without removal of the stem.*

After cementing, it is still possible to displace the Central part of the prosthesis caudally or cranially, for the purposes of exact anatomical positioning.

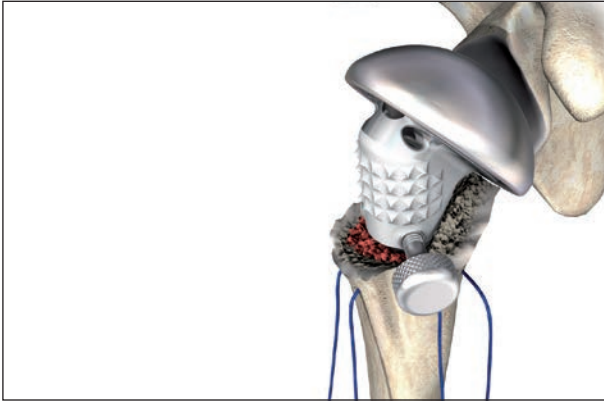


**Fig. 13**

Primary landmarks for correct height adjustment:

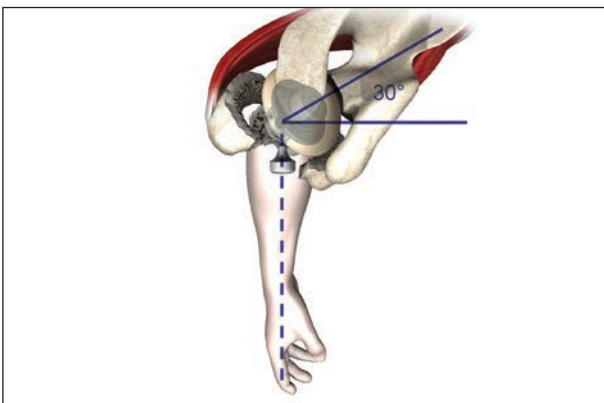
- The Central part is placed on the medial calcar, which usually remains static and is very suitable as a starting point for height adjustment. Calcar remnants on the humeral head have to be included in the calculation for the correct height adjustment.
- If there is an extreme comminution of the medial metaphysis, the anatomical repositioning using the medial calcar can become impossible. A further possibility for setting the correct height is then provided by the measurement method after Murachovsky et al (JSES 2006, 15, 675-678): Here, the height from the upper edge of the pectoralis major muscle attachment on the shaft of the humerus to the upper edge of the prosthesis head is measured. According to the anatomical study, this is 56 mm on average. For simplification, the distance from the pectoralis major to the shoulder of the Central part can be measured, with the adjustment value here being 43 mm.





**Fig. 14**

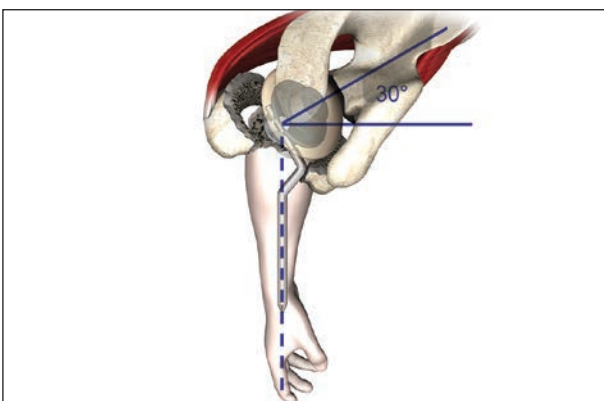
The use of extensive rinsing or Jet Lavage followed by insertion of a medullary plug as a cement restrictor is recommended. Bone cement is introduced into the medullary space in a retrograde manner, the anterior Fixation Screw or the Retrotorsion Pointer is aligned to the lower arm, and the pre-mounted prosthesis (Central part and stem) is inserted. Excess bone cement must be removed, so as not to hinder adjustment of the Central part. Any cavities remaining distally can be filled up with chips of cancellous bone.



**Fig. 15**

After the bone cement has hardened, the appropriate fine adjustment of height and retroversion is now carried out in accordance with the anatomical circumstances, with the aim of achieving an optimum ligament tension, as well as centring of the prosthesis to the glenoid.

For this, in a neutral position, the Adjusting screw is aligned to the lower arm. Alternatively, the Retrotorsion Pointer can also be used. With both methods, a retrotorsion of 30° to the lower arm or accordingly 20° to the transepicondylar axis is ensured.



**Fig. 16**

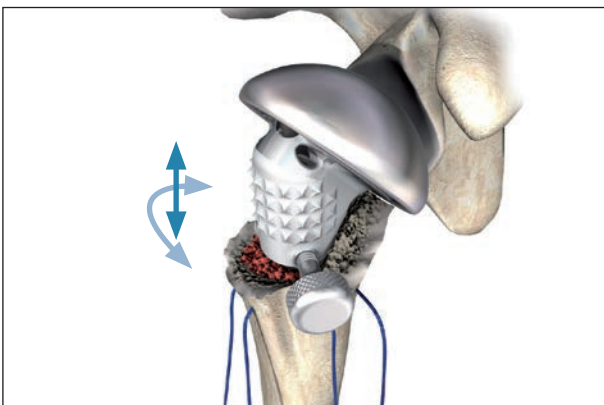
The Adjusting screw should be tightened as soon as the optimum setting has been achieved.



**Fig. 17**



*The Central part must completely cover the slits on the Stem (bracing mechanism).*



**Fig. 18**

The Adjusting screw is loosened, and the Affinis Fracture Central part is adjusted so as to be anatomically correct in terms of length and rotation.

Mount the Affinis Fracture trial head. The size of head depends on the calotte that has been removed. In order to avoid overstuffing, in cases of doubt the smaller head should be used.

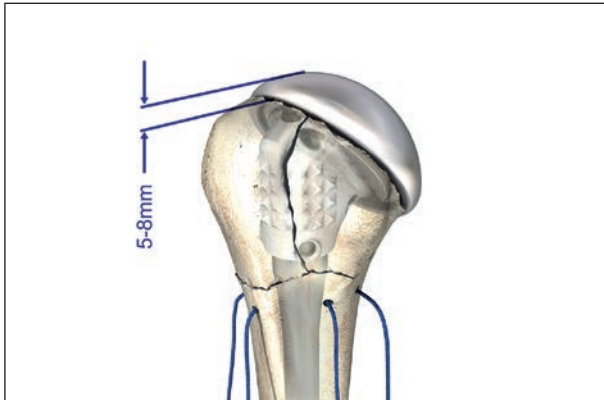
Perform trial reduction and check for appropriate implant positioning.

It is recommended to check the position of the implants and tubercles intraoperatively by x-ray.

Opportunities for monitoring during surgery:

- Checking is performed laterally through the placement of the greater tuberosity. The upper edge of the greater tuberosity should come to rest 5–8 mm below the calotte height, and as far as possible it should lie edge to edge on the lateral shaft.
- The acromio-humeral distance should be approx. 10 mm (rule of thumb: forefinger width between tendon and acromion).

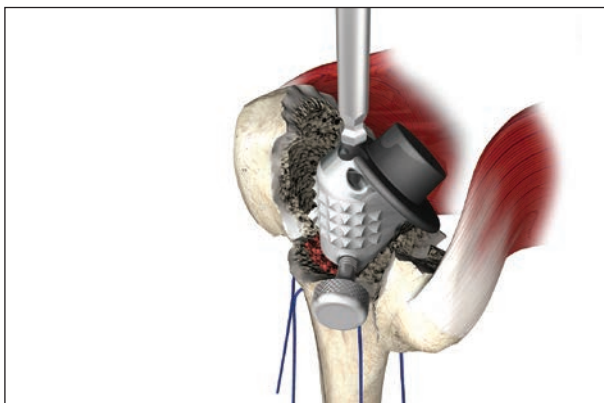
Reposition the Central part as required.



**Fig. 19**

After the desired position has been achieved, the Adjusting screw is tightened and the following parameters are checked by moving the arm whilst monitoring with an image converter:

- The distance between the greater tuberosity and the head should be 5–8 mm.
- The degree of retroversion (centring to the glenoid)
- The size of the head is anatomically acceptable.
- The prosthesis height (subacromial space, ligamentous tension) is anatomically acceptable.



**Fig. 20**

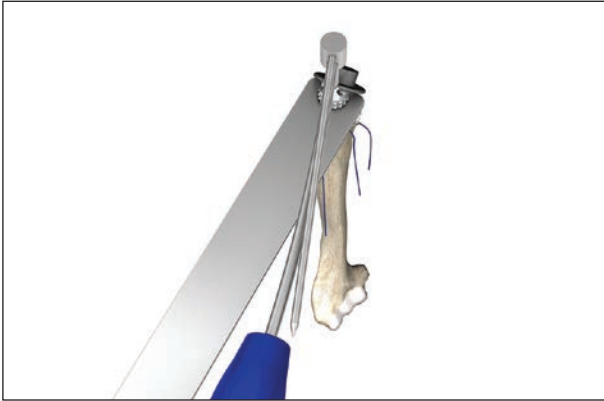
### **3.4.2 Central part and head implantation**

The trial head is now removed and the final fixation of the Central part to the stem is performed:

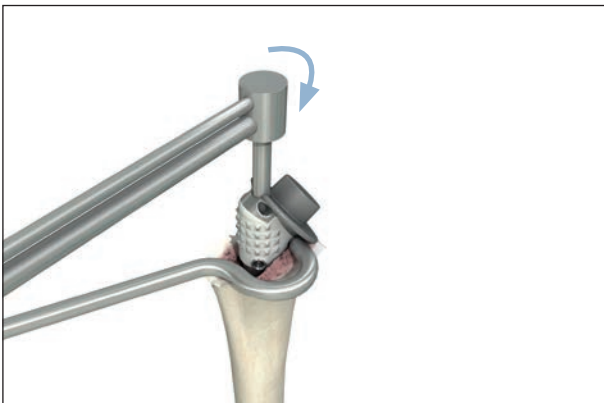
#### **1<sup>st</sup> step:**

Pre-fixation of the Central part with the Allen key, until a re-sistance is encountered. The Adjusting Screw can now be removed.

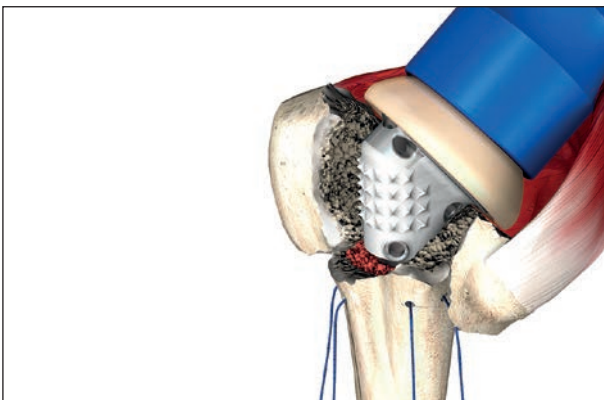




**Fig. 21**



**Fig. 22**



**Fig. 23**

## 2<sup>nd</sup> step:

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.

Tensioning takes place by turning the Torque wrench clockwise. When the indicator of the Torque wrench points next to the wrench handle, sufficient torque has been achieved.

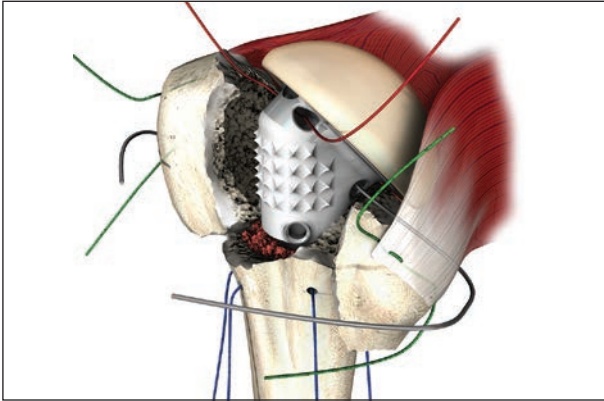


*Prior to impaction, make sure that both the cone of the stem and the recess of the head are absolutely clean and dry.*

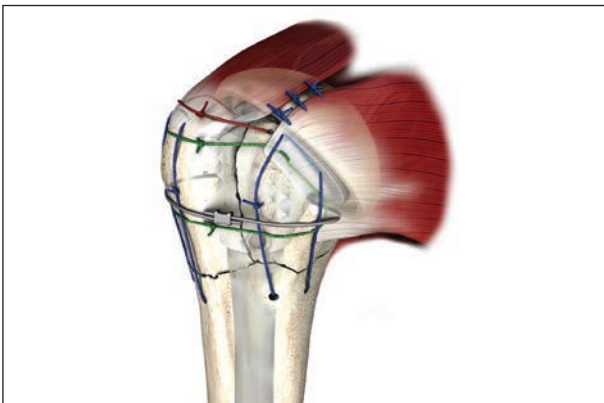
The definitive prosthesis head (corresponding to the size of the trial head) is then fixed through firm mounting and slight turning. The head impactor is placed onto the pole of the ceramic head. The head is then fixed permanently on the taper with a gentle stroke of the hammer on the Head Impactor in axial direction. During impacting, counter-pressure must be applied to the humerus.



*The head-taper connection should be checked by gently pulling the head manually. If the head disengages, it may be necessary to remove protruding bone or soft-tissue pieces from the head region.*



**Fig. 24**



**Fig. 25**

### **3.4.3 Tuberosity fixation**

The following steps lead to stable refixation:

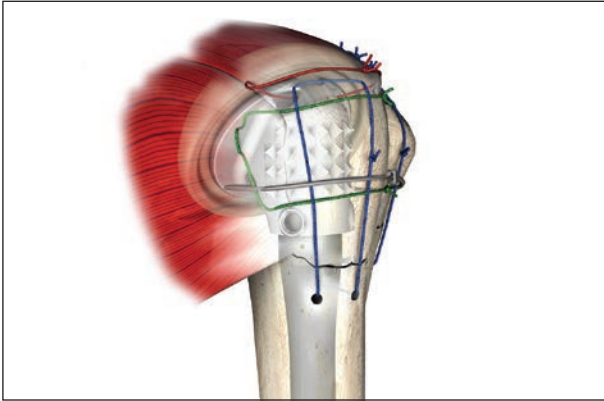
#### **Holding or fixation sutures**

1. Fixation of the greater tuberosity takes place in the bone/tendon transition in the lateral drilled hole for reintegration of the tuberosity close to the Head (red suture). This ensures the anatomical transition of the supraspinatus to the prosthesis head. Where possible, the lesser tuberosity should be included in this fixation.
2. The positioning and fixation of the two tuberosities is now carried out in anatomical position relative to one another and to the shaft (green suture).

#### **Fixation or compression sutures**

3. 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.
4. 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.

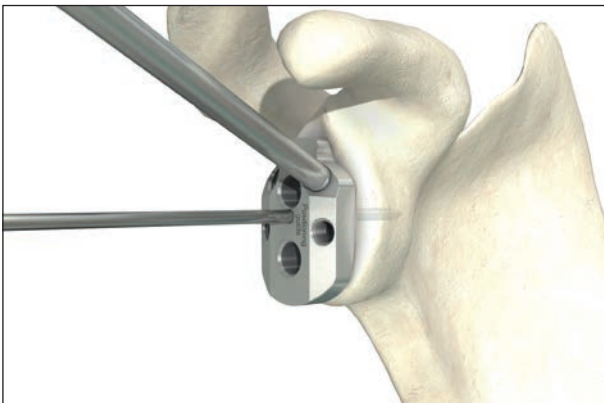
For the fixation of the tuberosities, cable (encompassing circular suture) and/or non-absorbable sutures should be used.



**Fig. 26**

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.



**Fig. 27**

### **3.5 Glenoid preparation**

Mount the holding/rotation rod onto the metaglene drill guide.

Use the metaglene drill guide to position the central Kirschner wire.

The inferior border of the guide must be flush with the inferior border of the glenoid.

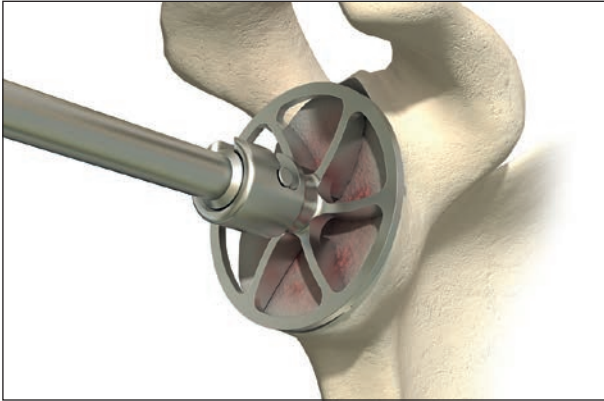


**Fig. 28**

The Kirschner Wire serves as a guide for the Reamer 1 and the Metaglene Drill-guide (Left/Right).

The modularity of the Reamer allows inserting it even in very narrow situations without removing or bending the Kirschner Wire.

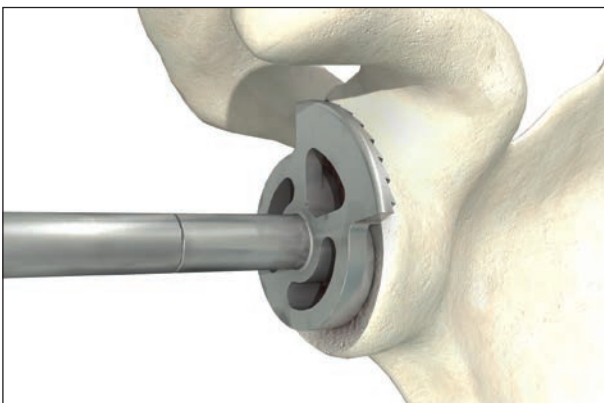
Insert the Reamer eccentrically over the Kirschner Wire and centre it on the face of the glenoid.



**Fig. 29**

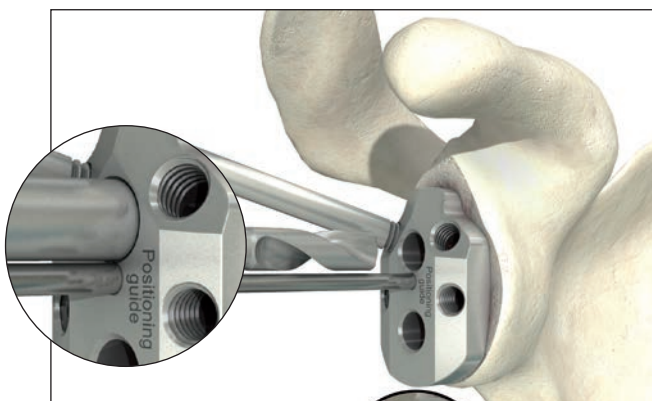
Slide the Handle Glenoid Reamer over the Kirschner Wire and connect it with the Reamer.  
Ream the glenoid. Stay in the subchondral bone. It is recommended to avoid reaming into the cancellous bone.

While reaming irrigate with saline solution to prevent heat buildup, which may lead to thermal damage of the surrounding bone.



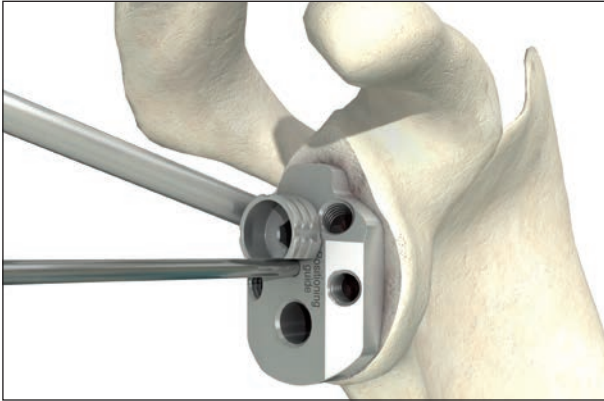
**Fig. 30**

Ream the glenoid with the Glenoid Reamer 42. The use of this reamer is required to avoid conflicts between the Inverse glenosphere and any tissue behind it. Make sure that the rim of the glenoid does not have any bony prominences or other tissue that could interfere with the glenosphere.



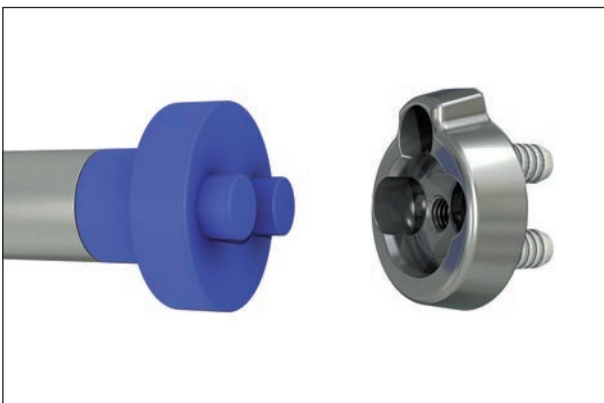
**Fig. 31**

To prepare the peg holes, slide the Metaglene Drill-guide (Left/Right) over the Kirschner Wire and align the guide to the desired orientation. Use the Drill Metaglene to drill the first anchoring hole. The drill has an automatic stop.



**Fig. 32**

Remove the drill and insert the Fixation Peg to prevent rotation of the guide. Drill the second anchoring hole. Remove the instruments.



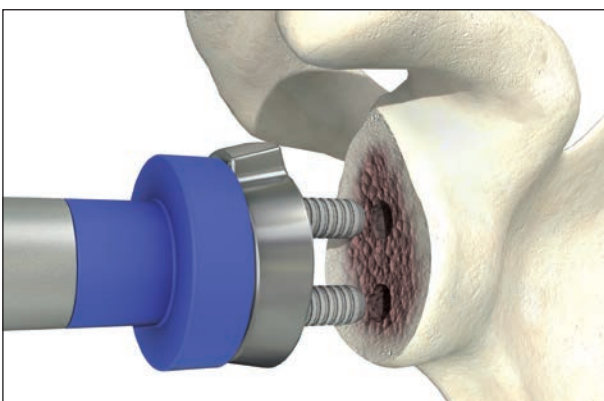
**Fig. 33**

### 3.6 Metaglene implantation

For implantation of the Affinis Inverse metaglene, use the adaptor Impactor Metaglene, Gen2. Screw the adaptor onto the Impactor. Place the metaglene onto the adaptor.



*Impacting the metaglene without the adaptor provided for this purpose may result in fracturing of the glenoid.*



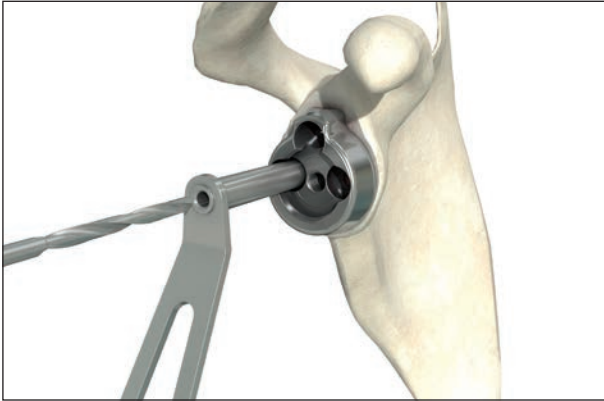
**Fig. 34**

Insert the metaglene into the two anchoring holes of the glenoid. By application of carefully controlled hammer strokes to the Impactor, the metaglene is implanted until it rests flat on the resected glenoid surface.



*Ensure that the metaglene is impacted parallel to the fixation holes to avoid the risk of fracturing the glenoid. Use a hook or other curved instrument to check the metaglene and make sure it rests flat on the prepared glenoid.*





**Fig. 35**

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  $10^\circ (\pm 5^\circ)$ . Insert the 3.2 mm drill bit and drill the holes for the lag screws parallel or slightly convergent to the pegs.



*To prevent breakage of the drill bit, avoid bending and excessive axial pressure. Particular attention should be taken when the drill bit reaches the far cortex to avoid deflection of the tip.*



**Fig. 36**

Measure the depth of the holes with the Depth Gauge to determine the appropriate screw length. Fix these two screws (4.5 mm) first in alternating mode. This will ensure that the metaglene becomes flush on the reamed glenoid.

The superior screw can be drilled with an angular freedom of  $30^\circ (\pm 15^\circ)$ . Using the Locking Screw Drill-guide in direction of the base of the coracoid process, drill with the 2.5 mm Drill-bit.



*Make sure to position the Drill-guide flush and central on the bone. Exceeding this angular freedom ( $\pm 15^\circ$ ) impairs the screw fixation.*

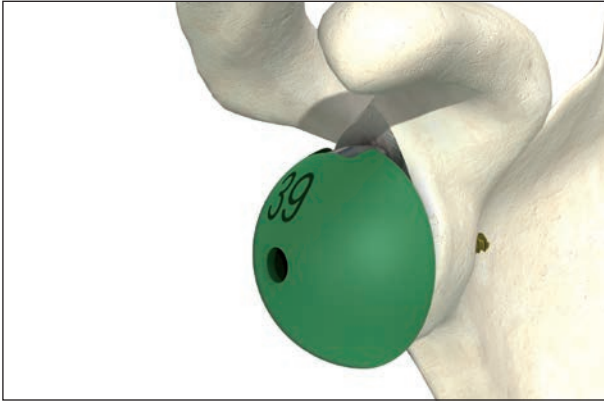


**Fig. 37**



*To prevent breakage of the drill bit, avoid bending and excessive axial pressure. Particular attention should be taken when the drill bit reaches the far cortex to avoid deflection of the tip.*

Measure the depth of the hole with the Affinis Inverse Depth Gauge to determine the appropriate screw length. Insert and tighten the superior locking screw (4.0 mm).



**Fig. 38**



**Fig. 39**

### **Optional technique**

The Trial Glenosphere can be mounted and secured to perform trial reduction.

### **3.7 Stem implantation**

Mount the Inv. Trial Body, Gen2 on the appropriate stem and secure it with the Affinis Fracture Inverse Alignment Rod.

The alignment rod indicates retroversion of 0° when aligned with the forearm.



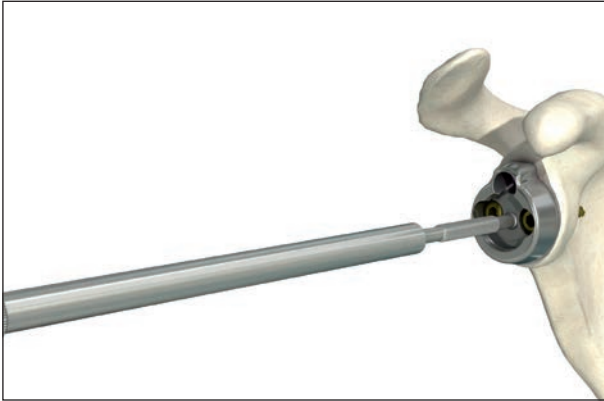
*The Central part is mounted in an inferior position, below the laser marking on the Stem. This will favour a subsequent tensioning of the soft tissues or conversion to a Affinis Fracture hemiprosthesis without removal of the stem.*

After cementing, it is still possible to displace the Central part of the prosthesis caudally or cranially for the purposes of adapting the soft tissue tensioning and implant version.

The use of extensive rinsing or Jet Lavage followed by insertion of a medullary plug as a cement restrictor is recommended.

Bone cement is introduced into the medullary space in a retrograde manner, the stem and central component are inserted and the Affinis Fracture Alignment Rod, Gen2 is aligned to the lower arm. Excess bone cement must be removed, so as not to hinder adjustment of the Central part. Any cavities remaining distally can be filled up with chips of cancellous bone.

Remove the trial components.

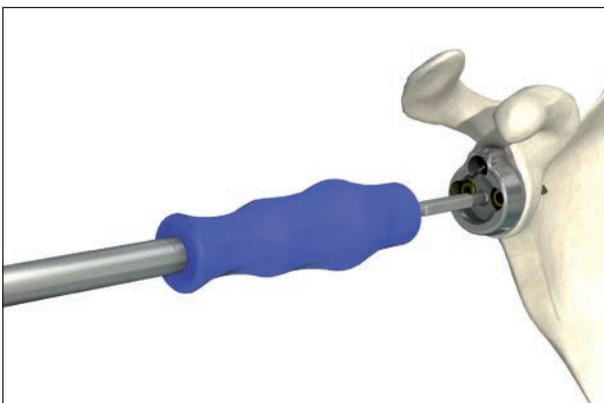


**Fig. 40**

### **3.8 Implantation of Glenosphere**

After having chosen the Glenosphere and inlay sizes screw the Metaglene Assembly Rod onto the Metaglene.

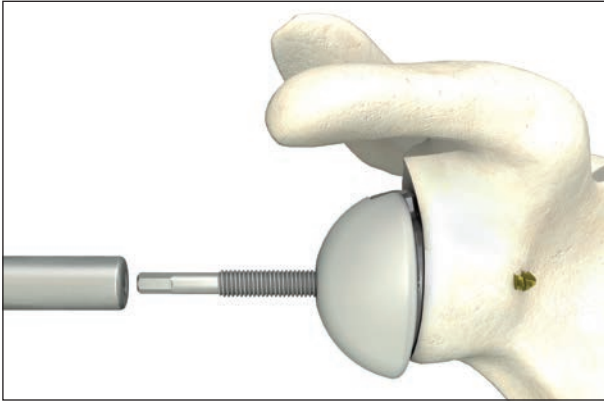
Secure it with the Assembly Rod Holder ...



**Fig. 41**

...or with the handle of the Glenosphere Pusher.



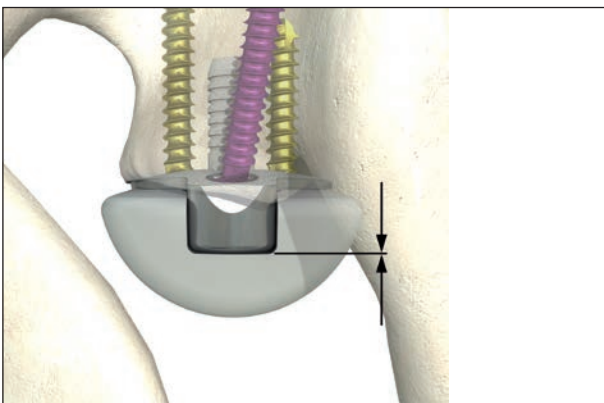


**Fig. 42**

Slide the Glenosphere carefully over the Metaglene Assembly Rod. Slide, and then screw the Glenosphere Pusher on the rod. This will push the Glenosphere onto the Metaglene.

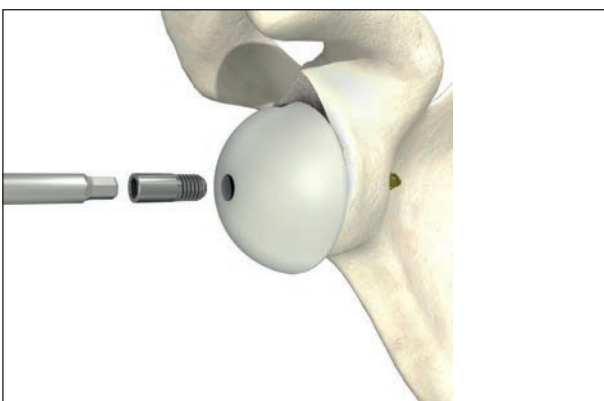
Stop as soon as you have to push with increased force. Turn back the Glenosphere Pusher and check if the Glenosphere is fully seated on the Metaglene. The Glenosphere will come off easily, if not fully seated.

Optionally, it is possible to first place the Glenosphere onto the Metaglene. Next, screw in the Metaglene Assembly Rod and press the Glenosphere onto the Metaglene using the Glenosphere Pusher.



**Fig. 43**

Check the complete connection between Glenosphere and Metaglene. The superior cut out of the Glenosphere needs to be flush with the Metaglene.



**Fig. 44**

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.*



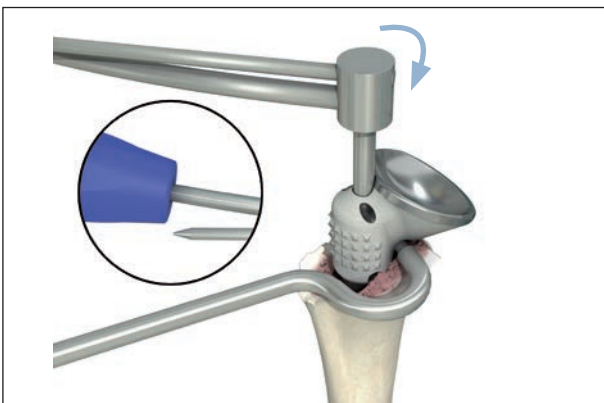
**Fig. 45**

### 3.9 Central part implantation

Check the optimal size, offset and height with the help of the trial body and trial inlay. Reduce the joint and test the position, range of motion and stability. Select the correct Affinis Fracture Inverse Central part and mount it on the shaft at the desired height and retroversion.



*The Central part must completely cover the slits on the Stem (bracing mechanism).*



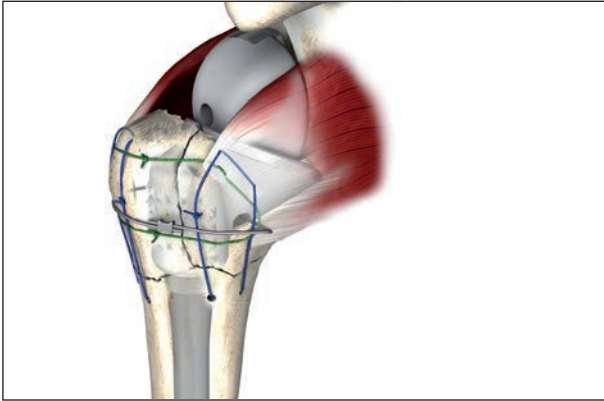
**Fig. 46**

The Adjusting Screw is used to fix the Central part and Stem temporarily.

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.

#### **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 reattach remaining tuberosities and/or rotator cuff tendons to improve rotation and stability of the shoulder joint.



**Fig. 47**

### **3.10 Tuberosity fixation**

The following steps lead to a stable refixation:

#### **Positioning sutures**

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

## 4. Revision

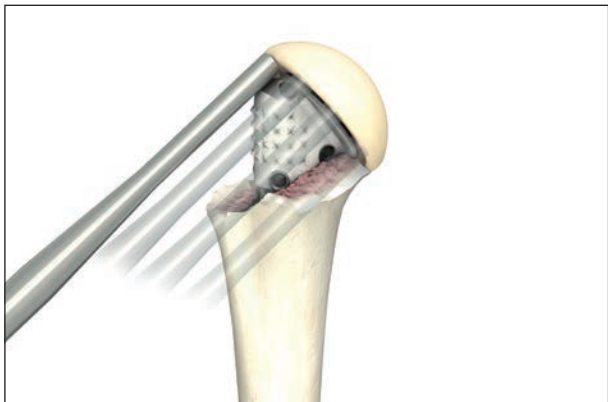


Fig. 48

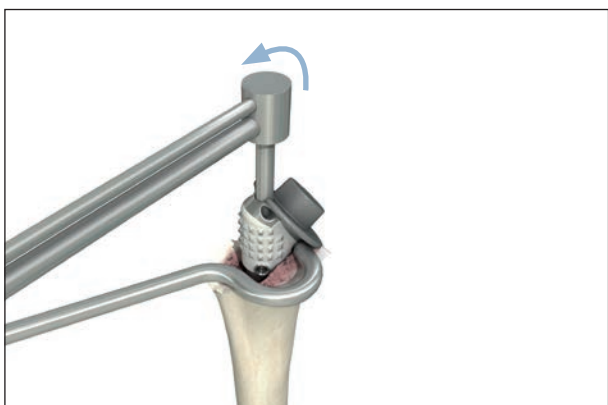


Fig. 49

### 4.1 Conversion from Affinis Fracture to Affinis Fracture Inverse

To make revision from primary fracture arthroplasty easier and less invasive, we have 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.

Removal of the prosthesis implant head:

To remove the prosthesis Head, perform light blows to the edges of the prosthesis Head with a bone tamp.

It is also possible to use two small chisels simultaneous at the ventral and dorsal interface.

### Removal of Fracture Central part

The Affinis Fracture Counter-wrench, Gen2 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 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.

To minimise the risk of infection we recommend to exchange the spreading screw with the:

Affinis Fracture Revision Screw (62.34.0078)

Proceed with the implantation of an Affinis Fracture Inverse prosthesis. To properly reduce the new implant, an extensive soft tissue release is necessary.



**Fig. 50**

#### **4.2 Removal of Affinis Fracture Inverse**

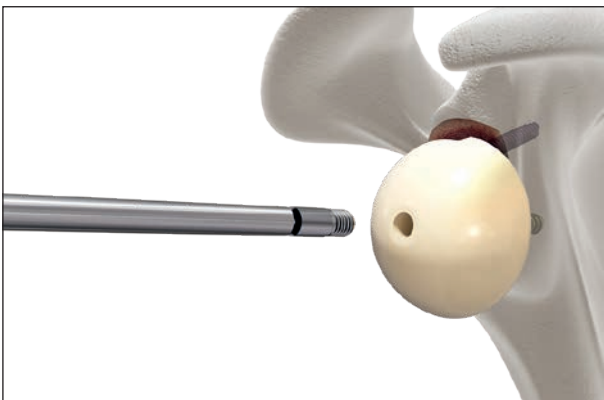
##### **Central part**

The Affinis Fracture Counter-wrench, Gen2 is mounted, to secure the Central part against rotation, and the Torque wrench is inserted.



*The use of the Counter-wrench is mandatory.*

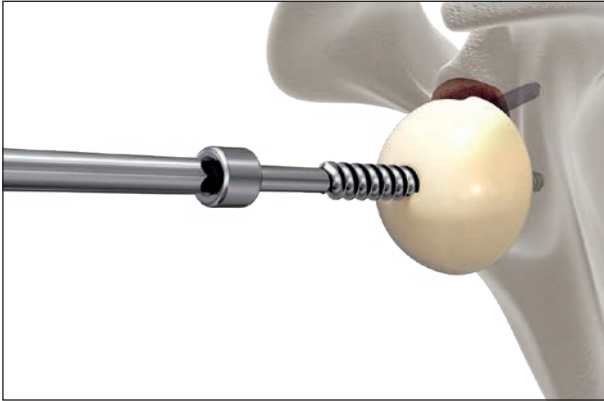
The Counter-wrench and the Torque wrench must be used by the same person, as this is the only way to be sure of avoiding stem rotation in the cement socket. Disconnection takes place by turning the Torque wrench counter-clockwise. Remove the Central part and check the stability of the Stem.



**Fig. 51**

#### **4.3 Glenosphere removal**

Remove the fixation screw of the glenosphere.



**Fig. 52**

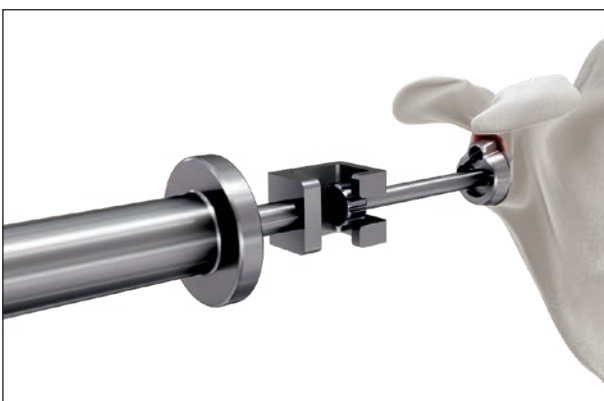
Screw the glenosphere extractor into the glenosphere. The glenosphere extractor removes the glenosphere from the metaglene. Providing the stability of the metaglene is secure, a new glenosphere can be implanted. Otherwise, the metaglene must also be revised.



**Fig. 53**

#### **4.4 Metaglene removal**

After removing the glenosphere, remove the lag and locking screws with the corresponding screwdrivers.



**Fig. 54**

To facilitate loosening and removal of the metaglene, attach the metaglene extractor and use the Slide Hammer.



*Ensure that the metaglene is extracted parallel to the fixation holes to reduce the risk of fracturing the glenoid.*



Fig. 55

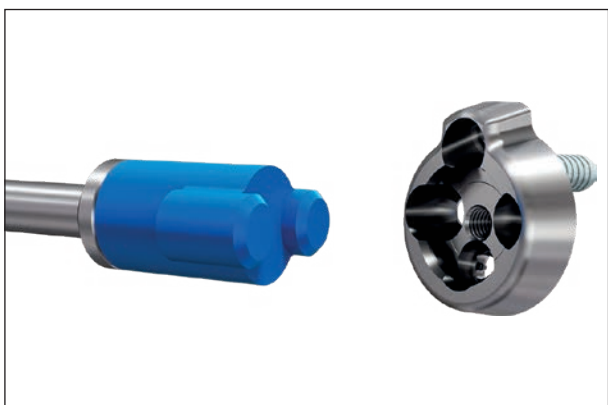


Fig. 56

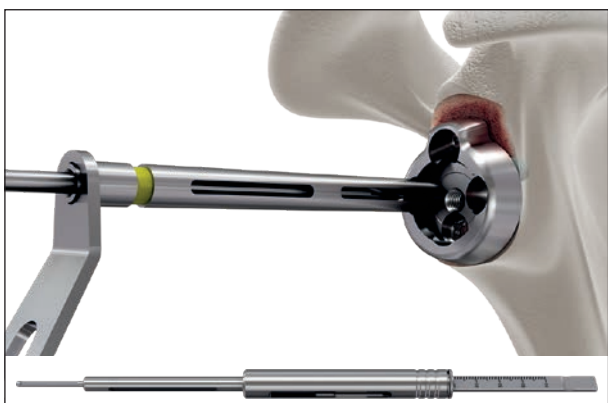


Fig. 57

#### 4.5 Revision metaglene implantation

When implanting an revision metaglene, insert a Kirschner Wire and ream the glenoid in the same manner as described for the standard metaglene component (see chapter 3.5.1).

To prepare the peg hole, slide the Metaglene Drill-guide (Left/Right) over the Kirschner Wire and align the guide to the desired orientation.

Use the Drill Revision Metaglene to drill the superior anchoring hole.



*When using the Affinis Inverse revision metaglene with one peg, use the drill marked «Drill Metaglene Revision».*

The drill has an automatic stop.  
Remove the instruments.

Impact the revision metaglene in the same manner as described for the standard metaglene component (see chapter 3.5.2).

Hold the Drill-guide 3.2 against the correspondent metaglene hole (anterior/posterior). The lag screws can be directed with an angular freedom of  $10^\circ (\pm 5^\circ)$ . Insert the Drill-bit 3.2 and drill the holes for the lag screws parallel or slightly convergent to the pegs of the metaglene.



*To prevent breakage of the drill bit, avoid bending and excessive axial pressure. Particular attention should be taken when the drill bit reaches the far cortex to avoid deflection of the tip.*

Measure the depth of the holes with the Depth Gauge to determine the appropriate screw length. Insert and tighten two 4.5 mm lag screws in alternating mode. This will ensure that the metaglene becomes flush on the reamed glenoid.



**Fig. 58**



**Fig. 59**



**Fig. 60**

Hold the Drill-guide 2.5 against the correspondent metaglene hole (superior/inferior). The locking screws can be directed with an angular freedom of 30° ( $\pm 15^\circ$ ). Insert the Drill-bit 2.5 and drill the holes for the locking screws divergent to the peg of the metaglene.



*Make sure to position the drill guide flush and central on the bone. Exceeding the angular freedom ( $\pm 15^\circ$ ) impairs the screw fixation.*



*To prevent breakage of the drill bit, avoid bending and excessive axial pressure. Particular attention should be taken when the drill bit reaches the far cortex to avoid deflection of the tip.*

Measure the depth of the holes with the Depth Gauge to determine the appropriate screw length. Insert and tighten the 4.0 mm locking screws.

#### **4.6 Fracture stem removal**

Unscrew the Fixation Screw in the prosthesis stem. Screw the Affinis Fracture Stem Adapter into the stem. Use the Affinis Slide Hammer to remove the stem. Extract the stem parallel to the axis of the humeral shaft.



## 5. Implants



### Affinis Fracture head

Item no.	Description
60.25.0042	Affinis Fracture head 42
60.25.0045	Affinis Fracture head 45
60.25.0048	Affinis Fracture head 48

**Material:** Ceramic ( $\text{Al}_2\text{O}_3$ )



### Affinis Fracture Central part

Item no.	Description
60.21.0000	Affinis Fracture Central part 1
60.21.0001	Affinis Fracture Central part 2

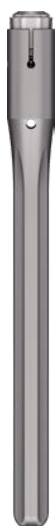
**Material:** Ti6Al4V, TiCP + CaP coated



### 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

**Material:** CoCrMo, TiCP + CaP coated



### Affinis Fracture stem

Item no.	Description
60.21.0006	Affinis Fracture stem 6/125
60.21.0009	Affinis Fracture stem 9/125
60.21.0012	Affinis Fracture stem 12/125
60.21.0209	Affinis Fracture stem 9/200
60.21.0212	Affinis Fracture stem 12/200
62.34.0078	Affinis Fracture revision screw

**Material:** Ti6Al4V



#### Affinis Inverse metaglene

Item no.	Description
60.30.3150	Affinis Inverse metaglene

**Material:** Ti6Al4V, TiCP + CaP coated



#### Affinis Inverse revision metaglene

Item no.	Description
60.30.3151	Affinis Inverse revision metaglene

**Material:** Ti6Al4V, TiCP + CaP coated



#### Affinis Inverse glenosphere

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

**Material:** UHMWPE / FeCrNiMoMn / Ti6Al4V



#### Affinis Inverse Glenosphere vitamys

Item no.	Description
62.34.0061	Affinis Inverse Glenosphere vitamys 39
62.34.0062	Affinis Inverse Glenosphere vitamys 42

**Material:** Vitamin E highly cross-linked polyethylene (VEPE) / FeCrNiMoMn / Ti6Al4V



#### Affinis Inverse lag screw

Item no.	Description
60.30.4418	Affinis Inverse lag screw 4.5 x 18
60.30.4422	Affinis Inverse lag screw 4.5 x 22
60.30.4426	Affinis Inverse lag screw 4.5 x 26
60.30.4430	Affinis Inverse lag screw 4.5 x 30
60.30.4434	Affinis Inverse lag screw 4.5 x 34
60.30.4438	Affinis Inverse lag screw 4.5 x 38

**Material:** Ti6Al4V



#### Affinis locking screw

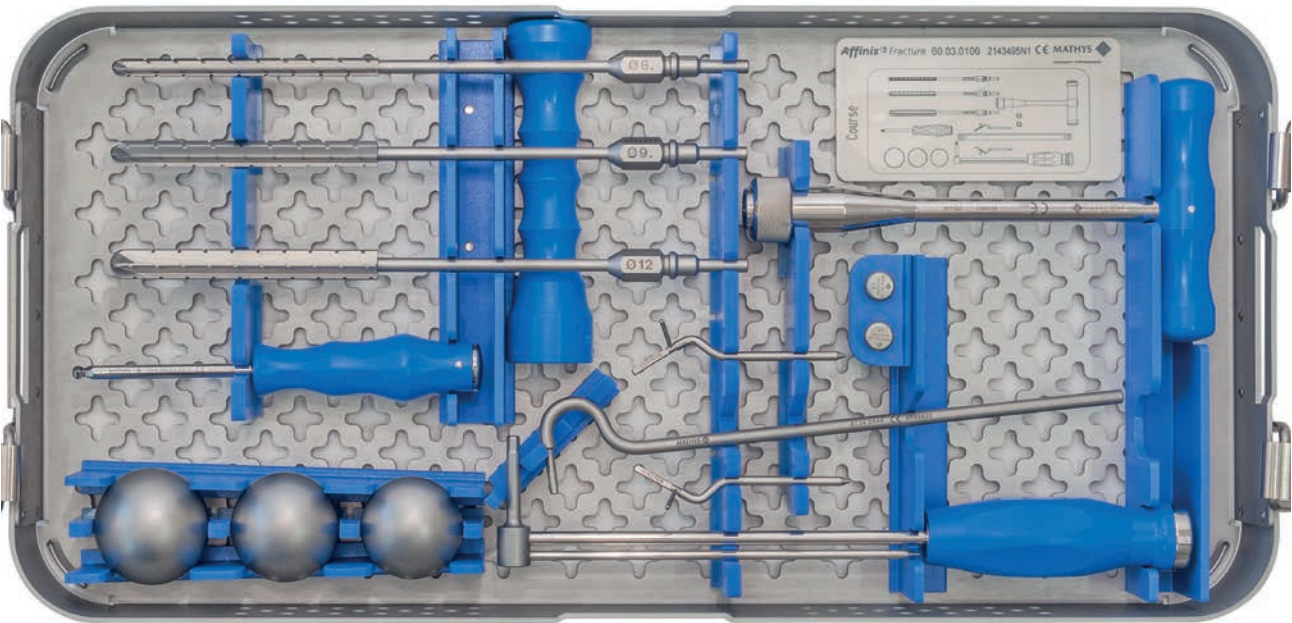
Item no.	Description
60.30.5424	Affinis locking screw 4.0 x 24
60.30.5430	Affinis locking screw 4.0 x 30
60.30.5436	Affinis locking screw 4.0 x 36
60.30.5442	Affinis locking screw 4.0 x 42
60.30.5448	Affinis locking screw 4.0 x 48

**Material:** Ti6Al4V

# 6. Instruments

## 6.1 Standard Instruments

### Affinis Fracture Instrument Set 60.01.0100A



Item no.	Description
60.03.0100	Affinis Fracture tray
60.03.0102	Affinis Fracture Lid



Item no.	Description
502.06.03.00.0	Affinis head impactor



Item no.	Description
502.06.10.06.0	Affinis medullary reamer 6
502.06.10.09.0	Affinis medullary reamer 9
502.06.10.12.0	Affinis medullary reamer 12



Item no.	Description
504.99.04.00.0	Affinis Screwdriver 5.0



Item no.	Description
5241.00.3	Handle



Item no.	Description
60.02.1010	Affinis fract. retrotorsion pointer left
60.02.1011	Affinis fract. retrotorsion pointer right



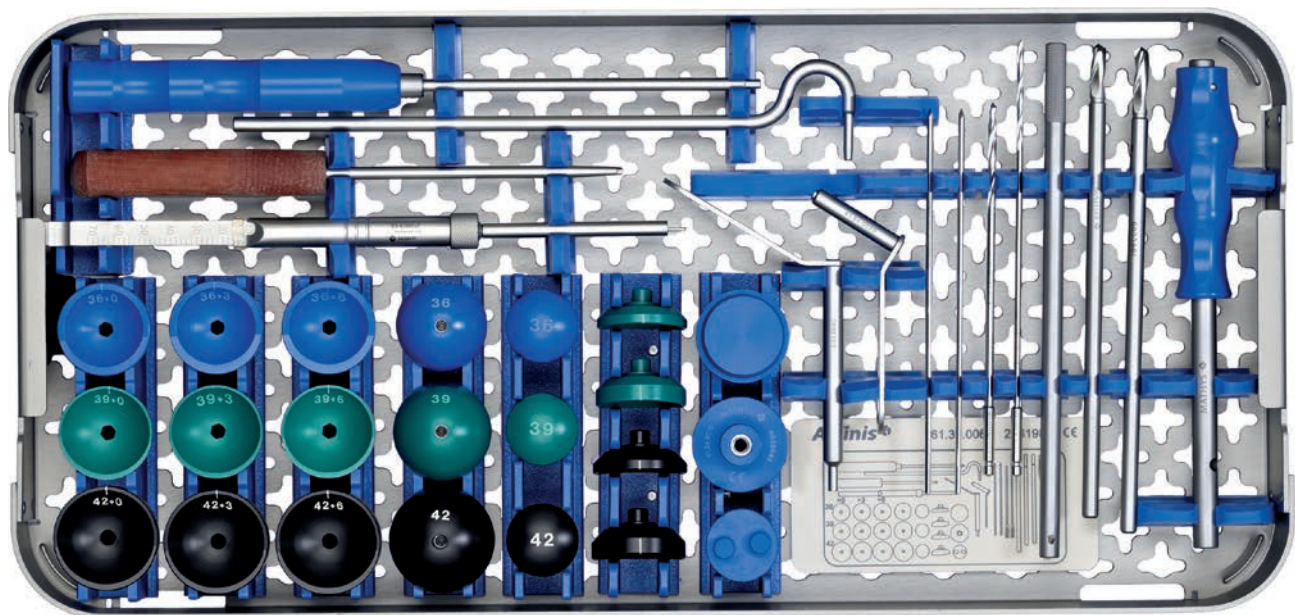
Item no.	Description
60.02.1042	Affinis Fracture trial head 42
60.02.1045	Affinis Fracture trial head 45
60.02.1048	Affinis Fracture trial head 48

Item no.	Description
6008.00.04	Adjusting screw

Item no.	Description
6020.00	Torque wrench

Item no.	Description
61.34.0048	Affinis Counter-wrench Inverse/Fracture

Affinis Inverse instrumentation 60.01.3000A



Item no.	Description
61.34.0031	Affinis Inverse tray
61.34.0065	Affinis Inverse Insert
60.02.2050	Affinis Inverse lid

Item no.	Description
292.250	Kirschner wire 2.5/150

Item no.	Description
5223.00	Impactor

Item no.	Description
60.02.2032	Affinis Inverse screwdriver 3.5

Item no.	Description
60.02.2034	Affinis Inverse holding/rotation rod

Item no.	Description
61.34.0001	Affinis Inverse metaglene drill guide





Item no.	Description
61.34.0154	Affinis Inv. Glenoid Reamer 28 modular

Item no.	Description
61.34.0155	Affinis Holder Glenoid Reamer

Item no.	Description
61.34.0003	Affinis Inverse glenoid reamer 42

Item no.	Description
61.34.0005	Affinis Inverse metaglene assembly rod

Item no.	Description
61.34.0006	Affinis Inverse glenosphere pusher

Item no.	Description
61.34.0007	Affinis Inverse peg drill metaglene

Item no.	Description
61.34.0009	Affinis Inverse metaglene impactor

Item no.	Description
61.34.0012	Affinis Inverse trial glenosphere 39
61.34.0013	Affinis Inverse trial glenosphere 42

Item no.	Description
61.34.0014	Affinis drill guide locking screw

Item no.	Description
61.34.0015	Affinis metaglene revision drill

Item no.	Description
61.34.0018	Affinis Inverse fixation peg

Item no.	Description
61.34.0019	Affinis Inverse depth gauge

Item no.	Description
61.34.0020	Affinis Inverse drill-guide lag screws



Item no.	Description
61.34.0184	Affinis Inverse Drill-bit 2.5, Gen 2
61.34.0185	Affinis Inverse Drill-bit 3.5, Gen 2



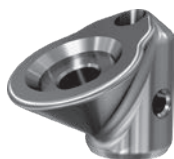
Item no.	Description
61.34.0023	Affinis Inverse screwdriver 2.5



Item no.	Description
61.34.0024	Affinis Inverse glenosphere extractor



Item no.	Description
61.34.0025	Affinis Fracture Inverse trial inlay 39+0
61.34.0026	Affinis Fracture Inverse trial inlay 39+3
61.34.0027	Affinis Fracture Inverse trial inlay 42+0
61.34.0028	Affinis Fracture Inverse trial inlay 42+3



Item no.	Description
61.34.0029	Affinis Fracture Inverse trial body



Item no.	Description
61.34.0033	Affinis Inverse assembly rod holder



Item no.	Description
61.34.0048	Affinis Counter-wrench Inverse/Fracture

## 7. Symbols



Manufacturer



Caution



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