MATHYS
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SURGICAL TECHNIQUE

Affinis Fracture & Fracture Inverse

Modular Fracture Shoulder Prosthesis
LC System with SMarT Instruments

Table of contents

Remark
Please make yourself familiar with the handling of the instruments, the product-related surgical technique and the warnings, the safety notes 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 are difficult to reconstruct. The modular platform system allows intraoperative decision-making and the conversion from a hemiprosthesis to an inverse prosthesis.

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. [1]

The anatomical and inverse Central part on the humeral side allow 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

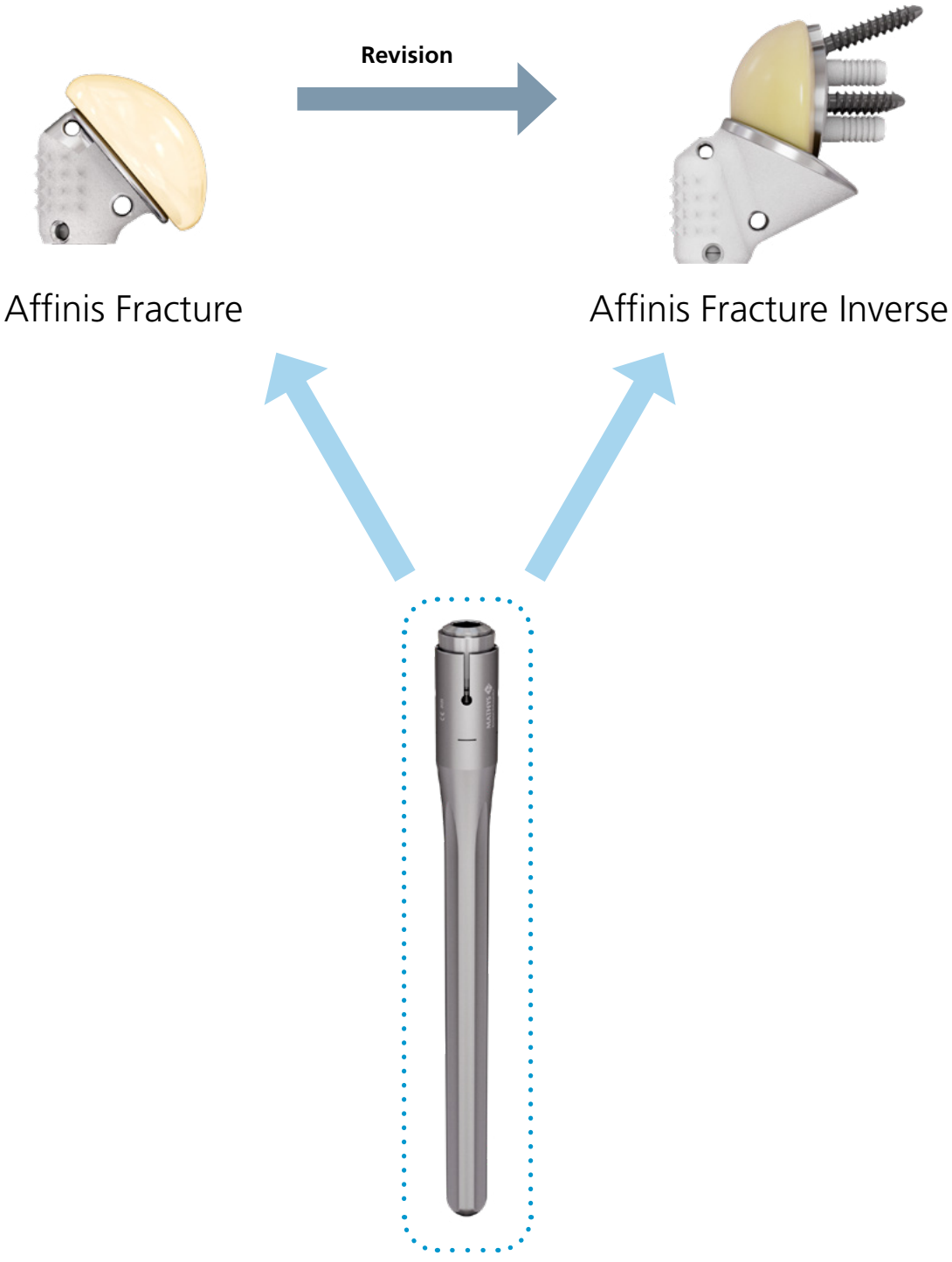
- Continuous height and rotation adjustment
- Modular platform system for less invasive revision surgeries [2, 3]
- Osteoconductive calcium phosphate coating for improved ongrowth of the tuberosities [1]
- Polished drill holes for suture or cable fixation
- Primary stem cementing

1 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.

2 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.

3 Reuther F, Irlenbusch U, Kääb MJ, Kohut G. Conversion of Hemiarthroplasty to Reverse Shoulder Arthroplasty with Humeral Stem Retention. J Clin Med. 2022;11(3):834.

Modular platform system

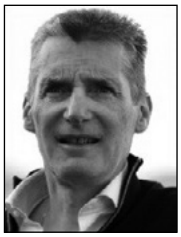


Surgeon design team

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. [4] This system was developed in cooperation with the following group of European shoulder specialists:

Affinis Fracture and Affinis Fracture Inverse
Prosthesis design and surgical technique


Prof. Ulrich Irlenbusch
Germany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Dr. Georges Kohut
Switzerland


Dr. Bernd Mühlhäusler
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Prof. Stefaan Nijs
Belgium


Dr. Falk Reuther
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Dr. Diethard Wahl
Germany

SMarT instrumentation


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Dr. Lars-Peter Götz
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Dr. Sergio Thomann
Switzerland

[4] 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

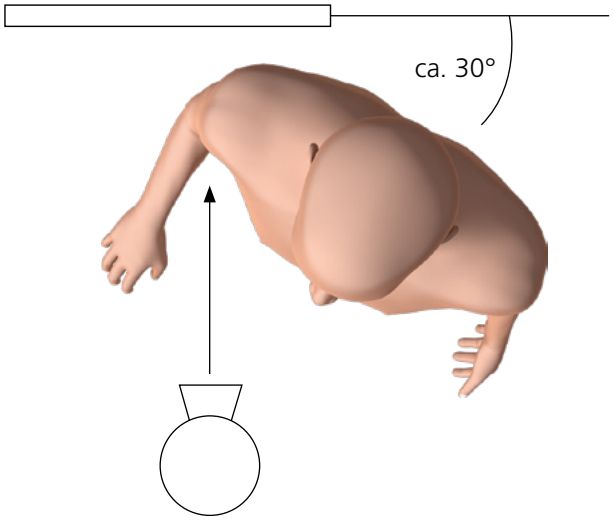
Contraindications for Affinis Fracture
- Severe soft tissue, nerve or vessel insufficiency that endangers the function and long-term stability of the implant
- Bone loss or insufficient bone substance which cannot provide adequate support or fixation for the implant
- Local, regional or systemic infection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



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

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.

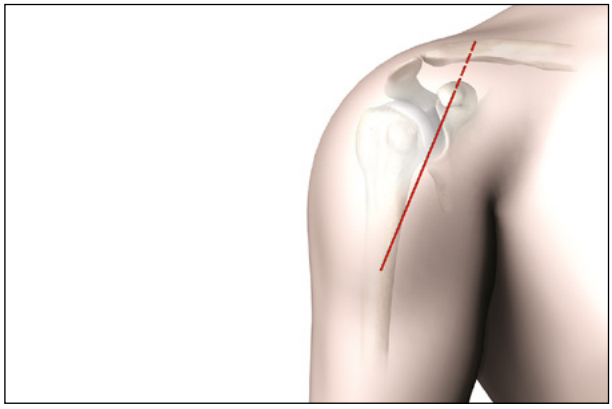


Fig. 2

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.

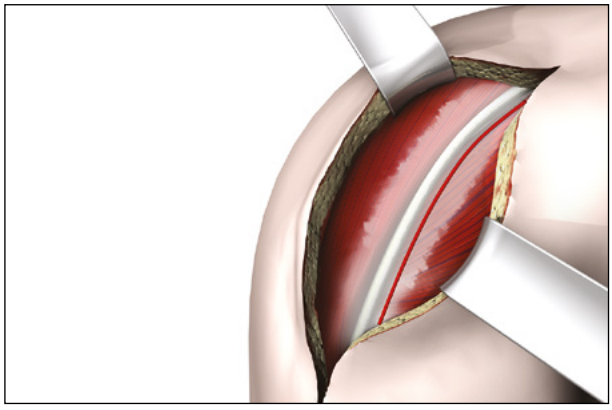


Fig. 3

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.

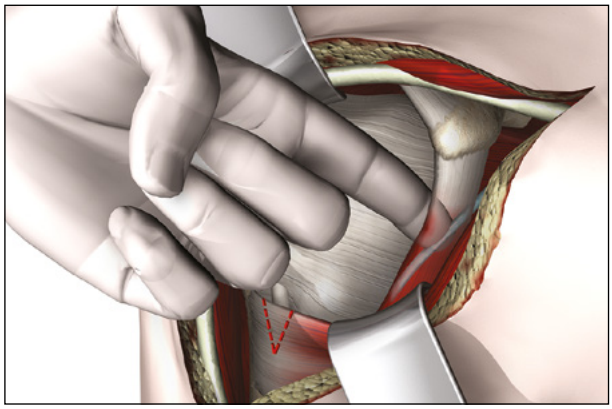


Fig. 4

This is followed by the vertical incision of the clavipectoral 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.

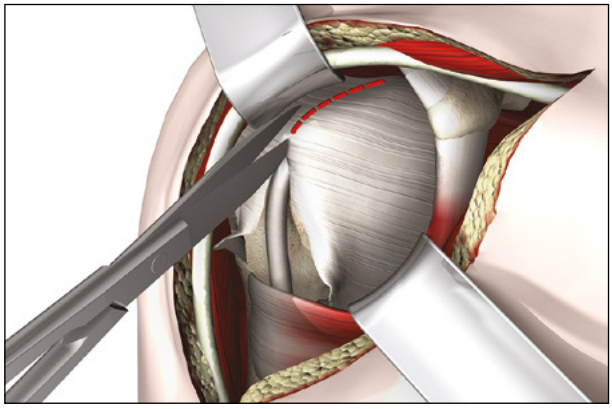


Fig. 5

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.

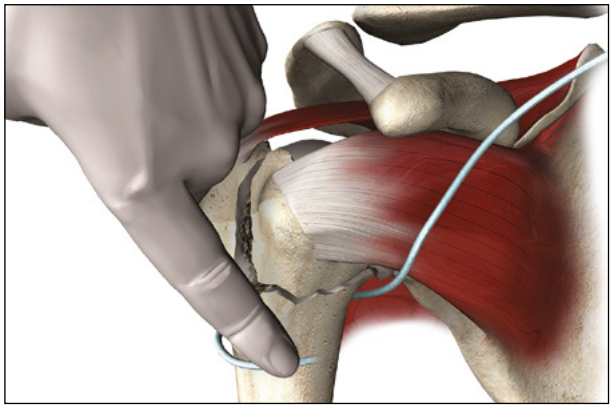


Fig. 6

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.

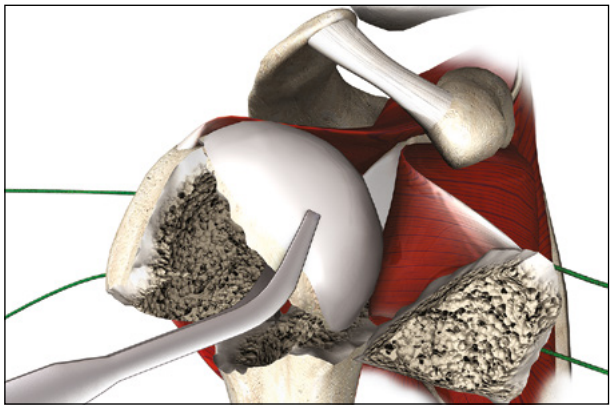


Fig. 7

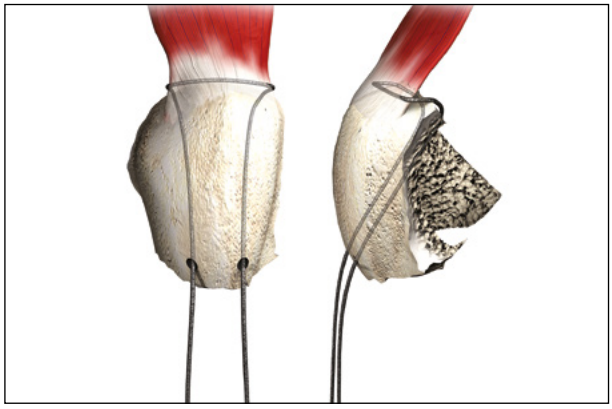


Fig. 8

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 Classic/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 sutures, using the Masen-Allen technique.

Fig. 9

3.3 Humeral preparation

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

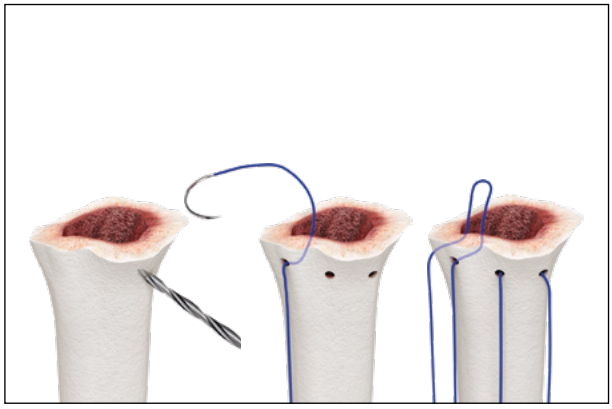


Fig. 10

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.

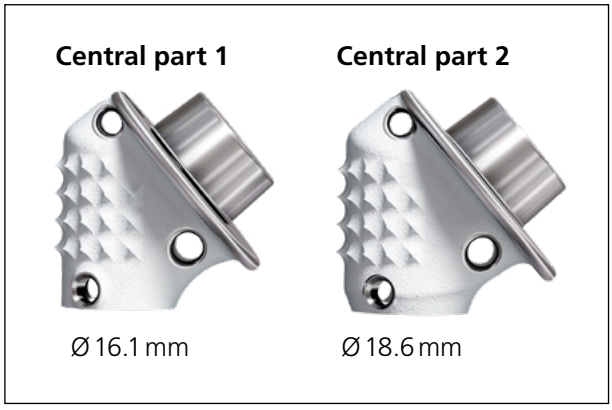


Fig. 11

3.4 Affinis Fracture implantation

3.4.1 Stem implantation

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

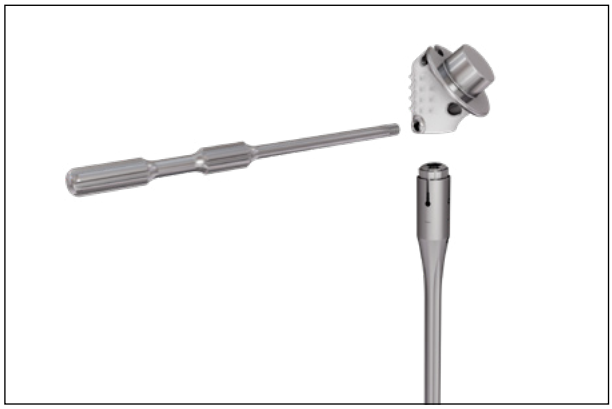


Fig. 12

Mount the Central part on the appropriate stem and secure it with the 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 [5]: 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.

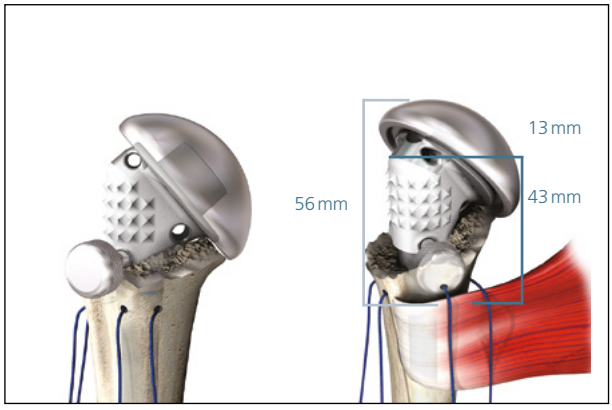


Fig. 14

[5] Murachovsky J, Ikemoto RY, Nascimento LG, Fujiki EN, Milani C, Warner JJ. Pectoralis major tendon reference (PMT): a new method for accurate restoration of humeral length with hemiarthroplasty for fracture. J Shoulder Elbow Surg. 2006;15(6): 675-678.

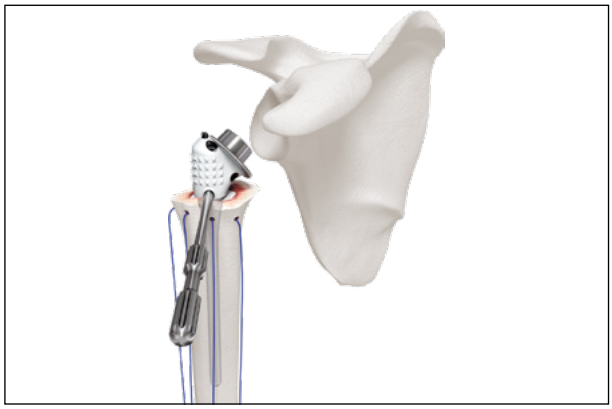


Fig. 15

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 cavity in a retrograde manner, the Alignment Rod 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.

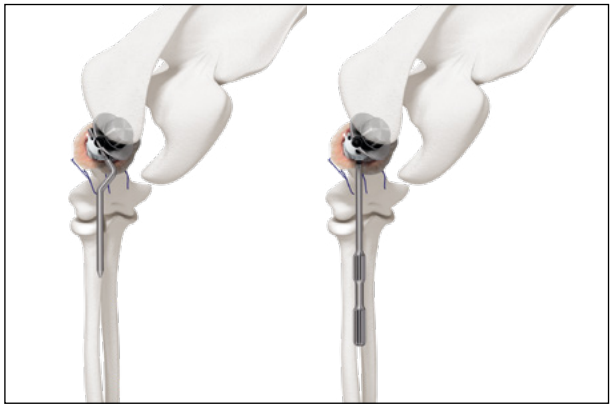


Fig. 16

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.
Alignment of the rod or pointer towards the lower arm corresponds to a retroversion of 30° and 20° to the transepicondylar axis.
The alignment rod should be tightened as soon as the optimum setting has been achieved.

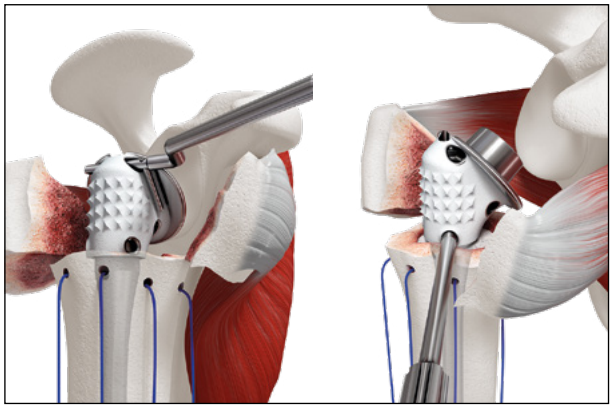


Fig. 17

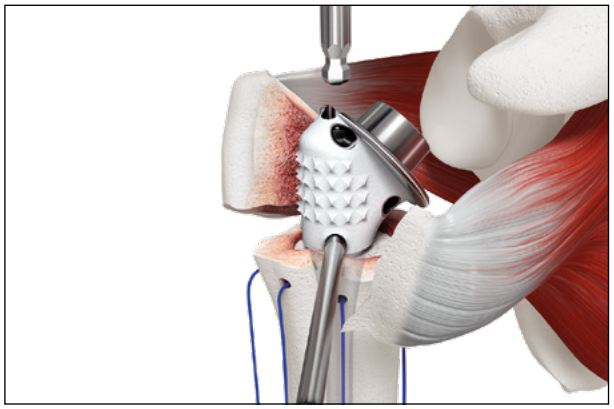


Fig. 18

Provisionally lock the Central part into place with the Screwdriver 5.0.

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

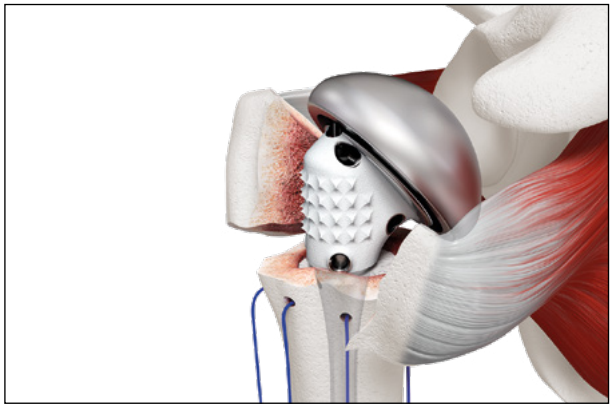


Fig. 19

Mount the trial head. The size of the head depends on the calotte that has been removed. If in doubt about the correct size, a smaller head should be used to avoid overstuffing.
Perform trial reduction and check for appropriate implant positioning and sizing.
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.
After the desired position has been achieved, the following parameters are checked by moving the arm whilst monitoring with an Image intensifier:

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

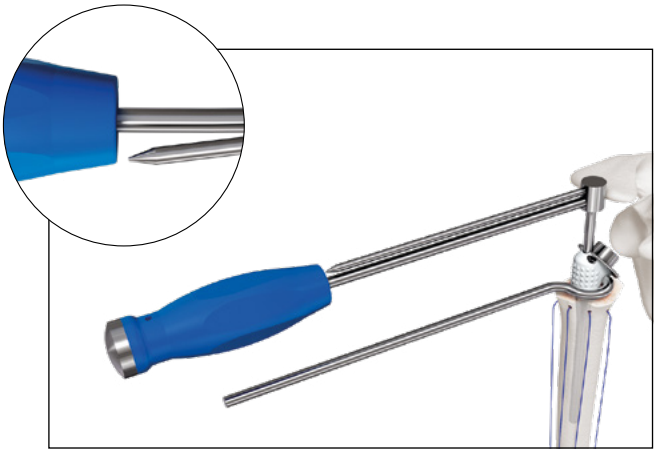


Fig. 20

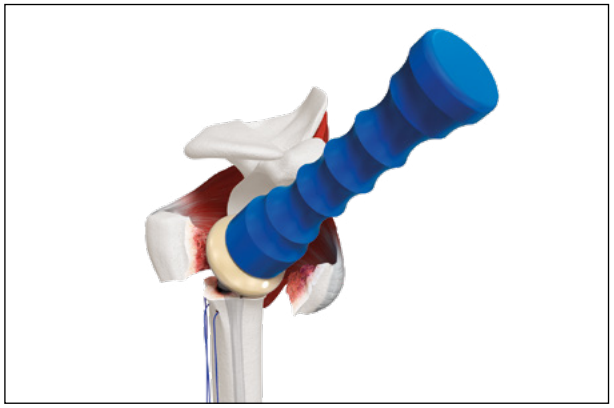


Fig. 21

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:
The Counter-wrench, Gen 2 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 away from 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 an 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.

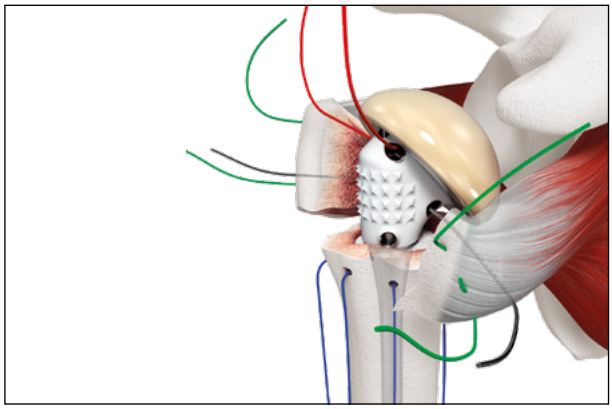


Fig. 22

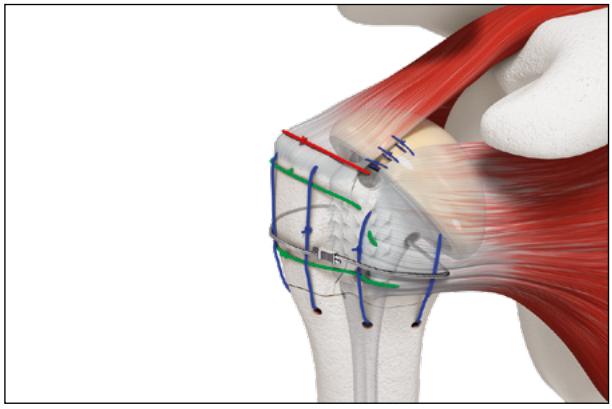


Fig. 23

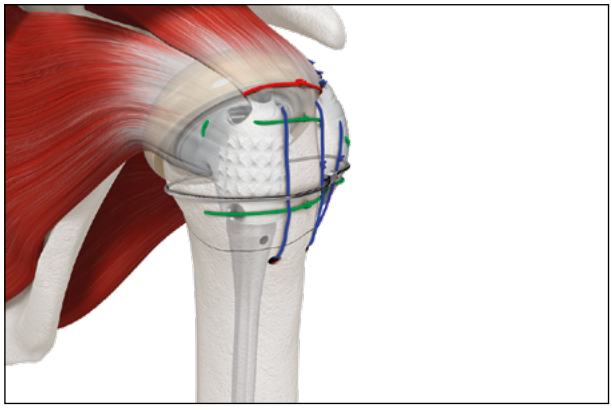


Fig. 24

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 osteoconductive coated Central part, by means of an 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 intensifier with image documentation, and wound closure via Redon drainage, is recommended.

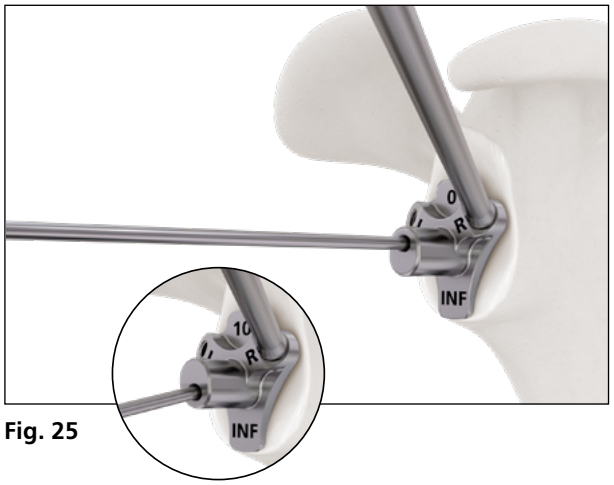


Fig. 25

3.5 Affinis Fracture Inverse Implantation

3.5.1 Glenoid preparation

Assemble the Handle Long on the relevant side of the Metaglene K-Wire Guide 0°. Align the k-wire guide with the inferior border of the glenoid and insert the Kirschner Wire 2.5/150.

The Metaglene K-Wire Guide 10° can be used in cases of superior erosion or to achieve an inferior tilt of the metaglene.

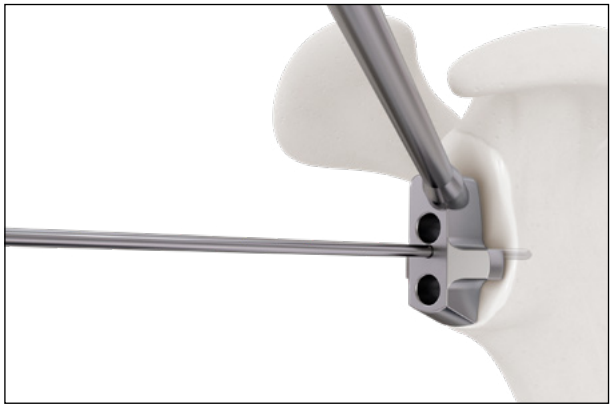


Fig. 26

Optional step

Align the Metaglene Drill-guide (Left/Right) with the inferior border of the glenoid and insert the Kirschner wire with 0° angulation.

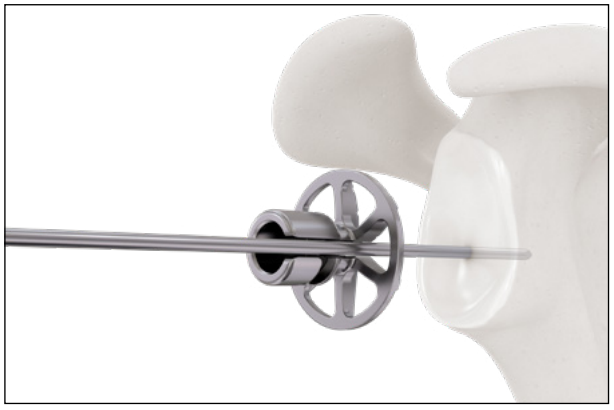


Fig. 27

The Kirschner wire serves as a guide for the vitamys 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.

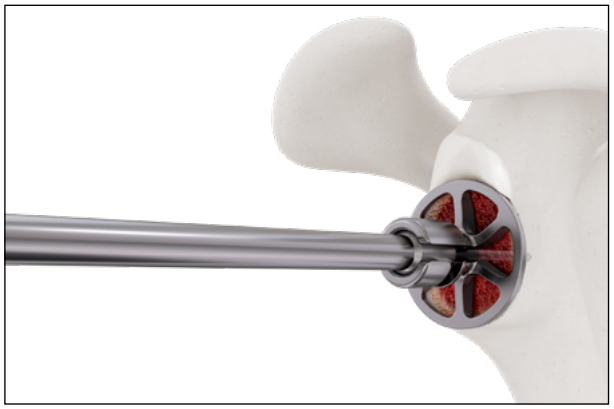


Fig. 28

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 build-up, which may lead to thermal damage of the surrounding bone.

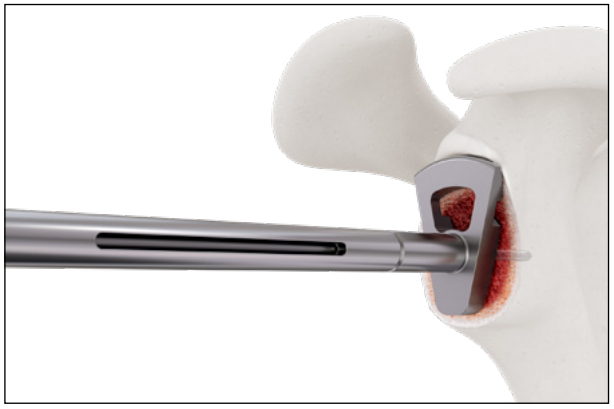


Fig. 29

Ream the glenoid with the Glenoid Reamer 42, Gen 2. 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.

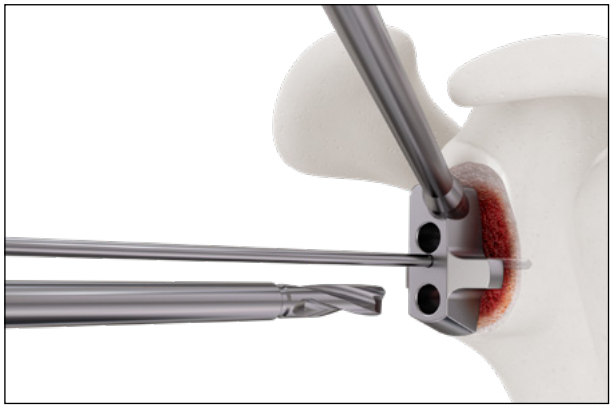


Fig. 30

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.

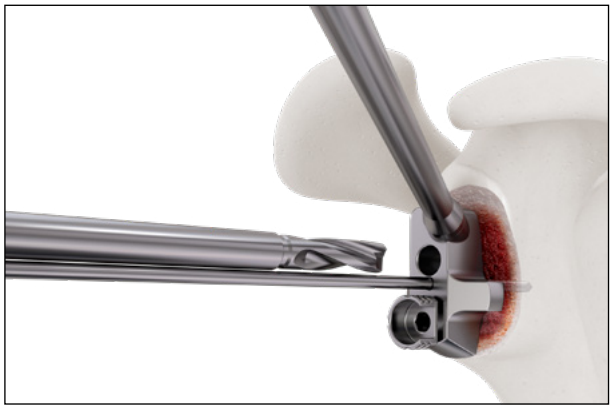


Fig. 31

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

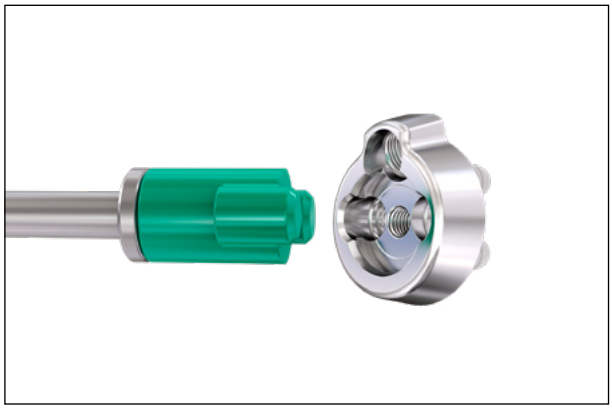


Fig. 32

3.5.2 Metaglene DP implantation

For implantation of the Inverse metaglene DP, use the Adaptor Impactor Metaglene CP.
Screw the adaptor onto the Impactor Handle. Place the metaglene onto the adaptor.

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

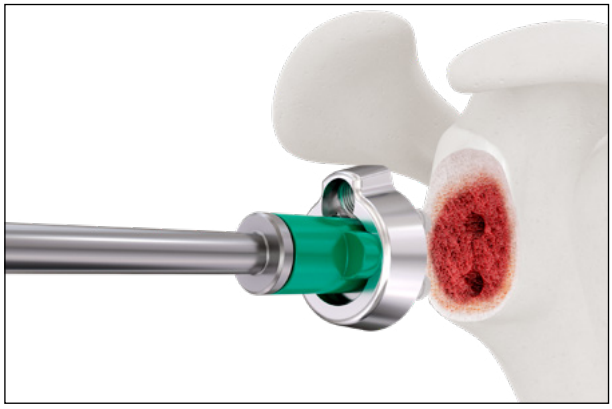


Fig. 33

Insert the metaglene into the two peg 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 pegs are impacted parallel to the peg 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. 34

Anterior and posterior screw fixation

Hold the Drill-Guide 3.0) into the screw holes in the metaglene. Insert the Drill Bit 3.0 and drill the holes for the screws parallel or slightly convergent to the pegs of the metaglene. The screws can be directed with an angular freedom of ±8°.

When using screws longer than 30 mm, drill parallel to the pegs to avoid screw to screw contact.

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. 35

Measure the depth of the holes with the Depth Gauge LC to determine the appropriate screw length. Insert and tighten the two screws with the Screwdriver T20 in alternating mode.

Fig. 36

Superior screw fixation

Hold the drill guide 3.0 against the screw hole. The superior screws can be directed with an angular freedom of ± 10° from the neutral axis of 20°. Insert the drill bit 3.0 and drill the hole for the screw.

Make sure to position the drill guide flush and central into the screw hole. Exceeding the angular freedom (± 10°) impairs the screw and locking cap 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.

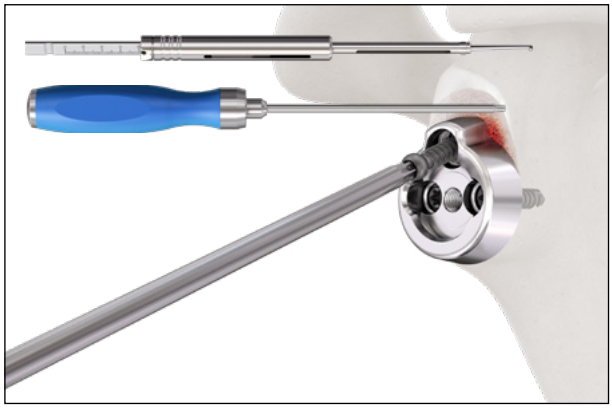


Fig. 37

Measure the depth of the hole with the depth gauge LC to determine the appropriate screw length. Insert and tighten the screw with the screwdriver T20.

Fig. 38

Assemble the Screwdriver T20 With Quick Coupling with the Torque Handle.
The superior screw must be fixed with the cap to lock the desired screw angle.

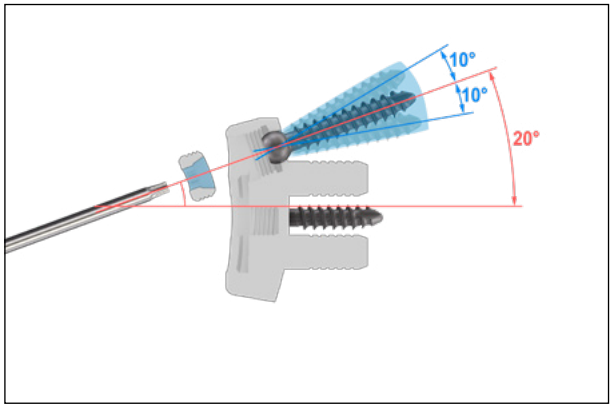


Fig. 39

Align the locking cap with the neutral screw orientation of 20° and the concave side facing the screw, then insert it. Tighten the cap with the torque handle until it clicks (tactile feedback).

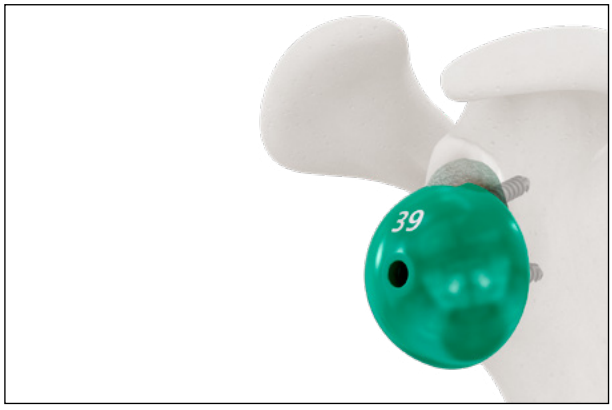


Fig. 40

Optional step
The Trial glenosphere can be mounted and secured with the 3.5 screw driver to perform trial reduction.

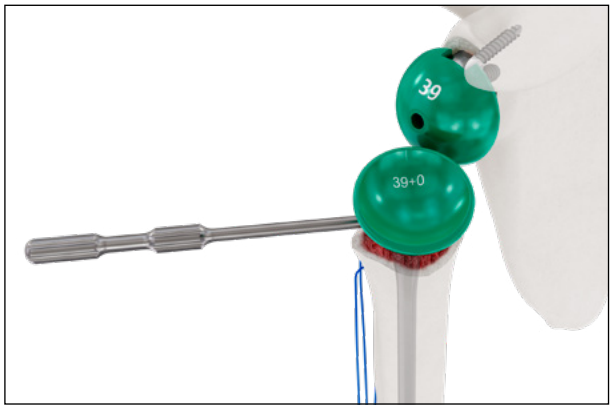


Fig. 41

3.5.3 Stem implantation

Mount the Inv. Trial Body, Gen 2 on the appropriate stem and secure it with the Fracture Inverse Alignment Rod.
The alignment rod indicates retroversion of 0° when aligned with the forearm.

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 Fracture Alignment Rod, Gen 2 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.

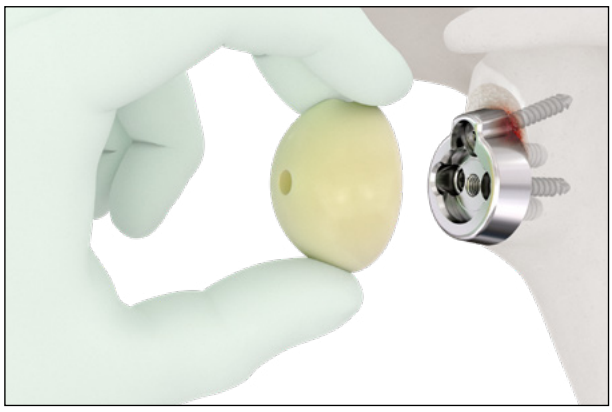


Fig. 42

3.5.4 Glenosphere implantation

After having chosen the glenosphere and inlay sizes, place the definitive glenosphere onto the metaglene.

Fig. 43

Screw in the Metaglene Assembly Rod. Secure it with either the Assembly Rod Holder or the handle of the Glenosphere Pusher.
Slide, and then screw the glenosphere pusher over the metaglene assembly rod. This will snap the glenosphere onto the metaglene.
Screw the glenosphere pusher until an increased force is felt. A firm resistance indicates that the glenosphere is seated on the metaglene. Unscrew the pusher and remove the assembly rod by using the backend of the glenosphere pusher or the assembly rod holder. Check if the glenosphere is fully seated on the metaglene, if not it will dislodge easily.

Fig. 44

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

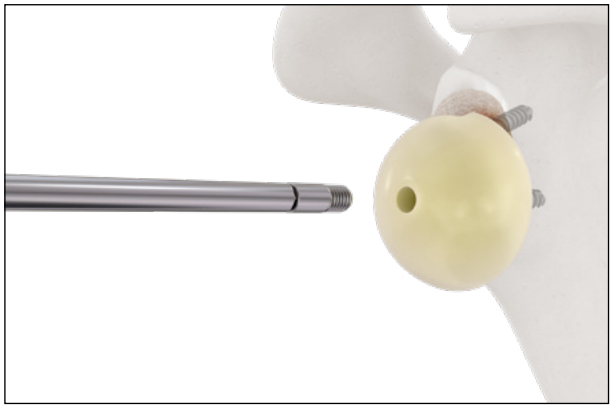


Fig. 45

Finally, screw in the fixation screw to secure the glenosphere using the 3.5 screw driver.

If the screw cannot be fixed completely, the glenosphere may not be fully fixed on the metaglene and the seating has to be checked again.

Fig. 46

Fig. 47

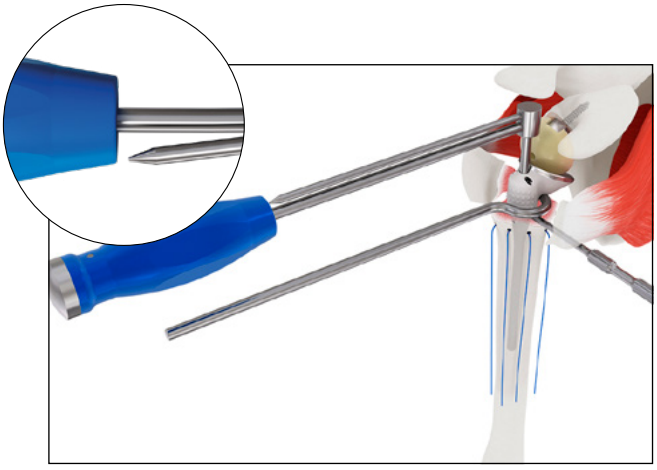


Fig. 48

3.5.5 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 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 (fixation mechanism).

The Fracture Inverse Alignment Rod is used to fix the central part on the stem temporarily.
When the correct positioning has been achieved, the Counter-wrench, Gen 2 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.
Tensioning takes place by turning the torque wrench clockwise. When the indicator of the torque wrench points away from the wrench handle, sufficient torque has been achieved.
After having secured the central part, reattach remaining tuberosities and/or rotator cuff tendons to improve rotation and stability of the shoulder joint.

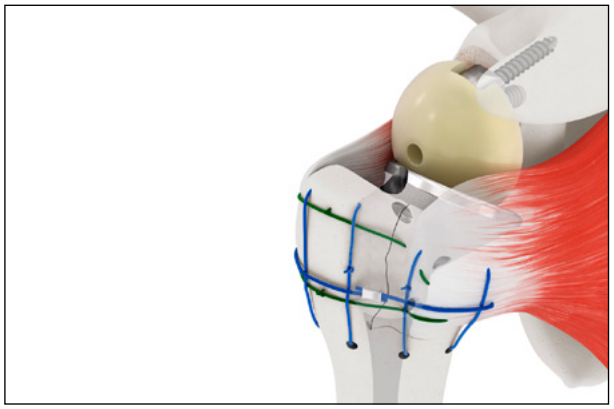


Fig. 49

3.5.6 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 osteoconductive 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 Intensifier with image documentation, and wound closure via Redon drainage, is recommended.

4. Revision

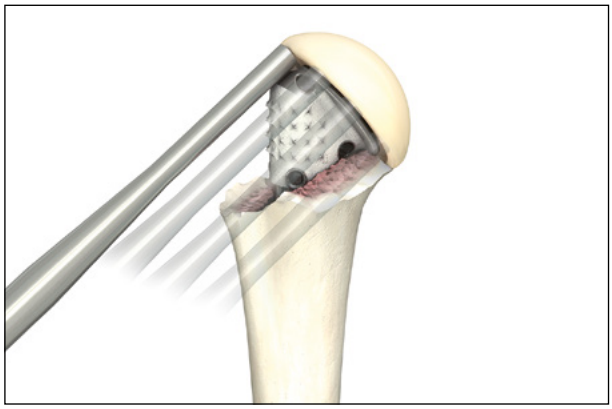


Fig. 50

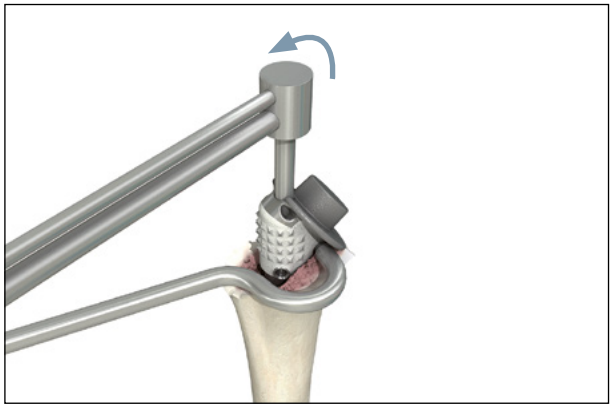


Fig. 51

4.1 Conversion from Affinis Fracture to Affinis Fracture Inverse

Failed fracture hemiarthroplasty can be converted to a fracture inverse arthroplasty whilst retaining the stem in situ.
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. Place a surgical sponge around the prosthesis to catch ceramic particles, if the ceramic head fractures on removal.

Removal of Fracture Central part

The Counter-wrench, Gen 2 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. 52

Fig. 53

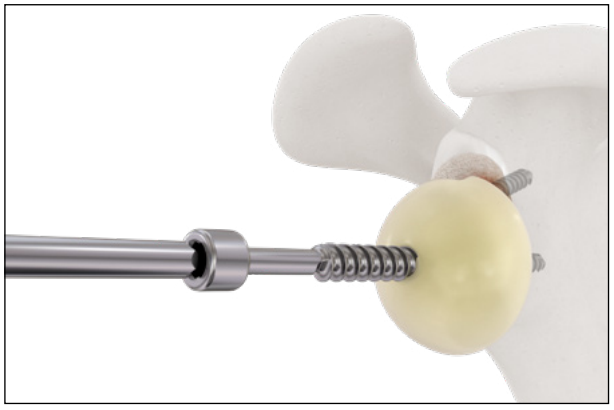


Fig. 54

4.2 Removal of Affinis Fracture Inverse Central Part

The Counter-wrench, Gen 2 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.

4.3 Glenosphere removal

Remove the fixation screw of the glenosphere with the 3.5 screw driver.

Using the 5.0 mm screw driver, screw the Glenosphere Extractor into the glenosphere. The glenosphere extractor removes the glenosphere from the metaglene.

Providing there remains
1. firm stability,
2. no visual damage,
3. or evidence of other functional deficits of the metaglene,

a new glenosphere can be implanted.
Otherwise, the metaglene must also be revised.

Fig. 55

4.4 Metaglene DP removal

After removing the glenosphere, remove the locking cap and all screws with the screwdriver T20.

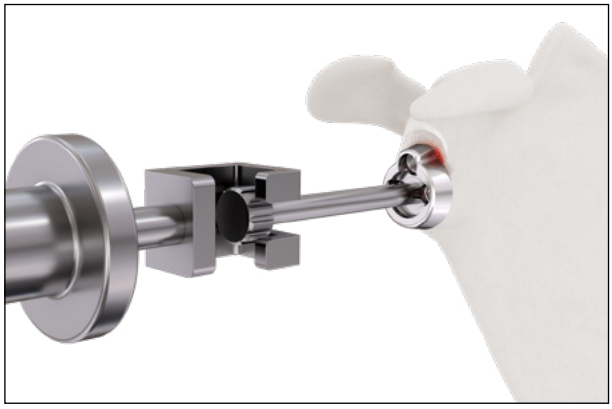


Fig. 56

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.

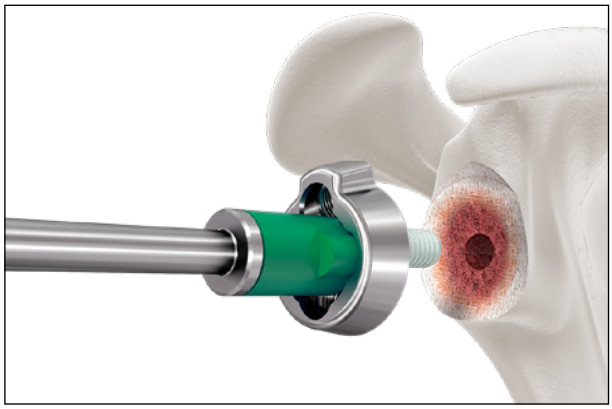


Fig. 57

4.5 Metaglene CP implantation

For further information about the metaglene CP, please consult the appropriate Affinis Inverse metaglene CP surgical technique (336.020.041).

Fig. 58

4.6 Fracture stem removal

Unscrew the Fixation Screw in the prosthesis stem. Screw the Stem Adapter into the stem. Use the 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 (Al_2O_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 revision screw

Item no.	Description
62.34.0078	Affinis Fracture revision screw

Material: Ti6Al4V

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

Material: 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 Glenosphere

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

Material: UHMWPE / FeCrNiMoMn / Ti6Al4V

Affinis Inverse metaglene DP

Item no.	Description
62.34.0181	Affinis Inverse metaglene DP

Material: Ti6Al4V, TiCP + CaP coated

Affinis Inverse screws with locking cap

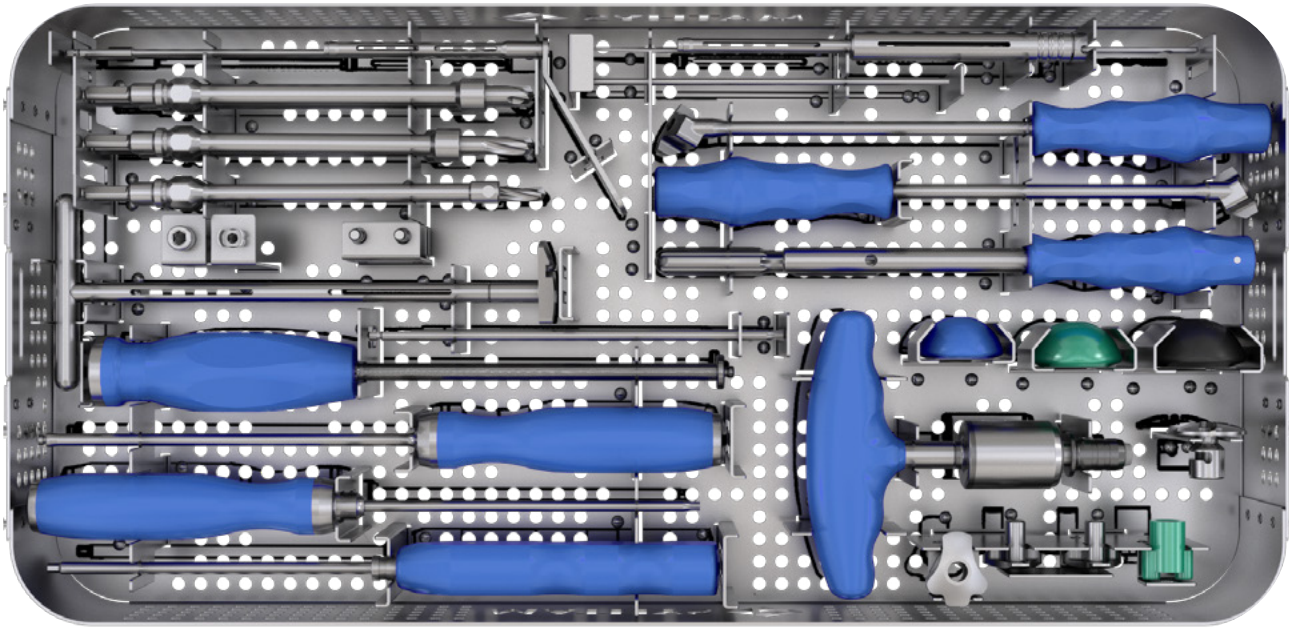
Item no.	Description
62.34.0168	Affinis Inverse screw w/cap 4.5x15
62.34.0169	Affinis Inverse screw w/cap 4.5x18
62.34.0170	Affinis Inverse screw w/cap 4.5x21
62.34.0171	Affinis Inverse screw w/cap 4.5x24
62.34.0172	Affinis Inverse screw w/cap 4.5x27
62.34.0173	Affinis Inverse screw w/cap 4.5x30
62.34.0174	Affinis Inverse screw w/cap 4.5x33
62.34.0175	Affinis Inverse screw w/cap 4.5x36
62.34.0176	Affinis Inverse screw w/cap 4.5x39
62.34.0177	Affinis Inverse screw w/cap 4.5x42
62.34.0178	Affinis Inverse screw w/cap 4.5x45
62.34.0179	Affinis Inverse screw w/cap 4.5x48
62.34.0180	Affinis Inverse screw w/cap 4.5x51

Material: Ti6Al4V

6. Instruments

6.1 SMarT Instruments

Affinis Inverse Glenosphere LC SMarT Instrument Set 61.34.0279A



Item no.	Description
61.34.0277	Affinis Inverse glenosphere LC tray
51.34.1105	Mathys lid

Item no.	Description
61.34.0263	Affinis Inv metaglene k-wire guide 0°

Item no.	Description
61.34.0264	Affinis Inv metaglene k-wire guide 10°

Item no.	Description
61.34.0266	Affinis Inverse handle long

Item no.	Description
61.34.0190	Affinis Inv Metaglene Drill-guide Left
61.34.0191	Affinis Inv Metaglene Drill-guide Right

Item no.	Description
61.34.0188	Affinis Inverse Metaglene Drill, Gen 2

Item no.	Description
61.34.0192	Affinis Inverse Fixation Peg, Gen 2

Item no.	Description
61.34.0267	Affinis Inverse impactor metaglene CP

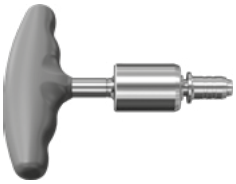
Item no.	Description
62.34.0155	Affinis Inv. Impactor, Gen 2

Item no.	Description
61.34.0299	Affinis Inverse drill bit 3.0

Item no.	Description
61.34.0269	Affinis Inverse drill guide 3.0

Item no.	Description
61.34.0270	Affinis Inverse depth gauge sleeve LC

Item no.	Description
61.34.0271	Affinis Inverse depth gauge scale LC



Item no.	Description
14.780-RAL5010	Torque handle with quick coupling

Item no.	Description
99-23078-00046	Screwdriver T20 with quick coupling

Item no.	Description
99-23078-00045	Screwdriver T20

Item no.	Description
292.250	Kirschner wire 2.5/150

Item no.	Description
61.34.0165	Affinis Glenoid vitamys Reamer 1

Item no.	Description
61.34.0155	Affinis Holder Glenoid Reamer

Item no.	Description
61.34.0208	Affinis Inverse Glenoid Reamer 42, Gen 2

Item no.	Description
61.34.0187	Affinis Inverse Screwdriver 3.5, Gen 2

Item no.	Description
61.34.0005	Affinis Inverse metaglene assembly rod

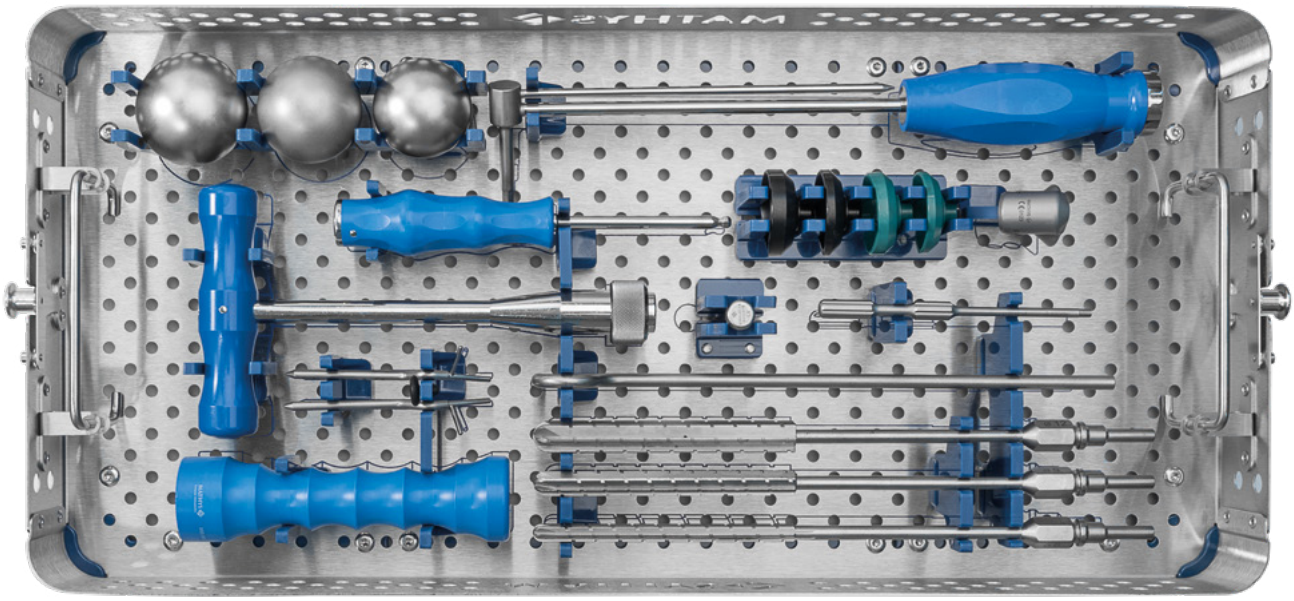
Item no.	Description
61.34.0209	Affinis Inv Assembly Rod Holder, Gen 2

Item no.	Description
61.34.0006	Affinis Inverse glenosphere pusher

Item no.	Description
61.34.0011	Affinis Inverse trial glenosphere 36
61.34.0012	Affinis Inverse trial glenosphere 39
61.34.0013	Affinis Inverse trial glenosphere 42

Item no.	Description
61.34.0024	Affinis Inverse Glenosphere extractor

Affinis Fracture / Fracture Inverse SMarT Instrument Set 61.34.0245A



Item no.	Description
61.34.0227	Affinis Lid
61.34.0228	Affinis Fracture/Fracture Inverse Tray

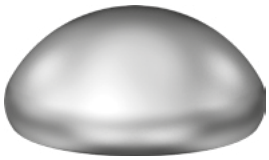
Item no.	Description
502.06.03.00.0	Affinis head impactor

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

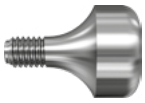
Item no.	Description
5241.00.3	Handle

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
61.34.0216	Affinis Fracture Inverse Alignment Rod



Item no.	Description
6008.00.04	Adjusting screw

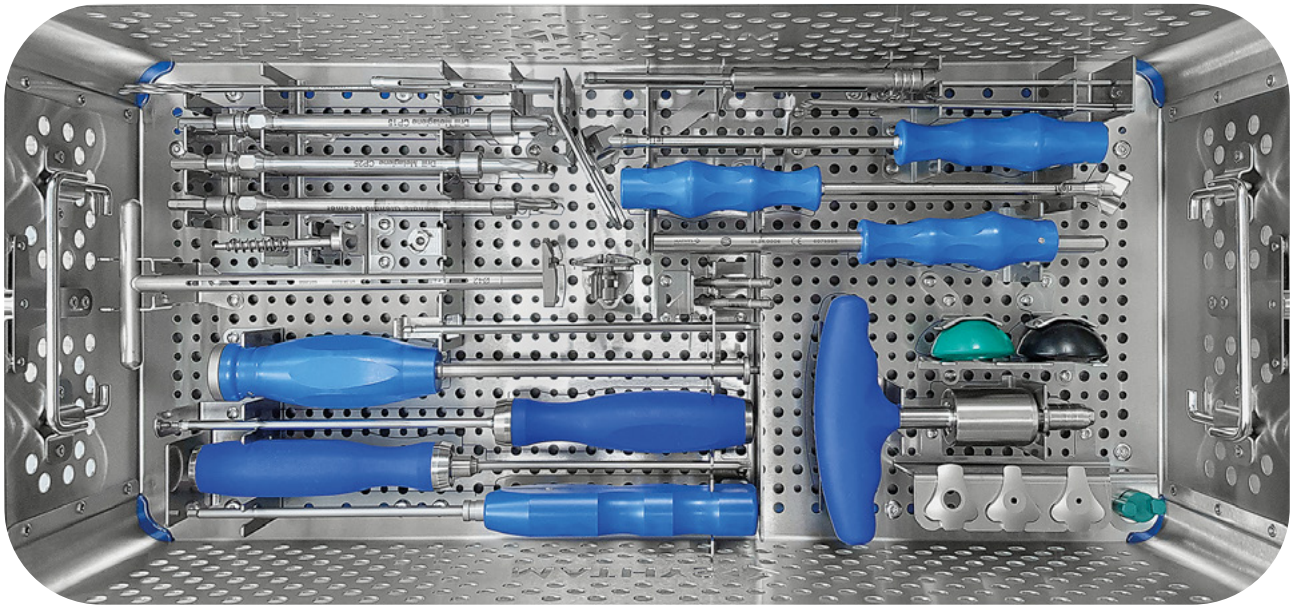
Item no.	Description
6020.00	Torque wrench

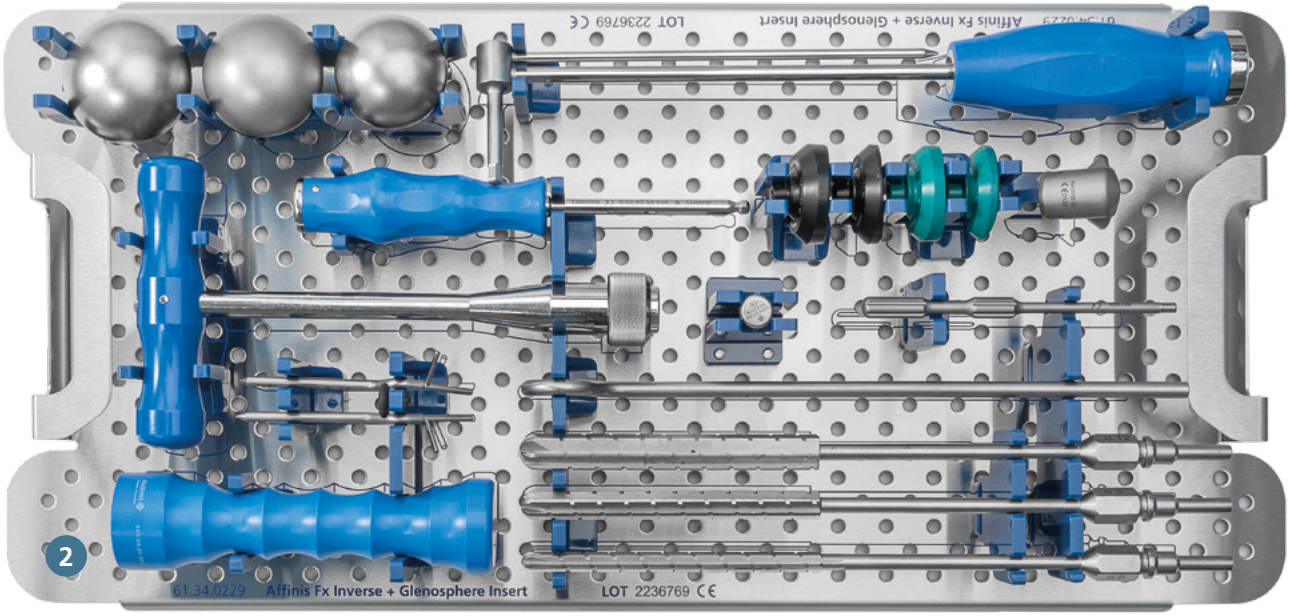
Item no.	Description
61.34.0025	Affinis Fracture Inverse trial inlay 39 + 0
61.34.0026	Affinis Fracture Inverse trial inlay 39 + 3
61.34.0027	Affinis Fracture Inverse trial inlay 42 + 0
61.34.0028	Affinis Fracture Inverse trial inlay 42 + 3

Item no.	Description
61.34.0214	Affinis Fracture Inv. Trial Body, Gen 2

Item no.	Description
61.34.0215	Affinis Fracture Counter-wrench, Gen 2

Affinis Fracture / Fracture Inverse + Glenosphere LC SMarT Instrument Set 61.34.0297A



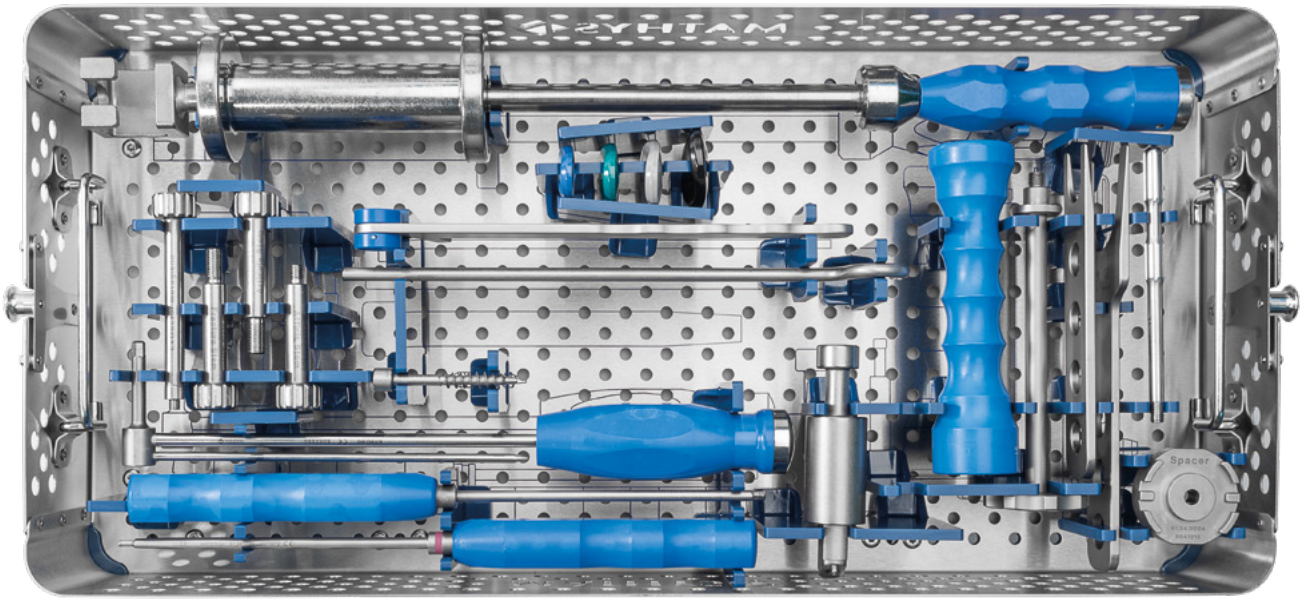


Item no.	Description	
61.34.0227	Affinis Lid	
61.34.0229	Affinis Fx Inv. + Glenosphere Insert	2
61.34.0295	Affinis Fx Inv. + Glenosphere LC Tray	1

The contents of Affinis Fracture/Fracture Inverse + Glenosphere LC SMarT Instrument Set (61.34.0297A) is identical to the following two sets combined:
61.34.0279A – Affinis Inverse Glenosphere LC SMarT Instrument Set
61.34.0245A – Affinis Fracture/Fracture Inverse SMarT Instrument Set

6.2 Revision Instruments

Affinis Revision Instrument Set 61.34.0250A



Item no.	Description
61.34.0239	Affinis Revision Tray
61.34.0227	Affinis Revision Lid

Item no.	Description
61.34.0215	Affinis Fracture Counter-wrench, Gen 2

Item no.	Description
6020.00	Torque wrench

Item no.	Description
61.34.0187	Affinis Inv. Screwdriver 3.5, Gen 2

Item no.	Description
61.34.0024	Affinis Inverse glenosphere extractor

Item no.	Description
61.34.0186	Affinis Inv. Screwdriver 2.5, Gen 2

Item no.	Description
61.34.0055	Affinis Inverse Metaglene Extractor

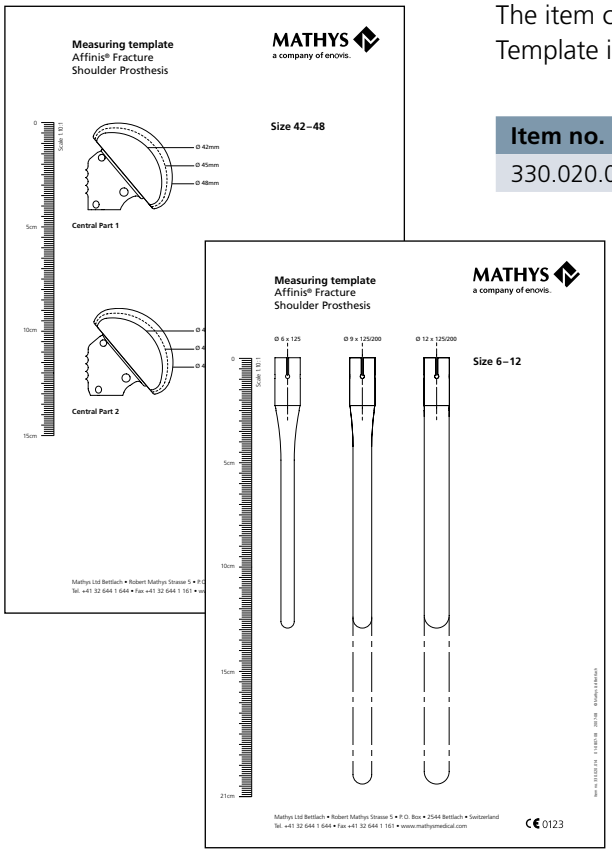
Item no.	Description
61.34.0050	Affinis Slide Hammer

Item no.	Description
61.34.0053	Affinis Fracture Stem Adapter

Item no.	Description
504.99.04.00.0	Affinis Screwdriver 5.0

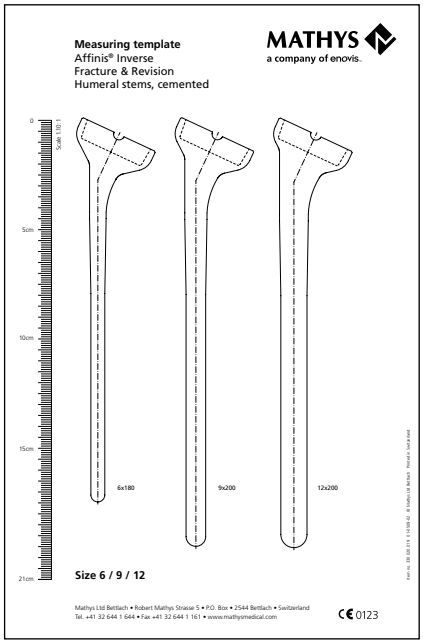
Item no.	Description
99-23078-00045	Screwdriver T20

7. Measuring template



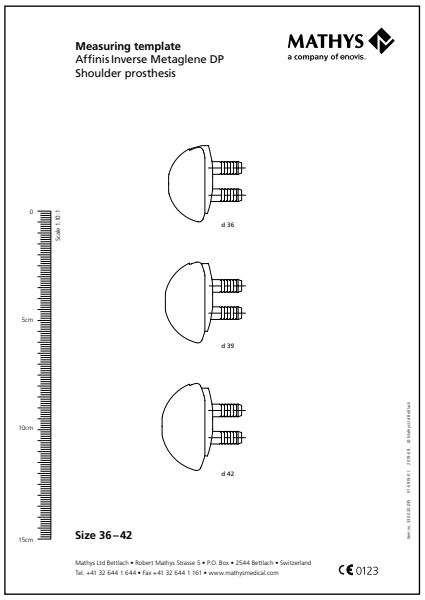
The item code for the two part Affinis Fracture Measuring Template is 330.020.014.

Item no.	Description
330.020.014	Affinis Fracture Template



The item code for the six part Affinis Inverse Fracture and Revision Measuring Template is 330.020.019.

Item no.	Description
330.020.019	Affinis Inverse Fracture & Revision Template



The item code for the one part Affinis Inverse metaglene DP Measuring Template is 330.020.035.

Item no.	Description
330.020.035	Affinis Inverse metaglene DP Template

8. Symbols

Manufacturer

Caution

CE 0123 CE marking for medical devices of Risk Class Ir, Is, Im, II and III

EC REP Authorized representative in the European Community/European Union

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a company of enovis™

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Local Marketing Partners in over 30 countries worldwide…

Item no. 336.020.047 01-0822-01 2022-08

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