MATHYS
European Orthopaedics

Surgical technique

Affinis Inverse

Reverse shoulder prosthesis
LC system with SMarT instruments

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

***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.

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

Inverse shoulder prostheses have become widely used in recent years. Although new designs have been developed, scapular notching, loosening and therefore high revision rates are still a concern. With its design features as well as inferior positioning of the metaglene, the Affinis Inverse was developed to address these concerns.

Ceramic and titanium provide a solution for patients with hypersensitivity to nickel, cobalt, chromium and molybdenum ions. Moreover, ceramys in combination with a vitamys glenosphere, in vitro tests showed a 5.4 times lower wear rate for this combination compared to the standard coupling CoCr with UHMWPE. [1] The vitamys material offers better wear rate, oxidation resistance and aging behaviour than standard UHMWPE. [1, 2, 3]

Features

- Inlay available in CoCr and ceramys (dispersion ceramic)
- Glenosphere from ultra-high molecular weight polyethylene (UHMWPE) and vitamys, highly cross-linked polyethylene enriched with vitamin E (VEPE)
- Titanium plasma spray (TiCP) and calcium phosphates (CaP) coated central peg metaglene for primary stability and secondary osseointegration for long-term stability
- Centric reaming but eccentric positioning of the metaglene for inferior overhang

1 Data on file. Mathys Ltd Bettlach

2 Delfosse D, Lerf R, Adlhart C. What happens to the vitamin E in a vitamin-stabilised HXLPE? Karl Knahr (Ed.), Tribology in Total Hip and Knee Arthroplasty. Book Chapter, 2014.

3 Lerf R, Zurbrügg D, Delfosse D. Use of vitamin E to protect cross-linked UHMWPE from oxidation. Biomaterials, 2010. 31(13): p. 3643-8.

4 Begand S, Oberbach T, Glien W, Schneider J. Kinetic of the phase transformation of ATZ compared to biograde Y-TZP. Key Eng Mater, 2008. 361-363: p. 763-766.

5 Gremillard L, Chevalier J, Martin L, Douillard T, Begand S, Hans K, Oberbach T. et al. Sub-surface assessment of hydrothermal ageing in zirconia-containing femoral heads for hip joint applications. Acta Biomaterialia, 2017.

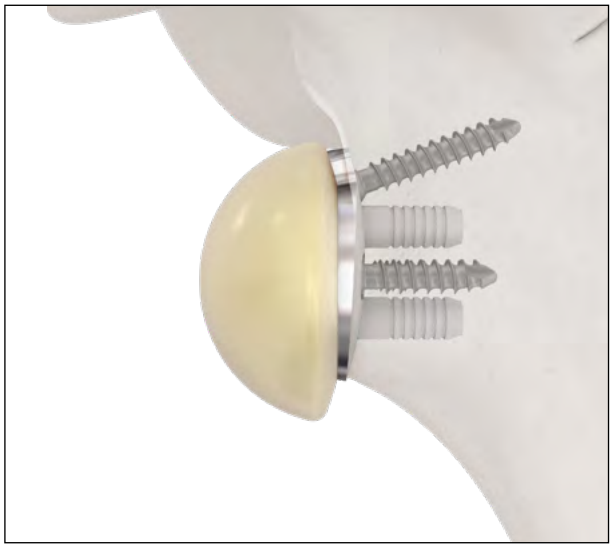
6 Dumbleton JH, Manley MT, Edidin AA. A literature review of the association between wear rate and osteolysis in total hip arthroplasty. J Arthroplasty, 2002. 17(5): p. 649-61.

7 Irlenbusch U and Kohut G. Evaluation of a new baseplate in reverse total shoulder arthroplasty - comparison of biomechanical testing of stability with roentgenological follow up criteria. Orthopaedics & Traumatology: Surgery & Research, 2015.

8 Irlenbusch U, Kaab MJ, Kohut G, Proust J, Reuther F, Joudet, T. Reversed shoulder arthroplasty with inversed bearing materials: 2-year clinical and radiographic results in 101 patients. Arch Orthop Trauma Surg, 2015. 135(2): p. 161-9.

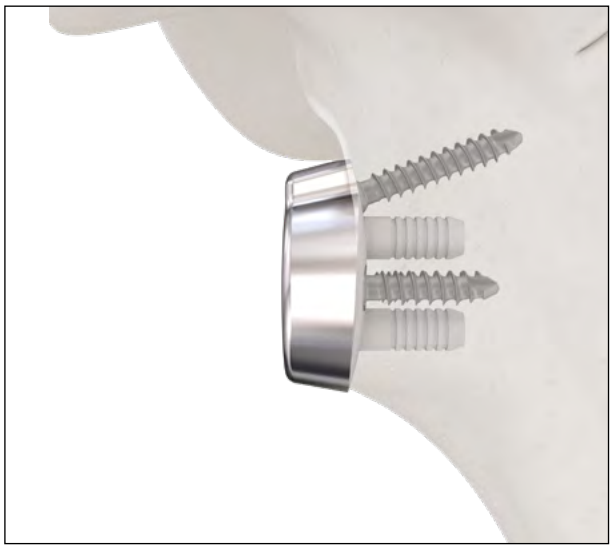
9 Kohut G, Dallmann F, Irlenbusch U. Wear-induced loss of mass in reversed total shoulder arthroplasty with conventional and inverted bearing materials. J Biomech, 2012. 45(3): p. 469-73.

10 Dumbleton JH, Manley MT, Edidin AA. A literature review of the association between wear rate and osteolysis in total hip arthroplasty. J Arthroplasty, 2002. 17(5): p. 649-61.



Advantages

- Reduced wear and aging with vitamys and ceramys [1, 2, 3, 4, 5]
- Ceramic and titanium provide a solution for patients with hypersensitivity to nickel, cobalt, chromium and molybdenum ions
- No implant/implant notching [1]
- No polyethylene contact to scapula – less PE particles leading to less osteolysis [6]
- Simple instrumentation [1]



Implant philosophy

- 2-peg design
- No inferior screw
- High primary and secondary stability [1, 7, 8]
- Avoid PE-induced osteolysis with inverted material bearings [9, 10]

Surgeon design team – **Affinis Inverse**

The Affinis Inverse shoulder prostheses and associated surgical technique provide a 155° Grammont style treatment with a simple instrumentation. [1] This system was developed in cooperation with the following group of European shoulder specialists:

Affinis Inverse
Prosthesis design and surgical technique


Prof. Ulrich Irlenbusch
Germany


Dr. Thierry Joudet
France


Dr. Max Kääb
Germany


Dr. Georges Kohut
Switzerland


Prof. Stefaan Nijs
Belgium


Dr. Falk Reuther
Germany

SMarT instrumentation


Dr. Philippe Clément
France


Dr. Yves Fortems
Belgium


Dr. Lars-Peter Götz
Germany


Dr. Sergio Thomann
Switzerland

[1] Data on file. Mathys Ltd Bettlach

1. Indications and contraindications

Indications

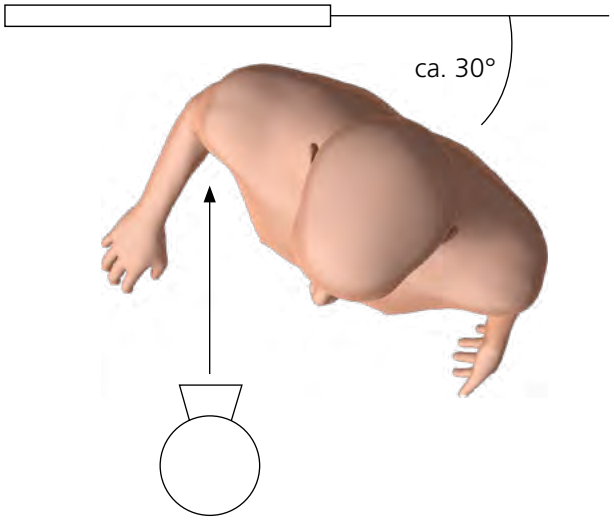
- Grossly deficient rotator cuff with arthropathy or irreparable functional deformity
- Revision of failed shoulder prosthesis or fracture treatment (conservative or surgical) with an irreparable rotator cuff
- Tumour-related structural defects of the proximal humerus

Contraindications

- 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 7).

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.

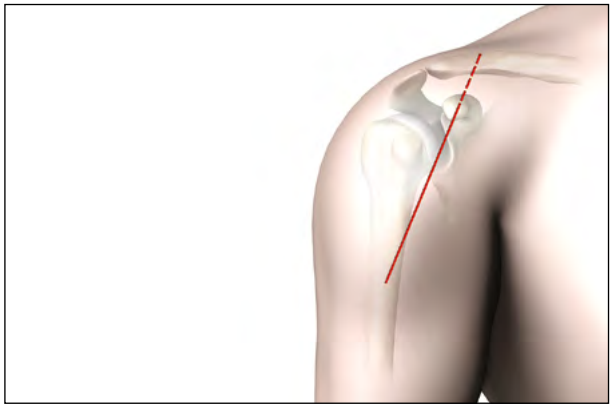


Fig. 2

3.2 Approach

In this surgical technique only the deltopectoral approach is described.
The standard instrumentation for humeral head resection is for the deltopectoral approach. Optional instruments for the lateral approach are also available.
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.

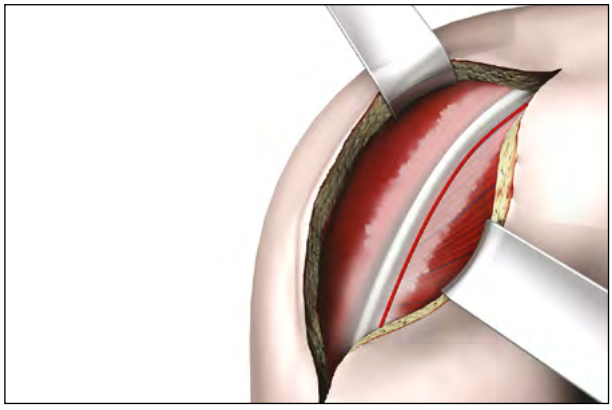


Fig. 3

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.

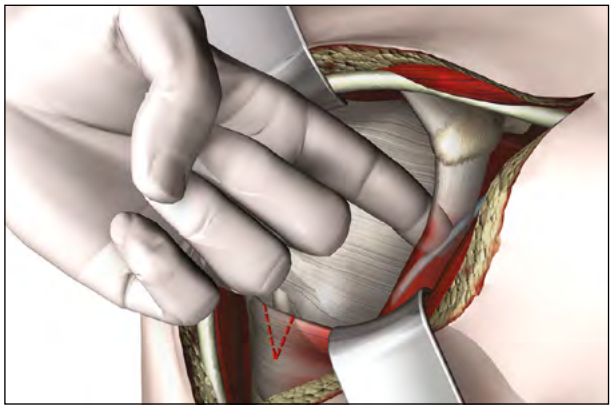


Fig. 4

This is followed by the vertical incision of the clavipectoral fascia.
After mobilisation of the coracobrachial tendon group in a medial direction, the musculocutaneous 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.
Additionally, the coracoacromial ligament can be incised.

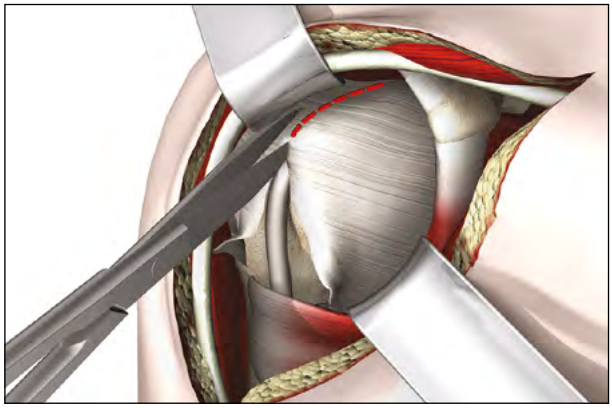


Fig. 5

Split the rotator cuff (if present) in the interval up to the base of the coracoid process.
The biceps tendon may be tenotomised and/or tenodesed on the proximal shaft (sulcus area). The intra-articular stump is resected.
After that, the axillary nerve can be palpated at the anterior and lower side of the subscapularis.
Identification can be difficult in the case of revisions, older fractures or adhesions.
The axillary nerve must be protected throughout the entire operation.
The subscapularis tendon is tenotomised approximately 1 cm from its insertion and is marked with stay sutures. In shoulders with contracted musculature, the tendon and muscle can be released distally when the joint capsule is released from the humerus (calcar).
Good exposure of the humeral head can be reached through anterosuperior dislocation by externally rotating the extended and adducted limb.
Make sure that the humerus is displaced cranially during the next step to avoid traction injury of the brachial plexus.

Fig. 6

3.3 Humeral head resection

Open the medullary cavity using the Awl at the highest point of the humeral head, centred and parallel to the shaft axis.

Fig. 7

Insert the Affinis Guide Rod for Resection. Ream the intramedullary cavity and leave the guide rod in place.

Fig. 8

Optional technique

Insert the Medullary Reamer 6 using the Handle. Ream the intramedullary cavity beginning with the 6 mm reamer and continue with 9 and 12 mm reamers depending on the diameter of the cavity.

Leave the final medullary reamer in place and remove the handle.

The resection instruments differ depending upon the approach you are using. If you are performing a deltopectoral or lateral approach, refer to the appropriate section of this surgical technique guide.

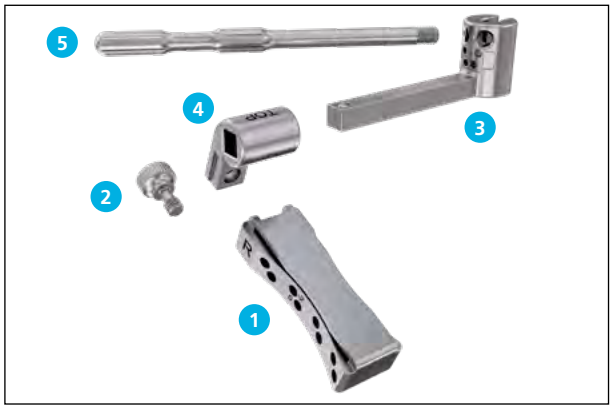


Fig. 9

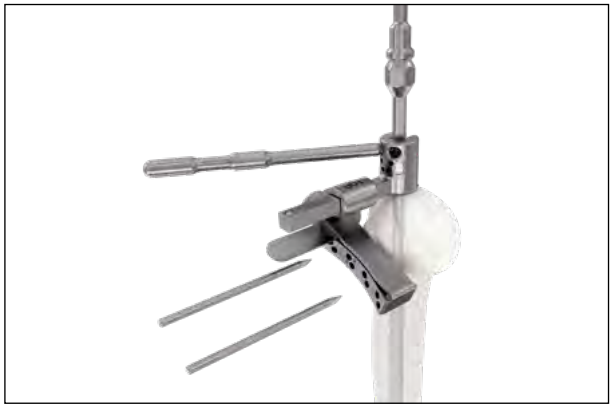


Fig. 10

Fig. 11

3.3.1 Deltopectoral approach

Assemble the resection guide for the right or left side. Use the 155° angled glider resection guide component.

The final assembly consists of the following components:

No.	Item no.	Description
1	502.06.01.05.0	Affinis cutting block
2	502.06.01.06.0	Affinis screw for resection guide
3	60.02.0002	Affinis holder for resection guide
4	61.34.0004	Affinis Inverse glider resection guide
5	61.34.0210	Affinis Alignment Rod, Gen 2

Place the resection guide on the medullary reamer. Place a Kirschner wire into the hole corresponding to the desired retroversion as needed. Adjust the desired retroversion by aligning the Alignment Rod or the Kirschner wire to the forearm.

The square sliding post of the Holder for Resection Guide indicates 0° of retroversion.

Use the Stylus to fine-tune the retroversion and resection height according to the anatomical conditions. The alignment rod locks the resection guide to the medullary reamer.

Predrill two 3.2 mm pinholes through at least two distal holes of the cutting block. Insert two 3.2 mm pins through the predrilled holes.

In certain anatomic situations, interference between the Pins and medullary reamer rod cannot be avoided. In this situation, remove the medullary reamer before fully inserting the Pins.

Loosen the screw for resection guide and the alignment rod and remove the assembly including the medullary reamer. Leave the cutting block in place.

Use the stylus to recheck the resection height and the retroversion. The stylus should be in line with the anatomical neck laterally.

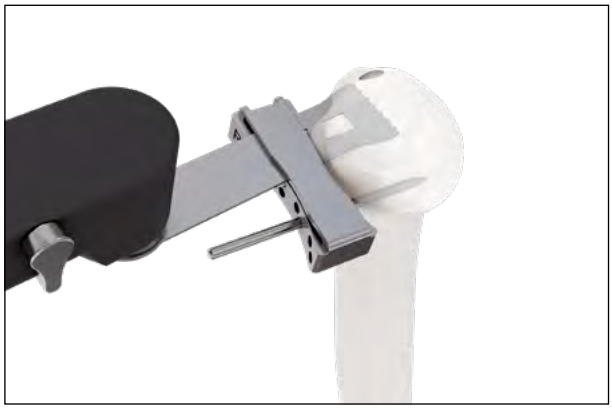


Fig. 12

Resect the humeral head through the slot of the cutting block with a sawblade of 0.89 mm thickness.
If a re-resection is necessary, transfer the cutting block onto the pins using the proximal holes (2 mm re-resection).

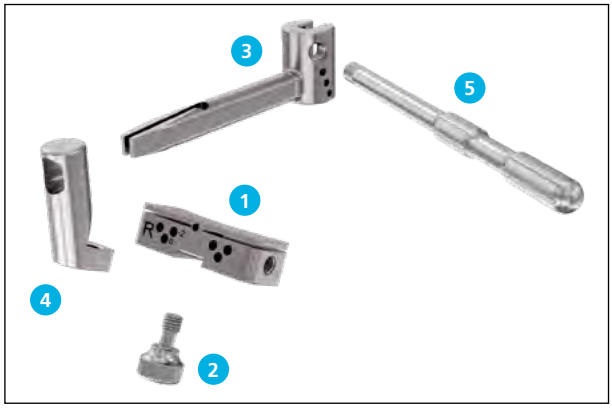


Fig. 13

3.3.2 Lateral approach

Assemble the resection guide marked «lateral».
Use the 155° angled Glider for Resection Guide Lateral component.
The final assembly consists of the following components:

No.	Item no.	Description
1	61.34.0252	Cutting Block lateral, Gen 2
2	502.06.01.06.0	Affinis screw for resection guide
3	61.34.0253	Holder for Resection Guide lateral, Gen 2
4	61.34.0255	Glider for Resection Guide lat 155°, Gen 2
5	61.34.0210	Affinis Alignment Rod, Gen 2

Fig. 14

Place the resection guide on the medullary reamer. Place a Kirschner wire into the hole corresponding to the desired retroversion as needed. Adjust the desired retroversion by aligning the Alignment Rod or the Kirschner wire to the forearm.
Use the stylus to fine-tune the retroversion and resection height according to the anatomical conditions. The alignment rod locks the resection guide to the medullary reamer.
Predrill two 3.2 mm pinholes through at least two distal holes of the cutting block. Insert two 3.2 mm pins through the predrilled holes.

Fig. 15

Loosen the screw for resection guide and the alignment rod and remove the assembly including the medullary reamer.
Use the stylus to recheck the resection height and the retroversion. The stylus should be in line with the anatomical neck laterally.

Fig. 16

Resect the humeral head through the slot of the cutting block with a sawblade of 0.89 mm thickness.
If a re-resection is necessary, transfer the cutting block onto the pins using the proximal holes (2 mm re-resection).

Fig. 17

3.4 Humeral preparation

Remove all instruments and check the height of the humeral cut.
Affinis Inverse system allows two options to continue with the procedures:

1. Perform the glenoid preparation now.
   (The Retroversion Guide can serve as a protection for the humeral resection plane while preparing the glenoid.)
2. Or fix a trial or implant stem first.

Fig. 18

Insert the Retrotorsion Guide and use the lateral and medial slots to mark the correct alignment of the rasp.

Fig. 19

Lock the Rasp firmly into the Positioner.
Screw the alignment rod into the hole corresponding to the desired retroversion. Align the alignment rod parallel to the patient's forearm to achieve the chosen setting.
Ream the medullary cavity step-by-step (beginning with the smallest size rasp).

Fig. 20

The correct depth has been reached when the laser marking on the positioner is in line with the resection plane.

Stem dimensions:

Rasp size	Trial Stem	Uncemented Stem	Cemented Stem
6.0	6	6.0 mm	6.0 mm
7.5		7.5 mm	
9.0	9	9.0 mm	9.0 mm
10.5		10.5 mm	
12.0	12	12.0 mm	12.0 mm
13.5		13.5 mm	
15.0	15	15.0 mm	15.0 mm

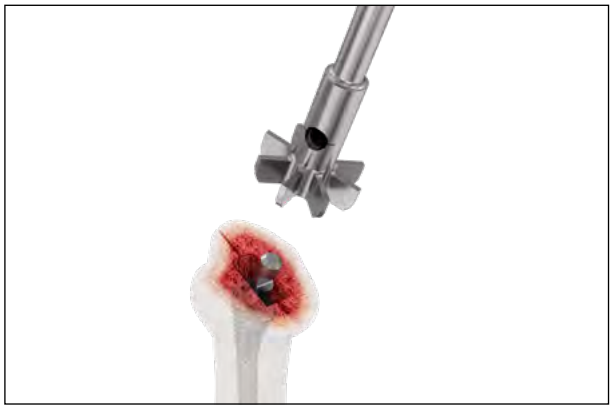


Fig. 21

Fig. 22

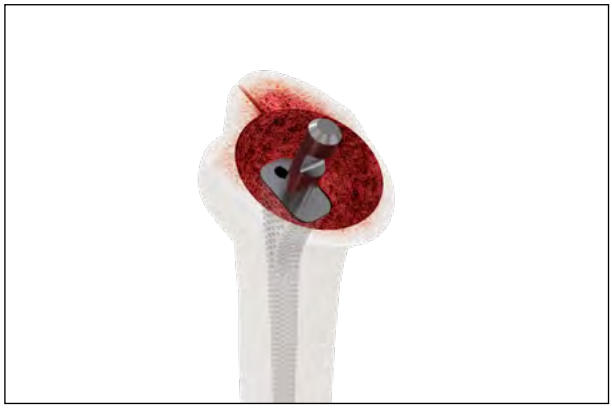


Fig. 23

Remove the positioner but leave the rasp in the humerus.
Ream the metaphyseal cavity with the Humeral Reamer 1. Sufficient reaming is achieved when the top of the reamer is aligned with the resection plane. Visually check the depth by aligning the laser marking of the reamer shaft with the top of the bolt on the rasp.

Fig. 24

To finalise humeral preparation, remove the rasp and finish the reaming of the metaphyseal cavity with the Humeral Reamer 2. Stop reaming as soon as the reamer is flush with the resection plane.

Fig. 25

3.5 Implantation of trial stem – optional technique

Screw the Guiding Bolt onto the appropriate Trial Stem. Lock the trial stem firmly into the positioner. Insert the trial stem into the prepared humeral cavity.

The trial stem does not confirm rotational stability. Do not impact or induce rotation on the trials, otherwise the humeral cavity and final implant press fit may be damaged.

Disconnect the positioner and the guiding bolt.

Fig. 26

Fig. 27

Optional step

It is recommended to use a Cover Disc to protect the humeral resection surface during preparation of the glenoid and implantation of the metaglene.

Screw the appropriate cover disc onto the trial stem with the Screwdriver 3.5.

Fig. 28

3.6 Implantation of implant stem

If you have used a trial stem, remove it.

Screw the guiding bolt onto the appropriate Inverse stem.

If using an uncemented stem: Lock the stem firmly into the positioner and impact the stem into the humeral cavity.

If using a cemented stem: The use of extensive rinsing or Jet Lavage followed by insertion of a medullary plug as a cement restrictor is recommended. Fill the humeral cavity with bone cement in a retrograde manner. Lock the stem firmly into the positioner and insert it into the humeral cavity. Remove excess cement.

Remove the positioner and the guiding bolt.

Fig. 29

Fig. 30

It is mandatory to use a cover disc to protect the humeral resection surface and the implant during preparation of the glenoid and implantation of the metaglene.
Screw the appropriate cover disc onto the stem with the Screwdriver 3.5.

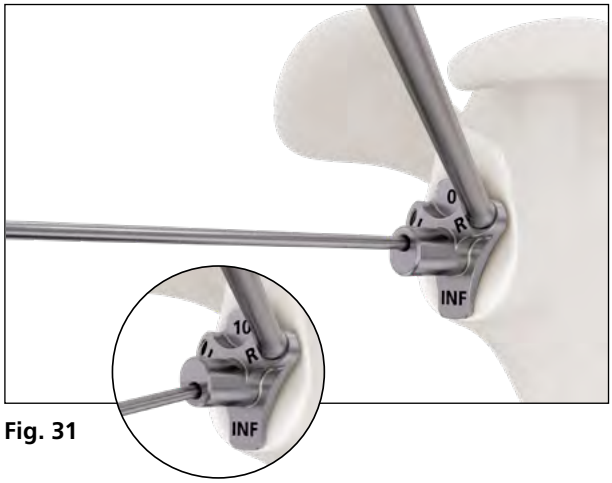


Fig. 31

3.7 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.

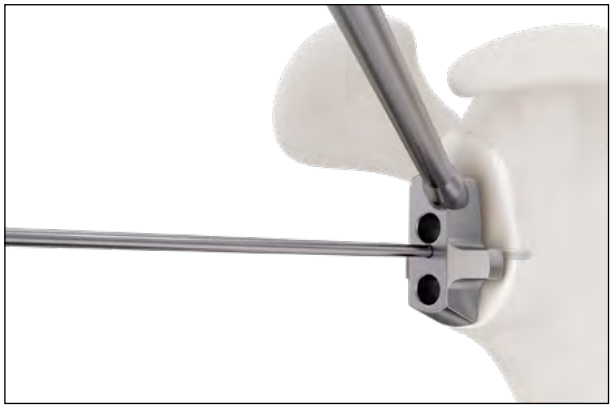


Fig. 32

Optional step

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

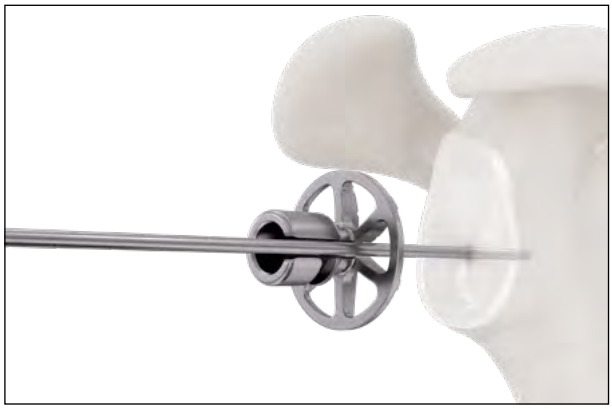


Fig. 33

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.

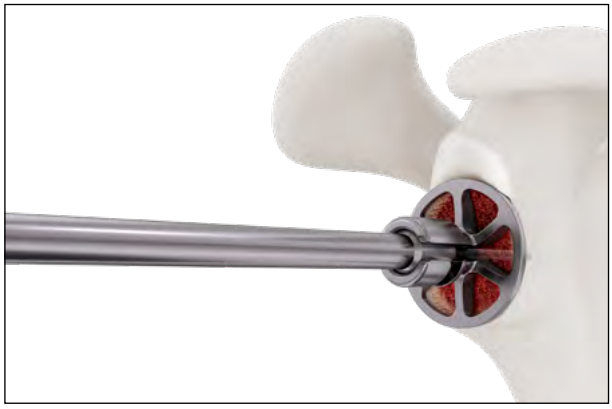


Fig. 34

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.

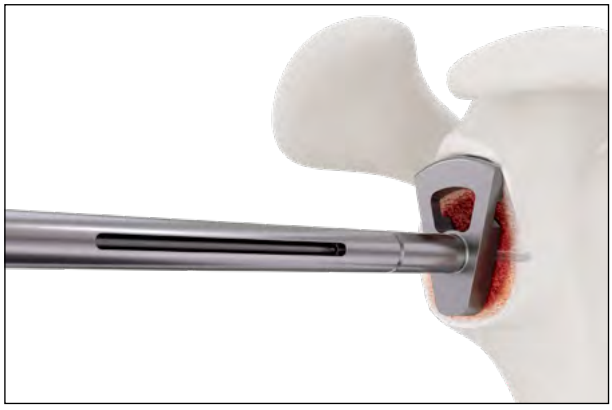


Fig. 35

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.

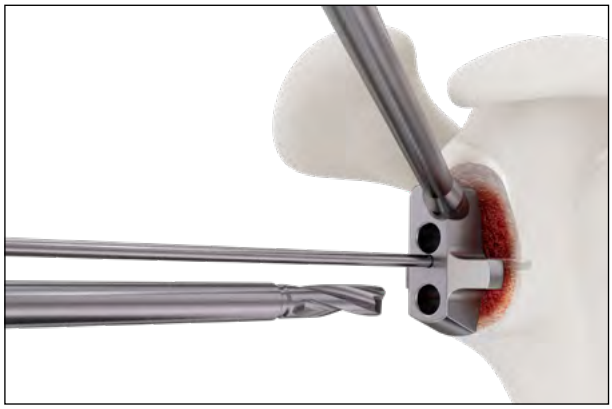


Fig. 36

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. 37

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

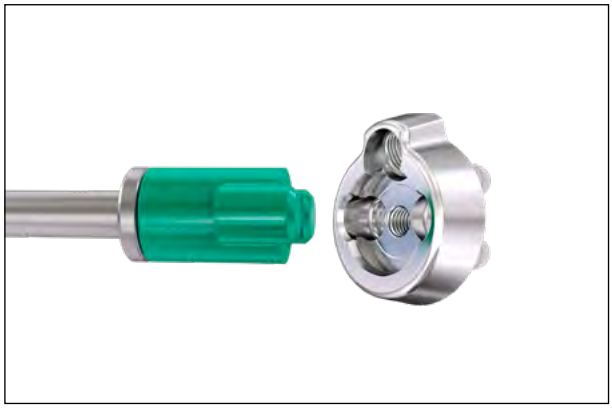


Fig. 38

3.8 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.

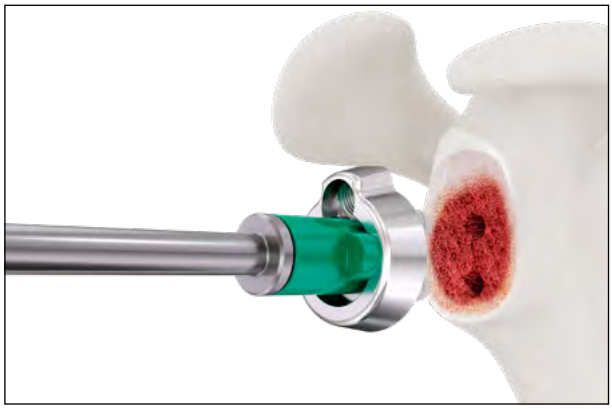


Fig. 39

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. 40

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°.

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.

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

Fig. 41

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. 42

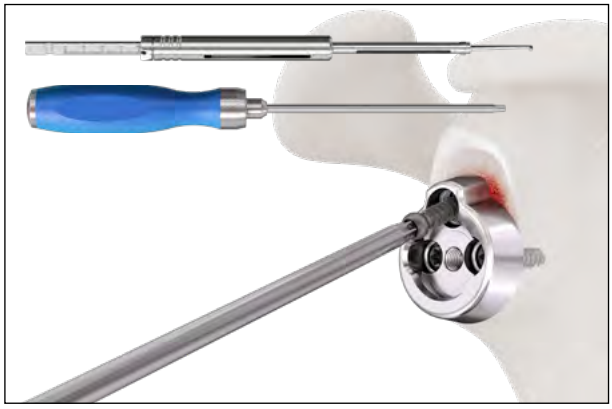


Fig. 43

Fig. 44

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.

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.

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.

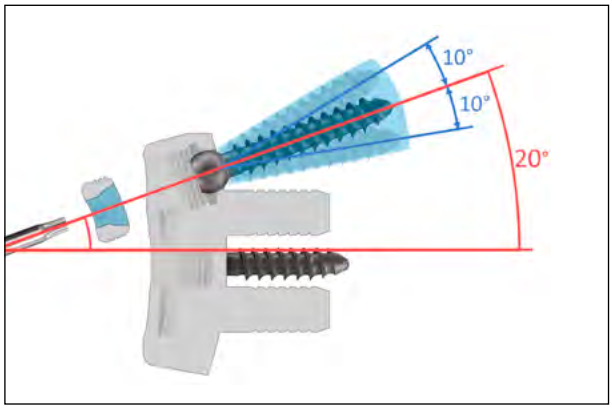


Fig. 45

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).

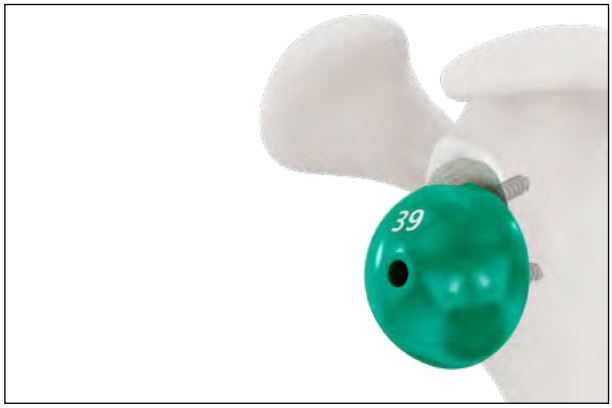


Fig. 46

3.9 Reverse trials

Optional step
The Trial glenosphere can be mounted and secured to perform trial reduction.

Fig. 47

Insert the Trial Inlay. Care must be taken to match the lateral laser marking of the trial inlay with the stem marking to ensure correct orientation.
Do not hammer in the trial inlay to ensure removal without difficulty.
Perform reduction and verify the function.
Remove the trial inlay with the Inlay Extractor.

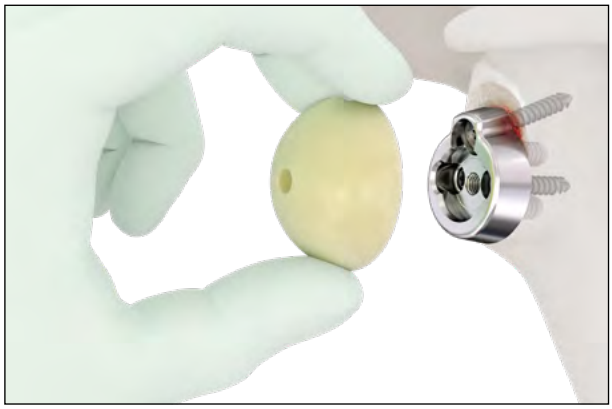


Fig. 48

3.10 Glenosphere implantation

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

Fig. 49

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. Turn back the pusher, remove the assembly rod and check if the glenosphere is fully seated on the metaglene. The glenosphere will come off easily, if not fully seated.

Fig. 50

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

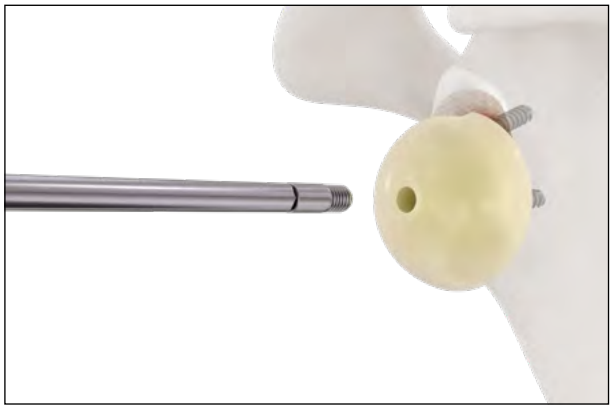


Fig. 51

Finally, screw in the fixation screw to secure the glenosphere.

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. 52

3.11 Inlay implantation

For implantation of the inlay, the Impactor Inlay with the appropriate diameter of the Inlay is used, as shown.

Insert the previously selected inlay into the stem. Care must be taken to match the lateral laser marking of the inlay with the stem marking to ensure correct implant orientation.

Clean and dry the taper seat of the stem. Insert the inlay with axial pressure without rotating it. Centrally place the Impactor Inlay in the polar region of the implant. Definitive fixation of the inlay is achieved by applying a distinct hammer stroke to the Impactor in axial direction.

Never place the impactor inlay for fixation of the inlay ceramys on the rim. This could damage the ceramic component during impaction. Never strike the ceramic implant directly with the metal hammer.

To make sure the inlay is seated firmly in place, pull the component manually. If it comes off, protruding pieces of bone or soft tissue may need to be removed.

Perform reduction and verify the function.

4. Revision

Fig. 53

4.1 Glenosphere removal
Remove the fixation screw of the glenosphere.

Fig. 54

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

4.2 Metaglene DP removal
After removing the glenosphere, remove the locking cap and all screws with the screwdriver T20.

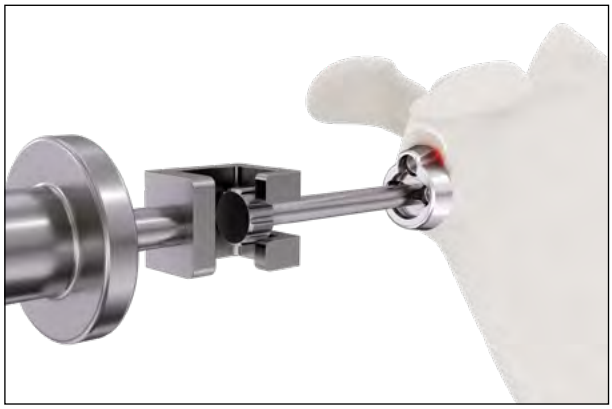


Fig. 56

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.

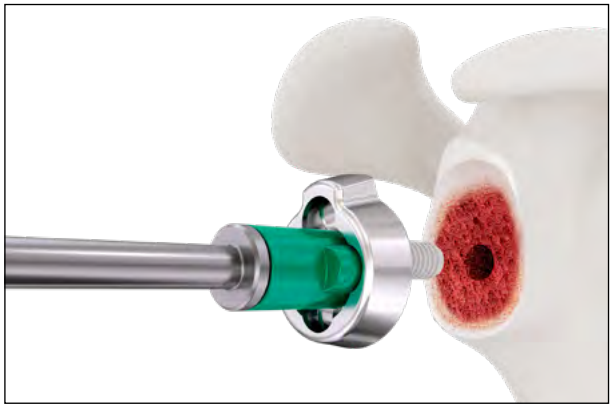


Fig. 57

4.3 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

4.4 Inlay removal

The Inlay Extractor is applied from the side between the stem and the inlay, and inserted between the two implants with light hammer blows. Thereby the Inlay disconnects from the stem.
The same instrument can also be used for the extraction of the test inlays.

To avoid damaging of the Affinis Inverse inlay ceramys, do not lever the Inlay Extractor. Only a transversal force should be applied to the instrument.

Fig. 59

4.5 Stem removal

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.

Fig. 60

4.6 Spacer and head adaptor implantation

The offset of the Affinis Inverse prosthesis sometimes has to be increased. The system offers an Affinis Inverse inlay spacer +9 (9 mm offset) that allows building increased offset up to 24 mm (2 x 9 mm spacers + 1 x 6 mm inlay).
If two spacers are used, the the separately packed fixation screw long must be used.

Fig. 61

Fig. 62

An Inverse head adaptor to convert a failed reverse prosthesis into standard hemi or total shoulder replacement is also available.
The Fracture head is 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, counterpressure must be applied to the humerus.
If a spacer is used in combination with the head adaptor, the separately packed fixation screw long must be used.

Before mounting the Affinis Fracture head, the taper must be cleaned and dried. The head-taper connection should be checked by gently pulling the Affinis Fracture head manually. If the head disengages, it may be necessary to remove protruding bone or soft-tissue pieces from the head region.

Both the Affinis Inverse inlay spacer +9 and the Affinis Inverse head adaptor must be secured with a fixation screw by the use of the counter adaptor and torque wrench.

For implantation of an Inverse head adaptor or spacer +9, use the Impactor Spacer as illustrated in figure 63. Insert the head adaptor or spacer into the stem. The components are fixated applying a distinct hammer stroke to the impactor in axial direction.

Fig. 63

The preliminary fixation of the screw of the head adaptor or spacer is performed with the Screwdriver 5.0.

Fig. 64

The adapter spacer and head adapter and alignment rod are mounted to secure the implant against rotation as a counter wrench.

The use of the counter wrench is mandatory.

One side of the adapter is used for the fixation of the head adaptor and the other side for the fixation of the inlay spacer +9.

Fig. 65

The Torque Wrench is inserted.
The Counter Wrench and the torque wrench must be used by the same person, as this is the only way to be sure of avoiding stem rotation in the bone or cement socket.
Tensioning takes place by turning the torque wrench clockwise. When the indicator of the torque wrench points away from the handle, sufficient torque has been achieved.

5. Implants

Affinis Inverse Stem, cemented

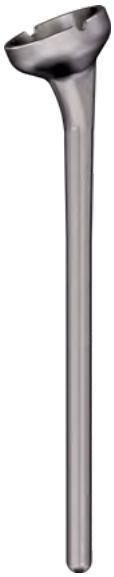
Item no.	Description
60.30.0006	Affinis Inverse stem 6 cem.
60.30.0009	Affinis Inverse stem 9 cem.
60.30.0012	Affinis Inverse stem 12 cem.
60.30.0015	Affinis Inverse stem 15 cem.

Material: Ti6Al4V

Affinis Inverse Stem, uncemented

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

Material: Ti6Al4V



Affinis Inverse Revision Stem, cemented

Item no.	Description
60.30.0186	Affinis Inverse rev. stem 6 x 180 cem.
62.34.0001	Affinis Inverse rev. stem 7.5 x 210 cem.
60.30.0209	Affinis Inverse rev. stem 9 x 200 cem.
62.34.0002	Affinis Inverse rev. stem 9 x 230 cem.
60.30.0212	Affinis Inverse rev. stem 12 x 200 cem.
62.34.0003	Affinis Inverse rev. stem 12 x 230 cem.

Material: Ti6Al4V

Affinis Inverse Revision Stem, uncemented

Item no.	Description
60.30.1186	Affinis Inverse rev. stem 6 x 180 uncem.
62.34.0004	Affinis Inverse rev. stem 7.5 x 210 uncem.
60.30.1209	Affinis Inverse rev. stem 9 x 200 uncem.
62.34.0005	Affinis Inverse rev. stem 9 x 230 uncem.
60.30.1212	Affinis Inverse rev. stem 12 x 200 uncem.

Material: Ti6Al4V

Affinis Inverse inlay ceramys

Item no.	Description
62.34.0066	Affinis Inverse inlay ceramys 36 + 0
62.34.0067	Affinis Inverse inlay ceramys 36 + 3
62.34.0068	Affinis Inverse inlay ceramys 36 + 6
62.34.0069	Affinis Inverse inlay ceramys 39 + 0
62.34.0070	Affinis Inverse inlay ceramys 39 + 3
62.34.0071	Affinis Inverse inlay ceramys 39 + 6
62.34.0072	Affinis Inverse inlay ceramys 42 + 0
62.34.0073	Affinis Inverse inlay ceramys 42 + 3
62.34.0074	Affinis Inverse inlay ceramys 42 + 6

Material: Ceramic (ZrO_2-Al_2O_3)

Affinis Inverse inlay

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

Material: CoCrMo

Affinis Inverse Glenosphere vitamys

Item no.	Description
62.34.0060	Affinis Inverse Glenosphere vitamys 36
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
60.30.3036	Affinis Inverse glenosphere 36
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

Affinis Inverse inlay spacer +9

Item no.	Description
60.30.2449	Affinis Inverse inlay spacer +9

Material: Ti6Al4V

Affinis Inverse head adaptor

Item no.	Description
60.30.7000	Affinis Inverse head adaptor

Material: Ti6Al4V

Affinis fixation screw long

Item no.	Description
60.30.7002	Affinis fixation screw long

Material: Ti6Al4V

The Affinis Fixation screw long is needed when the Affinis Inverse inlay spacer +9 is combined with a second Affinis Inverse inlay spacer +9 or with an Affinis Inverse head adaptor.

Affinis Fracture head

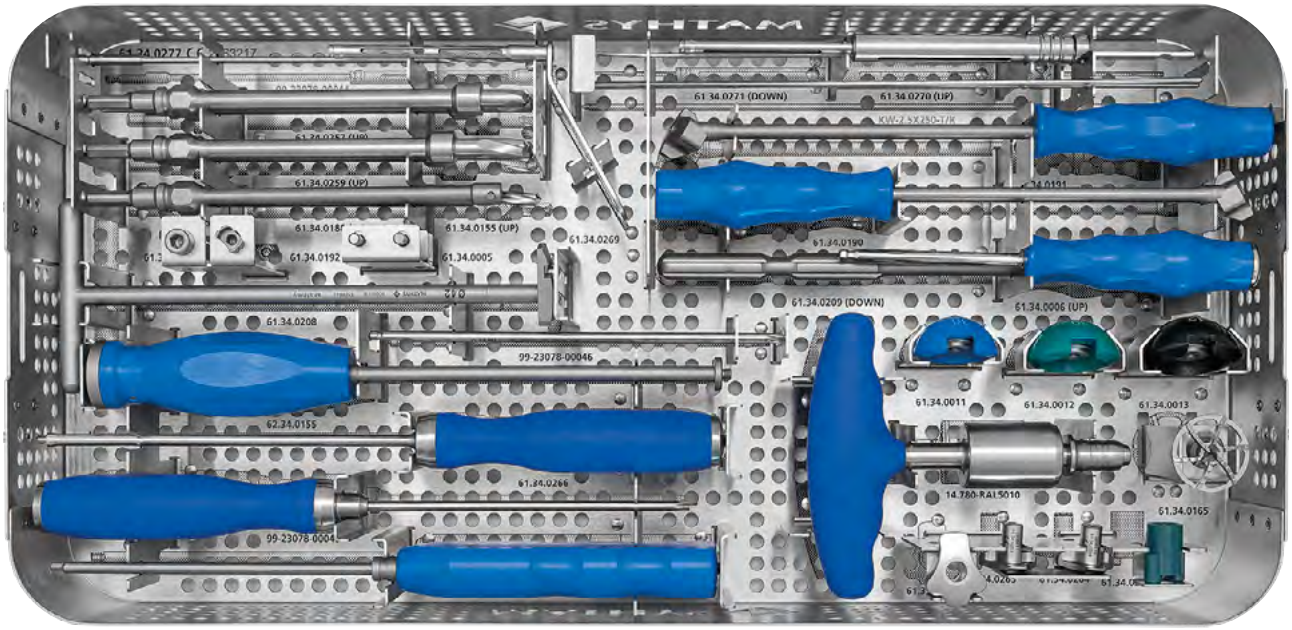
Item no.	Description
60.25.0042	Affinis Fracture head 42
60.25.0045	Affinis Fracture head 45
60.25.0048	Affinis Fracture head 48

Material: Ceramic (Al_2O_3)

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

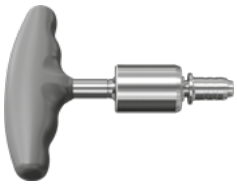
Item no.	Description
62.34.0155	Affinis Inv. Impactor, Gen 2

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

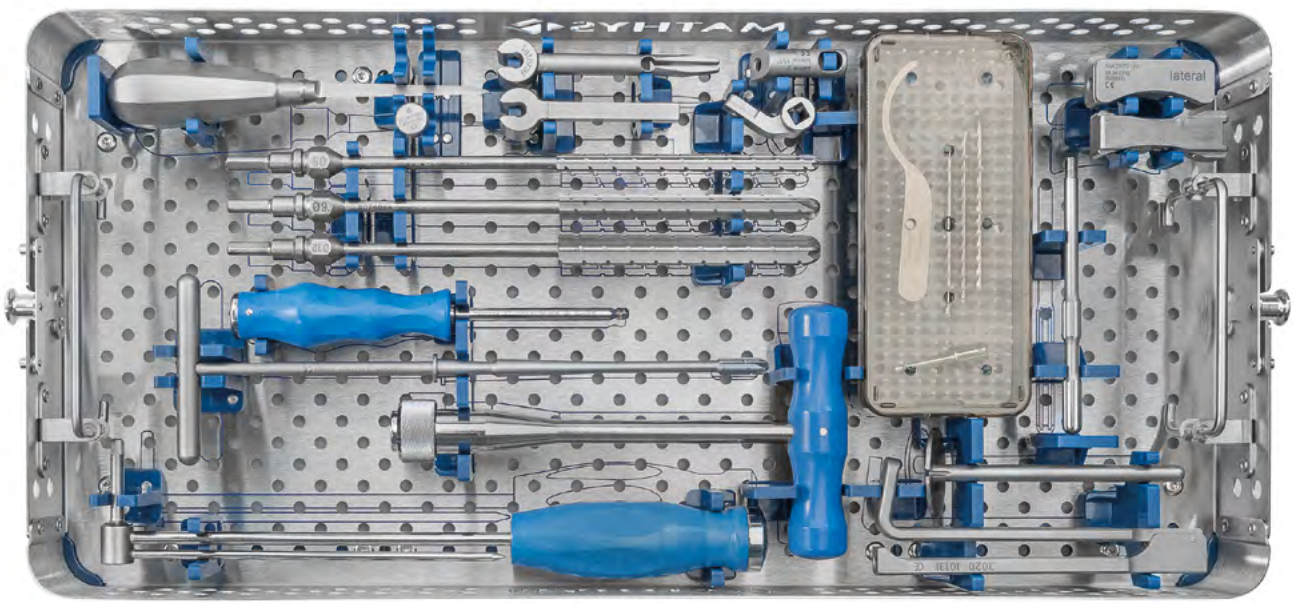
Item no.	Description
61.34.0209	Affinis Inv Assembly Rod Holder, Gen 2

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 Inverse Resection SMarT Instrument Set 61.34.0246A



Item no.	Description
61.34.0227	Affinis Lid
61.34.0234	Affinis Inverse Tray 1

Item no.	Description
504.99.02.01.0	Affinis awl

Item no.	Description
61.34.0217	Affinis Guide Rod for Resection

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
5241.00.3	Handle

Item no.	Description
502.06.01.05.0	Affinis cutting block

Item no.	Description
502.06.01.06.0	Affinis screw for resection guide

Item no.	Description
60.02.0002	Affinis holder for resection guide

Item no.	Description
61.34.0004	Affinis Inverse glider resection guide

Item no.	Description
61.34.0210	Affinis Alignment Rod, Gen 2

Item no.	Description
71.34.0647	Drill Pin 3.2/89/2.25

Item no.	Description
71.34.0787	Quick Coupling Square 2.25

Item no.	Description
3020-INNO	Pin Extractor

Item no.	Description
502.06.16.00.0	Affinis stylus

Item no.	Description
504.99.04.00.0	Affinis Screwdriver 5.0

Item no.	Description
6020.00	Torque wrench

Item no.	Description
60.02.2002	Affinis Inverse retrotorsion guide

Optional instruments

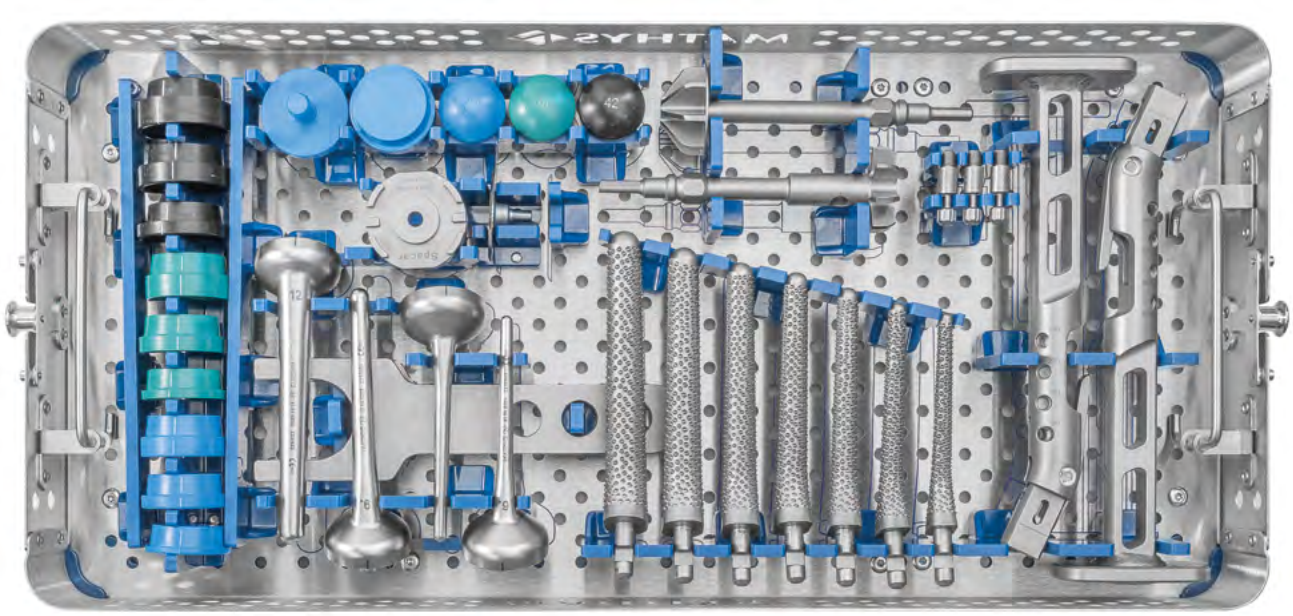
Item no.	Description
61.34.0041	Affinis medullary reamer 7.5 dia.
61.34.0042	Affinis medullary reamer 10.5 dia.
61.34.0043	Affinis medullary reamer 13.5 dia.

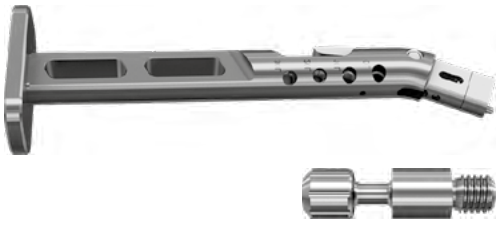
Item no.	Description
61.34.0253	Holder for Resection Guide lateral, Gen 2

Item no.	Description
61.34.0255	Glider for Resection Guide lat 155°,Gen 2

Item no.	Description
61.34.0252	Cutting Block lateral, Gen 2

Affinis Inverse Humeral Preparation SMarT Instrument Set 61.34.0247A





Item no.	Description
61.34.0227	Affinis Lid
61.34.0235	Affinis Inverse Tray 2

Item no.	Description
61.34.0203	Affinis Inverse Positioner, Gen 2

Item no.	Description
61.34.0193	Affinis Inverse Guiding Bolt, Gen 2

Item no.	Description
61.34.0196	Affinis Inverse Rasp 6, Gen 2
61.34.0197	Affinis Inverse Rasp 7.5, Gen 2
61.34.0198	Affinis Inverse Rasp 9, Gen 2
61.34.0199	Affinis Inverse Rasp 10.5, Gen 2
61.34.0200	Affinis Inverse Rasp 12, Gen 2
61.34.0201	Affinis Inverse Rasp 13.5, Gen 2
61.34.0202	Affinis Inverse Rasp 15, Gen 2

Item no.	Description
61.34.0194	Affinis Inverse Humeral Reamer 1, Gen 2

Item no.	Description
61.34.0195	Affinis Inverse Humeral Reamer 2, Gen 2

Item no.	Description
60.02.2017	Affinis Inverse trial inlay 36 + 0
60.02.2018	Affinis Inverse trial inlay 36 + 3
60.02.2019	Affinis Inverse trial inlay 36 + 6
60.02.2020	Affinis Inverse trial inlay 39 + 0
60.02.2021	Affinis Inverse trial inlay 39 + 3
60.02.2022	Affinis Inverse trial inlay 39 + 6
60.02.2023	Affinis Inverse trial inlay 42 + 0
60.02.2024	Affinis Inverse trial inlay 42 + 3
60.02.2025	Affinis Inverse trial inlay 42 + 6

Item no.	Description
62.34.0152	Affinis Inv. Impactor Inlay 36, Gen 2
62.34.0153	Affinis Inv. Impactor Inlay 39, Gen 2
62.34.0154	Affinis Inv. Impactor Inlay 42, Gen 2

Item no.	Description
61.34.0010	Affinis Inverse trial spacer + 9

Item no.	Description
62.34.0151	Affinis Inv. Impactor Spacer, Gen 2

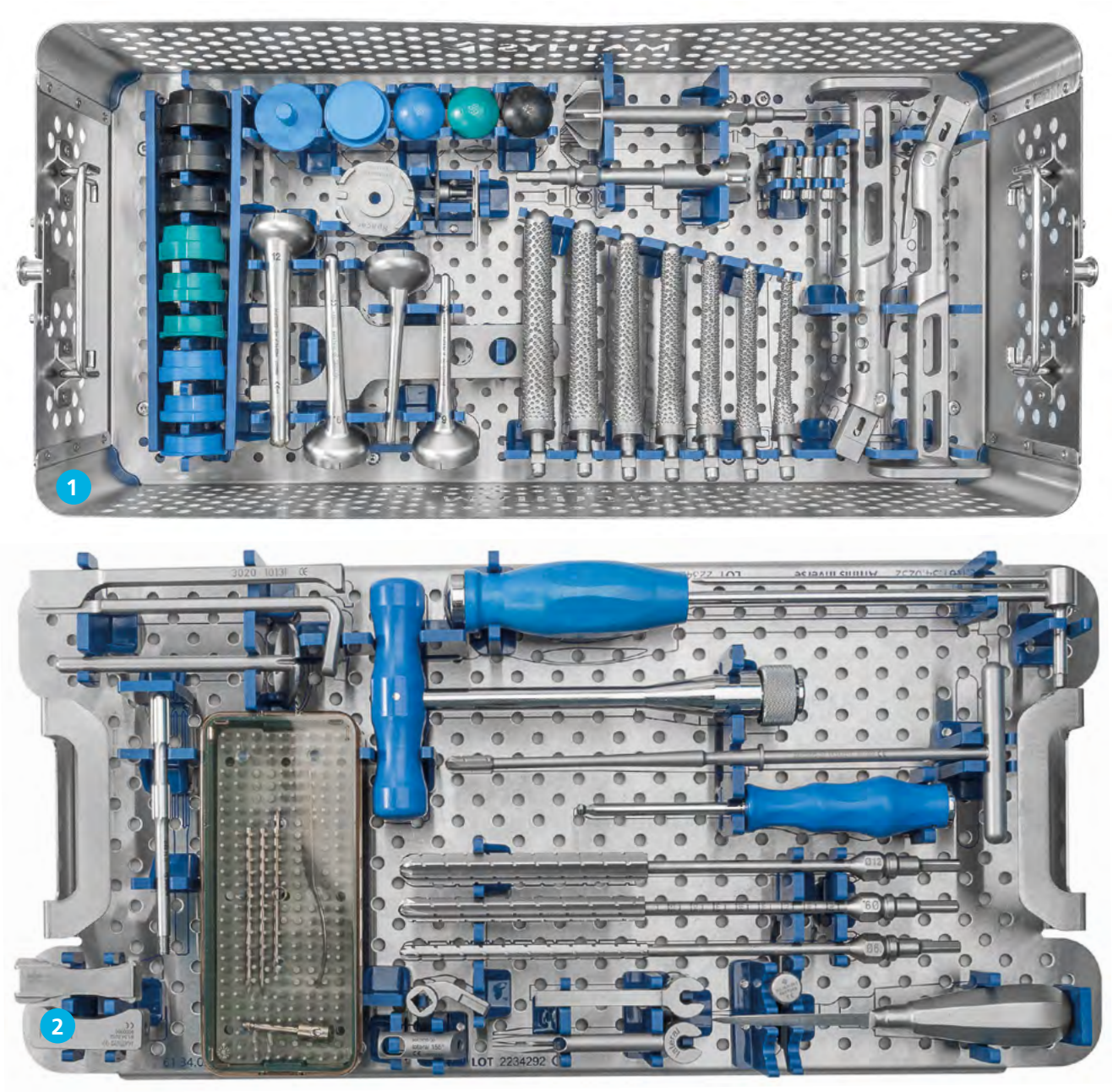
Item no.	Description
61.34.0034	Affinis Inv. adapter spacer + head adapter

Item no.	Description
61.34.0147	Affinis Inverse Inlay Extractor

Item no.	Description
61.34.0008	Affinis Inverse cover disc
61.34.0240	Affinis Inverse Cover Disc 47

Item no.	Description
61.34.0204	Affinis Inverse Trial Stem 6
61.34.0205	Affinis Inverse Trial Stem 9
61.34.0206	Affinis Inverse Trial Stem 12
61.34.0207	Affinis Inverse Trial Stem 15

Affinis Inverse Resection + Humeral Preparation SMarT Instrument Set 61.34.0249A



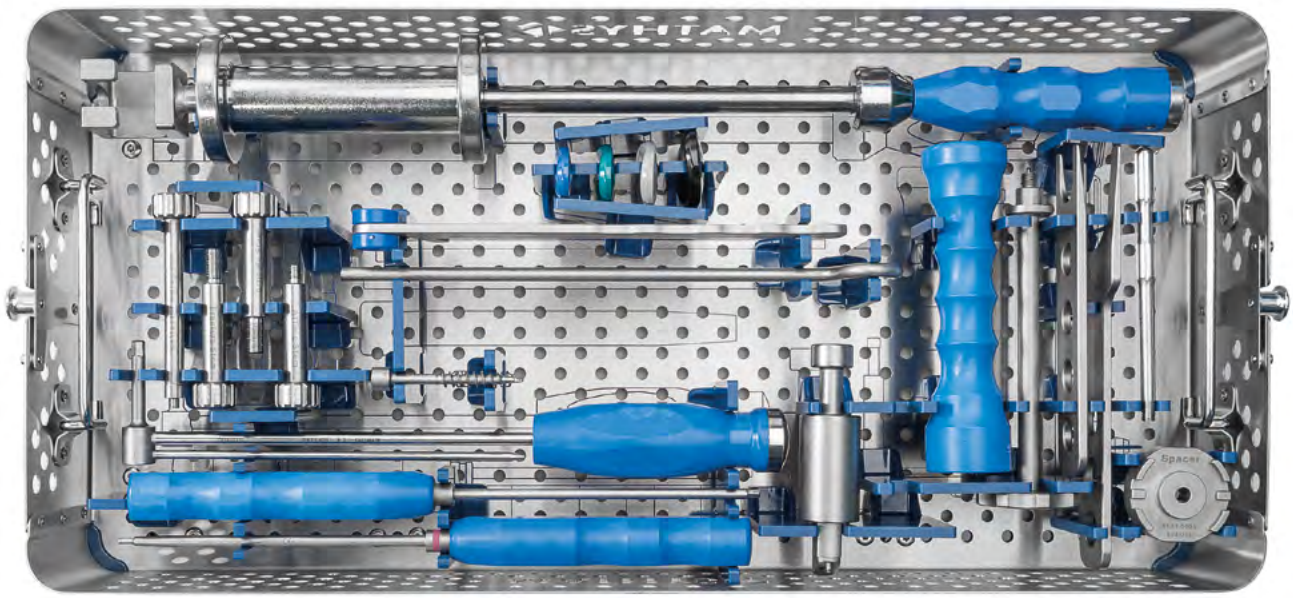
The contents of Affinis Inverse Resection + Humeral Preparation SMarT Instrument Set (61.34.0249A) is identical to the following two sets combined:

Item no.	Description	
61.34.0227	Affinis Lid	
61.34.0232	Affinis Inverse Humerus Insert	2
61.34.0233	Affinis Inverse Humerus Tray	1

Item no.	Description
61.34.0246A	Affinis Inverse Resection SMarT Instrument Set
61.34.0247A	Affinis Inverse Humeral Preparation 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 Lid

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

Item no.	Description
61.34.0024	Affinis Inverse glenosphere extractor

Item no.	Description
61.34.0055	Affinis Inverse metaglene extractor

Item no.	Description
61.34.0050	Affinis slide hammer

Item no.	Description
61.34.0147	Affinis Inverse Inlay Extractor

Item no.	Description
61.34.0054	Affinis Inverse stem adapter

Item no.	Description
60.02.2011	Affinis Inverse positioner screw

Item no.	Description
61.34.0034	Affinis Inv. adapter spacer + head adapter

Item no.	Description
61.34.0210	Affinis Alignment Rod, Gen 2

Item no.	Description
6020.00	Torque wrench

Item no.	Description
502.06.03.00.0	Affinis head impactor

Item no.	Description
504.99.04.00.0	Affinis Screwdriver 5.0

Item no.	Description
99-23078-00045	Screwdriver T20

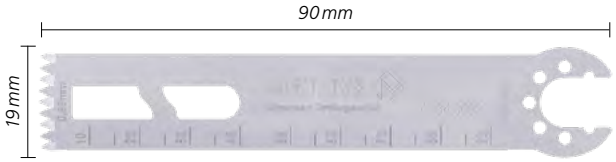
6.3 Sawblades

The following sawblades are compatible with the **Affinis** instruments:

Standard Sawblades (Single use)

Sawblade sterile 90 x 22 x 0.89

Item no.	Connection	Dimension
71.02.3111	DePuy Synthes	90 x 22 x 0.89

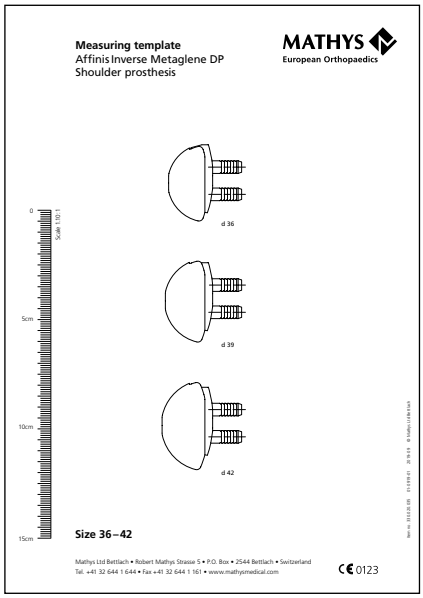


Sawblade sterile 90 x 19 x 0.89

Item no.	Connection	Dimension
71.34.0692	DePuy Synthes	90 x 19 x 0.89

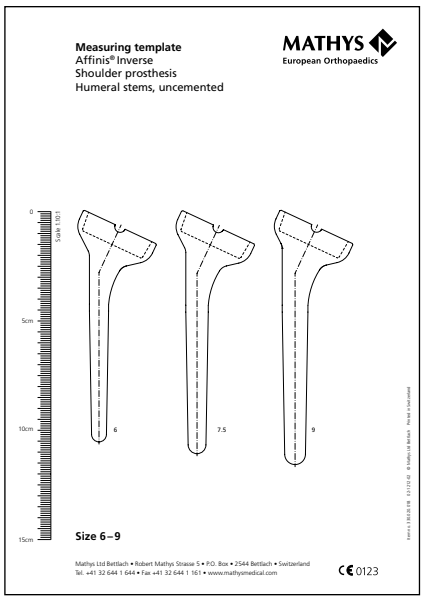
The shoulder sawblades are all sterile and individually packed.

7. Measuring template



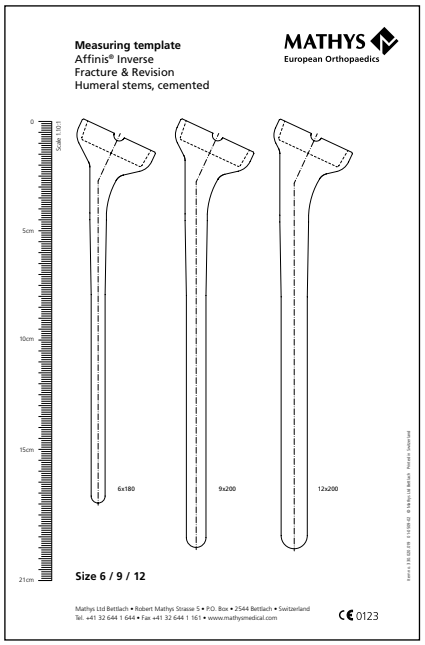
The item code for the one part Affinis Inverse metaglene DP Measuring Template is 330.020.035.

Item no.	Description
330.020.035	Affinis Inverse metaglene DP Template



The item code for the seven part Affinis Inverse Measuring Template is 330.020.018.

Item no.	Description
330.020.018	Affinis Inverse 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

8. Symbols

Manufacturer

Caution

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