

Affinis[®] Fracture
Trauma Shoulder Prosthesis
Surgical technique



Affinis  *Fracture*

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Note

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

1. Introduction



1.1 Introduction

The field of shoulder prosthesis has undergone rapid development in the last few years. Based on many years of very positive experience with the Articular prosthesis, the next generation, Affinis Fracture, has now been developed.

The aim of fracture prosthesis is to restore mobility and to eliminate pain, so that the patient can manage the activities of everyday life.

A main objective here is the anatomical reconstruction of the rotator cuff, which is achieved through the precise and secure fixation of the tuberosities to the shaft of the humerus and the prosthesis.

You can continue to rely on the existing benefits such as continuously variable adjustment of height and retroversion, as well as primary stability provided by the spikes. Based on CT-models the prosthesis has been anatomically redesigned. Additionally the latest findings in refixation techniques have been incorporated. On growth of the tuberosities is furthermore improved by the newly added bioactive CaP coating.

The result will please you too:

Affinis Fracture

1.2 New features

- Bioactive CaP coating of the central part
- Second lateral refixation hole for anatomical repositioning of the tuberosities close to the head
- Optimised refixation concept

1.3 Proven advantages

- Simple and precise instrumentation
- Continuously variable height adjustment
- Continuously variable retroversion adjustment
- Our proven surface structure with spikes for exact and firm fixation of the tuberosities
- Simple, functional surgical strategy with primary cementing of the stem, without the use of trial prostheses
- Optimum ligamentous balance





1.4 Implant philosophy

The Articula's anatomical shaping, as well as the spikes which ensure a high degree of primary stability, have also been adopted for other new innovative fracture prosthesis.

With the Affinis Fracture, we are now taking the next step, and are concentrating on improving the problem of the high number of «vanishing» tuberosities, which has remained unsolved to date. Stable reattachment of the tuberosities plays just as important a role here as the anatomical shaping of the metaphysial prosthesis component (central part) which supports ongrowth behaviour.

For this reason, the central part of the Affinis Fracture has been provided with a rough surface as well as a bioactive coating. Blood cells which stimulate bone growth are attracted through the porous surface structure. These cells activate the surrounding bone. Through this, the calcium phosphate is converted into endogenous bone within a short space of time (approx. 6 weeks). This leads to greatly improved adhesion of the tuberosities.

These factors ensure a high degree of primary stability as well as greater secondary stability, which is achieved through improved osteointegration of the tuberosities.

2. Indications

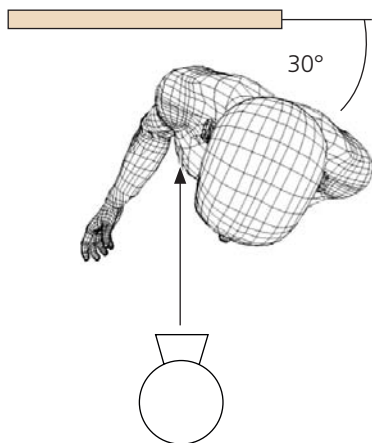
2.1 Indications

- Multi-fragment and comminuted fractures of the humeral head with a threat of a vascularisation disorder of the fragments
- Fractures of the proximal humerus that cannot be treated with osteosynthesis
- Secondary fragment dislocation following osteosynthesis in the proximal humerus in order to retain the joint function
- In certain tumourrelated modifications of the proximal humerus

2.2 Contraindications

- Acute or chronic infection, whether local or systemic (or the existence of a corresponding case history)
- Simultaneous paresis of the rotator cuff and of the deltoid muscle
- Any concomitant affection and addictions that could jeopardise the function of the implant
- Bone tumours in the region where the implant is anchored
- Neurogenic joint destruction (syringomyelia, Charcot)
- Defective humeral stem bone substance
- Hypersensitivity to the raw materials used, above all to metal (e.g. cobalt, chromium, nickel, etc.). To avoid allergic reactions, ceramic components are offered
- Immaturity of the skeleton

3. Pre-operative planning



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

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

- a.p. image centred on the joint cavity
- axial image
- CT image

4. Instructions for surgery

4.1 Positioning

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

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



Fig. 1

4.2 Approach

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

Other approaches are possible at the surgeons' discretion.

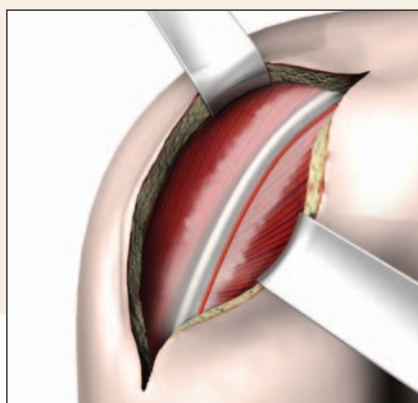


Fig. 2

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

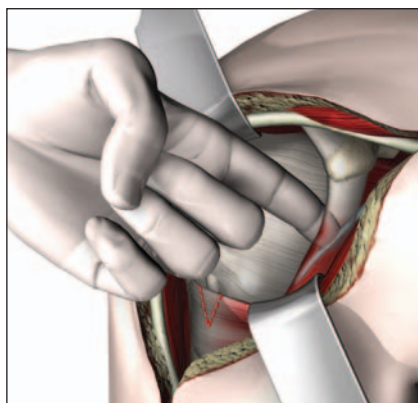


Fig. 3

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

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

For better exposure, the insertion of the pectoralis major muscle can be notched close to the humerus (approx. 2 cm). In this case, please mark the highest point of its insertion beforehand. This will allow you to use the insertion as a reference point later.

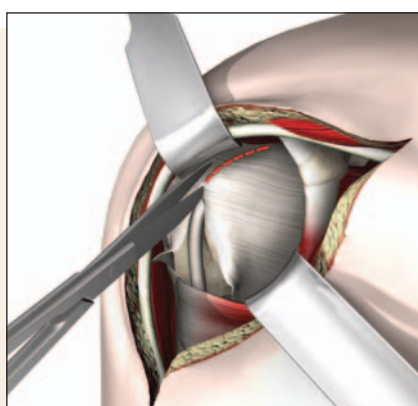


Fig. 4

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 coraco-acromial ligament, which can be partially notched 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 should be tenotomised and reinforced with non-absorbable threads for later tenodesis on the proximal shaft (sulcus area). The intra-articular stump is resected.



Fig. 5

After that, 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.

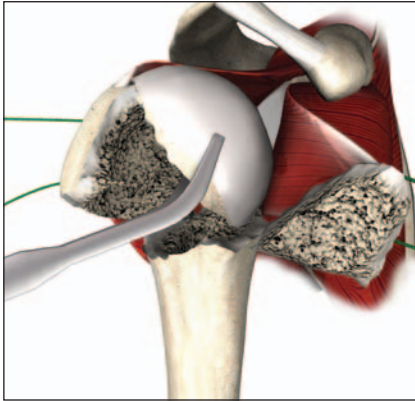


Fig. 6

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. The implantation of a glenoid component is described in the surgical technique for the Affinis total shoulder prosthesis.



Fig. 7

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-fragment 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 very 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 or modified Kirschmayr technique.



Fig. 8

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

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

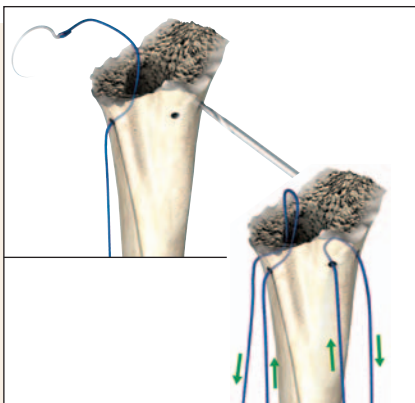


Fig. 9

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. 10

Before cementing the central part is mounted in a **central position** (laser marking) onto the stem. This means that after cementing, it is still possible to displace the central part of the prosthesis 5 mm caudally or cranially respectively, for the purposes of exact anatomical positioning.

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

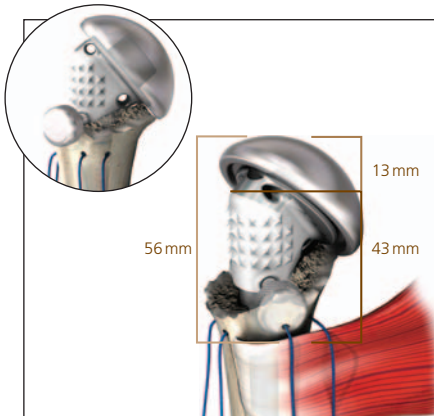


Fig. 11

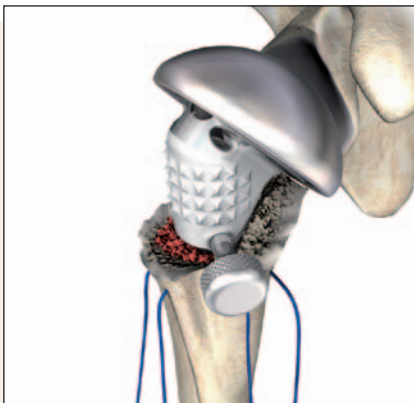


Fig. 12

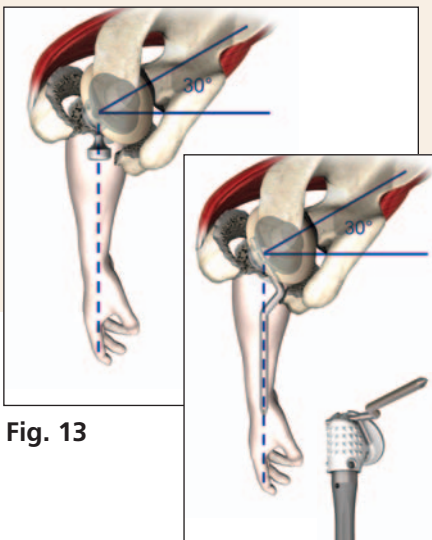


Fig. 13

Height positioning

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 length adjustment.
- If there is an extreme comminution of the medial metaphysis, the anatomical repositioning using the medial calcar can become impossible. A further possibility for setting the correct height is then provided by the measurement method after Murachovsky et al (JSES 2006, 15, 675-678):

Here, the height from the upper edge of the pectoralis major muscle attachment on the shaft of the humerus to the upper edge of the prosthesis head is measured. According to the anatomical study, this is 56 mm on average. For simplification, the distance from the pectoralis major to the shoulder of the central part can be measured, with the adjustment value here being 43 mm.

Bone cement is introduced into the medullary space, the anterior fixation screw or the retrotorsion pointer is aligned to the lower arm, and the pre-mounted prosthesis (central part and stem) is inserted. The alignment towards the lower arm corresponds to a retroversion of 30° to the lower arm and 20° to the transepicondylar axis.

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.

After the bone cement has hardened, the trial head is mounted (the size depends on the calotte that has been removed). In order to avoid overstuffing, in cases of doubt the smaller head should be used.

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

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

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



Fig. 14

Caution!

The central part must completely cover the slits on the stem (bracing mechanism).

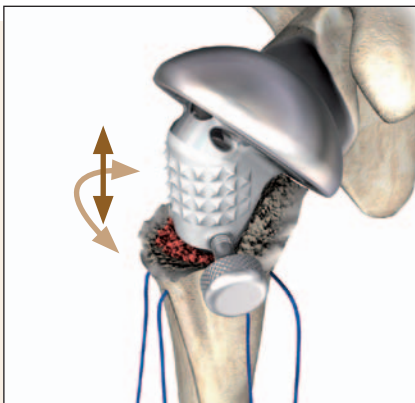


Fig. 15

To perform reduction

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

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).

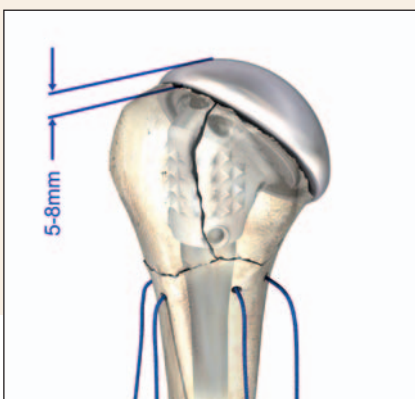


Fig. 16

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

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

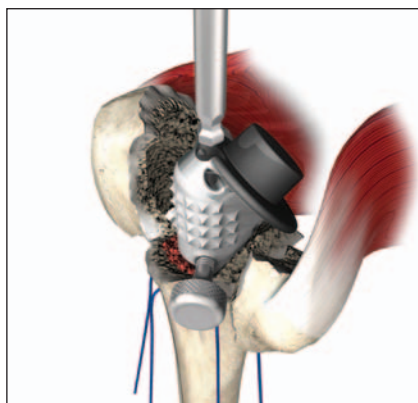


Fig. 17

The trial head is now removed and the final fixation of the central part to the stem is ensured with the following steps:

1st step:

Pre-fixation of the central part with the Allen key, until a resistance is encountered.

2nd step:

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

The use of the counter wrench is mandatory.

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

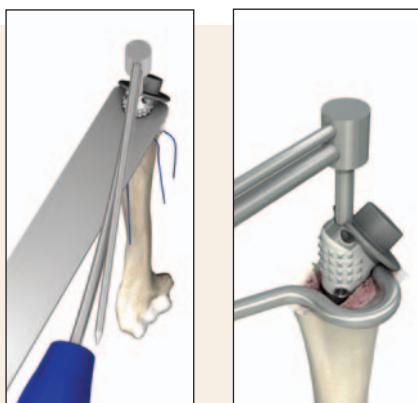


Fig. 18

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

The adjusting screw can now be removed.

The definitive prosthesis head (corresponding to the size of the trial head) is then fixed through firm mounting and slight turning.



Fig. 19

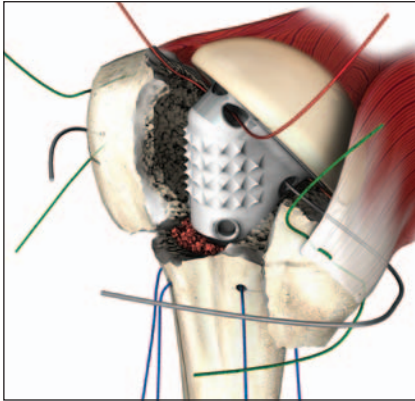


Fig. 20

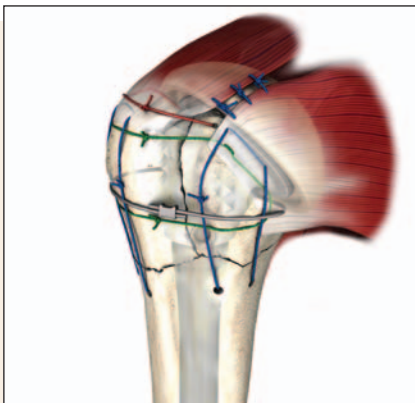


Fig. 21

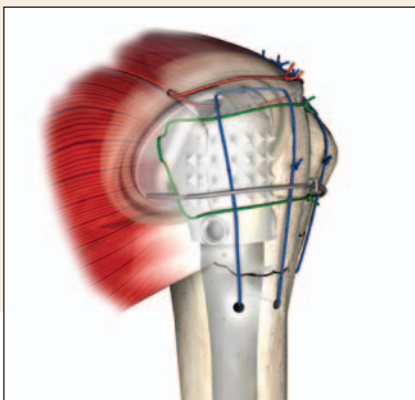


Fig. 22

The following steps lead to stable refixation:

Holding or fixation sutures

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

Fixation or compression sutures

3. Using the sutures placed in the shaft at the outset, the tuberosities are now fixed on the shaft of the humerus. These sutures must be tightened forcefully.
4. The whole package is then compressed onto the bioactively coated central part, by means of encircling suture or cable. A high degree of primary stability is thereby achieved. The course of the suture runs through the medial drilled hole, through the tendon/bone interval, and is fixed over the two tuberosities.

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

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

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

5. Overview of implants

Affinis Fracture 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



Affinis Fracture central part

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



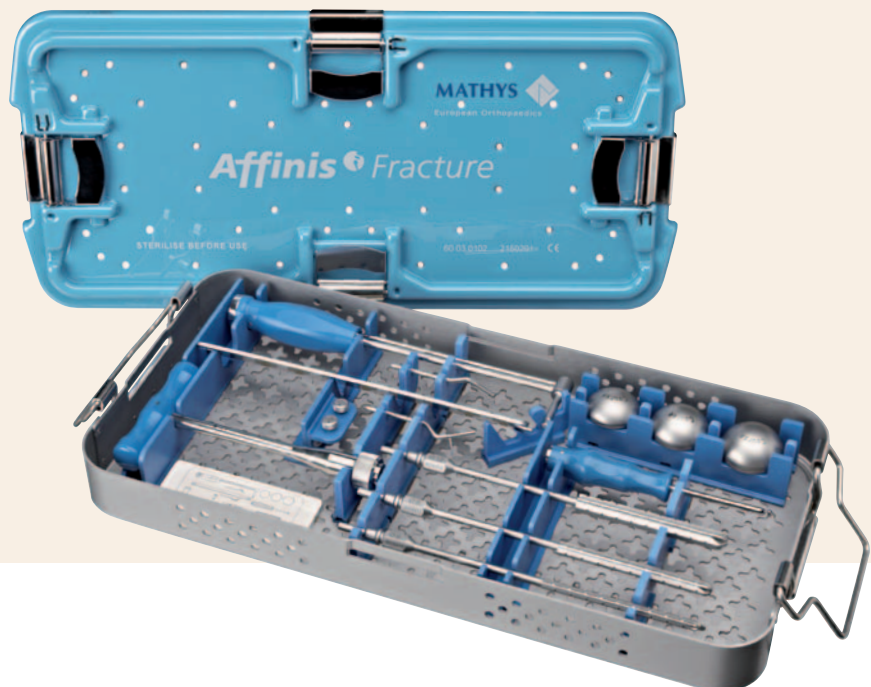
Affinis Fracture stem

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

6. Overview of instruments

Affinis Fracture instrument set (60.01.0100)

Item no.	Description
5241.00.3	Handle
6008.00.04	Adjusting screw
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
6020.00	Torque wrench
61.34.0048	Affinis counter-wrench Inverse / Fracture
60.02.1010	Affinis Fracture retrotorsion pointer left
60.02.1011	Affinis Fracture retrotorsion pointer right
504.99.04.00.0	Affinis hexagonal screwdriver
60.02.1042	Affinis Fracture trial head 42
60.02.1045	Affinis Fracture trial head 45
60.02.1048	Affinis Fracture trial head 48
60.03.0100	Affinis Fracture instrument tray
60.03.0102	Affinis Fracture lid



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