

EXCLUSIVE DISTRIBUTOR IN BRAZIL

ATTIS
M E D I C A L

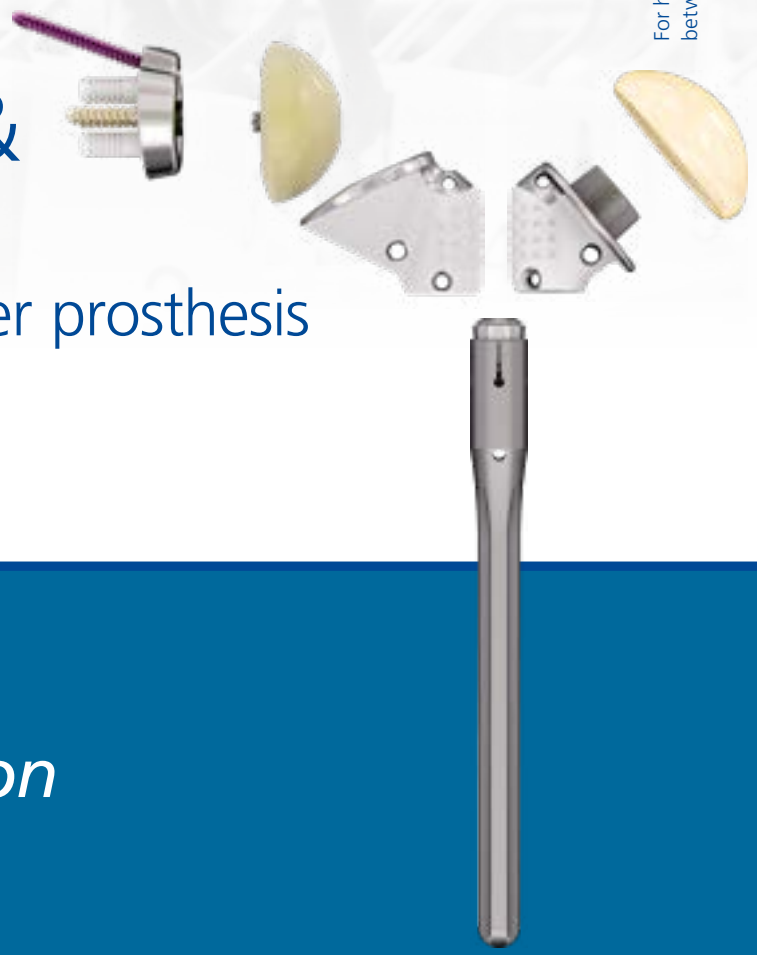
MATHYS 
European Orthopaedics



Surgical technique

Affinis Fracture & Fracture Inverse

Modular fracture shoulder prosthesis



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.

Introduction

Treatment with Affinis Fracture or Affinis Fracture Inverse is used when fractures of the humeral head which are difficult to reconstruct. The modular platform system allows intraoperative decision-making and the conversion from a hemiprosthesis to an inverse prosthesis and vice-versa.

The Affinis Fracture System is based on a cemented stem and allows conversion after poor healing of a primary implant into an inverse prosthesis. A securely anchored stem can be left in situ. In addition, the modularity allows the surgeon to decide between a hemiprosthesis or an inverse prosthesis during surgery.

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

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

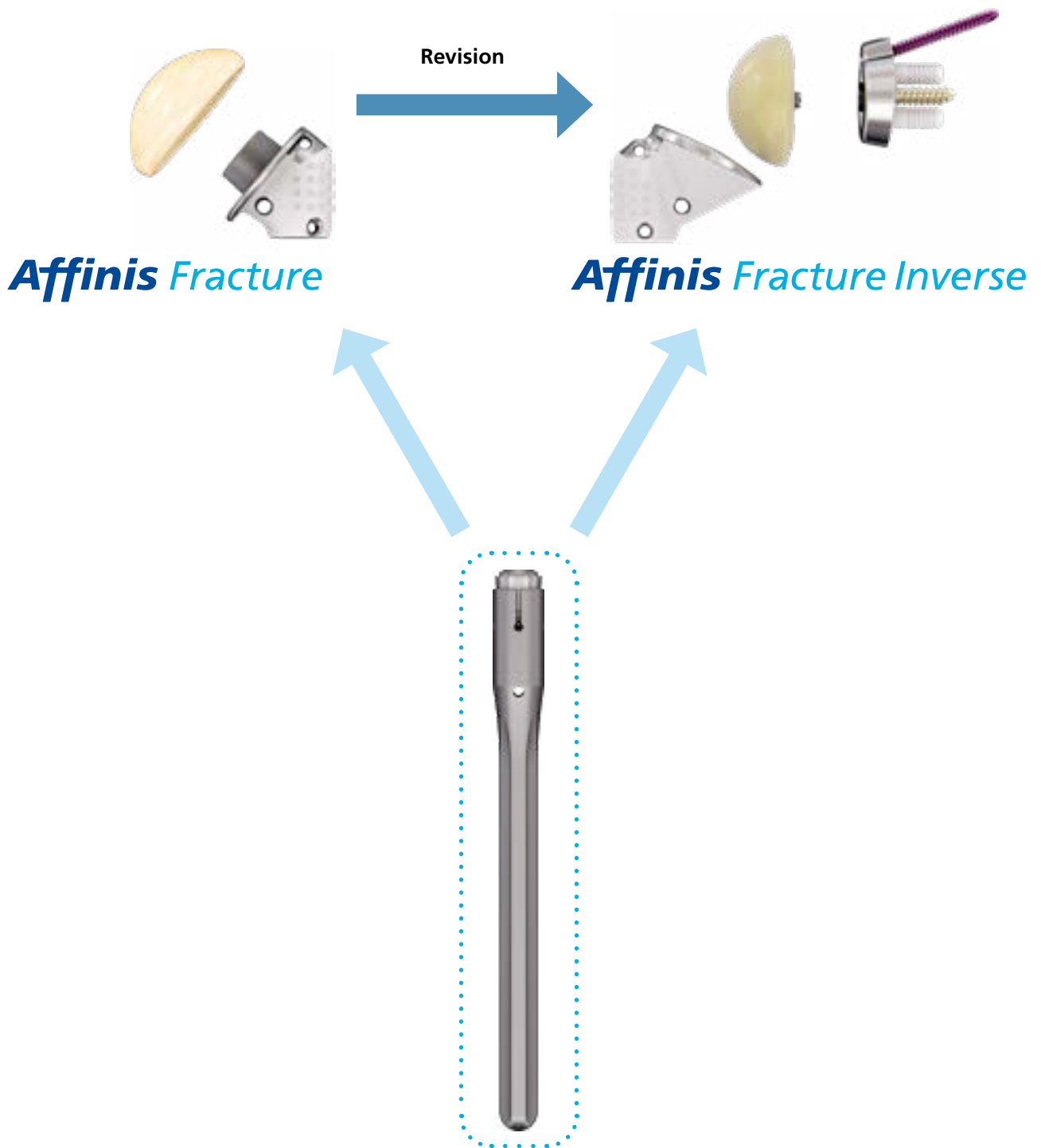
Advantages

- Continuous height and rotation adjustment
- Modular platform system for less invasive revision surgeries²
- Osteoconductive calcium phosphate coating for improved ingrowth of the tuberosities¹
- 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.

Modular platform system



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

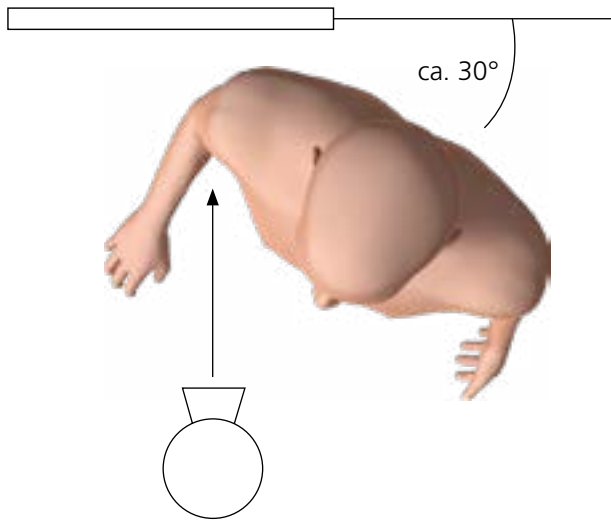
Indications for Affinis Fracture Inverse

- 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

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.

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 Stem

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

Material: Ti6Al4V



Affinis Inverse metaglène

Item no.	Description
60.30.3150	Affinis Inverse metaglène

Material: Ti6Al4V, TiCP + CaP coated



Affinis Inverse revision metaglène

Item no.	Description
60.30.3151	Affinis Inverse revision metaglène

Material: Ti6Al4V, TiCP + CaP coated



Affinis Inverse glensphere

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

Material: UHMWPE / FeCrNiMoMn / Ti6Al4V



Affinis Inverse Glensphere vitamys

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

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



Affinis Inverse lag screw

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

Material: Ti6Al4V



Affinis locking screw

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

Material: Ti6Al4V