MATHYS
European Orthopaedics

Affinis®
Total Shoulder Prosthesis
Surgical technique

Affinis

Contents

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.

Introduction

To move and live an active life – Mathys has lived by this maxim for over 50 years. This point of view enables us to achieve our objective: to give back a life of movement to as many people as possible; Affinis® contributes its part to it.

Total shoulder prosthesis

- Exact anatomical adjustability (reconstruction of the centre of rotation)
- The movable cone and eccentric head permit an easy and exact reconstruction of the proximal humerus
  - Mediolateral offset by the cone and the eccentric head
  - Anteroposterior offset by the eccentric head
- Guided resection while controlling retroversion
- Easy and precise instrumentation
- Rasp serves also as trial prosthesis

1. Indications

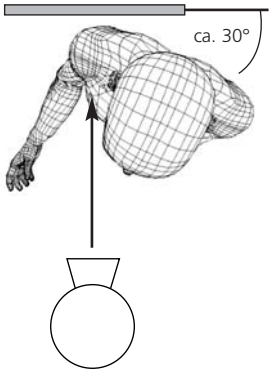
1.1 Indications

- Primary Osteoarthritis
- Secondary Osteoarthritis
  - Rheumatoid Arthritis
  - Posttraumatic Osteoarthritis
  - Cuff Tear Arthropathy (Hamada grade III or IV) in younger patients
  - Metabolic joint destruction (e.g. chondrocalcinosis, haemosiderosis, urate arthropathy)
- Fracture sequelae (malformation healing of humeral head fractures, non union healing/pseudarthrosis, head necrosis, locked dislocations)
- Avascular head necrosis

1.2 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

2. Preoperative planning



Transparent implant templates on the usual scale of 1.10:1 are available for the preoperative determination of the size of the stem, head and glenoid.

The following native X-rays of the affected shoulder are recommended:
- an anteroposterior X-ray in neutral rotation (0°), centred on the joint gap
- an axial x-ray.

A CT scan is recommended in order to plan the glenoid replacement.

A line drawn along the periphery of the head on the AP X-ray facilitates measuring of the head size. It may be necessary to make a comparative X-ray of the contralateral side, if the shape of the damaged humeral head cannot be determined accurately. Place the template onto the AP X-ray and establish the appropriate head diameter by means of the drawn line.

Determine also the size of the prosthetic stem on the AP X-ray. To achieve the best possible position for the prosthesis, the stem should almost fill the proximal and distal medullary cavity.

3. Surgical technique

Fig.1

Fig. 2

3.1 Humeral shaft

Open the medullary cavity using the awl centred in a mediolateral and anteroposterior direction relative to the intramedullary shaft axis (fig. 1).

Insert the medullary reamer using the handle. Select the 6, 9 or 12mm medullary reamer depending on the diameter of the medullary cavity (fig. 2).

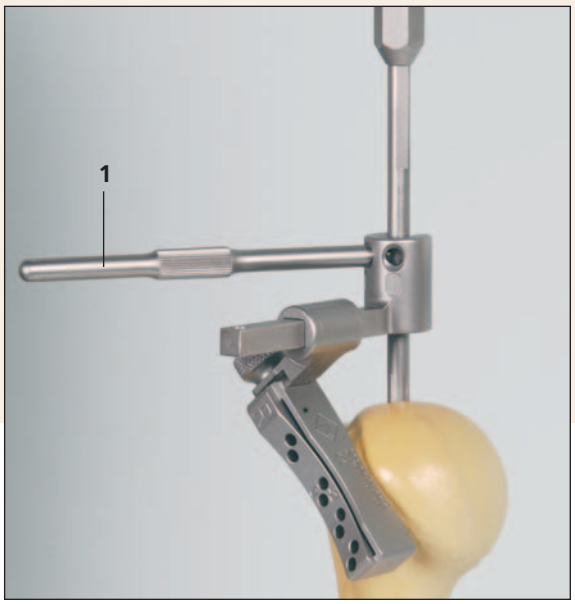


Fig. 3

Place the resection guide on the left or right side depending on the limb to be treated.
Roughly adjust the retroversion by aligning the alignment rod (1) with the forearm. This corresponds to a retroversion of 30° relative to the forearm, or 20° relative to the epicondylar axis.

Fig. 4

Use the stylus (2) to finely tune the retroversion and resection height according to the anatomical conditions. The alignment rod locks the resection guide to the medullary reamer.

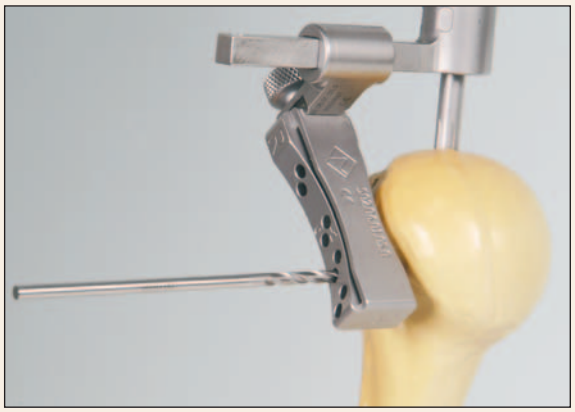


Fig. 5

Predrill the pinholes through at least two distal holes of the resection guide.

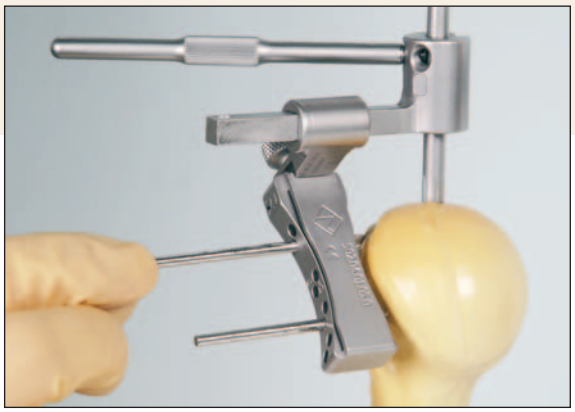


Fig. 6

Insert the 3.1mm pins.

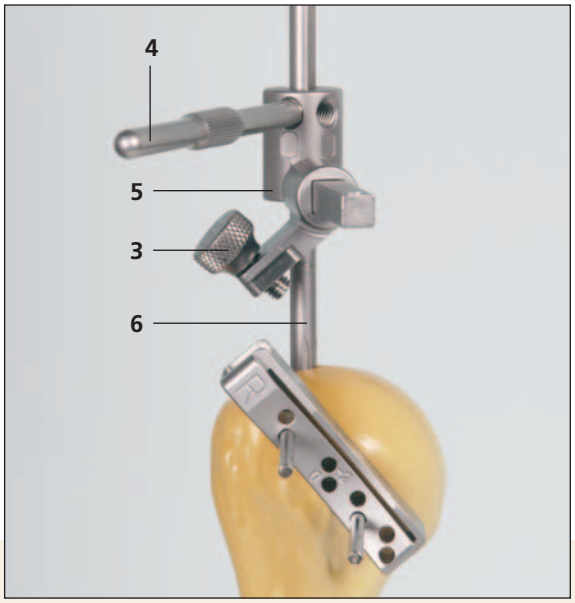


Fig. 7

Loosen the screw (3) of the resection guide and the alignment rod (4). Remove the holder (5), the medullary reamer (6) and the bearing rod.

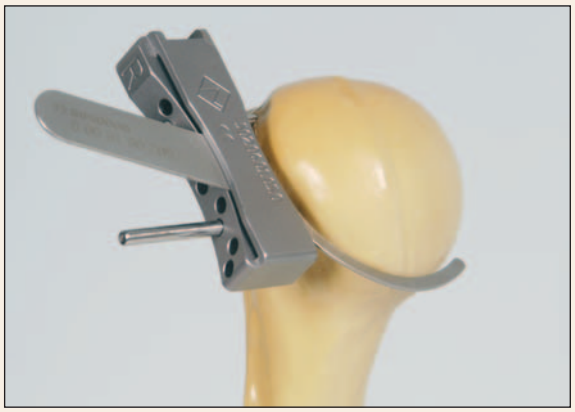


Fig. 8

Use the stylus to recheck the resection height and the retroversion.

Fig. 9

Resect the humeral head through the saw-blade guide of the resection guide. Carefully protect the rotator cuff and the long biceps tendon.

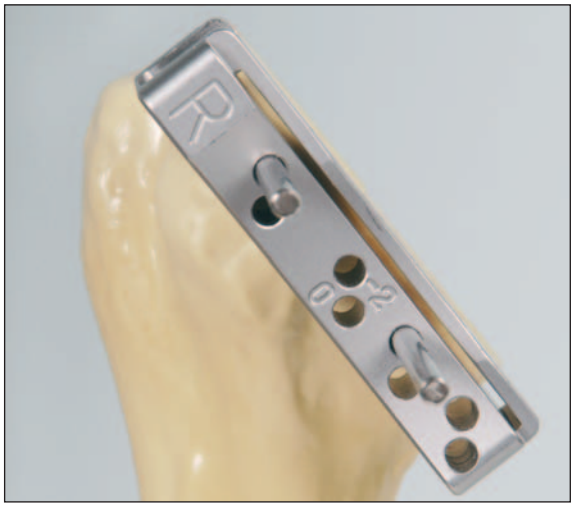


Fig. 10

If a reresection is necessary, transfer the resection guide onto the pins in the proximal holes (2mm reresection).

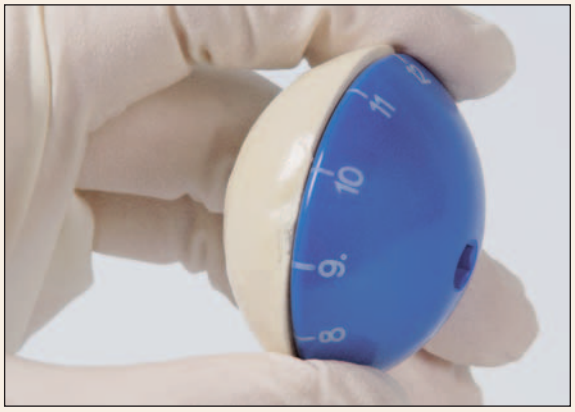


Fig. 11

Determine the head size by making a comparative measurement of the resected humeral head using the trial heads.

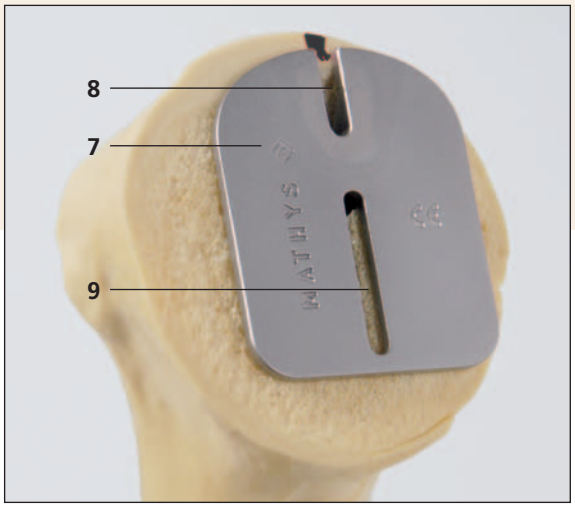


Fig. 12

Mark the retroversion position with the retroversion guide (7): Use the lateral (8) and medial slot (9) to mark the correct alignment of the rasp.

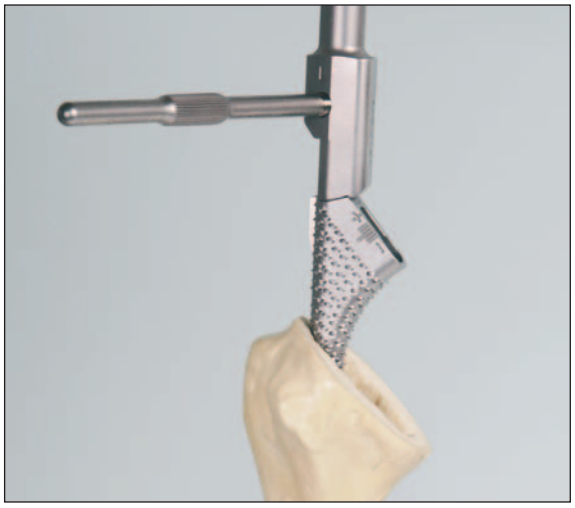


Fig. 13

Ream the medullary cavity step by step (beginning with the smallest size rasp).
Make sure the setting instrument is correctly placed and fixed firmly to the rasp during impaction.
Dimensioning of the stems within one size allows for a cement mantle in the cemented version or the press-fit of the cementless version.

Rasp size	Cementless stem	Cemented stem
6.0	6.0mm	6mm
7.5	7.5mm	
9.0	9.0mm	9mm
10.5	10.5mm	
12.0	12.0mm	12mm
13.5	13.5mm	
15.0	15.0mm	15mm

Fig. 14

Remove the setting instrument but leave the rasp in the humerus for trial reduction purposes.

If the resection and rasp plane do not concur, remove the cone and use the saw to correct the osteotomy plane with the rasp in place.

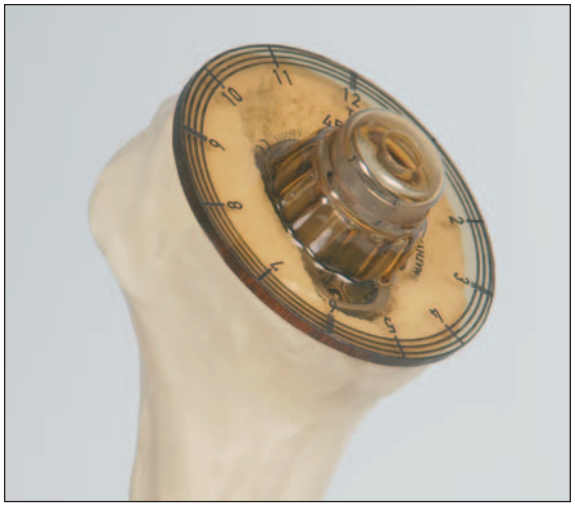


Fig. 15

3.2 Humeral head

Place the appropriate head-adjusting screen (size 39–43 or 45–51) onto the cone to determine the anatomical position of the head. Turning the adjusting screen and pushing the cone in a mediolateral direction can predetermine the medial and posterior offset and hence the optimal head size.
Fix the cone with the Allen key.

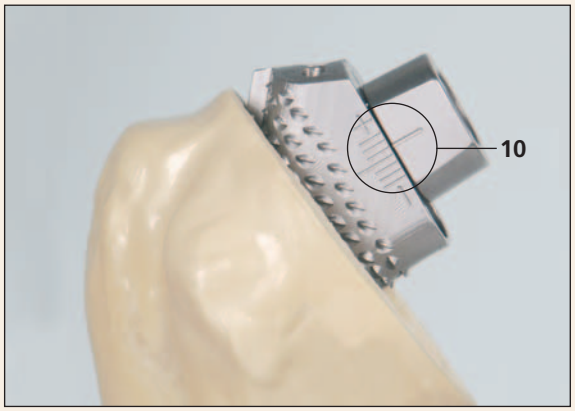


Fig. 16

Make a note of the head size (39–53), the eccentric position of the adjusting screen (1–12) relative to the lateral fin as well as of the cone position relative to the stem (10), (-3 to +3).

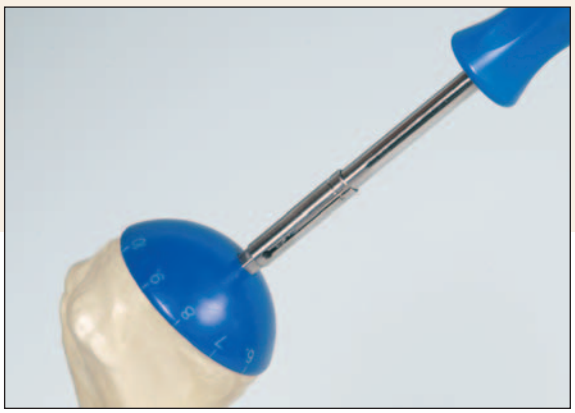


Fig. 17

Place the trial head onto the cone of the rasp in the appropriate eccentric position.
Perform a trial reduction, check the mobility as well as the articular tension, and correct both the size and the position of the head, if the result is not satisfactory.

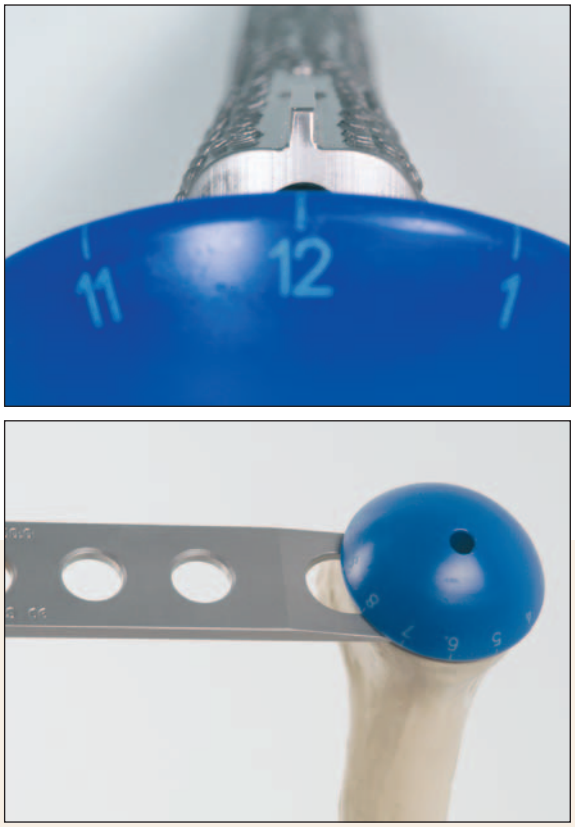


Fig. 18

Check the eccentric position of the head relative to the lateral fin, and use the positioner to remove the trial head (use the head extractor, if necessary) and the rasp.

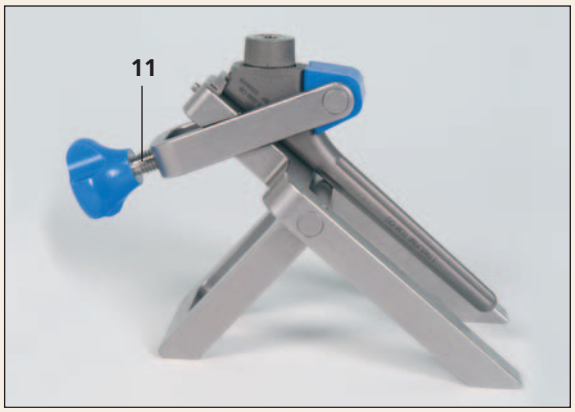


Fig. 19

Assemble the original prosthesis
Insert the stem into the assembly device.
Fix the prosthesis (11).

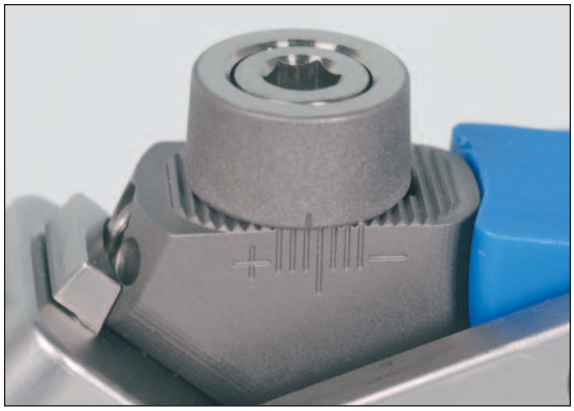


Fig. 20

Adapt the stem cone to the rasp-cone adjustment (fig. 16).

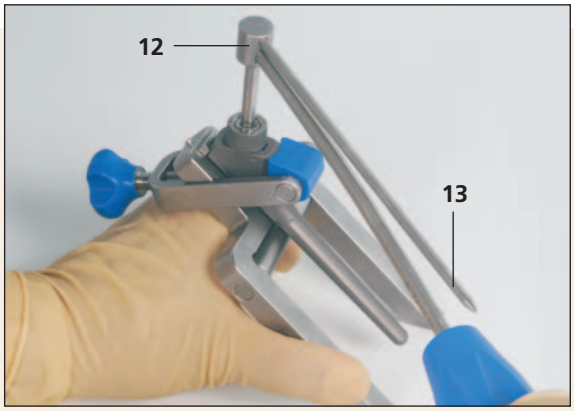


Fig. 21

Use the torque wrench (12) to block the cone/stem connection. Locking has occurred when the pointer (13) of the torque wrench moves to the outside edge of the wrench handle.

It is imperative to use the torque wrench for final blocking!

Fig. 22

Place the implant head onto the cone of the stem tightened in the assembly device in accordance with the previously noted eccentric position. Align the eccentric marking with the lateral stem fin and with the corresponding marking on the assembly device (14).
Make sure that both the stem cone and the cone recess of the head are absolutely clean and dry.

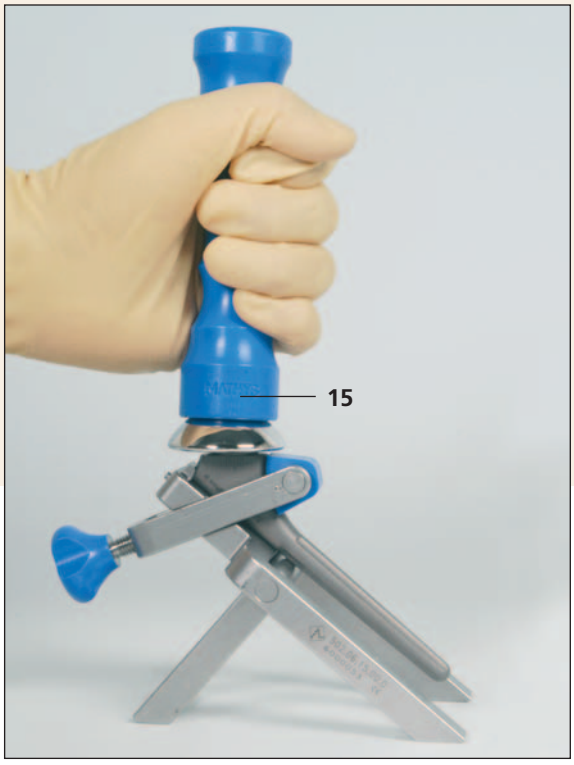


Fig. 23

Use head impactor (15) to connect the head with the stem applying **one** blow in direction of the cone axis.
Impact the cementless prosthesis or insert the cemented one as usual. The use of a bone plug is recommended!
Perform the reduction and verify the function.
Reconstruct the ligamentous apparatus and suture the capsule, the soft tissue, and the wound.

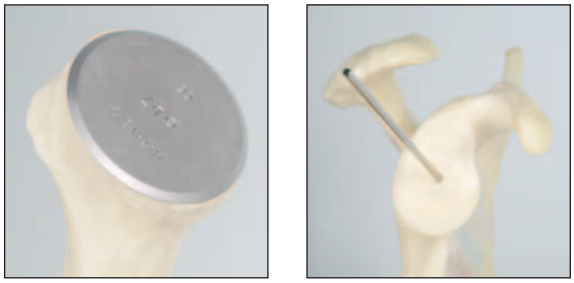


Fig. 24

3.3 Glenoid

The use of the humeral protection disc is recommended. This is inserted into the rasp to protect the humeral resection surface during preparation and implantation of the glenoid.

Centrally insert a Kirschner wire as guide for the glenoid reamer and the glenoid drill guide.

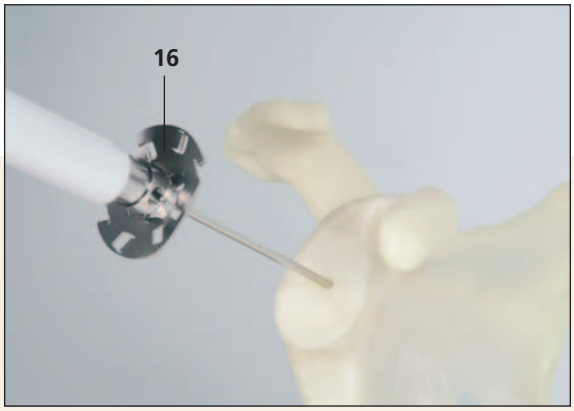


Fig. 25

Use the glenoid reamer (16) over the Kirschner wire (150mm x 2.5mm dia.) to ream the glenoid.

Glenoid reamer Ø	Glenoid size
32mm	1
36mm	2
44mm	3 + 4

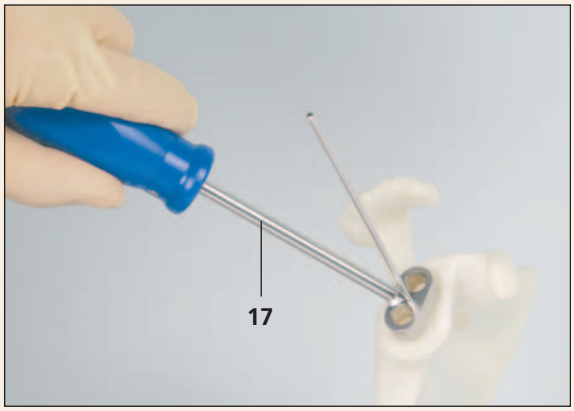


Fig. 26

Position the glenoid drill guide (17) over the Kirschner wire and correctly align the guide.

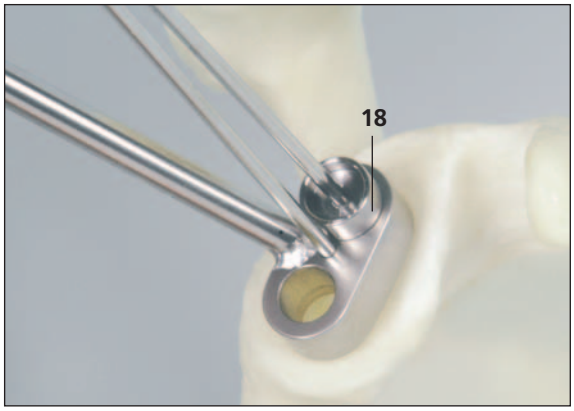


Fig. 27

Insert the 2.5mm glenoid drill sleeve (18) and a 2.5mm Kirschner wire (for rotational stability).

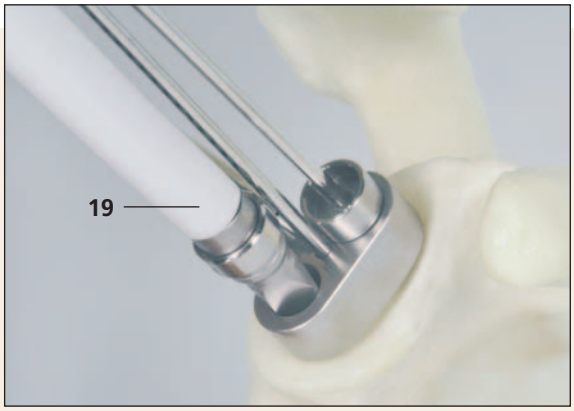


Fig. 28

Use the glenoid drill bit (19) to drill the first anchoring hole.

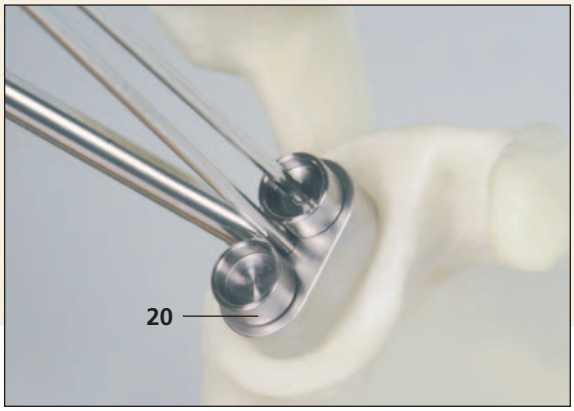


Fig. 29

Remove the drill guide and position the fixation peg (20).

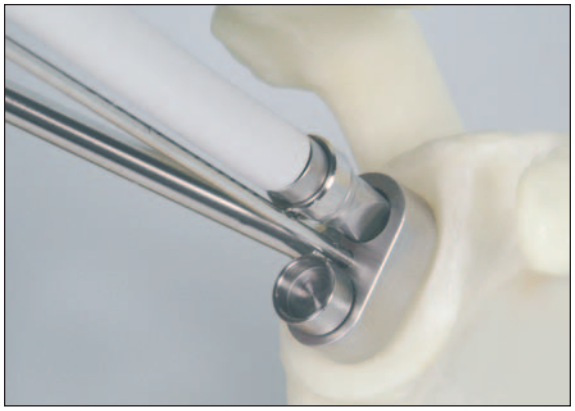


Fig. 30

Remove the 2.5mm glenoid drill sleeve with the respective Kirschner wire.

Use the glenoid drill bit to drill the second anchoring hole.

Remove the instruments.

Fig. 31

Select and insert the trial glenoid (can be held using the alignment rod).

Compatibility of head size and glenoid

Head	Glenoid
CoCr head 39/13	1
CoCr head 41/14	
CoCr head 43/15	2
CoCr head 45/16	
CoCr head 47/17	3
CoCr head 49/18	
CoCr head 51/19	4
CoCr head 53/20	

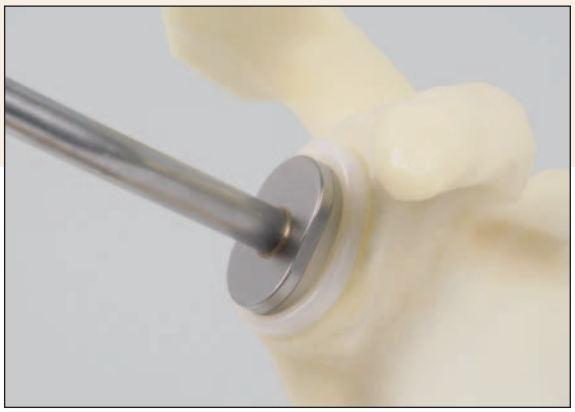


Fig. 32

Fill the reamed cavities with bone cement. Insert and adapt the glenoid component until it is flush with the spherical rest of the glenoid impactor.

Carefully remove the surplus cement. Hold it until the cement compound becomes effective.

4. Implants

4.1 Affinis® Stem

Cemented

Item no.	Description	Diameter
102.00.00.06.0	Stem	6mm
102.00.00.09.0	Stem	9mm
102.00.00.12.0	Stem	12mm
102.00.00.15.0	Stem	15mm

Cementless

Item no.	Description	Diameter
102.00.01.06.0	Stem	6mm
102.00.01.07.0	Stem	7.5mm
102.00.01.09.0	Stem	9mm
102.00.01.10.0	Stem	10.5mm
102.00.01.12.0	Stem	12mm
102.00.01.13.0	Stem	13.5mm
102.00.01.15.0	Stem	15mm

Material: TiAl6V4 alloy (sterile packed, CE marking)

4.2 Affinis® Head

Item no.	Description	Diameter	Height
102.02.00.13.0	CoCr Head 39/13 1*	39mm	13mm
102.02.00.14.0	CoCr Head 41/14 1	41mm	14mm
102.02.00.15.0	CoCr Head 43/15 2	43mm	15mm
102.02.00.16.0	CoCr Head 45/16 2	45mm	16mm
102.02.00.17.0	CoCr Head 47/17 3	47mm	17mm
102.02.00.18.0	CoCr Head 49/18 3	49mm	18mm
102.02.00.19.0	CoCr Head 51/19 4	51mm	19mm
102.02.00.20.0	CoCr Head 53/20 4	53mm	20mm

* Corresponds to the glenoid number (defined radial mismatch)

Material: Standard CoCrMo alloy (ISO 5832-4) (sterile packed, CE marking)

4.3 Affinis® Glenoid

Cemented

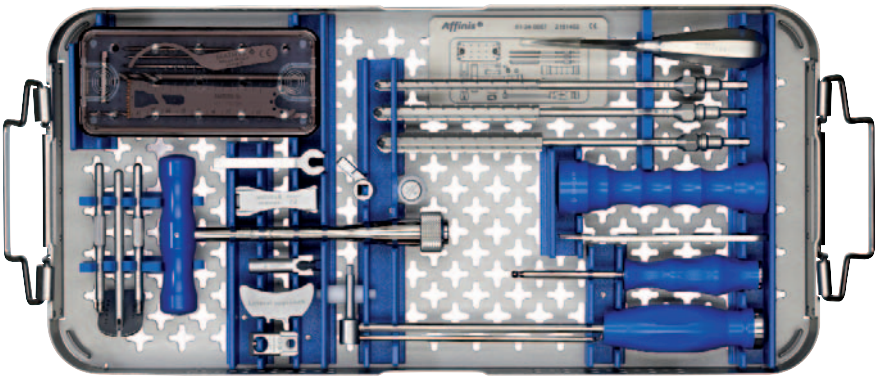
Item no.	Description	Size
102.07.02.31.0	PE Glenoid no. 1	1
102.07.02.35.0	PE Glenoid no. 2	2
102.07.02.39.0	PE Glenoid no. 3	3
102.07.02.43.0	PE Glenoid no. 4	4

Material: UHMW-PE (sterile packed, CE marking)

4.4 Affinis® Revision

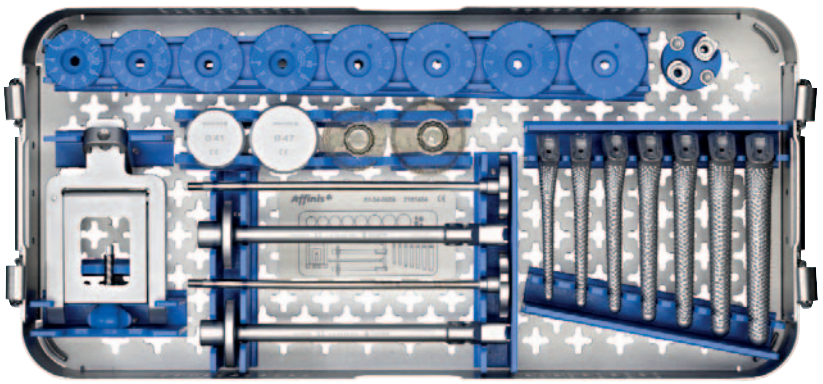
Item no.	Description	Diameter	Length
60.20.0009	Revision stem cem.	9	200mm
60.20.0012	Revision stem cem.	12	200mm
62.34.0031	Revision cone with screw		

5. Instruments



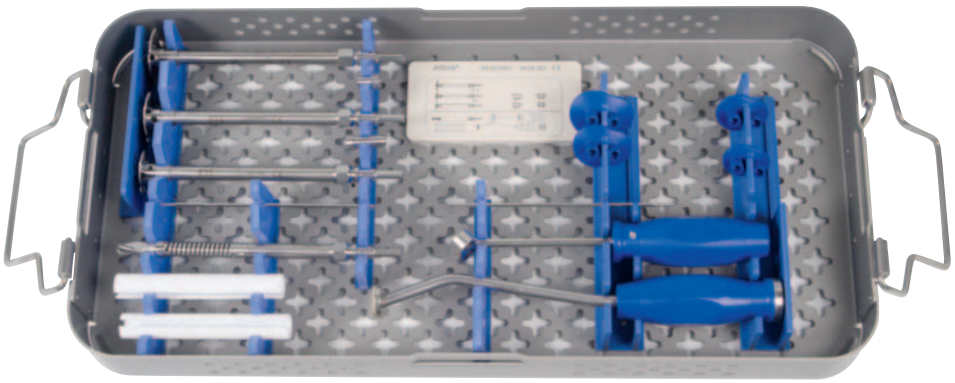
5.1 Instrumentation Affinis® Basic (61.34.0076)

Item no.	Description
61.34.0057	Affinis basic instruments tray
61.34.0058	Affinis basic instruments lid
502.06.01.03.0	Affinis glider for resection guide
502.06.01.05.0	Affinis cutting block
502.06.01.06.0	Affinis screw for resection guide
502.06.02.07.0	Affinis alignment rod
502.06.03.00.0	Affinis head impactor
502.06.07.00.0	Affinis retroversion guide
502.06.08.00.0	Affinis head extractor
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
502.06.16.00.0	Affinis stylus
503.08.07.75.0	Affinis pin 3.2/75
504.99.02.01.0	Affinis awl
504.99.04.00.0	Affinis hexagonal screwdriver
5241.00.3	Handle
60.02.0001	Affinis push-on sleeve f/trial head
60.02.0002	Affinis holder for resection guide
60.03.0005	Affinis small-instrument case
6020.00	Torque wrench
315.310	Drill bit 3.2
Optional	
502.06.17.00.0	Affinis opening drill bit
71.02.1101	Saw blade 90x22x0.9
71.02.3111	Saw blade 90x25x0.9



6.2 Instrumentation Affinis® (61.34.0077)

Item no.	Description
61.34.0059	Affinis tray
61.34.0060	Affinis lid
502.03.00.13.0	Affinis trial head 39/13/1
502.03.00.14.0	Affinis trial head 41/14/1
502.03.00.15.0	Affinis trial head 43/15/2
502.03.00.16.0	Affinis trial head 45/16/2
502.03.00.17.0	Affinis trial head 47/17/3
502.03.00.18.0	Affinis trial head 49/18/3
502.03.00.19.0	Affinis trial head 51/19/4
502.03.00.20.0	Affinis trial head 53/20/4
502.03.00.39.0	Affinis head adjusting screen 39-43
502.03.00.45.0	Affinis head adjusting screen 45-51
502.06.02.11.1	Affinis sleeve for positioner
502.06.02.12.1	Affinis rod for positioner
502.06.05.06.0	Affinis rasp 6
502.06.05.07.0	Affinis rasp 7.5
502.06.05.09.0	Affinis rasp 9
502.06.05.10.0	Affinis rasp 10.5
502.06.05.12.0	Affinis rasp 12
502.06.05.13.0	Affinis rasp 13.5
502.06.05.15.0	Affinis rasp 15
502.06.06.01.0	Affinis rasp cone
502.06.06.02.0	Affinis rasp screw
502.06.15.01.0	Affinis assembly device
502.06.18.41.0	Affinis cover disc 41
502.06.18.47.0	Affinis cover disc 47
504.09.01.08.0	Affinis screw for assembly device



5.3 Instrumentation Affinis® Glenoid (60.01.0003)

Item no.	Description
60.03.0007	Basic Tray for Affinis Glenoid
60.03.0008	Lid to Affinis Glenoid Tray
502.08.01.30.0	Affinis glenoid reamer, 32mm dia.
502.08.01.36.0	Affinis glenoid reamer, 36mm dia.
502.08.01.42.0	Affinis glenoid reamer, 44mm dia.
502.08.02.00.0	Affinis glenoid drill bit
502.08.09.00.0	Sleeve handle
502.08.10.00.0	Affinis glenoid drill guide
502.08.05.01.0	Affinis glenoid fixation peg
502.08.12.00.0	Affinis glenoid drill sleeve 2.5mm
502.08.11.31.0	Affinis trial glenoid no. 1
502.08.11.35.0	Affinis trial glenoid no. 2
502.08.11.39.0	Affinis trial glenoid no. 3
502.08.11.43.0	Affinis trial glenoid no. 4
502.08.07.00.0	Affinis glenoid impactor
292.250	Kirschner Wire, 2.5mm dia., with trocar tip, L 150mm

Notes

Notes

Notes

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