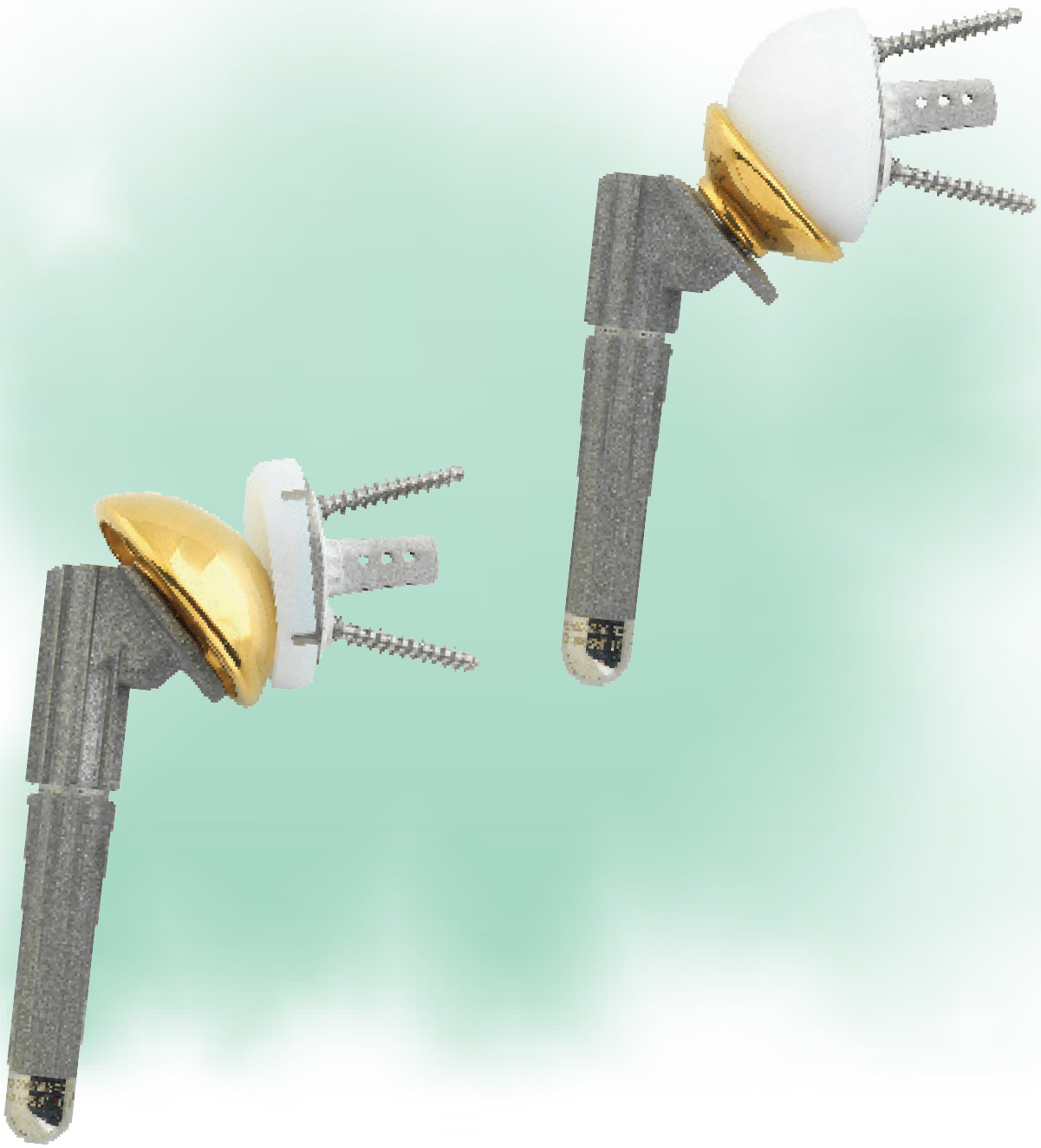
AGILON®

The modular shoulder system



implantcast

Surgical Technique
Omarthrosis Treatment
with long fit

AGILON®

The modular Shouldersystem Omarthrosistreatment

long fit

The following surgical technique was developed
in co-operation with Dr. N. Hellmers and
Dr. A. Betthäuser, Hamburg.

Table of contents

Nota Bene: The author of this technique has outlined the procedure for the uncomplicated surgical scenario. Ultimately however it is the operating surgeon who is best placed to assess and address the individual needs of each patient.

System overview

The highly modular AGILON® system provides multiple treatment options to closely match the individual requirements of each patient. A choice of trauma or omarthrosis metaphyseal components are available which can be used for anatomical or inverse geometry reconstruction. The modular design allows the surgeon to freely switch between geometries intraoperatively as well as to revise from an anatomic to an reverse geometry without necessarily changing the metaphyseal component. Additionally in the revision scenario the modular humeral diaphyseal stem and the modular glenoid plate can be left in-situ which not only shortens anaesthetic time but also preserves bone stock.

The cap offset, the metaphyseal length and the metaphyseal rotation can easily be interdependently adjusted after implantation of the diaphyseal stem offering enhanced intraoperative flexibility. However when using the omarthrosis metaphyseal option it may be preferable to preassemble the components for better press fit.

Pre-operative planning

Pre-operative planning and precise surgical techniques are mandatory for optimal results. The instructions and the procedure given in the surgical technique to the system must be adhered to. Familiarity with the recommended surgical technique and its careful application is essential to achieve the best possible outcome.
Before surgery a surgical planning with regard to the dimensions of the prosthetic model and the positioning of the implant components in the bone has to be carried out by the surgeon.

For this purpose, X-ray templates are available:

Digital templates: Digital templates are included in the data base of the common planning systems. For missing templates, please contact the provider of the planning software and request for these templates.

Radiographic templates: Alternatively radiographic templates are available in various scale factors, which can be obtained on demand from your local representative.

For the analysis of case, X-rays in three sections vertical to each other are necessary. Preoperativethe following X-rays have to be prepared:
- True A-P-Grashev view
- Y-view
- Axillary Lateral

Other studies that may be helpful:
- True A-P of the opposite shoulder
- Bilateral Long Humeral films with a length measuring gauge
- Thin slice CT or MRI

M/L view A/P view

Important information: Prior to surgery the following should be ensured:
- all needed components are available during surgery. An adequate number of various implant components should be available for surgery. It should be determined whether the implantation should be done with or without the use of bone cement.
- all instruments for the implantation are present and are matching the corresponding implants. The implants may only be used with the instruments of the implantcast GmbH. The only exception being standardized instruments used during surgery.

Note: For further information regarding postoperative instructions as well as indication, contraindication and risk factors please see the instruction for use for "Shoulder Endoprostheses" (09300031GB) and this surgical technique on page 48.

Compatibility

Humeral options

Heads

anatomical

AGILON® cap

AGILON® CTA cap

diameterr: 44, 47, 50 and 53mm
cap height: 14, 17 and 20mm

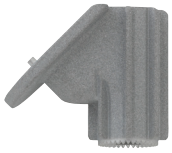
revers

AGILON® cap invers

AGILON® retentive cap invers

diameter: 36, 40 and 44mm
neck length: K, M (+3mm) and L (+6mm)

Metaphyseal components



length: 30 and 40mm*
metaphyseal angle: 135° and 155°

*For primary cases it is recimmended to use the 40mm metaphyseal component

Screws

length: 22,5mm - 40mm

Extension pieces

length: 7.5mm
10mm
12.5mm
15mm
17.5mm

Stems

cementless

diameter: 9-18mm*
length: 30mm**, 60mm, 120mm,
180mm and 240mm

*Stems of 30mm length are not available in diameter 9mm. Diameters of 17mm and 18mm are only available in length of 30mm and 60mm.

cemented

diameter: 6, 8, 10 and 12mm
length: 60mm, 90mm and 120mm,

→ compatible according to sizes/diameters

→ compatible to all sizes

glenoid options

cementless

PE-component

PE- glenoid

sizes: sz. 2
sz. 3
sz. 4

PE- glenosphere

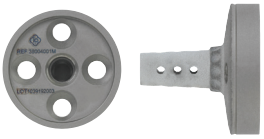
sizes: sz. 2
sz. 3
Ø: 36mm (neutral, eccentrical)
40mm (eccentrical)
44mm (eccentrical)

Cementless glenoid

anatomical

sizes: sz. 2
sz. 3
Versions: short
long

round



sizes: sz. 3

Screws

cancellous screw angle stable

length: 20mm - 40mm

cancellous screw

length: 26mm - 34mm

cemented

PE-glenoid

sizes: sz. 2
sz. 3
sz. 4

compatible according to sizes/diameters

compatible to all sizes

Compatibility humerus prosthesis to glenoid

cementless glenoid with PE-insert

cemented PE-glenoid

compatible to all sizes

AGILON® cap

AGILON® CTA cap

PE-glenosphere

compatible according to sizes/diameters

AGILON® cap invers

AGILON® retentive cap invers

Surgical Technique

Patient positioning

The patient should be placed in the Beach-chair-position (Fig. 1). The patients ipsilateral hip should be supported with a bean bag so that the arm clears the edge of the table (Fig. 2). A movable side table or commercially available arm holder for the forearm enables stable rotation control and bed for the forearm. Folded sheets under the medial scapula will angle the glenoid fossae anteriorly. The table may be tilted away from the surgeon during glenoid preparation to facilitate exposure.

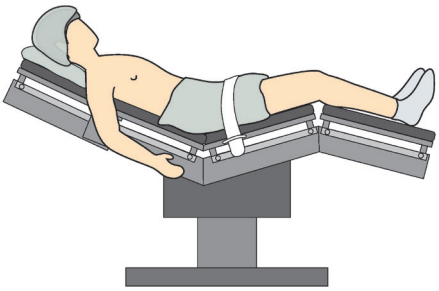


Fig. 1

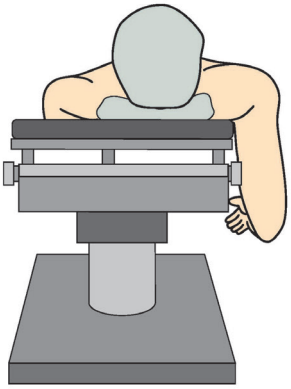


Fig. 2

Deltopectoral approach

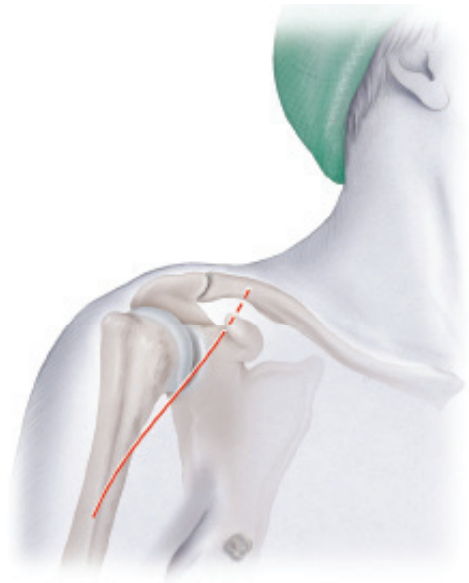


Fig. 3

Perform the deltopectoral skin incision (Fig. 3) from the top of the coracoid, following the front edge of the deltoid, straight to the humeral origin of the M. deltoideus.

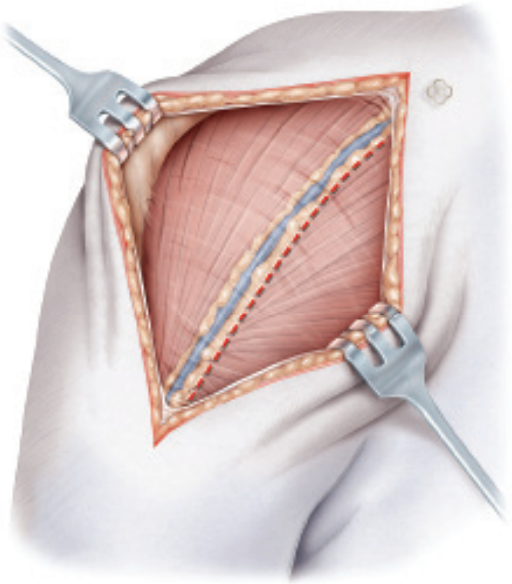


Fig. 4

After the skin incision and mobilization of the lateral skin flap, undertake the incision of the fascia between M. pectoralis and M. deltoid. The cephalic vein may be taken laterally as shown or medially (more tedious because of feeder vessels from deltoid but, more anatomic as it crosses the field when taken laterally and is at increased risk of damage from retractors) (Fig. 4).Wet lap sponges are placed over the deltoid.

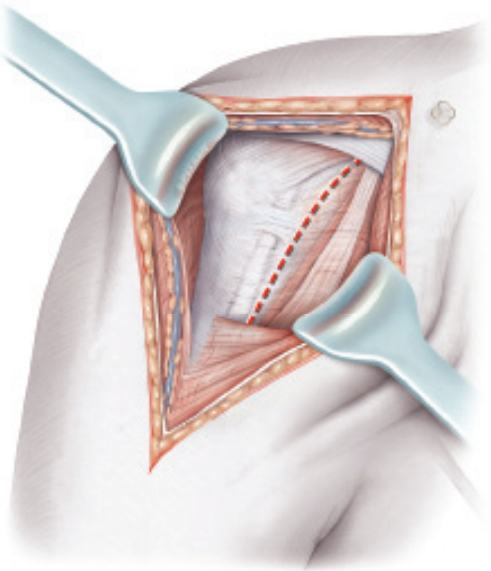


Fig. 5

Vertical incision of the clavi-pectoral fascia between the long and short biceps fiber up to but not through the coracoacromial ligament (Fig. 5).

Pictured here is the mobilization of the conjoined tendon as well as palpation of the musculocutaneus nerve (Fig. 6).

In addition the axillary nerve can be identified at the lower edge of the subscapularis to avoid iatrogenic damages at the further preparation. Both nerves must be protected during the whole operation. Avoid sharp blade self retractors under the conjoined tendon.
The long biceps tendon helps to the orientation for the identification of the greater and lesser tuberosities in fracture cases and the rotator interval in arthroplasty.

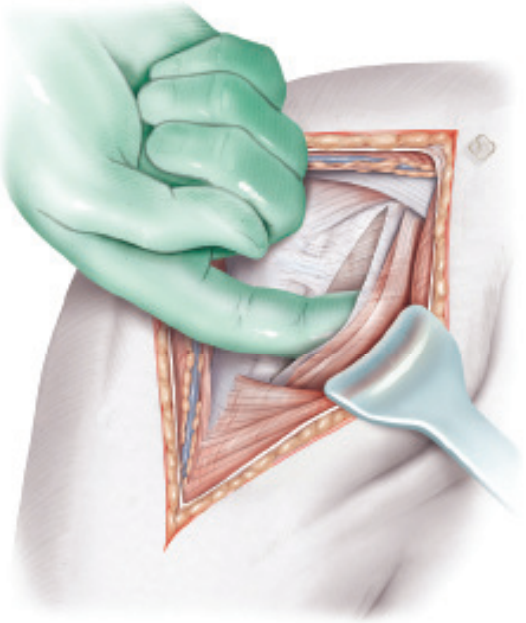


Fig. 6

Incision above the biceps fibre in proximal direction up to the Lig. Coracoacromial and splitting of the rotator cuff interval between Subscapularis and Supraspinatus (Fig. 7). A biceps tenotomy is performed. In general a biceps tenodesis is performed to the pectoralis major or rotator interval or the short head of the biceps.

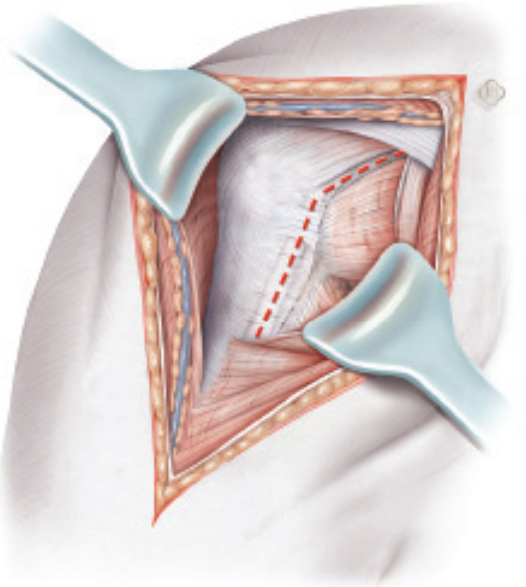


Fig. 7

Subscapularis take down is left to the individual surgeons preference. This can include lesser tuberosity osteotomy's of varying thicknesses, Subscapularis peel, Subscapularis tenotomy performed 10mm medial to the lesser tuberosity and in extreme cases Z-lengthening of the subscapularis can be performed when external rotation contractures are -30° or more. Likewise capsulotomy and/or capsulectomy can also be performed individually. At the very least the capsule must be incised from the labrum from 5:00 to 12:00 on the left or 12 to 7 on the right. In patients with posterior subluxation if an anatomic shoulder is to be performed no posterior release should be performed and one should be prepared to imbricate the posterior capsule.

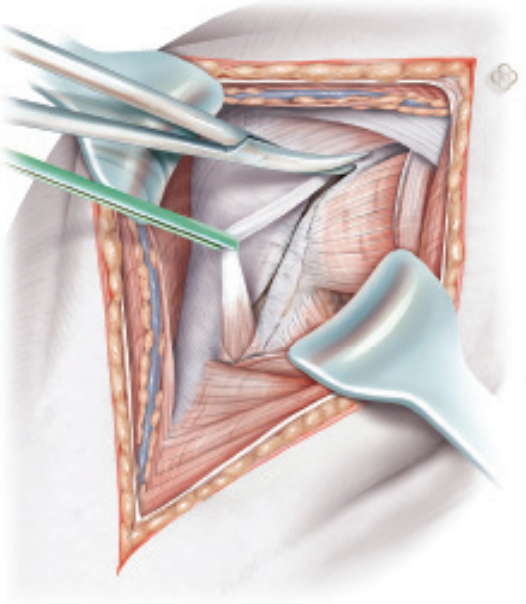


Fig. 8

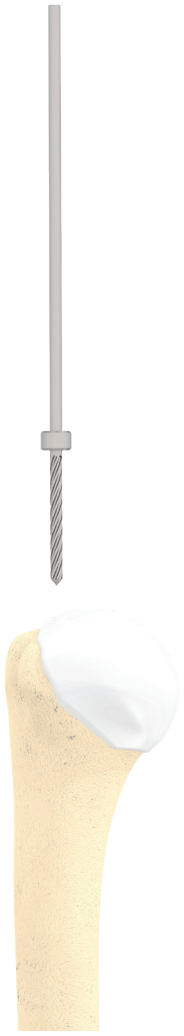


Fig. 9

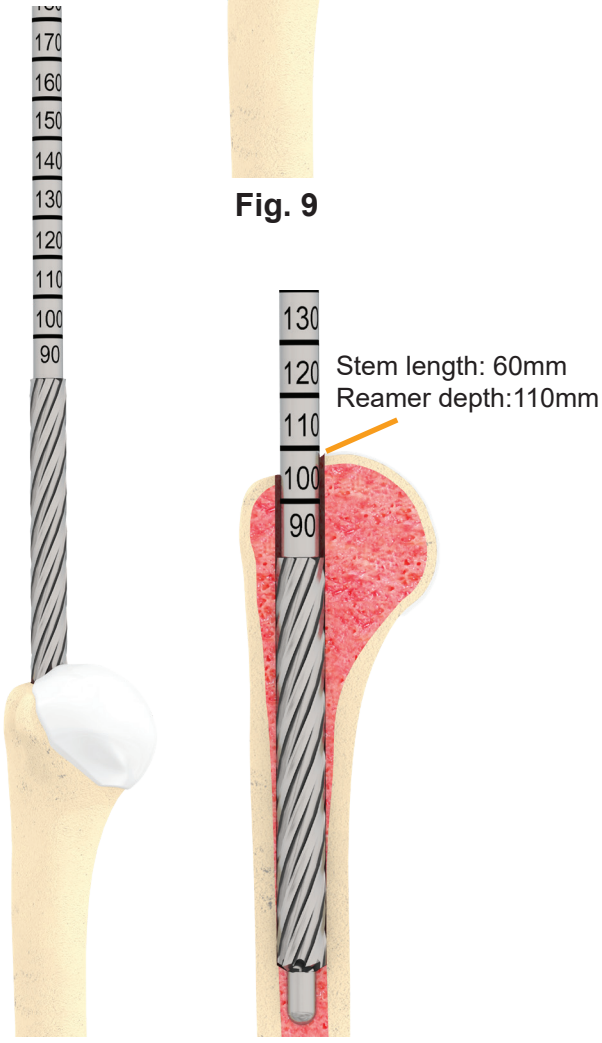


Fig. 10

Humeral preparation

Medullary cavity preparation

Open the medullary humeral canal by the use of the 3.2mm drill (Fig. 9). Ream the canal stepwise up to the diameter determined preoperatively.
Please perform the reaming of the medullary cavity manually by the use of the T-handle (Fig. 10).
Following the reaming depths are listed depending on the used metaphyseal component. In case an extension piece is used, the length of the extension piece needs to be added to the reaming depth.

stem length	Reamer depth	
	with short metaphysis	with long metaphysis (recommended for primary cases)
30mm	70mm	80mm
60mm	100mm	110mm
90mm	130mm	140mm
120mm	160mm	170mm
180mm	220mm	230mm
240mm	280mm	290mm

The reamers have engravings in 10mm steps. For 70 and 80mm there is no marks due to the reamers cutting edge. Assess the correct depth with the help of the 10mm steps above.

If cementless stems are used please ream to the same diameter as the cementless stem. For a cemented stem the reaming should be 2mm bigger than the diameter of the stem.

Note: Regularly the loan shipments include the cementless stem of the length of 30 to 120mm only. If a longer stem like 180mm and 240mm required, these stems have to be ordered separately.
When 180mm or 240mm long cementless stems are to be used, leave the last reamer in the medullary canal, as there are no trial stems available for these stem lengths.

Humeral resection

The aligment of the humeral cutting block is performed intramedullary. As reference either the last used reamer can be left in the intramedullary cavity or the trial stem can be used.
Therefore, connect the trial stem (diameter of the last used reamer) to the trial stem adapter and insert it in the medullary canal. As control for the correct depth the trial stem adapter shows markings.

Note: When using the trial stem as reference the proximal cavity need to be reamed up to a diameter of at least 12mm. Therefore, this portion of the bone is prepared with the 12mm reamer. A marking on the cutting edges shows the correct depth.

If a long metaphyseal component of 40mm is used, the trial stem has to be insert so far into the canal until the second bold laser marking reach the height of the humeral head (Fig. 11).

Note: In primary cases of an anatomical shoulder replacement the use of the long metaphyseal component of 40mm (or a short metaphyseal component 30mm together with and a 10mm extension piece) is recommended. This allows the surgeon to reduce the length of the prosthesis in case of a conversion to a reverse shoulder without removing a well fixed or cemented stem.

The lower bold laser marking on the trial stem adapter refers to the use of a short metaphyseal component 30mm. The thinner markings show the inserting depth when extension pieces (7.5, 10, 12.5, 15 and 17.5mm) are used (Fig. 11).

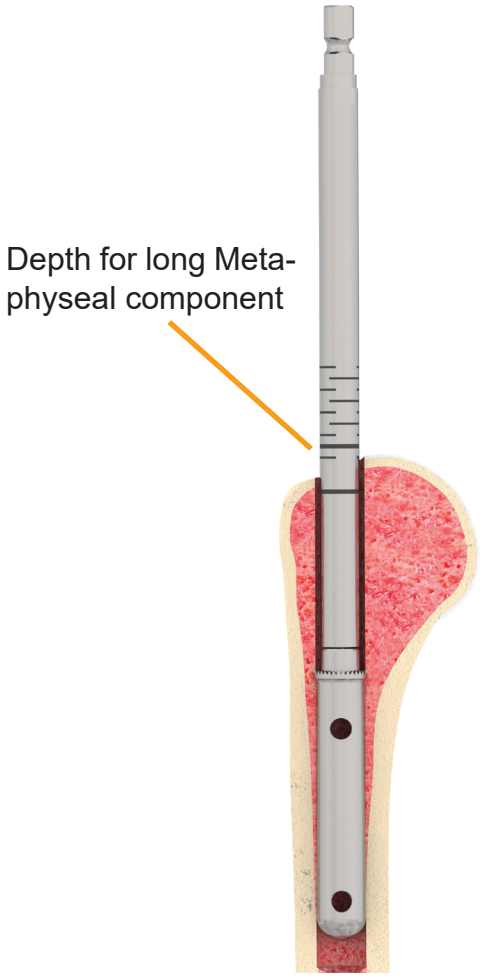


Fig. 11

Mount the cutting block of the chosen angle (135° or 155°) to the humeral aligment guide **(a)** and tighten the screw **(b)**.
Slide the assembly over the trial stem previously inserted into the cavity (Fig. 12).

Note: Turn the small movable loop on the distal edge of the aligment guide to secure the cutting block against falling down, if the screw gets loosen.

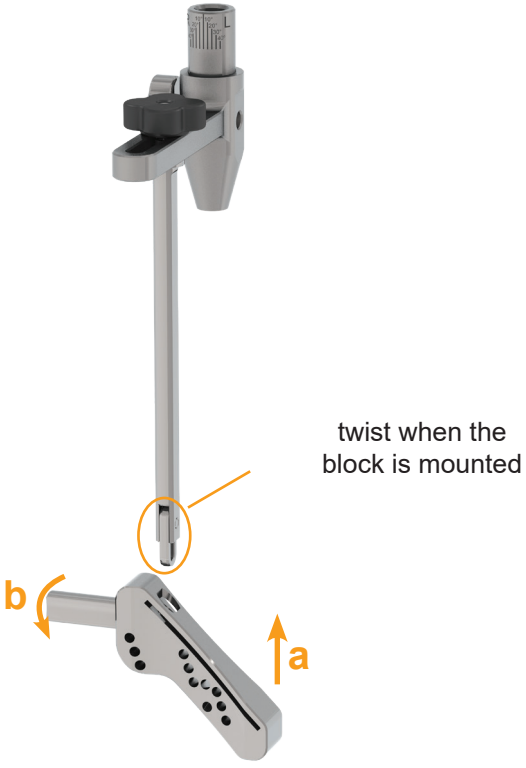


Fig. 12

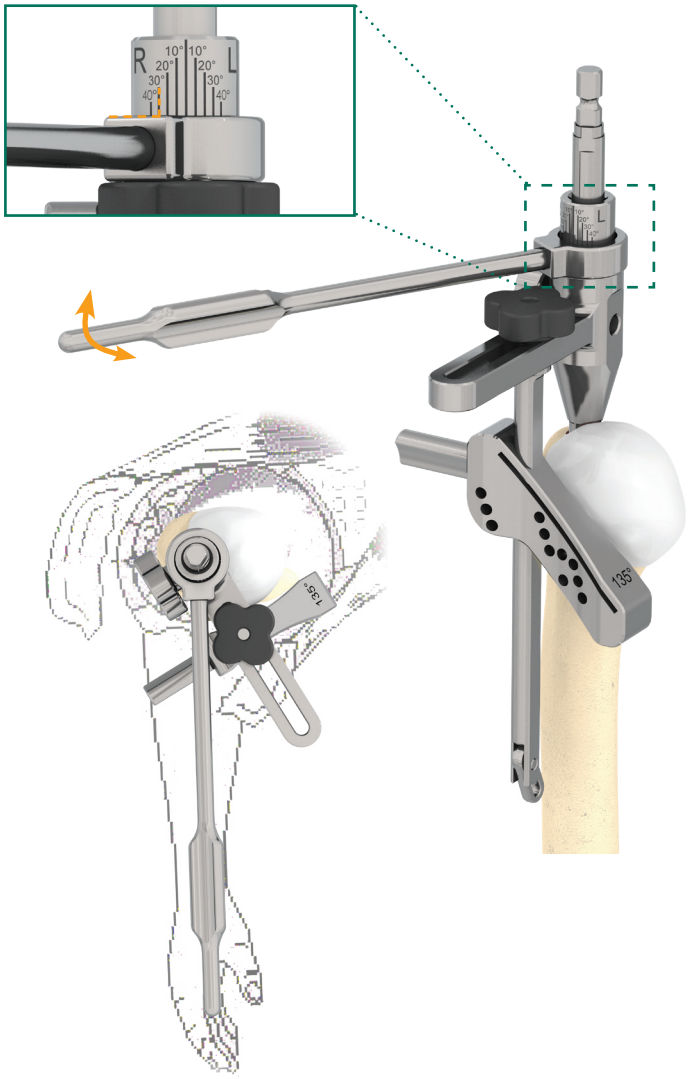


Fig. 13

Anatomical shoulder replacement
Use the guide rod to align the cutting block in the correct retrotorsion. Therefore, the guide rod is placed onto the alignment guide.

To adjust the retrotorsion the guide rod should align with the forearm (Fig. 13). Be aware of the correct side (right/left). When an anatomical shoulder replacement is performed usually a retrotorsion of 30° is recommended.

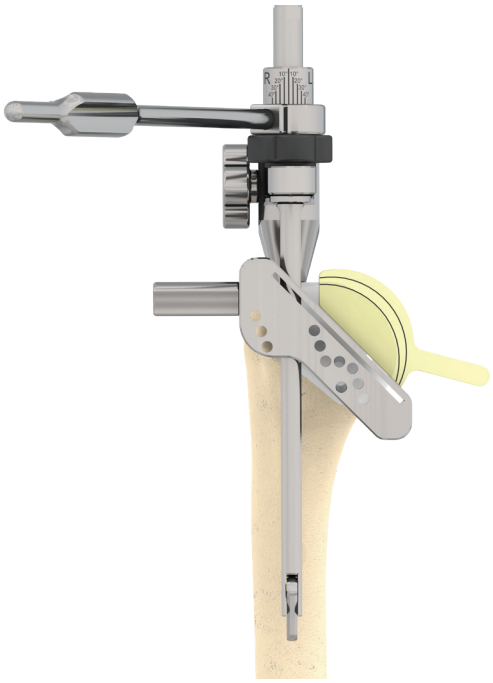


Fig. 14

The height of the cutting block is determined by the use of the sizing templates available in every cap size. The outer shape of the templates represents the cap with a cap height of 20mm. The two additional marked lines on the templates show the cap heights of 17mm and 14mm accordingly (Fig. 14).

After the retrotorsion and the cutting height are determined, please tighten the screw of the cutting block.

Note: The templates are designed to be used with both metaphyseal angle options.

Inverse shoulder replacement

Use the guide rod to align the cutting block in the correct retrotorsion. Therefore, the guide rod onto the alignment guide.

To adjust the retrotorsion the guide rod should align with the forearm (Fig. 15). Be aware of the correct side (right/left).

When a reverse shoulder replacement is performed, the surgeon may choose anatomic version or less. While a retrotorsion of 10° or even 0° is favoured by some authors, conversion back to hemiarthroplasty will be more successful if the humeral head can maintain a fulcrum under the acromion.

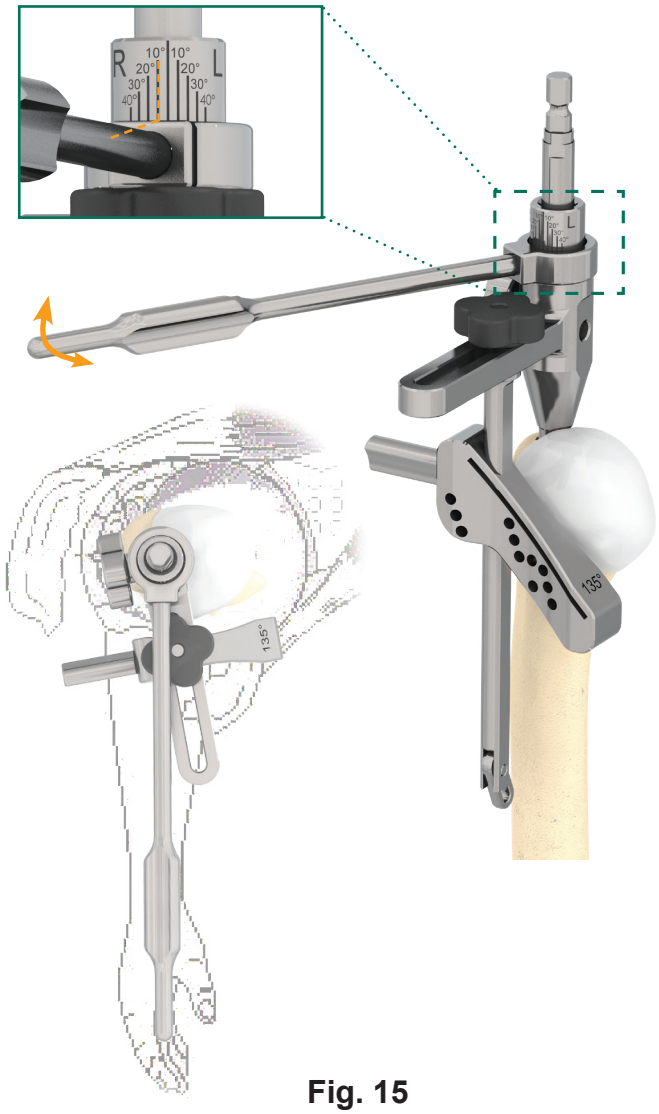


Fig. 15

The height of the cutting block is determined by the use of the sizing templates "invers" (Fig. 16).

The cutting height for an inverse shoulder prosthesis is usually increased by app. 10mm. The design of an reverse shoulder prosthesis requires a caudalization of the humeral stem. The oblique line on the inverse template shows the additional bone cut required for a minimal bone cut reference on the lower head mark of the template (it fits to the shortest neck length of the reverse caps). The second mark represents the medium neck length and the outer shape the longest neck length accordingly.

After the retrotorsion and the cutting height are determined, please tighten the screw of the cutting block.

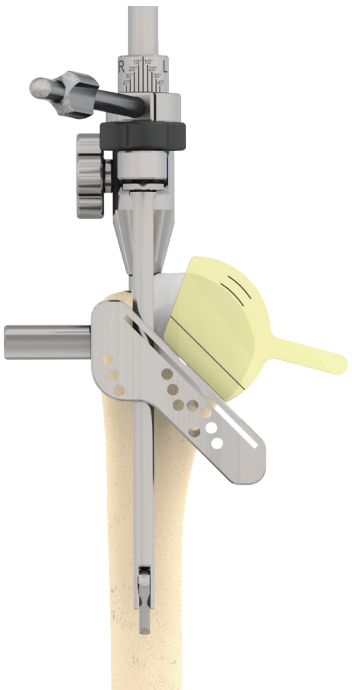


Fig. 16

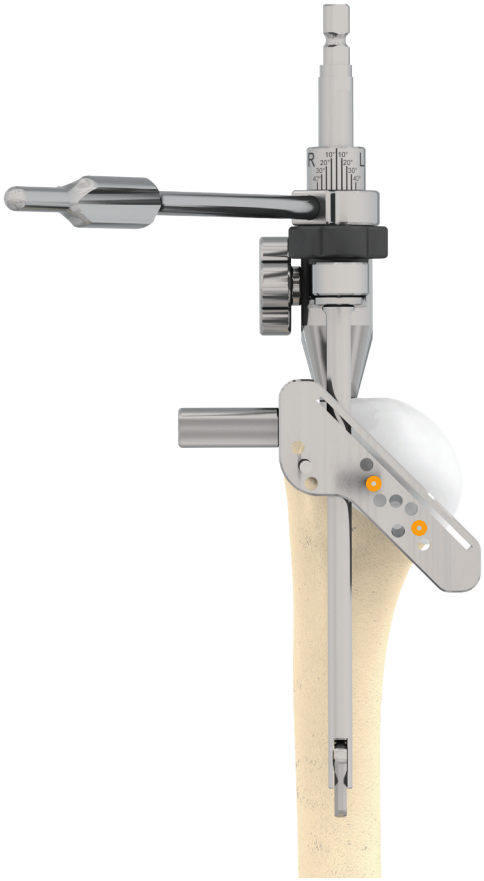


Fig. 17

Use two fixation pins (o) to fix the cutting block to the humeral bone. If necessary, please predrill with the 3,2mm drill (Fig. 17).

It is recommended to use the middle pin level, so the block can be shifted up or down by 2,5mm, if needed.

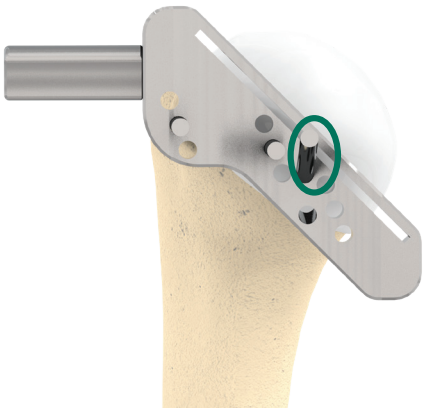


Fig. 18

Unlock the screw of the cutting block and remove the alignment guide together with the intramedullary instruments (trial stem or rigid drill). Leave the cutting block in place (Fig. 29).

For better stability a third pin might be inserted through the oblique pin hole (o). Direct this pin from cranial to caudal (Fig. 18).

Note: Please remove the screw from the cutting block before you resect. Because of the vibration during resection it otherwise might fall down.

Use a 1.47mm saw blade to cut through the slot of the cutting block (Fig. 19).

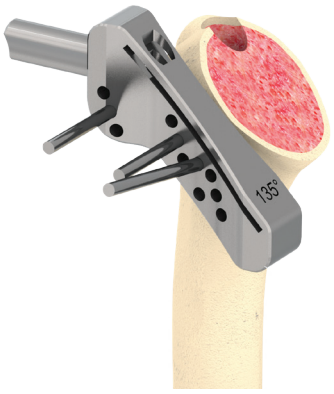


Fig. 19

Measure the resected head and determine the correct cap size and height (Fig. 20).

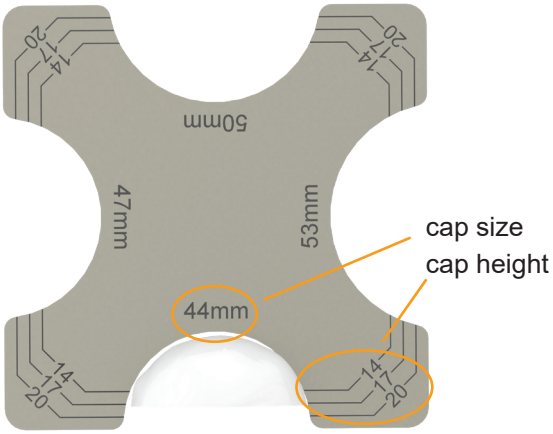


Fig. 20

Insert the previously used trial stem to the correct depth. Now as you have resected the bone proximally, the upper bold laser marking will appear higher and stays app. 10mm out of the intramedullary canal (Fig. 21).

Fig. 21

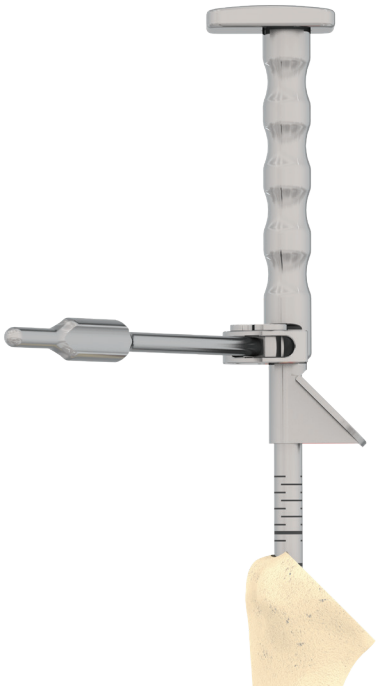


Fig. 22

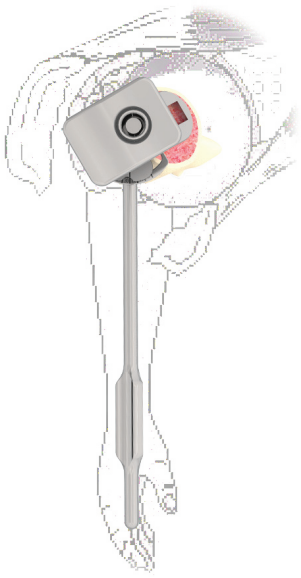


Fig. 23

The box chisel is guided by the intramedullary trial stem. Double check the retrotorsion of the chisel by the use of the modular retrotorsion instrument set to 30° or the version the surgeon proposes to be best for the patient. This instrument is used over the handle of the box chisel at the flat portion marked with R and L. If you are operating on a right shoulder the handle of the alignment instrument should be on the side facing R. On a left shoulder the handle should point to the L (Fig. 22). The check of the retrotorsion is referenced on the forearm (Fig. 23).

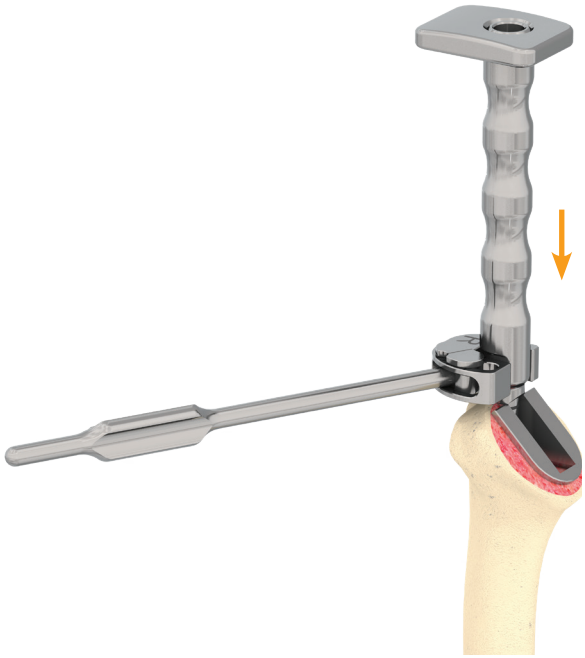


Fig. 24

Move the box chisel of the angle matching the resection downwards until it reaches the bone level (Fig. 24). Carefully impact the chisel. The box chisel is stoped by the collar.

The box chisel only prepares the rectangular shape of the metaphyseal component without the fins, as the press fit fixation shouldn't be compromised. Remove the box chisel.
Remove the excess bone, afterwards.

Remove all instruments.

If the replacement is a hemi arthroplasty without a replacement of the glenoid, you can directly continue with the trial reduction, described on page 21.

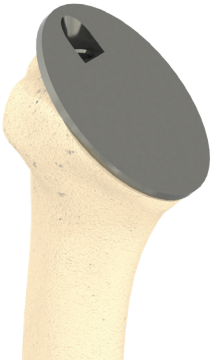


Fig. 25

If a replacement of the glenoid is considered, the protection plate can be placed onto the resected bone surface of the humerus (Fig. 25). Continue on page 16.

If an reverse prosthesis is performed, please continue with the descriptions for the glenoid preparation on page 17. For trial reduction continue on page 28.

Preparation cemented PE-glenoid

Determine the size by the use of the glenoid drill guide.

Connect the modular handle to the glenoid drill guide and place it onto the articulating bone surface of the glenoid (Fig. 26). If necessary repeat this step with the glenoid drill guide of the other size. After the size is determined, please insert a guide pin through the central hole of the glenoid drill guide (Fig. 27).

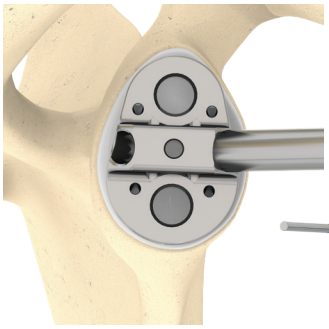


Fig. 26

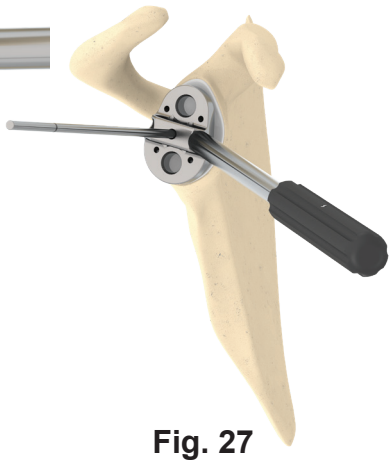


Fig. 27

Please remove the drill guide afterwards (Fig. 28). Choose the glenoid reamer of the correct size and remove the remaining cartilage and bone from the glenoid surface.

Glenoid size	reamer
2	universal reamer
3	universal reamer
4	reamer size 4

Make sure that the reamer is turning already at full speed before it hits the bone surface. Ream until the reamer has reached the subchondral bleading bone (Fig. 29).

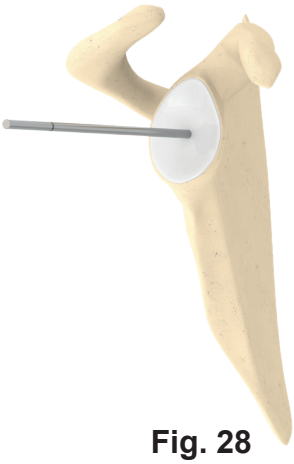


Fig. 28

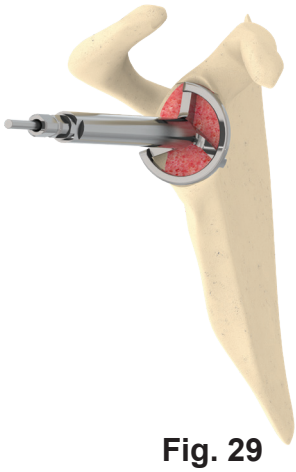


Fig. 29

Remove the reamer, but leave in the guide pin. Place again the previously used glenoid drill guide on the surface of the bone and drill the cranial and the caudal peg hole using the special drill with stop (Fig. 30).

Remove all instruments and continue with the trial reduction.

Impact the trial glenoid of the correct size (Fig. 31) and perform a trial reduction.

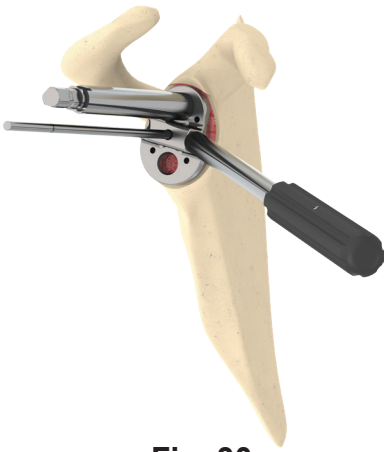


Fig. 30

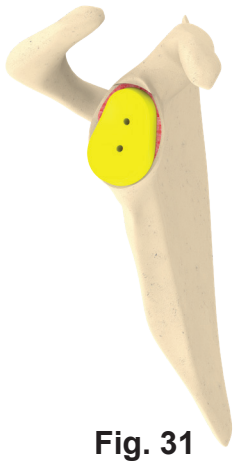


Fig. 31

Note: All glenoid components can be combined with all cap sizes.

Preparation cementless glenoid

Mark the centre of the glenoid (Fig. 32).

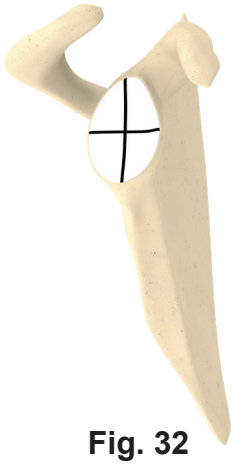


Fig. 32

Note: implantcast offers CT based patient specific drill guides on special request.

Connect the drill guide with the handle and place it onto the surface of the glenoid bone. It should be caudally positioned with full bone contact. Insert the 3.2mm bone pin through the central hole of the drill guide (Fig. 33). Remove the drill guide afterwards.

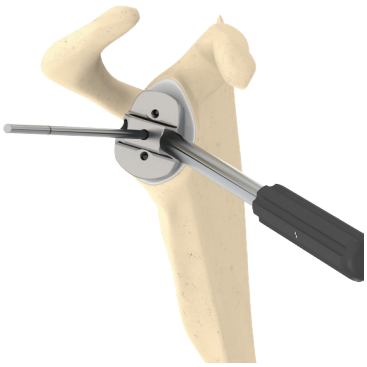


Fig. 33

Use the glenoid reamer 30mm to expose the subchondral bone. The reamer is guided by the guide wire (Fig. 34).

Use the cannulated drill to prepare the bone for the central peg (Fig. 35). The glenoid is available as short or long version, choose the correct canulated drill respectively.

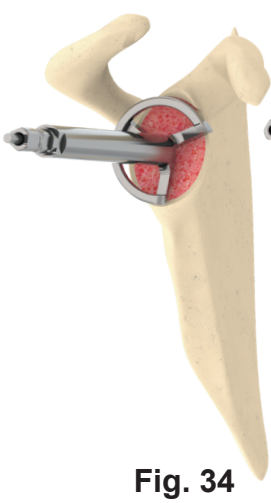


Fig. 34

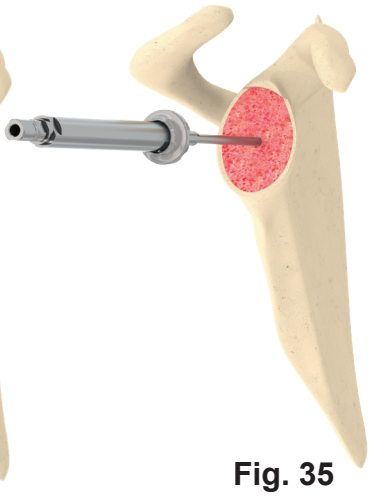


Fig. 35

In case of an inverse treatment use the glenoid preparator 44mm to remove bone that could hinder the optimal positioning of the glenosphere. Attach the glenoid preparator to the T-handle and slide it over the pin. Carefully rasp back and forth cranial and caudal to create room for the glenosphere (Fig. 36).

Remove the guide pin, afterwards.

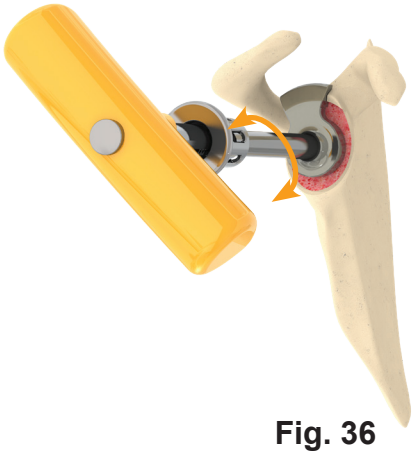


Fig. 36

Insert the special drill guide for the cranial and caudal groove of the implant (Fig. 37).
Use the drill with stop through the drill guide to prepare the holes for the grooves (Fig. 38).

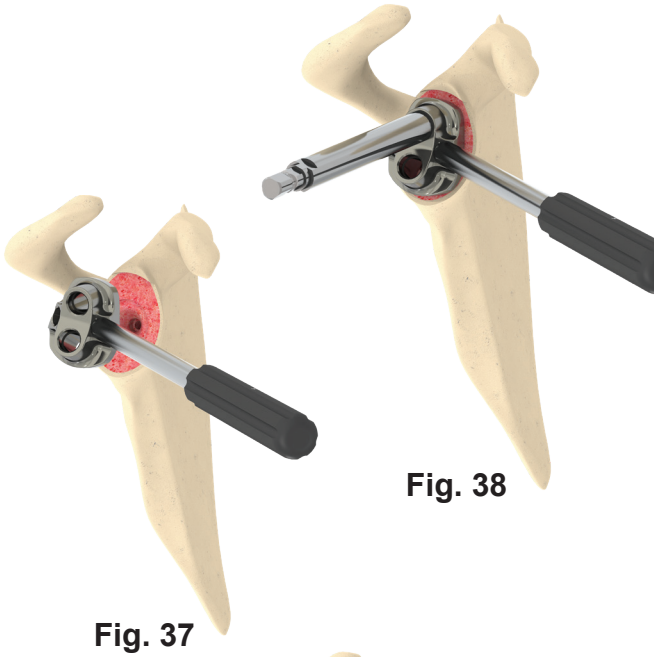


Fig. 38

Fig. 37

Implantation cementless glenoid
Remove the drill guide. Connect the glenoid with the cannulated glenoid impactor. Align the upper screw hole to the coracoid-base. If necessary reinsert the guide pin into the central hole.

Impact the implant carefully until the glenoid rests completely flush on the reamed bone surface (Fig. 39). Afterwards release the impactor from the implant and remove the guide pin.

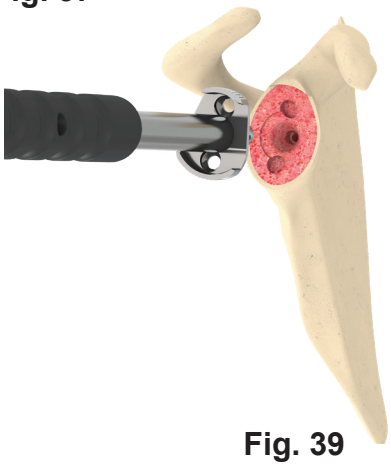


Fig. 39

Note: The central hole will be slightly smaller than the peg. The peg will be locked in the bone by pressfit. The subchondral bone offers the ideal mounting for the implant.

You can freely angle the screw up to 15°, as the screw head is self-threading into the glenoid material (Fig. 40).

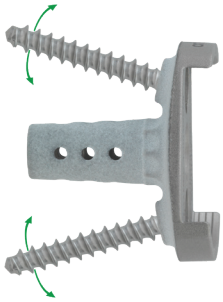


Fig. 40

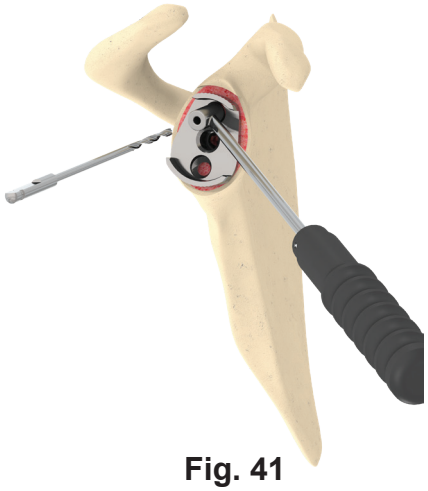


Fig. 41

Drill the holes for the locking screws with 2.5mm (alternatively 2.0mm) drill and the angled drill guide (Fig. 41).

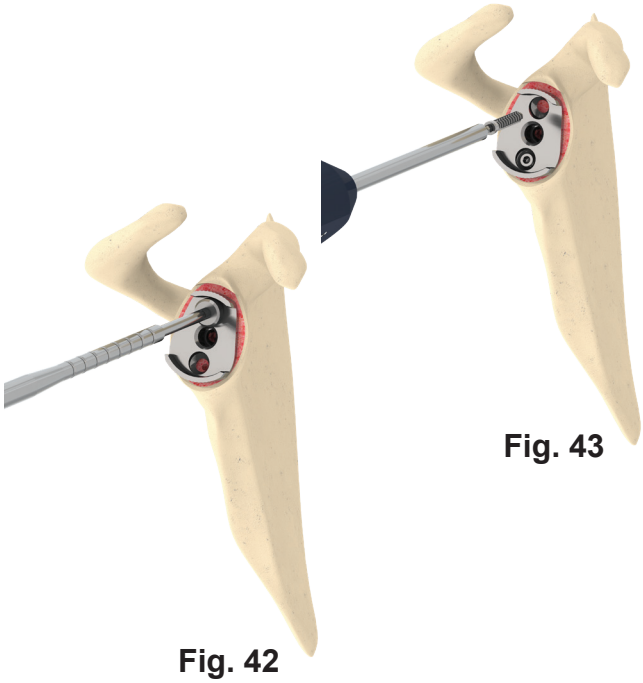


Fig. 43

Fig. 42

Determine the screw length using the depth gauge and insert the screws of the correct lengths (Fig. 42). Lock the screws with the hexagonal screw driver 2.5mm (Fig. 43). The screw head need to be in the glenoid base.

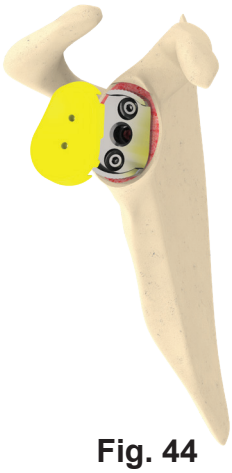


Fig. 44

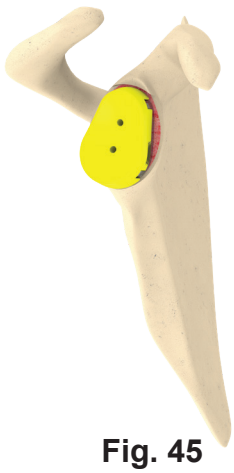


Fig. 45

Add the trial insert of the appropriate size (Fig. 44 and Fig. 45) and perform a trial reduction. Please note the correct comaptility:

size cementless glenoid	trial insert to be combined
2	2
3	3
3	4

Perform a trial reduction.

Trial reduction anatomical treatment

Remove the protection plate. Mount the correct trial stem, trial metaphyseal component and, if necessary, a trial extension piece and lock the components with a trial screw of the correct length , see table below (Fig. 46).

extension piece	length of the screw in combination with	
	short metaphysis (30mm)	long metaphysis (40mm)
none	22.5mm	32.5mm
7.5mm	30mm	40mm
10mm	32.5mm	
12.5mm	35mm	
15mm	37.5mm	
17.5mm	40mm	

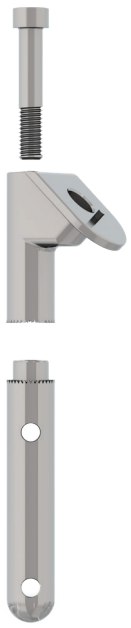


Fig. 46

Place the implant impactor onto the trial metaphyseal component and connect both with the screw.

Insert the assembled trial implant into the medullary canal. By using the special impator the trial can be guided in the correct position. Please double check the correct retrotorsion by the use of the modular retrotorsion guide if needed.
The collar should rest on the resected bone surface (Fig. 47).

Note: The body of the trial metaphyseal only has the core dimensions of the final implant component without fins. Thus the pressfit fixation is not compromised.

For trial reduction of the reverse protheseis, please continue on page 28.

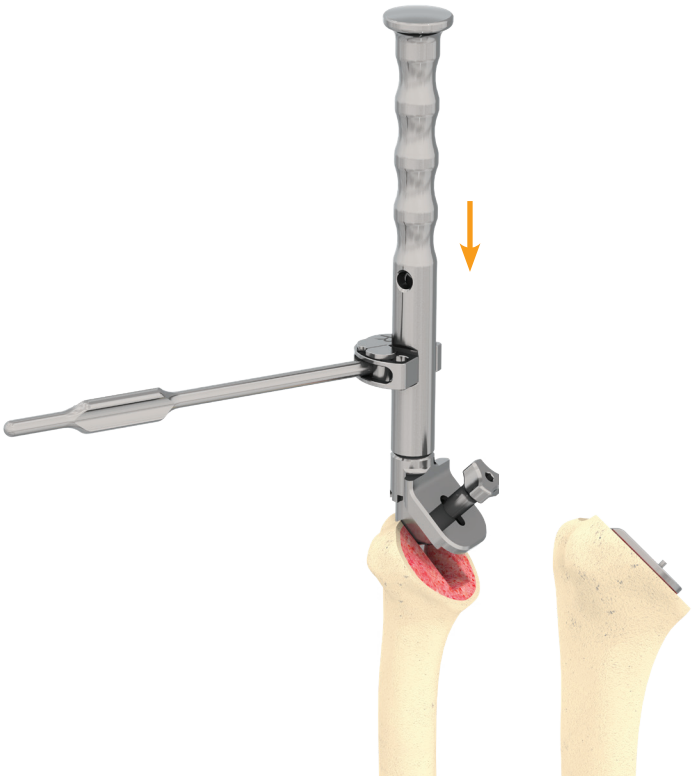


Fig. 47

Add the trial cap (Fig. 48) or the CTA trial (Fig. 49) cap of the previously determined size and height to the trial implant.

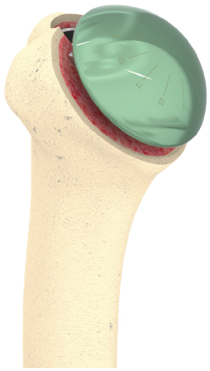


Fig. 48

Fig. 49

Note: A CTA cap is intended for the use as a hemi-arthroplasty, to treat a patient after an inverse shoulder has failed. Although the curvature of the caps allows the combination with all glenoid components it is normally not combined with a glenoid implant.

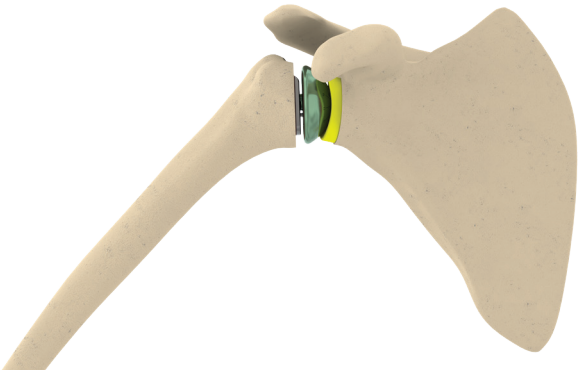


Fig. 50

Perform a trial reduction and check the range of motion and the stability as well as the offset of the joint (Fig. 50).

Adjustment of the Offset

The position and alignment of the prosthesis can be optimized by changing the modular parts (cap, extension piece, metaphyseal component).

If necessary, please change the eccentricity of the cap and adjust the rotation of the cap (Fig. 51) and the size and height of the cap. You will find the laser marks (1-12) on the back of the final implant components as well (Fig. 52).

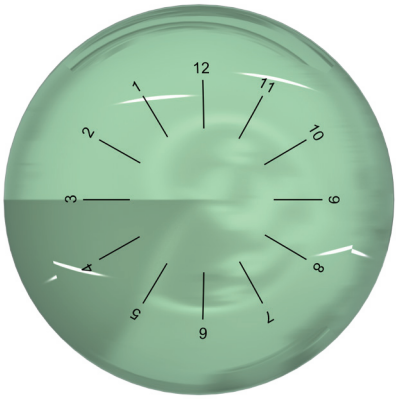


Fig. 51

To have the closest accurate reconstruction of the anatomy and to optimize the alignment of the prosthesis, the surgeon has the choice between 4 different cap diameters (44, 47, 50 and 53mm) with respectively 3 different heights (14, 17, 20mm).

The eccentricity of the caps enables the variation of the mediolateral offset between 1 and 12 o'clock positions (turn of respectively 30 degrees) between -2mm and +2mm.

Because of this choice, the surgeon can position any medial offset from 2.6mm and 12.8mm (4.7 to 10.7mm) shown on (Fig. 46, Fig. 47 and Fig. 48). Changing the height of the cap ±3mm effects a change of the medial offset ±2.1mm compared to the stated data.

Fig. 52

The exact height of the prosthesis can be changed by the use of the extension pieces of 7.5, 10, 12.5, 15 and 17.5mm.

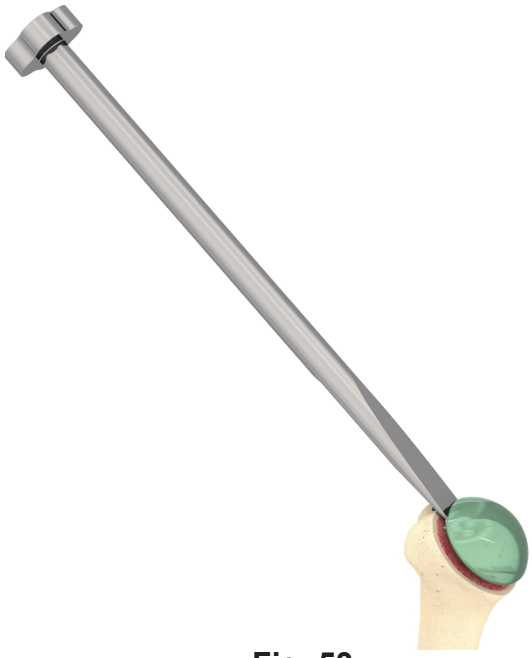


Fig. 53

After sucessful trial reduction, the trial components are removed from the bone.

First remove the cap from the trial implant by the use of the cap remover (Fig. 53).

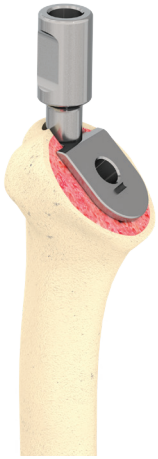


Fig. 54

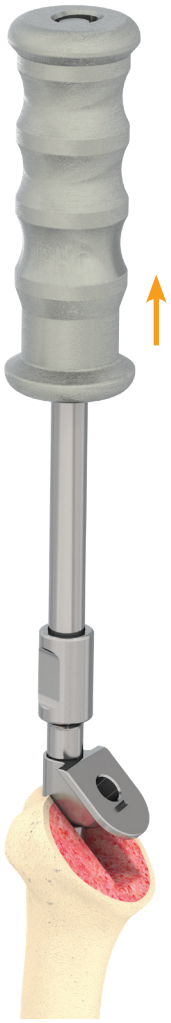


Fig. 55

Screw the adapter M10x1 into the thread of the trial metaphyseal component. Fix the slap hammer to the adapter and remove the trial implant (Fig. 54 and Fig. 55).

Implantation for anatomical treatment

cemented PE-glenoid

Please put bone cement on the glenoid surface. Impact the glenoid component by the use of the glenoid impactor (Fig. 56 and Fig. 57).

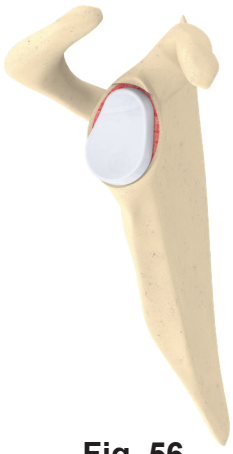


Fig. 56

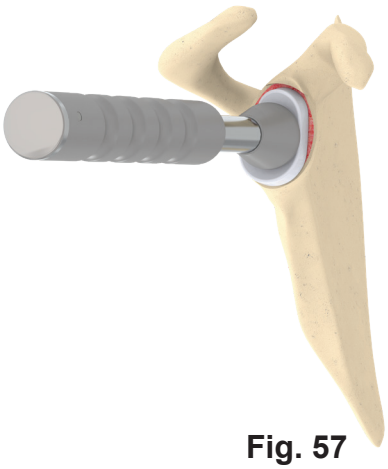


Fig. 57

cementless glenoid

Combine the PE-insert of the previously determined size with the glenoid (Fig. 58). Please note the correct comaptility:

size cementless glenoid	trial insert to be combined
2	2
3	3
3	4

Fig. 58

Impact the PE-insert by the use of the special impactor. Make sure that the insert is completely seated and has reached the inner surface of the glenoid (Fig. 59 and Fig. 60).

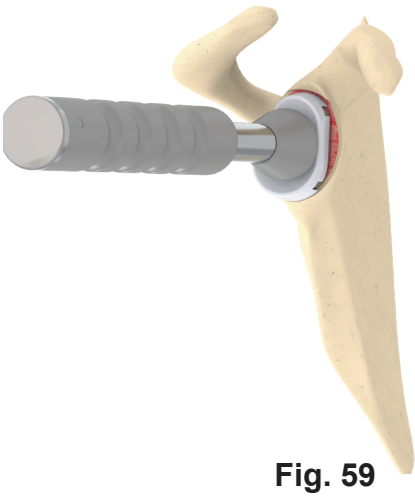


Fig. 59

Fig. 60

Fig. 61

Assemble the implant components of the correct sizes and lengths, determined during the trial reduction (Fig. 61). Add the screw of the correct length:

extension piece	length of the screw in combination with	
	short metaphysis (30mm)	long metaphysis (40mm)
none	22.5mm	32.5mm
7.5mm	30mm	40mm
10mm	32.5mm	
12.5mm	35mm	
15mm	37.5mm	
17.5mm	40mm	

Note: If a cemented stem is used, the stem implanted should be 2mm smaller than the trial stem. When a cementless stem is used, the diameter of the stem is the same as the trial stem.

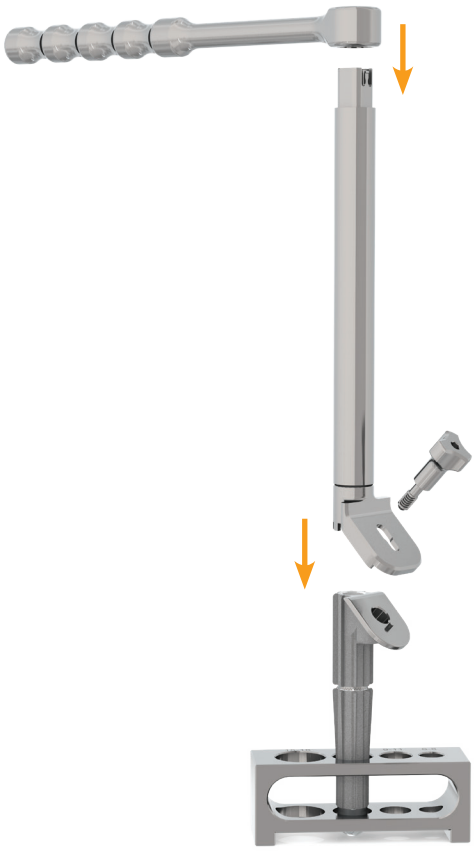


Fig. 62

Place the assembled implant in the correct hole of the assembling block.
Put the countering instrument on the top of the metaphyseal component (Fig. 62). Optionally, the countering instrument can be connected to the implanty by the use of the screw "omarthrosis".

Note: Stems with 30mm length should be assambled in the largest hole independent of the diameter.

Slide the torque screw driver through the sleeve of the countering instrument and lock the implant components (Fig. 63).

When the arrow on the handle of the torque screw driver has reached the 15Nm mark, the recommeded torque is applied.

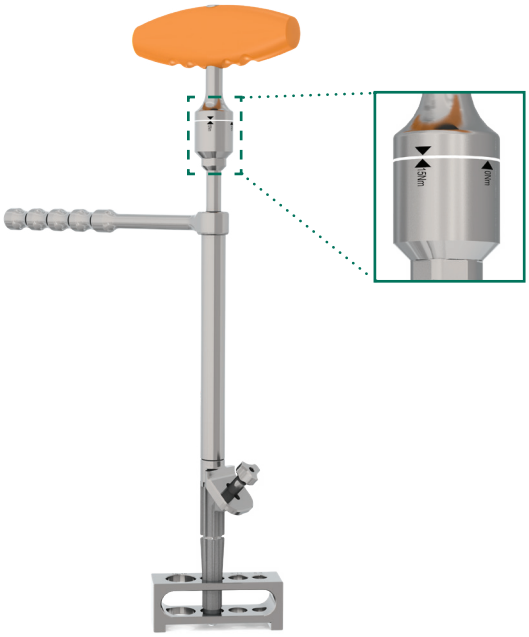


Fig. 63

Tighten the safety screw in the same way (Fig. 64).

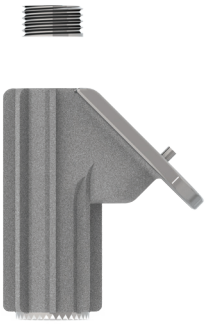


Fig. 64

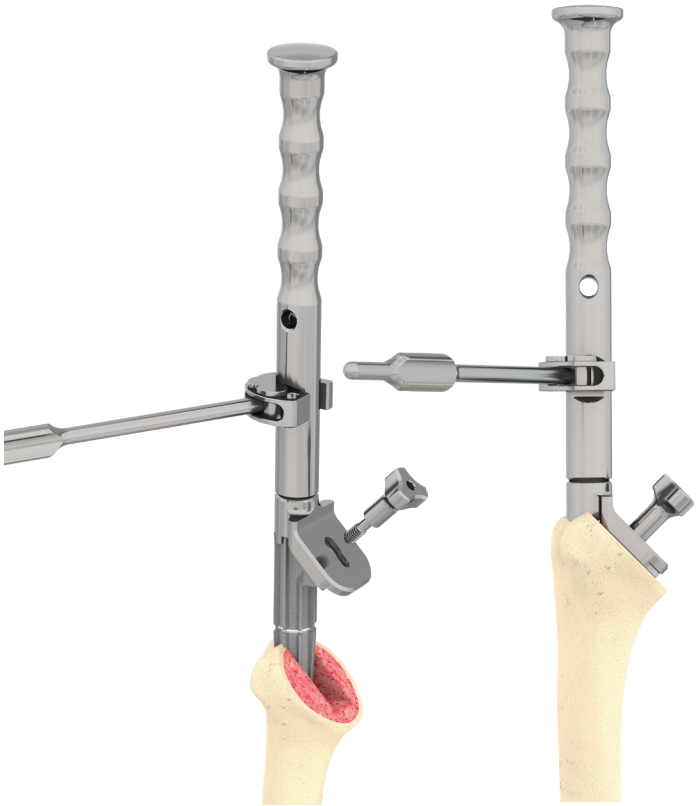


Fig. 65

Fig. 66

Place the implant inserter on the metaphyseal component and connect both with the screw (Fig. 65).

Note: For cemented implantation insert the intramedullary plug and the bone cement into the intramedullary canal, first. Only the stem component should be cemented, the metaphyseal component should not be cemented. Thus, a conversion to an inverse shoulder is possible without removing the stem.

Insert the implant in the intramedullary canal. Double chek the rotational alignment by using the modular retrotiosion guide set to 30°.
Carefully impact the implant, because the fins will prepare the proximal bone. Insert the implant and impact it until the collar will rest on the resected bone surface (Fig. 66).

Note: If a short 30mm cementless stem with a diameter larger than 16mm is used. It is recommended to use additional cancellous bone or bone replacement material in the area of the metaphyseal component, to ensure pressfit.

Fig. 67

Fig. 68

Please clean the taper of the metaphyseal component and impact the cap (Fig. 67) or the CTA cap (Fig. 68) of the correct size and height by the use of the cap impactor.
Reduce the joint and check the stability of the joint.

Reconstruction of the soft tissue

Existing lesions of the rotator cuff should be closed. It is also indicated to close the rotator cuff intermittent because it contributes to secure the anteroposterior cuff. Pay attention that the long biceps filament is undisturbed. If this is not possible a tenodose or resection has to be considered. The wound closure has to be done with redon drains.

Reverse prosthesis

Note: In case of an revision and a conversion from an antomical to an inverse prosthesis it is mandatory to reduce the height of the prosthesis and correct the retrotorsion from 30° to at least 10°(see page 12, Fig. 15). In a revision case the reduction of the height can be easily achieved by replacing the long metaphyseal component 40mm by the short metaphyseal component 30mm and leave the stem in place. Thus the following description show the implantation of a short metaphyseal component 30mm.

Fig. 69

Insert the inverse trial cap of a medium neck length M. The neck length of the inverse caps S, M and L differes by 3mm (Fig. 70).

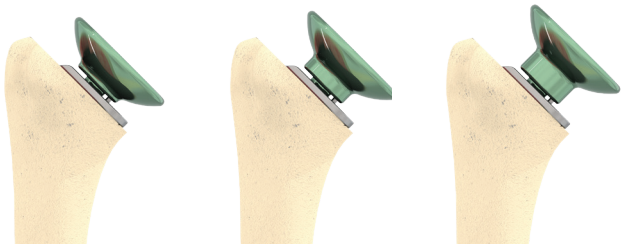


Fig. 70

To prevent inferior impingement of the articulating surfaces and the scapula bone, the glenospheres size 2 36, 40 and 44mm as well as size 3 40, 44mm can be placed in different eccentrical positions to create a caudal offset. The 9-3 o'clock markings on the trial as well as the implant should be positioned cranial (Fig. 71). Only the glenosphere size 3 with a diameter of 36mm is neutral.

Fig. 71

Screw the trial glenosphere to the previously implanted glenoid with the 3.5mm hexagonal screw driver (Fig. 72).

Perform a trial reduction and stability test as well as a range of motion check. If necessary adjust the eccentricity of the inverse cap and change the neck length (Fig. 70).

Fig. 72

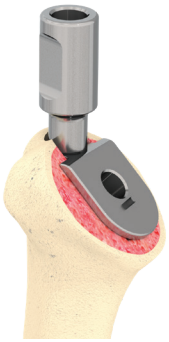


Fig. 73

Fig. 74

Remove the trial glenosphere first.

Screw the adapter M10x1 into the thread of the trial metaphyseal component. Fix the slap hammer to the adapter remove the trial implant (Fig. 73 and Fig. 74).

Fig. 75

Assemble the implant components of the correct sizes and lengths, determined during the trial reduction (Fig. 75). Add the screw of the correct length:

extension piece	length of the screw in combination with	
	short metaphysis (30mm)	long metaphysis (40mm)
none	22.5mm	32.5mm
7.5mm	30mm	40mm
10mm	32.5mm	
12.5mm	35mm	
15mm	37.5mm	
17.5mm	40mm	

Note: If a cemented stem is used, the stem implanted should be 2mm smaller than trial stem. When a cementless stem is used, the diameter of the stem is the same as the trial stem.

Place the assembled implant in the correct hole of the assembly block. Put the countering instrument (socket wrench) on the top of the metaphyseal component (Fig. 76). Optionally, the countering instrument can be connected to the implanty by the use of the screw "omarthrosis".

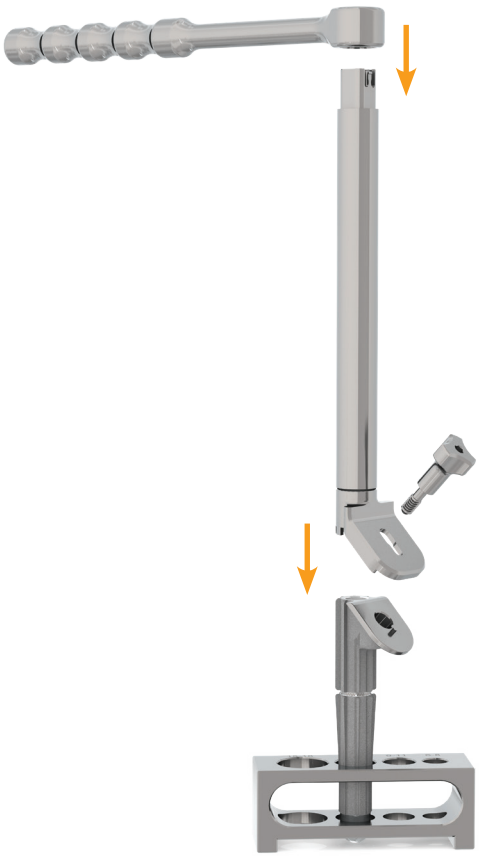


Fig. 76

Slide the torque screw driver through the sleeve of the countering instrument and lock the implant components (Fig. 77).

When the arrow on the handle of the torque screw driver has reached the 15Nm mark, the recommeded torque is applied.

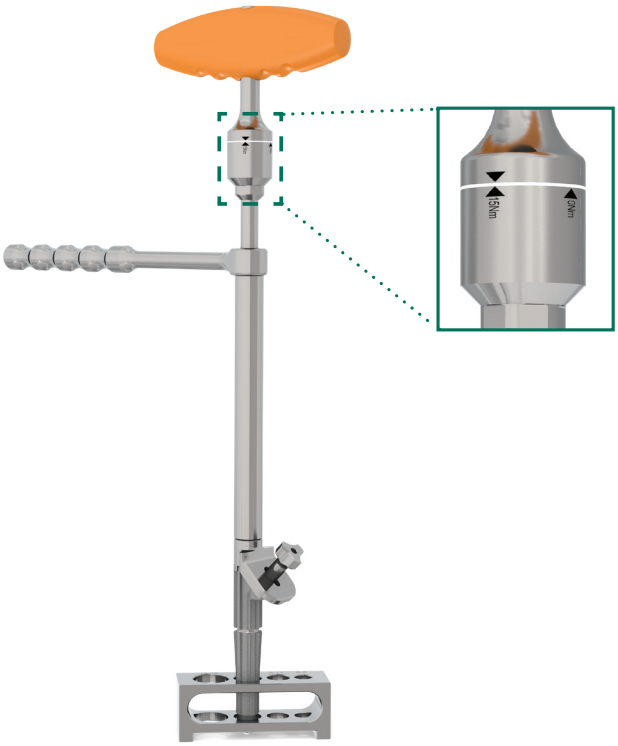


Fig. 77

Fig. 78

Fix the safety screw in the same way (Fig. 78).

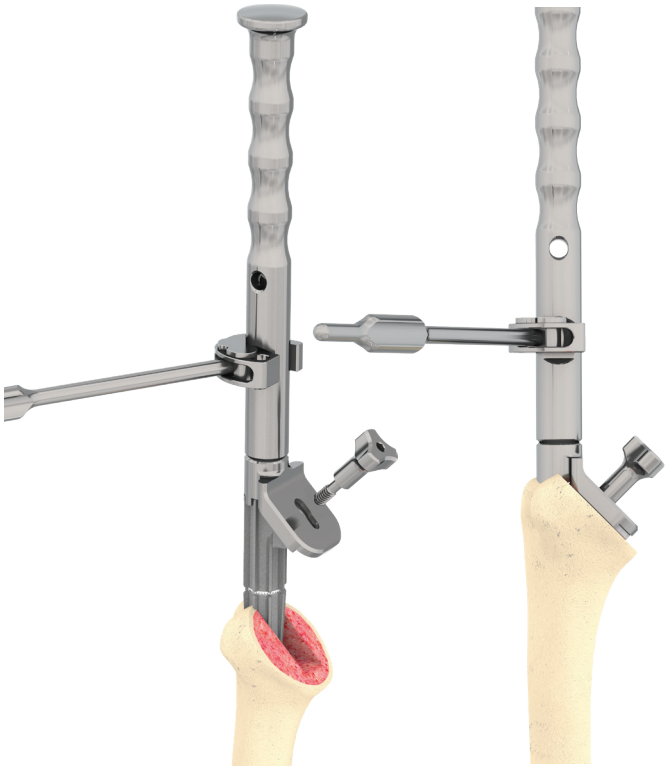


Fig. 79

Fig. 80

Place the implant inserter on the metaphyseal component and connect both with the screw (Fig. 79).

Note: For cemented implantation insert the intramedullary plug and the bone cement into the intramedullary canal, first. Only the stem component should be cemented, the metaphyseal component should not be cemented. Thus, a conversion to an inverse shoulder is possible without removing the stem.

Insert the implant in the intramedullary canal. Double chek the rotational alignment by using the modular retrotiosion guide set to 10°.
Carefully impact the implant, because the fins will prepare the proximal bone. Insert the implant and impact it until the collar will rest on the resected bone surface (Fig. 80).

Use of the captured glenosphere positioner
Choose the glenosphere of the previously determined size and place it into the captured glenosphere positioner. Lock the screw **1** clockwise until the two gripper arms hold the glenosphere in place (Fig. 81). If the gripper arms are loose previously turn screw **1** counterclockwise until stop and insert the arms. Then change direction to clockwise. Lock the screw **2** until the gripper arms hold the glenosphere in place.

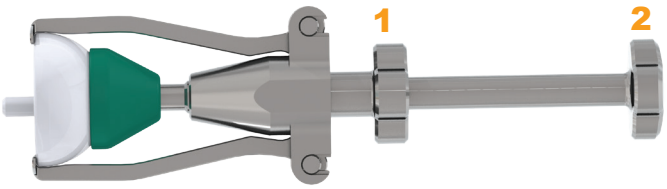


Fig. 81

Adjust the glenosphere to the correct, previously during the use of the trial glenosphere determined, rotation (Fig. 82 and Fig. 83). Make sure that the rotational marking (9 to 3 o'clock) is orientated towards the superior gripper arm and tighten the glenosphere by turning screw **2** clockwise (Fig. 81).

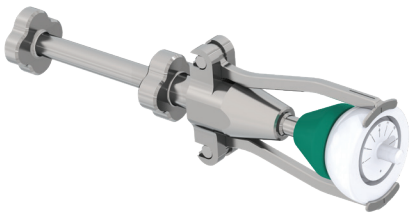


Fig. 82

Fig. 83

Impaction of the glenosphere
Position the glenosphere onto the glenoid. Make sure that the glenosphere is positioned with the correct eccentricity (Fig. 84).
Please hit the platform of the captured impactor lighty to lock the glenosphere to the glenoid.
Unlock the captured impactor by unlocking the screws **1** and **2**. The lip of the glenosphere is locked to the rim of the glenoid

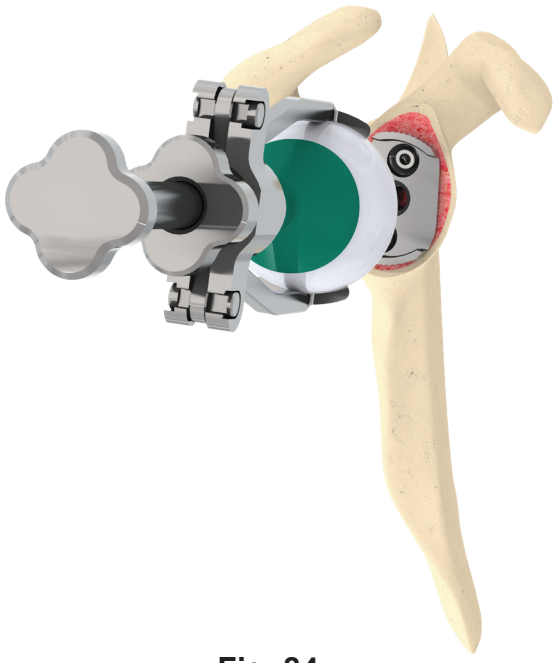


Fig. 84

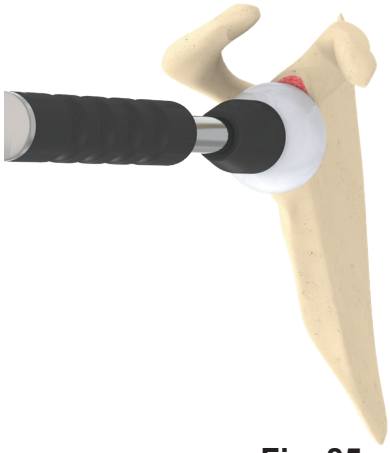


Fig. 85

Use the head impactor to ensure the connection between the components (Fig. 85).

Fig. 86

Fig. 87

Make sure the coupling of the two implant components is complete (Fig. 86). Use the AGILON® control gauche for glenosphere superior and inferior only very small movements of the gauche should be possible if the glenosphere is seated correctly (Fig. 87).

If needed perform another trial reduction by the use of the trial cap inverse.

Please clean the taper of the metaphyseal component and impact the inverse cap of the correct size an height previously determined during the trial reduction, by the use of the cap impactor (Fig. 88). Before impacting the cap make sure, that the pin is seated in the correct position.

Fig. 88

Reduce the joint and perform a final stability check of the joint (Fig. 89).

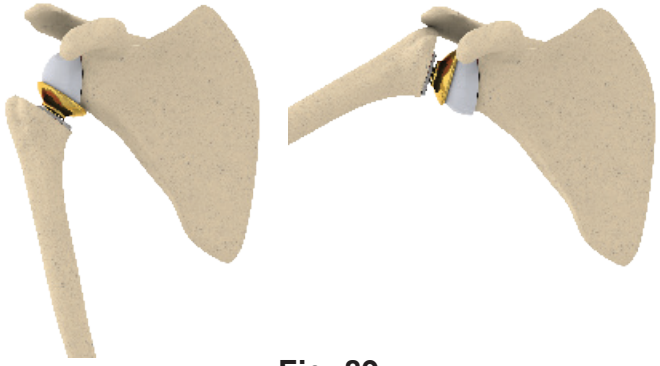


Fig. 89

If necessary, please use the retentive inverse cap to achieve joint stability (Fig. 90).

With the preservable structures the rotator cuff should be reconstructed.

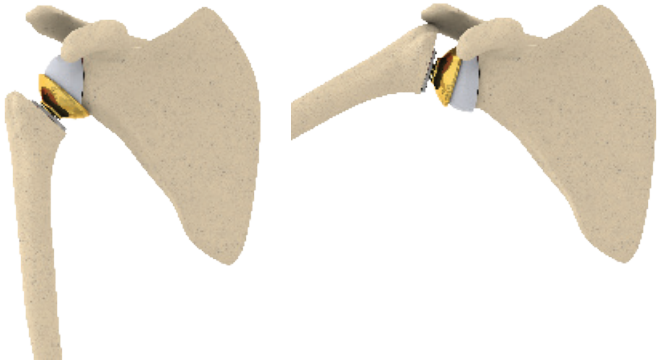


Fig. 90

Postoperative treatment and X-Ray controls

1. day:
- Gilchrist's bandage
- isometric exercises
- decongestant (ice) and tonus-lowering actions on the neck, shoulder girdle and arm

2. day:
- removal of the redon drains
- bearing of the arm on an abduction pad for 3 weeks at 30° secured inner rotation of the forearm
- 1. x-ray control in a.p.-layer

3. – 10. day:
- isometric exercises
- decongestant (ice, lymphatic drainage) and tonus-lowering actions on the neck, shoulder girdle and arm
- mobilization of the adjacent joints and scapula pattern

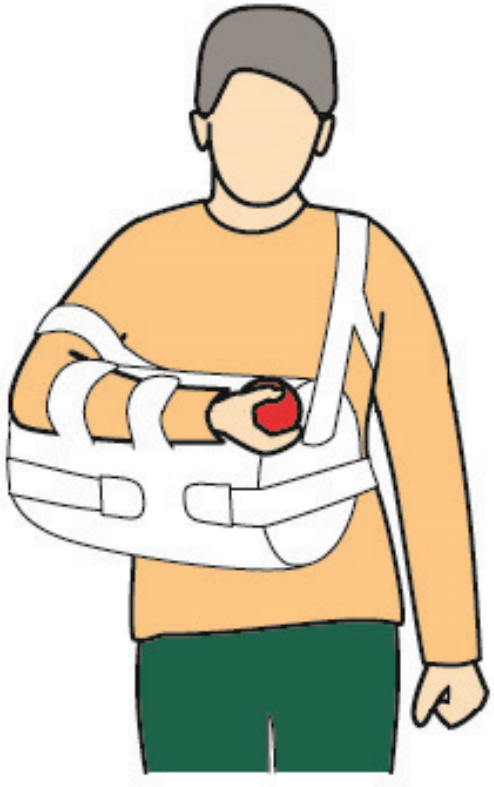
10. day:
- beginning of passive physiotherapy: 30° abd., 30° flex., 60° iro, 0° aro
- 2. x-ray control in 2 layers for the control of the position of the prosthesis and the tubercular. If a dislocation of the tubercular is detected, the revisional operation has to be made immediately

21. day:
- passive physiotherapy: 60° abd., 60° flex., 60° iro, 0° aro
- 3. x-ray control in 2 layers for the control of the postion of the prosthesis and the tubercular.

35. day:
- active assistive physiotherapy: 90° abd., 90° flex., 60° iro, 30° aro
- water aerobics without water resistance

42. day:
- liberalization of full range of motion
- active physiotherapy without resistance
- occupational therapy
- 4. x-ray control in 2 layers for the control of the position of the prosthesis and the tubercular

42. – 84. day:
- the intention is to reach a humane and fully function of the shoulder



Implants

AGILON® Cap

Mat.: implatan®; $TiAl_6V_4$ acc. to ISO 5832-3 with TiN-coating

	14mm	17mm	20mm
ø 44mm	3800-4414	3800-4417	3800-4420
ø 47mm	3800-4714	3800-4717	3800-4720
ø 50mm	3800-5014	3800-5017	3800-5020
ø 53mm	3800-5314	3800-5317	3800-5320

AGILON® CTA Cap

Mat.: implatan®;$TiAl_6V_4$ acc. to ISO 5832-3 with TiN coating

	14mm	17mm	20mm
ø 44mm	3822-4414	3822-4417	3822-4420
ø 47mm	3822-4714	3822-4717	3822-4720
ø 50mm	3822-5014	3822-5017	3822-5020
ø 53mm	3822-5314	3822-5317	3822-5320

AGILON® Cap inverse

Mat.: implatan®;$TiAl_6V_4$ acc. to ISO 5832-3 with TiN coating

	S	M	L
ø 36mm	3801-3600	3801-3605	3801-3610
ø 40mm	3801-4000	3801-4005	3801-4010
ø 44mm	3801-4400	3801-4405	3801-4410

AGILON® retentive Cap inverse

Mat.: implatan®;$TiAl_6V_4$ acc. to ISO 5832-3 with TiN coatin

	S	M	L
ø 36mm	3801-5600	3801-5605	3801-5610
ø 40mm	3801-6000	3801-6005	3801-6010
ø 44mm	3801-6400	3801-6405	3801-6410

Cancellous screw ø4mm

Mat.: implatan®;$TiAl_6V_4$ acc. to ISO 5832-3

REF	length
5793-4026	26mm
5793-4028	28mm
5793-4030	30mm
5793-4032	32mm
5793-4034	34mm

AGILON® screw M6

mat.: implavit® ; CoCrMo acc. to ISO 5832-12 with TiN coating

REF	length
3821-0022	22.5mm
3821-0030	30mm
3821-0032	32.5mm
3821-0035	35mm
3821-0037	37.5mm
3821-0040	40mm

AGILON® metaphyseal component incl. safety screw

Mat.: implatan®; $TiAl_6V_4$ acc. ISO 5832-3

REF	type	angle	length
3821-0002	Omarthrosis	135°	40mm
3821-0003	Omarthrosis	135°	30mm
3821-0001	Trauma	135°	30mm
3821-0012	Omarthrosis	155°	40mm*
3821-0013	Omarthrosis	155°	30mm*
3821-0011	Trauma	155°	30mm*

*metaphyseal components with a 155° angle are not shipped with loan shipments on the regular base and can be ordered additionally!

AGILON® extension piece M6

mat.: implatan®; $TiAl_6V_4$ acc. to ISO 5832-3

REF	length
3821-0075	7.5mm
3821-0100	10mm
3821-0125	12.5mm
3821-0150	15mm
3821-0175	17.5mm

AGILON® stem cementless M6

Mat.: implatan®; $TiAl_6V_4$ acc. to ISO 5832-3

	30mm**	60mm	120mm	180mm***	240mm***
ø 9mm		3850-6009	3851-2009	3851-8009	3852-4009
ø 10mm	3850-3010	3850-6010	3851-2010	3851-8010	3852-4010
ø 11mm	3850-3011	3850-6011	3851-2011	3851-8011	3852-4011
ø 12mm	3850-3012	3850-6012	3851-2012	3851-8012	3852-4012
ø 13mm	3850-3013	3850-6013	3851-2013	3851-8013	3852-4013
ø 14mm	3850-3014	3850-6014	3851-2014	3851-8014	3852-4014
ø 15mm	3850-3015	3850-6015	3851-2015	3851-8015	3852-4015
ø 16mm	3850-3016	3850-6016	3851-2016	3851-8016	3852-4016
ø 17mm	3850-3017	3850-6017			
ø 18mm	3850-3018	3850-6018			

** 30mm stems can not be used with the trauma metaphyseal components with REF 3821-0001 and REF 3821-0011!

*** stems with 2 interlocking holes ø4mm. These stems are not shipped with loan shipments on the regular base and might be ordered additionally!

AGILON® stem cemented M6 *N

Mat.: implavit® ; CoCrMo acc. to ISO 5832-4

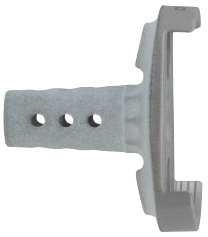
	30mm*	60mm	120mm
ø 6mm	3840-6006	3850-9006	3841-2006
ø 8mm	3840-6008	3850-9008	3841-2008
ø 10mm	3840-6010	3850-9010	3841-2010
ø 12mm	3840-6012	3850-9012	3841-2012

***N: For anti-allergic treatment TiN coated implants are available!**

glenoid cementless anatomical

Mat.: Pure titanium (cpTi) acc. to ISO 5832-2 with implaFix®; HA-coating acc. to ISO 13779-2

REF	size
3800-4028	2 short
3800-4029	2 long
3800-4009	3 short
3800-4010	3 long



glenoid PE-insert

Mat.: UHMW-PE acc. to ISO 5834-2

REF	size	comnined with
3803-1028	2	glenoid cementless size 2
3803-1032	3	glenoid cementless size 3
3803-1036	4	glenoid cementless size 3

AGILON® PE-glenosphere

Mat.: UHMW-PE acc. to ISO 5834-2

REF	glenoidsize	diameter
3803-2836	2	36mm eccentrical
3803-2840	2	40mm eccentrical
3803-2844	2	44mm eccentrical
3803-3236	3	36mm neutral
3803-3240	3	40mm eccentrical
3803-3244	3	44mm eccentrical

cancellous screw angle stable lock Ø 4,2mm

Mat.: implatan®; $TiAl_6V_4$ acc. to ISO 5832-3

REF	length
5794-4220	20mm
5794-4222	22mm
5794-4224	24mm
5794-4226	26mm
5794-4228	28mm
5794-4230	30mm
5794-4232	32mm
5794-4234	34mm
5794-4236	36mm
5794-4238	38mm
5794-4240	40mm

PE-Glenoid cemented

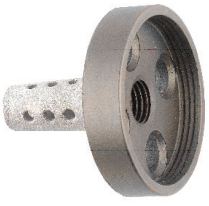
Mat.: UHMW-PE acc. to ISO 5834-2

REF	size
3803-0032	2
3803-0036	3
3803-0040	4

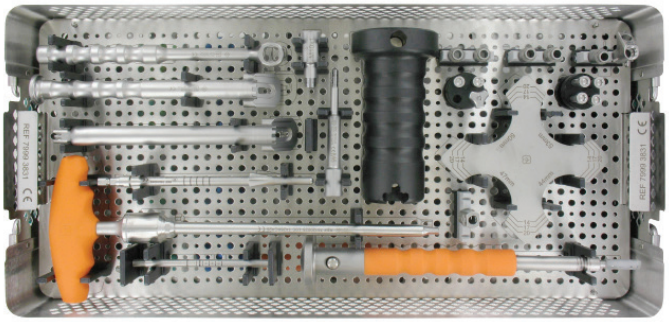
Glenoid zementfrei (Optional für die inverse Versorgung)

Mat.: Pure Titanium (cpTi) acc. to ISO 5832-2 with implaFix®; HA-coating acc. to ISO 13779-2

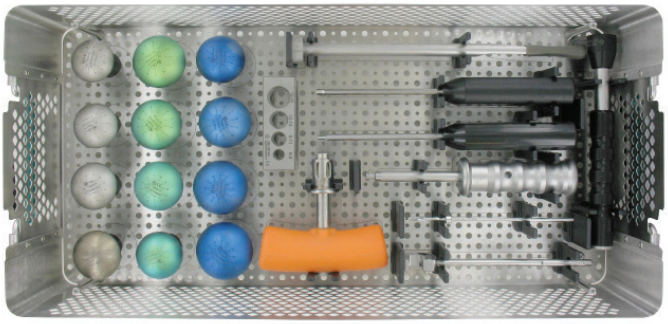
REF	size
3800-4001	3 round



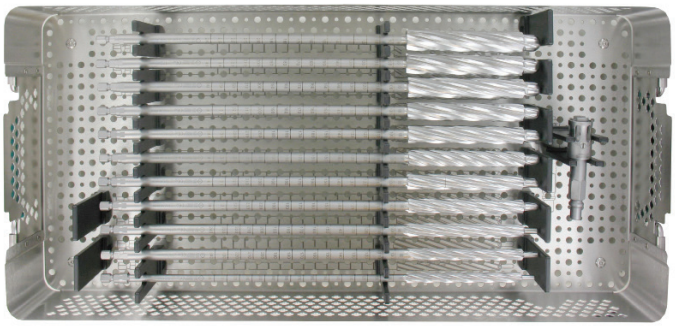
Instrument trays



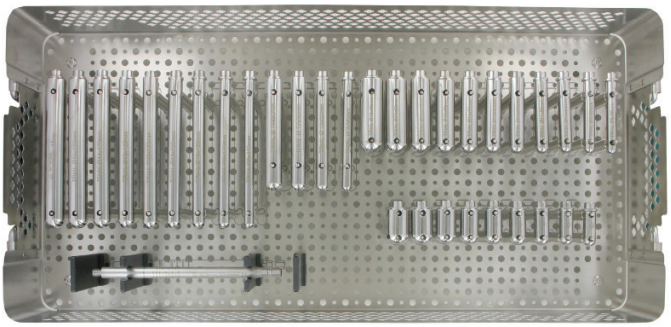
AGILON® basic container (upper tray)
7999-3831



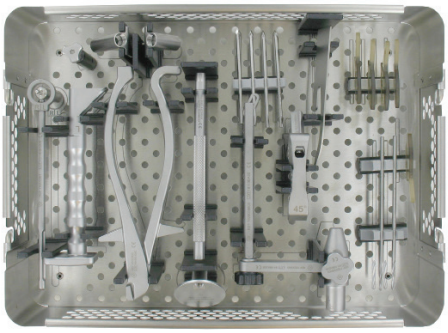
AGILON® basic container (lower tray)
7999-3831



AGILON® drill container
7999-3832

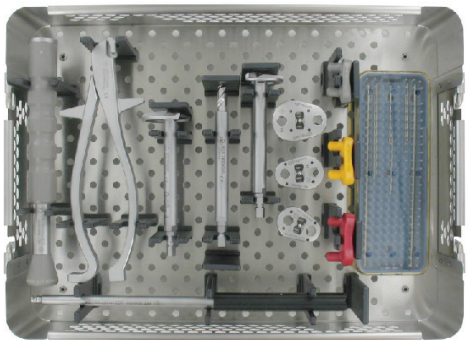


AGILON® trial stem container
7999-3833

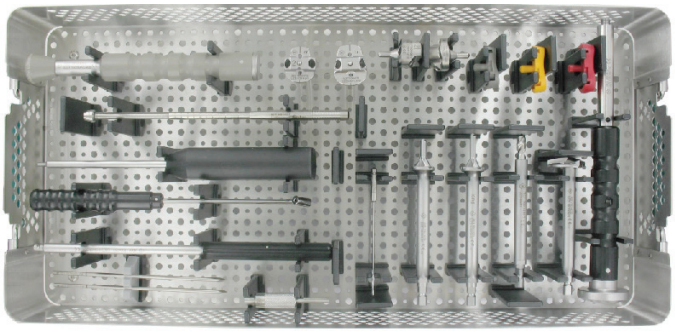


AGILON® omarthrosis container
7999-3834

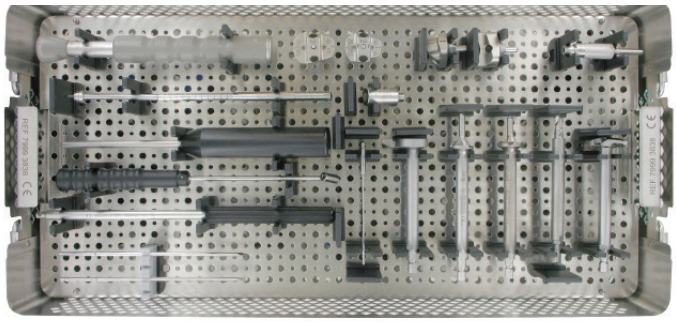
Note: The instruments are delivered nonsterile.



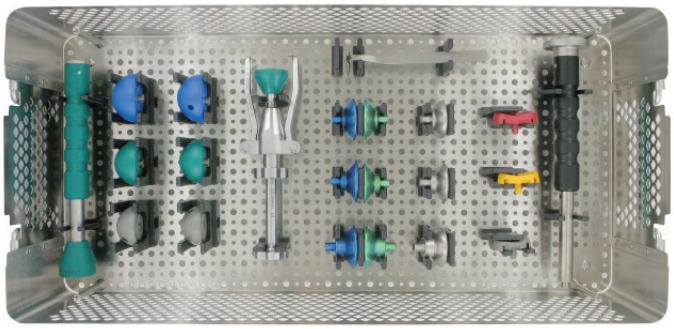
AGILON® glenoid cemented sz. 2-4 container
7999-3836



AGILON® glenoid cementless sz. 2-4 container
7999-3837

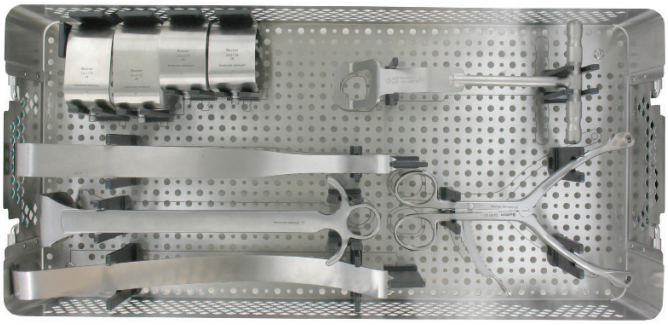


AGILON® glenoid cementless invers sz. 2-4 container (upper tray)
7999-3838

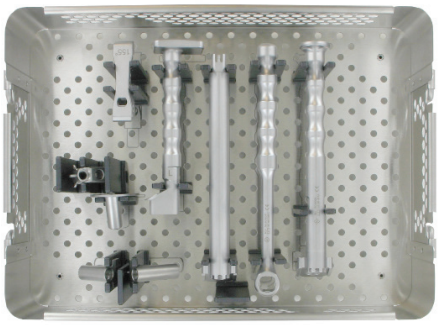


AGILON® glenoid cementless invers sz. 2-4 container (lower tray)
7999-3838

OPTIONAL

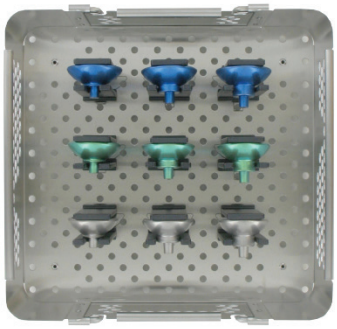


AGILON® retractor container
7999-3816



AGILON® omarthrosis container 155°
7999-3835

AGILON® CTA trial cap container
7999-3819



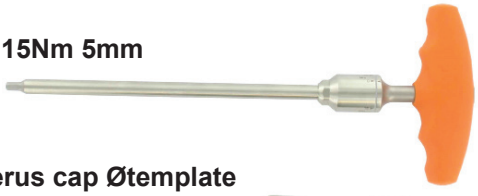
AGILON® retentive inverse trial cap container
7999-3822

Instruments

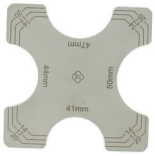
AGILON® Basic container (7999-3831) (upper tray)

AGILON® stem impactor
7801-0009

torque wrench 15Nm 5mm
7512-0025



AGILON® humerus cap Øtemplate
7801-4015



AGILON® reamer tapered
7801-0019

adapter for slap hammer M6
7801-0024

adapter for slap hammer M10x1
7801-0023

AGILON® Implantat Impactor 135°
7801-0126

AGILON® guide rod
7801-0115

AGILON® impaction screw Trauma
7801-0124

AGILON® impaction sleeve M6
7801-0125

AGILON® counter instrument part 1
7801-002001

AGILON® counter sleeve 135°
7801-0127

AGILON® cap assembly block
7820-0210

AGILON® trial metaphyseal component Trauma 135°
7821-0001

AGILON® trial screw M6

REF	*length*
7821-0022	22,5mm
7821-0030	30mm
7821-0032	32,5mm
7821-0035	35mm
7821-0037	37,5mm
7821-0040	40mm

AGILON® trial extension piece

REF	*size*
7821-0075	7,5mm
7821-0100	10mm
7821-0125	12,5mm
7821-0150	15mm
7821-0175	17,5mm

AGILON® Basic container (7999-3831) (lower tray)

head impactor
7512-4444

AGILON® retrotorsion guide modular
7820-0201

drill 3.2mm with stop
8100-2010

ic T-handle
4223-0023

hexagon screw driver

REF	*size*
0280-1007	3,5mm
7608-1050	5,0mm

humeral cap extractor
8003-6101

AGILON® assembling block
7801-0021

slap hammer short
4223-0031

AGILON® trial cap

size	*14mm*	*17mm*	*20mm*
ø44mm	7800-4414	7800-4417	7800-4420
ø47mm	7800-4714	7800-4717	7800-4720
ø50mm	7800-5014	7800-5017	7800-5020
ø53mm	7800-5314	7800-5317	7800-5320

AGILON® drill container (7999-3832)

rigid drill lenght: 240mm

REF	*diameter*
7820-2408	8mm
7820-2409	9mm
7820-2410	10mm
7820-2411	11mm
7820-2412	12mm
7820-2413	13mm
7820-2414	14mm
7820-2415	15mm
7820-2416	16mm
7820-2417	17mm
7820-2418	18mm

ic-adapter outside A/O, inside ic canulated
7512-3602

AGILON® trail stem container (7999-3833)

AGILON® trial stem adapter
7801-2430

AGILON® trial stem

REF	*length*	*diameter*
7850-3010	30mm	10mm
7850-3011	30mm	11mm
7850-3012	30mm	12mm
7850-3013	30mm	13mm
7850-3014	30mm	14mm
7850-3015	30mm	15mm
7850-3016	30mm	16mm
7850-3017	30mm	17mm
7850-3018	30mm	18mm
7850-6008	60mm	8mm*
7850-6009	60mm	9mm
7850-6010	60mm	10mm*
7850-6011	60mm	11mm
7850-6012	60mm	12mm*
7850-6013	60mm	13mm
7850-6014	60mm	14mm*
7850-6015	60mm	15mm
7850-6016	60mm	16mm
7850-6017	60mm	17mm
7850-6018	60mm	18mm
7850-9008	90mm	8mm*
7850-9010	90mm	10mm*
7850-9012	90mm	12mm*
7850-9014	90mm	14mm*
7851-2008	120mm	8mm*
7851-2009	120mm	9mm
7851-2010	120mm	10mm*
7851-2011	120mm	11mm
7851-2012	120mm	12mm*
7851-2013	120mm	13mm
7851-2014	120mm	14mm*
7851-2015	120mm	15mm
7851-2016	120mm	16mm

* trial stems also used for the cemented stems!

AGILON® omarthrosis container (7999-3834)

3.2mm drill length: 126mm (2x)
4221-0019

pin inserter
4223-0006

resection check
4223-0009

pins 3.2mm length: 77mm (4x)
4223-0029

pin extractor
7512-0800

AGILON® box chisel 135°
7801-0013

AGILON® humerus-resection protection cap 135°
7801-0022

humerus cutting block 135°
7820-0550

humerus alignment guide
7820-0560

humerus aligment rod
7820-0561

AGILON® sizing template

REF	*size*
7820-0572	44mm
7820-0573	47mm
7820-0574	50mm
7820-0575	53mm

AGILON® sizing template invers
7820-0576

AGILON® impaction screw omarthrosis
7820-0577

AGILON® trial metaphyseal component

REF	*type*
7821-0002	Omarthrosis 135° 40mm (long)
7821-0003	Omarthrosis 135° 30mm (short)

AGILON® 155° container (7999-3835)

AGILON® implant impactor 155°
7801-0028

AGILON® counter sleeve 155°
7801-0029

AGILON® countering instrument
7801-002001

AGILON® box chisel
7801-0120 155°

AGILON® humerus resection protection plate 155°
7801-0121

humerus cutting block 155°
7801-0122

AGILON® trial metaphyseal component Trauma 155°
7821-0011

AGILON® trial metaphyseal component Omarthrosis

7821-0012	155° 40mm (long)
7821-0013	155° 30mm (short)

AGILON® glenoid cemented sz. 2-4 container (7999-3836)

guide wire 1,8mm
0051-0918 1,8 x 35mm (4x)
7800-4052 1,8 x 75mm (2x)

guide wire 3,2mm x150mm (2x)
3911-0000

pin extractor
7512-0800

glenoid drill guide

REF	*size*
7800-4049	2
7800-4051	3
7800-4050	4

glenoid drill
7800-4061

glenoid reamer

REF	*size*
7801-4070	30mm universal
7800-4062	size 4

handle for drill guide
7800-4063

glenoid positioner
7800-4064

AGILON® trial glenoid

REF	*size*
7802-0032	2
7802-0036	3
7802-0040	4

AGILON® glenoid cementless sz. 2-4 container (7999-3837)

depth gauge
0282-1007

angled drill guide 2.5mm
0282-1025
(alternativ: drill guide 2.0mm angled 0282-1020)

guide wire 3,2mm x150mm (2x)
3911-0000

hexagon screw driver 2,5mm
7601-1001

drill 2,5mm AO
7700-0112
(alternativ. drill A/O chuck 2,0mm 7700-0020)

glenoid drill
7800-4061

handle for drill guide
7800-4063

glenoid positioner
7800-4064

Glenoid anatomical drill guide

REF	*size*
7800-4072	2
7800-4071	3

glenoid impactor
7800-4001

cannulated drill for glenoid cementless

REF	*type*
7801-4075	short
7801-4076	long

glenoid reamer 30mm universal
7801-4070

pep drill guide for glenoid anatomic cementless

REF	*size*
7800-4081	2
7800-4080	3

AGILON® Glenoid trial Insert

REF	*size*
7803-1028	2
7803-1032	3
7803-1036	4

A/O quick release chuck small
4224-0021

adapter for slap hammer M8/1
7801-0026

AGILON® glenoid cementless invers sz. 2-4 container (7999-3838) (upper tray)

glenoid positioner
7800-4064

Glenoid anatomical drill guide

REF	*size*
7800-4072	2
7800-4071	3

pep drill guide for glenoid anatomic cementless

REF	*size*
7800-4081	2
7800-4080	3

A/O quick release chuck small
4224-0021

depth gauge
0282-1007

adapter for slap hammer M8/1
7801-0026

hexagon screw driver 2,5mm
7601-1001

angled drill guide 2.5mm
0282-1025

handle for drill guide
7800-4063

guide wire 3,2mm x150mm (2x)
3911-0000

drill 2,5mm AO
7700-0112

glenoid reamer 30mm universal
7801-4070

cannulated drill for glenoid cementless

REF	*type*
7801-4075	short
7801-4076	long

glenoid drill
7800-4061

Glenoid präparator 44mm
7801-4071

AGILON® glenoid cementless invers sz. 2-4 container (7999-3838) (lower tray)

AGILON® Glenoid trial Insert

REF	*size*
7803-1028	2
7803-1032	3
7803-1036	4

AGILON® captured glenosphere positioner
7801-0030

glenoid impactor
7800-4001

glenosphere impactor
7801-0001

AGILON® trial cap inverse

size	*S*	*M*	*L*
ø36mm	7801-3600	7801-3605	7801-3610
ø40mm	7801-4000	7801-4005	7801-4010
ø44mm	7801-4400	7801-4405	7801-4410

AGILON® trial glenosphere

	size 2	
ø36mm	7802-2836	eccentrical
ø40mm	7802-2840	eccentrical
ø44mm	7802-2844	eccentrical

	size 3	
ø36mm	7802-3236	neutral
ø40mm	7802-3240	eccentrical
ø44mm	7802-3244	eccentrical

AGILON® control gauche for glenosphere
REF 7801-4079

AGILON® CTA trial cap container (7999-3819)

AGILON® CTA trial cap

	14mm	*17mm*	*20mm*
44mm	7820-4414	7820-4417	7820-4420
47mm	7820-4714	7820-4717	7820-4720
50mm	7820-5014	7820-5017	7820-5020
53mm	7820-5314	7820-5317	7820-5320

AGILON® retentive inverse trial cap container (7999-3822)

AGILON® retentive trial cap inverse

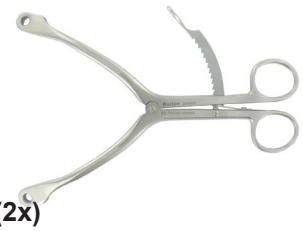
size	*S*	*M*	*L*
ø36mm	7801-5600	7801-5605	7801-5610
ø40mm	7801-6000	7801-6005	7801-6010
ø44mm	7801-6400	7801-6405	7801-6410

AGILON® retractor container (7999-3816)

Kölbel glenoid retractor 15mm
24-6012

Kölbel glenoid retractor 23mm
24-6013

Kölbel retractor frame
24-6102



Kölbel retractor blade 36 x 53mm (2x)
24-6104

Kölbel retractor blade 36 x 68mm (2x)
24-6105

Browne deltoid retractor
24-6123

retractor for humeral cap
7820-0211

Intended Use
The modular AGILON® Shoulder System is intended for hemi or total shoulder replacement. The system consists of different functional components designed to reconstruct the glenohumeral joint. Depending on indication, the humeral component may be used in conjunction with a glenoid component for conventional total shoulder replacement or to articulate directly with the natural glenoid in a hemi-shoulder application. The AGILON® Shoulder System is also intended for reverse shoulder replacement.

The AGILON® Cap and AGILON® CTA Cap (AGILON® CTA Head) are caps intended to replace the humeral head by articulation with the glenoid component or the natural glenoid. The AGILON® CTA Cap has an enlarged articulation surface which allows articulation with the acromion in case of a rotator cuff deficiency.

The AGILON® Cap Inverse and AGILON® Retentive Cap Inverse are caps intended to replace the humeral head by articulation with a glenosphere for a reverse shoulder replacement.

The AGILON® Glenoid Cementless Round and AGILON® Glenoid Baseplate Round are glenoid components intended for cementless fixation to replace the natural glenoid by combination with a glenosphere for a reverse shoulder replacement.

The AGILON® Glenoid Cementless Anatomical and AGILON® Glenoid Baseplate Cementless Anatomical are glenoid components intended for cementless fixation to replace the natural glenoid by combination with a glenoid PE-insert or a glenosphere for total shoulder replacement (anatomical or reverse).

The AGILON® Glenoid PE-Insert is intended to replace the surface of the natural glenoid in total anatomic shoulder replacement. The AGILON® PE-Glenosphere and Glenosphere are components intended to replace the natural glenoid by combination with the AGILON® Glenoid Cementless Round or AGILON® Glenoid Baseplate Round for a reverse total shoulder replacement.

The AGILON® PE-Glenoid Cemented and Glenoid Cemented are glenoid components intended for cemented fixation to replace the glenoid surface in case of an anatomical total shoulder replacement.

The AGILON® Extension Piece is intended for length adjustment in the case of a shoulder replacement.

The AGILON® Metaphyseal Component Trauma is a component intended to replace the metaphyseal part of the humerus in case of a traumatic destroyed shoulder joint.

The AGILON® Metaphyseal Component Omarthrosis is a component intended to replace the metaphyseal part of the humerus.

The AGILON® Stem is a stem for cemented or cementless fixation intended for diaphyseal anchorage of the shoulder joint replace-ment in the humerus.

Post-operative Instructions
Post-operative patient care, patient instructions and warnings are of the utmost importance. The use of an external support for a limited period, to stimulate healing is recommended.
Especially active and passive movements of the patients should be monitored.
The post-operative regime should be aimed at the prevention of overloading of the joint and stimulation of the healing process.
Regular monitoring of position and condition of the prosthetic components and the surrounding bone is recommended.

Indication
The decision for replacement of the joint should be based on careful evaluation. The indication for this type of surgery should only be made when all other conservative or surgical alternatives are less promising. Danger of post-operative complications can be limited by careful evalua-tion of the individual anatomical and load conditions, the condition of the soft tissues and the condition of the bone bed for the implants. The provision of prostheses is generally indicated only in patients whose skeleton is fully grown. Before intervention, preoperative examinations should be performed. The examinations depend on the patient’s history.

Under consideration of these conditions the shoulder joint replacement applies to the following indications:
- Non- inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- Post-traumatic osteoarthritis,
- Fractures,
- Rheumatoid arthritis.

The surgeon decides which version of prosthesis for the individual patient is used. This decision depends on several factors, such as the age and the patient's weight, bone quality, shape of the bone and deformation of the joint.

The main indications for the implantation of an **AGILON® shoulder prosthesis** are:
- Multifragmental comminuted fractures of the humeral head,
- 3- and 4-Fragment-fractures of the proximal humerus,
- Head-splitting fractures,
- Dislocated head-splitting fractures,
- Humeral head depression with more than 40% of joint surface de-pressed,
- Interlocking chronic dislocation with deep HILL-SACHS lesion,
- Fracture instability following internal fixation attempt in 3-fragment and 4-fragment fractures (secondary dislocation, material loosening),
- Posttraumatic humeral head necrosis,
- Omarthrosis.

AGILON® CTA heads are destined for treatment of stable types of rotator cuff tear arthropathy. In order to achieve satisfactory results with the CTA heads the fornix humeri and the subscapularis tendon must be intact.

The main indications for the implantation of an **AGILON® inverse shoulder prosthesis** are:
- Rotator cuff tear arthropathy,
- Chronic trauma shoulder,
- Decentering of the humeral head after implantation of a humeral head prosthesis.

AGILON® retentive caps invers are indicated in case of shoulder joint instability if the joint cannot be stabilized with a regular AGILON® cap inverse in combination with a Glenosphere.

Warning: The use of the AGILON® retentive caps invers entails a decrease of the Range of Motion of the prosthesis. The surgeon has to balance conscientiously the advantage of stabilization and the increased risk of scapula impingement.

Indications for **glenoid replacement** include patients with painful gleno-humeral incongruity,
- Cartilage defect of the glenoid accompanied by sclerosis and/or cyst formation,
- The loss of posterior glenoid concavity,
- Posterior subluxation of the humeral head,
- Secondary socket formation as a result of chronic posterior subluxa-tion of the humeral head.

Contraindication
The longevity of an orthopaedic joint replacement device can be reduced by biological aspects, material characteristics and biomechanical factors. Patient selection and indication should be carefully monitored especially in patients who are overweight, patients with high physical activity levels and patients younger than 60 years of age.
An absolute contraindication is a known allergy to any of the implant materials used. The label on the secondary packaging of each component specifies the material used. Indication for testing, it is strongly recommended to perform an allergy test.
Further absolute contraindications are infections.

The relative contraindications include:
1) Anatomic conditions, which preclude or are not expected to maintain an adequate bony support of the implant or do not allow the implantation of a sufficiently large prosthesis.
   - Insufficient quantity and quality of bone stock, e.g. as a result of osteoporosis or osteomalacia,
   - Vascular disease of the affected limb
2) Metabolic disorders that can affect a stable anchorage of the implant
3) Bone tumors in the implant fixation area
4) Neuromuscular diseases that can impair the affected limb
5) Lack of patient compliance
6) Mental or neurological conditions that affect the ability of patients to comply with medical instructions, especially during the healing phase
7) Obesity.

Further contraindications are extensive stiffening of the shoulder with little or no pain and irreversible pareses of the N. axillaris and the Plexus brachialis.

Glenoid resurfacing is contraindicated in patients with
- Inadequate glenoid bone stock (e.g. massive osteoporosis),
- Severe glenoid defect,
- Irreparable rotator cuff tears,
- Type C-glenoid with posterior glenoid dysplasia and posterior inclina-tion of 25°.

Extensive defects of the glenoid may prevent the implantation of the glenoid component and thus the application of the AGILON® inverse shoulder prosthesis. Also lesions of the N. axillaris or damages of the M Deltoideus are contraindications for the use of the inverse shoulder.

Warning: The use of forearm crutches for shoulder replacement patients should be avoided.

Risk factors
The following risk factors may affect the success of joint replacement:
- Nicotine and/or drug abuse,
- Alcoholism,
- Muscle insufficiency,
- Severe deformities, which lead to an impairment of the anchorage, the exact positioning or function of the implant,
- Excessive loading of the operated joint by strong physical work and/or inappropriate sports,
- Therapies that may affect bone quality.

For further information please see the instruction for use for "Shoulder Endoprostheses" (09300031GB).

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