

AGILON®

The modular shoulder system



 **implantcast**

Surgical Technique
trauma shoulder treatment
with long fit

AGILON®

The modular Shouldersystem trauma shoulder treatment long fit

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

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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.

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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 reverse 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.

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. Preoperatively the 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



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 43.

Compatibility

Humeral options

Heads	anatomical		revers	
	AGILON® cap	AGILON® CTA cap	AGILON® cap invers	AGILON® retentive cap invers
				
	Ø: 44, 47, 50 and 53mm cap height: 14, 17 and 20mm		Ø: 36, 40 and 44mm neck length: K, M (+3mm) and L (+6mm)	
metaphyseal angle: 135° and 155°		Screws		
Metaphyseal components				length: 22.5mm - 40mm
Extension pieces		length: 7.5mm 10mm 12.5mm 15mm 17.5mm		
Stems	cementless		cemented	
		Ø: 9-18mm (in 1mm steps)* length: 30mm**, 60mm, 120mm, 180mm and 240mm		Ø: 6-12mm (in 2mm steps) length: 60mm, 90mm and 120mm

*Stems of 30mm length are not available in diameter 9mm. Diameters of 17mm and 18mm are only available in length of 30mm and 60mm.
**30mm stems can not be used with the trauma metaphyseal components with REF 3821-0001 and REF 3821-0011!

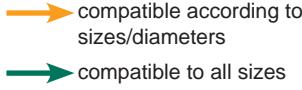
→ compatible according to sizes/diameters
 → compatible to all sizes

glenoid options

cementless

PE-component	glenoid PE-insert	PE- glenosphere	Screws
	sizes: sz. 2 sz. 3 sz. 4	sizes: sz. 2 sz. 3 Ø: 36mm (neutral, eccentric) 40mm (eccentric) 44mm (eccentric)	
Cementless glenoid	anatomical	round	cancellous screw angle stable length: 20mm - 40mm
	 sizes: sz. 2 sz. 3 Versions: short long	 sizes: sz. 3	cancellous screw length: 26mm - 34mm

cemented

PE- glenoid	 sizes: sz. 2 sz. 3 sz. 4
	 orange arrow: compatible according to sizes/diameters green arrow: compatible to all sizes

Compatibility humerus prosthesis to glenoid

cementless glenoid with PE-insert		cemented PE-glenoid		cementless glenoid with PE-glenosphere	
compatible to all sizes			compatible according to sizes/diameters		
AGILON® cap		AGILON® CTA cap		AGILON® cap invers	
compatible to all sizes			compatible according to sizes/diameters		
				AGILON® retentive cap invers	

Surgical Technique

Patient Positioning

The patient should be bedded in the „Beach-chair“-position (Fig. 1 and Fig. 2) at the edge of the table to dislocate and extend the arm freely. A movable side table for the forearm enables a stable rotation control and bed for the forearm.



Fig. 1



Fig. 2

Deltpectoral Approach

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



Fig. 3

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).

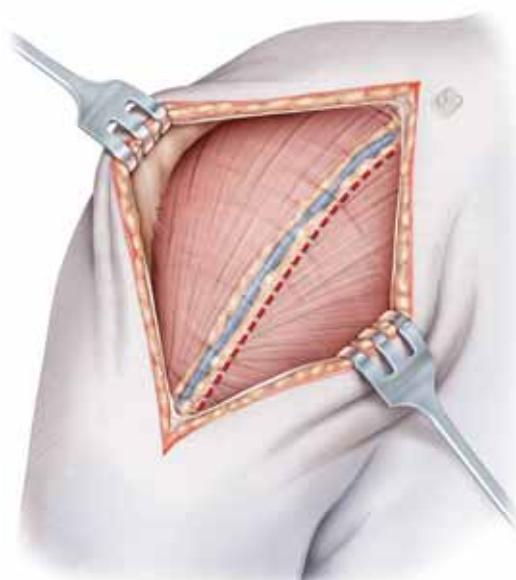
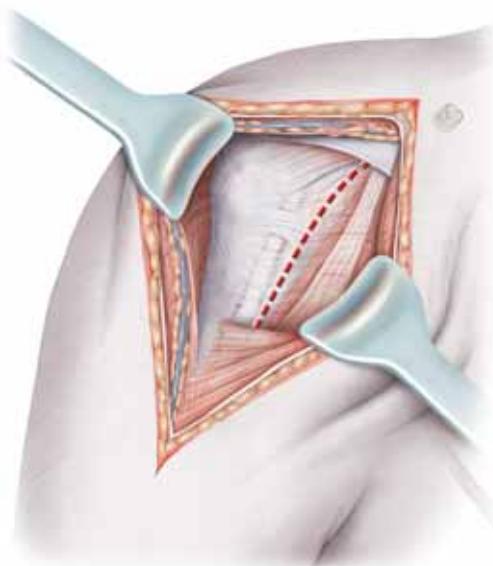


Fig. 4



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

Fig. 5

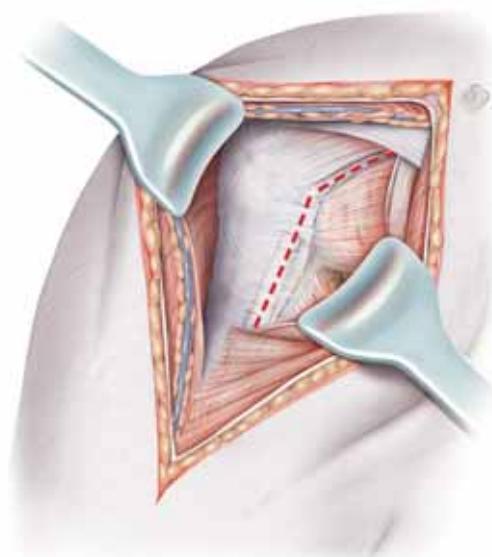


Mobilization of the conjoined tendon as well as palpation of the musculocutaneus nerve.

In addition the axillary nerve can be identified at the lower edge of the subscapularis to avoid iatrogenic damages at the further preparation (Fig. 6). 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 and Fig. 8). If possible the biceps tendon should be attached. 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 1cm 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 (Fig. 8). 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.

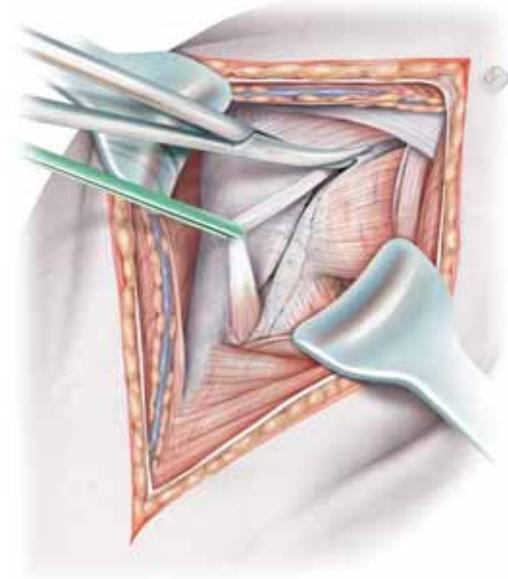


Fig. 8

Exposure of the fracture

Preparation of the head fragments and the adherent segments of the rotator cuff. Trace the biceps into the rotator interval then isolate the greater and lesser tuberosity fragments with the attached rotator cuff. Mobilization begins at the subscapularis including the lesser tuberosity complex (Fig. 9).

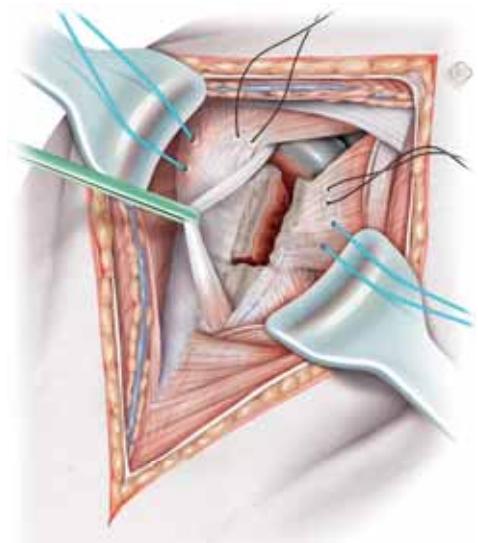


Fig. 9

Heavy retention sutures are placed at the junction of the muscle tendon and bone of the lesser tuberosity and these structures are retracted medially. Follow the same procedure with the greater tuberosity with its parts of the rotator cuff by attaching the sutures at the tendon bone junction. This fragment is retracted laterally posteriorly and superiorly and retracting to lateral

After finishing these maneuvers the view to the head fragment is unobstructed, however, the head fragment may be luxated or tilted dorsally or medially and stuck. It has to be removed carefully and kept for the determination of the dimension of the prosthetic head and also for cancellous bone to add for bone grafting (Fig. 10).

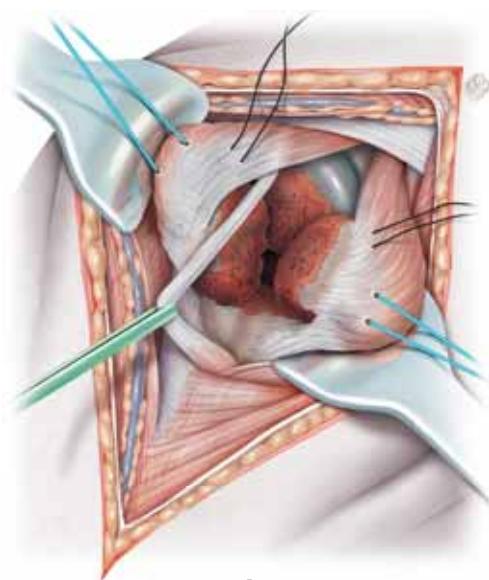


Fig. 10

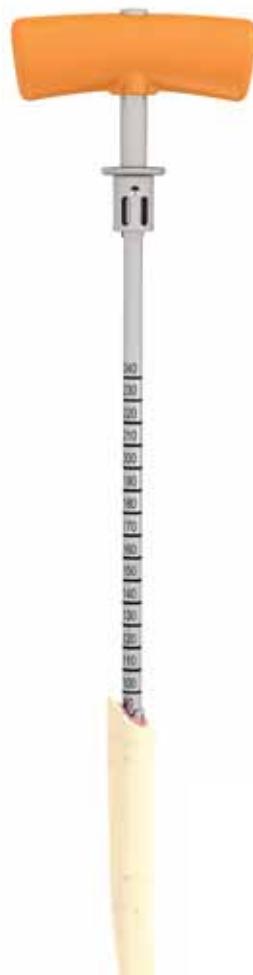


Fig. 11



Fig. 12

Preparation of the medullary cavity

The humerus stem is exposed distal to the fracture with sufficient length and illustrated with bone forceps. The end of the stem has to be cleaned. In order to have good access to the medullary cavity, the forearm is adjusted with the table to position the upper arm in abduction and vertical position.

Ream the intramedullary cavity according to the planned stem. Perform the reaming manually by use of the T-handle (Fig. 11). Start with the smallest reamer and increase the diameter (8-18mm) in 1mm steps.

Use of cemented stems

For a cemented stem the reaming should be 2mm bigger than the diameter of the stem to have sufficient space for bone cement. Be aware to add the length of the intramedullary plug to the reaming depth.

stem length (cemented stem)	reaming depth
60mm	85mm
90mm	105mm
120mm	145mm

Additionally, the conical stem portion need to be prepared for stems with a diameter up to 10mm. Use the conical reamer with the T-handle (Fig. 12).



Use of cementless stems

For cementless fixation the cavity should be reamed to the diameter of the planned cementless stem ("line to line").

stem length (cemented stem)	reaming depth
60mm	60mm
120mm	120mm
180mm	180mm
240mm	240mm

Note: Regularly the loan shipments include cementless stems from 60 to 120mm only. If longer cementless stems (180mm and 240mm) are required, these stems have to be ordered separately. Longer reamers are also required. When 180mm or 240mm long cementless are to be used, leave the last reamer in the medullary canal, as there are no trial stems available for these stems lengths.

For the suture, holes are drilled underneath the edge of the fracture into the humerus before implanting the stem. Following non absorbable high-strength suture material is attached to the stem for vertical refixation (Fig. 13).

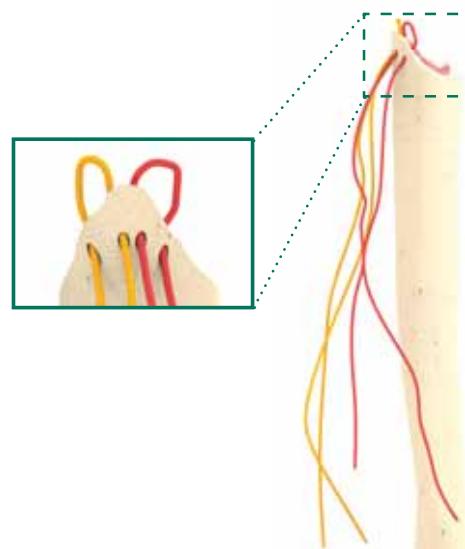


Fig. 13

cemented stem implantation

After preparing the medullary cavity for the cementation a intramedullary plug has to be inserted with the adequate instrumentation. Alternatively a cement stop of cancellous bone from the humeral head can be inserted into the medullary cavity.

Place the impaction sleeve M6 on the trial stem and connect both instruments with the impactor (Fig. 14).



Fig. 14

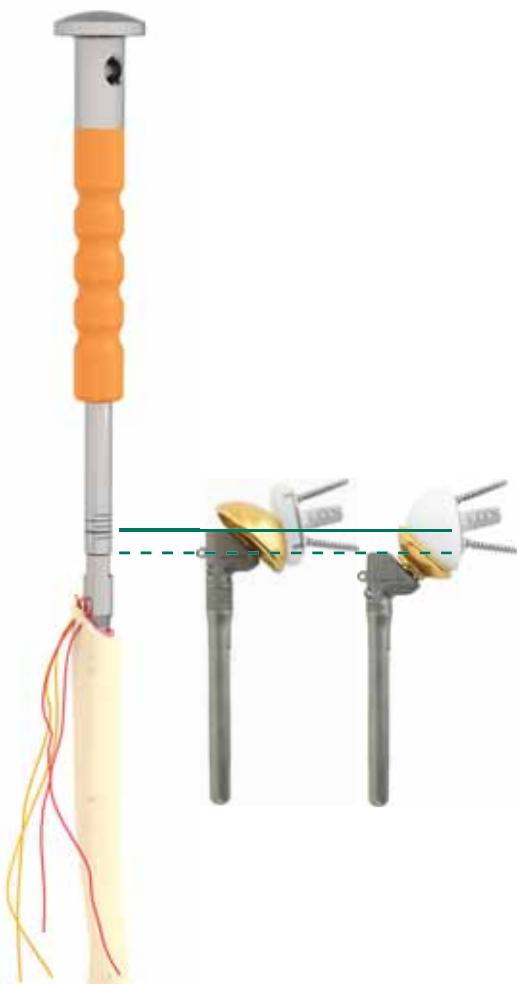


Fig. 15

Prior to stem implantation the height of the prosthesis is planned. Therefore the tubercles are repositioned around the stem impactor instrument. The expected height of the metaphyseal component can be seen on the stem impactor and can be brought in relation to the height of the tubercles. The bolt laser markings show the possible heights. If a 10mm extension sleeve is used the biggest line is reached. The slot between the impaction sleeve and the impactor shows the height, if only a metaphyseal component is used (i.e. for reverse shoulder) (Fig. 15).

For implanting the stem bone cement is placed in the medullary cavity and the selected stem with stem impactor and impaction sleeve is inserted up to the marking. If possible cemental residuals should be removed in soft condition. Take care that the serration for the extension piece or the metaphyseal component is free of cement.

Remove the impactor and the impaction sleeve afterwards (Fig. 16).

Note: If the impaction sleeve is hard to remove, the guide rod can be inserted to achieve a better stability when removing.

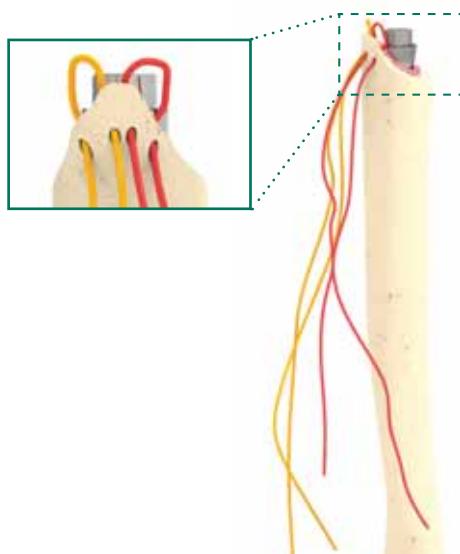


Fig. 16

cementless stem implantation

For cementless stem implantation, use the stem impactor and the impactor sleeve. The diameter of the cementless stem used should be the same as the last reamer used.

Remove the impactor and the impaction sleeve afterwards (Fig. 16).

Note: If the impaction sleeve is hard to remove, the guide rod can be inserted to achieve a better stability when removing.

Height and retrotorsional determination

After hardening of the cement, screw a guide rod on the implanted stem. Place the trial extension piece as well as the trial metaphyseal component over the guide rod on the stem (Fig. 17).

The choice of the extension piece determine the length of the screw, to connect the trial components. See below:

extension piece	screw
none	22.5mm
7.5mm	30mm
10mm	32.5mm
12.5mm	35mm
15mm	37.5mm
17.5mm	40mm

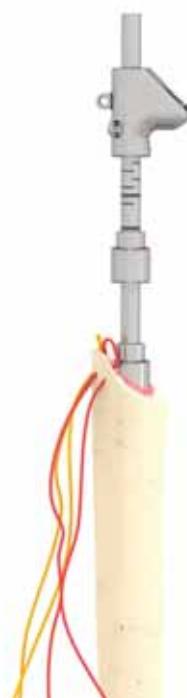


Fig. 17

Use of the anatomical setup

Place the implant impactor on the metaphyseal component. Optionally both can be connected by the screw (a).

For the alignment of the adequate retrotorsion of the prosthesis of 30° the alignment rod is set to 30° and positioned on the impactor (Fig. 18).

In parallel position of alignment rod and forearm axis at 90° flectional elbow joint, the prosthesis is in 30° retrotorsion (Fig. 19). Lock the items in this position by the use of an adequate trial screw.

Note: In case the implant components are changed into an reverse configuration during the surgery the height has to be reduced by app. 10mm and the retrotorsion has to be changed to 10° or 0°. Because of this it is highly recommended to **always use a 10mm extension piece in primary cases**. So the implant can be easily switched into an reverse implant by leaving stem in place.

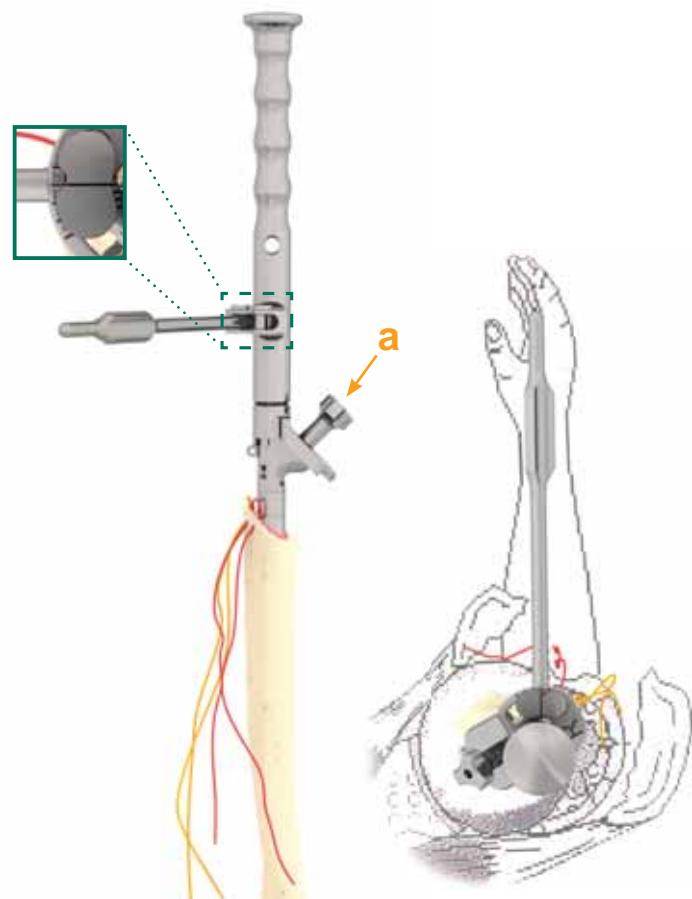


Fig. 18

Fig. 19

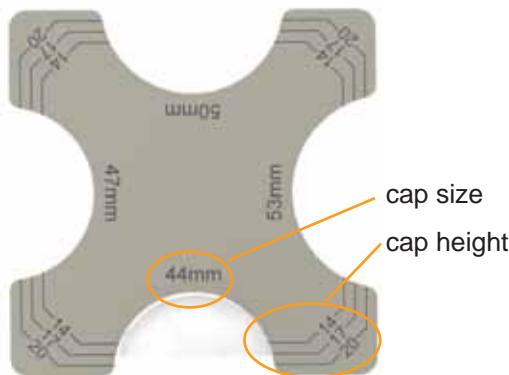


Fig. 20

The size of the trial cap is determined by the resected calotte head (or the fragments of this) with the measurement template (Fig. 20).



Fig. 21

Place the appropriate trial head on the implant (Fig. 21).

Note: If the glenoid should be replaced as well, please prepare this before repositioning. Follow the instructions on page 20 (cementless glenoid) or page 24 (PE-glenoid)

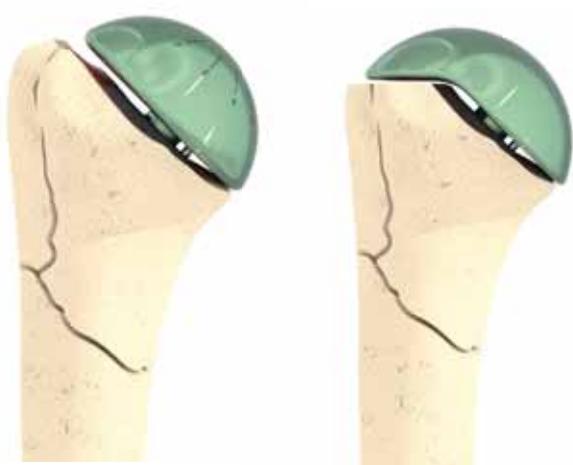


Fig. 22

Fig. 23

Perform the repositioning after attaching the adequate trial cap (Fig. 22 and Fig. 23).

By pulling and moving the arm, the exact adjustment of the length and the rotation of the prosthesis is controlled with the following points:

- distance between tuberculum majus and head (at least 5mm)
- level of retroversion
- head size
- articulation in different positions of the arm
- height of the prosthesis (subacromial space, ligament tension)

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. 24) and the size and height of the cap. You will find the laser markings (1-12) on the back of the final implant components as well (Fig. 25).

Additionally the position and alignment of the prosthesis can be optimized by changing the modular parts (cap, extension piece). To have the closest reconstruction of the anatomical circumstances 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 -2mm and +2mm within the steps between the 1 and 12 o'clock positions (turn of respectively 30 degrees). With this choice combined with the different cap heights options, the surgeon can position any medial offset from 2.6mm to 12.8mm.

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. 24



Fig. 25

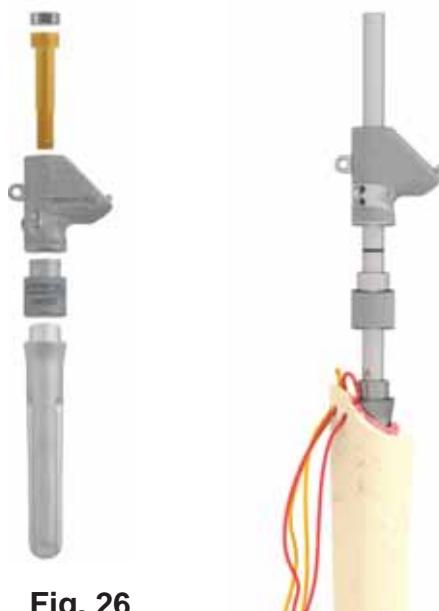


Fig. 26

Fig. 27

Implantation for anatomical treatment

After checking the function and obtaining a satisfying alignment of the prosthesis, the trial components can be replaced by the original components (Fig. 26).

Screw the guiding rod into the implanted stem. Slide the proximal implant components (the metaphyseal component and the extension piece) over the guiding rod (Fig. 27).

Make sure that the serration of all components are clean.

Please double check the correct retrotorsional alignment (Fig. 18 on page 12).

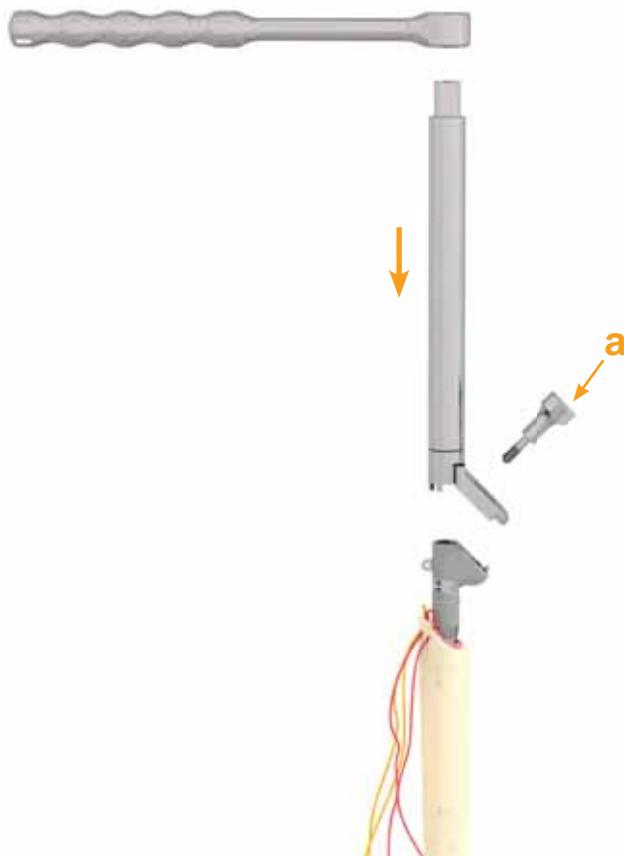


Fig. 28

extension piece	screw
none	22.5mm
7.5mm	30mm
10mm	32.5mm
12.5mm	35mm
15mm	37.5mm
17.5mm	40mm

Mount the two-part counteracting instrument on top. Optionally, the counteracting instrument can be connected to the implant by the screw "trauma" (a) (Fig. 28).

Slide the torque screw driver through the sleeve of the counteracting instrument and lock the implant components.

When the arrow on the handle of the torque screw driver has reached the 15Nm mark, the recommended torque is applied (Fig. 29).

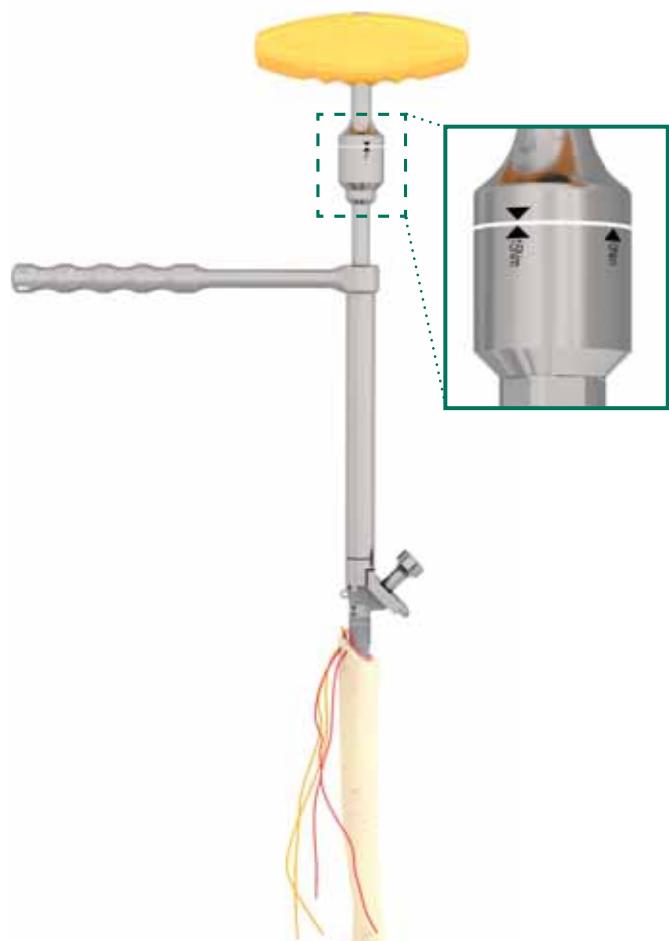


Fig. 29

Fix the safety screw in the same way (Fig. 30).



Fig. 30



Fig. 31

Please clean the taper of the metaphyseal component and impact the cap or CTA cap (of the correct size and height) by the use of the cap impactor in the correct previously determined position with a few slight strokes on the cap impactor (Fig. 31).

Note: A CTA cap is intended for the use as a hemi-arthroplasty without a glenoid component, to treat a patient after a reverse shoulder has failed. The curvature of the caps allow the combination with all glenoid components.



Fig. 32

Optionally, the components can be inserted and mounted in the cap assembly block if it is required to insert the mounted implant (Fig. 32).

Note: If necessary a cemented PE-glenoid is available (see page 24). Alternatively a cementless glenoid can be used, that is suitable both for anatomical or reverse treatments (see page 20).

Osteosynthesis of the tubercles

The fixation of the tubercula on the prosthesis is crucial for a successful treatment.

The suture technique below is a suggestion. The AGILON® trauma metaphyseal component is designed in a way that makes it compatible for various other suture techniques. Non resorbable high strength suture material should be used for the fixation of the tubercula.

Start by laying horizontal sutures for the fixation of the tubercula (blue Fig. 33). For fixation of the tuberculum majus pass the suture close to the bone through the infraspinatus tendon, followed by the posterior ear on the metaphyseal component and back. Proceed accordingly with the tuberculum minus. Pass the suture through the middle part of the subscapularis tendon and the anterior eye on the metaphyseal component.



Fig. 33

Next lay two horizontal cerclages (green and purple Fig. 34). The purple suture should be placed through the lower part of the infraspinatus tendon, around the medial prosthesis neck and through the lower part of the subscapularis tendon. Act accordingly with a second cerclage (green).

The lateral ear, located in 90°-position, can be used optionally. The tubercles have to be adapted and fixed in anatomical position at the prosthesis and the humeral stem.

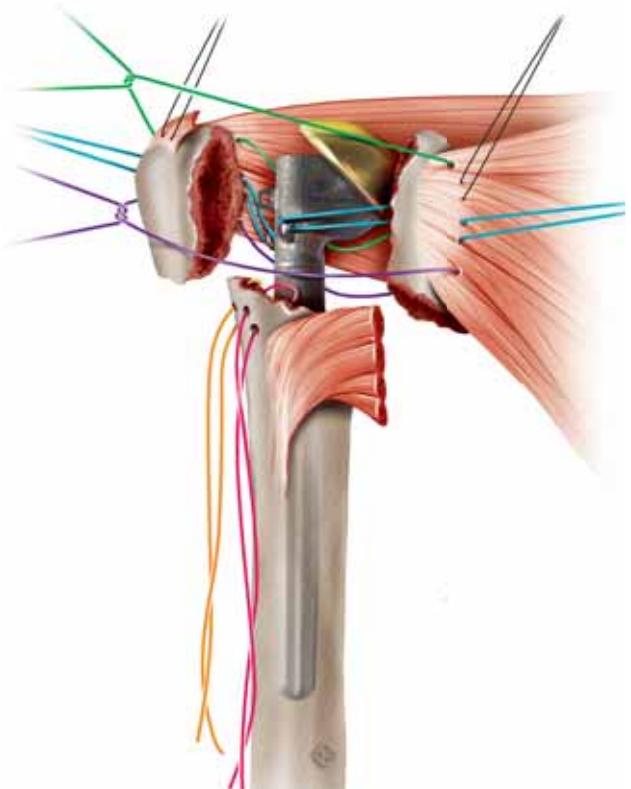


Fig. 34

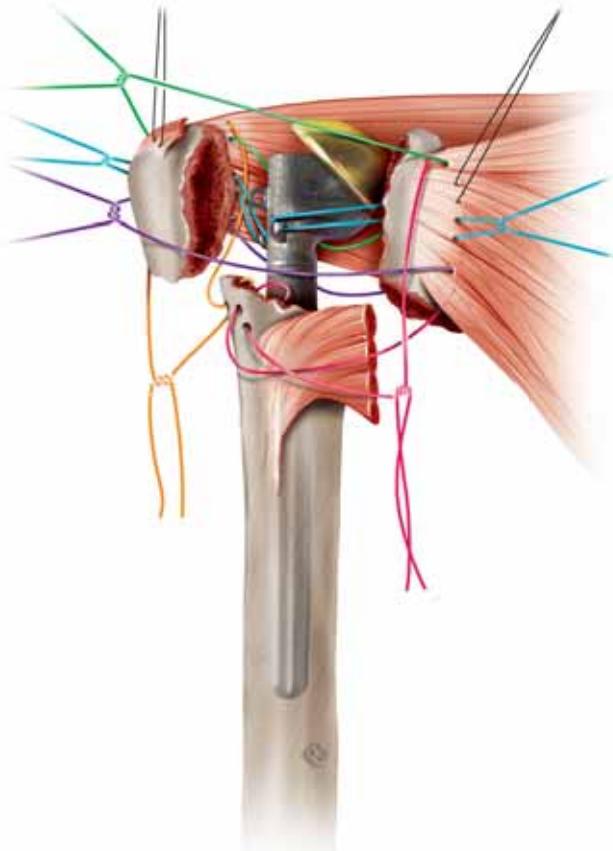


Fig. 35



Fig. 36

The fixation of the tubercles to the humeral stem is done with the previously placed transosseous fibers (Fig. 13 page 10) in vertical direction.

Take the posterior fibre (orange) through the infraspinatus tendon and the anterior vertical fibers (red) through the subscapularis tendon (Fig. 35).

The tubercula are brought to a anatomic position and adapted to the prosthesis if needed. Additional fragments and spongiosa bone from the natural calotte can be used to improve the osseointegration in the cavities and between tubercles and the neck of the prosthesis.

When the sutures are tighten pay attention to not change the position of the tubercula (Fig. 36). Fasten the blue fibers first. Leave the ends long for later use.

Next tighten the green and purple sutures as shown.

Afterwards fix the vertical fibers (orange and red) one after the other.

Connect the ends of the blue sutures.

Existing lesions of the rotator cuff should be closed. It is also indicated to close the rotator cuff intermittent with previously placed (Fig. 13 page 10) (black) fibers, because it contributes to secure the antero-posterior cuff. Pay attention that the long biceps filament is undisturbed. If this is not possible a tenodose or resection has to be considered. Redon-Drains are recommended for the wound closure.

The correct position of the tubercles should be checked by performing a trial reduction preferably using an image converter.

A good result is reached when the tubercle refixation is stable, secured and anatomically aligned.

Cementless glenoid preparation

Mark the centre of the glenoid (Fig. 37).

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



Fig. 37

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 (Fig. 38). The drill guide has the same size as the implant and its entire rear surface should be in contact with bone.

In cases with eroded glenoids a free handed placement leads to a better positioning: The guide pin should be in a perpendicular direction to the glenoid neck, compensating for any eroded glenoid surface (as for example posterior glenoid wear). Remove the drill guide afterwards.



Fig. 38

Use the universal glenoid reamer to expose the subchondral bone. The reamer is guided by the guide wire (Fig. 39). Make sure that the reamer is turning already at full speed before it hits the bone surface.

Insert the 3.2mm bone pin through the central hole of the drill guide (Fig. 40). Choose the length of the drill matching the planned glenoid peg length.

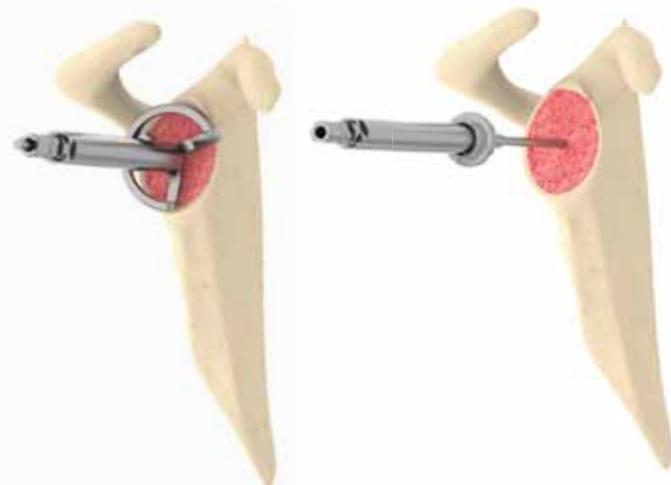


Fig. 39

Fig. 40

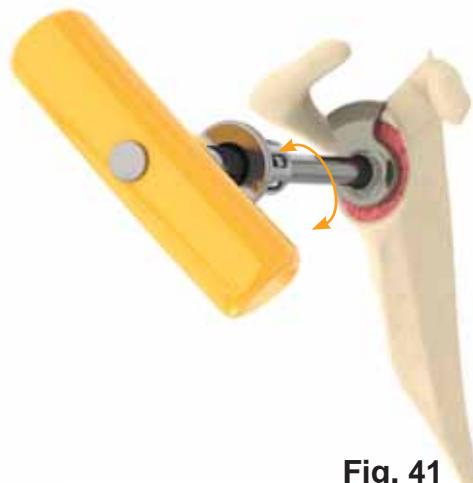


Fig. 41

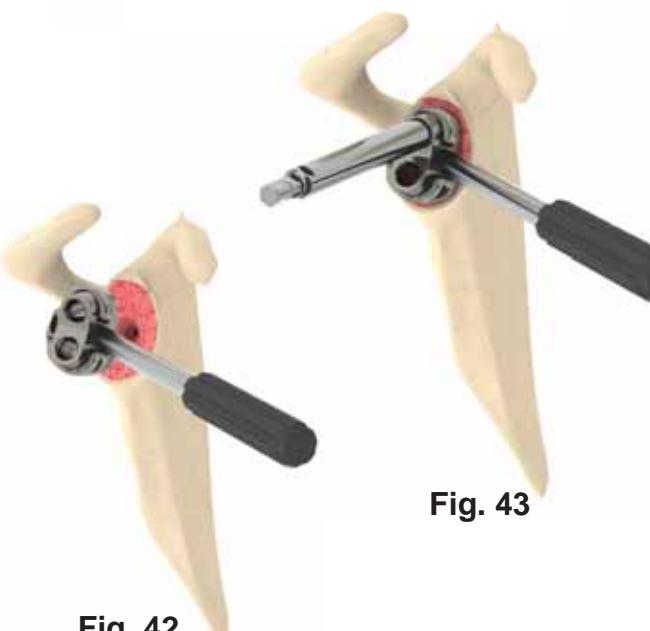


Fig. 42

Fig. 43



Fig. 44

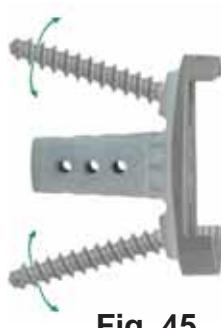


Fig. 45

Should an reverse treatment be planned you can optionally 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 (**do not use a machine** to prevent soft tissue damage) and slide it over the pin. Carefully rasp back and forth caudal and cranial to create room for the glenosphere (Fig. 42).

Remove the guide pin, afterwards.

Insert the special drill guide for the cranial and caudal groove of the implant (Fig. 43). Use the drill with stop through the drill guide to prepare the holes for the grooves (Fig. 46).

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 reinser the guide pin into the central hole.

Impact the implant carefully until the glenoid rests completely flush on the reamed bone surface (Fig. 47). Afterwards release the impactor from the implant and remove the guide pin.

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 of the implant.

You can freely angle the screw up to 15°, as the screw head is self-threading into the glenoid material (Fig. 48).

Drill the holes for the locking screws with 2.5mm (alternatively 2.0mm) drill and the angled drill guide (Fig. 49).



Fig. 46

Determine the screw length using the depth gauge and insert the screws of the correct lengths (Fig. 47). Lock the screws with the hexagonal screw driver 2.5mm (Fig. 48). The screw head need to be in the glenoid base.

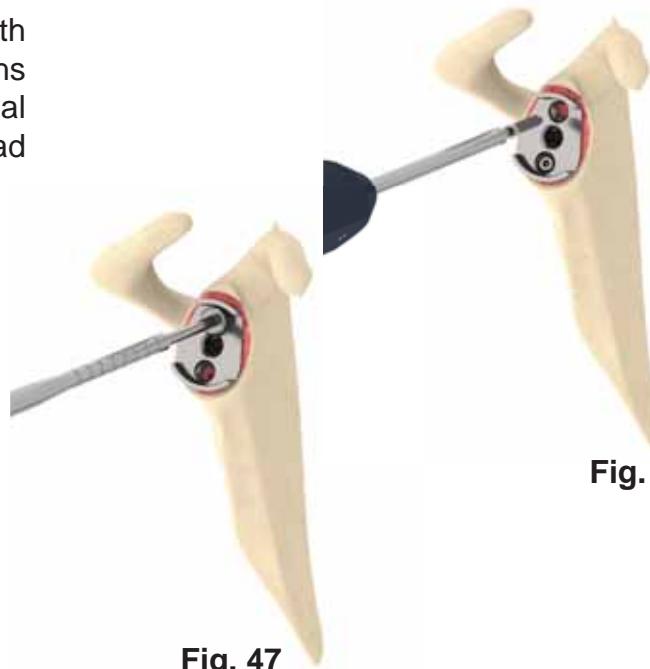


Fig. 48

Add the trial insert of the appropriate size (Fig. 49 and Fig. 50) and perform a trial reduction. Please note the correct compatibility:

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

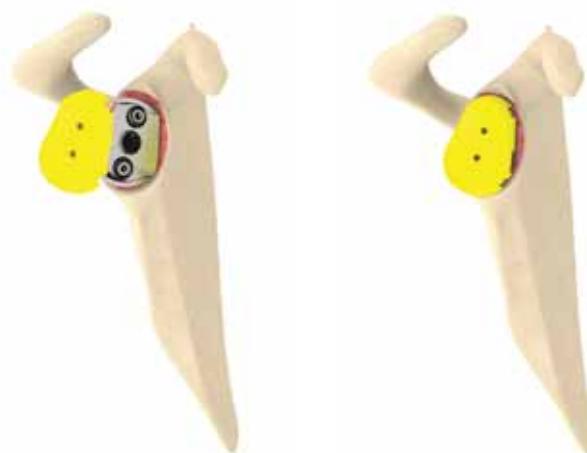


Fig. 49

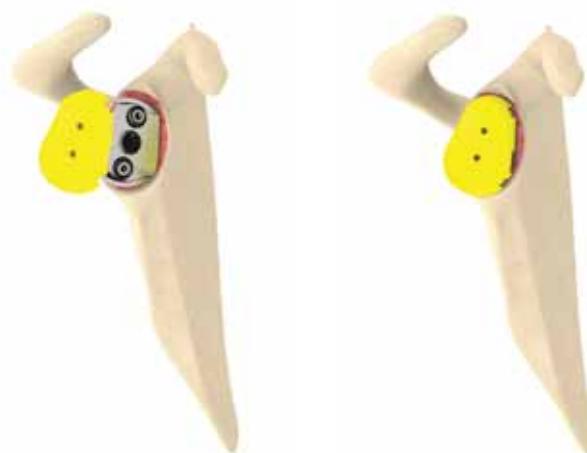


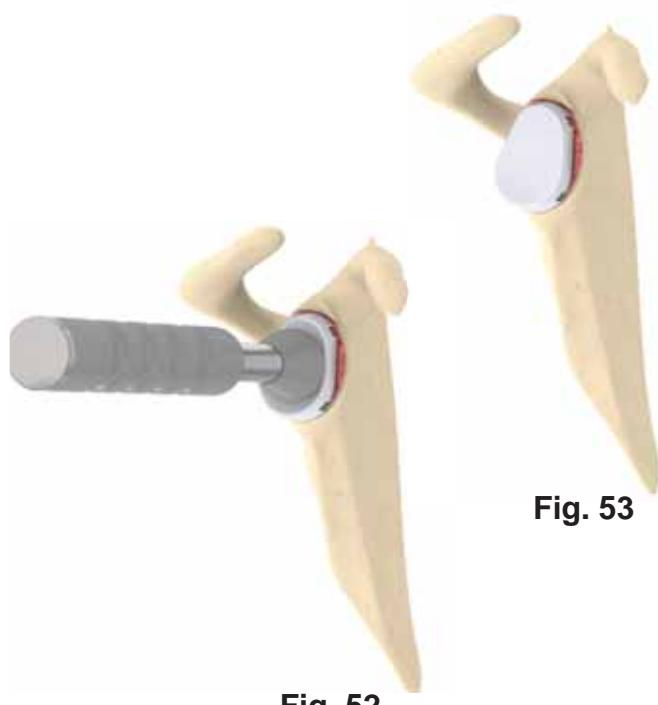
Fig. 50

Perform a trial reduction.

**Fig. 51****Implantation anatomical PE-insert for cementless glenoid**

Combine the PE-insert of the previously determined size with the glenoid (Fig. 51). Please note the correct compatibility:

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

**Fig. 53**

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. 52 and Fig. 53).

Cemented PE-glenoid preparation

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. 54). 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. 55).

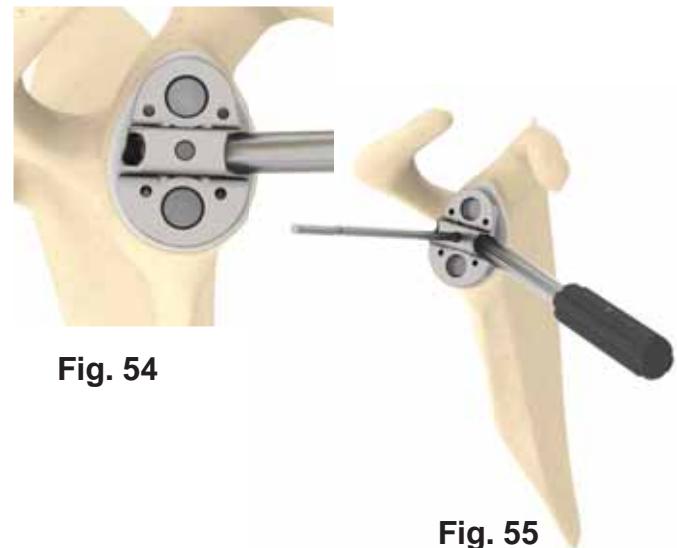


Fig. 54

Fig. 55

Please remove the drill guide afterwards (Fig. 56). 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 bleeding bone (Fig. 57).

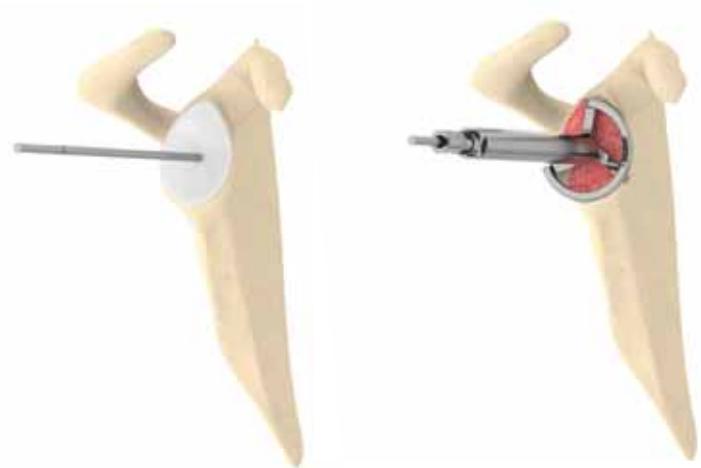
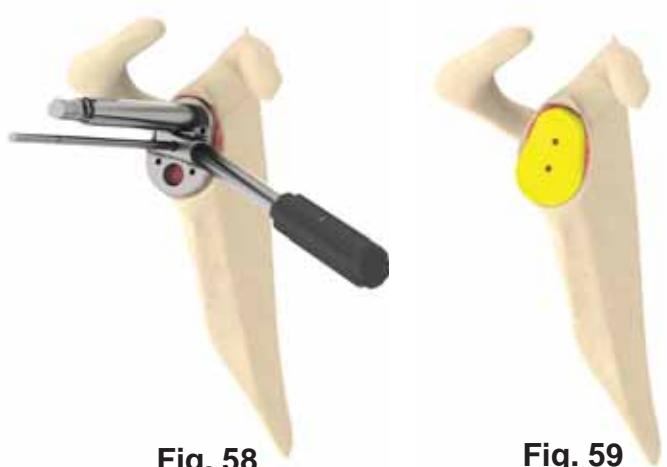


Fig. 56

Fig. 57

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. 58).



Remove all instruments and continue with the trial reduction.

Impact the trial glenoid of the correct size (Fig. 59) and perform a trial reduction.

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

Fig. 58

Fig. 59



Fig. 60



Fig. 61

Add the trial cap (Fig. 60) or the CTA trial cap (Fig. 61) of the previously determined size and height to the trial implant.

Note: A CTA cap is intended for the use as a hemi-arthroplasty, to treat a patient after an reverse 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.

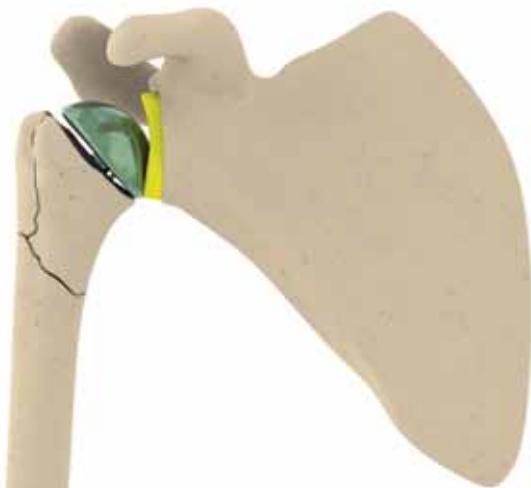


Fig. 62

Perform a trial reduction and check the range of motion and the stability as well as the offset of the joint (Fig. 62).

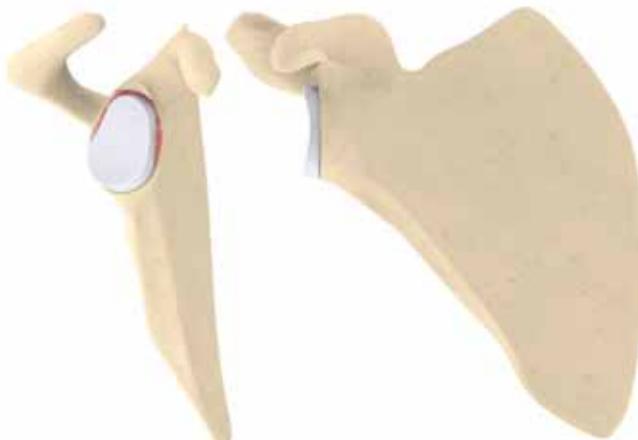


Fig. 63

Fig. 64

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. 63 and Fig. 64).

Reverse implantation

Double check the retrotorsion by the use of the alignment rod (Fig. 65). For reverse shoulder arthroplasty the retrotorsion should be set to 10° or even 0°.

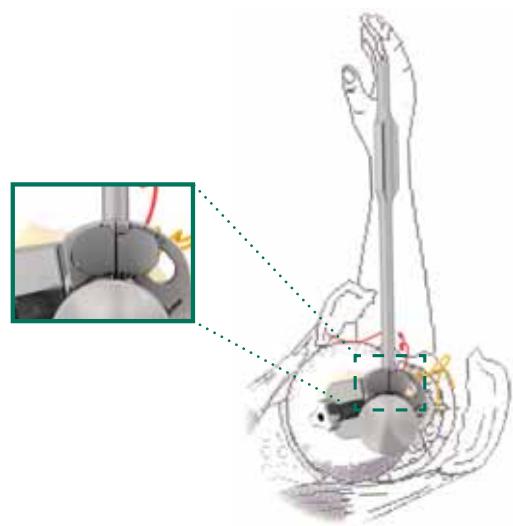


Fig. 65

Note: In case the implant components are changed into an reverse configuration during the surgery the height has to be reduced by app. 10mm and the retrotorsion has to be changed to 10° or 0°. Because of this it is highly recommended to **always use a 10mm extension piece in primary cases**. So the implant can be easily switched into an reverse implant by leaving stem in place.



Fig. 66



Fig. 67



Fig. 68



Fig. 69

Reverse cementless glenoid

Attachment of the glenosphere: To avoid an inferior impingement of the articulating surfaces on the scapula the glenospheres of the sizes 36, 40 and 44mm can be positioned eccentrically. Therefore the trial glenospheres show a degree adjustment with the clock between 9 and 3 o'clock. These markings can be found on the inner surface of the implant and should be positioned cranial (Fig. 68). This positions the overhang caudal.



Fig. 70

Then screw the trial glenosphere onto the glenoid using the 3.5mm hex screw driver (Fig. 70) and perform a trial reduction. The markings on the trial glenosphere help to obtain the optimal position of the glenosphere (Fig. 69).



Fig. 71

Check the range of motion (ROM) and the eccentricity of the glenosphere. If necessary, please adjust the neck length of the inverse cap. The difference of the caps S, M and L is 3mm neck length (Fig. 71).

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. 72). 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. 72

Adjust the glenosphere to the correct, previously during the use of the trial glenosphere determined, rotation (Fig. 73 and Fig. 74). 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. 72).



Fig. 73

Fig. 74

Impaction of the glenosphere

Position the glenosphere onto the glenoid. Make sure that the glenosphere is positioned with the correct eccentricity (Fig. 75).

Please hit the platform of the captured impactor lightly 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. 75

Use the head impactor to ensure the connection between the components (Fig. 76).



Fig. 76



Fig. 77



Fig. 78

Make sure the coupling of the two implant components is complete (Fig. 77). Use the AGILON® control gauché for glenosphere superior and inferior only very small movements of the gauché should be possible if the glenosphere is seated correctly (Fig. 78).

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 and height previously determined during the trial reduction, by the use of the cap impactor (Fig. 79). Before impacting the cap make sure, that the pin is seated in the correct position.



Fig. 79

Reduce the joint and perform a final stability check of the joint (Fig. 80).

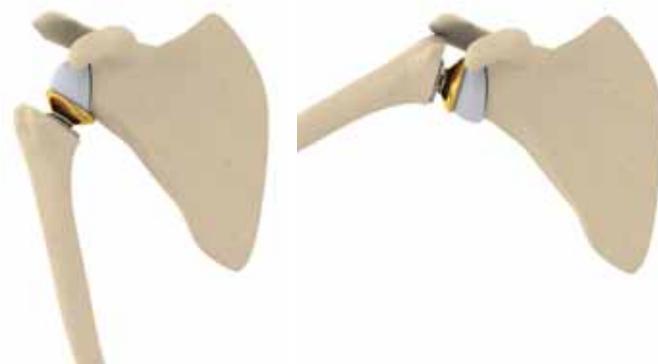


Fig. 80

If necessary, please use the retentive inverse cap to achieve joint stability (Fig. 81).

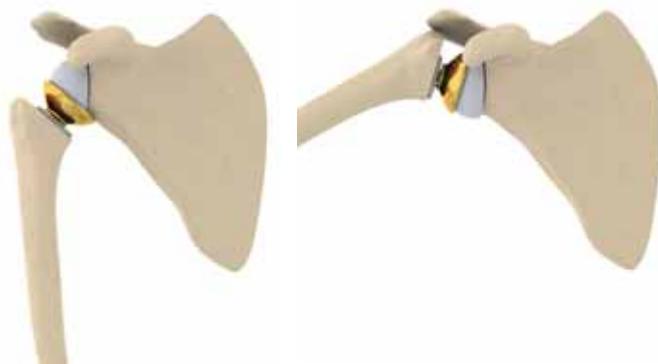


Fig. 81

With the preservable structures the rotator cuff should be reconstructed.

Postoperative treatment and X-Ray controls after AGILON® Trauma Treatment:

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 position 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

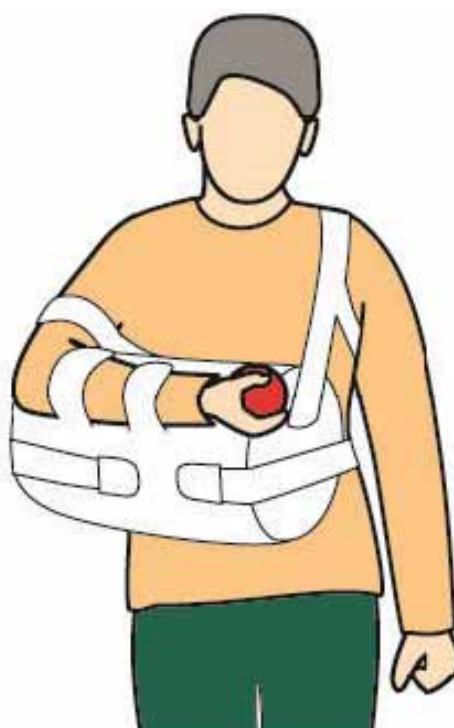


Fig. 82

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 coating

	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
3821-0001	Trauma	135°	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



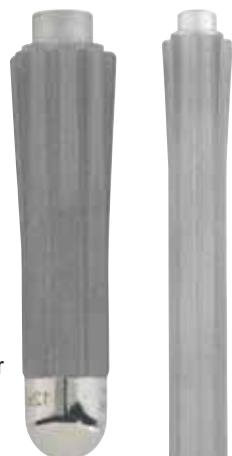
AGILON® stem cementless M6

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

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

	60mm	90mm	120mm
ø 6mm	3840-6006	3840-9006	3841-2006
ø 8mm	3840-6008	3840-9008	3841-2008
ø 10mm	3840-6010	3840-9010	3841-2010
ø 12mm	3840-6012	3840-9012	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	combined 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	glenoid size	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®, TiAl₆V₄ 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

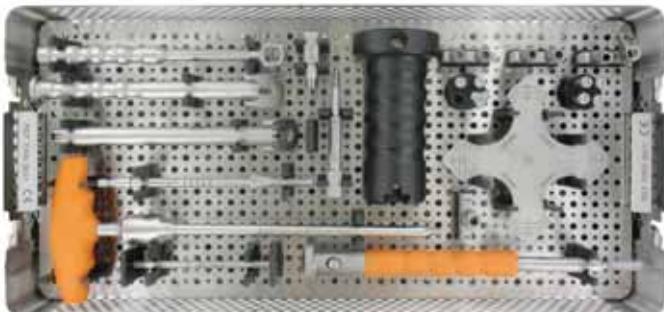
**Glenoid cementless (optional for inverse option)**

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

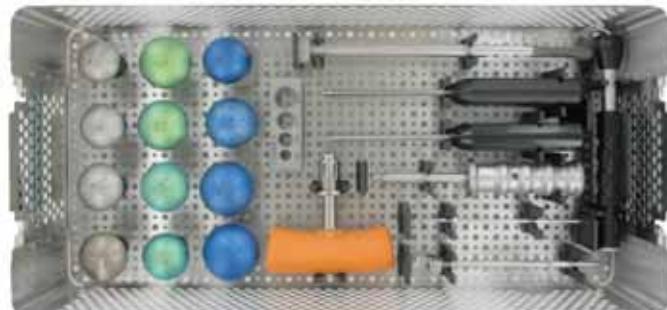
REF	size
3800-4001	3 round



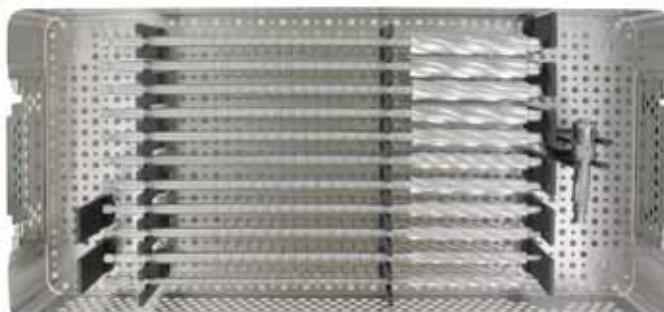
Instrument trays



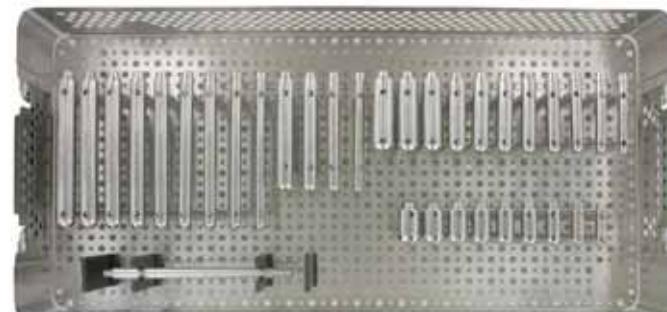
AGILON® basic container (upper tray)
7999-3831



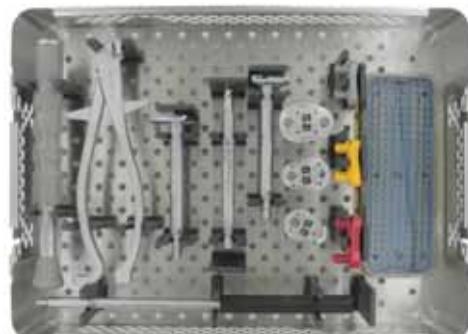
AGILON® basic container (lower tray)
7999-3831



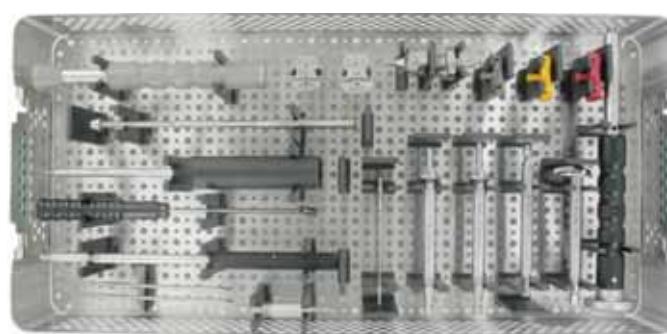
AGILON® drill container
7999-3832



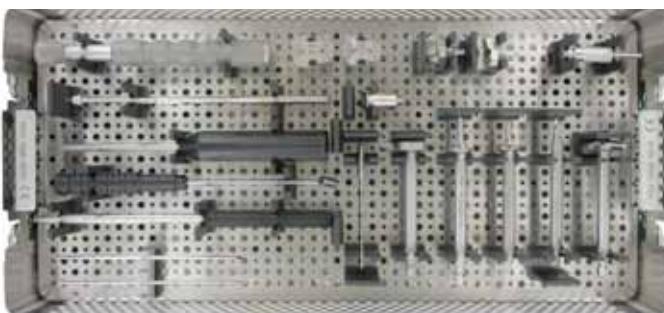
AGILON® trial stem container
7999-3833



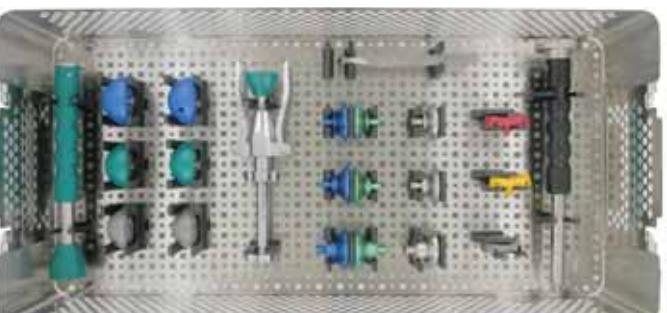
**AGILON® glenoid cemented
sz. 2-4 container**
7999-3836



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

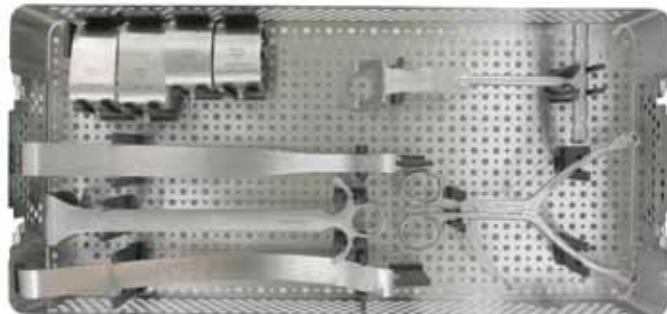


**AGILON® glenoid cementless invers
sz. 2-4 container (upper tray)**
7999-3838



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

Note: The instruments are delivered nonsterile.

OPTIONAL

AGILON® retractor container
7999-3816



AGILON® omarthrosis 155° container
7999-3835



AGILON® CTA trial cap container
7999-3819



AGILON® retentive trial cap container
7999-3822

Note: The instruments are delivered nonsterile.

Instruments

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

AGILON® stem impactor

7801-0009



torque wrench 15Nm 5mm

7512-0025



AGILON® humerus cap template

7801-4015



AGILON® reamer tapered

7801-0019



adapter for slap hammer M6

7801-0024



adapter for slap hammer M10/1

7801-0023



AGILON® Implantat Impactor 135°

7801-0126



AGILON® guide rod

7801-0115



AGILON® impactor 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 bar screw

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 Zimmer-Jakobs

4223-0023



hexagon screw driver

REF *size*

0280-1007 3,5mm (short)

7608-1050 5,0mm



humeral head 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 length: 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® trial 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® 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	Größe 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

7608-1001


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



peg 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

**peg 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**

7608-1001

**angled drill guide 2.5mm**

0282-1025
(alternativ. drill A/O chuck 2,0mm
7700-0020)

**handle for drill guide**

7800-4063

**guide wire 3,2mm x150mm (2x)**

3911-0000

**drill 2,5mm AO**

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

**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	size 3
ø36mm	7802-2836	7802-3236
ø40mm	7802-2840	7802-3240
ø44mm	7802-2844	7802-3244

**AGILON® control gauche for glenosphere**

REF 7801-4079

**AGILON® CTA trial cap container**

(7999-3819)

AGILON® CTA trial head

	14mm	17mm	20mm
ø44mm	7820-4414	7820-4417	7820-4420
ø47mm	7820-4714	7820-4717	7820-4720
ø50mm	7820-5014	7820-5017	7820-5020
ø53mm	7820-5314	7820-5317	7820-5320

**AGILON® omarthrosis container 155° (7999-3835)****AGILON® implant impactor 155°**

7801-0028

**AGILON® counter sleeve 155°**

7801-0029

**AGILON® counter instrument part 1**

7801-002001

**AGILON® box chisel 155°**

7801-0120

**humerus resection protection plate 155°**

7801-0121

**humerus cutting block 155°**

7801-0122

**AGILON® trial metaphyseal component**

7821-0011 Trauma 155°

**AGILON® trial metaphyseal component**

7821-0012 Omarthrosis 155° 40mm (long)

7821-0013 Omarthrosis 155° 30mm (short)



**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 replacement 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 evaluation 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 subluxation 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 inclination 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 Deltoides 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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