Surgical Schnigue Reversed Shoulder Prosthesis

Aequalis[®]-Reversed Fracture



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TABLE OF CONTENTS

IMPLANT DESCRIPTION	p. 4 p. 6
IMPLANT	p. 6
1. INDICATIONS AND CONTRAINDICATIONS	
TECHNIQUE OPÉRATOIRE	р. 7
1. PREOPERATIVE PLANNING	
2. PATIENT POSITIONING	
3. SURGICAL APPROACH	
4. FRACTURE EXPOSURE	
5. GLENOID EXPOSURE AND PREPARATION	
 6. PREPARATION OF THE HUMERUS 6.1 Humeral Reaming 6.2 Drilling of two holes in the diaphysis to pass vertical sutures 6.3 Assembly of Prosthesis Holder 6.4 Positioning of the Trial Stem 6.5 Bone Graft Placement 6.6 Cementing the implant 6.7 Insertion of final humeral implant 6.8 Impaction de l'insert huméral 6.9 Reduction of implant 6.10 Tuberosities Fixation 6.11 Trial and Closure 	
7. REHABILITATION	
 8. COMPLICATIONS 9. AEQUALIS[®]-REVERSED HEMI-PROSTHESIS ADAPTOR TECHNIQUE 9.1 Preparation of metaphyseal implant 9.2 Affixing the adaptor cap-metaphysis union screw 9.3 Implantation of adaptor 9.4 Impaction of humeral head 	
COLOR CODING	p. 24
INSTRUMENTATION	р. 24 р. 26 р. 28
IMPLANTS	р. 28

AEQUALIS®-REVERSED FRACTURE

IMPLANT DESCRIPT

DESIGN ADAPTED FOR REDUCTION, FIXATION AND STRENGTHENING OF TUBEROSITIES

Single metaphysis diameter

Same cup diameter is used for the 2 articular diameters of 36 mm and 42 mm.

Metaphysis covered by HA-coating

Stem is covered in its metaphyseal part to enhance osteointegration of tuberosities.

Lateral flat plate

This allows anatomic positioning of tuberosities to facilitate reduction and enhance conservation of osseous tissue.

Polished tunnels

Polished tunnels serve to anchor soft tissue, especially when muscle tissue is transfered.

Polished Neck

Allows passage of suture threads without risk of abrasive wear of sutures.

Distal grooved design

This enhances better distal fixation in the cement. Stem design assures antirotation fixation of implant.

Metaphysis Window

Bone graft material can be put in the window to optimize consolidation of tuberosities.

Stem and monobloc Metaphysis

Stem is monobloc to avoid risk of postoperative unscrewing of stem from metaphysis. Large selection of diameters and lengths in cement version to adapt to anatomic variations and need for surgical revisions.

ION



Lateralization Spacer

Optional 9 mm spacer allows increase in lateralization and height of Aequalis®-Reversed Fracture prosthesis. With polyethylene insert this spacer can increase the thickness to 15, 18 or 21 mm to increase deltoid tension.



Two series of polyethylene inserts of 36 mm or 42 mm

Allow optimizing deltoid tension and implant stability while avoiding risk of acromial impingement.

• Centered inserts are available in different

- thicknesses of 6 mm, 9 mm and 12 mm
- Constrained inserts are available in different thicknesses of 6 mm, 9 mm and 12 mm

IMPLANT

• 1. INDICATIONS AND CONTRAINDICATIONS

Aequalis[®]-Reversed Fracture prosthesis is indicated for patients with functional deltoid muscle:

• In the context of total shoulder replacement to relieve pain and significant disability following arthropathy associated with a massive and non-repairable rotator cuff tear.

• In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3-or 4-part fractures of proximal humerus.

• In case of bone defect in proximal humerus.

• The Aequalis[®]-Reversed Fracture Shoulder Prosthesis is also indicated for prosthetic revisions with grossly deficient rotator cuff when other treatments or devices have failed.

If during the primary surgery the glenoid bone stock appears to be insufficient to support the glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components to transform the Aequalis® Reversed Fracture Shoulder Prosthesis into a non-reversed hemi-prosthesis.

If the glenoid bone stock appears to be insufficient to implant a base plate and sphere of a Aequalis[®]-Reversed prosthesis during revision of a Aequalis[®]-Reversed Fracture Shoulder Prosthesis, the use of the hemi-prosthesis adaptor and union screw allows for the transformation of the Aequalis[®]-Reversed Fracture Shoulder Prosthesis into a non-reversed hemi-prosthesis to avoid revision of the humeral components.

The Aequalis[®]-Reversed Fracture Shoulder humeral stem is used in association with glenoid components of the Aequalis[®]-Reversed Shoulder Prosthesis.

The Aequalis®-Reversed fracture humeral stem is for cemented use only.

Complete list of contraindications can be found in the "Instructions For Use" packaged with the implants.

• 1. PREOPERATIVE PLANNING

Thorough patient evaluation with history and physical examination is advised.

Considering the age of these patients, it is important to assess their overall health status and address any medical comorbidities that can preclude safe administration of anesthesia. Associated traumatic lesions such as hip fracture or radius fracture are frequently found in these patients and must be taken into account during preoperative planning.

Evaluation of the contralateral shoulder should be done since there can be limited range of internal rotation of a reversed prosthesis. The deltoid muscle must be evaluated by clinical examination. Weakness of the deltoid does not constitute a strict contraindication to a reversed fracture prosthesis.

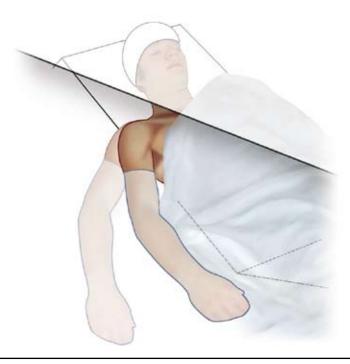
The preoperative studies should include computed tomographic (CT) scan to classify the fracture, determine the displacement and status of the tuberosities, and evaluate indirectly the status of the rotator cuff by analysis of fatty infiltration of the muscles, as well as determine the glenoid bone stock.

Bilateral X-rays of the whole humerus allow evaluation of bone loss in comminuted fractures and help the surgeon estimate the approximate stem height of the prosthesis by comparing measurements of the contralateral side of the humerus with measurements of the fractured side.

-• 2. PATIENT POSITIONING

Patient is placed in a beach chair position with shoulder off the table.

The patient is vertically inclined with the angle determined according to the surgical approach selected.



• 3. SURGICAL APPROACH

The superolateral approach is usually recommended for these cases.

The deltopectoral approach can also be used.

Patient is placed in a beach chair position.

A longitudinal incision is made, starting from the acromioclavicular ligament and running distally for 4 cm following the anterior edge of the acromion. The anterior and middle deltoid muscles are separated with respect to the lateral edge of the acromion.

It is important to be careful with the dissection to avoid an axillary nerve injury since this nerve is found about 4 cm away on the lateral side of the acromion. (Fig. 1)



• 4. FRACTURE EXPOSURE

The first step is to identify the fracture fragments. The rotator space is opened along the bicipital groove between the subscapularis and the supraspinatus. (Fig. 2)

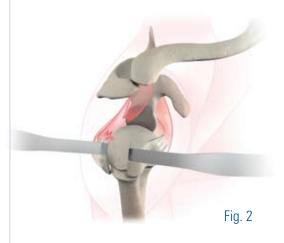
The supraspinatus tendon is then resected to the glenoid rim.

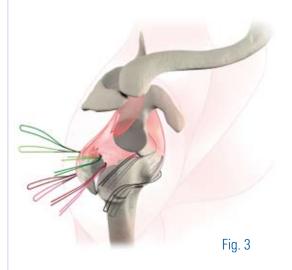
The proximal portion of the long head of the biceps tendon is resected and the humeral head fragment is removed.

The greater tuberosity is mobilized posteriorly, and four mattress sutures (green and rose colored) are placed from inside to outside by means of a crimping suture needle. (Fig. 3)

The lesser tuberosity is identified anteriorly, and two sutures are placed through the subscapularis tendon to facilitate its manipulation at the time of fixation of the tuberosities.

The lesser tuberosity is retracted anteriorly for glenoid exposure. (Fig. 3, gray suture)

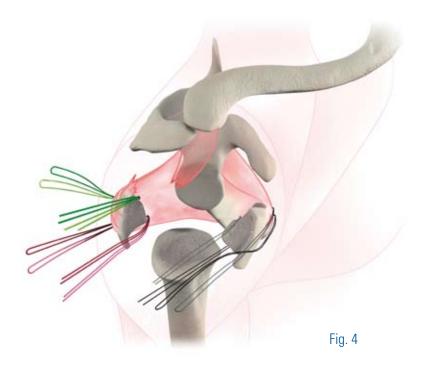




• 5. GLENOID EXPOSURE AND PREPARATION

The characteristics of the fracture usually allow easy exposition of the glenoid (Fig. 4).

The various surgical steps for exposition and implantation of the baseplate and glenoid sphere are described in the Surgical Technique of Aequalis®-Reversed (UDRT et UDXT) :



• 6. PREPARATION OF THE HUMERUS

6.1 Humeral Reaming

The medullary cavity of the humeral shaft is progressively reamed with reamers of increasing diameter (7, 9, 11, 13, 15 mm) until the reamer contacts the cortical bone. (Fig. 5)

The last reamer that was used determines the size of the humeral stem.

Each diameter corresponds to a color code that easily identifies which instrument to use. (Fig. 6)

Fig. 6

Fig. 5

NOTE: In case of revision, it is important to remove as much cement residue as possible to not interfere with tuberosity consolidation.

6.2 Drilling of two holes in the diaphysis to pass vertical sutures

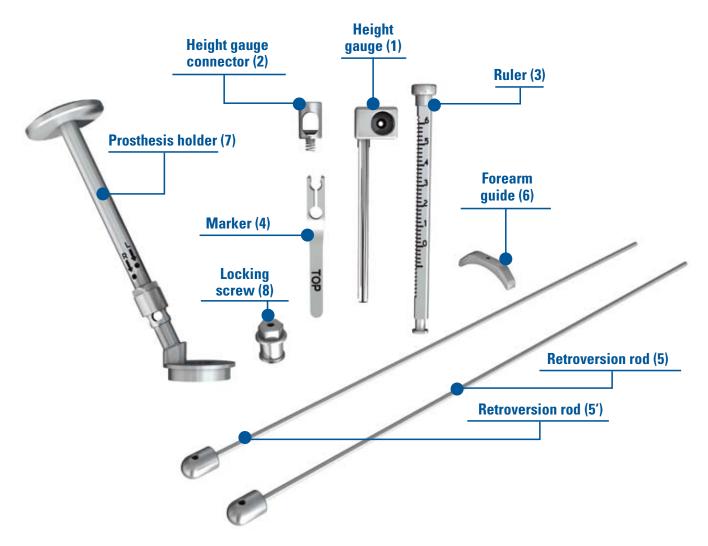
Two holes are drilled laterally in the bicipital groove at 2 cm under the fracture site. Two nonabsorbable sutures are passed from outside to inside and then from inside to outside. (Fig. 7)



Fig. 7

6.3 Assembly of Prosthesis Holder

6.3.1 Prosthesis Holder components



NOTE: Height gauge and retroversion rod are assembled onto the stem holder depending on operative side and approach chosen.

6.3.2 A Assembly of height gauge

Assemble the height gauge (1) with the height gauge connector (2). (Fig. 8)

Push the release button on the tip of the height gauge connector to insert the height gauge ruler (3).

Assemble the height gauge marker (4) onto the height gauge ruler (3).

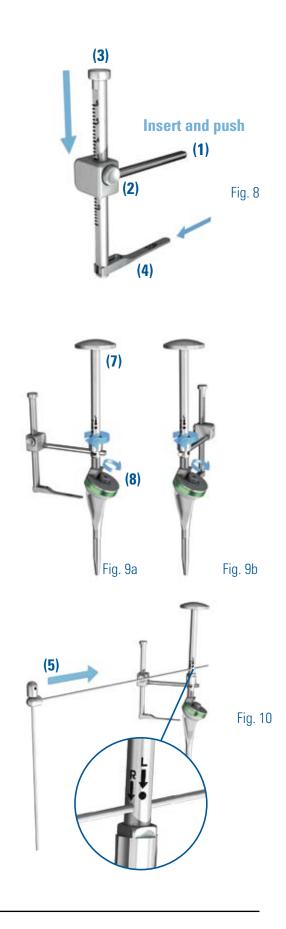
6.3.3 Assembly of prosthesis holder

Connect the height gauge to prosthesis holder (7) and secure the device with locking screw.

Two positions (fig 9 a-b) are possible according to surgical approach used.

Identify the appropriate side (L for Left and R for right) and attach the retroversion rod **(5)** to prosthesis holder **(7)**. (Fig. 10)

Secure the assembly to the trial stem or final stem with locking screw (8).



6.3.4 Assembly of retroversion rod

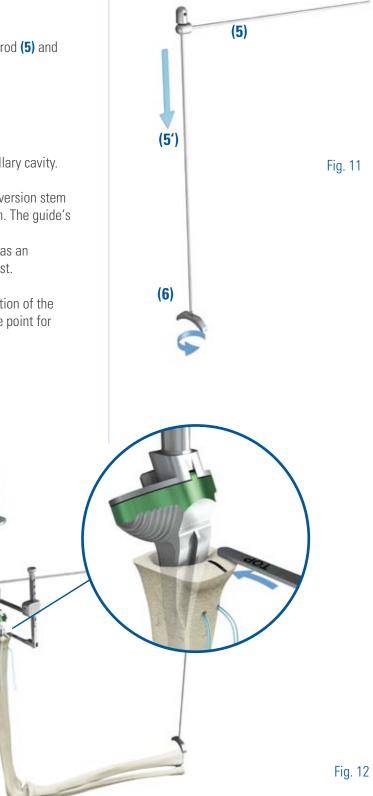
Connect retroversion rod (5') to retroversion rod (5) and attach the forearm guide (6). (Fig. 11)

6.4 Positioning of the Trial Stem

• Insert the trial stem into the reamed medullary cavity.

• Retroversion rod is adjusted with the retroversion stem that must be parallel to the patient's forearm. The guide's suggested retroversion angle is 25°. The second perpendicular stem can be used as an orthogonal reference by placing it on the wrist.

• The electrocautery knife can mark the position of the stem's lateral wing and be used as reference point for placement of final implant. (Fig. 12)



• The prosthesis holder is removed. Prosthesis is reduced in the joint.

• The reduction with trial implant can be done once the prosthesis holder is removed.

• The prosthesis must be stable after reduction and before reduction of the tuberosities.

• Height adjustment is done by decreasing the greater tuberosity and by assuring that its superior edge is tangent to the stem's upper part.

• Inspect the reduction of the greater tuberosity for confirmation of proper positioning of the stem. (Fig. 13).

• If the stem has too low a position, then a stem of greater diameter may be inserted once the height of the trial prosthesis is determined. The height gauge is positioned on an anatomic landmark. The height is then read on the ruler. This reference will be used again when the final implant is put into place.

• Before removing the trial stem, the gauge marker is placed on a bony anatomic landmark to be repositioned with the final implant.

6.5 Bone Graft Placement

Bone grafting is recommended to enhance consolidation of the tuberosities. Two bone grafts are harvested from the humeral head using the bone graft cutter. In case of revision, or if the bone quality of the humeral head is not sufficient, autografts or allografts can be used.

The turning grip of the graft cutter is **unscrewed** and the humeral head is placed in the cup of the bone graft cutter. (Fig. 14)

The bone graft cutter handles are firmly tightened to extract the bone graft tissue.

In the case of exceptionally hard bone, a mallet can be used to strike the clamp.

The dural part of the harvested graft is cut with a gouge-forceps before it is removed. (Fig. 15) $\,$

The graft is extracted by screwing down the cutting wheel. (Fig. 16)



The graft is placed in the window of the final prosthesis before the final prosthesis is placed in the humerus. (Fig. 17)

6.6 Cementing the implant

After a placement of a diaphyseal plug, the humeral canal is dried and cement is injected using a large syringe.

A surgical drain can be temporarily placed in the medullary cavity. (Fig. 18)



The final prosthesis can be inserted into the medullary cavity with the prosthesis holder.

The height is adjusted to the same level as was defined during the trials.

Retroversion is adjusted by aligning the lateral wing of the prosthesis with the mark previously made by the electrocautery. This is then confirmed using the retroversion stem attached to the prosthesis holder. (Fig. 19)

Excess cement is removed with a curette.



6.8 Impaction of humeral insert

After the cement is dry, the selected polyethylene insert is positioned by aligning the insert's orientation notch with the metaphyseal pin.

Reduction with different sizes of the trial humeral inserts can be done to find the best muscular stability.

The metaphyseal component is thoroughly cleaned and dried.

A metaphyseal plug can be inserted and screwed into the base of the metaphysis.

The final insert is impacted into the metaphysis or on the lateralized spacer with a humeral insert impactor.

(Fig. 20a, b, c)

The prosthesis is then reduced.

If reduction is difficult, a prosthesis reducer can then be used.

NOTE: If a lateralization spacer is used, the spacer is impacted into the metaphyseal cup with the humeral cap adaptor impactor.

After impaction, the central securing screw is inserted and fully tightened with the 4.5 mm screwdriver, thus securing the spacer onto the metaphysis.

6.9 Reduction of implant

Sutures are placed around the prosthesis neck at the level of the polished area. The prosthesis is then reduced into the joint.

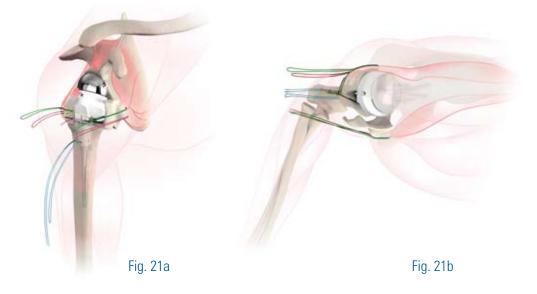


6.10 Tuberosities Fixation

6.10.1 Placing two horizontal cerclage sutures around the greater tuberosity

Fixation of the tuberosities begins with fixation of the greater tuberosity.

The arm is placed in neutral position. A clamp is used to pull the greater tuberosity anteriorly, reducing the greater tuberosity to the prosthesis. The two horizontal cerclage sutures (one superior, one inferior) are then tied to secure the greater tuberosity to the prosthesis. (Fig. 21a, b)



6.10.2 Placing two horizontal cerclage sutures around greater and lesser tuberosities

The next step is the reconstruction of the lesser tuberosity.

The two remaining horizontal sutures, which had initially been passed through the posterior rotator cuff tendon and around the prosthetic neck, are then passed through the subscapularis tendon.

One runs through the superior part and the other through the inferior part, from inside to outside and are then tied.

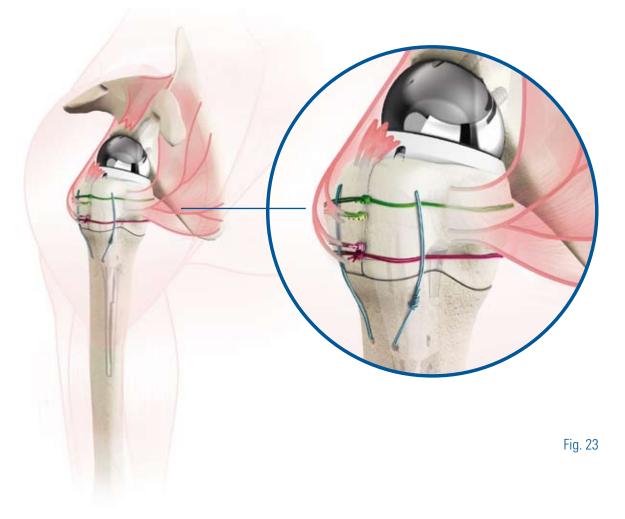
The sutures thereby give lateral stability to the tuberosities. (Fig. 22a, b)



6.10.3 Securing by double shrouds around the greater and lesser tuberosities

Final tightening creates a vertical staying from the diaphysis by means of a nonabsorbable suture. The shroud goes behind the infraspinatus and in front of the subscapularis. It is then tied.

This technique allows solid and reproducible fixation of the tuberosities on the diaphysis . (Fig. 23)



6.10.4 Closing and tenodesis of long head of the biceps

After resecting the intra-articular portion of the long head of the biceps, a nonabsorbable suture is passed through the tendon of the long head of the biceps. It is then reinserted in the bicipital groove.

6.11 Trial and Closure

Peri-operative Trial

Pull the arm away from the body after reduction and fixation of tuberosities to ensure that there is no "pistoning" effect. Complete separation of the prosthesis whilst pulling indicates inadequate tensioning of the deltoid.

Abduction of the arm is performed to check that there is no impingement and that anterior elevation and abduction have been restored.

External rotation with the elbow at the side (ER-1) checks for passive external rotation.

External rotation with the elbow abducted (ER-2) checks for risk of possible future subluxation.

Internal rotation with the elbow at the side (IR-1) and in abduction (IR-2). Forearm must be parallel to the thorax for IR-2 trial. This reflects the patient's future ability to move the hand to the back.

Adduct the arm to check that there is no impingement between the pillar of the scapula and the humeral implant. After reduction of the prosthesis, the coraco-biceps tendon should usually have sufficient muscular tension.

Closure

In the superolateral approach, the anterior deltoid is reattached to the acromion with a trans-osseous nonabsorbable suture.

In the deltopectoral approach, full or partial reinsertion of the subscapularis is performed if possible.

Be prepared to place a surgical drain in the sub-acromial space to reduce the risk of hematoma , such as is common in fracture cases.

• 7. REHABILITATION

The arm is placed in a brace with the elbow close to the body in neutral or internal rotation.

An **abduction splint** can be used, especially in cases of anterior deltoid detachment when the superolateral surgical approach was used.

Plan an early rehabilitation adapted to the status of the patient's bony structures and soft tissues.

• **Strengthen deltoid musculature** from the sixth week with active exercises against resistance. Strengthen external rotators with elbow close to body by means of isometric exercises against resistance. If the deltoid attachment has not been disrupted, mobility is usually rapidly recovered.

• Subluxation risk:

Retropulsion and external rotation must absolutely be avoided postoperatively, especially when the patient is in decubitus position.

• 8. COMPLICATIONS

Postoperative stiffness

In case of significant preoperative stiffness, it may be difficult to regain mobility postoperatively. Surgical arthrolysis in conjunction with capsulotomy may be required with the removal of soft tissue adhesions and possibly removal of the tuberosities.

Postoperatively, the arm is usually immobilized in a shoulder abduction splint in 60 degrees abduction. Passive elevation above the splint in the scapular plane is started immediately.

Prosthesis instability

This is the consequence of insufficient deltoid tension. Possible causes:

- Too much humeral bone cut
- Loss of humeral bone in cases of surgical revision.

In case of early postoperative dislocation, closed reduction under general anesthesia is performed. If the prosthesis is in good position with retroversion and good overall fracture alignment, then immobilization for 6 weeks duration normally restores stability of the prosthesis.

With early recurrence of instability, surgical revision is needed to check the prosthesis' position. Increase the humeral lateralization as necessary by adding a lateralized spacer at the level of the humeral implant.

Scapula notch

Impingement between the pillar of the scapula and the humeral implant can lead to scapular bone erosion that causes a scapular notch. This notch usually does not affect function or mobility. X-ray follow-ups are recommended.

Absence of active external rotation

The absence of the teres minor and infraspinatus due to tendon cuff tear or fatty infiltration may be the cause of loss of active external rotation.

In this case one may consider latissimus dorsi transfer to the greater tuberosity of the humerus performed at the same time as the Aequalis[®]-Reversed Fracture prosthesis procedure is done.

• 9. AEQUALIS[®]-REVERSED HEMI-PROSTHESIS ADAPTOR TECHNIQUE

Indications

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the implant of the glenoid components or when glenoid bone fracture occurs intraoperatively, the hemi-prosthesis adaptor and union screw can be adapted to the humeral components to transform the Aequalis[®]-Reversed Fracture prosthesis into a non-reversed hemi-prosthesis.

When the Aequalis[®]-Reversed Fracture prosthesis is revised and glenoid bone stock appears to be insufficient to implant again a baseplate and sphere of Aequalis[®]-Reversed series, then the hemi-prosthesis adaptor and union screw can transform the Aequalis[®]-Reversed Fracture prosthesis into a hemi-prosthesis to avoid revision of the humeral components.

9.1 Preparation of metaphyseal implant

If necessary, the polyethylene implant can be removed with an osteotome. (Fig. 24)

9.2 Affixing the adaptor cap-metaphysis union screw

The adaptor cap-metaphysis union screw is screwed into the threads found in the internal part of the metaphysis. Tighten the screw with the 14 mm wrench. (Fig. 25)

9.3 Implantation of adaptor

Clean the inner part of the metaphysis carefully. Two adaptor sizes are available with diameters of 36 mm or 42 mm. Its size must be the same the metaphyseal component's size.

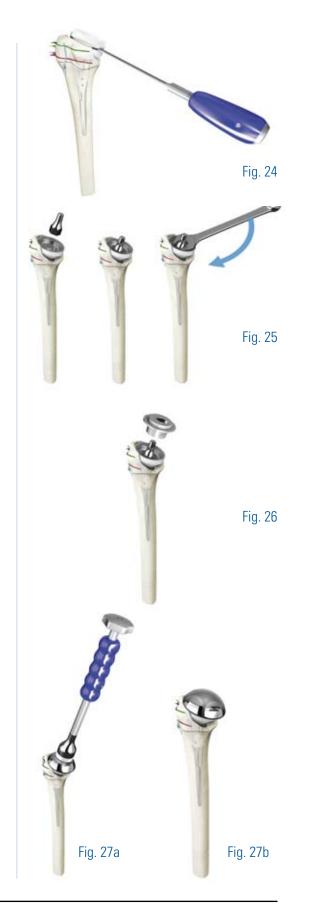
Be sure to position the adaptor notch in line with the metaphyseal lug.

The hemi-prosthesis impactor is then assembled by screwing to the handle of the humeral insert impactor. The adaptor is then impacted with the hemi-prosthesis impactor. (Fig. 26)

9.4 Impaction of humeral head

After the adaptor is in place, the exposed tapered cone is carefully dried and cleaned.

The Aequalis[®] adaptor cap of the selected diameter is impacted on the tapered cone of the union screw using the glenoid sphere impactor. (Fig. 27a-b)

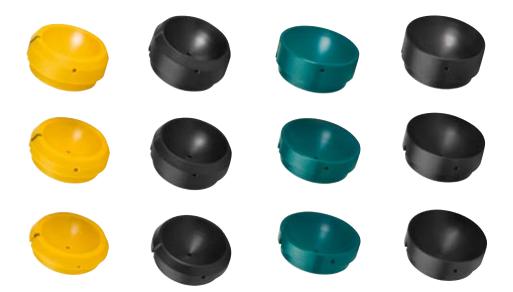


COLOR CODING

• Humeral Side

Trial Insert	Color	Reference
Ø 36 mm centered + 6 mm		MWD060
Ø 36 mm centered + 9 mm	Yellow	MWD061
Ø 36 mm centered + 12 mm		MWD062
Ø 36 mm constrained + 6 mm		MWD970
Ø 36 mm constrained + 9 mm	Black	MWD971
Ø 36 mm constrained + 12 mm		MWD972
Ø 42 mm centered + 6 mm		MWB985
Ø 42 mm centered + 9 mm	Green	MWB986
Ø 42 mm centered + 12 mm		MWB987
Ø 42 mm constrained+ 6 mm		MWD973
Ø 42 mm constrained + 9 mm	Black	MWD974
Ø 42 mm constrained + 12 mm		MWD975

Trial Inserts



COLOR CODING

Diameter	Color	Ref. Reamers	Ref. Trial Stems	Ref. Final Stems
Ø 7 mm	Yellow	MWD211	MWD911	DWD911
Ø 9 mm	Green	MWD212	MWD912	DWD912
Ø 11 mm	Blue	MWD213	MWD913	DWD913
Ø 13 mm	Rose	MWD214	MWD914	DWD914
Ø 15 mm	Gray	MWD215	MWD915	DWD915

Reamers

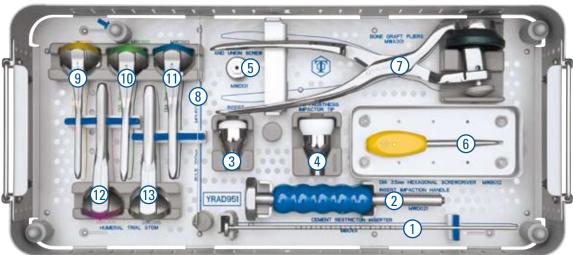


Trial Stems



INSTRUMENTATION

Instrumentation - Humeral YRAD951



Ref. YRAD951

Cases

Description	Reference	Quantity
Box / base	YRAD951	1
Box / insert	YRAD952	1
Box lid	NCR009	1

Instrumentation

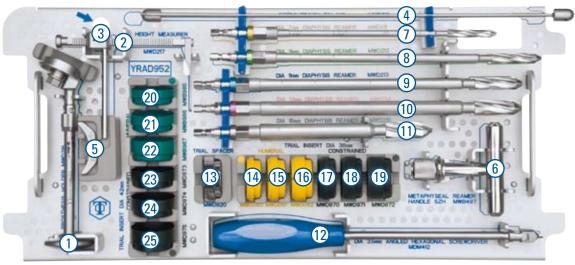
N°	Description	Reference	Quantity
1	Plug Positioner	MB0101	1
2	Humeral insert impaction handle	MWD021	1
3	Tip for humeral insert impaction	MWD023	1
4	Tip for impaction of hemi-prosthesis adaptor	MWD024	1
5	Wrench for metaphyseal plug and union screw	MWD131	1
6	Screwdriver 3.5 mm flathead	MWB012	1
7	Bone graft pliers	MWA301	1
8	Ruler 200 mm	MDU502	1

Trial stem instrumentation

N°	Description	Reference	Quantity
9	Humeral trial stem Ø 7 mm	MWD911	1
10	Humeral trial stem Ø 9 mm	MWD912	1
11	Humeral trial stem Ø 11 mm	MWD913	1
12	Humeral trial stem Ø 13 mm	MWD914	1
13	Humeral trial stem Ø 15 mm	MWD915	1

INSTRUMENTATION

Instrumentation - Humeral YRAD952



Ref. RAD952

Instrumentation

N°	Description	Reference	Quantity
1	Prosthesis Holder	MWD216	1
2	Height Gauge	MWD217	1
3	(with support foot)	MWD220	1
4	Retroversion Stem	MWD218	2
5	Positioner	MWD219	1
6	Metaphyseal Reamer Handle SZH	MWB497	1
7	Diaphyseal Reamer Ø 7 mm	MWD211	1
8	Diaphyseal Reamer Ø 9 mm	MWD212	1
9	Diaphyseal Reamer Ø 11 mm	MWD213	1
10	Diaphyseal Reamer Ø 13 mm	MWD214	1
11	Diaphyseal Reamer Ø 15 mm	MWD215	1
12	Screwdriver, universal joint, 3.5 mm, flathead	MDM412	1

Instrumentation Ø 36 mm

N°	Description	Reference	Quantity
13	Trial humeral spacer + 9 mm Ø 36 mm	MWD920	1
14	Trial humeral insert Ø 36 mm + 6 mm	MWD060	1
15	Trial humeral insert Ø 36 mm + 9 mm	MWD061	1
16	Trial humeral insert Ø 36 mm + 12 mm	MWD062	1
17	Constrained trial insert Ø 36 mm + 6 mm	MWD970	1
18	Constrained trial insert Ø 36 mm + 9 mm	MWD971	1
19	Constrained trial insert Ø 36 mm + 12 mm	MWD972	1

Instrumentation Ø 42 mm

N°	Description	Reference	Quantity
20	Humeral trial insert Ø 42 mm + 6 mm	MWB985	1
21	Humeral trial insert Ø 42 mm + 9 mm	MWB986	1
22	Humeral trial insert Ø 42 mm + 12 mm	MWB987	1
23	Constrained trial insert Ø 42 mm + 6 mm	MWD973	1
24	Constrained trial insert Ø 42 mm + 9 mm	MWD974	1
25	Constrained trial insert Ø 42 mm + 12 mm	MWD975	1

IMPLANTS

Humeral Implants

Aequalis [®] -Reversed Fracture Stems			
Diameter	Length	Reference	
7 mm	130 mm	DWD911	
9 mm	130 mm	DWD912	
11 mm	130 mm	DWD913	
13 mm	130 mm	DWD914	
15 mm	130 mm	DWD915	
Metaphyseal Pl	DWB010		

Long Stems - Reversed Fracture Stem HA*

-			
Diam.\L	170 mm	180 mm	210 mm
7 mm	DWD941		
9 mm		DWD942	DWD961
11 mm		DWD943	DWD962
13 mm		DWD944	DWD963



Lateralized humeral Inserts

AEQUALIS®-REVERSED FRACTURE

Diameter	Thickness	Reference
36 mm	+ 6 mm	DWD860
36 mm	+ 9 mm	DWD861
36 mm	+ 12 mm	DWD862
42 mm	+ 6 mm	DWD866
42 mm	+ 9 mm	DWD867
42 mm	+ 12 mm	DWD868

Constrained Humeral Inserts*

Diameter	Thickness	Reference
36 mm	+ 6 mm	DWD970
36 mm	+ 9 mm	DWD971
36 mm	+ 12 mm	DWD972
42 mm	+ 6 mm	DWD973
42 mm	+ 9 mm	DWD974
42 mm	+ 12 mm	DWD975

Humeral Spacer

 Height
 Reference

 + 9 mm
 DWD920

 with locking screw for spacer

 DWD921



Hemi-prosthesis

Description	Diameter	Height	Reference
Hemi-prosthesis adaptor	36 mm	-	DWD922
Including union screw metaphysis / adaptor	-	-	DWD923
Humeral Head CoCr	50 mm	19 mm	DWB251
Humeral Head CoCr	52 mm	23 mm	DWB253

* On request only

