Surgical Technique

Aequalis® Resurfacing Humeral Head

TORNIER

SCIENTIFIC VISION. SURGICAL LEADERSHIP.

The Aequalis® Resurfacing Humeral Head has been developed in conjunction with Drew Miller, MD - Atlanta, GA.

The Aequalis® Resurfacing Humeral Head dimensions follow the recommendation published in the anatomical study by Gilles Walch, MD and Pascal Boileau MD, J Bone Joint Surg Br.; 1997, 79(5):857-65.

Proper surgical procedures and techniques are the responsibility of the medical professional. Individual surgeon evaluation of the surgical technique should be performed based on his or her personal medical training and experience. This essential product information does not include all of the information necessary for selection and use of a device. Please see full labeling on package insert for all necessary information.

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DESIGN RATIONALE

Anatomic Design

- Reproduces the anatomy of the humeral head
- Restores soft tissue balance of the shoulder joint
- Restores the center of rotation and the biomechanics of the shoulder

Modular System

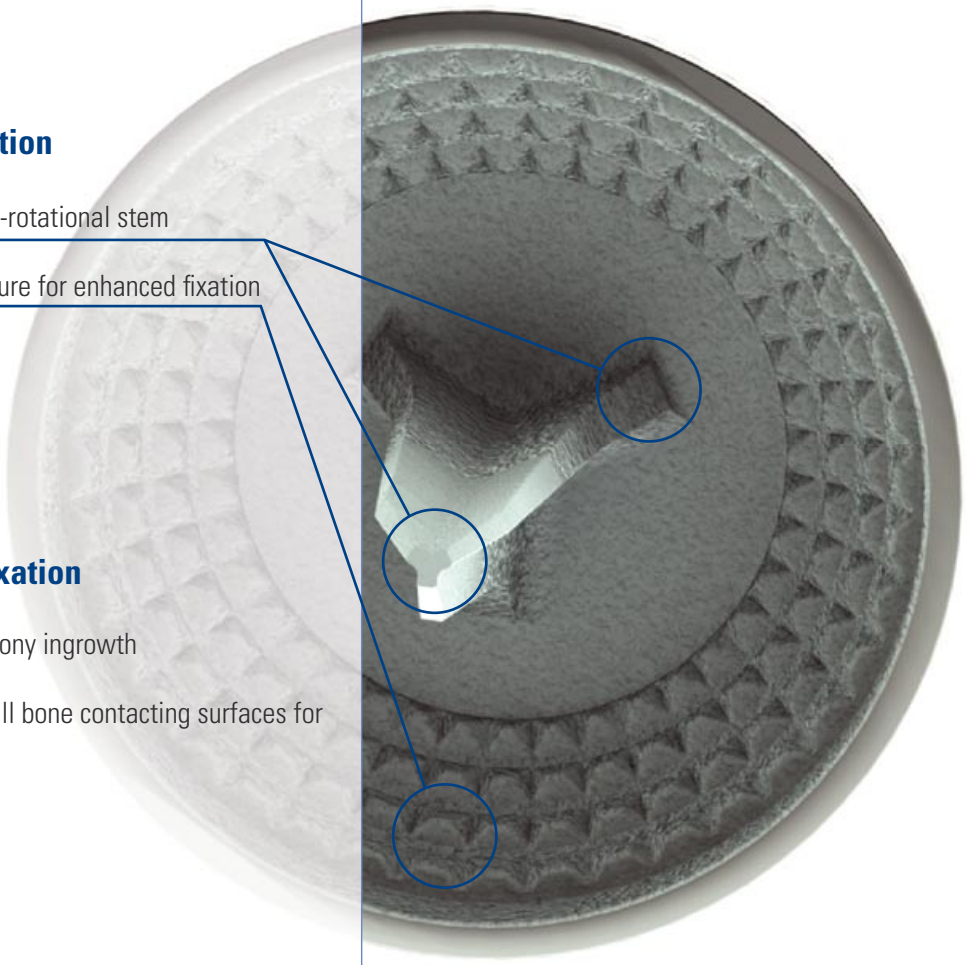
- 12 sizes / 3 stem lengths to fit all humeri

Excellent Primary Fixation

- Tapered press-fit, tri-fin anti-rotational stem
- Diamond-shaped macrotexture for enhanced fixation
- Cementless use only

Superior Secondary Fixation

- Titanium plasma spray for bony ingrowth
- Hydroxyapatite coating on all bone contacting surfaces for biological fixation



STRAIGHT-FORWARD ANATOMICAL RECONSTRUCTION

Less Invasive Surgery

- Accomodates different surgical approaches
- Specially designed retractors for humeral head exposure

Accurate Positioning

- Cannulated instruments and Alignment Pin
- Initial Trial Head to assure accuracy of reaming

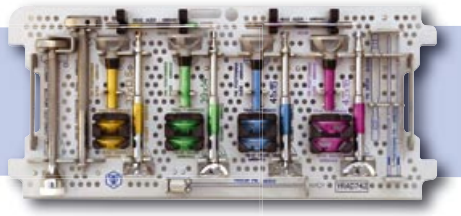
Surgeon-Friendly Instrumentation

- Easy reference color-coded instruments

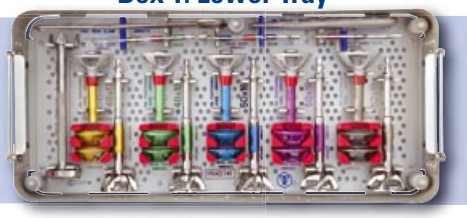
The color-coding scheme allows a quick identification of the group of instruments to be used for each given humeral head size.

Head Size	Instruments and Trial Color	Stem Punch Color
37 x 13.5		30 mm
39 x 14		
41 x 15		
43 x 16		
46 x 17		35 mm
48 x 18		
50 x 16		
50 x 19		
52 x 19		
52 x 23		40 mm
54 x 23		
54 x 27		

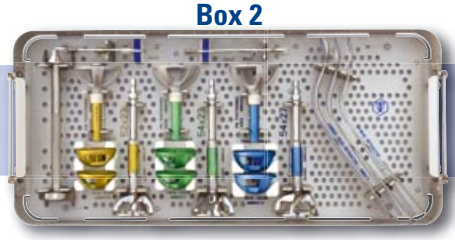
Box 1: Upper Tray



Box 1: Lower Tray

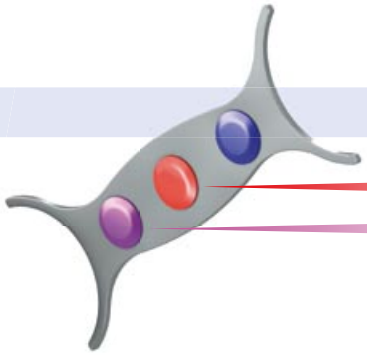


Box 2



COLOR CODING

Step 1: Head Sizing



Stem Punch Color

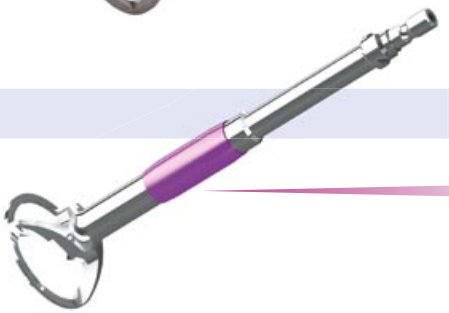
Instruments and Trial Color

Step 2: Insertion of Alignment Pin

Instruments and Trial Color

Stem Punch Color

Step 3: Reaming



Instruments and Trial Color

Step 4: Initial Trial Head. Assessing the Depth of Reaming

Instruments and Trial Color

Step 5: Preparation of Stem

Stem Punch Color

Step 6: Final Trial Head

Instruments and Trial Color

INDICATIONS

The Aequalis® Resurfacing Humeral Head shares the same indications as shoulder arthroplasty in general, including the various types of arthritis and conditions resulting in loss of articular cartilage, joint incongruity, pain, and stiffness.

Indications include:

1) Osteo and Inflammatory Arthritis

2) Avascular Necrosis

3) Post-Traumatic Arthritis

CONTRAINDICATIONS

1) Inadequate humeral head bone stock

2) Active glenohumeral or systemic infection

Note: This implant is intended for cementless use only.

ADVERSE EVENTS

The following are the most frequent adverse events after shoulder arthroplasty: component loosening, dislocation, subluxation, iatrogenic fracture and traumatic fracture below the humeral component and possible metal sensitivity.

PREOPERATIVE PLANNING

Radiographs should be templated preoperatively to anticipate humeral head size (fig.1).

Both AP and axillary x-rays are critical in determining humeral head bone stock. CT scanning may also be used to further delineate humeral head anatomy, bone stock, and deformity.

The use of the x-ray templates during preoperative planning can offer an estimate of the insertion depth of the Alignment Pin required to engage the lateral cortex. The corresponding calibration marks on the Alignment Pin will confirm the length of insertion. This will ensure that the Alignment Pin is not inserted too far, risking injury to the axillary nerve.

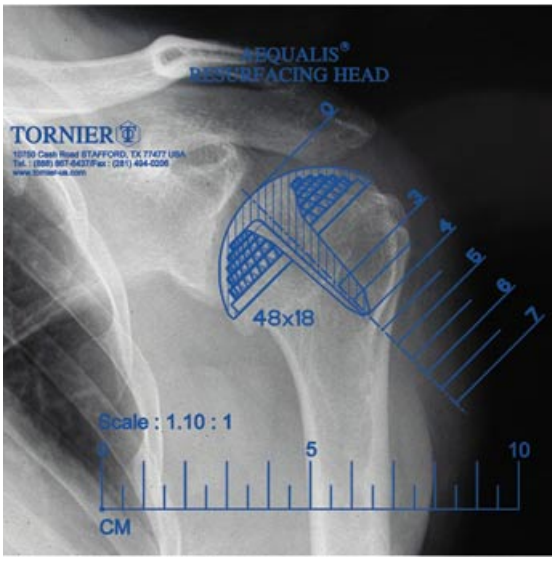


fig.1

DELTOPECTORAL APPROACH

An incision is made from the tip of the coracoid along the deltopectoral interval (fig.2). The cephalic vein is mobilized. A deep self-retaining retractor is used to retract the deltoid laterally and the pectoralis medially. The upper portion of the pectoralis may be released in order to improve external rotation.

The clavipectoral fascia is incised along the lateral border of the conjoined tendon. The conjoined tendon is retracted to expose the subscapularis and the circumflex vessels. These vessels may be ligated to maintain hemostasis throughout the remainder of the procedure. The axillary nerve can be palpated and protected.

The subscapularis is then released and reflected to expose the proximal humerus. The humeral head is gradually externally rotated as the subscapularis and capsule are reflected from the proximal humerus. The inferior capsule is released from anterior to posterior, exposing humeral head osteophytes. The humeral head is then delivered out of the incision (fig.3).

(continued on next page - "Preparation of Humeral Head")

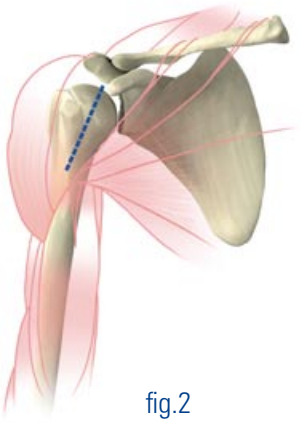


fig.2

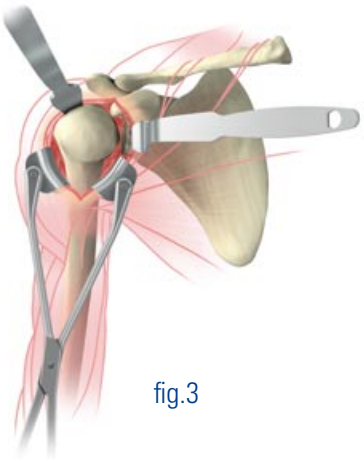


fig.3

SUPERO-LATERAL APPROACH

The incision is made from the AC joint along the anterior border of the acromion extending laterally approximately 4 cm (fig.4). The deltoid is split along the interval between the anterior and middle deltoid, and the anterior deltoid is released from the acromion. A stay suture is placed laterally to protect the axillary nerve. Care should be taken to preserve the coraco-acromial ligament for later repair along with the deltoid. An acromioplasty and/or a distal clavicle resection may be performed.

A deep self-retaining retractor is used to retract the deltoid and expose the humeral head. The rotator interval capsule is incised, and the subscapularis is reflected from its humeral insertion. In this approach, it may be possible to preserve some of the inferior subscapularis, but the entire humeral head must be exposed to remove humeral osteophytes. With external rotation, adduction, and extension, the humeral head is delivered out of the incision (fig.5).

fig.4

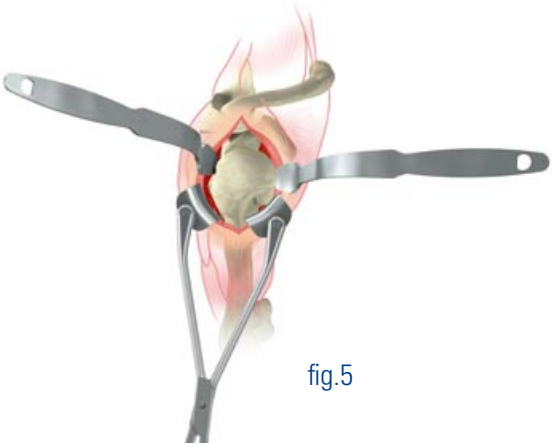


fig.5

PREPARATION OF HUMERAL HEAD

Retractors (fig.6) designed specifically for exposure of the humeral head are used to reflect the capsule, rotator cuff, and biceps tendon. Next, care must be taken to remove all osteophytes circumferentially in order to expose the anatomic neck of the proximal humerus. This step is critical because head sizing and head orientation are based off the anatomic neck.

fig.6

HUMERAL HEAD SIZING

Once osteophytes are removed circumferentially to expose the humeral anatomic neck, the humeral head may be sized. The diameter of the humeral head is determined by using the Head Sizer (fig.7) to measure along the superior - inferior and anterior - posterior axes while assuring that both tips are in close contact with the anatomic neck. If between sizes the smaller size is usually selected.

The color coding scheme allows a quick identification of the group of instruments to be used for each given humeral head size.

The color of the metallic button at the end of the Head Sizer corresponds to the color of the appropriate Pin Positioning Guide, Reamer, Initial and Final Trial Heads to be used in subsequent steps.

The color of the central plastic button corresponds to the color of the appropriate Stem Punch to be used in a subsequent step.

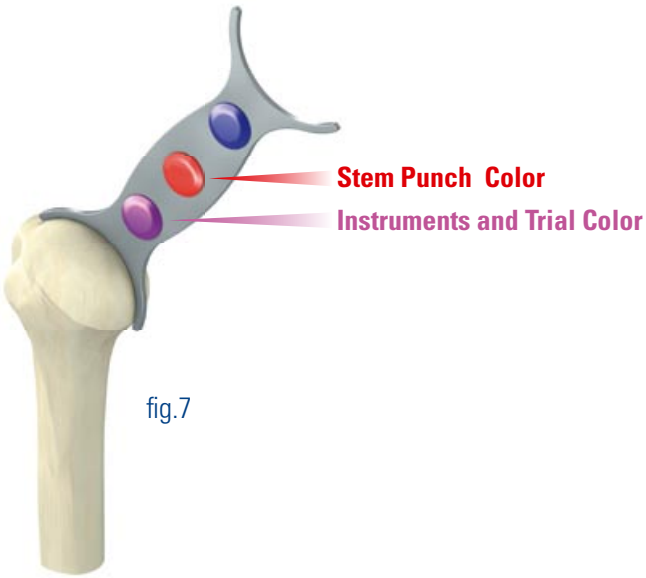


fig.7

CONFIRMING HEAD SIZE AND INSERTION OF ALIGNMENT PIN

The humeral head size is confirmed by using the Pin Positioning Guide.

The initial guide corresponds to the color of the Head Sizer chosen in the previous step.

The Pin Positioning Guide should be placed such that there is complete contact with the anatomic neck of the humerus, and the articular surface should be uniformly covered (fig.8).

fig.8

This represents a final determination of head size, and assures that the Alignment Pin is placed along the axis of the anatomic neck. The Alignment Pin must be placed in the center of the humeral head.

Surgical Note: If the actual humeral head appears to be in between sizes, the smaller size is usually selected.

The Pin Positioning Guide is then hand-held in place, and the Alignment Pin is inserted using power until the Alignment Pin penetrates the lateral cortex. Placement through the lateral cortex will prevent pin migration during subsequent steps (fig.9).

fig.9

Once the Alignment Pin is placed, the positioning guide is removed. A final check should be performed to ensure that the Alignment Pin has been inserted into the center of the humeral head (fig.10). It is important that the Alignment Pin remains straight throughout the surgical procedure otherwise it should be exchanged.

fig.10

HUMERAL HEAD REAMING

The appropriate size Reamer is selected, based on previous selection of the Pin Positioning Guide ensuring that the color of the two instrument handles match.

The Reamer is assembled to power and then passed over the Alignment Pin (fig.11).

The Reamer is started prior to engaging the humeral head. The humeral head is reamed until the border of the Reamer is in contact with the humeral neck.

A visual control of the depth of reaming can be achieved by observing the humeral head through the windows in the Reamer as well as by observing the periphery of the Reamer and its position with respect to the humeral neck (fig.12).

The Reamer has been designed such that the advancing edge clears enough bone to allow easy seating of the implant. The Reamer creates a ridge against which the final implant will rest (fig.13).

Surgical Note: Care should be taken to prevent the Reamer edges from damaging the rotator cuff insertion.

A rongeur is used to clear any remaining osteophytes.

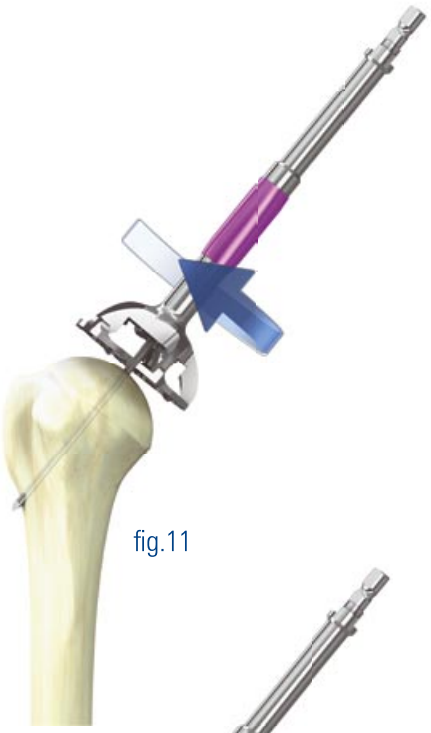


fig.11

fig.12

fig.13

INITIAL TRIAL HEAD - ASSESSING THE DEPTH OF REAMING

Before preparation of the central stem, the Initial Trial Head (without the stem) is used to assess the reamed surface of the humeral head and assure conformity with the internal surface of the implant.

The Initial Trial Head is used to confirm size before preparing the stem.

The color of the appropriate Initial Trial Head is matched to the color of the Reamer and the instruments used in the previous steps. The Initial Trial Head is positioned over the Alignment Pin (fig.14).

fig.14

Proper fit can be visualized through the windows in the trial. The Initial Trial Head should rest completely on the humeral neck.

Surgical Note: In cases of non-uniform contact, it may be necessary to perform additional reaming or re-ream if a different head size is finally selected.

The Initial Trial Head is identical to the Final Trial Head except for the stem.

STEM PREPARATION

The tri-fin stem allows for rotational control of the implant.

A cannulated Stem Punch is used to create a precise path for the final implant. The Stem Punch is smaller in length and width than the final implant, allowing for an additional press-fit of the stem on the final implant.

Three Stem Punches are available according to the humeral head size selected. The color code allows easy selection of the appropriate Stem Punch.

The Stem Punch is positioned over the Alignment Pin and oriented with one fin pointing laterally and two fins pointing medially. Care is taken to avoid bending the Alignment Pin maintaining a central location of the Stem Punch to the reamed flat on the dome of the humeral head. The Stem Punch is impacted up to the collar (fig.15 and fig.16).

The Stem Punch is removed leaving the Alignment Pin in place (fig.17).

fig.15

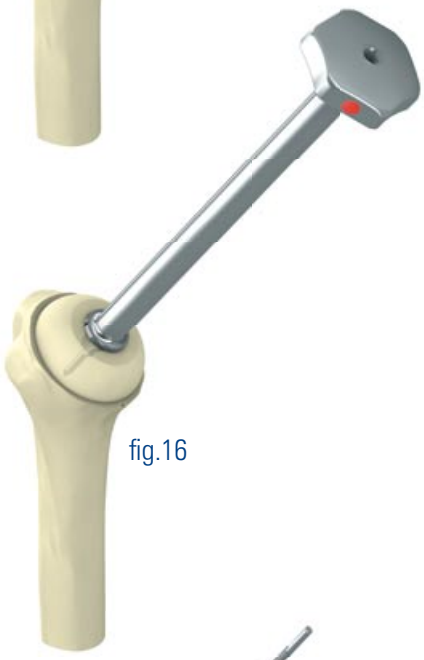


fig.16

fig.17

FINAL TRIAL HEAD

The stem on the Final Trial Head maintains stability during trial reduction.

The appropriate size and color of the Final Trial Head is selected and then positioned over the Alignment Pin (fig.18 and fig.19) and impacted into place using the cannulated Impactor (fig.20).

fig.18

fig.19

Visual inspection of the windows in the Final Trial Head confirms complete seating of the trial. The Alignment Pin is removed with the Pin Puller (fig.21) and a trial reduction is performed.

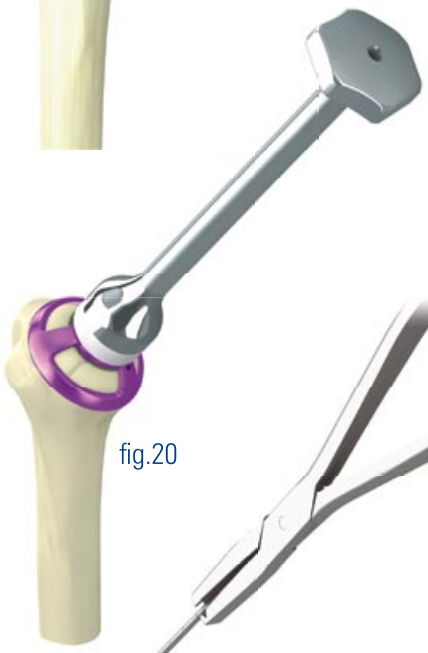


fig.20

Soft tissue balance is assessed and additional soft tissue releases may be performed.

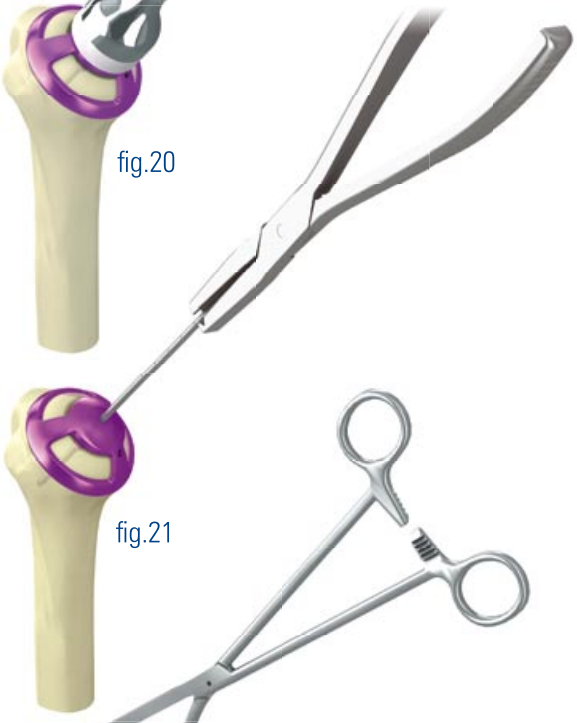


fig.21

As in general shoulder arthroplasty, with the humerus in neutral rotation and slight abduction, posterior stress should result in approximately 50% posterior translation of the implant

The subscapularis should be able to reach its point of reattachment. The Final Trial Head can then be removed with the trial head clamp (fig.22).

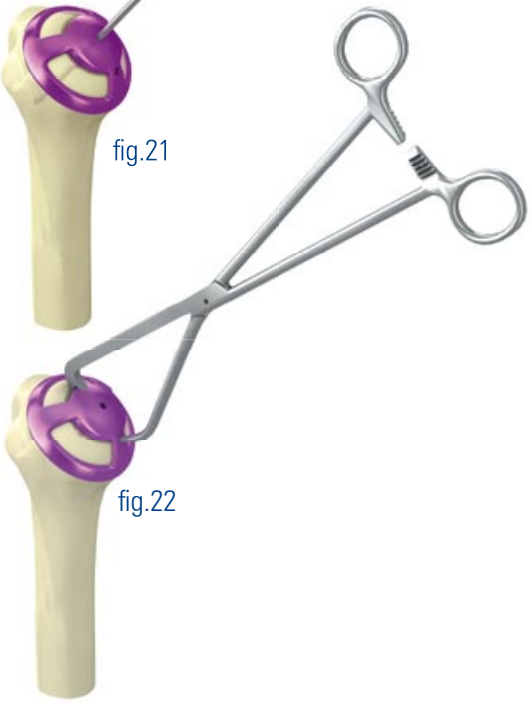


fig.22

GLENOID PREPARATION
(When Applicable)

After removal of the Final Trial Head, the glenoid can be prepared for insertion of a glenoid component, biological resurfacing, or further soft tissue preparation such as labral excision, capsular release, or capsular plication.

Note: When retracting the humeral head, care must be taken to avoid damage to the reamed surface of the humeral head. The Final Trial Head maybe left in place to protect the reamed surface.

The Aequalis® Resurfacing Head is compatible with the full range of Aequalis® Glenoids. Refer to the Aequalis® Glenoid surgical technique for more detailed information.

fig.23

fig.24

FINAL IMPLANT SEATING

After final irrigation and exposure of the reamed surface of the humeral head, the final component is positioned by hand to properly orient the stem with the tri-fin pattern previously created with the Stem Punch (fig.23 and fig.24).

The Impactor is then used to impact the final implant to its fully seated position (fig.25).

fig.25

The implant should completely contact the ridge created by the Reamer (fig.26).

The humerus is then reduced and proper soft tissue balance should be confirmed.

fig.26

CLOSURE

The subscapularis is repaired in a tendon-to-tendon fashion if it was released in an intra-tendinous plane, or directly to the proximal humerus adjacent to the implant. When repairing directly to bone, the tendon is usually recessed medially to allow for increased external rotation. Suture anchors may also be utilized. The amount of external rotation without undo tension ("safe zone") is observed. Routine closure is then performed and an immobilizer is placed (fig.27).

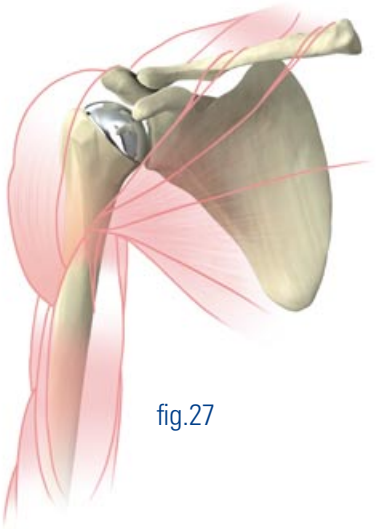


fig.27

POSTOPERATIVE CARE

Aftercare is the same as routine shoulder arthroplasty, and is guided on an individual basis according to intraoperative pathology, quality of soft tissue, and the patient's ability to comply with postoperative rehabilitation.

On postoperative day one pendulum exercises and passive range of motion within the safe zone, established intraoperatively, are usually begun. The immobilizer is used for protection for the first six weeks, at which time passive stretching and isometrics of the deltoid, rotator cuff, and scapular muscles are started.

These exercises are advanced over the next three to six months, at which time recreational activities are allowed.

BOX 1: UPPER TRAY

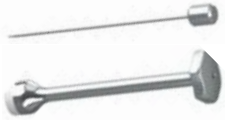
Ref. YKAD 74/2

Instruments	Reference	Color	
Head Sizer	MWB481	37 x 13.5	39 x 14
	MWB482	41 x 15	43 x 16
Pin Positioning Guide	MWB441	37 x 13.5	
	MWB442	39 x 14	
	MWB443	41 x 15	
	MWB444	43 x 16	
Reamer	MWB421	37 x 13.5	
	MWB422	39 x 14	
	MWB423	41 x 15	
	MWB424	43 x 16	
Initial Trial Head	MWB461	37 x 13.5	
	MWB462	39 x 14	
	MWB463	41 x 15	
	MWB464	43 x 16	
Final Trial Head	MWB401	37 x 13.5	
	MWB402	39 x 14	
	MWB403	41 x 15	
	MWB404	43 x 16	
Stem Punch 30 mm	MWB490		
Trocar Pin	MCI514		
Cannulated Impactor	MWB072		







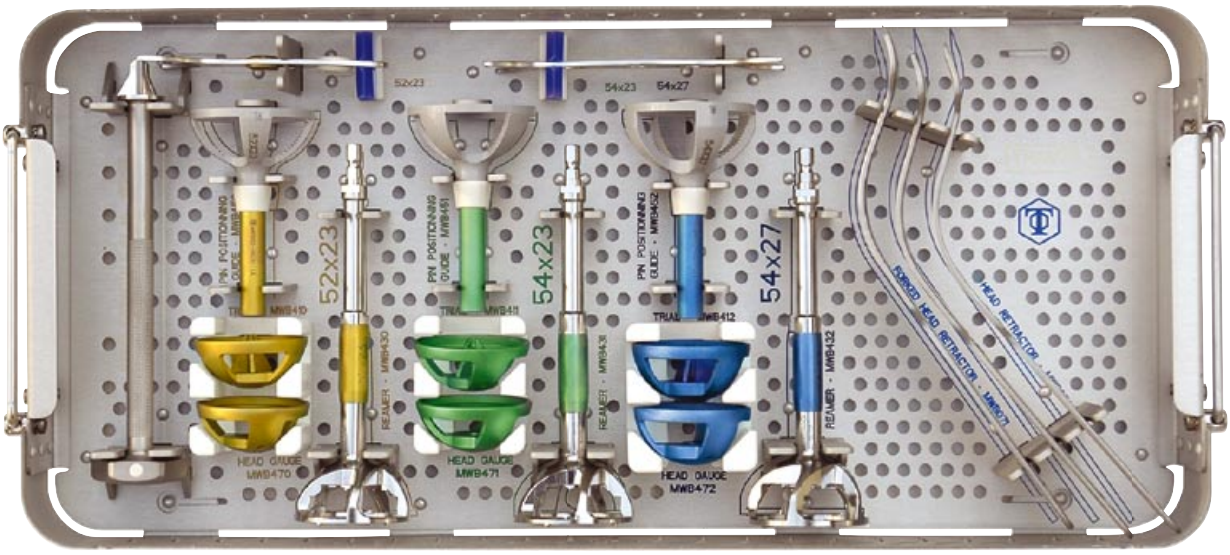


BOX 1: LOWER TRAY

Ref. YKAD 74/1

Instruments	Reference	Color		
Head Sizer	MWB483	46 x 17	48 x 18	
	MWB484	50 x 16	50 x 19	
	MWB485	52 x 19		
Pin Positioning Guide	MWB445	46x17		
	MWB446	48x18		
	MWB447	50x16		
	MWB448	50x19		
	MWB449	52 x 19		
Reamer	MWB425	46 x 17		
	MWB426	48 x 18		
	MWB427	50 x 16		
	MWB428	50 x 19		
	MWB429	52 x 19		
Initial Trial Head	MWB465	46 x 17		
	MWB466	48 x 18		
	MWB467	50 x 16		
	MWB468	50 x 19		
	MWB469	52 x 19		
Final Trial Head	MWB405	46 x 17		
	MWB406	48 x 18		
	MWB407	50 x 16		
	MWB408	50 x 19		
	MWB409	52 x 19		
Stem Punch 35 mm	MWB491			
Trial Head Clamp	MWB074			
Pin Puller	MWB062			

BOX 2



Ref. YKAD75

Instruments	Reference	Color		
Head Sizer	MWB486	52 x 23		
	MWB487	54 x 23	54 X 27	
Pin Positioning Guide	MWB450	52 x 23		
	MWB451	54 x 23		
	MWB452	54 x 27		
Reamer	MWB430	52 x 23		
	MWB431	54 x 23		
	MWB432	54 x 27		
Initial Trial Head	MWB470	52 x 23		
	MWB471	54 x 23		
	MWB472	54 x 27		
Final Trial Head	MWB410	52 x 23		
	MWB411	54 x 23		
	MWB412	54 x 27		
Stem Punch 40 mm	MWB492			
Resurfacing Head Extractor	MWB070			
Forked Resurfacing Head Retractor (x2)	MWB071			

IMPLANTS

Reference	Size	Stem Length (mm)
DWD801	Head 37 x 13.5	30 mm
DWD802	Head 39 x 14	30 mm
DWD803	Head 41 x 15	30 mm
DWD804	Head 43 x 16	30 mm
DWD805	Head 46 x 17	35 mm
DWD806	Head 48 x 18	35 mm
DWD807	Head 50 x 16	35 mm
DWD808	Head 50 x 19	35 mm
DWD809	Head 52 x 19	35 mm
DWD810	Head 52 x 23	40 mm
DWD811	Head 54 x 23	40 mm
DWD812	Head 54 x 27	40 mm

SINGLE USE ITEMS

Reference	Description
DWD064	Ø 3 x 170 mm Alignment Pin

TORNIER

SCIENTIFIC VISION. SURGICAL LEADERSHIP.

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