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#### **Indication/Contraindication**

#### **Intended Use**

The Anatomical Shoulder System is intended for long-term implantation into the human shoulder joint in primary or revision total or hemi shoulder arthroplasty. The system is intended to help relieve pain and to help restore function in patients with adequate bone stock to support the prosthesis.

#### **Indication:**

The *Anatomical Shoulder Domelock*System is indicated for

- Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis
- Avascular necrosis
- Conditions consequent to earlier operations
- Omarthrosis
- Revision of shoulder prosthesis

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used in a total shoulder application, the *Anatomical Shoulder* Pegged and Keeled Glenoids Cemented are intended for cemented use only.

#### **Contraindication:**

Patient's physical conditions that would impair adequate implant support and/or prevent the use of an appropriately sized implant, e.g., previous surgery, insufficient quality or quantity of bone, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to endanger the success of the intervention e.g., absence of musculoligamentous supporting structures, joint neuropathy or other conditions that may lead to inadequate skeletal fixation.

- Signs of infection
- Severe instability secondary to advanced loss of osteochondral structure
- Charcot's shoulder (neuroarthropathy)
- Complex 3 and 4 part fractures of the proximal humerus

#### **Precise – Variable – Reproducible – Simple**

### Prosthesis designed to adapt to given anatomy

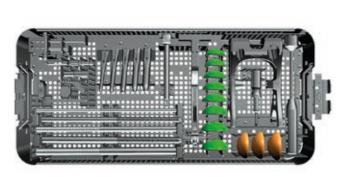
The Anatomical Shoulder Domelock arthroplasty system aims to offer an anatomical shoulder joint reconstruction which is designed to adapt to the given patient anatomy without procedural complexity, to help recover the normal kinematics for which the body has adapted. This includes the normal joint center, muscle moment arms, ligament positions, and loading to improve functional performance.

Consideration of the long term care of the patient is essential. The *Anatomical Shoulderl* Humeral Stem, by virtue of its design, should enable future options for revision or upgrade to a reverse solution, by using the same stem, therefore no stem removal should be necessary.

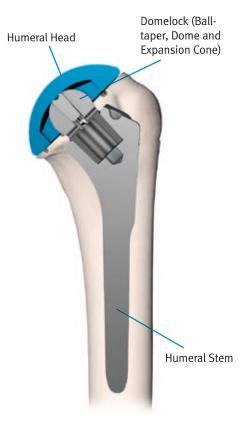
For primary and revision every *Anatomical Shoulder* Humeral Stem allows the combination with the regular Humeral Heads or with the Reverse components.

The position between Humeral Stem and Humeral Head in the *Anatomical Shoulder Domelock* system is entirely independent and variable, designed to allow for an anatomically driven reconstruction.

The Anatomical Shoulder Domelock arthroplasty system uses a straightforward timesaving surgical technique that aims to enable placement of the device in just a few steps – saving valuable OR time without compromising functional outcomes.

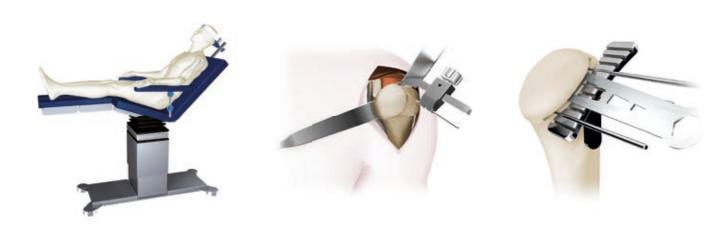


Anatomical Shoulder Domelock Instrument Tray ZS01.04558.001

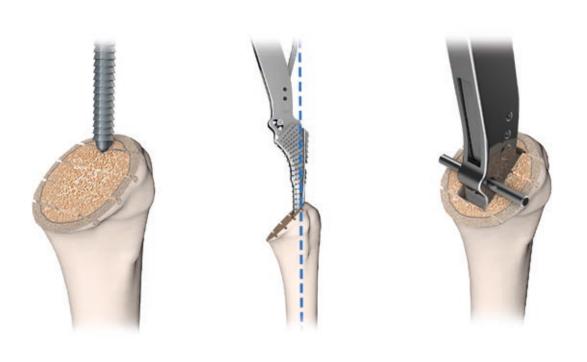


#### **Key Surgical Steps**

#### 1. Humeral Head Identification, Preparation and Resection



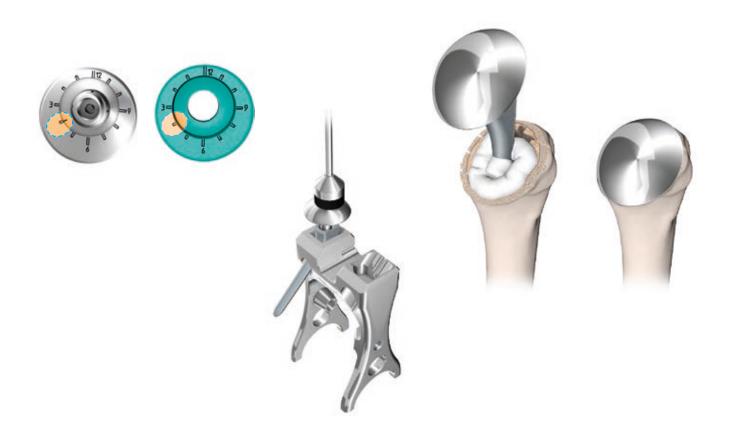
#### 2. Humeral Stem Size Preparation and Determination



#### 3. Head Size Determination, Orientation and Fixation



#### 4. Head Preparation and Implantation



#### **Preoperative Templating**

Preoperative evaluation of the humerus using the *Anatomical Shoulder Domelock* System.

Templates help determine the size of the prosthesis and level of the head resection. The goal is to make a resection that matches the anatomy of the patient.





X-ray templates:
X-Ray Templates for *Anatomical Shoulder* Cemented Stems, REF 06.02506.000
X-Ray Templates for *Anatomical Shoulder* Uncemented Stems, REF 06.02507.000
X-Ray Templates for *Anatomical Shoulder* Fracture Stems, REF 06.02508.000

X-Ray Templates for *Anatomical Shoulder Domelock* Heads, REF 06.02509.000

#### **Patient Positioning and Exposure**

#### **Patient Positioning**

The patient should be placed in a beach chair position on the edge of the operating table (Fig. 1).

The target shoulder should extend laterally over the edge of the table so the arm can be brought into full extension and adduction. An armrest is optional.

The upper part of the operating table has to be open to allow shoulder extension (shoulder table).



#### **Initial Incision**

The incision should start in front of the AC joint 1 to 2cm lateral from the tip of coracoid running straight downwards to the humeral delta insertion (Fig. 2).



# 1. Humeral Head Identification, Preparation and Resection

With the humeral head fully exposed remove any unwanted osteophytes to restore the humerus to near native anatomy. The humeral head should be resected exactly at the level of the anatomical neck.

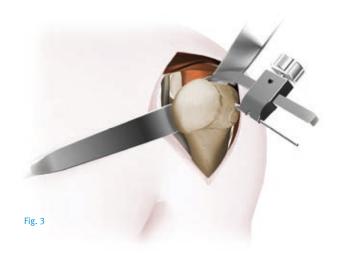
Two humeral head resection techniques are possible with *Anatomical Shoulder Domelock* Instrumentation: a freehand cut and an alignment guide "Supraspinatus" resection technique (Fig. 3).

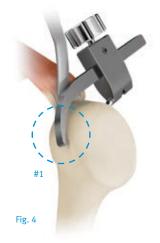
In the superior and anterior superior aspects, the anatomical neck corresponds to the insertions of the tendons of the supraspinatus and uppermost section of the subscapularis.

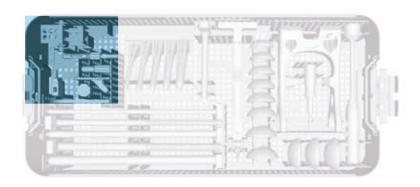
In the inferior aspect, there is a smooth transition between the cartilage of the head and the cortical bone of the humerus.

In the posterior aspect, in the region of the infraspinatus and teres minor is the sulcus, which is a groove of 6 to 8 mm in length, without cartilage or attached tendons. The resection must start exactly on the cartilage.

**Note:** Do not resect the cartilage-free area.







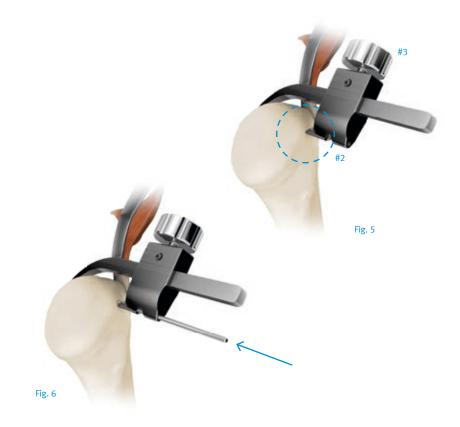
### Positioning of the Alignment Guide "Supraspinatus"

The superior part of the cut should be at the medial border of the insertion of the supraspinatus tendon #2 (Fig. 5).

The Kirschner Wire (K-Wire) should exit at the posterior edge of the cartilage medial to the bare area #1 (Fig. 4). After defining the position, the displaceable part of the Alignment Guide "Supraspinatus" can be fixed with the screw #3 (Fig. 5).

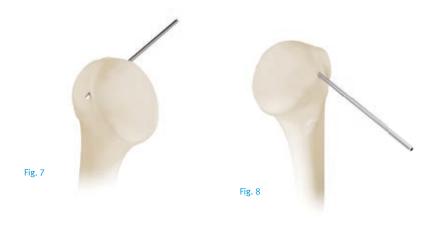
Place the K-Wire 2x100 mm into the Alignment Guide "Supraspinatus" (Fig. 6).

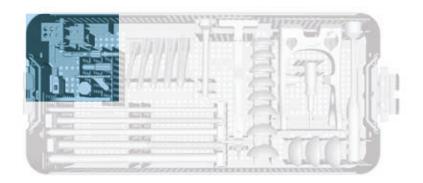
Use the Pin Retractor 2 mm to place the K-Wire.



Remove the Alignment Guide "Supraspinatus".

The first K-Wire 2x100 mm, also called "supraspinatus pin", defines the retroversion (Fig. 7 and 8).





The "Resection Guide" is mounted over the 1st K-Wire (Fig. 9), the "Supraspinatus- Pin" which identifies the retroversion.



#### Inclination angle identification

Align the position of the 2nd K-Wire by identifying the correct inclination angle. Due to patient requirements, there are 2 mm K-Wires in 100 mm and 70 mm lengths.

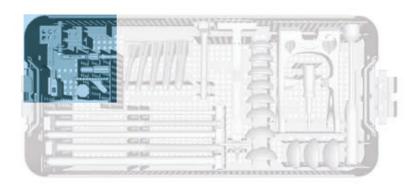
The "Supraspinatus attachment" will additionally guide you laterally. Use the Pin Retractor 2 mm to place the K-Wire.



Set additional K-Wires as per 3rd and 4th K-Wire to your requirements (Fig. 11 and 12).

Use the *Pin Retractor 2 mm* to place the K-Wire.





Resect the Humeral Head, guided by Resection Guide and K-Wires (Fig. 13 and 14).

**Note:** Do not use a saw blade with downward facing teeth.



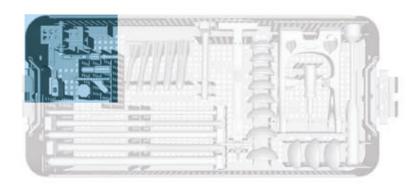
**Note:** For TSA (Total Shoulder Arthroplasty) please continue with the *Anatomical Shoulder* Glenoid – Surgical Technique,

Lit.No.: 06.02652.012









### 2. Humeral Stem Size Preparation and Determination

Begin insertion of the reamer just under the highest point of the resection, directly medial to the bicipital tendon (Fig. 15), in line with the shaft axis.

For this purpose, the arm is externally rotated and extended, with the elbow resting on the body.



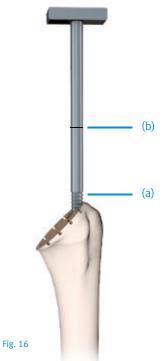
Now, the medullary cavity is opened, start reaming with the smallest reamer.

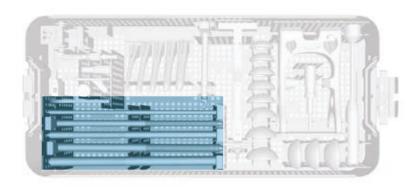
#### Note

Standard reamers available in sizes: 7-9-10.5-12-14 Optional additional reamers sizes are: 5-6-16-18

#### Note

The depth of penetration is defined by the uppermost tooth (Fig. 16 (a)). Care should be taken to ensure that the uppermost tooth of the reamer is fully inserted into the medullary cavity. If a revision stem is used, the additional marking (Fig. 16 (b)) is used as reference.





The proximal section of the humerus is prepared with the aid of modular rasps. Connect the rasp handle with the rasp (Fig. 17) and start rasping with the smallest rasp. To connect or disconnect the rasp from the rasp handle, press the lever arm (Fig. 18).

The lateral fin of the reamer is directed towards a point approximately 9 mm behind the sulcus.

#### Tip

The movable crosspin should ideally sit in the middle of the resection surface, anterior – posterior (Fig. 20).

The proximal section of the humerus is then prepared stepwise with rasps up to the size of the previously used reamer.

#### Note

Standard rasps available in sizes: 7-9-10.5-12-14 Optional additional rasp sizes are: 5-6-16-18

Care should be taken to ensure that the rasps are fully inserted into the humerus, i.e. until the movable crosspin is visibly in contact with both anterior and posterior metaphyseal surfaces (Fig. 19 and 20).

#### Note

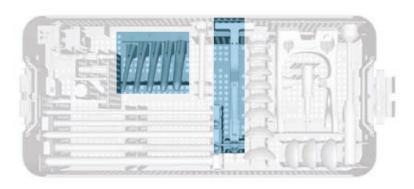
If full insertion of the rasp to this extent is not possible, the definitive implant of this size may not be used. The last rasp size which was placed sucessfully to the required depth is recommended.











The rasp handle is now removed and the modular rasp left in the humerus (Fig. 21). The rasp is now seated 5 mm below the resection line (Fig. 22).

The cutout created by the lateral fin of the rasp is now visible posterior to the bicipital tendon.

#### Cement mantle:

The average thickness of the cement mantle is 1 mm.

#### Press-fit:

Fixation of the uncemented stems is achieved through the eight 1mm fins along the length of the stem.

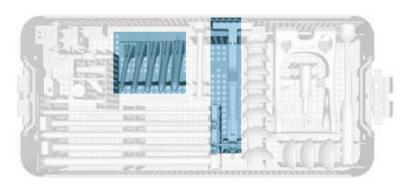
The preparation of the humerus is now complete.

#### Note

For the variable *Domelock* system continue on the following page. For the T-Dome system continue the optional surgical steps on page 27.







### 3. Head Size Determination, Orientation and Fixation

Choose a Trial Head size that covers the resected humeral osteotomy (Fig. 23).

#### Note

Standard humeral heads are available in sizes:

38-13, 40-14, 42-15, 44-16, 46-16, 48-17, 48-20, 50-18, 50-21, 52-19, 52-23

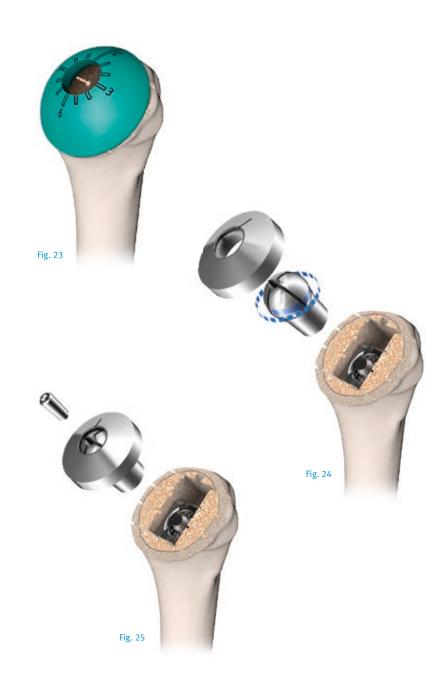
Optional additional humeral head sizes are:

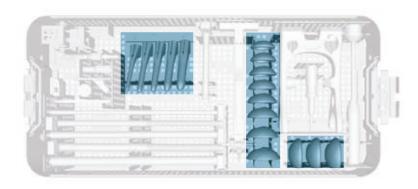
36-12, 36-15, 38-16, 40-17, 42-18, 44-19, 46-19, 54-20, 54-23, 56-21, 56-24

There are no identified restrictions between any combination of head and stem sizes.

Assemble the Dome onto the Ball-Taper over the ring machined around the ball of the Ball-Taper, so that it is loosely assembled (Fig. 24).

Gently press the expansion pin into the Ball-Taper (Fig. 25).





Press the selected trial head onto the Dome (Fig 26).

#### Tip

Aim to align the laser mark on the Dome to the 12 o'clock mark on the trial head, this will simplify the alignment of the definitive head later on.

Place the trial head assembly onto the oval internal profile of the modular rasp (Fig. 27).

#### Tip

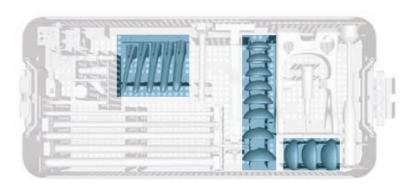
The lasermark on the Ball-Taper should face toward the supraspinatus, this avoids misalignment of the oval cone into the definitive stem later on.

The trial head can now be adjusted so that it covers the resection plane of the humerus (Fig. 28).

#### Note

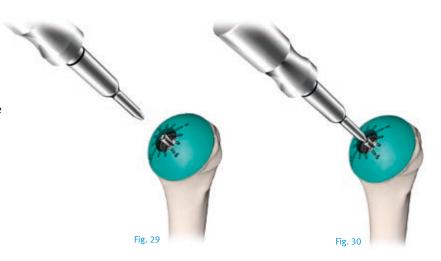
If a good coverage of the resection surface cannot be achieved with this trial head size, then consider using an alternative size.





Firmly tap the expansion pin into the assembled trial head construct, using the pin impactor (Fig. 29) to establish a firm connection between the Dome – Balltaper.

The patient specific orientation of the Dome is now pre-locked (Fig. 30).



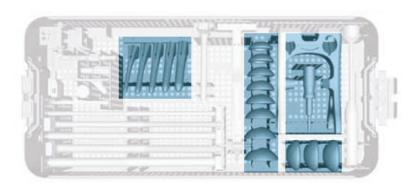
Take note of the relative orientation of the laser mark on the Dome to the trial head (f.e. 4 o'clock) (Fig. 31).



Remove the pre-locked Dome (Fig. 32) and place it into the assembly block (Fig. 33).



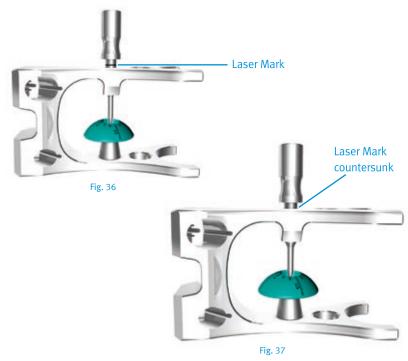


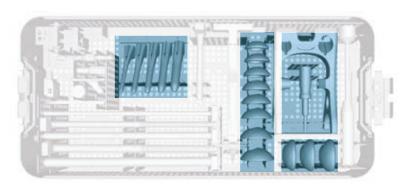


Using the assembly block (Fig. 34), firmly impact the expansion pin into the pre-locked Dome using the pin impactor (Fig. 35).



Continue to impact the expansion pin until the laser mark on the pin impactor (Fig. 36) is no longer visible above the assembly block (Fig. 37).





A final visual check should be done, to control that the top surface of the expansion pin sits flush or beneath the top of the ball taper component (Fig. 38).

#### Note

If the pin is not fully positioned as described, continue the impaction steps.

Now the Dome is permanently fixed on the Ball-Taper in the position identified as optimal for the patient and can be carefully removed from the assembly block.

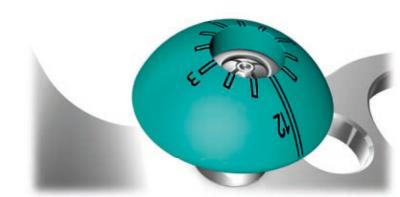
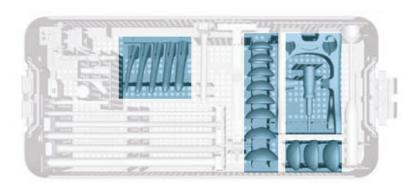


Fig. 38



### 4. Head Preparation and Implantation

Remove the trial head (Fig. 39) and place the definitive Humeral Head at the same clockwise position onto the Dome. In this case the dome's laser mark is aligned to the trial head's 4 o'clock mark (Fig. 40).

Press the head and dome ball-taper construct together.

#### Note

All taper surfaces must be dry, clean and free from surface damage to achieve a good taper connection.

#### Note

Visually inspect to ensure that the taper is evenly seated around its circumference (Fig. 40).

#### **Optional**

Re-place the assembled head onto the rasp to confirm correct alignment.

Remove the rasp by using the rasp-handle (Fig. 41). The appropriate cemented or uncemented stem is determined by the last used modular rasp, and can now be unpacked.

#### Note

If the rasp handle can not be attached, the rasp can also be removed from the humerus by means of the rasp extraction instrument (Fig. 42).

Top view





Bottom view



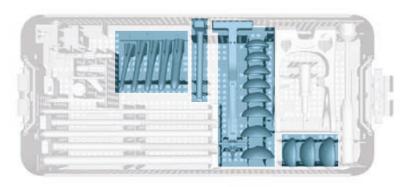


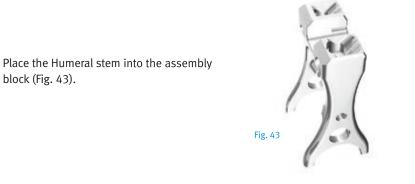
Fig. 40





Trays and Instruments





The assembled head prosthesis is now placed on the stem with appropriate rotation (Fig. 44 and 45).

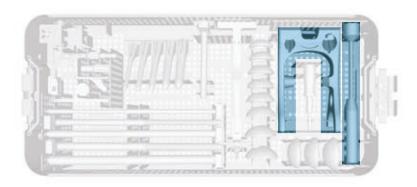
Tip

Take the head and orientate the laser mark on the ball-taper towards the lateral fin of the stem. (Align the laser mark to the supraspinatus)

With the head impactor apply 1 firm impact, in a direction perpendicular to the table, as shown in Fig. 46, to fully lock the taper connections.







#### **Cemented Stem Technique**

With the cemented prosthesis, a cement restrictor can be inserted into the humerus, followed by the cement in a relatively fluid consistency (Fig. 47).



The implant is now inserted into the humerus (Fig. 48) by applying controlled force with the thumb on the head.

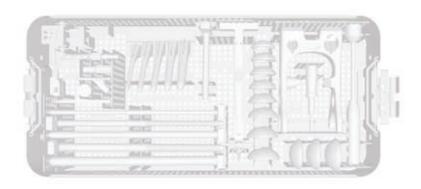
#### Note

All exposed cement must be removed to prevent damage to the glenohumeral joint (Fig. 49).

The *Anatomical Shoulder Domelock* System is now implanted (Fig. 49).







### **Uncemented, press-fit Stem Technique**

The uncemented, press-fit prosthesis is now inserted into the humerus (Fig. 50).

#### Note

If it is not possible to seat the implant with the thumb until you reached a maximum of 1cm distance (Fig. 51) between proximal humerus resection line and the bottom of the humeral head, extract the implant and re-ream with the last rasp size used.

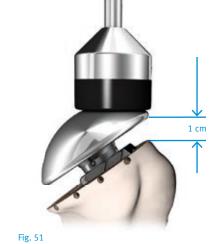
The lateral stem fin is used as an orientation aid.
The implant is brought into the final position with careful blows to the humeral head using the head impactor.

This is done until the lower side of the Humeral Head is resting on the osteotomy of the humerus.

Now use a burr or a rongeur to remove any residual osteophytes or any bone extending beyond the periphery of the humeral head. This should prevent potential impingement with the Scapula.

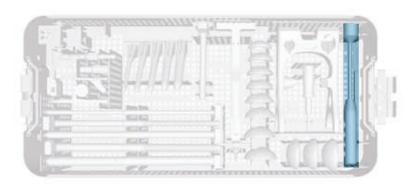
The *Anatomical Shoulder Domelock*System is now implanted
(Fig. 52 and 53).





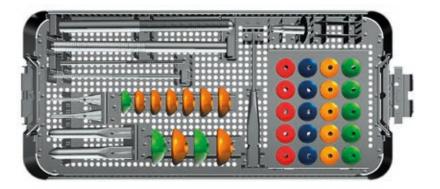




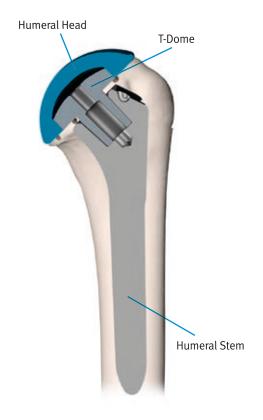


### Optional – Further Combination Possibilities

**Anatomical Shoulder Domelock T-Dome Steps** 



Optional available Anatomical Shoulder Domelock Instrument Tray II ZS01.04558.002



# 3. Optional Head Size Determination, Orientation and Fixation

Choose a Trial Head size that covers the resected humeral osteotomy (Fig. 54 and 55).

#### Note

Standard humeral heads are available in sizes: 38-13, 40-14, 42-15, 44-16, 46-16,

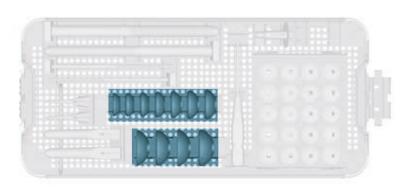
38-13, 40-14, 42-15, 44-16, 46-16, 48-17, 48-20, 50-18, 50-21, 52-19, 52-23

Optional additional humeral head sizes

36-12, 36-15, 38-16, 40-17, 42-18, 44-19, 46-19, 54-20, 54-23, 56-21, 56-24







Insert the Rasp Adapter onto the rasp. The correct alignment is described by superior and inferior laser marks on the instrument (Fig. 56).

Place the *Anatomical Shoulder Domelock* Angle Identification Card for left or right Shoulder onto the rasp adapter and identify first the inclination (e.g. C–D) and second the retroversion (e.g. D–A) of the humeral osteotomy.

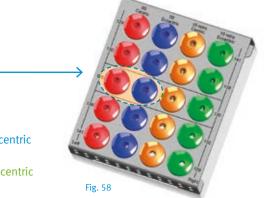
In Fig. 57, a left Shoulder with a 135° inclination and 0° retroversion correction were identified.

These identified angles correspond to 2 trial T-Domes as illustrated in Fig. 58 as an example.

In this case:

Trial T-Dome 135L00 / 135R00 - centric Trial T-Dome 135L00 / 135R00 - eccentric Fig. 56



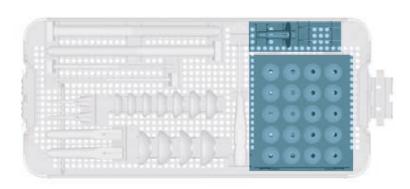


T-Domes: no retroversion, centric

 $\label{eq:T-Domes:no retroversion} \textbf{T-Domes: no retroversion , 2mm eccentric}$ 

T-Domes: 10° retroversion, centric

T-Domes: 10° retroversion, 2mm eccentric



Place first the identified centric trial T-Dome onto the oval internal profile of the modular rasp (f.e. the red Trial T-Dome 135L00 / 135R00 – centric) as shown in Fig. 59. Take care to correctly align the appropriate T-Dome identifying text, L for left Shoulder and R for right Shoulder, towards the supraspinatus.

Connect the selected trial head first through the centric T-Dome (e.g. the Trial T-Dome 135L00 / 135R00 – centric) and after through the eccentric T-Dome (e.g. the Trial T-Dome 135L00 / 135R00 – eccentric) and place the trial head assembly onto the oval internal profile of the modular rasp.

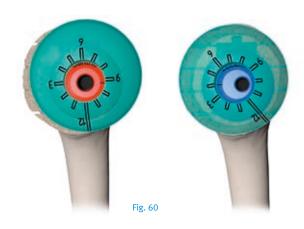
Turn the selected trial head over the trial T-Dome until the trial head optimally covers the resected plane of the humerus.

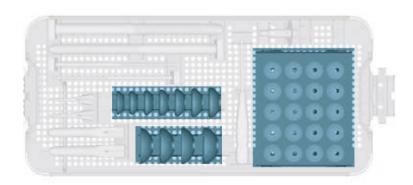
Select the centric or the eccentric T-Dome which provides the better coverage of the resection (Fig. 60).

#### Note

Further optimization may be achieved through the use of different trial head sizes.







## 4. Optional Head Preparation and Implantation

Unpack the defined Humeral Head and the identified T-Dome.

Now, place the definitive Humeral Head at the same clockwise position (e.g. 4 o'clock) onto the T-Dome.

#### Note

The clockwise position can be identified either on the top or bottom surfaces of the trial components.

Press the head and T-Dome construct together.

#### Note

All taper surfaces must be dry, clean and free from surface damage to achieve a good taper connection.

#### Note

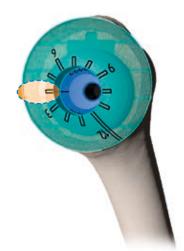
Visually inspect to ensure correct taper seating.

#### Optional

Re-place the assembled head onto the rasp to confirm correct alignment.

Continue at page 22, with the rasp removal and final steps on the surgical technique.

Top view



Bottom view

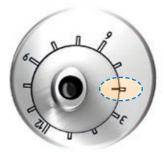
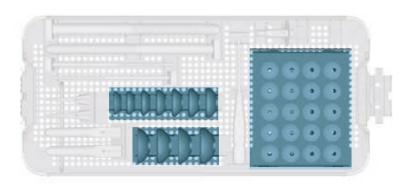


Fig. 61



#### **Postoperative Treatment**

It is the responsibility of the doctor to decide which postoperative treatment is appropriate depending on each patient's health condition with the understanding that an uncemented implant will generally perform better when load activities in the first few weeks are not too aggressive. The following outlines recommendations which are generally made by surgeons. From the first day after the operation the patient may take the arm out of the immobilizing dressing several times a day to stretch his elbow. On the day of the operation pendulum exercises may be started, on the first day with passive flexing exercises, best performed using a cord passed over a roller. Depending on the intra-operative findings, active exercises may be started from the third week. If the rotator cuff was sutured or reconstructed, an abduction splint may be necessary for 4 to 6 weeks.

#### Disclaimer

This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

Please refer to the package inserts for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects.

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