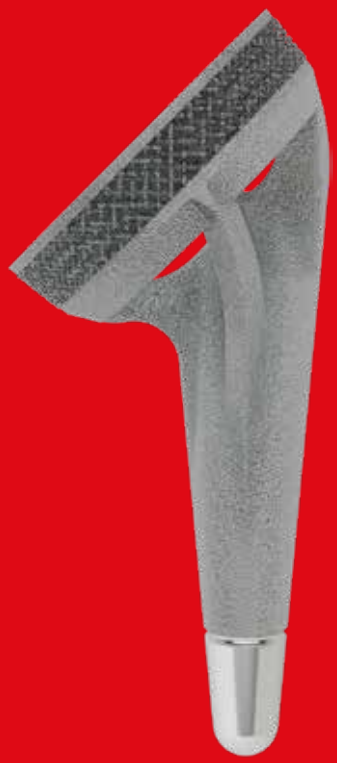
prima

PRIMA STEM

SURGICAL TECHNIQUE

Lima Corporate
Orthopaedic motion



PRIMA Stem

Limacorporate spa is a manufacturer of prosthetic implants and as such does not perform medical procedures. This documentation concerning surgical techniques, which provides surgeons with general guidelines for implanting the PRIMA Humeral System, which was developed with the advice of a team of surgical experts. All decisions as to the type of surgery and most suitable technique are obviously the responsibility of the health care professional. Surgeons must make their own decisions as to the adequacy of each planned implant technique based on their training, experience and the clinical condition of the patient.

Indications, Contraindications, Warnings and Risk Factors

Warnings

Consult instruction for use provided in the product package

In selecting patients for surgery, the following factors can be critical to the eventual success of the procedure:

- Partial Shoulder replacement: in cases of a deficient and unreconstructable rotator cuff, a CTA-head is indicated;
- Total Shoulder replacement: the rotator cuff must be functional, intact or reconstructable. In cases of a deficient and unreconstructable rotator cuff, a hemiprosthesis with a CTA head or a Reverse Total Shoulder Arthroplasty is indicated;
- Reverse Shoulder replacement: the bone stock of the glenoid and humerus must be able to support the implant. In cases of significant bone loss or in which adequate fixation on the glenoid side cannot be obtained, a hemiarthroplasty with a CTA-head should be performed.

Note. For SMR Shoulder System components refer to the proper Instructions for Use leaflet.

Contraindications

Absolute contraindications include:

- local or systemic general infection;
- septicaemia;
- persistent acute or chronic local or systemic osteomyelitis;
- confirmed neurologic lesion compromising shoulder joint function;
- in case of reverse prosthesis, deltoid muscle insufficiency;
- poor bone stock compromising stability of the implant (severe fracture of the proximal humerus, meta- epiphyseal pseudoarthrosis, osteoporosis, osteomalacia, extended bone loss after previous prosthetic or non-prosthetic surgery);
- tumor;
- serious muscular, neurological, or vascular diseases compromising stability of the implant.

Relative contraindications include:

- proximal humerus fracture sequelae with inadequate bone stock;
- vascular or nerve diseases affecting the concerned limb;
- metabolic disorders which may impair fixation and stability of the implant;
- any concomitant disease that might affect the implanted prosthesis;
- metal hypersensitivity to implant materials (CoCrMo);
- patient with significant renal impairment.

Risk Factors

The following factors may result in poor results with this prosthesis:

- overweight*;
- strenuous physical activities (active sports, heavy physical work);
- incorrect implant positioning;
- muscle deficiencies;
- multiple joint disabilities;
- refusal to modify postoperative physical activities;
- patient history of infections or falls;
- systemic diseases and metabolic disorders;
- local or disseminated neoplastic diseases;
- drug therapies that adversely affect bone quality, healing, or resistance to infection;
- drug use or alcoholism;
- immunocompromised patients (HIV, tumour, infections);
- severe deformity leading to impaired anchorage or improper positioning of implants;
- use or combination with products, prosthesis or instruments of another manufacturer.

**According to the definition of World Health Organization (WHO), Body Mass Index (BMI) greater than or equal to 25 Kg/m².*

Indications

The PRIMA Humeral System is intended for partial or total, primary or revision, shoulder joint replacement in skeletally mature patients. The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The PRIMA Stem is intended for use in cementless applications.

The PRIMA Anatomic implant is indicated for partial or total, primary or revision shoulder joint replacement, in patients suffering from pain and disability due to:

- non-inflammatory degenerative joint disease (i.e., osteoarthritis);
- inflammatory degenerative glenohumeral joint disease such as rheumatoid arthritis;
- avascular necrosis of the humeral head;
- cuff tear arthropathy (CTA Heads only).

The PRIMA Reverse implant is indicated for primary reverse total shoulder replacement or for revision when converting an anatomic PRIMA arthroplasty to a reverse total shoulder arthroplasty (i.e., in case of cuff tear arthropathy or in a grossly rotator cuff deficiency joint with severe arthropathy).

Revision surgery with retention of the PRIMA Stem is intended as conversion surgery from anatomic to reverse, where the stem is stable, well positioned and tissue integrated. Other revisions of the humeral prosthesis part should be treated with traditional shoulder prostheses.

The PRIMA Reverse implant is indicated for patients suffering from pain and disability due to:

- rotator cuff tear arthropathy;
- osteoarthritis with rotator cuff tear;
- rheumatoid arthritis with rotator cuff tear;
- massive irreparable rotator cuff tear.

The PRIMA Humeral System consists of the following single use components:

- Anatomic configuration:
  - stem,
  - adaptor for humeral heads,
- Reverse configuration:
  - stem,
  - reverse insert.

System		Components	Material
A	R		
✓	✓	PRIMA Stem	Ti6Al4V 3D printed
✓		Adaptor for Humeral Heads	Ti6Al4V
	✓	Reverse Insert	CoCrMo
Material Standards			
Ti6Al4V (ISO 5832-3 - ASTM F1472), Ti6Al4V 3D printed (ISO 5832-3) CoCrMo (ASTM F1537 and ISO 5832-12)			
A = Anatomic, R = Reverse			

The PRIMA Humeral System is intended to be used with all glenoid implants belonging to the SMR Shoulder System. Instructions for use of SMR Shoulder System should be consulted for warnings that apply to these systems.

The SMR Shoulder System components which are compatible with PRIMA Humeral System components in anatomical and in reverse configuration are:

System		Components
A	R	
✓		SMR Humeral Heads (Standard, CTA)
✓	✓	SMR TT Metal Back (Baseplate and Peg)
✓		SMR Axioma Metal Back Liner
✓	✓	SMR Axioma TT Glenoid (Baseplate and Peg)
✓	✓	SMR Metal Back Glenoid
✓	✓	SMR TT Hybrid Glenoid
✓		SMR Cemented Glenoid
✓		SMR Cemented Glenoid 3-Pegs
✓		SMR Metal Back Liner
	✓	SMR Connectors with screw
	✓	SMR Glenospheres
	✓	SMR TT Augmented 360 (Baseplate and Peg)
	✓	SMR TT Hybrid Glenoid Reverse Baseplate + Screw
	✓	SMR Bone Screw
A= Anatomic / R=Reverse		

Table 2 SMR Shoulder System components compatible with PRIMA Humeral System

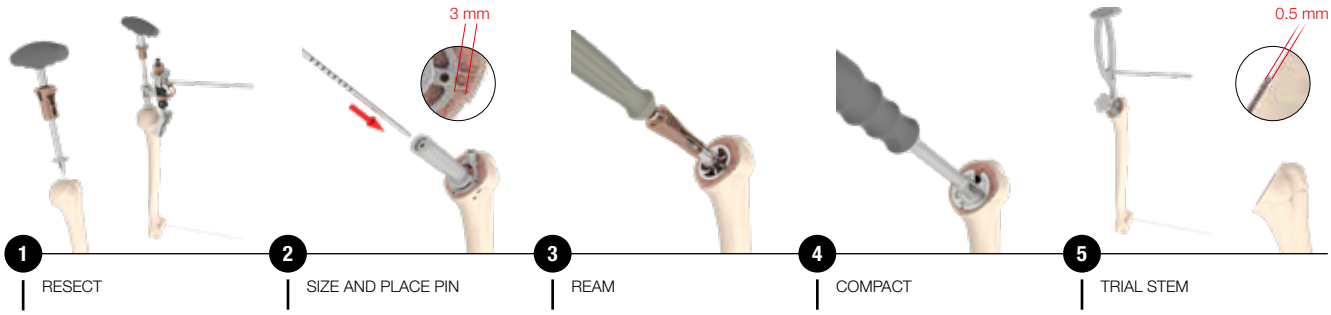
The following table identifies the allowed (✓) / not allowed (**X**) combinations between the SMR Lateralized Connectors and the SMR Glenospheres.

HP Glenospheres		Connectors	
Diameter	Ecc.	LAT+4	LAT+2
Ø40mm	0	✓	✓
Ø44mm	0	X	✓
Ø44mm Corrective	4	X	X

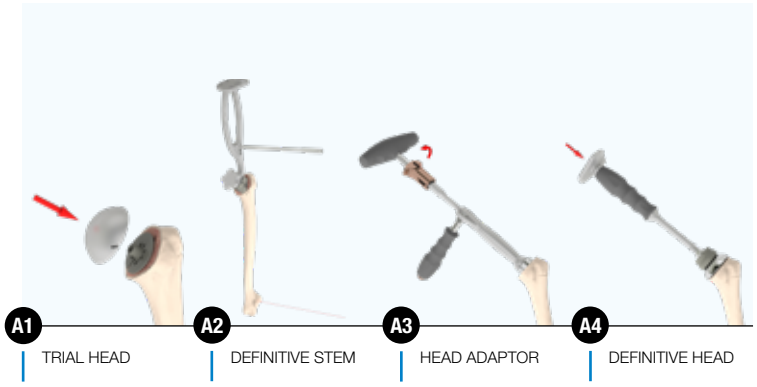
Note. ***SMR Humeral Heads diameter 38 mm are not allowed to be coupled to PRIMA Humeral System. SMR Humeral Heads Dia 40mm H13, Dia 42mm H13 both neutral and eccentrical versions are not allowed to be coupled to PRIMA Humeral System.***

Note. ***The CTA head must be used only in case of good stability of PRIMA Stem. If the CTA Head has to be used, an Eccentric Adaptor must be used (the coupling with the Concentric Adaptor is not allowed) and that the eccentricity is in the cranial direction only.***

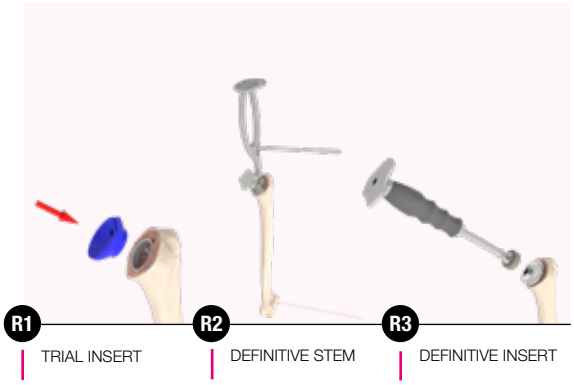
Surgical Steps



ANATOMIC



REVERSE



Introduction

Preoperative planning

LimaCorporate products should be implanted only by surgeons familiar with the joint replacement procedures described in the specific surgical techniques. Pre-operative planning, through radiographic templates in different formats, provides essential information regarding the type and size of components to be used and the correct combination of required devices based on the anatomy and specific conditions of each patient. Inadequate pre-operative planning can lead to improper selection of the implants and/or incorrect implant positioning. In selecting patients for surgery, the following factors can be critical to the eventual success of the procedure: the bone stock of the glenoid and humerus must be able to support the implant. In cases with significant bone loss and in which adequate fixation on the glenoid side cannot be obtained, a hemiarthroplasty with a CTA-head should be performed.

Positioning

Shoulder arthroplasty is normally performed in a “beach- chair” position; the surgeon needs complete access to the shoulder joint. The arm is free or stabilized by arm-holders. The shoulder must be positioned off the edge of the table to afford unobstructed arm extension.

The patient’s head must be supported and stabilized in the neutral position. Nerve injury due to brachial plexus traction during positioning and surgery must be avoided.

The surgeon must have a complete anterior view of the shoulder and positioning should allow unobstructed movement of the shoulder joint.

Access

There are two recommended surgical approaches to the shoulder joint. As in every surgical procedure, the access depends on diagnosis, planned surgical procedure and the experience of the surgeon.

Shoulder range of motion may be evaluated with the patient under anesthesia to confirm the preoperative assessment and the extent of capsular release needed to restore the ROM postoperatively.

Delto-pectoral approach

Anterior vertical incision starts 1 cm later to the coracoid bone, slanting towards the axillary’ pouch.

If there is a metaphyseal fracture, slant the incision laterally towards the deltoid insertion at the humerus. The cephalic vein is retracted laterally with the deltoid muscle. The clavipectoral fascia is incised along the lateral edge of the conjoined tendon up to the coracoacromial ligament.

A retractor can easily be placed over the superolateral aspect of the humeral head to retract the deltoid. The conjoined tendon is retracted medially.

The musculocutaneous nerve penetrates the lateral coracobrachialis muscle 3 to 8 cm distally of the tip of the coracoid process. The position of the axillary nerve should be identified along the anterior surface of the subscapularis muscle, below the conjoined tendon.

The axillary nerve crosses the inferolateral border of the subscapularis 3 to 5 mm medially of its musculotendinous junction and has an intimate anatomic relation with the inferior capsule of the shoulder joint.

The anterior humeral circumflex artery and veins are visualized, ligated and divided.

The subscapularis tendon is released, divided 1 cm medially to its attachment or released with a bone chip of the lesser tuberosity. Separation of the subscapularis from the capsule and incision of the capsule is performed to the inferior border of the glenoid rim, protecting the axillary nerve with a blunt retractor. Release the subscapularis and perform a 360° capsular release.

Antero-lateral (deltoid splitting) approach

Begin the incision at the anterolateral tip of the acromion and carry it distally over the deltoid muscle about 5 cm. Define the tendinous interval on 4 to 5 cm long between the anterior and middle thirds of the deltoid; splitting the muscle here provides an avascular approach to underlying structures.

Incise the thin wall of the subdeltoid bursa and explore the rotator cuff as desired by rotating and abducting the arm to bring different parts of it into view in the floor of the wound.

Closure

After the definitive prosthesis has been implanted, repair of the subscapularis is recommended for reverse shoulder arthroplasty and required for anatomic shoulder arthroplasty.

In case of anatomic reconstruction evaluate after reattachment of the subscapularis if closure of the rotator interval is needed for further stability or not. Closure of the deltopectoral fascia, subcutaneous adaptation and skin closure is then performed.

Humerus Preparation

Foreward

To complete the joint replacement hereby described, a power tool featuring a pin drive, Zimmer-Hudson connection and cutting saw blade is required.

Preoperative Planning

Pre-operative planning is highly recommended with the use of templates showing a 5% enlarged image of the profiles. Normally standard AP and Axial view of the shoulder joint are used; in some cases, a preoperative CT-Scan is recommended to perform a more accurate planning. Select the stem size and resection level of the humeral head, which will serve as a reference for the final implant height.

The PRIMA prosthesis can be implanted with one of the usual approaches:

- delto-pectoral
- antero-lateral (deltoid splitting)

The surgical technique described hereafter refers to the delto-pectoral approach.

Dislocation of the humeral head

Detach the subscapularis tendon at its insertion on the lesser tuberosity and medialize the tendon, dividing it from the underneath capsule. Perform an anterior-oblique capsulotomy, paying attention to avoid injury of the axillary nerve. A retractor, placed between the capsule and the tendon, can be used for protecting the nerve. With careful external rotation and extension (the humerus may be osteoporotic and osteophytes may block the rotation process), the humeral head is dislocated anteriorly. All humeral osteophytes are carefully removed from the humeral head so that the anatomic neck can be identified.

Humeral head resection

The humeral head resection technique is performed with the PRIMA instrumentation. The humeral head resection is performed with an anatomical angle (135°) for both PRIMA Anatomic and PRIMA Reverse implants.
Open the proximal end of the humerus with the awl connected to the T-handle with Zimmer connection (Figure 1). Insert the awl into the humerus until the stopper flange comes in contact with the surface of the humeral head.
Connect the Ø 6 mm humeral intramedullary rod to the T-handle with AO connection and attach the cutting jig connector, finally insert the assembly into the humerus.
Prepare the anatomic resection jig by properly connecting it to the guide for resection jigs (Figure 2).
Connect the alignment rod to the assembly on the LEFT or the RIGHT hole of the delto-pectoral (DP) side to obtain the chosen retroversion angle (0°, 20° and 30° positions are available).
Finally connect the assembly to the Ø 6 mm intramedullary rod according to the side that is being operated. For a left shoulder, the mark LEFT shall be frontally visible on the guide and vice versa the mark RIGHT for a right shoulder.

Figure 1

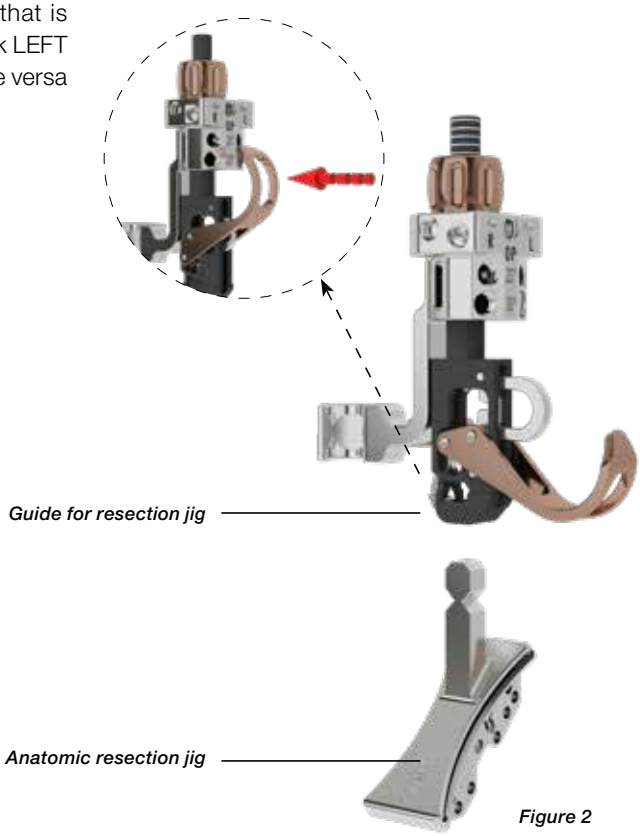


Figure 2

Retroversion

Keeping the forearm flexed at 90°, rotate the resection guide until the ***alignment rod*** and the forearm are parallel (Figure 3). Then fix the selected retroversion by screwing the threaded rod (Figure 4).
A resection with the chosen retroversion will then be performed in this position. If less or more retroversion is required, the rod should be externally or internally rotated, respectively.

Figure 3

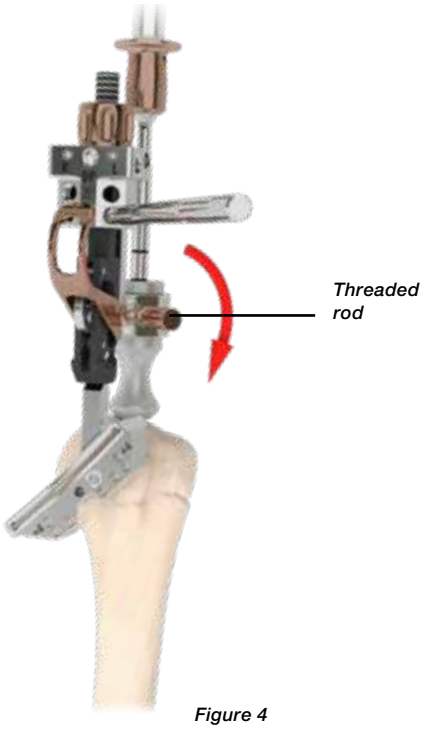


Figure 4

Head Resection

Adjust the height of the resection jig level until it is aligned with the anatomic neck.
Turn the red knob clockwise or counter-clockwise to move the jig proximally or distally respectively (Figure 5). A graduated scale is available to support the visualization of the height during this phase.
Use the sickle to assess the resection height and once the selected height is reached secure the guide to the humerus with two Ø 3 mm pins (Figure 6).

Once the jig is secured to the humerus with the 3mm pins, remove the IM guide by releasing the red lever and slide the guide for resection jig upwards (Figure 7). Next, remove the central Ø 6 mm intramedullary rod from the humeral canal, leaving only the cutting jig secured onto the humerus.
Resect the humeral head with a blade through the guided slot of the jig (Figure 8) finally, remove the pins and the jig.
If a glenoid replacement is required, please refer to the dedicated surgical technique.

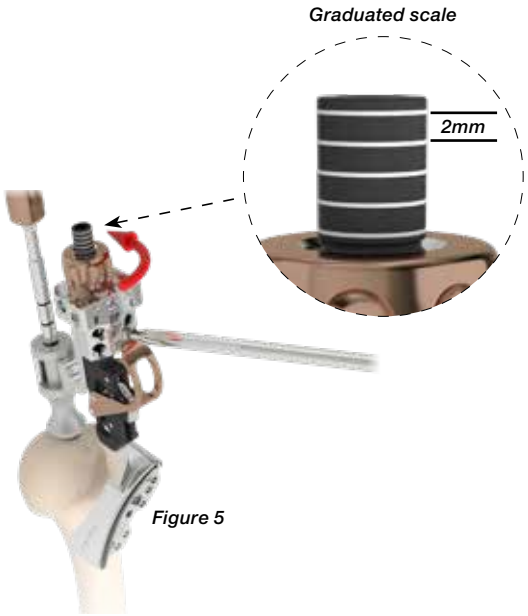


Figure 5

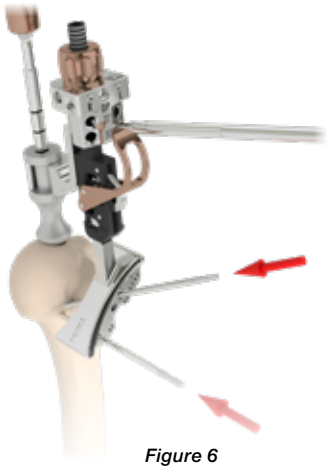


Figure 6

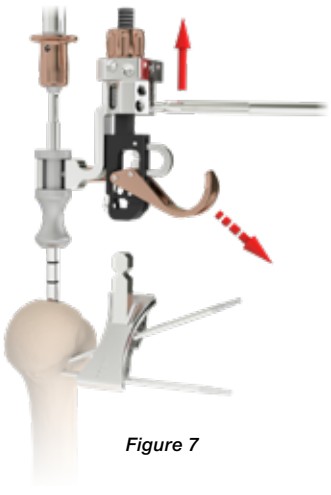


Figure 7

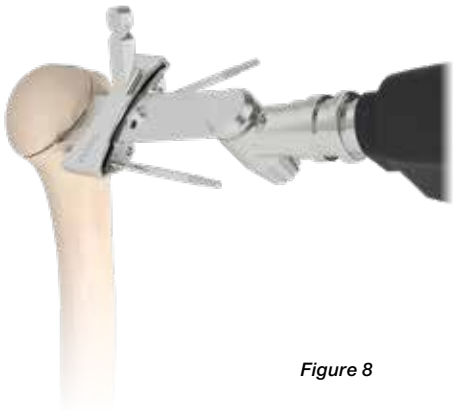


Figure 8

If needed, the PRIMA instrumentation includes humeral covers to be applied to protect the resected humeral cut. Two options are available for this purpose: humeral plate with spikes to be applied to the humeral resections plane (Figure 9A) and monolithic humeral cover to be used with PRIMA stem trial (Figure 9B).

Figure 9A

Figure 9B

Humeral head resection using the extramedullary cutting template

Take from the instrument set the cutting template; screw the alignment rod in the chosen retroversion hole (0°, 20° and 30° positions are available). A black laser marking allows to visualize the available retroversion holes (Figure 10).
For a left shoulder, the mark “L” shall be visible on the front of the template and vice versa the mark “R” for a right shoulder.
Place the cutting template onto the humerus (Figure 11) and align the alignment rod with the forearm flexed at 90°, finally fix the cutting template using the Ø 3 mm pins included into the instrument set (Figure 12). A distal hole for k-wire is available to further stabilize the template, if needed (Figure 10A).
The humeral head should be resected exactly at the level of the anatomical neck. Perform the head resection with an oscillating saw.

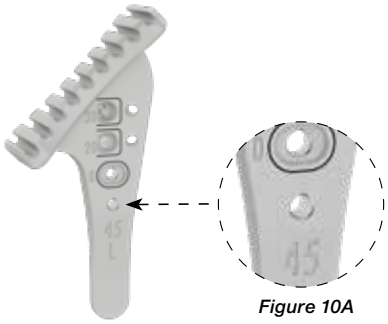


Figure 10A

Figure 10

Figure 11

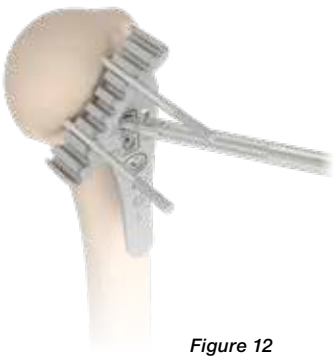


Figure 12

Determination of the PRIMA Stem size

The instruments feature color coding to support the surgical team using the system. The PRIMA Stem is available in 5 sizes and the table below indicates the corresponding color coding.

PRIMA Stem Size	Color Code
#1	No Color
#2	Yellow
#3	Orange
#4	Magenta
#5	Blue

Carefully remove all humeral osteophytes from the humeral head so that the size of the PRIMA Stem can be determined.
Determine the size of the PRIMA stem using the metaphyseal sizer rings.

As optional, the spike bushing could be used in this surgical phase to hold the metaphyseal sizer ring onto the resected humeral plane. Pre-assemble the spike bushing to the sizer ring on the back table, till the first click is heard (Figure 13). Then slide the metaphyseal sizer ring into the Ø 6 mm intramedullary rod and place it over the resected surface (Figure 14). The PRIMA stem will be aligned with the intramedullary canal of the humerus.
To determine the correct implant, the outer rim of the selected ring should be central on the resected humeral surface without overlying the cortex (Figure 15A).
The metaphyseal sizer ring has protrusions that are 3mm larger than the outer rim of the ring and should be used as reference tool for the positioning. The protrusions should be contained within the trabecular portion of the resected surface (Figure 15B) and should not extend beyond the cortical rim. If not satisfied substitute the sizer ring with a different size.

Figure 13

Figure 14

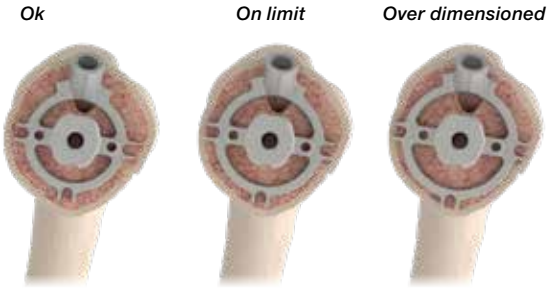


Figure 15A

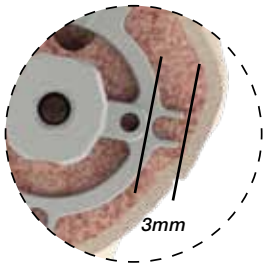


Figure 15B

It is possible to reposition the metaphyseal sizer ring on the resected humeral surface after removing the Ø 6mm intramedullary rod (Figures 16-17). In this case, PRIMA Stem won't be any more aligned with the intramedullary canal of the humerus.

Warning: ***Modifying the position alters the alignment of the stem within the humeral canal, and in extreme cases diaphyseal impingement may occur.***

Secure the ***metaphyseal sizer ring*** to the humeral resection plane in the desired position on the resection plane by sliding the spike bushing over it until the second click is heard (Figure 18).

Once the metaphyseal sizer ring is secured to the humerus, remove the Ø 6 mm intramedullary rod and insert the ***checking rod*** all the way down in the metaphyseal sizer ring.
Make sure there is no cortical contact in this phase. If the checking rod is not flush on the metaphyseal sizer ring, impingement is occurring (Figure 19).
Optional: mark the AP and ML reference lines along the sizer's ring slots which can help verify the humeral trial and final implant version.
Remove the checking rod and insert the ***metaphyseal K-Wire*** through the central hole in the ***metaphyseal sizer ring*** until engaged in the lateral cortex (Figure 20).

Note. ***During this phase, to prevent soft tissue damage especially the axillary nerve, use of a Homann or other retractor as protection during drilling phase is recommended.***

Finally remove the sizer ring and the spike bushing.

Figure 16

Figure 17

Figure 18

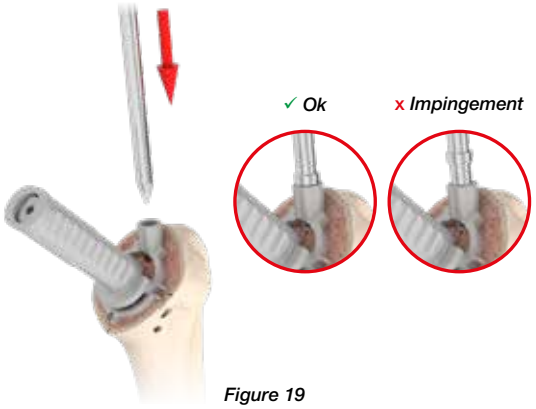


Figure 19

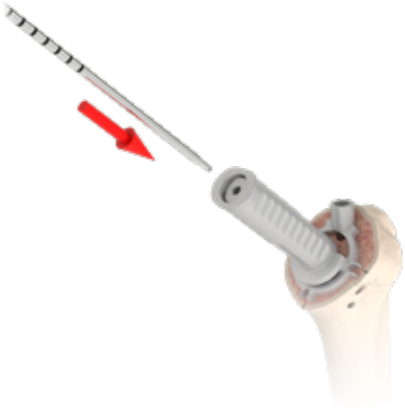


Figure 20

Humerus Reaming

Assemble the ***proximal reamer*** of the selected size to the ***reamer shaft*** (Figure 21) and ream the humeral metaphysis, using the K-wire as a guide.
The reaming is completed once the collar of the reamer sits flush with the resected surface (Figure 22).
Remove the reamer, leaving the K-wire in place.

Complete the preparation of the metaphyseal portion of the humerus using the proximal compactor. Assemble the proximal compactor of the selected size to the compactor & positioning handle.
Impact the ***proximal compactor*** using the k-wire as a guide until the compactor's collar sits flush on the humeral resection.

Optional. If the stem entry point is closed due to the previous reaming step, remove the k-wire and align the mediolateral reference line marked previously on the bone along the proximal compactor's slot, insert the checking rod into the dedicated hole to refresh the stem entry point (Figure 23).
Remove the compactor by tapping it out using the handle and remove the k-wire.

Note. ***Be aware high impact force may cause fracture of the humerus.***

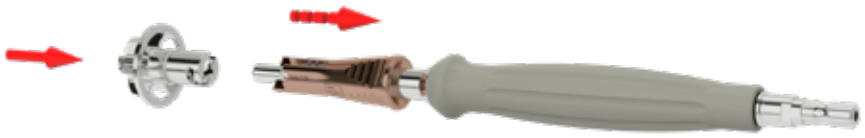


Figure 21

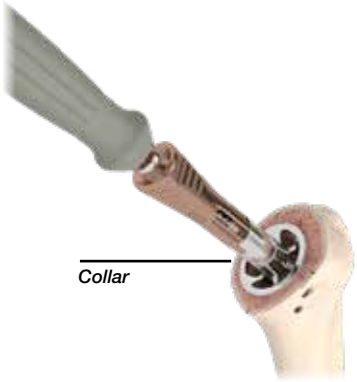


Figure 22

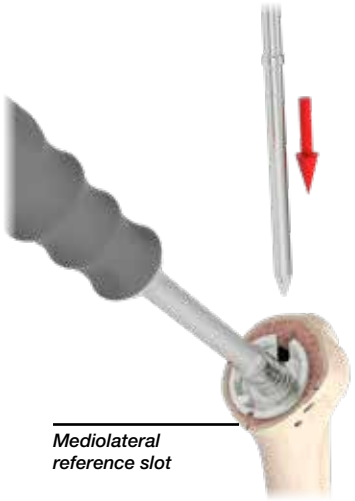


Figure 23

Insertion of the Trial Stem

For this step, the impactor must be assembled onto the PRIMA Trial Stem by using the proper size adaptor. Connect the proper size adaptor to the impactor, then assemble the trial stem to the impactor.
The retroversion may be verified by screwing the alignment rod in the marked screw holes of the impactor (0°, 20° or 30°) (Figure 24).
For a left shoulder, the mark “L” shall be visible on the front of the impactor and vice versa the mark “R” for a right shoulder.
Impact the trial stem of the selected size into the humerus (Figure 25). The impactor has been designed to provide two impaction directions, along the axis of the stem and perpendicular to the resected surface.
During insertion it is possible to verify the proper insertion by utilizing the ML marking on the trial stem that should be aligned with the medial marking, if performed during the sizing step (Figure 26).

Additionally, the impactor features a mark to visualize the trial stem axis (Figure 27).
Stop impacting when the adaptor comes fully in contact with the resected surface. Remove the impactor and adaptor from the trial stem. Optional during this phase, the impactor knob features a central hole for the 3.5mm hexagonal screwdriver to support the removal of the impactor from the implanted trial stem.
Once the impactor and the adaptor are removed, the trial stem will be 0.5mm protruded from the resection plane to compensate the subsidence during subsequent phases (Figure 28).

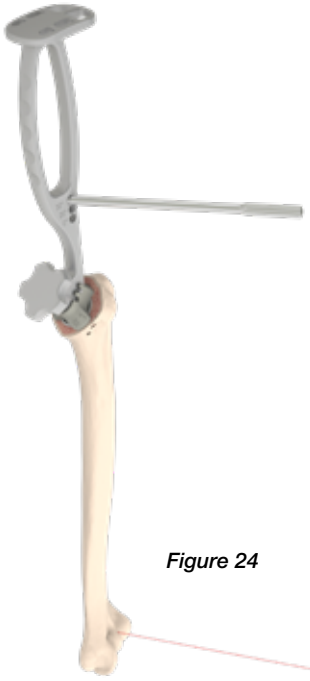


Figure 24

Figure 25

Figure 26

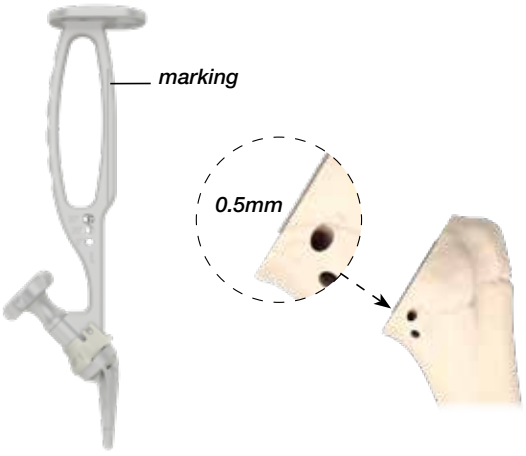


Figure 27

Figure 28

Humeral cover use

To prevent fracture or damage to the cut humeral surface during the glenoid preparation, humeral covers are provided with the PRIMA Instrumentation.
The humeral covers are available in three sizes (Small, Medium and Large) in order to fit with the humerus dimensions; please note that they are not related to the PRIMA stem sizes.
Two options are available for this purpose: humeral plate with spikes to be applied to the humeral resection plane and monolithic humeral cover to be used with trial or definitive PRIMA Stem (Figure 29).
The humeral cover with spikes is intended to be used after resection of the humeral head: the cover is placed on the resected surface and the fixation is obtained by means of the spikes.
The monolithic humeral cover is used with trial stem in situ.
If anatomic prosthesis is performed, proceed as described in “PRIMA Anatomic” on page 22.
In case of reverse prosthesis, follow the surgical steps described in “PRIMA Reverse” on page 26.

Figure 29

PRIMA Anatomic

Trial reduction

Insert the ***anatomical trial adaptor*** into the PRIMA trial stem using the extracting pliers for reverse trial inserts (Figure 30). Apply the neutral ***trial adaptor taper*** to the ***trial humeral head*** by hand and fit the head to the adaptor on the trial stem (Figure 31). Reduce the joint and check the match with the glenoid.
If it is not well aligned with the cut humeral surface, substitute the neutral trial adaptor taper with an eccentric one (2 mm, 4 mm and 6 mm are available). To remove trial adaptor tapers from the trial humeral head use the ***extracting pliers for trial adaptors*** (Figure 32).
If an eccentric adaptor is used, mark the position of the eccentricity with an electric scalpel, using the arrow of the trial humeral head as a reference (Figure 33). This procedure helps to place the final head in the correct position.

After trial reduction remove the trial head, trial adaptor taper using the extractor, and the trial adaptor using the extracting pliers for reverse trial inserts.

Finally remove the trial stem using the positioning handle.

Note. ***The trialing phase may also be performed on the definitive PRIMA Stem to assess range of motion and implant size selection, at the discretion of the surgeon, paying attention to avoid any stress to the implanted stem.***

Figure 30

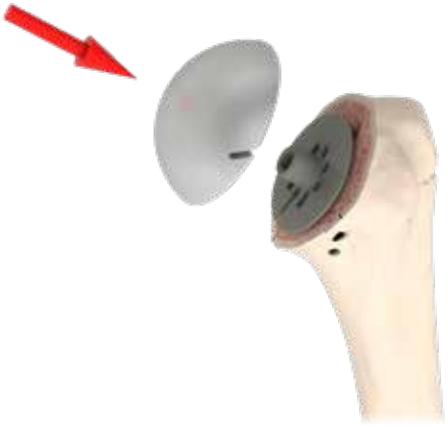


Figure 31

Figure 32

Figure 33

Insertion of the definitive components

Remove the PRIMA stem of the chosen size from sterile packaging and impact it into the prepared humerus using the impactor with the impactor adaptor of the chosen size (Figure 34). The retroversion may be verified by screwing the alignment rod in the marked screw holes of the impactor (0°, 20° or 30°). For a left shoulder, the mark “L” shall be visible on the front of the impactor and vice versa the mark “R” for a right shoulder. Place the PRIMA stem in the same position as the trial implant. The impactor has been designed to provide two impaction directions, along the axis of the stem and along the axis of the trial stem taper. Additionally, the impactor features a mark to visualize the PRIMA Stem axis.

Stop impacting when the adaptor comes fully in contact with the resected surface. Then remove the impactor by unscrewing it from the stem. Optional during this phase, the impactor knob features a central hole for the 3.5mm hexagonal screwdriver to support the removal of the impactor from the implanted stem. Once the impactor and the adaptor are removed, the PRIMA stem will be 0.5mm protruded from the resection plane to compensate the subsidence during subsequent phases.

Remove the appropriate final adaptor taper and final head from the sterile packaging. Apply the adaptor taper to the definitive stem. If an eccentric adaptor taper is used, insert it by aligning the marking with the previous marked reference (Figure 35).

A safety screw is used to secure the coupling between the adaptor taper and the PRIMA stem (Figure 36).

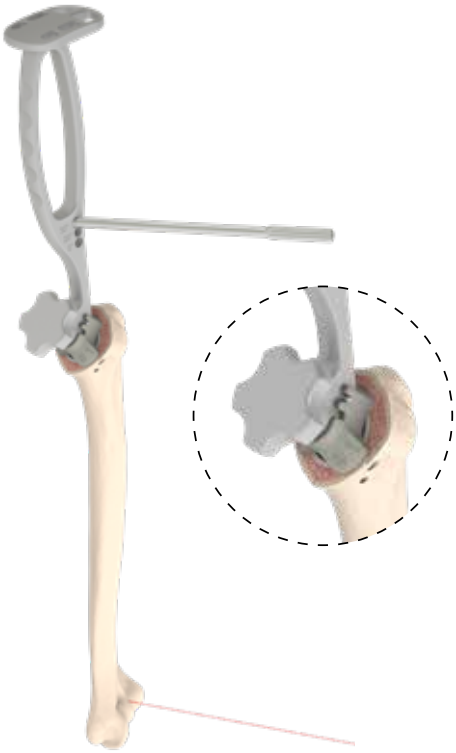


Figure 34

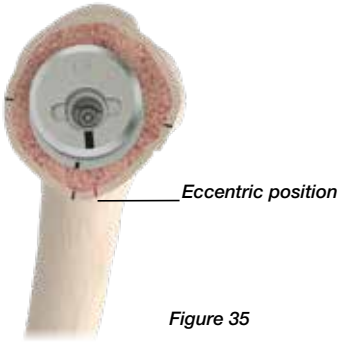


Figure 35

Figure 36

Tighten the screw using the ***3.5 mm allen wrench*** with the ***T-handle with Zimmer connection*** and the ***counter torque*** attached to the ***multipurpose handle*** to prevent load transmission (Figure 37).
Apply the definitive humeral head to the adaptor taper (Figure 38) and secure the coupling by tapping with the ***humeral head impactor*** and handle assembly (Figure 39). The head should sit flush on the osteotomy plane.

Make sure that the contact surfaces are perfectly clean and that the head or adaptor does not contact the bone, as this could compromise the stability of the morse taper coupling. Finally reduce the shoulder joint.

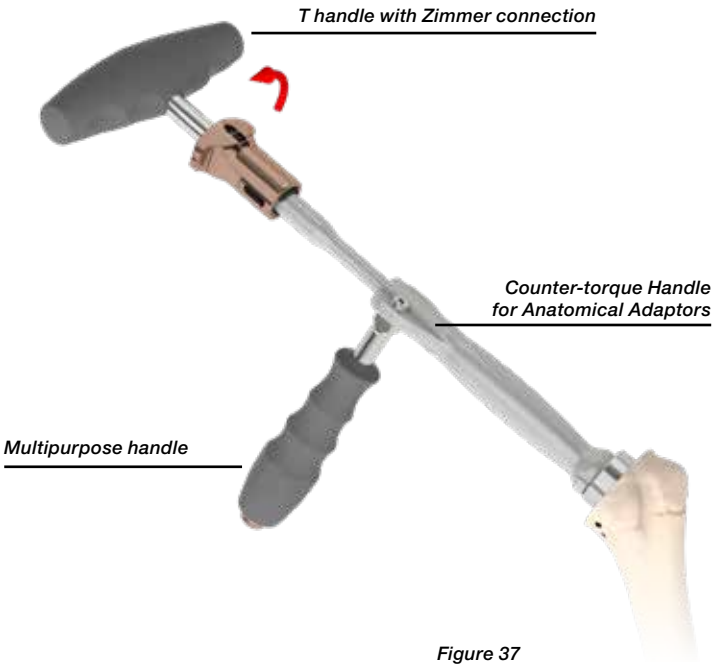


Figure 37

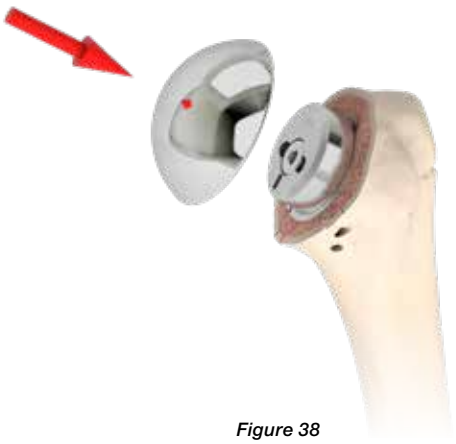


Figure 38

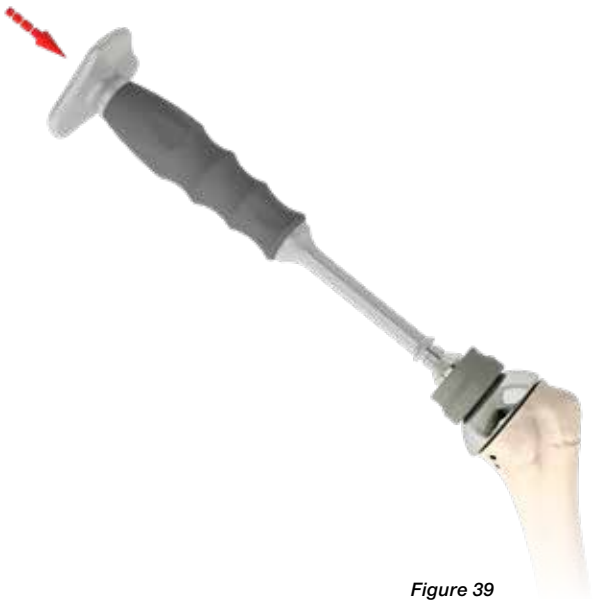


Figure 39

CTA heads use

The clinical indication for prosthetic treatment with a CTA head is by rotator cuff tear arthropathy.

Note. ***The CTA head must be used only in case of good stability of the PRIMA stem. If the CTA Head has to be used, make sure that an Eccentric Adaptor is used (the coupling with the Concentric Adaptor is not allowed) and that the eccentricity is in the cranial direction only.***

To prepare the seat for the CTA Head, connect the trial humeral head dia. 40 mm (in case of dia. 42 and 46 mm definitive CTA Head) or dia. 46 mm (in case of dia. 50 and 54 mm definitive CTA Head) to the PRIMA stem by means of the dedicated *connector for trial adaptor* and the *trial adaptor taper ecc. 2 mm, ecc. 4 mm or ecc. 6mm*. Use the slots of trial head as reference to evaluate the area of the greater tuberosity where the bone has to be removed to host the CTA heads (Figure 40). Use the *trial CTA heads* with the trial adaptor taper ecc. 2 mm, ecc. 4 mm or 6mm to properly assess the prepared seat. Refine the seat if required until perfect seat of the trial CTA Head is achieved prior to implanting the final CTA Head.

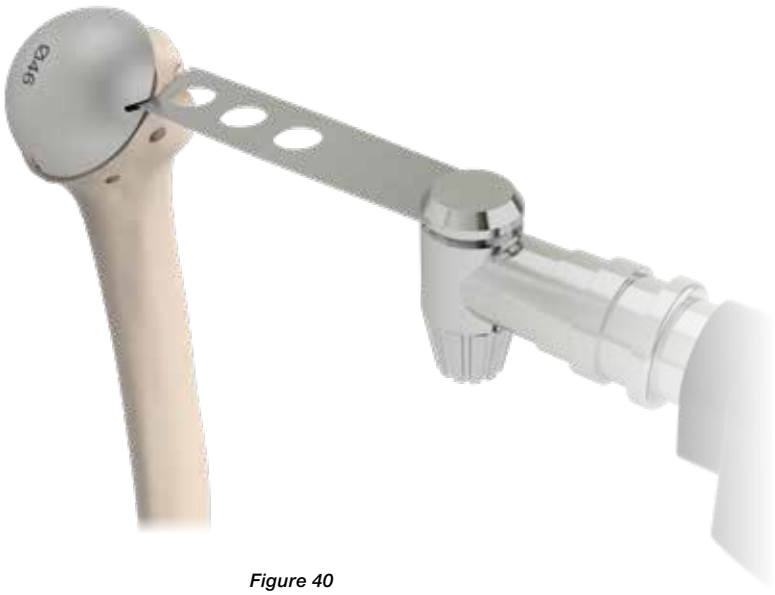


Figure 40

PRIMA Reverse

Important! ***In the reverse configuration PRIMA Stem is intended for use only with SMR 40 mm or 44mm glenospheres. The surgeon can further choose between regular and lateralized connectors, according to the joint tensioning.***

Trial reduction

The trial components feature color coding to support the surgical team using the system.

PRIMA reverse insert	Color code
Dia. 40mm	Blue
Dia. 44mm	Green

Choose the *trial reverse insert* according to the implanted 40 mm or 44 mm glenosphere and insert it into the trial stem by means of the extracting pliers for reverse trial inserts (Figure 41).

PRIMA reverse insert	Size
Insert Short	0mm
Insert Medium	+3mm
Insert Long	+6mm
Insert Medium - Offset	+3mm, 3mm offset
Insert Long - Offset	+6mm, 3mm offset

The trial reverse insert is available with 0° and 7° angle. If using a 7° or an OFFSET trial reverse insert, mark the position of the slit of the trial insert on the resected surface in order to reproduce it with the final implant (Figure 42).

Reduce the implant to verify the shoulder tensioning and address any laxity by replacing with the next liner size. The choice of liner thickness is made by the surgeon to ensure the correct tension, prevent any laxity in the joint, restore the correct offset of the joint. To remove and replace the trial reverse insert use the extracting pliers for reverse inserts.

Note. ***The trialing phase may also be performed on the definitive PRIMA stem to assess range of motion and implant size selection, at the discretion of the surgeon, paying attention to avoid any stress to the implanted stem.***

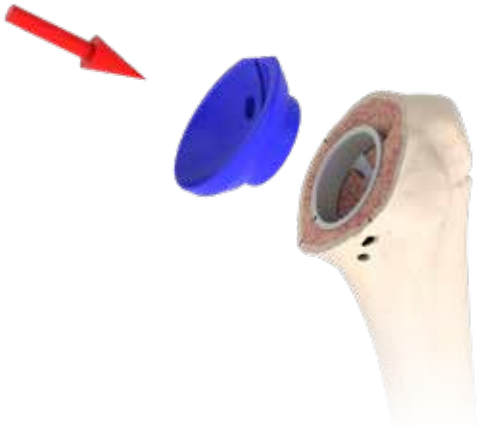


Figure 41

Figure 42

Insertion of the definitive components

Remove the PRIMA stem of the chosen size from sterile packaging and impact it onto the humerus cavity using the impactor with the impactor adaptor of the chosen size (Figure 43). The retroversion may be verified by screwing the alignment rod in the marked screw holes of the impactor (0°, 20° or 30°) (Figure 44). For a left shoulder, the mark “L” shall be visible on the front of the impactor and vice versa the mark “R” for a right shoulder.

Place the PRIMA stem in the same position as the trial implant. The impactor has been designed to provide two impaction directions, along the axis of the stem and along the axis of the trial stem taper. Additionally, the impactor features a laser mark to visualize the PRIMA Stem axis.

Stop impacting when the adaptor enters in contact with the resected surface. Then remove the impactor from the stem. Optional during this phase, the impactor knob features a central hole for the 3.5mm hexagonal screwdriver to support the removal of the impactor from the implanted stem. Once the impactor and the adaptor are removed, the PRIMA stem will be 0.5mm protruded from the resection plane to compensate the subsidence during subsequent phases (Figure 45).

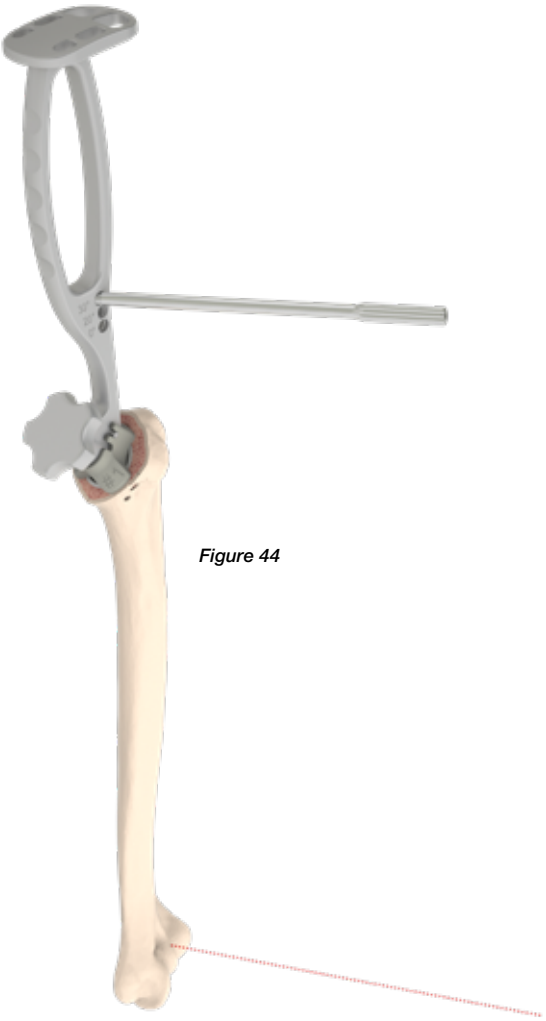


Figure 44

Figure 43

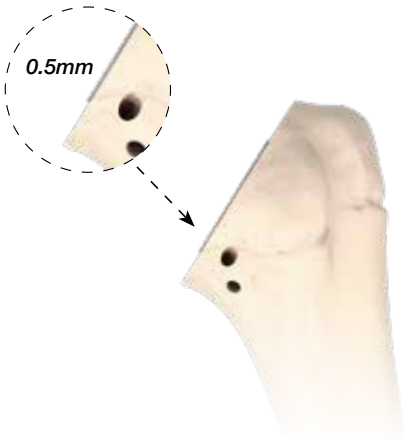


Figure 45

Insertion of final PRIMA reverse insert

Open the packaging of the reverse insert that was selected during the trial reduction.
Clean the PRIMA Stem and impact the insert on the stem by means of the reverse insert pusher assembled to the handle (Figure 46).
If a 7° or an offset reverse insert is chosen, make sure to align the marking on the insert to the marking performed during trialing phase (Figure 47).
Make sure that the contact surfaces are perfectly clean and that the insert does not contact the bone, as this could compromise the stability of the morse taper coupling.
The shoulder joint may then be reduced with gentle manipulation, with or without use of the Namba slide.

Figure 46

Figure 47

Components Removal

Humeral head removal

To remove the humeral head, slide the ***anatomic head extractor*** between the collar of the PRIMA stem and the undersurface of the humeral head (Figure 48). Firmly tap the end of the instrument to loosen the head. It may be necessary to use more than one direction to accomplish the extraction.
Using the ***3.5 mm allen wrench*** plus ***T-handle with Zimmer connection*** remove the safety screw inside the adaptor whilst using the counter torque and the multipurpose handle to prevent load transmission.
Then insert the ***humeral head adaptors extractor*** attached to the ***T-handle*** into the ***counter torque*** (Figure 49). Tighten the extractor until the disassembly operation has been completed.

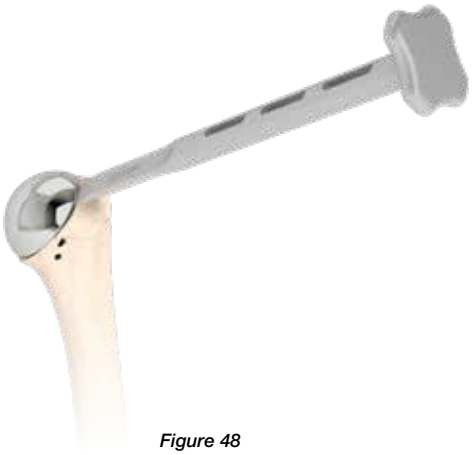


Figure 48

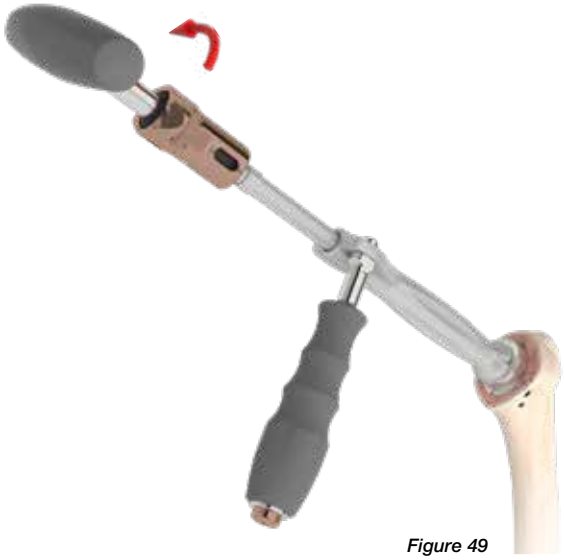


Figure 49

Reverse insert removal

To remove the reverse insert from the PRIMA Stem, slide the reverse insert extractor between the collar of the PRIMA stem and the undersurface of the reverse insert. Firmly tap the end of the instrument to loosen the insert (Figure 50).
For the removal of the glenoid component refer to the related surgical technique.

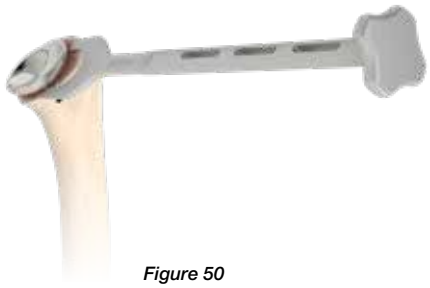


Figure 50

PRIMA Stem removal

If necessary to remove the PRIMA Stem, screw the ***stopper for removal reamer*** into the PRIMA stem (Figure 51). Select the ***removal reamer*** according to the implanted size and attach it to the reamer shaft.
Introduce the reamer onto the stopper and proceed with the reaming of the bone in the proximal area (Figure 52).
A small osteotome may be gently inserted along the length of the PRMIA stem through the windows in the metaphyseal portion of the prosthesis at the surgeon's discretion. Then remove the PRIMA stem by securing the positioning handle to the prosthesis and back slapping gently with a mallet.

Glenoid components removal

For the removal of the glenoid component refer to the SMR Surgical Techniques.
In case of revision of the SMR TT Augmented 360 Metal Back and SMR TT Metal Back, refer to the surgical steps showed in the related surgical techniques.

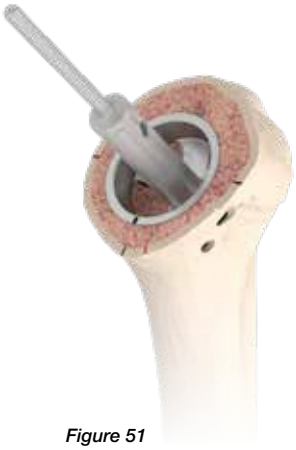


Figure 51

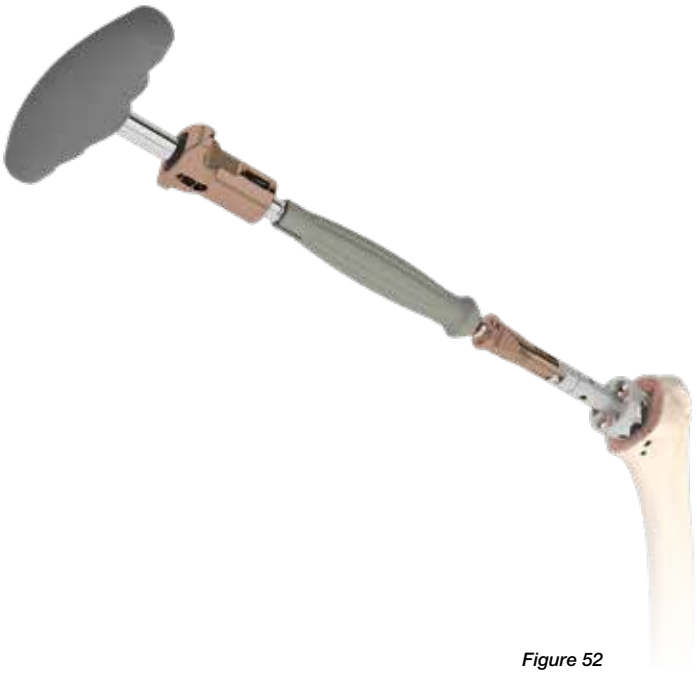


Figure 52

Conversion from Anatomic to Reverse

Note. ***The conversion of the implant must be performed only in case of good stability of the implanted PRIMA Stem.***

Removal of the humeral head and adaptor

Remove the humeral head and the adaptor as described on page 29 of the PRIMA surgical technique.
If no metal back glenoid has been implanted previously, proceed with the glenoid preparation as described in the SMR surgical technique.

Previous glenoid implant

Remove the anatomical component on the glenoid side as described in the SMR surgical technique.

Humeral side trialing

Expose the humerus and select the trial reverse insert according to the implanted 40 mm or 44 mm glenosphere and insert it into the PRIMA stem as described on page 26 of the PRIMA surgical technique (Figure 41). Reduce the implant to verify the shoulder tensioning and address any laxity by replacing with the next liner size.

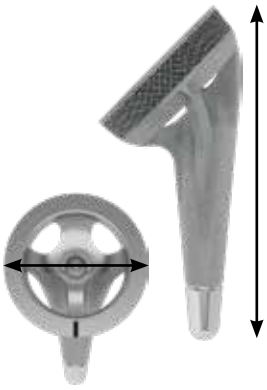
Insertion of the definitive components

Open the packaging of the reverse insert that was selected during the trial reduction. Clean the PRIMA Stem and insert the final reverse insert as described at page 28 (Figure 46). Refer to the SMR surgical technique (SMR Metal Back, SMR Axioma TT Metal Back, SMR TT 360 Augmented Glenoid and SMR TT Hybrid Glenoid reverse baseplate) for the glenoid implantation.
Finally reduce the shoulder joint.

Figure 53

Figure 54

Annex 1:
Measurement chart



PRIMA Stem

	SIZE	LENGHT (mm)	PROXIMAL DIA (mm)
1357.14.028	#1	66.0	28
1357.14.030	#2	66.7	30
1357.14.032	#3	67.4	32
1357.14.034	#4	68.1	34
1357.14.036	#5	68.9	36

PRIMA REVERSE INSERTS 40mm

	THICKNESS (mm)	OFFSET (mm)
1367.09.200 SHORT 0°	0	
1367.09.203 MEDIUM 0°	+3	
1367.09.206 LONG 0°	+6	
1367.09.270 SHORT 7°	0	
1367.09.273 MEDIUM 7°	+3	
1367.09.276 LONG 7°	+6	
1367.09.403 MEDIUM 0° 3mm Offset	+3	+3
1367.09.406 LONG 0° 3mm Offset	+6	+3

PRIMA REVERSE INSERTS 44mm

	THICKNESS (mm)	OFFSET (mm)
1367.09.300 SHORT 0°	0	
1367.09.303 MEDIUM 0°	+3	
1367.09.306 LONG 0°	+6	
1367.09.370 SHORT 7°	0	
1367.09.373 MEDIUM 7°	+3	
1367.09.376 LONG 7°	+6	
1367.09.503 MEDIUM 0° 3mm Offset	+3	+3
1367.09.506 LONG 0° 3mm Offset	+6	+3

PRIMA HUMERAL HEAD ADAPTOR WITH SCREW	
	ECCENTRICITY (mm)
1367.15.700	neutral
1367.15.702	+2 eccentrical
1367.15.704	+4 eccentrical
1367.15.706	+6 eccentrical

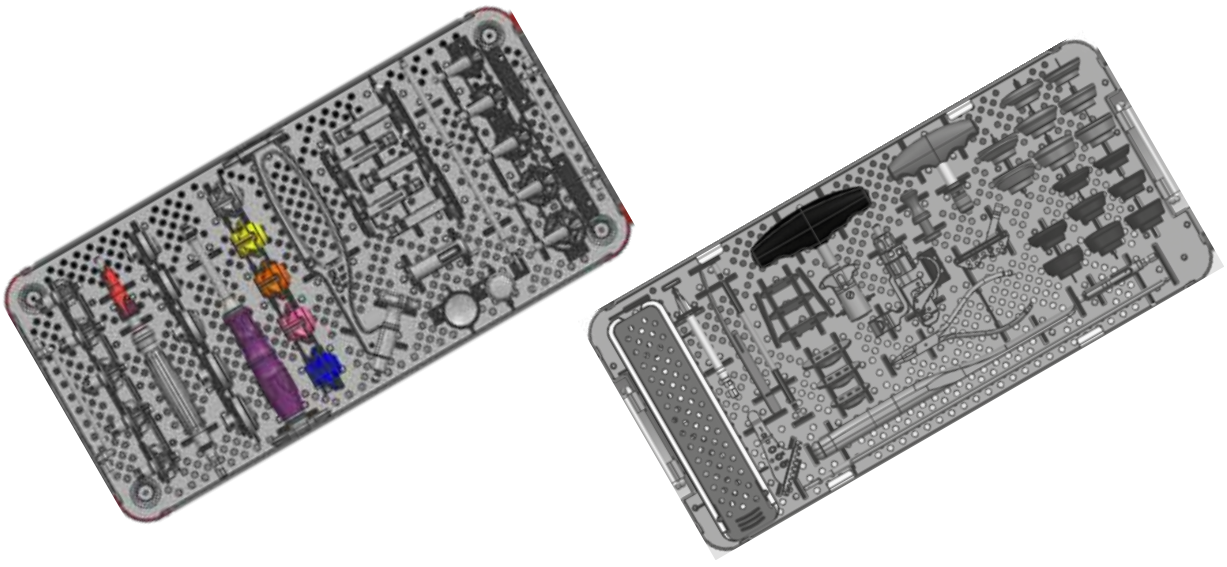
PRIMA Stem Instrument set

9013.68.000 PRIMA General and Reverse Set 1/2

Ref.	Code	Description	Qty.
A68	9013.50.305	Sickle	1
B68	9013.55.010	Cutting Jig Connector	1
C68	9013.60.101	Extracting Pliers for Reverse Trial Liners	1
D68	9013.67.001	Humeral Starting Awl	1
E68	9013.67.005	Guide for Resection Jig	1
F68	9013.67.015	Humeral Intramedullary Rod	1
G68	9013.67.016	Checking Rod	1
H68	9013.67.020	Anatomic Resection Jig	1
I68	9013.67.025	Cutting Template	1
J68	9013.67.028	Alignment Rod	1
K68	9013.67.030	Humeral Plate Small	1
K68	9013.67.031	Humeral Plate Medium	1
K68	9013.67.032	Humeral Plate Large	1
L68	9013.67.035	Humeral Cover Small	1
L68	9013.67.036	Humeral Cover Medium	1
L68	9013.67.037	Humeral Cover Large	1
M68	9013.67.075	Pin Dia. 3x100mm	4
N68	9013.67.080	Metaphyseal K-Wire	2
O68	9013.67.100	Reamer Shaft	1
P68	9013.67.101	Proximal Reamer #1	1
P68	9013.67.102	Proximal Reamer #2	1
P68	9013.67.103	Proximal Reamer #3	1
P68	9013.67.104	Proximal Reamer #4	1
P68	9013.67.105	Proximal Reamer #5	1
Q68	9013.67.121	Trial Stem #1	1
Q68	9013.67.122	Trial Stem #2	1
Q68	9013.67.123	Trial Stem #3	1
Q68	9013.67.124	Trial Stem #4	1
Q68	9013.67.125	Trial Stem #5	1
R68	9013.67.140	Impactor	1
S68	9013.67.141	Impactor Adaptor #1	1
S68	9013.67.142	Impactor Adaptor #2	1
S68	9013.67.143	Impactor Adaptor #3	1
S68	9013.67.144	Impactor Adaptor #4	1
S68	9013.67.145	Impactor Adaptor #5	1
T68	9013.67.160	Spike Bushing	1
U68	9013.67.161	Metaphyseal Size Ring #1	1
U68	9013.67.162	Metaphyseal Size Ring #2	1
U68	9013.67.163	Metaphyseal Size Ring #3	1
U68	9013.67.164	Metaphyseal Size Ring #4	1
U68	9013.67.165	Metaphyseal Size Ring #5	1
V68	9013.67.191	Humeral Head Impactor	1
W68	9013.67.192	Reverse Insert Pusher	1

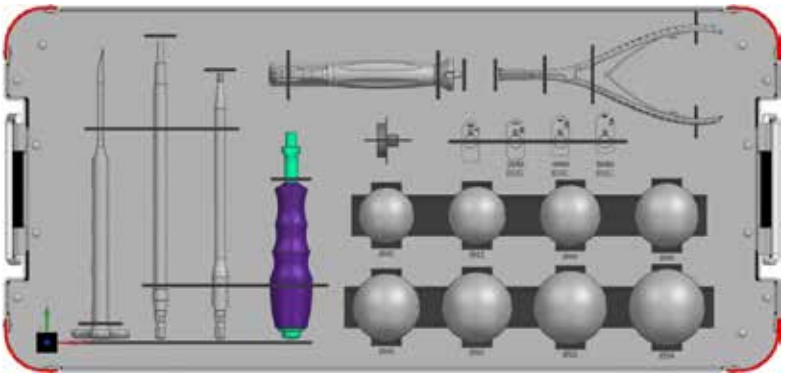
9013.68.000 PRIMA General and Reverse Set 2/2

Ref.	Code	Description	Qty.
X68	9013.67.200	Trial Insert Dia.40mm SHORT 0°	1
X68	9013.67.201	Trial Insert Dia.40mm MEDIUM 0°	1
X68	9013.67.202	Trial Insert Dia.40mm LONG 0°	1
X68	9013.67.203	Trial Insert Dia.40mm SHORT 7°	1
X68	9013.67.204	Trial Insert Dia.40mm MEDIUM 7°	1
X68	9013.67.205	Trial Insert Dia.40mm LONG 7°	1
X68	9013.67.206	Trial Insert Dia.40mm MEDIUM 0° 3mm Offset	1
X68	9013.67.207	Trial Insert Dia.40mm LONG 0° 3mm Offset	1
X68	9013.67.208	Trial Insert Dia.44mm SHORT 0°	1
X68	9013.67.209	Trial Insert Dia.44mm MEDIUM 0°	1
X68	9013.67.210	Trial Insert Dia.44mm LONG 0°	1
X68	9013.67.211	Trial Insert Dia.44mm SHORT 7°	1
X68	9013.67.212	Trial Insert Dia.44mm MEDIUM 7°	1
X68	9013.67.213	Trial Insert Dia.44mm LONG 7°	1
X68	9013.67.214	Trial Insert Dia.44mm MEDIUM 0° 3mm Offset	1
X68	9013.67.215	Trial Insert Dia.44mm LONG 0° 3mm Offset	1
Y68	9013.67.420	Compactor & Positioning Handle	1
Z68	9013.67.611	Proximal Compactor #1	1
Z68	9013.67.612	Proximal Compactor #2	1
Z68	9013.67.613	Proximal Compactor #3	1
Z68	9013.67.614	Proximal Compactor #4	1
Z68	9013.67.615	Proximal Compactor #5	1
	9013.68.990	Instrument Tray	1
Z68	9095.11.120	Powered Pin Driver	1
Γ68	9095.11.203	T-Handle Zimmer Connection	1
Δ68	9095.11.206	T-Handle with AO Connection	1
Θ68	9095.11.911	Namba Shoulder Slide	1



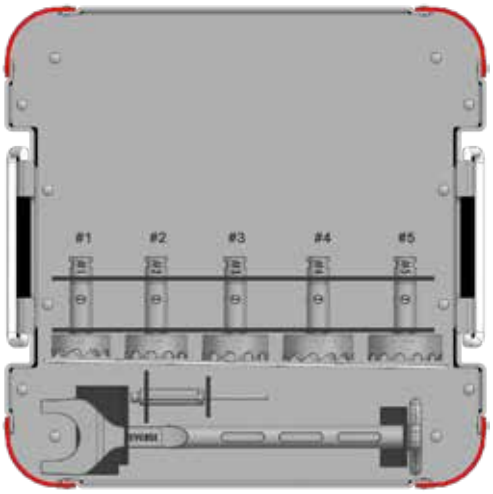
9013.69.000 PRIMA Anatomic Set

Ref.	Code	Description	Qty.
A69	9013.22.405	Trial Humeral Head Dia. 40mm	1
A69	9013.22.425	Trial Humeral Head Dia. 42mm	1
A69	9013.22.445	Trial Humeral Head Dia. 44mm	1
A69	9013.22.465	Trial Humeral Head Dia.46mm	1
A69	9013.22.485	Trial Humeral Head Dia. 48mm	1
A69	9013.22.505	Trial Humeral Head Dia. 50mm	1
A69	9013.22.525	Trial Humeral Head Dia. 52mm	1
A69	9013.22.545	Trial Humeral Head Dia. 54mm	1
B69	9013.30.011	Trial Adaptor Taper Neutral	1
C69	9013.30.016	Trial Adaptor Taper Ecc. 2mm	1
C69	9013.30.021	Trial Adaptor Taper Ecc. 4mm	1
D69	9013.30.026	Trial Heads Ecc. 6mm Adaptor	1
E69	9013.67.180	Anatomical Trial Adaptor	1
F69	9013.67.190	Counter-torque Handle for Anatomical Adaptors	1
G69	9013.67.360	Humeral Head Adaptors Extractor	1
H69	9013.67.500	Anatomic Head Extractor	1
	9013.69.990	Instrument Tray	1
I69	9066.35.610	Extracting Plier for Trial Adaptors	1
J69	9095.10.228	Screwdriver Shaft	1
G69	9095.11.255	Multipurpose Handle	1



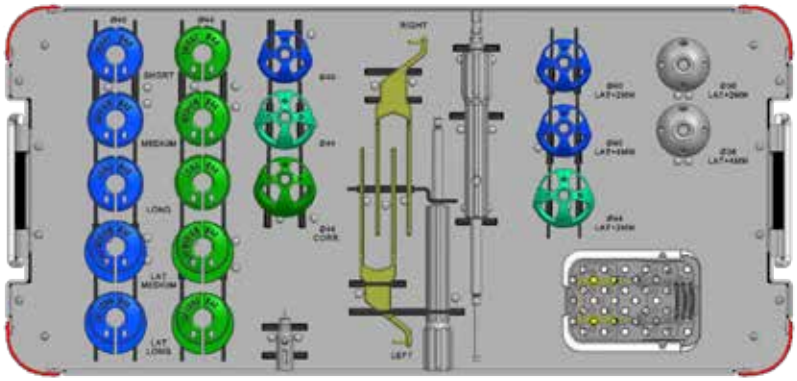
9013.74.000 PRIMA Stem Revision Set

Ref.	Code	Description	Qty.
C74	9013.67.401	Metaphyseal Removal Reamer #1	1
C74	9013.67.402	Metaphyseal Removal Reamer #2	1
C74	9013.67.403	Metaphyseal Removal Reamer #3	1
C74	9013.67.404	Metaphyseal Removal Reamer #4	1
C74	9013.67.405	Metaphyseal Removal Reamer #5	1
D74	9013.67.410	Metaphyseal Removal Reamer Stopper	1
E74	9013.67.501	Reverse Insert / Tray Assembly Extractor	1
	9013.74.990	Instrument Tray	1



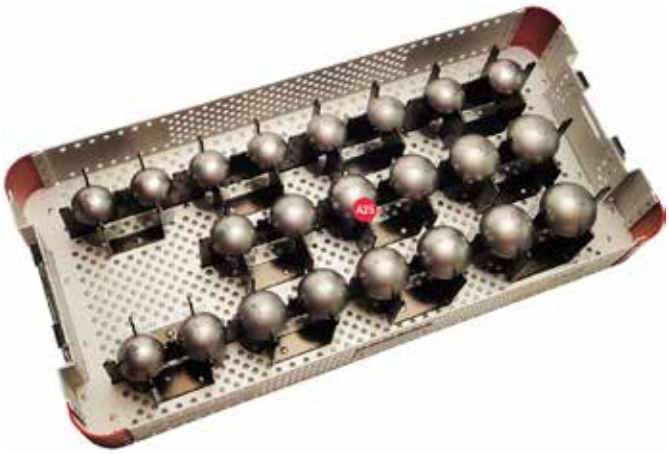
9013.92.000 SMR Reverse HP & Lateralized Glen. Set

Ref.	Code	Description	Qty.
A92	9013.62.011	Reverse Trial Liner Dia. 44mm Short	1
A92	9013.62.016	Reverse Trial Liner Dia. 44mm Medium	1
A92	9013.62.021	Reverse Trial Liner Dia. 44mm Long	1
A92	9013.62.116	Reverse Trial Liner LAT. Dia. 44mm Medium	1
A92	9013.62.121	Reverse Trial Liner LAT. Dia. 44mm Long	1
A92	9013.65.011	Reverse Trial Liner Dia. 40mm Short	1
A92	9013.65.016	Reverse Trial Liner Dia. 40mm Medium	1
A92	9013.65.021	Reverse Trial Liner Dia. 40mm Long	1
A92	9013.65.116	Reverse Trial Liner LAT. Dia. 40mm Medium	1
A92	9013.65.121	Reverse Trial Liner LAT. Dia. 40mm Long	1
B92	9013.74.105	Guide Screw for Trial Glenosphere Small-R	2
B92	9013.74.120	Guide Screw for Trial Glenosphere	2
C92	9013.74.144	Glenosphere Impactor	1
D92	9013.74.145	Glenosphere Extractor	1
E92	9013.74.312	Trial Glenosphere Lat. +2mm Dia. 36mm	1
E92	9013.74.314	Trial Glenosphere Lat. +4mm Dia. 36mm	1
E92	9013.74.402	Trial Glenosphere Dia.40mm	1
E92	9013.74.441	Trial Glenosphere Dia.44mm	1
E92	9013.74.445	Trial Glenosphere Dia. 44mm Corrective	1
E92	9013.74.502	Trial Glenosphere Lat. +2mm Dia. 40mm	1
E92	9013.74.504	Trial Glenosphere Lat. +4mm Dia. 40mm	1
E92	9013.74.542	Trial Glenosphere Lat. +2mm Dia. 44mm	1
F92	9013.74.606	Inserter for Glenosphere Plug	1
G92	9013.74.651	Dia. 40-44mm Glenosphere Orienter LEFT	1
G92	9013.74.652	Dia. 40-44mm Glenosphere Orienter RIGHT	1
	9013.92.990	Instrument Tray	1



9013.25.000 SMR Variable Height Humeral Heads Instrument Set

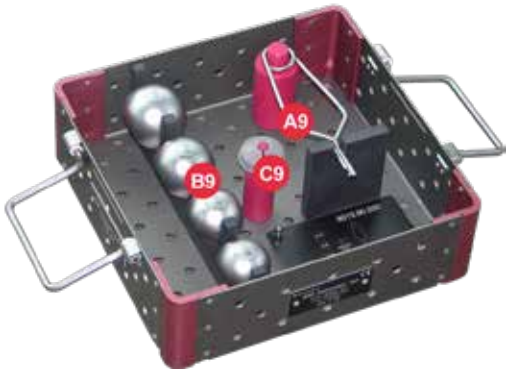
Ref.	Code	Description	Qty.
A25	9013.21.401	Trial Humeral Head Dia.40 - H13mm Neutral	1
A25	9013.21.402	Trial Humeral Head Dia.40 - H13mm Ecc.2mm	1
A25	9013.21.404	Trial Humeral Head Dia.40 - H13mm Ecc.4mm	1
A25	9013.21.407	Trial Humeral Head Dia.40 - H13mm Ecc.7mm	1
A25	9013.21.421	Trial Humeral Head Dia.42 - H13mm Neutral	1
A25	9013.21.422	Trial Humeral Head Dia.42 - H13mm Ecc.2mm	1
A25	9013.21.424	Trial Humeral Head Dia.42 - H13mm Ecc.4mm	1
A25	9013.21.427	Trial Humeral Head Dia.42 - H13mm Ecc.7mm	1
A25	9013.21.441	Trial Humeral Head - Dia.44 H14mm	1
A25	9013.21.461	Trial Humeral Head - Dia.46 H15mm	1
A25	9013.21.481	Trial Humeral Head - Dia.48 H16mm	1
A25	9013.22.501	Trial Humeral Head - Dia.50 H16mm	1
A25	9013.22.521	Trial Humeral Head - Dia.52 H17mm	1
A25	9013.22.541	Trial Humeral Head - Dia.54 H18mm	1
A25	9013.24.401	Trial Humeral Head - Dia.40 H17mm	1
A25	9013.24.421	Trial Humeral Head - Dia.42 H17mm	1
A25	9013.24.441	Trial Humeral Head - Dia.44 H18mm	1
A25	9013.24.461	Trial Humeral Head - Dia.46 H19mm	1
A25	9013.24.481	Trial Humeral Head - Dia.48 H20mm	1
A25	9013.24.501	Trial Humeral Head - Dia.50 H21mm	1
A25	9013.24.521	Trial Humeral Head - Dia.52 H22mm	1
A25	9013.24.541	Trial Humeral Head - Dia.54 H23mm	1
	9013.25.990	Instrument Tray	1



PRIMA Stem Instrument set

9013.90.000 'CTA' Instrument Set for SMR Shoulder Prosthesis

Ref.	Code	Description	Qty.
A9	9013.30.100	Pliers for Trial Adaptor	1
B9	9013.23.420	Trial CTA Head Dia. 42 mm	1
B9	9013.23.460	Trial CTA Head Dia. 46 mm	1
B9	9013.23.500	Trial CTA Head Dia. 50 mm	1
B9	9013.23.540	Trial CTA Head Dia. 54 mm	1
C9	9013.23.600	Trial Adaptor Dia. 36 mm	1
	9013.90.950	Instrument Tray	1



PRIMA Stem Product codes

PRIMA STEM	
Ti6Al4V	
1357.14.028	#1
1357.14.030	#2
1357.14.032	#3
1357.14.034	#4
1357.14.036	#5

PRIMA HUMERAL HEAD ADAPTOR WITH SCREW	
Ti6Al4V	
1367.15.700	0mm neutral
1367.15.702	+2mm eccentrical
1367.15.704	+4mm eccentrical
1367.15.706	+6mm eccentrical

PRIMA REVERSE INSERTS 40mm

CoCrMo	
1367.09.200	SHORT 0°
1367.09.203	MEDIUM 0°
1367.09.206	LONG 0°
1367.09.270	SHORT 7°
1367.09.273	MEDIUM 7°
1367.09.276	LONG 7°
1367.09.403	MEDIUM 0° 3mm Offset
1367.09.406	LONG 0° 3mm Offset

PRIMA REVERSE INSERTS 44mm

CoCrMo	
1367.09.300	SHORT 0°
1367.09.303	MEDIUM 0°
1367.09.306	LONG 0°
1367.09.370	SHORT 7°
1367.09.373	MEDIUM 7°
1367.09.376	LONG 7°
1367.09.503	MEDIUM 0° 3mm Offset
1367.09.506	LONG 0° 3mm Offset

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