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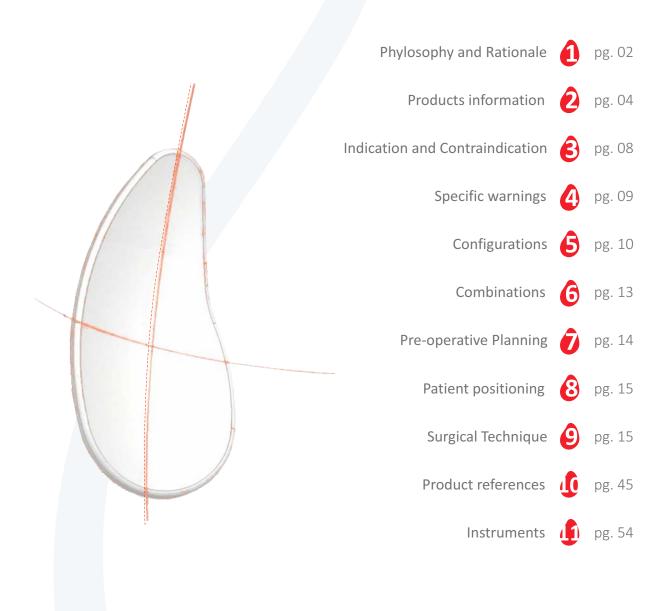
MODULAR SHOULDER SYSTEM



Surgical Technique



Index



This surgical technique is intended to be a guide to the orthopaedic surgeon for the implantation of MIRAI[®] Modular Shoulder System.

The procedure was written by a team of qualified orthopaedic surgeons, experienced in shoulder replacement, with the aim to provide the user with a complete information about the device, from it's development phylosophy to the implantation and recommended postoperative treatments.

Permedica Orthopaedics as manufacturer of orthopaedic devices is not responsible of the clinical practice. The indications, as well as the evaluation of the patient and his clinical situation are necessarily under each surgeon's responsibility.

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Shoulder arthroplasty is a reliable procedure for the treatment of severe gleno-humeral joint disorders to relieve pain and restore the functionality of the shoulder. The first shoulder arthroplasty was designed for the treatment of humeral fractures, therefore the presence of a humeral stem was necessary.

However, the complications related to the use of a stem are frequent, such as bone loss (especially in revisions), intra and post-operative periprosthetic fractures, malpositioning of the humeral component, periprosthetic infections difficult to eradicate and intraoperative blood loss due to the opening of the diaphysis.

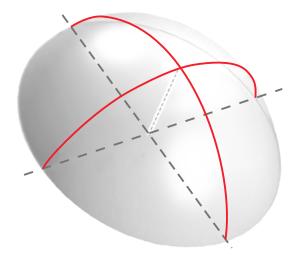
The goal of a stemless prosthesis is to restore the humeral head anatomy without the need of a diaphyseal stem, with a bone sparing and automatic centering system.

In cases of insufficient bone support in primary implantation, revision or conversion, a metaphyseal interface permiting the connection of the anatomically implanted humeral core to the humeral diaphysis allows to restore the anatomy with a correct CCD angle and offset thus supplying the necessary implant stability, joint functionnality and releive of pain.

The event of mobilization glenoid prosthetic component in total shoulder replacement is considered as the result of several concomitant factors, including an eccentric load caused by the failure of the rotator cuff or other soft tissue imbalance, local reactions to polyethylene wear particles, an inadequate cementing technique, a malpositioning of the implant or overstuffing of the gleno-humeral joint.

The survival of a glenoid implant with base-plate (metal back) can be increased from the first up to the latest implants generation, by improving the anchoring between the metal back and the bone thanks to the development of innovative materials (such as trabecular titanium) and through an anatomical reconstruction respecting the double curvature of the glenoid, with a radius of the anterior-posterior profile and a radius for the supero-inferior profile.





1 Phylosophy & Rationale

The current use of a spherical humeral head, with an incongruous profile respect to the profile of the glenoid surface, allows translation between head and glenoid however, it is a trade-off that reduces the contact area on the glenoid component that may result in component wear.

The use of a non-spherical head with a more conformable glenoid component may reduce the risk of wear by allowing the gleno-humeral translation movement and increasing its contact area.

A non-spherical prosthetic head, imitating the anatomy of the original humeral head, accurately replicates the shape of the head of the humerus, the rotational movement and kinematic of the gleno-humeral joint.

A non-spherical prosthetic head increases the stability of the original gleno-humeral joint.

The elliptical shape of the base of the prosthetic humeral head is accentuated by the increase of its size. As a consquence, by combining the reversal of the articulating materials (polyethylene head - metal insert) with the greater congruence between head and glenoid insert, joint stability is increased while polyethylene wear decreases. Since the metal components can be realized in thicknesses thinner than the polyethylene components, the risk of over-stuffing of the gleno-humeral joint in conventional total shoulder arthroplasty is considerably reduced by using a trabecular titanium metal-back glenoid component anchored to the bone and provided with a thin glenoid metal insert.

Whenever a conversion from anatomic to reverse total shoulder prosthesis should be necessary, the glenoid metal insert can be removed, leaving the osteointegrated metal-back in site and replaced with a polyethylene glenosphere fixed to the metal-back by means of a proper adapter.

Permedica MIRAI[®] Shoulder System has been conceived and developed by maintaining the concept of modularity on both glenoid and humeral sides, providing solutions for a broad spectrum of typical indications in shoulder arthroplasty surgery.

The prosthetic system allows anatomical or reverse shoulder arthroplasty using the same stemless humeral core cage that does not need to be replaced in case of surgical revision if it is stable and osteointegrated.



Permedica Shoulder System (MIRAI[®]) hereinafter called "System", is intended for the replacement of the scapular glenoid and humera head in primary or revision total shoulder arthroplasty, or the only humeral head in partial shoulder arthroplasty. The components are intended to be implanted by biological fixation (press-fit technique without use of bone cement) or by using bone cement (monoblock glenoid and cemented stems).

The mai target of MIRAI[®] System is to reproduce the shoulder joint anatomy by reducing the pain and restoring the joint function to the patient.

The System includes the following types of components:

Figure Ref.	Prosthetic Component	Description
A	Humeral stem	Humeral stem for the stemmed prosthetic configuration. It has the function to anchor the Humeral Core to the humeral diaphysis. Available in primary and revision version and for both cementless biological fixation (press-fit) and cemented fixation.
В	Metaphyseal Humeral Component	Component by which the Humeral Stem is fixed to the Humeral Core. Allows to switch from a stemless to a stemmed prosthetic configuration.
С	Humeral Core Cage	It represents the stemless humeral component that can be used both in anatomic and reverse configuration and allows intraoperatively switch from a stemless to a stemmed configuration. It consists of a titanium cage with a trabecular structure to be housed in the meta-epiphyseal region, consisting of 3 asymmetrically superimposed rings of decreasing diameter. Anchoring to the bone is achieved by cementless press-fit fixation.
D	Anatomic Humeral Head Adapter	Component used to assemble the Anatomic Humeral Head onto the Humeral Core.
E	Anatomic Humeral Head	Joint component used only for the anatomical configuration. For the total prosthesis is made of plastic material and has an elliptical convex surface for coupling with the glenoid insert. For the partial prosthesis or total prosthesis for coupling with the plastic glenoid component is made of metal and It has a spherical convex surface for direct coupling with the glenoid component.
F	Anatomical Glenoid Insert	Glenoid joint component used only in the anatomical prosthetic configuration. It has an asymmetric anatomical shape for the glenoid and a two-radii concave surface for coupling with the head. It is mounted over the glenoid base plate. It is coated with TiNbN.
G	Glenoid Base-Plate	Metal component with asymmetric anatomical shape which anchors to the glenoid bone. In the anatomical prosthesis configuration the component is assembled with the anatomical glenoid insert. In the reverse configuration, it is assembled with the glenosphere. 2 holes allow for infero-superior stabilization by inserting peg-screws or fixation screws. The bone contact surface has a titanium trabecular structure. Anchoring to the bone is achieved by cementless press-fit fixation.

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2	Product	information
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Figure Ref.	Prosthetic Component	Description
Н	Peg-screws for Glenoid Base-Plate	Stabilizing components to be assembled to the glenoid base-plate in order to provide rotational stability as an alternative to the infero-superior screws. The bone contact surface has a trabecular titanium structure.
I	Central Peg for Glenoid Base-Plate	Component to be connected to the Glenoid Base-plate for anchoring to the glenoid bone without cement. The bone contact surface has a trabecular titanium structure.
J	Glenoid Base-Plate Fixation Screw	Cortical screw to be used as alternative to the screw pins of the glenoid base-plate.
К	Glenoid Base-Plate Central Fixation Screw	Bicortical compression screw to be used as an alternative to the central peg of the glenoid base-plate. A JUMP flat head screw can also be used.
L	Humeral Insert for Reverse Prosthesis	Metal joint component used in the reverse prosthesis configuration. It has a spherical concave articulating surface that articulates with the glenosphere. An augment is also available permitting COR lateralization.
Μ	Glenosphere for Reverse Prosthesis	Polyethylene joint component used only for the reverse prosthesis configuration. It is also available in a "corrective" version.
Ν	Glenosphere Safety Screw	Screw for the fixation of the Glenosphere to the Glenoid Base-plate. It come in 2 sizes: Long and Short. Both versions must be used with the proper Glenosphere Adapter grub screw (supplied together with each Safety Screw).
0	Glenosphere Adapter	Component used to fit the Glenosphere onto the Glenoid Base-plate.
Ρ	Humeral Core Trauma	Element consisting of humeral core and metaphyseal humeral body united in a single monobloc component, available in versions for biological fixation (press-fit) and with bone cement. In the cementless version, the external surface of the humeral core has a trabecular structured band and the metaphyseal component has a sandblasted finish. In the cemented version the entire surface is polished.
Q	CTA Humeral Head	Articular component utilized only for partial prosthesis in massive rotator cuff tear. It is made of metal and characterized by a spherical convex surface with cranial extension for direct coupling with the glenoid compartment and the acromion.



2 Product Information

Materials & Technologies

MIRAI[®] Shoulder System is made using the most advanced manufacturing technologies and the most advanced materials available in prosthetic field.

TRASER®

The Selective Laser Melting additive manufacturing process (SLM) is an innovative advanced technology that offers the ability to make complex titanium trabecular structures with any desired geometry and porosity using titanium powder.

SLM has a high degree of dust melting precision and thus has the ability to create three-dimensional solid parts with high precision and high definition detail with a melting resolution of 0.01 mm.

Thanks to SLM technology Permedica developed the innovative **TRASER®** trabecular titanium structure.

Products realized with **TRASER**[®] technology open new technological opportunities in orthopaedics, joining unique implants design with its innovative trabecular structure.

BIOY[®]

The PVD (Physical Vapor Deposition) TiNbN coating improves the tribological behaviour in titanium/polyethylene coupling, protects the prosthetic metal substrate from corrosion thus reducing metal ions release and bacterial adhesion.

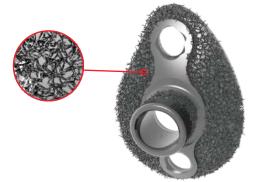
The **BIOLOY®** TiNbN coating by Permedica has a thickness of 3-6 μ m and > 2000HV hardness with high adhesion to the substrate.

BIOLOY® is an ideal coating in those patients with known or suspect metal hypersensibility.

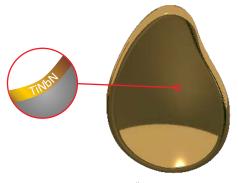
VITAL-E®

The MIRAI[®] Shoulder System utilizes the latest generation polyethylene: UHMWPE melted with 0.1% of Vitamin E (*VITAL-E®*) and Ethylene Oxide sterilized. Eliminating any irradiation process keeps the original mechanical properties of polyethylene unaltered, while the presence of Vitamin E prevents oxidative degradation of polyethylene by prolonging the life of the implant.

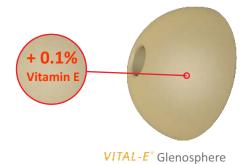




TRASER^{*}Glenoid Base-Plate



BIOLOY Glenoid Insert



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Indications & Contraindications

Indications for use

The System is intended for total or partial replacement, both anatomic and reverse, of the glenohumeral joint.

The use of the stemmed or stemless configuration depends on the bone quality (pre-existing surgery, pseudarthrosis, osteoporosis, bone defects, etc.) of the epi-metaphyseal part of the humerus.

The indications for use are:

- primary non-inflammatory degenerative joint diseases;
- secondary arthrosis due to post-traumatic degenerative factors or degenerative disorders of the rotator cuff;
- avascular necrosis of the humeral head;
- articular degeneration secondary to rheumatoid arthritis, psoriatic arthritis or similar diseases;
- acute fractures of the humeral head or glenoid;
- failures of previous arthroplasties or osteosynthesis of the gleno-humeral joint.

Absolute Contraindications

- Persistent chronic or acute infections and all septic conditions in the area surrounding the joint;
- septicaemia;
- persistent osteomyelitis local or systemic;
- allergy to the substances contained in the materials of the implanted components;
- acute or chronic neurological and/or muscular impairment which compromises the shoulder joint function such as an axillary nerve injury affecting the deltoid muscle.

Relative Contraindications

- Chronic or acute infections, local or systemic, even far from the implant site (risk of haematogenous spread of the infection to the implant site);
- inadequate bone structure, proximal or distal to the joint, which cannot guarantee stability to the prosthetic components;
- severe vascular, nerve or muscular disorders, which compromise related extremities;
- marked osteoporosis, osteomalacia;
- hypotrophy of the periarticular soft tissues;
- dysmetabolic diseases such as, for example, kidney failure or systemic diseases;
- obesity;
- nicotine addiction;
- intense physical activity (sports activity, heavy physical work);
- malpositioning of the prosthetic components;
- multiple joint disorders or disabilities that can lead to unnatural joint mobility;
- muscular insufficiency;
- refusal of the patient to understand or follow the doctor's instructions;
- history of infections and recurrent falls;
- pharmaceuticals, alcohol or drug abuse;
- HIV, tumors;
- severe deformities which could lead to insufficient anchoring or malpositioning of the implant.

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The following aspects are fundamental to the successful implant outcome:

- the glenoid bone, with or without bone graft, must provide the necessary support for the glenoid component's stability;
- the *Glenoid Base-Plate* must be mandatorily used with a modular *Central Peg* or the *Central Fixation Screw*;
- the *Central Peg* of the *Glenoid Base-plate* is available in various lengths for a better primary stability depending on the quality and quantity of the glenoid bone;
- we recommend using the *Central fixation Screw* of the *Glenoid Base-plate* for bi-cortical compression or if *Central Peg* should not provide adequate primary stability of the *Glenoid Base-plate*;
- it is recommended to use the *Fixation Screws* (lower and upper) in case of implantation of the system in the reverse configuration or even in the anatomical configuration in case of unsatisfactory rotational stability of the *Glenoid Base-plate*.

- The Anatomic Glenoid Insert must be mandatorily of the same size and side of the Glenoid Base-plate;
- the *Glenosphere* must be mandatorily connected to the *Glenoid Base-plate* by means of the pertinent *Glenosphere Adapter* and secured by means of the appropriate *Safety Screw*;
- it is compulsory to use the *Long Glenosphere Safety Screw* when using the *Central Peg* of the *Glenoid Base-plate*;
- it is compulsory to use the Short Glenoid Safety Screw together with its grub screw when using a Central Fixation Screw;
- the size (diameter) of the *Humeral Insert* must be the same size (diameter) of the *Glenosphere*;
- the Anatomic Humeral Head can be coupled only with the Anatomical Humeral Head Adapters;
- it is compulsory to use the *Metal Humeral Head* together with the *Monobloc Glenoid* in case of a total arthroplasty.

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The System allows for stemmed or stemless anatomic and reverse configuration, for both primary and revision procedures.

The peculiarity of the System is its modularity that allows switching from one configuration to the other by adding and / or replacing the components thanks to their modularity.

The System can be used in the following typical configurations:

ID	PROSTHETIC COMPONENT		ANATOMIC DTHESIS		ANATOMIC HESIS	TOTAL REVERSE PROSTHESIS	
		STEMLESS	STEMMED	STEMLESS	STEMMED	STEMLESS	STEMMED
А	Humeral Stem				•		
В	Metaphyseal Humeral Component						
С	Humeral Core Cage		•		•		
D	Humeral Head Adapter	•	•	٠	۲		
Е	Elliptical Anatomic Humeral Head						
E	Spherical Metal Humeral Head		۲				
F	Anatomic Glenoid Insert						
G	Glenoid Base-plate		•				
Н	Central Peg for Glenoid Base-Plate		٠				
I	Glenoid Base-plate Fixation Screw		٠				
J	Glenoid Base-plate Central Fixation Screw						
К	Humeral Insert for Reverse Prosthesis						
L	Glenosphere						
Μ	Glenosphere Safety Screw						
Ν	Glenosphere Adapter						
0	Trauma Humeral Core				•		
Р	CTA Humeral Head				•		

Mandatory

At Surgeon's discretion

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The **partial anatomic version** (replacement of the humeral part only) is specifically indicated in the event of:

- necrosis or fracture of the humeral head;
- massive rotator cuff tear (CTA head);
- Insufficient bone quantity and quality or inadequate glenoid anchorage.

The **total anatomic version** (replacement of the humeral and glenoid parts) is specifically indicated in the event of:

- primary arthrosis of the glenohumeral joint with an intact, functional rotator cuff;
- necrosis of the humeral head or glenoid;
- aseptic arthritis (rheumatoid and psoriatic arthritis) with an intact rotator cuff.

The **total reverse version** is specifically indicated in the event of:

- arthrosis of the glenohumeral joint on a large rotator cuff tear (cuff arthropathy, disabling shoulder);
- irreparable massive rotator cuff tear;
- outcomes of serious fractures to the proximal portion of the humerus that cannot be reconstructed with a total anatomic prosthesis;
- revision of total or partial shoulder arthroplasty.

The decision to use a stemless or stemmed (anatomic or reverse) version depends on the epiphysealmetaphyseal bone quality as well as the morphology of the humeral diaphysis and the eventual presence of any osteosynthesis device.

Adequate bone quantity and quality is required in any stemless humeral implantation procedure in order to achieve good osseointegration. Whenever osteoporotic bone and/or general metabolic diseases should affect the quality of the bone or in case of acute fractures of the humeral head or metaphysis, it is advisable to use the stemmed version.

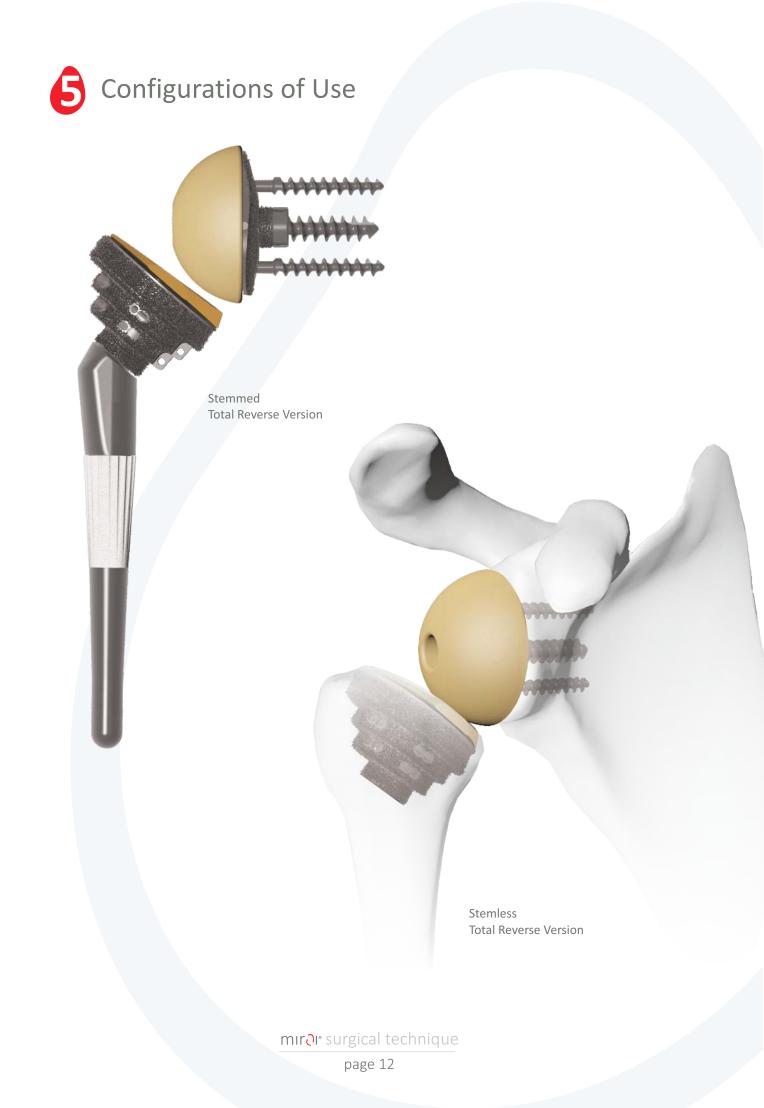
Glenoid bone grafting

With the preoperative planning, the version and the eventual medialization of the glenoid to be reconstructed are assessed.

The correct bone graft must be positioned between the Glenoid Base-plate and the bone.

Stability is ensured either by a modular Central Peg, which is available in various lengths, or by a central bicortical Fixation Screw in compression, more than the 2 inferosuperior Fixation Screws.

Stemmed Total Anatomic Version Stemless Total Anatomic Version





Glenoid Base-Plate	Anator	nic Hum	eral Head	Glenosphere			
Size	Recommended Size	Permitted Size	NOT permitted Size (*)	Recommended Size	Permitted Size	NOT permitted Size (*)	
XS	36-40	42-46	48-56	40 40 CORR.	36 36 CORR.	44, 44 CORR. 48, 48 CORR.	
S	38-42	36 44- 48	50- 56	40 CORR.	36 40	36 CORR. 44, 44 CORR. 48, 48 CORR.	
Μ	40-46	38 48- 52	36 54- 56	44 CORR.	40 44	36, 36 CORR. 40 CORR. 48, 48 CORR.	
L	46-50	42, 44 52- 56	36- 40	44 48 CORR.	48	36, 36 CORR. 40, 40 CORR. 44 CORR.	
XL	50-56	46, 48	36-44	48 48 CORR.	44	36, 36 CORR. 40, 40 CORR. 44 CORR.	

Glenoid Base-plate	Glenosphere Adapter
Size	Size
XS	XS
S	S
Μ	M-L-XL
L	M-L-XL
XL	M-L-XL

Size compatibility table of the *Glenoid Base-plate* with the *GlenosphereAdapter*.

Size compatibility table of the *articular components* with the *Glenoid Base-plate*. * The use of NOT permitted sizes may potentially lead to lower clinical outcomes.

Humoral

Humeral Core Cage	Humeral Head Adapter	Anatomic Humeral Head			Humeral Insert Reverse configuration (**)		
Size	Offset	Recommended Size	Permitted Size	NOT permitted Size (*)	Recommended Size	Permitted Size	NOT permitted Size (*)
	+ 0 mm	36-56		• • •			
XS	+ 2 mm	42-56	40	36, 38	40	36	44, 48
	+ 4 mm	48-56	46	36-44			
	+ 0 mm	38-56	36		40	36, 44	48
S	+ 2 mm	44-56	42	36-40			
	+ 4 mm	50-56	48	36-46			
	+ 0 mm	40-56	38	36	44	40	36, 48
Μ	+ 2 mm	46-56	44	36-42			
	+ 4 mm	52-56	50	36-48			
	+ 0 mm	42-56	40	36, 38		48	
L	+ 2 mm	48-56	46	36-44	44		36, 40
	+ 4 mm	54-56	52	36-50			
	+ 0 mm	44-56	42	36-40			
XL	+ 2 mm	50-56	48	36-46	6 48 44	44	36, 40
	+ 4 mm	56	54	36-52			

Size compatibility table of the *articular components* with the *stemless Humeral Core*.

*The use of NOT recommended sizes may potentially lead to lower clinical outcomes

** IMPORTANT: in this cases the possibility of their use with the appropriate spacer should be considered.

Humeral Core Cage	Humeral Head Adapter	CTA Humeral Head		Trauma Humeral Core	Humeral Head Adapter	CTA Hur	neral Head
Size	Offset	Permitted Size	NOT permitted Size (*)	Size	Offset	Permitted Size	NOT permitted Size (*)
XS - S	+ 0 mm	40, 44, 48, 52		S - 140°	+ 0 mm	40, 44, 48, 52	
М	+ 0 mm	44, 48, 52	40	S - 150°	+ 0 mm	40, 44, 48, 52	
L	+ 0 mm	48, 52	40, 44	M - 140°	+ 0 mm	44, 48, 52	40
XL	+ 0 mm	48, 52	40, 44	M - 150°	+ 0 mm	44, 48, 52	40

Size compatibility table of the *articular components* with the *Humeral Components*

*The use of NOT recommended sizes may potentially lead to lower clinical outcomes.

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Preoperative Planning

Inadequate preoperative planning can result in a wrong components selection and/or their incorrect positioning and/or a incorrect configuration of the prosthetic system. The procedure must be accurately planned basing on the radiographic report. Before the intervention, it is also necessary to investigate about any possible allergic reaction to the materials in the implantable devices.

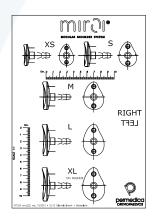
Preoperative planning using conventional or digital X-Rays templates provides essential information about the type of components to use and the correct components' combination according to the anatomy and specific conditions of each patient.

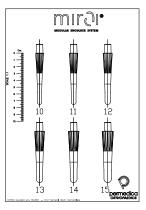
A preoperative MRI or CT scan is essential for the choice of the correct System configuration.

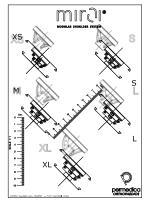
The operation must be performed by having all types and sizes of the necessary prosthetic components, in the combinations permitted by Permedica, using all the instruments necessary for the execution of the implant. For most prosthetic components, trial components and/or masks are provided, which must be carefully used for the advanced definition of the size to be implanted. It is particularly advisable use of the trial components for the glenoid, humeral core and the metaphyseal humeral component, when using stemmed prostheses, in order to check the correct preparation of the implant site as well as the correct size and positioning of the components.

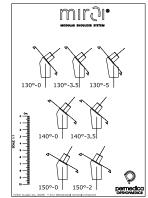
The correct choice of each prosthetic component, their configuration, correct positioning and implantation is extremely important. The incorrect choice of type, configuration, positioning, alignment, anchorage of the prosthetic components can result in abnormal shear forces and pressures that may adversely affect the performance and survival of the implant.

In the event of significant bone defects in the humeral and/or glenoid side, use of a guided PSI system based on CT scans should be considered.











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8 Positioning of the Patient

In Total Shoulder Arthroplasty procedures patients are commonly placed in "Beach Chair" position. This positioning keeps the shoulder in an elevated anatomical position, facilitating access and visualization of the glenohumeral joint.

This position also provides improved access to the respiratory tract, reduces bleeding and reduces the risk of damage to the brachial plexus.

In contrast to these advantages, there are several significant neurological complications including the risk of severe neurocognitive complications caused by cerebral ischemia.

To reduce the risks of these complications, in the "Beach Chair" position it is not recommended a backrest inclination of more than 30°.

The arm should be unrestricted, level with the table and/or held in a brace.

The first assistant should be positioned behind the patient's back, while the second assistant should be positioned beside the patient, opposite the side being operated on. The patient's head should be held in a central position by a head brace to prevent damage to the neck during the surgical procedure.

9 Surgical Technique

The surgical procedure for the MIRAI® Modular Shoulder System is a philosophy and a combination of articulating materials that complement one another: the metal portion for the cancave side and the polyethyene portion for the convex side of the prosthetic joint.

The humeral head is anatomically resected according to the patient's anatomy for the *Humeral Core* implantation. The *Glenoid Base-plate*, which is used in both anatomic and reverse configuration, is an anatomic component and must be implanted according to the anatomic shape of the patient's glenoid. When using the System in the anatomic configuration, a metal *Glenoid Insert* is applied on top of the *Glenoid Baseplate* and a polyethylene *Anatomic Humeral Head* with an elliptic base is applied to the *Humeral Core Cage*.

When using the System in the reverse configuration, a polyethylene *Glenosphere* is implanted on top of the *Glenoid Base-plate* and a metal *Humeral Insert* is applied on top of the *Humeral Core Cage*.



1. SURGICAL ACCESS TO THE GLENO-HUMERAL JOINT

The deltopectoral approach is commonly used for shoulder arthroplasty procedures.

The patient is placed in beach chair position (backrest inclination of 30°, arm of the involved shoulder free to bend, rotate inwards and outwards and turn back). Disinfection and sterile covering of the area, deltopectoral incision.

The deltopectoral incision begins 1 cm lateral to the *coracoid process* and ends at the insertion of the *pectoralis major* on the humeral axis.

Following the incision of the subcutaneous layer, the deltopectoral fascia is inspected and an incision made in it. The *cephalic vein* indicates the interval between the *deltoid muscle* and the *pectoralis major*. The *cephalic vein* together with the *collateral veins* passing through the *deltoid muscle* are shifted laterally.

Any subdeltoid adhesions are released and a "Roux" retractor is positioned beneath the *deltoid muscle*, laterally. The *coracobrachialis muscle* is visualized and retracted using a blunt Hohmann retractor. In the event of adhesive capsulitis or for revision procedures, it is sometimes advisable to perform an incision in the *tendon* of the *pectoralis major* 5-8 mm away from the site of the humeral insertion.

By carefully externally rotating (eventual caudal osteophytes of the *humeral head* blocking the joint may lead to a spiral fracture of the *humeral shaft*!) visualization of the *tendon* and the *subscapularis muscle*, the *rotator interval* between the *subscapularis* and the *supraspinatus* as well as the *circumflex vessels* showing the distal part of the *subscapularis tendon*.

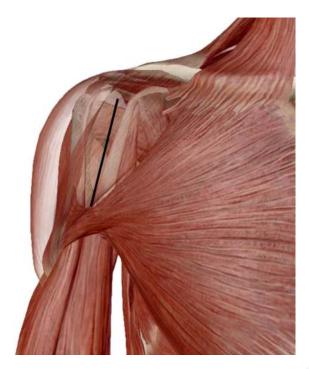
As a first step, exposure and ligature of these veins and arteries.

In case of a total anatomic or reverse prosthesis, incision of the subscapularis tendon at 10mm from its humeral insertion, exposure of the anterior capsule.

Osteotomy of the *tuberosity* is not recommended in stemless procedures to prevent weakening of the cortical bone that will host the *Humeral Core*. Use of a minimally invasive approach that preserves the *subscapularis tendon* insertion may reduce the risk of postoperative failure of the *tendon*.

A blunt Hohmann retractor is inserted between the subscapularis tendon and the capsule, resting on the lower portion of the glenoid bone. In this way the anterior capsule is totally exposed and can be incised while the axillary nerve is protected caudally by the Hohmann retractor.

Anterior, inferior and posterior capsulotomy is performed. Following incision of the capsule, the axillary nerve is briefly exposed. The blunt Hohmann is inserted intraarticularly, the humerus is rotated externally and the humeral head exposed. As a first step, removal of any osteophyte around the humeral head.



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9.2 Humeral head resection

For the humeral head resection, in both anatomic or reverse configuration, the *Humeral Resection Guide* is used. This guide comprises a *Template* (Figure 1-A) and a *Cutting Block S70021* (Figure 1-B).

The *Template* is available in 3 angles:

S70030 Template 130°

S70031 Template 140°

S70032 Template 150°

The *Humeral Resection Guide* is rested on the humerus, which is rotated externally, with the forearm bent at a 90° angle to the humerus.

The *Template* (A) should be positioned so that it is in contact with the humeral bone and aligned with the diaphysis.

The *Cutting Block* (**B**) should be rested on the metaphysis of the humerus, with the resection plane aligned with the resection plane of the humeral head.

The letter "R" or "L" should be visible, depending on whether the Left or Right side is being operated on.

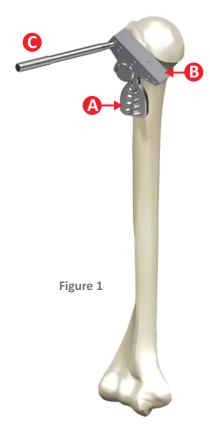
The *Cutting Block* (**B**) can be grasped more easily using a *Handle S70020*, screwed into the appropriate hole (**Figure 1-C**).

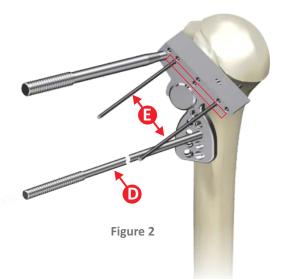
The CCD angle of the humeral resection is given by the *Template* selected (130° - 140° - 150°).

The 9 holes in the *Template* (**A**), into which a *Retroversion Rod S70022* (**Figure 2 - D**) can be inserted, indicates the degree of retroversion ($0^{\circ} - 10^{\circ} - 20^{\circ} - 30^{\circ} - 40^{\circ}$) of the humeral head resection plane: the proximal hole corresponds to a neutral position 0° , the 4 holes marked "R" and "L" indicates a retroversion of $10^{\circ} - 20^{\circ} - 30^{\circ} - 40^{\circ}$ for each side.

In order to assess the retroversion of the humeral resection plane, the *Retroversion Rod* (**D**) must be positioned parallel to the forearm. In this way, the *Cutting block* will be placed parallel to the humeral head plane, with the same retroversion angle as the humeral head.

The 3 holes placed more distally on the *Cutting Block* are used to insert two or 3 K (Kirschner) wires to stabilize the *Cutting block* (Figure 2 - E).





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9.2 Humeral head resection

The humeral head resection is then checked with the *Feeler Gauge S70026-8* (**Figure 3 - A**), which is available in 3 sizes (S, M, L) prior to carrying out the osteotomy.

The *Feeler Gauge* is placed on top of the *Cutting Block* using the *Feeler Gauge Support S70025*, which features a magnetic attachment (**Figure 3**).

The *Feeler Gauge Support* can move freely on the *Cutting Block* and the *Feeler Gauge* can be used in different positions (**Figure 4**).



IMPORTANT! A humeral resection with a CCD angle of 140° is recommended in stemmed reverse total shoulder prosthesis procedures.

The *Cutting Block* offers further 5 additional holes, 2 mm more proximal, allowing a repositioning of the *Cutting Block* using the preplaced K wires, if a resection of the humeral head need to be 2 mm more distal (**Figure 6**).

The humeral resection is now covered by the *Humeral Protection S70035-37*, which comes in 3 sizes (40 mm, 46 mm and 52 mm) and is placed by means of the *Clamp S70038*.

This disc protects the humeral metaphysis from fractures and damages while working on the glenoid (**Figure 7**).

The humerus is then moved behind the glenoid; a Hohmann retractor is inserted in the dorsal portion of the glenoid.

Figure 5

Figure 6



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Full view exposure of the glenoid and capsulectomy at 270°. Removal of the glenoid labrum and any osteophytes (Figure 8).

The eventual glenoid deformity is confirmed during the preoperative phase using an assessed CT scan.

The preparation of the Glenoid then starts using the *Glenoid Pin Guide*.

The Glenoid Pin Guide (Figure 9 - A) is identical in shape and size to the final Glenoid Base-plate and and Glenoid Insert. It comes in 5 sizes (XS, S, M, L and XL) per side (ref. S70321-35) and fits on the Small Silicone Handle S70205 with quick coupling (Figure 9 - B).

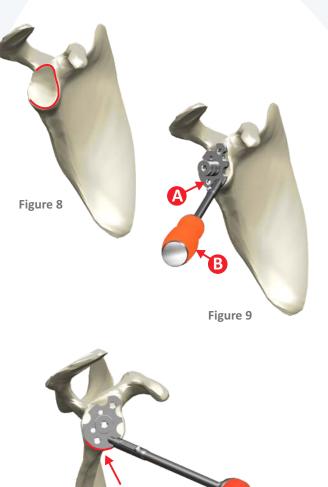
The *Glenoid Pin Guide* is positioned, taking care to align the lower edge of the template with the lower bone margin of the glenoid to ensure that the central *Guide Pin* is positioned low enough, in relation to the portion of the scapula with the greatest bone stock (**Figures 9, 10**).

The correct size of *Glenoid Pin Guide* (and consequently of the *Base-plate*) should allow to align the lower edge of the template with the lower bone margin of the glenoid (**Figure 10**).

If the template is positioned too centrally in relation to the longitudinal axis of the Glenoid, the *Guide Pin* will be inserted too high and will result in the incorrect placement of the *Glenoid Base-plate*, too high and not in an anatomic position (**Figure 11**).

This will cause housing of the *Central Peg* (or *Central Screw*) in a portion of the scapula with poor bone stock (particularly if large size of *Central Peg* or a long *Central Screw* is used).

An Antirotation Pin S70538 is eventually available to stabilize the Glenoid Pin Guide.



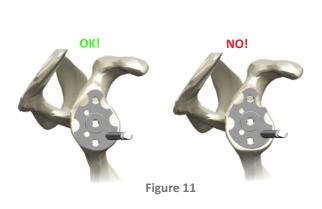


Figure 10

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The *Glenoid Pin Guide* is fitted with a modular cannulated *Sleeve*, which comes with a 0° hole *S70536* (Figure 12 - A) or with a 10° sloped hole *S70537* (Figure 12 - B).

Depending on whether any glenoid grafts are made, a *Glenoid Deformity Wedge* can be assembled dorsally to the *Glenoid Pin Guide* (Figure 12 - C). This Wedge is available with 3 correction angles (10°, 20°, 30°) per side and in 2 sizes (XS-S e M-L-XL).

The central *Guide Pin* (K-wire) \emptyset 3 mm of a suitable length (75, 100 or 150mm) is inserted through the *Glenoid Pin Guide* sleeve (**Figure 13**).

The Glenoid Pin Guide is then removed (Figure 14).

The *Glenoid Reamer* of the same size of the *Glenoid Pin Guide* coupled onto the *Reamers Handle** is inserted over the *Guide Pin* (Figures 15, 16).

The *Glenoid Reamer* comes in 5 sizes (XS, S, M, L and XL) and determines the antero-posterior radius of the *Glenoid Base-plate*.

By means of the *Glenoid Reamer* remove the glenoid cartilage, taking care to leave the subchondral bone intact (Figure 17).

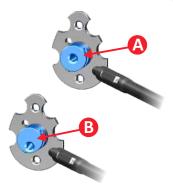




Figure 12

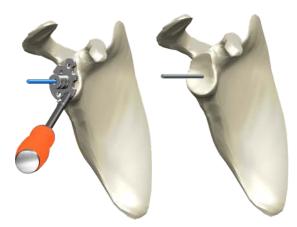
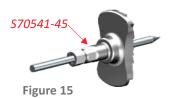


Figure 13

Figure 14





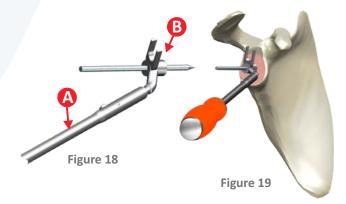
* The *Reamers Handle* is available with Hudson connection (*S70539*) or AO-Synthes connection (*S70540*).

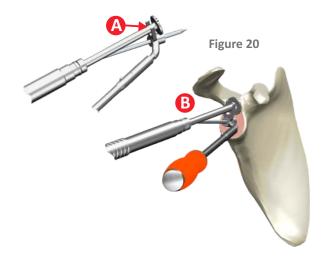
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The *Peripheral Glenoid Reamer Guide* is used for milling the upper portion of the Glenoid, connected to the *Small Silicone Handle S70205* (Figure 18 - A).

It comes in 5 sizes (XS, S, M, L, XL) with differing spaces between the hole for the *Guide Pin* and the fork (**Figure 18-B**).

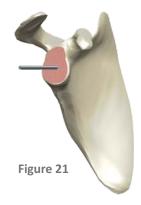
After reaming the glenoid centrally, the *Peripheral Glenoid Reamer Guide* is inserted above the central *Guide Pin* (Figure 19).





The *Peripheral Glenoid Reamer S70357* is inserted above the fork of the *Peripheral Glenoid Reamer Guide* (Figure 20 - A) and the upper portion of the glenoid is reamed, completing the infero-superior profile of the *Glenoid Base-plate* (Figure 20 - B).

The *Peripheral Glenoid Reamer* is available in one size with hexagonal quick coupling connection.



The cartilage of the glenoid is removed taking care to leave the subchondral bone intact (**Figure 21**).

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At this point for both anatomic and reverse configuration the following stabilization options can be chosen:

1. Central PEG option:

the *Glenoid Base-plate* is combined with the *Central Peg* (**Figure 22**). The length of the *Central Peg* is assessed during the preoperative planning.

This case is indicated for primary implantation procedures in either anatomic or reverse configurations with good bone quality that should ensure a good press-fit fixation of the *Central Peg*.

2. Central Fixation Screw option :

The *Glenoid Base-plate* combined with the *Central Locking Screw*, a bicortical compression screw (Figure 23).

This option is preferable:

- in case of poor bone quality that does not guarantee an adequate press-fit of the *Central Peg*;
- when a glenoid bone graft is necessary;
- in revision procedures in case of *Glenoid Base-plate* loosening.

In the **option 1** with *Central Peg*, the hole for the modular *Central Peg* is drilled to the length specified during the preoperative planning stage.

The *Glenoid Central Peg Reamer* is available in 3 lengths (**Figure 24**) to be inserted on the *Reamers Handle S70539-40* connected to the drill.

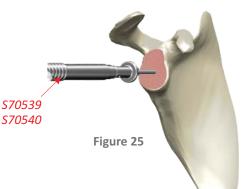
The depth of the reaming, corresponding to the length of the selected *Central Peg*, is established by the length of the *Glenoid Central Peg Reamer*.

The (cannulated) reamer is then inserted over the *Guide Pin* (Figure 25).









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The hole is reamed until the stopper of the *Glenoid Reamer* reaches the bone (**Figure 26, 27**).





In the **option 2 with** *Central Fixation Screw*, the hole is reamed only for the cylindrical portion of the *Glenoid base-plate*.

The *Glenoid Central Screw Reamer S70605* (Figure 28) is inserted on the *Reamers Handle S70539-40* connected to the drill.

The (cannulated) *Reamer* is then inserted over the \emptyset 3 *mm Guide Pin* and the hole is reamed untill the stopper of the *Glenoid Reamer* reaches the bone (**Figure 26, 27**).

The *Glenoid Pin Guide* (in the same size previously used and positioned in the same place) is then used to prepare the cranial and caudal holes in the glenoid bone (**Figure 29**) by means of *Twist Drills* mounted on the *Drill Bit Shaft*, *Rigid* (*S30008*) or *Flexible*(*S30014*).

The *Twist Drill* \emptyset 2.5 mm S70628 is used to drill the holes for the two *Peg-screws* of the *Glenoid Base-plate* (usually used for the anatomic prosthesis) by drilling about 5mm or for the infero-superior *Fixation Screws* \emptyset 4,5mm (advised for total reverse prosthesis).

The *Twist Drill* \emptyset 1,7 mm S70629 is used to drill the holes for the infero-superior *Fixation Screws* \emptyset 3,5mm.

A *Drill Guide Sleeve* S70374 is available to better drive the *Twist Drills.*

The \emptyset 3 mm Guide Pin is then removed from the glenoid (Figure 30).



Figure 28

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9.4.1 Anatomic configuration

The definitive *Glenoid Base-plate* is selected accordingly to the size of the Glenoid Pin Guide used. The Base-plate can be eventually equipped with 2 infero-superior Pegscrews supplied separately, by screwing them (Figure 31) into the provided holes using the Hexagonal Screwdriver Shaft Ø 2.5 mm S70297 assembled with the Universal silicone handle S70206.

Option with Central Peg:

If the Central Pea is used:

The Central Peg is selected according to the desired length and assembled with the Glenoid Base-plate (Figure 31) on the scrub nurse's table or back-table by means of the Assembly Press S70250.

Place onto the inferior side of the Assembly Press the Support for Base-plate/Peg assembly S70101 with the Glenoid Base-plate over, and connected to the Central Peg. Place on the superior side of the Assembly Press the Adapter for Base-plate/Peg assembly S70107 (Figure 32).

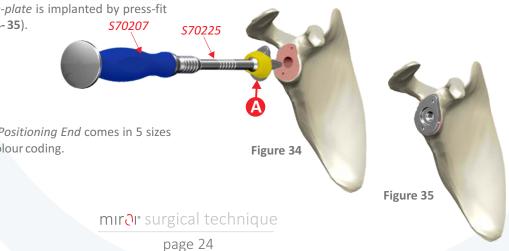
Secure the connection between the *Central Peg* and the *Glenoid Base-plate* by means of the the *Torque Wrench* for Press S70195 and the Hexagonal Screwdriver Shaft 5,0mm S70299 inserted onto the Universal silicone Handle S70206 (Figure 33).

WARNING: the Torque Wrench for Press S70195 needs to be checked periodically by the manufacturer to test the achievement of the expected torque. Before proceeding with its use, it is therefore necessary to CHECK THE EXPIRATION DATE marked on the device itself and, if necessary, return the instrument to the manufacturer for the necessary checks.

With the Glenoid Base-plate Positioning End (A) of corresponding size inserted onto the Universal Impactor Handle S70225 fitted onto the Silicone impacting handle S70207 the Glenoid Base-plate is implanted by press-fit on the glenoid (Figures 34-35). S70207

The Glenoid Base-plate Positioning End comes in 5 sizes per side identified by a colour coding.





If the *Glenoid Base-plate* is not sufficiently stable, it is possible to:

• Change the size of the Central Peg:

Remove the *Glenoid Base-plate* (refer to chapter **9.9.3**, page 48).

Disassemble the *Central Peg* from the *Glenoid Baseplate* by the *Assembly Press* using the specific press instruments:

place onto the inferior side of the Assembly Press the Support for Peg disassembly S70105 with the Glenoid Base-plate placed over with the Central Peg into the central hole of the Support. Place on the superior side of the Assembly Press the Adapter for disassembly S70109 (Figure 36).

Disassemble with the press the *Central Peg* from the *Glenoid Base-plate* by pushing the metal pin of the *Adapter for disassembly* into the central hole of the *Glenoid Base-plate* (Figure 37).

Then assemble the new *Central Peg* to the *Glenoid Base-plate* repeating the procedure previously described (page 24, **Figures 31-33**).

Reposition the *Guide Pin* to reuse the *Glenoid Central Peg Reamer* of the desired length, and ream the central peg hole to the new size. Then remove the *Guide Pin* again.

Implant the *Glenoid Base-plate* with the longer *Central Peg*.

Use the infero-superior Locking Screws:

Whenever not yet done, with the *Twist Drill* mounted on the *Drill Bit Shaft* (*Rigid S30008* or *Flexible S30014*) prepare the holes for the infero-superior locking screws (**Figure 38**).

Use the Twist Drill \emptyset 2.5 mm S70628 for the Fixation Screws \emptyset 4,5mm (advised for total reverse prosthesis) or the Twist Drill \emptyset 1,7 mm S70629 for the Fixation Screws \emptyset 3,5mm (only for Base-plates size XS and S).

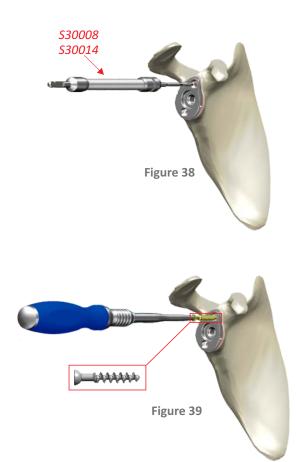
Use the *Drill Guide Sleeve S70374* to better drive the *Twist Drills*.

Proceed then with *Screws* insertion (**Figure 39**). The *Screws* have round heads and can be angled through about 15°.



Figure 36

Figure 37



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Use the Central Locking Screw option as described below:

If the *Central Locking Screw* is used with a bicortical compression:

Drill the hole for the Central Locking Screw (Figure 40) using the Drill Guide Sleeve S70574 with Twist Drill \emptyset 3.5x70 mm S30016 mounted on the Drill Bit Shaft (Rigid S30008 or Flexible S30014).

The length of the *Central Locking Screw* (and therefore the hole) is established during the preoperative planning and confirmed during surgery by measuring the length of the hole with the *Depth Gauge S70570* (Figure 41).

The *Glenoid Base-plate* is implanted by press-fit insertion in the glenoid, as previously described (page 24, **Figures 34, 35**).

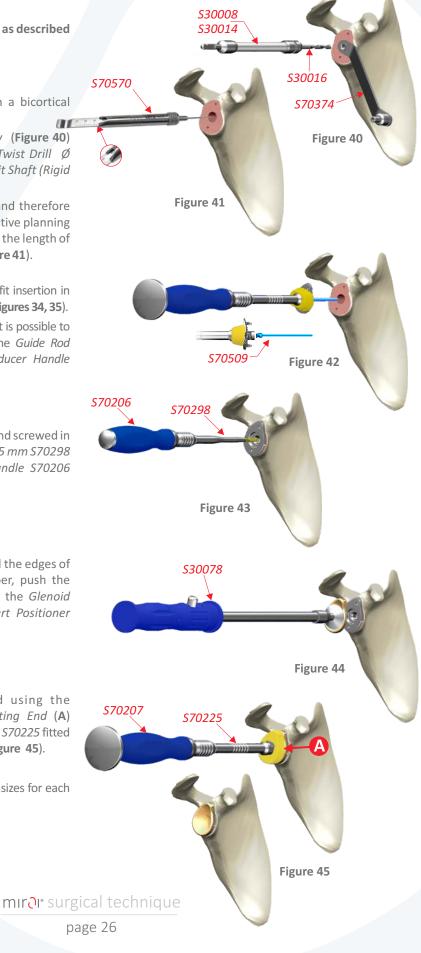
In this case, since the *Central Peg* is not used, it is possible to better drive the insertion with the aid of the *Guide Rod S70509* screwed onto the *Universal Introducer Handle S70225* (Figure 42).

The Central Locking Screw is then inserted and screwed in using the Hexagonal Screwdriver Shaft \emptyset 3.5 mm S70298 assembled with the Universal silicone handle S70206 (Figure 43).

After having carefully cleaned the inner and the edges of the *Glenoid Base-plate* female morse taper, push the *Glenoid Insert* of corresponding size onto the *Glenoid Base-plate* by means of the *Suction Insert Positioner S30078* (Figure 44).

The *Glenoid Insert* is then impacted using the corresponding size *Glenoid Insert Impacting End* (A) mounted onto the *Universal Impactor Handle S70225* fitted onto the *Silicone impacting handle S70207* (Figure 45).

The *Glenoid Insert Impacting End* comes in 4 sizes for each side, identified by colour coding.



9.4.2 Reverse configuration with ALL POLY Glenosphere

The preliminary steps for the glenoid preparation and *Glenoid Base-plate* with *Central Peg* implantation are the same for both reverse and anatomic configurations.

\$70207 \$70641 Figure 46 Figure 47 S70206 s702[']98 Figure 48

Figure 49

• If the *Glenoid Base-plate* is implanted with the *Central Peg*:

once the *Glenoid Base-plate* has been implanted, and the infero-superior *Locking Screws* have been screwed in and tightened, as in the anatomic configuration procedure, the "*All-Poly*" *Glenosphere Adapter* is assembled on top of the *Glenoid Baseplate* using the "*All-Poly*" *Glenosphere Adapter Positioning Rod S70641* fitted onto the *Silicone impacting handle S70207* (Figure 46, 47).

The normal or corrective "All-Poly" Trial Glenosphere (A) with 40, 44 and 48 mm size is screwed onto the "All-Poly" Glenosphere Adapter using the Hexagonal Screwdriver Shaft \emptyset 3.5 mm S70298 assembled with the Universal silicone handle S70206 (Figure 48).

Whenever a *Corrective Trial Glenosphere* is selecteded, it is possible to rotate the component in the desired position by inserting a PIN into one of the holes available before tightnening the screw (**Figure 49**).

The humerus is then prepared as described in the next section (**9.5.** page 31).

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After the preparation of the humerus is completed and the functional evaluations are carried out, the definitive *Glenosphere* can be implanted.

Proceed with the assembly of the *Glenosphere* by means of the "*All-Poly*" *Glenosphere Positioning device* which is composed of the following parts (**Figure 50**):

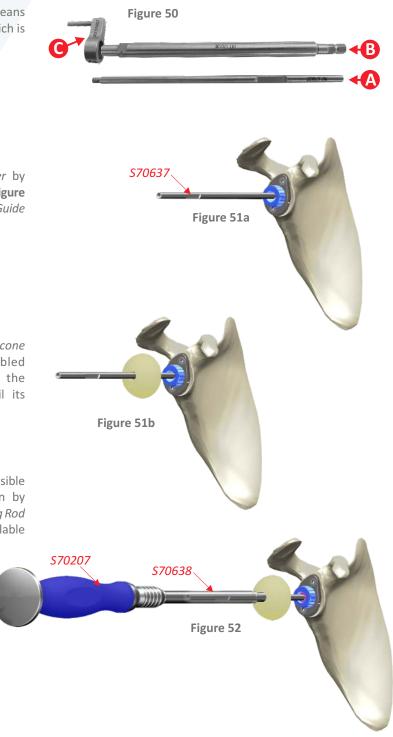
A	S70637	Guide Rod
B	<i>S70638</i>	Impacting Rod
Õ	<i>S70639</i>	Orienting End

Insert the *Guide Rod S70637* through the *Adapter* by screwing its threaded end into the hole of the PEG (**Figure 51a**) then insert the *Glenosphere* by sliding it on the *Guide Rod* until it engages against the *Adapter* (**Figure 51b**).

Now connect the *Impacting Rod S70638* to the *Silicone impacting handle S70207*, insert the assembled instrument over the *Guide Rod* and impact the *Glenosphere* onto the *Adapter* (Figure 52) until its complete seating.

In the case a *Corrective Glenosphere* is used, it is possible to rotate the component in the desired position by inserting the *Orienting End* on the tip of the *Impacting Rod* and engaging the tooth into one of the holes available (**Figure 53**) before proceeding with impaction.





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S70206

The Long Safety Screw is then screwed to secure the Glenosphere to the Glenoid Base-plate using the Torque wrench for Screw S70296 assembled with the Universal silicone handle S70206 (Figure 54a-b).

WARNING:

the *Torque Wrench for Screws S70296* needs to be checked periodically by the manufacturer to test the achievement of the expected torque. Before proceeding with its use, it is therefore necessary to <u>CHECK THE EXPIRATION DATE</u> marked on the device itself and, if necessary, return the instrument to the manufacturer for the necessary checks.

The Long Safety Screw is screwed into the modular Central PEG, thus tightening by compression both the Glenosphere and the Glenosphere Aadapter against the Glenoid Base-plate (Figure 55a-b: components assembling sequence).

WARNING:

the *Adapter grub screw,* whenever eventually present in the package of the *Long Safety Screw,* has no function and must not be used.

If the Glenoid Base-plate is to be implanted with the Central Locking Screw:

Ream the hole only for the cylindrical portion of the *Glenoid base-plate* as previously described (page 23, **Figures 26-28**).

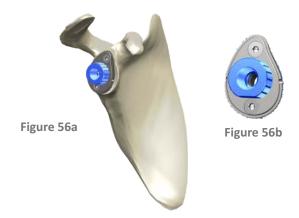
Drill the hole for the *Central Locking Screw* as described on page 26 (**Figures 40,41**) taking care of adding +5 mm to the measure which corresponds to the *Glenosphere Adapter* length.

The *Glenoid Base-plate* is implanted using the same procedure as for the anatomic configuration (page 24 **Figures 34,35**).

The "All-Poly" Glenosphere Adapter is assembled over the Glenoid Base-plate as previously described (page 27, Figures 46,47).

ATTENTION: the "All-Poly" Glenosphere Adapter size XS and S have a chamfer that must be positioned in correspondence of the inferior hole of the *Baseplate* to allow removal of the *Peg-screw* and the insertion of the *Locking Screw* (Figure 56a-b).





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The Central Locking Screw is then inserted through the Glenosphere Adapter and screwed in the scapular bone using the Hexagonal Screwdriver Shaft \emptyset 3.5 mm S70298 assembled with the Universal silicone handle S70206 (Figure 57).

The infero-superior *Peg-screws* are removed and replaced with 2 *Fixation Screws* as previously described (page 25, **Figure 38-39**).

Only once the *Central Fixation Screw* has been positioned, the *Adapter grub screw* supplied with the *Short Glenosphere Safety Screw*, is secured in the threaded hole of the *Glenosphere Adapter* using the *Hexagonal Screwdriver Shaft* \emptyset 5.0 mm S70299 assembled with the *Universal silicone handle S70206* (Figure 58).

The *Trial "All-Poly" Glenosphere*, which comes in 40, 44 and 48 mm sizes in Standard and Corrective version, is then positioned as previously described (page 27, **Figure 48**).

The humerus is then prepared as described in the next section (**9.5.** page 31).

The final "All-Poly" Glenosphere is inserted over the "All-Poly" Glenosphere Adapter following the same procedure previously described (page 28, **Figures 51-53**) <u>but now screwing the Guide Rod S70637 into the Adapter</u> <u>grub screw.</u>

The Short Safety Screw is screwed to secure the Glenosphere to the Glenoid Base-plate using the Torque wrench for Screw S70296 assembled with the Universal silicone handle S70206 (Figure 54).

The Short Safety Screw is screwed into the Glenosphere Adapter grub screw, which is in turn screwed into the Glenosphere Adapter. The adapter is then tightened by compression onto the Glenoid Base-plate by the Central Fixation Screw (Figure 59a-b components assembly sequence).

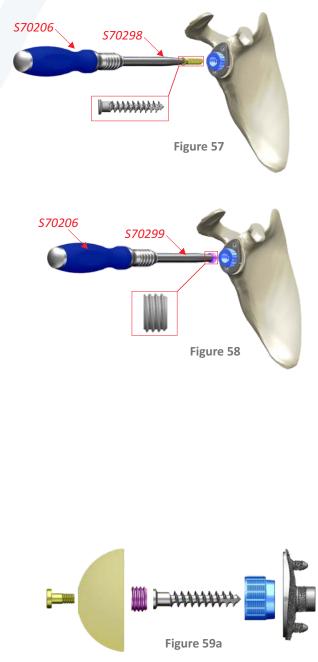




Figure 59b

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9.5 Preparation of the humerus

The posterior and anterior Hohmann retractors are removed and the humerus is exposed again in external rotation.

A further Hohmann retractor is placed in the dorsal portion, one in the ventral portion and one in the cranial portion around the humeral metaphysis.

The Humeral protection is removed with the specific Clamp \$70038.

Preparation of the humerus.

By resting the Trial Anatomical Head of the size that best replicates the anatomy, identify and mark the center of the humeral metaphysis where the Ø 3 mm Guide Pin will be inserted (Figure 60).

The Humeral Pin Guide is rested on the humeral metaphysis with reference to the landmark and the correct Humeral Core size is evaluated.

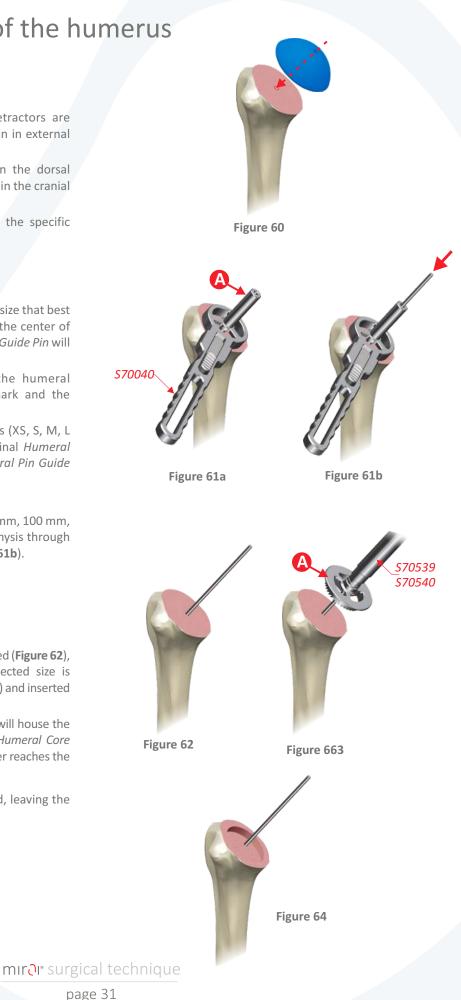
The Humeral Pin Guide (A) comes in 5 sizes (XS, S, M, L and XL) with the same diameter of the final Humeral Core. It is modular and fits with the Humeral Pin Guide Handle S70040 (Figure 61a).

A Ø 3 mm Guide Pin of suitable length (75 mm, 100 mm, 150 mm) is inserted in the humeral metaphysis through the sleeve of the Humeral Pin Guide (Figure 61b).

Once the Humeral Pin Guide has been removed (Figure 62), the Humeral Core Reamer (A) of the selected size is mounted on the Reamers Handle (S70539-40) and inserted over the Humeral Pin.

The metaphyseal part of the humerus, that will house the Humeral Core, is reamed (Figure 63). The Humeral Core *Reamer* must be fully inserted until its stopper reaches the humeral resection bone.

The Humeral Core Reamer is then removed, leaving the Guide pin in situ (Figure 64).

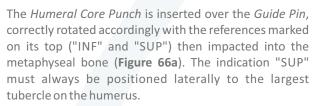


9.5 Preparation of the humerus

The humeral metaphysis is then compacted with the *Humeral Core Punch* which comes in 5 sizes (XS, S, M, L and XL) and has the same dimensions as the final *Humeral core*.

The Humeral Core Punch is modular and has to be screwed with its Humeral Core Punch Handle S70230 assembled with the Silicone impacting handle S70207 (Figure 65). Boththe instruments are cannulated for the Guide Pin.

The *Humeral Core Punch* must to be selected to match the same size of the final *Humeral Core*.



The *Humeral Core Punch* must be fully inserted until it reaches the humeral resection level (**Figure 66b**).

Unscrew the Humeral Core Punch Handle S70230 and remove the Guide Pin, leaving the Humeral Core Punch in the humerus (Figure 67).

ATTENTION: whenever the *Humeral Core Punch* should not show an optimal primary stability, or such a situation should not even occur after implantation of the definitive *Humeral Core*, it is advisable to proceed with a stemmed implant (refer to chapter **9.7**, page 39).



Figure 67

1111

S70207

Figure 66a

\$70231-35

\$70230

Figure 65

Figure 66b

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9.6 Implantation of the stemless Humeral Component

9.6.1 Anatomic Configuration

The *Trial Anatomic Humeral Head Adapter* is then positioned over the selected *Humeral Core Punch* (which also serves as the *Trial humeral core*) manually or using the *Clamp S70038* (Figure 68).

The *Trial Anatomic Humeral Head* is also positioned (**Figure 69**) and stability and joint motion tests can be carried out.

If the soft tissues tension is good, the joint is dislocated and the trial components are removed using the specific instruments: use the *Clamp S70038* to remove the *Humeral Head Adapter*, then the *Humeral Core Punch Handle S70230* mounted on the *Silicone impacting handle S70207* to remove the *Humeral Core Punch*.

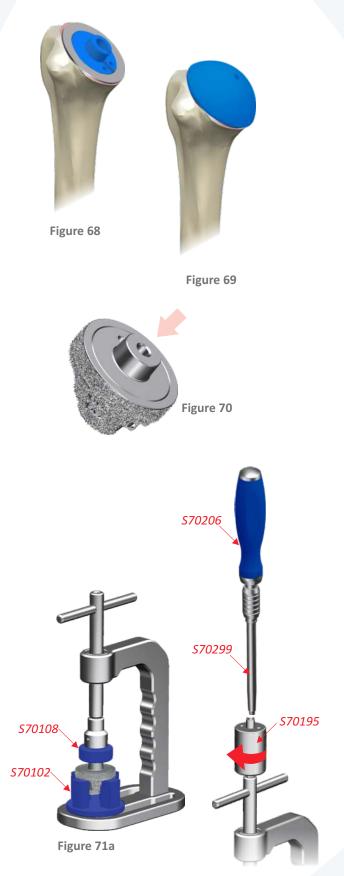
The final *Humeral Head Adapter* is assembled on top of the final *Humeral Core Cage* of the same size of the *Humeral Core Punch* (Figure 70) using the *Assembly Press S70250*.

Place onto the inferior side of the Assembly press the 4pegged Support for Core/Adapter assembly (stemless) S70102 with the Humeral Core and the Humeral Head Adapter centrally positioned over.

Place on the superior side of the Assembly Press the Adapter for Core/Adapter assembly S70108 (Figure 71a).

Secure the morse taper connection between the *Humeral Core Cage* and the *Humeral Head* adapter using the *Torque Wrench for Press S70195* and the *Hexagonal Screwdriver Shaft 5,0mm S70299* inserted onto the *Universal silicone Handle S70206* (Figure 71b).

WARNING: the *Torque Wrench for Press S70195* needs to be checked periodically by the manufacturer to test the achievement of the expected torque. Before proceeding with its use, it is therefore necessary to <u>CHECK THE EXPIRATION</u> <u>DATE</u> marked on the device itself and, if necessary, return the instrument to the manufacturer for the necessary checks.



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Figure 71b

9.6 Implantation of the stemless Humeral Component

The final *Humeral Core Cage* is implanted using the *Universal Impactor Handle S70225* fitted onto the *Silicone impacting handle S70207*. The *Universal Impactor Handle* is screwed into the threaded hole of the *Humeral Head Adapter* (Figure 72).

The *Humeral Core Cage* must be perfectly impacted, taking care that its circular ring is completely sunk into the metaphyseal bone, leveled with the resection plane (**Figure 73-75**). An excessive sinking or imperfect leveling would lead to an impingement of the *Anatomical humeral head* (especially if large-sized) with the bone preventing proper assembly over the *Humeral head adapter*.



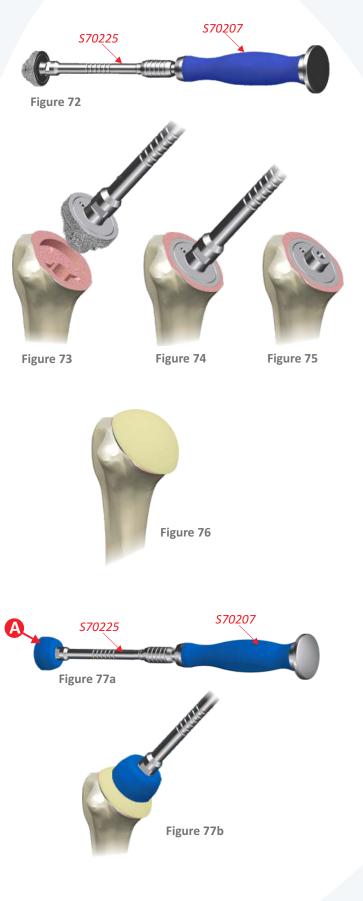
ATTENTION: the standard concentric *Humeral Head Adapter* is the correct version to use for the stemless anatomic configuration. In the stemmed configuration instead, in which it is not possible to faithfully match the patient's anatomy, the most appropriate *Humeral head adapter* will be chosen from *Standard*, *Eccentric 2 mm* or *Eccentric 4 mm*.

The final *Anatomic Humeral Head* is manually engaged above the implanted *Humeral Core* (Figure 76).

The size of the Anatomic Humeral Head is selected according to both the dimensions of the native humeral head and the allowed combinations between the Anatomic Humeral Head and Glenoid Base-plate, as shown in the table in section 6. The Anatomic Humeral Head is oriented following the notches marked on its equatorial edge which correspond to the head major axis aligned to the coronal plane.

The Anatomic Humeral Head is lightly impacted using the Anatomic Humeral Head Impacting End (A) of corresponding size screwed with Universal Impactor Handle S70225 fitted onto the Silicone impacting handle S70207 (Figure 77a-b).

WARNING! It is recommended to place a gauze between *Anatomic humeral head impacting end* and the final *Anatomic humeral head* to prevent any damage to the articular surface.



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9.6 Implantation of the stemless Humeral Component

9.6.2 Reverse configuration

In the case of a reverse total shoulder option the *Stemless Humeral Core Punch* is always used to carry out the trial evaluation (**Figure 78**) by inserting the *Trial Humeral Insert* of corresponding size using the *Clamp S30078* (**Figure 79**).

The *Trial Humeral Insert* (*S70171-79*) comes in sizes 40, 44, 48 mm, each of them available in 3 CCD angle with 4 different thicknesses. The elevated rim of the trial insert should be positioned in correspondence to the lower medial margin.

The shoulder tension, stability and range of movements are tested. If there is insufficient tension in the tissues, it is advisable to test a thicker *Trial Humeral Insert* or use, in coupling with, the *Trial Humeral Insert Spacer S70281* to gain a 9 mm elongation.

Remove the *Trial Humeral Insert* with the *Clamp S70038* and the *Humeral Core Punch* with the *Humeral Core Punch Handle S70230* fitted on the *Silicone impacting handle S70207*.

The definitive *Humeral Core Cage* is then inserted using the *Humeral Core Positioning End for reverse prosthesis S70226* fitted on the *Silicone impacting handle S70207* (**Figure 80**).

The *Humeral Core Cage* must be perfectly impacted, taking care that its circular ring is completely sunk into the metaphyseal bone, leveled with the resection plane **(Figure 81a-b).**

Once the *Humeral Core Cage* has been implanted, the *Trial Humeral Insert* can be positioned again for stability and movements testing, or the definitive correctly-sized *Humeral Insert* can be inserted straight away (**Figure 82**) using the *Suction Insert Positioner S30078*.

ATTENTION: If the anteversion of the *Humeral Insert* needs correcting, it can simply be rotated before it is impacted on the *Humeral Core* morse taper.

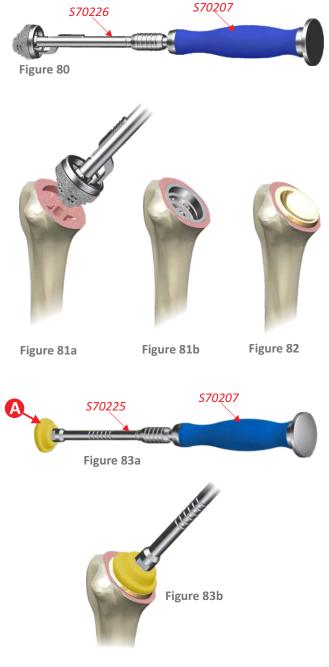
The Humeral Insert is impacted using the Humeral Insert Impacting End (A) of corresponding size screwed with Universal Impactor Handle S70225 fitted onto the Silicone impacting handle S70207 (Figure 83a-b). The joint is then finally reduced.





Figure 78

Figure 79



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The preliminary steps for the humerus preparation are exactly the same as for stemless procedure, up to the reaming of the humeral metaphysis for *Humeral Core* seating. After that the *Guide Pin* \emptyset 3 mm is removed (**Figure 84**).

It is not necessary to ream the humeral metaphysis if the bone quality is poor.

The humeral diaphysis is started using the *Diaphyseal Starting Awl S70071*, that can be equipped with the *Humeral Rasp Handle Stopper*, with magnetic coupling, available in CCD angles of 130°, 140° and 150° to match the humeral resection (**Figure 85**).

The cancellous bone is then compacted using the *Humeral Rasps S70301-16* of progressively increasing diameters (**Figure 86**).

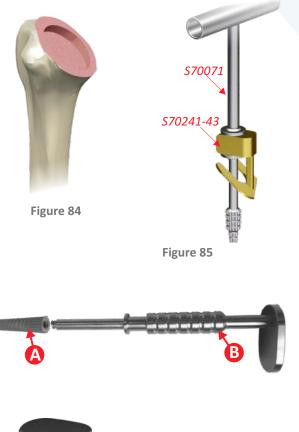
The Humeral Rasp (A) is screwed onto the Humeral Rasp Handle S70319 (B).

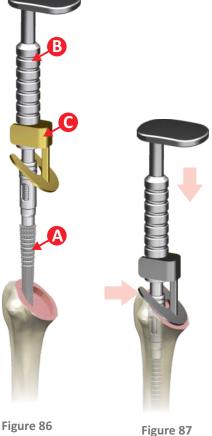
The *Rasp Handle* can be also equipped with the *Stopper* (C) in order to limit the rasp sinking to the desired level. The *Stopper* to be used must be with the same CCD angle matching the angle of the humeral resection.

The *Humeral Rasp* must be impacted in the diaphyseal canal and then removed. The rasp is unhooked from the *Humeral Rasp Handle* by unlocking the twist-lock ring then pushing on the hooking/unhooking plate.

Progressively larger rasps are used until a stable fit in the diaphyseal canal is achieved, with the *Stopper* against the humeral resection (**Figure 87**).

WARNING! Do not unhook the *Humeral Rasp* from the *Handle* when it is fitted in the diaphyseal canal since rehooking would be difficult, with the risk to make it sink further.





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The trial stemmed humeral components are assembled (Figure 88).

The following components are assembled on the backtable:

- A Humeral Rasp S70301-16, in the final size, on which the Threaded Trial Adapter S70318 is screwed;
- B Trial Metaphyseal Component S70251-57, selected with the correct offset and CCD angle, assessed during the preoperative planning;
- C Trial Humeral Core S70261-65, available in 5 sizes (XS, S, M, L, XL);
- D Stemmed Trial Components Holder S70290;
- E Retroversion Rod S70022.

A is assembled with B. C is assembled with A-B (C is free to rotate on B). D is then assembled with A-B-C.

To achieve the correct medio-dorsal eccentricity of the *Anatomic Humeral Head*, it may be necessary to rotate the *Trial Humeral Core* (**C**) leaving the ring nut of the *Stemmed Trial Components Holder* (**D**) slack, before carrying out the implantation.

After rotating the *Trial Humeral Core* in the desired position, the ring nut of the holder is tightened, using the *Hexagonal Screwdriver Shaft 5,0mm S70299* fitted onto the Universal silicone Handle S70206, and proceed with the trial components implantation.

ATTENTION:

The standard version of the *Trial Metaphyseal Component* (**B**) for the stemmed reverse configuration is the one with a 140° CCD angle and 0 mm offset.

The trial humeral components are implanted in the diaphyseal canal by gently hitting the *Stemmed Trial Components Holder* with a mallet until the *Trial Humeral Core* seats into the metaphysis, aligned with the humeral resection.

The *Retroversion Rod* (E) can be used to adjust the retroversion of the stemmed humeral component by inserting it into one of the 10 holes (5 per side) on the *Stemmed Trial Components Holder* matching the same retroversion angle used for the humeral resection.

The *Retroversion Rod* must always be positioned parallel to the forearm (**Figure 88**).

Once the trial stemmed humeral component has been implanted, remove the *Trial Stemmed Components Holder S70290* (Figure 89).



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9.7.1 Anatomic Stemmed configuration

Using the *Clamp S70038* the *Trial Humeral Head Adapter* of corresponding size is positioned inside the *Trial Humeral Core* and the selected *Trial Anatomic Humeral Head* placed over it (**Figure 90**).

The joint is reduced and the joint stability and movements are tested.

ATTENTION! Before removing the trial humeral components from the diaphyseal canal (after removal of the *Trial Humeral Head and Adapter*) it is recommended to trace at least two reference marks on the humeral bone in correspondence of the 2 shortest arms of the *Humeral Core*. These landmarks will help to give the correct rotation during insertion of the definitive *Humeral Core* (Figure 91).

The trial humeral components must then be removed from the diaphyseal canal using the *Stemmed Trial Components Holder S70290*.

The definitive prosthetic components (Figure 92) are then assembled on the back-table by means of the *Assembly Press S70250*:

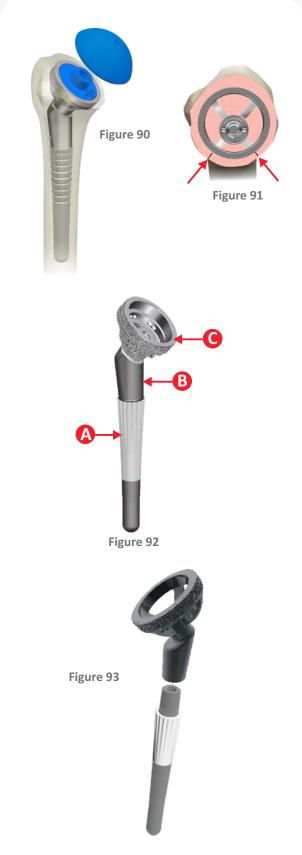
- A Humeral Stem
- B Metaphiseal Humeral Component
- C Humeral Core Cage.

WARNING! Before assembling the final components with the *Press*, make sure that the *Humeral Core Cage* and the *Metaphyseal Humeral Component* have the same orientation established with trial components.

OPTION WITH HUMERAL CORE TRAUMA

The *Humeral Core Trauma* is a component that brings together in a single monobloc element the *Humeral Core* and the *Metaphyseal Humeral Component* (Figure 93) to be used as an alternative to simplify the procedure avoiding the assembly of two components.

It is available with a CCD angle of 140 $^\circ$ and 150 $^\circ$ and in sizes S and M.



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2. CORE/METAPHYSEAL COMPONENT ASSEMBLY

Place onto the inferior side of the Assembly Press the 10° angular landmarked Support for Core/Metaphyseal Component assembly S70106 with the Humeral Core and the Metaphyseal Humeral Component positioned over, with the same previously assessed relative rotation.

Place on the superior side of the Assembly Press the Adapter for Core/Metaphyseal Component assembly S70110-6 which comes in 7 versions: 130°, 130° +3.5mm, 130° +5mm, 140°, 140° +3.5mm, 150°, 150° +2mm (Figure 94a).

Secure the morse taper connection between the *Humeral core cage* and the *Metaphyseal Humeral Component* using the *Torque Wrench for Press S70195* and the *Hexagonal Screwdriver Shaft 5,0mm S70299* inserted onto the Universal silicone Handle S70206 (Figure 94b).

Whenever it would be necessary to disassemble the components to change their orientation, place onto the inferior side of the Assembly Press the Support for Core/Adapter assembly (stemmed) S70104 with the assembled Humeral Core cage and Metaphyseal Humeral Component rested over, and on the superior side the Adapter for CORE/CAP disassembly S70109 (Figura 95).

Push with the *Press* to disassemble the components.

3. CORE/METAPHYSEAL COMPONENT SAFETY SCREWASSEMBLY

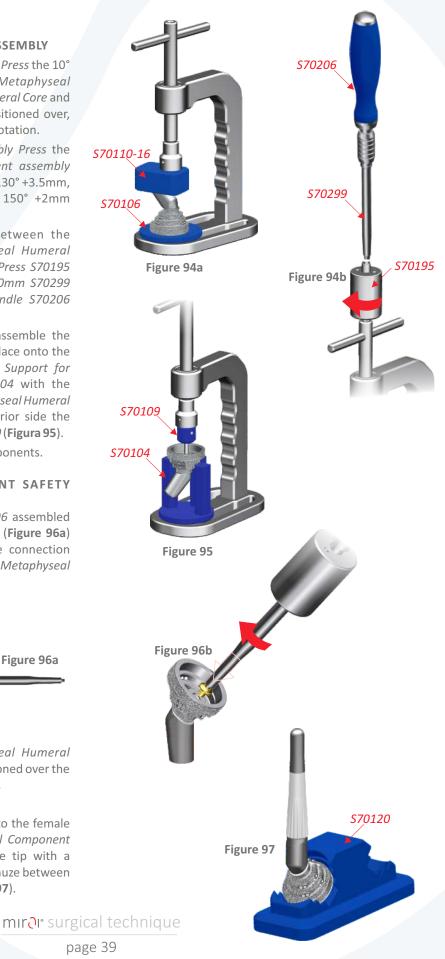
Using the *Torque wrench for Screw S70296* assembled with the *Universal silicone handle S70206* (Figure 96a) tighten the *Safety Screw* to secure the connection between the *Humeral core cage* and the *Metaphyseal Humeral Component* (Figure 96b).



5. HUMERAL STEM ASSEMBLY

The assembled components: *Metaphyseal Humeral Component* + *Humeral Core Cage* are positioned over the *Support for Humeral Stem assembly S70120*.

The *Humeral Stem* is manually engaged into the female morse taper of the *Metaphyseal Humeral Component* and secured by slightly impacting on the tip with a hammer, taking care to place a protective gauze between the hammer and the tip of the stem (**Figure 97**).



WARNING! Before assembling the final components with the *Press*, make sure that the *Humeral Core Cage* and the *Metaphyseal Humeral Component* have the same orientation established with trial components.

The definitive prosthetic components are then implanted using the *Stemmed Components Holder S70291* (Figure 98a) until the stemmed humeral component is fully seated and stable in the humerus (Figure 98b).

WARNING!

Take care to ensure that the upper edge of the *Humeral Core Cage* is aligned with or fully outside of the humeral resection plane. An excessive sinking or imperfect leveling (**Figure 99**) would lead to an impingement of the *Anatomical humeral head* (especially if large-sized) with the bone preventing proper assembly over the *Humeral head adapter*.



Remove the *Stemmed Component Holder S70291* from the stemmed humeral component and check that the *Humeral Core Cage* is correctly seated (**Figure 100a**).

The Humeral Head Adapter is placed into the Humeral Core ring by means of the Universal Impactor Handle S70225 fitted onto the Silicone impacting handle S70207 and impacted (Figure 100b-c).

The Anatomic Humeral Head is manually engaged over the Humeral Head Adapter and lightly impacted using the Anatomic Humeral Head Impacting End (A) of corresponding size screwed with Universal Impactor Handle S70225 fitted onto the Silicone impacting handle S70207 (Figure 101).

WARNING! It is recommended to place a gauze between *Impacting End* and the final *Anatomic Humeral Head* to protect the articular surface.



9.7.2 Stemmed reverse configuration

The humerus preparation steps are the same previously decribed for the anatomic configuration (pages 35,36) up until implantation of the trial humeral component (Figure 102).

ATTENTION: the standard version of the *Metaphyseal Humeral Component* for the stemmed reverse configuration is the 140° CCD angle and 0 mm offset version.

The *Trial Humeral Insert* of corresponding size is positioned in the Trial Humeral Core (Figure 103) using the *Clamp S30078*. The joint is then reduced and stability and range of movements are tested.

The trial humeral components must then be removed from the diaphyseal canal using the *Stemmed Trial Components Holder S70290*.

Proceed with assembly and implantation of the final prosthetic components by following the procedure described for the stemmed anatomic configuration (pages 39-40).

The *Stemmed Component Holder S70291* is removed from the stemmed humeral component, ensuring that the *Humeral Core Cage* is correctly seated (**Figure 104**).

It is possible a further evaluation of joint stability and motion by inserting the *Trial Humeral Insert* using the *Clamp S30078*.

Place the definitive *Humeral Insert* by means of the *Suction Insert Positioner S30078* (Figure 105).

The *Humeral Insert* is impacted using the *Humeral Insert Impacting End* (**A**) of corresponding size screwed with *Universal Impactor Handle S70225* fitted onto the *Silicone impacting handle S70207* (Figure 106a-b).

Joint reduction.

Re-fixation of the subscapularis tendon, closure of the deltopectoral fascia, closure of the subcutaneous and intradermal layers.

Sterile dressing.





Figure 102

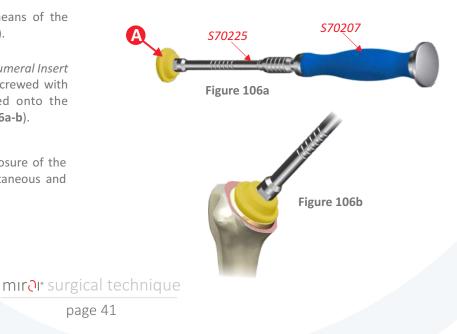
Figure 103





Figure 104

Figure 105



9.8 Conversion from anatomic to reverse configuration

9.8.1 Conversion of the humeral compartment

In case it should be necessary to convert a total shoulder prosthesis from anatomic to reverse configuration, only the humeral and glenoid bearing components need to be replaced, once assessed that the glenoid and humeral components appear to be stable and well osseointegrated. The conversion is carried out as follows:

After exposure of the joint and dislocation of the humeral head by rotating the humerus externally, the Anatomic Humeral Head is disassembled from the Humeral Head Adapter using the Humeral Head Extractor S70621 screwed on the Universal Impactor Handle S70225 and inserted onto the Silicone impacting handle S70207.

Insert the fork blade of the *Humeral Head Extractor* into the gap between the *Anatomic Humeral Head* and the *Humeral Head Adapter* and gently hit to disassemble the components (**Figure 107**).

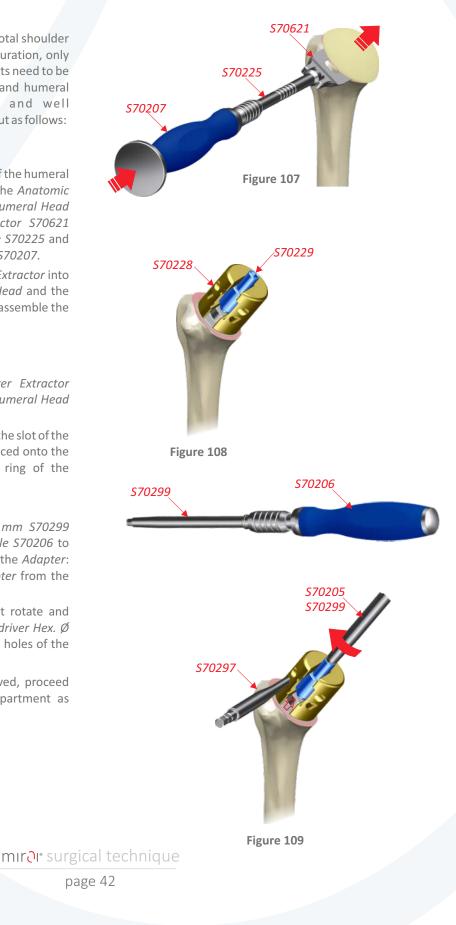
By means of the Humeral Head Adapter Extractor S70228-29 proceed in disassembling the Humeral Head Adapter from the Humeral Core.

The *Threaded Shaft S70229* is inserted into the slot of the *Main Body S70228* and the assembly is placed onto the *Humeral Head Adapter* rested onto the ring of the *Humeral Core* (Figure 108).

Use the Hexgonal Screwdriver Shaft Ø5 mm S70299 connected to the Universal silicone handle S70206 to screw the Threaded Shaft into the hole of the Adapter: this will pull out the Humeral Head Adapter from the Humeral Core.

To contrast the torque in order to do not rotate and loosen the *Humeral core*, insert the *Screwdriver Hex*. \emptyset 2.5 mm S70297 throughout the transversal holes of the *Extractor's Main Body S70228* (Figure 109).

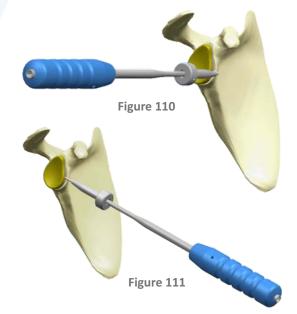
Once the *Humeral Head Adapter* is removed, proceed with the conversion of the glenoid compartment as described in the following page.



9.8 Conversion from anatomic to reverse configuration

9.8.2 Conversion of the glenoid compartment

The *Glenoid Insert* is disassembled from the *Glenoid Base-plate* using the *Glenoid Insert Extractor* available *Straight* and *Curved S70623-4*. The *Glenoid Insert* is detached by inserting and pulling the extractor's pin into the two holes on the edge between *Glenoid Insert* and *Glenoid Base-plate* (Figure 110, 111).



If the *Glenoid Base-plate* is implanted with the modular *Central Peg* (**option 1**):

The *Glenosphere Adapter* is inserted onto the *Glenoid Base-plate* and the trial and definitive *Glenosphere* is inserted with the appropriate *Long Safety screw*, as described in section **9.4.2.** (page 28) and **9.4.3.** (page 32).

If the *Glenoid Base-plate* is implanted with the bi-cortical *Central Locking Screw* (**option 2**):

Unscrew and remove the *Central Locking Screw*. The *Glenosphere Adapter* is then assembled on the *Glenoid Base-plate*, the *Central Locking Screw* (or a longer sized one) is re-screwed in and the *Adapter grub screw* is screwed into the *Glenosphere Adapter*. Then the trial and definitive *Glenosphere* is inserted with the *Short Safety Screw*, with the same procedure as described in section **9.4.2.** (page 29) and **9.4.3.** (page 33).

The trial and definitive *Humeral Insert* for the reverse configuration is inserted, with the same procedure as described in sections **9.6.2** (page 35) and **9.7.2** (page 41).

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9.9 Components removal

9.9.1 Removal of the All-Poly Glenosphere

In case it should be necessary to remove the Glenosphere from the Glenoid Base-plate it is available a proper extraction device consisting of the following instruments:

A	<i>S70661</i>	Guide rod
B	S70662	Extractor main body
C	S70663	Pressure rod

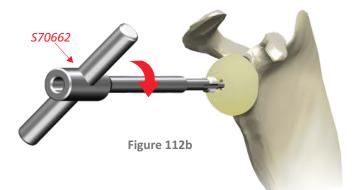
Unscrew the Glenosphere safety screw first, then screw the Guide rod S70661 in the Glenosphere (Figure 112a).

In case of Central Fixation Screw the Guide rod is screwed into the Grub of the Adapter.

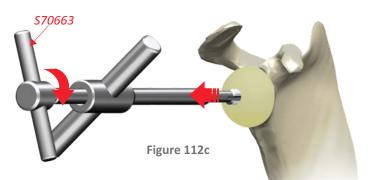
In case of *Central Peg* the *Guide rod* is inserted through the Adapter and screwed directly into the thread of the Central Peg.

Insert the Extractor main body S70662 over the Guide rod and screw the self-threading end directly into the polyethylene of the Glenosphere (Figure 112b).

S70661 Figure 112a



Insert the Pressure rod S70663 inside the Extractor main body by turning the T handle clockwise: this will push onto the Guide rod thus allowing the extraction of the *Glenosphere* from the *Adapter* (Figure 112c).



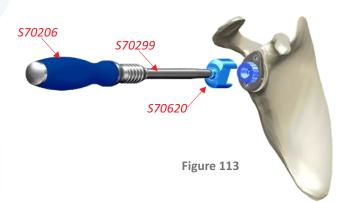
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9.9 Components removal

9.9.2 Removal of the Glenosphere Adapter

In case of removal of the *Glenos*phere *Adapter* from the *Glenoid Base-plate*, insert the *Glenos*phere *Adapter Extractor S70620* onto the *Glenos*phere *Adapter*. With the *Hexagonal Screwdriver Shaft* Ø 5 mm *S70299* connected to the *Universal silicone handle S70206* screw the threaded end of the *Extractor* into the threaded hole of the *Adapter* to pull it out from the *Base-plate* (Figure 113).

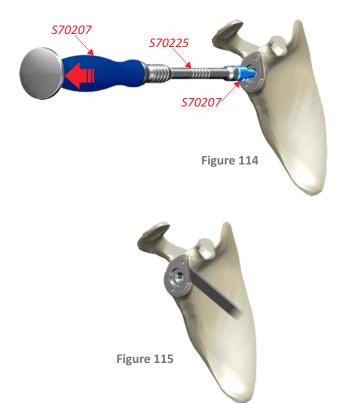
WARNING! In case the *Glenoid Base-plate* was fixed with the *Central Fixation Screw*, this last must be removed before using the *Extractor*.



9.9.3 Removal of the Glenoid Base-plate with central Peg

In case of removal of the *Glenoid Base-Plate* with *Central Peg*, assemble the *Extractor for Baseplate/PEG assembly S70622* to the *Universal Impactor Handle S70225* and the *Silicone impacting handle S70207*, then screw the threaded end in the central hole of the *Base-Plate* (Figure 114).

Hit on the impacting plate (in extraction) to remove the *Base-Plate* together with the *Central Peg* from the glenoid bone.



WARNING! If the *Base-plate* is integrated, in order to facilitate its removal, it is advisable to weaken the bone-prosthesis interface by striking it with a thin osteotome (**Figure 115**).

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PRESS-FIT HUMERAL	STEM Ti6AI4V (ISO 5832/3) - HA (ISO 2	13779/2)
*Sizes available on request	SIZE	REFERENCE
	10 L.75mm	70010
	11 L.75mm	70011
	12 L.75mm	70012
	13 L.75mm	70013
	14 L.75mm	70014
	15 L.75mm	70015
	16 L.75mm	70016
	17 L.75mm	70017
	18 L.75mm	70018
	19 L.75mm	70019
	20 L.75mm	70020
	21 L.75mm	70021
	22 L.75mm	70022
	23 L.75mm	70023*
	24 L.75mm	70024*
	25 L.75mm	70025*
	26 L.75mm	70026*

CEMENTED HUMERAL STEM Ti6AI4V (ISO 5832/3)

*Sizes available on request



SIZE	REFERENCE
10 L.75mm	70110
11 L.75mm	70111*
12 L.75mm	70112
13 L.75mm	70113*
14 L.75mm	70114
15 L.75mm	70115*
16 L.75mm	70116
17 L.75mm	70117*
18 L.75mm	70118
19 L.75mm	70119*
20 L.75mm	70120
21 L.75mm	70121*
22 L.75mm	70122

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PRESS-FIT HUMERAL STEM - REVISION Ti6AI4V (ISO 5832/3) - HA (ISO 13779/2)

SIZE	REFERENCE
10 L.150mm	70201
10 L.180mm	70202
13 L.150mm	70206
13 L.180mm	70207
14 L.150mm	70211
14 L.180mm	70212
15 L.150mm	70216
15 L.180mm	70217
16 L.150mm	70221
16 L.180mm	70222
18 L.150mm	70226
18 L.180mm	70227

CEMENTED HUMERAL STEM - REVISION Ti6AI4V (ISO 5832/3)

*Sizes available on request

SIZE	REFERENCE
13 L.150mm	70251
13 L.180mm	70252
13 L.210mm	70253*
15 L.150mm	70261
15 L.180mm	70262
15 L.210mm	70263*



METAPHYSEAL HUMERAL COMPONENT TI6AI4V (ASTM F 3001)

SIZE	REFERENCE
130°	70301
130° offset 3,5mm	70303
130° offset 5mm	70305
140°	70311
140° offset 3,5mm	70315
150°	70321
150° offset 2mm	70322

HUMERAL CORE CAGE TRASER® TI6AI4V



SIZE	REFERENCE
SIZE	REFERENCE
XS	70411
S	70412
Μ	70413
L	70414
XL	70415

HUMERAL CORE TRAUMA TRASER® TI6AI4V



SIZE	REFERENCE
S 140°	70421
S 150°	70423
M 140°	70422
M 150°	70424

HUMERAL CORE TRAUMA CEMENTED TIGAI4V

*Sizes available on request	

SIZE	REFERENCE
S 140°	70441*
S 150°	70443*
M 140°	70442*
M 150°	70444*

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ELLIPTICAL ANATOMIC HUMERAL HEAD - VITAL-E UHMWPE + VITAMIN E (ISO 5834/1) TI6AI4V (ISO 5832/3)

*Sizes available on request



SIZE	REFERENCE
36 mm	70536E*
38 mm	70538E
40 mm	70540E
42 mm	70542E
44 mm	70544E
46 mm	70546E
48 mm	70548E
50 mm	70550E
52 mm	70552E
54 mm	70554E
56 mm	70556E

ELLIPTICAL ANATOMIC HUMERAL HE	AD - UHMWPE UHMWPE (ISO 58	334/1) Ti6AI4V (ISO 5832/3)
Sizes available on request		
	SIZE	REFERENCE
	36 mm	70536*
	38 mm	70538*
	40 mm	70540*
	42 mm	70542*
	44 mm	70544*
	46 mm	70546*
	48 mm	70548*
	50 mm	70550*
	52 mm	70552*
	54 mm	70554*

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56 mm

70556*



SPHERICAL ANATOMIC HUMERAL HEAD PM734 ISO 5832/9

*Sizes available on request



SIZE	REFERENCE
36 mm	70836*
38 mm	70838*
40 mm	70840*
42 mm	70842*
44 mm	70844*
46 mm	70846*
48 mm	70848*
50 mm	70850*
52 mm	70852*
54 mm	70854*
56 mm	70856*

CTA HUMERAL HEAD PM734 ISO 5832/9



SIZE	REFERENCE
40 mm	70661
44 mm	70662
48 mm	70663
52 mm	70664

ANATOMICAL HUMERAL HEAD ADAPTER TI6AI4V (ISO 5832/3)



SIZE	REFERENCE
Standard	70501
Eccentric (2mm)	70502
Eccentric (4mm)	70503

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GLENOID BASE-PLATE STANDARD V.2 TI6AI4V

*Sizes available on request

	SIZE
-	RIGHT - XS
	RIGHT - S
	RIGHT - M
	RIGHT - L
	RIGHT - XL
	LEFT - XS
	LEFT - S
	LEFT - M
	I FFT - I

SIZE	REFERENCE
RIGHT - XS	70821
RIGHT - S	70822
RIGHT - M	70823
RIGHT - L	70824
RIGHT - XL	70825*
LEFT - XS	70826
LEFT - S	70827
LEFT - M	70828
LEFT - L	70829
LEFT - XL	70830*

PEG-SCREWS for GLENOID BASE-PLATE V.2 Ti6A14V + TiNbN (ISO 5832/3)



SIZE	REFERENCE
M5 (XS)	70746
M6 (S-M-L-XL)	70745

ANATOMIC GLENOID INSERT TI6A14V + TINbN (ISO 5832/3)

*Sizes available on request

	SIZE	REFERENCE
	RIGHT - XS	70801
	RIGHT - S	70802
	RIGHT - M	70803
	RIGHT - L	70804
	RIGHT - XL	70805*
	LEFT - XS	70806
	LEFT - S	70807
	LEFT - M	70808
	LEFT - L	70809
	LEFT - XL	70810*

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CENTRAL PEG for GLENOID BASE-PLATE TI6AI4V

	SIZE	REFERENCE
	18 mm	70718
	25 mm	70725
	30 mm	70730

	SIZE	REFERENCE
	Ø 6,5x20 mm	36720
	Ø 6,5x25 mm	36725
	Ø 6,5x30 mm	36730
	Ø 6,5x35 mm	36735
	Ø 6,5x40 mm	36740
	Ø 6,5x45 mm	36745
	Ø 6,5x50 mm	36750
	Ø 6,5x60 mm	36760

FIXATION SCREWS for GLENOID BASE-PLATE TIGAI4V (ISO 5832/3)





SIZE	REFERENCE	
Ø 3,5x20 mm	70750	
Ø 3,5x25 mm	70751	
Ø 3,5x30 mm	70752	
Ø 3,5x35 mm	70753	
Ø 3,5x40 mm	70754	
Ø 3,5x45 mm	70755	
Ø 3,5x50 mm	70756	
Ø 4,5x20 mm	70760	
Ø 4,5x25 mm	70761	
Ø 4,5x30 mm	70762	
Ø 4,5x35 mm	70763	
Ø 4,5x40 mm	70764	
Ø 4,5x45 mm	70765	
Ø 4,5x50 mm	70766	

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HUMERAL INSERT for REVERSE PROSTHESIS V.2 Ti6AI4V + TiNbN (ISO 5832/3)



SIZE	REFERENCE
36 / 0°+ 0mm	70561
	70562
36 / 3°+ 3mm	70302
36 / 6°+ 6mm	70563
40 / 0°+ 0mm	70564
40/3°+3mm	70565
40 / 6°+ 6mm	70566
40/10°+10mm	70567
44 / 0°+ 0mm	70568
44 / 3°+ 3mm	70569
44 / 6°+ 6mm	70570
44 / 10°+ 10mm	70571
48 / 0°+ 0mm	70572
48 / 3°+ 3mm	70573
48 / 6°+ 6mm	70574
48 / 10°+ 10mm	70575

HUMERAL INSERT SPACER for REVERSE PROSTHESIS Ti6AI4V (ISO 5832/3)



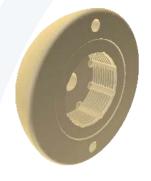
SIZE	REFERENCE
9 mm	70618



"ALL-POLY" GLENOSPHERE for REVERSE PROSTHESIS - UHMWPE UHMWPE (ISO 5834/1/2)

*Sizes available on request		
	SIZE	REFERENCE
	36 Standard	70912*
	40 Standard	70913*
	44 Standard	70914*
	48 Standard	70915*
	36 Corrective	70919*
	40 Corrective	70916*
	44 Corrective	70917*
	48 Corrective	70918*

"ALL-POLY" GLENOSPHERE for REVERSE PROSTHESIS - VITAL-E UHMWPE + VITAMIN E (ISO 5834/1)



SIZE	REFERENCE
36 Standard	70912E
40 Standard	70913E
44 Standard	70914E
48 Standard	70915E
36 Corrective	70919E
40 Corrective	70916E
44 Corrective	70917E
48 Corrective	70918E

"ALL-POLY" GLENOSPHERE ADAPTER TI6AI4V (ISO 5832/3)



SIZE	REFERENCE
XS	70935
S	70936
M-L-XL	70937

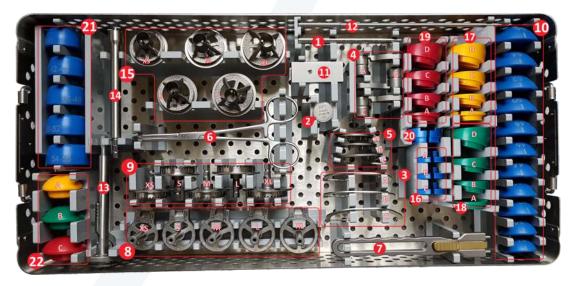
GLENOSPHERE SAFETY SCREW V.2 Ti6AI4V (ISO 5832/3)

SIZE	REFERENCE
S	70908
L	70909

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MIRAI[®] INSTRUMENTS SET TRAY # 1 - S70015



S70015 INSTRUMENTS TRAY #1 - v2

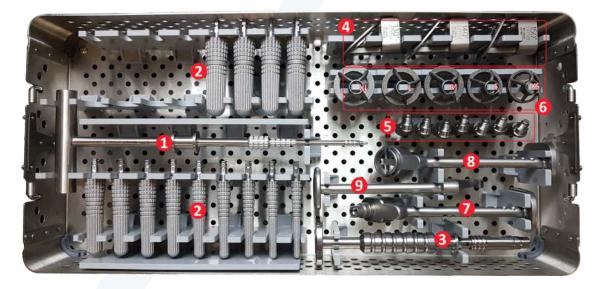
	570015			
e	S70020	Humeral Resection Guide - HANDLE	11 \$70221 12 \$70222	Humeral Resection Guide - CUTTING BLOCK v2
e	S70025	S70025 Humeral Resection Guide - FEELER GAUGE SUPPORT		Humeral Resection Guide - RETROVERSION ROD v2
]	A S70026	Humeral Resection Guide - FEELER GAUGE SMALL	13 S70226	Humeral CORE Positioning End v2 (for reverse prosthesis)
E	B S70027	Humeral Resection Guide - FEELER GAUGE MEDIUM	14 S70230	Humeral CORE Punch Handle v2
l	— C S70028	Humeral Resection Guide - FEELER GAUGE LARGE	S70231	Humeral CORE Punch v2 - Size XS
[A \$70030	Humeral Resection Guide - TEMPLATE 130°	S70232	Humeral CORE Punch v2 - Size S
4	B S70031	Humeral Resection Guide - TEMPLATE 140°	15 S70233	Humeral CORE Punch v2 - Size M
l	— C \$70032	Humeral Resection Guide - TEMPLATE 150°	S70234	Humeral CORE Punch v2 - Size L
[A \$70035	Humeral Protection - Size 40	S70235	Humeral CORE Punch v2 - Size XL
e	B S70036	Humeral Protection - Size 46	A S70266	Trial Humeral Head Adapter v2 - Offset 0mm
l	—C \$70037	Humeral Protection - Size 52	16 B S70267	Trial Humeral Head Adapter v2 - Offset 2mm
e	S70038	CLAMP	C S70268	Trial Humeral Head Adapter v2 - Offset 4mm
e	S70040	Humeral PIN Guide Handle	A \$70271	Trial Humeral Insert v2 - Size 40 Offset 0°
1	— S70041	Humeral PIN Guide - Size XS	B \$70168	Trial Humeral Insert v2 - Size 40 Offset 3°
	S70042	Humeral PIN Guide - Size S	C \$70272	Trial Humeral Insert v2 - Size 40 Offset 6°
6	S70043	Humeral PIN Guide - Size M	D \$70273	Trial Humeral Insert v2 - Size 40 Offset 10°
	S70044	Humeral PIN Guide - Size L	A \$70274	Trial Humeral Insert v2 - Size 44 Offset 0°
l	- S70045	Humeral PIN Guide - Size XL	B S70169	Trial Humeral Insert v2 - Size 44 Offset 3°
1	— S70051	Humeral CORE Reamer - Size XS	C \$70275	Trial Humeral Insert v2 - Size 44 Offset 6°
	S70052	Humeral CORE Reamer - Size S	D S70276	Trial Humeral Insert v2 - Size 44 Offset 10°
9	S70053	Humeral CORE Reamer - Size M	A \$70277	Trial Humeral Insert v2 - Size 48 Offset 0°
	S70054	Humeral CORE Reamer - Size L	B \$70170	Trial Humeral Insert v2 - Size 48 Offset 3°
l	- S70055	Humeral CORE Reamer - Size XL	C \$70278	Trial Humeral Insert v2 - Size 48 Offset 6°
1	— S70136	Trial Anatomic Humeral Head - Size 36T	D \$70279	Trial Humeral Insert v2 - Size 48 Offset 10°
	S70138	rial Anatomic Humeral Head - Size 38	20 S70281	Trial Humeral Insert Spacer v2
	S70140	Trial Anatomic Humeral Head - Size 40	S70512	Anatomic Humeral Head Impacting End - Size 36-38-40
	S70142	Trial Anatomic Humeral Head - Size 42	S70513	Anatomic Humeral Head Impacting End - Size 42-44
1		Trial Anatomic Humeral Head - Size 44	21 \$70514	Anatomic Humeral Head Impacting End - Size 46-48
٩	S70146	Trial Anatomic Humeral Head - Size 46	S70515	Anatomic Humeral Head Impacting End - Size 50-52
	S70148	Trial Anatomic Humeral Head - Size 48	\$70516	Anatomic Humeral Head Impacting End - Size 54-56
	S70150	Trial Anatomic Humeral Head - Size 50	A \$70517	Humeral Insert Impacting End - Size 40
	S70152	Trial Anatomic Humeral Head - Size 52	22 B S70518	Humeral Insert Impacting End - Size 44
	S70154	Trial Anatomic Humeral Head - Size 54	C \$70519	Humeral Insert Impacting End - Size 48
l		Trial Anatomic Humeral Head - Size 56		

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11 Instruments Reference

MIRAI[®] INSTRUMENTS SET TRAY # 2 - S70016

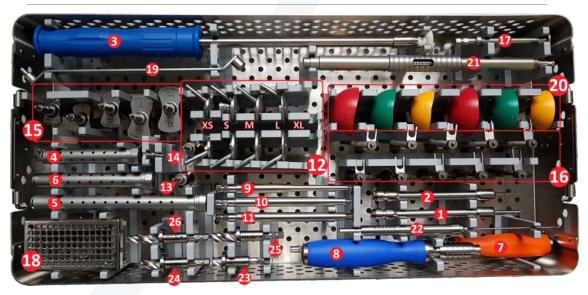


S70016	INSTRUMENTS TRAY #2 - v2
1 \$70071	Diaphyseal Starting Reamer
\$70080	Humeral Rasp - Size 10
S70081	Humeral Rasp - Size 11
S70082	Humeral Rasp - Size 12
S70083	Humeral Rasp - Size 13
S70084	Humeral Rasp - Size 14
2 \$70085	Humeral Rasp - Size 15
S70086	Humeral Rasp - Size 16
S70087	Humeral Rasp - Size 17
S70088	Humeral Rasp - Size 18
S70089	Humeral Rasp - Size 19
S70090	Humeral Rasp - Size 20
\$70091	Humeral Rasp - Size 21
\$70092	Humeral Rasp - Size 22
3 \$70072	Humeral Rasp Handle v3
\$70241	Humeral Rasp Handle Stopper v2 - 130°
4 \$70241 \$70242	Humeral Rasp Handle Stopper v2 - 140°
\$70242	Humeral Rasp Handle Stopper v2 - 150°
\$70251	Trial Metaphyseal Component v2 - 130°
S70252	Trial Metaphyseal Component v2 - 130° offset 3,5 mm
S70253	Trial Metaphyseal Component v2 - 130° offset 5 mm
5 \$70254	Trial Metaphyseal Component v2 - 140°
S70255	Trial Metaphyseal Component v2 - 140° offset 3,5 mm
S70256	Trial Metaphyseal Component v2 - 150°
└── S70257	Trial Metaphyseal Component v2 - 150° offset 2 mm
\$70261	Trial Humeral Core v2 - Size XS
\$70262	Trial Humeral Core v2 - Size S
6 S70263	Trial Humeral Core v2 - Size M
S70264	Trial Humeral Core v2 - Size L
└── S70265	Trial Humeral Core v2 - Size XL
7 \$70290	Stemmed Trial Components Holder v2
 7 \$70290 8 \$70291 9 \$70292 	Stemmed Implant Components Holder v2
9 \$70292	Stemmed Implant Extractor

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MIRAI[®] INSTRUMENTS SET TRAY # 3 - S70017

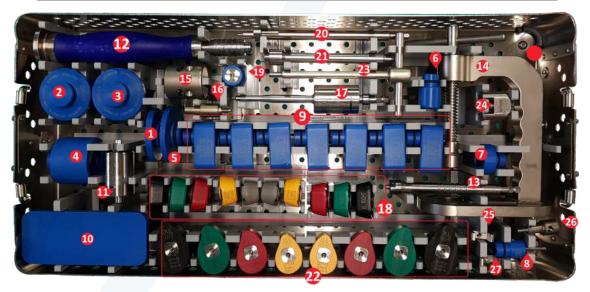


	S70017	INSTRUMENTS TRAY #3 - v2		S70349	Peripheral Glenoid Reamer Guide v2 - Size L - RIGHT
1	S30008	RIGID DRILL BIT - SHAFT		S70350	Peripheral Glenoid Reamer Guide v2 - Size XL - RIGHT
2	S30014	FLEXIBLE DRILL BIT - SHAFT		S70351	Peripheral Glenoid Reamer Guide v2 - Size XS - LEFT
3	S30078	INSERTS POSITIONER with Sucker End	16	S70352	Peripheral Glenoid Reamer Guide v2 - Size S - LEFT
	- S30016	DRILL BIT Ø 3,5x70mm		S70353	Peripheral Glenoid Reamer Guide v2 - Size M - LEFT
4	S70628	TWIST DRILL Ø 2,5mm		S70354	Peripheral Glenoid Reamer Guide v2 - Size L - LEFT
L	- S70629	TWIST DRILL Ø 1,7mm		S70355	Peripheral Glenoid Reamer Guide v2 - Size XL - LEFT
	- S70185	Guide PIN Ø 3.0x75mm	Ð	S70357	Peripheral Glenoid Reamer v2
6	S70186	Guide PIN Ø 3.0x100mm		S70358	Glenoid Deformity Wedge v2 - 10° Size XS-S/RIGHT
	- S70187	Guide PIN Ø 3.0x150mm		S70359	Glenoid Deformity Wedge v2 - 20° Size XS-S/RIGHT
6	S70188	Guide PIN Ø 2.0x100mm		S70360	Glenoid Deformity Wedge v2 - 30° Size XS-S/RIGHT
0	S70205	SMALL SILICONE HANDLE		S70361	Glenoid Deformity Wedge v2 - 10° Size M-L-XL/RIGHT
8	S70206	UNIVERSAL SILICONE HANDLE		S70362	Glenoid Deformity Wedge v2 - 20° Size M-L-XL/RIGHT
9	S70297	Hexagonal Screwdriver Shaft v2 - 2,5mm	18	S70363	Glenoid Deformity Wedge v2 - 30° Size M-L-XL/RIGHT
10	S70298	Hexagonal Screwdriver Shaft v2 - 3,5mm		S70364	Glenoid Deformity Wedge v2 - 10° Size XS-S/LEFT
1	S70299	Hexagonal Screwdriver Shaft v2 - 5mm		S70365	Glenoid Deformity Wedge v2 - 20° Size XS-S/LEFT
	- S70321	Glenoid PIN Guide v2 - Size XS/RIGHT		S70366	Glenoid Deformity Wedge v2 - 30° Size XS-S/LEFT
	S70322	Glenoid PIN Guide v2 - Size S/RIGHT		S70367	Glenoid Deformity Wedge v2 - 10° Size M-L-XL/LEFT
	S70323	Glenoid PIN Guide v2 - Size M/RIGHT		S70368	Glenoid Deformity Wedge v2 - 20° Size M-L-XL/LEFT
	S70324	Glenoid PIN Guide v2 - Size L/RIGHT		S70369	Glenoid Deformity Wedge v2 - 30° Size M-L-XL/LEFT
	S70325	Glenoid PIN Guide v2 - Size XL/RIGHT		S70509	Universal Introducer Handle - Guide Rod
Ψ	S70331	Glenoid PIN Guide v2 - Size XS/LEFT		S70538	Glenoid PIN Guide v2 - Antirotation Pin
	S70332	Glenoid PIN Guide v2 - Size S/LEFT	19	S70374	Drill Guide Sleeve v2
	S70333	Glenoid PIN Guide v2 - Size M/LEFT		S70642	ALL-POLY Trial Glenosphere - Size 40
	S70334	Glenoid PIN Guide v2 - Size L/LEFT		S70643	ALL-POLY Trial Glenosphere - Size 40 CORRECTIVE
	- S70335	Glenoid PIN Guide v2 - Size XL/LEFT	20	S70644	ALL-POLY Trial Glenosphere - Size 44
13	S70336	Glenoid PIN Guide v2 - SLEEVE 0°		S70645	ALL-POLY Trial Glenosphere - Size 44 CORRECTIVE
14	S70337	Glenoid PIN Guide v2 - SLEEVE 10°		S70646	ALL-POLY Trial Glenosphere - Size 48
Г	- S70341	Glenoid Reamer v2 - Size XS		S70647	ALL-POLY Trial Glenosphere - Size 48 CORRECTIVE
	S70342	Glenoid Reamer v2 - Size S	A	S70539	Reamers Handle - HUDSON coupling
₫	S70343	Glenoid Reamer v2 - Size M	4	S70540	Reamers Handle - AO coupling
	S70344	Glenoid Reamer v2 - Size L	2	S70570	Depth Gauge
Ļ	S70345	Glenoid Reamer v2 - Size XL	23	S70605	Glenoid Central SCREW Reamer
	S70346	Peripheral Glenoid Reamer Guide v2 - Size XS - RIGHT	24	S70606	Glenoid Central PEG Reamer Size 18
16	S70347	Peripheral Glenoid Reamer Guide v2 - Size S - RIGHT	2	S70607	Glenoid Central PEG Reamer Size 25
	S70348	Peripheral Glenoid Reamer Guide v2 - Size M - RIGHT	26	S70608	Glenoid Central PEG Reamer Size 30

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MIRAI[®] INSTRUMENTS SET TRAY # 4 - S70018



18

_	S70018	INSTRUMENTS TRAY #4 - v2
1	S70101	PRESS - Support for BASE-PLATE/PEG assembly
2	S70102	PRESS - Support for CORE/ADAPTER assembly (Stemless)
3	S70104	PRESS - Support for CORE/ADAPTER assembly (Stemmed)
4	S70105	PRESS - Support for PEG disassembly
4 5	S70106	PRESS - Support for CORE/METAPHYSEAL COMP. Assembly
6	S70107	PRESS - Adapter for BASE-PLATE/PEG assembly
0	S70108	PRESS - Adapter for CORE/ADAPTER assembly
8	S70109	PRESS - Adapter for CORE CAP disassembly
	- S70110	PRESS - Adapter for CORE/METAPHYSEAL COMP. Assembly - 130-0
	S70111	PRESS - Adapter for CORE/METAPHYSEAL COMP. Assembly - 130-3.5
	S70112	PRESS - Adapter for CORE/METAPHYSEAL COMP. Assembly - 130-5
ø	S70113	PRESS - Adapter for CORE/METAPHYSEAL COMP. Assembly - 140-0
Y	S70114	PRESS - Adapter for CORE/METAPHYSEAL COMP. Assembly - 140-3.5
	S70115	PRESS - Adapter for CORE/METAPHYSEAL COMP. Assembly - 150-0
	- S70116	PRESS - Adapter for CORE/METAPHYSEAL COMP. Assembly - 150-2
10	S70120	Support for HUMERAL STEM Assembly
1	S70195	Torque Wrench for Press
Ð	S70207	Silicone Impacting Handle
	S70225	Universal Introducer Handle v2
14	S70250	Humeral Head Adapter Extractor v2 - MAIN BODY
Ð	S70228	Humeral Head Adapter Extractor v2- THREADED SHAFT
đ	S70229	ASSEMBLY PRESS v2
đ	S70296	Torque Wrench for Screws v2

WARNING:

the Torque Wrench for Press S70195 and the Torque Wrench for Screws S70296 needs to be checked periodically by the manufacturer to test the achievement of the expected torque. Before proceeding with their use, it is therefore necessary to CHECK THE EXPIRATION DATE marked on the devices itself and, if necessary, return the instruments to the manufacturer for the necessary checks.

S70375 Glenoid Baseplate Positioning End v2 - Size XS/RIGHT S70376 Glenoid Baseplate Positioning End v2 - Size S/RIGHT S70377 Glenoid Baseplate Positioning End v2 - Size M/RIGHT S70378 Glenoid Baseplate Positioning End v2 - Size L/RIGHT S70379 Glenoid Baseplate Positioning End v2 - Size XL/RIGHT S70380 Glenoid Baseplate Positioning End v2 - Size XS/LEFT S70381 Glenoid Baseplate Positioning End v2 - Size S/LEFT S70382 Glenoid Baseplate Positioning End v2 - Size M/LEFT S70383 Glenoid Baseplate Positioning End v2 - Size L/LEFT S70384 Glenoid Baseplate Positioning End v2 - Size XL/LEFT 19 S70398 Glenosphere Adapter Positioning End v2 S70637 ALL-POLY Glenosphere Positioner: Guide Rod .5 🙍 S70638 ALL-POLY Glenosphere Positioner: Impacting Rod S70639 ALL-POLY Glenosphere Positioner: Orienting End 21 S70641 ALL-POLY Glenosphere Adapter Positioning Rod S70610 Glenoid Insert Impacting End Size XS/S - RIGHT S70611 Glenoid Insert Impacting End Size M - RIGHT S70612 Glenoid Insert Impacting End Size L - RIGHT S70613 Glenoid Insert Impacting End Size XL - RIGHT S70614 Glenoid Insert Impacting End Size XS/S - LEFT S70615 Glenoid Insert Impacting End Size M - LEFT S70616 Glenoid Insert Impacting End Size L - LEFT S70617 Glenoid Insert Impacting End Size XL - LEFT S70619 Glenosphere Extractor - Threaded S70620 Glenosphere Adapter Extractor S70621 Humeral Head Extractor S70622 Extractor for Baseplate/PEG assembly S70625 Glenosphere Extractor

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