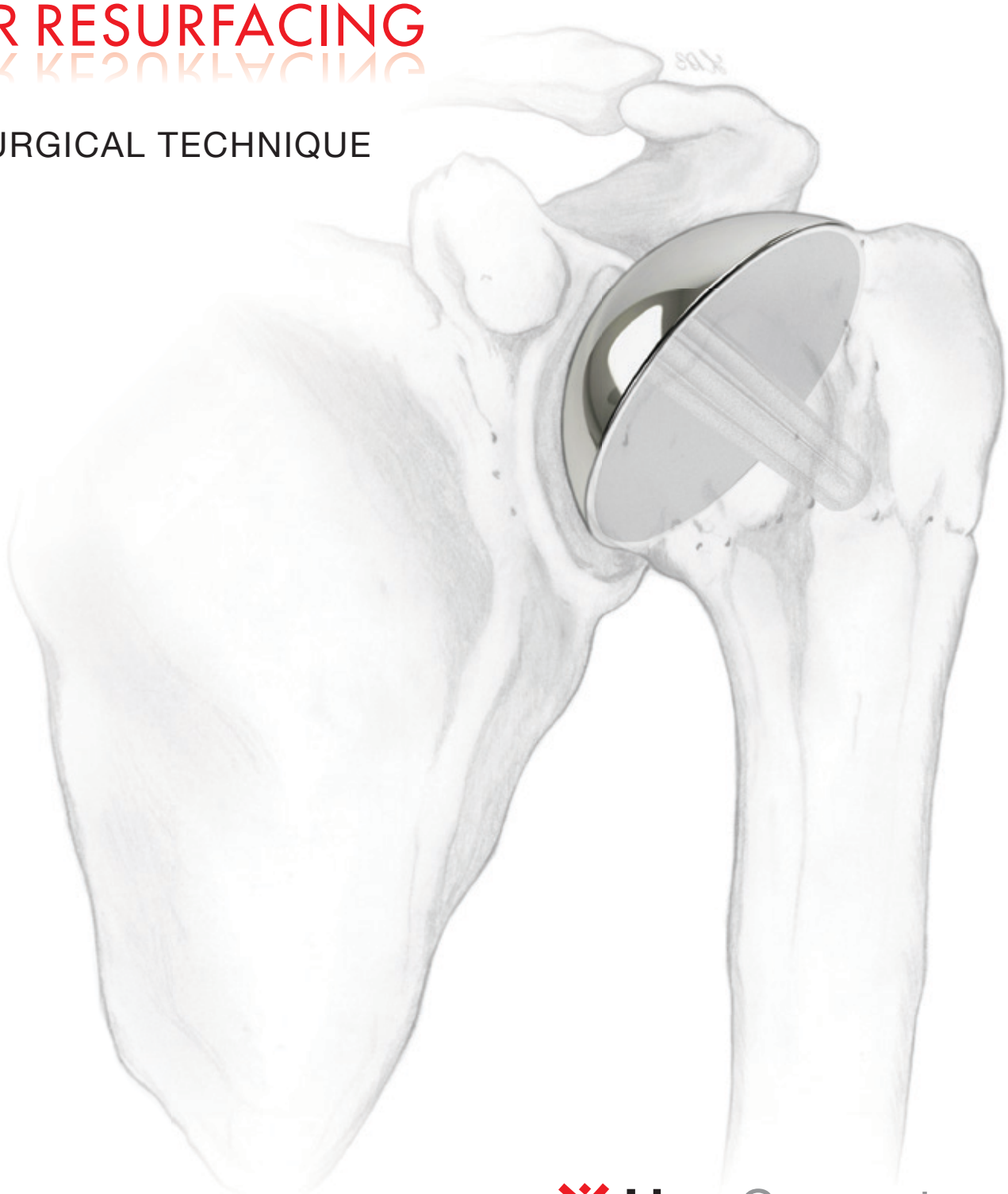
SMR

MODULAR SHOULDER REPLACEMENT

SMR RESURFACING

SURGICAL TECHNIQUE

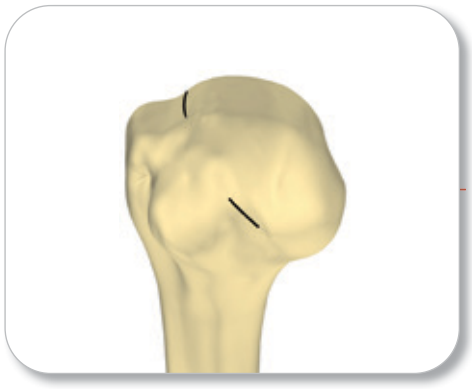


Lima Corporate

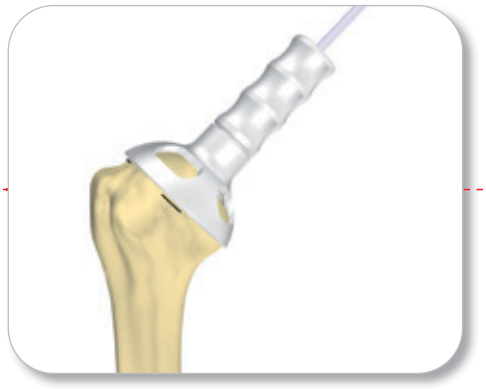
Orthopaedic motion

SMR RESURFACING SURGICAL TECHNIQUE

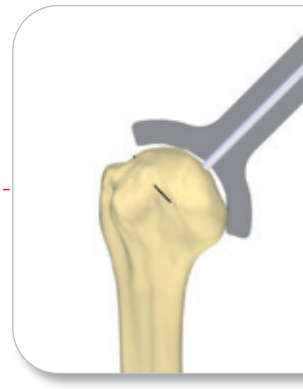
Surgical steps



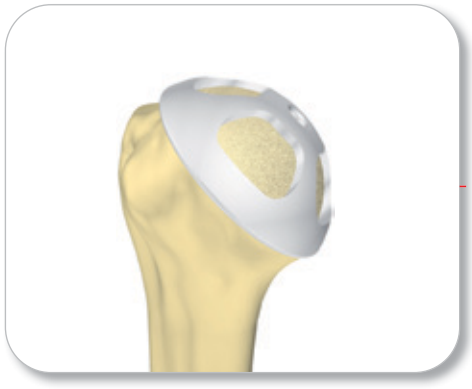
1. Head exposure



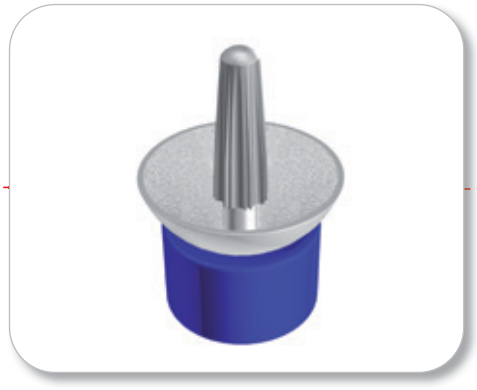
2. Guide wire insertion



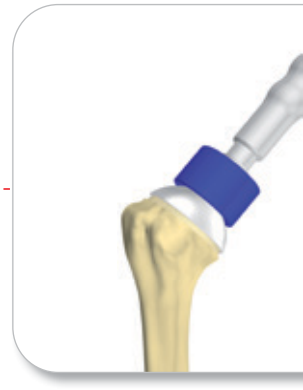
3. Head measurement



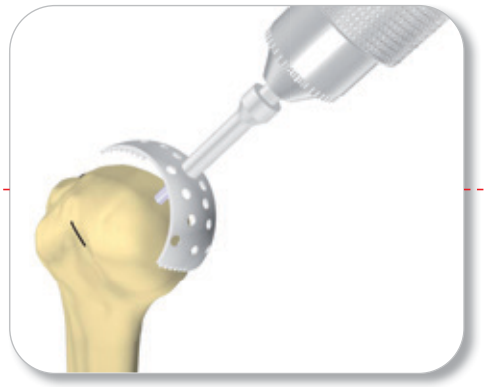
6. Trial head



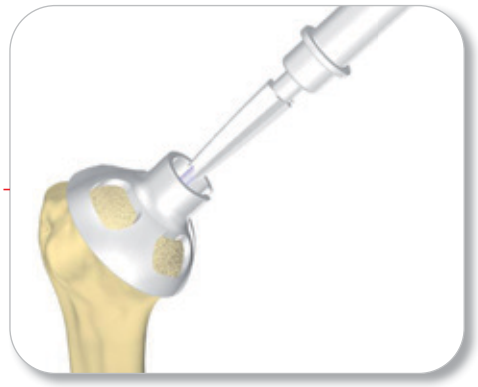
7. Implant preparation



8. Prosthesis implantation

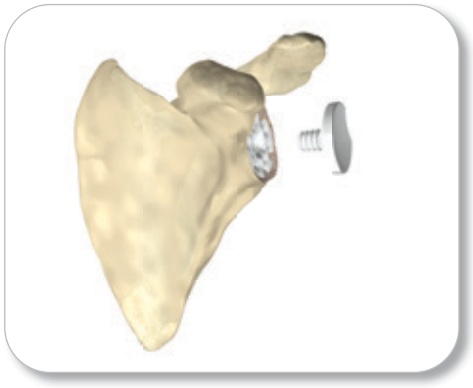


4. Surface reaming



5. Stem reaming

9. In case of CTA head use



10. Cemented or uncemented Glenoid implant *("optional")*

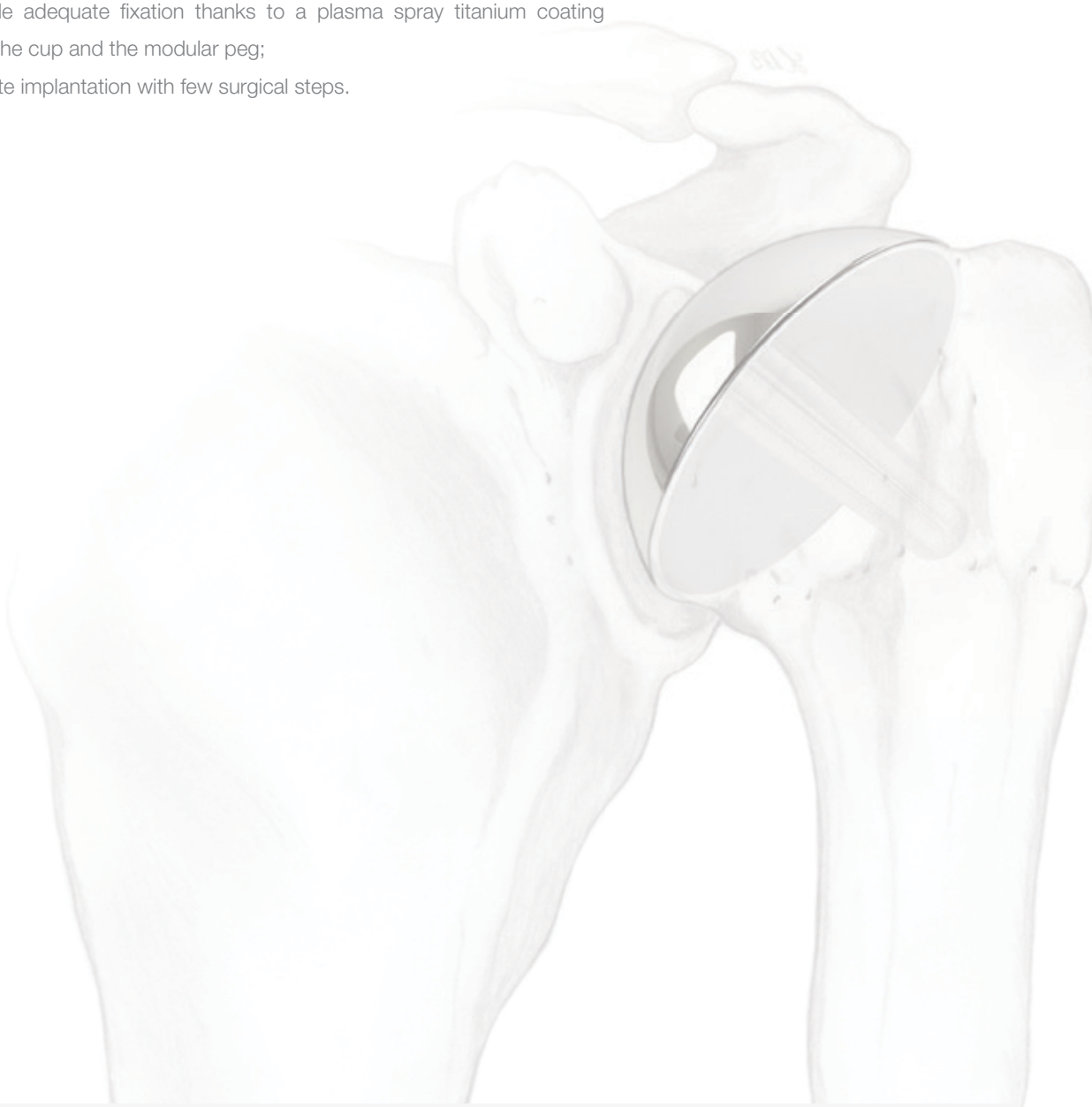
SMR RESURFACING SURGICAL TECHNIQUE
Index

Limacorporate S.p.A., as manufacturer of prosthesis device, does not practice medicine. This surgical technique brochure has been developed in consultation with an experienced surgeons team and provides the surgeon with general guidance when implanting SMR RESURFACING. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training, experience and clinical evaluation of each individual patient. For further information about our products, please visit our web site at www.limacorporate.com

Introduction

The SMR Resurfacing system is a humeral head resufacing option part of our modular system. Since 2004, Lima Corporate has been developing the SMR-R System, based on the following goals:

- To re-establish the natural morphology of the humeral head with minimal bone resection [1];
- To provide adequate fixation thanks to a plasma spray titanium coating beneath the cup and the modular peg;
- To facilitate implantation with few surgical steps.



BIBLIOGRAHY:

[1] Merolla G, Bianchi P, Lollino N, Rossi R, Paladini P, Porcellini G. Clinical and radiographic mid-term outcomes after shoulder resurfacing in patients aged 50 years old or younger. Musculoskelet Surg. 2013 Jun;97(Suppl 1):23-9.

SMR RESURFACING SURGICAL TECHNIQUE
Indications, contraindications and warnings

INDICATIONS

The SMR Resurfacing Shoulder Prosthesis system is indicated for partial or total primary shoulder replacement in skeletally mature patients where the humeral head and neck have sufficient bone stock to support the prosthesis.
The anatomical Standard Resurfacing heads are indicated for partial or total shoulder replacement when the rotator cuff is intact or reconstructable. Specific indications include:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- post-traumatic osteoarthritis;
- rheumatoid arthritis.

The SMR CTA Resurfacing Heads are indicated for partial shoulder replacement in patients with rotator cuff tears and arthritis. Specific indications include:

- Rotator cuff tear arthropathy.

The SMR Resurfacing humeral heads and stems are intended for uncemented use only. In case of total shoulder arthroplasty the glenoid component consists of a cemented all polyethylene glenoid or a cementless metal back assembled with a liner.

Consult instruction for use provided in the product package

CONTRAINDICATIONS

Absolute contraindications include:

1. local or systemic infection;
2. septicaemia;
3. persistent acute or chronic osteomyelitis;
4. confirmed nerve lesion compromising shoulder joint function;
5. deltoid muscle insufficiency.

Relative contraindications include:

- vascular or nerve diseases affecting the concerned limb;
- poor bone stock (for example due to osteoporosis) compromising the stability of the implant;
- metabolic disorders which may impair fixation and stability of the implant;
- any concomitant disease and dependence that might affect the implanted prosthesis;
- metal hypersensitivity to implant materials.

RISK FACTORS

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

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

WARNINGS

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

- In cases with a deficient and unreconstructable rotator cuff, a partial shoulder replacement using a CTA head is indicated.
- The humeral head and neck must have sufficient bone stock to allow fixation of the resurfacing prosthesis. If the surgeon finds intraoperatively that the bone stock is not sufficient for a resurfacing prosthesis, a conventional shoulder arthroplasty should be performed. The surgeon should therefore be prepared to perform an alternative procedure.

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

COMBINATIONS ALLOWED/NOT ALLOWED

The following table identifies the allowed (✓) / not allowed (×) combinations between the SMR Resurfacing Humeral Heads and SMR TT Hybrid Glenoid:

		SMR RESURFACING HUMERAL HEADS DIAMETER (MM)							
		40	42	44	46	48	50	52	54
HYBRID GLENOID SIZE	SMALL LOW	✓	✓	✓	✓	✓	×	×	×
	SMALL	✓	✓	✓	✓	✓	✓	✓	✓
	STANDARD LOW	✓	✓	✓	✓	✓	✓	✓	×
	STANDARD	✓	✓	✓	✓	✓	✓	✓	✓
	LARGE LOW	✓	✓	✓	✓	✓	✓	✓	✓
	LARGE	✓	✓	✓	✓	✓	✓	✓	✓

Anaesthesia and patient positioning

FOREWORD

Lima Corporate, as manufacturer of prosthesis device, does not practice medicine. This surgical technique brochure has been developed in consultation with an experienced surgeon team and provides the surgeon with general guidance when implanting SMR Resurfacing. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional.
Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training, experience and clinical evaluation of each individual patient.

To complete the joint replacement hereby described, a power tool featuring a pin driver, Zimmer-Hudson, and Jacobs connections is required.

PRE-SURGERY PLANNING

Pre-surgery planning using templates is an important step to determine which modular component sizes to use in the operation and the correct position of the prosthesis. Templates are provided in AP view with external rotation. First, place the template of the cephalic component over the shoulder X-rays and make rotational and translational movements along the cervicodiaphyseal axis in order to determine which size, out of those available, is most suitable for head resurfacing. Then, select the size and the anatomical varus / valgus position, carefully preserving any tendon insertions on the greater tuberosity and avoiding the “rasp” effect near the lower rim of the glenoid. Place the stem template alongside the shoulder and determine which of the two sizes available ensures the best filling of the humeral metaphysis. The stem should fill the humeral metaphysis without being in contact with the lateral cortex.

ANAESTHESIA AND PATIENT POSITIONING

The SMR Resurfacing prosthesis can be implanted either under general or local anaesthesia (interscalenic block), or combining both methods. The patient is placed in a horizontal and supine position with legs flexed by 30/40° and the chest slightly lifted (beach chair position) (Fig. 1). The joint must be accessible from the upper and back side of the shoulder. Therefore, it is important to keep the patient’s arm protruding slightly from the cot and to avoid any back supports which lock the joint physiologically.

figure 1

OPTION A – DELTOPECTORAL APPROACH

Perform a skin incision of about 10 cm from the anterior rim of the clavicle and continue towards the distal insertion of the deltoid (Fig. 2). Identify the cephalic vein behind the bicipital groove, isolate the latter from the pectoral muscle and push it laterally after having tied it together to the deltoid fasciae. Slightly release the upper fibers of the large pectoral muscle if a larger exposure of the lower portion of the joint is required. Localize the conjoined tendon of the coracobrachialis and the short head of the biceps; then, use them as a guide to incise the clavipectoral fascia from the upper insertion of the coracoacromial ligament. During the following incisions of the deep fasciae, pay attention to the musculocutaneous and axillary nerves.

Depending on the mobility of the joint in external rotation, determine if a release of the sub scapular muscle tendon portion, or even the detachment of the small tuberosity and its subsequent medial reinsertion, is required.

OPTION B – ANTERO-SUPERIOR "MACKENZIE" APPROACH

The "Mackenzie" approach procedure can be used with SMR Resurfacing products. The skin incision extends distally in a straight line from the acromion for a distance of 9 cm.

The approach courses between the mid and anterior deltoid. The deltoid fibers are split for a distance of more than 6 cm (Fig. 3). The acromial attachment of the deltoid is lifted. The rotator interval is identified and longitudinaly incised along the line of the long head of the biceps to identify the exact insertion of the subscapularis. The subscapularis is held by stay sutures and disinserted. The joint capsule is then released anteriorly and inferiorly while taking care to protect the axillary nerve. The humeral head is anteriorly dislocated using specifics retractors to expose the epiphysis and preserve the postero superior insertion of the rotator cuff.

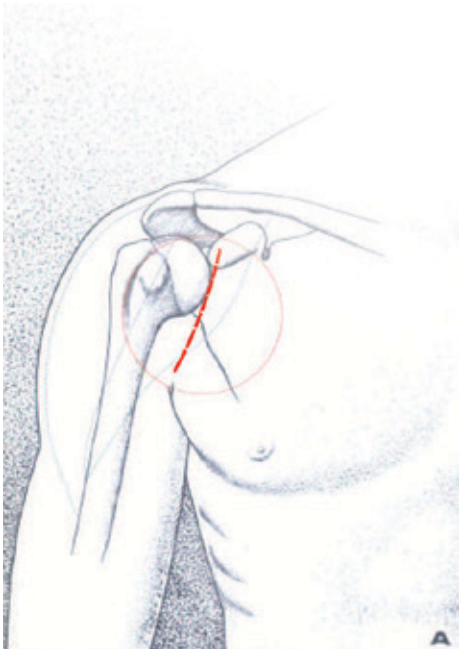


figure 2

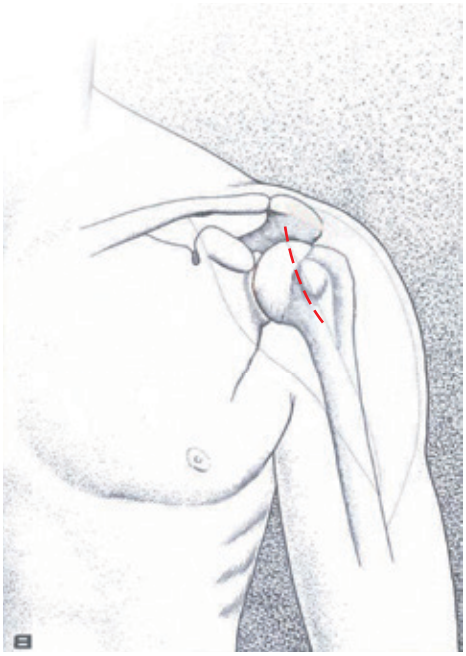


figure 3

Exposure of the Humeral Head & Measurement of the Diameter

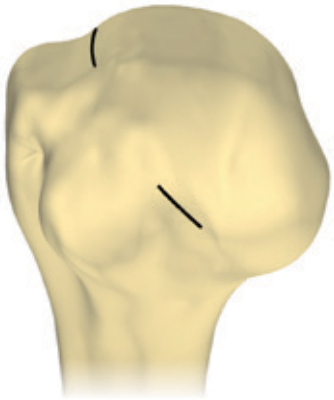


figure 4

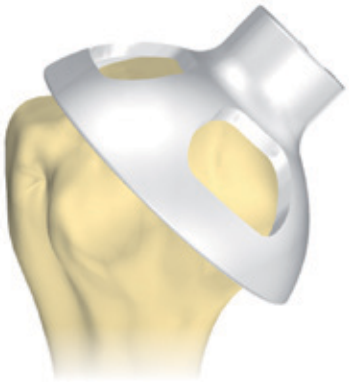


figure 5

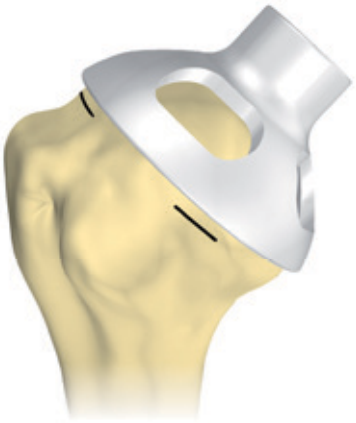


figure 6

EXPOSURE OF THE HUMERAL HEAD

Disengage the humeral head from the glenoid cavity with a soft extension and external rotation of the limb. Use the corresponding retractors to expose the epiphysis and preserve the postero-superior insertion of the rotator cuff. Use a chisel to clean any osteophytes (bone spurs) and mark the contour of the anatomic neck clearly.

Note. The humeral head and neck must have sufficient bone stock to allow fixation of the resurfacing prothesis. If surgeon finds intraoperatively that the bone stock is not sufficient for a resurfacing prosthesis, a conventional shoulder arthroplasty should be performed. The surgeon should therefore be prepared to perform an alternative procedure.

MEASUREMENT OF THE DIAMETER

With an electrosurgical scalpel mark the articular rim of the humeral head (Fig. 4). Use this landmark as a reference to place the *cap (E)* used for head measuring. Take a medium size cap from the instrument set and place it over the bone surface.

Check to what extent the head is contained inside the cap. If the landmarks remain under the cap and are not visible (Fig. 5), replace the cap with a smaller one so that the landmarks made with the electric scalpel remain near the equatorial edge of the selected cap (Fig. 6).

On the other hand replace the cap with a bigger one until the cap's rim matches the landmarks of the humeral head. This procedure is used to position the final prosthesis with the correct cervicodiaphyseal angle and the adequate retroversion.

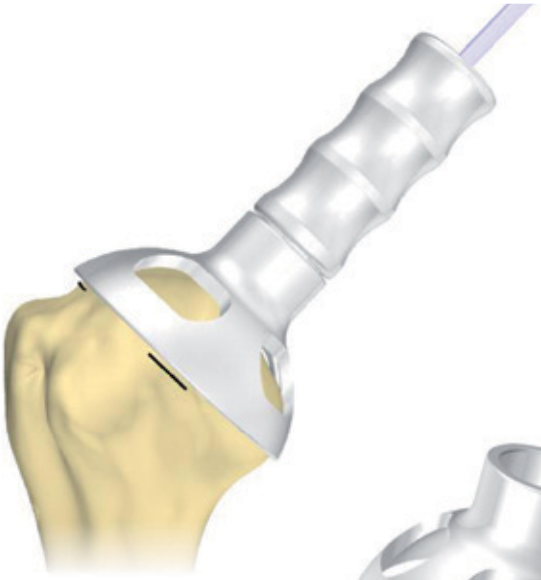


figure 7

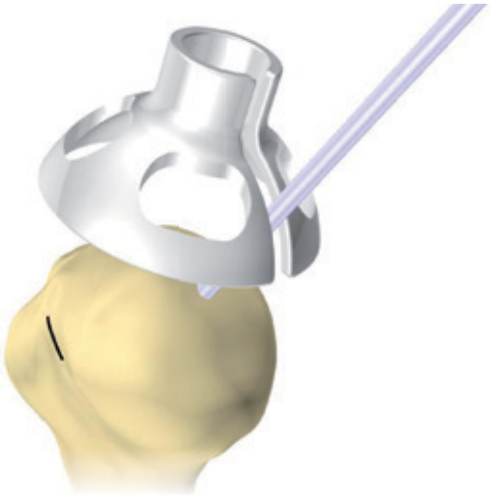


figure 8

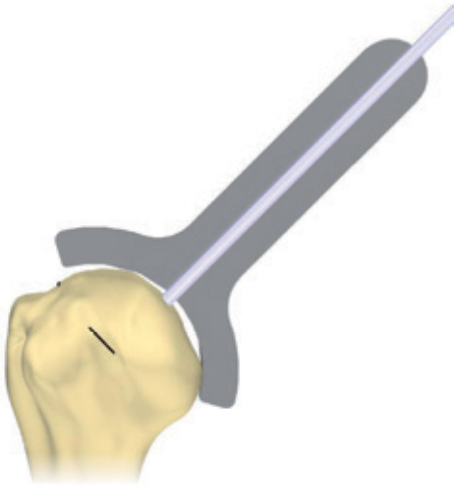


figure 9

INSERTION OF THE GUIDE WIRE

Insert the cannulated *K wire guide (G)* in the upper cavity and, keeping the device tightly in its seat, insert a 3 mm *Kirschner wire (K)* through the hole (Fig. 7). Make sure that the K-wire end does not protrude from the lateral cortex in order to prevent any risk of axillary nerve injury during subsequent steps.

Extract the wire guide and remove the cap by the corresponding slot created along the side (Fig. 8). Insert the measuring *gauge (D)* along the wire until it is in contact with the humeral head. The internal profile of the gauge reproduces exactly the external surface of the prosthetic head, thus indicating the exact component size to be used (Fig. 9).

The procedure will now be guided by the inserted Kirschner wire, and no subsequent corrections are foreseen. Therefore, it is recommended to further check the wire direction and, if it is not inserted correctly, repeat the insertion procedure carefully.

Cephalic Reaming

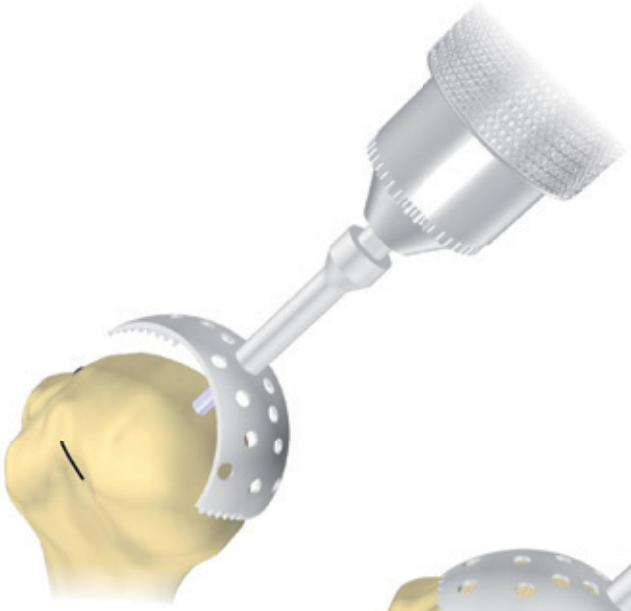


figure 10

figure 11

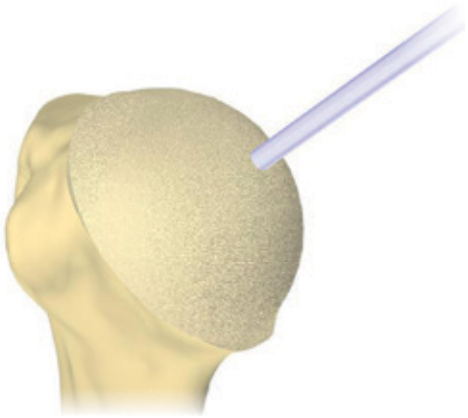


figure 12

CEPHALIC REAMING

Depending on the cap used, take the *spherical reamer (F)* of the previous measured size, connect it to the power tool and mill the bone surface along the guide wire (Fig. 10). The shape of the device, with curved profile and reduced surface, facilitates its insertion in the soft tissues and reduces the overall space needed during the operation. This solution also allows for real-time visualization of the bone tissue removed (Fig. 11).

Proceed with the removal until the anatomic neck is reached (Fig. 12). Take care not to damage the insertions of the cuff in the tuberosities.

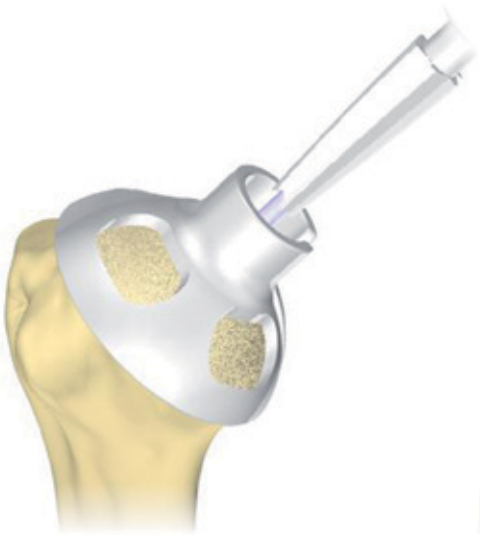


figure 13

figure 14

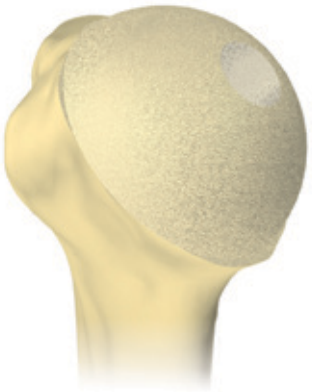


figure 15

BORING OF THE STEM SEAT

The SMR Resurfacing prosthesis includes a press-fit cementless stem complete with longitudinal fins. The star-shaped section of the stem is designed to ensure adequate fixation inside the spongy bone to resist rotation and provide primary stability of the implant. To prepare the anatomic seat, ream it along the guide wire by means of the reamer.

Reposition the *cap (E)* previously used (Fig. 13), then, along the guide wire, insert the 11 or 13 mm *reamer (B)* chosen during the preoperative planning and proceed with the operation until the cutting device collar is in contact with the upper rim of the cap (Fig. 14), hereby used like a stop device. The coring drill shows self centering features against the hole and avoids the need of hand balacing the stop device for the surgeon. Then, remove all instruments used, the guide wire included (Fig. 15).

Trial Prosthesis

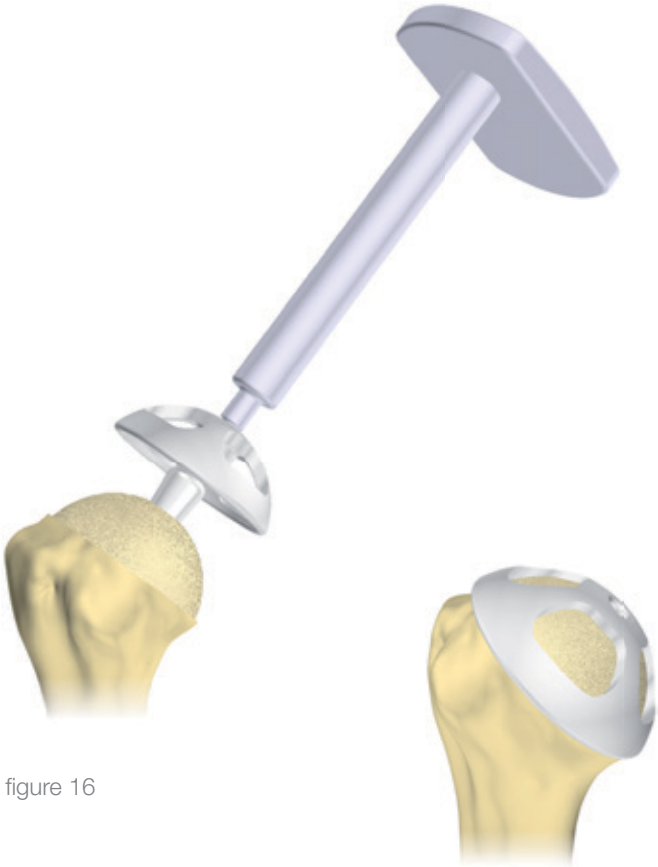


figure 16

figure 17

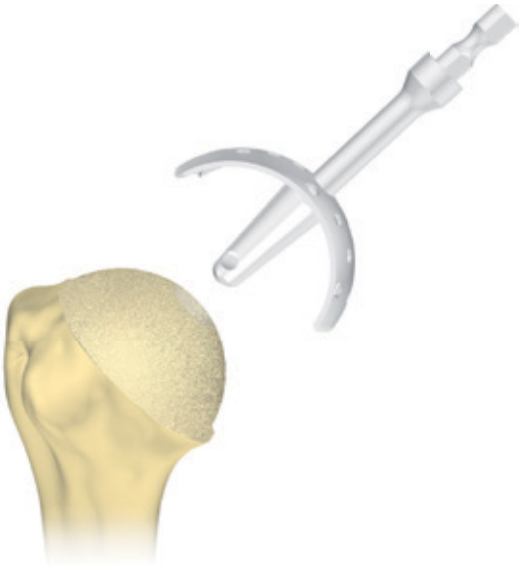


figure 18

TRIAL PROSTHESIS

The trial implant has been designed to determine the fit required by the selected size and the dynamic stability of the new joint, which is verified with the trial reduction.

Screw the *trial stem (A)*, which has a polished finish, to the *trial head (H)* of the pre-determinated size, connect the system to the *stem impactor (C)* and insert it into the stem cavity using an impactor (Fig. 16). Through the slots, make sure that the internal surface of the head is in close contact with the reamed surface and that the external edge of the trial piece is in contact with the bone step created on the anatomic neck (Fig. 17).

If this is not the case, remove the trial prosthesis and ream the surface again using the *spherical reamer (F)* previously used. Screw the trial stem along the axis of the reamer handle near the polar hole, then reinsert it into the cavity using the conical stem as a guide device (Fig. 18).

Perform a humerus reduction on the glenoid cavity and check the articular stability and the tension of the surrounding soft tissues.

If the surgeon has decided to perform a total shoulder arthroplasty refer to the "SMR PRIMARY" surgical technique. Glenoid preparation of a total resurfacing shoulder replacement is carried out after the humeral head has been prepared and before insertion of the final humeral prosthesis.

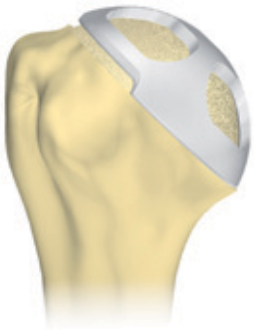


figure 19

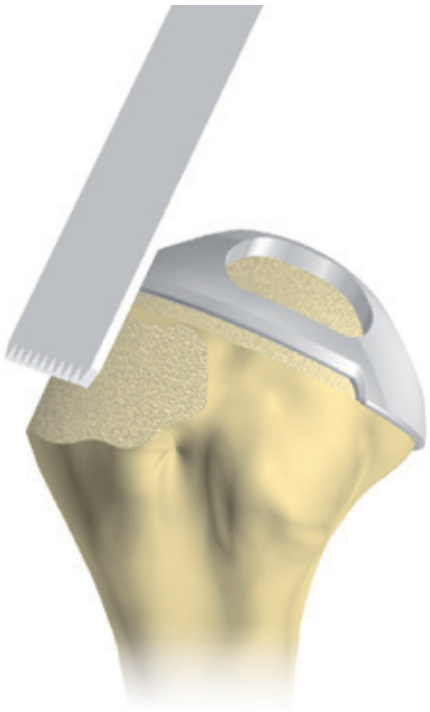


figure 20a

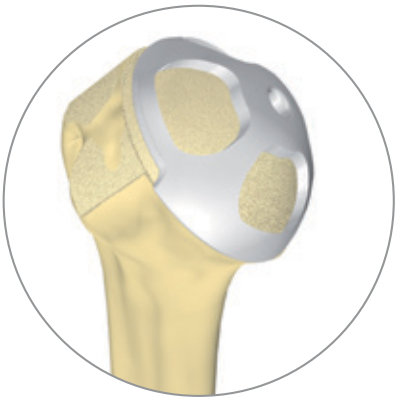


figure 20b

USE OF THE CTA HEAD

To implant an SMR Resurfacing prosthesis in cuff arthropathies involving eccentricity, a CTA head with lateral extension is required. The CTA head resurfaces the greater tuberosity and, therefore, requires removal of additional bone tissue. The trial heads (dia. 42, 46, 50 and 54 mm) have a contour depression near the lateral extension of the head (Fig. 19).

Use an oscillating blade to remove the bone tissue near that area until a curved osteotomy plane is created (Fig. 20a-20b).

During this surgical operation take care not to damage the sub scapularis insertion (if present). Remove the trial head, here used as a guide for the cutting device, and assemble a trial implant with a *trial CTA head (l)* of the chosen size. Impact it on the epiphysis and proceed with the trial reduction.

Final Prosthesis

figure 21

figure 22

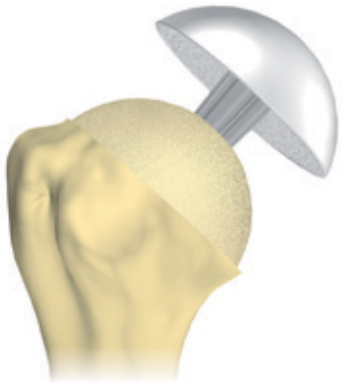


figure 23

FINAL PROSTHESIS

From the sterile packages take the stem and the head of the selected sizes. The components are coupled conically. Unscrew the plastic portion of the *humeral head impactor (J)* and use it as a support for the head. Lean the component on the support and forcibly insert the stem end onto the peg (Fig. 21-22); protect the upper end with a gauze, then impact it with a hammer.

Expose the humeral head so that the proximal end of the humerus can be accessed by the surgeon.

Remove the trial prosthesis, then insert the flanged pin into the hole (Fig. 23). Hit the head with the *humeral head impactor (J)* until the space between the perimetric rim of the cephalic component and the reamed rim of the humerus bone surface is eliminated (Fig. 24). This way the complete insertion is ensured and secondary integration of the implant is facilitated.

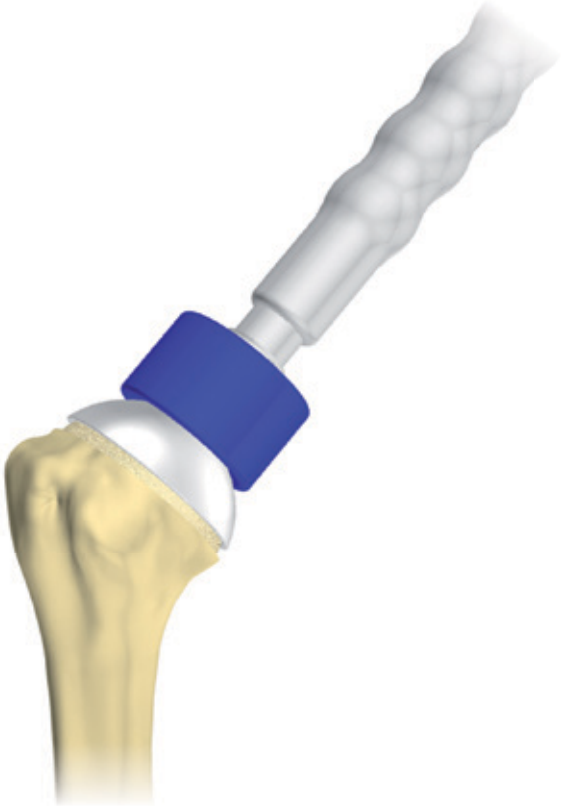


figure 24

EXTRACTION OF THE IMPLANT

Indications for revision may include infection, glenoid wear, implant loosening or dislocation. In some cases, removal of the implant may be required during revision surgery.

Expose the humerus as previously described. Use a saw to cut the periphery of the humerus at the bone-implant junction. The implant and the contained bone can then be removed together.

Attention: after this procedure only a stemmed, traditional shoulder implant can be used.

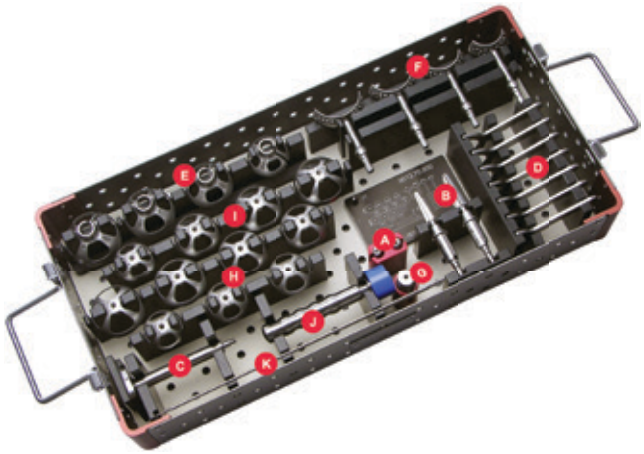
CLOSURE

Repair the tendon-muscle insertion of the sub scapularis according to the techniques used for its detachment (partial release or complete detachment). Once this operation is completed, check the joint space so that the angle reached by the arm in external rotation is 30° at the lowest.

Then suture the rotator interval according to the post operative joint stability. Perform a radiograph to view the final position of the prosthesis.

SMR RESURFACING SURGICAL TECHNIQUE
Instrument set

9013.70.000 SMR Resurfacing Instrument Set



Ref.	CODE	DESCRIPTION	Qt.
A	9013.17.010	Trial Stem Dia. 11 mm	1
A	9013.17.020	Trial Stem Dia. 13 mm	1
B	9013.17.110	Reamer Dia. 11 mm	1
B	9013.17.120	Reamer Dia. 13 mm	1
C	9013.17.300	Stem Impactor	1
D	9013.27.042	Gauge Dia. 42 mm	1
D	9013.27.044	Gauge Dia. 44 mm	1
D	9013.27.046	Gauge Dia. 46 mm	1
D	9013.27.048	Gauge Dia. 48 mm	1
D	9013.27.050	Gauge Dia. 50 mm	1
D	9013.27.052	Gauge Dia. 52 mm	1
D	9013.27.054	Gauge Dia. 54 mm	1
E	9013.27.142	Cap Dia. 42-44 mm	1
E	9013.27.146	Cap Dia. 46-48 mm	1
E	9013.27.150	Cap Dia. 50-52 mm	1
E	9013.27.154	Cap Dia. 54 mm	1
F	9013.27.242	Spherical Reamer Dia. 42-44 mm	1
F	9013.27.246	Spherical Reamer Dia. 46-48 mm	1
F	9013.27.250	Spherical Reamer Dia. 50-52 mm	1
F	9013.27.254	Spherical Reamer Dia. 54 mm	1
G	9013.27.200	K. Wire Guide	1
H	9013.27.420	Trial Head Dia. 42 mm	1
H	9013.27.440	Trial Head Dia. 44 mm	1
H	9013.27.460	Trial Head Dia. 46 mm	1
H	9013.27.480	Trial Head Dia. 48 mm	1
H	9013.27.500	Trial Head Dia. 50 mm	1
H	9013.27.520	Trial Head Dia. 52 mm	1
H	9013.27.540	Trial Head Dia. 54 mm	1
I	9013.28.420	Trial CTA Head Dia. 42 mm	1
I	9013.28.460	Trial CTA Head Dia. 46 mm	1
I	9013.28.500	Trial CTA Head Dia. 50 mm	1
I	9013.28.540	Trial CTA Head Dia. 54 mm	1
J	9075.10.120	Humeral Head Impactor	1
K	9084.45.010	Calibrated Kirschner Wire	2
	9013.70.950	Sterilizable Box	1

RESURFACING STEMS

Ti6Al4V	1317.15.010	Dia. 11 L 32 mm
	1317.15.020	Dia. 13 L 36 mm

RESURFACING HEADS

CoCrMo+ PoroTi +HA	1327.11.400	Dia. 40 mm	■
	1327.11.420	Dia. 42 mm	
	1327.11.440	Dia. 44 mm	
	1327.11.460	Dia. 46 mm	
	1327.11.480	Dia. 48 mm	
	1327.11.500	Dia. 50 mm	
	1327.11.520	Dia. 52 mm	
	1327.11.540	Dia. 54 mm	

RESURFACING HEADS FDA

CoCrMo+ PoroTi	1327.10.400	Dia. 40 mm	■
	1327.10.420	Dia. 42 mm	
	1327.10.440	Dia. 44 mm	
	1327.10.460	Dia. 46 mm	
	1327.10.480	Dia. 48 mm	
	1327.10.500	Dia. 50 mm	
	1327.10.520	Dia. 52 mm	
	1327.10.540	Dia. 54 mm	

RESURFACING CTA HEADS

CoCrMo+PoroTi+HA	1328.11.420	Dia. 42 mm
	1328.11.460	Dia. 46 mm
	1328.11.500	Dia. 50 mm
	1328.11.540	Dia. 54 mm

RESURFACING CTA HEADS FDA

CoCrMo+PoroTi	1328.10.420	Dia. 42 mm
	1328.10.460	Dia. 46 mm
	1328.10.500	Dia. 50 mm
	1328.10.540	Dia. 54 mm

■ Upon Request

Notes

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Notes

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