

Tornier BIO-RSA[®] Angled

Operative technique



Disclaimer

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Important

The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.

- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing.
- Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (ifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Tornier BIO-RSA Angled

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Concept

Bony increased offset RSA (BIO-RSA Angled)

**The BIO-RSA is a biologic lateralization of glenoid component.
Bony Lateralization.**



Operative technique

Pre-operative planning

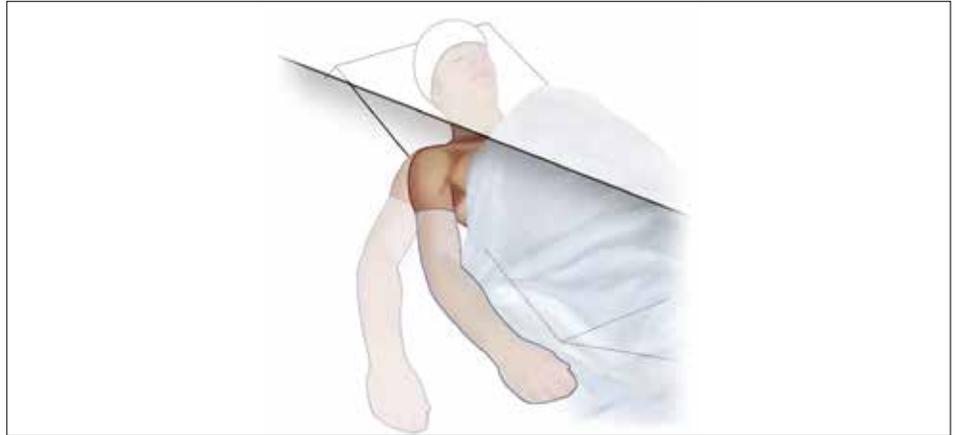
Pre-operative planning is performed using X-ray templates of known magnification on the frontal and sagittal views. Appropriate implant size and positioning are then determined. The use of a CT scan or MRI is recommended to determine the orientation of the glenoid and the quality of its bone stock. X-ray templates allow the surgeon to assess:

- The size and the optimal length of the gleno-humeral implants.
- The diameter of the metaphysis, the insert, and the glenoid sphere.

The final decision should be taken preoperatively.

Patient positioning

Beach chair position with the shoulder positioned sufficiently lateral to allow full arm extension. The patient is vertically inclined depending on the chosen surgical approach.



Operative technique

Humeral exposure

Delto-pectoral approach

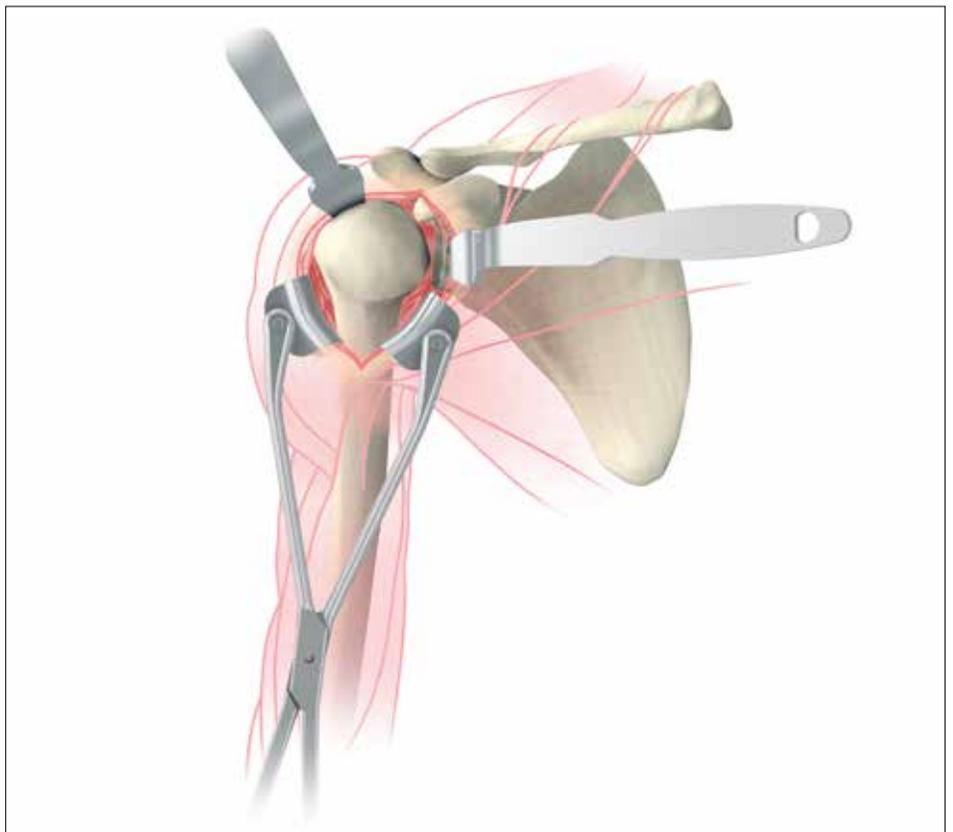
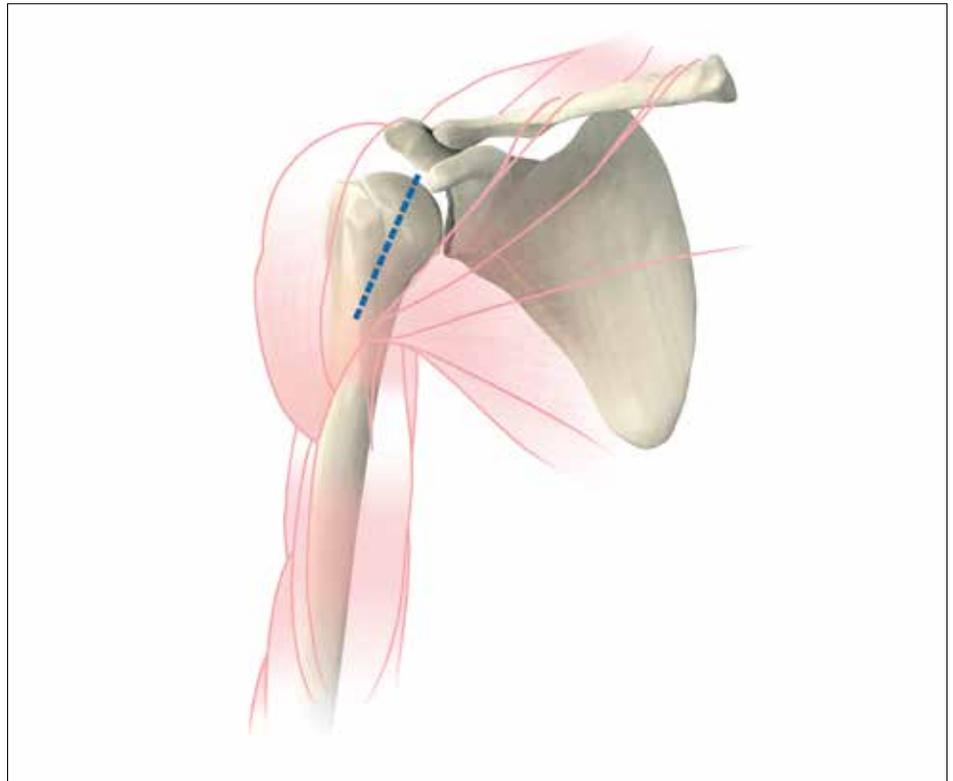
An incision is made from the tip of the coracoid along the delto-pectoral groove, slightly lateral to the axillary fold. The pectoralis major is identified. The deltoid and cephalic veins are retracted laterally to open the delto-pectoral groove.

The coracoid process is identified. A Hohmann retractor is positioned behind the coracoid. Care should be taken to preserve the origin and insertion of the deltoid.

The clavi-pectoral fascia is incised at the external border of the coraco-brachialis. The axillary nerve is then identified before opening the subscapularis.

As the arm is externally rotated, a conservative anterior and inferior capsule release from the humerus to the glenoid may be performed.

With adequate releases, the humeral head is then dislocated into the delto-pectoral interval by abduction of the arm and progressive external rotation and extension. In cases of severe restriction of external rotation (0° or less), it is recommended to release more of the upper pectoralis insertion.



Operative technique

Humeral preparation

Pin positioning

NOTICE

The specific pin guide is placed first prior to use standard Aequalis Reversed cutting guide!

Place the pin guide onto the humeral head with the handle inline with the humeral shaft.

To define the prosthetic retroversion, a retroversion rod is positioned into one of the appropriate holes along the axis which allows for retroversion between 0° and 20° (“R” for right arm and “L” for left arm).

The pin guide is turned until the retroversion rod is aligned with the patient’s forearm or the desired location.

The pin guide will create 145° of inclination and establish the desired retroversion.

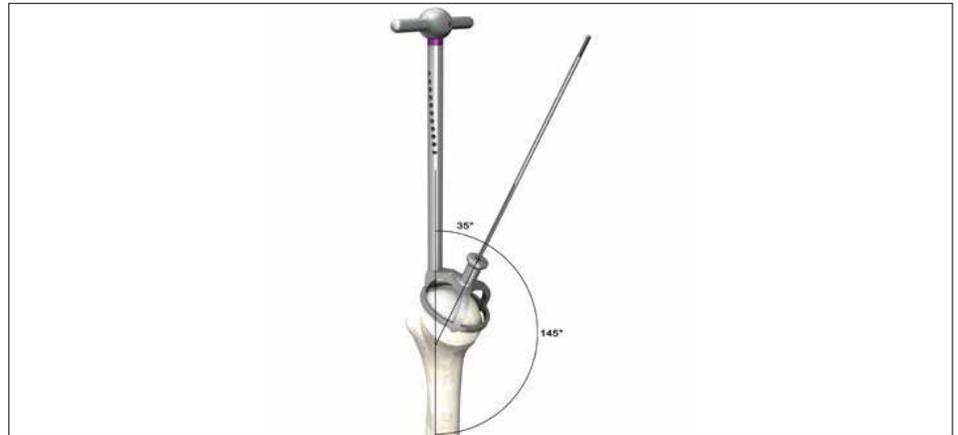


Fig. 1

Once the humeral head pin guide is properly placed, a 2.5mm alignment pin is placed through the top of the humeral head pin guide (fig. 1). Once the alignment pin is placed the humeral pin guide is then removed. A final check should be performed to ensure the pin is properly placed. Additionally, it is important that the alignment pin remains straight throughout the surgical procedure. If bent or damaged the alignment pin should be replaced.

Operative technique

Graft reaming

The Angled BIO-RSA graft reamer allows to ream while performing the central hole at the same time thanks to the 2-in-1 instrumentation (fig. 2).

NOTICE

That the Angled BIO-RSA graft reamer will harvest only a 29mm bone graft and reaming should stop once good quality bone is encountered.

Additionally, it is ideal to ream until a flat surface is created and free from articular cartilage (fig. 3).

In instances of hard bone, the 29mm cannulated flat glenoid reamer may be used prior to the graft reamer to remove the articular cartilage and hard bone. The bone graft is then completed using the Angled BIO-RSA graft reamer.

The reamer is removed leaving the alignment pin in place (fig. 4).



Fig. 2



Fig. 3



Fig. 4

Operative technique

Cutting the graft

Once the alignment pin is removed the appropriate humeral cutting guide is selected based on the size of the humerus. Four cutting guides exist with a 12.5° cut (large/medium and right/left) within the instrumentation of the Angled Bio-RSA (fig. 5).

NOTICE

The cutting guides are designed with a single slot, offering an asymmetrical 12.5° cut.

It is important to ensure the humeral cutting guide covers the entire humerus while minimizing the gap between the cut guide and bone. To position the cut guide, align the bottom of the cut guide with the edge of the graft created by the graft reamer.

The graft is resected using an oscillating saw through the cut slot (fig. 6).

The slot is designed to accommodate a 0.8mm thick blade. In order to perform a complete cut the length of the blade should be at least 75mm.



Fig. 5



Fig. 6

CAUTION

Caution should be taken to ensure the proper window is selected prior to making the cut. Failure to select the correct size may impact the ability to reduce the prosthesis.

Operative technique

Graft extraction

The bone graft may be contained within the humeral cutting guide upon removal. The bone graft remover is then used to safely remove the bone graft from the cutting guide. Be sure to note the difference in thickness of one of the extensions used to remove the graft. This extension must be oriented toward the cut slots in order to advance (fig. 7). Once removed the graft should be inspected to ensure the bone quality is adequate for use with the Angled BIO-RSA technique. The Angled BIO-RSA technique should never be used with poor quality bone, as it may compromise bone healing. A standard Reversed technique should be used in patients with poor bone quality.



Fig. 7

Metaphyseal diaphyseal preparation

NOTICE

Refer to the standard Reversed or Reversed II or Tornier Flex Shoulder system operative technique for humeral (metaphyseal/diaphyseal) reaming.

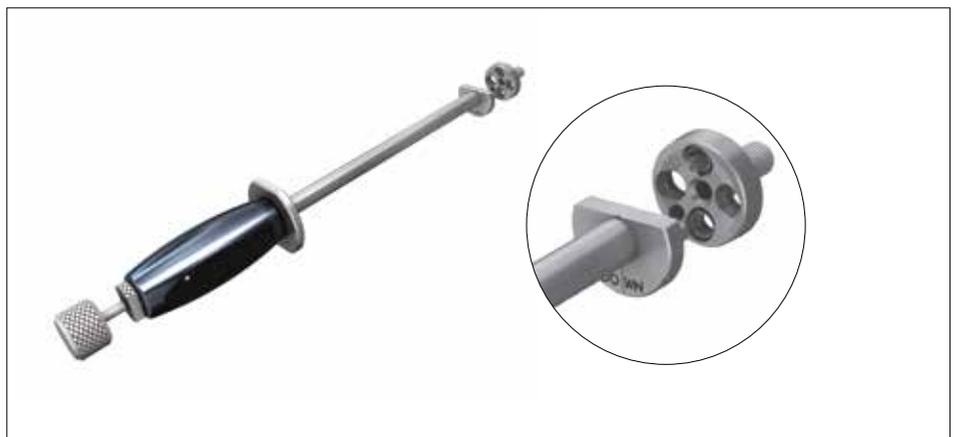


Fig. 8

Glenoid preparation

Assembling of the baseplate

NOTICE

Use only a 29mm long post baseplate with the graft.

The glenoid baseplate is attached to the baseplate impactor through its central hole using a screw in the impactor central shaft (fig. 8).

Care should be taken to ensure that the two pegs on the impactor seat properly into their respective holes on the implant baseplate (fig. 9).

NOTICE

There is no baseplate trial.

Operative technique

Graft preparation

NOTICE

It is important to use the long post baseplate for Angled BIO-RSA technique. The pure cancellous bone graft harvested from the humerus is then inserted onto the long post baseplate until it reaches the posterior surface of the baseplate (fig. 10).

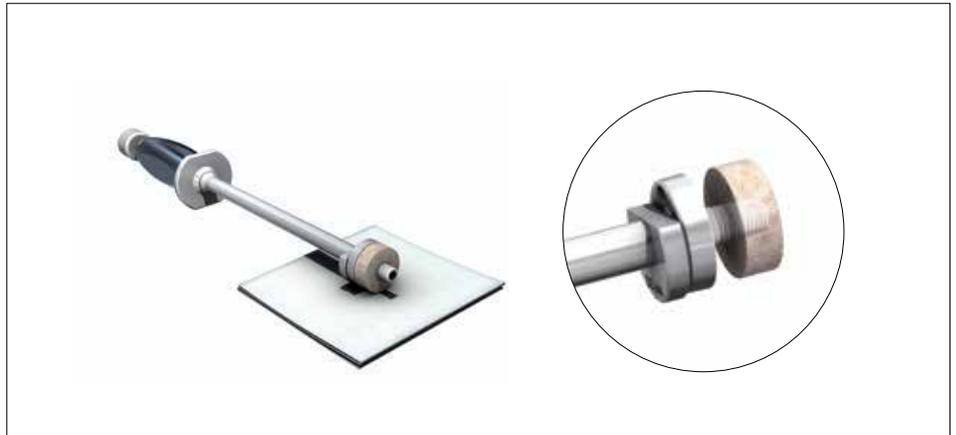


Fig. 10

In case of an asymmetrical bone graft, a mark may be drawn with a sterile pencil to orient. The graft is inserted onto the baseplate in a direction that best accommodates the surface of the glenoid.

NOTICE

During the glenoid preparation. The surgeon may consider keeping the baseplate with the bone graft on the back table in a wet sponge.

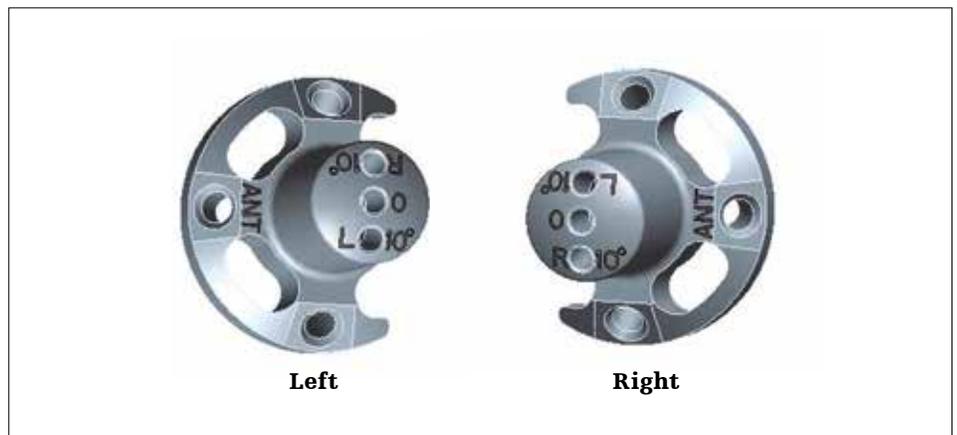


Fig. 11

Glenoid pin alignment

The glenoid is prepared using the same drilling and reaming technique as a Reversed procedure. When using a cannulated approach, a 0° or 10° tilt can be applied using the glenoid pin guide.

To create more compression on the graft a 10° inferior tilted is preferred to increase bone graft integration. This guides are left and right specific (fig. 11).

NOTICE

The 36mm and 42mm peripheral glenoid reamers are no longer necessary.

Operative technique

Glenoid reaming

To obtain proper seating and secure fixation of the glenoid baseplate, it's important to prepare a flat surface on the glenoid.

A circular cannulated reamer, to the same diameter as the prepared Angled BIO-RSA graft, is available, that will prepare the glenoid bone (fig. 12).

Connect the 29mm reamer to power, slide the assembly onto the guide pin and ream (fig. 13).

It is recommended to start the reamer before contacting the glenoid surface and ream until the glenoid surface is flat.

If insertion of reamer is difficult, remove or reposition retractors for greater exposure. A T-handle is available if manual reaming is preferred.

It is desirable to preserve as much bone as possible to support proper primary fixation.

It is believed that the glenoid surface must be cancellous and/or bleeding to optimize the chances of bone healing.

If the guide pin is damaged or bent, use a new guide pin.



Fig. 12



Fig. 13

NOTICE

The peripheral glenoid ream step (36mm or 42mm) is not required for the BIO-RSA technique.

Operative technique

Glenoid central hole drilling

Remove the guide pin.

Position the glenoid pin guide onto the reamed surface and position the guide pin through the 10° hole.

The guide pin must go through the same hole that has been previously used with the first guide pin positioning (fig. 14).

The glenoid central hole is enlarged using the 7.5mm cannulated drill bit to enable a press-fit when impacting the final glenoid base plate (the baseplate central post is 8mm diameter).

Select the appropriate drill bit and connect it to power. Slide the assembly onto the guide pin and drill the central hole until the stop contacts the bone (fig. 15).

Remove the drill bit.

Remove the guide pin using power (fig. 16).

NOTICE

Once the glenoid surface has been prepared, small drill holes should be made at the periphery of the glenoid face to obtain a bleeding surface.

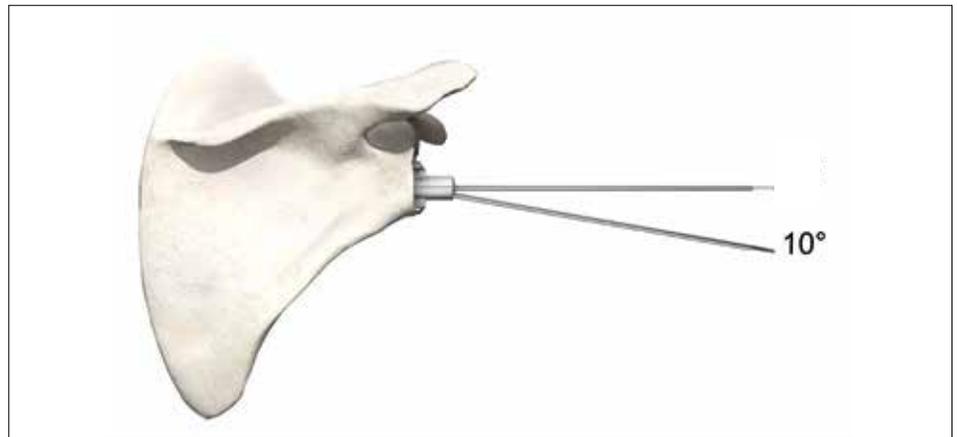


Fig. 14



Fig. 15



Fig. 16

Operative technique

Glenoid bone graft and baseplate fixation

The baseplate and bone graft construct is impacted into the central drill hole. Upon impaction, it is important to verify that the baseplate is fully seated against the glenoid. Additionally, the distal portion of the baseplate post must be within native glenoid bone (fig. 17).

The remainder of the Reversed procedure is completed as outlined in the surgical guidelines (fig. 18).

NOTICE

Consideration should be given to the orientation of the screws in order to avoid protrusion through the outside wall of the graft.

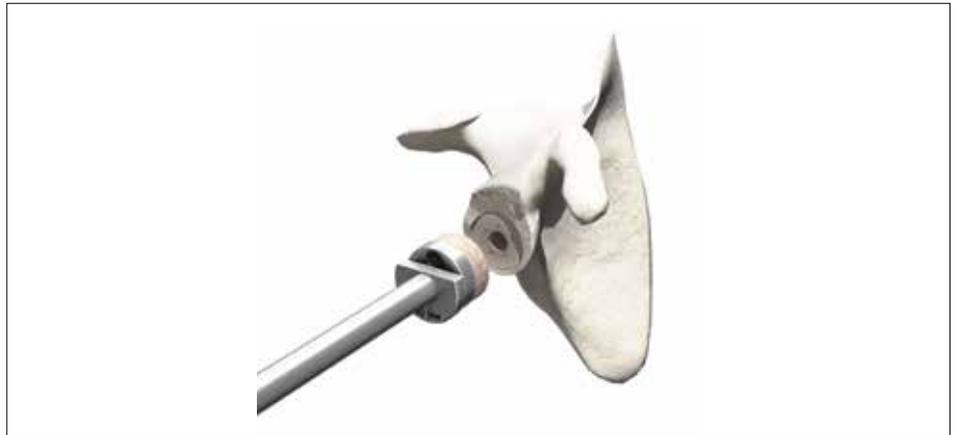


Fig. 17



Fig. 18

Glenoid sphere implantation reduction and closure

The rest of the procedure is exactly the same as the standard Reversed procedure (fig. 19).

NOTICE

A centered standard sphere should be chosen when using the BIO-RSA.

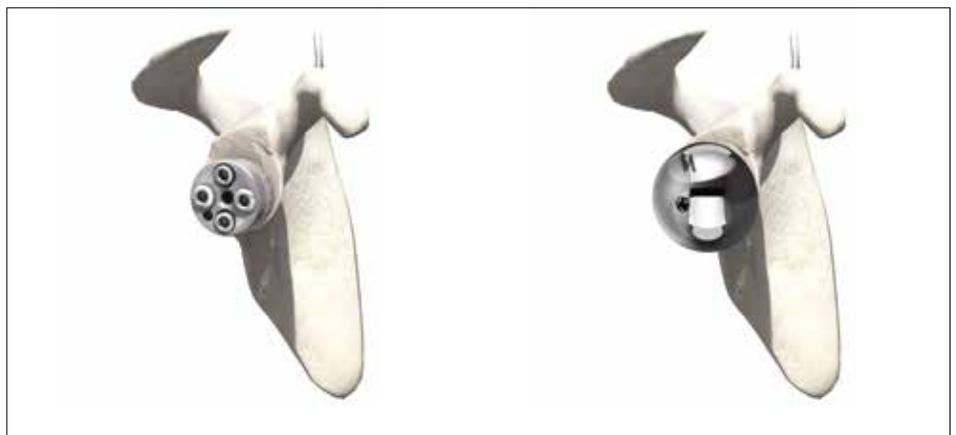
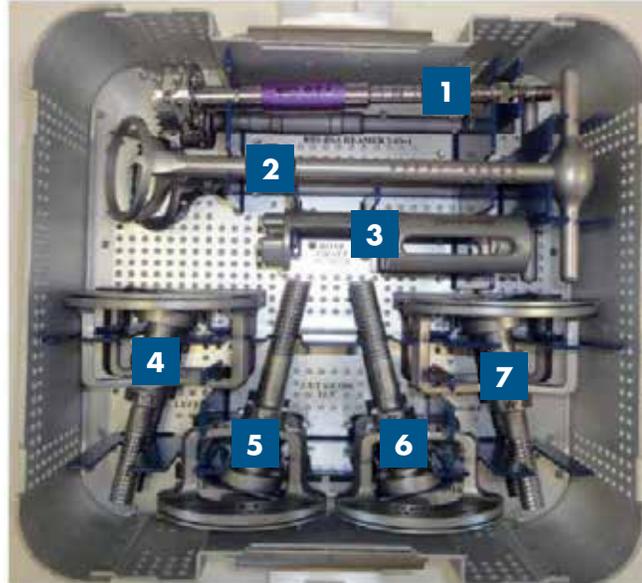


Fig. 19

System components



Box BIO-RSA Angled

YKAD237

Item	Ref #	Description
1	MWF702	BIO-RSA reamer 3 in 1
2	MWF701	Humeral pin guide 145°
3	MWF707	Bone graft pusher
4	MWF704	Cutting guide 12.5 - left - medium size
5	MWF703	Cutting guide 12.5 - left - small size
6	MWF705	Cutting guide 12.5 - right - small size
7	MWF706	Cutting guide 12.5 - right - medium size
Storage	YRAD237	Box / base
	NCR237	Box lid

Notes

Notes

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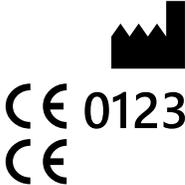
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