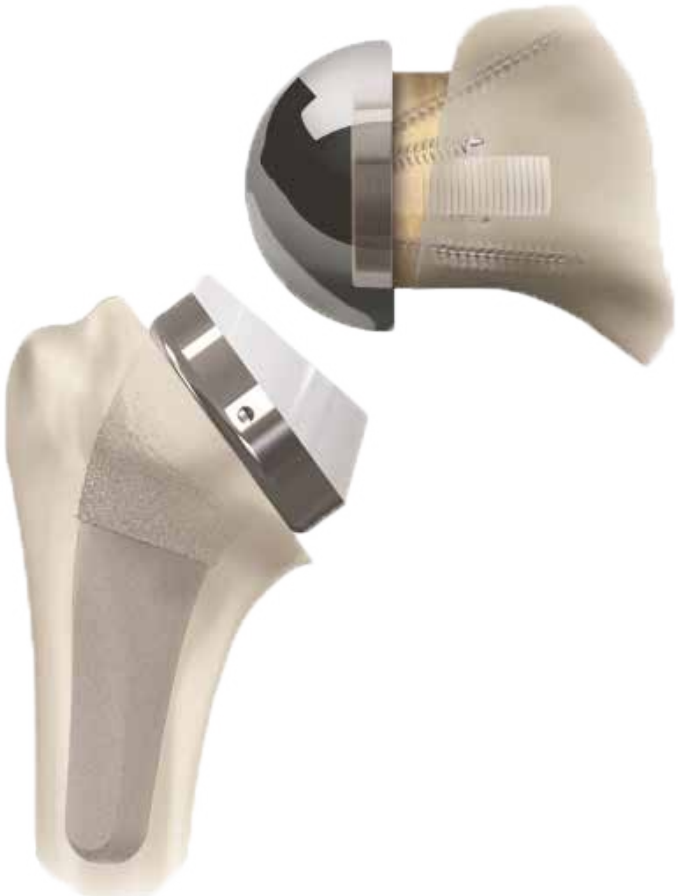
stryker

Tornier BIO-RSA®

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

Contents

Concept

Bony increased offset reversed shoulder arthroplasty (BIO-RSA) concept

⚠ WARNING

BIO-RSA operative technique is not recommended to be used in cases of: severe glenoid bone deficiency, not autologous humeral head bone graft, humeral head necrosis, revision of failed hemi or total arthroplasty and humeral head fractures.

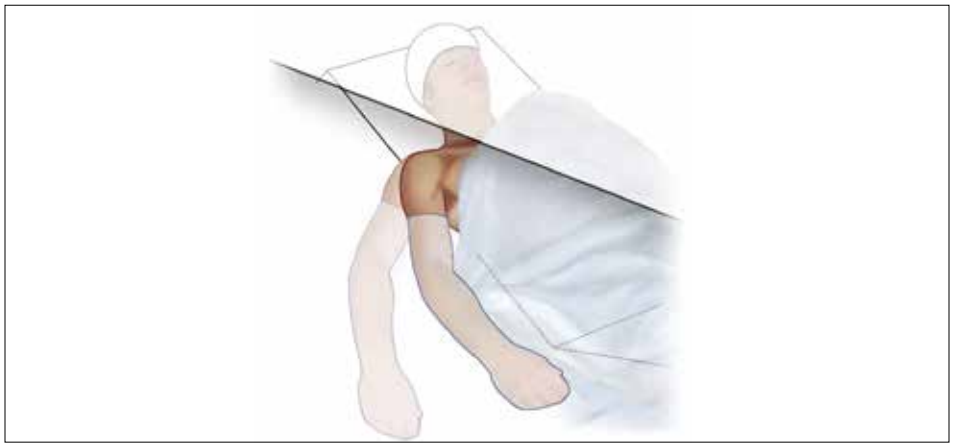
Operative technique

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

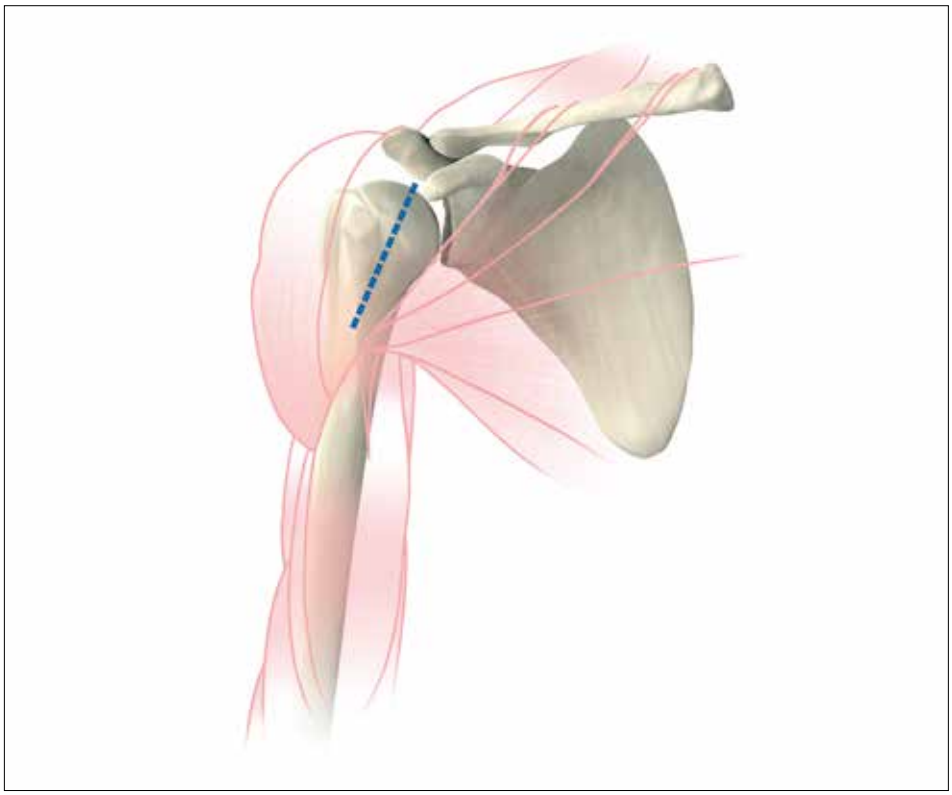
Delto-pectoral approach

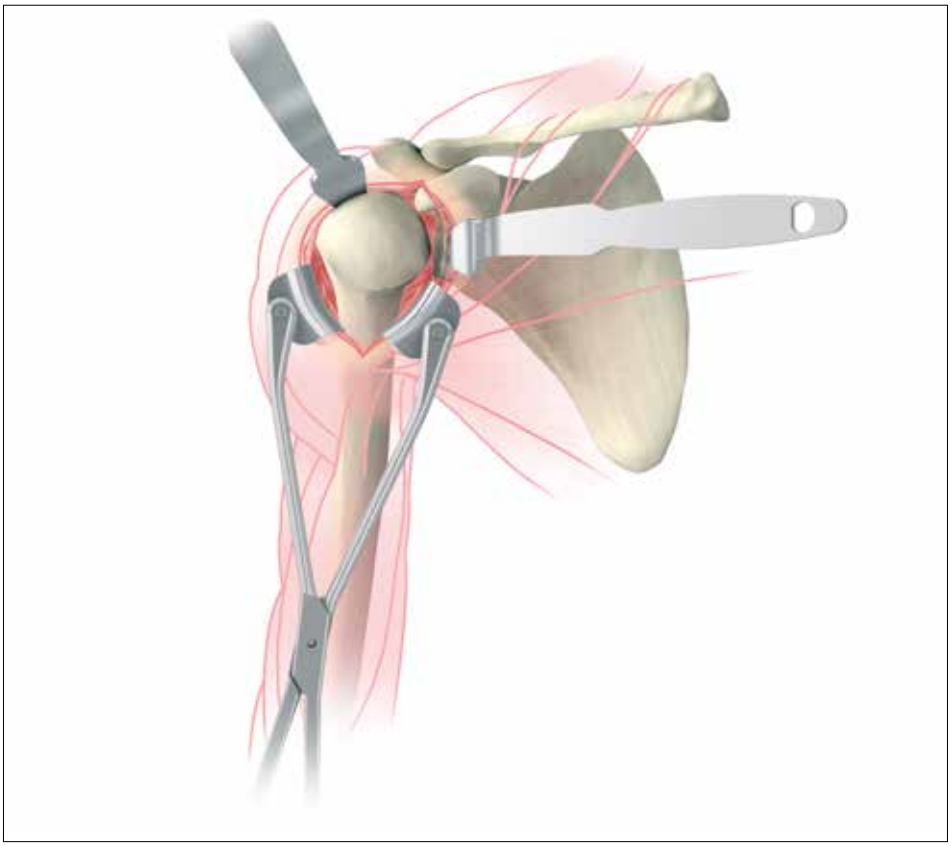
An incision is made from the tip of the coracoid along the delto-pectoral groove, slightly lateral to the axillary fold. The pectoralis major is identified. The deltoid and cephalic veins are retracted laterally to open the delto-pectoral groove.

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 (fig. 1).
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 25° („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 155° of inclination and establish the desired retroversion.

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. 2). The humeral pin guide will be removed after placing the alignment pin (fig. 3). 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 alignement pin should be replaced.

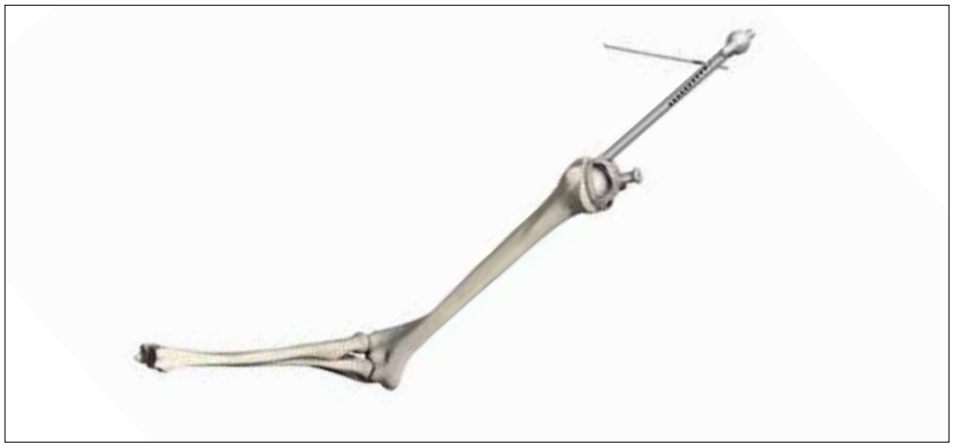


Fig. 1

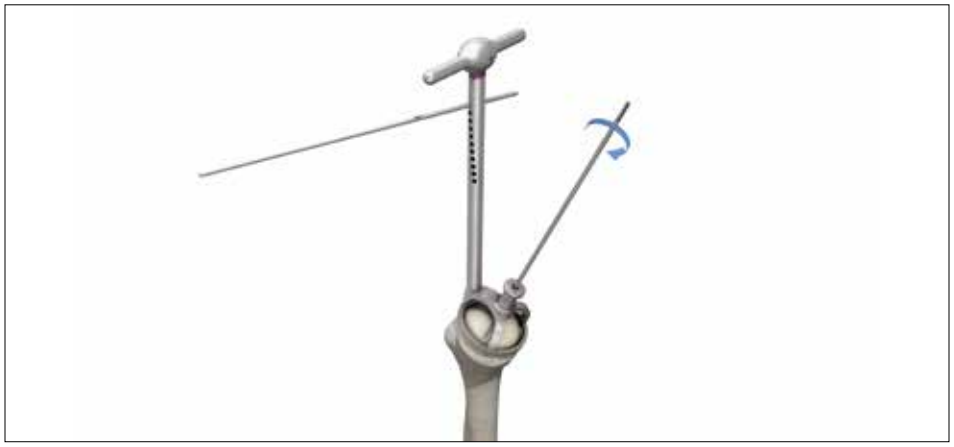


Fig. 2

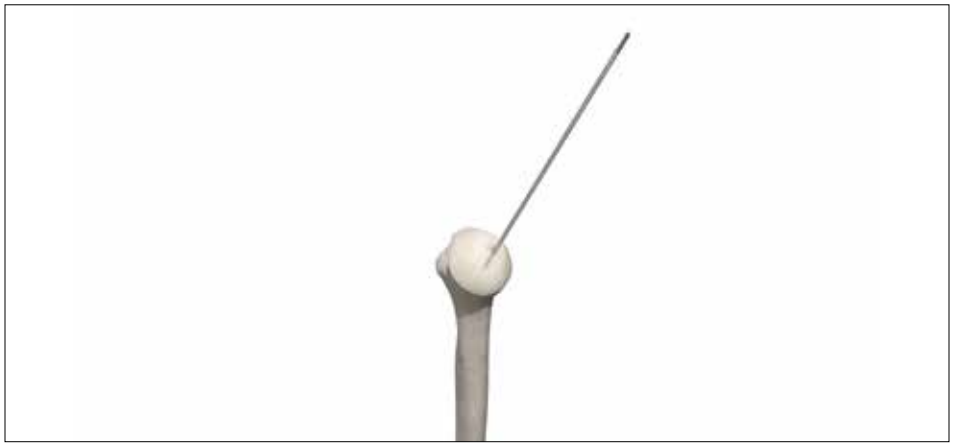


Fig. 3

Operative technique

Graft reaming

The BIO-RSA Graft Reamer is assembled to power and then passed over the alignment pin (fig. 4). Note that the BIO-RSA Graft Reamer will harvest only a 29mm bone graft and reaming should be stopped once good quality bone is encountered.

Additionally, it is ideal to ream until a flat surface is created (fig. 5). 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 BIO-RSA Graft Reamer.

The reamer is removed leaving the alignment pin in place (fig. 6).

Fig. 4

Fig. 5

Fig. 6

Operative technique

Graft drilling

Once the reaming is completed, the 8.3mm cannulated drill bit is advanced over the alignment pin to create the hole for the bone graft (fig. 7).

The drill is advanced until the step of the drill contacts the surface of the prepared bone (fig. 8).

Once drilling is complete the alignment pin can be removed (fig. 9).

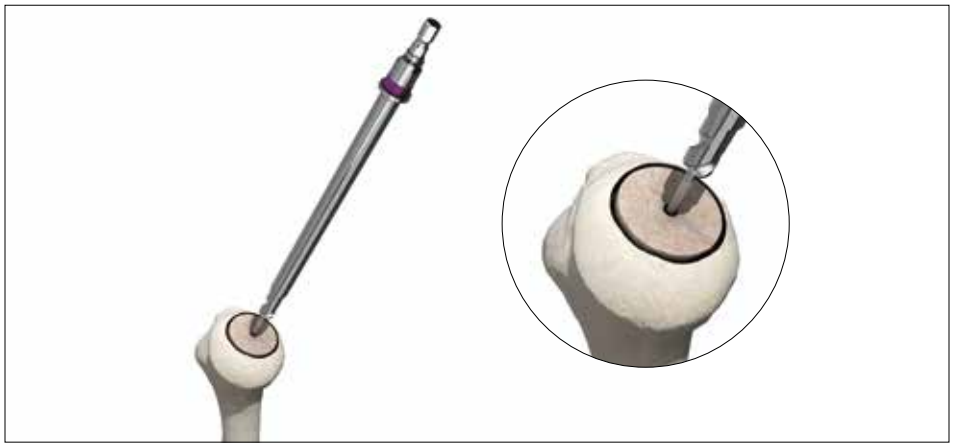


Fig. 7

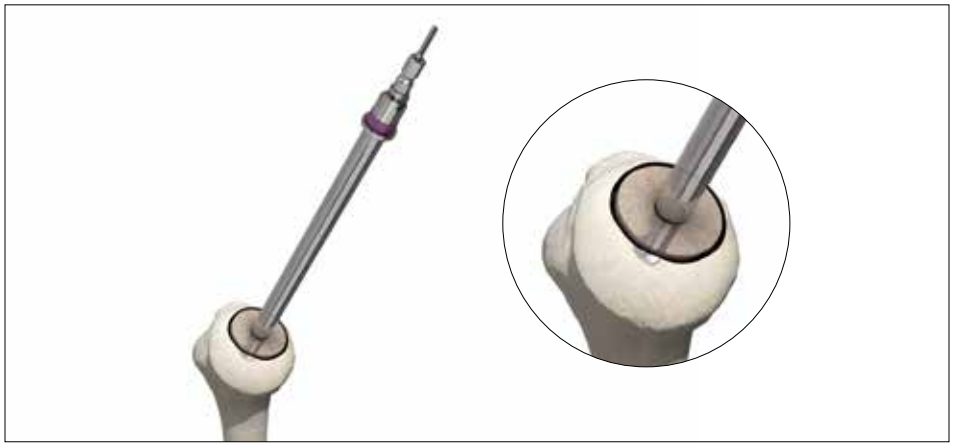


Fig. 8

Fig. 9

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. BIO-RSA Cutting Guides are available in both Large or Extra Large (fig. 10).

NOTICE

That there are two cut slots available (7mm and 10mm) for producing the bone graft. Equal lateral offset is created when a 10mm graft is used with the 36mm sphere, and a 7mm graft is used with the 42mm sphere (fig. 11).

It is important to ensure the humeral cutting guide covers the humeral head 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 (fig. 12a). If the cut guide does not fit easily, the central hole may be enlarged using the 8.3mm drill bit. The graft is resected using an oscillating saw through the chosen cut slots 7 or 10mm (fig. 12b). The solt is designed to accomodate a 0.8mm thick blade. In order to perform a complete cut the length of the blade should be at least 75mm.

⚠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.

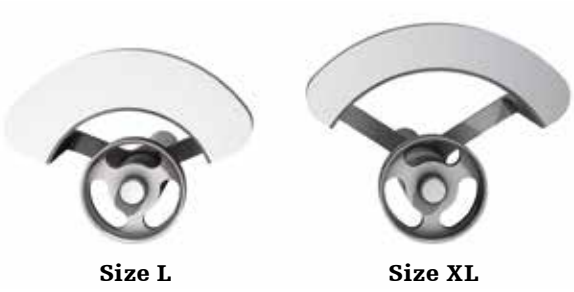


Fig. 10

7mm graft (42mm sphere)
10mm graft (36mm sphere)

Fig. 11

Fig. 12a

Fig. 12b

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 (fig. 13). 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. Once removed the graft should be inspected to ensure the bone quality is adequate for use with the BIO-RSA technique. The 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. 13
Smaller prong oriented in the direction of the cut guide

Operative technique

Metaphyseal diaphyseal preparation

NOTICE

Refer to the standard Aequalis Reversed or Aequalis Reversed II operative technique for humeral (metaphyseal/ diaphyseal) reaming (fig. 14).

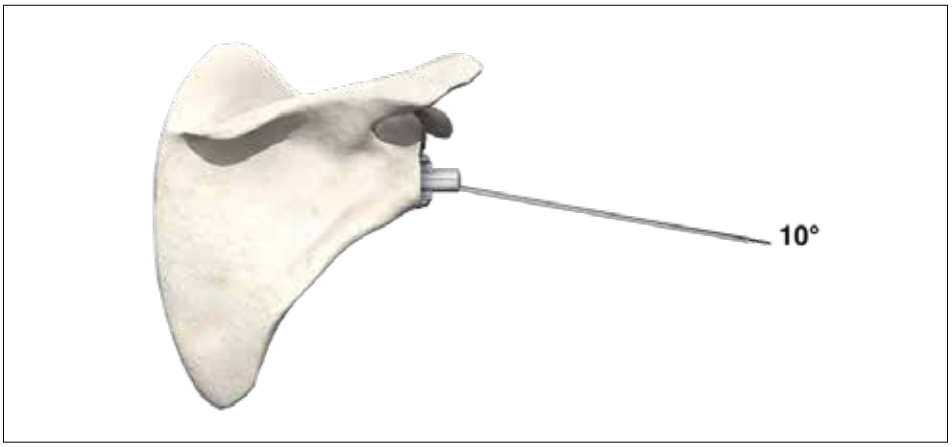


Fig. 14

Glenoid preparation

Assembling of the baseplate

NOTICE

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

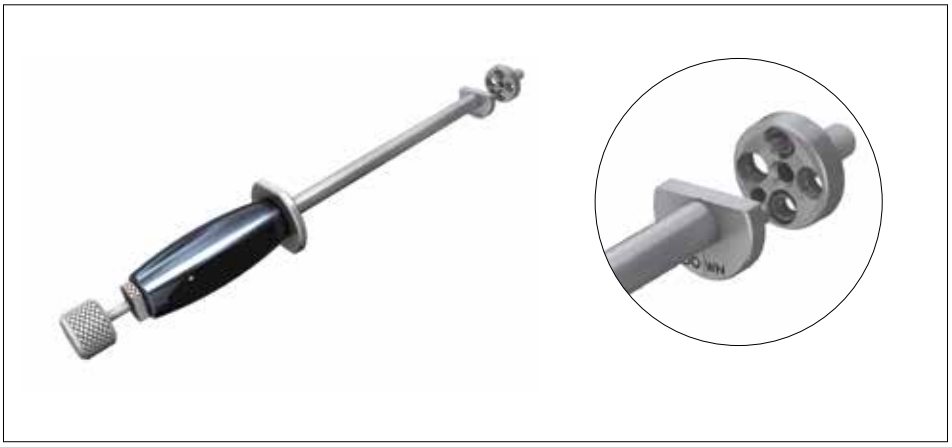


Fig. 8

The glenoid baseplate is attached to the baseplate impactor through its central hole using a screw in the impactor central shaft (fig. 15a).

Care should be taken to ensure that the two pegs on the impactor seat properly into their respective holes on the implant baseplate (fig. 15b).

NOTICE

There is no baseplate trial.

Operative technique

Graft preparation

NOTICE

It is important to use the long post baseplate for 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. 16). In case of an asymmetrical bone graft, a mark may be drawn with a sterile pencil to orient the graft properly. The graft is inserted onto the baseplate in a direction that best accomodates 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. 17).

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 (fig. 18a).
To create more compression on the graft a 10° inferior tilted is preferred to increase bone graft integration (fig. 18b). This guides are left and right side dedicated.

NOTICE

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

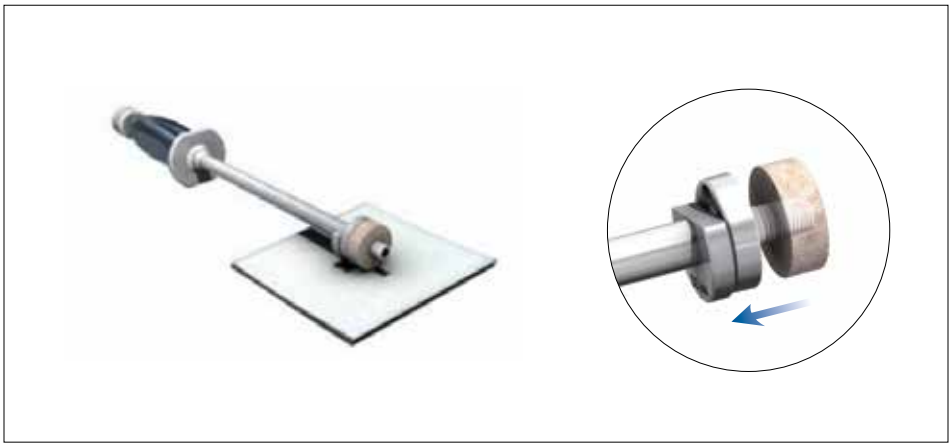
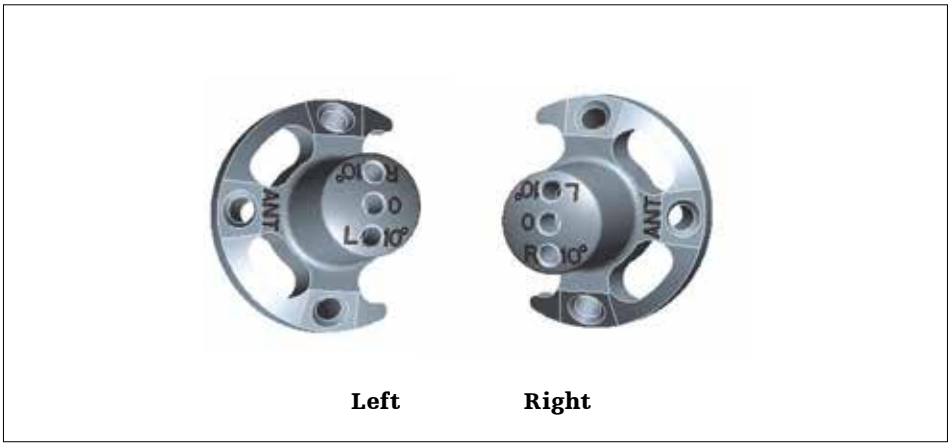


Fig. 17 **Fig. 16**



Left **Right**

Fig. 18a

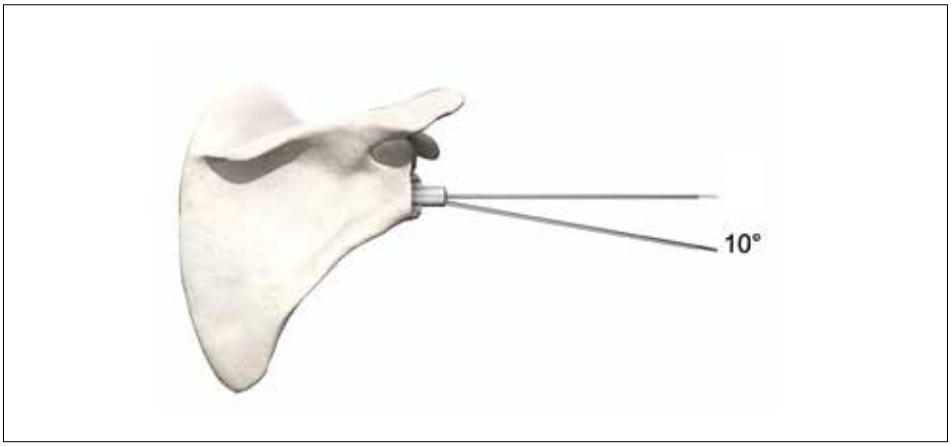


Fig. 18b

Glenoid Pin Guides

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, with the same diameter as the prepared BIO-RSA graft, is available, and will be preparing the glenoid bone.

NOTICE

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

Connect the 29mm reamer to power, slide the assembly onto the guide pin and ream (fig. 19).

It is recommended to start the reamer before contacting the glenoid surface and ream until the glenoid surface is flat (fig. 20).

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 desireable to preserve as much bone as possible to support proper primary fixation.

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

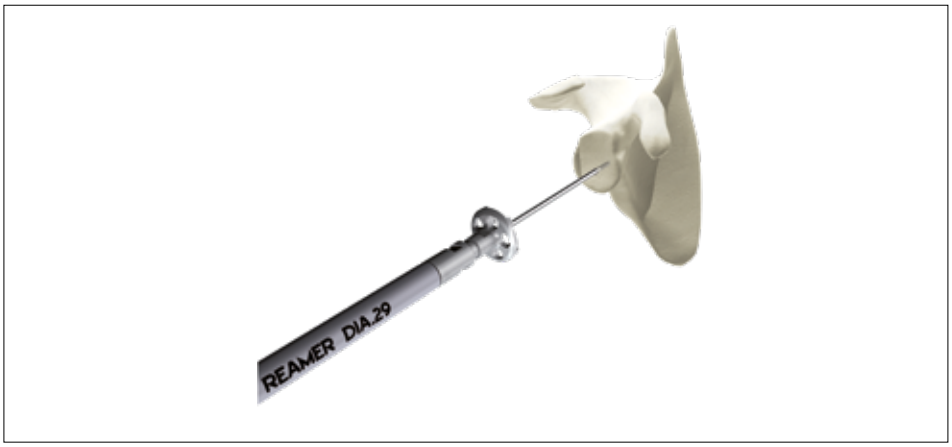


Fig. 19

Fig. 20

Operative technique

Glenoid central hole drilling

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). Two 7.5mm cannulated drill bits are available according to the length of the glenoid baseplate central post:

- A 15mm drill bit.
- A 25mm drill bit.

The Ø7.5mm long post drill bit (25mm long) should be used when preparing the glenoid for use with a 7mm graft to ensure the baseplate will fully seat against the glenoid during impaction. The Ø7.5mm short post drill bit (15mm long) is adequate when preparing the glenoid for use with a 10mm graft. When using a cannulated approach with the 29mm reamer 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. 21a-b). Remove the drill bit.

Remove the guide pin using power (fig. 22).

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.

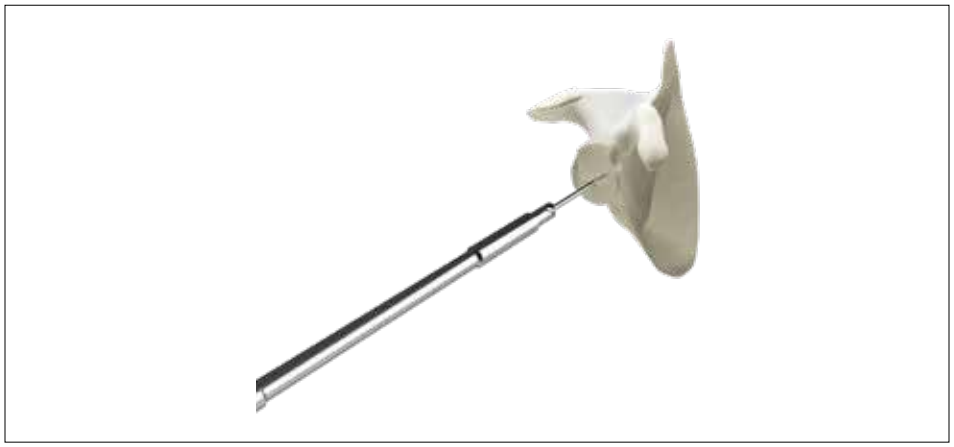


Fig. 21A

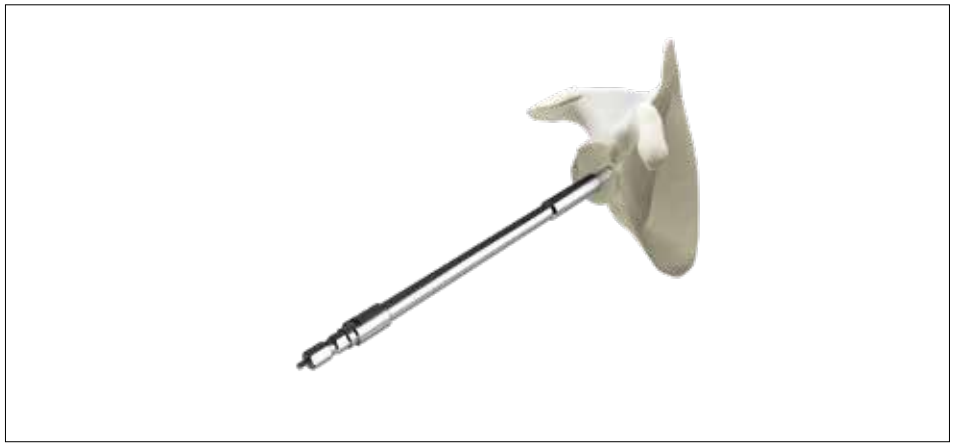


Fig. 21b

Fig. 22

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. 23a-b).

The remainder of the Reversed procedure is completed as outlined in the surgical guidelines.

NOTICE

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

Glenoid sphere implantation reduction and closure

The rest of the procedure is exactly the same as the standard Reversed procedure (fig. 24a-b).

NOTICE

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

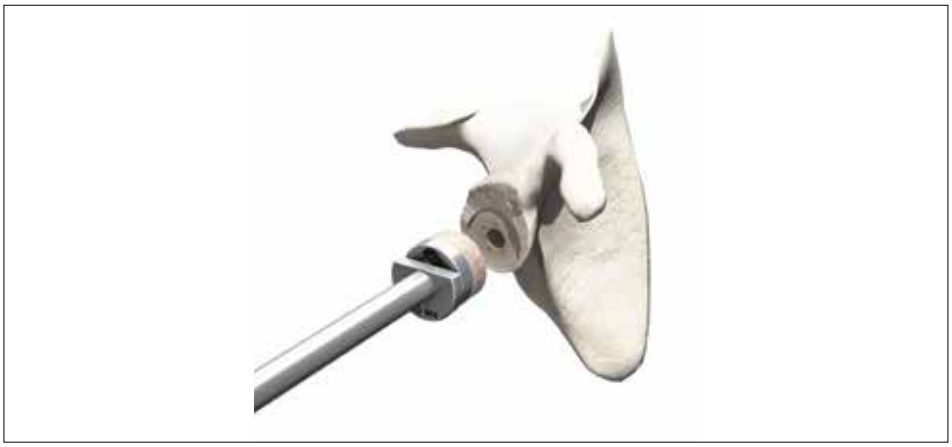


Fig. 23a

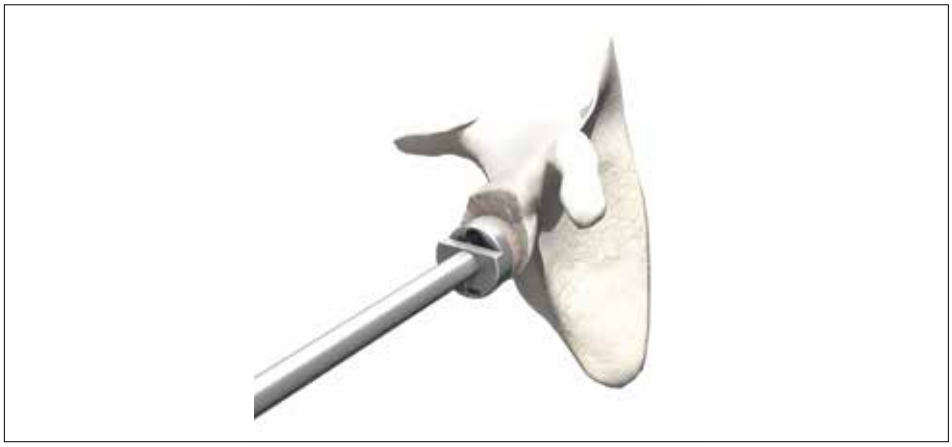


Fig. 23b

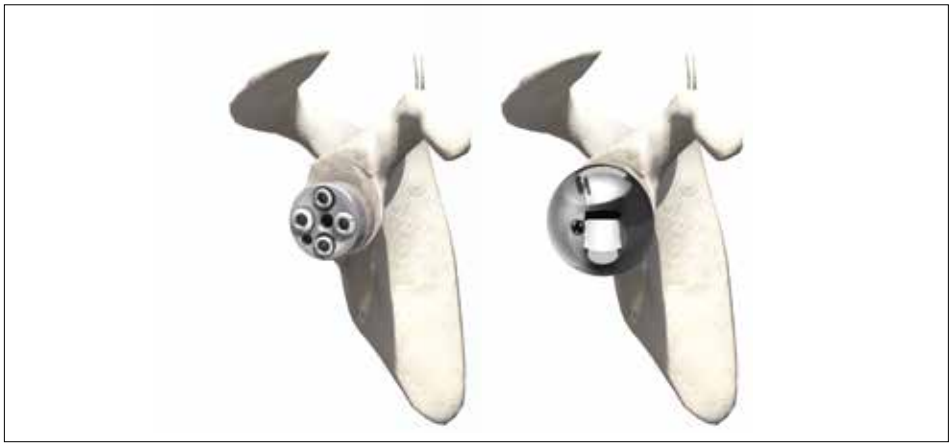


Fig. 24a **Fig. 24b**

System components

Humeral pin guide

Graft reamer

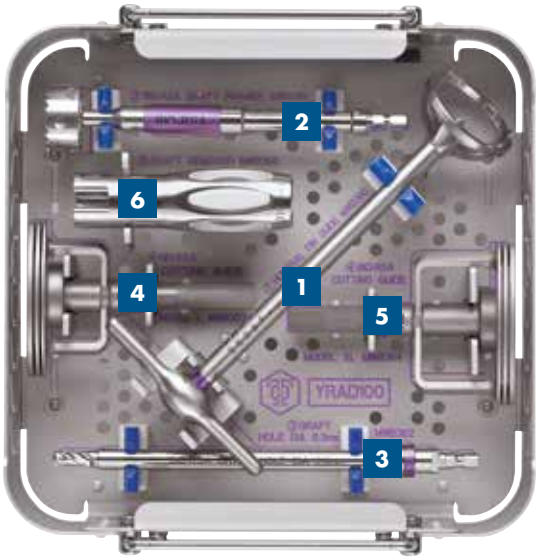
BIO-RSA reamer 3 in 1

Cannulated drill

Cutting guide

Graft pusher

System components



BIO-RSA instrument set

YKAD100

Item	Ref #	Description	Quantity
1	MWB360	Humeral guide pin	**1**
2	MWB361	Bellsaw dia. 29mm	**1**
3	MWB362	Drill bit dia. 8.3mm	**1**
4	MWB363	Large cutting guide	**1**
5	MWB364	Extra-large cutting guide	**1**
6	MWB366	Bone graft pusher	**1**
7	MWF702	BIO-RSA reamer 3 in 1	1

NOTICE

All BIO-RSA instruments are color coded purple for identification.

System components – implants

Aequalis Reversed II 29mm glenoid baseplates

Ref #	Description
DWD068	Ø29mm Glenoid baseplate with 25mm long post
DWE830	Ø29mm Threaded post baseplate with 30mm long post
or DWE835	Ø29mm Threaded post baseplate with 35mm long post

Aequalis Reversed II glenoid spheres for Ø29mm baseplate

Ref #	Description
DWD190	Centered glenoid sphere Ø36mm for Ø29mm baseplate
DWD193	Centered glenoid sphere Ø42mm for Ø29mm baseplate

Screw caddy

Ref #	Description
MGB 389	E.A.P baseplate screw caddy

Tornier glenoid baseplates screws

Ø4.5mm compression screw

Ref # Non Sterile	Ref # Sterile	Length (mm)
VDV218	VDV118	L 18mm
VDV220	VDV120	L 20mm
VDV223	VDV123	L 23mm
VDV226	VDV126	L 26mm
VDV229	-	L 29mm
VDV232	VDV132	L 32mm
VDV235	-	L 35mm
VDV238	VDV138	L 38mm
VDV241	-	L 41mm
VDV245	VDV145	L 45mm
VDV250	-	L 50mm

System components – implants

Tornier glenoid baseplates screws

Ø4.5mm multidirectional screw

Ref # Non Sterile	Ref # Sterile	Length (mm)
DWD020	DWD120	L 20mm
DWD023	-	L 23mm
DWD026	DWD126	L 26mm
DWD029	-	L 29mm
DWD032	DWD132	L 32mm
DWD035	-	L 35mm
DWD038	DWD138	L 38mm
DWD041	-	L 41mm
DWD044	DWD144	L 44mm
DWD047	-	L 47mm
-	DWD150	L 50mm

Sterile instruments

Ref #	Description
DWD055	Ø3mm drill bit L220mm
DWD063	Ø2.5mm Pin L200mm
DWD065	Ø2.5mm Pin L150mm
DWD164	Removable pilot for cannulated reamer
DWD167	Ø3.5mm Hex screwdriver bit L25mm
DWD163	Retroversion rod

Notes

Notes

Notes

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the product label and/or Instructions for Use, including the instructions for Cleaning and Sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The Instructions for Use, Operative Techniques, Cleaning instructions, patient information leaflets and other associated labeling may be requested online at ifu.stryker.com. If saving the Instructions for Use, Operative Techniques, Cleaning instructions from the above mentioned websites, please make sure you always have the most up to date version prior to use.

The products listed above are CE marked.

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Manufacturer:
Tornier SAS
161 rue Lavoisier,
38330 Montbonnot
Saint Martin, France
+33 (0)4 76 61 35 00

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CE