stryker

Tornier Simpliciti®
Shoulder System

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 (www.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

Simpliciti Shoulder System

Contents

Indications and contraindications

Indications

The Tornier Simpliciti Shoulder "system" is intended for total and hemi-arthroplasty of the shoulder.

- Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
- Fracture of the humeral head where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.
- Proximal humerus malunion with humeral head degeneration.
- Avascular necrosis of the humeral head.
- The metaphyseal humeral components are indicated for press-fit un-cemented use.
- Glenoid components are labeled "for cemented use only" and are indicated only for use with bone cement.
- This device is for single use.

Contraindications

For total shoulder or hemi-shoulder:

- The Tornier Simpliciti Shoulder system is contraindicated in the following situations:
- Lack of sufficient sound bone to seat and support the implant, including that resulting from skeletal immaturity, osteoporosis or erosive arthritis metal allergies or sensitivity.
- Infection at or near the site of implantation.
- Distant or systemic infection.

Operative technique

Exposure

Position the patient in a beach chair position with the operative arm draped free. For optimal access, the patient should be positioned near the edge of the operating table such that the shoulder can be fully extended. A bump can be placed under the operative shoulder to stabilize the scapula. Using a standard delto-pectoral approach, releases are performed and the subscapularis is prepared per surgeon discretion.

The shoulder is gently dislocated anteriorly. This can be facilitated by placing a Darrach retractor within the glenohumeral joint and performing gentle adduction and external rotation of the humerus. As the humeral head is fully dislocated, the inferior capsule is released up to the posterior aspect of the humeral head. Identification, palpation and protection of the axillary nerve during this release is important. An anterior capsulotomy is performed with a release of the middle and inferior glenohumeral ligaments off the glenoid. Mobilization of the subscapularis muscle is necessary to allow for tension-free reinsertion following the procedure.

Once these releases have been performed, the humeral head is fully dislocated by adduction of the arm with progressive external rotation and extension. Consider further release of the pectoralis insertion if full external rotation is not obtained.

Fig. 1

Humeral head resection

Before making the humeral head resection, it may be helpful to remove all humeral osteophytes

If a guided resection is desired, use one of the four cut rings provided.

To use the cut rings, select the size cut ring that most closely matches the humeral head diameter. Align the top of the cut ring with the anatomic neck and place the 3 mm guide pins through the cut rings using the pin driver (fig. 1).

Use the flat superior surface of the guide to make the humeral head resection. Once the resection is complete, remove the pins and guide.

Operative technique

Sizing and centering

NOTICE

If the humeral osteophytes were not removed before the humeral resections, they must be removed prior to sizing the osteotomy.

To size for the humeral implant, attach one of the three sizer disks to the self-leveling handle and place the sizer onto the resected humerus (fig. 2).

Choose the largest sizer that does not overhang the humerus at any point (fig. 3).

Center the sizer on the resected humerus, checking for a consistent gap between the edge of the sizer and the anterior, superolateral and posterior aspects of the humerus. (Any excess medial bone can be trimmed with Rongeurs once the definitive implant is in place.)

With the sizer centered and flat on the resected humerus, place the guide pin by hand into the central hole of the sizer. Attach the pin driver to power and advance the pin until it engages the lateral cortex. The pin must engage the lateral cortex, but doesn't need to penetrate the lateral cortex (fig. 4).

Remove the sizer disk and visually assess the position, orientation and stability of the pin. The pin should be centered anterior to posterior and just slightly superior and perpendicular to the resection plane. If the pin is not in the correct orientation or position, remove the pin, re-center the sizer disk and reinsert the pin in the correct orientation.

If the pin is not stable, place the sizer disk over the pin and advance the pin to ensure that it has reached the lateral cortex. If the pin is still not stable due to poor patient bone quality, it may be advisable to switch to a stemmed implant.

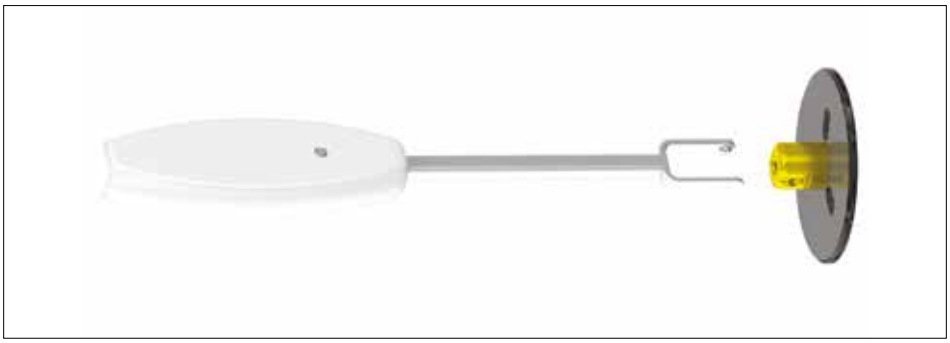


Fig. 2

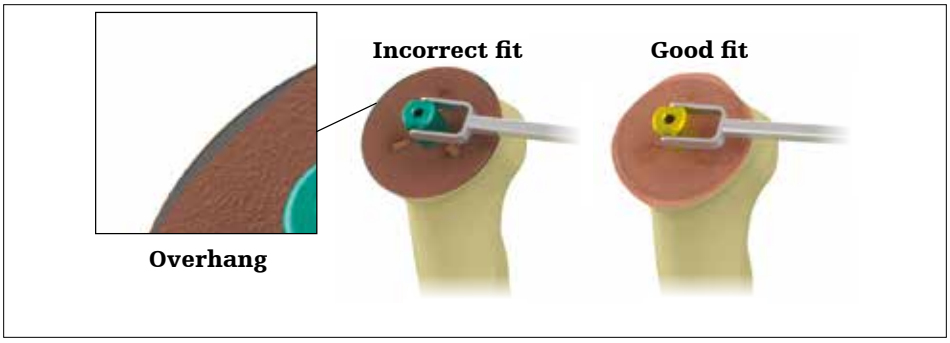


Fig. 3

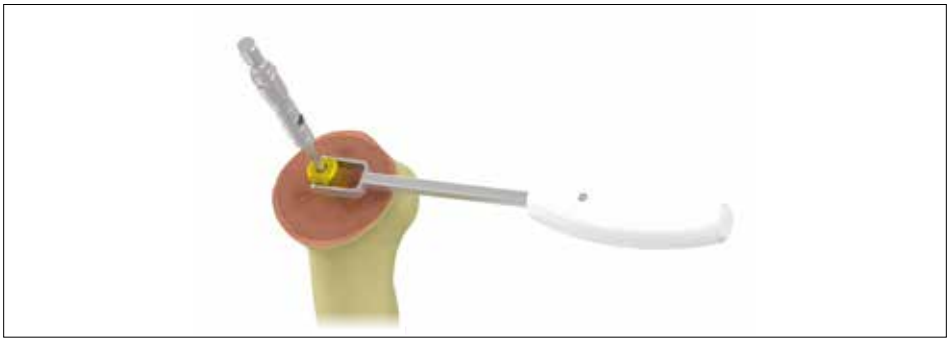


Fig. 4

NOTICE

It is important that the pin remains perpendicular to the resection throughout the surgical procedure. If the pin is damaged or bent during preparation, replace it with a new pin.

Operative technique

Preparing the metaphysis

With the guide pin in place, select the surface planer that corresponds with the sizer disk from the previous step. The instrument set has been color coded by size for the operative team's convenience. Attach the surface planer to power and place it over the guide pin (fig. 5).

Before initiating power, place the planer flat on the humeral cut and assess the planer's fit to the bone. An ideal fit would cover the entire resected surface without interfering with the rotator cuff.

Once the planer size has been deemed appropriate, back the planer off the bone, initiate power and advance the planer to engage the bone.

Windows have been provided in the planer to allow the surgeon to see the bone surface. Using these windows, watch for small concentric witness marks that will be created by the planer. When all aspects of the humerus show the witness marks, the surface is perfectly flat and no additional planing is necessary (fig. 6).

Next, attach the core drill to power, place it over the guide pin and drill until the collar is flush against the cut humerus surface (fig. 7).

To prepare the fin tracks, attach the previously selected size fin blazer to the fin blazer impactor handle and place it over the guide pin (fig. 8).

Fig. 5

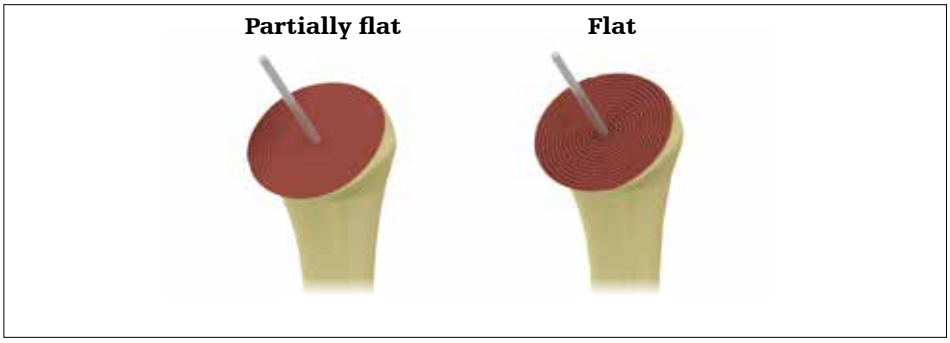


Fig. 6

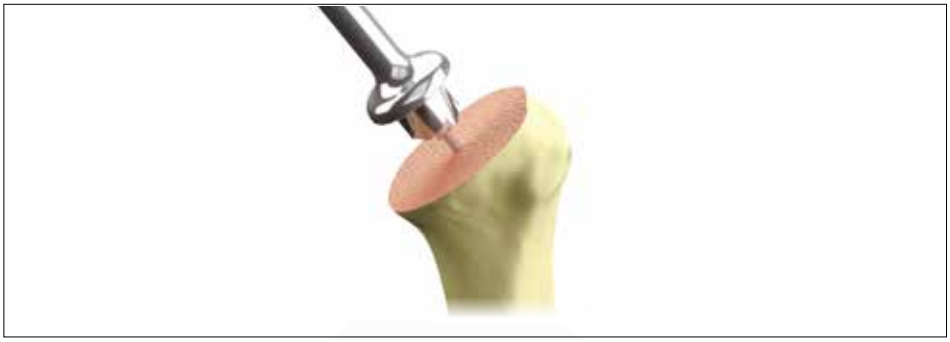


Fig. 7

Fig. 8

Operative technique

Preparing the metaphysis

Position the blazer so that one fin points directly superiolaterally (fig. 9).

Impact the fin blazer until the collar is flush with the cut surface of the humerus, taking care not to advance the collar of the handle into the bone (fig. 10).

It is important to note that the fin blazer will also act as the trial and is to be left in place after impaction. To remove the handle, simply unthread it from the fin blazer and then remove the guide pin.

A cut protector can be attached to the fin blazer to protect the humeral cut surface from retractors during glenoid preparation.

Attach the handle to the side of the cut protector that is laser etched, "This side up."

This is done by applying inward pressure on each side of the handle and then inserting the feet of the handle into the holes of the cut protector. When the inward pressure is released, the handle will securely hold the cut protector (fig. 11).

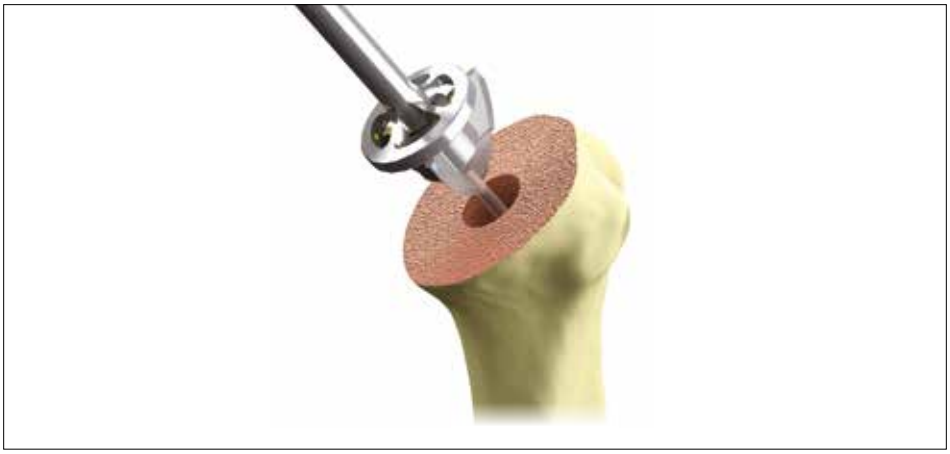


Fig. 9

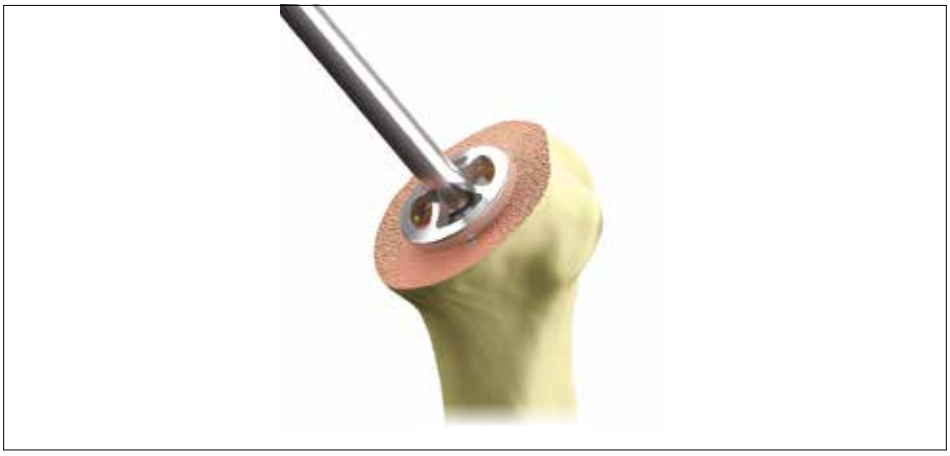


Fig. 10

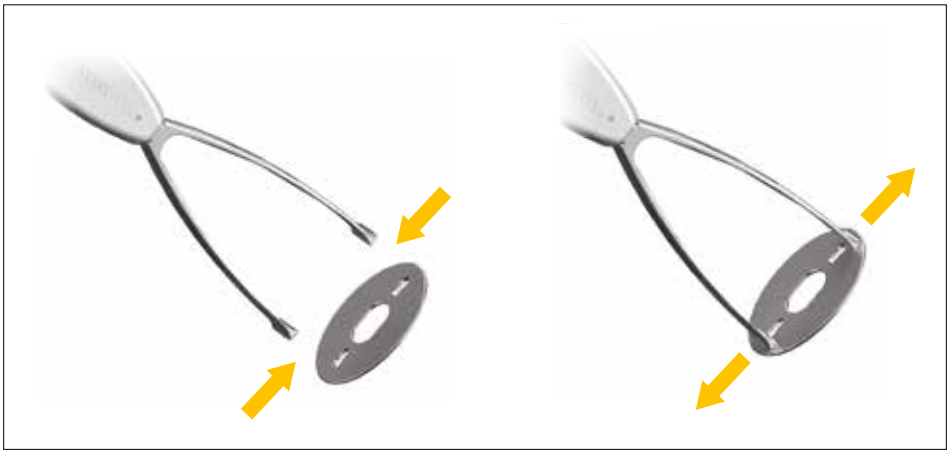


Fig. 11

Operative technique

Preparing the metaphysis

To attach the cut protector to the fin blazer, align the laser marks and place the cut protector onto the fin blazer. Next, turn the cut protector 90 degrees or until it is securely attached to the fin blazer (fig. 12).

When the cut protector is stable, apply inward pressure on each side of the handle and remove the handle.

The glenoid can now be prepared.

Once the glenoid has been implanted, the cut protector can be removed.

To remove the cut protector, attach the handle and rotate the cut protector to align the marks on both the cut protector and blazer. Next, simply lift the cut protector off the blazer.

Fig. 12

Operative technique

Sizing the humeral head

The Tornier Simpliciti metaphyseal implant, which is referred to as the nucleus, is only compatible with centered Tornier Simpliciti humeral heads. Tornier Simpliciti eccentric humeral heads are not available. The humeral head attaches to the nucleus via a Morse taper and has unique advantages which are described in detail below.

The Tornier Simpliciti humeral heads were specifically developed for surgeons who prefer to replace the diseased humeral head based on normal (non-arthritic) anatomic parameters.

The initial size of the trial head can be determined by mimicking the resected head, except in the case of severe deformity. This can be accomplished by placing the resected head against a trial head and determining which size trial head most closely represents the resected head (fig. 13).

In case of severe deformity of the native humeral head, pre-operative radiographic templating may be utilized to determine the optimally sized humeral implant.

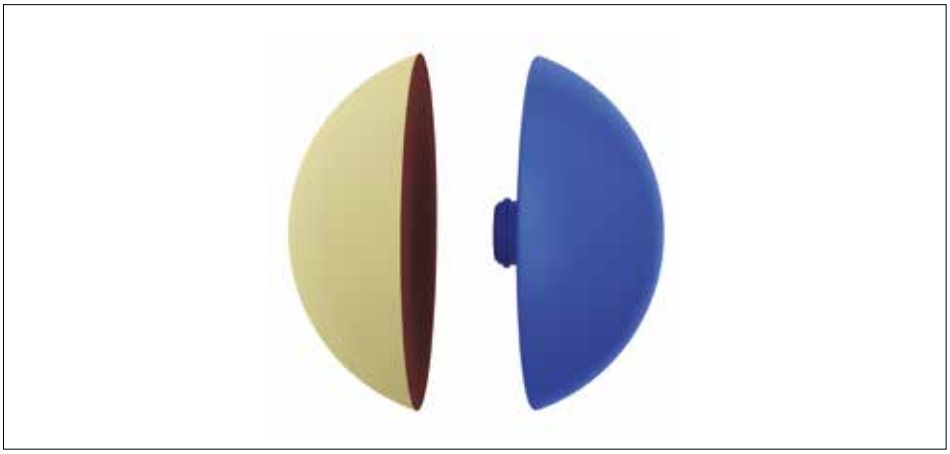


Fig. 13

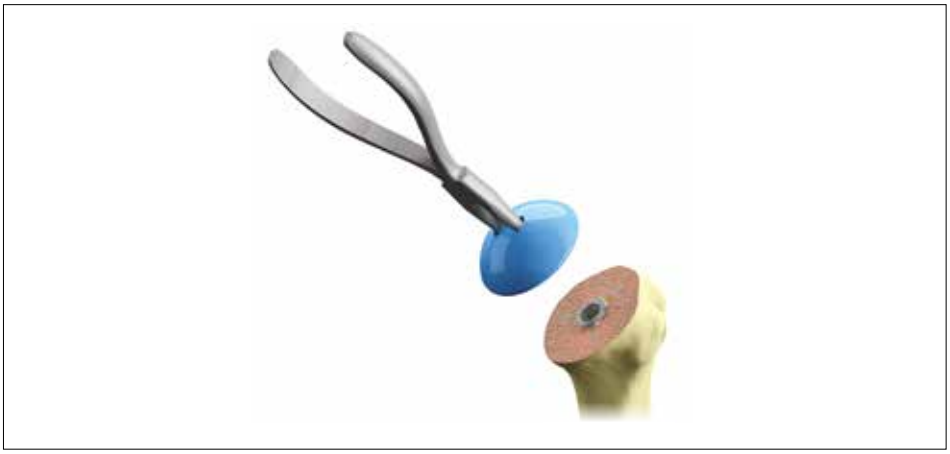


Fig. 14

To place the trial head, insert the tips of the grasper into the holes of the trial head and then place the male taper of the trial head into the female taper of the fin blazer (fig. 14).

Evaluate the coverage of the humeral head and adjust sizes if necessary.

NOTICE

The trial head should not be impacted once placed onto the fin blazer. The trial heads may also be used on the final implant.

Operative technique

Trial reduction

Reduce the humeral head trial into the glenoid.

After the shoulder joint is reduced, posterior force on the humeral head should allow for subluxation of 50% of the width of the joint.

If less than 50% subluxation is possible, remove the humeral head and replace it with the next smaller head.

If direct posterior force dislocates the humeral head, remove the trial head and replace it with the next larger humeral head.

Mobility testing

The arm is abducted to 90 degrees and internally rotated. 60 degrees of internal rotation should be obtained. If less than 60 degrees of internal rotation is demonstrated, further capsular release off the inferior humeral neck and glenoid may be necessary for optimal function.

Once the humeral head size has been determined, dislocate the shoulder, remove the trial head with the grasper, re-attach the blazer impactor to the fin blazer and remove the fin blazer.

Planning the subscapularis repair

Prior to seating the final humeral assembly, the surgeon must plan the subscapularis tendon reattachment. The subscapularis is repaired per surgeon preference. If repair sutures must be placed through the humeral bone, this should be completed at this time.

Operative technique

Implanting the final prosthesis

NOTICE

The surgeon should inspect the implant taper and articular surfaces for debris or blemishes before assembly. The humeral head should be assembled to the definitive nucleus with clean gloves.

To implant the final prosthesis, select the appropriately sized nucleus and attach the implant to the impactor handle via the treads in the bottom of the taper. Take care not to over tighten the threads (fig. 15).

Place the fins of the nucleus into the previously prepared cavity. Check to ensure that the implant is inserted perpendicular to the resected surface and impact the implant until the collar is resting a few millimeters above the resected humerus and detach the impactor handle (fig. 16).

Next, place the definitive humeral head onto the nucleus. Attach the head impactor tip onto the blazer/head impactor handle and place the impactor tip onto the humeral head. Impact until the implant is flush against the humeral cut. Excess force should be avoided during impaction and care should be taken not to damage the articular surface of the implant (fig. 17).

Fig. 15

Fig. 16

Fig. 17

NOTICE

Some surgeons may choose to fully seat the nucleus prior to impacting the humeral head. If this is done, take care not to advance the collar of the implant into the cancellous bone as this could compromise the taper engagement of the implants.

Operative technique

Closure

After the final implants are in position and the shoulder has been reduced, the subscapularis is repaired per surgeon preference.

The remainder of the wound closure is performed per surgeon preference.

Fig. 18

Post-operative rehabilitation

Remove sling the first morning after surgery.

Begin active assisted forward elevation and external rotation on the first day after surgery. Place no limit to forward elevation, but limit external rotation to the side to 40 degrees.

At two weeks, begin internal rotation stretching. Encourage active use of the arm for activities of daily living.

At eight weeks, begin active shoulder strengthening as necessary.

Fig. 19

Consideration for revision surgery

Should a revision become necessary, the Tornier Simpliciti system offers specific instrumentation to facilitate the removal of the humeral head and nucleus.

Removal of the humeral head is accomplished by placing the tip of the humeral head distractor into the gap between the humerus and the humeral head and impacting to free the Morse taper (fig. 18).

Once the humeral head has been disassembled, the nucleus can be removed.

The first step in removing the nucleus is to separate the bone from the porous coating on the implant. A specific osteotome with depth stops is available and should be impacted through the slots located on the face of the implant collar (fig. 19).

Operative technique

Next, place the three osteotome fins of the core extractor into the three curved slots located on the face of the implant collar. Impact the osteotome fins until the core extractor is resting flush on the collar (fig. 20).

Using the t-handle, rotate the instrument clockwise. This will place the undercuts on the osteotome fins under the collar of the implant (fig. 21).

Fig. 20

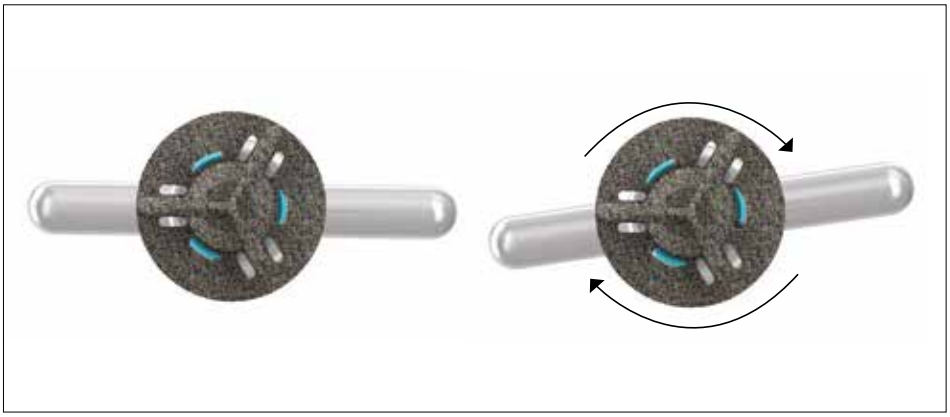


Fig. 21

Operative technique

While maintaining clockwise pressure on the t-handle, use the slotted mallet and backslap the core extractor to remove the nucleus (fig. 22).

If it is not possible to rotate the core extractor to capture the implant, an alternative extraction method is available. First, remove the core extractor and then attach the threaded extractor to the nucleus via the female thread at the bottom of the taper. Take care not to over tighten the extractor. Next, use the slotted mallet and backslap the extractor to remove the nucleus. (fig. 23).

NOTICE

Do not use excessive force when backslapping the threaded extractor.

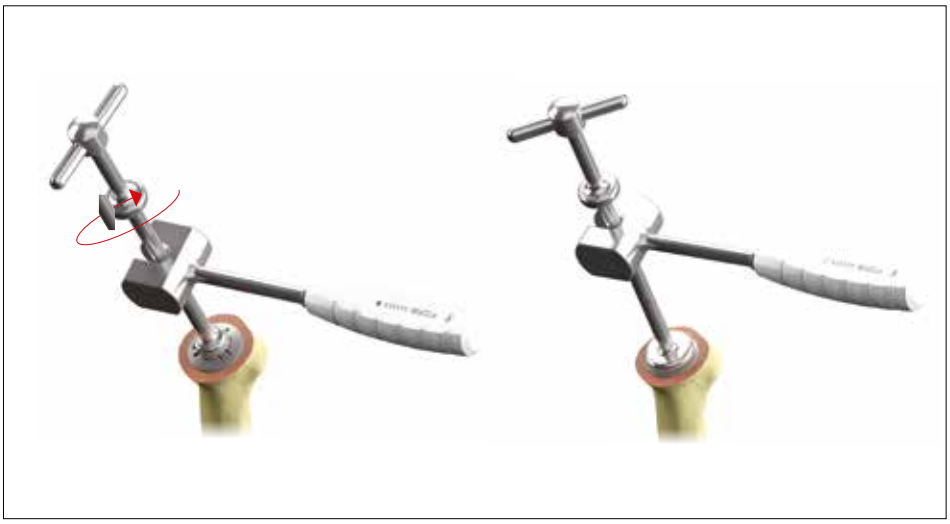
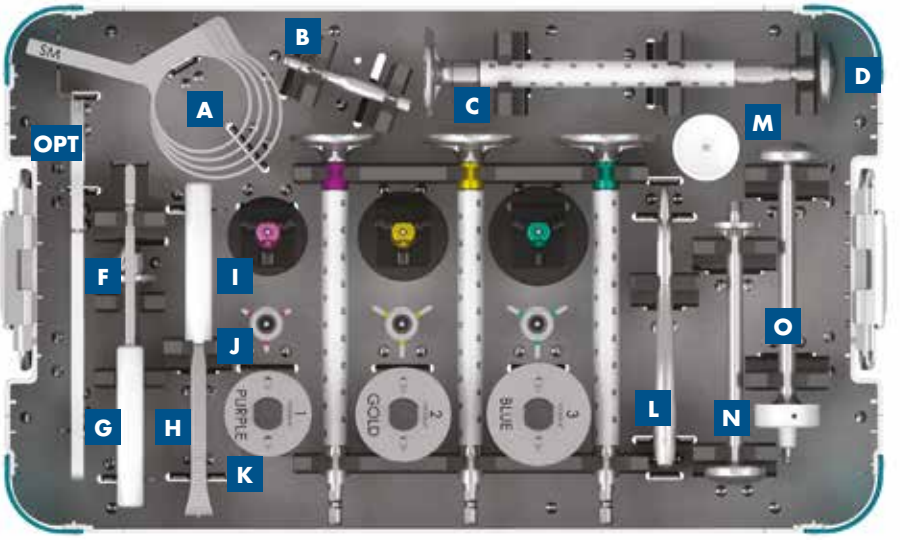


Fig. 22

Fig. 23

System components

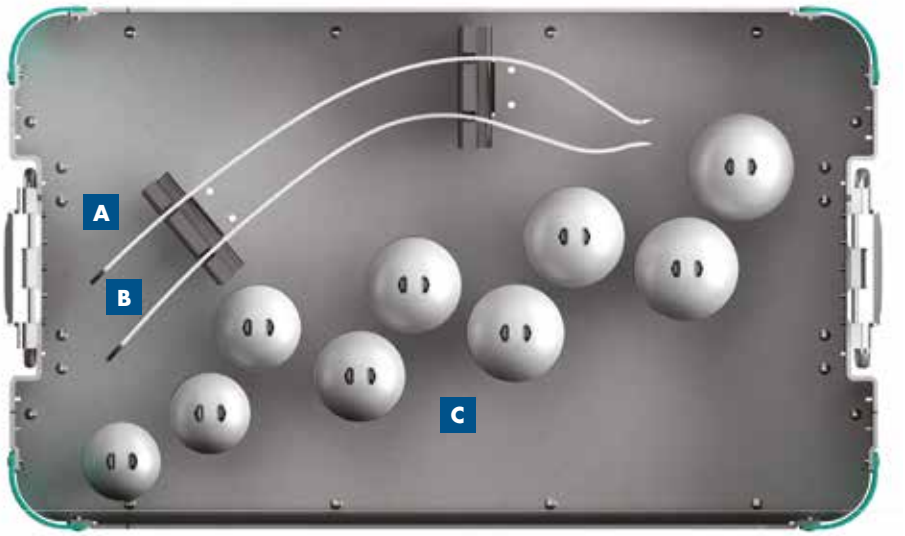


Tornier Simpliciti general instrument tray YKAD202

Item	Ref #	Description
A	9722926	Small cut ring
A	9722927	Medium cut ring
A	9722928	Large cut ring
A	9722929	X-large cut ring
B	9722885	Pin driver
D	9722886	Size 0 surface planer
C	9722887	Size 1 surface planer
C	9722888	Size 2 surface planer
C	9722889	Size 3 surface planer
D	9722903	Simpliciti head distractor
E	9722905	Inclination guide*
F	9722890	Core drill
G	9722884	Self-leveling sizer handle
H	9722899	Cut protector handle
I	9722881	Size 1 sizer disk
I	9722882	Size 2 sizer disk
I	9722883	Size 3 sizer disk
J	9722891	Size 1 fin blazer trial
J	9722892	Size 2 fin blazer trial
J	9722893	Size 3 fin blazer trial
K	9722896	Size 1 cut protector
K	9722897	Size 2 cut protector
K	9722898	Size 3 cut protector
L	9722895	Simpliciti grasper
M	9722902	Head impactor tip
N	9722894	Blazer/head impactor
O	9722900	Nucleus impactor

* Optional

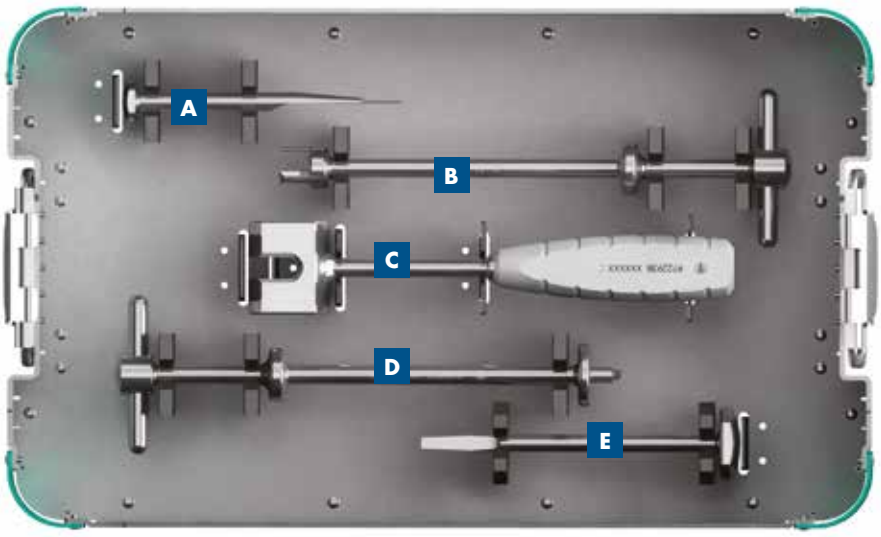
System components



Tornier Simpliciti trial head tray YKAD203

Item	Ref #	Description
A	MWA681	Wide kolbel
B	MWD046	Narrow kolbel
C	9722917	39 x 14 Simpliciti humeral head trial
C	9722918	41 x 15 Simpliciti humeral head trial
C	9722919	43 x 16 Simpliciti humeral head trial
C	9722920	46 x 17 Simpliciti humeral head trial
C	9722921	48 x 18 Simpliciti humeral head trial
C	9722922	50 x 16 Simpliciti humeral head trial
C	9722923	50 x 19 Simpliciti humeral head trial
C	9722924	52 x 19 Simpliciti humeral head trial
C	9722925	52 x 23 Simpliciti humeral head trial

System components



Tornier Simpliciti revision tray YKAD205

Item	Ref #	Description
A	9722935	Small osteotome
B	9722936	Core extractor
C	9722938	Slotted mallet
D	9722937	Threaded extractor
E	9722903	Simpliciti head distractor

System components

Tornier Simpliciti implants

Ref #	Description
7122865	Tornier Simpliciti nucleus, Size 1
7122866	Tornier Simpliciti nucleus, Size 2
7122867	Tornier Simpliciti nucleus, Size 3
7122868	39 x 14 Tornier Simpliciti humeral head
7122869	41 x 15 Tornier Simpliciti humeral head
7122870	43 x 16 Tornier Simpliciti humeral head
7122871	46 x 17 Tornier Simpliciti humeral head
7122872	48 x 18 Tornier Simpliciti humeral head
7122873	50 x 16 Tornier Simpliciti humeral head
7122874	50 x 19 Tornier Simpliciti humeral head
7122875	52 x 19 Tornier Simpliciti humeral head
7122876	52 x 23 Tornier Simpliciti humeral head

Available separately

Ref #	Description
9722906	Simpliciti humeral head templates
9722907	Simpliciti nucleus templates
9722908	Sterile 3 x 75 mm guide pin

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The Instructions for Use, Operative Techniques, Cleaning instructions, patient information leaflets and other associated labeling may be requested online at www.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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CE 2797

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