TORNIER

SIMPLICITI™

Shoulder System

SURGICAL TECHNIQUE

WRIGHT

FOCUSED EXCELLENCE

Table of Contents:

Indications

The SIMPLICITI™ Shoulder System is intended for total arthroplasty of the shoulder.

- Severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis.

Note:
- The metaphyseal humeral components are indicated for uncemented use only.
- Glenoid components are labeled "for cemented use only" and are indicated only for use with bone cement.
- These devices are for single use only.

Contraindications

For Total Shoulder:

The SIMPLICITI Shoulder System is contraindicated in the following situations:

- Lack of sufficient sound bone to seat and support the implant, a condition that results from skeletal immaturity, osteoporosis or erosive arthritis.
- Metal allergies or sensitivity.
- Infection at or near the site of implantation.
- Distant or systemic infection.

System Compatibility

The SIMPLICITI nucleus has been designed to be compatible with the humeral head components for both the SIMPLICITI and SIMPLICITI STB Systems. Additionally, both humeral head systems, in certain combinations, are compatible with the AEQUALIS™ Shoulder System and AFFINITI™ glenoid systems. For more information on the cleared combinations, refer to SIMPLICITI mismatch charts (CAW-3185).

Pre-Operative Planning

Four shoulder X-rays are recommended:
1. A-P View
2. True A-P (Grashey View)
3. Supraspinatus Outlet View (SOV)
4. Axillary View

CT scan may be appropriate to assist in evaluating glenoid morphology.

MRI scan may be appropriate for some shoulders to assess the rotator cuff muscles and tendons.

Using a glenoid prosthesis in patients with cuff tear arthropathy could increase the risk of glenoid loosening due to proximal migration and non-anatomic loading.

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. It is not advisable to perform a complete lesser tuberosity osteotomy.

The shoulder is gently dislocated anteriorly. This is 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.

Humeral Head Resection

- Before making the humeral head resection, it may be helpful to remove all humeral osteophytes.
- After the osteophytes have been removed, the shaft of the inclination guide can be aligned with the humeral diaphysis to assist in determining the native inclination.
- Next, align the proximal body of the guide with the anatomic neck of the humerus. (Figure 1)

Figure 1

- This is done by pulling down on the trigger and pivoting the proximal body. (Figure 2)
- Releasing the trigger will lock the guide in the selected position, providing a reference for the native humeral inclination.
- Once the guide has been properly aligned, the neck angle may be marked with electrocautery.

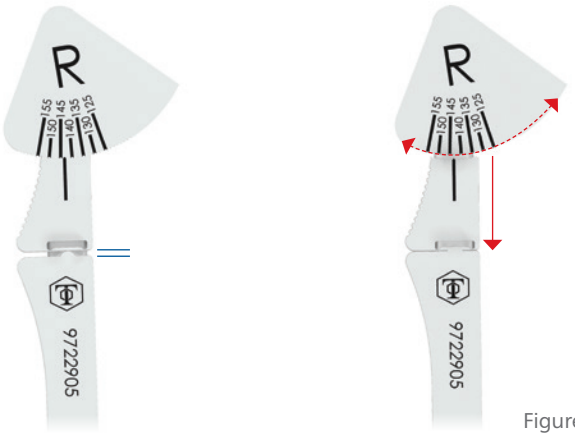


Figure 2

Freehand Resection

- If a freehand resection is to be made, consider placing the Crego retractor under the biceps tendon, if it is still present, and around the humeral head. This will help protect the biceps and rotator cuff tendons. With the Crego in place, cut along the previously marked neck angle. (Figure 3)

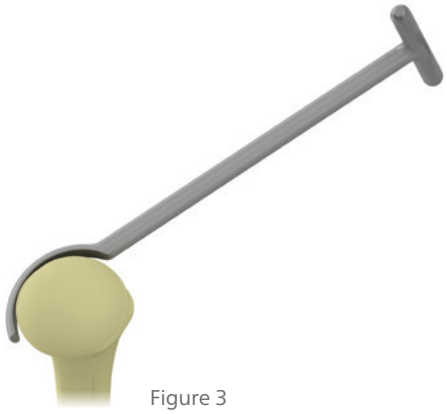


Figure 3

Note: Take special care to direct the saw blade or osteotome directly towards the Crego retractor. A misdirected cut has the potential to damage the rotator cuff tendons.

Guided Resection

- If a guided resection is preferred, 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. (Figure 4)

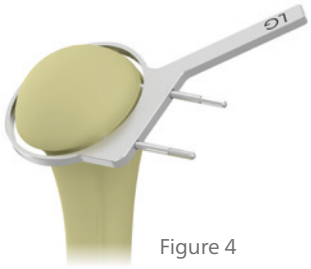


Figure 4

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

Sizing & Centering

Note: 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. (Figure 5)

Figure 5

- Choose the largest sizer that does not overhang the humerus at any point. (Figure 6)

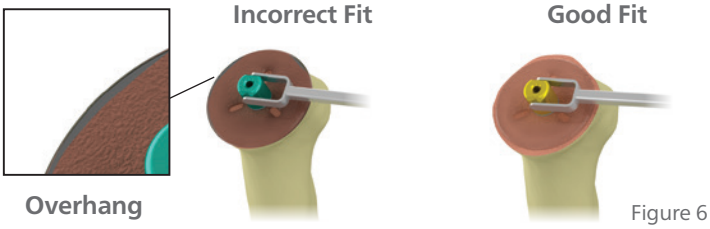


Figure 6

- 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. (Figure 7)

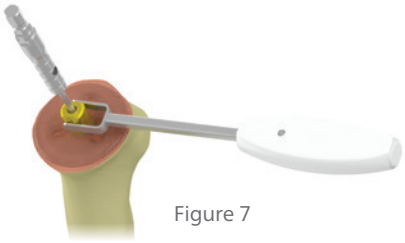


Figure 7

- 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.

Note: 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.

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. (Figure 8)

Figure 8

- 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. (Figure 9)

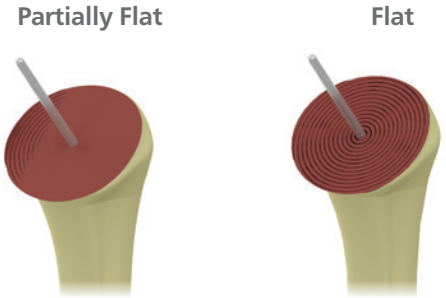


Figure 9

- 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. (Figure 10)

Figure 10

Preparing the Metaphysis *continued*

- 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. (Figure 11)

Figure 11

- Position the blazer so that one fin points directly superiolaterally. (Figure 12)

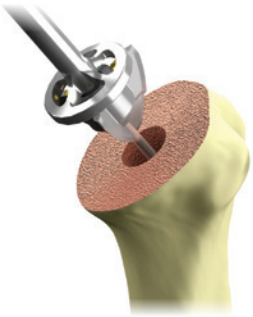


Figure 12

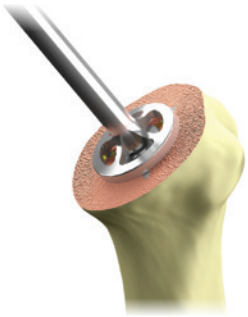


Figure 13

- 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. (Figure 13)
- 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. (Figure 14)

Figure 14

- 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. (Figure 15)

Figure 15

- 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.

Safe Combination

Please refer to the safe combination of Humeral Heads and Glenoids. The information is provided in document reference number CAW-3185.

- 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.

Selecting the Humeral Head System

Two humeral head options are compatible with the SIMPLICITI™ metaphyseal implant, which is referred to as the nucleus. Both humeral head options attach to the nucleus via a Morse taper and have unique advantages that are described in detail below.

Option 1: Soft-Tissue Balancing Approach

The SIMPLICITI STB system was designed to offer surgeons intra-operative flexibility when treating diseased and deformed anatomy. The intra-operative flexibility is accomplished by offering three humeral head thicknesses for each of the five articular diameters, allowing the surgeon to balance the joint without changing the articular curvature and resulting glenohumeral mismatch.

Option 2: Anatomic Approach

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

Sizing the Humeral Head

- 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. (Figure 16)
- In case of severe deformity of the native humeral head, pre-operative radiographic templating may be utilized to determine the optimally sized humeral implant.
- 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. (Figure 17)
- Evaluate the coverage of the humeral head and adjust sizes if necessary.

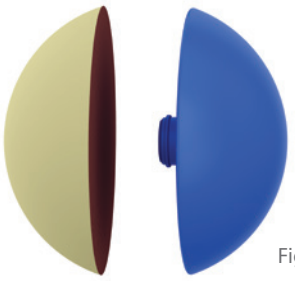


Figure 16

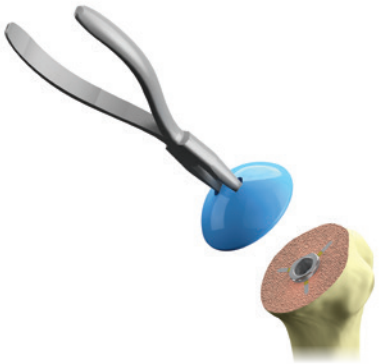


Figure 17

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

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.

Implanting the Final Prosthesis

Note: 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. (Figure 18)

Figure 18

- 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. (Figure 19)
- 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. (Figure 20)

Figure 19

Figure 20

Note: 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.

Closure

- After the final implants are in position and the shoulder has been reduced, the subscapularis is repaired per surgeon preference. Following the subscapularis repair, a hemovac drain may be placed to prevent postoperative hematoma formation.

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

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.

Consideration for Revision Surgery

- Should a revision become necessary, the 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. (Figure 21)

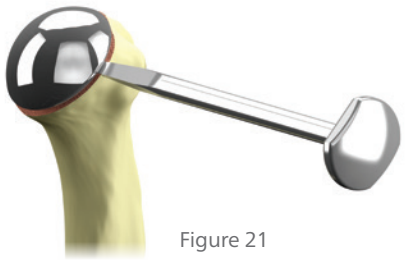


Figure 21

Consideration for Revision Surgery *continued*

- 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. (Figure 22)

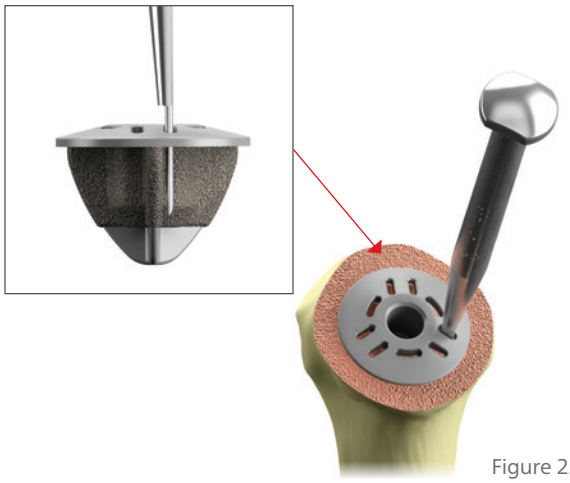


Figure 22

- 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. (Figure 23)

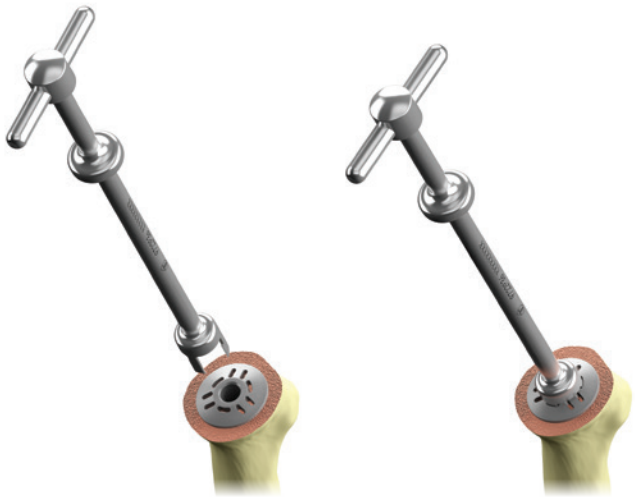


Figure 23

- Using the t-handle, rotate the instrument clockwise. This will place the undercuts on the osteotome fins under the collar of the implant. (Figure 24)

Figure 24

- While maintaining clockwise pressure on the t-handle, use the slotted mallet and backslap the core extractor to remove the nucleus. (Figure 25)
- 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. (Figure 26)

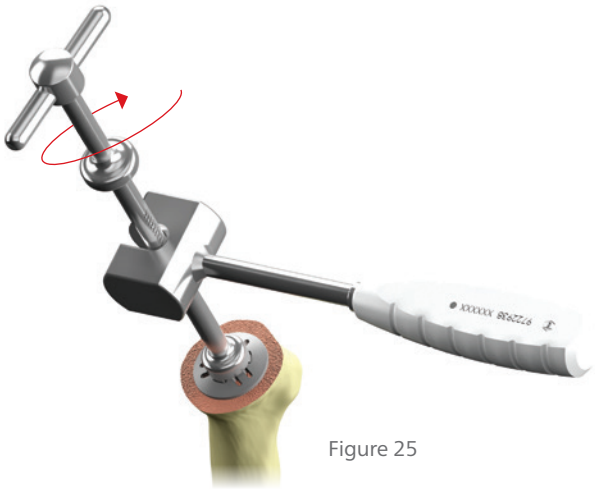


Figure 25

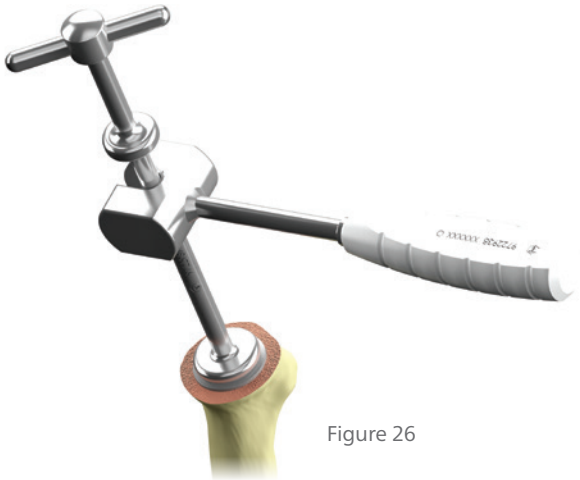
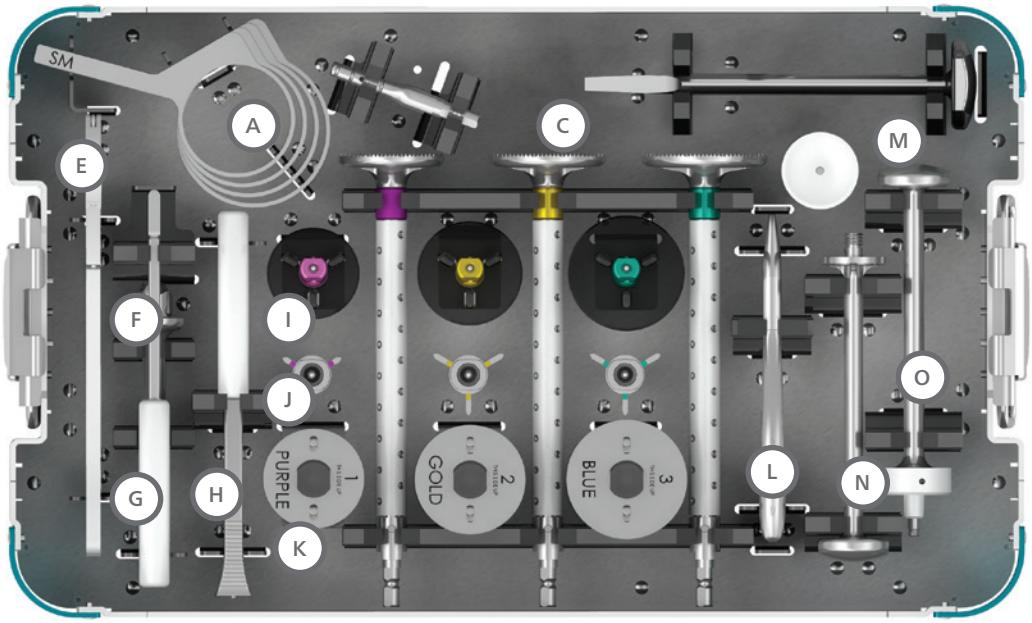


Figure 26

Note: Do not use excessive force when backslapping the threaded extractor.

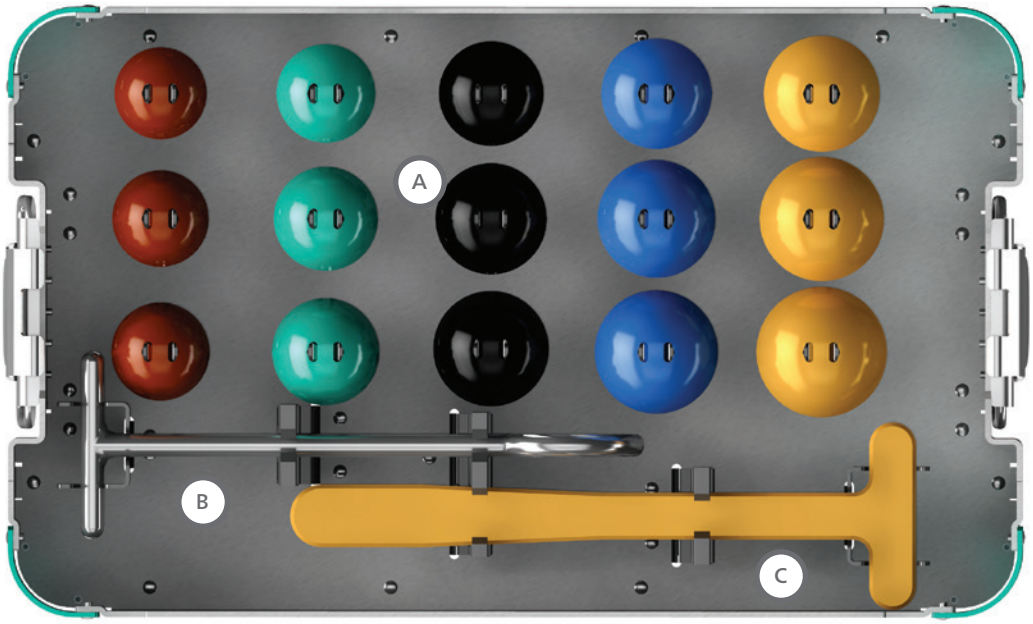
SIMPLICITI™ General Instrument Tray



Description	P/N	Label
Small Cut Ring	9722926	A
Medium Cut Ring	9722927	A
Large Cut Ring	9722928	A
X-Large Cut Ring	9722929	A
Pin Driver	9722885	B
Size 1 Surface Planer	9722887	C
Size 2 Surface Planer	9722888	C
Size 3 Surface Planer	9722889	C
SIMPLICITI Head Distractor	9722903	D
Inclination Guide	9722905	E
Core Drill	9722890	F
Self-leveling Sizer Handle	9722884	G
Cut Protector Handle	9722899	H

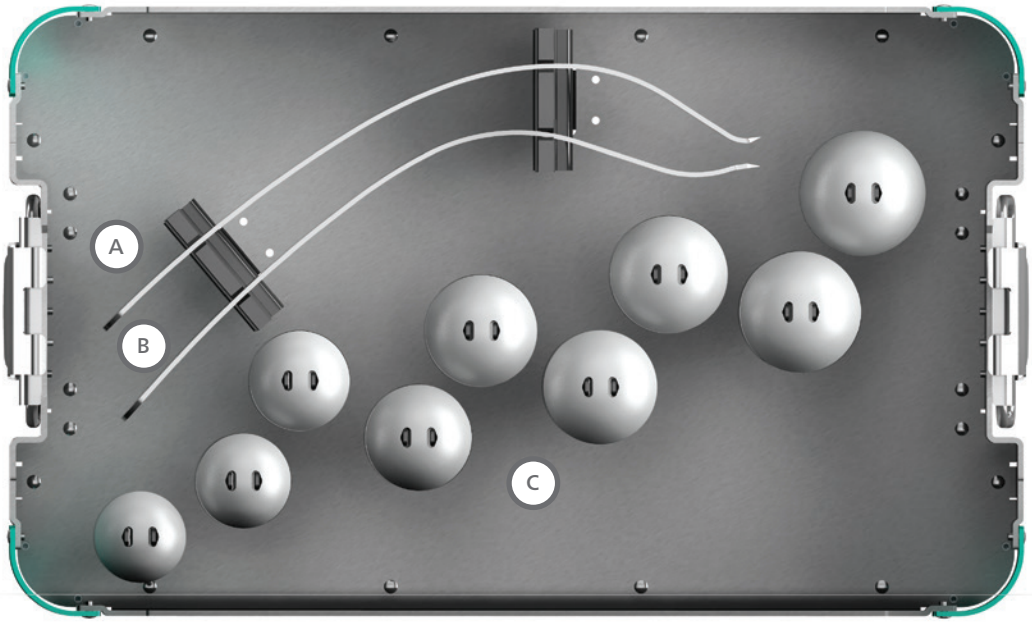
Description	P/N	Label
Size 1 Sizer Disk	9722881	I
Size 2 Sizer Disk	9722882	I
Size 3 Sizer Disk	9722883	I
Size 1 Fin Blazer Trial	9722891	J
Size 2 Fin Blazer Trial	9722892	J
Size 3 Fin Blazer Trial	9722893	J
Size 1 Cut Protector	9722896	K
Size 2 Cut Protector	9722897	K
Size 3 Cut Protector	9722898	K
SIMPLICITI Grasper	9722895	L
Head Impactor Tip	9722902	M
Blazer/Head Impactor	9722894	N
Nucleus Impactor	9722900	O

SIMPLICITI™ STB Trial Head Tray



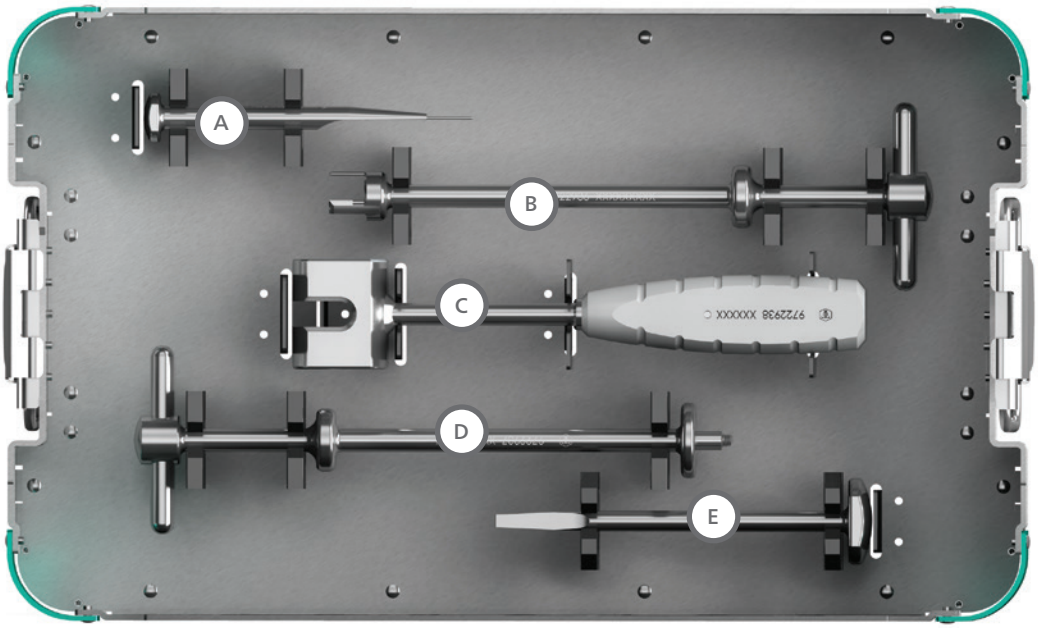
Description	P/N	Label
40 X 15 SIMPLICITI STB Head Trial	9723084	A
40 X 18 SIMPLICITI STB Head Trial	9723085	A
40 X 21 SIMPLICITI STB Head Trial	9723086	A
44 X 15 SIMPLICITI STB Head Trial	9723087	A
44 X 18 SIMPLICITI STB Head Trial	9723088	A
44 X 21 SIMPLICITI STB Head Trial	9723089	A
48 X 15 SIMPLICITI STB Head Trial	9723090	A
48 X 18 SIMPLICITI STB Head Trial	9723091	A
48 X 21 SIMPLICITI STB Head Trial	9723092	A
52 X 15 SIMPLICITI STB Head Trial	9723093	A
52 X 18 SIMPLICITI STB Head Trial	9723094	A
52 X 21 SIMPLICITI STB Head Trial	9723095	A
56 X 15 SIMPLICITI STB Head Trial	9723096	A
56 X 18 SIMPLICITI STB Head Trial	9723097	A
56 X 21 SIMPLICITI STB Head Trial	9723098	A
Crego Retractor	9000384	B
Plastic Darrach	9000381	C

SIMPLICITI™ Trial Head Tray



Description	P/N	Label
Wide Kolbel	MWA681	A
Narrow Kolbel	MWD046	B
39 x 14 SIMPLICITI Humeral Head Trial	9722917	C
41 x 15 SIMPLICITI Humeral Head Trial	9722918	C
43 x 16 SIMPLICITI Humeral Head Trial	9722919	C
46 x 17 SIMPLICITI Humeral Head Trial	9722920	C
48 x 18 SIMPLICITI Humeral Head Trial	9722921	C
50 x 16 SIMPLICITI Humeral Head Trial	9722922	C
50 x 19 SIMPLICITI Humeral Head Trial	9722923	C
52 x 19 SIMPLICITI Humeral Head Trial	9722924	C
52 x 23 SIMPLICITI Humeral Head Trial	9722925	C

SIMPLICITI™ Revision Tray



Description	P/N	Label
Small Osteotome	9722935	A
Core Extractor	9722936	B
Slotted Mallet	9722938	C
Threaded Extractor	9722937	D
SIMPLICITI Head Distractor	9722903	E

SIMPLICITI™ Implants

Description	Qty Per Pkg	Catalog No.
SIMPLICITI Nucleus, Size 1	1	DWG 401
SIMPLICITI Nucleus, Size 2	1	DWG 402
SIMPLICITI Nucleus, Size 3	1	DWG 403
39 x 14 SIMPLICITI Humeral Head	1	7122868
41 x 15 SIMPLICITI Humeral Head	1	7122869
43 x 16 SIMPLICITI Humeral Head	1	7122870
46 x 17 SIMPLICITI Humeral Head	1	7122871
48 x 18 SIMPLICITI Humeral Head	1	7122872
50 x 16 SIMPLICITI Humeral Head	1	7122873
50 x 19 SIMPLICITI Humeral Head	1	7122874
52 x 19 SIMPLICITI Humeral Head	1	7122875
52 x 23 SIMPLICITI Humeral Head	1	7122876

SIMPLICITI™ STB Heads

Description	Qty Per Pkg	Catalog No.
40 x 15 SIMPLICITI STB Humeral Head	1	7122877
40 x 18 SIMPLICITI STB Humeral Head	1	7122878
40 x 21 SIMPLICITI STB Humeral Head	1	7122879
44 x 15 SIMPLICITI STB Humeral Head	1	7122880
44 x 18 SIMPLICITI STB Humeral Head	1	7122881
44 x 21 SIMPLICITI STB Humeral Head	1	7122882
48 x 15 SIMPLICITI STB Humeral Head	1	7122883
48 x 18 SIMPLICITI STB Humeral Head	1	7122884
48 x 21 SIMPLICITI STB Humeral Head	1	7122885
52 x 15 SIMPLICITI STB Humeral Head	1	7122886
52 x 18 SIMPLICITI STB Humeral Head	1	7122887
52 x 21 SIMPLICITI STB Humeral Head	1	7122888
56 x 15 SIMPLICITI STB Humeral Head	1	7122889
56 x 18 SIMPLICITI STB Humeral Head	1	7122890
56 x 21 SIMPLICITI STB Humeral Head	1	7122891

Available Separately

Description	Qty Per Pkg	Catalog No.
SIMPLICITI Humeral Head Templates	1	9722906
SIMPLICITI Nucleus Templates	1	9722907
Sterile 3 x 75 mm Guide Pin	1*	9722908

Notes

Proper surgical procedures and techniques are the responsibility of the medical professional. This material is furnished for information purposes only. Each surgeon must evaluate the appropriateness of the material based on his or her personal medical training and experience. Prior to use of any Tornier implant system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting Wright. Contact information can be found in this document and the package insert.

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