stryker

Tornier Simpliciti®
Shoulder System

Operative technique

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 (https://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

Table of contents

Indications

The Tornier 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 Tornier 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 Tornier Simpliciti Nucleus has been designed to be compatible with the humeral head components for both the Tornier Simpliciti and Tornier Simpliciti STB Systems. Additionally, both humeral head systems, in certain combinations, are compatible with the Tornier Perform Anatomic, Tornier Perform Anatomic Augmented and Affiniti Glenoid Systems. For more information on the cleared combinations, refer to Tornier Simpliciti mismatch charts (AP-015308).

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. 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.

Note: 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**
- 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 1

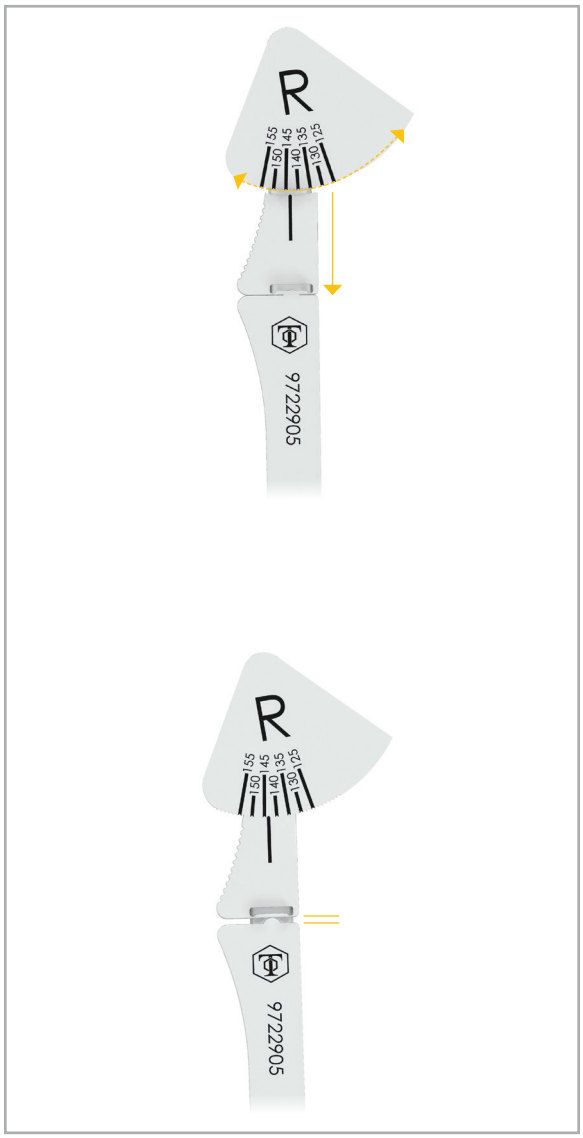


Figure 2

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**

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.

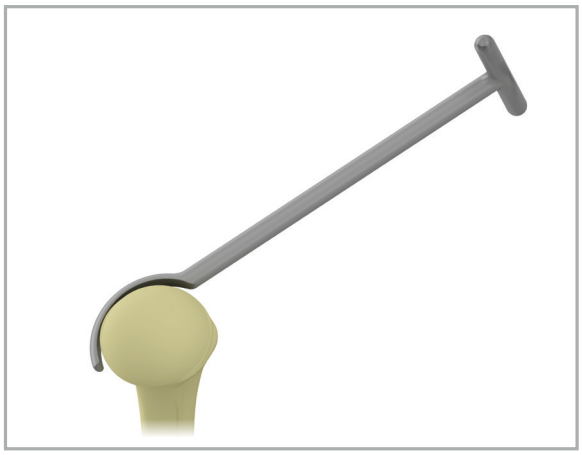


Figure 3

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 3mm guide pins through the cut rings using the pin driver. **| 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.

Figure 4

Sizing and 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**
- Choose the largest sizer that does not overhang the humerus at any point. **| 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**
- 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.

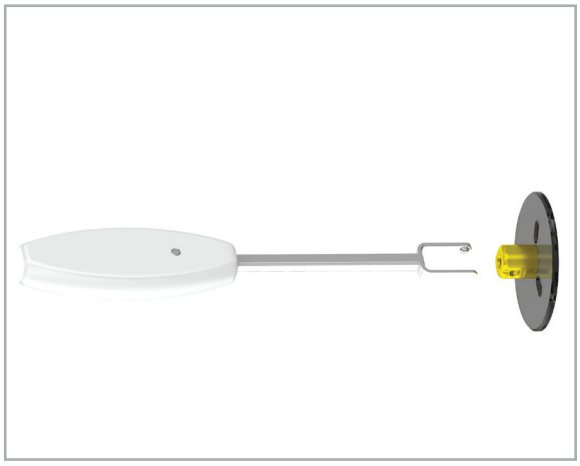


Figure 5

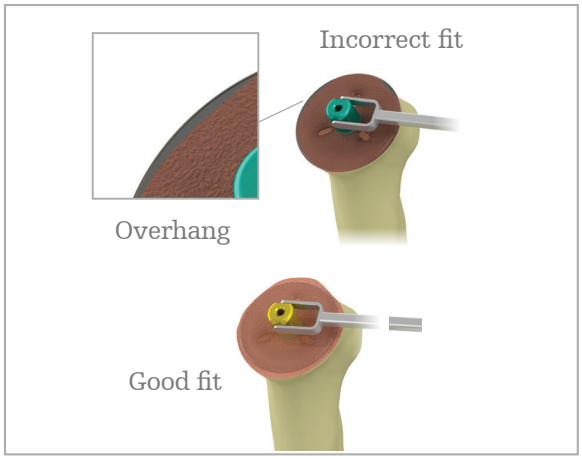


Figure 6

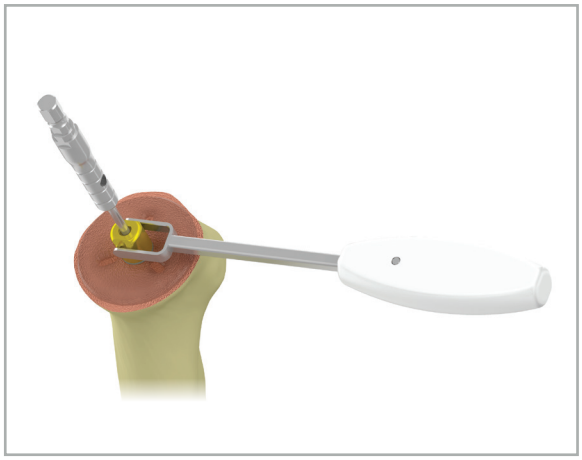


Figure 7

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**
- 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**
- 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**

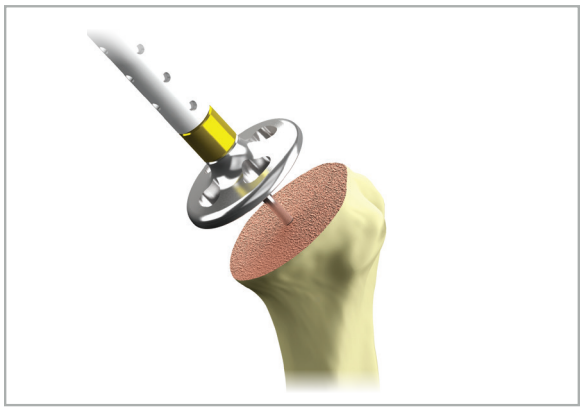


Figure 8

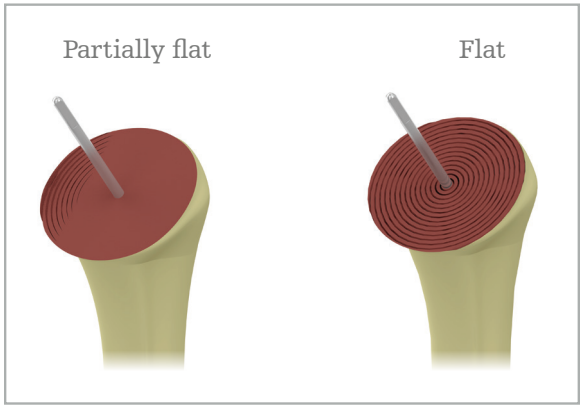


Figure 9

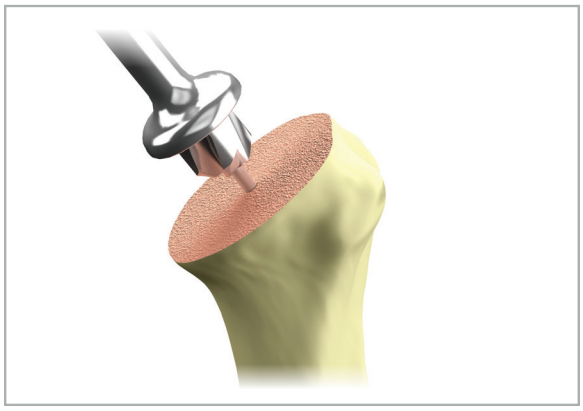


Figure 10

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**
- Position the blazer so that one fin points directly superolaterally. **| Figure 12**
- 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.

Figure 11

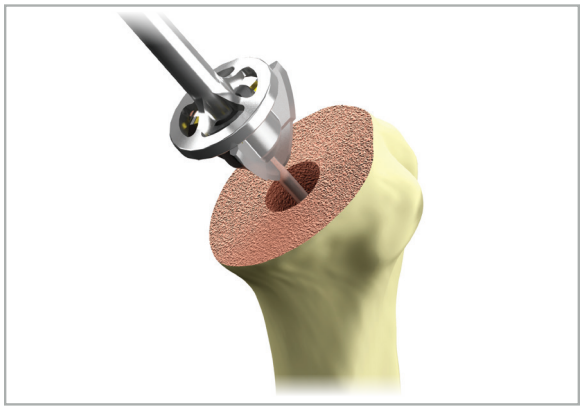


Figure 12

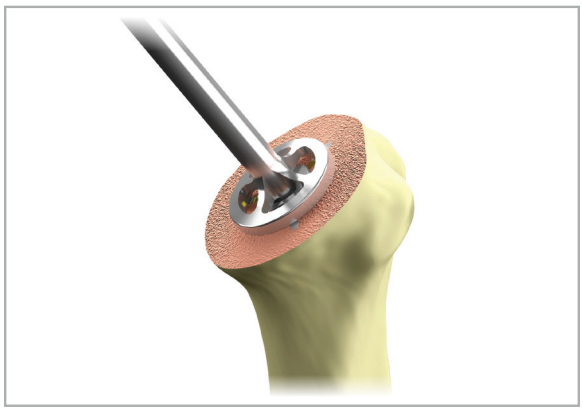


Figure 13

- 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**
- 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 90º or until it is securely attached to the fin blazer. **| 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 AP-015308.

- 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.

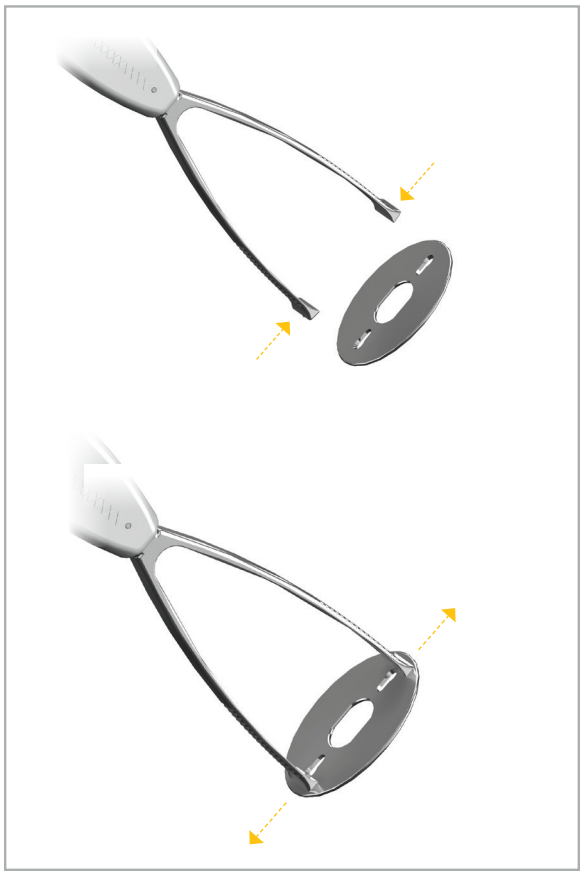


Figure 14

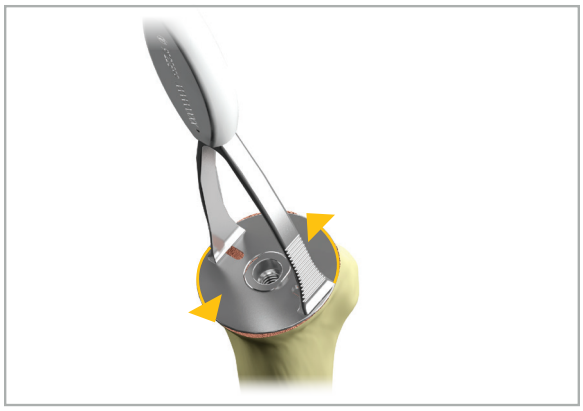


Figure 15

Selecting the humeral head system

Two humeral head options are compatible with the Tornier Simpliciti Metaphyseal Implant, which is referred to as the nucleus. Both humeral head options attach to the nucleus via a Morse taper.

Option 1: Soft-tissue balancing approach

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

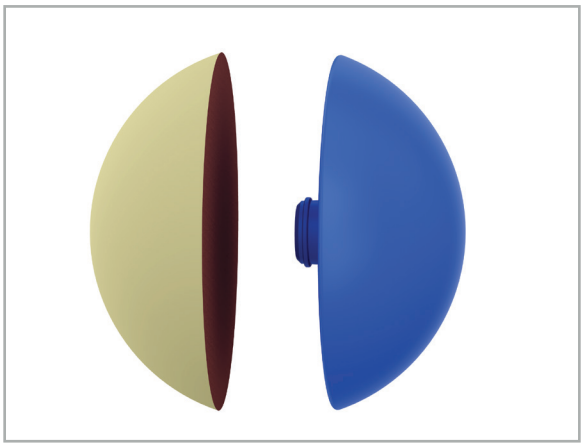


FIGURE 16

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.

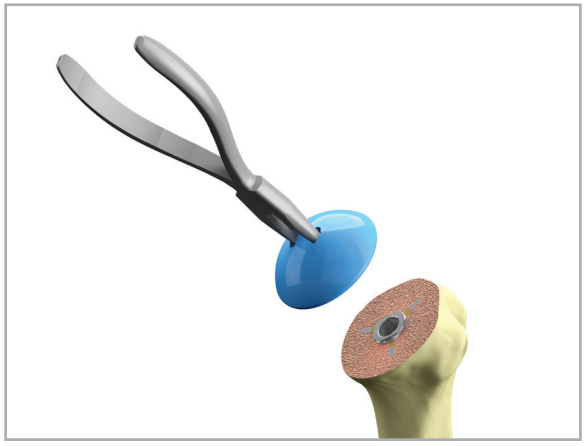


Figure 17

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 90º and internally rotated. 60º of internal rotation should be obtained. If less than 60º 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**
- 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.

Note: Excess force should be avoided during impaction and care should be taken not to damage the articular surface of the implant. **| 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.

Figure 18

Figure 19

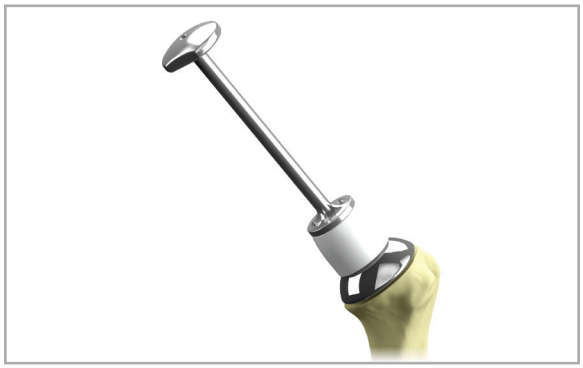


Figure 20

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°.
- 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 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. **| Figure 21**

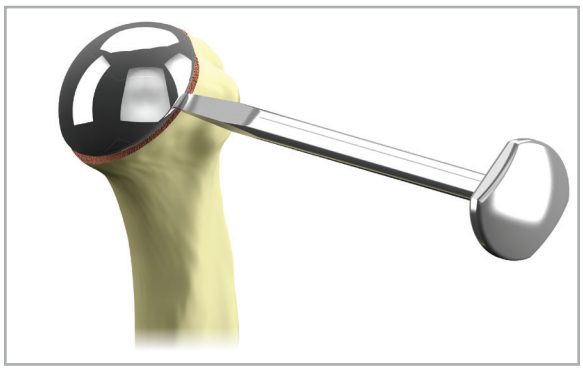


Figure 21

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**
- 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**

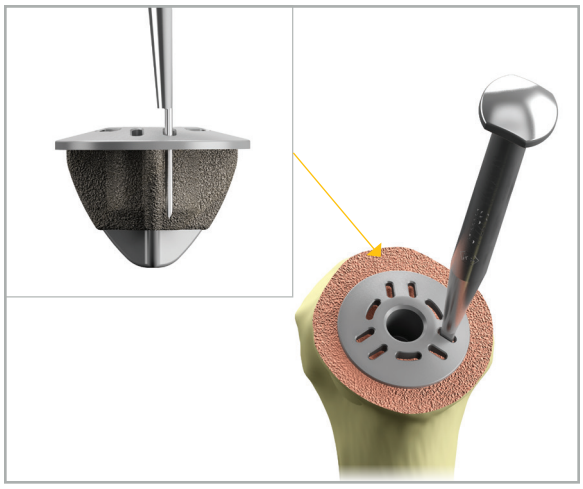


Figure 22

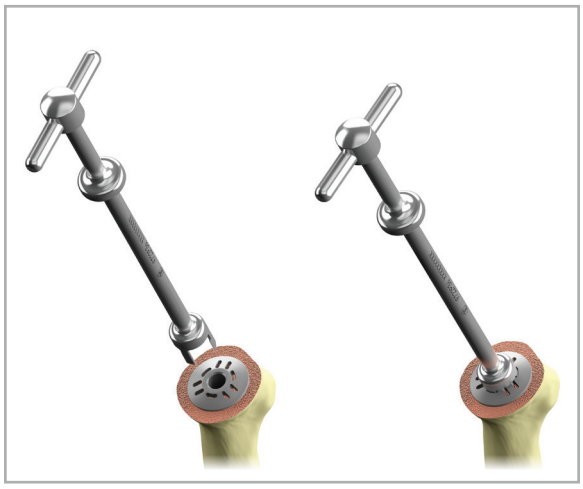


Figure 23

- 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**
- 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**

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

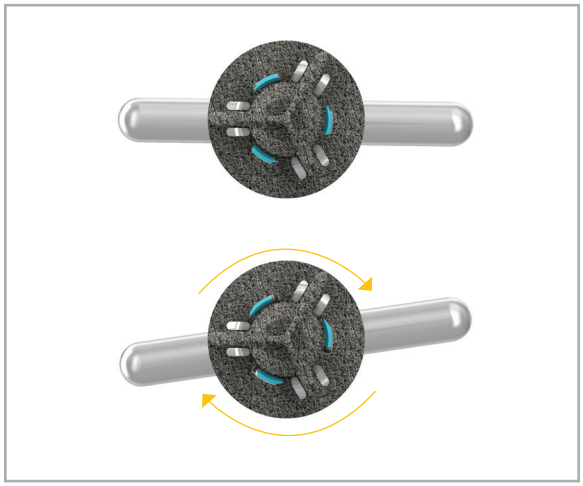


Figure 24

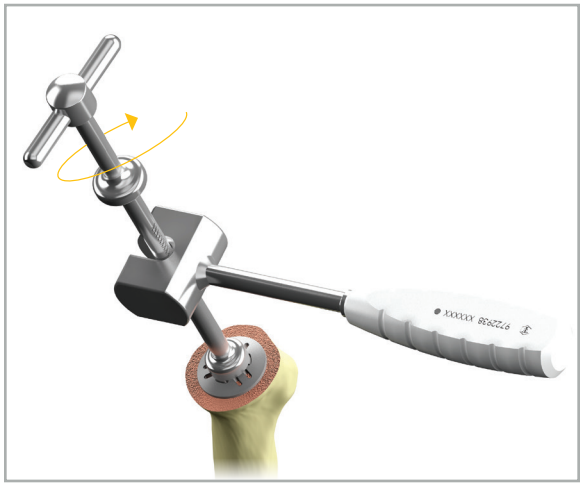
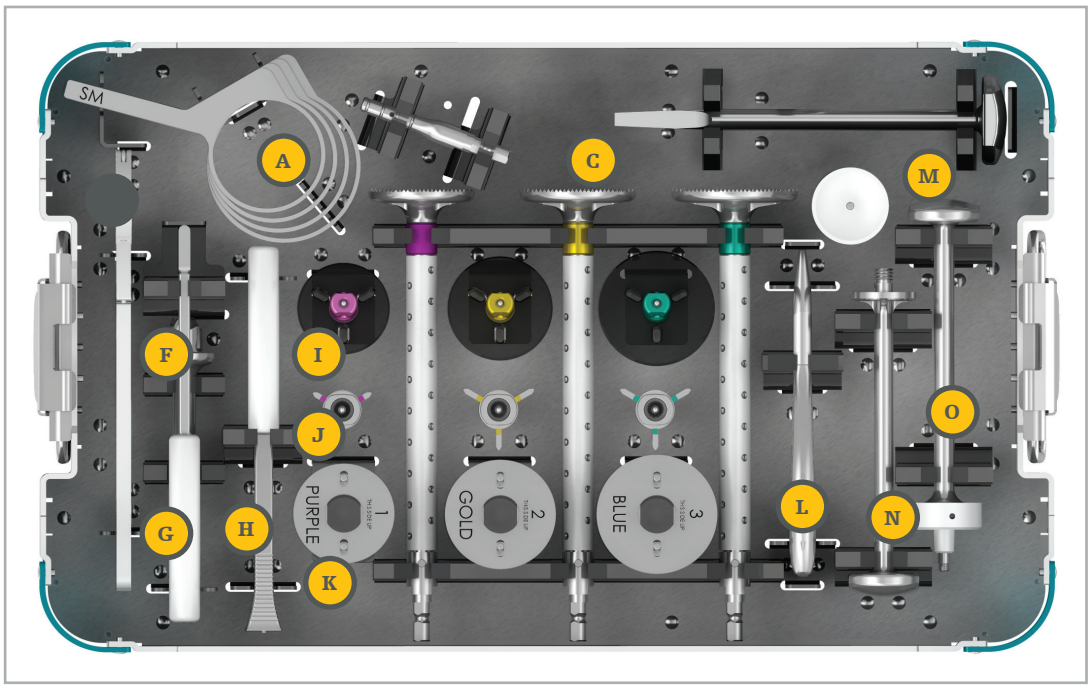


Figure 25

Figure 26

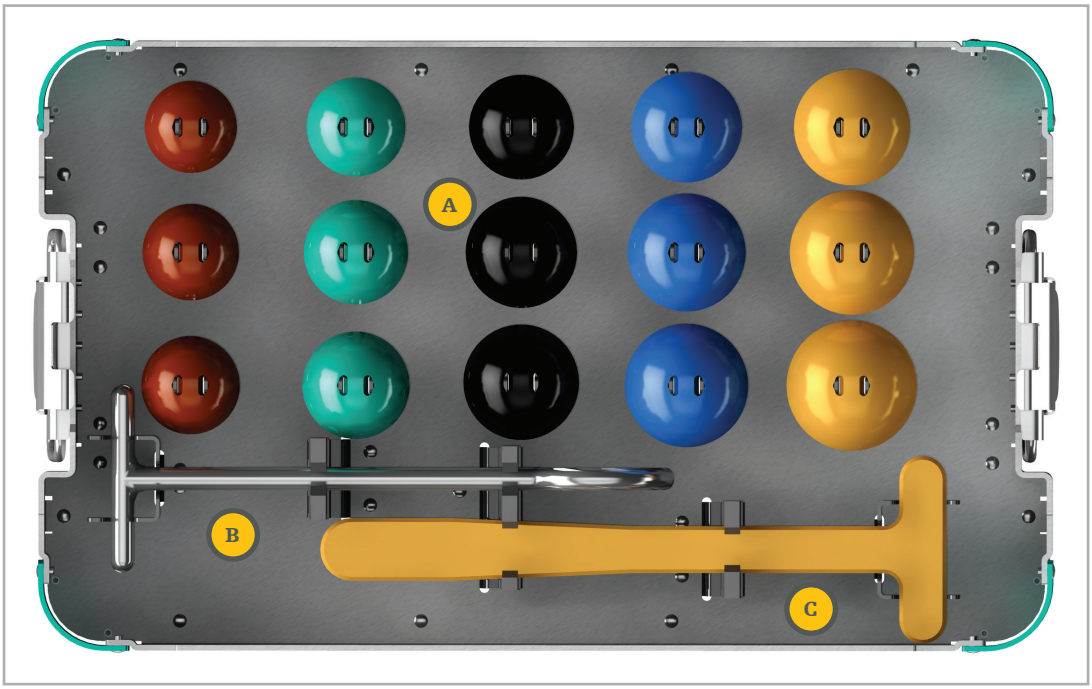
Tornier Simpliciti General Instrument Tray



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
Tornier Simpliciti Head Distractor	9722903	D
Inclination guide	9722905	E
Core drill	9722890	F
Self-leveling sizer handle	9722884	G
Cut protector handle	9722899	H

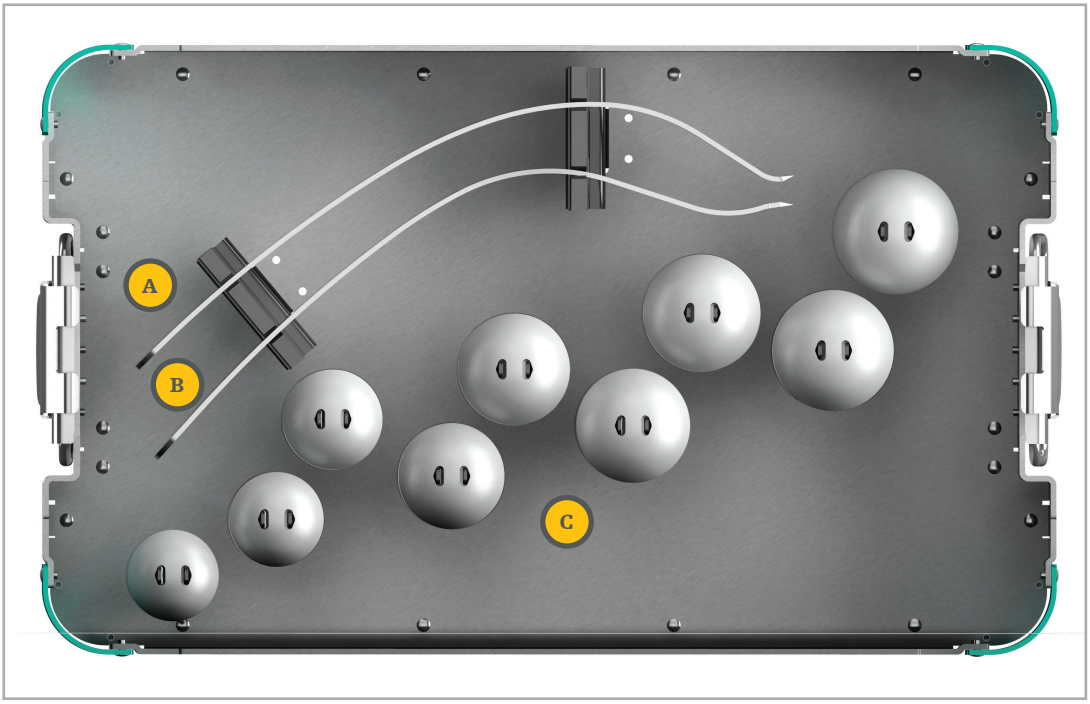
Description	P/N	Label
Size 1 sizer disk	9722881	I
Size 2 sizer disk	9722882	I
Size 3 sizer disk	9722883	I
Size 1 fin blazer trial	9722891	J
Size 2 fin blazer trial	9722892	J
Size 3 fin blazer trial	9722893	J
Size 1 cut protector	9722896	K
Size 2 cut protector	9722897	K
Size 3 cut protector	9722898	K
Tornier Simpliciti Grasper	9722895	L
Head impactor tip	9722902	M
Blazer/head impactor	9722894	N
Nucleus impactor	9722900	O

Tornier Simpliciti STB Trial Head Tray



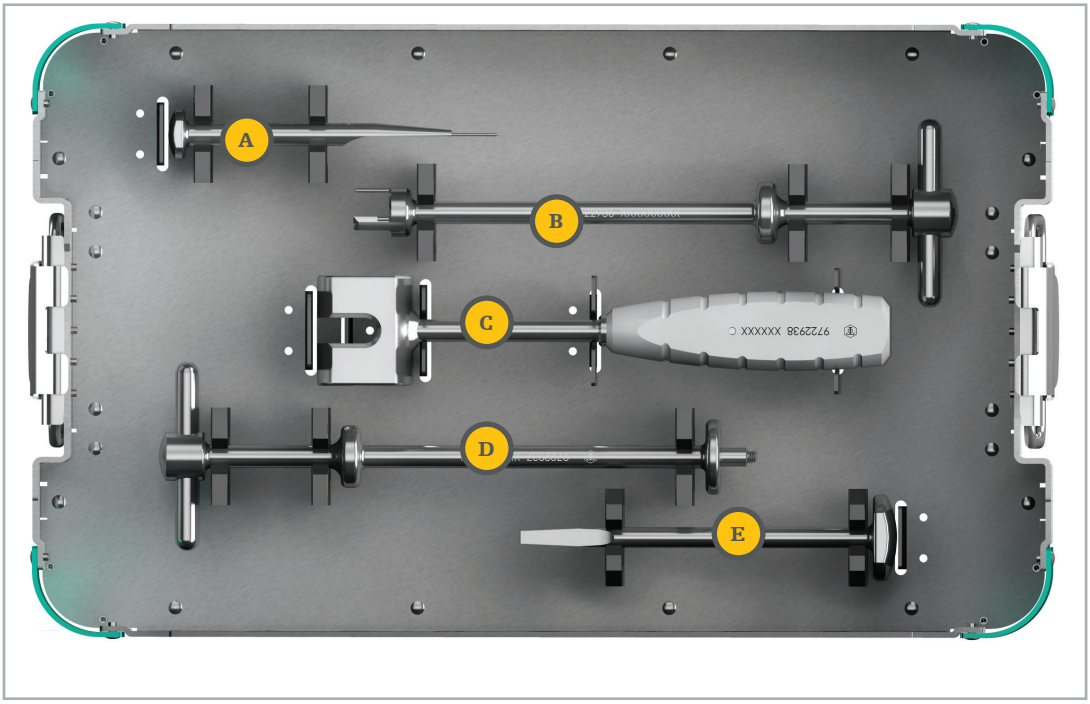
Description	P/N	Label
40 X 15 Tornier Simpliciti STB Head Trial	9723084	A
40 X 18 Tornier Simpliciti STB Head Trial	9723085	A
40 X 21 Tornier Simpliciti STB Head Trial	9723086	A
44 X 15 Tornier Simpliciti STB Head Trial	9723087	A
44 X 18 Tornier Simpliciti STB Head Trial	9723088	A
44 X 21 Tornier Simpliciti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

Tornier Simpliciti Trial Head Tray



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

Tornier Simpliciti Revision Tray



Description	P/N	Label
Small osteotome	9722935	A
Core extractor	9722936	B
Slotted mallet	9722938	C
Threaded extractor	9722937	D
Tornier Simpliciti Head Distractor	9722903	E

Tornier Simpliciti Implants

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

Tornier Simpliciti STB Heads

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

Available separately

Description	Qty Per Pkg	Catalog No.
Tornier Simpliciti Humeral Head Templates	1	9722906
Tornier Simpliciti Nucleus Templates	1	9722907
Sterile 3mm x 75mm guide pin	1*	9722908

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.

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The instructions for use, operative techniques, cleaning instructions, patient information leaflets and other associated labeling may be requested online at ifu.stryker.com or 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.

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