stryker

Tornier Flex

Shoulder System
Reversed Shoulder Arthroplasty

Operative technique addendum

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 Flex

Shoulder System Reversed Shoulder Arthroplasty

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Operative technique

Humeral head resection

The humeral head resection is made at a fixed inclination of 132.5º. A resection cut guide is available to assist in the humeral head resection during reversed shoulder arthroplasty.

The tip of the reversed cutting guide is inserted inline with the humeral shaft at the hinge point of the humeral head. This should be centered in the anterior/posterior plane. Advance the guide until the ring sits flush on the humeral head. **| Figures 1 and 2**

To define appropriate humeral version prior to humeral head resection, a version rod can be positioned into the desired version hole along the axis of the cut guide. The guide is then rotated until the version rod is aligned with the patient's forearm. With the guide aligned, the head is then resected at the B 132.5º inclination with an oscillating saw below the ring of the cut guide.

In order to achieve a reversed neck shaft angle (NSA) of 135º, the humeral head resection is made at 127.5º. An extramedullary angle indicator guide is available to assist in the humeral head resection.

Note:
A compactor locked at the A 127.5º angle can be used as an angle indicator.

Note:
For the final implantation of an onlay construct, please refer to the standard operative technique for the Tornier Flex Shoulder System, while keeping the desired final reversed neck shaft angle in mind.

Note:
The glenoid can now be prepared. Once the glenoid has been implanted, preparation of the humerus can begin.

Figure 1

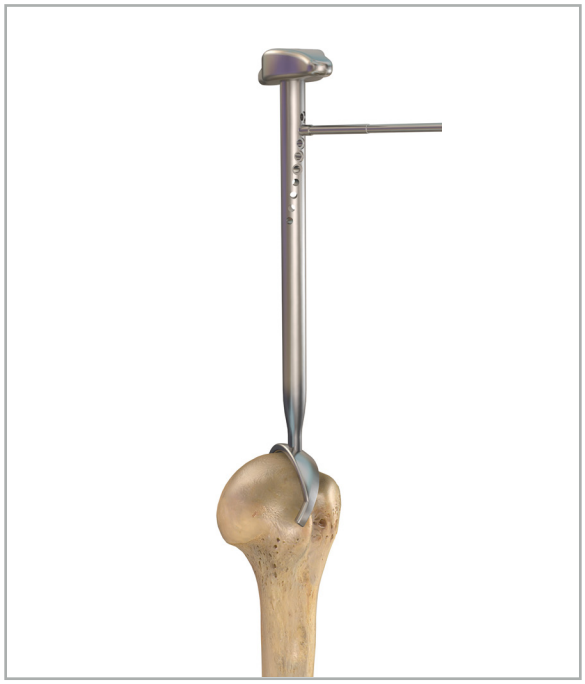


Figure 2

Inlay reaming

Preparing the resected humeral head surface:

- Insert the inlay reamer into the surgical drill or T-handle.
- Center the tip of the inlay reamer on the resected humeral head surface. Do not force the tip into the resected bone surface.
- Confirm circumferentially that there is no soft tissue touching the inlay reamer.
- Gently engage power and apply minimal force to ream until the collar of the inlay reamer is level with the resected humeral surface. **| Figures 3 and 4**

Figure 3

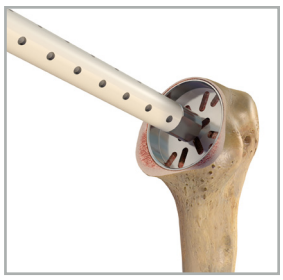


Figure 4

Note:
The inlay reamer has a 40mm diameter. Before using the inlay reamer, ensure that patient anatomy is large enough to accommodate the instrument.

Note:
The completion of the inlay ream will result in approximately 7mm-10mm deep of humeral preparation.

Figure 5

Figure 6

Starter awl

Using the starter awl, create a pilot hole inline with the humeral canal at the hinge point of the resection. **| Figure 5**

The starter awl should be advanced until the large fluted diameter is just below the level of the resection. This will provide a pilot hole for the first sounder. **| Figure 6**

Distal preparation

Sizing the medullary canal

The sounders (sizes: 1-2, 3-4, 5-6, 7-8) are utilized to determine the upper size limit of the humeral stem size. The sounders have been designed to compact bone, which creates a dense bony bed for the final implant.

Each sounder is color coded to correspond with instrumentation to be utilized in subsequent steps. Version holes have been incorporated into the proximal shaft of each sounder. A version rod can be placed in the appropriate hole to ensure the sounders are utilized in the same humeral version established during the original humeral head resection. **| Figure 7**

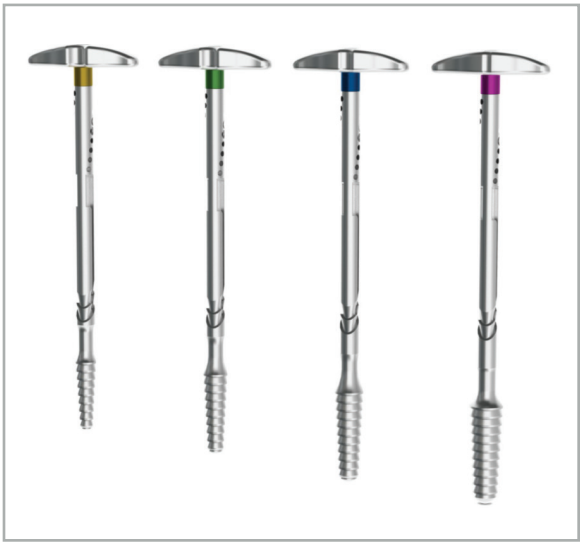


Figure 7

To begin sounding, insert the sounders through the pilot hole starting with the size 1-2 and progressively increasing until contact is made with the cortical wall of the humeral canal. It is important to orient the sounders so the oblong flats of the sounder align with the plane of the resection. These flats align the flutes of the sounders with the distal portion of the anatomic humeral implant geometry. This also serves as a depth stop indicator and identifies the threshold for humeral implant sizing. **| Figure 8**

When the sounder reaches the cortical wall and fits securely, stop and read the number closest to the resection. This number will indicate the largest size stem that can safely be implanted. If the sounder seats in between sizes, select the lower of the two numbers. It is important to leave the sounder in place at this time. **| Figure 9**

Figure 8

Figure 9

Note:
The sounders are not intended to cut cortical bone. As a result, a reaming motion should not be used when cortical contact is made.

Caution:
Do not impact the sounder.

Note:
Before completing the medial punch, note the location of the punch template to ensure there is no medial cortex contact. If contact is noticed, remove the punch template and use a smaller size punch template, or remove the sounder and advance to the compacting step.

Proximal preparation

Guided metaphyseal punching

With the final sounder in place, select the corresponding punch template. As verification, check to ensure the color of the punch template matches that of the sounder. **| Figure 10**

Attach the punch template to the sounder via the axial slots and slide it down the sounder until the template rests flat on the resection. Place the corresponding punch into the template and impact the punch until it bottoms out on the template. **| Figure 11**

The scored bone must be removed by pulling the sounder, punch and punch template vertically out of the proximal humerus.

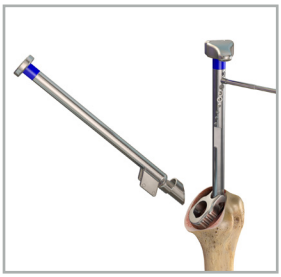


Figure 10

Figure 11

Metaphyseal compaction

Compactor overview

The Tornier Flex Shoulder System offers both short and long stems and therefore offers both short and long compactors.

Short stems are offered in three angles (A 127.5º, B 132.5º, C 137.5º) and are intended to be utilized as both an anatomic and reversed implant. When utilized in the reversed configuration, select the A 127.5º or B 132.5º angle. Long stems are offered only in the B 132.5º angle and are intended to be utilized as a reversed or revision implant.

Short and long compactors have been designed with a proximal body that pivots about the mid-point, allowing a single compactor to adjust to all three stem angles. The proximal body is locked into position via a set screw at the bottom of the taper that is manipulated with the 2.5mm locking inclination driver.

Assembling the compactor

When preparing for a reversed implant, it is recommended to lock the proximal body of the compactor desired A 127.5º or B 132.5º angle prior to impaction. This angle can be read off the back of the compactor.

To assemble the compactor to the inserter handle, ensure the handle of the inserter handle is in the fully unlocked position and place the clamp feet of the inserter handle into the medial and lateral slots on the compactor. Next, squeeze and lock the handle to secure the assembly. There is an optional depth stop that will attach to the inserter handle to ensure the stem rests flush on the resection surface.

The inserter handle has optional version holes designed to accept the version rod to assist in orienting the compactors to the previously determined version. If utilized, be sure the version rod is placed on the side of the inserter handle that corresponds with the operative side of the patient (left or right). It is recommended to remove the version rod prior to extraction.

Compacting

It is recommended to begin with the size 1 compactor and compact sequentially until satisfactory fixation is achieved. Satisfactory fixation can be assessed by a slight torque motion of the inserter handle. The compactor should not move within the humerus during this test.

Place the tip of the compactor into the pilot hole created by the sounders and orient the assembly in the preselected version. This will ensure the version created with the resection is maintained during the compacting step. Alternatively, the optional version rod described above could be utilized in reference to the forearm to orient the compactor to the desired version. **| Figure 12**

Advance the compactor until the compactor rests flush on the resected surface of the humerus. Continue with progressive compaction until the satisfactory fit described above is achieved. **| Figure 13**

Figure 12

Figure 13

Note:
When not utilizing the depth stop, it is important not to impact the compactor past the level of the resected surface.

Loosen the handle of the inserter handle and leave the compactor inside the humerus as the trial implant. It may be advisable to retighten the set screw prior to removing the handle. **| Figure 14**

Figure 14

Note:
Metaphyseal compaction for cemented stems. When implanting a cemented stem, please note that the stems are undersized to the compactors.

Note:
It is important not to use a compactor larger than the size measured by the sounder to avoid risk of humeral fracture.

Reversed preparation

Trialing reversed components

Trialing the reversed component is critically important to ensure a successful clinical outcome.

The Tornier Flex Shoulder System Reversed Components are comprised of reversed trays that are placed onto the humeral stem and reversed inserts that "snap" into and line the reversed tray. **| Figure 15**

When assembled, these two components are collectively referred to as the reversed adapter.

Reversed tray

There are multiple reversed trays offered in the Reversed Tray Shoulder System.

Note:
Refer to the Tornier Flex Shoulder System standard operative technique for all reversed tray options.

Note:
Upon request, additional inserts are available for cases of instability.

Choose the reversed tray offset that covers the entire "inlay" humeral surface when placed on the compactor. Select the +0 trial of that particular offset. Insert the tips of the trial clamp into the holes located on the sides of the trial. The trial can then be placed onto the compactor and rotated to the desired location.

Note:
It may be necessary to utilize a rongeur to remove excess bone if the tray does not fit as desired.

With the trial placed in the desired location, insert the 3.5mm retaining driver into the screw of the reversed tray trial and advance the screw to lock the trial into position. **| Figure 16**

Next, select the desired +6 reversed insert trial that matches with the diameter of the glenoid sphere. Orient the insert trial so the laser mark is positioned at the most lateral position of the humerus. As a check, the thinnest portion of the insert trial should be lateral (superior) and the thickest portion of the insert trial should be medial (inferior). **| Figure 17**

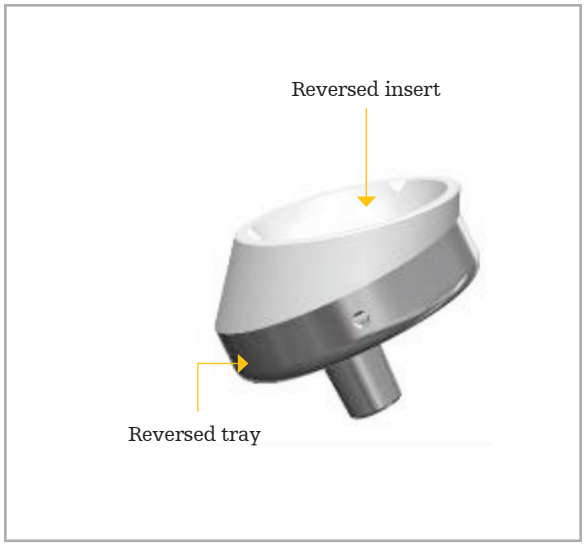


Figure 15

Figure 16

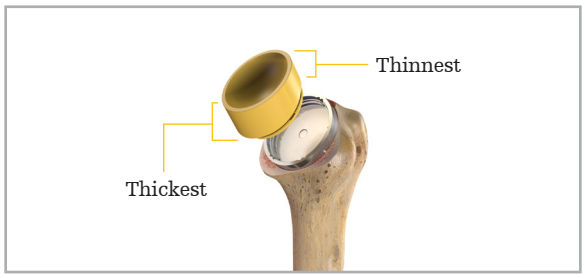


Figure 17

The humeral trial is then reduced into the joint to check deltoid tension, stability, range of motion and impingement. If needed, the thickness of the trial implant can be adjusted to provide optimal deltoid tension.

Removing the trial construct

Once the reversed trial components have been confirmed, dislocate the shoulder and remove the trial construct. (It is important to leave the trial construct assembled and remove it as one piece as this will provide information necessary for assembling the final implant.)

To remove the trial construct, thread the tip of the trial slaphammer (with handle all the way at the bottom to stabilize the tip) into the threads located in the screw head of the reversed tray trial. It is important to not overtighten the threads. **| Figure 18**

Next, slide the handle of the trial slaphammer away from the trial. This will free the pivoting joint allowing the handle to move in any direction. Orient the handle in a superior position and with incremental backslaps remove the trial construct. **| Figures 19 and 20**

After removing the trial construct, unthread the trial slaphammer. If an offset tray was utilized, determine the rotation by orienting the trial construct so the bottom of the reversed tray trial is visible.

A clock-like face with numbers ranging from 1-12 is marked on the bottom of the offset trays. Take note of the number that falls closest to the lateral most edge of the compactor. This number will determine the position of the final reversed tray as it relates to the notch on the lateral edge of the final stem.

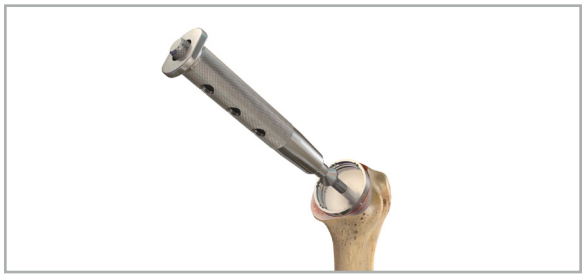


Figure 18

Figure 19

Figure 20

Final implantation

Note:
The surgeon should inspect the implant tapers and mating surfaces for debris or blemishes before assembly.

- The tapers should be clean and dry for assembly.
- The implants should be assembled with clean gloves.
- The final implant can be assembled on the back table or in-vivo.

Back table assembly

Place the chosen definitive humeral stem (respecting the size and angle of the trial) into the appropriate slot of the impaction stand.

The standard stem slots are located on one side of the impaction block and the long stem slots are located directly opposite the standard stem slots. Each side of the impaction block is then divided into two sections depending on size (1-4, 5-8). **| Figures 21 and 22**

With the definitive stem in hand, orient the selected reversed tray to the previously determined position. Next, place the implant assembly into the appropriate slot of the impaction block. Using the impactor handle with the head/tray impactor tip, seat the taper. **| Figure 23**

Apply the holding plate to the tray oriented in the correct up/down orientation, and connect the inserter handle. **| Figure 24**

Place the definitive humeral implant in the prepared humeral canal and impact until the previously determined depth of the inlay tray is flush with the prepared humerus. Take care to maintain the preselected version (use the version rod if necessary) and do not insert the tray deeper than the previous trial. **| Figures 25 and 26**

Place the definitive polyethylene, impact into place using impactor handle with the head/tray impactor tip and reduce the humeral implant. **| Figure 27**

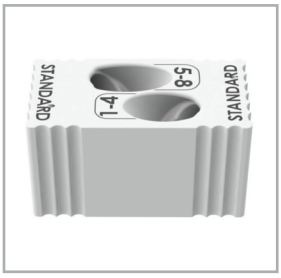


Figure 21

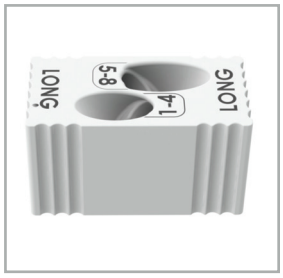


Figure 22

Figure 23

Figure 24

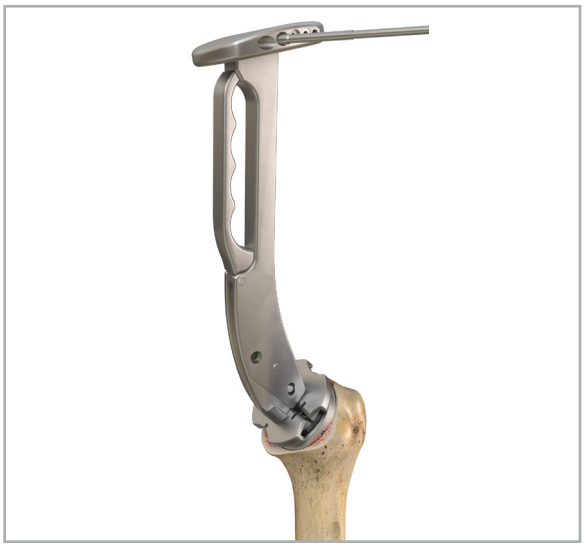


Figure 25

Figure 26

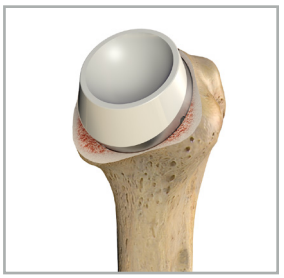


Figure 27

In-vivo assembly

It is not recommended to use the in-vivo technique in patients with poor bone quality.

Assemble the final stem onto the inserter handle, ensure the handle of the inserter handle is in the fully unlocked position and place the clamp fee of the inserter handle into the medial and lateral slots on the final stem. Next, squeeze and lock the handle to secure the assembly. If utilized, be sure the version rod is placed on the side of the inserter handle that corresponds with the operative side of the patient (left or right).

Tornier Flex PTC Stem

Note:
It is recommended to use the in-vivo assembly for the cemented stem.

To implant an Tornier Flex Stem, insert the stem into the prepared humerus taking care to maintain the version of the resection. Impact the stem until the top of it is flush on the resected surface of the humerus. **| Figures 28 and 29**

Remove the inserter handle and orient the selected reversed tray to the desired location. Seat the taper using the impactor handle with the head/tray impactor tip and continue to impact until the bottom of the reversed tray is flush with the cut and check implant stability. **| Figures 30, 31 and 32**

Figure 28

Figure 29

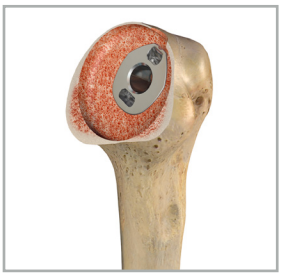


Figure 30

Figure 31

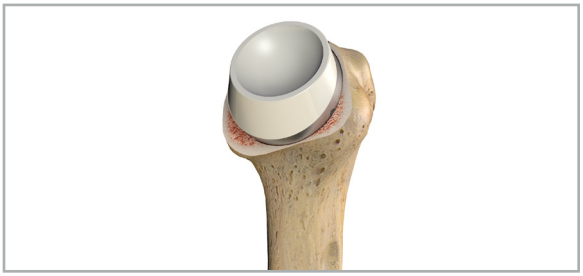


Figure 32

Tornier Flex Cemented Stem

To implant an Tornier Flex Cemented Stem, irrigate and dry the humeral canal, then insert a cement restrictor. Inject cement into the medullary canal using a standard cementing technique and insert the stem into the humeral canal. Advance the stem until top of it is flush on the resected surface of the humerus, taking care not to countersink the implant.

Remove the inserter handle and any excess cement. Clean and dry the stem taper. Orient the selected size reversed tray to the desired location. Seat the taper using the impactor handle with the head/tray impactor tip. To place the insert, select the size and thickness determined during the trailing step and orient the insert so the laser mark is aligned with the most lateral aspect of the tray. As a check, the thinnest portion of the insert should be lateral and the thickest portion of the insert should be medial. With the insert aligned, use the impactor handle with the insert impactor tip to seat the insert into the tray.

Considerations for revision surgery

When revising an inlay, it may be necessary to make a bone window in the proximal humerus in order to gain access to the reversed tray insert taper. To achieve this, use an osteotome or rongeur to remove a small section of bone near the reversed tray. Now that the taper can be accessed, wedge the head distractor in between the taper and the humeral stem and use a mallet to further disengage the taper. **| Figures 33 and 34**

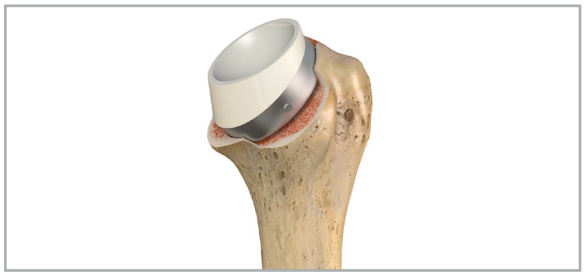


Figure 33

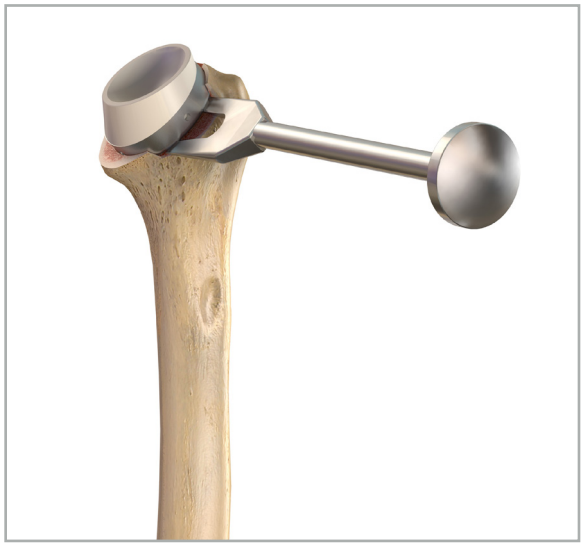
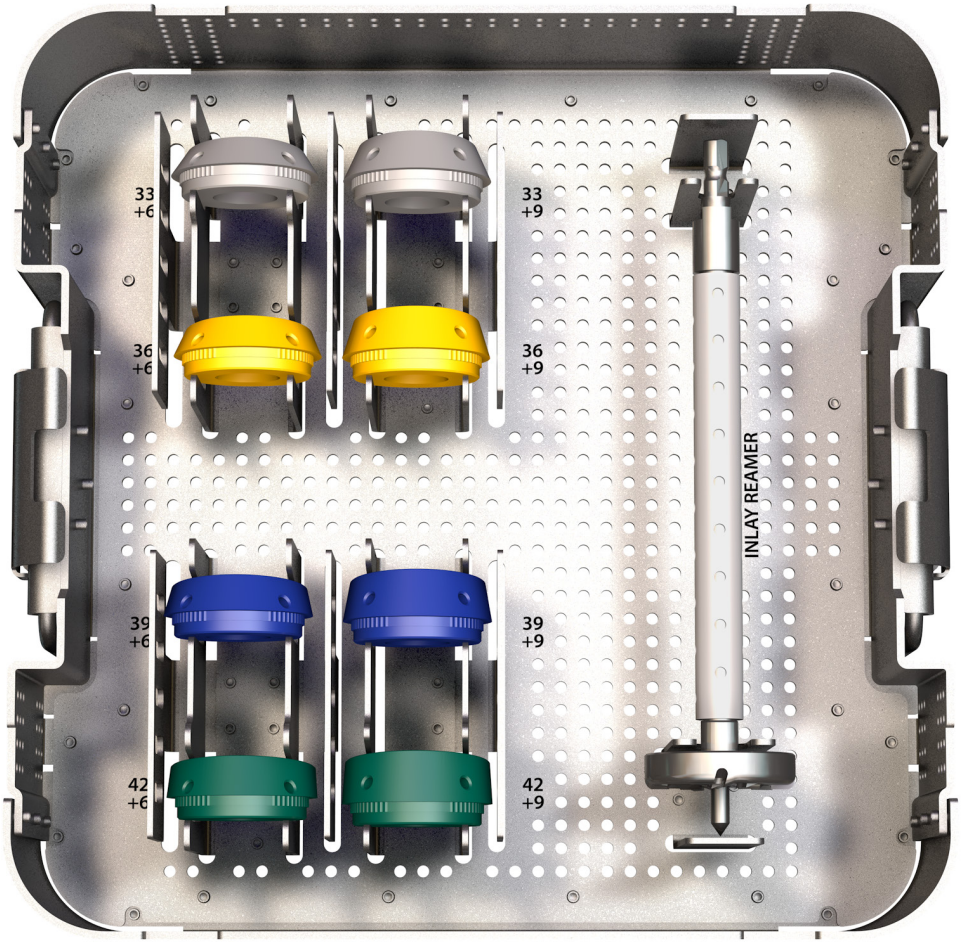


Figure 34

Instrumentation



Tornier Flex 135° Reversed Instruments (YKAD135)*

Reference	Description	Diameter	Thickness	Angle
MWF356C	Reversed insert trial	33mm	+6	C 7.5°
MWF357C	Reversed insert trial	33mm	+9	C 7.5°
MWF361C	Reversed insert trial	36mm	+6	C 7.5°
MWF362C	Reversed insert trial	36mm	+9	C 7.5°
MWF391C	Reversed insert trial	39mm	+6	C 7.5°
MWF392C	Reversed insert trial	39mm	+9	C 7.5°
MWF421C	Reversed insert trial	42mm	+6	C 7.5°
MWF422C	Reversed insert trial	42mm	+9	C 7.5°
ARS742900	Inlay reamer			

*This set is only available upon request and is mandatory to achieve a reversed neck shaft angle of 135°.

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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