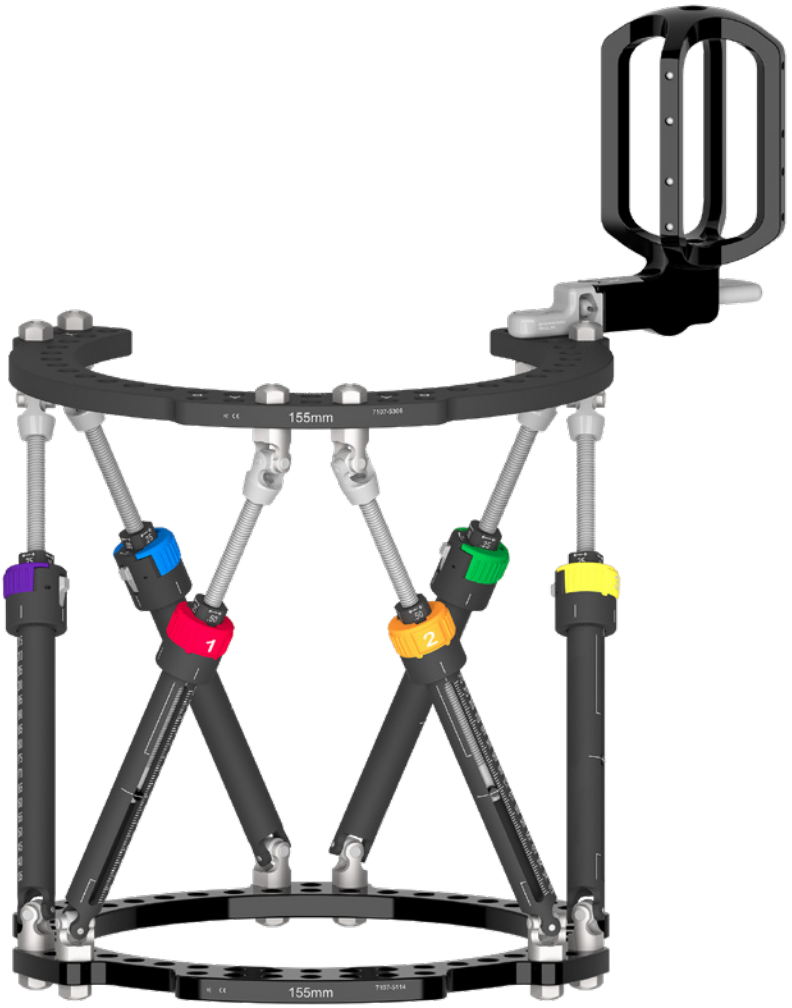
Surgical Technique

smith&nephew

# SMART TSF◇

Circular Fixator



# SMART TSF◇ Surgical Technique

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**Note Bena**

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the SMART TSF, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

# System Overview

## Device Description

SMART TSF® is a Ring-based External Fixator used in the management of fractures and correction of long bone deformities.

The TSF construct consists of two Rings and six telescoping Struts in the specific configuration described in “TSF Assembly.”

The TSF is applied to bone according to Ilizarov principles.[1,2]

HA-Coated Half Pins of 4.5mm or 6mm diameter, and Wires of 1.5mm or 1.8mm diameter connect the Rings to the bone.

Once TSF has been surgically applied, the parameters of the deformity and the details of the hardware can be entered in the web-based application SMART-TSF.com. The program will generate a prescription of Strut adjustments that reduce the angulations, rotations and translations to zero. The patient performs the Strut adjustments at a rate and rhythm determined by the surgeon. The Strut adjustments cause movement of one Ring relative to the other. The Strut adjustment schedule may last a number of weeks. Thereafter, the patient enters the consolidation phase of bone healing.

The TSF system offers the following clinical benefits:

- Early and progressive weight-bearing[3-6]
- Fixation in good bone with soft tissue coverage, staying away from the compromised zone of injury[6]
- Anatomic reduction and alignment can be refined post-operatively[7,8]
- No hardware left behind after treatment
- Restoration of the mechanical axis of the limb[9]

SMART TSF components are compatible with all existing TAYLOR SPATIAL FRAME® Hardware. SMART TSF Software supports constructs assembled using classic TAYLOR SPATIAL FRAME Hardware. A complete list of components is detailed in the ILIZAROV™ and TAYLOR SPATIAL FRAME Pocket Guide (Literature no 29781)

## New Features on SMART TSF◇

### Hardware

New **Struts** with 0.25mm adjustability.

A study has shown that finer and frequent adjustments are conducive to optimal osteogenesis.[2]

**Struts** can be mounted to a Step-off plate, providing more options in constructs where Rings are close together.

Struts can be dynamized with the **Dynamization Kit**, which is designed to introduce controlled axial dynamization.

The **Conversion Kit** enables a static frame construct, alternative to a hexapod, by using Threaded Rods to connect Rings that are not parallel.

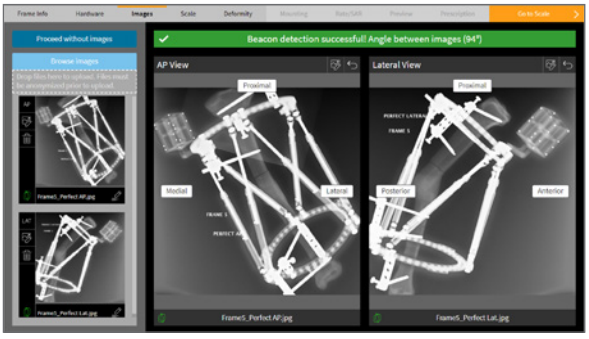
The **Wire Tensioner** has been re-designed to improve its handling, make calibrations more visible and eliminate need for disassembly for cleaning.

**Torque Wrench** handle extends away from the frame, designed to eliminate hardware collisions.

**Wire Fixation Bolt** combines slotted and cannulated option in one design. Hex recess enables control with the 3mm Set Screwdriver.

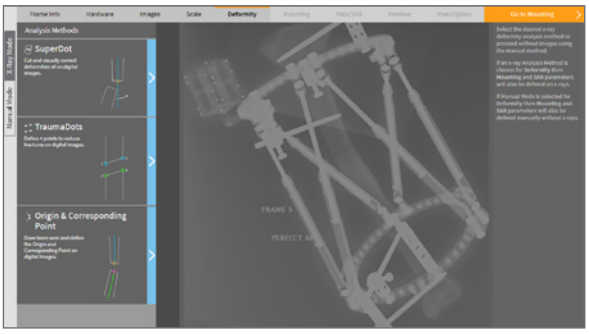
### Software

The SMART TSF Beacon can be attached to the TSF and captured in X-ray images. When uploaded to the SMART TSF software, the Beacon serves to scale and calibrate the X-ray image. When the Beacon is used, Mounting Parameters are digitally calculated and deformity or fracture parameters can be input using digital image analysis tools now included within SMART-TSF.com.




There are four deformity analysis methods in SMART TSF:

1. Manual entry based on measurements taken outside of the software
2. Origin and Corresponding Point method using digital X-ray images within the software
3. **TraumaDots –** define the edge points of two bone segments on X-ray images in the software to view the digitally-reduced fracture
4. **SuperDot –** define the rotation point on X-ray images in the software and digitally restore the alignment




SMART TSF components are retrospectively compatible with all existing TAYLOR SPATIAL FRAME◇ Hardware. SMART TSF Software supports constructs assembled using classic TAYLOR SPATIAL FRAME Hardware. A complete list of components is detailed in the ILIZAROV™ and TAYLOR SPATIAL FRAME Pocket Guide (Lit No 29781).

# Constructing a Stable Frame

## TSF° Rules

The shared connection points for Struts 1&2, 3&4, and 5&6 are always on the proximal Ring. The shared connection points for Struts 2&3, 4&5, and 6&1 are always on the distal Ring.

The shared connection point for Struts 1&2, located on the proximal Ring, is defined as the Master Tab.

The Master Tab is always on the proximal Ring.

The Master Tab is always directly anterior unless the rotary frame angle is a value other than zero.

Struts are always numbered in a counterclockwise manner from the patient's perspective:.

1. Red
2. Orange
3. Yellow
4. Green
5. Blue
6. Violet


Post-operative X-rays used for deformity analysis and Mounting Parameter calculation should always be taken orthogonal to the reference fragment.

If distal referencing, DO NOT flip the frame upside down. The Master tab is still on the proximal Ring.

When distal referencing, use the empty tab located between Struts 1&2 on the distal Ring as an anterior reference. This is the Anti-Master Tab.

When distal referencing, the AP and Lateral translations will be reversed. Describe the deformity in terms of the proximal fragment relative to the distal fragment.

Always describe the deformity you see; not the direction in which you want the frame to move.

Always verify the images and displayed values throughout a program prior to printing a prescription for a patient.

Deformity Parameters - the Corresponding Point is angulated/translated/rotated ... relative to the Origin.

Mounting Parameters - the frame (center of the Reference Ring) is offset...relative to the Origin.

## TSF° Assembly

### Option 1: Pre-Operative Assembly

Collect all six Struts and remove all Shoulder Bolts

Attach Strut #1 to the Proximal Ring, in the hole marked with a complete circle on the Ring

Attach Strut #2 to the same tab, on the other hole marked with a complete circle. The Tab where Struts 1&2 meet is defined as the Master Tab, and is always on the Proximal Ring.

On a Full Ring, skip a Tab between Strut connections. On a 2/3 Ring, all Tabs will have Struts. Struts are attached in a counter-clockwise direction, from a top-down perspective.

On the Distal Ring, the Tab opposite the Master Tab stays empty. Connect Strut #1 to the Tab adjacent to this on the Distal Ring.

Continue connecting Struts 2 through 6 in this pattern, skipping a Tab on Full Rings, and filling all Tabs on 2/3 Rings.

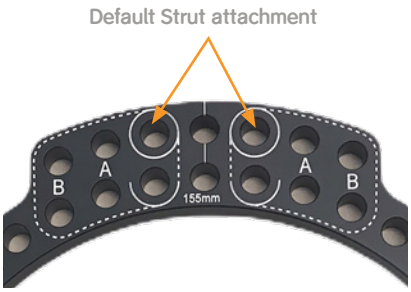
Struts can be positioned either threaded rod end up or down, determined by how the patient will optimally view the scale on each Strut.

All twelve shoulder Bolts should be tightened with Torque Limiting Wrench 7107-5410.

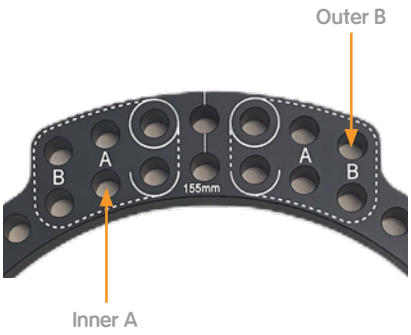
Identify Struts #1 through #6 by placing the sterile-packed colored ID Band on each one, and the ID Cap on the Shoulder Bolts that the patient will see. This can be done before attaching the frame to the limb to help orient the construct.

Struts can be re-positioned intra-operatively if required. The holes included within the dashed line boundaries indicate where Custom Strut Mounting is available.

All mating connections should be tightened securely once fixation has been achieved. It is good practice to confirm all connections are tightened before the patient leaves the OR.







## Option 2: Rings First Method

Rings are secured to bone with at least 3 points of fixation each. A Ring block provides greater stability. A Ring block is two Rings per segment with at least two points of fixation per Ring.

Ring blocks can obscure detection of the Beacon on X-ray. For optimal Beacon detection, attach the Beacon Mount to a Ring that is not part of a Ring block.

The Master Tab will be defined by the connection of Struts 1&2 on the Proximal Ring.

On Full Rings an empty Tab will occur between Tabs with Struts. On 2/3 Rings, all Tabs have Struts connected.

Struts are connected in a counter-clockwise sequence from the patient's perspective.

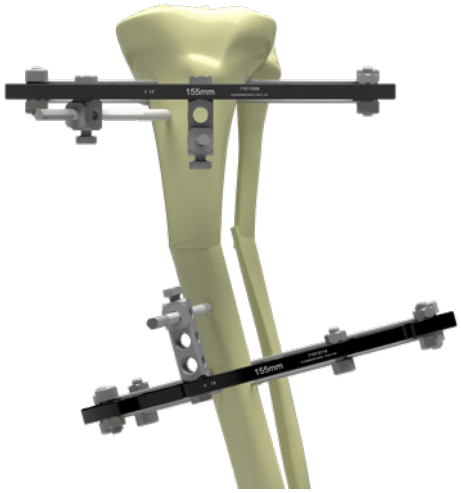
Struts can be positioned with the threaded rod end up or down, determined by how the patient will optimally view the scale on the Strut.

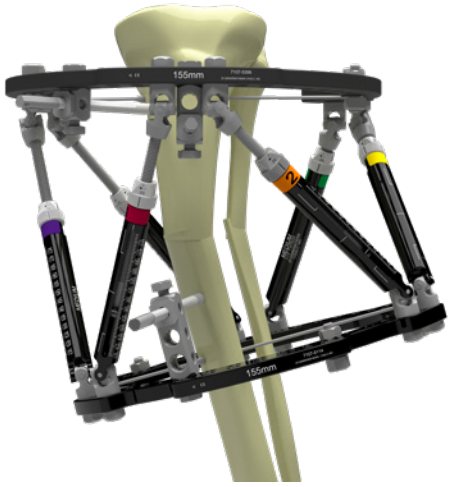
Once all Struts are connected, tighten the twelve Shoulder Bolts using Torque Wrench 7107-5410.

Place the ID Bands on each Strut as indicated in the diagram.

Complete the TSF° construct by adding additional fixation to the Rings.

All mating connections should be tightened securely once fixation has been achieved. It is good practice to confirm all connections are tightened before the patient leaves the OR.




Refer to the Atlas for the Insertion of Transosseous Wires and Half-Pins for appropriate placement of fixation for TSF at each anatomical level.

**ATLAS**

**FOR THE INSERTION OF TRANSOSSEOUS WIRES AND HALF-PINS**

**ILIZAROV METHOD**

## Wire Fixation Bolt

If the Wire lands centered on a hole on the Ring, use the center cannulation of the Wire Fixation Bolt to capture the Wire.

If the Wire lands to one side of a hole, use the eccentric slot of the Wire Fixation Bolt to capture the Wire.

Hand tighten a 10mm Nut (103300) onto the threads of the Bolt on the opposite side of the Ring from the Wire.

Secure Wire in place by tightening the 10mm Nut with a 10mm Wrench while holding the head of the Bolt stationary with another 10mm Wrench.

Alternatively, the 3mm Set Screwdriver (112717 or 112719) can be used to capture the hex recess on the Wire Fixation Bolt, while tightening the Nut.

Note the 3mm Set Screwdriver should not be used for the Russian tensioning method. A pair of 10mm Wrenches are more appropriate for Russian tensioning.

| Catalog No. | Description |
|---|---|
| 7107-5284 | Wire Fixation Bolt |
| 7107-5283 | Wire Fixation Bolt Long |

**Unit of Measure:** each

**Function:** Used with 10mm Nut to secure a Wire to a TSF° Ring. Compatible with 1.5mm – 1.8mm Wires. Long used when a washer is present.

## Wire Tensioner

Secure Wire to the Ring using Wire Fixation Bolt + 10mm Nut on both sides.

Secure one side using 2 x 10mm Wrenches. For Olive Wires, tighten the side where the Olive lies first.

Choose Tensioner Modular Attachment.

Attach by opening the latch on the Tensioner and securing the Modular Attachment.

Ensure Tensioner is fully open – turn the T-handle counter-clockwise until hard stop.

Tension from the side of the Wire that has not been tightened fully to the Ring.

Insert Wire through the cannulation of the Tensioner and advance until the jaws or prongs contact the Ring or other fixation hardware.

Apply tension to desired level by turning the T-handle in a clockwise motion and reading the tension level from the laser-marked scale toward the rear of the device.

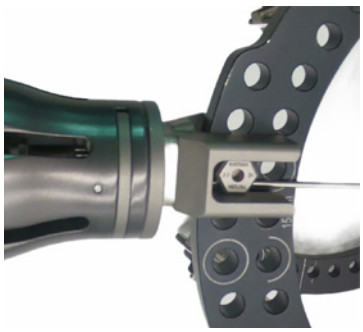
The scale is marked to indicate a tension range from 50 to 130 kg. Wires are tensioned according to surgeon's judgement, considering patient's weight, bone quality and type of wire.

Tighten the Wire to the Ring on the side being tensioned using a 10mm Nut on the Wire Fixation Bolt.

Open the Tensioner jaws fully by turning the T-handle counter-clockwise until hard stop.

Remove the Tensioner from the Wire.

| Catalog No. | Description |
|---|---|
| 7107-5341 | SMART TSF◇ Tensioner |
| 7107-5342 | SMART TSF Tensioner Standard Modular Attachment |
| 7107-5343 | SMART TSF Tensioner Wrench Modular Attachment |



**UoM:** each

**Function:** Tension Wires of diameter 1.5mm to 1.8mm

## Extended HA Coated Pins

Pre-drill the bone using 4.8mm Drill for 6mm Pin, 3.8mm Drill for 4.5mm Pin.

Use Pin Driver 7105-0031

Use a Rancho Cube or Adjustable Pin Fixation Clamp of required height to connect the Pin to the Ring.

Centralize the Pin using a 6mm Centering Sleeve in the Rancho.

Secure the Pin with a Set Screw (112727) or 8mm Bolt (100550) in the Centering Sleeve.

Tighten the construct using 13mm Wrench and 10mm Wrench.

HA Pins can be cut with HA Pin Cutter 7107-0849.

HA Pins can be capped with Pin Cap 7107-0290.

5-6mm Pin Stopper (1222-4220) can be used to secure an ILIZAROV™ Sponge (102140) around the Pin at the pin site.

| Catalog No. | Description |
|---|---|
| 71076520 – 71076570 | 6mm x 150mm Length with Thread 15mm – 70mm |
| 71076020 – 71076090 | 6mm x 200mm Length with Thread 15mm – 90mm |
| 71074510 - 71074550 | 4.5mm Thread 10mm – 50mm with 6mm Shank |

**UoM:** each, Sterile

**Function:** Attach TSF to Bone

**HA Pin T-Handle**
7105-0031

**4-6mm Pin Cutter**
7107-0849

**Wire Stopper**
1222-4220

Currently not CE-marked

**ILIZAROV® Sponge**
102140

**6mm Pin Caps**
7107-0290

## Conversion Clamp

Secure a Ring or Ring block to each bone segment with Pins or Wires as per standard technique.

Insert the threaded post of Conversion Clamp through any hole on a TSF° Ring. The Conversion Clamp can be oriented to face in or out.

Secure with a 10mm Nut (103300) and hand-tighten.

Connect a 6mm Threaded Rod to the Clamp by pushing it against the black translating top jaw of the Clamp. If the top jaw is not moving freely, back off the retained nut of the Clamp a few turns.

Connect the Threaded Rod on the opposing Ring using either two 10mm Nuts (one above and one below the Ring), with or without Conical Washers (201700), or another Conversion Clamp.

Once the Clamp with Threaded Rod is positioned as desired, the Clamp must be tightened to the TSF Ring and the jaws of the Clamp must be tightened on the Threaded Rod.

Tighten the Clamp to the Ring with a 10mm Nut using a 10mm Wrench. A 10mm Wrench can also be used to hold the base of the Conversion Clamp to keep it from rotating while tightening. Alternatively, if crowding prevents access to the Clamp with a Wrench, the 90 degree 3mm Set Screwdriver (112717) can be used to stabilize the Clamp while securing the Nut.

Tighten the jaws of the Clamp onto the Threaded Rod by tightening the retained nut of the Clamp using a 10mm wrench. Do not over-tighten the Clamp on the Threaded Rod. Holding the Wrench near the Nut prevents inadvertent over-tightening.

The final frame construct is two Rings (or two Ring blocks) connected by four Threaded Rods. Connecting the Threaded Rods with the Conversion Clamp removes the constraint of requiring the Rings to be parallel to each other. Conversion Clamps also help connect Rings of different diameter.

The conversion can be performed on a frame with Struts as an out-patient procedure.

Apply four (4) Threaded Rods to one Ring, choosing a length that reaches the Ring on the other side of the deformity. Space the Threaded Rods evenly around the circumference.

Attach a Conversion Clamp to each Threaded Rod.

Insert the post of each Conversion Clamp to the Ring and secure with a 10mm Nut (103300).

Tighten all components tight using 2 x 10mm Wrenches.

Once the frame is stabilized by four Threaded Rods, the six Struts can be removed.

| Catalog No. | Description |
|---|---|
| 7107-8550 | Conversion Clamp |

**UoM:** Box of 2 Sterile

**Function:** Connect two Rings that are not parallel with Threaded Rods

## SMART TSF° Rings

The TSF construct is made up of two Rings with six Struts. SMART TSF Rings have laser-marking to indicate standard inner and outer Strut mounting locations as well as custom Strut mounting locations and recommended positions for the Beacon Mount. Rings are attached to bone using Half Pins and Wires.

Full Rings are the most rigid Ring type.

Ring Blocks – meaning two Rings per bone segment joined by Threaded Rods or Sockets – are more stable than single Rings.

Two Half Rings make a Full Ring. Half Rings can also be used to close a Foot Ring and capture fixation on the dorsal surface of the foot.

2/3 Rings have an opening to permit flexion.

Foot Rings match the anatomy of the foot. The opening of the Foot Ring should be bridged with hardware before applying tension to the Wires through the metatarsals.

U-Rings are used in pairs to configure a Butt Frame. They can also be used as a Foot Ring on small anatomy.

Rings should be mounted such that two finger-breadths of clearance is maintained between the inner diameter of the Ring and the soft tissue.

The tabs on the Rings are designated connection points for Struts.

Markings indicate where Struts can be connected.

Markings at NE, NW, SW, SE indicate where the Beacon Mount can be placed, assuming 0° of Rotary Frame Offset. Equator lines indicate the mid-point of the Ring.

See Appendix for larger image indicating where the Beacon Mount can be placed on TSF Rings without these additional markings.



| Catalog No. | Description |
|---|---|
| 71075112 – 71075117 | Full Rings 105mm – 230mm |
| 71075132<br>71075127<br>71075306 – 71075309 | 2/3 Ring 105mm – 230mm |
| 71075123 – 71075127 | Half Rings 130mm-230mm |
| 71075302 – 71075305 | U Ring 105mm – 180mm |
| 71075144<br>71075145 | Foot Ring 155mm and 180mm Long |
| 71075154<br>71075155 | Foot Ring 155mm and 180mm Short |

Select Rings are available in Pink, Blue and Red are available by adding P, B, or R after the above Catalog Numbers

**UoM:** each

**Function:** A TSF is made up of two Rings and six Struts. SMART TSF Rings have additional markings to indicate where the Beacon Mount can be placed as well as to denote Custom Strut Mounting options.

## SMART TSF° Beacon Mount

The most important consideration for placement of the SMART TSF Beacon is that it should not be placed in the direct anterior or lateral view. The Beacon functions optimally when detected at an angle. Suggested locations are at the NE, NW, SE and SW positions.

At the time of surgery, the Surgeon will designate the Beacon mounting position by placing a Beacon Mount on one Ring. The Beacon Mount stays in this position throughout treatment. If it must be re-positioned, then both AP and Lateral X-rays should be re-taken.

The Beacon Mount must be attached to the Reference Ring. The Beacon Mount requires two holes for rotational stability, and therefore can only be positioned on a Tab. Furthermore, correct software recognition of the Beacon assumes the location to be in the center two holes of the Tab. The 'X' laser-marks on the Ring indicate options for positioning assuming 0° Rotary Frame Offset. These marks occur at NE, NW, SE, SW positions on Full Rings and corresponding holes on 2/3, Foot and U Rings.

Choose a location on the Shoulder Bolt side of the Ring, to minimize interference of Struts on X-ray.

For double-stacked frames, two Beacon Mounts will be used – one on each of the most proximal and most distal Rings.

The Beacon Mount cannot be placed immediately adjacent to a Step-Off Plate, due to the footprint of each component.



| Catalog No. | Description |
|---|---|
| 7107-5554 | SMART TSF Beacon Mount |

**UoM:** each

**Function:** The Beacon Mount designates the positioning of the Beacon for X-ray capture.

**Note** See SMART TSF Web Application User Manual for detailed information on how the Beacon interacts with the SMART TSF Software.

## SMART TSF° Beacon

The most important consideration for placement of the SMART TSF Beacon is that it should not be placed in the direct anterior or lateral view. The Beacon functions optimally when detected at an angle. Suggested locations or at the NE, NW, SE and SW positions.

At the time of surgery, the Surgeon will designate the Beacon mounting position by placing a Beacon Mount on one Ring.

At the time of X-ray, the X-ray technician will attach the Beacon to the Beacon Mount.

Insert the Beacon into the Beacon Mount and turn the wing through ¼ turn to lock in place. The arrow on the wing will point to “LOCK.”

Capture AP and Lateral X-rays with respect to the anatomy being tested. At least one of the images should be a true orthogonal view of the anatomy. SMART TSF software allows selection of either AP or Lateral image as the “driving” image for analysis.

Ensure to capture the Beacon and the anatomy in the X-ray view.

The image must capture 3 of the 4 rows of metal beads in the Beacon.

Once X-ray images are captured, the Beacon can be removed. The Beacon Mount is never removed.

The Beacon can be surface-cleaned with disinfectant wipes. It should not be steam-sterilized or autoclaved. When not in use the Beacon should be kept safe in the protective foam-lined case provided.



| Catalog No. | Description |
|---|---|
| 7107-5555 | SMART TSF Beacon |

**UoM:** each

**Function:** The Beacon serves as a marker to calibrate and scale X-ray images.

**Note** See SMART TSF Web Application User Manual for detailed information on how the Beacon interacts with the SMART TSF Software.

## SMART FX° Struts

The Acute Adjustment Band keeps the Strut in fully adjustable mode. Removing the band puts the Strut in gradual mode. Acute adjustability can still be achieved by pressing the acute adjustment button or re-attaching the Acute Adjustment Band. The ID Band covers the acute adjustment button to prevent the Strut being inadvertently adjusted acutely outside of the OR. Gradual adjustments are performed by turning the patient adjustment dial.

SMART FX Struts have a mm scale on the body. The end of the scale indicates the 0.25mm position

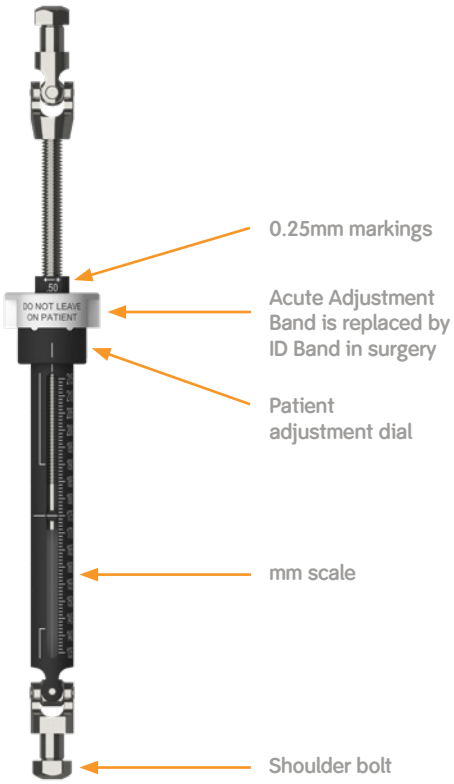
The Strut adjusts in 0.25mm increments read from the four flat faces on the adjustment nut. The arrow indicates the direction to turn in order to extend the Strut, the opposite direction will shorten the Strut.

Struts can be oriented up or down or a combination. Struts are connected to tabs on the Ring. Complete circles indicate default mounting location. Dashed circles indicate optional positions and can be defined in the Software. Struts can also be connected to Step-off Plates.

Struts are connected to Rings or Step-off Plates with Shoulder Bolts. Shoulder Bolts are tightened using the Torque Wrench.

ID Bands designate the Strut number and protect the patient from performing an acute adjustment.

**Never leave the Acute Band on the Strut when the patient is leaving the OR.**




| Catalog No. | Description |
|---|---|
| 7107-5705 | SMART FX Strut X-short |
| 7107-5710 | SMART FX Strut short |
| 7107-5720 | SMART FX Strut medium |
| 7107-5730 | SMART FX Strut long |

**UoM:** each

**Function:** Six (6) SMART FX Struts are used to construct the SMART TSF assembly. Struts are adjusted post-operatively by the patient according to a prescription generated in the SMART TSF web-based software. Strut Adjustments cause one TSF Ring to be moved relative to the other and drive the gradual correction of the bone. SMART FX Struts can be acutely adjusted only by the surgeon in the OR.

## SMART Standard Struts

SMART Standard Struts are adjusted gradually only, and have no acute adjustment mode.

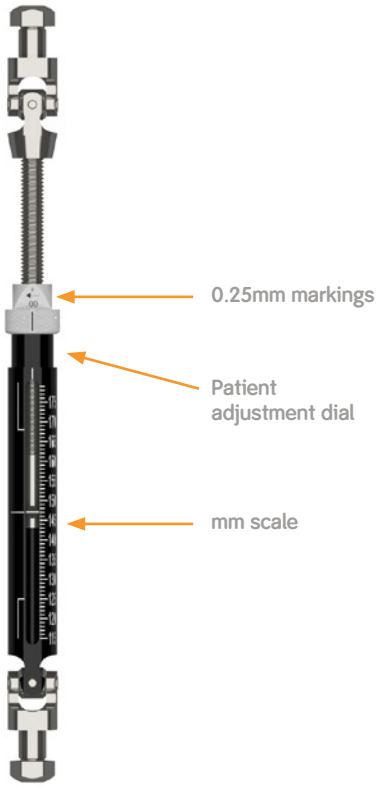
SMART Standard Struts have a mm scale on the body. The end of the scale indicates the 0.25mm position

The Strut adjusts in 0.25mm increments read from the four flat faces on the adjustment nut. The arrow indicates the direction to turn in order to extend the Strut, the opposite direction will shorten the Strut.

Struts can be oriented up or down or a combination. Struts are connected to tabs on the Ring. Complete circles indicate default mounting location. Dashed circles indicate optional positions and can be defined in the Software. Struts can also be connected to Step-off Plates.

Struts are connected to Rings or Step-off Plates with Shoulder Bolts. Shoulder Bolts are tightened using the Torque Wrench.

ID Bands and Caps (7107-5050) designate the Strut number.




| Catalog No. | Description |
|---|---|
| 7107-5200 | SMART Standard Strut XX-short |
| 7107-5205 | SMART Standard Strut X-short |
| 7107-5210 | SMART Standard Strut short |
| 7107-5220 | SMART Standard Strut medium |
| 7107-5230 | SMART Standard Strut long |

**UoM:** each

**Function:** Six (6) Struts are used to construct the SMART TSF assembly. Struts are adjusted post-operatively by the patient according to a prescription generated in the SMART TSF web-based software. Strut Adjustments cause one TSF Ring to be moved relative to the other and drive the gradual correction of the bone.

## ID Band Kit

ID Bands are attached to the Strut body. ID Caps fit into the hex recess in the top of the Shoulder Bolt and should be placed where the patient can see them when looking down on their frame.

Struts are numbered 1 through 6 in an anti-clockwise direction from the patient's perspective.

The tab where Struts 1&2 join defines the Master Tab. The Master Tab is always proximal.

If the Master Tab is over the anterior cortex, Rotary Frame Angle is zero.

1. Red
2. Orange
3. Yellow
4. Green
5. Blue
6. Violet


| Catalog No. | Description |
|---|---|
| 7107-5040 | SMART FX ID Band Kit |
| 7107-5050 | SMART Standard ID Band Kit |

**UoM:** 6 Bands + 6 Caps Sterile

**Function:** ID Bands and Caps designate the Strut number by color and number 1 to 6.

## Step-off Plates

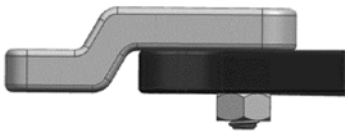
Step-off Plate needs two holes to achieve rotational stability – use on tabs of Ring only.

Position Step-off Plate on the Ring and secure with a 10mm Nut (103300). Hand tighten.

Tighten the Nut on Step-off Plate to Ring with a 10mm Wrench.

Attach the Strut to the Step-off Plate using the Shoulder Bolt, in the same way it would be attached to a Ring.

Tighten the Shoulder Bolt on Strut with the Torque Wrench.

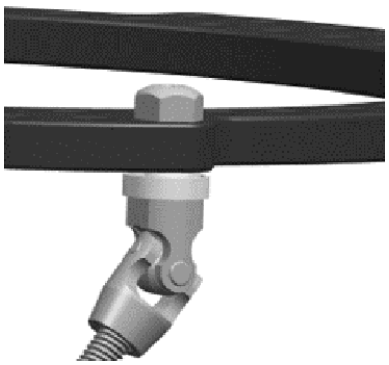


| Catalog No. | Description |
|---|---|
| 7107-5275 | Step-off Plate Neutral |
| 7107-5285 | Step-off Plate 30mm |

**UoM:** each

**Function:** Attach a Strut offset from the Ring.

## Dynamization Kit



Attach the Frame Stabilizer assembly to the TSF® to act as a 7th Strut.

Remove Shoulder Bolt from one Strut adjacent to the Frame Stabilizer.

Replace with one Long Shoulder Bolt and Dynamization Washer.

Silicone face of Washer should contact the Ring and the metal face of the washer should contact the Strut clevis.

Tighten the long Shoulder Bolt with the Torque Wrench (7107-5410) and a 10mm Open Wrench (7107-5905).

Moving the Frame Stabilizer to appropriate locations, repeat this process for every Strut on the Ring to be dynamized until all 6 are complete.

Remove the Frame Stabilizer assembly.

Note the Shoulder Bolt in Dynamization Kit is longer than the standard Shoulder Bolt. It is readily identified by the black laser mark on the top of the bolt.

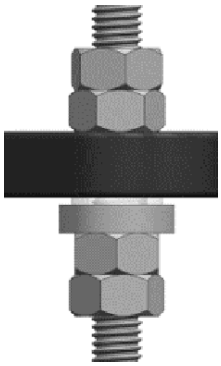
| Catalog No. | Description |
|---|---|
| 7107-5315 | Dynamization Kit |

**UoM:** Sterile kit contains 6 Washers and 6 Long Shoulder Bolts

**Function:** Add to a Strut to allow controlled axial dynamization.

## Dynamization Washer

Orient the Dynamization Washer such that the silicone surface contacts the Ring on the inside of a frame construct (washer must be between the Rings – below the proximal ring or above the distal ring).



Place two 10mm Nuts (103300) against the metal surface of the Dynamization Washer and tighten those two Nuts against one another with 10mm Wrenches to hold the Washer in the desired position.

Place two 10mm Nuts on the opposite side of the Ring from the Dynamization Washer (outside the frame construct – above the proximal Ring or below the distal Ring) and tighten those two Nuts against one another with 10mm Wrenches to hold the Ring in the desired position without compressing the silicone part of the Dynamization Washer.

| Catalog No. | Description |
|---|---|
| 7107-5316 | Dynamization Washer |

**UoM:** Box of 4 Sterile

**Function:** Add to a Threaded Rod to allow controlled axial dynamization

# Removal of TSF◇

All components can be loosened with a pair of 10mm x 13mm Wrenches (L202002 or 7107-5900).

Set Screw removal requires 3mm Hex Driver (112719).

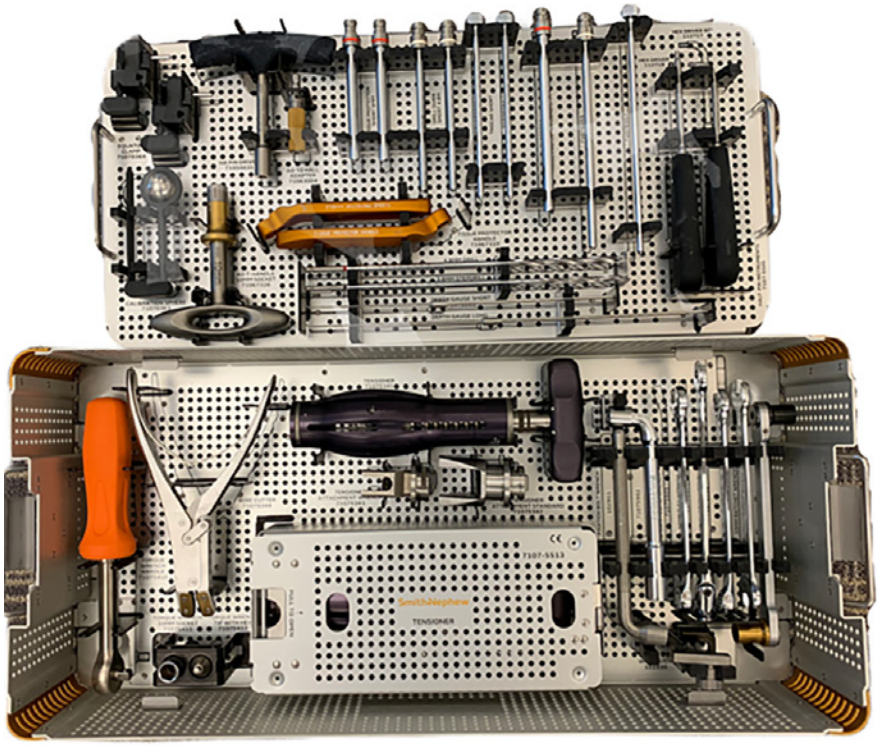
Wires should be cut close to the skin and pulled through using Wire Cutters (7107-0344). Always pull Olive Wires from the side with the olive, indicated by the black lines.

Pins can be reversed with a Universal Chuck T-Handle Driver (7117-0183) or the HA Pin Driver (7105-0031).

All External Fixation components are single use and should be disposed of in line with local biohazardous waste policy.

# Tray Layout

## Instrument Tray

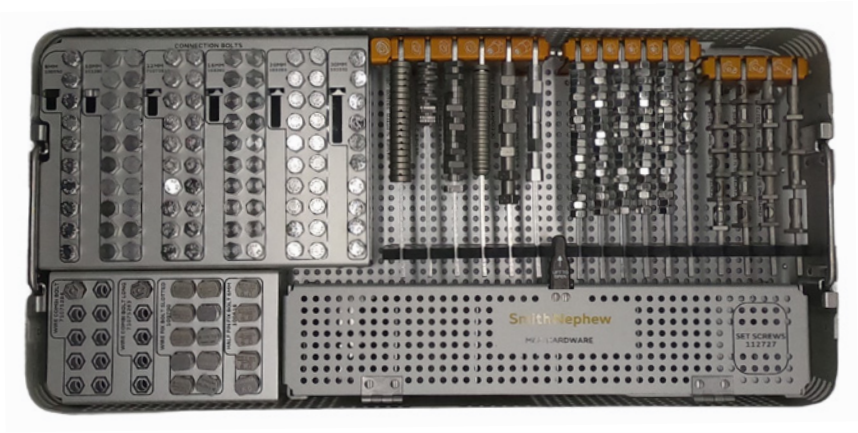


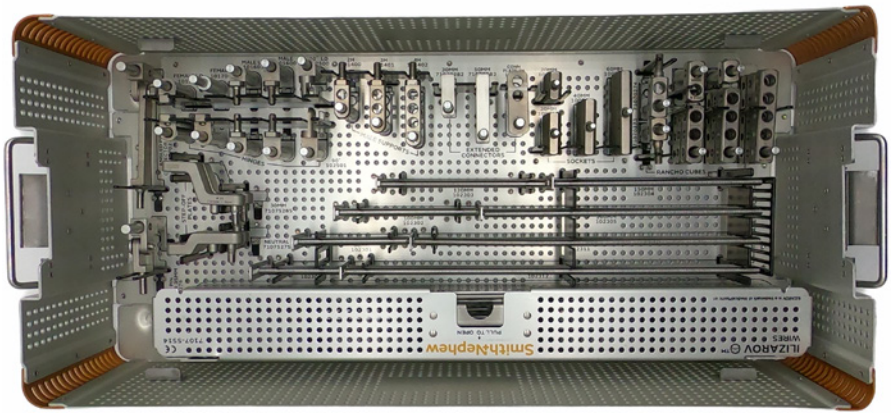
- Drill Guides, Handles, Screwdrivers, Tensioner and Wrenches
- One Tensioner is standard, with space for second one
- Alternatively, second Tensioner can be housed in its own caddy and wrapped separately
- Drills are supplied Sterile

| Reference | Description | Qty |
|---|---|---|
| 7107-5500 | SMART TSF Instrument Case | 1 |
| 7107-5501 | SMART TSF Instrument Case Lid | 1 |
| 7107-5505 | Half Pin Instrument Case | 1 |
| **Bottom Tray** | | |
| 7107-5410 | Torque Wrench Handle | 1 |
| 7107-5411 | Torque Wrench Hex Tip | 1 |
| 7107-5412 | Torque Wrench Socket | 1 |
| 71070344 | Wire Cutter | 1 |
| 7107-5341 | Wire Tensioner | 2 |
| 7107-5342 | Tensioner Jaw Attachment | 2 |
| 7107-5343 | Tensioner Wrench Attachment | 2 |
| 7107-5513 | Tensioner Caddy | 1 |
| 102911 | Fixation Bolt Wrench | 1 |
| 102910 | Slotted Hex Wrench | 1 |
| 71075902 | Tubular Angulated Wrench | 1 |
| 71075905 | Combination Wrench 10mm | 1 |
| 71075900 | 10mm x 13mm Wrench | 2 |
| 71075367 | Ratchet Wrench | 1 |
| 102930 | Wire Guide Assembly | 1 |

| Reference | Description | Qty |
|---|---|---|
| **Top Tray** | | |
| 71070363 | Calibration Sphere | 1 |
| 71070364 | Equator Clamp | 2 |
| 71067326 | T-Handle | 1 |
| 71050031 | HA Pin T-Handle | 1 |
| 71063004 | AO to Hall Adapter | 1 |
| 71067310 | Tissue Protector Handle | 2 |
| 71070352 | Tissue Protector - Short | 2 |
| 71070353 | Tissue Protector - Long | 1 |
| 71070354 | Drill Tissue Protector - Short | 2 |
| 71070355 | Drill Tissue Protector - Long | 1 |
| 71070356 | Trocar Short | 2 |
| 71070357 | Trocar Long | 1 |
| 112717 | HEX-FIX 90° Hexdriver | 1 |
| 112719 | HEX-FIX Straight Hexdriver | 1 |
| 71070361 | Depth Gauge Short | 1 |
| 71070362 | Depth Gauge Long | 1 |

## Hardware Tray




- Rods, Supports, Posts, Hinges, Nuts, Bolts, Washers, Ranchos and Plates
- Two level tray, can be split and housed as two Trays by using Hardware Tray Half Size
- Measure for Bolts on Bolt caddy.
- Stair-step configuration to match Bolt length
- Rack system for cannulated components. Silicon Stopper keeps them in place
- Utility spaces for any optional add-ons required by user
- Wire Caddy houses up to 48 Wires of any design to be loaded

| Reference | Description | Qty |
|---|---|---|
| 7107-5502 | SMART TSF Hardware Case | 1 |
| 7107-5501 | SMART TSF Hardware Case Lid | 1 |
| 7107-5504 | SMART TSF Hardware Upper Tray | 1 |
| 7107-5503 | SMART TSF Hardware Half Tray (option) | 1 |
| 7107-5511 | SMART TSF Hardware Half Tray Lid (option) | 1 |
| **Bottom Tray** | | |
| 7107-0278 | Angled Pin Connector 85mm | 2 |
| 7107-0276 | Angled Pin Connector 35mm | 2 |
| 7107-5275 | Step Off Plate Neutral | 2 |
| 7107-5285 | Step Off Plate 30mm | 2 |
| 101702 | Low Profile Female Hinge | 4 |
| 101700 | Female Hinge | 4 |
| 101602 | Low Profile Male Hinge | 4 |
| 101600 | Male Hinge | 4 |
| 102500 | Hinge 90° Low Profile | 2 |
| 102501 | Hinge 90° | 2 |
| 101400 | Male Support 2 Holes | 2 |
| 101401 | Male Support 3 Holes | 2 |
| 101402 | Male Support 4 Holes | 2 |
| 7107-0282 | Extended Connector Short 30mm | 2 |
| 7107-0283 | Extended Connector Long 50mm | 2 |
| 101800 | Short Connection Plate 3H 45mm | 2 |
| 100900 | Threaded Socket 20 mm | 4 |
| 100910 | Threaded Socket 30 mm | 4 |
| 100901 | Threaded Socket 40 mm | 4 |
| 100911 | Threaded Socket 60 mm | 4 |
| 7107-0273 | Rancho Cube with Post 1H | 2 |
| 7107-0274 | Rancho Cube with Post 2H | 2 |
| 103452 | Rancho Cube 2H | 2 |
| 103453 | Rancho Cube 3H | 4 |
| 103451 | Rancho Cube 1H | 2 |
| 103454 | Rancho Cube 4H | 4 |
| 103455 | Rancho Cube 5H | 4 |
| 102300 | 60mm Threaded Rod | 5 |
| 102301 | Threaded Rod 80mm | 5 |
| 102302 | Threaded Rod 100mm | 5 |
| 102303 | Threaded Rod 120mm | 5 |
| 102304 | Threaded Rod 150mm | 5 |
| 102305 | Threaded Rod 200mm | 5 |
| 102311 | Threaded Rod 250mm | 5 |
| 102312 | Threaded Rod 300mm | 5 |
| 7107-5514 | Wire Caddy (fill with preferred selection of Wires) | 1 |
| 102102 | Wire 1.8mm Bayonet Tip Smooth | 12 |
| 102107 | Wire 1.8mm Bayonet Tip Olive | 12 |

| Reference | Description | Qty |
|---|---|---|
| **Top Tray - Wire Fixation Bolt Caddy** | | |
| 7107-5284 | Wire Combi Bolt | 10 |
| 7107-5283 | Wire Combi Bolt Long | 5 |
| 100700 | Slotted Wire Fixation Bolt | 10 |
| 100616 | Half Pin Fixation Bolt 6mm | 5 |
| **Top Tray - Bolt Caddy** | | |
| 100550 | Bolt 8mm | 10 |
| 103200 | Bolt 10mm | 20 |
| 7107-0515 | Bolt 12mm | 20 |
| 103201 | Bolt 16mm | 20 |
| 103203 | Bolt 20mm | 20 |
| 103202 | Bolt 30mm | 10 |
| **Top Tray - Skewer Rack** | | |
| 102600 | Washer Slotted 4 x 14mm | 20 |
| 102706 | Washer 2.0mm Fixation Bolt | 20 |
| 102707 | Washer 4.0mm Fixation Bolt | 20 |
| 201700 | Conical Washer Couple | 15 |
| 103302 | DC Counter | 6 |
| 7107-0285 | Russian Long Nut | 5 |
| 103300 | Nut 10mm | 100 |
| 103301 | Nylon Nut 10mm | 10 |
| 103405 | Centering Sleeve 5mm | 6 |
| 103406 | Centering Sleeve 6mm | 12 |
| 7107-0272 | Centering Sleeve 6mm Long | 4 |
| 7107-5521 | Silicon Stopper for Hardware Tray (pack of 8) | 2 |
| **Misc Hardware Caddy - utility space for extra components** | | |
| 112727 | Set Screw | 10 |

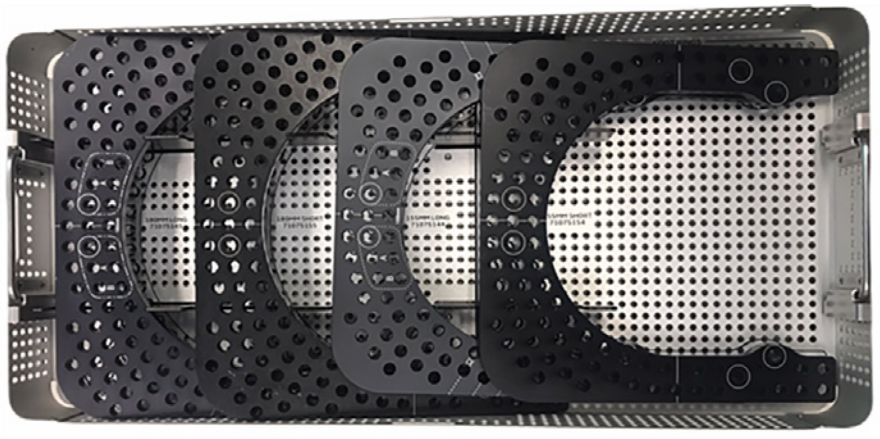
## SMART TSF° Rings Case


- Ring Module houses 8 Rings up to 205mm
- Ring Module should be pulled out straight (do not pull up)
- Ring Module can be stored on its own, with Lid
- Labels slide into window on Module. Blank labels supplied, for custom-labelling.
- Bumpers are optional to prevent small Rings from sliding side-to-side

| Reference | Description | Qty |
|---|---|---|
| 7107-5506 | SMART TSF Ring Case - houses 2 Ring Modules | 2 |
| 7107-5507 | SMART TSF Ring Module | 5 |
| 7107-5508 | SMART TSF Ring Module Lid | 1 |
| 7107-5522 | Silicon Bumper for Ring Module (pk8) | 1 |
| 7107-5520 | SMART TSF Labels for Ring Module | 1 |
| 7107-5112 | SMART TSF Full Ring 105mm | 2 |
| 7107-5113 | SMART TSF Full Ring 130mm | 2 |
| 7107-5114 | SMART TSF Full Ring 155mm | 2 |
| 7107-5115 | SMART TSF Full Ring 180mm | 2 |
| 7107-5116 | SMART TSF Full Ring 205mm | 2 |
| 7107-5117 | SMART TSF Full Ring 230mm | 0 |
| 7107-5123 | SMART TSF Half Ring 130mm | 2 |
| 7107-5124 | SMART TSF Half Ring 155mm | 2 |
| 7107-5125 | SMART TSF Half Ring 180mm | 2 |
| 7107-5126 | SMART TSF Half Ring 205mm | 2 |
| 7107-5132 | SMART TSF 2/3 Ring 105mm | 2 |

| Reference | Description | Qty |
|---|---|---|
| 7107-5133 | SMART TSF 2/3 Ring 130mm | 2 |
| 7107-5306 | SMART TSF 2/3 Ring 155mm | 2 |
| 7107-5307 | SMART TSF 2/3 Ring 180mm | 2 |
| 7107-5308 | SMART TSF 2/3 Ring 205mm | 2 |
| 7107-5302 | SMART TSF U Ring 105mm | 2 |
| 7107-5303 | SMART TSF U Ring 130mm | 2 |
| 7107-5304 | SMART TSF U Ring 155mm | 2 |
| 7107-5305 | SMART TSF U Ring 180mm | 2 |
| 7107-5509 | Foot Module | 1 |
| 7107-5511 | Lid for Struts / Foot / Inner Hardware | 1 |
| 7107-5144 | SMART TSF Foot Ring 155mm Long | 1 |
| 7107-5145 | SMART TSF Foot Ring 180mm Long | 1 |
| 7107-5154 | SMART TSF Foot Ring 155mm Short | 1 |
| 7107-5155 | SMART TSF Foot Ring 180mm Short | 1 |

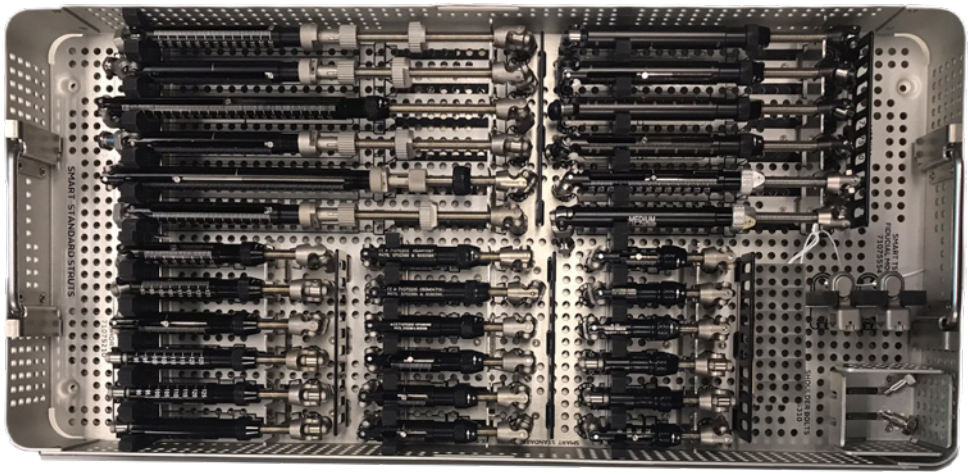
## Foot Tray



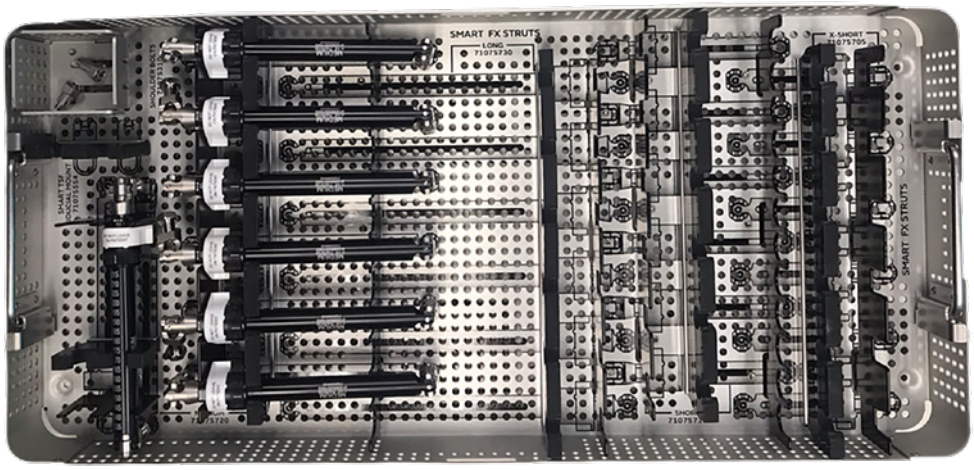
One of each 155mm & 180mm Short and Long

## Strut Tray

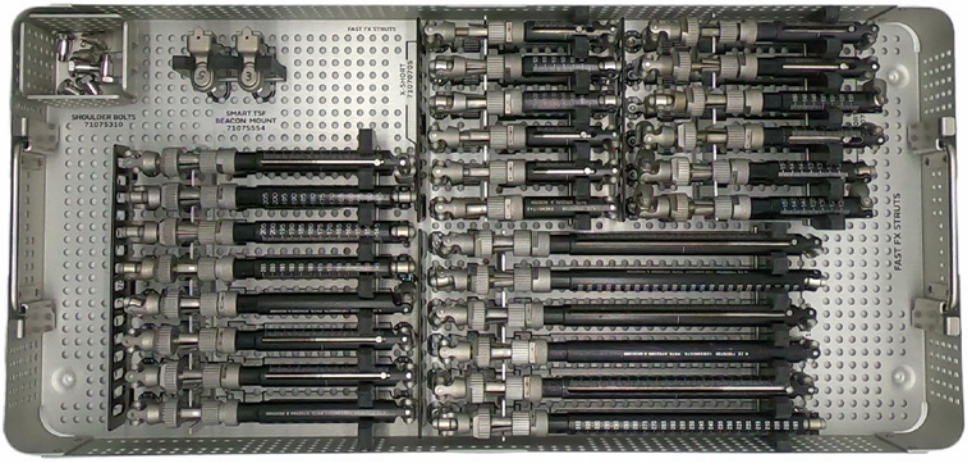
### Standard Strut Tray




### SMART FX Strut Tray

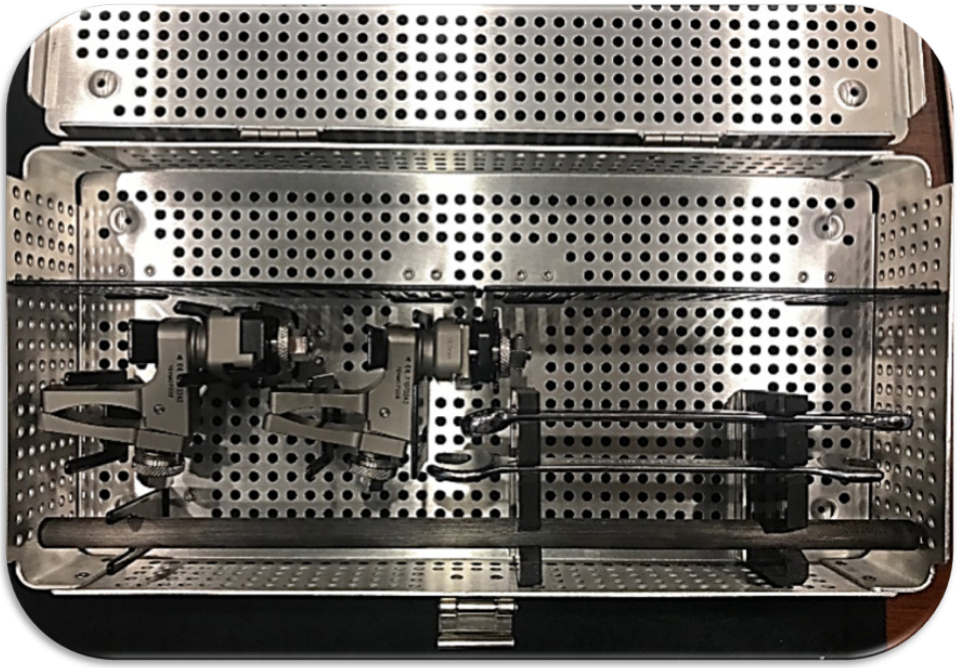



### FAST FX◇ Strut Tray



| Reference | Description | Qty |
|---|---|---|
| 7107-5512 | SMART STANDARD Strut Tray | 1 |
| 7107-5200 | SMART STANDARD Strut XX-Short | 6 |
| 7107-5205 | SMART STANDARD Strut X-Short | 6 |
| 7107-5210 | SMART STANDARD Strut Short | 6 |
| 7107-5220 | SMART STANDARD Strut Medium | 6 |
| 7107-5230 | SMART STANDARD Strut Long | 6 |
| 7107-5510 | SMART FX Strut Tray | 1 |
| 7107-5705 | SMART FX Strut X-Short | 6 |
| 7107-5710 | SMART FX Strut Short | 6 |
| 7107-5720 | SMART FX Strut Medium | 8 |
| 7107-5730 | SMART FX Strut Long | 6 |
| 7107-5020 | Acute Adjustment Clip | 6 |
| 7107-5516 | FAST FX® Tray | |
| 7107-0705 | FAST FX Strut X-Short | 6 |
| 7107-0710 | FAST FX Strut Short | 6 |
| 7107-0720 | FAST FX Strut Medium | 8 |
| 7107-0730 | FAST FX Strut Long | 6 |
| 7107-5554 | SMART TSF® Beacon Mount | 2 |
| 7107-5310 | SMART Strut Shoulder Bolt | 6 |
| 7107-5511 | SMART TSF Strut Tray Lid | 1 |

## Clinic Set



- Designed to support hardware adjustments in the Out-Patients Clinic
- 300mm Bar and two Frame Stabilization Tools are used to stabilize the TSF° while a Strut need to be swapped out, or Dynamization applied.
- Two 10 x 13mm Wrenches included
- Utility space allows storage of miscellaneous components
- The set can be sterilized for use in the OR if required

| Reference | Description | Qty |
|---|---|---|
| 7107-5515 | Clinic Set Tray | 1 |
| L202002 | 10mm x 13mm Wrench | 2 |
| 7106-2300 | 300mm JetX Bar | 1 |
| 7107-0343 | Frame Stabilizer Tool | 2 |

# Catalog Information

## Extended HA Coated Pins Sterile

| Reference | Description | Qty |
|---|---|---|
| 7107-4510 | Extended HA Pin 4.5mm 10mm x 150mm | 2 |
| 7107-4515 | Extended HA Pin 4.5mm 15mm x 150mm | 2 |
| 7107-4520 | Extended HA Pin 4.5mm 20mm x 150mm | 2 |
| 7107-4525 | Extended HA Pin 4.5mm 25mm x 150mm | 2 |
| 7107-4530 | Extended HA Pin 4.5mm 30mm x 150mm | 2 |
| 7107-4535 | Extended HA Pin 4.5mm 35mm x 150mm | 2 |
| 7107-4540 | Extended HA Pin 4.5mm 40mm x 150mm | 2 |
| 7107-4550 | Extended HA Pin 4.5mm 50mm x 150mm | 2 |
| 7107-6515 | Extended HA Pin 6mm 15mm x 150mm | 2 |
| 7107-6520 | Extended HA Pin 6mm 20mm x 150mm | 2 |
| 7107-6525 | Extended HA Pin 6mm 25mm x 150mm | 2 |
| 7107-6530 | Extended HA Pin 6mm 30mm x 150mm | 2 |
| 7107-6535 | Extended HA Pin 6mm 35mm x 150mm | 2 |
| 7107-6540 | Extended HA Pin 6mm 40mm x 150mm | 2 |
| 7107-6545 | Extended HA Pin 6mm 45mm x 150mm | 2 |
| 7107-6550 | Extended HA Pin 6mm 50mm x 150mm | 2 |
| 7107-6555 | Extended HA Pin 6mm 55mm x 150mm | 2 |
| 7107-6560 | Extended HA Pin 6mm 60mm x 150mm | 2 |
| 7107-6565 | Extended HA Pin 6mm 65mm x 150mm | 2 |
| 7107-6570 | Extended HA Pin 6mm 70mm x 150mm | 2 |
| 7107-6015 | Extended HA Pin 6mm 15mm x 200mm | 2 |
| 7107-6020 | Extended HA Pin 6mm 20mm x 200mm | 2 |
| 7107-6025 | Extended HA Pin 6mm 25mm x 200mm | 2 |
| 7107-6030 | Extended HA Pin 6mm 30mm x 200mm | 2 |
| 7107-6035 | Extended HA Pin 6mm 35mm x 200mm | 2 |
| 7107-6040 | Extended HA Pin 6mm 40mm x 200mm | 2 |
| 7107-6045 | Extended HA Pin 6mm 45mm x 200mm | 2 |
| 7107-6050 | Extended HA Pin 6mm 50mm x 200mm | 2 |
| 7107-6055 | Extended HA Pin 6mm 55mm x 200mm | 2 |
| 7107-6060 | Extended HA Pin 6mm 60mm x 200mm | 2 |
| 7107-6065 | Extended HA Pin 6mm 65mm x 200mm | 2 |
| 7107-6070 | Extended HA Pin 6mm 70mm x 200mm | 2 |
| 7107-6080 | Extended HA Pin 6mm 80mm x 200mm | 2 |
| 7107-6090 | Extended HA Pin 6mm 90mm x 200mm | 2 |

## Drill for HA Pins

| Reference | Description | Qty |
|---|---|---|
| 7107-0345 | 3.8mm Drill Short for 4.5mm Pins | 2 |
| 7107-0348 | 3.8mm Drill Long for 3.5mm Pins | 2 |
| 7107-0346 | 4.8mm Drill Short for 6mm Pins | 2 |
| 7107-0349 | 4.8mm Drill Long for 6mm Pins | 2 |

## SMART TSF◇ Sterile Accessories

| Reference | Description | Pk Qty |
|---|---|---|
| 7107-5050 | SMART STD ID Band Kit | 1 |
| 7107-5040 | SMART FX ID Band Kit | 1 |
| 7107-5315 | Dynamization Kit - 6 Bolts and 6 Washers | 6 |
| 7107-5316 | Dynamization Washer | 4 |
| 7107-8550 | Coversion Clamp | 2 |
| 7107-0290 | Half Pin Cap 6mm (Orange) | 6 |

## SMART TSF Beacon

| Reference | Description | Qty |
|---|---|---|
| 7107-5555 | SMART TSF Beacon* | 1 |

*The Beacon is supplied and housed in a dedicated carry-case

# Appendix

## Reference Parameters on Hardware

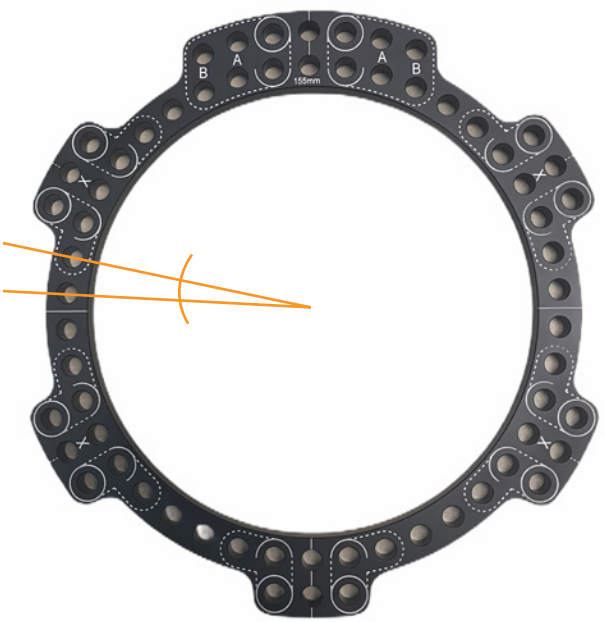
The SMART TSF◇ Beacon is the most accurate method for calibrating X-ray images as it minimizes the error of parallax. If the Beacon is not available, a calibration sphere can be used, or reference dimensions on hardware such as the inner diameter of a Ring or Rancho Cubes. When scaling with known dimensions of hardware, accuracy will be improved by measuring large components. If these calibration strategies are used, then attention should be paid to measuring them in the same plane as the bone.

### Size of Ranchos*

1H 15.75mm
2H 28.45mm
3H 41.15mm
4H 53.85mm
5H 66.54mm
Hole-to-hole distance 12.7mm

### Angles between holes on inner radius of Ring*

105mm 12°
130mm 10°
155mm 8.6°
180mm 7.5°
205mm 6.7°
230mm 6°
255mm 5.5°
275mm 5°
300mm 4.6°




*Measurements provided are nominal values within tolerated ranges for manufacturing specifications

## Struts Reference*

| Measured deformity | Struts to lengthen | Struts to shorten |
|---|---|---|
| **Left limb adjustments** | | |
| Medial translation | #2, 5 | #1, 4 |
| Lateral translation | 1, 4 | 2, 5 |
| Posterior translation | 3, 6 | 1, 2, 4, 5 |
| Anterior translation | 1, 2, 4, 5 | 3, 6 |
| Varus | 6 (1, 5) | 3 (2, 4) |
| Valgus | 3 (2, 4) | 6 (1, 5) |
| Apex Anterior | 4, 5 | 1, 2 |
| Apex posterior | 1, 2 | 4, 5 |
| External rotation | 1, 3, 5 | 2, 4, 6 |
| Internal rotation | 2, 4, 6 | 1, 3, 5 |
| Short limb | All struts | NA |
| **Right limb adjustments** | | |
| Medial translation | 1, 4 | 2,5 |
| Lateral translation | 2, 5 | 1, 4 |
| Posterior translation | 3, 6 | 1, 2, 4, 5 |
| Anterior translation | 1, 2, 4, 5 | 3, 6 |
| Varus | 3 (2, 4) | 6 (1, 5) |
| Valgus | 6 (1. 5) | 3 (2, 4) |
| Apex Anterior | 4, 5 | 1, 2 |
| Apex posterior | 1, 2 | 4, 5 |
| External rotation | 2, 4, 6 | 1, 3, 5 |
| Internal rotation | 1, 3, 5 | 2, 4, 6 |
| Limb-lenthening | All struts | NA |

*Assumes proximal ring reference and no rotary frame offset.

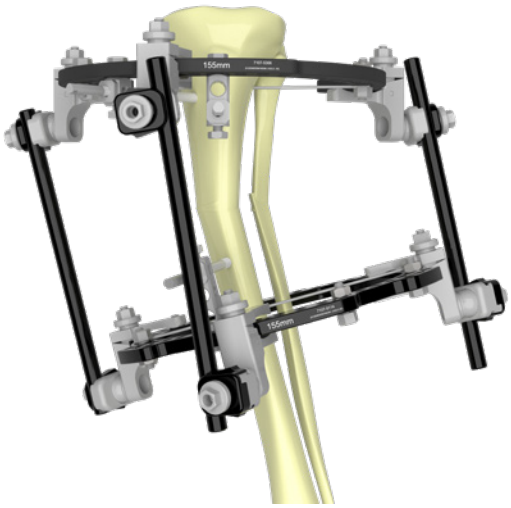
## MR Safety Information

TSF® is MR Unsafe

TSF Struts and Threaded Rods are MR Unsafe, and these are an essential part of all TSF constructs. If a patient requires an MRI while TSF is in place, the Struts and Threaded Rods can be temporarily replaced by 6 Frame Stabilizer Tools and 3 Carbon Fiber Bars.

MR Conditionality is subject to the following parameters.

- The external fixator must remain outside of the MRI scanner bore.
- The patient must weigh at least 120 pounds.
- All struts must be removed. A maximum of two rings should be incorporated in the TSF. The rings of the TSF must be connected by carbon fiber rods using a maximum of 6 frame stabilizer tools.
- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 2,127 G/cm (21.3 T/m).
- Whole body averaged specific absorption rate (SAR) of 2.0 W/kg.
- The above SAR restrictions refer to whole body RF transmit coil using a circularly polarized transmit mode.



## Beacon Mount Placement on classic TSF° Rings

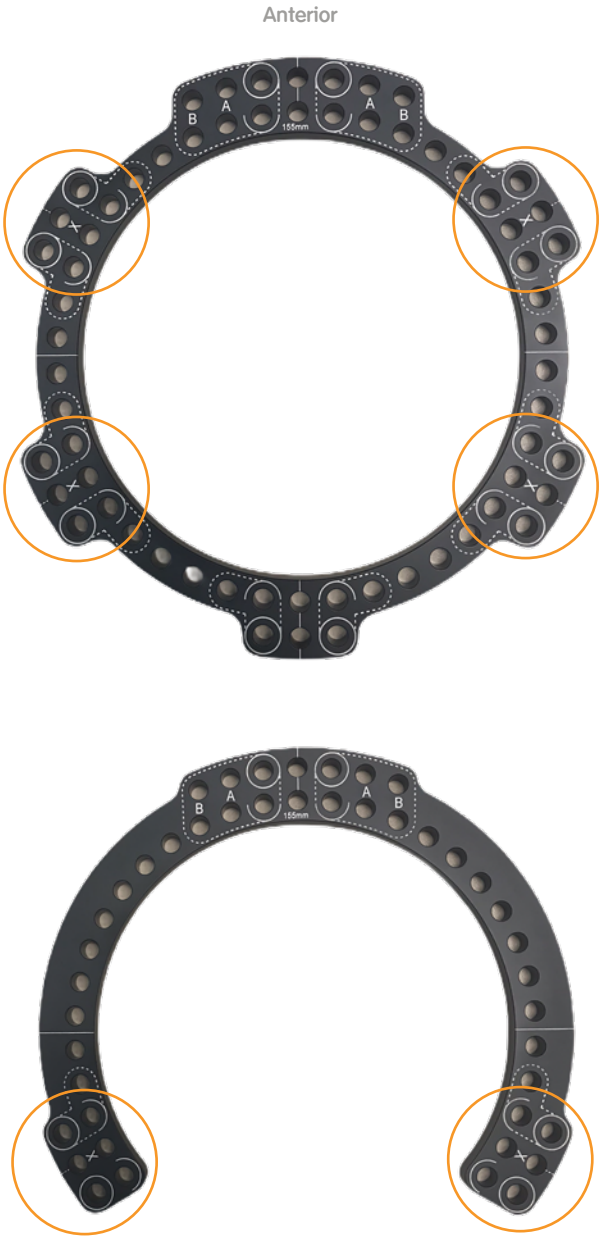
The original TSF Rings can still be used and are compatible with all features of SMART TSF hardware and software.

The only difference is absence of the markings shown here. Use this as a reference when applying original TSF Rings

Dashed lines indicate where Custom Strut Mount is an option

'X' indicates where the SMART TSF Beacon can be mounted assuming 0° Rotary Frame Offset

The central holes of the 7-hole tab and the opposing 3-hole tab are also options for Beacon mounting locations, if Rotary Frame Offset is present. The objective is to attach the Beacon to a tab that is not in the true AP or true Lateral position.



## Beacon Mount Placement on classic TSF° Rings *continued*

The original TSF Rings can still be used and are compatible with all features of SMART TSF hardware and software.

The only difference is absence of the markings shown here. Use this as a reference when applying original TSF Rings.

Dashed lines indicate where Custom Strut Mount is an option

'X' indicates where the SMART TSF Beacon can be mounted.

The Beacon should not be mounted in the true AP or true lateral. Ideal placement is in the NW, NE, SW or SE positions.

## References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