



Rx only

The **WishBone Medical Smart Correction® System** offers a simple External Fixation frame configuration that allows for postoperative strut adjustment. Adjustments are to be performed following a schedule prescribed by your surgeon on a daily basis which will gradually correct the alignment of the affected limb. This document provides detailed instructions for how to perform your adjustments at home. This process must be monitored by your physician, and they may alter your prescription for adjustments based on how your healing is progressing. Regularly scheduled follow-up appointments with your physician are critical to safe and effective correction.

Your *Smart Correction* frame may contain the following components (See Figure 1):

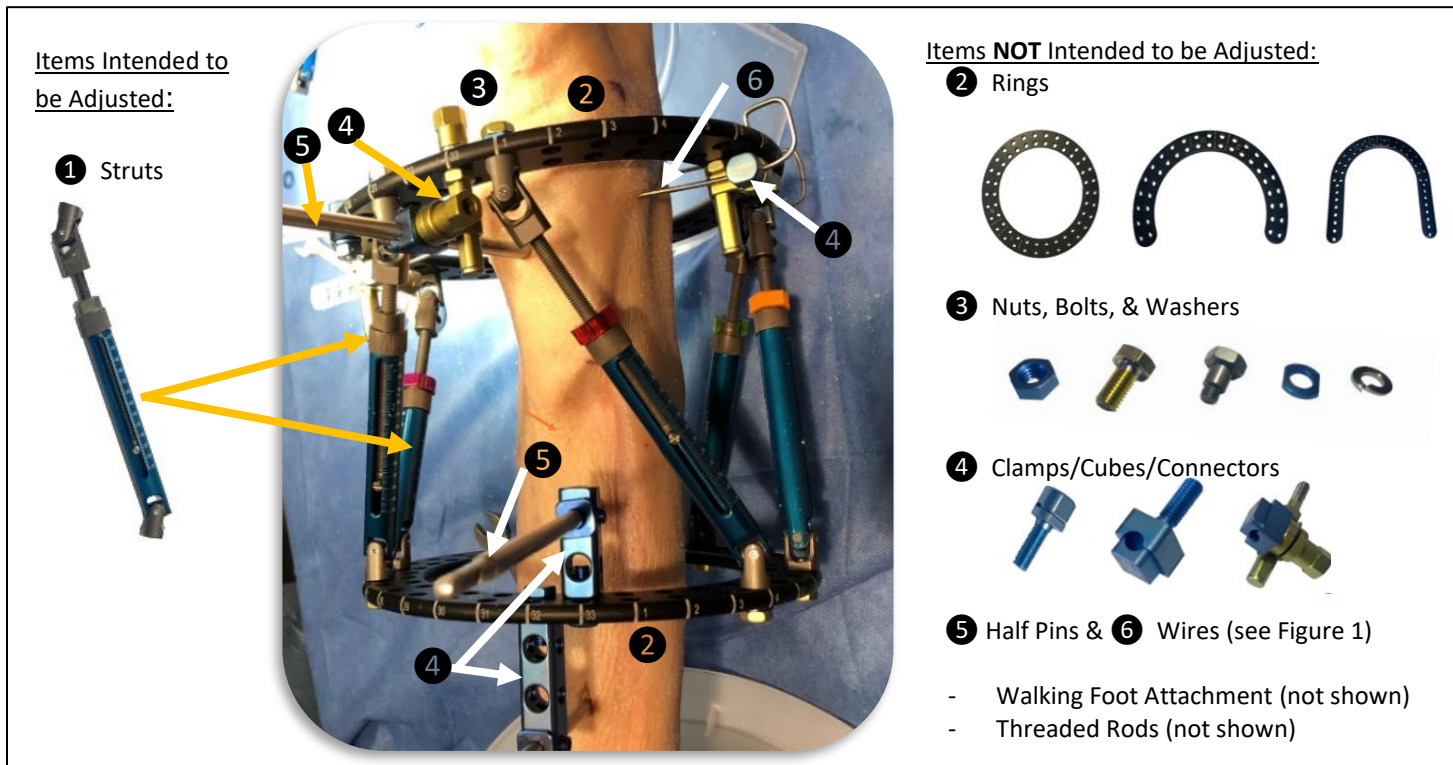


Figure 1: Smart Correction Example Frame Components

Accessories that may be Reattached/Replaced:

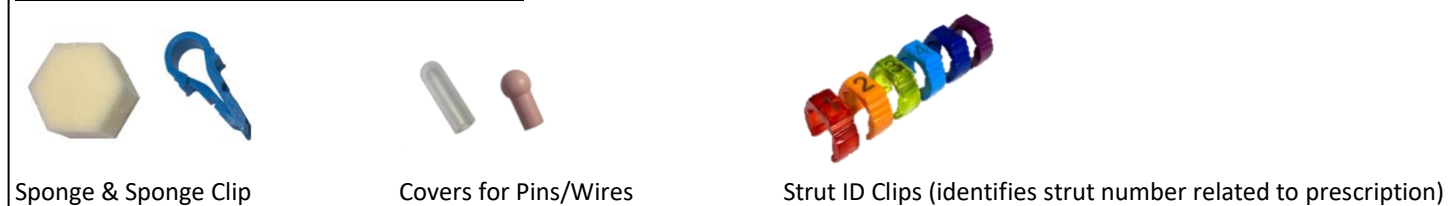


Figure 2: Smart Correction Accessories

FRAME MAINTENANCE

- Patients who are unable to perform proper maintenance should have a designated caregiver to monitor the frame's structure, cleanliness, and daily strut adjustments.
- It is important to keep the frame clean. Consult with your physician for specific cleaning instructions.
- Do not attempt to remove or alter the frame. Only make the strut adjustments prescribed by your physician. Do not adjust any nuts, bolts, or clamp elements; only adjust the strut position per the prescription and these instructions.
- Avoid making unnecessary contact with the fixator. Do not use other objects to scratch the area around the site of the frame.
- Always consult with your physician before performing any weight bearing activities.
- Do not get the frame wet unless specifically cleared by your physician.

HALF PIN & WIRE MAINTENANCE

Plastic protectors should be secured on wire/pin ends in order to prevent injury to the patient and/or caregiver.

- **Detached or lost Pin/Wire Covers** should be replaced. Please contact your physician to provide you with new covers.

- **Pin tract infection** is inflammation and subsequent infection at the metal-skin interface. The signs and symptoms of infection around the pin or wire may require the administration of an antibiotic, pin/wire removal, or surgical debridement. To prevent pin tract infection, ensure the pins/wires are kept clean. Consult with your physician for specific cleaning instructions. Sponges and sponge clips are available for use through your physician to aid in keeping pins/wires clean. If sponges become detached from your frame or need to be replaced for any other reason, consult with your physician to get replacements. Sponges should be placed next to the skin around the pin/wire. Sponge clips should be clipped onto the pin/wire so that it holds the sponge against the skin (Figure 3).

- **Contact your surgeon and/or clinic if signs of infection occur, including¹:**

- Increasing redness, warmth and/or swelling at the pin sites.
- Extreme tenderness at pin sites.
- Persistent fever of 100.5° F or higher (taken orally).
- Thick, cloudy, white, yellow or green drainage (clear, yellow or slightly bloody drainage is normal).
- Odor at the pin sites.

- Contact your physician immediately if pins/wires appear damaged or detached from clamps. Do not attempt to repair/reposition the frame or components.

THREADED ROD INSPECTION

The nuts used to connect threaded rods should not be loosened or tightened (Figure 4). If threaded rods or nuts become loosened or damaged, contact your physician immediately.



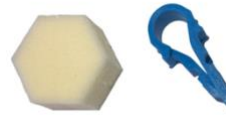
Pin/Wire Covers



Pin Cover on Half Pin



Wire Cover on Wire



Sponge & Sponge Clip

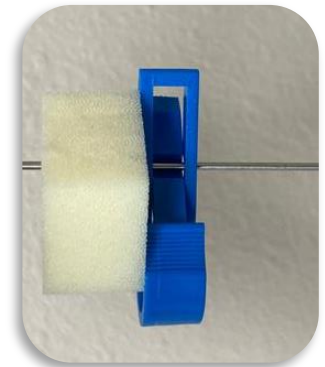


Figure 3: Sponge to be placed next to the skin, then clip placed to hold sponge against skin.

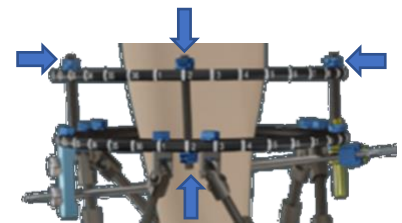


Figure 4: Locations of nuts that secure the threaded rods to the frame (**Do Not Adjust**)

1. National Association of Orthopaedic Nurses. An Introduction to Orthopaedic Nursing. 2nd ed. New Jersey: Anthony J. Janetti, Inc., 1999.

STRUT MAINTENANCE

The bolts used to connect struts to the rings should not be loosened or tightened. If struts or bolts become loosened or damaged, contact your physician immediately.

STRUT ADJUSTMENTS

Your surgeon will provide a prescription to indicate the length markings per day which determine how much each strut is lengthened or shortened each day. It is important to adjust the strut to the correct length each day to allow the limb to be corrected.

The color shown next to the strut matches the Strut ID Clip (see Figures 6 and 7). The Strut ID Clips are positioned on the struts in different locations dependant on strut type (Standard Strut vs. Express Strut).

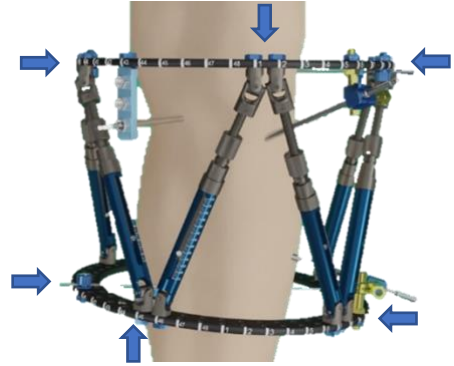


Figure 5: Locations of bolts that secure the struts to the frame (**Do Not Adjust**)

Day	Date	Strut 1 ■	Strut 2 ■	Strut 3 ■	Strut 4 ■	Strut 5 ■	Strut 6 ■
0	27 Mar 2020 Fri	170 ^M	131 ^S	134 ^S	142 ^M	146 ^M	165 ^M
1	28 Mar 2020 Sat	167 ^M	135 ^S	136 ^S	144 ^M	147 ^M	162 ^M
2	29 Mar 2020 Sun	165 ^M	138 ^S	138 ^S	145 ^M	147 ^M	160 ^M

Figure 6: Example of prescription for strut adjustments

Struts are positioned counter-clockwise as shown in Figure 8. Strut identification clips are provided to match the struts on the frame to the prescribed struts on the prescription (Figure 7).



Figure 7: Strut ID Clips

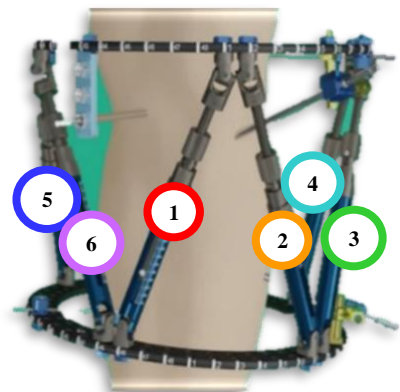


Figure 8: Struts positioned counterclockwise; identified with Strut ID Clips color coded to prescription

Strut length is adjusted by holding the blue portion of the strut in place with one hand and rotating the gray portion of the strut located directly above the length markings with the other (Figure 9).

1 full turn = 1mm of adjustment.

If the gray portion of the strut is difficult to adjust by hand, the 10mm Wrench can be used (Figure 10). Attach the 10mm Wrench to the gray portion of the strut directly above the length markings. For Express Struts, remove the Strut ID clip from the strut prior to attaching the 10mm Wrench. The Strut ID Clip must be returned to its original position after adjustment with the wrench. Be sure the position of the Strut ID Clips still matches the prescription.

Arrows with +/- symbols (Directional Arrows) are marked on the struts to indicate which direction the strut should be rotated to increase or decrease length (Figure 11). The strut should “click” when each full turn is complete. If this click is not audible when using the wrench, refer to the length marking scale to confirm the 1mm adjustment (Figure 11).

CAUTION: The wrench is not to be used for tightening or loosening any frame components.

Markings on the struts correspond to the length listed in the prescription (Figure 11). **If the patient is unable to perform correct strut adjustments, the patient’s caregiver must be available and responsible for ensuring that the prescribed adjustments are performed daily.**

- Adjust struts according to the prescription at approximately the same time each day.
- Do not skip adjustments on any given day.
- Ensure that struts are adjusted to the correct length each day.
- If an adjustment is missed or performed incorrectly, contact your physician. A revised prescription may be required to complete the treatment plan.
- Rapid adjustments are only to be performed by your physician. If the express strut becomes loosened or unlocked, contact your physician immediately (See Figure 12).

The strut fixation bolts should not be loosened or tightened (see Figure 5). The nut on the threaded region of the Express Struts should always be locked in place. If struts or bolts become loosened or damaged, contact your physician immediately.

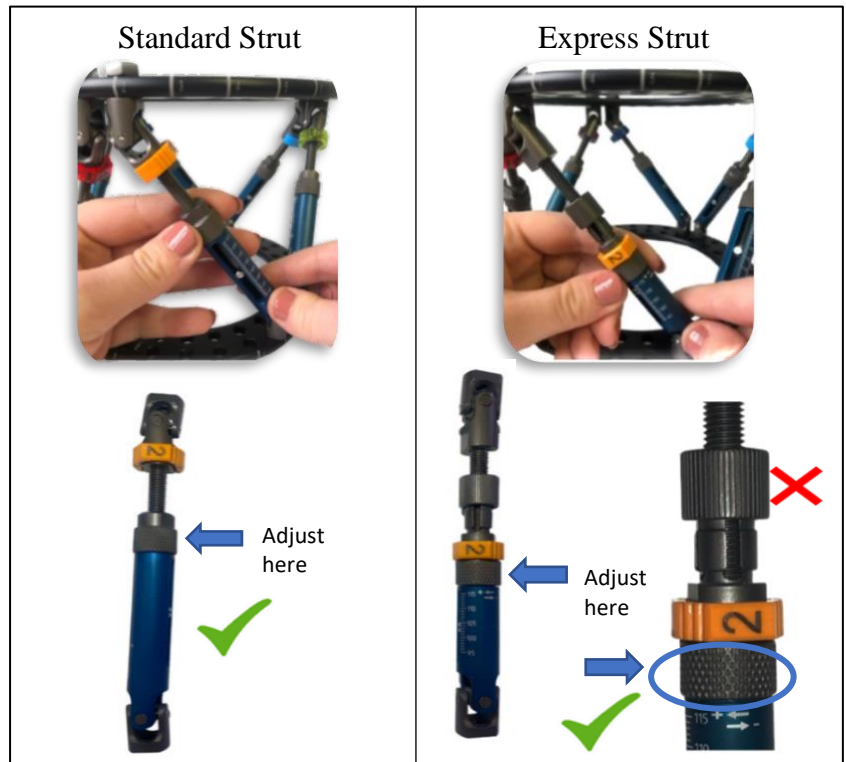


Figure 9: Proper Strut Adjustment Locations



Figure 10: Strut Adjustment Using 10mm Wrench

Figure 11: Indicator reflects strut length; adjust per prescription

Warning: Do NOT rotate the nut on the threaded region of the Express Struts. This portion of the strut (Shown in Figures 9 & 12) should be frequently checked to ensure it is always locked in place.



Figure 12: Improper Express Strut Adjustment

FOOT AND ANKLE FRAME MAINTENANCE

Foot and ankle frames designed for partial weight bearing may contain foot ring walking attachments to protect the rings. If the foot ring walking attachment breaks, wears excessively, loosens, or detaches from the frame, contact your physician for a replacement. Consult with your physician regarding appropriate footwear and duration of weight bearing activity throughout the treatment plan.



Walking Foot Attachment

Contact your physician and/or clinic **immediately** if:

- Any components appear to be damaged or loosened.
- Strut ID bands fall off or are lost.
- Pin/Wire covers fall off or are lost.
- Strut adjustments are not performed as prescribed.
- Signs of infection occur, including (but not limited to):
 - Increasing redness, warmth and/or swelling at the pin sites.
 - Extreme tenderness at pin sites.
 - Persistent fever of 100.5° F or higher (taken orally).
 - Thick, cloudy, white, yellow or green drainage. (clear, yellow or slightly bloody drainage is normal).
 - Odor at the pin site.



FOR FURTHER INFORMATION

Please contact your physician for further information about this product.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN. Rx only

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The MR environment presents risks to patient with metal implants. Physicians should consider the risks when recommending MR imaging for patients with metal implants. The WishBone Medical Smart Correction® System components have not been evaluated for safety and compatibility in MR environment.



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