MAXFRAME AUTOSTRUT™

Multi-Axial Correction System

Physician User Manual

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

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Physician User Manual


Image intensifier control

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1. Welcome

1.1 About this Document

This document is intended for the use by the physician. It familiarizes you with MAXFRAME AUTOSTRUT™ Multi-Axial Correction System hardware and software and provides you step-by-step procedures for MAXFRAME AUTOSTRUT control system and hexapod strut usage, MAXFRAME AUTOSTRUT Software operation and the assembly instructions for use in conjunction with the DePuy Synthes MAXFRAME Multi-Axial Correction System.

■ Note:

The following terms all refer to the MAXFRAME AUTOSTRUT hardware and software described in this user's document:

- MAXFRAME AUTOSTRUT
- OrthoSpin AutoStrut
- AutoStrut G2

1.2 Notes and Precaution Statements

Notes and precaution statements are used throughout this document to provide additional information and emphasize important information. You should read these statements to ensure safety, prevent potential harm to the patient, and allow for effective use of the device.

1.3 Information Security

Information security is provided by the following procedures:

- All passwords and Personal Health Information are encrypted.
- Physician use of the system requires login with username and password.
- MAXFRAME AUTOSTRUT hardware and software do not utilize wireless communication (BT- Bluetooth, BLE- Bluetooth Low Energy, WiFi).
- The device is mounted on the patient, and no connection to the system can be performed without patient awareness.
- The PC is to be monitored and protected by anti-virus software.

2. Introduction

This section describes the features and benefits of the MAXFRAME AUTOSTRUT System including hardware and software, intended use and indications, and computer requirements for operating software.

2.1 MAXFRAME AUTOSTRUT System Features and Benefits

MAXFRAME AUTOSTRUT System consists of both hardware and software components as follows:

- MAXFRAME AUTOSTRUT Hexapod Struts (Struts come in three sizes – short, medium and long)
- MAXFRAME AUTOSTRUT Automated Hexapod Control System Kit
  - Control System consists of Control Box connected via wire cables to six motorized struts
  - Kit also contains all MAXFRAME AUTOSTRUT Accessories
- MAXFRAME AUTOSTRUT Accessories:
  - Control box ring interface and screws
  - Motor attachment clips
  - Electric cables attachment means
  - Assembly tools
  - Magnetic USB cable
  - Post treatment gear locker
  - Patient quick guide
- MAXFRAME AUTOSTRUT Software (Software allows physicians to download the treatment plan to the device, chart patient progress and, if required, easily change the treatment schedule.)

MAXFRAME AUTOSTRUT System is compatible with the DePuy Synthes MAXFRAME System. The MAXFRAME AUTOSTRUT System automatically adjusts the motorized struts according to the prescribed treatment regimen supplied by the MAXFRAME System software.
The motorized struts are designed to produce a similar speed and accuracy as the manual strut adjustment required by MAXFRAME treatment plan.

This document is to be used with the MAXFRAME Multi-Axial Correction System instructions for use (IFU) and surgical technique. Please refer to the instructions detailed in this document for MAXFRAME AUTOSTRUT strut and control box assembly and MAXFRAME AUTOSTRUT Software use.

MAXFRAME AUTOSTRUT System enables:

- Highly accurate frame adjustments.
- Reduced dependency on patient compliance.

2.2 Indications for Use

The MAXFRAME AUTOSTRUT System is indicated for the following treatments in adults, and in both children (3–12) and adolescents (12–21) in which growth plates have fused or will not be crossed with hardware: fracture fixation (open and closed), pseudoarthrosis of long bones, limb lengthening (epiphyseal or metaphyseal distraction), joint arthrodesis, infected fractures or nonunions, correction of bony or soft tissue deformities, correction of segmental defects.

2.3 Contraindications

The MAXFRAME AUTOSTRUT System is not intended for use in the spine.

2.4 Software User Profile

The use of the software is limited to health care professionals. Patients will not use the software.

2.5 General Warnings

- MAXFRAME AUTOSTRUT System hardware and software must only be used with the MAXFRAME System hardware and software.
- MAXFRAME AUTOSTRUT is not to be used for diagnosis.
- The patient and/or post operative care team must be capable of understanding the system operation, indications (lights/sounds) made throughout the treatment, and provide timely communications back to their surgeon.
- MAXFRAME AUTOSTRUT Control System is powered by batteries. In the case that the battery power goes below ~30% capacity, LED lights indicating LOW BAT will illuminate (see example "System Indicators" in Section 3). The system will continue to work according to plan until the battery is fully empty.
- Care should be taken during product unpacking to ensure the product is not damaged.
- Electromagnetic compatibility (EMC):
  - Electric medical units are subject to special precautionary measures with regard to EMC and may only be installed and put into operation in compliance with the EMC information and safety instructions specified in this document, and exclusively for intended purposes.
  - Accuracy of positioning is essential for safe use of the MAXFRAME AUTOSTRUT System. Use of MAXFRAME AUTOSTRUT System in environment with EM disturbances beyond specified in CL. 7.4 can lead to degradation of accuracy and lead to hazardous situation.
- Exposure to electromagnetic disturbances may cause damage to the control unit requiring replacement.
    - Airport metal detectors emit electromagnetic energy. If the patient plan to travel on an airplane, the security metal detector will alarm and may interfere with the MAXFRAME AUTOSTRUT System functionality. Patient should request a hand-pat search and avoid the metal detector. Additionally, patient may get asked by airport security about the device and if it has batteries. The device contains two 9-volt lithium batteries and meets the criteria for air travel per regulation 49 CFR 175.10.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MAXFRAME AUTOSTRUT system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Electric medical units are subject to special precautionary measures with regard to EMC and may only be installed and put into operation in compliance with the EMC information contained in this document.
- Portable and mobile radiofrequency communication devices can influence electric medical devices.
- Patient should take care to avoid impact to the MAXFRAME AUTOSTRUT System (e.g., hitting against or colliding with other objects) as such activity can result in detached and/or damaged components (i.e., cables, cable splitters, motors etc.).

2.6 Restrictions

MAXFRAME AUTOSTRUT Automated Hexapod Control System is designed to be installed on the frame outside the sterile field.

2.7 MRI Safety Information

Prior to MRI, the MAXFRAME AUTOSTRUT Control System (including motors) must be removed. Then the MAXFRAME AUTOSTRUT hexapod struts must be removed and substituted with corresponding MAXFRAME Quick Adjust or Standard struts.

The original MAXFRAME System is MR conditional; please see its IFU for specific conditions.

2.8 Software Requirements

In order to install the MAXFRAME AUTOSTRUT Software, the physician will need administrator privileges on the computer.

- **Operating system:**
  The MAXFRAME AUTOSTRUT Software can be used with the following minimum operating systems: Microsoft Windows 7, 8 and 10 (preferred). The most recent information regarding supported operating systems can be found at the OrthoSpin web page www.orthospin.com
- **Computer hardware:**
  To use the MAXFRAME AUTOSTRUT Software, your computer must meet the following minimal hardware requirements:
  - CPU: 1.2 GHz or faster.
  - RAM: 2 GB or more.
  - Available hard disk space: 10 GB or more.

3. Product Description

3.1 Hardware

The MAXFRAME AUTOSTRUT System consists of both hardware components (struts and control system with attached lightweight motors) and software. The hardware components are attached to a circular external ring fixation frame, the MAXFRAME System. The hardware is validated for use with the MAXFRAME AUTOSTRUT Software.

MAXFRAME AUTOSTRUT System components are compatible with the DePuy Synthes MAXFRAME Multi-Axial Correction System (“MAXFRAME”). The MAXFRAME System hardware is coupled with the MAXFRAME Software for use in the creation of patient treatment plans, which detail required strut adjustments. Supplementary to the use of MAXFRAME Software, is the MAXFRAME AUTOSTRUT Software controlling and recording the struts adjustments.

The MAXFRAME AUTOSTRUT system includes the following hardware components:

3.1.1 Struts

MAXFRAME AUTOSTRUT hexapod struts are designed to shorten and lengthen according to the treatment regimen prescribed by the physician.

MAXFRAME AUTOSTRUT struts are compatible with MAXFRAME hardware (ring sizes 90–270 mm). Three sizes of MAXFRAME AUTOSTRUT hexapod struts are available – short, medium and long. The lower section design is identical across all sizes. The only difference between the struts is the length of the upper section and the range of travel. X-Short and XX-Short strut sizes are not available. Treatment plans requiring X-Short or XX-Short struts cannot be accommodated and will be rejected by the AUTOSTRUT Software.

Size	mm
Long	185–309
Medium	126–193
Short	97–135

Figure 1: MAXFRAME AUTOSTRUT hexapod struts without motor (struts are attached to frame rings in operating room; OR)

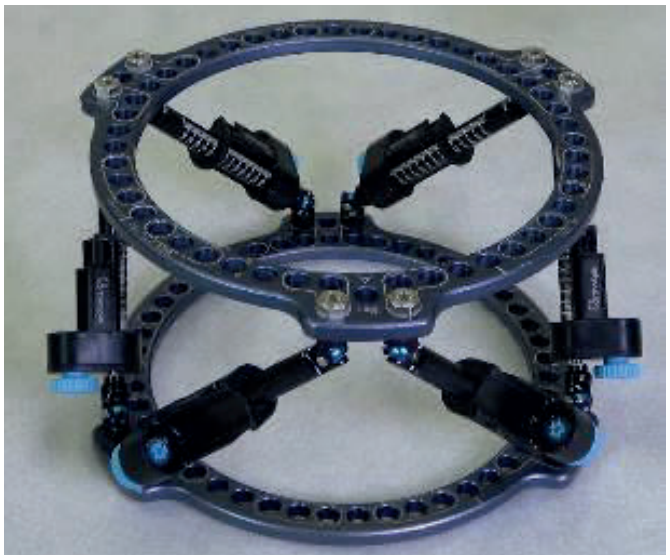


Figure 2: Struts assembled on the rings in the OR

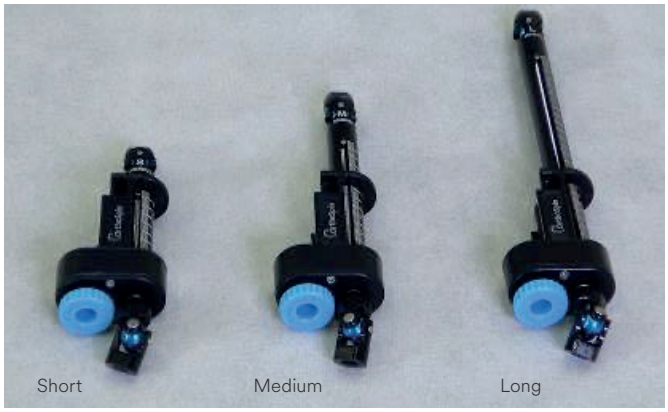


Figure 3: MAXFRAME AUTOSTRUT Strut sizes

3.1.2 Control System

The MAXFRAME AUTOSTRUT Control System is comprised of a control box which is connected to 6 strut motors via electrical cables. The control system is provided non-sterile, hence should be mounted and operated in an outpatient clinic or other location that is non-sterile.
Or, if mounted and operated in the OR, it should be done outside of the sterile field.

The control box is located on the upper MAXFRAME ring, it is connected directly to two adjacent MAXFRAME AUTOSTRUT struts, and connected indirectly to the other four struts by two cable splitters located on the ring sides (each cable splitter is connected to two struts).

The control system kit contains the following components:

1. Control box, containing:
   a. Two 9V Lithium batteries

      ■ Note:

      The battery cannot be replaced by the user.

   b. Electronic control board
   c. Emergency-stop button. Located on the front side of the control box.
   d. LED Display Unit and Sound Indicator Display System: located on the upper side of the box.
2. 6 strut motors
3. Box – ring interface and 2 screws
4. Wire attachment accessories
5. 6 motor attachment clips
6. Allen key for securing the box interface to ring
7. 6 strut gear lockers
8. USB cable
9. Motor clip removal tool
10. Patient quick guide

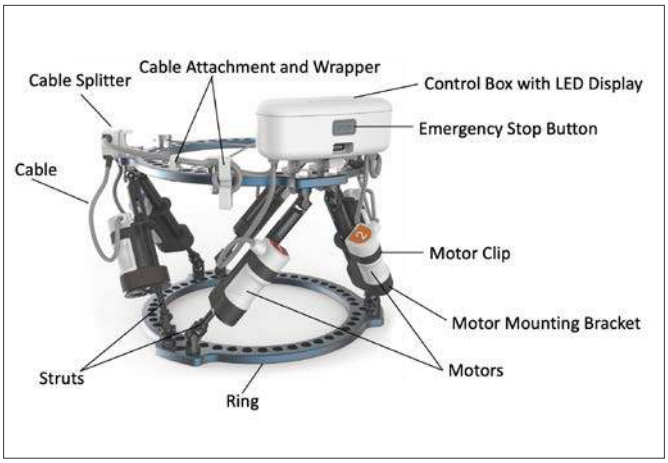


Figure 4: MAXFRAME AUTOSTRUT control system and 6 MAXFRAME AUTOSTRUT hexapod struts assembled on MAXFRAME System rings (outside of a sterile environment).

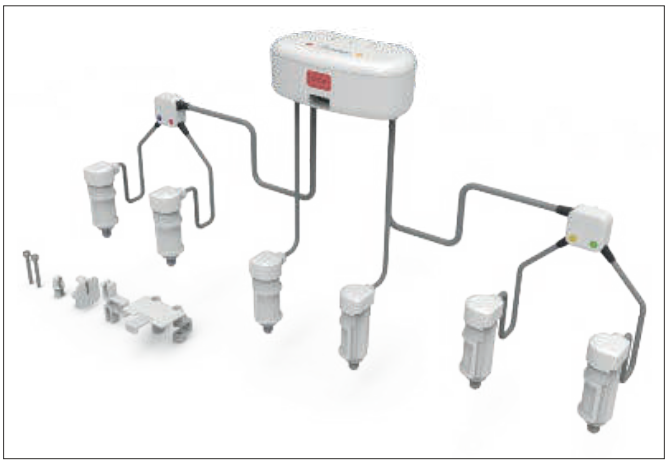
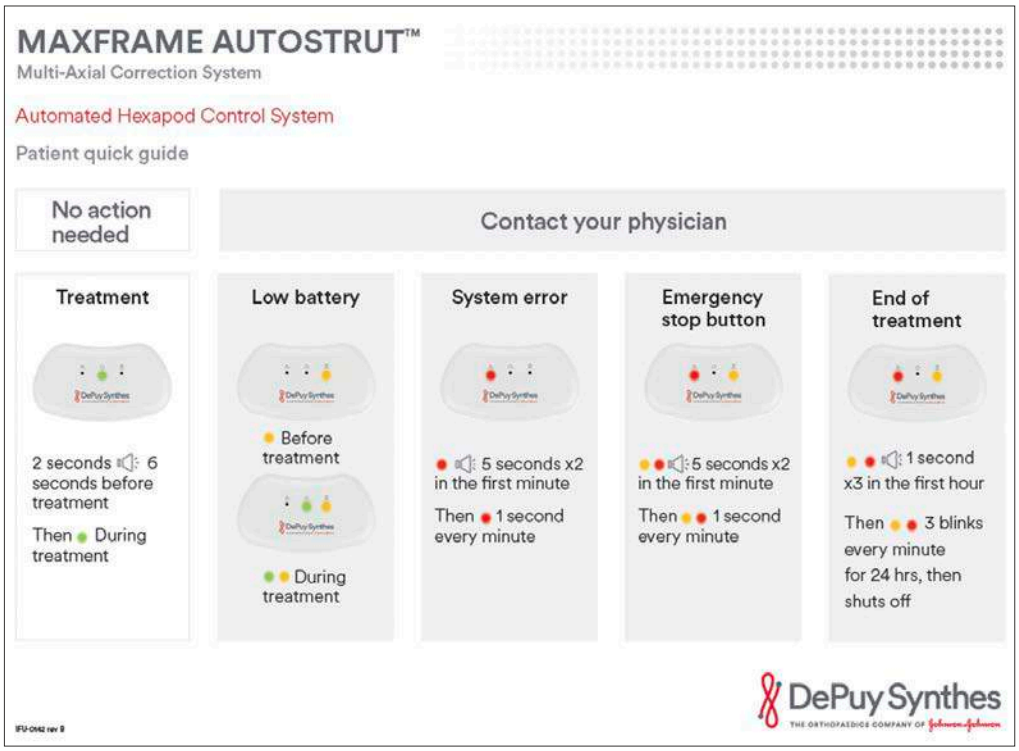


Figure 5: Control system elements

The system indicators include:



3.1.3 Instruments

MAXFRAME AUTOSTRUT System utilizes the following instruments:

- Wrench ∅ 8.0/11.0 mm
- Torque Wrench 10 Nm
- 3 mm Allen Wrench

The instruments are used for connecting MAXFRAME AUTOSTRUT hexapod struts and control system interface to the MAXFRAME System.

3.2 Software

MAXFRAME AUTOSTRUT Software is used by the physician.

Applications of the software include:

1. Converting the treatment plan file supplied by MAXFRAME Software.
2. Downloading the treatment plan to the control system.
3. Activating the MAXFRAME AUTOSTRUT strut motors according to treatment plan.

■ Note:

Treatment plans exceeding 90 days at 20 strut adjustments per strut per day may require a control system replacement, as battery life may be depleted prior to completion of the treatment plan.

4. Surgical Technique

4.1 Frame Assembly on Patient

4.1.1 Attach Struts

Instruments	
03.311.007	Wrench ∅ 8.0/11.0 mm
03.312.851	Torque Wrench, 10 Nm

1. Choose an appropriate strut type and length

Choose the appropriate size (i.e., short, medium or long) according to the distance between the rings. Strut size selection is correct when strut can be placed and secured between the rings without drawing the rings together and without pushing the rings apart. Strut length adjustment may be made by rotating the blue manual rotation knob.

Before use, strut assemblies should be cleaned manually or mechanically with a manual pre-clean. Ultrasonic cleaning is not recommended. Sterilize the struts by using pre-vacuum steam autoclave using the following parameters:

- 3 pre-vacuum phases with at least 60 mbar.
- Sterilization temperature: of 132°C.
- Holding/exposure: 4 min.
- Drying: 20–30 min.

Do not exceed recommended temperature or time.

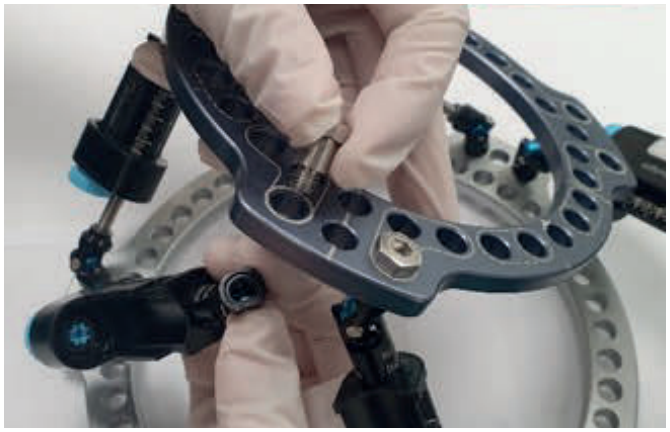
New product can be sterilized up to three sterilization cycles, unless had a direct or indirect contact with any body fluids.

Open MAXFRAME AUTOSTRUT strut packaging and verify that it is not damaged and that the manual knob is inserted to its position.

2. Strut Assembly in the operating room

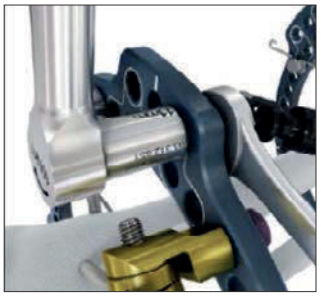
2.1. Orient the MAXFRAME AUTOSTRUT Strut so that the motor socket is facing outward and the blue manual knob is facing away from where the control unit is going be mounted.

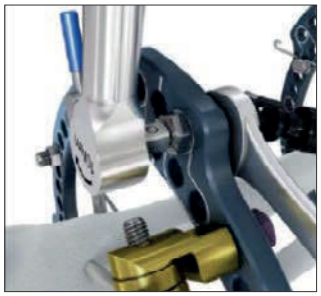
Take care with implant placement to ensure the connecting elements will not interfere with the planned control unit mounting location.



2.2. Attach the MAXFRAME AUTOSTRUT Strut to the proximal ring.

Align the MAXFRAME AUTOSTRUT with the intended hole on the proximal ring.
It is recommended to place struts in default holes when adjacent hardware allows. This will simplify the MAXFRAME Software workflow.
Thread the shoulder bolt through the hole in the ring and into the MAXFRAME AUTOSTRUT.

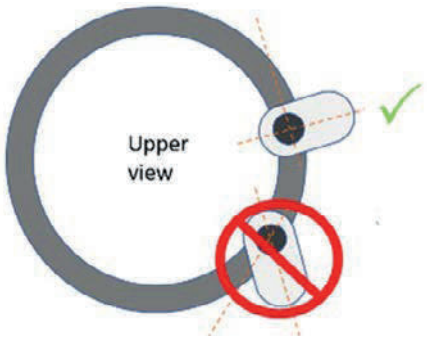




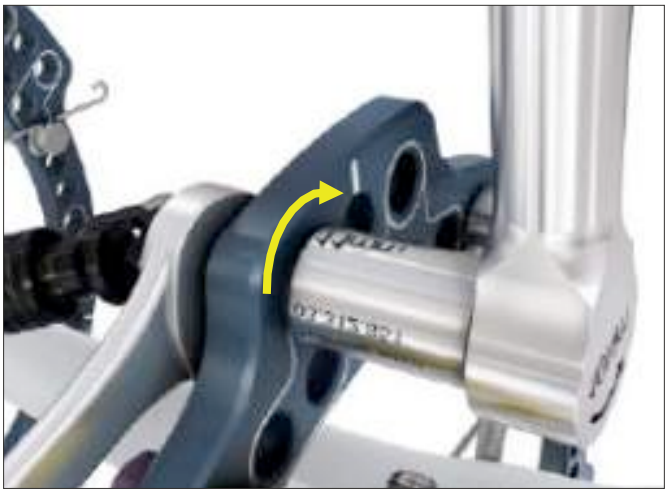
Place the 11 mm end of the Wrench 8.0/11.0 mm on the flats at the end of the spherical hinge to provide counter torque.
Before final lock – verify that motor adaptor is perpendicular to ring tangent (especially important in the small struts) – see lower picture.

▲ Precaution:

If counter-torque is not provided the force of the Torque Wrench, 10 Nm could damage the strut.



Using the Torque Wrench, 10 Nm, tighten the shoulder bolt until you feel the wrench slip, indicating it has reached the appropriate torque. Ensure that the wrench is fully seated.



Notes:

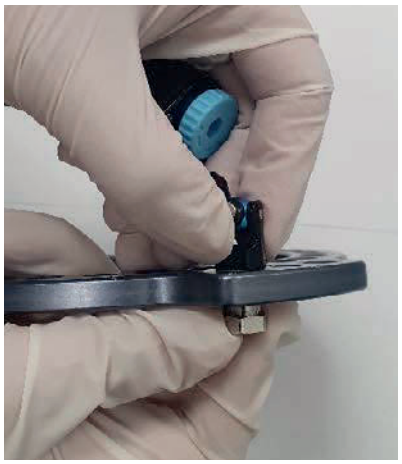
- If there is not enough room to place the 11 mm socket of the Torque Wrench, 10 Nm, remove the socket on the torque wrench to expose a 5 mm hex that mates with the internal recess on the head of the shoulder bolt.
- Remember that both ends of the strut should be locked to the rings.

Rotate the knob until you are at the right length.

2.3. Attach MAXFRAME AUTOSTRUT to appropriate hole in the distal ring using a shoulder bolt.

Thread the shoulder bolt into the MAXFRAME AUTOSTRUT into the hole in the ring.

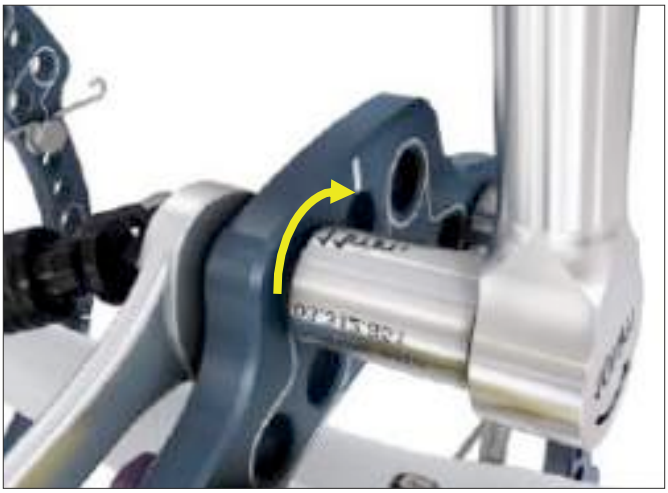
Place the 11 mm end of the Wrench 8.0/11.0 mm on the flats at the end of the spherical hinge to provide counter torque.



▲ Precaution:

If counter-torque is not provided the force of the Torque Wrench, 10 Nm could damage the strut.

Using the Torque Wrench, 10 Nm, tighten the shoulder bolt until you feel the wrench slip, indicating it has reached the appropriate torque. Ensure that the wrench is fully seated.

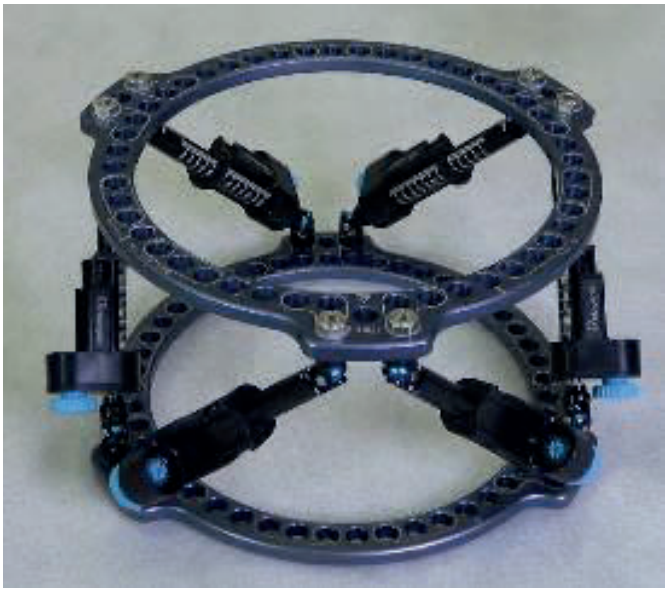


■ Notes:

- If there is not enough room to place the 11 mm socket of the Torque Wrench, 10 Nm, remove the socket on the torque wrench to expose a 5 mm hex that mates with the internal recess on the head of the shoulder bolt.
- Remember that both ends of the strut should be locked to the rings.

2.4. Repeat the process of attachment to the ring by way of the shoulder bolts for the remaining five struts.

Record strut lengths and remove the blue manual knobs.



■ Note:

The Surgeon Planning Worksheet can be utilized to capture this information. For more information on the Surgeon Planning Worksheet, see “Surgeon Planning Worksheet” section in MAXFRAME System Surgical Technique.

2.5. Perform final tightening of all shoulder bolts on the proximal and distal rings.

Place the 11 mm end of the Wrench 8.0/11.0 mm on the flats provided on the end of the spherical hinge to provide counter-torque.

▲ Precaution:

If counter-torque is not provided the force of the Torque Wrench, 10 Nm could damage the strut.

Using the Torque Wrench, 10 Nm, tighten the shoulder bolt in both sides of the strut until you feel the wrench slip, indicating it has reached the appropriate torque.

4.1.2 Control System Assembly and Treatment Plan Downloading

Instruments	
03.311.007	Wrench 8.0/11.0 mm
	Allen Key

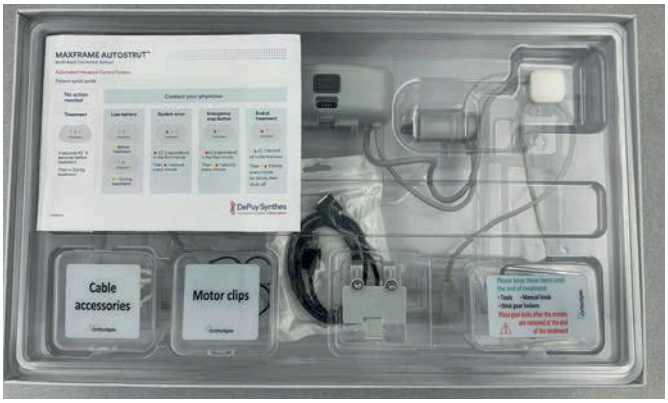
1. Outside of the sterile field and before the patient leaves the hospital, attach the MAXFRAME AUTOSTRUT Control Box interface to appropriate holes in the proximal ring.

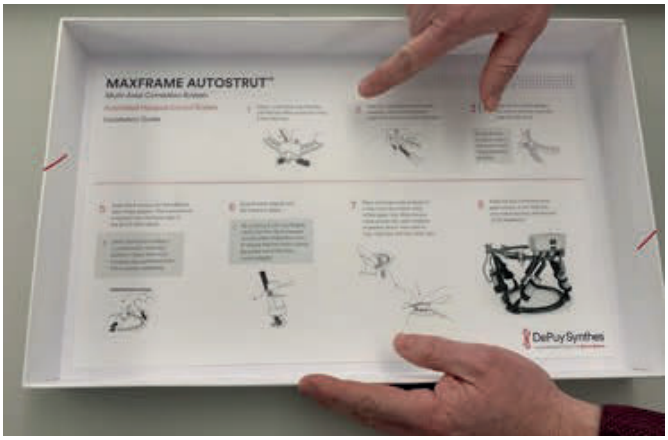
Verify that all strut bolts are firmly tightened by using the Wrench 8.0/11 mm.

Check product expiration date on the label located on the control box bottom and verify the product expiration date.

Expiration date is related to the battery.

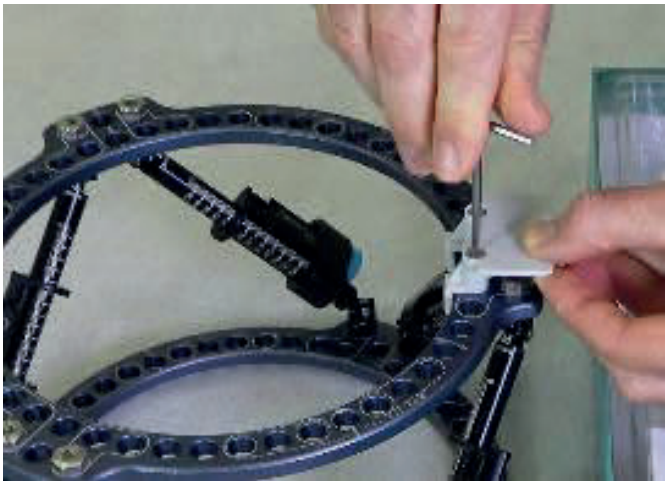
Open the control box package and follow the instructions listed at the inner side of the cover.



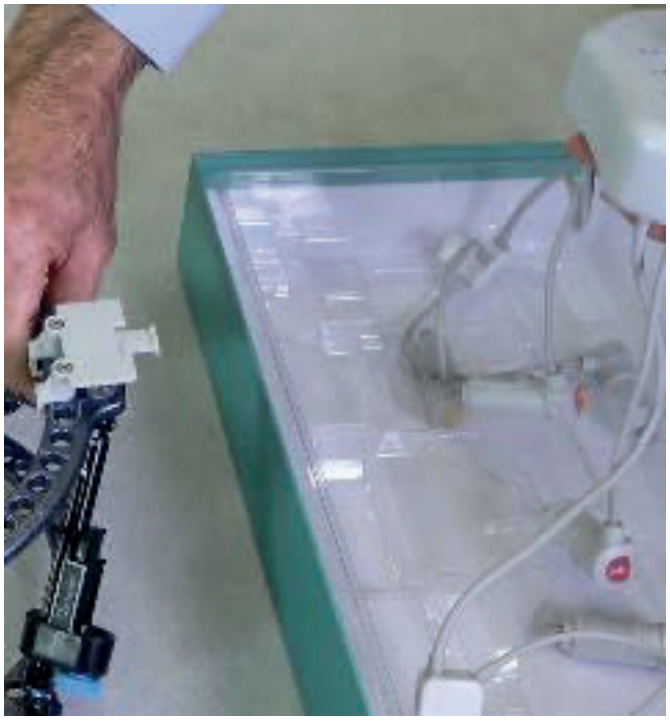


Take out the control box ring interface.

Attach control box ring interface with the 2 Allen screws by using 3 mm Allen key.
You can place it in any free space near the master tab.

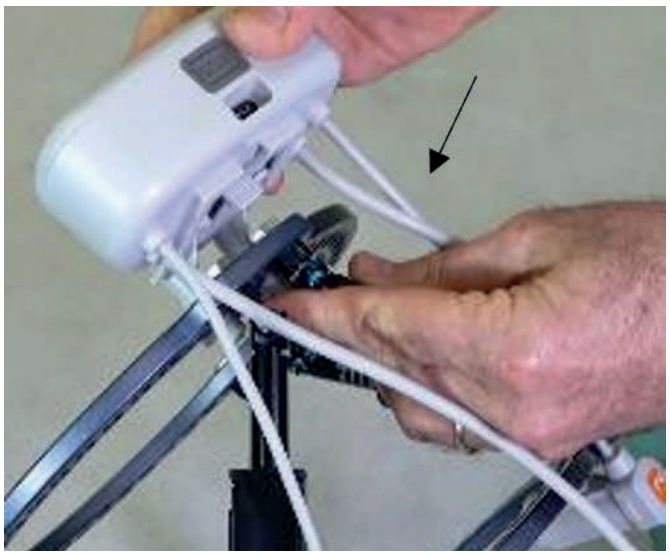


Carefully pull out the control system with the 6 motors attached to it.

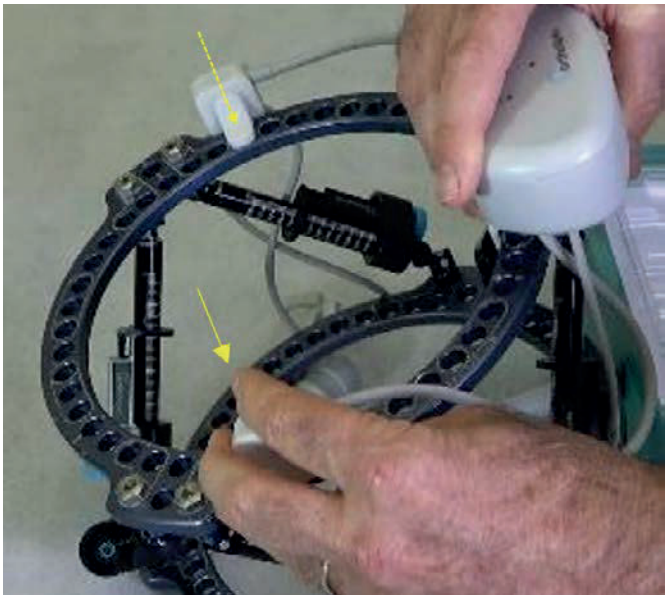


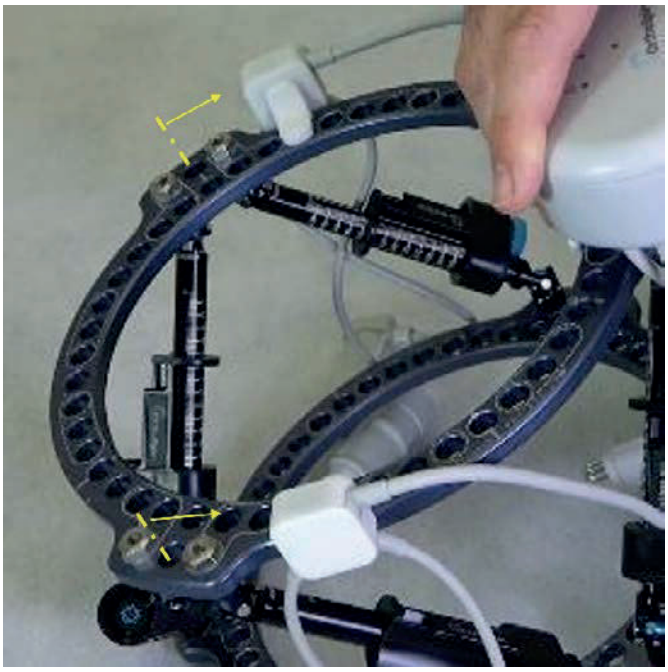
Slide the control box onto the box interface until it clicks in place.

Verify that it can’t slide back.



Snap the two cable splitters into their place on the upper ring.
You can place them in any free space near the connection with the side struts. It is preferred to place them as close to the control box as possible.

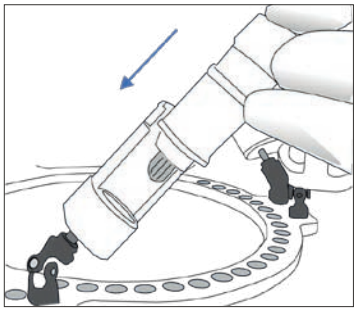


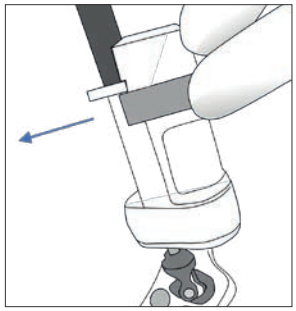


Insert the 6 motors to the adjacent strut motor adaptors and secure them with the motor clips. If blue manual knobs are still present, they will be ejected from the lower side of the struts.

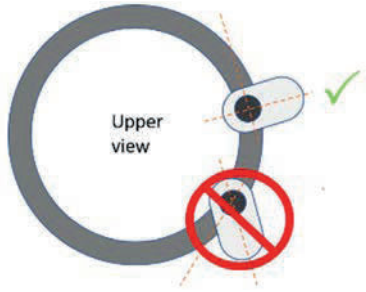
Verify that the clip is snapped on both sides.

Confirm the clip is engaged by gently pulling the motor to ensure the motor cannot be displaced.



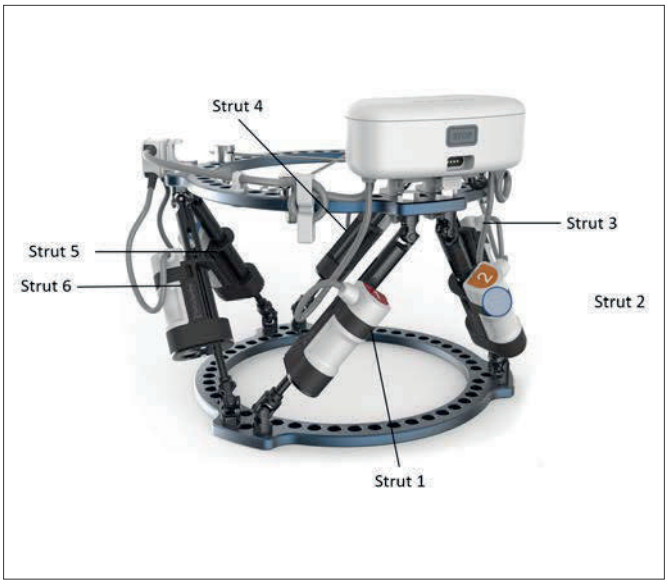


Verify that motor adaptor and motor are perpendicular to ring tangent (especially important in the small struts) so that the motor enclosure does not touch the upper ring. If the motor is too close, release the bolt screw that locks the strut, rotate the strut so that the motor does not touch the ring, and lock again with the torque wrench. (See upper view picture.)

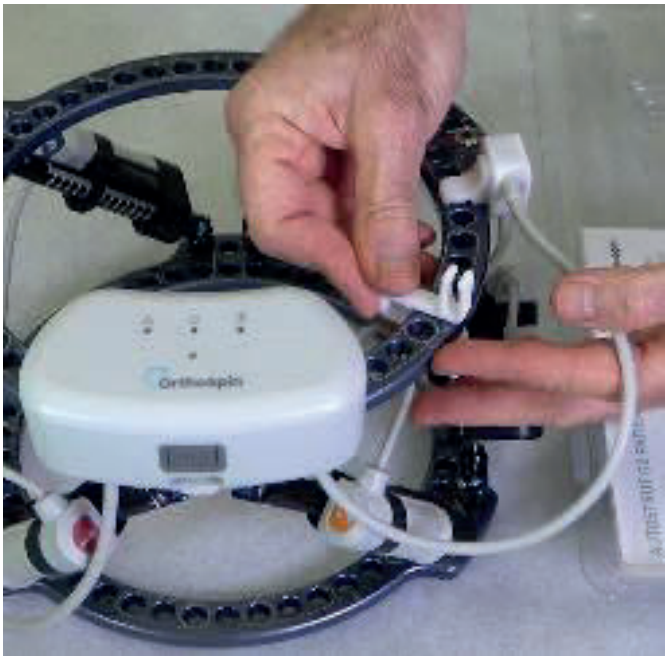


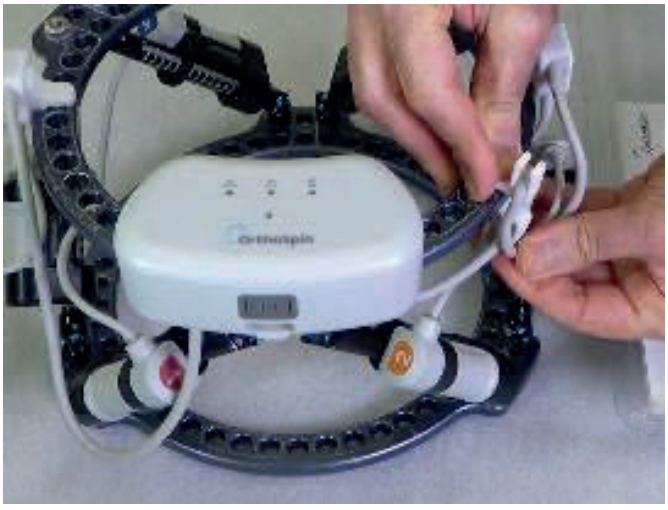
Please keep at least one knob for future use (such as strut size replacement).

Verify that motor number 1 is positioned in the correct strut according to the MAXFRAME plan. Check that motor numbers are continuous from 1 to 6 counter-clockwise.

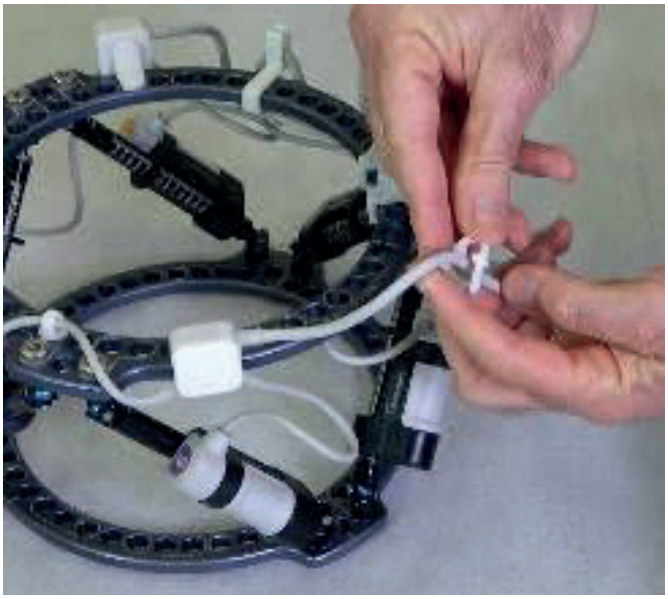


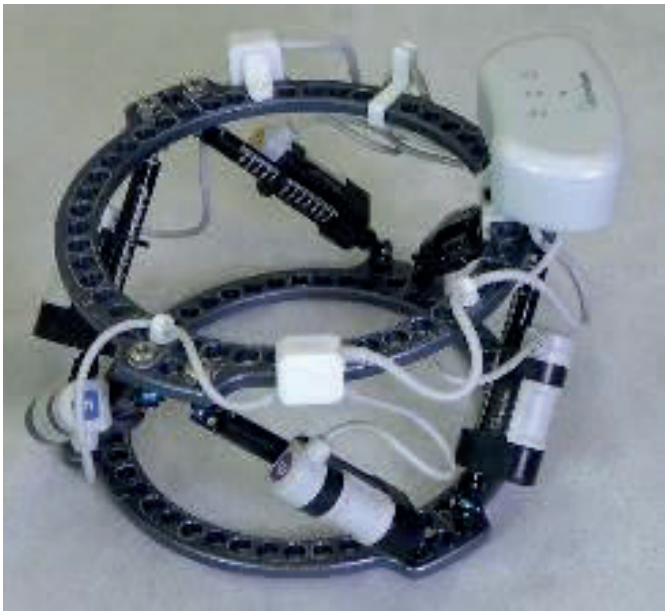
Place and snap cable wrapper in a free space on both sides of the upper ring. Wrap excess cable around the cable wrapper.





If needed, attach free cable to free rings holes with the cable clips.



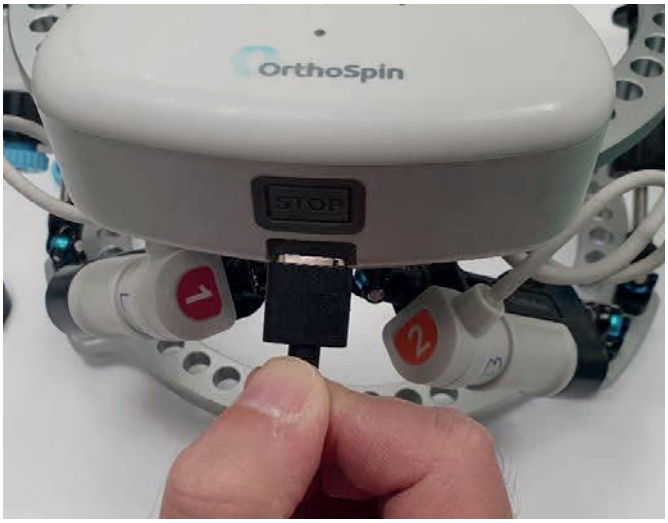


Keep strut lockers, 3 mm Allen key and motor clip tool for the end of the treatment.

You are now ready for system activation.

2. In the clinic (or outside of sterile field), attach computer running MAXFRAME AUTOSTRUT Software to the main control box via provided USB cable for downloading treatment plan.

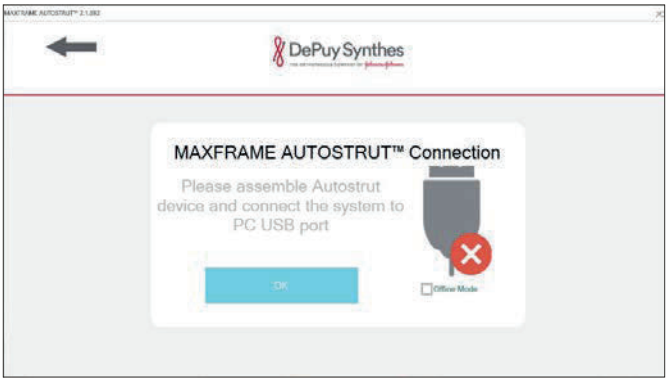
Connect the magnetic USB in the appropriate orientation to the connector at the front side of the control box.

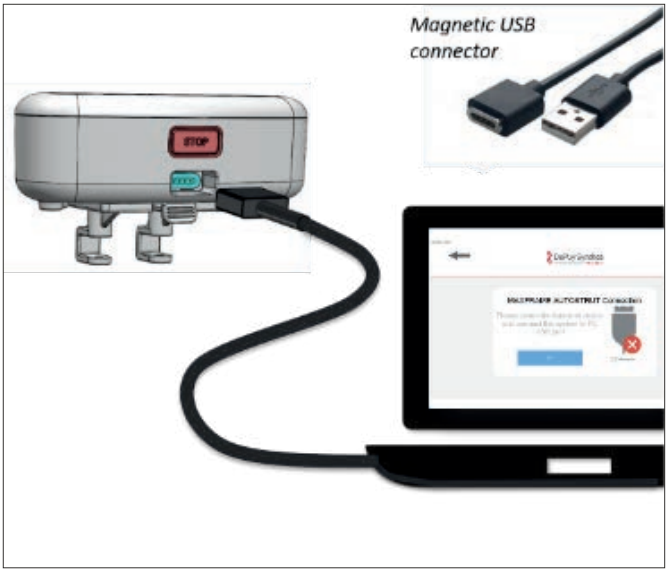


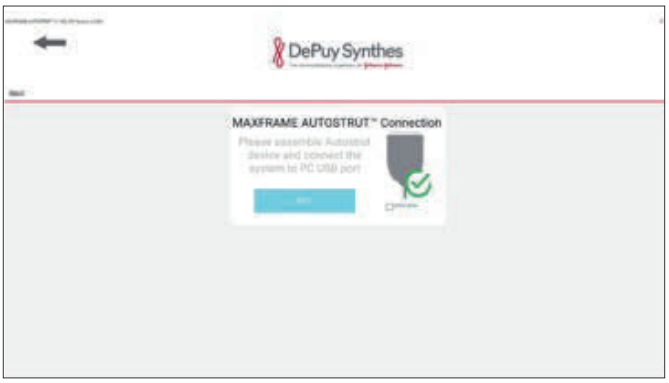
Open MAXFRAME AUTOSTRUT Software. Login using your MAXFRAME 3D II Software user name and password. If you do not have a MAXFRAME 3D II Software user account, click “Request a User Account” and you will be redirected to the MAXFRAME 3D II landing page where you can request an account.

Connect USB connector to PC and press OK. (On the device, you will hear 2 beeps and see a flashing orange light to indicate you are connected. On the PC application you will see a green check.)

There is a an “Offline Mode” checkbox on this page. If this box is checked, it is possible to advance through the software without being connected via USB cable to the Control System. This is useful for training or familiarizing yourself with the software functionality. Do not check this box if you desire to upload a treatment program to the Control System.



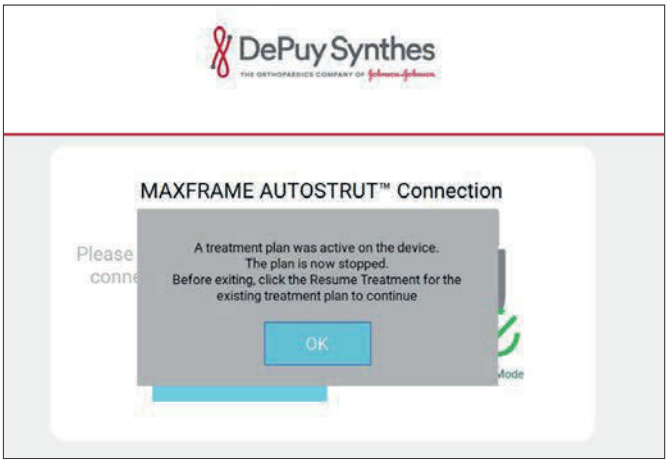


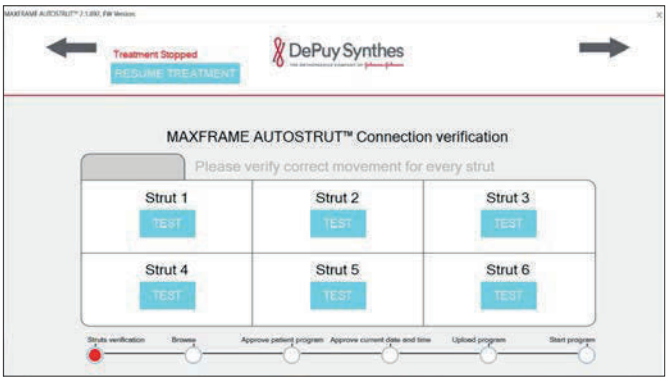


New Treatment

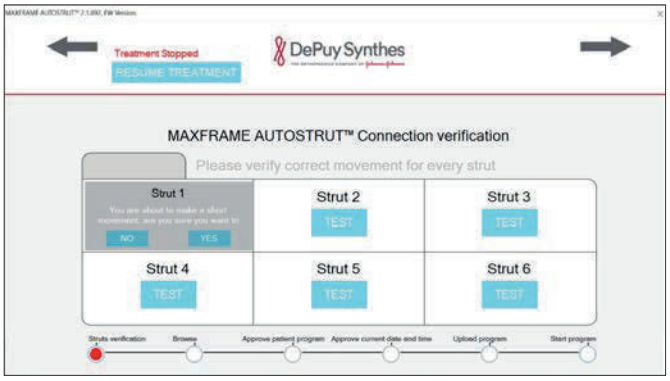
Select New Treatment

If the device has a prior treatment plan loaded, it will be stopped. This Resume Treatment notice is displayed and the “Resume Treatment” button will appear in the header.

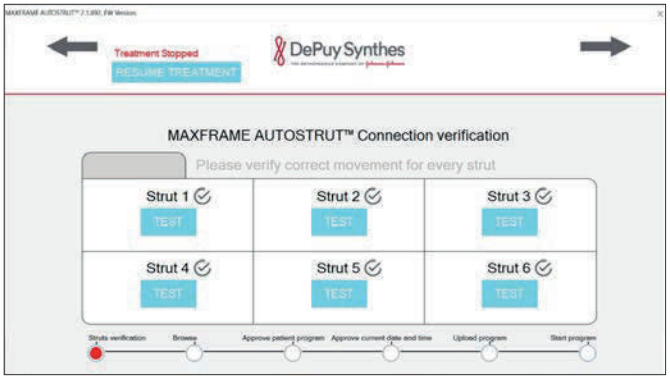




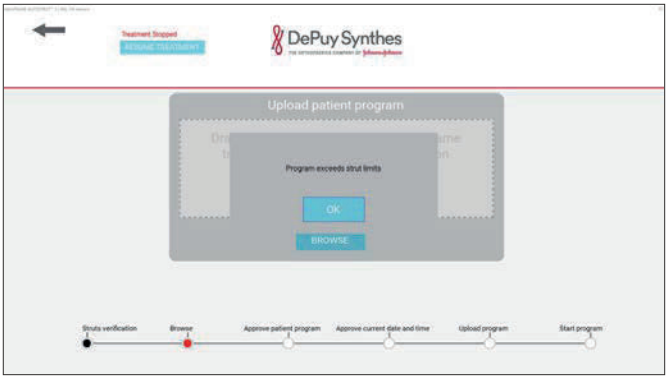
Verify the movement of every strut by pressing its test button while holding the strut by the hand and physically feeling its movement. (A check will appear if each motor test passes.)



After all motors passed, press the top right arrow to move to the next step.
If the battery is low, a warning message is displayed.

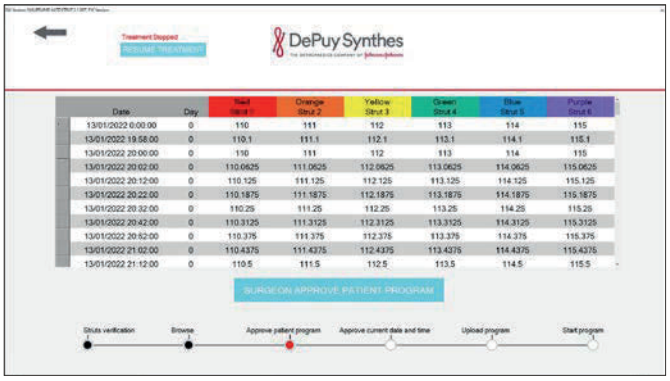


Upload patient treatment plan.
Only MAXFRAME treatment plans within strut size short, medium and long are allowed.
Treatment plans containing X-Short and XX-Short strut sizes will be rejected.



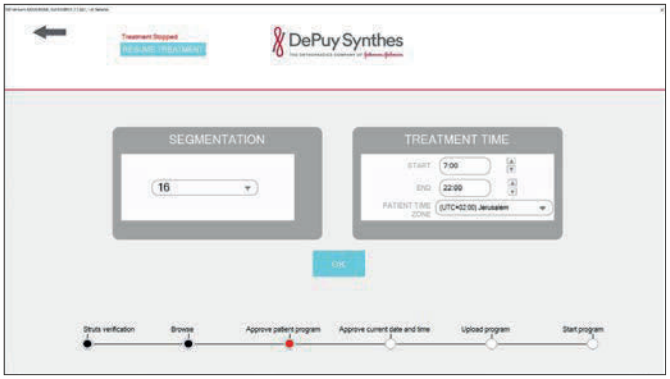
Approve patient name.

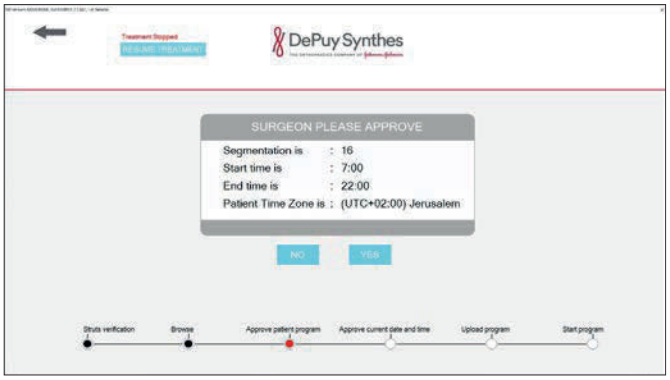
Review and approve selected treatment plan.



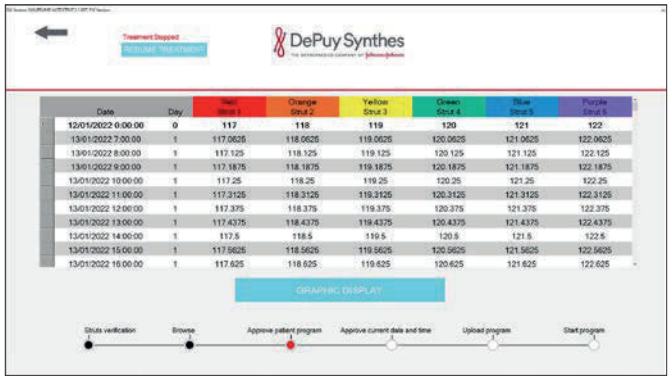
Select the number of segmentations per day (up to 20) and treatment time according to patient's daily activity.

Verify that the time refers to patient time zone.



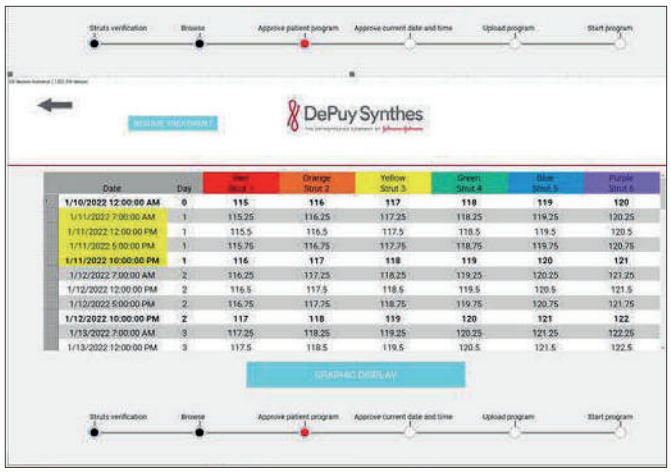


Review and verify that the presented plan matches the desired treatment plan.
(Original pre-segmentation data is shown in bold.)

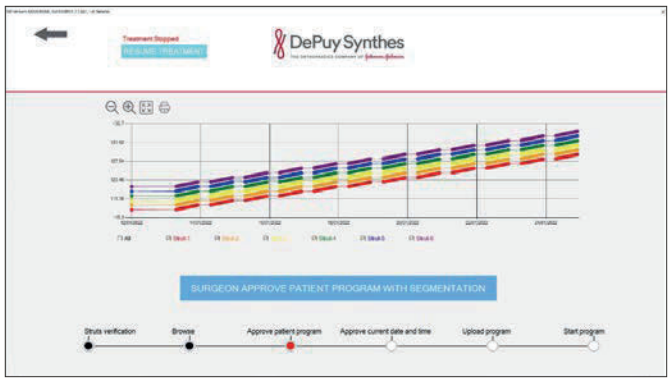


■ Note:

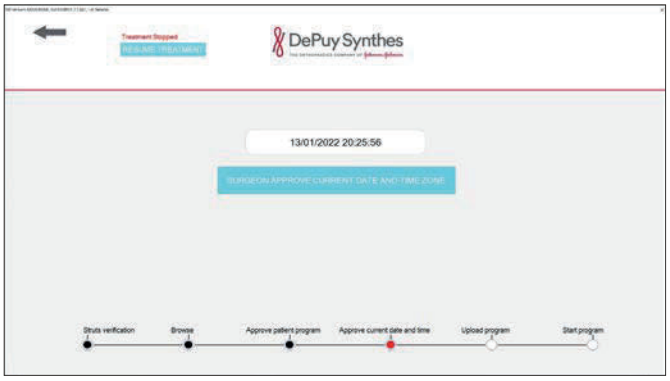
Any strut length changes that exceed 1mm per adjustment OR when treatment days are not valid (such as dates in the past for example), will be highlighted in yellow. Correction prior to treatment plan upload is required. The treatment plan will not load until all areas in yellow are fixed.

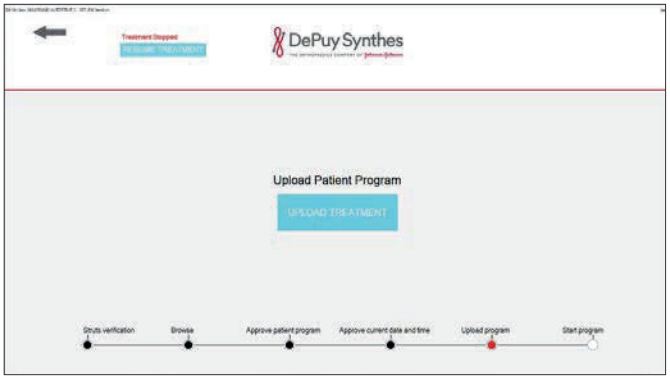


View treatment graphics display and verify that it is linear, has no “jumps” nor irregular pattern and that it generally makes sense from clinical aspect.

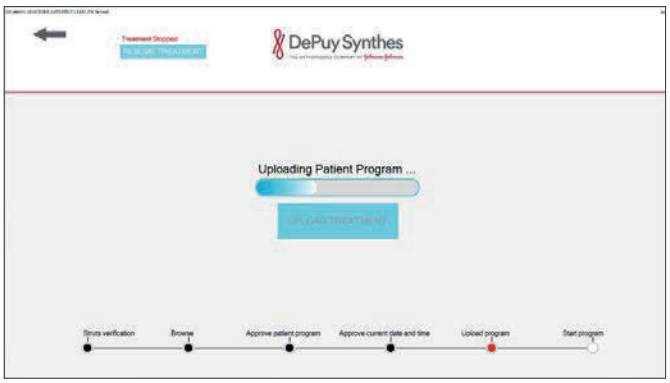


Approve the physician's current local date and time. If you are using a computer that is set to a time zone other than the current local time zone, you will need to first set your computer to the current local time zone.





Upload treatment plan. When uploading or downloading data from the device, you will see a rapid blinking orange light. The data transfer may take some time. When the data transfer is complete, the light will stop blinking.

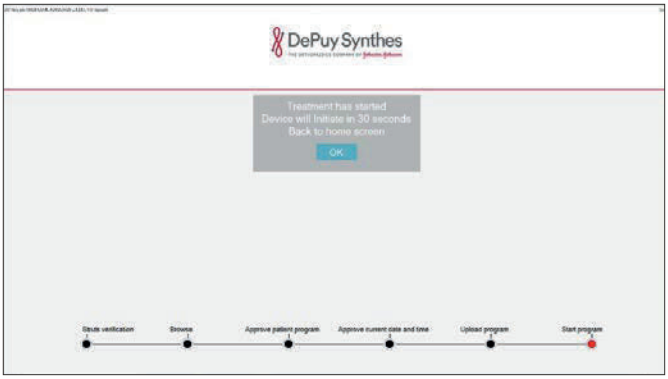


Start the treatment.

The orange LED in the control system will turn off. Treatment plan PDF contains private patient information and will automatically be deleted from the laptop computer.

Disconnect USB cable.

After 30 seconds, each strut will lengthen by 0.1mm. Then, after another 2 minutes, each strut will shorten by 0.1mm. This is done to verify the system works properly.

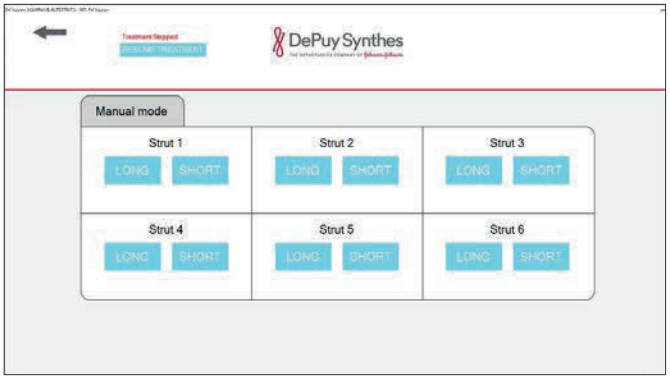


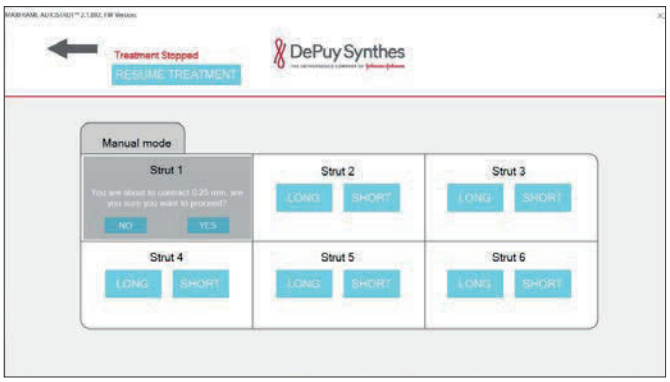
Replanning

When initiating a replan, if desired, surgeon can move the struts to the nearest integer value as defined in the MAXFRAME Software replan by utilizing manual software mode or manual adjustment knob.

Manual Mode

The use of this mode is for lengthening or shortening each one of the struts electronically, in case of such clinical need.
Press the “manual mode” button to open the relevant screen.
Select the desired strut and the movement direction and press on the relevant button. Each press will move the selected strut 0.25 mm in the desired direction.

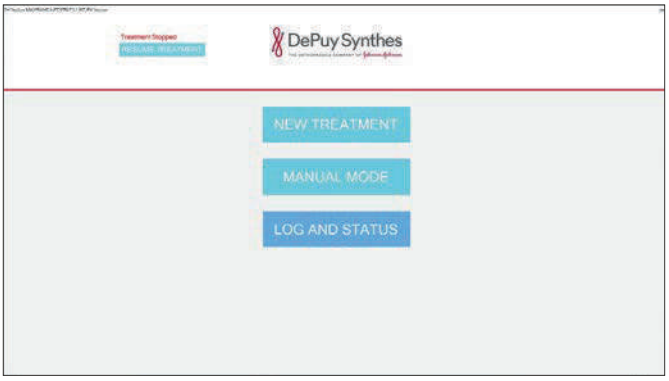




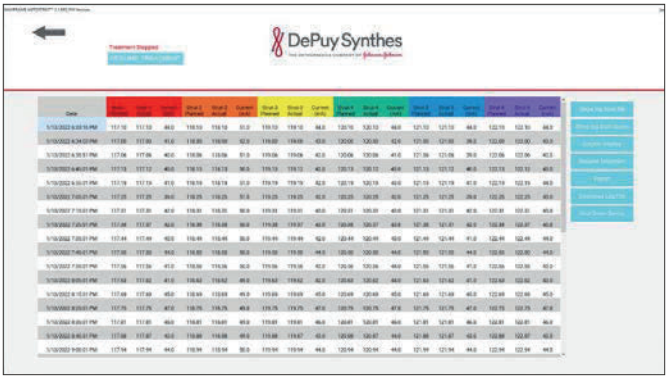
Log and Status

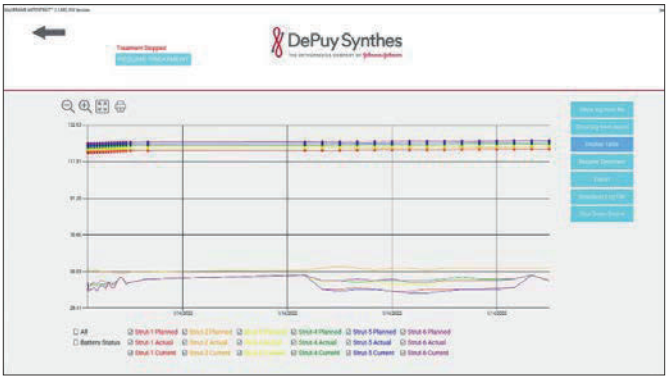
This selection enables visual presentation of any current or past treatment plan:

- Planned vs. actual
- Struts motor current



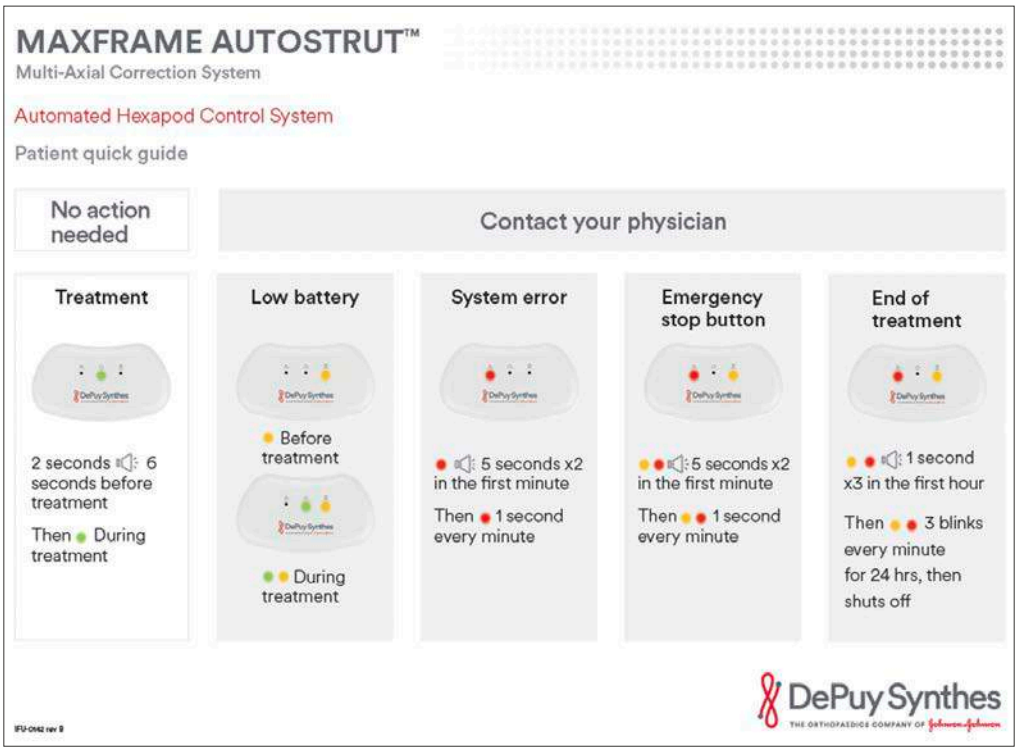
Select a local log file and view relevant treatment data, show log from device, view graphical display, resume treatment, export CSV log file, download text log file or shut down device. When uploading or downloading data from the device, you will see a rapid blinking orange light. The data transfer may take some time. When the data transfer is complete, the light will stop blinking.





3. Prior to treatment beginning, instruct the patient regarding the treatment and device LED indicators.

Provide the Patient quick guide. There is also a Patient User Manual available at OrthoSpin.com.



■ Note:

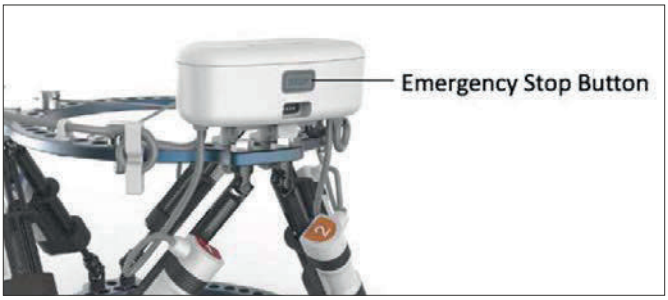
The MAXFRAME AUTOSTRUT system contains motors, LED and sound indicators that are activated during treatment. These produce lights and sounds that are subtle enough to let the patient know when the system is performing a treatment. You should ask your patients if they have any questions or concerns related to the system's lights and sounds.

▲ Precaution:

The patient and/or post operative care team must be capable of understanding the system operation, indicators (lights/sounds) made throughout the treatment, and provide timely communications back to their surgeon.

4. Emergency Stop Button Information.

The emergency stop button is located on the side of the control box.



It is a switch that will disable the motors from moving. The button is there to enable the patient to stop the device in case of emergency. You should help your patient to understand what types of situations would be considered and emergency.

If pressed during active treatment, the motors will stop moving immediately. The System will beep for 5 seconds twice and will display the red and orange LED lights. After that, the red and orange lights will blink for one second every minute. If pressed while the device is not in active treatment, nothing will happen until it is time for the next active treatment to occur. When this time comes, the device will sense that the emergency stop button has been pressed and will not start treatment. Instead, it will display the emergency stop sound and lights described.

■ Note:

Treatment is stopped until system is reactivated by the physician. The patient should contact the physician as soon as possible for any situation in which the emergency stop button was pressed. The patient cannot restart the device on their own.

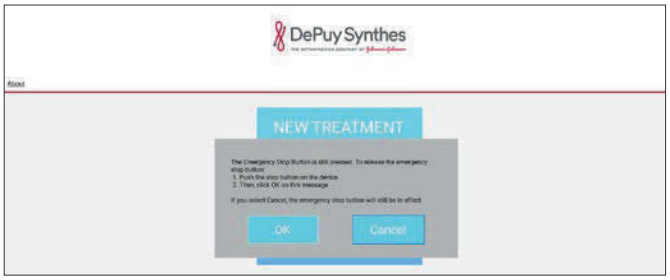
If the patient has pressed the emergency stop button, and the physician has determined that the System should be started again, a new PDF treatment plan will need to be created and uploaded to address the residual deformity.

When the device is connected to the software, you will see this message.

To continue, push button on the device all the way down until you hear a click and release. Then press OK in the software and proceed through the software workflow.

If you press OK and the button is not released, you will see a message indicating that the emergency stop button still needs to be released to continue.

If you press cancel without pressing the Emergency Stop Button on the device, you will be able to enter the software, but the device will not respond to motor tests or manual mode movements.
After clearing the emergency stop button, proceed to “New Treatment” in the software to begin the process of loading the new treatment plan on the device.



Troubleshooting Guide – Physician's actions:

Error	Action
Low Battery	Replace the control system with a new one.
System error	Replace the control system with a new one.
End of treatment	Please verify that the struts are at their final position according to plan. Remove the control system from the patient. Attach strut gear lockers to each strut. See section 4.1.4.
Treatment does not occur (for example: struts do not move/dead system, hardware failure, or unable to upload treatment plan.)	Replace the control system with a new one. If a replacement is not available, remove MAXFRAME AUTOSTRUT Control System and Struts and replace with MAXFRAME Quick Adjust or Standard Struts. The MAXFRAME AUTOSTRUT System is backwards compatible with the manual struts found within MAXFRAME Multi-Axial Correction System. Refer to the MAXFRAME surgical technique guide for details.

4.1.3 Strut Length Change

During the course of a treatment plan, the physician may need to perform a change to the length of the struts. Strut changes are determined by the physician, during patient follow-up.

■ Note:

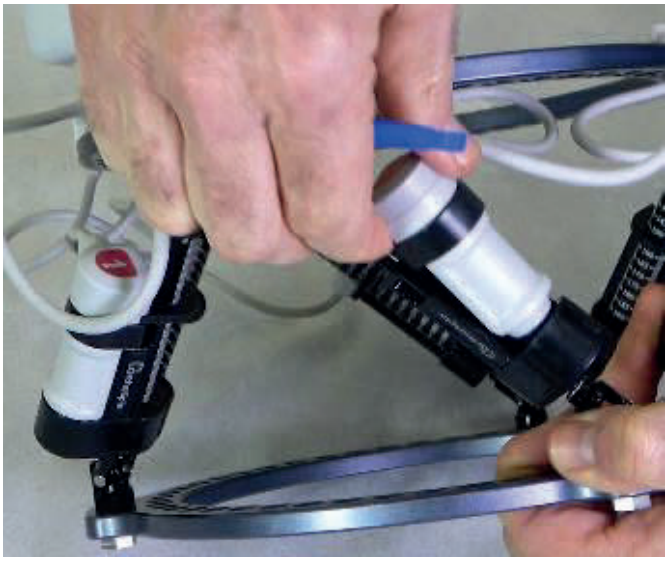
Prior to strut removal, reinforcement of the frame with the MAXFRAME System Strut Swap Kit is required. Refer to the MAXFRAME System surgical technique for details.

Instruments	
03.311.007	Wrench 8.0/11.0 mm
03.312.851	Torque Wrench, 10 Nm
01.312.012	Strut Swap Kit

1. In the clinic, release the distal side of the strut by opening the shoulder bolt.

According to the defined activation clock, verify that the replacement is not performed during the next session.

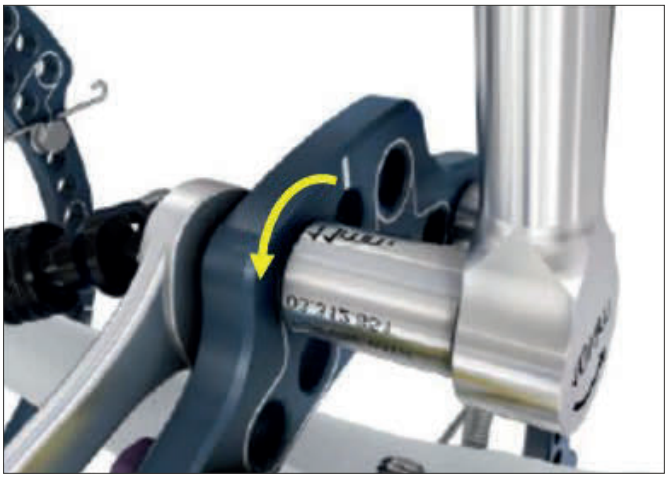
Release the relevant motor by taking out its clip using clip tool.



Loosen the shoulder bolt on both ends of the affected Strut to be changed using the 8 mm/1 mm wrench. Provide counter-torque.

▲ Precaution:

Do not use the 10 Nm Torque Wrench for loosening as it may damage the torque wrench. The 10 Nm Torque Wrench is calibrated for one direction only.



Fully unscrew the shoulder bolts and keep them for reinstallation.

Using blue strut knob, adjust new strut to match the removed strut length.

By using the bolts removed from the previous strut, tighten the new strut in place. With torque wrench, 10 Nm, tighten the shoulder bolt until you feel the wrench slip, indicating it has reached the appropriate torque. Ensure that the wrench is fully seated.

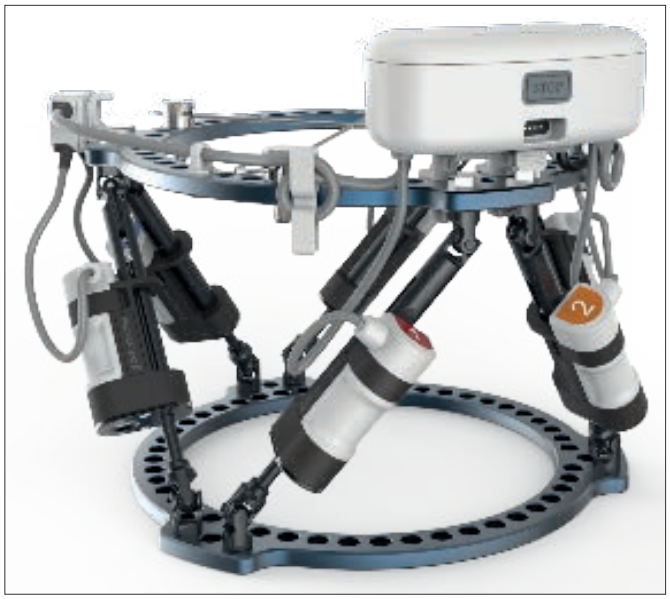
Reposition the relevant motor into the new strut socket and click back the motor clip.

Verify that the clip is snapped on both sides.

Confirm the clip is engaged by gently pulling the motor to ensure the motor cannot be displaced.

If removed motor activates during a strut swap procedure, physician will need to determine if the missed strut movement is of clinical significance and adjust the strut manually with the blue knob before reinstalling the motor.

2. Repeat the process of changing strut configuration as needed for the remaining struts.



3. Perform final tightening of all shoulder bolts on the proximal and distal rings.

Place the 11 mm end of the Wrench 8.0/11.0 mm on the flats provided on the end of the spherical hinge to provide counter-torque.

▲ Precaution:

If counter-torque is not provided the force of the Torque Wrench, 10 Nm could damage the strut.

Using the Torque Wrench, 10 Nm, tighten the shoulder bolt in both sides of the strut until you feel the wrench slip, indicating it has reached the appropriate torque.

4.1.4 Control system dismantling after the motorized treatment is ended

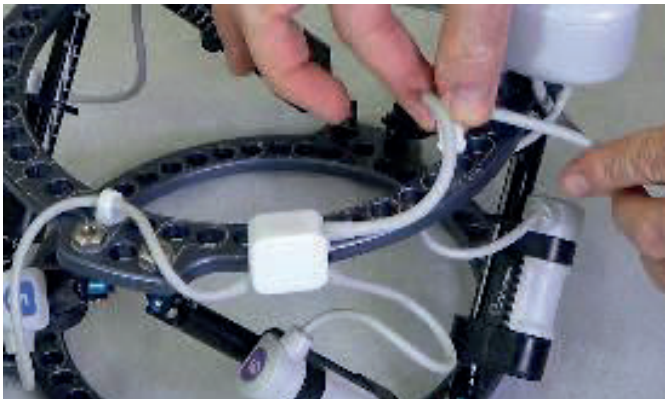
After the motorized treatment is ended, the control system and motors are dismantled from the struts and ring. Instead of the motor, a gear locker must be inserted into each of the struts.

Instruments
Motor clip tool
3 mm Allen key

1. In the clinic, release the motors from the struts and detach the control box from the control box interface and splitters from the upper ring. Then release the control box interface from the upper ring.

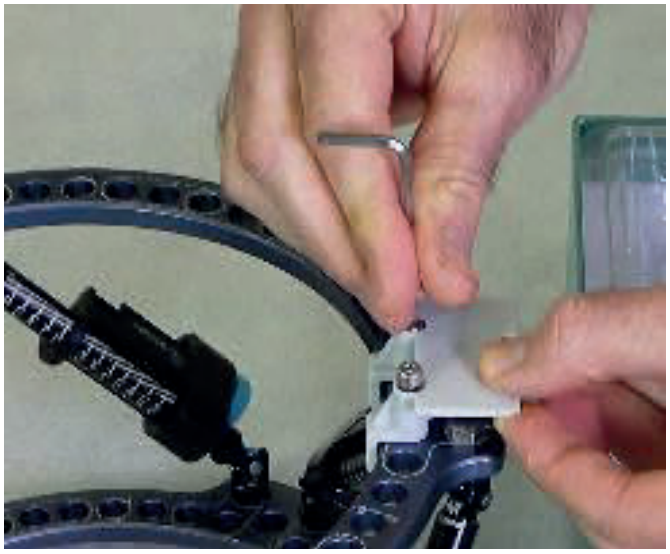
Release the relevant motor by taking out its clip using clip tool Release all 6 motors.

Release wire attachments and cable splitters from the ring.



Press down control box release button and pull out the control box.

Unlock the screws holding the control box interface.



▲ Important:

Insert gear lockers in each of the struts to prevent any undesired strut movement when the motors are not engaged.

Place upper part in place according to adaptor contour. Then insert the locking pin from the opposite side and press it against the upper part till “click” is heard and both parts are fully attached to the adaptor body.

5. Care and Maintenance

After each use, all instruments should be cleaned. Instruments with removable parts should be dismantled prior to cleaning. Steel brushes must not be used to clean the instruments. Cannulated instruments must be thoroughly cleaned and opened prior to washing and disinfection.
Prior to autoclaving, instruments should be inspected for cleanliness. Instruments with moving parts must be lubricated with Synthes Autoclavable Oil (519.97).

▲ Important:

Prior to use, and while cleaning, visually inspect the instrument. Do not use the instrument if damaged. Examples of damage include, but are not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear.

The MAXFRAME AUTOSTRUT hardware components carry an Ingress Protection (IP) rating of IP68, meaning that the system can be submerged and operated in up to 2m deep water for up to 30 min (including bath and shower).
For more information, please refer to “Care and Maintenance” section in MAXFRAME System Surgical Technique.

■ Note:

Dispose of equipment at the end of service life in accordance with your local regulations.

6. Software Updates or Patches

- Manufacturer may release software updates or patches from time to time and if needed.
- Such software updates and patches will be released according to Manufacturer's procedures and will adhere to all regulations.
- User will be prompted to download updates or patches to the software as needed when logging in.

7. Symbols Glossary

Following are the symbols and their descriptions used in the MAXFRAME AUTOSTRUT System:

Symbol	Standard Number and Title	Symbol Number	Symbol Title	Description
	EN ISO 15223-1	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	EN ISO 15223-1	5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1	5.1.3	Date of manufacture	Indicates the date the device was manufactured.
	21 CFR 801.109	–	Prescription Use Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
	ISO 15223-1	5.4.2	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single user during a single procedure.
	ISO 15223-1	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 15223-1	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	ISO 15223-1	5.1.1	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1	5.3.9	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 15223-1	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1	5.7.10	Unique Device Identifier (Barcode)	Indicates a carrier that contains Unique Device Identifier information.

Symbol	Standard Number and Title	Symbol Number	Symbol Title	Description
	ISO 15223-1	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 7010	M002	Refer to Instruction Manual	Signifies that the instruction manual/booklet must be read.
	ISO 15223-1	5.2.7	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7000	-	Quantity	Indicates the amount of product included.
	ASTM F2503-13	-	MR Unsafe	Medical device which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
IP68	IEC 60529	-	Degrees of protection provided by enclosures (IP Code)	No ingress of dust; complete protection against contact (dust-tight). The equipment is suitable for continuous immersion in water depth up to 2 meters for 30 minutes (these conditions are specified by the manufacturer).
Type BF	IEC 60417	5333	Type BF applied part	Identifies a type BF applied part complying with IEC 60601-1.
	EN 50419 in accordance with article 11(2) of Directive 2002/96/EC (WEEE)	–	Recycle: Electronic equipment	To indicate that the product shall be separated when disposed.
Rating	–	–	Rated power input/ battery, d.c.	To indicate a d.c. rated power input/battery

8. Specifications

8.1 Dimensions and Weight

	Dimensions	Weight
Short Size Strut (S)	97–135	65 g
Medium Size Strut (M)	126–193	74 g
Long Size Strut (L)	185–309	87 g
Control Box (LWH)	110 × 60 × 50	600 g

8.2 Storage Conditions

Temperature range: –30 °C to +60 °C/–22 °F to +140 °F

8.3 Operating Conditions

Temperature range: 5 °C to 40 °C/41 °F to 104 °F

8.4 Electromagnetic Compatibility (EMC) Declarations

Guidance and manufacturer's declaration – electromagnetic emissions

The MAXFRAME AUTOSTRUT System is intended for use in the electromagnetic environment specified below. The customer or the user of the MAXFRAME AUTOSTRUT System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1 Class A	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The system is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **▲ WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the system or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

MAXFRAME AUTOSTRUT System is intended for use in the electromagnetic environment specified below.
The customer or the user of the MAXFRAME AUTOSTRUT System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines N/A	The main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/ output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth N/A	The main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	The main power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

■ Note:

UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

MAXFRAME AUTOSTRUT System is intended for use in the electromagnetic environment specified below.
The customer or the user of the MAXFRAME AUTOSTRUT System should assure that it is used in such an environment.

Declaration – electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V, 6 V	3 Vrms, 6 V	$d = [\frac{3,5}{V1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m	3 V/m	$d = [\frac{12}{V2}]\sqrt{P}$ $d = [\frac{12}{E1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E1}]\sqrt{P}$ 80 MHz to 2.5 GHz
	3 V from 0.15 to 80 MHz; 6 V from 0.15 to 80 MHz and 80% AM at 1 kHz	3 V from 0.15 to 80 MHz; 6 V from 0.15 to 80 MHz and 80% AM at 1 kHz	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol:
	3 V/m from 80 MHz to 2.7 GHz	3 V/m from 80 MHz to 2.7 GHz	

Recommended separation distances between portable and mobile RF communications equipment and the system

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V1}]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = [\frac{12}{V2}]\sqrt{P}$	**80 MHz to 800 MH** $d = [\frac{12}{E1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{23}{E1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band[a)](MHz)	Service[a)]	Modulation[b)]	Maximum power (W)	Distance (m)	Immunity test level (V/m)	Com-pliance level (V/m)
385	380–390	TETRA 400	Pulse modulation[b)] 18 Hz	1.8	0.3	27	27
450	430–470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704–787	LTE Band 13, 17	Pulse modulation[b)] 217 Hz	0.2	0.3	9	9
745							
780							
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b)] 18 Hz	2	0.3	28	28
870							
930							
1720	1 700– 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b)] 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b)] 217 Hz	2	0.3	28	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation[b)] 217 Hz	0.2	0.3	9	9
5500							
5785							

9. Product Information

Part Number	Description
1100012-01	MAXFRAME AUTOSTRUT™ Hexapod Strut – short
1100010-01	MAXFRAME AUTOSTRUT™ Hexapod Strut – medium
1100011-01	MAXFRAME AUTOSTRUT™ Hexapod Strut – long
1100007-01	MAXFRAME AUTOSTRUT™ Automated Hexapod Control System Kit
1100022-01	MAXFRAME AUTOSTRUT™ Automated Hexapod Accessories
1110005-01	MAXFRAME AUTOSTRUT™ Software
01.314.000	MAXFRAME AUTOSTRUT™ Hexapod Strut Set

10. Standards and compliance for EMC

This equipment complies with international and national standards and regulations relating to electromagnetic compatibility (EMC) for this type of product, if used for the intended purposes.
Such standards and regulations define the electromagnetic emissions level coming from the product and the requested immunity against electromagnetic interferences from external sources.

Not all products are currently available in all markets.
This document is available as a PDF file at www.orthospin.com

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