MAXFRAME AUTOSTRUT™

Multi-Axial Correction System

Patient User Manual

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THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Welcome

1. About this Manual

This User's Manual is intended for use by the patient. It familiarizes you with MAXFRAME AUTOSTRUT™ Multi-Axial Correction System (MAXFRAME AUTOSTRUT™ System, or just “System” for short) and will help you to understand the elements and operation of the system.
It is important to carefully read the instructions detailed in this manual.
This Patient User Manual is intended only as an instructional guide. For additional information and questions, please contact your physician.

■ Note:

The following terms all refer to the MAXFRAME AUTOSTRUT™ System:

- MAXFRAME AUTOSTRUT
- OrthoSpin AutoStrut
- AutoStrut G2

1.1 Notes Statements

Notes statements are used throughout this manual to provide additional information and emphasize important information. You should read these statements to ensure your safety and allow for effective use of the device.

1.2 General Warnings and Cautions

- Exposure to electromagnetic disturbances may affect the system and cause delayed treatment.
  - Airport metal detectors emit electromagnetic energy. If you plan to travel on an airplane, the security metal detector will alarm and may interfere with the MAXFRAME AUTOSTRUT System functionality. You should request a hand-pat search and avoid the metal detector. Additionally, you may get asked by airport security about your device and if it has batteries. Your device contains two 9-volt lithium batteries and meets the criteria for air travel per regulation 49 CFR 175.10.
- Devices that emit RF (radiofrequency) energy should be used no closer than 30 cm (12 inches) to any part of the MAXFRAME AUTOSTRUT System. Otherwise, degradation of the performance of the System could result.
- Care should be taken to prevent 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.). In case of detachment of components, the dislodgement of motors, or damage to any component, please contact your physician as soon as possible.

■ Note:

As with any prescription medical device, failure to follow product instructions which includes tampering with the device or changing settings may lead to improper product performance and the potential for serious injury. Do not tamper with the device.

2. Product Description

The MAXFRAME AUTOSTRUT System is installed and programmed by your physician.
It is important that you are familiar with the system components for situations which require your attention or in situations where you will need to contact your physician (see Figure 1).

Struts

There are six struts attached to your device. They are designed to shorten and/or lengthen according to the treatment plan programed by the physician. Each strut has a motor mounting bracket into which the motors are inserted and attached to the strut with a motor clip. Struts are attached to the rings of the frame.

Control System

The Control System is comprised of a Control Box with LED display which is connected to 6 strut motors via electrical cables and two cable splitters. The control box also has an emergency stop button.

Electrical cables are managed with cable attachments and wrappers.

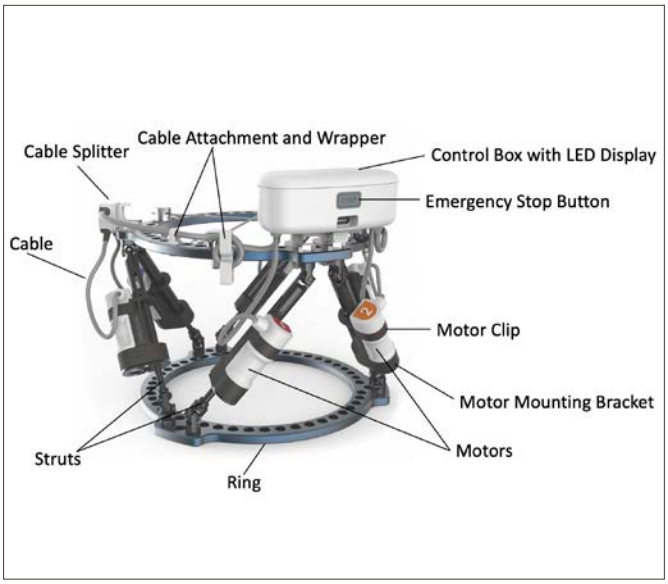

Figure 1: MAXFRAME AUTOSTRUT System Components

3. Instructions for the Patient

After surgery, your physician will upload the treatment plan program from a laptop computer to the control box. This program tells the struts when and how much to move.

The System will perform automated daily strut adjustments according to the treatment plan. You should pay attention to the LED display lights and sounds, as they provide important information that you might need to share with your physician.

■ Note:

You should be aware of when your first strut adjustment is scheduled to occur (it may be several days after your surgery) so that you can confirm the system starts operation at that time. If it does not, please contact your physician as soon as possible.

3.1. System Sound and Light Indicators

It is important that you understand the system's LED displays and sound indicators, and the actions required by you in these situations.

Figure 2 below is the Patient quick guide. It explains how to tell if the device is working properly or if you need to contact your physician. Each of these conditions is explained further below.

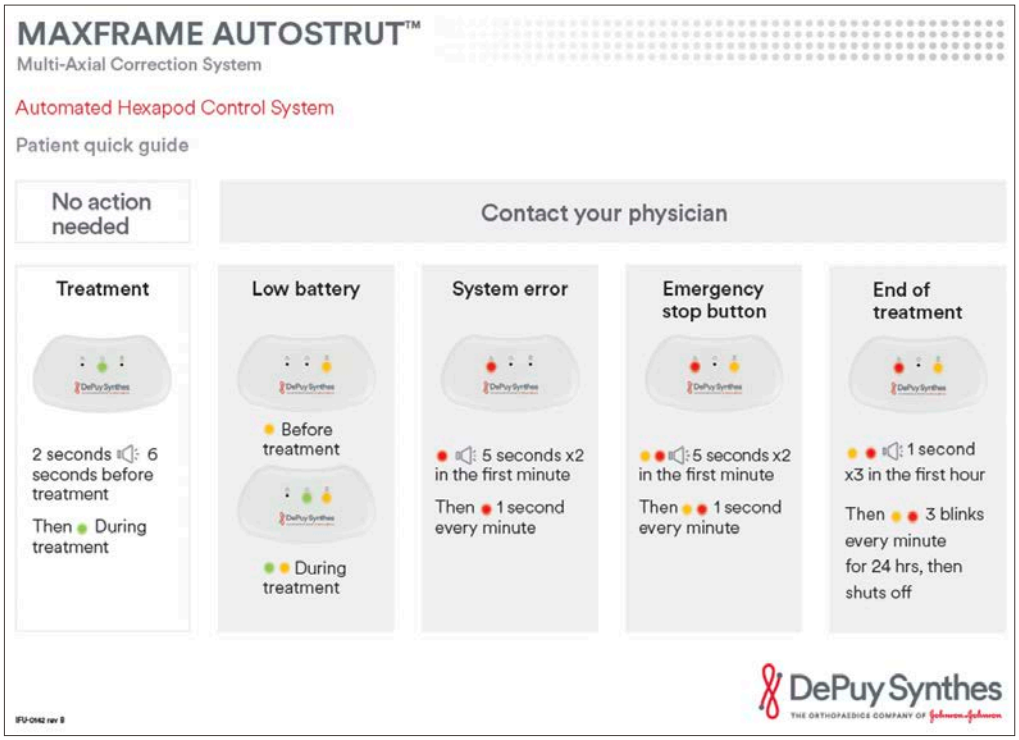

Figure 2: Patient quick guide

3.1.1 Treatment

"Treatment" is the word used to describe the activation of the motors that turn the struts. Your physician will determine how frequently this occurs each day up to a maximum of 20 times per day. He or she will set the hours of activation, which is usually during the day while you are awake but may also occur during the night while you are sleeping.

Six seconds before the motors move for a treatment, the device will beep for two seconds. A green LED light will appear on the Control Box while the motors are moving (see Figure 3). Additionally, a light on each strut will illuminate as it is moving.

When this happens, the device is working properly, and you do not need to take any action.

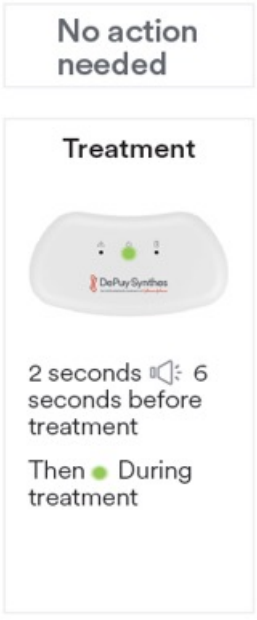

Figure 3: Treatment

■ 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 you know the system is performing a treatment. The system may be programmed by your physician to not activate while you are sleeping. If you have any concerns related to the system's lights and sounds or if the system does not activate during expected treatment times, please contact your physician as soon as possible.

3.1.2 Low Battery – Contact Your Physician

The device is designed to last the full length of most treatment plans. In most cases, you will not experience a low battery. However, if the battery does become low, the orange light will appear before treatment. Then, during treatment, both the orange and green light will appear (see Figure 4). Treatment will continue as normal until the battery dies. Once the battery dies, treatment stops. Therefore, if you get a low battery indicator, please contact your physician as soon as possible.

Figure 4: Low Battery

■ Note:

The battery on the device is not designed to be replaced. Do not attempt to remove or replace the battery yourself.

3.1.3 System Error – Contact Your Physician

If a system error occurs, your device will beep for 5 seconds twice and will show the red LED light. This will happen within the first minute of the system error occurring. After that, the device will blink the red LED light for one second every minute (see Figure 5).

■ Note:

A system error means that treatment is stopped. Please contact your physician as soon as possible.

Figure 5: System error

3.1.4 Emergency Stop Button

The System emergency stop button is located on the side of the control box (see Figure 6). It is a switch that will disable the motors from moving. The button is there to enable you, as the patient, to stop the device in case of emergency. Your physician can help you to understand what types of situations would be considered an 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 as shown in Figure 7. 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 sounds and lights as described already in Figure 7.

Figure 6: Emergency stop button

■ Note:

Treatment is stopped until system is reactivated by the physician. Please contact your physician as soon as possible for any situation in which the emergency stop button was pressed. You will not be able to restart the device yourself and you will be required to go to your physician's clinic for reactivation.

Figure 7: Emergency stop button

3.1.5 End of Treatment – Contact Your Physician

Your doctor will determine how many days your treatment plan will last. After the last treatment has completed, the device will alert you that you have reached the end of the treatment plan by displaying the orange and red lights and beeping for one second three times in the first hour after treatment completes. After that, the device will display the orange and red lights for three blinks every minute for 24 hours. After 24 hours, the device will shut off (see Figure 8). When this happens, no lights will be displayed. Please let your physician know that you have reached the end of treatment.

Figure 8: End of treatment

3.2 Motor Reattachment

Your device contains six motors attached to six struts, each with a motor clip. Each motor is numbered 1 to 6 and must be attached ONLY to the corresponding strut. If a motor clip comes off, the motor may become dislodged and come out of the strut mounting bracket (see Figure 9).

If this happens, please contact your physician as soon as possible. Your physician may tell you to come into the office or he/she may ask you to reattach the motor yourself.

The motor can be reattached by placing the motor back in the strut mounting bracket and installing the clip (or a new clip) around the motor and to the mounting bracket (see Figures 10 and 11).

Please be sure that both sides of the motor clip are firmly seated in the motor mounting bracket. After the clip is attached, gently pull the motor to ensure it cannot be displaced.

After your strut motor has been reattached, your device should continue to operate normally. If you have any concerns, do not hesitate to contact your physician.

■ Note:

If more than one motor has become displaced, do not attempt to reattach them yourself. You should contact your physician as soon as possible. The physician or authorized health care professional should reattach the motors to ensure that they are all placed in the correct struts.

In case of Control Box detachment, please contact your physician as soon as possible.

Figure 9: Picture of dislodged motor.

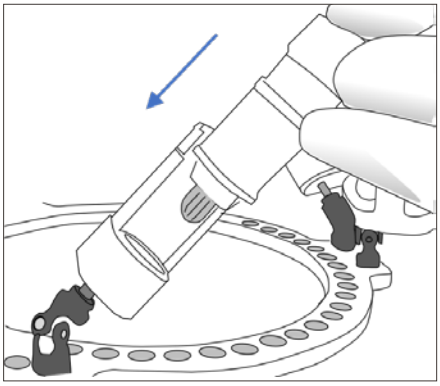

Figure 10

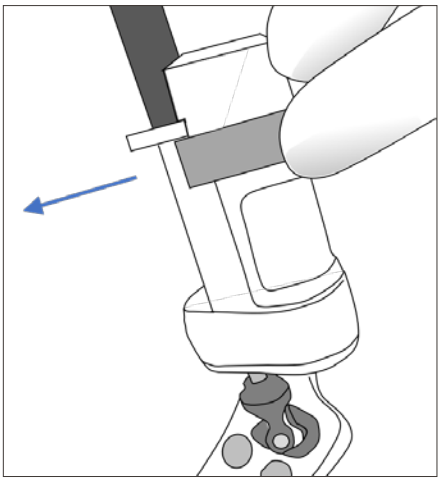

Figure 11

3.3 General Maintenance of the System

Please follow your surgeon's instruction regarding showering and bathing with the device. The MAXFRAME AUTOSTRUT System has a water Ingress Protection (IP) rating of IP68 which means the system can be exposed to water. However, your surgeon may not want you to get your surgical site/wound area or pin sites wet. Therefore, you should always follow your surgeons' instructions regarding bathing and showering. If your surgeon allows you to shower with the device, please avoid pointing the water stream directly on the system components and wipe the system gently with a dry cloth after the shower.

- Occasionally, the system should be cleaned gently with a dry or damp cloth, with water alone.
- Make sure that the cleaning procedure does not take place when the system is performing a treatment.
- Do not allow animals to lick the device.
- Removal and disposal of the MAXFRAME AUTOSTRUT System is to be performed by authorized healthcare professional at the end of service life in accordance with local regulations.

3.4 MRI Safety Information

You should not get an MRI with the MAXFRAME AUTOSTRUT System. If you need an MRI, your physician will need to first remove the Control System with motors and struts. They will be replaced with other MAXFRAME System equipment that has a rating of "MRI Conditional". Your physician should refer to MRI safety information contained in the MAXFRAME System and MAXFRAME AUTOSTRUT System Instructions for Use.

3.5 Operating Conditions

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

3.6 Questions and Further Information

For questions or further information, please contact your physician. Please make sure you go to all scheduled follow up appointments with your physician.

Not all products are currently available in all markets.
Intended use, Indications and Contraindications can be found in the corresponding system Instructions for Use and Surgical Technique available at www.OrthoSpin.com.

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