

Hoffmann® LRF smartheX™

Patient user guide



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Introduction

Safety information

Explanation of symbols on labels. Table 1 describes the symbols used with the smartHEX Strut Controller.

Table 1 — Symbol glossary

Symbol	Title	Description	Reference	Section
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1	5.1.1
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1	5.1.6
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1	5.1.7
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1	5.1.5
	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1	IEC 60601-1	5333
	Electronic waste should be collected separately for recycling per the European Community Waste Electrical and Electronic Equipment (WEEE) Directive.	To indicate that separate collection for waste electric and electronic equipment is required per European Community Directive 2012/19/EU	IEC 60417	6414
IP24	Ingress Protection	2: Protected against solid foreign objects of 12,5mm Ø and greater 4: Protected against splashing water	IEC 60529	4
	Direct Current	Operating Voltage = 3VDC	IEC 60417	5031
	Refer to the instruction manual/booklet.	To signify that the instruction manual/booklet must be read		
	Bluetooth logo	To indicate this device uses Bluetooth wireless or enabled technology	ISO 7010	M002

Symbol	Title	Description	Reference	Section
	CSA Certification for Canada and the US	To identify Canadian Standards Association as the IEC 60601 certification authority	Bluetooth Special Interest Group (SIG)	N/A
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1	5.3.7
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1	5.3.8
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 15223-1	5.3.9
Rx Only	Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician	FDA Guidance	N/A
	Do not re-use	Indicates a medical device that is intended for one single use only.	ISO 15223-1	5.4.3
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 15223-1	5.2.8
	Keep dry	Indicates a medical device that needs to be protected from moisture	ISO 15223-1	5.3.4
	Consult instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1	5.4.3
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1	5.2.7
	MR unsafe	Indicates an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	F2503	N/A
	Australian/New Zealand Regulatory Compliance Mark for electrical and electronic equipment	The RCM shows the equipment complies with the requirements imposed upon or covered by regulations in Australia and New Zealand	AS/NZS 4417.1	Part 1
	FCC declaration of conformity	United States wireless compliance labeling content: This device complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.		

Introduction

What is Hoffmann LRF?

Hoffmann LRF is a circular fixation system that uses a combination of pins and wires to hold the limb in place. Depending on your condition, the frame may be periodically adjusted to gradually restore anatomy.

Your LRF device is comprised of rings that are used to securely fasten the pins and wires in place, and struts to support you and your frame.

If your surgeon decides that you will need to make adjustments to the device, he or she will instruct you on the specific part of the frame that needs to be adjusted. It's important that you only make adjustments to this part of the frame. Touching other areas of the frame may result in a delay in your treatment plan or cause further injury to the affected limb. Always contact your surgeon if you notice any part of your frame that looks damaged or observe any loose components.

Your surgeon will provide you with an adjustment schedule, stating which struts to adjust, how to adjust, and when. During the course of treatment your surgeon may provide you with updates on the progress of your correction. Further along in this guide you will find detailed information on how to make your adjustments.

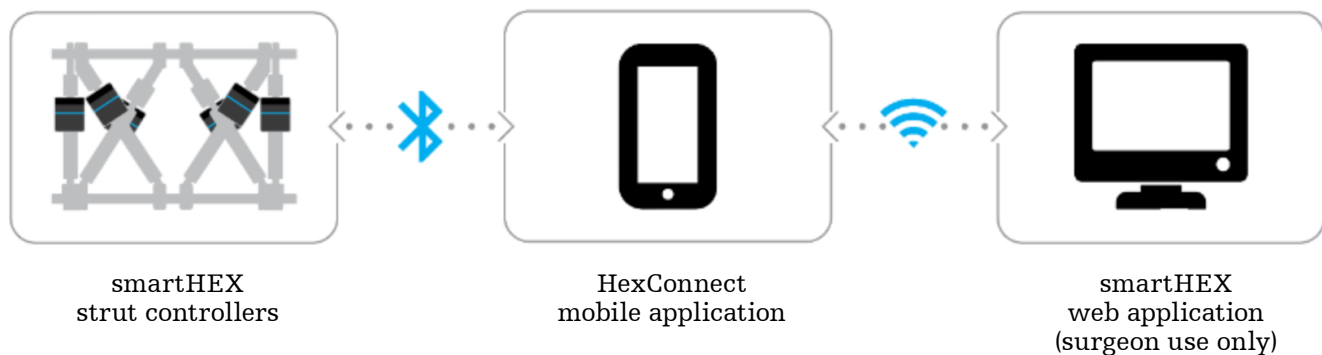


Introduction

About your smartHEX device

The Hoffmann LRF smartHEX platform is designed to guide you through the recovery process following surgical application of an external fixation device by automatically performing the necessary corrections after you initiate each correction at the appropriate times, as prescribed by your care team.

The Hoffmann LRF smartHEX platform consists of an external fixation device, smartHEX struts and strut controllers, and the HexConnect Mobile Application.



The smartHEX strut controllers are attached to the smartHEX struts, and the HexConnect mobile application pairs with the strut controllers. This pairing process enrolls the strut controllers in the mobile application. Once enrolled, the strut controllers can adjust the frame according to the prescribed correction plan by using wireless control commands from the HexConnect mobile app.

Key terms

- **Care team:** this is the healthcare team that includes the prescribing surgeon and the support staff of physicians and nurses dedicated to your care
- **Frame:** also known as an external fixation device or external fixator; this is the construct of rings, pins and wires worn during the course of treatment
- **Hexapod:** a hexapod is a type of frame that is connected by six hexapod struts; the smartHEX device is a hexapod frame
- **smartHEX strut:** this is the piece of hardware within your frame that connects the rings together
- **Strut controller:** sometimes shortened to just “controller”; this is the electromechanical device that is mounted to each smartHEX strut on your frame

Introduction

General warnings and cautions

Warnings

- Always use smartHEX strut controllers as directed. The smartHEX strut controllers, in conjunction with the HexConnect mobile application, are intended to be used by adults or under adult supervision. Keep all parts away from pets and children to avoid injury from sharp edges and moving parts, choking on small parts, and avoid damage that may impact device performance.
- Do not submerge strut controllers in water or any other liquid. The strut controller enclosure provides IP24 ingress protection, meaning that independent testing confirmed that access to hazardous parts is prevented and protected against splashing water from any direction during normal use. The enclosure is not intended to provide protection against dust ingress or water immersion. Contact your care team if you have submerged your frame with the strut controllers attached.
- Do not remove or replace strut controller batteries. Batteries should only be replaced by qualified healthcare professionals.
- Do not alter or modify the strut controllers. If any strut controller is modified accidentally or otherwise, contact your care team.

Cautions

- Set up the HexConnect Mobile Application with your care team. The smartHEX strut controllers must be enrolled by a qualified healthcare professional. Improper enrollment and setup of the smartHEX strut controllers may result in injury and impact the recovery process.
- To minimize the risk of device damage due to falls and to ensure timely care, all medical devices must be handled with care. You must promptly report any instance of fall or damage of a strut controller to your care team. Prompt reporting and replacement of devices helps to prevent delays in your care caused by device malfunction or breakage.
- Always complete corrections at the dates and times indicated by the HexConnect application and as instructed by a qualified healthcare professional. Failure to do so could result in pain or injury or have an impact on the recovery process.
- In order to protect your personal data, only allow trusted members of your care team, and trusted personal caregivers to use your mobile device. Use of the HexConnect application will require your care team to access your mobile device to enroll or replace strut controllers and to monitor your recovery. Unauthorized access to your mobile device may put your personal data at risk.
- If strut controllers are removed for any reason (e.g., swimming, bathing), replace the numbered strut controllers on the corresponding numbered struts (i.e., Strut 1 to Controller 1, Strut 2 to Controller 2). A strut controller mismatch could result in pain, injury, or have an impact on your recovery process.
- When executing a correction, do so from a seated or lying position, keeping the frame clear from loose clothing, bedding, and bandages. This allows the strut controllers to work more efficiently. Failure to do so could result in malfunction.
- If your correction plan is suspended due to too many missed corrections, or if it is fully stopped, you must contact your care team to re-evaluate your progress and provide you with a new correction plan.
- The HexConnect application is designed to be used with system notifications that provide you with a reminder when a correction is due. You must use caution when disabling notifications in application settings, and you must always allow notifications for the HexConnect application.
- Some mobile devices will change notification behavior when in battery saver mode, typically by delaying or limiting less important notifications in order to conserve battery life. Minimize the time spent in battery saver mode to ensure correction notifications are received in a timely manner.
- Date and time settings should be set to "Set Automatically" to ensure the mobile device is always set to your current date and time.
- The mobile device must remain within five meters (approximately 16 feet) of the strut controllers during corrections and firmware updates. Do not turn off the mobile device or disable Bluetooth during these operations.

Introduction

MR safety information



The Hoffmann LRF System is MR Unsafe.

Do not enter an MRI scanner room or an MR system. Doing so may result in severe injury or death. For additional MR safety information, please refer to the Hoffmann LRF Medical Device Card (H-IMC-1-EN Rev AA) and/or discuss with your care team. .

Indications for use

The Stryker Hoffmann LRF System is indicated in pediatric (2 through 21 years of age) and adult patients for the treatment and fixation of:

- Open and closed fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis or non-union of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of comminuted intra-articular fractures of the distal radius
- Bone transport

The Hoffmann LRF System is indicated in adults for:

- Osteotomy
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Lisfranc dislocations

For an explanation of the information provided on this page, including indications (the medical conditions that the Hoffman LRF smartHEX is meant to treat) and contraindications (medical conditions or other factors your surgeon will consider when determining whether the Hoffman LRF smartHEX is an appropriate treatment for you), please refer to the supplemental information on page 10. If you have any questions regarding the indications or contraindications please ask your healthcare provider.

Use environment

The Hoffmann LRF smartHEX platform is a prescription device that is intended for use in accordance with the directions of a healthcare provider. The device is intended to be used in a professional or home health-care environment by the patient or homecare provider.

Contraindications

Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized.

Conditions presenting an increased risk of failure include:

- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device
- Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site
- Previous history of infections
- Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period
- Malignancy in the fracture area
- Mental, physical or neurological conditions which may impair the patient's ability to cooperate with the postoperative regimen

Introduction

What can circular external fixation treat?

Circular external fixation can be used to treat a broad spectrum of conditions. See below for some of the indications that your frame may be used for. Circular external fixation may be appropriate to treat adult patients with the conditions below. In certain instances (as noted on page 9), circular external fixation may be appropriate for pediatric (2-21 years of age) patients. A qualified healthcare professional should determine what patients the device may be used to treat.

Some medical conditions or circumstances may make this device inappropriate or less effective. A healthcare professional will evaluate your overall health and determine whether this device is appropriate for your condition. The conditions listed on page 9 under “Contraindications” are situations in which this device may not be recommended or may require additional consideration.

Every patient is different. Only your treating healthcare professional can determine your proper course of treatment, including whether this device may be appropriate for you, based on a complete understanding of your individual medical circumstances.

Please review this information with your healthcare provider in detail, along with your complete medical history. Please work with your healthcare provider to fully understand all contraindications, risks, benefits and potential implications of using this device as it relates to your unique clinical situation. If you do not fully understand any of the terms and/or information provided herein, it is important that you consult your healthcare team.

Open and closed fractures including Lisfranc dislocation

Open fractures occur when the fractured bone protrudes outside of the skin. In a closed fracture, the broken bone does not puncture through the surface of the skin. A Lisfranc dislocation occurs when the bones and ligaments in the middle of the foot are forced out of their normal position.

Post-traumatic joint contracture

When a bone is fractured near a joint, thickening of the tendons and ligaments may occur. This thickening may lead to a reduced amount of motion in the joint.

Fractures and disease

Infections of the bone may require removal of the infected area. This removal of bone may result in a loss of length and create a subsequent deformity.

Pseudoarthrosis or non-union of long bones

Sometimes the body cannot heal the fracture site on its own and needs interventional support to stimulate the healing process. Non-union can also occur when an earlier treatment does not successfully heal the fracture, requiring a revision procedure to help the bone heal properly.

Bone transport/lengthening

If a segmental loss or growth defect is present that leaves a limb disproportionately shorter than the other, external fixation can aid in restoring normal limb length.

Correction of bony or soft tissue deformity

Soft tissue deformities such as clubfoot and bony deformities such as bow legs can both be treated using external fixation.

Joint arthrodesis

Often times when a joint becomes too painful due to symptomatic arthritis, the surgeon will elect to fuse the joint, removing all of its motion.

Bone reconstruction procedures

External fixation can aid in reconstructing bones that have been fractured in multiple locations due to an injury.

Charcot foot reconstruction

In patients with Charcot, the quality of bone is often deteriorated to the point where the bone cannot provide and hold the same structure as normal bone would. In these situations, external fixation can be used to help maintain proper bone alignment until the condition can be treated and fusion of the joints can occur.

Introduction

Pin tract care

Your doctor may recommend different cleaning techniques or solutions depending on the type of external device and the extent of your injury or fracture. Always use care when cleaning your external fixation device. Wash your hands well before cleaning your pin sites or the device. Be gentle and thorough, and dry all areas thoroughly. The cleaning process should be performed routinely even if your doctor has prescribed antibiotics as a preventative measure.

Get organized

You should gather everything you'll need and keep it handy and dry in a central location. You'll need cleansing solution (sterile water), disposable cups, sterile cotton swabs, sterile gauze pads (in two-inch and four- inch squares) and a small trash bag to dispose of waste.

Cleanse the pin sites

After washing your hands thoroughly, it is recommended to dry with a fresh paper towel and discard after use. Use your fingertips to lightly touch and press the skin around the pins. This will encourage any drainage to come to the surface. Use a cotton swab saturated with cleansing solution to remove any crust or drainage from the sites. Always work in a gentle, circular motion, moving away from the site. Use a fresh swab for each pin site.

Clean the pins

Use a fresh two-inch sterile gauze pad to clean each pin. For the first few days, your doctor may advise you to wrap sterile gauze around each pin site. Once no further drainage is present, the pin sites may be left uncovered.

Clean the device

Use cotton swabs and the larger gauze pads to clean the entire device carefully. Dispose of all the soiled swabs and pads. Wash and dry your hands.

Shower

After 10 days or so (your doctor will advise you), you may be allowed to shower with your external fixator. After showering, dry the device thoroughly with a clean towel and follow all other cleaning instructions for the pin sites. Be sure to talk with your doctor if you have any questions on how to care for your device and the pin sites

Infection symptoms

There is an inherent risk of infection with any exposed wound. Contact your doctor immediately if you observe redness or swelling at the pin site, thick or colored discharge, tenderness or pain, or any wiggling, play or movement within the pins.

Nerve issues

Pay attention to possible signs of nerve damage. If you start having pain in areas other than the pin/wire sites, it may be a sign that nerve damage is occurring. Any decreased or increased sensitivity in the area of the external fixation device should be reported to your surgeon as soon as possible. This may be an indicator of possible nerve irritation.

NOTICE

Keeping pin sites clean is extremely important in order to avoid infection. Pets should be kept away from the affected limb in order to minimize the risk of exposure to bacteria. The limb should be treated as an open wound and kept free of any debris.

Set-up guidance for patients

Download the HexConnect Mobile Application

The HexConnect App is installed on the patient's mobile device from the Apple App Store or Google Play Store. Once the app is downloaded, it must be linked to your correction plan.

Welcome message receipt

After your surgeon creates your correction plan in the smartHEX Web Application, they should set up your account and send you a welcome email with information and instructions. (Figures 1-2)

The welcome email should contain:

- Notes from your surgeon
- A link to download your correction plan
- Links to the Apple Store and Google Play Store to download the HexConnect Mobile Application

Click the correction plan download link included in the email to open up your correction plan in the HexConnect app on your mobile device. Now your correction plan is linked to the app.



NOTICE

If you unexpectedly lose access to your mobile device during a correction period, a PDF version of your correction plan may be provided by your care team to guide manual adjustments. Removal of all strut controllers is required to initiate manual adjustments

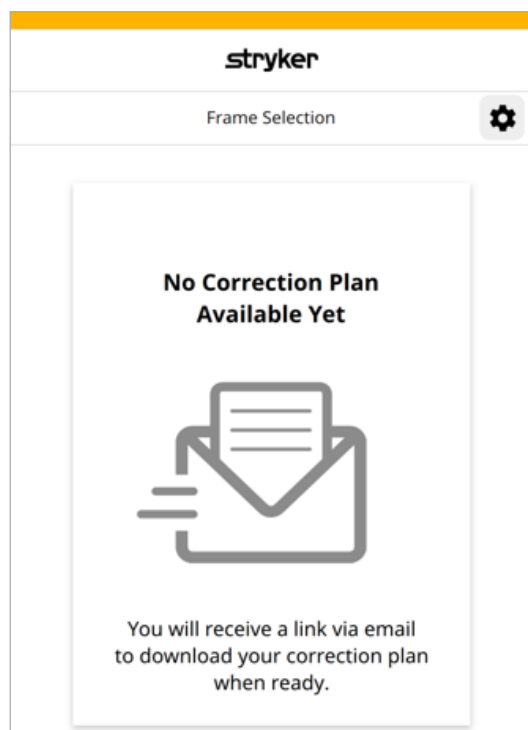


Figure 1

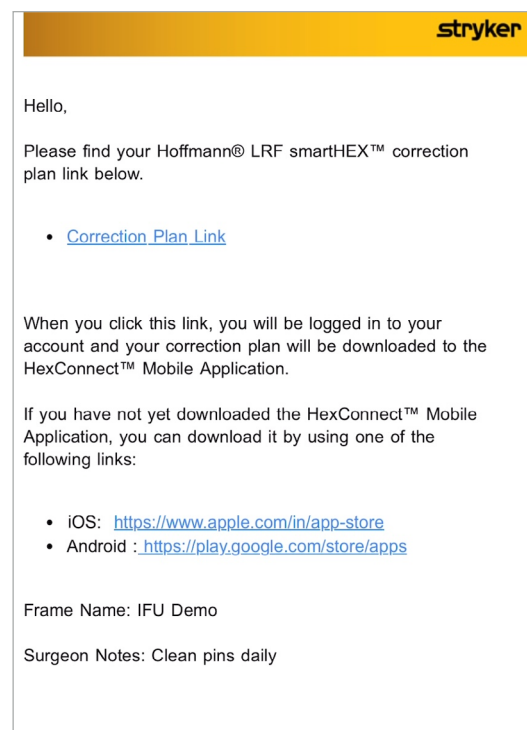


Figure 2



Set-up guidance for patients

When the application opens

End User License Agreement

There will be a prompt to review the End User License Agreement (EULA). **(Figure 3)** To accept the agreement, check the box at the end of the agreement and select “I Agree”.

Enable notifications

A dialog box will request permission to send notifications. **(Figure 4)** Select “Allow” to enable notifications. Enabling notifications is important for receiving important reminders about your corrections.

Your correction plan will begin downloading. **(Figure 5)** This may take several minutes. If the correction plan start date has already passed, you will receive an error message. **(Figure 6)** Reach out to your care team for an updated download link.

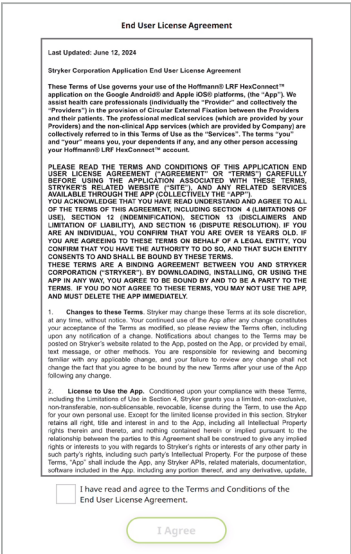


Figure 3

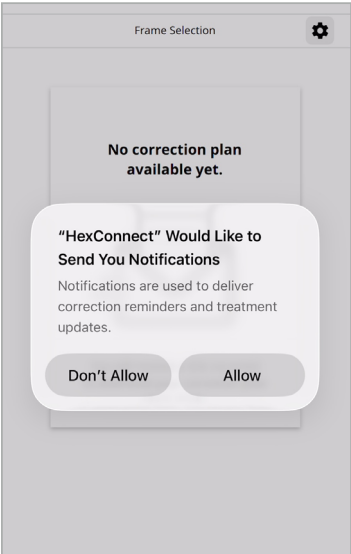


Figure 4

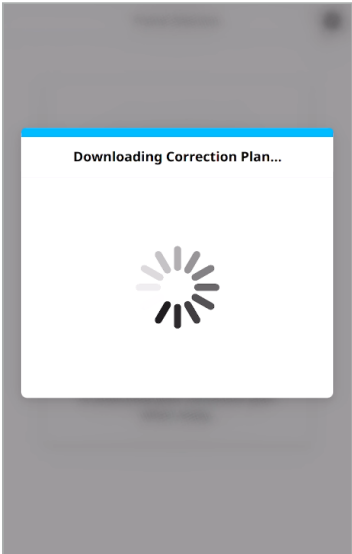


Figure 5

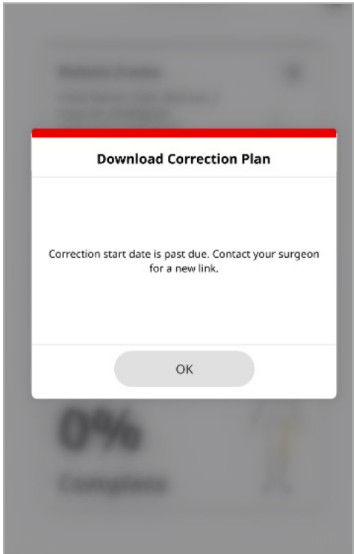


Figure 6

Enable Bluetooth

A dialog box will prompt you to enable Bluetooth. **(Figure 7)** Select “Allow” to allow the app to utilize Bluetooth Technology. Enabling Bluetooth is necessary for the mobile device to pair with the smartHEX strut controllers.

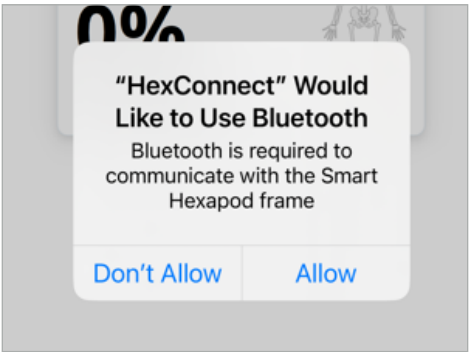


Figure 7



Set-up guidance for patients

Open your correction plan

The app’s start page displays your case details, which include your case name, case ID, frame name, deformity location and percent completion. **(Figure 8)**



If the displayed case information is incorrect or you suspect that it does not match your actual case, contact your care team for assistance.

Click on the case to open it. Once opened, the home page for your case is displayed. **(Figure 9)** The back arrow button may be used to navigate back to the start page.

If you have a second prescribed case, it will also appear on the start page and may be accessed in the same way.

If you are a “mobile app user”, meaning you are not utilizing the smartHEX strut controllers and will be performing manual strut adjustments, skip to the section [Instructions for Mobile App Users](#).

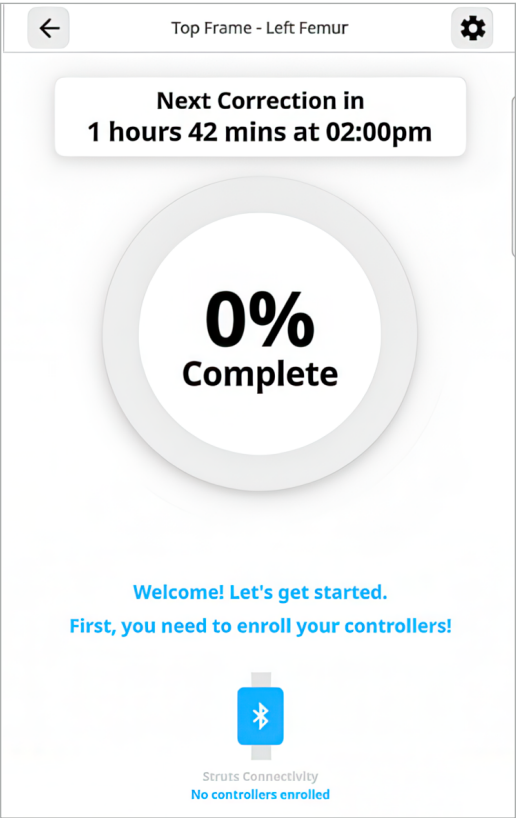


Figure 8

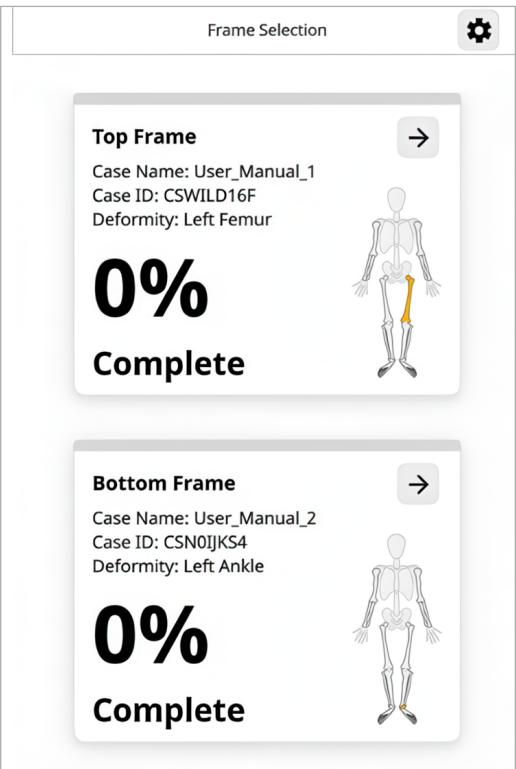


Figure 9

About your device



Your smartHEX device is set up by your care team for your specific needs but will generally consist of rings and six smartHEX struts with or without strut controllers. Each strut is assigned a number 1-6 and will be labeled with the appropriate color ID cap and ID safety clip.

Device set-up

Important: Your care team is responsible for setting up, mounting and enrolling your strut controllers.

Battery insertion must be performed by a qualified healthcare professional. The strut controller automatically turns on when the battery is inserted, and the door is closed.

NOTICE

Initial battery installation and replacement should be performed by a healthcare professional to ensure proper handling and safety.





About your device

Strut controller activation

Once batteries are installed, the controller will turn on and activate the LED light indicator with a flashing blue light for approximately 40 seconds. After 40 seconds, the strut controller will enter sleep mode to conserve power.

Strut controller battery status

Check an enrolled strut controller’s battery status at any time from within the mobile application by selecting the strut’s battery power icon on the main page. **(Figure 10)** The battery icon for each strut controller will show the battery status and percentage of battery remaining. **(Figure 11)**

Table 2 details the battery status color indicators, percentage remaining and implications for completing corrections.

Table 2: Strut controller battery status

Battery status	Color	Percent range remaining	Able to complete correction?
High	Green	61-100%	Yes
Medium	Yellow	41-60%	Yes
Low	Orange	21-40%	Yes
Critical	Red	0-20%	No

NOTICE

If a battery icon displays as the color red, indicating a critical status, corrections cannot be completed.

From this screen, controller connectivity may also be checked by tapping the strut number icons. **(Figures 12-13)**

Battery removal and replacement

If a battery needs to be replaced for any reason, contact your care team. When the battery is successfully replaced, the controller will light up green for approximately 40 seconds.

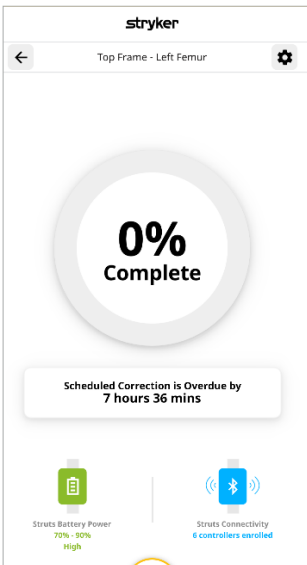


Figure 10

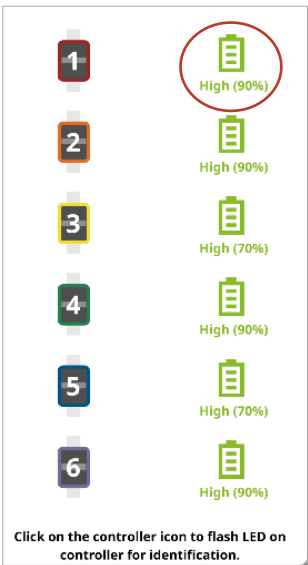


Figure 11

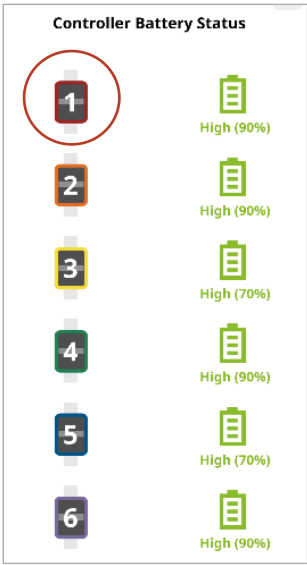


Figure 12

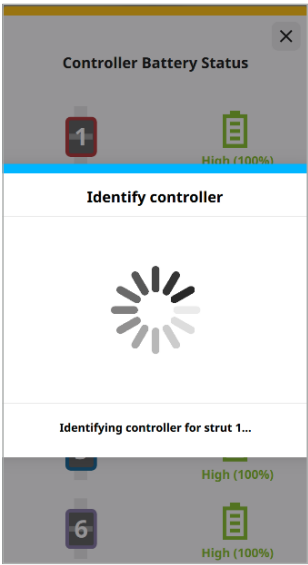


Figure 13

About your device

Mounting the strut controllers

Your care team will mount each of the six strut controllers to the smartHEX struts on your frame and apply ID caps or stickers that match the numbers on each strut. **(Figure 14)**

Enrolling the strut controllers

Once the HexConnect mobile application has been successfully linked to your correction plan, the smartHEX strut controllers may be enrolled.

Your care team should lead the process of enrollment using your own personal device; however, these steps are intended to help you follow along.

From the home page of the selected case, navigate to the Controller Connectivity page by tapping the strut controller icon. The controller connectivity page shows the enrollment status of all six controllers. **(Figure 15)**

The enrollment process links your correction plan to each of the strut controllers. The enrollment process is necessary to ensure that the strut controllers operate effectively.

The controller connectivity screen displays all six controllers with the enrollment status. Controllers may be enrolled in any order, as long as each enrolled controller is mounted on the corresponding strut.

Enrollment steps (performed by care team)

1. From the Controller Connectivity page, tap the Enroll button for Strut 1.
2. Should a controller firmware update be necessary, it will be performed automatically at this time. **(Figure 16)**
Upon completion, the enrollment process will continue.
3. Strut controllers may be enrolled through an automatic or manual process. From Controller 1 – Pairing Options screen, the user may choose the enrollment pathway.

NOTICE

Ensure that the mobile device is within 5 meters (approximately 16 feet) of the strut controllers while performing the enrollments.



Figure 14

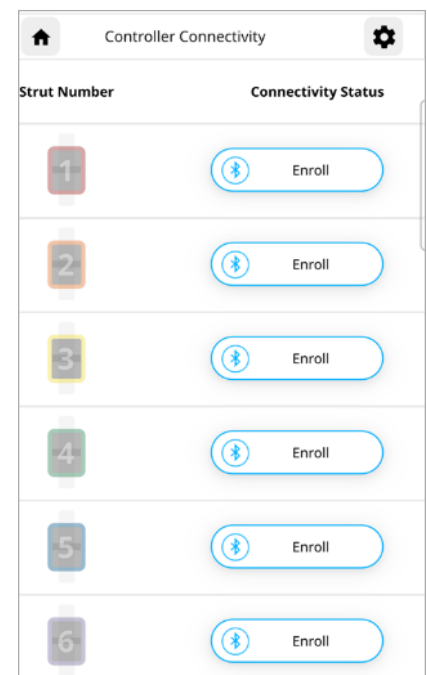


Figure 15

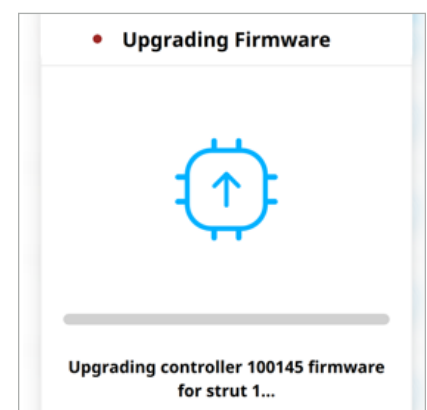


Figure 16

About your device

Automatic

- From the Enrollment Options screen, select the second option: **“Scan QR Code”**.
- A dialog box will request permission to access the mobile device’s camera
- Select **“Allow”** to enable camera access. If the camera cannot be accessed, proceed with manual enrollment.
- Aim the camera at the QR code on the front of the strut controller. Take care to avoid accidentally scanning the QR code of a nearby controller.
- When the QR code is successfully captured, the screen will display the enrollment progress. **(Figures 17-19)** Upon successful enrollment, the app will display a verification message **(Figure 20)** and play a tone.

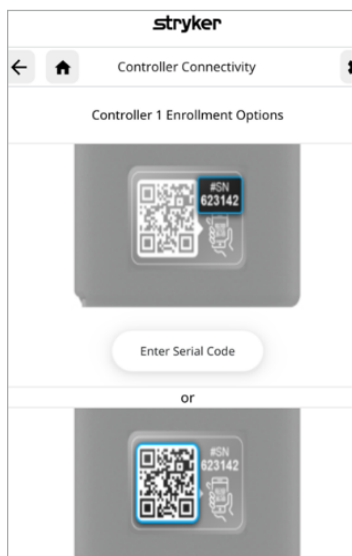


Figure 17

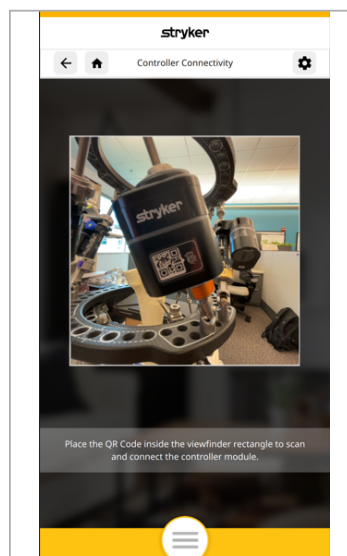


Figure 18

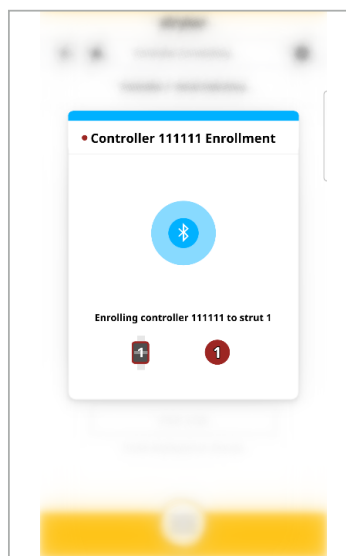


Figure 19

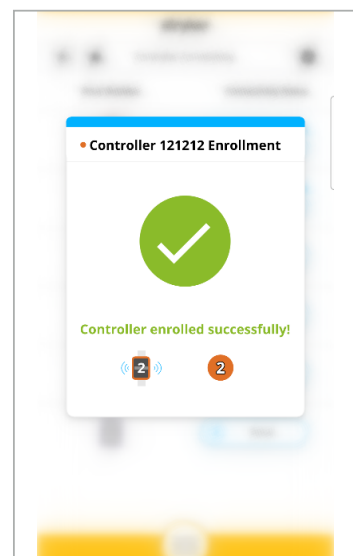


Figure 20

Manual

- From the Pairing Options screen, select the first option: **“Enter Serial Code”**.
- Locate the strut controller’s unique serial code, which can be found on the front of the strut controller, printed to the right of the QR code. **(Figure 21)** Enter the serial number into the text field and tap **Continue**.
- If the serial code is successfully captured, the screen will display the enrollment progress. Upon successful enrollment, the app will display a verification message and play a tone.

NOTICE

An automatic operational efficiency check will occur upon successful enrollment of a strut controller. The strut controller will automatically adjust slightly in the clockwise and counterclockwise direction and then return to the starting position. The purpose of this adjustment is to ensure that there is adequate engagement of the strut controller with the strut so that the device can operate effectively.



Figure 21



About your device

Enroll the remaining strut controllers

Return to the Controller Connectivity screen and repeat the same enrollment steps to pair the remaining controllers. (Figure 22)

NOTICE

When all strut controllers are enrolled, confirm the app-to-controller pairings are correct by tapping each strut number icon from the Controller Connectivity screen. If one or more strut controllers are mis-paired, proceed with the “Replace Enrollment” process. For example: Tapping icon #1 causes Strut Controller 1 to light up. No action is required. Tapping icon #2 causes Strut Controller 3 to light up. There is a pairing mismatch, so “Replace Enrollment” is required.

Replace enrollment

In some circumstances, a strut controller’s enrollment may need to be revised, either due to accidental enrollment during scanning or because of a device malfunction. The Replace Enrollment feature can be utilized to re-enroll individual controllers.

- Tap the Replace Enrollment button for the strut number to be replaced. (Figure 23)
- Select “Yes” to proceed with Enroll Replacement. (Figure 24)

If enrollment has already been locked, your surgeon must unlock the controllers via the smartHEX Web Application. Once unlocked, the replace enrollment steps may be completed.

Exchanging a strut controller

In some circumstances, a strut controller may need to be exchanged with a new one because of damage or issues with functionality. Contact your care team for assistance.

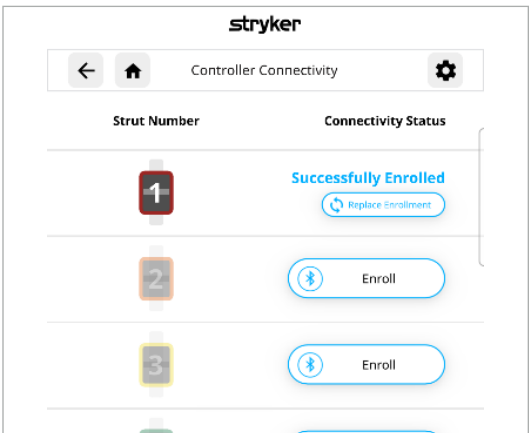


Figure 22

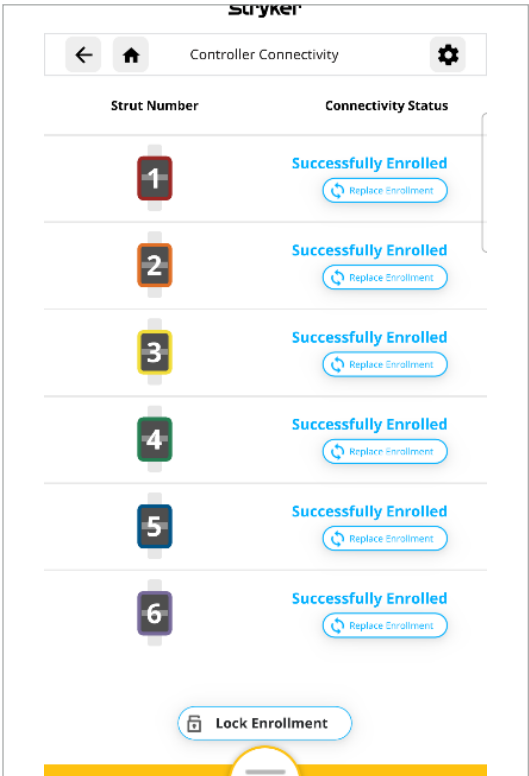


Figure 23

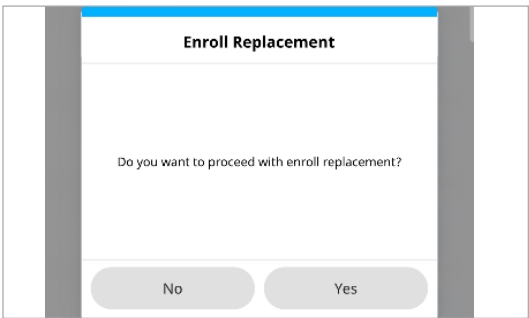


Figure 24



About your device

Lock enrollment

Once all the controllers have been successfully enrolled and there is no foreseeable need for replacement, the enrollment should be locked. Locking the enrollment prevents misuse caused by the incidental exchange of strut controllers and helps ensure that the correction plan executes according to plan. To lock enrollment, tap the Lock Enrollment button (**Figure 25**) and select “OK”. (**Figures 26-27**) If not manually locked shortly after enrollment, the app will automatically lock enrollment after two hours. Once enrollment is locked, it must be unlocked by your surgeon.

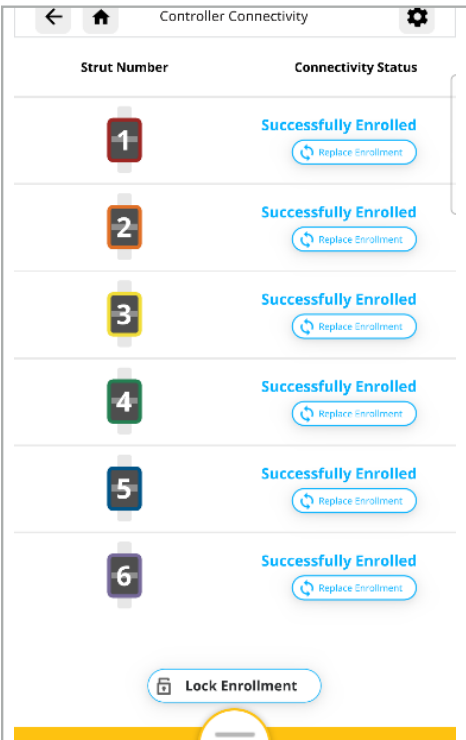


Figure 25

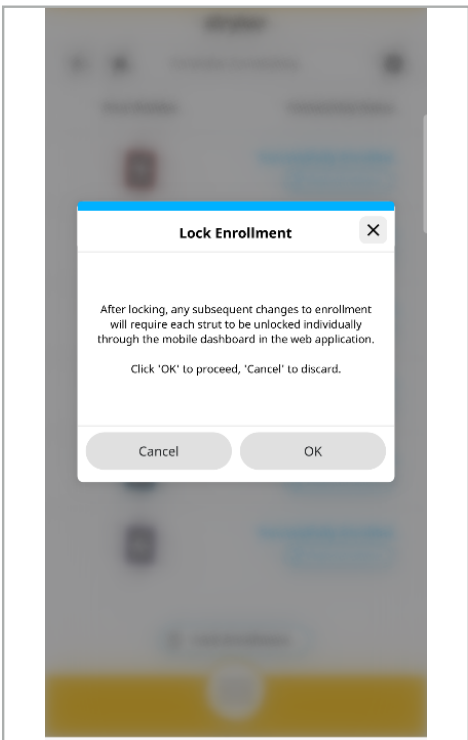


Figure 26

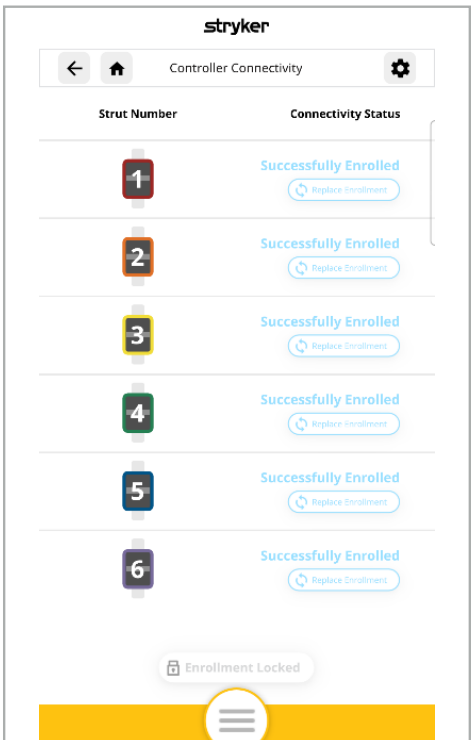


Figure 27



About your device

Navigating the app

Main menu

The main menu can be accessed from the home page using the menu button toward the bottom center of the home screen. **(Figure 28)**

The main menu contains links to the following pages:

- Controller Connectivity
- Correction Plan
- Controller Details
- Deformity Details
- Frame Simulation

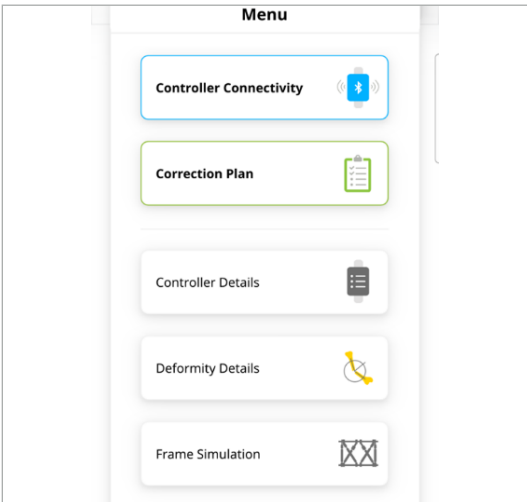


Figure 28

Controller connectivity

The controller connectivity page displays the enrollment status of the strut controllers. From this page, users can: enroll controllers, replace enrollment, lock enrollment, replace controllers, and perform an identity-check of the controller. **(Figure 29)**

Tapping any of the strut number icons for Struts 1-6 will flash the LED light indicator on the corresponding strut controller to identify the strut. If enrollment is not locked, the strut controller will also adjust slightly as part of an operational check.

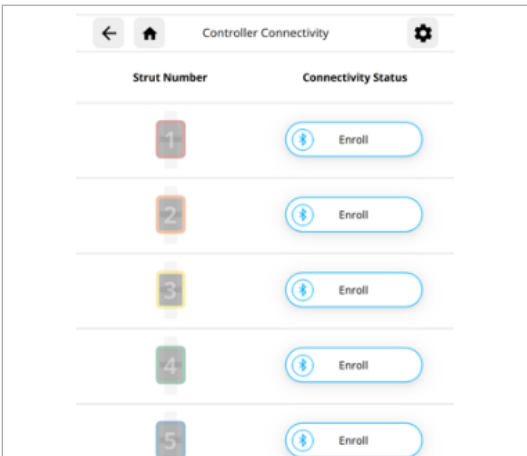


Figure 29

Correction plan

The Correction Plan page houses the patient’s correction plan. From this page, users can initiate a scheduled adjustment. The page displays the entire correction plan including any required surgeon visits for strut adjustments or change-outs. **(Figure 30)**

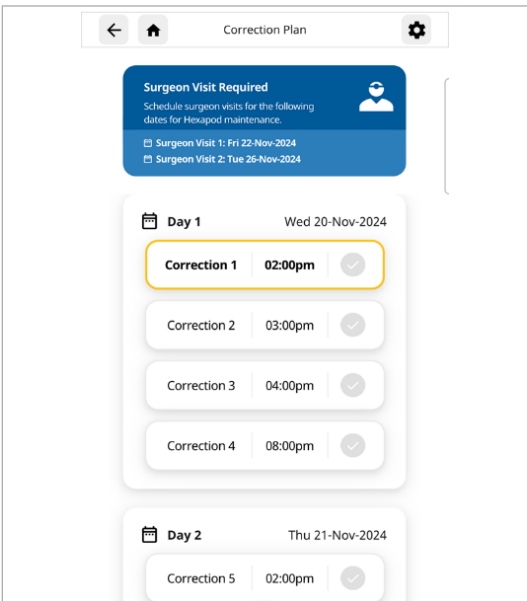


Figure 30



About your device

Controller details

The Controller Details page displays the software version of each strut controller. Your surgeon may ask for this information if an issue arises with the device, or if a firmware update is required. **(Figure 31)**

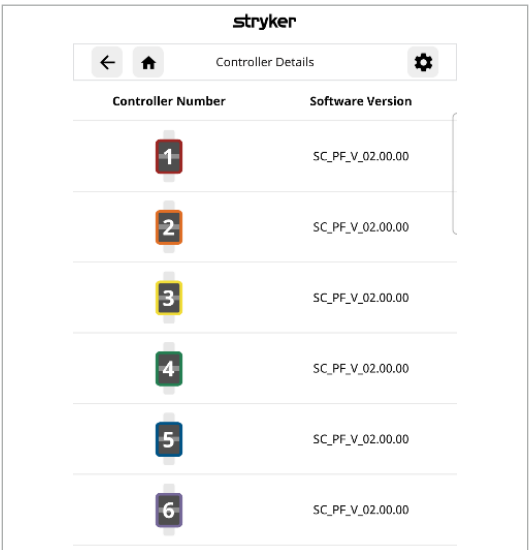


Figure 31

Deformity details

The Deformity Details page displays a report of your deformity correction plan, including an image showing the different views of your deformity as input by the prescribing surgeon. **(Figure 32)**

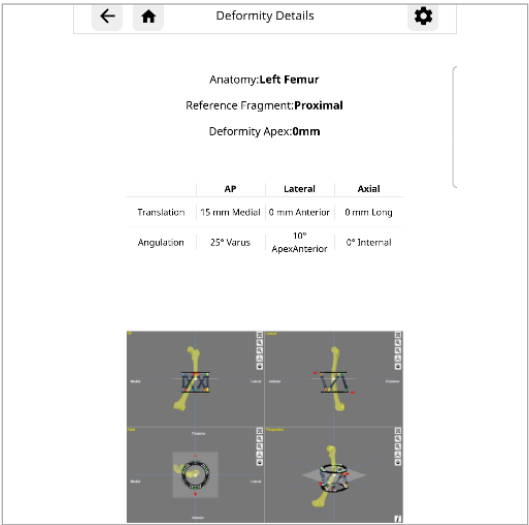


Figure 32

Frame simulation

The Frame Simulation page displays an animated simulation of your correction progression over time. The play button activates the animation, and the slider tool can fast-forward to any part of your correction. **(Figure 33)**



Figure 33

About your device

Settings

The settings menu can be accessed from home page using the gear icon toward the upper right corner of the screen. The settings menu contains links to:

- Product Information
- Reminder notifications
- Terms and Conditions

Product information

The Product Information page contains instructional videos for the HexConnect mobile application and smartHEX strut controllers as well as a Frequently Asked Questions (FAQ) section. There is a link to Stryker's Hoffmann LRF Hexapod patient website (external site), which contains additional information for patients and caregivers. **(Figures 34-36)**

Reminder notifications

The Reminder Notifications page allows you to adjust the timing of reminders before a scheduled correction is due. The notifications can be set between 5 minutes (default) and 60 minutes. **(Figure 37)**

Repeated reminders: a checkbox turns on or off repeated reminders to perform a correction. Repeated reminders are sent every 5 minutes (starting from the set notification time) until the time of the scheduled correction.

Reminders for overdue corrections are sent every 30 minutes until the correction is executed.

Terms and conditions

The Terms and conditions page contains the full list of Terms and Conditions of the mobile application, which can be reviewed at any time.

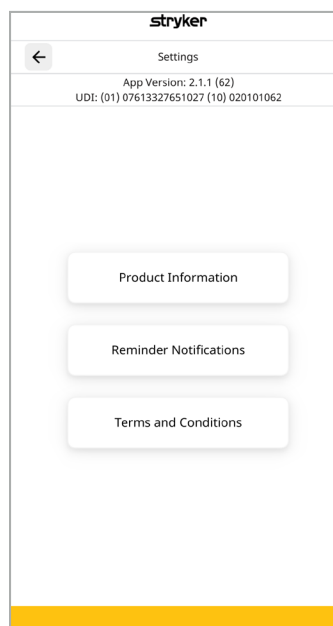


Figure 34

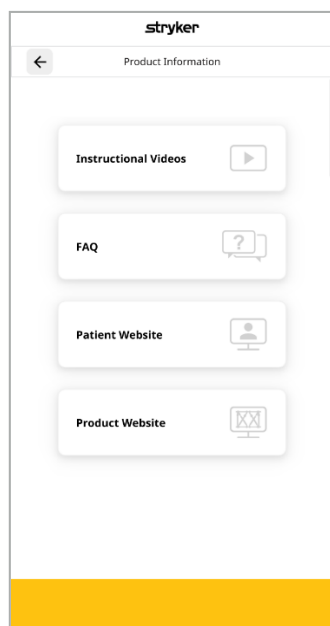


Figure 35

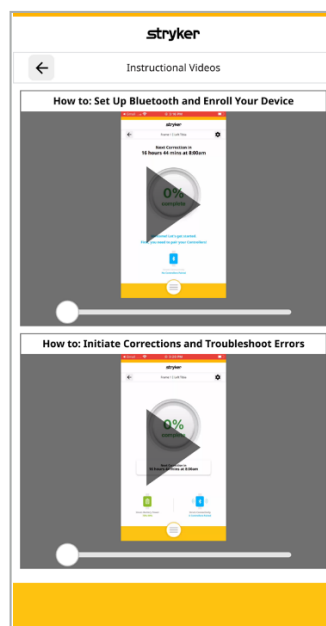


Figure 36

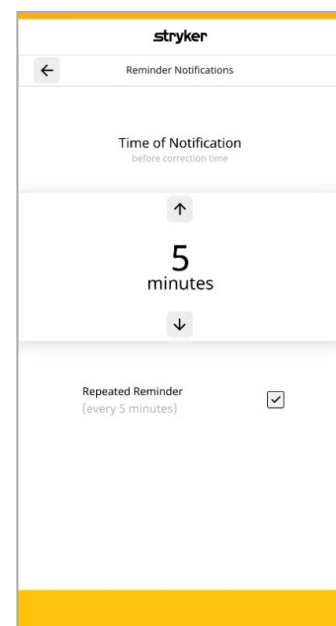


Figure 37

Executing the correction plan

Access the scheduled correction

- Open the HexConnect mobile application and navigate to the correction plan using the app menu located near the bottom of the screen. You can also access the plan by tapping the “Next Correct In...” button. **(Figure 38)**
- Open the correct case. If there is more than one case prescribed, ensure that the relevant one is selected.
- From the case home screen, on the “Next correction in...” button, or
- Navigate to the correction plan using the pop-up menu and choosing Correction Plan.

Strut correction reminders

When a correction is due, a reminder notification is sent. Tap the banner notification to be directed to the correction plan. The upcoming correction will be highlighted with a gold box. **(Figure 39)**

If a scheduled correction is missed, the app will send a reminder notification every 30 minutes until you execute the correction.

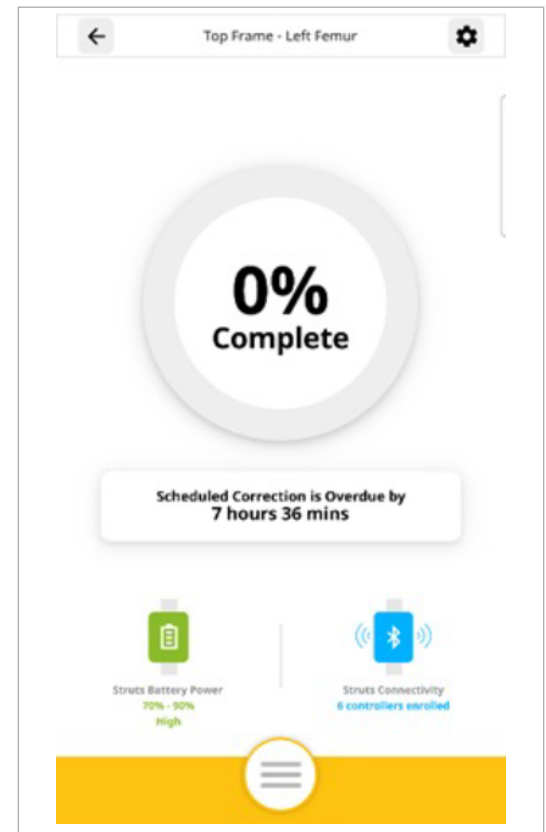


Figure 38

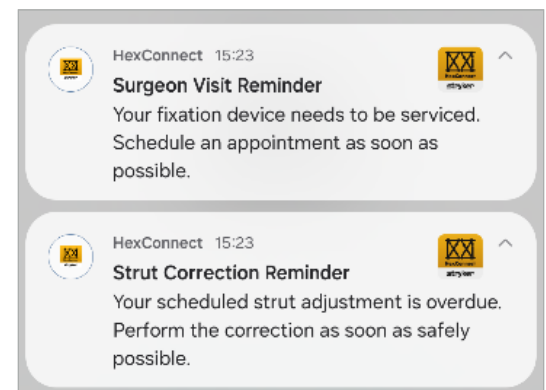


Figure 39

Executing the correction plan

Performing a correction

The Correction Plan page lists past and upcoming corrections as well as when an in-person visit with the surgeon may be required for strut change-outs or adjustments. **(Figure 40)**

- Tap to open the next scheduled correction (highlighted in a gold box).
- Review and accept the Adjustment Cautions notification by selecting the “X” in the upper right corner, which will close the dialogue box. **(Figure 41)** This notification reminds you to be positioned comfortably and non-weight bearing before initiating a correction.
- When you are seated or lying comfortably and ready, tap the Start Strut Adjustment button toward the bottom of the screen to begin the correction. **(Figure 42)**

Within a few moments, the strut controllers will begin to light up green. This indicates that the strut controllers are communicating with the mobile device and that battery checks are in progress. The application checks the status of each strut controller **(Figure 43)** before starting a correction to ensure they are functioning properly and that there is enough battery power to complete the correction.

- When all battery checks are completed, the strut controllers will automatically adjust the strut to execute the correction.
- The strut controllers will continue to adjust until all struts have been corrected according to the plan. Upon successful completion of the corrections, the message “Successful adjustment complete!” will display **(Figure 44)**, and the app will play a tone.
- You will then wait until the next scheduled correction to repeat this adjustment process.

CAUTION

Use of smartHEX strut controllers in an aircraft is not recommended. If air travel is necessary while being treated with a smartHEX device, the corrections schedule should be adjusted at the care team’s discretion.

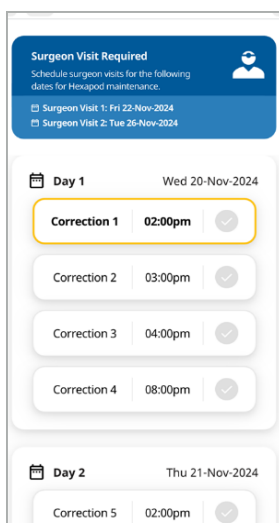


Figure 40

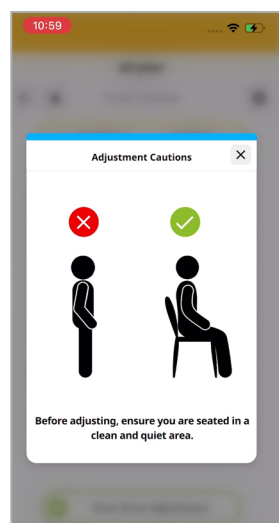


Figure 41

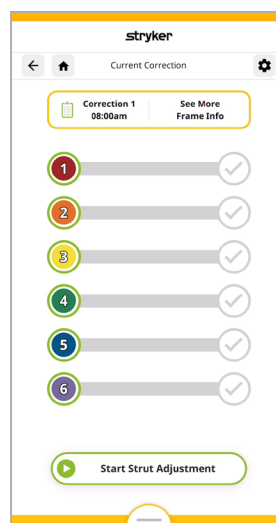


Figure 42

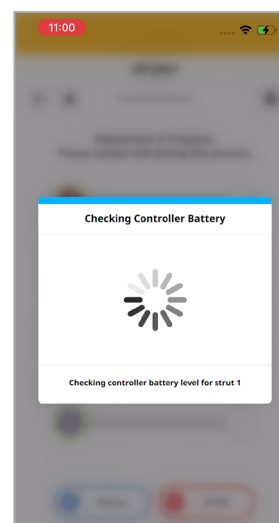


Figure 43

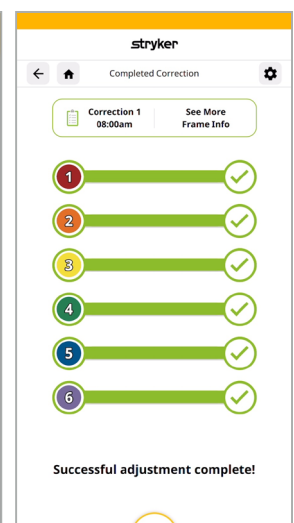


Figure 44

Executing the correction plan

Pausing or stopping a correction plan

If a correction needs to be suspended for any reason, a pause and stop button are located toward the bottom of the correction screen. (Figures 45-46)

Pause function

Allows for temporarily pausing a correction. Corrections that have been paused may be resumed. Reasons for pausing a correction may include convenience, encountering a disturbance, or discomfort experienced while performing the correction.

To pause a correction:

- Tap the Pause button. After a moment, the strut controllers will pause movement one by one.

NOTICE

Allow up to 15 seconds for all strut controllers to stop moving.

Allow up to 15 seconds for all strut controllers to stop moving.

- When ready to resume the correction, tap the Resume button. After a moment, the strut controllers will start moving again and the correction will resume where it left off.

Stop function

The stop feature is intended for emergency use and will completely halt the correction plan. Due to the definitive nature of this function, a “Stop Action” disclaimer will request the user to confirm the decision to stop. (Figure 47) Once a correction plan is stopped, the prescribing surgeon must reissue the correction plan.

To stop the correction:

- Tap the STOP button. After a moment, the strut controllers will pause movement one by one.

NOTICE

Allow up to 15 seconds for all strut controllers to stop moving.

- When the “Stop Action” disclaimer appears, select “Yes, STOP”. This will suspend the plan. (Figure 47)
- A confirmation message will display at the top of the screen: “Correction has been STOPPED. You must contact your surgeon to send an updated correction plan.” (Figure 48)
- Once the correction plan has been reissued by the prescribing surgeon, a new email containing an updated correction plan link will be sent to you.

NOTICE

If the STOP button was pressed in error, select “No, go back” to resume the correction plan.



Figure 45

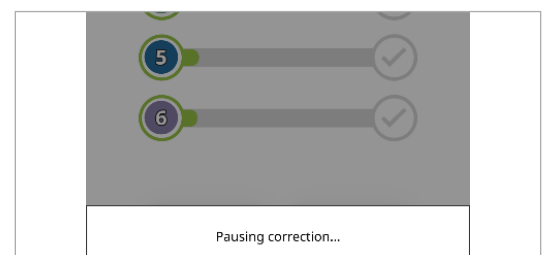


Figure 46

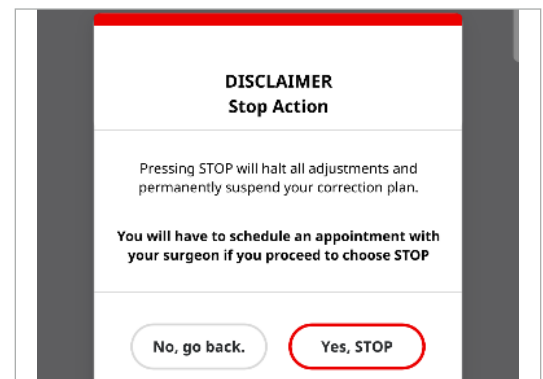


Figure 47

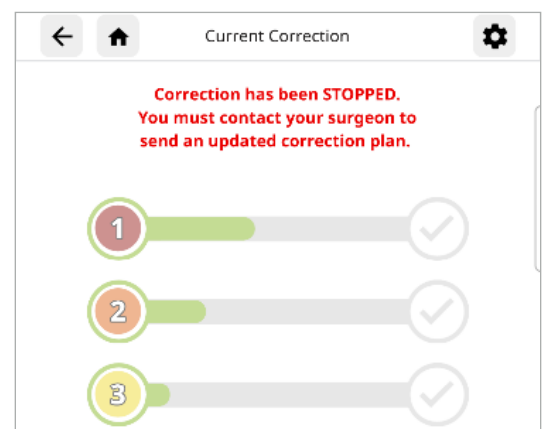


Figure 48



Executing the correction plan

Managing missed corrections

In the event that a scheduled correction is missed, it can be executed later in same calendar day, up until midnight, without any effect on the correction plan.

If one or more missed corrections is not executed within the same calendar day, the correction will be highlighted with a red border and marked as “Missed”, and correction schedule will adjust accordingly.

The missed correction(s) will be postponed to the following calendar day, and the remainder of the correction plan will shift back for each missed correction.

Example 1:

Correction 8 was due at 2:00 pm on Day 2, Tuesday (**Figure 49**) but was not executed during that calendar day and was marked as missed. (**Figure 50**) Correction 8 has moved to Day 3, Wednesday, and the remainder of the corrections have adjusted back one day accordingly. (**Figure 51**)

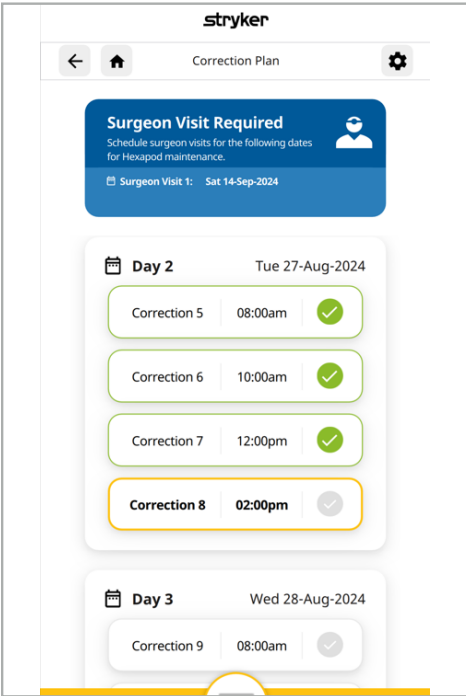


Figure 49

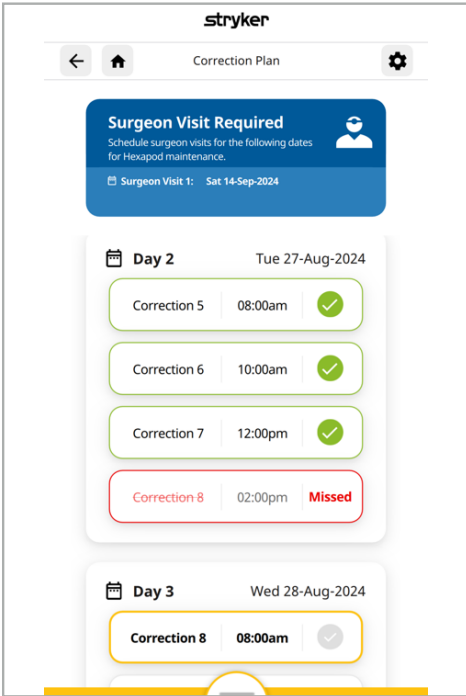


Figure 50

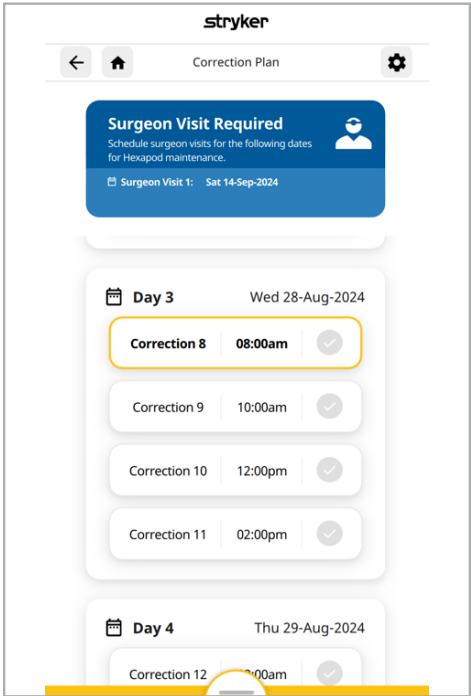


Figure 51



Executing the correction plan

Example 2:

Correction 8 was scheduled for 8:00pm on Day 2, Friday but was not executed during that calendar day. It was postponed to Day 3, Saturday and the remainder of the corrections were shifted back accordingly. On Day 3, all four scheduled corrections (Corrections 8-11) were not executed. They are now postponed to Day 4, Sunday, starting with Correction 8. **(Figure 52)**

Missing consecutive days

If more than two days of consecutive corrections are missed, the correction plan will be automatically suspended, preventing any further corrections. A suspended plan is indicated by a correction with a gold border that is marked "Suspended". **(Figures 53-55)**



Your care team must be contacted immediately if a correction plan is suspended. This will allow your surgeon to check on your progress and reissue a new correction plan as appropriate.

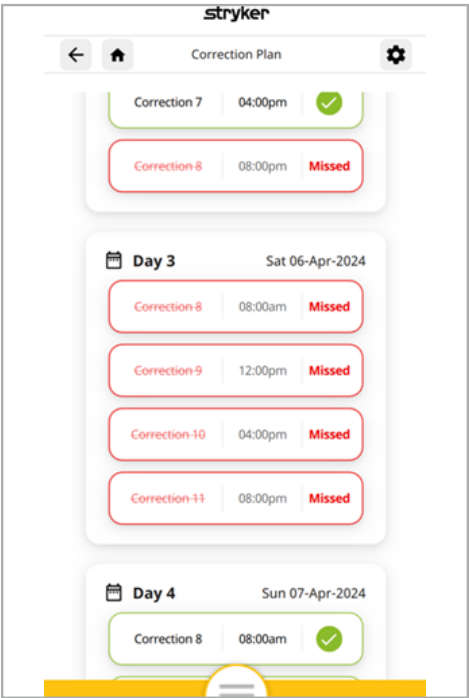


Figure 52

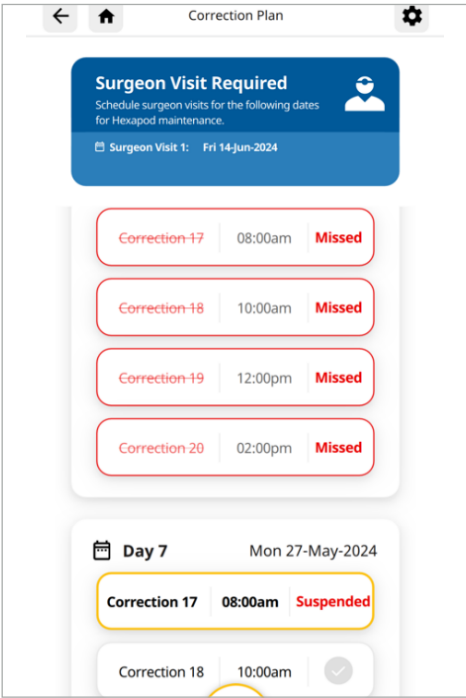


Figure 53

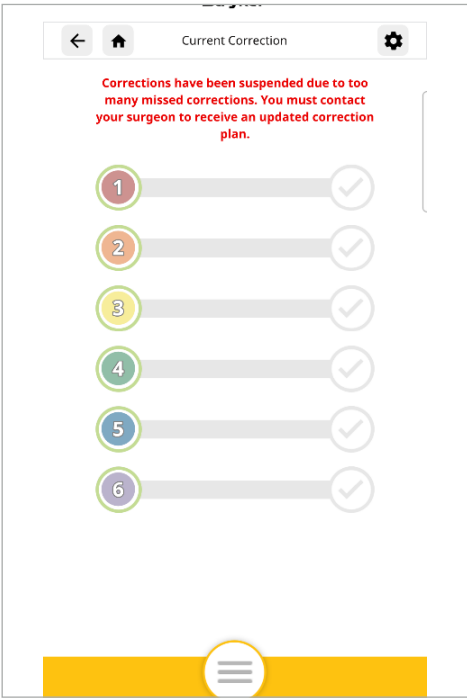


Figure 54

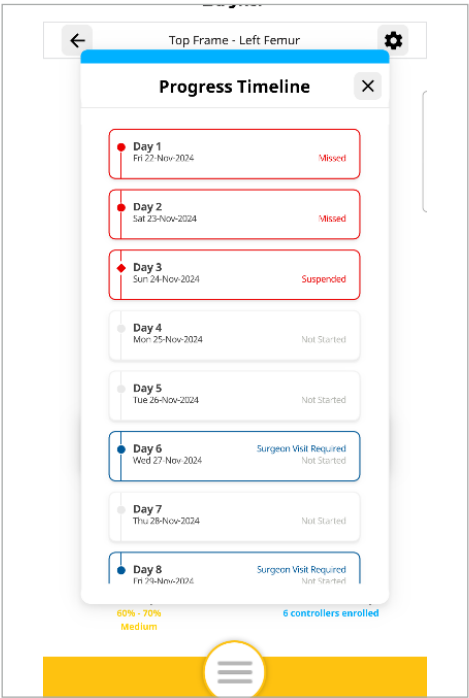


Figure 55

Indications and errors

The LED light indicator on the strut controller is designed to alert users to the various normal indications and errors that can arise while using the device. It's important to understand how to identify each error so that efficient troubleshooting can occur.

The LED light indicator illuminates for approximately 40 seconds for each indication. After that, the controller re-enters sleep mode to conserve battery power. More information on the individual indications may be found in the mobile application. **Table 3** outlines the indications and errors.

Table 3: Indications and Errors

LED status	Presentation	Bluetooth status	Correction status	Enrolled status	Errors	Patient action
Flashing green (2 blinks/ second)		Connected/ Not connected	Correction in progress (struts moving)	Enrolled	No errors	No action required
Solid green		Connected/ Not connected	Correction in progress (communication, battery check, etc.)	Enrolled	No errors	No action required
Flashing blue (2 blinks/ second)		Not connected	Correction not in progress	Not enrolled	No errors	No action required; awaiting enrollment
Solid blue		Connected	Correction not in progress	Not enrolled	No errors	No action required; awaiting enrollment
Solid red		Connected/ Not connected	Correction not in progress	Enrolled/ Not enrolled	Controller error	Low battery, motor over current, or out of Bluetooth range; follow instructions in Mobile Application (or in troubleshooting section below)

Indications and errors

Troubleshooting

Errors with the strut controller device may represent hard faults or soft faults. Soft faults may be resolved with a device reset by turning the strut controller off and back on by opening and closing the battery door. Hard faults require replacement of the strut controller by your care team.

The HexConnect mobile application is equipped with numerous error messages to help describe issues with device connectivity or battery levels. These error messages and recommended troubleshooting actions for the strut controllers and mobile application are outlined in **Table 4**.

For additional troubleshooting support, contact your care team.

Table 4: Error messages and recommended actions

Strut controller			
Indication	Error message	Fault status	Recommended action
Solid Red LED Light Ring	Controller has failed, Software issue, error code (0x0001) – over current error	Soft Fault	Check for excessive debris on the strut or that the strut is not jammed. Press Resume to try again. If pain is present or the strut is physically jammed, do not resume, contact your healthcare professional.
	Controller has failed, Software issue, error code (0x0002) – motor failure	Hard Fault	Contact your healthcare professional for controller replacement. In the event of a hard fault, device operation is stopped. Operation of the controller may also be terminated by your care team by removing the battery as described in the battery removal and replacement section above.
	Controller has failed, Software issue, error code (0x0004) – encoder failure	Hard Fault	Contact your healthcare professional for controller replacement. In the event of a hard fault, device operation is stopped. Operation of the controller may also be terminated by your care team by removing the battery as described in the battery removal and replacement section above.
	Controller has failed, Software issue, error code (0x0008) – heartbeat error	Soft Fault	Communication with your device was lost during the correction. This could be caused by a broken device, the device turned off, or dead battery. Repair, recharge, or turn the device back on, navigate to the last correction, and press Resume to continue the correction.
	Controller has failed, Software issue, error code (0x0010) – five-volt error failure	Hard Fault	Contact your healthcare professional for controller replacement. In the event of a hard fault, device operation is stopped. Operation of the controller may also be terminated by your care team by removing the battery as described in the battery removal and replacement section above.

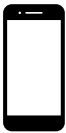
Indications and errors

Strut controller			
Indication	Error message	Fault status	Recommended action
Solid Red LED Light Ring	Controller has failed, Bluetooth connectivity issue	Soft Fault	Move your mobile device closer to your frame and press resume.
	Controller has failed, turn on Bluetooth to perform corrections	Soft Fault	Check your devices settings and ensure Bluetooth is turned on. When Bluetooth turned back on press Resume.
	Insufficient controller battery level to execute correction	Soft Fault	Contact your healthcare professional for battery replacement.

Mobile application			
Problem	Error message	Fault status	Recommended action
Unable to enroll	Enrollment – Failed to register controller X (1–6) with strut	None	An internet connection must be present to enroll a strut and link it to the correction plan. Pairing and enrollment is completed by your care team.
Unable to perform a correction	A surgeon visit is required for this correction.	None	Contact your care team for required strut change or adjustment. The surgeon must mark the visit as complete in the web portal before you can continue.
Unable to perform a correction	Checking controller battery – Failed to read battery level of one or more controllers	None	Move your mobile device closer to your frame and try again.
Unable to perform a correction	Insufficient phone battery to execute correction- less than 20%	None	Recharge device to greater than 20%.
Unable to perform a correction	Correction has been STOPPED. You must contact your surgeon to send an updated correction plan.	None	After pressing the STOP button, you must contact your care team to verify everything is okay and get a new correction plan.
Unable to perform a correction	Checking controller battery error	None	Press OK and try again. If the issue persists, contact your care team for support.
Unsuccessful Strut Adjustment	Controller has failed – Unable to connect with the controller	Solid Red LED Light Ring (30 sec)	Ensure Bluetooth functionality of your mobile device. Move your mobile device closer to your frame and press resume.
None - Informational message	The battery level for one or more controllers is running low	None	Contact your care team for a battery replacement.



Instructions for mobile app users (manual adjustments)



Mobile app user: struts are adjusted manually by the patient or caregiver in accordance with the correction plan generated by the web application. Your surgeon will instruct you on how to make the manual strut adjustments. The correction plan is accessed through the patient’s HexConnect Mobile Application, which can also provide reminder notifications and instructions.

After downloading and opening up your correction plan in the HexConnect application, you will have access to your correction schedule. This schedule is designed to guide you in the manual adjustment of your smartHEX struts. **(Figure 56)**

From the correction plan screen, select the current correction. Each strut is listed with the number and direction of clicks as well as the adjustment length.

For example: Strut 1 should be adjusted 2 clicks in the clockwise (+) direction. When the adjustment is complete, the scale on the side of the strut should read 135.5. **(Figure 57)**

Strut	Clicks	Length	Status
1	2	135.5	Mark Complete

Each adjustment can be marked complete by tapping “Mark Complete”. A full correction is considered complete when all struts are adjusted and the status is changed for each, indicated by six green check marks. **(Figure 58)**

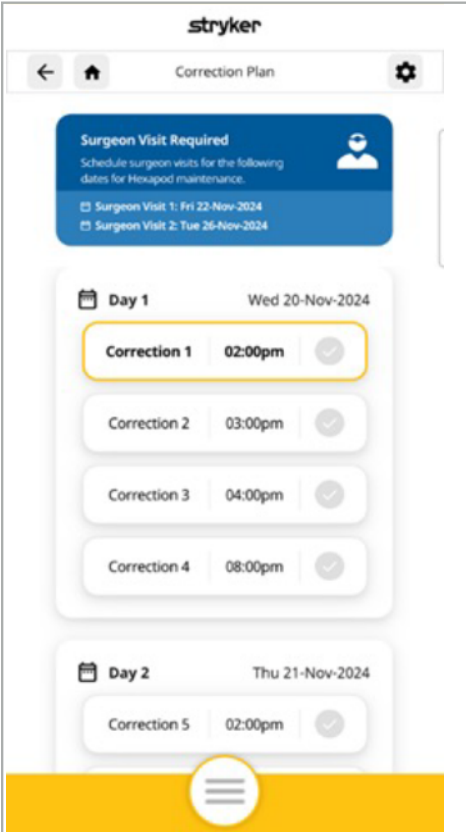


Figure 56

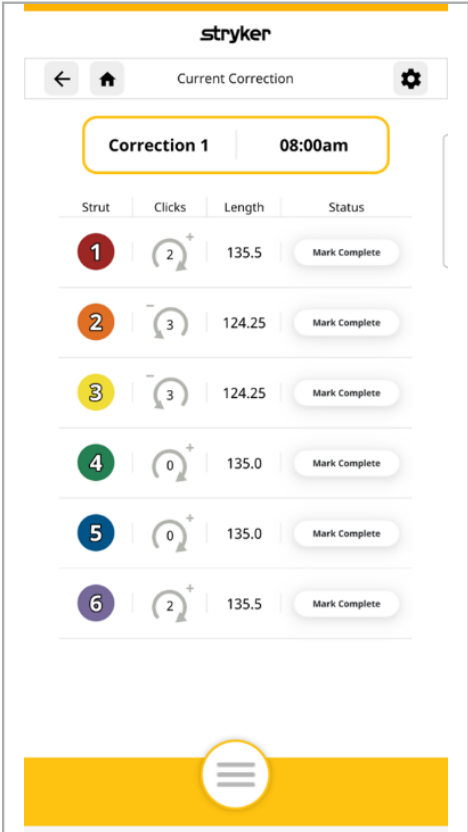


Figure 57

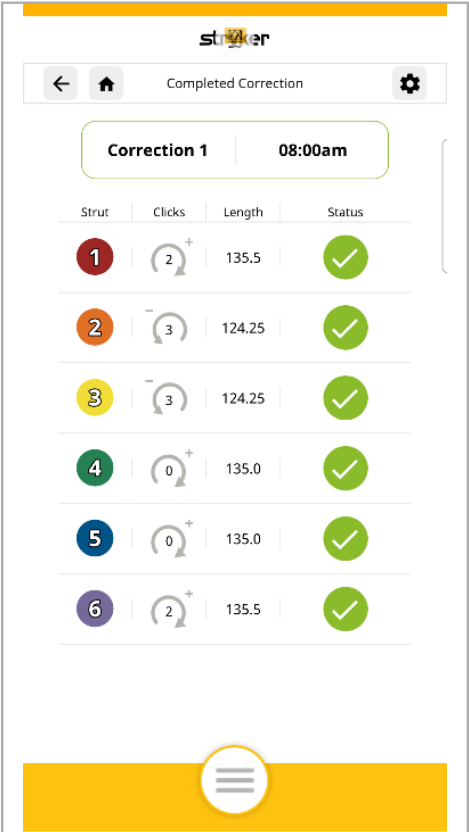


Figure 58

Cybersecurity

Your smartHEX strut controllers communicate with the HexConnect mobile application over a Bluetooth Low Energy (BLE) connection. This connection is encrypted using industry standard methods designed to reduce the risk of unauthorized devices communicating with the strut controller.

To help keep your device and information secure:

- Only allow trusted members of your care team and personal caregivers to use the mobile device running the HexConnect app.
- When the app needs internet access, connect only to a secure, password-protected private network. Avoid public or open Wi-Fi networks.
- Keep the HexConnect app updated when updates are made available.

If you believe your device, the app, or your information has been tampered with or accessed without authorization, contact your care team or Stryker or assist at **+1 (844) 393 4933**.

Connecting the device to a network

The Strut Controller does not connect directly to a Wi-Fi or cellular network. Instead, it communicates through the HexConnect Mobile Application, which uses your smartphone or tablet's internet connection — whether via Wi-Fi or cellular data—to transfer data securely. While not required for completing corrections, failure of the device to upload data for a period of two days will require you to connect to a network in order to proceed. Therefore, ensure the mobile device has frequent internet access through either a secure private Wi-Fi network or cellular data.

To connect to a Wi-Fi network, follow these steps:

1. Turn on the device and go to the settings or network menu.
2. Select “Wi-Fi Settings” and ensure that Wi-Fi is enabled.
3. Choose the desired Wi-Fi network from the list of available networks.
4. Enter the Wi-Fi password, then confirm to connect. The device will indicate a successful connection.

For reliable operation, connect only to secure, password-protected private networks. Avoid using public or open networks. If needed, consult your router's manual or your internet provider for help managing your home Wi-Fi settings. Always place the device within range of the wireless router to ensure a strong and stable connection. The use of Wi-Fi must not interfere with the safe operation of the device—refer to the section below for details on wireless compatibility and performance.

FCC compliance statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential environment. This equipment generates, uses, and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference.

However, there is no guarantee that interference will not occur. If this device does cause interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to correct the interference by one or more of the following measures:

- Re-orient or re-locate the smartHEX frame and strut controllers.
- Increase the distance between the smartHEX frame and strut controllers and the receiver.
- Contact Stryker OR Assist Customer Service at: +1 (844) 393-4933. For non-urgent requests, contact the Hoffmann LRF help desk via email at: smarthex@stryker.com

The Intentional Radiator is subject to the FCC Certification procedure, the composite Unintentional Radiator (such as Digital device, Data Interface) is covered by the FCC Suppliers Declaration of Conformity procedure 47 CFR Part 15, Subpart C.

FCC caution

Changes or modifications not expressly approved by Stryker could void the user's authority to operate the equipment.

Strut controller specifications

Weight and dimensions

- Weight (with battery): 100g
- Dimensions: 57mm (height) × 46mm (depth) × 52mm (width)

Storage and transport conditions

- Ambient temperature: +2°C to +38°C
- Humidity: 15% to 90%, non-condensing
- Atmospheric pressure: 700hPa to 1060hPa

Operating conditions

- Ambient temperature: +5°C to + 40°C
- Humidity: 15% to 90%, non-condensing
- Atmospheric pressure: 700 hPa to 1060 hPa

Duty cycle

- The strut controller operates for less than 1.5 minutes per/day, therefore it's duty cycle is 0.1%

Accuracy

- +/- 3.24 degrees per 90 degree rotation

Battery

- Battery type: Panasonic CR2 (Lithium Manganese Dioxide)
- Dimensions: 27mm long × 15.6mm diameter
- Nominal voltage: 3VDC
- Nominal capacity: 850mAh
- Weight: Approx. 11g
- Operating temp: -40°C to 70°C
- Storage temp: 5°C to 35°C

Device transmitter

- Bluetooth Low Energy (BLE) version: 5.0
- Frequency band: 2.402 GHz to 2.480 GHz
- Transmitted power: -8dBm
- Operating range: 5m indoor
- Antenna type: 2.4 GHz Chip antenna

Cleaning instructions for strut controllers

The strut controllers may be cleaned with a soft, lint free cloth dampened with a mild soap and water solution. Gently wipe the surface of the device, avoiding openings. Wipe off any residual soap solution with a clean damp cloth. The strut controllers must not be submerged or cleaned with harsh chemicals.

To remove excessive soil, remove the strut controller from the strut and clean the mounting bracket and gear area with a slightly dampened cotton swab.

The strut controller enclosure provides IP24 ingress protection, meaning that independent testing confirmed that access to hazardous parts is prevented and protected against splashing water from any direction during normal use. The enclosure is not intended to provide protection against dust ingress or water immersion. Contact your care team if you have submerged your frame with the strut controllers attached.

The prescribing surgeon may permit patients to bathe with a light shower during the course of treatment. The strut controllers must not be used for bathing in bath or swimming pool. Always follow the advice of your care team.

NOTICE

Strut controllers are not designed to be submerged in water or any liquid and may be subject to irreparable damage if submersion occurs. Patients must contact their care team if a smartHEX device with the strut controllers attached has been submerged in liquid for any time.

NOTICE

If the care team determines that the patient must submerge the smartHEX device in water for any reason, the strut controllers must be removed prior to submersion.

Environmental considerations for safe use

The strut controllers are intended for use in a home healthcare environment. For proper operation and safety, please observe the following precautions:

- **Dust and lint:** Do not operate the strut controllers in environments with excessive dust or lint (e.g., near open windows, vents, or laundry areas). Accumulation may interfere with device operation.
- **Loose clothing and linens:** Avoid covering the strut controllers with loose clothing, blankets, or bed linens during operation. Obstruction of the gears may result in jamming of the struts, impaired function, or inaccurate readings.
- **Ambient light:** Avoid direct exposure to strong light sources (e.g., sunlight or bright lamps) that may impair LED display function.
- **Pets and pests:** Keep the strut controllers out of reach of pets. Damage from chewing, scratching, or urination can impair safety and performance. Protect the device from insects or rodents that could damage the device and interfere with operation.
- **Children:** This device is not a toy. Do not allow children to play with or operate the smartHEX system unsupervised. Small parts may pose a choking hazard.



Device disposal

When disposing of smartHEX strut controllers and lithium batteries, follow local regulations and facility guidelines for the disposal of electronic waste. Do not discard the strut controllers or batteries in household trash or recycling bins. Contact the prescribing healthcare facility for disposal information or check with local waste management authority or recycling center to identify designated e-waste collection points or recycling programs in the area.

Electromagnetic Compatibility (EMC)

Hoffmann LRF smartHEX Strut Controller - FCC ID: 2BOED-SMHEX, IC: 33821-SMHEX

- The smartHEX system needs special precautions regarding EMC and needs to be used according to the EMC information provided in this manual.
- 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 properly.
- Portable RF communications equipment (including antenna cables and external antennas) should be used no closer than 30 centimeters (12 inches) to any part of the smartHex system. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories and cables other than those specified or provided by Stryker could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- There are no special instructions for maintaining basic safety and essential performance due to EMC for the expected service life of 140 days.



Guidance and manufacturer’s declaration

Electromagnetic emissions

The smarHEX strut controllers are intended for use in the electromagnetic environment specified in **Table 5**. The customer or the user of the system should assure that it is used in such an environment.

Table 5: Guidelines for electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The system uses RF energy for short range communication between the strut controller and the companion device, therefore RF emissions are very low and unlikely to cause interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The smarHEX system is suitable for use in all environments, including home use environments, hospital environments and healthcare facility environments.

Guidance and manufacturer's declaration

Electromagnetic immunity

The smartHEX strut controllers are intended for use in the electromagnetic environment specified in **Table 6**. The customer or the user of the system should assure that it is used in such an environment.

Table 6: Guidelines for electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Flooring should be wood, concrete or tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF fields IEC 61000-4-3	3 V/m 80 MHz to 2700 MHz	3 V/m	Portable RF communications equipment (including antenna cables and external antennas) should be used no closer than 30 centimeters (12 inches) to any part of the smartHex system. Otherwise, degradation of the performance of this equipment could result.
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 those found in a typical domestic, commercial, or hospital environment.
Proximity magnetic fields IEC 61000-4-39	9 kHz to 150 kHz - 30 kHz – 8 A/m - 134.2 kHz – 65 A/m	9 kHz to 150 kHz - 30 kHz – 8 A/m - 134.2 kHz – 65 A/m	Proximity magnetic fields should be at levels characteristic of those found in a typical domestic, commercial, or hospital environment.
	150kHz to 26 MHz - 13.56 MHz – 75 A/m	150kHz to 26 MHz - 13.56 MHz – 75 A/m	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table below	Compliance to the tested levels	Portable RF communications equipment (including antenna cables and external antennas) should be used no closer than 30 centimeters (12 inches) to any part of the smartHex system. Otherwise, degradation of the performance of this equipment could result.



Guidance and manufacturer’s declaration

Table 7 lists the immunity levels at specific test frequencies for testing the effects of some wireless communications equipment. The frequencies listed in the table are representative examples in various locations where the smartHEX strut controllers may be used.

Table 7: Immunity levels by test frequency

Frequency in MHz	Test level in V/m	Polarization	Modulation
385	27	H/V	PM 18 Hz, DC 50%
450	28	H/V	PM 18 Hz, DC 50%
710 745 780	9	H/V	PM 217 Hz, DC 50%
810 870 930	28	H/V	PM 18 Hz, DC 50%
1720 1845 1970	28	H/V	PM 217 Hz, DC 50%
2450	28	H/V	PM 217 Hz, DC 50%
5240 5500 5785	9	H/V	PM 217 Hz, DC 50%

Trauma & Extremities

The information presented in this brochure is for educational purposes only. Stryker is not dispensing medical advice. Please speak to your doctor to decide which type of surgery is right for you. Only your doctor can make the medical judgment which products and treatments are right for your own individual condition. As with any surgery, trauma surgery carries certain risks. Your surgeon will explain all the possible complications of the surgery, as well as side effects. Additionally, the lifetime of a trauma product is not infinite and varies with each individual. Also, each patient will experience a different post-operative activity level, depending on their own individual clinical factors. Your doctor will help counsel you about how to best maintain your activities in order to potentially prolong the lifetime of the device. Such strategies include not engaging in high impact activities. It is important to closely follow your doctor's instructions regarding post-surgery activity, treatment and follow-up care.

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