LANTERN® HIP
INSTRUCTIONS FOR USE

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CAUTION

Rx ONLY Federal (USA) law restricts this device to sale by or on the order of a physician

HOW SUPPLIED

Lantern® Hip (includes reference sensor CR2 battery and femur sensor battery).

STERILE EO DO NOT REUSE

Lantern Hip Instruments:
Lantern Hip instruments are provided NON-STERILE and must be cleaned and sterilized prior to each use.

INDICATIONS FOR USE

Lantern Hip is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. Lantern Hip facilitates the accurate positioning of implants relative to these alignment axes. The system aids the surgeon in controlling leg length and offset discrepancies.
Lantern Hip is indicated for Total Hip Arthroplasty with the Direct Anterior Approach and the patient in the supine position, or through a posterior-based approach with the patient in the lateral position. Note, offset is only available with the Direct Anterior Approach.

INTENDED USE

Lantern Hip is designed to assist the physician in obtaining the following during orthopedic surgical procedures:
Total Hip Arthroplasty

- Acetabular shell orientations ranging from 0-30° anteversion and 25-55° abduction.
- Measurement of the change in leg length within ±15mm of the initial registration position (available with the patient in the supine or lateral position).
- Measurement of the change in lateral offset within ±15mm of the initial registration position (available only with the patient in the supine position).

DESCRIPTION

Lantern Hip is a computer-assisted surgery device designed to assist the surgeon during Total Hip Arthroplasty.
For the Direct Anterior Approach and the patient in the supine position, Lantern Hip assists the surgeon in:

- Navigating acetabular cup inclination and anteversion
- Measuring changes in leg length and offset
- Establishing the orientation of the pelvic plane and determining the abduction (inclination) angle and the anteversion angle of the shell impactor relative to the anterior pelvic plane in total hip arthroplasty, or to a reference frame adjusted for pelvic tilt in total hip arthroplasty: anterior approach.
- Measuring the change in femoral position in both the superior-inferior, and the medial-lateral directions, from the native anatomic state to the post joint reduction state in total hip arthroplasty.

Lantern Hip does not display measurement values when it is oriented outside of its operating range.
For posterior-based approaches and the patient in the lateral position, Lantern Hip assists the surgeon in:

- Navigating acetabular cup inclination and anteversion.
- Measuring changes in leg length.
- Establishing the orientation of the pelvic plane and determining the abduction (inclination) angle and the anteversion angle of the shell impactor relative to the coronal plane in total hip arthroplasty.
- Measuring the change in femoral position in the superior-inferior direction from the native anatomic state to the post joint reduction state in total hip arthroplasty.

Lantern Hip does not display measurement values when it is oriented outside of its operating range.
Lantern Hip consists of the sterile, single-use Lantern Hip Navigation Unit (packaging includes reference sensor CR2 battery and femur sensor battery) and associated reusable instrumentation supplied non-sterile.
The Lantern Hip Navigation Unit is sterile unless package is opened or damaged. The Lantern Hip Navigation Unit is for single use only.
For total hip arthroplasty, the Lantern Hip Navigation Unit is used in conjunction with the Lantern Hip Instrument Set.
Lantern Hip provides measurement accuracy of ±3.0º with at least 95% confidence when measuring the angle of the shell impactor relative to the frame of reference defined by the registered landmarks. This measurement accuracy does not incorporate other sources of error that are known to affect the overall shell placement accuracy, such as variability in selection of the landmarks.
For the Direct Anterior Approach and the patient in the supine position, Lantern Hip has been validated in bench testing to achieve acetabular shell navigation accuracy, relative to an adjusted reference frame (the APP rotated to correct for pelvic tilt) of ±3.0° with 95% confidence for abduction and ±3.0° with 95% confidence for anteversion.
For the Direct Anterior Approach and the patient in the supine position, Lantern Hip has been validated in bench testing to achieve measurement accuracy of ±3.0mm with at least 95% confidence for changes in femoral position in the superior-inferior direction (“leg length”) and ±3.0mm with at least 95% confidence in the medial-lateral direction (“offset”).
For posterior-based approaches and the patient in the lateral position, Lantern Hip has been validated in bench testing to achieve acetabular shell navigation accuracy, relative to a user-registered Coronal reference frame of ±3.0° with 95% confidence for abduction and ±3.0° with 95% confidence for anteversion.
For posterior-based approaches and the patient in the lateral position, Lantern Hip has been validated in bench testing to achieve measurement accuracy of ±3mm with 95% confidence for changes in femoral position in the superior-inferior direction (“leg length”).
For measurement of change in femoral position, Lantern Hip directly registers coordinates of a fiduciary fixated to the femur.
For The Direct Anterior Approach and the patient in the supine position, Lantern Hip directly registers the anterior pelvic plane defined by the following three points: left and right anterior superior iliac spine and pubic tubercle. Shell impactor measurements are displayed relative to this (APP) plane, or relative to a modification of this plane rotated to correct for pelvic tilt.
For posterior-based approaches and the patient in the lateral position, Lantern Hip establishes the coronal reference frame by registration of patient positioning on the operating table. Shell impactor measurements are displayed relative to this frame.
The Lantern Hip Instrument Set is comprised of registration jig, adapter clips and clamps, reference sensor, femur sensor, hex driver, femoral registration instruments, registration wand and associated liner registration trials, and fixation pins. Lantern Hip instruments are provided NON-STERILE and must be cleaned and sterilized prior to each use.
Refer to the Lantern Hip Supine Surgical Technique Guide (001391) and Lantern Hip Lateral Surgical Technique Guide (001490) for detailed instructions on use of the instruments.

CONTRAINDICATIONS

Total Hip Arthroplasty

- In any hip arthroplasty procedures where there is a significant loss of bone and the required landmarks cannot be identified or there is severe deformity at the landmark sites. In cases of previous pelvic fracture, previous pelvic osteotomy or severe

dysplasia, for example, the required landmarks should be examined to ensure that severe deformity is not present.
- Atypical bony anatomy at the fixation site, extremely large or small femurs, excessive soft tissue interference or severe osteoporosis.
- The presence of infection.
- Any contraindication associated with hip arthroplasty surgery.

Early experience with these procedures should consider the technical difficulty and complicated nature of this procedure and should be restricted to straightforward cases. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.

ADVERSE EFFECTS

Total Hip Arthroplasty

There is a possibility of implant malalignment. Depending on the severity of the malalignment it may shorten the useful life of the implant and increase the likelihood of impingement or dislocation. It may impact a revision procedure. Lantern Hip is a tool to assist the surgeon in judging the alignment and should not supersede the surgeon's judgment.

There is a possibility of a leg length or offset discrepancy. Depending on the severity of the discrepancy it may affect the clinical outcome and/or patient satisfaction. Lantern Hip is a tool to assist the surgeon in judging the femoral position and should not supersede the surgeon's judgment. Lantern Hip contains instruments which have magnetic attachments.

Possible adverse effects include heart rhythm disruption. There is a possibility of a delay in the procedure from system issues. Other possible adverse effects include infection, irritation, fever, pain, tissue injury, foreign body reaction, electrical shock, burns, reduced joint function, nerve damage and bone fracture.

WARNINGS

Warning: Do not resterilize the Lantern Hip Navigation Unit. This product is provided sterile for single use only. It contains electronic components that could be damaged. Discard any unused product.

Warning: Lantern Hip is not indicated for alignment in the attachment of any device to the posterior elements of the cervical, thoracic, or lumbar spine.

Warning: Replace the Lantern Hip Navigation Unit if dropped. Do not use reference sensor if dropped. Do not use the femur sensor if dropped. Replace and return to OrthAlign.

Warning: It is the surgeon's responsibility to be familiar with this technique prior to surgery. For further details, refer to the appropriate surgical technique guide.

Warning: If sterile packaging is damaged, sterility may be compromised. Do not use the device.

Warning: Remove battery from the reference sensor and/or femur sensor if it is not intended to be used for some time.

Warning: Do not service reference sensor and/or femur sensor while in use with a patient. If necessary, remove from patient to replace battery.

Warning: No modification of this equipment is allowed.

Warning: The reference sensor and femur sensor can contain a battery that needs to be removed and discarded prior to cleaning. If battery is left in the reference sensor and/or femur sensor it could damage instruments in the tray or the sterilizer equipment during steam sterilization.

Warning: The instruments are designed for very specific tasks and misuse may cause damage. Prior to use, check the instruments thoroughly for wear or damage. Do not use damaged instruments as they may compromise the surgical outcome. Replace damaged or worn instruments before next use.

Warning: The instruments are provided clean, but not sterile, and must be cleaned and sterilized prior to each use.

Warning: The strong magnetic fields near a neodymium magnet can affect pacemakers, ICDs, and other implanted medical devices. Keep instruments with magnets at least six inches away from any such heart device.

Warning: The surface of the Lantern Hip Navigation Unit can reach temperatures of up to 50°C.

Warning: The CR2 battery must be installed within the reference sensor per the markings on the device. The correct polarity of battery installation is clearly marked.

Warning: The femur sensor battery must be inserted in the correct orientation and fully seated to power on the device.

INSTRUMENTS CLEANING AND STERILIZATION

For your own safety, be familiar with the procedures at your institution for handling contaminated instruments before following these instructions. Clean and sterilize all instruments prior to first use and after every use. Refer to the Lantern Hip Surgical Technique Guide for instructions on operation and dismantling of instrumentation.

DO NOT DISCARD OR DISASSEMBLE REFERENCE SENSOR AND FEMUR SENSOR. REMOVE BATTERIES PRIOR TO CLEANING.

Ultrasonic Cleaning Process

1. Remove and discard the battery from the reference sensor and femur sensor.
2. Clean the instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse or use moist towels or sponges soaked with distilled or de-ionized water to keep moist prior to cleaning.
3. Disassemble instruments into their component parts and unlock and extend levers as much as possible. **Remove the battery from the femur sensor and reference sensor. Keep battery cover attached to reference sensor for cleaning and sterilization.**
4. Immerse into the prepared enzymatic detergent following the detergent manufacturer's instructions. Soak for five (5) minutes.
5. Actuate all moving parts of instruments, as applicable and use a soft bristle brush and syringe to aid in cleaning all lumens, crevices, and hard to reach areas. Ensure all visible soils are removed.
6. Thoroughly rinse the devices under lukewarm running tap water for a minimum of one (1) minute. Ensure all hard-to-reach areas are flushed.
7. Fully immerse the instruments in an ultrasonic bath containing a second enzymatic detergent prepared according to the manufacturer's instructions and sonicate for ten (10) minutes.
8. Thoroughly rinse the instruments with RO/DI water to remove all detergent residues.
9. Dry the instruments with a clean, soft cloth. Filtered, pressurized air can be used if applicable.
10. Visually examine each instrument for cleanliness. Inspect each instrument with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances, and other debris) has been removed from surfaces, lumens, crevices, and serrations, if applicable. If visible soil remains, repeat the cleaning procedure until there is no adherent visible soil.

Manual Cleaning Process

1. Remove and discard the battery from the reference sensor and femur sensor.
2. Clean the instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, or use moist towels or sponges soaked with distilled or de-ionized water to keep moist prior to cleaning.
3. Disassemble instruments into their component parts. **Remove the battery from the femur sensor and reference sensor. Keep battery cover attached to reference sensor for cleaning and sterilization.**
4. Rinse the instruments under running cold utility (tap) water for 2 minutes.
5. Immerse into a prepared enzymatic detergent bath following the detergent manufacturer's instructions. Soak for 10 minutes.
6. Thoroughly rinse the devices under cold utility (tap) water for a minimum of 2 minutes. Ensure all hard-to-reach areas are flushed.

7. Immerse into a second prepared enzymatic detergent bath following the detergent manufacturer's instructions. Soak for 5 minutes.
8. While immersed, actuate all moving parts on instruments, as applicable, and use a soft bristle brush and syringe to aid in cleaning all lumens, crevices, and hard-to-reach areas. Ensure all visible soils are removed.
9. Thoroughly rinse the instruments with RO/DI water to remove all detergent residues for 2 minutes.
10. Dry the instruments with a clean, soft cloth. Filtered, pressurized air can be used if applicable.
11. Visually examine each instrument for cleanliness. Inspect each instrument with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g. blood, protein substances, and other debris) has been removed from the surfaces, lumens, crevices, and serrations, if applicable. If visible soil remains, repeat the cleaning procedure until there is no adherent visible soil.

Note: Use of water-soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.

AUTOCLAVE STERILIZATION OF RE-USABLE INSTRUMENTS

Use FDA-cleared sterilization wraps or appropriate FDA-cleared accessory that has been validated to allow sterilant penetration and to subsequently maintain sterility.

Do not stack trays during sterilization.

- Wrapped pre-vacuum, four (4) minutes minimum at 270°F (132°C). Minimum dry time is 50 minutes. Post cycle handling may be necessary under ST79. Recommendation of 30-minute wire rack cool down.

For emergency situations ONLY (e.g., intraoperative contamination):

- Unwrapped pre-vacuum ("Flash" or "Immediate Use"), four (4) minutes minimum at 270°F (132°C)

Reference sensor and femur sensor must be cooled prior to use: 15 minutes minimum for air-cooling. The reference sensor and femur sensor need to operate at room temperature. If sensors are still hot from autoclave, they can be cooled in sterile water.

The recommended sterilization process has been validated to product a sterility assurance level of (10^{-6}) when parts have been cleaned to the instructions above. Other steam cycles and cleaning procedures have not been evaluated and must be qualified by the user.

Prior to use, inspect reference sensor and femur sensor for moisture ingress. Do not use if moisture is detected.

Effective sterilization is predicated on thorough cleaning and drying processes. Failure to do so will compromise the sterilization process and render the processed instrument unsuitable for clinical use.

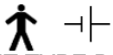
DISPOSAL

Do not throw Lantern Hip navigation unit in trash. Contains batteries and electronic PCBs that must be disposed of per local regulations.

OPERATING CONDITIONS

Temperature: 15 to 25°C; Humidity: 10 to 70% RH; (non-condensing); Pressure: 70 kPA to 106 kPA.

ELECTRICAL SAFETY

Protection against electrical shock: 

INTERNALLY POWERED EQUIPMENT TYPE B APPLIED PART.

THE LANTERN HIP NAVIGATION UNIT IS STERILE ON RECEIPT. ONE TIME USE – DO NOT ATTEMPT TO STERILIZE

EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.

Device is battery operated. No connection to external power.

Mode of Operation: Continuous Operation, Battery life 2.5 hours.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive (EN 55011 Class A and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate receiving device.
- Increase the separation between the equipment.
- Consult OrthAlign or authorized representative for help.

IEC 60601-1-2:2014 Electromagnetic Compatibility Guidance

This section provides the appropriate specification tables for Lantern Hip as per IEC 60601-1-2.

Table 1 Manufacturer's Declaration – Electromagnetic Emissions

Lantern Hip is intended for use in the electromagnetic environment specified below. The customer or user of Lantern Hip should assure that it is used in such an environment.	
Emissions Test	**Compliance Level**
RF Emissions CISPR 11	Group 1
	Class A

Table 2 Manufacturer's Declaration – Electromagnetic Immunity

Lantern Hip is intended for use in the electromagnetic environment specified below. The customer or user of Lantern Hip should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 6000 MHz	3 V/m 80MHz to 6000 MHz
Power frequency (50/60 Hz) magnetic field immunity IEC 61000-4-8	30 A/m	30 A/m

Caution: 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, the equipment and other equipment should be observed to verify that they are operating normally.

Caution: This equipment controls portable RF communications equipment which may affect medical electric equipment. This equipment should be used no closer than 40cm (16in) to any part of other medical electrical equipment or medical electrical systems.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

FCC ID: 2AVMS-406012 (Navigation Unit), FCC ID: RYYEYSGCN (Reference Sensor), and FCC ID: SQGBL653U (Femur Sensor).

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.

The maximum transmitted power is 8dBm

STORAGE AND TRANSPORTATION

Temperature: -30 to 60 ºC; Humidity: 10 to 95% RH; (non-condensing); Pressure: 60 kPa to 101 kPa.

Handle with care. Products should be stored in a clean, cool, dry area, away from chemical fumes.

CYBERSECURITY INFORMATION AND SECURE USE GUIDANCE

This section provides cybersecurity transparency information for Lantern Hip and associated system components. The information in this section is intended to help healthcare providers and users understand the system's cybersecurity protections and how to operate the system securely.

Cybersecurity is a shared responsibility between OrthAlign, healthcare providers, and users of Lantern Hip. This section describes the system's built-in cybersecurity protection and provides guidance for secure operation throughout the device lifecycle.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

1. SYSTEM OVERVIEW

Lantern Hip is a computer-assisted surgical navigation system intended to assist surgeons during knee or hip arthroplasty procedures. The system provides intraoperative guidance to assist surgeons in determining alignment axes and positioning instrumentation relative to anatomical structures. Lantern Hip consists of the following primary components:

Component	Description
Single-Use Navigation Unit	Sterile, single-use navigation device running custom software that provides surgical workflows and a touchscreen user interface.
Reference Sensor	Reusable wireless inertial sensor used to measure orientation and motion during surgical procedures
Femur Sensor	Reusable wireless sensor used during hip procedures to provide additional alignment and positioning information

During operation, the Navigation Unit communicates wirelessly with the Reference Sensor and Femur Sensor using Bluetooth Low Energy (BLE). The Navigation Unit uses Reference and Femur Sensor transmitted data to calculate and display surgical alignment information.

The Navigation Unit is intended for single use and is shipped in sterile packaging sealed with tamper-evident materials.

The Reference Sensor and Femur Sensor are reusable devices with limited authorized use counts enforced internally by the system.

Lantern Hip is designed to operate as a standalone surgical navigation system and does not require connection to hospital networks or external information systems during normal clinical operation.

2. CONNECTIVITY AND INTERFACES

Lantern Hip uses limited connectivity designed specifically for communication between authorized system components and authorized servicing activities. The following interfaces are present within the system hardware:

Interface	Purpose	Direction	Notes
Bluetooth Low Energy (BLE)	Communication between Navigation Unit, Reference Sensor, and Femur Sensor	Bidirectional	Primary wireless interface used during clinical operation
Wi-Fi	Manufacturing configuration and software servicing activities	Bidirectional	Disabled in fielded clinical devices and not used during surgical procedures
USB / UART service interfaces	Manufacturing programming, diagnostics, and servicing operations	Bidirectional	Restricted to authorized OrthAlign manufacturing and service personnel

BLE communication supports transmission of:

- Alignment and orientation data
- Sensor status information
- System operational status
- Diagnostic event information

The system does not require hospital network connectivity for clinical use.

3. BULT-IN CYBERSECURITY FEATURES

Lantern Hip incorporates multiple cybersecurity protections intended to maintain software integrity, preserve system functionality, and prevent unauthorized modification or misuse.

OPERATING SYSTEM SECURITY

The Navigation Unit operates using a customized Android-based software platform configured with multiple operating system security protections, including:

- Security Enhanced Linux (SELinux) operating in enforcing mode
- Mandatory access control policies applied to system processes
- Restriction of hardware access to authorized signed applications only
- Disabled Android Debug Bridge (ADB) and serial debugging interfaces during clinical use
- Disabled Wi-Fi programming interface following manufacturing activities

These protections help prevent unauthorized applications or software components from executing on the device.

SOFTWARE AND FIRMWARE INTEGRITY PROTECTIONS

The system incorporates mechanisms intended to ensure only authorized software and firmware can execute on system components. Examples include:

- Operating system and application signing on the Navigation Unit
- Bootloader verification of firmware authenticity
- Cryptographic verification of firmware updates using ECDSA P-256 digital signatures
- Dm-verity integrity verification on the Navigation Unit file system

Firmware updates that fail integrity or authenticity verification are rejected.

WIRELESS DEVICE AUTHENTICATION

The Navigation Unit will only recognize and communicate with approved Reference Sensors and Femur Sensors configured within an internal whitelist of authorized Bluetooth device addresses.

This control helps reduce the risk of unauthorized wireless devices communicating with the Navigation System.

PHYSICAL ANTI-TAMERING PROTECTIONS

The Navigation Unit is shipped in sterile packaging sealed with tamper-evident materials and a sterilization indicator sticker.

Users should inspect the packaging and tamper-evident indicators prior to use. Evidence of damaged packaging or tampering may indicate the device has been compromised, and the system should not be used clinically.

SELF-TEST AND INTEGRITY MONITORING

The system performs validation checks during startup and operation to verify proper device functionality. Examples include:

- Firmware integrity validation
- Electrical self-tests
- Power voltage monitoring
- Sensor communication verification
- Stale or invalid IMU data detection
- Calibration data validation
- BLE communication monitoring

If required checks fail, the system may display an error condition, sever communication between devices, or prevent clinical operation.

4. EVENT DETECTION AND LOGGING

Lantern Hip records operational and diagnostic events during use to support troubleshooting and service activities. Examples of logged events include:

- BLE connection and disconnection events
- Communication interruptions
- Device fault conditions
- Startup validation failures
- Diagnostic event information

The Navigation Unit records Reference and Femur Sensor BLE link event information that may be used by OrthAlign service personnel for troubleshooting or device investigation.

5. PROTECTION OF CRITICAL FUNCTIONALITY

Lantern Hip incorporates safeguards to maintain safe device operation under abnormal conditions or communication failures. Examples include:

- Prevention of angle display when communication is interrupted
- Detection of unstable sensor conditions

- Hardware watchdog functionality that automatically resets the Navigation Unit processor if required system heartbeat signals are not detected
- Integrity checks that prevent execution of unauthorized firmware
- Fault notifications are presented to the user when system abnormalities are detected

If communication with the Reference Sensor is lost, the Navigation Unit will display alignment information only after communication is restored and system stability is verified.

6. USE COUNT ENFORCEMENT AND LIMITED SERVICE LIFE

Lantern Hip incorporates controls intended to prevent use beyond the validated service life of each device component. Examples include:

- The Navigation Unit is limited to a single authorized use
- The Reference Sensor contains a limited number of authorized uses
- The Femur Sensor contains a limited number of authorized uses

Following completion of a procedure, the system decrements the remaining authorized use count stored internally on the applicable devices. Devices with no remaining authorized uses will not be permitted to operate further.

7. SOFTWARE UPDATES AND MAINTENANCE

Software and firmware updates for Lantern Hip are controlled by OrthAlign. The system is designed with a limited operational lifespan and is not intended to receive software or firmware updates during deployed clinical operation.

Manufacturing and servicing activities involving software loading or programming are restricted to OrthAlign or authorized OrthAlign service personnel. Firmware loaded during manufacturing is authenticated and verified prior to installation to ensure integrity and authenticity.

Users should contact OrthAlign customer support regarding any servicing or cybersecurity-related questions.

8. SECURE OPERATION GUIDANCE

Users should follow the recommendations below to help maintain safe and secure operation of the system:

- Use only OrthAlign-approved system components
- Use only approved Reference Sensors and Femur Sensors with the Navigation Unit
- Inspect sterile packaging and tamper-evident seals prior to use
- Do not use devices with damaged packaging or evidence of tampering
- Do not attempt to modify device hardware, firmware, or software
- Do not connect unauthorized accessories, programming tools, or diagnostic equipment to device interfaces
- Follow OrthAlign instructions for handling, servicing, storage, and disposal of reusable components
- Remove devices from service if repeated communication failures or abnormal system behaviors are observed

Unauthorized modification of the system may affect system functionality, cybersecurity protection, and patient safety.

9. DATA HANDLING

Lantern Hip does not store patient-identifiable clinical data.

Information stored on the system is limited to operational and device-related information, such as:

- Device configuration data
- Diagnostic logs
- Calibration information
- Operational status information
- Remaining authorized use counts

The system is not intended to store Protected Health Information (PHI) or Personally Identifiable Information (PII).

10. VULNERABILITY REPORTING

OrthAlign maintains processes for evaluating and responding to cybersecurity vulnerabilities and reported security concerns.

Users who identify suspected cybersecurity issues, abnormal device behavior, or potential vulnerabilities should contact OrthAlign customer support using the contact information on the device label.

OrthAlign evaluates reported issues and may provide additional guidance, servicing recommendations, or safety communications when appropriate.

11. DEVICE DECOMMISSIONING AND DISPOSAL

When removing system components from service:

1. Dispose of single-use Navigation Units after completion of the authorized procedure in accordance with local regulations governing electronic medical devices and batteries.
2. Dispose of reusable components after the authorized use count has been exhausted or if the device becomes damaged or nonfunctional.
3. Contact OrthAlign for additional disposal or return instructions if required.

Because the system does not store PHI or PII, decommissioning activities are limited primarily to device retirement and disposal rather than data sanitization activities.

12. ADDITIONAL CYBERSECURITY DOCUMENTATION

Additional cybersecurity documentation may be available from OrthAlign upon request, including:

- Manufacturer Disclosure Statement for Medical Device Security (MDS2)
- Software Bill of Materials (SBOM) information
- Cybersecurity advisories
- Servicing guidance
- Safety notifications

FOR FURTHER INFORMATION

If further information on this product is needed or you wish to obtain a return product authorization, please contact OrthAlign Customer Service at toll free 866-582-0879 or 949-715-2424 (available PST 8:00 a.m. - 5:00 p.m.) in the USA or your authorized representative, or at customerservice@orthalign.com

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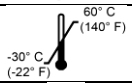
SYMBOL LEGEND

	Caution, See Instructions for Use
Warning:	Warning: Indicate instructions present to avoid potentially serious injury to the patient and/or user of the system.
	Note: Indicate information which may be valuable to the user in improving efficiency and/or general usability of the system.
	Manufacturer
	Serial Number
	Catalog Number
QTY	Quantity of Units
CONF	Configuration
SW	Software
SW P/N	Software Part Number
R_x Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Sterilized Using Ethylene Oxide
	Battery Operated
	Class B Installation
	Do Not Dispose in Trash (WEEE)
	Keep Dry
	Storage Temperature
	Fragile Handle with Care
	Expiration Date
	Do Not Reuse
	Follow Instructions for Use
	Consult Instructions for Use
	Do Not Impact
FCC ID: XXXXX- XXXXXX	This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) Device must not cause harmful interference (2) Device must accept any interference received, including interference that may cause undesired operation.