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IMPORTANT INFORMATION FOR PHYSICIANS, SURGEONS, AND STAFF

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

"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.
2. This device must accept any interference received, including interference that may cause undesired operation."

Device Description

The Ruthless Spine RJB device is an intraoperative surgical angle measurement guide that attaches to surgical instruments to measure the angle of the instrument relative to a vertical plumb line in line with gravity. The device can measure the axial and sagittal angles relative to gravity. The RJB system only provides measurements for angles in two planes relative to the vertical gravitational plumb line. As such, the RJB device does not provide surgical assistance, guidance, or navigation against patient anatomy. The RJB device is not intended to replace a surgeon's clinical judgement and has not undergone clinical evaluation. No clinical benefit has been demonstrated or is claimed.

The RJB device is provided sterile for single use and utilizes Bluetooth Low Energy (BLE) to connect to a tablet computer and display the angle measurements via the RJB Application (App). A set of handles and instruments compatible with the RJB are provided with the device for use in lumbosacral pedicle screw placement. The following components are part of the RJB system:

- RJB Device
- Quick Connect Axial Ratcheting Handle
- Straight Probe
- Duckbill Probe
- RJB Application

Note, a Tablet Computer is required to operate the device. The Tablet is not provided to the end user.

See Appendix A for a complete listing of system components, part numbers, and accompanying images/illustrations.

Device Characteristics
Model: RJB6
Precision of Displayed Values: User choice of 0.5 or 1° in app
Procedural Measurement Accuracy*: ±3°
*Measurements made relative to a vertical plumb line in line with gravity. This measurement accuracy was determined through simulated use testing of the device in a lumbar pedicle screw placement procedure.

Operating Condition: -18 – 55°C, 15 – 90% relative humidity, 70 – 106 kPa

Wireless Technology
RJB uses low energy Bluetooth (Bluetooth Core Specification 4.0)
Bluetooth module FCC ID: SH6MDBT42Q
RJB has a Qualified Design ID (QDID) of 125047

Indications for Use
The Ruthless Spine RJB device is intended to measure the angle of surgical instruments in two planes relative to a vertical plumb line in line with gravity. It is indicated for use during lumbosacral pedicle screw implantation in conjunction with applicable spinal instrumentation and as an adjunct to fluoroscopy or intraoperative x-ray. The RJB device is not intended to replace a surgeon's judgment and has not undergone clinical evaluation. No clinical benefit has been demonstrated or is claimed.

Limitations
No clinical studies, Real World Data (RWD) or Real World Evidence (RWE), or other information are available to evaluate the effect of patient demographics, such as race and ethnicity, on RJB device performance.

Warnings
RJB devices are provided STERILE and must never be reused under any circumstances. Discard any devices that are opened in the operating room but are not used. Re-use of this device may result in serious cross infection or be harmful to the patient.

Do not re-sterilize. Re-sterilization may adversely affect material properties and device performance.

Do not use devices that are received damaged or missing a pull tab.

No modification of the RJB system is allowed.

The RJB device shall only be used by physicians or surgeons trained in lumbosacral pedicle screw procedures. The RJB app may be used by a designated, trained user outside of the sterile field.

During RJB use, the instrument may be tilted in the axial and sagittal planes simultaneously but should not be axially rotated about the slotted handle shaft. Rotation of the RJB device around the handle axis during intraoperative angle measurement can introduce significant error.

The RJB system provides measurements for angles in two planes (axial and sagittal) relative to the vertical gravitational plumb line and does not consider patient anatomy or orientation. The RJB is a spatial tool and not a navigation system providing trajectory guidance.

Contraindications
The device is contraindicated for use in any procedure except for those listed in the Indications for Use.

Cleaning and Sterilization
RJB devices are provided sterile (ethylene oxide sterilization) and are single use. Do not clean or re-sterilize devices. Unused or contaminated devices should be disposed of in accordance with facility protocol. Following use, devices should also be disposed of in accordance with facility protocol.

RJB instruments and handles are provided visually clean and non-sterile and must be sterilized prior to use. None of the provided instruments or handles are reusable. The following sterilization cycle has been validated for the instruments and handles:

Method:	**Steam**
Cycle:	**Pre-Vacuum**
Temperature:	**270°F (132°C)**
Exposure Time:	**4 minutes**
Dry Time:	**20 minutes**

Instruments should be placed in an FDA-cleared tray and double wrapped in an FDA-cleared sterilization wrap both indicated for the sterilization parameter included in the Instructions for Use. Instruments should be positioned to allow the steam to come into contact with all surfaces. Remove all packaging material prior to sterilization. Only sterile instruments should be used in surgery.

Do not clean or re-sterilize instruments. Unused or contaminated instruments should be disposed of in accordance with facility protocol. Following use, instruments should also be disposed in accordance with facility protocol.

Storage and Handling
Store sterile packaged devices in a manner that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.

Storage Condition: -18 – 50°C, 15 – 90% relative humidity, 70 – 106 kPa

Tablet and App Installation Instructions
The tablet used for running the RJB App is supplied by the user and must be dedicated to RJB App use and not be used for any other purpose. The following are the minimum tablet specifications required for the RJB App:

Minimum Tablet Requirements:

Apple
iPad Pro 11” (4th Generation) and above
Storage: 128GB
iOS: 14 and above
Camera: Camera access is desirable but not required (device barcode may be input manually)
Bluetooth: 4.0 and above
Wi-Fi: Is required to download the app but is not necessary for App usage
Cellular connectivity: Not required

Minimum Tablet Requirements (cont'd):

Android
Storage: 32GB
Android OS: 10 and above
Processor Specifications: 2.0 GHz
Memory: 2GB RAM
Camera: Camera access is desirable but not required (device barcode may be input manually).
If camera function is utilized, minimum camera resolution is an 8MP main camera with auto-focus.
Bluetooth: 4.0 and above
Wi-Fi: Is required to download the app but is not necessary for App usage
Cellular connectivity: Not required

Do not download or install any applications or programs on the tablet apart from the RJB App and security-based tablet software. A Wi-Fi connection is not required for RJB App usage but must be enabled for app installation and updating. Install all tablet operating system updates prior to App use using only known safe and secure networks outside of the hospital. App updates should only be performed when the user is directed to update the app. The user will be informed directly by Ruthless Spine of the need for an update and does not need to rely on Apple or Google Play store update notifications. Do not enable Wi-Fi or connect the tablet to any network during App use. Turn off all other Bluetooth devices in the operating room (use environment) during RJB pairing with the tablet. Do not allow the tablet to be plugged into any external USB computers, networks, or other peripherals during App use. Only factory delivered charging cables and adapters should be used.

1. Download the RJB App from the iTunes store (Apple tablets) or from a one-way download link provided directly to the user (Android tablets) using a known safe and secure Wi-Fi network outside of the hospital.
2. Turn on Do Not Disturb Mode on tablet.
    a. Apple: Go to Settings → Do Not Disturb and turn it ON. The options should be as follows: Scheduled is OFF, Silence is "Always", Phone is "Allow Calls From No One", Repeated Calls is OFF.
    b. Android: Go to Settings → Notifications → Do Not Disturb and turn it ON. The options should be as follows: Turn On as Scheduled is OFF, Duration is "Until I Turn it Off", Hide Notifications → Hide All is ON, Allow exceptions → Calls From is "None", Repeat Callers is OFF, Messages From is "None", Alarms is OFF, Media Sound is ON, Touch Sounds is ON, Calendar Events is OFF, Reminders is OFF.
3. Turn off Wi-Fi on tablet.
    a. Apple: Go to Settings → Wi-Fi, Wi-Fi is OFF.
    b. Android: Go to Settings → Connections, Wi-Fi is OFF.

RJB Operating Instructions

1. Turn on the RJB device by removing and discarding the battery pull tab.
2. Insert the RJB device into the handle slot. Follow the markings for device orientation. The slot should only allow the device to be inserted in one way.
3. Deploy the Ruthless RJB app on a tablet.
4. When the app is opened, a tablet screen prompts to pair the RJB device. The RJB identifier can be scanned from the label or manually inputted.
5. After pairing the device, a prompt will appear to select the instrument type.
6. Once the instrument type is selected, the starting screen will appear. From here, the user can see the angle of the device, hold the angle, offset the angle, edit the instrument name, choose display precision, and watch tutorial videos.

    a. Hold and offset features are controlled via touchscreen buttons in the tablet app.
7. For use, the instrument should be oriented such that the face of the RJB (marked with 'UP' and 'DOWN' and visible through the front of the handle slot) is in a plane parallel with the plane of the operating table, without introducing rotation about the instrument shaft. During use, the instrument may be tilted in the axial and sagittal planes simultaneously but should not be rotated about its own shaft. Use the marked face of the RJB to reference the position of the instrument throughout the procedure.
8. When using the RJB, it is recommended that the surgeon follow standard fluoroscopy-guided technique, utilizing fluoroscopy as necessary to confirm pedicle screw trajectory intraoperatively. The RJB is a spatial tool and not a navigation system providing trajectory guidance.
9. If Bluetooth connection is lost (displayed angles disappear or freeze), restart app.
    a. If RJB device does not pair, turn on, or app does not restart, discard the device by disposing in accordance with facility protocol. Revert to standard fluoroscopy-guided technique to complete the procedure.
10. To terminate operation of the device, close the RJB app. Remove RJB from the instrument handle and dispose in accordance with facility protocol.

Product Complaints

Any healthcare professional (e.g., customer or user) who has a complaint or who has experienced any dissatisfaction in the product quality, durability, reliability, safety, effectiveness, and/or performance should notify the distributor and/or Ruthless Spine:

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When reporting a complaint, please provide the unique identification number (UDI) or the lot number, your name and phone number, and the nature of the problem.

The surgical technique is available at no charge upon request.

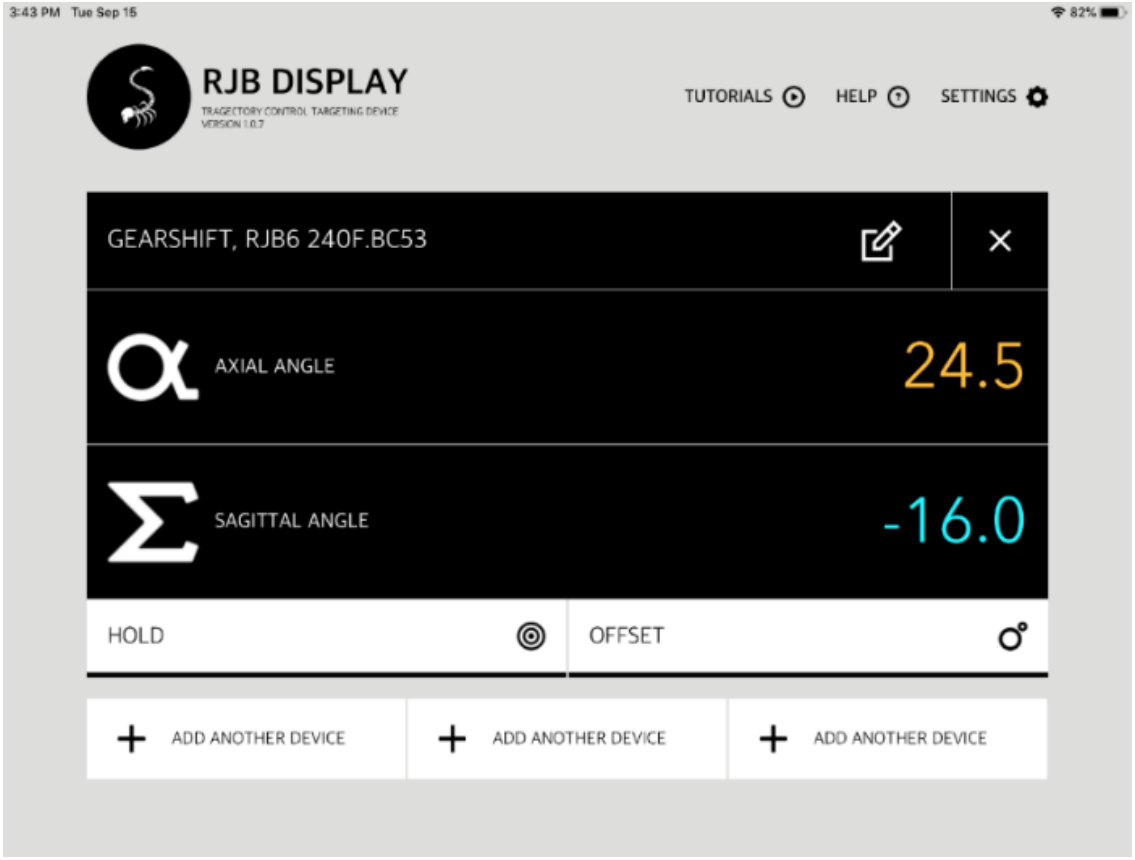
Label Symbols

Symbol (Reference Number)	Meaning	Standard of Origin
 (5.1.1)	Manufacturer, indicates the medical device manufacturer	ISO 15223-1 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
 (5.1.4)	Use-by-date, indicates the date after which the medical device is not to be used	
 (5.1.5)	Batch bode, indicates the manufacturer's batch code so that the batch or lot can be identified	
 (5.1.6)	Catalog number, indicates the manufacturer's catalog number so that the medical device can be identified	
 (5.2.3)	Sterilized using ethylene oxide, indicates the medical device has been sterilized using ethylene oxide	
 (5.2.7)	Non-sterile, indicates a medical device that has not been subjected to a sterilization process. Instruments and handles are provided non-sterile and should be cleaned and sterilized per the Instructions for Use prior to use.	
 (5.2.8)	Do not use if package is damaged, indicates a medical device that should not be used if the package has been damaged or opened	
 (5.3.7)	Temperature limit, indicates the temperature limits to which the medical device can be safely exposed	
 (5.3.8)	Humidity limitation, indicates the range of humidity to which the medical device can be safely exposed	
 (5.3.9)	Atmospheric pressure limitation, indicates the range of atmospheric pressure to which the medical device can be safely exposed.	

(5.4.2)	Do not re-use, indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	
(5.4.3)	Consult instructions for use, indicates the need for the user to consult the instructions for use.	
Rx	Prescription use, indicates that the device is intended for prescription use only	21 CFR 801.109

Appendix A – System Component Identification

Part Number	System Component Description	Image/Illustration
RJB6	RJB Device	 (Left = device front, Right = device back)
RJB-HND1	Quick Connect Axial Ratcheting Handle	 (Example illustration, handles provided may have a different color)
RJB-PRB1	Straight Probe	 (Example illustration, handles provided may have a different color)

RJB-PRB2	Duckbill Probe	 (Example illustration, handles provided may have a different color)
N/A	RJB Application	 (Example screenshot)