WalterLorenz® Surgical Assist Arm

PRODUCT MANUAL
WAL100S and WAL100L
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</tr>
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<td>B</td>
<td>Appendix: Breakdown and Cleaning Reference Guide</td>
<td>34</td>
</tr>
</tbody>
</table>
Section 1: Contents of the WalterLorenz Surgical Assist Arm

The following components are included with the WalterLorenz Surgical Assist Arm system, WAL100S or WAL100L (hereafter referred to as “Surgical Assist Arm, the Arm, or Assist Arm”), and packaged within a Pelican case. Check to see that all of these components are available before proceeding:

- WalterLorenz Surgical Assist Arm
- Rotating Table Rail Clamp
- External Power Supply with Cord
- Pelican Case

If any of these components are missing, contact the manufacturer immediately:
Biomet Microfixation • 1520 Tradeport Drive • Jacksonville, FL 32218-2480 USA
Phone: 800.874.7711 or 904.741.4400 • www.zimmerbiomet.com

The following items are sold separately, but are necessary for operation of the WalterLorenz Surgical Assist Arm:

<table>
<thead>
<tr>
<th>REQUIRED FOR USE</th>
<th>USE WITH EITHER/OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>WalterLorenz End Effector</td>
<td>WalterLorenz Universal Instrument Holder(s)</td>
</tr>
<tr>
<td>Sterile Electronic Activation Button and Drape</td>
<td>WalterLorenz Direct Connection Instrument(s)</td>
</tr>
</tbody>
</table>

All trademarks herein are the property of Zimmer Biomet or one of its subsidiaries unless otherwise indicated.
Section 2: Introduction

The WalterLorenz Surgical Assist Arm is a table-mounted, electromechanical holding arm for use in professional health care facilities. The primary function of the WalterLorenz Surgical Assist Arm is to hold and stabilize instrumentation for controlled retraction and/or positioning. The device is to be used by a trained medical professional for the indicated uses only.

The WalterLorenz Surgical Assist Arm is indicated for tissue retraction, anatomical positioning, instrument positioning/holding, and scope holding during surgical use. The WalterLorenz Surgical Assist Arm should be used in combination with instrumentation and surgical tools to provide visualization, access, and steady holding throughout surgical procedures. It is repositioned as needed using electromechanical functionality activated by either a distal unlock button or the unlock button on the User Interface Keypad.

The WalterLorenz Surgical Assist Arm should not be utilized in procedures where unanticipated patient movement could cause harm without properly immobilizing the patient or anatomy relative to the operating table (such as retraction of the orbit without stabilizing the head).

This manual describes the recommended procedures for setting up and operating the WalterLorenz Surgical Assist Arm. It does not describe how any medical procedure is to be performed on a patient using the device. The manufacturer does not practice medicine and therefore, medical professionals should ultimately make the appropriate decisions regarding retraction and placement of the device, in order to meet the needs of the surgical plan for each patient.

The surgeon is to be familiar with the equipment, instruments, and surgical procedure prior to performing surgery. This device should only be used for its intended purpose. Failure to use the device according to all labeling and instructions may result in injury to the patient or user, or damage to the device.

The information contained within this manual, and all associated labeling and literature, should be read and understood prior to use of the WalterLorenz Surgical Assist Arm. It is important that you read, understand, and comply with all the indicated safety precautions, warnings, instructions, markings, and symbols. Failure to follow this safety information could result in injury to the patient or user, or damage to the device. Do not use the device outside of a professional health care facility; the device is not intended for use by a patient or in the home environment.

To maintain this device in optimal conditions, follow all recommendations in this manual for handling, cleaning, and storage.

The device is to be used by trained medical professionals for the indicated uses only.
Section 3: Regulatory Compliance

Operating surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities for which they are involved prior to handling and use of this product.

Federal law (USA) restricts this device to sale by or on the order of a physician, dentist, or properly licensed practitioner.

- This device complies with IEC 60601-1 and all collateral standards, as required.
- This device complies with Electromagnetic Compatibility per IEC 60601-1-2.
- This device complies with part 15 of the FCC rules.
- This device complies with the Waste Electrical and Electronic Equipment directives.
- This device complies with AIM 7351731

GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC EMISSIONS

The WalterLorenz Surgical Assist Arm is intended for use in the electromagnetic environment specified below. The customer or the user of the Surgical Assist Arm should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The WalterLorenz Surgical Assist Arm uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td>The WalterLorenz Surgical Assist Arm is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
## Section 3: Regulatory Compliance

### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The WalterLorenz Surgical Assist Arm is intended for use in the electromagnetic environment specified below. The customer or the user of the Arm should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±8 kV contact</td>
<td>±8 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>±2 kV, ±4 kV, ±6 kV, ±8 kV, ±15 kV air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±1 kV for input/output lines 100 kHz repetition frequency</td>
<td>Not Applicable for input/output lines, &lt; 3 meters 100 kHz repetition frequency</td>
<td></td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±0.5 kV, ±1 kV differential mode</td>
<td>±0.5 kV, ±1 kV differential mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±0.5 kV, ±1 kV, ±2 kV common mode</td>
<td>±0.5 kV, ±1 kV, ±2 kV common mode</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and</td>
<td>0 % $U_i$: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td>
<td>0 % $U_i$: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Surgical Assist Arm requires continued operation during power mains interruptions, it is recommended that the Arm be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>voltage variations on power supply input lines IEC 61000-4-11</td>
<td>% $U_i$: 1 cycle 70 % $U_i$: 25/30 cycles for 50 Hz and 60 Hz, respectively Single phase: at 0°</td>
<td>% $U_i$: 1 cycle 70 % $U_i$: 25/30 cycles for 50 Hz and 60 Hz, respectively Single phase: at 0°</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0 % $U_i$: 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°</td>
<td>0 % $U_i$: 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

**NOTE:** $U_i$ is the a.c. mains voltage prior to application of the test level.
# Section 3: Regulatory Compliance

## GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY

The WalterLorenz Surgical Assist Arm is intended for use in the electromagnetic environment specified below. The customer or the user of the Surgical Assist Arm should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Surgical Assist Arm, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
<td>3 Vrms</td>
<td>Recommended separation distance</td>
</tr>
<tr>
<td></td>
<td>ISM bands</td>
<td>6 Vrms</td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td></td>
<td>between 0,15 MHz and 80 MHz</td>
<td>9 V/m to 28 V/m</td>
<td>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td>3 V/m</td>
<td>3 V/m</td>
<td>$d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz</td>
</tr>
<tr>
<td></td>
<td>80 MHz to 2.7 GHz</td>
<td></td>
<td>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m).</td>
</tr>
<tr>
<td></td>
<td>Per Table 9 of 60601-1-2.2014</td>
<td></td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, shall be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m</td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
<tr>
<td></td>
<td>80 MHz to 800 MHz</td>
<td></td>
<td>📡</td>
</tr>
</tbody>
</table>

### NOTE 1
At 80 MHz and 800 MHz, the higher frequency range applies.

### NOTE 2
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

---

*a* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EUT is used exceeds the applicable RF compliance level above, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT.

*b* Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.
**Section 3: Regulatory Compliance**

**RECOMMENDED SEPARATION DISTANCES**
**BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE WALTERLORENZ SURGICAL ASSIST ARM**

The WalterLorenz Surgical Assist Arm is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Arm can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
<th>150 kHz to 80 MHz</th>
<th>80 MHz to 800 MHz</th>
<th>800 MHz to 2.7 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td></td>
<td>0.12</td>
<td>0.12</td>
<td>0.23</td>
</tr>
<tr>
<td>0.1</td>
<td></td>
<td>0.38</td>
<td>0.38</td>
<td>0.73</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>1.20</td>
<td>1.20</td>
<td>2.30</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td>3.79</td>
<td>3.79</td>
<td>7.27</td>
</tr>
<tr>
<td>100</td>
<td></td>
<td>12.00</td>
<td>12.00</td>
<td>23.00</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Section 4: Technical Specifications

Power Supply
Input voltage: 100-240VAC, 50-60Hz
Output voltage: 18 VDC
Output current: Up to 1.67A (30 Watts)
Power connector: Barrel Plug 2.5mm ID x 5.5mm OD
Classification: Certified to EN 60601-1
Mode of operation: Continuous

Environmental
Operating temperature: 10°C to 40°C (50°F to 104°F)
Operating humidity: 10% to 85% RH, non-condensing
Operating pressure: 70-106 kPa
Operating altitude: ≤ 2,000m
Storage/transport temperature: -29°C to 60°C (-20°F to 140°F)
Storage/transport humidity: 0% to 85% RH, non-condensing
Storage/transport pressure: 70-106 kPa

Expected Product Life 2 years
The WalterLorenz Surgical Assist Arm system and components should be treated as Medical Electrical Equipment (ME Equipment) per IEC 60601-1. Applied parts, that in normal use of ME equipment, come into contact with the patient must be Type CF applied parts. Contact the manufacturer with any questions regarding appropriate connections for the WalterLorenz Surgical Assist Arm.
## Section 5: LED Status Codes

<table>
<thead>
<tr>
<th>LED LIGHT COLOR</th>
<th>MEANING</th>
</tr>
</thead>
<tbody>
<tr>
<td>No lights illuminated</td>
<td>The device is in the unlocked state or powered off.</td>
</tr>
<tr>
<td>Blue</td>
<td>The device is powered on and in the locked state.</td>
</tr>
<tr>
<td>Yellow</td>
<td>Battery has 10% charge remaining. Note that the battery indicator will show one bar illuminated.</td>
</tr>
<tr>
<td>Slow Flashing Red</td>
<td>Battery has 5% charge remaining. Note that the battery indicator will show one bar illuminated.</td>
</tr>
<tr>
<td>Fast Flashing Red</td>
<td>Shut down will occur within 20 seconds. Note: If this occurs, device will be able to be powered back on once so that it may be unlocked and quickly removed from the operating field.</td>
</tr>
<tr>
<td>Solid Red</td>
<td>Fault in the device. Contact your sales representative or the manufacturer.</td>
</tr>
<tr>
<td>Red, Yellow, Blue Sequence</td>
<td>The device is being powered on.</td>
</tr>
</tbody>
</table>

Note that battery indicator bars will not illuminate if the device is powered off.

The light ring around the button will illuminate and match the color indication of the LED lights at the top of the Base Unit. It is important to be aware of any changes in the light ring or LED color as yellow and red indicators should be addressed immediately.
Section 6: Warranty Information

The WalterLorenz Surgical Assist Arm System (Items WAL100S & WAL100L), including Base Unit, Power Supply with Cord, and Rotating Table Rail Clamp; End Effectors, Universal Holders, and Direct Connection Instrumentation, when purchased and delivered to the end user (“User”) in new condition in the original container (collectively “the WalterLorenz Surgical Assist Arm”), are warranted to perform in accordance with the WalterLorenz Surgical Assist Arm Product Manual (“Product Manual”) and be free from defects in material or workmanship for one year from the date of invoice (“Warranty Period”) from Biomet Microfixation (“Zimmer Biomet”) to the User (the entire paragraph shall be collectively referred to as “Warranty”).

Within the above listed time period, parts that are returned, freight prepaid by purchaser and/or User, to Zimmer Biomet and are determined to be defective will be repaired or replaced without charge for parts and labor (shipping methods and costs shall be solely determined by Zimmer Biomet) within a reasonable time. This warranty does not cover products intended for single patient use beyond the initial use for consumable items.

The above Warranty by Zimmer Biomet shall constitute your exclusive remedy and Zimmer Biomet’s sole obligation under this warranty for any such defects in material or workmanship. Zimmer Biomet shall not be responsible for warranty claims made after the expiration of the Warranty Period, regardless of whether the alleged defect occurred during the Warranty Period. To obtain warranty repair service, you must contact Zimmer Biomet, prior to the expiration of the Warranty Period, to obtain a Return Goods Authorization (“RGA”) number, and then return the device to Zimmer Biomet or to a service facility authorized by Zimmer Biomet. The RGA number and a complete explanation of the problem must be included with the WalterLorenz Surgical Assist Arm being returned to Zimmer Biomet for warranty service. The WalterLorenz Surgical Assist Arm to be repaired must be returned in its original box and packaging, or a similar box and packaging affording an equivalent degree of protection. Upon completion of repairs, Zimmer Biomet will return the device to the User.

Zimmer Biomet shall have no liability or obligation for a WalterLorenz Surgical Assist Arm that has been subjected to any of the following:
Failure caused by or attributable to Acts of God, improper use, abuse, negligent care or handling, accident, faulty installation, improper cleaning, improper maintenance, or other indications of excess voltage. This warranty is also void if the device has been repaired or modified by anyone other than Zimmer Biomet without prior written authorization from Zimmer Biomet, if the User has failed to follow the instructions or heed the warnings or specifications in the WalterLorenz Surgical Assist Arm Product Manual, or if the device’s serial number has been removed or altered.

EXCEPT FOR THE FOREGOING WARRANTIES, ZIMMER BIOMET HEREBY DISCLAIMS AND EXCLUDES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY AND/OR ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ZIMMER BIOMET HEREBY DISCLAIMS ANY REPRESENTATIONS OR WARRANTY THAT THIS WALTERLORENZ SURGICAL ASSIST ARM OR ANY OF ITS PARTS IS COMPATIBLE WITH NON-ZIMMER BIOMET PRODUCTS AND USER ASSUMES ALL RISK FOR SUCH USE WITH NON-ZIMMER BIOMET PRODUCTS. THE LIABILITY OF ZIMMER BIOMET, IF ANY, AND USER’S SOLE AND EXCLUSIVE REMEDY FOR DAMAGES FOR ANY CLAIM OF ANY KIND WHATSOEVER, REGARDLESS OF THE LEGAL THEORY, SHALL NOT BE GREATER IN AMOUNT THAN THE PURCHASE PRICE OF THE DEVICE SOLD TO USER/PURCHASER BY ZIMMER BIOMET. IN NO EVENT SHALL ZIMMER BIOMET BE LIABLE TO USER/PURCHASER FOR ANY SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY KIND.
## Section 7: List of Symbols

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="REF" /></td>
<td>Part Number</td>
</tr>
<tr>
<td><img src="image2.png" alt="LOT" /></td>
<td>Lot</td>
</tr>
<tr>
<td><img src="image3.png" alt="SN" /></td>
<td>Serial Number</td>
</tr>
<tr>
<td><img src="image4.png" alt="Charging Port" /></td>
<td>Charging Port</td>
</tr>
<tr>
<td><img src="image5.png" alt="Consult the Instructions for Use" /></td>
<td>Consult the Instructions for Use</td>
</tr>
<tr>
<td><img src="image6.png" alt="Unlock Button Port" /></td>
<td>Unlock Button Port</td>
</tr>
<tr>
<td><img src="image7.png" alt="Type CF Applied Part" /></td>
<td>Type CF Applied Part</td>
</tr>
<tr>
<td><img src="image8.png" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image9.png" alt="WEEE Compliant" /></td>
<td>WEEE Compliant</td>
</tr>
<tr>
<td><img src="image10.png" alt="Non-Ionizing Radiation" /></td>
<td>Non-Ionizing Radiation (Interference may occur in the vicinity of equipment marked with this symbol.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image11.png" alt="ETL Classification" /></td>
<td>ETL Classification</td>
</tr>
<tr>
<td><img src="image12.png" alt="Unlock Button" /></td>
<td>Unlock Button</td>
</tr>
<tr>
<td><img src="image13.png" alt="Battery Life" /></td>
<td>Battery Life</td>
</tr>
<tr>
<td><img src="image14.png" alt="Charging Status" /></td>
<td>Charging Status</td>
</tr>
<tr>
<td><img src="image15.png" alt="Power Button" /></td>
<td>Power Button</td>
</tr>
<tr>
<td><img src="image16.png" alt="Federal Law (USA) restricts this device to sale by or on the order of a physician, dentist or properly licensed practitioner." /></td>
<td>Federal Law (USA) restricts this device to sale by or on the order of a physician, dentist or properly licensed practitioner.</td>
</tr>
<tr>
<td><img src="image17.png" alt="Temperature Limit" /></td>
<td>Temperature Limit</td>
</tr>
<tr>
<td><img src="image18.png" alt="Humidity Limitation" /></td>
<td>Humidity Limitation</td>
</tr>
<tr>
<td><img src="image19.png" alt="Atmospheric Pressure Limitation" /></td>
<td>Atmospheric Pressure Limitation</td>
</tr>
</tbody>
</table>
Section 8: Product Features and Specifications

The WalterLorenz Surgical Assist Arm is a table-mounted, electromechanical holding arm and is designed for controlled retraction and/or positioning of instruments. The device connects to OR table rails and may be adjusted to multiple heights and positions depending on the procedure and set-up required. Once set up, the WalterLorenz Surgical Assist Arm is easy to maneuver and position by depressing the actuation button twice and holding to unlock the device, allowing it to move with 6 degrees of freedom.

Manual instruments such as retractors, forceps, and elevators may be connected to the WalterLorenz Surgical Assist Arm via one of two methods: (1) A proprietary direct connection to the End Effector or (2) utilizing a Universal Instrument Holder.

The WalterLorenz Base Unit
Base Unit is comprised of the Distal Arm, Proximal Arm with Counterbalance, Control Box, and Pole.

The Control Box houses the electronics and permanent battery pack for the WalterLorenz Surgical Assist Arm. It features a User Interface Keypad with a power button, an unlock button, and a battery gauge indicator for an estimation of remaining battery power. LED lights above the User Interface Keypad illuminate according to the status of the device. A key describing the colors of the LED status lights is provided in Section 5.

Two ports are located on the underside of the control box for attachment of the power cord and the cable connected to the Sterile Electronic Activation Button. The Charging Port marked 🌌 should be used to connect the power cord for charging of the WalterLorenz Surgical Assist Arm. The Unlock Button Port marked 🪝 should be used to connect the Sterile Electronic Activation Button.

WalterLorenz Surgical Assist Arm Anatomy

1. Distal Arm (Long or Short) *
2. Proximal Arm
3. Control Box with User Interface Keypad
4. Pole (not shown, attached below the Control Box)

*Long Distal arm is shown above
Note: The Base Unit consists of the distal arm, proximal arm, control box with user interface keypad, and straight pole.
Section 8: Product Features and Specifications

The WalterLorenz Surgical Assist Arm
The WalterLorenz Surgical Assist Arm can be ordered with either a short or long distal arm based on the customer’s preference. The Short or Long distal arms will be permanently attached to the proximal arm and not removable.

Rotating Table Rail Clamp
The Rotating Table Rail Clamp allows the user to attach the WalterLorenz Surgical Assist Arm to OR table rails. The clamp provides the ability to adjust the height of the device as well as providing the ability to maintain the required vertical orientation of the pole (90° to the floor) if the OR table is repositioned at an angle during the surgical procedure. The provided rail clamp fits all standard OR table rails (3/8" [1 cm] wide by 1 1/8" [2.9 cm] height).

External Power Supply
The External Power Supply with Cord is used to connect the Base Unit to a power outlet for battery charging. The device may be used while the battery is charging. The total cord length is 14.7 feet.
Section 8: Product Features and Specifications

**End Effector**
The End Effector provides the connection between the Distal Arm and the instrumentation. It also provides attachment points for the Sterile Electronic Activation Button and the sterile drape. The End Effector features a proprietary connection that holds Direct Connection Instruments or Universal Instrument Holders.

**Sterile Electronic Activation Button and Drape**
The Sterile Electronic Activation Button is a sterile, disposable accessory provided separately and serves as a convenient activation point on the Arm for unlocking the WalterLorenz Surgical Assist Arm. The Sterile Electronic Activation Button cable is plugged into the Base Unit on the underside the Control Box.

Packaged with the Sterile Electronic Activation Button is a sterile drape. The drape is intended to cover the WalterLorenz Surgical Assist Arm to maintain a sterile field during surgical procedures.

**Direct Connect Instrumentation**
Instrumentation is available with a direct connection end for attachment and use with the WalterLorenz Surgical Assist Arm. An example of a Direct Connect Instrument is shown to the right. Contact your Sales Representative or the Manufacturer for more product offerings.
Section 8: Product Features and Specifications

Universal Instrument Holders
Universal Instrument Holders are available to accommodate various surgical instruments and handle patterns without the direct connect feature.

WalterLorenz Surgical Assist Arm Universal Instrument Holder Flat - WAL301

WalterLorenz Surgical Assist Arm Universal Instrument Holder Small - WAL302

WalterLorenz Surgical Assist Arm Universal Instrument Holder Large 90° - WAL316

WalterLorenz Surgical Assist Arm Universal Instrument Holder Large Inline - WAL317

WalterLorenz Surgical Assist Arm Universal Forceps Holder - WAL304

WalterLorenz Surgical Assist Arm Scope Holder
The Scope Holder is a surgical device intended to hold scopes (such as endoscopes, arthroscopes, etc) during general and neurologic procedures. The holder accommodates a range of scope sizes from 2.7mm - 10mm.

WalterLorenz Surgical Assist Arm Scope Holder - WAL305
Section 9: Safety Information

The information contained within this manual, and all associated labeling and literature, should be read and understood prior to use of the WalterLorenz Surgical Assist Arm. It is important that you read, understand, and comply with all the indicated safety precautions, warnings, instructions, markings, and symbols. Failure to follow this safety information could result in injury to the patient or user, or damage to the device.

To avoid user/patient injury and damage to this device:

• Always ensure that the WalterLorenz Surgical Assist Arm is fully locked before the user releases control of the device. During use, it is possible to achieve positions or orientations that may not be strong enough to maintain the rigidity of the device for the desired application. It is imperative that the user be aware of the device performance at all times and ensure that when the user releases the unit, the Arm does not move, give, or twist. If any signs are observed that the device is not stable for the desired application, it should be immediately inspected for correct assembly, repositioned or use discontinued, as the device may not be appropriate for the application.

• Excessive force should not be applied to the WalterLorenz Surgical Assist Arm. Excessive force or torque may damage the device, cause harm to the patient, user, or third party, or leave the devices susceptible to further damage or fracture.

• The surgeon is to be familiar with the equipment, instruments, and surgical procedure prior to performing surgery. This device should only be used for its intended purpose. Failure to use the device according to all labeling and instructions may result in injury to the patient or user, or damage to the device.

• The patient is to be made aware and warned of general surgical risks, including but not limited to: nerve damage, dural puncture or damage, bone perforation and bone fracture, and to follow the instructions of the treating physician.

• To reduce the risk of infection and cross-contamination, the WalterLorenz Surgical Assist Arm must be properly draped prior to use. The Surgical Assist Arm must be properly draped following the guidelines in the package insert accompanying the Sterile Electronic Activation Button and Drape (IFU 01-50-1640) or this product manual (IFU 01-50-1720).

• Use of the device in a CT environment has not been tested. Use in that environment may create image artifact in the area of interest.

• Do not use in a Magnetic Resonance (MR) environment.

• The WalterLorenz Surgical Assist Arm mounts to the side rails of the operating room (OR) table. Therefore, it is important to thoroughly inspect the side rails for loose screws or defects that could interfere with the stability or performance of the device. If a defect is found, stop using the WalterLorenz Surgical Assist Arm immediately and do not use the device until the OR table rails have been secured.

• In the event of suspected damage or failure, DISCONTINUE USE OF THE DEVICE. Contact the manufacturer to have the device inspected by qualified personnel.

• Only use a dedicated WalterLorenz Surgical Assist Arm End Effector to connect instruments or Universal Instrument Holders to the Distal Arm. Failure to use the appropriate compatible End Effector may result in injury to the user or patient as the instruments may not be secured properly to the WalterLorenz Surgical Assist Arm.

• Only use dedicated WalterLorenz Surgical Assist Arm components and accessories (End Effector, Sterile Electronic Activation Button and Drape, Direct Connect Instruments, and Universal Instrument Holders). Use of any other devices may introduce the risk of shock, injury or death to the user or patient.

• Only use dedicated Power Supply with Cord. Use of power supply that is not provided by the manufacturer may involve risk of shock, injury or death to user or patient.

• This device has not been tested for use with high frequency surgical equipment.

• The Power Cord is a tripping hazard. Do not route the cord in a way that creates a tripping hazard or requires medical personnel to step over the cord.

• Not for use in an oxygen rich environment with an oxygen concentration greater than 25% for ambient pressures up to 110kPa or the partial pressure of oxygen is greater than 27.5 kPa at ambient pressures exceeding 110kPa.

• Intraoperative fracture or breaking of instruments has been reported. Always ensure instruments are in proper working order prior to surgical use. It is recommended that all instruments be regularly inspected for wear and disfigurement prior to use. Surgical instruments are subject to wear with normal usage. Failure to regularly inspect instruments for wear prior to use may result in injury to the patient or user, or damage to the device.
Section 9: Safety Information

To avoid fire hazard and electrical shock:

- The Charging Port and Unlock Button Port are intended to connect the WalterLorenz Surgical Assist Arm Base Unit with the Power Supply and Sterile Electronic Activation Button, respectively. Connection of any other devices may introduce the risk of shock, injury, or death to the user or patient.
- Do not operate the device with cords or cables that show signs of damage. Always inspect the cords or cables prior to use and discard immediately if signs of damage are present. Contact the manufacturer for replacement parts, if needed. Never attempt to cut or repair the cords or cables.
- Do not operate the device with any power supplies other than the one provided with the unit.
- Do not attempt to open the Base Unit or replace the battery. Attempting to open the base unit or replace the battery will damage the device.
- The WalterLorenz Surgical Assist Arm does not have any field-replaceable parts. Do not disassemble or open. Opening the unit will void the Warranty and introduce a risk of shock, injury, or death.
- Do not attempt to service or repair the device. Contact the manufacturer to have the device inspected by qualified personnel only.
- Do not operate the WalterLorenz Surgical Assist Arm in an explosive atmosphere (e.g. in the presence of flammable anesthetics, etc.). Possible explosion may occur if used in the presence of flammable anesthetics or other explosive gas mixtures.
- Device is made of conductive materials; care should be taken to keep energized instruments away from the WalterLorenz Surgical Assist Arm and its components.
- Connect to a properly grounded hospital-grade outlet only.
- Only use a dedicated WalterLorenz Surgical Assist Arm Sterile Electronic Activation Button. Promptly discard the Sterile Electronic Activation Button after use and do not reuse the button. Do not re-sterilize the button.
- Do not operate this product if there are signs of tampering or damage to the device.
- Do not allow foreign objects inside of the device.
- Do not soak, immerse, or spray the Sterile Electronic Activation Button with water, disinfecting fluid, or other liquids as this may cause the button to stop working. Ensure gloves are not excessively coated in water, blood, or other liquids before pressing the button.
- Do not sterilize the Base Unit of the device. Do not place the Base Unit in an automated washer or submerge in liquids of any kind. Only clean using the instructions provided in Section 14. Personal injury or damage to the device may result if instructions are not followed.

To isolate the WalterLorenz Surgical Assist Arm from mains power, unplug the Power Supply from the wall socket. Always unplug the power cord if:

- The device has been exposed to moisture, liquids have been spilled on the device, or if the device or any of its components have been soaked or immersed in liquids.
- The device has been dropped.
- The device does not operate properly, the device does not turn on, or the performance of the device is noticeably different.
- The device displays signs of tampering or damage, such as damage to the power supply, broken enclosures, etc.

To avoid electromagnetic interference:

- Special precautions are required regarding the electromagnetic compatibility (EMC) of the WalterLorenz Surgical Assist Arm. The system needs to be installed and put into service according to the EMC information provided in this manual.
- WARNING: Use of accessories, transducers and cords or cables other than those provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- This device should not be used adjacent to other equipment. Should use adjacent to other equipment become necessary, the system should be observed to verify normal operation in that configuration.
- Do not use in a Magnetic Resonance (MR) environment.
Section 10: Basic Usage

The WalterLorenz Surgical Assist Arm is indicated for tissue retraction, anatomical positioning, instrument positioning/holding, and scope holding during surgical use. The WalterLorenz Surgical Assist Arm should be used in combination with instrumentation and surgical tools to provide visualization, access, and steady holding throughout surgical procedures. It is repositioned as needed using electromechanical functionality activated by either a distal unlock button or the unlock button on the User Interface Keypad.

The device should be set up and draped according to the procedure outlined in Section 12. To be ready for use in a surgical procedure, the device must be properly set up, draped, powered on, and in a locked position.

The device is powered using a permanent integrated battery inside the Base Unit. The device can be powered by battery alone, as long as the battery is charged prior to the surgical procedure. Alternatively, it can be used while plugged into a power outlet using the External Power Supply with Cord. The user should routinely check the battery supply of the Base Unit to ensure power is available for operation of the device. If the battery is exhausted during use, the device will remain in the same state (locked or unlocked) that it was in upon losing power.

There are two Unlock Buttons that function in the same manner; one is located on the User Interface Keypad. The other button is a sterile, disposable Distal Unlock Button which is connected to the End Effector and plugged into the Control Box on the base unit. Both Unlock Buttons function to actively unlock the arm in the following manner: the user should depress and release the button quickly followed by depressing and holding the button. This shall be known moving forward as a “double press and hold”. The button must remain pressed in order to maintain the unlocked state while the device is manipulated.

Always ensure that the WalterLorenz Surgical Assist Arm is fully locked before the user releases control of the device. During use, it is possible to achieve positions or orientations that may not be strong enough to maintain the rigidity of the device for the desired application. It is imperative that the user be aware of the device performance at all times and ensure that when user releases the unit, the Arm does not move, give, or twist. If any signs are observed that the device is not stable for the desired application, it should be immediately inspected for correct assembly, repositioned or use discontinued, as the device may not be appropriate for the application.

General requirements for the safe use of the device:
• In the event of a loss of system function during a procedure, the medical professional shall discontinue the use of the WalterLorenz Surgical Assist Arm and proceed with patient care as needed, using other methods of surgical retraction/positioning. Holding and stabilization must only be performed with a fully functional system.
• Do not rotate the Arm a full 360 degrees relative to the Control Box. If the Arm resists rotation, rotate back the opposite direction and reposition.
• Proper draping and sterile field preparation should be conducted with every use of the device. Failure to follow instructions, damage to the sterile drape, or improper positioning of the drape may result in a loss of sterility and an adverse patient reaction.
Section 11: Charging the Device

Upon initial receipt of the WalterLorenz Surgical Assist Arm, it is recommended that the Base Unit be plugged in to fully charge the battery prior to the first use. Charging time will be approximately one hour. Connect the provided External Power Supply via the cord to the Charging Port on the Base Unit labeled ⚡. Connect the other end of the External Power Supply cord to a power outlet that has been approved for medical use. The charging icon ⚡ on the User Interface Keypad will blink when the device is connected to the power source and charging.

The WalterLorenz Surgical Assist Arm can be charged in between cases either in the pelican case or attached to an unused OR table. It is important that the Surgical Assist Arm units are fully charged at least once per week to avoid full battery depletion.
Section 12: Setup and Draping Procedure

Please see illustration of the set up in Appendix A: Quick Start Reference Guide

Proper initial setup is essential to preparing the sterile field and proper use of the device. Prior to each use, check the device to ensure that there are no unintended rough surfaces, sharp edges, or protrusions that may cause a safety hazard to the patient or user; or cause damage to the equipment and other accessories. Failure to follow the instructions or improper handling of the components may result in damage to the device or injury to the user or patient.

Sterile Attire and Preparing the Sterile Field
Two people are required to properly setup the WalterLorenz Surgical Assist Arm. One person must be wearing sterile protective attire; the other may be wearing non-sterile attire, if preferred.

The following guidance is provided for convenience and as the minimum procedures that should be followed for safe use of the device. Always be sure to follow all local hospital procedures regarding preparing the sterile field, sterile attire, aseptic technique, and cleaning of medical electrical equipment.

For clarity in the setup directions the following symbols will be utilized:

SP This symbol of “SP” with a circle around it will indicate steps that should be performed by a team member wearing sterile protective attire. It is recommended that the sterile attire include wearing two sets of sterile gloves initially, so that the outer layer may be removed during the draping process. Always be sure to follow all local hospital procedures regarding preparing the sterile field and dressing in sterile attire.

NSP This symbol of “NSP” with a circle around it will indicate steps that may be performed by a team member wearing non-sterile attire, if preferred.

Rotating Table Rail Clamp Installation
The WalterLorenz Surgical Assist Arm attaches to the OR table rail using the Rotating Table Rail Clamp, and attachment is performed by the non-sterile person. Take care when attaching the Rotating Table Rail Clamp and wear clean, dry gloves during handling; improper handling or wet gloves may result in injury to the user or patient if the clamp is dropped.

NSP Remove the Rotating Table Rail Clamp from the storage case.

NSP Attach the Rotating Table Rail Clamp onto the OR table rail at the desired location, coming from the top of the rail with the Zimmer Biomet logo facing up. Adjust the position, if necessary.

Base Unit Installation
After the Rotating Table Rail Clamp is installed and in the desired position, The Base Unit should then be attached. DO NOT POWER ON THE DEVICE AT THIS TIME.

NSP Turn the Rotating Table Rail Clamp handle counter-clockwise to ensure the clamp is ready to receive the base pole.

NSP Remove the Base Unit from the storage case and insert the Pole into Rotating Table Rail Clamp.

NSP Adjust the Pole until the desired height and rotation is achieved. Then, turn the Rotating Table Rail Clamp handle clockwise to tighten the clamp.

Remember that the WalterLorenz Surgical Assist Arm pole should be perpendicular to the floor. If necessary, adjust the Rotating Table Rail Clamp to keep the pole perpendicular to the floor. The Arm should be directed away from the OR table/sterile field for draping.
Section 12: Setup and Draping Procedure

**Power Up**

The non-sterile person should NOW POWER ON THE DEVICE by depressing the power button on the User Interface Keypad for one full second. Upon powering on, the device will lock into place after the red, yellow, blue sequence. Check the battery level on the User Interface Keypad to ensure there is enough battery power for the procedure. If necessary, connect the provided External Power Supply cord to the Charging Port labeled ⚡. Connect the other end of Power Supply Cord to a power outlet that has been approved for medical use. The charging icon 🌂 on the User Interface Keypad will blink when the device is connected to the power source and charging.

The non-sterile person should then use the permanent Unlock Button on the User Interface Keypad to position the Arm as shown in Appendix A and direct it away from the OR table. To unlock the Arm, depress twice and hold the button while moving the Arm into place. The Arm will lock into position upon release of the permanent Unlock Button.

**End Effector Installation**

Once the device is powered on and the Arm has been positioned for draping, the sterilized End Effector should be attached with the help of a sterile person.

It is recommended that the sterile person be wearing two sets of sterile gloves at this step. While the Arm is in the locked position, the sterile person connects the sterilized End Effector to the Arm by inserting the taper into the corresponding receptacle on the distal end of the Arm, and rotating the sterilized End Effector collar until a tight connection is achieved. Do not over-torque or apply excessive force when rotating as the device may be damaged or difficult to remove. Care should be taken to avoid contact with the non-sterile portion of the Arm. If wearing two sets of gloves, remove outer set before proceeding with draping.

The non-sterile person should be sure not to touch the sterilized End Effector.

**Sterile Electronic Activation Button Installation**

Proper installation of the Sterile Electronic Activation Button is critical to the performance of the device. The disposable Sterile Electronic Activation Button and Drape are provided in the same carton, but are individually packaged. Personnel should verify the expiration date and the package integrity of the Sterile Electronic Activation Button and Drape prior to use. Do not use if there is a loss of sterility of the products. Do not use products that are expired, have damaged packaging, or have been previously opened, as they may cause infection if used in a surgical procedure.

Do not soak, immerse, or spray the Sterile Electronic Activation Button with water, disinfecting fluid, or other liquids as this may cause the button to stop working. Ensure gloves are not excessively coated in water, blood, or other liquids before pressing the button.

Both devices are sterile and single use only. They should be discarded after each surgical procedure. Do not attempt to clean or re-sterilize these products. After use, these products may be a potential biohazard.

The non-sterile person should open the outer carton of the Sterile Electronic Activation Button and Drape. The non-sterile person should transfer the Button to the sterile person in an aseptic manner.

The sterile person connects the Sterile Electronic Activation Button to the sterilized End Effector by inserting the plastic tip of the button into the receptacle located on the End Effector and pressing it down until it fully snaps into place. Note that the flat portion of the cable will cover the release tab; this is normal and intended to prevent unwanted release from occurring. DO NOT plug the button into the Base Unit prior to verifying that the button is fully seated in the End Effector.

The sterile person then drops the remaining cable into the hands of the non-sterile person.

The non-sterile person connects the Sterile Electronic Activation Button to the Base Unit by plugging the attached cable into the Unlock Button Port labeled ⚡. To prevent injury to the user when plugging the cable into the Unlock Button Port, ensure hands are away from the User Interface Keypad so that buttons are not accidentally depressed.
Section 12: Setup and Draping Procedure

Draping
The Base Unit of the WalterLorenz Surgical Assist Arm and Sterile Electronic Activation Button cable must be draped prior to use. The Arm should remain positioned away from the OR table throughout the draping process.

1. The non-sterile person should transfer the drape to the sterile person in an aseptic manner.

2. The sterile person introduces the drape to the Arm and pulls the drape down over the Arm and down to the OR table surface ensuring that the elasticized tip is sealed on the End Effector collar, as shown in Appendix A.

3. The non-sterile person continues pulling the drape down below the OR table until it covers the Rotating Table Rail Clamp, being sure to properly maintain a sterile environment.

4. The sterile person places an elastic band or tape around the drape tip to secure it in place on the End Effector collar, as shown in Appendix A.

5. The sterile person may now reposition the Arm within the sterile field using either the Sterile Electronic Activation Button or the permanent Unlock Button on the Base Unit (through the drape). The device is unlocked when one of the buttons is depressed twice and held; when the button is released, the device will lock in place. Verify the range of motion to ensure the Arm can reach the desired surgical positioning. Ensure that the sterile field is properly maintained throughout the process.

6. If the Arm is not able to reach the desired location, adjust the base unit within the Rotating Table Rail Clamp or location of the Rail Clamp on the OR table rails.

Instrument/Holder Attachment and Removal
Before using the WalterLorenz Surgical Assist Arm to hold or stabilize a surgical instrument, check the outer surfaces of the instrument to ensure that there are no unintended rough surfaces, sharp edges, or protrusions that may cause a safety hazard to the patient or user, or cause damage to the equipment and other accessories. All damaged instruments should be discarded immediately.

The WalterLorenz Surgical Assist Arm holds a wide range of surgical tools and instruments using a direct connection. Alternatively, a WalterLorenz Surgical Assist Arm Universal Instrument Holder may be used with a variety of standard, manual instruments. Both the Universal Instrument Holder and the Direct Connection Instruments connect to the End Effector in the same manner.

Take care when attaching or removing instruments from the Holder/End Effector as to prevent damage to the instrument or holder. Never force or otherwise exert extreme forces on instruments or holders when installing or removing; doing so may damage the instrument, holder, or Arm. Prior to use in a surgical procedure, ensure that the instrument and/or Universal Instrument Holder is securely positioned and locked into the End Effector. If using a Universal Instrument Holder, ensure that the handle of the instrument is securely fixed to prevent unintended instrument movement.

1. To install a WalterLorenz Surgical Assist Arm instrument with a direct connection or a Universal Instrument Holder, align the key features on the instrument to the openings on the front of the End Effector instrument connection.

2. Insert the tapered end and key features into the End Effector.

3. Rotate the instrument clockwise until it is tight and the End Effector pin engages the instrument connection. Instruments and Holders can be attached to the End Effector in two orientations and final orientation should be selected based on user preference.

4. To release the instrument, grasp the End Effector and pull back on the sliding release pin. Rotate the instrument in a counter-clockwise motion and pull the instrument out of the End Effector.
Section 12: Setup and Draping Procedure

WalterLorenz Surgical Assist Arm Universal Instrument Holders
The following Universal Instrument Holders accommodate various handles commonly used for manual instruments. Additional holders may be available; check product brochures for full listing of available items.

- Large Universal Instrument Holder – Inline and 90°
  To attach an instrument to the Large Universal Instrument Holder:
  Turn the knob on the holder counter-clockwise until the jaws are wider than the handle of the instrument. Slide the instrument into the opening of the jaws. Turn the knob clockwise to tighten the holder to the instrument handle. Check that the instrument is secure before positioning the instrument into the operating field.

- Small Universal Instrument Holder
  To attach an instrument to the Small Universal Instrument Holder:
  Turn the larger knob on the top of the holder counter-clockwise until the jaws are wider than the handle of the instrument. Slide the instrument into one of the openings in the jaws. Turn the knob clockwise to tighten the holder to the instrument handle. The Small Universal Instrument Holder can also be rotated relative to the End Effector, by turning the smaller adjustment knob on the bottom (counter-clockwise to loosen and clockwise to tighten). Check that the instrument and rotational knobs are secure before positioning the instrument into the operating field.
Section 12: Setup and Draping Procedure

- **Flat Universal Instrument Holder**
  To attach an instrument to the Flat Universal Instrument Holder: Turn the knob on the holder counter-clockwise until the jaws are wider than the handle of the instrument. Slide the instrument into the opening of the jaws. Turn the knob clockwise to tighten the holder to the instrument handle. Check that the instrument is secure before positioning the instrument into the operating field.

- **Forceps Universal Instrument Holder**
  To attach an instrument to the Forceps Universal Instrument Holder: Turn the larger knob on the top of the holder counter-clockwise until the jaws are wider than the handle of the instrument. Slide the instrument into one of the grooves. Turn the knob clockwise to tighten the holder to the instrument handle. The Forceps Universal Instrument Holder can be rotated relative to the End Effector by turning the smaller adjustment knob on the bottom (counter-clockwise to loosen and clockwise to tighten). The Forceps Universal Instrument Holder also features a tab extending off the main body of the holder. This tab can be used to open and close the forceps during a procedure, without loosening the instrument in the holder. Check that the instrument and rotational knobs are secure before positioning the instrument into the operating field.

- **Torque Relief Tool**
  To remove an instrument from a Universal Instrument Holder, turn the larger knob on the holder counter-clockwise to release the instrument. Take care that the instrument does not fall out of the device when released from the End Effector or Universal Instrument Holder. Failure to do so could result in harm to the patient, user, or damage to the device. Instruments that fall outside the sterile field should not be used and must be cleaned and sterilized prior to reuse. If it is difficult to turn the knob and release the instrument, the Torque Relief Tool can be utilized. The Torque Relief Tool fits around the outside of the large knob, aligning with the grooves on the knob, and allows the user to apply more torque to the holder in order to loosen the grip on the instrument. This tool can be used with any of the Universal Instrument Holders. **Do not use this tool to tighten an instrument into a holder, doing so may cause damage to the Universal Instrument Holder or the instrument.**
**Section 13: System Power-Down Procedure**

*Please see illustration of the set up in Appendix B: Breakdown and Cleaning Reference Guide*

When finished using the WalterLorenz Surgical Assist Arm, reposition the Arm away from the surgical field. Do not turn the Arm off until instructed to do so in the following directions, however, always disconnect the WalterLorenz Surgical Assist Arm from the wall power supply prior to performing cleaning.

**Remove the Instrument and/or Universal Holder**
Remove the instrument or Universal Instrument Holder from the End Effector by pulling back the release pin and turning the instrument or Instrument Holder counter clockwise. Pull the instrument or Universal Holder from the End Effector instrument connection while holding the release pin.

**Remove the Single-Use Drape and Sterile Electronic Activation Button**
Remove and discard the drape.

Disconnect the disposable Sterile Electronic Activation Button from the Base Unit by pulling the end of the cable out of the receptacle. On the End Effector, disconnect the Button by moving the flat cable aside and then pulling back and up on the release tab, and discard the Button. Ensure that the whole button including plastic clip, is removed from the End Effector prior to cleaning/sterilizing the End Effector.

When disposing of the single-use Drape and Sterile Electronic Activation Button, follow procedures for biologically hazardous materials.

**Remove the End Effector**
Ensure the WalterLorenz Surgical Assist Arm is in a locked state before removing the End Effector. Doing so will make it easier to remove the End Effector. Remove the end effector by turning the collar counter-clockwise and pulling it out of the Arm receptacle. Care should be taken that only the collar is rotated during loosening of the end effector; if excessive torque is applied to the arm, damage to the device may occur.

**Power Down the Device**
Once the End Effector is removed, the Arm is ready to be powered down. The Arm should always be in the unlocked state when powering down and storing the device. First, depress twice and hold the button to unlock the device from the locked state. Be sure to support the Arm or place it in a safe resting position, to ensure that it does not drop while unlocking. While still holding the Unlock Button, press and hold the power button for two full seconds. The device should now be powered off and the Arm should be able to move freely.

Follow the appropriate cleaning instructions per Section 14 for wiping down the Arm, Base Unit, and Control Box.
Section 14: General Cleaning of WalterLorenz Surgical Assist Arm

The following section describes the method(s) for cleaning and maintaining the WalterLorenz Surgical Assist Arm. The following guidance is provided for convenience and as the minimum procedures that should be followed for cleaning and maintaining the device. Never immerse or soak any part of the WalterLorenz Surgical Assist Arm in any liquid, as this may cause significant damage to the device that is not covered by the warranty.

**WARNING:** RISK OF SHOCK. Do not autoclave the WalterLorenz Surgical Assist Arm, or Sterile Electronic Activation Button. Do not soak or immerse in disinfecting fluids.

**Cleaning and Wipe-Down Procedure for WalterLorenz Surgical Assist Arm**

Local hospital procedures may be followed for cleaning of electrical equipment; however, at a minimum the following instructions must be followed.

Using a lightly damp cloth, wipe down the entire WalterLorenz Surgical Assist Arm, and Rotating Table Rail Clamp. Take special care to wipe the outer surface of the Joint 1 ball, as shown in Appendix B. Allow the system to dry before using it again or storing the device. Do not use highly saturated cloths or pour liquid directly on the device or components.

Any blood on the WalterLorenz Surgical Assist Arm can be removed using cotton or gauze that has been lightly dampened with alcohol. Alcohol is preferred over disinfectant wipes in order to maintain the cosmetic appearance of the device. Use of disinfectant wipes is not prohibited, but cosmetic damage or discoloration may occur.

**CAUTION:** Do not sterilize the WalterLorenz Surgical Assist Arm, Rotating Table Rail Clamp, or any of the electronic components. Do not perform calibration or maintenance on device.
Store the WalterLorenz Surgical Assist Arm under appropriate storage conditions as stated in the Technical Specifications. It is important that WalterLorenz Surgical Assist Arm units are fully charged at least once per week to avoid full battery depletion.

Uninstall the Base Unit from the Rotating Table Rail Clamp by turning the clamp handle counter-clockwise to loosen it. Remove the Base Unit and return it to its Pelican case or storage location. Remove the Clamp from the OR table rail and return it to its Pelican case or storage location.

Do not store disinfecting fluids above, in, or on the WalterLorenz Surgical Assist Arm or Pelican case.
**Section 16: Troubleshooting**

The following table lists potential issues that the WalterLorenz Surgical Assist Arm may experience. Follow the guidance provided to test whether the issue can be resolved on-site. If the guidance does not resolve the problem, always contact your local Zimmer Biomet Sales Representative or the manufacturer directly:

Biomet Microfixation • 1520 Tradeport Drive • Jacksonville, FL 32218-2480 USA
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Do not attempt to use the WalterLorenz Surgical Assist Arm on a patient or in a surgery if it is not functioning properly. Use of the device outside of normal operating conditions may involve incalculable risks to the patient, user, or 3rd Party. Do not attempt to service the device; this includes opening, dismantling, rewiring, or replacing any internal component of the system. The battery cannot be replaced by the user or facility.

<table>
<thead>
<tr>
<th>SET-UP/ASSEMBLY/DRAPING</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>What should I do if the arm does not power on?</td>
<td>Ensure that the power button is depressed for one full second.</td>
</tr>
<tr>
<td></td>
<td>Ensure that the battery is charged.</td>
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<tr>
<td></td>
<td>If the battery is completely exhausted due to transit time or disuse, the device may not function properly until the battery is fully charged (See Section 11 for charging instructions). When powering on the device, you will see the LED status lights signal the powering on sequence by running through the Red, Yellow, Blue light sequence.</td>
</tr>
<tr>
<td>What should I do if the drape tears?</td>
<td>Follow hospital procedures for a compromised sterile field. Obtain a new Sterile Electronic Activation Button and Drape, if necessary.</td>
</tr>
<tr>
<td>What if the Surgical Assist Arm pole creates a gap in the patient drape interrupting the sterile field.</td>
<td>Follow hospital procedures for a compromised sterile field. A second self-adhesive sterile drape can be added/attached to preserve the sterile field, as determined appropriate by hospital staff.</td>
</tr>
<tr>
<td>What do I do if the Pole is not perpendicular to the ground?</td>
<td>If the Pole is not perpendicular to the ground, the Rotating Table Clamp should be repositioned. Loosen the Rotating Clamp while supporting the Arm so that the Pole does not move unintentionally. Reposition the Rotating Table Clamp such that the Pole is perpendicular to the ground and tighten the clamp back in the desired position.</td>
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<thead>
<tr>
<th>SURGICAL USE</th>
<th></th>
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<tr>
<td>What happens if the battery runs out during surgery?</td>
<td>Always be aware of the remaining battery power of the device; LED indicators (Section 5) will alert the user when battery power is low or fully exhausted. The Arm will remain in the current state (locked or unlocked) when the battery runs out. The user should connect the power cord immediately or stop using the device.</td>
</tr>
</tbody>
</table>
### Section 16: Troubleshooting

<table>
<thead>
<tr>
<th>What if the Sterile Electronic Activation Button does not respond/unlock the Arm?</th>
<th>Test whether the permanent Unlock Button on the Base Unit functions. If that button is functioning, check that the Sterile Electronic Activation Button cable is fully inserted into the Unlock Button Port on the Base Unit and that the connection is secure. If the permanent Unlock Button functions and the connection is secure, but the Sterile Electronic Activation Button is still not responsive turn the Base Unit off and then back on. If the Sterile Electronic Activation Button still does not respond, change the disposable Sterile Electronic Activation Button by opening another Sterile Electronic Activation Button and Drape. Ensure the sterile field is maintained, as appropriate. *Note: If the permanent Unlock Button is functional, it can be used for the remainder of the surgical procedure.</th>
</tr>
</thead>
<tbody>
<tr>
<td>What does a slow flashing red LED light mean?</td>
<td>Battery is running out of charge; plug the device in immediately.</td>
</tr>
<tr>
<td>What does a fast flashing red LED light mean?</td>
<td>Battery has completely run out of charge; device will shut down in 20 seconds if not plugged into an electrical outlet. If the device shuts down, it will remain in the current state (locked or unlocked). The device can be temporarily powered back on once so that it may be unlocked and quickly removed from the operating field.</td>
</tr>
<tr>
<td>What does a steady red LED light mean?</td>
<td>A steady red LED light indicated there is a fault condition in the system.</td>
</tr>
<tr>
<td>What if the battery does not hold a charge? (i.e. the lightning bolt LED symbol is blinking while plugged in, but once the device is unplugged, it cannot operate on battery power).</td>
<td>Turn the Base Unit off and then back on. If the device still does not charge, check the electrical outlet or try a different electrical outlet. If the battery still will not hold a charge, the device can still be used while plugged into an outlet.</td>
</tr>
<tr>
<td>What if the arm does not lock upon start-up?</td>
<td>Cycle through a full unlock/lock/unlock cycle (by depressing the Unlock Button twice and holding upon the second press, releasing the Unlock Button, and then depressing the Unlock Button twice and holding again to check the unlocked state). If the joint does not unlock as intended, try to gently manipulate each of the joints to release.</td>
</tr>
<tr>
<td>What if one or more joints do not lock or unlock as intended?</td>
<td>Cycle through a full unlock/lock/unlock cycle (by depressing the Unlock Button twice and holding upon the second press, releasing the Unlock Button, and then depressing the Unlock Button twice and holding again to check the unlocked state). If the joint does not unlock as intended, try to gently manipulate each of the joints to release.</td>
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</table>
## Section 16: Troubleshooting

<table>
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<tr>
<th>Scenario</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td><strong>What if an instrument won't lock into the End Effector?</strong></td>
<td>Examine the End Effector and instrument connection to ensure there is no damage or unintended material or debris interfering with the engagement of the connection. If End Effector or instrument connection is damaged, discontinue use of the damaged components. If material is found, re-clean and sterilize the instruments according to the Instructions for Use. Select a different instrument or End Effector to see if the issue persists. Make sure that the sterile field is maintained during this procedure. If the sterile field is compromised, the device will need to be redraped using a new Sterile Electronic Activation Button and Drape.</td>
</tr>
<tr>
<td><strong>What if an instrument or Universal Instrument Holder cannot be removed from the End Effector?</strong></td>
<td>Check that the “thumb release” button is free from unintended material, debris, or damage and can slide freely. If the End Effector is damaged, discontinue use of the damaged component. If material is found, re-clean and sterilize the instruments according to the Instructions for Use. If the thumb-release button is free from material, the entire End Effector/Universal Instrument Holder unit can be replaced using alternates from the set (if available). Make sure that the sterile field is maintained during this procedure. If the sterile field is compromised, the device will need to be re-draped using a new Sterile Electronic Activation Button and Drape.</td>
</tr>
<tr>
<td><strong>What if an instrument cannot be removed from the Universal Instrument Holder?</strong></td>
<td>The Torque Relief Tool can be used to apply greater torque to the knob to remove an instrument. If the tool does not release the instrument, the entire Universal Instrument Holder/instrument unit can be replaced with alternates from the set (if available). Do not use this tool to tighten an instrument into a holder, doing so may cause damage to the Universal Instrument Holder or the instrument.</td>
</tr>
<tr>
<td><strong>What if I rotate the Arm towards the User Interface Keypad and it won't rotate anymore?</strong></td>
<td>The Arm is not intended to rotate a full 360 degrees (approximately 300 degrees) relative to the Base Unit due to internal components. If the Arm won't rotate any more, rotate the Arm back the other direction and reposition the Arm in the Rotating Table Rail Clamp.</td>
</tr>
</tbody>
</table>
# Section 16: Troubleshooting

| **What if the Arm is completely unresponsive during use?** | Perform the relevant troubleshooting steps identified in the question "What if the Sterile Electronic Activation Button does not respond/unlock the Arm?"  
Turn the Base Unit off and then back on.  
If the issue persists, turn the base unit off and then back on. If needed, attempt to safely discontinue use of the device. Suggested methods may include:  
• Remove instrument from End Effector  
• Loosen and/or remove End Effector from Arm  
• Remove unit from Rotating Table Rail Clamp  
• Slide the Rotating Table Rail Clamp, with unit secured, along OR table rail  
Ensure that the sterile field is not compromised. |
| **DISASSEMBLY/STORAGE/CHARGING/CLEANING** |  |
| **What should I do if the arm does not power off?** | Ensure that the power button is depressed for two full seconds. |
| **What if the battery does not charge when it is plugged in? (Note: The lightning bolt LED symbol next to the battery gage should be blinking if the device is charging)** | Turn the Base Unit off and then back on. If the device still does not charge, check the electrical outlet or try a different electrical outlet.  
Confirm that the External Power Source cord is plugged into the Charging Port on the Base Unit securely. Once the device is fully charged, the lightning bolt LED will not blink and will not be illuminated. |
| **What if I can't remove the End Effector from the Arm?** | Ensure that the Arm is in the locked state when trying to remove the End Effector.  
If the Arm is locked, ensure that gloves are not wet or slippery, which may prevent obtaining an adequate grip on the End Effector. |
Appendix A: Quick Start Reference Guide

For clarity in the setup directions the following symbols will be utilized:

This symbol of “SP” with a circle around it will indicate steps that should be performed by a team member wearing sterile protective attire. It is recommended that the sterile attire include wearing two sets of sterile gloves initially, so that the outer layer may be removed during the draping process. Always be sure to follow all local hospital procedures regarding preparing the sterile field and dressing in sterile attire.

This symbol of “NSP” with a circle around it will indicate steps that may be performed by a team member wearing non-sterile attire, if preferred.

1. Attach the Table Rail Clamp

2. Insert Base Unit into Clamp
   NOTE: Ensure pole is perpendicular to floor.

3. Power on the Device

4. Reposition Arm Upright
   NOTE: Sterile person should be double-gloved for next step.
Appendix A: Quick Start Reference Guide

5. Attach End Effector
NOTE: Remove outer set of gloves after completing step.

6. Attach Sterile Electronic Activation Button to End Effector

7. Plug Sterile Electronic Activation Button into Base Unit
NOTE: Look for the unlock symbol.

8. Pull Drape Over Arm
NOTE: Ensure drape seal edges come to rest between the body and the collar of the End Effector.
Appendix A: Quick Start Reference Guide

9. Secure Drape by Using Rubberbands and/or Tape
   CAUTION: Do not wrap tape tightly as it could inhibit range of motion.

10. Reposition Arm Over the Table

Select the desired Direct Connect Instrument or Universal Holder
Appendix B: Breakdown and Cleaning Reference Guide

1. Position Arm Away from Surgical Field
2. Remove Sterile Drape
3. Unplug Sterile Electronic Activation Button from Base Unit
3. (cont.) Remove and Discard Button

Ensure that the whole button including plastic clip, is removed from the End Effector prior to cleaning/sterilizing the End Effector.
Appendix B: Breakdown and Cleaning Reference Guide

4. Remove the End Effector and Place in Instrument Tray
Care should be taken that only the collar is rotated during loosening of the end effector; if excessive torque is applied to the arm, damage to the device may occur.

5. Move Device into Rest Position

6. Power Off in Unlocked State
Double press and while holding the Unlock Button press the power button for 2 seconds.

7. Wipe Down Distal Arm
NOTE: Never Immerse or Soak Any Part of the Device in Any Liquid.
Appendix B: Breakdown and Cleaning Reference Guide

7. (cont.) Wipe Down Distal Arm

8. Remove and Wipe Base Unit Pole
   
   **NOTE:** Never Immerse or Soak Any Part of the Device in Any Liquid. Return Base Unit to case when dry.

8. (cont.) Remove and Wipe Base Unit Pole

9. Remove and Wipe Rotating Table Rail Clamp
   
   Return Rotating Table Rail Clamp to case when dry.