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**IMPORTANT**

The OnPoint™ 1.2mm Scope System is indicated to provide illumination and visualization of anatomy in an interior cavity of the body through a natural or surgical opening. This device is indicated for diagnostic and operative arthroscopic and endoscopic procedures. The device is to be used by a trained physician for the indicated uses only.

This manual describes the recommended procedures for preparing and operating the OnPoint System. It does not describe how any medical procedure is to be performed on a patient with this instrument.

Read all instructions in this manual carefully before using the OnPoint 1.2mm Scope System.

Carefully follow all safety instructions to prevent injury to the user or patient, fire hazards, electrical shock, and damage to the device.

To maintain this device in optimal condition, follow all recommendations in this manual for handling, cleaning, and storage.
1.0 Introduction
Thank you for your purchase of the OnPoint™ 1.2mm Scope System. This piece of equipment is designed and built to give you the latest technology and the best performance. This manual will help you make the most of your equipment investment.

1.1 The OnPoint™ 1.2mm Scope System
The OnPoint system combines several essential surgical requirements into a single compact & portable package:

Xenon Fiber Optic Light Source
By employing state-of-the-art lamp power supply technology, a proprietary xenon arc lamp incorporates an enhanced reflector and delivers near 175-watt illumination performance for outstanding image quality.

Proprietary High-Resolution Camera System
The OnPoint camera is a high-resolution 480-line digital camera. It uses a quick-release optical connector that adapts to a wide variety of surgical endoscopes. A proprietary single cable design eliminates the complexity and cost of the traditional dual-cable system approach.

Integrated Video Display with Multiple Outputs
The OnPoint high-resolution 6.4” LCD monitor combines the performance of the Xenon Fiber Optic Light Source and High Resolution Camera System to deliver a brilliant, high-resolution video image for clear detail recognition and outstanding color reproduction.

Multiple Output options on the OnPoint unit allow you to connect larger external video monitors, video printers, and video recording devices.

MediaCaptureUSB
A full-featured, fully-integrated image capture system is included in every OnPoint system. Every OnPoint has the capability to capture video, still images, full-resolution video, and audio-tagged still images. Using the popular CompactFlash® media format, MediaCaptureUSB enables users to quickly and conveniently document their procedures. Connect directly to a computer via USB and use the OnPoint to browse captured media or capture still images and video directly to your practice management software, running on Windows 2000 or Windows XP.

Camera System: CMAR-01
High-Resolution endoscopic/arthroscopic camera system with integrated light cable and MediaCaptureUSB capture button.
1.2 Indications for Use
The OnPoint 1.2mm Scope System is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures.

1.3 Contraindications
The OnPoint 1.2mm Scope System is contraindicated for use in applications where high intensity light might damage tissue, such as neonate transillumination and ophthalmic procedures. For other contraindications, consult the literature accompanying the instrumentation utilized with this device.

1.4 Regulatory Compliance
The OnPoint 1.2mm Scope System complies with all regulations to be marketed in the United States of America, Canada, and the European Union.

This device complies with EN60601-1 and all collateral standards.

This device complies with part 15 of the FCC rules.


Federal law restricts this device to sale by or on order of a physician licensed by the law of the state in which he practices to use or order the use of this device.
1.4.1 Electromagnetic Compatibility (IEC 60601-1-2)

Guidance and Manufacturer’s Declaration- Electromagnetic Emissions

The OnPoint™ is intended for use in the electromagnetic environment specified below. The customer or the user of the OnPoint™ should assure that it is used in such an environment.

### Emissions Test

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions</td>
<td>Group 1</td>
<td>OnPoint™ 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>CISPR 11</td>
<td>Class B</td>
<td>The OnPoint™ 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>Harmonic Emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations / Flicker Emissions</td>
<td></td>
<td>IEC 61000-3-3</td>
</tr>
</tbody>
</table>

### Guidance and Manufacturer’s Declaration- Electromagnetic Immunity

The OnPoint™ is intended for use in the electromagnetic environment specified below. The customer or the user of the OnPoint™ should assure that it is used in such an environment.

#### Immunity Test

<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)</td>
<td>+ 6 kV contact</td>
<td>+ 6 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>+ 8 kV air</td>
<td>+ 8 kV air</td>
<td>If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical Fast Transient/Burst</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>IEC 61000-4-4</td>
<td>+1 kV for input/output lines</td>
<td>+1 kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>Voltage Dips, short interruptions and voltage variations on power supply input lines.</td>
<td>&lt;5% UT(&gt;95% dip in UT for 0.5 cycles)</td>
<td>100% dip for 0.5 cycles</td>
<td>Mains power quality should be that of a typical commercial of hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>40% UT (60% dip in UT) for 5 cycles</td>
<td>60% dip for 5 cycles</td>
<td>If the user of the OnPoint™ requires continued operation during power mains interruptions, it is recommended that the OnPoint™ be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>70% UT (30% dip in UT) for 25 cycles</td>
<td>30% dip for 25 cycles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5% UT (&gt;95% dip in UT) for 5 sec.</td>
<td>100% dip for 5 seconds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power Frequency (50/60Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 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:** UT is the ac mains voltage prior to application of the test level.

#### Guidance and Manufacturer’s Declaration- Electromagnetic Immunity

The OnPoint™ is intended for use in the electromagnetic environment specified below. The customer or the user of the OnPoint™ should assure that it is used in such an environment.

#### Immunity Test

<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>3 V rms</td>
<td>10 V rms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the OnPoint™ including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150 kHz to 80 MHz outside of ISM bands</td>
<td>10 V/m</td>
<td>Recommended separation distance</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>10 V/m</td>
<td>100% dip for 5 seconds</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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>10 V/m</td>
<td>d = (3.5/3) P</td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol ———————————— symbol</td>
</tr>
<tr>
<td>150 kHz to 80 MHz in ISM bands</td>
<td>10V/m</td>
<td>100% dip for 5 seconds</td>
<td></td>
</tr>
<tr>
<td>10 MHz to 2.5 GHz</td>
<td></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. 

### Recommended separation distances between portable and mobile RF communications equipment and the OnPoint™

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

#### Rated maximum output power of transmitter (W)

<table>
<thead>
<tr>
<th>Transmitter Power (W)</th>
<th>Separation distance according to frequency of transmitter</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.035, 0.035, 0.07</td>
</tr>
<tr>
<td>0.1</td>
<td>0.11, 0.11, 0.22</td>
</tr>
<tr>
<td>1</td>
<td>0.35, 0.35, 0.7</td>
</tr>
<tr>
<td>10</td>
<td>1.12, 1.12, 2.21</td>
</tr>
<tr>
<td>100</td>
<td>3.5, 3.5, 2.21</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance is 6 in meters (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.
1.5 Warranty Information
When delivered to the end user in new condition in the original container, the OnPoint 1.2mm Scope system is warranted to be free from defects in material or workmanship for one year from the date of shipment from Biomet Microfixation to the end user.

Within the above listed time periods, parts that are returned, freight prepaid, to Biomet Microfixation and are determined by Biomet Microfixation to be defective will be repaired or replaced by BioVision Technologies without charge for parts, labor, or return ground shipping costs. Biomet Microfixation will make every effort to accomplish this repair or replacement within a reasonable time. After the warranty period, the purchaser must pay all charges for repair and replacement. This warranty does not cover products intended for single patient use beyond the initial use or consumable items.

The above actions by Biomet Microfixation shall constitute your exclusive remedy and Biomet Microfixation’s sole obligation under this warranty. Biomet Microfixation shall not be responsible for warranty claims made after the warranty period. To obtain warranty repair service, you must contact Biomet Microfixation to obtain a Return Material Authorization (“RMA”) number, then return the product, freight prepaid, to Biomet Microfixation. The RMA number and a complete explanation of the problem must be included with the product being returned to Biomet Microfixation for warranty service. The product 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, Biomet Microfixation will return the product to the end user, freight prepaid.

The warranty period for replacement parts shall begin upon shipment of same, but shall in no event exceed the warranty period of the defective part. Biomet Microfixation shall have no liability or obligation for a product 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 product has been repaired or modified without prior written authorization from Biomet Microfixation, if the end-user has failed to follow the instructions or heed the warnings or specifications in the Operation and Care Manual, or if the product’s serial number has been altered or removed.

EXCEPT FOR THE FOREGOING WARRANTIES, BIOMET MICROFIXATION 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. BIOMET MICROFIXATION HEREBY DISCLAIMS ANY REPRESENTATIONS OR WARRANTY THAT THIS PRODUCT OR ANY OF ITS PARTS IS COMPATIBLE WITH NON-BIOMET MICROFIXATION PRODUCTS OTHER THAN VIDEO EQUIPMENT ATTACHED TO ITS VIDEO OUTPUTS, AS DESCRIBED IN THE OPERATOR’S MANUAL. THE LIABILITY OF BIOMET MICROFIXATION, IF ANY,
AND PURCHASER’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 PRODUCT SOLD BY BIOVISION TECHNOLOGIES THAT CAUSED ANY ALLEGED DAMAGE. IN NO EVENT SHALL BIOMET MICROFIXATION BE LIABLE TO PURCHASER FOR ANY SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY KIND.

Contact Biomet Microfixation for warranty information

904.741.4400 • 800.874.7711

www.biometmicrofixation.com

Distributed by Biomet Microfixation

1.6 How to Use This Manual
The intention of this document is to convey the proper and prescribed operation and care of the OnPoint™ 1.2mm Scope System.

1.7 Manual Conventions
This manual adheres to a set of conventions to help you easily find the information you need and inform you of important information that will help you efficiently and effectively use your equipment.

Sections and sub-sections are noted as follows:

1.0 Section Title
1.1 Sub-section title

Special and important information is called out using notes and warnings. Notes usually pertain to a recommended protocol that will help extend the life of your equipment. Warnings pertain to protocols that delineate appropriate actions which maintain a safe and healthy work environment. Notes and warnings are called out in the following manners:

Note: This is a note.

⚠️ WARNING: This is a warning.

1.8 List of Symbols (used in this manual and product labels)
2.0 Product Specifications
The following section describes the components and features of the OnPoint™ system.

2.1 Contents
The following components are included in your OnPoint system:

- OnPoint™ Integrated Visualization System (Base Unit)
- Medical Grade Power Cord
- Operation and Care Manual

Check to see that you have all of these components before proceeding. If any of these components are missing, contact Biomet Microfixation immediately using the contact information below:

Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218-2480
Phone: 800.874.7711 or 904.741.4400
www.biometmicrofixation.com
2.2 Features and Specifications

2.2.1 OnPoint Features

- Microphone
- PS2 Keyboard Connection
- USB Connection
- Mode
- Delete
- Left Select
- Right Select
- Stop/Enter
- Power Indicator
- Power Button
- Speaker
- CompactFlash® Media Slot
- Integrated LCD Monitor
- Integrated LCD Monitor
- Ventilation Exhaust
- Camera Connector/Light port

Rear

- Ventilation Exhaust
- VR Connector
- Composite Video
- S-Video
- Fuse Holder
- Power Connector
2.2.2 Technical Specifications

Electrical
- Input voltage: 120/230VAC, 50/60Hz
- Input current: 3.0/1.5A maximum
- Power connector: IEC 320
- Classification: IEC60601-1 Class I, Type BF equipment
- Mode of operation: Continuous
- Fuse: 3.15A 250V Type F

Environmental
- Operating altitude: -304.8 to 3657.6m (-1000 to 12000 ft) MSL
- Operating temperature: 0ºC to 40ºC (-32ºF to 104ºF)
- Operating humidity: 0% to 95% RH, non-condensing
- Storage/transport altitude: -304.8 to 10668m (-1000 to 35000 ft) MSL
- Storage/transport temperature: 0ºC to 50ºC (-32ºF to 122ºF)
- Storage/transport humidity: 0% to 95% RH, non-condensing

Video / Display
- Input video format: NTSC Composite, 75Ω, 1Vp-p
- Video output 1: NTSC Composite, 75Ω, BNC
- Video output 2: NTSC Y/C, 75Ω, 4-pin circular DIN
- Video output 3: NTSC Composite, 75Ω, 4-pin VR glasses connector
- Display type: LCD 16.25 cm (6.4 in) TFT, active matrix (960Hx 234V)

Light Source
- Type: Xenon Arc
- Lamp: BL35Wxe
- Power: 35W

MediaCaptureUSB
- Storage media: CompactFlash®
- Still image file format: JPEG
- Still image size: 640x480 pixels
- Video file format: AVI (MJPEG codec)
- Video size/frames rate: 640x480 pixels/30fps

2.3 Safety Information

General requirements for the safe use of the device:
- It is important that you read, understand, and comply with all of the following safety precautions, markings, labeling, and all accompanying literature.
- Failure to follow these precautions could result in injury to the patient or user, or damage to the OnPoint™ unit.
- When used in the presence of other energized, endoscopically-used devices and accessories, such as Lasers and High Frequency Surgical equipment, the safety precautions for such equipment must also be followed.
• Before each use, check the outer surface of the arthroscope and arthroscopic accessories to ensure 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.
• In the event of use with other surgical tools, such as shavers, care shall be taken to avoid damage to the arthroscope or any arthroscopic accessories. All damaged instruments shall be discarded immediately.
• In the event of a loss of system function during a procedure, no further visualization is necessary, and the procedure is ended, the physician shall remove the arthroscope and proceed with closure or further patient care as needed. Further arthroscopic examination shall only be performed with a fully functional system, for which a backup unit is recommended.

To avoid personal injury and damage to this device:
• Do not block ventilation slots or openings. Always ensure sufficient clearance for ventilation by not placing any other equipment or objects on or near the vents on either side of the OnPoint™ unit.
• Always place and keep the OnPoint unit on a flat, level, and secure surface.
• In the event of suspected damage or failure, DO NOT OPERATE and have the device inspected by qualified personnel.

Sufficient clearance is maintained by allowing an area six inches by six inches both behind and on the left side of the OnPoint™ unit.

A flat surface will provide the optimal performance.
To avoid fire hazard and electrical shock:

- Do not operate the device outside of the specified input voltage range.
- Only use medical-grade power cords with the OnPoint™ system.
- Connect to a properly grounded hospital-grade outlet only.
- Use only the fuse type and rating specified for this device.
- DO NOT operate the OnPoint™ system in an explosive atmosphere (e.g. in the presence of flammable anesthetics, etc.).
- The OnPoint™ unit does not have any field-replaceable parts. DO NOT disassemble or open the front cover or any other covers or panels. Opening the front cover will void the manufacturer’s warranty.
- Do not operate this product if there are signs of tampering or any of the covers are removed.
- Do not allow foreign objects inside of the device.
- Before performing any kind of maintenance (e.g. cleaning the OnPoint™ system, replacing fuses, etc.), always perform the following:
  - Unplug the power cord.
  - Allow unit to cool for at least ten (10) minutes after turning off.
  - Do not allow spilling of liquids on the OnPoint™ unit.
  - Do not immerse any of the components in liquids.

**IPX0** - Do not operate in wet or damp conditions.
- If any maintenance or repair is needed beyond superficial cleaning or replacing fuses, contact Biomet Microfixation or your authorized service representative.

Always unplug the power cord if:

- The device has been exposed to moisture, liquids has been spilled on the device, 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 cord, broken enclosures, etc.

⚠️ **WARNING:** In the event of use with other energized endoscopically-used instruments and accessories, the PATIENT LEAKAGE currents may be additive.

⚠️ **WARNING:** Possible explosion if used in the presence of FLAMMABLE ANESTHETICS or other EXPLOSIVE GAS MIXTURES.

⚠️ **WARNING:** This device is not intended to be used in the presence of HIGH FREQUENCY SURGICAL EQUIPMENT.

⚠️ **WARNING:** This device is not intended to be used in the presence of LASER EQUIPMENT.

⚠️ **WARNING:** Awareness of the possibility of a gas embolism whenever compressed gases are used in a patient procedure. To minimize the risk, you must verify that adequate space exists for the egress of any patient applied gases.

⚠️ **WARNING:** USB connector is never to be used when the device is in contact with a patient.

⚠️ **WARNING:** The lamp and reflector are not intended for field replacement. Attempts to service or replace the lamp may result in injury or damage to the device, and void the warranty.

⚠️ **WARNING:** Do not look directly into the light emitting windows of the endoscope or handpiece. This may result in eye damage.

⚠️ **WARNING:** After removing the endoscope, do not touch the light emitting window of the handpiece or the light receiving window of the endoscope. They may become hot after long periods of use.

⚠️ **WARNING:** Do not touch the light receiving port of the handpiece upon disconnection. The tip of the port may become hot after long periods of use.

⚠️ **WARNING:** DO NOT IMMERSE the camera handpiece in liquids of any kind, personal injury or damage to the device may result.
To avoid electromagnetic interference:

- Special precautions are required regarding the electromagnetic compatibility (EMC) of the OnPoint™ system. The system needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile radio frequency (RF) communications equipment can affect any medical electrical equipment including the system.
- Only cables and accessories provided by the manufacturer may be used with the system. The use of any other cables or accessories may have an adverse effect in the electromagnetic compatibility of the device such as increased emissions or decreased immunity.
- This device should not be used adjacent to or stacked with other equipment. Should use adjacent to other equipment become necessary the system should be observed to verify normal operation in that configuration.

"Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department."

3.0 Setup and Basic Usage

The following section describes how to set up and use the OnPoint™ system for surgical procedures.

3.1 Setup

Proper initial setup is essential to provide you and your staff the best access to operational and visual performance while conducting procedures.

3.1.1 OnPoint System

For best performance, always operate and keep the OnPoint unit on a flat, level, and secure surface. Images on the Integrated Video Display are best viewed at an angle perpendicular to the display.

Do not tilt the OnPoint unit. For better viewing, adjust the height and display angle.
3.1.2 Attaching a Camera Handpiece and Arthroscope

The OnPoint camera handpieces attach via a combination fiberoptic/electric connector. This connector seats in the receptacle on the front of the unit (See also: § 2.2.1 Front).

Before connecting a camera or handpiece to the OnPoint™ unit, the camera or handpiece must be properly cleaned (Ref. Section 4.0).

Note: For best image quality and to ensure patient safety, verify that both ends of the camera or handpiece are free of foreign particles.

Connect the scope to the camera by pulling the sliding sleeve and inserting the scope. Ensure that the light port is aligned with the bottom of the handpiece and the red dot on the back of the scope lines up with the coupler top-indicator.

Release the sliding sleeve to secure the scope in place. The proper technique must be utilized in order to preserve the sterile field through the drape that is attached to the endoscope.

Turn the power on. The monitor will power up within about fifteen (15) seconds. Hold the distal tip of the scope approximately 2.0cm from a surface with fine details such as your palm or surgical drape.

Turn the focus adjustment knob in either direction until the fine-detailed surface at the distal end of the scope comes into optimal focus on the LCD video monitor.

See also: § 3.2.2 Setup for Each Procedure
3.1.3 Attaching External Video Devices

In some cases, you may need a larger display than what is provided by the OnPoint™ Integrated Video Display. For this reason, the OnPoint unit has connections for multiple video outputs.

The OnPoint can be connected to a standard video monitor or an S-Video monitor, or both. Consult your monitor manual for the corresponding connections.

To make these connections, plug the connecting cable(s) into the video output(s) on the rear of the OnPoint™ and the corresponding video input(s) of the external devices.

A BNC-to-RCA adapter is supplied with the OnPoint for use with an RCA cable, so that such connections can be made with an RCA cable as well as a BNC cable. The adapter allows an RCA cable to be plugged into the BNC video output on the rear of the OnPoint video box.

Note: The S-Video connector on the back of the OnPoint is rotated 45 degrees to the left. Most S-Video cables have an arrow on the connectors to indicate the “top” of the connector. Finding this arrow and rotating it to the left will help when connecting this type of cable to the OnPoint.
The OnPoint™ can also be connected to a standard VCR/DVR. Consult your VCR/DVR manual for the corresponding connections.

The OnPoint™ can also be connected to a standard camcorder. Consult your camcorder manual for the corresponding connections.
3.1.4 Attaching Virtual Reality Glasses
1. To attach the iWear VR glasses, simply take the connector on the end of the glasses and find the 6-pin connector on the back of the OnPoint™.

2. To disconnect the iWear VR glasses, pull the knurled ring on the glasses connector directly away from the OnPoint unit. The ring will move and the connector will disconnect.

3.1.5 Setting Up and Operating MediaCaptureUSB
The MediaCaptureUSB is a full-featured, fully integrated image-capture system that is included with every OnPoint™ system. MediaCaptureUSB is also able to be activated from the sterile field via the camera connected to the system. Your hand never has to leave the camera to capture what you need.

Note: All functions that appear on the OnPoint display are also projected on any external display (e.g. computer monitor, BioVision VR glasses, etc.).

3.1.5.1 Modes
The MediaCaptureUSB has three separate modes of operation:

1. Still Capture Mode – for capturing still images (“pictures”)

2. Video Capture Mode – for capturing video images (“movies”)

3. Image/Video Review Mode (or “Review Mode”) – for reviewing image captures (available only if a CompactFlash® card is inserted in the OnPoint™ system’s media slot, and the card already contains captured media).
If you have audio tag recording enabled, you can also include audio with any still images you capture. Refer to the Setup section for more information on audio tag recording. Audio tags are always recorded with video image captures.

The OnPoint system will beep every time you press a button on the MediaCaptureUSB panel (just under the OnPoint display).

To move between the different modes – in the above order – press the Mode button under the OnPoint™ display (or press the F5 key on your keyboard).

3.1.5.2 Accessories & Attachments
You can also connect different accessories to your OnPoint system:

Note: Refer to Section 2.2.1 for the location of connectors.
If you have audio tag recording enabled with your image captures, audio can be played back and heard from the OnPoint™ unit’s speaker.

If you want to add a Name & ID tag to a card, then you will need to connect a PS/2 keyboard to the OnPoint system. To do this, insert the keyboard plug into the keyboard jack on the left side of the OnPoint display.

Note: This connection does not support USB keyboards with PS/2 converters.

To connect the OnPoint system to a separate computer, insert the appropriate USB plug into the USB jack on the left side of the OnPoint display. Your computer will display “New Hardware Detected” (or similar) messages as a result of this connection and you can view the files on your CompactFlash® card through your computer (as well as directly from the OnPoint system).

The MediaCaptureUSB software installation provides drivers that allow Windows 2000 and XP systems to use the OnPoint system as a video source. These drivers will also be available for other software on your system that is aware of such multimedia devices. The “BioVision VICAM III Utilities > VICAM III AMCAP” software (also included with this installation) provides a window on your main computer monitor that mirrors the OnPoint display.

Note: If you have not already installed the MediaCaptureUSB software on the appropriate computer, you will need to do so at this point:

1. Disable all virus protection software on this computer, and close any other programs that may be running.
2. Locate the MediaCaptureUSB software, start the installation program (“install.exe”), and follow the installation wizard’s instructions.
3. When the installation process is completed, restart your computer.
4. If you experience any problems with this process, check with your system administrator.

3.1.5.3 CompactFlash® Card

To begin capturing and reviewing images, insert a CompactFlash® (e.g. SanDisk™, etc.) card into the media slot at the top of the OnPoint™ display until it is fully seated.

Note: MediaCaptureUSB supports CompactFlash® Type I and Type II cards. Video capture will benefit from faster cards such as SanDisk™ Ultra II or Extreme III series or comparable cards.

3.1.5.4 Entering Name and ID Stamping

If a Name & ID have already been entered for this card, they will appear on the OnPoint display.

If you want to add or edit the Name & ID for this card, press the Esc key on your keyboard (you will need to attach a keyboard to the OnPoint system, as described in the “Connecting Accessories” section). The Name/ID Entry Mode will appear on the OnPoint display.
The cursor initially sits in the Name field. Use your keyboard to enter a Name (or edit the current Name). The name field allows a maximum of 15 characters.

Press the Tab key to move to the ID field and enter (or edit) an ID.

When you are finished entering this information, press the Enter key on your keyboard to accept it and exit this mode.

3.1.5.5 Capturing Images

Three ways to activate a capture on MediaCaptureUSB:
1. Press the Stop/Enter button under the OnPoint™ display.
2. Press the F9 key on the optional, attached keyboard.
3. Press the Capture button on your camera.

3.1.5.5a Still Capture Mode

Activate the capture for about one (1) second. The light above the Stop/Enter button will blink once and the system will beep. The image that appears on the OnPoint display at the time you press this button is the image that will be captured. It will be saved on the card as a “JPEG (JPG)” graphics file. The file’s name will be based on the date & time it was captured (e.g. “MM-DD-YY-HH-MM-SS.JPG”).

When you have finished with this image capture, the OnPoint system will return to Still Capture Mode.
If you want to immediately review this image capture, press the Mode button (F5 key) twice to switch to Review Mode. The image you just captured should appear highlighted in the upper-left corner of the thumbnail gallery with a "STILL" label.

Note: To include an audio tag with this still-image capture, perform the image capture in the following manner:

First, make sure that you have enabled audio tag recording (refer to the Setup section for instructions on how to do this) and in the setup menu set capture mode to "single mode button”

Activate the capture for about three (3) seconds. The light above the Stop/Enter button will blink once and the system will beep, as with a regular still-image capture.

Continue to hold down the Stop/Enter button (F9 key) until the light above the Stop/Enter button turns on and stays on; this signifies the activation of audio tag recording. The screen will display “AUDIO RECORDING”.

Speak clearly into (no more than ten (10) feet away from) the OnPoint system’s microphone to have it properly record the audio tag, and then press the Stop/Enter, (F9 key) or the camera button, until the light above the Stop/Enter button turns off, the system beeps again, and the audio tag recording is saved on the card as a “Wave (.WAV)” audio file. The file’s name will be based on the date & time the image was captured (e.g. “MM-DD-YY-MM-SS.WAV”); please note that both the still image file (.JPG) and the audio tag file (.WAV) will have the same name. When you have finished with this image capture, the OnPoint system will return to Still Capture Mode.

If you want to immediately review this image capture, press the Mode button (F5 key) twice to switch to Review Mode. The image you just captured should appear highlighted in the upper-left corner of the thumbnail gallery with an “AUDIO” label (representing a still-image capture with an audio tag attached).

3.1.5.5b Video Capture Mode

Activate the capture for about one (1) second. The light above the Stop/Enter button will turn on and stay on, and the system will beep. This signifies the activation of video recording.

The length of this recording depends on the Recording Limit you specified in the Setup:

If you chose the “10 Second Recording Limit” option, the recording will last (and the light above the Stop/Enter button will remain on) for ten (10) seconds.

If you chose the “No Recording Limit” option, the recording will last (and the light above the Stop/Enter button will remain on) until you press the Stop/Enter button again, or up to the file size limit (i.e. the amount of free space remaining on the card, or 2 GB total).

Please refer to the Setup section for more information on the Recording Limit option.
Continue with the video capture, moving the camera as necessary:

Audio is always recorded with video-image captures. Speak clearly into (no more than ten (10) feet away from) the OnPoint system’s microphone to have it properly record the audio.

This video recording will be saved on the card as an “Audio-Visual (.AVI)” video file. The file’s name will be based on the date & time it was captured (e.g. “MM-DD-YY-HH-MM-SS.AVI”). When you have finished with this image capture, the OnPoint™ system will return to Video Capture Mode.

If you want to immediately review this image capture, press the Mode button (F5 key) twice to switch to Review Mode. The image you just captured should appear highlighted in the upper-left corner of the thumbnail gallery with a “VIDEO” label. Press the Stop/Enter button (F9 key) to review the entire video file.

3.1.5.5c Reviewing Images

To switch from capturing images to reviewing them, press the Mode button (or F5 key) until you are in Review Mode. A thumbnail gallery of the four (4) most recent images you captured will appear on the OnPoint™ display with STILL, VIDEO, or AUDIO labels.

Press the  buttons (or F7 and F8 keys, respectively) to move back & forth through the thumbnail gallery.
To see a full-size display of the currently highlighted image, press the Stop/Enter button (or the F9 key).

If this is a Still capture (with “STILL” on its thumbnail), it will appear in full on the OnPoint™ display.

If this is an Audio-tagged Still capture (i.e. with “AUDIO” on its thumbnail), the still-image capture will appear in full on the OnPoint display and the audio tag will also be heard.

If this is a Video capture (i.e. with “VIDEO” on its thumbnail), then it will appear and play in full on the OnPoint display.

To scroll through image captures while they are being displayed in full, press the < Select or Select > buttons (or the F7 or F8 keys, respectively).

To return to the thumbnail gallery (displaying four (4) images at a time), press the Stop/Enter button (F9 key) again.

To delete the currently highlighted image, press the Delete button (or the F6 key). The following menu will appear:

Remove Current Record – deletes the currently displayed image from the card.

Remove All Records on Card – deletes all images from the card.

Press the < Select or Select > buttons (F7 or F8 keys) to highlight your Delete choice, and then press the Delete button (F6 key). You will then be prompted to confirm this deletion by pressing the Delete button (F6 key) one more time. At this point you will see a “Record Deleted” confirmation message and you will be returned to the Review Mode.

If you wish to cancel the delete process at any point, press the Stop/Enter button (F9 key) to return to the Review Mode.
3.1.5.6 Setup
To enter Setup Mode for the MediaCaptureUSB feature, hold down both the < Select and Select > buttons under the OnPoint™ display (or press the F10 key on your keyboard). A menu will appear with the following setup options:

```
***SURGVIEW SETUP MENU ***
USE < > TO SELECT OPTION:
-SET RECORDING TIME LIMIT
-SET CLOCK TIME & DATE
-SET AUDIO SETTING
-FILE SYSTEM MANAGER
-OSD OVERLAY POSITION
-LAMP COUNTER SETUP
-VIDEO PLAYBACK MODE
-VGA GAMMA SETUP
-PRINT FILE FORMAT
-CAPTURE MODE SETUP
-VIDEO OUTPUT TEST

PUSH STORE TO GO TO OPTION
PUSH DELETE TO EXIT SETUP
```

To select one of these options, press the Store/Enter button (or the F9 key).

To exit the Setup Mode/Menu, press the Delete button (or the F6 key). You will be returned to the mode you were in before (e.g. if you were in the Still Capture Mode when you selected the Setup Mode, then you will be returned to the Still Capture Mode, etc.).

The following section describes each Setup option in greater detail:

3.1.5.7 Set Recording Time Limit
This option pertains to Video Mode only. Press the < Select or Select > buttons (or the F7 or F8 keys, respectively) to highlight one of the following recording time limit options for video captures, and then press the Store/Enter button (F9 key) to select it and return to the Setup menu:

10 Second Recording Limit – this option provides up to ten (10) seconds of recording time for video captures.

No Recording Limit – this option provides for “unlimited (depending on the amount of free space remaining on the CompactFlash® card)” video recording time. If you choose this option, then you will have to press the Stop/Enter button (F9 key) twice: once to start the video recording, and once more to stop it. Recording will stop automatically if you reach the file size limit (i.e. the amount of free space remaining on the card, or 2 GB total).
3.1.5.8 Set Clock Time & Date

The current setting for the Date (in MM-DD-YYYY format) and Time (in 24-hour HH:MM:SS format). Note also the following “additional buttons” displayed at the bottom of the The OnPoint™ display (and the way they correspond to the buttons under the display / keys on the keyboard):

The cursor initially sits under the Month in the Date. Press the - (Mode / F5) button to move the date “down” (e.g. to go from August/08 to July/07, etc.), or press the + (Delete / F6) button to move it up.

When you are finished setting the Month, press the › (Select › / F7) button to move to the Day of the Date and make the same adjustments. Then do the same with the Year, Hour, and Minutes (adjusting the Minutes will reset the Seconds to 00).

When you are finished adjusting the Date and Time, press the Done (Stop/Enter / F9) button to set them and return to the Setup menu.

3.1.5.9 Set Audio Setting

This option allows you to add an audio tag to every image or video you capture. Press the ◀ Select or Select ◀ buttons (or the F7 or F8 keys, respectively) to highlight one of the following tag recording options and then press the Stop/Enter button (F9 key) to select it and return to the Setup menu:

- Enable Audio Tag Recording
- Disable Audio Tag Recording
- Set Speaker Volume
- Use + (mode) or - (delete) buttons to increase or decrease the speaker volume
3.1.5.10 File System Manager
This option provides information on the number and size of images you have already captured on this CompactFlash® card. Specifically:

Type of Capture (Still, Video, or Audio);
Number of Records Captured (in each of the above modes);
Amount of Space Used on this card (for each of the above modes, in Megabytes – “MB”).

When you are finished with this information, press the Stop/Enter button (F9 key) to return to the Setup menu.

3.1.5.11 “Format Media” Option
To format (i.e. erase all information on, and “re-initialize”) this card, perform the following steps:

Hold down both the Delete and Select buttons at the same time or press the F11 key on the keyboard.

To confirm formatting of this card, hold down both the Select and Select buttons at the same time or press F11 on the keyboard. This will start the formatting and re-initialization process. When this process is complete, you will return to the File System Manager screen.

To cancel this process, press the Stop/Enter button (F9 key). You will return to the File System Manager screen.

3.1.5.12 OSD Overlay Position
This option allows you to adjust the vertical positions of the Name/ID and Date/Time strings that are included with every image you capture.

Note: The Name/ID string appears at the top of the display. The Date/Time string appears at the bottom of the display.

To select a string to move, press the Select and Select buttons. (or the F7 or F8 keys, respectively) to highlight that string.

To move the string up/higher in the display, press the Mode button (F5 key).
To move the string down/lower in the display, press the Delete button (F6 key).

When you are finished with these adjustments, press the Stop/Enter button (F9 key) to accept them and return to the Setup menu.

3.1.5.13 Lamp Counter Notification
This is a password-protected factory setting that can only be accessed by BioVision Technologies authorized personnel. Press the Stop/Enter button (F9 key) to exit and return to the Setup menu.
3.1.5.14 Video Playback Mode
This option can help reduce the amount of “jitter” that occurs in some video-image captures. The following choices are available:

| Dual Field Video Playback | Single Field Video Playback |

If you are experiencing “jitter” in your video-image captures, simply switch to the other playback mode. To select a specific playback mode, press the `< Select or Select >` buttons (or the F7 or F8 keys, respectively) to highlight that mode and then press the Stop/Enter button (F9 key) to save it and return to the Setup menu.

3.1.5.15 VGA Gamma Setup (Not used)
Full Screen - The image field is set on a black background
Print Image - A white box is placed around the live image. The image is stored in this format and uses less black ink when printed.

3.1.5.16 Print File Format
This option allows selection of screen formatting preferences for printing.

3.1.5.17 Capture Mode Setup
This option allows assigning the camera button single and dual mode functions.

Dual Mode Button - This mode allows both still and video images to be stored using a single button on the camera. When in “Dual Mode Button”, pressing the camera button will store still image. If the button is held down for two (2) seconds the system will start storing video. Pressing the button again will stop video recording.

Single Mode Button - This mode allows for audio to be recorded with still images if “Audio Tag recording” is enabled. To record a still image with audio press and hold the camera button for two (2) seconds; [AUDIO RECORDING] will appear on the screen. To stop audio recording, press the camera button again. To record video, press the “Mode” button to select the “Video Capture” mode. Pressing the camera button will start video recording; pressing it again will stop recording.

NOTE: Using a fast CF card (15M/s or better) will minimize choppy video recording.

3.1.5.18 Video Output Test
This mode displays SMPTE color bars on the system screen and all external outputs

3.2 Basic Usage
The OnPoint™ 1.2mm Scope System is indicated to be used in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use include, but are not limited to, procedures on the knee, shoulder, ankle, elbow, wrist, temporomandibular joint (TMJ), ear/nose/throat (ENT).
3.2.1 Setup for Each Procedure

Ensure that the voltage selector, located on the bottom of the unit, is in the correct position for the line voltage in your area. The switch has two positions: 115V and 230V. 115V is for U.S. use. 230V is typically for use in Europe.

Connect the medical-grade power cord to the OnPoint™ unit. Connect the other end of this cord to a power outlet that has also been approved for medical use.

Turn on the OnPoint™ unit by pressing the Power button (just below the Integrated Video Display). The lamp will start operating immediately. Approximately fifteen (15) seconds later, MediaCaptureUSB will display the time & date, “Still Capture Mode” and Patient/ID information (if available).
Connect the combination connector to the matching connector on the front of the OnPoint™ unit.

Note: These instructions are for basic usage of the OnPoint system. Refer to section 1.2 for the “Indication for Use”

3.2.2 Power-Down Procedures
When you are finished using the OnPoint system, turn off the system in order to conserve lamp life.

Always disconnect the OnPoint unit from its power source when performing any kind of maintenance (e.g. cleaning, replacing fuses, etc.).

3.2.3 Single-use Endoscope Disposal
When disposing of the single-use endoscope and endoscope accessories, follow procedures for biologically hazardous materials.

4.0 Cleaning and Maintenance
The following section describes the proper method(s) for cleaning and maintaining your OnPoint system.

Note: Never immerse or soak any part of the OnPoint system in any liquid, as this can cause significant damage not covered by the warranty.

4.1 General Cleaning of the OnPoint System
Use a lightly damp cloth. Wipe down the entire OnPoint unit with it.

Allow the unit to dry before using it again.

Any blood on the OnPoint unit can be removed using cotton or gauze soaked in alcohol.
4.2 Sterilization of the OnPoint™

⚠️ **CAUTION:** Do not sterilize the OnPoint 1.2mm Scope System or any of its components. Refer to cleaning section for instructions.

⚠️ **WARNING:** RISK OF SHOCK. Do not autoclave. Do not soak or immerse in disinfecting fluids.

⚠️ Do not use or store disinfecting fluids above or on the OnPoint Integrated Visualization System.

4.3 Lamp Life Monitoring and Replacement

Each time you turn on the OnPoint unit, the monitor will display the number of hours of lamp life remaining:

<table>
<thead>
<tr>
<th>Hours Remaining</th>
<th>Display Format</th>
<th>Display Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>51 or more</td>
<td>LAMP HOURS REMAINING #</td>
<td>5 seconds</td>
</tr>
<tr>
<td>26 - 50</td>
<td>LAMP HOURS REMAINING #</td>
<td>10 seconds</td>
</tr>
<tr>
<td>6 - 25</td>
<td>LAMP HOURS REMAINING #</td>
<td>20 seconds</td>
</tr>
<tr>
<td>1 - 5</td>
<td>REPLACE LAMP</td>
<td>30 seconds</td>
</tr>
<tr>
<td>0</td>
<td>REPLACE LAMP</td>
<td>120 seconds</td>
</tr>
</tbody>
</table>

Field replacement of the lamp should never be attempted. For service, contact your Biomet Microfixation representative.

4.4 Recommendations for the Disposal of the Device

For the disposal of the OnPoint unit, follow the guidelines in Directive 2002/96/EC Waste Electrical and Electronic Equipment (WEEE), or send the equipment to Biomet Microfixation for proper disposal free of charge. For the disposal of the single use endoscope, accessories, and procedure kit follow the procedures for the disposal of bio-hazardous materials.

4.5 Fuse Replacement

1. Unplug the OnPoint power cord from the wall outlet to ensure that no electrical power is present.

2. Use a standard screwdriver to pry the fuse holder free from the back of the unit as shown.
3. Disengage the fuses as shown. Replace with new fuses.

WARNING: USE 3.15A, 250V, TYPE F FUSES ONLY.

4. Place the fuse holder back in the unit. Push firmly until it snaps into place.
5.0 Troubleshooting

Scenario

A: The unit will not operate. No fans blowing, with a blank screen.

1. Check all power connections to the OnPoint™ unit. Check the power cable connection to the wall outlet and the rear of the OnPoint unit.

See § 3.2.2 Setup for Each Procedure

2. Ensure that the voltage-selector switch is in the appropriate position.

See § 3.2.2 Setup for Each Procedure

3. Check fuses.

See § 4.5 Fuse Replacement

4. Check the building breaker controlling the outlet you are using. You may need to consult the proper building administration to ensure power to your outlet.

5. Should these measures fail, please contact Biomet Microfixation for technical support and/or service.

B: The unit’s fans are blowing but the monitor is blank.

1. Ensure the camera cable connector is properly seated in the receptacle on the front of the unit.

See § 3.2.2 Setup for Each Procedure

2. Check for light output. If there is none, replace the lamp.

See § 4.3 Lamp Replacement

3. Contact Biomet Microfixation for technical support and/or service. Make a note of the camera you are using. If you have multiple camera attachments, the support person may ask you to try another camera. It may be necessary to send the camera you are using for service along with the OnPoint unit.
C. The image is blurry.

1. If you are using a camera coupler, rotate the focus ring to bring the image into focus.

2. The scope, coupler or camera optics may be dirty. Please refer to the manuals that came with your camera and scope for proper care and cleaning.

D. There is no light or light output is low.

1. If light output seems low, check the connection between the light output on the camera and the scope for particles and foreign objects.

2. If the output is still low or there is no light, your lamp may be bad. Please contact your service representative.

See § 4.3 Lamp Replacement

3. If your lamp is good or is now replaced, and light output is now still low, the light fibers in the camera cable may be damaged. Please contact Biomet Microfixation for service.

Contact Biomet Microfixation for Customer Care

904.741.4400
(press 5 for customer service)

800.874.7711

www.biometmicrofixation.com

Please copy your serial number here for future reference: ________________________________

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1520 Tradeport Drive
Jacksonville, FL 32218-2480
www.biometmicrofixation.com

OnPoint™ Scope System is manufactured by BioVision Technologies, LLC
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