Sesamoid® Plasty V2

User Guide

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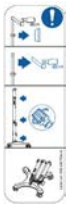
Table of Contents

Symbols and Icons

The following symbols and icons can be found on the Sesamoid Plasty or on the labeling of components.

Symbol	Meaning	Location
	General warning sign	Computer
	Power Indicator	Camera front panel
	Camera status indicator (tracking mode)	Camera front panel
	Camera error indicator	Camera front panel
	Manufacturer	Computer, camera, stand, laser pointer
	Laser radiation warning	Laser pointer
	Warning to avoid eye exposure to laser beam	Laser pointer
	Symbol for “Authorized EC Representative”	Computer, camera, stand
	Steps to put the system in its transport position	Stand
	No pushing label	Stand
	Mandatory action: When dissassembling the system, the computer and camera must be taken out before using the tree knobs to fold the stand.	Stand
	Refer to instruction manual	Computer
	Symbol for “Disposal of WEEE (Waste Electrical and Electronic Equipment).” In the EU, refer to www.weee.zimmer.eu for information.	Laser pointer

Introduction

The Sesamoid Plasty is Zimmer Biomet's hardware platform for the unicondylar*, total knee and total hip replacement* applications. The platform and its applications are designed to allow surgeons the ability to precisely and intraoperatively visualize the positioning of the instrumentation relative to bony structures in real time and in three dimensions.

The Sesamoid Plasty includes both the Sesamoid Plasty Computer and the Sesamoid Plasty Camera, which are housed on the same stand.

Under normal conditions, the Sesamoid Plasty's expected useful life is 5 years.

- **CAUTION:** Do not put any component of the system in contact with the patient or with users that will be in contact with the sterile field. The system is developed for use outside of the sterile field and its components are not sterile.
- **CAUTION:** Ensure that no one touches an accessible connector contact and the patient simultaneously.
- **CAUTION:** Only connect items that have been specified as part of the Sesamoid System

For any problem or question on the Sesamoid Plasty, contact Zimmer CAS Customer Support:

Phone number: 1 (514) 395-8883
US toll free phone number: 1 (866) 336-7846
7:00 AM to 5:00 PM EST

Operating Principle of the Sesamoid Plasty

The laser pointer is used to orient the camera toward the sterile field where optical trackers are fixed on the patient's bones and surgical instruments. The Sesamoid Plasty Camera emits an infrared light and detects its reflection by retro-reflective markers on the trackers. From this, the tracker position and orientation are acquired and the navigation information is able to be computed via the pre-installed ORTHOsoft Universal Applications. The navigation information is then displayed on the Sesamoid Plasty Computer. This will enable the surgeon to determine axial alignment in relation to anatomical landmarks for precise placement of instruments. The Sesamoid Plasty Stand supports the camera and computer, and is mobile for ease of use.

This user guide is the main primary training material for use of the Sesamoid Plasty. It contains all the information needed to operate the system and provides system-specific warnings, assembly/disassembly, transport, storage and cleaning.

*Not available in the US

Platform Overview

Main components of the Sesamoid Plasty (Figure 1):

1. Camera
2. Laser pointer
3. Camera arm
4. Computer
5. Stand

Sesamoid Plasty Assemblies and Accessories:

Computer kit

Camera kit

Stand

LEMO® Cable

Computer power cable

HDMI cable (optional)

Ethernet cable

CAUTION: It is recommended that if the Sesamoid Plasty is used with any configuration other than that shipped by Zimmer Biomet, users should verify compliance with General Requirements for Basic Safety and Essential Performance for Medical Devices IEC 60601-1.

Figure 1

Sesamoid Plasty Computer

The Sesamoid Plasty Computer has an internal battery that allows for approximately 15 minutes of autonomy. This power backup is provided to prevent data loss if there is a main power outage. The battery cannot supply sufficient power to operate the Sesamoid Plasty Camera. Therefore, it is not possible to use the system to navigate while it is in power backup mode. A warning is provided to the user if the main power is disconnected and the computer runs on the battery.

Figure 2 summarizes all connections that can be found on the back of the Sesamoid Plasty Computer.

Connector Panel on the Sesamoid Plasty Computer

1. Equipotential ground connector
2. AC power inlet
3. Computer power inlet (do not unplug permanent connection)
4. USB ports (do not unplug permanent connection)
5. VGA port (do not use)
6. HDMI port
7. Ethernet connectors (do not unplug permanent connection)
8. Serial ports (do not use)

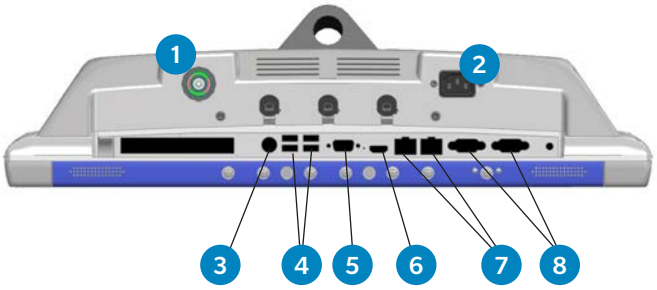


Figure 2

CAUTION: Do not remove the caps on the serial ports (callout 8 in Figure 2) for safety reasons, these ports are not to be used.

CAUTION: Never disconnect the three permanent connections at the bottom panel of the Sesamoid Plasty Computer.

Connections

- Only use the HDMI cable provided by Zimmer Biomet to connect the Sesamoid Plasty to an external display.
- Only use the Ethernet cable provided by Zimmer Biomet to connect the Sesamoid Plasty to a local network. No restrictions are in place for this type of connection.
- The built in ground connector serves to equalize potentials or reduce differences of potential between the Sesamoid Plasty's metal components that can be touched simultaneously or between it and conductive objects.

CAUTION: To avoid the risk of electric shock, this equipment must be connected to a supply main with protective ground.

CAUTION: For safe use, connect the Sesamoid Plasty to the surgical room's equipotential grounding system.

CAUTION: Only connect items that have been specified as part of the Sesamoid Plasty.

CAUTION: Do not position the Sesamoid Plasty in a way that makes unplugging the power cord difficult.

Sesamoid Plasty Computer (cont.)

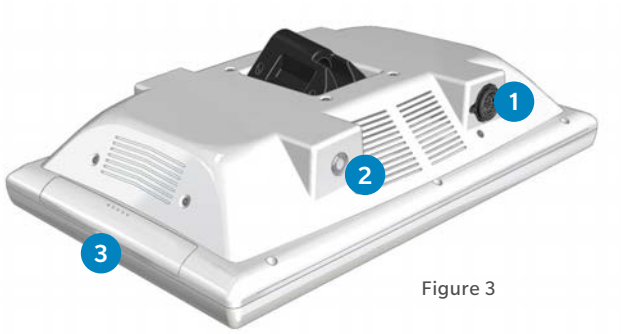


Figure 3

Rear View of the Sesamoid Plasty Computer (Figure 3):

1. Camera connector
   (for use with next generation camera)
2. Polaris Spectra® Camera Connector
3. Additional USB ports

Figure 4

View of the Sesamoid Plasty Computer's Button Commands:

1. Power switch and power indicator
2. Volume adjustment (+/-)
3. Light
4. Touchscreen activation/deactivation (Do not use)
5. Lights activation/deactivation
6. Light
7. Luminosity adjustment (+/-)

- **CAUTION:** Do not remove the cap on the camera connector, this port is reserved for future use and not to connect to a local network.
- **CAUTION:** The openings on the enclosure are for air convection to protect the equipment from overheating. Do not block the openings.
- **CAUTION:** If one of the following situations arise, get the equipment checked by service personnel:
  - The power cord or plug is damaged.
  - Liquid has entered the equipment.
  - The equipment has been exposed to moisture.
  - The equipment does not work well, or you cannot get it to work according to the user's manual.
  - The equipment has been dropped and damaged.
  - The equipment has obvious signs of breakage.
  - The date and time function stops functioning properly.
- **CAUTION:** No modification of this equipment is allowed. For safety reasons, only qualified service personnel should open or bring modifications to the Sesamoid Plasty Computer or Sesamoid Plasty Camera, as they contain no replaceable parts.
- **CAUTION:** Never insert a foreign object in the Sesamoid Plasty Computer's openings. This may cause electric shock or fire, or it may damage hardware components.

Sesamoid Plasty Camera

Overview of the Polaris Spectra Camera

- **CAUTION:** Depending on ambient temperature, it could take several minutes for the Sesamoid Plasty Camera to reach operating temperature from a cold-start at normal temperature (the power LED will flash when warming up and stay lit when ready).
- **CAUTION:** The tracking operation, if affected, will be automatically inhibited by the application until the normal operating temperature is reached, resulting in tracked items not being displayed temporarily.
- **CAUTION:** It is recommended to recalibrate the Polaris Spectra Camera once a year, or if the user feels that the performance of this component has degraded. This component is sensitive and impacts beyond normal use could affect its performance. For more information, contact Zimmer CAS Customer Support.
- **CAUTION:** The Sesamoid Plasty Camera utilizes infrared signals to determine positional information which results in the following:
  - The system may potentially interfere with other devices that utilize or are sensitive to infrared signals if they are in the same frequency range (i.e. pulse oximeters). The standard precaution is to shield these devices from the infrared light of the camera. The user manuals of these devices should be consulted for specific instructions on how to reduce the chances of interference.
  - The presence of strong infrared sources, including some lighting systems or infrared reflectors in the vicinity of the reflective markers, can cause interference and affect its performance.

Figure 5

Front View of the Polaris Spectra Camera (Figure 5):

1. Sensor: Tracks IRED markers (active trackers) and/or retro-reflective targets (passive trackers).
2. Illuminator ring: An array of IREDs provides infrared light for reflective markers, and initiates marker activation for active wireless tools.
3. Power LED: Flashes green when warming up and stays lit when ready.
4. Status LED: Displays steady green light when the camera is communicating with the Sesamoid Plasty Computer.
5. Error LED: Flashes amber if a bump is detected. It stays lit if a critical error is detected (if such an error occurs, contact Zimmer CAS Customer Support).

Figure 6

Back View of the Polaris Spectra Camera (Figure 6):

1. LEMO Connector that provides power and communication to the camera.

Laser Positioning System

The laser pointer helps approximate the correct camera aim by projecting a low-power laser beam along the center of the camera's field of view. Press the "On/Off" trigger button to activate the laser, and release the button to deactivate the laser.

CAUTION: The laser pointer transmits laser radiation. Use caution when operating the device, and never aim the laser at someone's eye. Laser radiation, even at low levels, can damage the eyes.

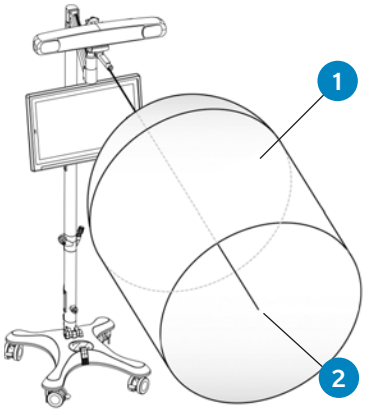


Figure 6

Laser Position (Figure 6)

1. Camera field of view
2. Laser beam

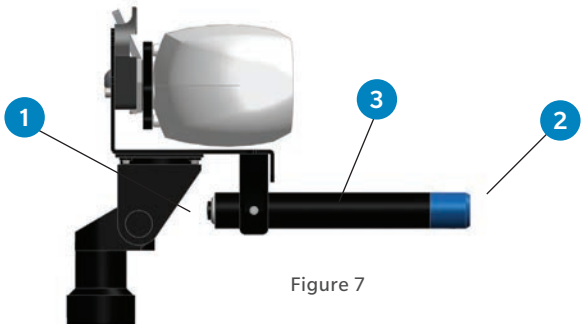


Figure 7

Laser (Figure 7)

1. Laser activation button
2. Laser aperture

3, Laser explanatory label

Laser Batteries

There are three 1.5V LR1 (or type N) alkaline batteries in the laser pointer. The batteries provided with the laser pointer do not contain lead.

To change the batteries:

1. Unscrew the laser pointer shell assembly.
2. Take out the batteries.
3. Insert new 1.5V 'N' alkaline batteries, taking into account the polarity of the batteries and the shell.
4. Screw down the laser pointer. The batteries should be disposed of per appropriate methods (not to be disposed of in normal household waste and must be disposed of separately). See the Symbols section, page 2, for further information.

Cleaning and Disinfection

- **CAUTION:** Always isolate the equipment from the main electrical supply prior to cleaning and disinfection in order to prevent electrical shocks.
- **CAUTION:** Immersing or soaking the Sesamoid Plasty Computer or the Sesamoid Plasty Camera into liquid could result in malfunction of the unit. Do not spray a cleaning agent on the enclosure.
- **CAUTION:** Never allow water or other liquids to enter the equipment since they may cause subsequent short-circuits or corrosion.

Cleaning

Enameled parts and aluminum surfaces should only be wiped clean with a damp cloth and mild detergent, and then rubbed down with a dry woolen cloth. Never use corrosive cleaning agents, solvents or abrasive detergents or polishes. If you are uncertain of the nature of a cleaning agent, do not use it. Do not use abrasive polishes.

Disinfection

All parts of the equipment, including accessories and connecting cables, can be disinfected by wiping them with a cloth dampened with a mild, alcohol-based cleaning agent. Never use corrosive or solvent disinfectants. If you are in any doubt of the nature of a disinfecting agent, do not use it.

- **CAUTION:** Disinfecting medical equipment with sprays is not recommended since the vapor can enter the equipment causing electrical short-circuits or corrosion.

Transportation and Storage

Assembly of the Sesamoid Plasty

1. Unfold the first pole section located close to the base of the Sesamoid Plasty Stand. Tighten the locking mechanism of that pole section and complete the same operation for each pole section.
2. Insert the camera arm into the hole situated on the upper pole section.
3. Install the Sesamoid Plasty Camera on the camera arm.
   - To attach the Sesamoid Plasty Camera, slide its connector in the Manfrotto™ Connector located at the end of the camera arm.
   - A "click" is heard once the camera is firmly attached to the camera arm.
4. Install the computer on the holding post by sliding its back bracket on the post.

Figure 8

Assembly (Figure 8)
Attach the camera from the camera arm

Moving the Sesamoid Plasty while Assembled

The Sesamoid Plasty must be handled with care. You must avoid any type of impact to the Sesamoid Plasty System, and in particular to the camera. The Sesamoid Plasty must be stored in a dry and cool area. Prior to moving the Sesamoid Plasty System (while it is assembled), the user must always put the camera in its lower forward position to minimize tilting hazards.

CAUTION: To move the Sesamoid Plasty, put the camera arm in its lowest position. Do not move the system while out of this position.

Transportation Configuration Label

Transportation and Storage (cont.)

Disassembly of the Sesamoid Plasty

The steps to fold down the Sesamoid Plasty (shown in Figure 9) are:

a. Remove the Sesamoid Plasty Computer from the stand.

b. Remove the Sesamoid Plasty Camera and the camera arm from the stand.

- To remove the camera from the arm, press and hold the button on the Manfrotto Connector located on the camera arm (Figure 9) and slide the camera connecting device out from the bottom to the top of the camera arm connector.

c. Undo successively the top, middle and bottom stand locking mechanisms.

d. Fold the stand towards the floor holding the previously folded segments to prevent them from swinging unexpectedly.

CAUTION: Remove the Sesamoid Plasty Camera and the Sesamoid Plasty Computer prior to undoing any of the locking mechanisms to fold the stand. Failure to follow these instructions will result in an unexpected tilt of the Sesamoid Plasty Stand.

CAUTION: The Sesamoid Plasty must never be submerged in water or exposed to high levels of humidity.

CAUTION: Do not leave the equipment in an uncontrolled environment where the storage temperature is below –20˚ C or above 50˚ C. This may damage the equipment.

CAUTION: The Sesamoid Plasty must be kept away from conditions of extreme heat or cold.

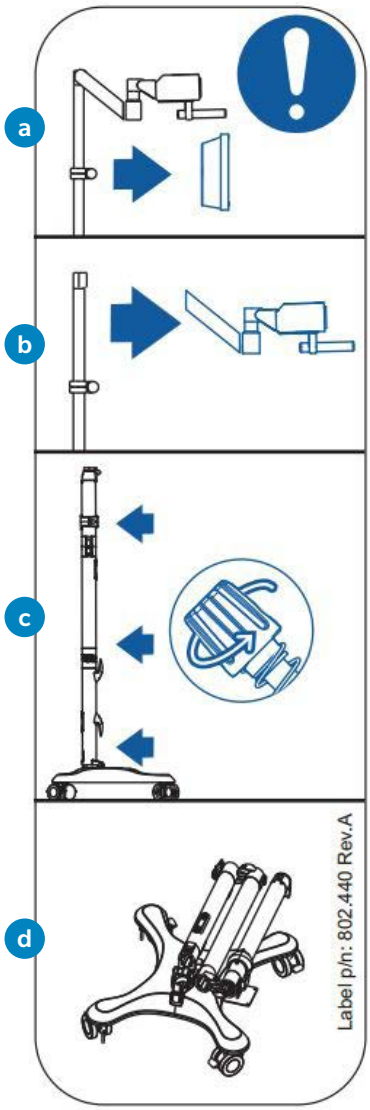


Figure 9

Disassembly of the Sesamoid Plasty Stand

Packaging the Sesamoid Plasty

Transport Cases

If the Sesamoid Plasty is to be frequently shipped, a series of reusable packaging material is available (Figure 10).

A. The large box contains the Sesamoid Plasty Stand and the camera arm.

B. The Sesamoid Plasty Computer goes in the medium box.

C. The small box contains the Sesamoid Plasty Camera.

D. The boxes can be assembled together for easy transport.

CAUTION: The transport cases were designed and tested for transport by plane and car/truck, but not by ship or train.

Figure 10

Packaging of the Sesamoid Plasty

Care of Cables and Connectors

To avoid damage to cables, make sure the cables are not bent at sharp angles. Handle the connectors with care, paying particular attention to the following points:

- Pull connections apart by gripping the connector. Do not pull them apart by tugging on the cable as this can damage the connecting cable and connector pins. The system has a lanyard on the LEMO® Sleeve, which can be pulled directly to unmount the connector.
- Do not leave cable connectors where they will get damaged, particularly on the floor, where they can easily be stepped on or rolled over by heavy equipment.
- Do not put heavy objects on cables or cable connectors.
- Never force a connection.
- Make sure that the red dots on the LEMO Connectors are lined up with each other before connecting (the double keys of the connector should be aligned).

CAUTION: For safety reasons and to ensure proper functioning of the system, do not use cables other than those distributed by Zimmer CAS.

Preventive Inspection and Maintenance

CAUTION: All user maintenance must be done by appropriately trained personnel. Individual components of the Sesamoid Plasty Camera and Computer contain no user-serviceable parts. Maintenance by untrained personnel may present an electric shock hazard.

The only user replaceable accessories are:

- The laser pointer system's batteries
- The power, HDMI and Ethernet cables

CAUTION: It is recommended to recalibrate the Sesamoid Plasty Camera once a year. Contact Zimmer CAS Customer Support for more information.

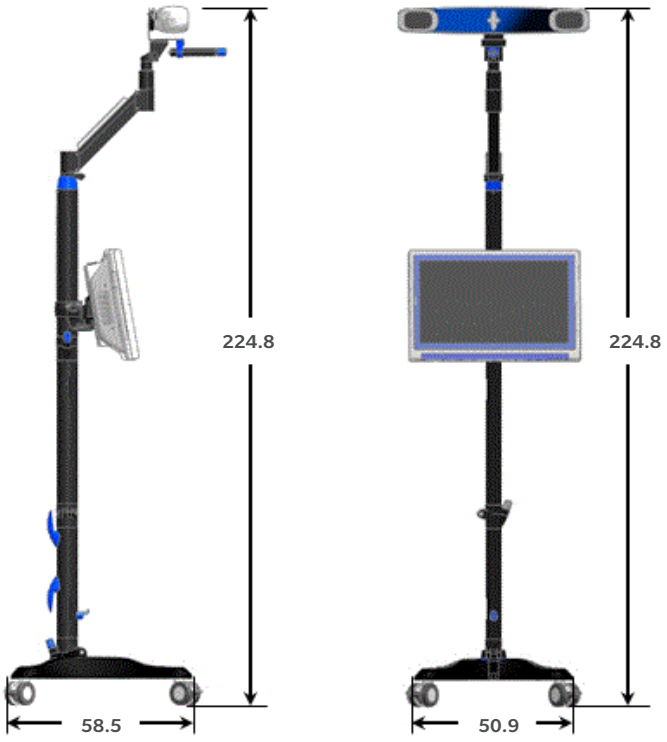
CAUTION: Contact Zimmer CAS Customer Support with any doubt regarding the camera's accuracy.

Technical Specifications

The specifications listed apply to system operation under typical conditions.

Sesamoid Plasty Approvals

ANSI/AAMI ES 60601-1
CAN/CSA-C22.2 No. 60601-1
IEC/EN 60601-1 ed 3.1
IEC/EN 60601-1-2 ed 4
FCC Class B



Figures 11a and 11b

Sesamoid Plasty Specifications

SESAMOID PLASTY FOOTPRINT

58.5 cm x 50.9 cm.

SESAMOID PLASTY HEIGHT

The maximum possible height of the system is 224.8 cm.

SESAMOID PLASTY WEIGHT

27.9 kg (including Sesamoid Plasty Computer, Camera and Stand).

CLASSIFICATIONS

Electric shock protection	Class 1 – protectively earthed with power from supply mains, without applied parts.
Flammable atmosphere	Not suitable for use in presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

POWER

AC input requirements	100 - 240 V 1A max 50-60 Hz

OPERATING CONDITIONS

Humidity	10 ~ 90% (Non-condensing)
Temperature	10˚ C to 40˚ C
Atmospheric pressure	70 kPa - 101.3 kPa

TRANSPORT/STORAGE CONDITIONS

Humidity	80% relative humidity at high temperature
Temperature	-18˚ C to 49˚ C

USER DEVICES

Touch screen

Technical Specifications (cont.)

Sesamoid Plasty Specifications (cont.)

MONITOR DIMENSIONS

55 cm x 36 cm x 11.4 cm (irregular)

MONITOR WEIGHT

11.3 kg

CAMERA DIMENSIONS

6.13 cm x 10.4 cm x 0.86 cm

CAMERA WEIGHT

1.9 kg

- **CAUTION:** The Sesamoid Plasty has been tested and is in compliance with the electromagnetic compatibility (EMC) requirements for emissions. In some situations, it is still possible that radiated electromagnetic fields such as those from portable and mobile devices may cause performance degradation.
- **CAUTION:** Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to the Sesamoid Plasty, including cables. Otherwise, degradation of the performance of the equipment could result.
- **CAUTION:** Use of this equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Technical Specifications (cont.)

The Sesamoid Plasty is designed for use in the operating room, with the following exceptions:

- Near portable and mobile RF communication equipment that radiate electromagnetic fields as those may cause performance degradation.
- In the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

To ensure adequate communication between the Sesamoid Plasty Camera and Computer, display of the correct navigation values and to avoid latency in the system, it is important to use the Sesamoid Plasty in the recommended use environment.

Use of the Sesamoid Plasty outside of a suitable environment can result in:

- Misleading/erroneous navigation information.
- Asynchronous information relative to current state of instruments.
- Unintentional manipulations of the system.

CAUTION: The emission characteristics of the Sesamoid Plasty make it suitable for use in industrial areas and hospitals (CISPR 11 class A). The Sesamoid Plasty is not adequate for use in a residential environment as it might not offer adequate protection to RF communication services.

Product Regulatory Notices

Wireless Communications

The Sesamoid Plasty Computer contains an RF transmitter with the following characteristics:

- Transmission frequency: 2.4/5 GHz
- Network Standard: Compliant with IEEE 802.11n, 802.11g, 802.11b,802.11d, 802.11e, 802.11j and 802.11i
- Modulation: OFDM with BPSK, QPSK, 16 QAM, 64 QAM;DQPSK, CCK, G-FSK, π/4-DQPSK, 8-DPSK
- Supported Data Rates: IEEE 802.11a 6 - 54 Mbps, IEEE 802.11b 1 - 11 Mbps, IEEE 802.11g 6 - 54 Mbps, IEEE 802.11n 6.5 - 300 Mbps
- Effective isotropic radiated power: 21 dBm

Technical Specifications (cont.)

Product Regulatory Notices (cont.)

FCC Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Technical Specifications (cont.)

Guidance and Manufacturer's Declaration

Electromagnetic Emissions

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Sesamoid Plasty 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.
RF emissionsCISPR 11	Class B	The Sesamoid Plasty Computer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The Sesamoid Plasty Computer is intended for use in the electromagnetic environment specified below. The customer or the user of the system controller computer should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV line(s) to line(s) ± 1 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5, ± 1 kV line(s) to line(s) ± 0.5, ± 1, ± 2 kV line(s) to ground for power supply lines ± 2 kV line(s) to ground for input/ output lines	± 0.5, ± 1 kV line(s) to line(s) ± 0.5, ± 1, ± 2 kV line(s) to ground for power supply lines ± 2 kV line(s) to ground for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

Technical Specifications (cont.)

Guidance and Manufacturer's Declaration (cont.)

Electromagnetic Immunity

The Sesamoid Plasty Computer is intended for use in the electromagnetic environment specified below. The customer or the user of the System Controller Computer should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Sesamoid Plasty, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d=1.2 √P d=1.2 √P 80 to 800 MHz d=2.3 √ P800 MHz to 2.5 GHz 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[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: 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 Sesamoid Plasty is used exceeds the applicable RF compliance level above, the Sesamoid Plasty Computer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sesamoid Plasty.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Disposal of Equipment

In the European Union, components bearing the symbol (shown right) must be disposed of using local recycling initiatives, or returned to Zimmer Biomet for recycling. See Symbols section, page 2, for further information.

The batteries directive 2006/66/EC includes requirements on the removability of batteries from waste equipment in EU Member States. To comply with this directive, this device has been designed for the safe removal of the batteries at end-of-life by a waste treatment facility.

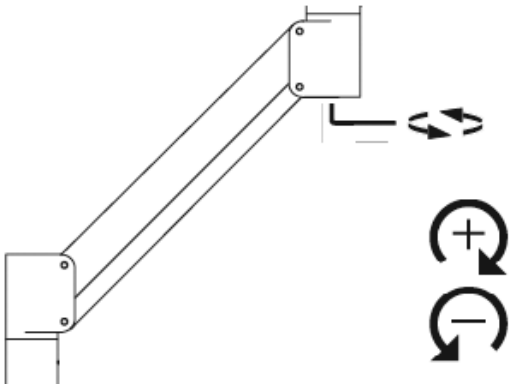
Troubleshooting of the Sesamoid Plasty

Camera Arm not Holding its Position

In some occasions, the camera may not hold its position while orienting it to the operating field. The following steps might fix this issue.

Note: In order to calibrate the spring load of the Camera Arm, the camera must be attached to it. The Sesamoid Plasty must therefore be assembled to proceed.

1. Using a 5.5 mm Allen key, tighten the set screw located underneath the camera arm. Turning the screw clockwise will increase the stiffness of the arm.
2. To decrease the stiffness, loosen up the screw by turning it counter clockwise.
3. Verify and adjust the stiffness of the camera arm until it holds its position.



Location of the set screw that adjusts the stiffness of the camera arm.

Figure 12

Communication Errors

When the Sesamoid Plasty Camera communication error message is displayed

1. Verify that both LEDs are on and green.
3. Verify that the cable is plugged firmly into the camera.
4. Verify that pins inside all connectors are not bent.
5. Make sure that the LEMO Connector sleeve is tightly in place. Do not twist the cable at anytime.
6. Try changing USB ports.
7. Contact Zimmer CAS Customer Support if the error is not resolved.

Bump Detection

When the internal bump detection message is displayed, contact Zimmer CAS Customer Support.

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Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

20-8000-71-21 Sesamoid Plasty V2

EC REP

Authorized Representative
Zimmer U.K. Ltd.
9 Lancaster Place
South Marston Park
Swindon, SN3 4FP, UK

Legal Manufacturer
Zimmer CAS
75, Queen Street, Suite 3300
Montreal (Québec) H3C 2N6
Canada

Tel : 1 (514) 395-8883
Fax : 1 (514) 878-3801

zimmerbiomet.com

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