Quadsense System Instructions For Use

Product Description

The Quadsense Sensor is a single-use device for comparing the forces at the patellofemoral joint, during Total Knee Arthroplasty procedures. The device is for use both before and after resurfacing the tibia and femur.
All Quadsense Sensor components are supplied as sterile. The end-user should not re-use or re-process the device.
The Quadsense Sensor should only be used in conjunction with the provided Panel PC:

- CyberMed NB20 Fanless Medical Grade PC W/Hot Swap Batteries (Eventum Product Code: PC001)

The provided Panel PC has pre-installed Quadsense software and attached dongle (Product Code: CA001) which is essential for use of the device.

Indications For Use

The Quadsense is indicated for use in primary Total Knee Arthroplasty (TKA), where the patella is resurfaced.
For use as a comparative tool to measure patellofemoral joint force.
The Quadsense Sensor is sterile, for single patient use.

The device does not make a diagnosis and is not intended to replace a surgeon's clinical judgement.

Contraindications For Use

The Quadsense System should not be used if:

- the patient presents with an active infection.
- the equipment is found to be damaged during pre-operative inspection.
- the sterile packaging of the Quadsense Sensor is found to be compromised at any point.
- the end-user does not have the necessary qualifications and experience to perform Total Knee Arthroplasty procedures safely and correctly.

Precautions

Read and understand the user instructions before use.
Do not use the device in a surgical procedure without appropriate training.
Do not power the device using any other method.
Do not connect the Quadsense Sensor to any other display units or PCs than the one provided.

Warnings

Warning: All device components of the Quadsense Sensor are supplied as sterile. If the packaging is found to be compromised before the surgery, then do **not** use the device.
Warning: Do not reuse or re-process the Quadsense Sensor. The Quadsense Sensor has been designed to have an intended lifetime of a single surgical procedure.

- Re-using or re-processing the device may compromise the structural integrity of the device, ability to meet performance specifications and impact the device calibration, which may result in patient injury.
- Re-using or re-processing a sterile device may create a risk of contamination (transmission of infectious material), which may result in patient cross infection.

Warning: The Quadsense shims do not correlate in size and shape with patella implant sizes.
Warning: Do not use the device after the expiration date on the label.
Warning: The use of Quadsense may add additional operative time as well as increase risk of infection.
Warning: Improper device use may result in adverse surgical decisions and increase risk of soft tissue damage (e.g. Re-cutting may lead to overcutting the patella, fracturing the patella, or compromising patellar component fixation).
Warning: A resection that reduces the thickness of the Patella to 12 mm or less could risk patella fracture.

Cautions

Caution: If any components are damaged upon opening package from manufacturer, do **not** use and contact Eventum to organise replacement.
Caution: Do not use if the pin protector has come loose from the sensor before opening the packaging. The sensor pins may have compromised the packaging and the device may no longer be sterile.
Caution: Do not use if the Panel PC has insufficient battery capacity for the procedure.
Caution: Do not impact the device with surgical tools as this may damage intricate components of the device.
Caution: Maintenance and servicing activities including software maintenance and updates must not be performed during clinical use of the Quadsense device.
Caution: The sensor has small metal pins that are intended to insert into the patella. Take care when handling the sensor and follow standard hospital procedure if these pins cause a needle stick injury.
Caution: If the device breaks during the procedure, ensure no fragments remain in the patient's wound.
Caution: Do not modify equipment.
Caution: Do not disassemble the device beyond intended use stated in the user instructions.
Caution: Do not detach the Quadsense Sensor from the Cable during use. This will disrupt the Quadsense software workflow.
Caution: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Caution: Only use appropriate accessories from Eventum with Quadsense.
Caution: Use of accessories, transducers and cables other than those specified or provided for use with the Quadsense system could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
Caution: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Quadsense system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Caution: After use, the device should be treated as biological waste with sharp components and disposed of in accordance with hospital protocol and local regulations.

Undesirable side effects

There are currently no known side effects associated with the device. The surgeon is responsible for any complications that may result from incorrect surgical technique or inadequate aseptic techniques such as:

- Damage to soft tissue
- Infection
- Pain due to over-resecting or improper angular cuts to the patella

Instructions

The Quadsense Sensor is intended for use in Total Knee Arthroplasty. The surgical lead should proceed with their preferred surgical workflow for the procedure and refer to the Quadsense Sensor Surgical Technique when needed.

1. Ensure Panel PC is turned on, operational and displaying the Quadsense Software, disconnected from mains power, and has sufficient battery power to complete the procedure. A fully charged battery is recommended.
2. Prepare the patient for the procedure.
3. Remove the sensor device and all components from the sterile packaging pouch. Keep all components, except the cable, within the sterile field at all times.
   Warning: Do **not** use if the packaging is damaged before opening. The device will not be sterile.
4. Check for visible signs of damage.
   Warning: Do **not** proceed with use of the device if it appears to be damaged.
5. Peel the adhesive sticker off the underside of the control puck, then stick the control puck to the patient's draped leg. Ensure the control puck is close enough to the patella so that the cable isn't taut, and that the arrow button on the keypad is pointing towards the patient's hip.
6. Attach the long single-use cable to the provided re-usable cable, attached to the Panel PC. The single-use cable will pass out of the sterile field.
7. Resect the patella to create a flat surface to accommodate the sensor.
8. Remove the protective cover from the sensor. This will reveal the underside of the sensor, with the metal pins that will insert into the patella.
9. Take an initial reading.
   a. The shim used should be the same depth as the resection (e.g. 6 mm).
   b. After taking the reading and removing the shim from the sensor, mark the patella with the position of the sensor with methylene blue at the sensor indents.

Take a reading:

1. Place the sensor centrally on the resected surface of the patella, and press the metal pins into the patella until the underside of the sensor is flush with the patella surface, and stable.
2. Attach the shim to the sensor.
3. Enter the shim dimensions onto the software.
4. Press the relevant button on the control puck, or the Record button on the Panel PC to start a reading.
5. Move the leg through full flexion and extension at a consistent pace, three times. Twelve seconds are allotted to take a reading.
   a. The results graph will appear on the Panel PC and can be viewed now and referred to later in the operation.
6. Remove the sensor from the patella and attach to the clip on the puck.
10. Proceed with resurfacing the tibia and femur following the surgeon's preferred workflow.
11. Take another reading using the same shim used previously (e.g. 6 mm), following the same methodology.
    a. Use the markings made by the methylene blue as an aid to position the sensor in the same place
12. Compare the second reading to the initial reading and use the data to determine if another shim would give a reading more similar to the initial reading. Complete further readings with shims to best match the initial reading.
13. Proceed with standard workflow for patella implant trial and positioning.
    a. Please refer to the implant's surgical technique booklet for further instructions.
14. Close the incision point.
15. Dispose of the single-use sensor and components, following the hospital's standard protocol for disposal of biohazardous waste and sharps.
16. Power down the Panel PC by holding the power button.
17. Wipe down Panel PC and reusable cable following manufacturer's instructions.

Troubleshooting

Issue	Cause	Solution
The Panel PC software will not respond to a button on the control puck being pressed.	The cable between the puck and the Panel PC may be disrupted.	Check the cable is fully connected to the re-usable cable from the Panel PC. Check all cables for visible signs of damage. If the problem persists but the sensor can still take readings, then you can move through the workflow using the touchscreen. Alternatively, you can unpack a new product to use, or discontinue use of the product and follow standard surgical technique.
The results of the reading are not appearing on the Panel PC.	The single use cable may have disconnected from the re-usable cable. The sensor may have not started recording.	Ensure the cable is properly connected. Press the relevant button on the control puck to start the recording.
The sensor will not attach to the patella.	The protective cover may still be attached to the underside of the sensor. The sensor may not be in the correct orientation.	Remove the protective cover from the sensor to reveal the metal pins and discard the cover. Attempt to attach the sensor to the patella. Examine the sensor and ensure the face of the sensor that has the metal pins is facing down onto the bone. The sensor should be centralised on the patella and flush on the bone. If the sensor is not flush, the patella surface may not be flat.
An error message is	The software has registered	Reconnect the sensor to the cable. If no readings have

returned on the software, that the sensor has been disconnected.	that the Quadsense Sensor has been disconnected.	been taken, start the software workflow again. If readings have been previously taken, these will not be stored and the surgeon may have to revert to standard technique.

Storage and handling

The Quadsense Sensor device must be stored in the original packaging until use.
The Quadsense Sensor device should be stored in a clean, dry environment under ambient humidity conditions and between 10°C - 35°C (50°F - 95°F).
The Quadsense Sensor device should be handled with care to avoid damage and maintain sterile condition.

Product Return for Complaint Investigation

The device should be returned to Eventum if it is damaged upon opening the packaging. Do not return any damaged device that has been used on a patient and is contaminated with biohazardous waste. The end-user should document the problem with the device and notify Eventum to organise replacement.

Device Specification

The Quadsense Sensor (SE001) is a sterile, single-use device, sterilised by ethylene oxide. The Dongle Assembly (CA001), Panel PC (PC001) and Trolley (TR001) are non-sterile, reusable devices. These components comprise The Quadsense System.
The Quadsense Sensor is powered from the re-usable Panel PC, and therefore does not contain a battery.
The sensor casing, control puck casing and adjustment shims are composed of ABS resin. The underside of the sensor has stainless steel pins.
A medical grade 26 AWG (TPU5040) shielded cable connects the sensor to the control puck and another cable extends from the puck to connect to the Panel PC. This cable attaches to a provided re-usable Dongle Assembly connected with the Panel PC.
The Quadsense System is intended to be used in an operating room environment within a healthcare facility.

The Quadsense Sensor should be powered by the provided re-usable Panel PC (PC001) that is part of the medical electrical system. The Panel PC is intended to be operated on battery power during clinical use. The Panel PC is intended to be re-charged using mains power connection between surgical procedures. The Panel PC will supply power via a USB 2.0 port at 5V voltage to the Quadsense Sensor device. Refer to the Panel PC instructions for rated supply voltage and additional electrical safety information. The Quadsense Sensor is the applied part and has a Type BF classification.

Product code: SE001
In one packaged product, the following are provided:
1 x Sensor, Control Puck and Interconnecting cables
4 x Adjustment Shims

- 6 mm shim
- 7 mm shim
- 6 mm 2.5 degree shim
- 7 mm 2.5 degree shim

The operating ambient temperature range for this device is 5°C - 40°C (41°F - 104°F).
The maximum altitude this device can be operated at is 2000m above sea level.

Electrical Safety and EMC compatibility

This equipment has been tested and is compliant with applicable requirements of IEC 60601-1 and IEC 60601-1-2 with no deviations. The testing was conducted between 10°C - 40°C ambient temperature range, 30 – 70% relative humidity range and 70,0 kPa – 106,0 kPa atmospheric pressure range. EMC performance characteristics verified in battery operated mode.

The Quadsense System may be adversely impacted during electromagnetic disturbances, including degradation or loss of performance in device user interface controls and sensor performance. Performance is restored after electromagnetic disturbances cease.

The Panel PC includes a WiFi module, refer to Panel PC instructions for regulatory information on wireless radio frequency characteristics and compliance.

The Quadsense System has been tested to the following IEC 60601-1-2 and related EMC test standards and passed all acceptance criteria;

EMC Test Standard	Test conditions
IEC/EN 61000-4-2 Electrostatic Discharge Immunity	Up to 8 kV – Contact Discharge Up to 15 kV – Air Discharge
IEC/EN 61000-4-3 Radiated RF Immunity	3 V/m – 80 MHz to 1 GHz, Modulation 1 3 V/m – 1 GHz to 2.7 GHz, Modulation 1
IEC/EN 61000-4-3 Radiated RF Immunity – Intentional Transmitters	Frequency Range 80 MHz – 6 GHz, 10s dwell time
IEC/EN 61000-4-4 Electrical Fast Transient/Burst Immunity	Signal lines testing up to ±1000V. Note: AC and DC supply line testing not applicable.
IEC/EN 61000-4-6 Conducted RF Immunity Test	Frequency Range 150 kHz to 80 MHz, 3V rms and 6V rms (ISM and Amateur Radio Bands)
IEC/EN 61000-4-8 Power Frequency Magnetic Field Immunity	Passed in all orientations at 30 A/m test level, 60 Hz, 60s dwell time.
IEC/EN 61000-4-39 Radiated Fields Close Proximity Immunity	Pass on all test points and test frequencies. Note: 30 kHz not tested. Not applicable to use in professional healthcare facilities.
CISPR 11 / EN 55011 (30 – 1000 MHz)	Class A, Group 1 30 MHz to 6 GHz (3m)
ANSI C63.4, FCC CFR 15.107 / ICES-003 Conducted Emissions – Mains Port	Class A, 150 kHz – 30 MHz
ANSI C63.4, FCC CFR 15.109 / ICES-003 Radiated Emissions	Class A, 30 MHz to 40 GHz (3m)

NOTE: The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). The equipment is not intended for use in a residential environment (for which CISPR 11 class B is normally required). If used in a residential environment this equipment might not offer adequate

protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

IT & Network Requirements

The Panel PC includes WiFi connection capabilities. The Quadsense System should only be connected to a maintained healthcare institution network suitable for use with connected medical devices. The WiFi connection should use WPA2 protocol or higher levels of connection encryption. Physical connection data ports are intentionally disabled to prevent connection of incompatible equipment and reduce IT security exposure, which includes inability to connect USB peripherals and other external data drives.

The Panel PC runs Windows OS and is configured to allow use of the Quadsense PC application on start up. No other applications may run on the device during clinical use. OS, software and hardware maintenance functions are restricted to qualified maintenance users authorised by the manufacturer.

Cybersecurity Requirements

If a user becomes aware of or suspects any cybersecurity events, they should immediately contact customerservices@eventumortho.com.

The device hardware and software is encrypted to protect the device software from cybersecurity events and has been tested to ensure these protections.

Vulnerability Disclosure: When a vulnerability patch or fix is ready for release, the company discloses it by releasing an advisory to affected stakeholders. The disclosure information shall be published on the company website.

At the end of support, the company may no longer be able to reasonably provide security patches or software updates. If the device remains in service following the end of support, the company will communicate through the coordinated vulnerability disclosure the potential cybersecurity risks that can be expected to increase over time.

The software bill of materials (SBOM) may be available for certain customers. Please contact support for further information.

Manufacturer Contact Information

For further information, contact Eventum Orthopaedics on:
For Non-US Customers:
Email: customerservices@eventumortho.com
Tel: (+44) 0204 5428754
For US Customers:
Email: customerservicesusa@eventumortho.com
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Address: Richmond House
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Redvers Close
Leeds
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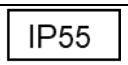
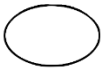
United Kingdom

Date of issue of IFU: 2024-10-23

Symbols	Explanation
	The device is single-use. Do not reuse.
	The product has been sterilised via ethylene oxide.
	Type BF applied part
	Use-by date
	The temperature range that the device can be safely stored at.
	Refer to the user instructions before use.
	Do not use if packaging is damaged and consult Instructions for Use.
	Manufacturer
	Catalog number
	Batch Code
	Quantity
	GTIN code
	IP Rating of the Quadsense Sensor
	Caution: Federal Law restricts this device to sale by or on the order of a physician
	Indicates the level of packaging which forms the single sterile barrier for the Quadsense Sensor
	UKCA mark with Approved Body Number

UK CA 0120