Reusable Shims and Extraction Tools Instructions for Use

Product Description

The Reusable Shims and the Extraction Tools are for use with The Quadsense and Quadsense Pro System. The devices are designed to be used by a qualified orthopaedic surgeon during knee arthroplasty surgery. The Reusable Shims allow for controlled comparison of forces through the patellofemoral joint before and after knee arthroplasty making it easier for the surgeon to achieve the required final patella resection angle and depth. The Extraction Tools enable the removal of the Reusable Shims from the Quadsense Sensor and Quadsense Pro Sensor within the sterile field. The Reusable Shims and Extraction Tools are re-usable and supplied as clean but non-sterile.

Indications

The Reusable Shims and Extraction Tools are indicated for any medical condition in which primary Total Knee Arthroplasty (TKA) would be indicated, and the patella is resurfaced.

Contraindications

The contraindications for the device are aligned to the current contraindications for total knee surgery. The device should not be used if:

- the patient presents with an active infection
- the surgeon decides resection of the patella is not appropriate for the patient's condition
- the equipment has not been cleaned, decontaminated, and sterilised in accordance with manufacturer's recommendations
- the equipment is found to be damaged or deteriorated during the pre-operative inspection
- the sterile packaging is found to be compromised during the pre-operative inspection
- the end-user does not have the necessary qualifications and experience to perform Knee arthroplasty procedures safely and correctly.

Precautions

The surgeon should read and understand user instructions for the device before surgical use.
The device should only be used with the Quadsense Sensor or Quadsense Pro Sensor.
All device components are re-useable and supplied as clean but not sterile. The end-user is required to decontaminate and sterilise the device before each surgical use. The end-user must ensure the device is disassembled before decontamination and sterilisation.
A pre-operative inspection of equipment should be completed before each use to check all components are present and to check for signs of damage, deterioration or residue build-up. If any of these are observed, the device should not be used. The end-user should then notify Eventum and return the device for reprocessing and replacement.
Handle device with care at all times, to ensure longevity.
The device is not intended to assist in resection of any other bones than the patella. Doing so would result in a poor outcome.

Warnings

Warning: The Reusable Shims do not correlate in size and shape with patella implant sizes.

User/Patient Safety

It is the responsibility of the end-user to ensure the equipment is appropriately sterilised before each surgical use. Equipment that is not sterilised will put the patient at risk of serious infection.
If the sterilisation tray packaging is found to be damaged in the pre-operative inspection, do not use, and send back to sterilisation facility for decontamination and sterilisation.
If any components are damaged upon opening package from manufacturer, do not use and contact Eventum Orthopaedics for return and replacement.
Do not impact the device with surgical tools as this may damage intricate components of the device.
The end-user should wear personal protective equipment when using the device and when handling used equipment and cleaning the device.
Do not modify equipment outside approved functional modification.
Do not use the device without the Quadsense Sensor or Quadsense Pro Sensor.

Instructions

The Reusable Shims and Extraction Tools are only involved in the preparation of the patella for resurfacing in Total Knee Arthroplasty. The surgical lead should proceed with the Total Knee Arthroplasty, following their preferred surgical technique and workflow, and follow user instructions when resurfacing the patella.

1. Thoroughly inspect all components of the device before surgery to ensure there is no damage or deterioration.
   Warning: Do **not** use if there are any signs of damage or deterioration.
2. Proceed with the initial steps of use of the Quadsense Sensor or Quadsense Pro Sensor device, following the surgical technique, until the surgeon is ready to take a sensor reading.
3. Attach a shim to the sensor.
4. Take a reading with the sensor against the patient's native knee.
5. Proceed with positioning of the femoral and tibial trials.
6. Take another reading with the sensor, with the same shim, with the femoral and trial implants in situ.
7. If taking further sensor readings with different shims, remove the currently attached shim from the sensor using the Extraction Tools.
8. Select a shim to take a sensor reading and attach to the sensor.
9. Take a sensor reading with the attached shim.
10. Remove the shim from the sensor using the extraction tool.
11. Proceed with the subsequent steps of TKA procedure following surgeons' preference.
12. After use of the device is complete, ensure all Reusable Shims have been removed from the sensor. The Reusable Shims and Extraction Tools should be promptly cleaned and decontaminated of biohazardous material.
13. The device should be sterilised at an appropriate facility, following manufacturers recommendations.

Troubleshooting

Issue	Cause	Solution
A physical component has discolouration,	The component is damaged.	Do not use. The component is not safe for use and should be

pitting, chipping or deformation.		returned to Eventum Orthopaedics.

Decontamination

All device components are composed of the polymer Polyether ether ketone (PEEK) or stainless steel. The device can be cleaned and decontaminated following the hospital's standard protocol for cleaning and decontamination of stainless steel and similar metals. This protocol should be in accordance with ISO 17664-1:2021 standard. Cleaning and decontamination are required for return to manufacturers and before sterilisation for surgical use.
The manufacturer's recommendation for decontamination are as follows.

Pre-cleaning

- Remove excess biohazardous material with a clean, damp cloth.
- Immerse all components in enzymatic detergent or a high pH detergent at the correct dilution recommended by the manufacturer.
- Use a brush to manually clean off dirt from crevices.
- Allow the device components to soak in the solution for the duration recommended by the detergent manufacturer.
- Flush all components.
- Rinse all components.

Manual cleaning

- Immerse all components in an ultrasonic bath with neutral pH detergent at the correct dilution recommended by the manufacturer.
- Use a syringe to flush small intricate parts of the components.
- Allow components to soak in the solution for 10 minutes at 40°c.
- Rinse with distilled water and flush intricate parts with a syringe.
- Dry with a clean cloth.

Automated cleaning

- Automated cleaning should only be used following manual cleaning.
- Place all components inside an automated machine.
- Select an appropriate setting for the device material.

Sterilisation

All device components are suitable for autoclave sterilisation.
The sterilisation facility should sterilise the device components by autoclave steam sterilisation, in accordance with the ISO 17665-1:2024 standard. The temperature used determines the duration of the process, as shown in the table below. The cooling and drying time should be appropriate for the tray, and in accordance with the mentioned standards. If any water is left on the device or tray, allow the device to dry and repeat the decontamination process, including cleaning.

Temperature	Duration
121°c	15 minutes
132°c	4 minutes
134°c	3 minutes

Storage and handling

The device should be stored in a secure sterilisation tray in a dry and clean environment, in accordance with hospital protocol.
The device should be handled with care to avoid damage and maintain sterile condition.

Maintenance

All components should be regularly inspected for detergent residue build-up.

Decontamination of Product Returned for Complaint Investigation

The device should be returned to Eventum Orthopaedics if damage or deterioration is detected. The device must be decontaminated to remove biohazardous waste before return. The end-user can follow decontamination recommendations written in this IFU.
If the device has been exposed to a patient with an infectious disease, such as HIV or CJD, then the device should **not** be returned to Eventum, but destroyed. The end-user should document the problem with the device and notify Eventum to organise replacement.

Device Specification

Device components:

Product Type	Name	Product code
Reusable Shims	Reusable 6mm shim	RS001
	Reusable 7mm shim	RS002
	Reusable 6mm 2.5 degree shim	RS003
	Reusable 7mm 2.5 degree shim	RS004
	Reusable 5mm Pro shim	RS500
	Reusable 6mm Pro shim	RS600
	Reusable 7mm Pro shim	RS700
	Reusable 8mm Pro shim	RS800
	Reusable 5mm 2.5 degree Pro shim	RS50A
	Reusable 6mm 2.5 degree Pro shim	RS60A
	Reusable 7mm 2.5 degree Pro shim	RS70A
	Reusable 8mm 2.5 degree Pro shim	RS80A
Extraction Tools	Extraction Tool	ET001
	Extraction Tool for Quadsense	ET002
	Extraction Tool for Quadsense Pro	ET003

The end life of the device is generally determined by wear or damage during surgery. At end of life, dispose of the device in accordance with hospital protocol and local regulations for disposal of plastic medical devices.
If damage or deterioration is observed, the end-user should contact Eventum to organise reprocessing or replacement.
There is a 12-month warranty from date of purchase. Eventum will replace damaged or deteriorated devices free of charge, as long as the end-user has followed the guidelines in the user instructions.

Manufacturer Contact Information

For further information, contact Eventum Orthopaedics on:
For Non-US Customers:
Email: customerservices@eventumortho.com
Tel: (+44) 0204 5428754
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Symbols	Explanation
STERILISE BEFORE USE	The end user must decontaminate and sterilise all device components prior to surgical use.
	Read the user instructions prior to use.
	Date of Manufacture
	Legal Manufacturer
REF	Catalog Number
QTY	Quantity
LOT	Batch Code
GTIN	GTIN code
Rx	Caution: Federal Law restricts this device to sale by or on the order of a physician
UK CA 0120	UKCA mark with notified body number.