Depth and Angle Adaptors (Mark 1) Instructions for Use

Product Description

The Eventum Depth and Angle Adaptors are intended for use in Total Knee Arthroplasty procedures to aid the surgeon in controlled resection of the patella.
The device allows the surgeon to adjust the depth and angle of resection of the patella by a factor of 1mm and 1.25 degrees, respectively. The adaptors are designed to attach to the provided Enztec Premium Patella Saw Guide.
All physical components of the Depth and Angle Adaptors are re-usable and supplied as clean but non-sterile.
The Depth and Angle Adaptors are compatible with all patella implants and can be used alongside other relevant orthopaedic enabling technology.

Indications

The Depth and Angle Adaptors should be used if resection of the patella bone is recommended during a Total Knee Arthroplasty.
The Depth and Angle Adaptors should only be used by an orthopaedic surgeon that is capable and experienced at Total Knee Arthroplasty procedures.
The Depth and Angle Adaptors should only be used with the Enztec Premium Patella Saw Guide.

Contraindications

The Depth and Angle Adaptors 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 surgeon does not have an available Enztec Premium Patella Saw Guide for the procedure.
- the equipment has not been cleaned, decontaminated and sterilised in accordance with manufacturer's recommendations.
- the equipment is found to be damaged during 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 Total Knee Arthroplasty procedures safely and correctly.

Precautions

The surgeon should read and understand user instructions for the device before surgical use.
The Depth and Angle Adaptors should not be used with any other patella resection guide. The adaptors are designed to insert onto the stylus of the Enztec Premium Patella Saw Guide only.
The Depth and Angle Adaptors 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 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.

- Any damage to components could expose the patient to internal non-sterile surfaces.
- Damage to the adaptors could affect the depth or angle of cut applied to the patella, implicating patients' joint function.

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.

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 for return and replacement.
Do not impact the device with surgical tools as this may damage intricate components of the tools and reduce resection accuracy.
The end-user should wear personal protective equipment when using the device and when handling used equipment and cleaning the device.
The end-user should be careful when handling the device and follow hospital guidelines if the device causes a torn glove.

Instructions

The Depth and Angle Adaptors are only involved in the resection of the patella. 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. Attach the First Cut adaptor to the stylus of the Cutting Guide and resect the patella 6mm to create a flat surface.
3. Decide size of implant required for patient and determine the cut needed to be applied to the patella.
4. Attach depth adaptors and angle adaptors to the Cutting guide to achieve the desired cut.
5. Place the chosen implant on the underside of the patella and evaluate joint function.
6. Use the same methodology to create further patella cuts if required.
7. Proceed with subsequent steps of TKA procedure following surgeon's preference.
8. After the operation, the device should be promptly cleaned and decontaminated of biohazardous material.
9. The device should be sterilised at an appropriate facility, following manufacturers recommendations.

Troubleshooting

Issue	Cause	Solution
An adaptor will not attach to the Enztec Premium Patella Saw Guide.	Adaptors are intended to be non-reversible (one side up) and only attach to the stylus of the	Ensure the adaptor is the correct orientation for attachment. The debossed symbols should be facing up and in the correct

	Enztec Premium Patella Saw Guide.	orientation when holding the guide by the handle.
A physical component has discolouration, pitting, chipping or deformation.	The component is damaged.	Do not use. The component is not safe for use and should be returned to Eventum Orthopaedics.

Decontamination

All Mark 1 Depth and Angle Adaptor device components are composed of titanium alloy. 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

- Ensure all adaptors are removed from the Cutting Guide and the depth adaptors are not attached to the angle adaptors.
- 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 17665-1:2006 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

The adaptors should be regularly tested on ability to attach and detach from the stylus of the Enztec Premium Patella Saw Guide.
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 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

The Mark 1 Depth and Angle Adaptors are composed of a titanium alloy, Ti64, that is biocompatible.
Device components:

- First cut adaptor (-6mm depth)
- Resection depth adaptors
  - 1 x -1 mm depth adaptor
  - 1 x -2mm depth adaptor
  - 1 x -3mm depth adaptor
  - 1 x -4mm depth adaptor
  - 1 x -5mm depth adaptor
- Resection angle adaptors
  - 1 x 0 degree angle adaptor
  - 1.25 degree angle adaptor set of 4
  - 2.5 degree angle adaptor set of 4

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 metal 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.

Additional Warnings

Do not modify equipment outside approved functional modification.
Do not use the device to resect any bones other than the patella.
Do not use the device without the Enztec Premium Patella Saw Guide.

For non-US customers please contact:
customerservices@eventumortho.com
sales@eventumortho.com
+44 (0) 2045 428753
For US customers please contact:
customerservicesusa@eventumortho.com
salesusa@eventumortho.com
+44 (0) 2045 428753

Manufacturer: Eventum Orthopaedics Ltd.
Address: Richmond House
Lawnswood Business Park
Redvers Close
Leeds
LS16 6QY
United Kingdom

Distributed in NZ by: Orthomed NZ LIMITED
Address: 132 Peterborough Street,
Christchurch,
Canterbury, 8013
NEW ZEALAND

Distributed in US by: Eventum Orthopaedics Inc
Address: 75 State Street, Suite 100
Boston,
Massachusetts
02109
United States

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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	Catalogue Number
QTY	Quantity
LOT	Batch Code
GTIN	GTIN code
UK CA	UKCA mark