INSTRUCTION FOR USE

1. INSTRUCTIONS FOR USE

DESCRIPTION AND INTENDED USE

The Endeavor Orthopaedics Summit Patella Plate surgical system is a sterile kit containing surgical instruments for preparation of patella fracture fragments, manipulation/reduction of the patella, provisional fixation of the fracture, plate placement, and finally, provisional and definitive fixation of plate to the dorsal surface of the patella. The system also includes sutures which may be used to pass through the tendons and attach to the plate for supplemental fixation. This system is intended to be used by licensed, professional surgeons.

KIT CONTENTS

1 ea. Plate: Ti-6Al-4V
3 ea. Sutures: UHMWPE
12 ea. Locking Screws: Cobalt-Chrome
1 ea. T8 Driver: Stainless steel/Lexan
1 ea. T8 Driver Shaft: Stainless steel
1 ea. 1.8mm Drill: Stainless steel
4 ea. 1.6mm K-Wire: Stainless steel
2 ea. Olive Wire: Stainless steel
1 ea. Locking Drill Guide: Stainless steel
1 ea. Variable Angle Locking Drill Guide: Stainless steel

STORAGE

Store in a cool, dry place out of direct sunlight
Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use. Do not use when packaging is damaged.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged or date of expiration has passed.

INDICATIONS FOR USE

The Summit Patella Plating System is indicated for use in surgical stabilization of patella fractures during open reduction internal fixation (ORIF) procedures, in skeletally mature individuals. Each system includes a plate, screws, surgical suture, and instruments to facilitate provisional and definitive fixation of the patella and surrounding soft tissue. These devices are provided in a sterile procedure kit and all devices are intended for single use.

ACTIONS

HS Fiber sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. HS Fiber sutures are not absorbed, nor is there any significant change in tensile strength retention known to occur in vivo.

CONTRAINDICATIONS

Contraindications for the Summit Patella Plating System includes the following conditions:

- Presence of active or latent infection
- Sepsis
- Osteoporosis and/or insufficient quantity or quality of bone
- Any patient with inadequate tissue coverage over the site of the implantation of the plate
- Skeletally immature patients
- Patients with any known allergy or reaction to the materials.
- Conditions which tend to limit the patient's ability to restrict activities or follow directions during the healing period.

WARNINGS

- For safe, effective use of the Summit Patella Plating System, the surgeon must be thoroughly familiar with the devices within the system, their instructions for use and the surgical technique. Please review the surgical technique for the system prior to use.
- Patients must be given adequate postoperative instructions. The patient's ability and willingness to follow postoperative instruction is extremely important to fracture management. The surgeon should warn the patient that failure to follow postoperative care instructions may cause the implant and/or treatment to fail. The device can break when subjected to increased loading associated with nonunion or delayed union. Internal fixation devices are load sharing devices that hold a fracture in alignment until healing occurs. If healing is delayed or does not occur, the implant may break, bend, or fail.
- Avoid fixation screw perforation of the articular surface of the patella bone by selection of the correct screw length. See the Summit Patella Plating System surgical technique for details on screw selection.
- The size and shape of human bones present limitations on the ability of anatomically designed plates to fit every patella, therefore, correct selection of the device size will improve surgical outcomes.
- Do not modify implants. Do not notch or bend implants. Notches or scratches imposed on the implant during surgery may contribute to breakage.
- Avoid excess torque on the screws. The screw may fracture if excess torque is applied during implantation.
- Devices within the Summit procedure kit are for single use only. Do not reuse. Reuse on another patient may pose biological and other risks. While used implants may appear undamaged, previous mechanical stresses may reduce the service life of the implant.
- Do not use any component from an opened or damaged package. Do not use implants after expiration date.
- Re-sterilization must NOT be performed on any of the devices within the Summit System, as this may affect device performance.

  As with any foreign body, prolonged contact of any suture with salt solutions may result in calculus formation.
- Discard opened or unused sutures.
- Users should be familiar with surgical procedures and techniques involving sutures before employing HS Fiber non-absorbable sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.
- Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

PRECAUTIONS

- Specific instruments have been designed for implanting the patella plate construct. The use of implants or instruments not included within the Summit Patella Plating System may damage the implants or compromise the construct integrity, causing failure.
- Surgical instruments should only be used for their intended purposes.
- In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
- Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

CAUTION

- U.S. Federal law restricts this device to sale by or on the order of a licensed physician.
- Clinician judgment, as related to individual patient presentations, must always supersede recommendations in any device Instructions for Use (IFU). Additional technical information is available upon request from Endeavor Orthopaedics. Contact your local representative with any questions you have regarding the Summit Patella Plating System
- This device is for single use only and must not be re-used. Do not re-sterilize the device. Do not use beyond the expiration date listed on the label. Do not use if product package shows signs of tampering or damage.
- Do not drill through the articular surface of the patella. Caution must be taken when drilling; see the Summit Patella Plating System surgical technique.

ADVERSE REACTIONS

Adverse effects associated with the use of the suture include wound dehiscence, calculi formation when prolonged contact with salt solutions occur, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

STERILIZATION

Devices are supplied sterile within a double pack procedure kit. Sterilization is achieved by E-beam irradiation to achieve a Sterility Assurance Level (SAL) of 10-6. Re-sterilization must NOT be performed as this may affect device performance.

MRI STATEMENT

No specific MRI testing has been completed on this device system. The devices have not been tested for safety and compatibility in the MR environment. Known effects associated with MR scanning of passive implants made of similar materials may include heating, migration, and image artifacts. The patient must inform the MRI healthcare professional of the presents of the patella implant prior to MR scanning in order for the healthcare professional to make decisions regarding MR scan safety, as the implants effects depends on the characteristics of the MR system, selected scan conditions and other factors.

SURGICAL TECHNIQUE

Please see the surgical technique for further information and details on the use of the Summit Patella Plating System.

2. SYMBOL GLOSSARY

Endeavor Orthopedics product packaging and labeling may feature symbols from the list below.

This list provides a glossary of these symbols.

Standards Development Organization (SDO)	Symbol	Title	Reference Number	Description
21 CFR 801.109		Prescription Only	N/A	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician
ISO 15223-1:2016		Catalogue Number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified
ISO 15223-1:2016		Batch Code	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified
ISO 15223-1:2016		Use-by date	5.1.4	Indicates the date after which the medical device is not to be used
ISO 15223-1:2016		Caution	5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warning and precautions that cannot, for a variety of reasons be presented on the medical device itself.
ISO 15223-1:2016		Consult instructions for use	5.4.3	Indicates the need for the user to consult the instructions for use.
ISO 15223-1:2016		Do not re-use	5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
ISO 15223-1:2016		Do not resterilize	5.2.6	Indicates a medical device that is not to be re-sterilized.
ISO 15223-1:2016		Do not use if package is damaged	5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened.
ISO 15223-1:2016		Sterilized using irradiation	5.2.4	Indicates a medical device that has been sterilized using irradiation
ISO 15223-1:2016		Manufacturer	5.1.1	Indicates the medical device manufacturer