Instructions for Use
Reprocessed Zimmer Biomet Exodus Revision Hip System for Femoral Stem Removal

a) These devices have been reprocessed by Green OR.
b) These devices are reprocessed devices designed for an additional Single Use.
c) These devices have been sterilized using Ethylene Oxide Gas. Do not use these devices if the packaging has been prematurely opened or damaged.
d) Federal law restricts this device to sale by or on the order of a licensed physician.
e) To ensure the safe and effective use of this device, read the Instructions for Use in its entirety prior to using this device.
f) For further information regarding this device, contact Green OR at 1-866-783-6006.

Device Description:
The Exodus Revision Hip System is a specialized orthopedic surgical instrument set made by Zimmer Biomet, designed specifically to assist surgeons in removing a hip femoral stem during a revision total hip arthroplasty procedure (when a previously implanted hip stem needs to be extracted) rather than performing an extended trochanteric osteotomy.

The entire kit contains three pre-sterilized, single-use blades (osteotomes) including:

- Curved Lateral Blade – contours around the lateral shoulder of the implant.
- Medial Slotted (Stem Contouring) Blade – designed with a slot to work around the neck geometry and access bone interface at the medial side of the implant.
- A/P Chisel Blade – a thin osteotome for following the implant surface without bending.

Following the use of any one of these devices within a clinical setting, Green OR received the devices and subsequently performed a complete reprocessing of the device including identification, decontamination, cleaning, refurbishing, testing, inspection, packaging, labeling, and sterilization with ethylene oxide.

Indications for Use:
The Exodus system is intended for revision hip arthroplasty procedures, specifically for extracting femoral stems with minimal bone loss, reducing the need for more invasive techniques like an extended trochanteric osteotomy (which carries higher risk of additional bone trauma).

Contraindications for Use:
These devices are contraindicated in the following situation:

a) Active Infection
Presence of acute or chronic local or systemic infection at the surgical site or in the patient — because infection significantly increases risk and compromises outcomes.
b) Poor Bone Quality or Minimal Bone Stock
Severely osteoporotic or deficient bone that cannot support instrumentation or secure implant anchorage (risking fracture or failure).
c) Insufficient Soft Tissue / Muscular Support
Severe muscular, neural, or vascular disease compromising limb function or healing potential.
d) Allergy or Sensitivity to Materials
Known allergies to metal or implant materials, which may increase local adverse reactions (for instruments and implants in general, if involved).
e) Patient Unsuitability for Revision Procedure Conditions that make surgery unjustified (e.g., terminal illness, inability to tolerate anesthesia/surgery) requiring clinical judgment.
f) Lack of Surgeon Experience
Lack of surgeon expertise or inability to perform safe revision with alternative approaches.

a) Original Equipment Manufacturers (OEMs) provide Instructions for Use (IFUs) with the original device. When a health facility reprocesses that original device through a third-party FDA registered reprocessing company, the health facility needs to keep the original OEM IFU as this original OEM IFU, and any materials associated with it supersede all other instructions.
b) These instructions apply to Green OR's reprocessed Exodus Revision Hip System only and are not to be used as instructions for use for any other arthroscopic device or techniques, nor are they intended to be used as instructions for use of the complementary components used with these devices.
c) This device is intended for use by a licensed physician who has a thorough understanding of the techniques and principles of arthroscopic surgical procedures and in particular has received training on the use of orthopedic manual devices.
d) Inappropriate use may result in injury to the patient and/or the physician or may cause damage to the medical equipment being used for this procedure. If further information is required, consult medical literature regarding use, techniques, principle complications and hazards prior to the use of this device.
e) Verify compatibility of all device components with each other.
f) Careful handling of this device is necessary to avoid damage or breakage. Always inspect the device prior to use to ensure device integrity and do not use the device if any damage is identified.
g) To avoid inadvertent injury to the patient and/or damage to the device, make sure that the distal tip of the device, (the working end of the device) is visible during the use of this device. If you do not have a clear visual of the working tip of this device during the procedure, do not activate this device.
h) Do not allow these devices to come in contact with other metal objects, such as the operating room table, IV poles, other devices, staples, or clips while the device is activated as such action may cause damage to the device and may cause injury to the patient.
i) Do not bend or alter the shape of these devices.

j) All used surgical devices which come in contact with blood and/or other bodily fluids should be treated as "potentially infectious materials" after use. Wear appropriate personal protective equipment when handling any potentially infection material. Return the used orthopedic manual devices to Green OR in the collection containers provided to your facility.

k) All employees who are exposed to "potentially infectious materials" must be offered immunization against hepatitis B by their healthcare facility.

Directions for Use:

General

a) Store orthopedic manual devices away from moisture, freezing, and direct heat.

b) Do not use expired devices. If the expiration date has passed, either return the device to Green OR for consideration to be reprocessed or discard the device.

c) Select the arthroscopic device to be used based upon its size, tip configuration and function that will be the most appropriate for the patient and the procedure.

d) For a complete set of directions on the use of complimentary components used with this device, consult the manufacturer's Operator's Manual.

Packaging

a) Inspect the packaging before opening. Since the contents of this package are intended to be sterile, if the package has been damaged or compromised in any way, do not use this device as sterility may be compromised. Return the device with this packaging to Green OR will evaluate whether or not the device can be successfully reprocessed for another single use.

b) If the packaging has been opened or compromised, but the device has not been used, do not attempt to re-sterilize the device and do not use this device on a subsequent procedure. Return the device with this packaging to Green OR will evaluate whether or not the device can be successfully reprocessed for another single use.

c) The packaging of this device contains removable labels which can be affixed to the patient's medical records file.

Device Inspection

a) With the use of sterile technique, remove the device from the packaging and place it in a sterile work area.

b) Inspect the device to ensure its physical integrity. If the device is damaged in a way that would make it unacceptable for surgery, do not use the device. Return the damaged device along with this packaging to Green OR for evaluation.

c) Prior to utilizing the device, verify the overall compatibility of the device with its complimentary accessories.

Device Usage

a) Prepare the patient pre-operatively according to standard procedures.

b) Follow suitable surgical protocol throughout this procedure.

c) Do not reuse or re-sterilize this device. Return the used device to Green OR in the collection containers provided to your facility.

Note: The names of other companies and products which may have been mentioned herein may be trademarks of their respective companies

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Note: Green OR is not liable for any damages caused by any defect in material, design, or workmanship by the OEM or by any act of omission by the OEM.

Packaging Symbols

	Production batch number
	Green OR, LLC's part number
	Quantity of devices in package
	Manufacturer
	Date of manufacture
	Date of expiry
	Sterilized using ethylene oxide
	Caution, consult accompanying documents
	Do not reuse
	Do not re-sterilize

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