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LENKBAR™ FLEXMETRIC® ACETABULAR DRILL

LENKBAR

Carefully read all instructions and be familiar with the surgical technique prior to use. Use universal precautions when handling contaminated or biohazard components/materials.

Before using a product placed on the market, the operating surgeon should carefully study the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature, written surgical techniques).

Lenkbar, LLC is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection, and similar matters outside the control of Lenkbar, LLC.

Lenkbar™ Flexmetric® Acetabular Drill is supplied in a sterile package, for single use only, and is not designed for re-sterilization.

DESCRIPTION

- Intended Use: The Lenkbar™ Flexmetric® Acetabular Drill is indicated for use in Total Hip Arthroplasty (THA) to facilitate a pilot hole for the placement of acetabulum screws, if required to secure an acetabulum cup after the preparation of the bone and placement of the implant.
- Lenkbar™ Flexmetric® Acetabular Drill is provided sterile and is sterilized using Gamma Irradiation (25-40kGy).
- Lenkbar™ Flexmetric® Acetabular Drill is equipped with a modified Hudson connector attachment for use with a standard surgical drill.
- Failure to follow these instructions could result in instrument or provisional breakage, infections and potential adverse effects on user(s) or patient.
- Misuse reduces useful life and/or increases the risk of injury to user(s) and patient.

INSTRUCTIONS FOR USE

- Carefully read all instructions and be familiar with the surgical technique prior to use. Use universal precautions when handling contaminated or biohazard components/materials.
- Before using the Lenkbar™ Flexmetric® Acetabular Drill, the operating surgeon should study carefully the following recommendations, cautions, warnings and instructions, as well as the available product specific information (e.g., product literature, written surgical technique).
- The Lenkbar™ Flexmetric® Acetabular Drill is indicated for use inside a surgical site to facilitate the pre-drilling of a pilot hole into bone to support the placement of an implantable screw.
- All drills will be provided within a double pouched Tyvek®-Mylar sterile barrier configuration and is sterilized using Gamma Irradiation (25-40kGy).
- Determine the Drill bit length, diameter and body lengths. Drill bits are provided in 3.2mm, 4.0mm and 4.5mm diameters and 38mm, 52mm and 66mm lengths.
- Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised.
- Warning: Do not use the device if the sterility has been compromised. Compromised package sterility could lead to patient infection.
- Lenkbar™ Flexmetric® Acetabular Drill is a single-use device. Re-sterilization of the Lenkbar™ Flexmetric® Acetabular Drill is strictly forbidden, regardless of the method that might be employed.
- Remove device from the package and place it in a sterile work area using an aseptic technique.
- Inspect the device for overall condition and physical integrity. Do not use if any damage is noted. Attach Lenkbar™ Flexmetric® Acetabular Drill to power source.
- Follow a suitable orthopedic surgery protocol. The selection of the appropriate drill size depends on the judgement of the surgeon regarding the requirements of the implant system selected by the surgeon.
- The surgeon should become thoroughly familiarized with the technique of the associated implant system by reading literature and training in the operative skills and techniques required in total hip arthroplasty.
- After use, dispose of Lenkbar™ Flexmetric® Acetabular Drill following internal protocol and applicable laws and regulations.

REUSE

Lenkbar™ Flexmetric® Acetabular Drill is labeled as single-use device and shall not be reused. While a single-use instrument may appear undamaged after use, the instrument may have acquired contaminants that compromise sterility and/or blemishes, nicks or latent compromise of its integrity.

POTENTIAL SIDE EFFECTS

Warning: Incorrect handling may render the Lenkbar™ Flexmetric® Acetabular Drill unsuitable for their intended use and allow corrosion, dismantling, distortion and/or breakage or cause injury to the patient or operating staff.

Metal instruments or fragments can be located by radiography or fluoroscopy.

Non-metal instruments or fragments can be located by radiography or fluoroscopy and should be accounted for at the end of the surgical procedure.

- Any decision to remove a broken drill or drill fragments is left to the surgeon's discretion and must consider the associated risks.

Below is a list, albeit not exhaustive, of potential complications:

- Lesion of soft tissue, hard tissue or the joints in the event of incorrect use or breakage of the instruments, due to instruments being subject to high load and/or impact.
- Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.
- Cutting the gloves or skin of surgical staff.
- Tissue lesions on the patient or surgical staff and/or an increase in operating time as a result of having to dissemble the instruments during surgery.
- Do not use cutting/sharp instruments with dull or deformed edges or instruments/provisional that are deformed, corroded, damaged or worn. They may not perform as intended.

As a result of the mechanical features required, most of the components are made of non-implantable materials. In the event an instrument breaks no fragment shall remain in the patient, as this could cause post-operative complication of biological nature associated with the release of metal components, possibly requiring further intervention. Final discretion is left to the surgeon.

PRECAUTIONS

- Inspect all instruments/provisionals carefully prior to each use.
- Any decision to remove a broken drill or drill fragments is left to the surgeon's discretion and must consider the associated risks.

PACKAGING

- Lenkbar™ Flexmetric® Acetabular Drill is sold sterile and is sterilized using Gamma Irradiation (25-40kGy).
- Lenkbar™ Flexmetric® Acetabular Drill is solid sterile and is presented in individual packaging and is clearly labeled as sterile on the package label.
- The sterile Lenkbar™ Flexmetric® Acetabular Drill packaging must be intact at the time of receipt and the integrity of the packaging shall be checked prior to use.

STORAGE

- Sterile packaged instruments should be stored in a designated, limited-access area that is well ventilated, and provides protection from dust, moisture, insects, vermin and temperature and humidity extremes.
- Maintain storage 23°±1°C (73.4±2°F) and 50±2% relative humidity. Tyvek® and polyethylene can be subject to phenolic yellowing due to prolonged exposure to UV light.
- Sterile, packaged instruments should be examined carefully prior to opening to ensure there has been no loss of package integrity.

INSPECTIONS PRIOR TO USE

- Before utilization, it is necessary to verify the sterility expiration date, which is indicated as the "use by" date. Product found to be beyond the "use by" date should not be used and should be discarded. Lenkbar, LLC cannot be held responsible for use of products beyond the specified expiration date.
- It is recommended to verify the integrity of the primary package before use. Sterility is ensured only if there is no trace of damage to the packaging.
- Lenkbar™ Flexmetric® Acetabular Drill is a single-use device. Re-sterilization of the Lenkbar™ Flexmetric® Acetabular Drill is strictly forbidden, regardless of the method that might be employed.
- Lenkbar™ Flexmetric® Acetabular Drill should be visually examined for damage by doctors and staff in operating centers prior to and after surgery.

CAUTION

- Federal Law (U.S.A) restricts this device to sale by or on the order of a licensed physician.

COMPLAINTS

- Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity durability, reliability, safety, effectiveness and/or performance, should notify Lenkbar, LLC or their representative. Moreover, if the Lenkbar™ Flexmetric® Acetabular Drill has malfunctions or is suspected of having malfunctioned, Lenkbar, LLC or their representative shall be notified immediately.
- If the Lenkbar™ Flexmetric® Acetabular Drill has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or Lenkbar, LLC must be informed as soon as possible by telephone, fax or writing.
- For all complaints, please contact Lenkbar, LLC and provide the name of the product, reference number and the lot number of the Lenkbar™ Flexmetric® Acetabular Drill, your name and address and a detailed description of the event to help Lenkbar, LLC understand the nature of the complaint.

For further information or complaints, please contact:

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Patent Number: 8,366,559

Printed in the U.S.A
LB-IFU-6 Revision 3
Issued: 03/04/2019
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℞ ONLY

Sterilized using irradiation

STERILE R

Single use only

Caution

Do not use if package is damaged

Keep dry

EC REP

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CE
0086