1. **Device Description:** A Hip Prosthesis is an artificial joint surgically implanted when the natural hip can no longer function due to fracture, trauma, or degenerative disease. It is used in hemiarthroplasty procedures to replace the damaged or fractured femoral head while preserving the natural acetabulum, thereby restoring mobility, stability, and relieving pain. The prosthesis is anatomically designed to replicate the natural shape and function of the femoral head, ensuring proper articulation and load distribution. There are several types of hip prostheses used in hemiarthroplasty procedures, including Bipolar, Austin Moore, and Thompson prostheses. Each design has specific structural features and clinical applications:
   - **Bipolar Hip Prosthesis:** The Bipolar Hip Prosthesis consists of a bipolar head and a bipolar insert. It is typically used during hemiarthroplasty procedures, where it is combined with a plug-in femoral head and a hip stem. The prosthesis allows controlled movement between the inner head and the outer shell, reducing acetabular wear. Various sizes of bipolar outer shell diameters are available to suit patient anatomy.
   - **Austin Moore Hip Prosthesis:** The Austin Moore prosthesis is a unipolar hemiarthroplasty device designed to replace the function of the femoral head in patients with osteoarthritis or hip fractures. Its design closely mimics the anatomical shape of the natural femoral head, providing stability and ease of fixation within the femoral canal.
   - **Thompson Hip Prosthesis:** The Thompson Prosthesis is another unipolar hip prosthesis commonly used for hemiarthroplasty. It is specifically designed to replace the femoral head (the ball component of the hip joint) and restore joint function following hip fractures or degenerative conditions.
2. **Material (s):** Hip Prostheses are manufactured from Stainless Steel (AISI 316L) in accordance with ASTM A276. This high-grade stainless steel is widely recognized for its excellent mechanical strength, biocompatibility, and superior resistance to corrosion and fatigue. The material offers outstanding durability under physiological conditions and maintains structural integrity when exposed to body fluids. Its proven performance ensures long-term implant stability and minimizes the risk of corrosion-related complications or adverse tissue reactions.
3. **Intended Use:** The Hip Prosthesis is intended for use in hemiarthroplasty procedures to replace the damaged or fractured femoral head and restore normal hip joint function.
4. **Indications:**

S. No	Product Name	Indications for Use
1	Bipolar Prosthesis - Standard Stem - Non - Fenestrated - Sterile	Indicated for use in hemiarthroplasty procedures to replace the damaged or fractured femoral head, particularly in cases of femoral neck fractures, osteoarthritis, or avascular necrosis where the acetabulum remains intact.
2	Bipolar Prosthesis - Standard Stem - Fenestrated - Sterile	Indicated for hemiarthroplasty of the hip to restore joint function in patients with femoral neck fractures or degenerative hip conditions. Fenestrations facilitate cement fixation for enhanced implant stability.
3	Bipolar Prosthesis - Narrow Stem - Non - Fenestrated - Sterile	Intended for hemiarthroplasty in patients with narrow femoral canals requiring femoral head replacement following fracture or degenerative hip disease.

S. No	Product Name	Indications for Use
4	Bipolar Prosthesis - Narrow Stem - Fenestrated - Sterile	Used in hemiarthroplasty to replace the femoral head in patients with smaller femoral canals. Fenestrations allow for improved cement interlock and fixation.
5	Bipolar Prosthesis - Extra Long Stem Non - Fenestrated - Sterile	Indicated for hemiarthroplasty in cases requiring additional stem length to achieve stability in patients with extended femoral canal damage or bone loss.
6	Bipolar Prosthesis - Long Neck - Small - Sterile	Intended for replacement of the femoral head in hemiarthroplasty procedures where a small-sized long-neck configuration is required to restore limb length and joint stability.
7	Bipolar Prosthesis - Long Neck - Medium - Sterile	Indicated for use in hemiarthroplasty where a medium long-neck configuration is needed to maintain proper joint biomechanics and restore normal hip function.
8	Bipolar Prosthesis - Long Neck - Large - Sterile	Used in hemiarthroplasty to replace the femoral head in cases requiring a large long-neck configuration to optimize offset, limb length, and stability.
9	Austin Moore Hip Prosthesis - Excel - Standard Stem - Sterile	Indicated for hemiarthroplasty to replace the femoral head in patients with femoral neck fractures, avascular necrosis, or degenerative conditions, supplied sterile for immediate surgical use.
10	Austin Moore Hip Prosthesis - Excel - Narrow Stem - Sterile	Intended for use in hemiarthroplasty procedures involving femoral head replacement in patients with narrow femoral canals, supplied sterile to maintain surgical asepsis.
11	Thompson Hip Prosthesis - Excel - Standard Stem - Sterile	Used in hemiarthroplasty for replacement of the femoral head in patients with femoral neck fractures or osteoarthritis, supplied sterile for surgical implantation.
12	Thompson Hip Prosthesis - Excel - Narrow Stem - Sterile	Intended for hemiarthroplasty in patients with narrow femoral canals requiring femoral head replacement, supplied sterile to ensure implant safety and sterility.

5. **Contraindications:** Hip Prostheses must not be used in patients with any of the following conditions, as implantation may lead to device failure, poor fixation, or adverse clinical outcomes:
   - Active or suspected latent infection (local or systemic), including osteomyelitis or soft-tissue infection near the hip joint.
   - Acute or chronic inflammatory joint conditions that may interfere with healing, implant integration, or increase infection risk.
   - Known or suspected hypersensitivity or allergic reaction to metallic implants or materials used in the prosthesis.
   - Insufficient bone stock or severe osteoporosis that cannot provide adequate support or fixation for the implant.
   - Severe degenerative joint disease, arthritis, or joint instability at the hip or surrounding joints that may compromise implant function.
   - Neuromuscular disorders, ligamentous laxity, or severe muscle weakness that could lead to dislocation or suboptimal outcomes.

- Distorted acetabulum or conditions precluding proper use of the natural acetabulum, including congenital deformities or prior surgeries.
- Obesity or other patient-specific factors that may compromise implant integrity or surgical outcomes.
- Any general contraindications to surgery, including poor systemic health, uncontrolled diabetes, severe cardiopulmonary disease, or inability to tolerate anaesthesia.

Note: The surgeon must carefully evaluate each patient's condition, comorbidities, and risk factors prior to proceeding with hip prosthesis implantation.

6. **Warnings:**
   - Improper selection, handling, or implantation of Hip Prostheses may result in severe complications, implant loosening, dislocation, fracture, or failure to restore hip function.
   - Incorrect choice of prosthesis type, size, stem length, or neck offset can lead to leg-length discrepancy, malalignment, mechanical instability, or abnormal joint biomechanics.
   - Premature weight-bearing or excessive mechanical loading during the postoperative period can cause implant subsidence, dislocation, loosening, or failure of bone-prosthesis integration.
   - **Patient Factors:** The risk of complications may increase in patients with the following conditions:
     - Severe osteoporosis or poor bone quality
     - Anatomical abnormalities, post-traumatic deformities, or prior hip surgeries
     - Hypersensitivity or immune response to metallic implants
     - Malnutrition, metabolic bone disease, obesity, or endocrine disorders affecting bone healing
     - Psychological, psychiatric, or compliance-related issues affecting postoperative rehabilitation
   - **Do Not Re-Use or Reprocess:** Hip Prostheses are supplied sterile for single use only. Reuse, reprocessing, or re-sterilization may compromise sterility, mechanical integrity, or material properties, increasing the risk of infection, implant failure, or other adverse outcomes.
   - The hip prosthesis must be implanted with validated surgical instruments and approved techniques specific to the device. Use of incompatible components from other manufacturers may result in misfit, corrosion, or mechanical instability.
   - The device must only be implanted with validated Siora surgical instruments and approved surgical techniques. Any deviation from recommended procedures may result in improper fixation or postoperative complications.
   - Regular Radiographic and Clinical Monitoring is mandatory postoperatively to ensure satisfactory implant position, fixation, and hip joint function.
   - Avoid Damage to the Implant Surface during handling or insertion, as scratches or deformations can reduce corrosion resistance and long-term durability.
7. **Precautions:** To minimize complications and ensure optimal device performance, the following precautions should be observed:
   - The implanting surgeon must be trained and experienced in hip arthroplasty procedures and fully understand the design, function, and limitations of the specific Hip Prosthesis being used.

- Detailed preoperative planning must include radiographic evaluation to select the correct prosthesis type, size, stem length, and neck configuration appropriate for the patient's anatomy and pathology.
- Avoid excessive force during implantation, repeated insertion attempts, or improper reaming that could damage bone or compromise the implant.
- Ensure accurate alignment, leg length, and joint stability before final implantation; verify seating and orientation of the prosthesis to prevent dislocation or malposition.
- Do not force modular components, as this may damage the prosthesis or compromise mechanical stability.
- Postoperative care must include instructions to the patient to avoid premature or high-impact activities until adequate healing and implant stability are confirmed.
- The use of components or instruments from other manufacturers has not been validated and may result in dimensional mismatch or mechanical incompatibility.
- Pregnant or breastfeeding patients should be carefully evaluated before undergoing surgical implantation of metallic hip devices.

Note: Patients should be informed of all possible risks, consequences, and adverse reactions associated with hip prosthesis implantation.

8. **Target Patient Group:** Hip Prostheses are intended for skeletally mature patients who require hemiarthroplasty or replacement of the femoral head due to femoral neck fractures, osteoarthritis, avascular necrosis, or other degenerative conditions. Patients with contraindicated conditions, insufficient bone stock, active infection, or systemic diseases that may impair bone healing or integration of the prosthesis should not be considered suitable candidates for implantation.
9. **Intended User Group:** Hip Prostheses are intended for use only by qualified Orthopedic surgeons who have specialized training and experience in hip arthroplasty procedures, including hemiarthroplasty and replacement of the femoral head.
10. **MRI Compatibility:** Hip Prostheses have not been evaluated for safety and compatibility in the MRI environment. The device has not been tested for potential heating, displacement, or image artifacts during magnetic resonance imaging procedures. Patients implanted with these prostheses should avoid MRI scans unless specific device-related MRI data becomes available. The presence of metallic hip implants may also interfere with the quality of diagnostic imaging.
11. **Combination of Medical Device:** Hip Prostheses are supplied as complete, self-contained implants and are intended to be used as provided. Use of non-approved implants, modular components, or instruments from other manufacturers has not been validated and may result in dimensional incompatibility, poor fit, or compromised mechanical performance. To ensure safety and optimal function, the prosthesis should be implanted only with manufacturer-approved instruments and according to the recommended surgical technique.
12. **Performance Characteristics:** Hip Prostheses exhibit the following performance characteristics:
    - High mechanical strength to withstand physiological loads during ambulation and daily activities.

- Optimized stiffness and geometry designed to restore hip biomechanics, maintain proper leg length, and provide stable articulation with the acetabulum.
- Excellent corrosion resistance and biocompatibility, ensuring long-term compatibility with body tissues and fluids.
- Precision-engineered modular interfaces, ensuring secure fit of femoral heads, stems, and adapters, providing rotational and axial stability.
- Anatomical design, with femoral stems and heads contoured to match the natural anatomy of the hip joint, facilitating accurate placement and minimizing intraoperative adjustments.

13. **Potential Adverse Effects:** Potential complications and adverse events that may occur following implantation of a Hip Prosthesis include, but are not limited to, the following:
    - Infection or inflammation at the surgical site, which may involve superficial tissues or the joint itself, potentially leading to osteomyelitis or wound breakdown.
    - Implant-related mechanical issues, such as loosening, dislocation, migration, or breakage of the prosthesis components.
    - Hypersensitivity or allergic reactions to the materials used in the prosthesis.
    - Fracture of the femur or acetabulum, either intraoperatively or postoperatively, due to surgical technique, trauma, or weakened bone.
    - Nerve or vascular injury associated with surgical exposure or implant placement.
    - Deep vein thrombosis (DVT), pulmonary embolism, or thromboembolic events related to postoperative immobility.
    - Soft tissue irritation, impingement, or leg-length discrepancy, potentially resulting from malposition or improper sizing of the implant.
    - Heterotopic ossification or abnormal bone growth around the prosthesis.
    - Need for revision or removal surgery due to infection, dislocation, loosening, breakage, or patient intolerance.
    - Pain, swelling, or reduced mobility, potentially related to implant mechanics or individual biological response.
14. **Preoperative Care:** The following steps and precautions must be undertaken prior to performing hip arthroplasty procedure:
    - Verify availability of the selected hip prosthesis and all manufacturer-approved surgical instruments.
    - Confirm correct implant selection based on preoperative imaging, anatomical assessment, and patient-specific requirements.
    - Review the latest surgical technique guide provided by the manufacturer.
    - Ensure that all instruments and implants are supplied sterile and handled according to aseptic procedures.
    - Conduct a thorough patient evaluation, including bone quality, vascular supply, infection risk, and systemic health conditions that may affect implant integration.
    - Obtain informed consent, ensuring the patient understands the nature of the procedure, potential risks, and expected outcomes.

- Prepare the surgical site according to aseptic techniques, and ensure imaging equipment is functional for intraoperative verification of implant positioning.

15. **Postoperative Care:** Postoperative care and rehabilitation following hip prosthesis implantation are essential to ensure optimal outcomes and to prevent complications. The following measures should be strictly followed:
    - Initial immobilization or restricted weight-bearing may be required, followed by gradual mobilization as directed by the surgeon.
    - Progressive physiotherapy and rehabilitation should be undertaken to restore range of motion, muscle strength, and hip joint function, avoiding premature or excessive loading.
    - Patients should avoid high-impact activities until adequate healing and implant stability are confirmed radiographically.
    - Routine clinical and radiological follow-up is necessary to monitor implant integration, detect complications, and assess functional recovery.
    - If implant loosening, dislocation, or mechanical failure occurs, revision surgery may be indicated based on clinical evaluation.
    - Patients should report pain, swelling, redness, warmth, or reduced hip mobility promptly for early diagnosis and management.
    - Postoperative infection control measures, including prophylactic antibiotics, should be administered as per surgeon discretion and hospital protocol.
16. **Packaging:** Hip Prostheses are individually packed in a Class 10000 cleanroom environment. The primary packaging depends on the prosthesis type:

    Bipolar Hip Prosthesis is sealed in a double primary sterile barrier system consisting of Tyvek paper and PET blister film.

    Austin Moore and Thompson Hip prosthesis is sealed in Tyvek Pouches.

    The primary package is placed inside an inner carton box, which is then placed in a protective outer carton with bubble wrap to prevent mechanical damage during handling and transportation. Finally, the outer carton is shrink-wrapped for added protection.
17. **Labelling:** Labelling is carried out during primary packaging stage in a class 10000 cleanroom environment. The labels contain information such as lot number, manufacturing date, expiry date and necessary symbols in accordance with ISO 15223-1 standards. Labels comply with applicable regulatory requirements for traceability and user information.
18. **Sterilization:** Hip Prostheses are supplied sterile. Sterilization is carried out by Gamma Irradiation using Cobalt-60 as the radiation source. High-energy gamma photons penetrate the packaging and effectively inactivate microorganisms. The Sterility Assurance Level (SAL) is maintained at 10^{-6} with a standard dose of 25 kGy. The devices are intended for single use only, and re-sterilization or reuse is not recommended.
19. **Shelf Life:** The shelf life of Hip Prostheses is 5 years from the date of manufacture when stored under recommended conditions.

20. **Storage:** The devices must be stored at room temperature in a clean, dry, and dust-free environment. Keep away from direct sunlight, moisture, and radioactive sources. Avoid stacking or placing heavy objects on the packaging to prevent deformation or damage.
21. **Disposal:** Used, damaged or contaminated Hip Prosthesis must be disposed of in accordance with hospital biohazard waste management procedures and local regulatory requirements. Metallic implants that have come into contact with biological tissue or body fluids should be treated as biohazardous material. Packaging material should be disposed of carefully and kept out of reach of children.
22. **Important Information:**
    - The implantation of Hip Prostheses should be performed only by experienced and qualified Orthopedic surgeons trained in hip arthroplasty procedures.
    - The Surgeons are responsible for educating patients about postoperative restrictions, rehabilitation protocols, and the importance of follow-up visits to ensure proper recovery and early detection of complications.
    - The longevity and performance of the hip prosthesis depend on patient factors such as bone quality, anatomical suitability, surgical technique, implant selection, and adherence to postoperative care instructions.
    - The Use of implants outside their intended purpose or beyond validated surgical protocols may result in compromised performance, mechanical failure, or adverse clinical outcomes.
23. **Details of Symbols used in Labelling:**

Symbol	Title	Description
	Keep away from Sunlight	Indicates a medical device that needs protection from light sources
	Manufacturer	Indicates the medical device manufacturer
	Date of Manufacture	Indicates the date when the medical device was manufactured
	Use-by date	Indicates the date after which the medical device is not to be used
	Do not re- use	Indicates a medical device that is intended for one single use only
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Keep Dry	Indicates a medical device that needs to be protected from moisture

Symbol	Title	Description
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Do not use if package is damaged	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Consult Instructions for use	Indicates the need for the user to consult the instructions for use
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
	Do not Re-sterilize	Indicates a medical device that is not to be resterilized
	Prescription Only	Indicate prescribed item; Caution: Federal law restricts this device to sale by or on the order of a physician

24. Contact Information:

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