Possible Adverse Effects

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed of similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.

2. Infection or allergic reaction.

3. Loosening, migration or loss of fixation of implant.

4. Fretting and crevice corrosion can occur at the interface between the implant components.

5. Fatigue fracture of the implants as a result of bone resorption around the implant components.

6. Wear and damage to the implant articulating surface.

7. Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures.

8. Intraoperative or postoperative bone fracture.

Sterility

Prosthetic components are sterilized by exposure to gamma irradiation. Do not resterilize. Do not use components if packaging is opened or damaged. Do not use components if beyond expiration date.
Instructions for Use

1. Use **Drill Guide** to locate the axis normal to the articular surface and central to the defect. Choose the correct **Drill Guide** diameter sufficient to circumscribe the defect. Confirm the appropriate **Articular Component** diameter by matching it to the **Drill Guide** diameter. Place **Guide Pin** into a Cannulated Powered Drill and secure at the etch marking on the **Guide Pin**. Advance **Guide Pin** into bone making sure that it is central to the defect. (It is important to verify the **Drill Guide** is seated on the curved surface such that all 4 points of contact are established on the articular surface. A normal axis and correct **Articular Component** diameter are necessary for proper implant fit.)

2. Place cannulated **Drill** over **Guide Pin** and drive until the proximal shoulder of **Drill** is flush to the articular surface. (Use lavage during drilling to prevent possible tissue damage from heat effects.)

3. Tap hole to etched depth mark on **Tap**.

4. Place the **Driver** into the **Screw** and advance the **Screw** until the line on the **Driver** is flush with the cartilage surface.

5. Clean taper in **Screw** with **Taper Cleaner**. Place **Trial Cap** into **Screw** to confirm correct depth of **Screw**. The height of the **Trial Cap** must be flush or slightly below the existing articular cartilage surface to avoid the **Articular Component** from being placed proud or above the surface of the defect. Adjust depth if needed using the **Driver** to rotate the **Screw** (rotate clockwise to advance and counterclockwise to retract). Remove **Trial Cap**.

6. Place **Centering Shaft** into taper of **Screw**. Place **Contact Probe** over **Centering Shaft** and rotate around shaft. Read **Contact Probe** to obtain offsets at indexing points and mark each of the identified offsets on the appropriate Sizing Card. Select appropriate **Articular Component** using Sizing Card.

7. Remove **Centering Shaft** and replace with **Guide Pin**. Advance **Circle Cutter** onto the articular surface by twisting the **Circle Cutter** back and forth avoiding any bending of the **Guide Pin**.

8. Choose the appropriate **Surface Reamer** based on the offsets. Confirm selection by matching the color code on the **Articular Component** package with the colored band on the **Surface Reamer** shaft. Drive **Surface Reamer** over **Guide Pin** until it contacts the top surface on **Screw**. (Use lavage during drilling to prevent possible tissue damage from heat effects.) Make sure not to bend the **Guide Pin** during drilling as it may result in **Articular Component** malalignment.

9. Clean taper in **Screw** with **Taper Cleaner** and remove any debris from the surrounding implant bed.

10. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **HemiCAP® Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed.

11. Before placing the **Articular Component** on the **Implant Holder** make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **Articular Component** on the **Implant Holder**. For non-spherical **Articular Components** orient the etch marks on the back of the **Articular Component** with the etch mark on the handle of the **Implant Holder**. Align the **Articular Component** with the appropriate offsets. Insert into taper of **Screw**.

12. Use a slight tap on the **Impactor** to seat **Articular Component**. Progressively tap the **Impactor** until the **Articular Component** is firmly seated on the bone.