

Patient Labeling
Cormet
Hip Resurfacing
System

Patient Product Information

The information presented in this brochure is for educational purposes only. Stryker is not dispensing medical advice. Please speak to your doctor to decide if joint replacement surgery is right for you. Only your doctor can make the medical judgment which products and treatments are right for your own individual condition. As with any surgery, joint replacement carries certain risks. Your surgeon will explain all the possible complications of the surgery, as well as side effects. Additionally, the lifetime of a joint replacement is not infinite and varies with each individual. Also, each patient will experience a different post-operative activity level, depending on their own individual clinical factors. Your doctor will help counsel you about how to best maintain your activities in order to potentially prolong the lifetime of the device. Such strategies include not engaging in high-impact activities, such as running, as well as maintaining a healthy weight.

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Glossary of Terms

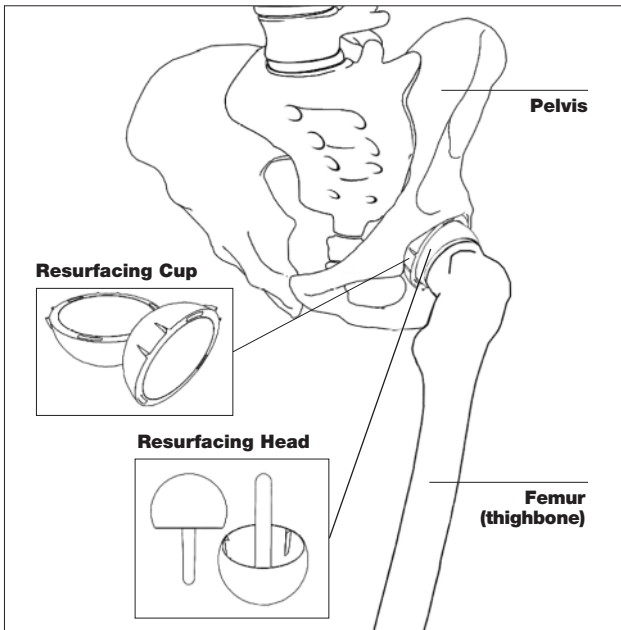
Acetabulum	– Hip socket
Activity modification	– Changing or avoiding certain activities
Adverse	– Harmful or unfavorable
Anesthetic	– Drug used to eliminate the feeling of pain
Arthroplasty	– Creation of an artificial or man-made joint
Artificial	– Man-made
Avascular necrosis	– Death of bone
Avulsed lesser trochanter	– Condition resulting when an injury causes a ligament or tendon to tear away (avulse) a small piece of a bone
Brittle	– Easily broken, cracked or shattered
Calcification	– Hardening of tissue
Debris	– An accumulation of foreign material
Deterioration	– To weaken or grow worse
Degenerative	– Gradual loss of function
Femoral	– Related to the thighbone
Femur	– Thighbone
Fixation	– The stabilization of an implant to surrounding bone or cement
Friction	– The act of rubbing
Fusion	– Uniting or bringing together
Intra-operative	– During surgery
Invasive	– Involving entry into the body through incision of the skin or insertion of an instrument
Latent	– Potential for development, though currently inactive
Lubrication	– To make smooth or slippery
Metal ions	– Particles from the hip implant that are released into the body in trace amounts as the parts rub against each other
Modifications (limits)	– Small alterations or adjustments
Mortality	– The number of deaths in a given time or place
Osteoarthritis	– Non-inflammatory degenerative disease of the joint characterized by degeneration of cartilage
Osteotomy	– The removal of a wedge of bone to improve alignment
Post-operative	– Following surgery
Predecessor	– One that comes before another
Pre-operative	– Before surgery
Rehabilitating (recovering)	– To restore to good health or useful life, as through therapy and education
Resumption	– To begin again, resume
Revision	– Replacement of a failed implant with a new implant
Rheumatoid arthritis	– Condition occurring from the body's own immune system attacking the lining of the joints as it would with foreign bacteria
Skeletal immaturity	– Bones lacking complete growth or development
Subsidence	– To sink or settle down
Traumatic arthritis	– Condition resulting when the joint or the ligaments surrounding it are damaged by fracture, dislocation, or accident related injury
Wear Resistance	– Able to withstand deterioration

1. What is the Cormet Hip Resurfacing System?

The Cormet Hip Resurfacing System consists of two parts: an acetabular component (or cup), and a femoral resurfacing component (or head).

- Acetabular component: The cup is used to replace the damaged surface of your hip socket without the use of bone cement for fixation.
- Femoral resurfacing component: The head is used to cover the ball of your hip (the ball shaped part of your hip at the top of the thighbone). The head component features a small stem that is inserted into the top of your thighbone. Bone cement is used for fixation of the head to the bone.

The Cormet head swivels within the cup. The surfaces that rub against each other are both made from highly polished metal. This type of hip device, therefore, is called a *metal-on-metal* hip resurfacing device.



2. What are the reasons for hip resurfacing? (Indications for Use)

Hip resurfacing is most appropriate for active patients with good bone quality near the ball (femoral head) and socket (acetabulum) of the hip joint with the following conditions:

- Non-inflammatory degenerative joint disease such as osteoarthritis and avascular necrosis;
- Inflammatory joint disease such as rheumatoid arthritis.

Hip resurfacing arthroplasty is intended as a first line joint replacement for patients who are at risk of requiring more than one hip joint replacement over their lifetimes. While it is not possible to predict if a patient will require a future hip joint revision, several factors such as gender, age, weight, and activity level may increase the risk of the need for revision surgery.

3. What are the reasons to avoid hip resurfacing? (Contraindications)

Hip resurfacing is not recommended for patients with the following conditions:

- Active or suspected infection in or about the hip joint;
- Any nerve or muscle disease that your surgeon feels would compromise the success of the procedure;
- Poor bone quality which your surgeon feels could not support the implant;
- Patients who are expected to grow taller after the surgery;
- Any known allergy to metal (e.g., jewelry);
- Extreme overweight (overload on device that would lead to failure);
- Pregnancy;
- Plans for pregnancy;
- Weak immune system due to disease or certain medications (e.g., corticosteroids);
- Kidney failure;
- Inability to follow post surgery life style directions;
- Inability to appear for repeated surgeon's visits, and
- Inability to face repeated surgeries.

4. What are some of the limitations of the Cormet Hip Resurfacing procedure?

- Hip resurfacing implants have limitations. For example, extreme forces placed on the implants through excessive patient weight or activities such as running and jumping can affect the artificial joint. Patients should govern their activities accordingly.
- The artificial hip joint may not restore function to the same level as normal, healthy bone so the patient should not have unrealistic expectations.
- The life span of the artificial hip joint components is difficult to estimate, however, it cannot be expected to equal that of normal healthy bone.
- The components of the artificial hip joint are affected by many biological and mechanical factors, which cannot be determined ahead of time.
- Metal sensitivity reactions have been reported following joint replacement.
- Adverse effects may result in a need for additional surgeries including the removal of the implants and replacing them with total hip replacement implants.

5. What are some of the potential benefits of the Cormet Hip Resurfacing System?

Your surgeon has decided that you will likely benefit from hip replacement surgery. When thinking about the benefits of the Cormet Hip Resurfacing System, you should compare the possible risks and benefits of the Cormet Hip Resurfacing System to the risks and benefits of other types of artificial hip replacement devices:

- Hip resurfacing versus a total hip replacement:
With a hip resurfacing device, the surgeon covers your hip socket (acetabulum) with a metal cup and covers your hip ball (femoral head) with a metal cap. The Cormet System is a hip-resurfacing device.
- With a total hip replacement device, the surgeon covers your hip socket with a cup and replaces your hip ball (femoral head) with a metal ball that is then attached to a long metal stem. The metal stem is inserted into your thighbone (femur).
- Metal-on-metal versus metal-on-plastic or ceramic-on-ceramic:
With metal-on-metal systems, the cap (ball) and the socket components are made from highly polished metal. The Cormet System is a metal-on-metal system. Other hip systems can have a metal ball with a plastic lined hip socket (metal-on-plastic), or a ceramic ball with a ceramic-lined hip socket (ceramic-on-ceramic).

Each of the device types discussed above may improve hip pain and function. However, specific potential benefits of the Cormet System include:

- The Cormet System's metal cup will not chip or crack as ceramic components can.
- The Cormet System does not cause thighbone (femur) fractures as total hip replacement systems can.
- The Cormet System may make future revision surgery easier because hip-resurfacing surgery leaves your hip ball (femoral head) in place and there is no large metal stem placed in the thighbone (femur). Revision surgery of a total hip replacement where your hip ball (femoral head) has already been removed and a large stem is already in place can be a more difficult operation.
- Dislocation of the ball head from the socket is less common with the Cormet device than with total hip replacement devices. In the clinical study, 0.2% (2/1148) of the all enrolled population of the Cormet hips experienced dislocation. This is similar to the dislocation rate previously reported in the literature (0.75%).

6. What are the adverse events, complications, and risks expected from hip resurfacing?

Some of the possible complications of any metal-on-metal hip resurfacing system are:

- Hip ball (femoral head) and hip socket (acetabulum) may separate (hip dislocation);
- Device loosening from the surrounding bone;
- Allergic reaction to the implant's materials. As the parts rub against each other, metal ions are released into the body, which may cause an allergy. There are no known medical consequences of these ions at this time, however, studies are ongoing.
- Audible sounds during motion;
- Femoral neck fracture – your bone below the ball of the hip may break;
- Femoral head collapse – the bone in the ball of the hip could break;
- Premature wear or breakage of the implants;
- Bone loss around the implant;
- Change in the length of the treated leg;
- Hip pain and stiffness;
- Loss of flexibility of the hip joint;
- Nerve damage;
- Calcification.

The surgery to implant the device may also be complicated by:

- Nerve damage;
- Allergic reaction to medical treatments during surgery and/or blood transfusion;
- Excessive bleeding;
- Infection;
- Blood clots in the legs and/or lungs due to the surgery;
- Other medical problems such as heart attack or pneumonia while awaiting or recovering from surgery.

7. Why choose the Cormet Hip Resurfacing System?

Laboratory testing and the long use of metals have shown them to be hard, and have good lubrication, friction, and wear properties.

There are total hip systems that also feature metal-on-metal sockets. When compared with these devices, the potential benefit of the metal-on-metal Cormet Resurfacing device is that the resurfacing device leaves your hip ball (femoral head) in place. This means that if you eventually wear out this resurfacing device, your surgeon may have an easier time replacing your hip in the future as more of your original, natural bone is left intact.

If you were to get a *total* hip replacement, however, your surgeon must remove the top of your thighbone (femur) neck shaft. This means that if you eventually wear out your first total hip replacement or need a revision due to other reasons, your surgeon may have a more difficult surgery and may need to take even more of your natural bone.

Safety and Effectiveness

A clinical study was performed to evaluate the safety and effectiveness of the Cormet device. Complication (safety) information was collected from the entire group of 1148 study procedures. Effectiveness information was collected from the 337 Pivotal Study Unilateral Patients. There is at least a two year follow-up for 283 of these 337 patients.

Harris Hip Score

The Harris Hip Score (HHS), the most widely used scoring system for evaluating the effectiveness of total hip arthroplasty, has been demonstrated to be both valid and reliable. Published literature tends to present HHS patient success based on a total point value at a specific post-operative interval rather than on a point differential. This includes literature associated with the use of modern hip resurfacing systems. FDA approved the effectiveness of the control ceramic total hip system based on a composite HHS of 70 points or more as indicating patient success. A total HHS of 80 or greater is considered good to excellent. Hip arthroplasty procedures are known to be highly successful with high patient satisfaction. Separating the population into those with HHS greater than or equal to 80 and those below 80 gives an evaluation of patient success based on at least adequate (good) relief of pain and return to function that has come to be expected as a result of the surgery.

There was no statistically significant difference with the control population for the Composite Clinical Success with over 95% of the patients in each group having a composite HHS of >80 points at Month 24 (p=0.650).

Device Related Events

The protocol definition of device related adverse event (AE) was “an AE that occurs due to the design and/or material composition of the implant and/or implant instrumentation.”

From this definition, the category was refined to include:

- Bone breakage around the implanted components (acetabular or femoral fracture);
- Loosening of the components for reasons other than infection (acetabular or femoral loosening);
- Breakage of the device components (stem fracture, acetabular liner fracture, etc.);
- Movement of the components in the bone (subsidence);
- Dislocation of the hip;

- Revision (adverse event necessitating removal or replacement of the original surgical device. A revision is considered to be the most severe adverse event as it indicates total failure of the surgical procedure or device.)

These complications very rarely could lead to leg amputation or death. Speak to your surgeon about your risks.

- The risk of acetabular component loosening – There were 11 events (1.0%) of acetabular loosening in the All Enrolled investigational group of the clinical study.
- The risk of dislocation – There were 2 events (0.2%) of dislocation in the All Enrolled investigational group of the clinical study.
- The risk of femoral component loosening – There were 14 events (1.2%) in the All Enrolled investigational group of the study.
- The risk of post-operative femoral neck fracture – There were 26 events (2.3%) in the All Enrolled investigational group of the study.
- The risk of revision within 24+ Months of the procedure – There were 44 events (8.3%) out of 532 subjects at 24+ Months follow-up in the All Enrolled investigational group of the study.

8. What other ways can a damaged hip joint be treated?

Your surgeon should discuss with you other procedures that could be used for your condition. These include:

- Conservative, non-surgical treatment, such as activity modification, weight reduction, pain medication, physical therapy, cortisone injections, and walking aids
- Hip osteotomy – cutting a hole in the bone to relieve pressure and promote healing
- Hip fusion – making the thighbone (femur) and hip socket (acetabulum) a stable, yet unbending joint.
- A total hip replacement, which can be made of a combination of metal, plastic and/or ceramic parts.

After discussing the above options with your surgeon, you may decide to have no treatment at all at the present time.

9. How is hip resurfacing performed?

Resurfacing a hip is similar to a total hip replacement from a surgical perspective. Instead of cutting off the arthritic top of the thighbone (femoral head), the head is reshaped and resurfaced with a metal mushroom-like cap. This is secured in place with a type of cement. The hip socket (acetabulum) is prepared in a similar fashion to a total hip replacement. Once the diseased cartilage is removed, a cup is press-fitted into place. Hip resurfacing leaves more of your natural bone in place and does not remove the thighbone (femur) neck shaft. The hip resurfacing surgery usually takes two to four hours to perform. The procedure may be performed under epidural, spinal or general anesthesia. The choice is made in consultation with your surgeon and anesthesia provider.

All components of the hip resurfacing implants are made of standard materials that have a long history of use in the human body.

10. What may happen after a Cormet Hip Resurfacing?

Recovery from any operation varies from patient to patient and post-operative rehabilitation programs vary from hospital to hospital and surgeon to surgeon.

After surgery you will need to rest your hip to allow proper healing. Your activity will be restricted during this healing period. During the first weeks after surgery, you may be advised to put a pillow between your legs when turning over in bed, wear elastic stockings, use raised toilet seat, take showers rather than baths, restrict activities such as sudden twisting or turning, crossing legs, exposing the scar to sunlight, and driving. Follow carefully your surgeon's instructions regarding progression to normal weight bearing and resumption of normal physical activity. Individual results will vary and all patients will experience different activity levels post-surgery.

Your surgeon will give you detailed post-operative instructions before you leave the hospital.

Even after the healing period, excessive loads placed on the implants through sudden trauma or high impact activities, such as running and jumping, can damage the artificial joint.

The majority of your therapy and rehabilitation will occur once you are discharged from the hospital. Your Physical Therapist (PT) should design an exercise program to increase the motion and strength of your hip and will make sure that you know proper form before you begin the program. The rate and effectiveness of your rehabilitation is critically dependent on your commitment to the physical therapy program as well as other clinical factors.

Your surgeon may want you to meet with a PT even before the surgery. The PT may give you some tips on preparing your house for rehabilitation and on how you should sleep, get out of bed, sit, stand from a sitting position, and walk following surgery.

Special precautions

Call your surgeon if you experience any of the following symptoms:

- Redness, burning, swelling, or drainage from your operated area;
- Fever of 100 degrees or higher;
- Pain that does not lessen with rest;
- Acute, severe pain in the hip associated with twisting, turning, or injury.

Please ask your surgeon to discuss with you any of the above complications that are not familiar to you.

11. What may I expect when I travel?

Your new hip device may activate metal detector alarms. Tell the security attendant about your artificial hip when passing through security checkpoints in airports, stores, and public buildings.

12. Is there anything else to know about hip resurfacing?

Consult your surgeon regarding pre-operative considerations, post-operative rehabilitation, and expectations for surgery. It is important to begin planning for your return home from the hospital before your surgical procedure. Your physical therapist (PT) or occupational therapist (OT) may suggest tips to prepare your home for after surgery. For example, get an apron or belt with pockets to carry things while you are on crutches, buy or borrow a cordless phone, remove scatter rugs and other obstacles for safe walking using crutches, have a high seated chair and commode accessories available. Above all, during this time, treat yourself well, eat balanced meals, get plenty of rest, and, if requested by your surgeon, donate your own blood so it can be transfused during and after surgery.

13. How to obtain user assistance information?

Please discuss any questions regarding your hip surgery with your surgeon. For further information regarding the Cormet Hip Resurfacing System components, you may also contact the device distributor in the USA, Stryker Orthopaedics, or the device manufacturer, Corin Group PLC:

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