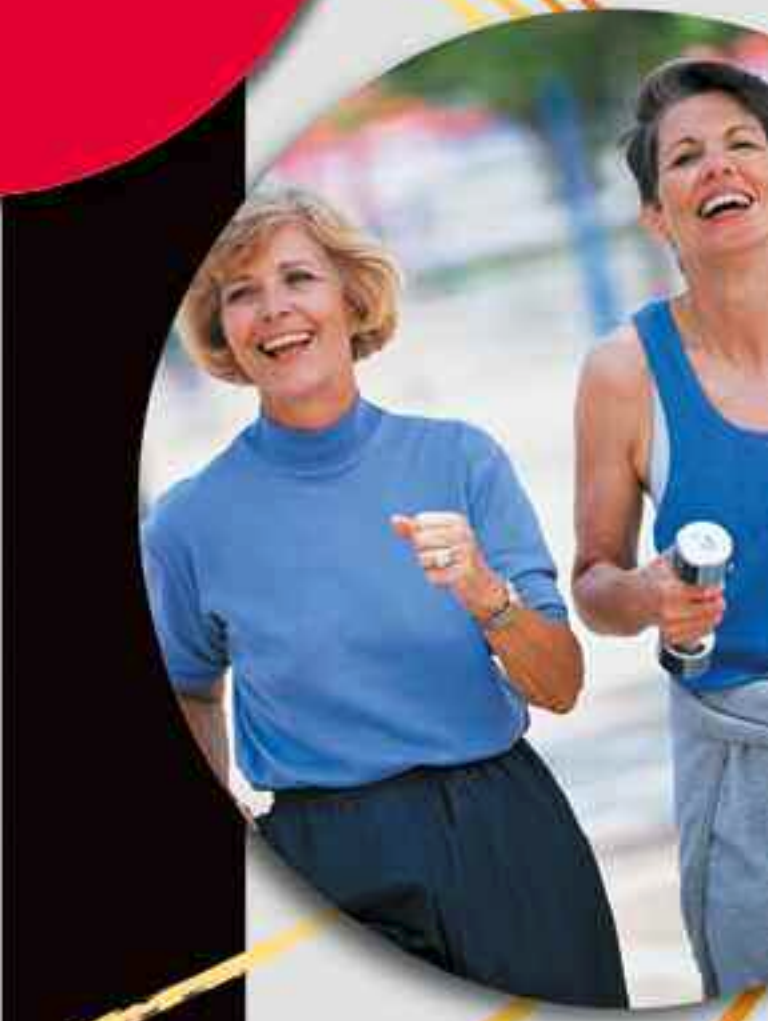
Hip Implant Options



Bearing Basics

Today's hip implant patients are fortunate. Doctors can now choose from advanced implant materials. One choice doctors make when selecting the implant for you is called the "bearing." In this patient education brochure, you'll discover why the bearing is so important. The good news is today's bearing materials offer excellent performance. Your surgeon can choose the material best suited for you. Please discuss with your surgeon the potential advantages and disadvantages of the implants you are considering.

In this brochure you will:

- Discover the importance of a key part of the artificial hip implant – the bearing.
- Compare advances in materials that give your surgeon excellent bearing materials to choose from: metal-on-polyethylene, metal-on-metal, ceramic-on-polyethylene, and ceramic-on-ceramic.

Keep in mind:

Some of this information may seem a bit technical, which only demonstrates that an artificial joint is a highly sophisticated medical device based on the best available science. If you or someone you love plans to have a hip implant, you may find this information very useful, even if it seems a bit technical at first glance!

Implant Components

In total hip replacement surgery, doctors replace the diseased hip with an implant (prosthesis) consisting of a stem, ball, liner and socket.

- The stem, made of metal, is inserted into the thighbone and anchors the artificial hip in place.
- The ball is attached to the top of the stem.
- The socket is anchored into the pelvis and the ball, which is attached to the top of the stem, fits into a liner within the socket.

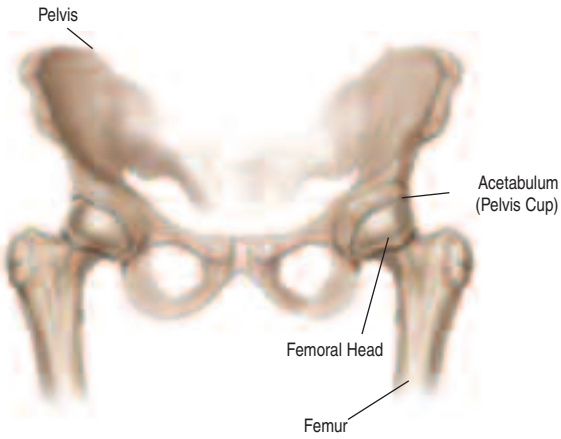
What Exactly Is a "Bearing"? Why Is It Important?

The point where the moving parts of the implant connect is known as the bearing. The bearing gives the ball of the hip implant a smooth surface on which to glide and rotate. The term "bearing" actually refers not just to a single part of the implant, but also to the point at which the ball and socket rub together. Most doctors use more than one type of bearing in their practice, selecting the best material for each patient.

For many years, a very tough medical-grade plastic, ultra high molecular weight polyethylene, has been used in the bearings of artificial joints. Today, due to innovations in the orthopaedic industry, surgeons can choose from polyethylene, metal or ceramic materials, used in different combinations to create the optimum bearing surface for you. These materials will be explained in more detail later in this brochure.

As a patient, why should you be concerned with the bearing surface? The answer is simple; the bearing surface plays a critical role in the durability of an artificial hip.

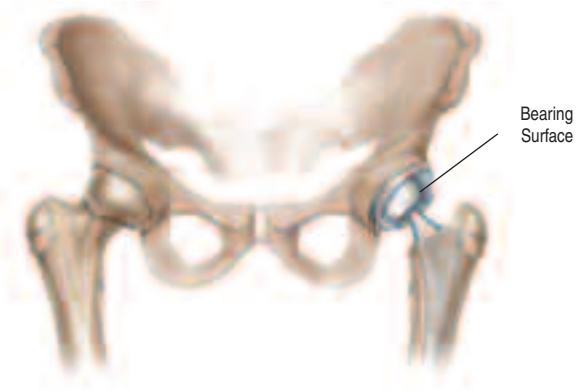
How Your Hip Works



The hip joint forms where the top of the thigh-bone (femur) meets the socket of the pelvic bone. The top of the femur is ball-shaped and fits snugly in the socket.

The bones of the hip joint are covered by cartilage that protects the bones while allowing easy motion. Surrounding the hip joint is the synovial lining, which produces a lubricant. Tough fibers, called ligaments, connect the bones of the joint and hold them in place, while adding strength and elasticity for movement. Muscles and tendons also play an important role in keeping the hip joint stable.

The Role of Bearing Material in Hip Replacement Surgery



The bearing is the point where the loads and motions of the patient's body are transferred from the pelvis to the femur. You often hear of ball bearings used in moving parts of machines; the concept is the same.

The bearing affects how well the prosthetic joint performs. It affects mobility, flexibility, and range-of-motion of the joint. Range of motion is the arc created by the bending of the limb at the joint, called flexion, and is usually expressed in degrees.

The bearing also affects how well the implant will stand up over time; how long the implant will last; how stable it will be in the patient's body; and whether the patient will encounter difficulties if the bearing begins to wear down.

The bearing supports the motion in the joint. When fitted with the ball, the bearing must serve many functions and have a combination of:

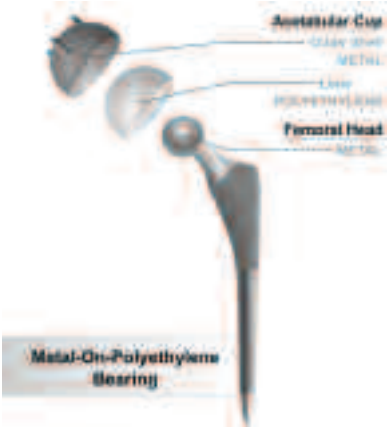
- Ultra-smooth surface for sliding and rotating the joint
- Stability
- High strength and resistance to fracture
- High resistance to wear, corrosion and friction
- Optimum range of motion
- Nontoxic to the body

The choice of plastic, metal or ceramic is one of the most dynamic areas of hip-replacement technology. No material or combination is best for all patients and medical conditions. Each of the materials has distinct advantages and disadvantages. Your surgeon will discuss these with you and choose the material that suits your needs the best, based on many variables which include your age, lifestyle and weight.

Three main categories of bearing materials are cross-linked polyethylene, metal, and ceramic. Each has positive attributes and potential drawbacks that doctors assess when making a choice for each patient. As you become familiar with these, remember that the bearing itself is not one part, but the point where the ball and liner meet; so the bearing can be the joining of different combinations of materials.

Cross-Linked Polyethylene Bearings

The bearing component most commonly used for total hip replacement in the U.S. is a metal femoral head (ball) made of either stainless steel, cast or wrought cobalt-base alloy against a polyethylene-lined acetabular cup.



Polyethylene has a long, successful clinical history, is not toxic to the human body, and has adequate toughness for most total hip bearing applications.

For years, polyethylene has been the leading artificial hip component material chosen by surgeons because of its durability and performance.

Polyethylene accommodates the wide range of motion needed to function with the hip. It is slippery, which makes it effective in a mobile joint like the hip.

Polyethylene can accommodate various sized femoral heads, so surgeons can choose the size that allows for the best fit. This gives the surgeon a great degree of control over the customization of the implant and the way it fits in the body to achieve stability.

Polyethylene offers the surgeon a range of versatile options while the operation is underway to obtain precise insertion in the body. This ability to adapt and customize during the surgical procedure itself is an important attribute of polyethylene.

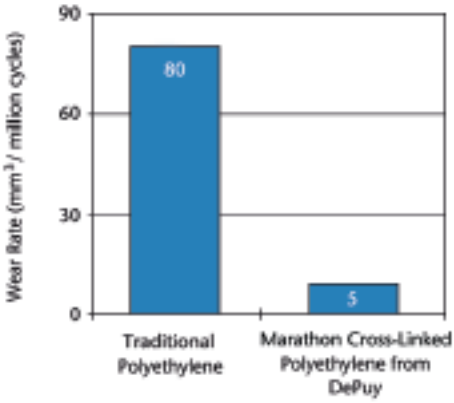
As with all implants, there is a potential for polyethylene to begin to wear down over time. This can lead to:

- **Osteolysis** – This term refers to "particle-disease." When two surfaces rub against each other, material is removed, often as small particles. There is more loss of material, or wear, from the softer material. A common example is automobile tires. In the body, such wear particles can cause inflammation and breakdown bone, and may require another operation.

- **Difficult Repeat Surgeries** – When an implant wears out or fails, it may be necessary to do more surgery. Doctors call this "revision surgery." Bone loss due to osteolysis makes revision operations more difficult.

DePuy Orthopaedics, Inc., developed Marathon® Cross-linked Polyethylene. In laboratory tests, the wear of Marathon Cross-linked Polyethylene has demonstrated a 86% reduction in wear.[1] Not all polyethylene bearings are manufactured and processed the same. Researchers at DePuy continually try to develop materials to improve durability and reduce wear.

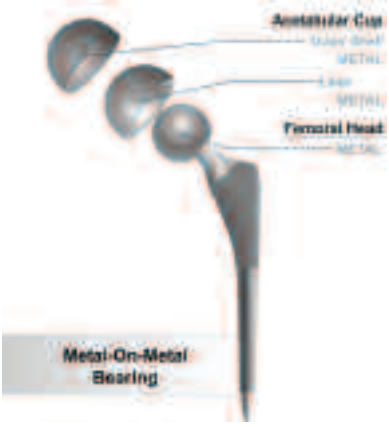
Wear Rate: Marathon vs. Traditional Polyethylene



But you don't need to be a molecular scientist to understand the basics about polyethylene bearing materials in hip implants. Doctors can choose Marathon Cross-linked Polyethylene for its stability and versatility. Doctors weigh those benefits against the wear rate that polyethylene exhibits to answer the key question: "Will this product meet the demands of this patient?"

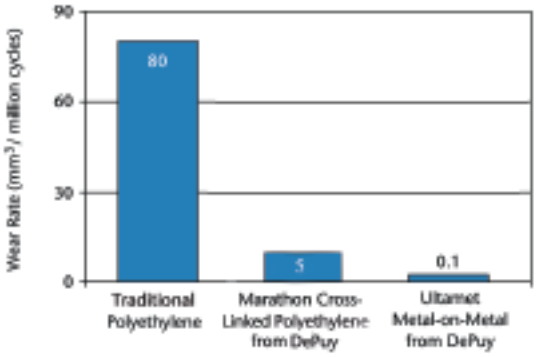
Metal Bearings

When a metal bearing is used with a metal femoral head (ball), doctors refer to the implant as a "metal-on-metal" design. Metal-on-metal bearings were first used in the United States when joint replacement began in the late 1960s.



Because polyethylene was so successful though, it dominated the scene for many years. However enhanced designs and increased demands from patients for stronger, longer lasting implants have generated renewed interest in metal bearings in recent years in the United States.

Wear Rate: Metal vs. Polyethylene



Metal bearings are made of cobalt chromium. Among the advantages of metal bearings: they are less likely than polyethylene bearings to release particles into the body and "wear" less over time. These are important factors in reducing the risk for complications such as inflammation and loosening.

A metal-on-metal bearing provides advantages over a metal-on-polyethylene bearing surface. Tests in hip simulators — machines that put a hip implant through the type of stress that mimics real-world conditions — have showed that metal-on-metal bearing surfaces generate fewer particles than metal-on-polyethylene. Since both surfaces are hard without being brittle, they are resistant to scratching and wear.

Laboratory wear rates for metal-on-metal bearings are lower than those for metal-on-polyethylene bearings.[2] Because they can stand up well to wear, metal bearings can be used with large femoral heads (36mm or greater). Large femoral heads provide increased range of motion and greater stability, which can significantly reduce the greatest risk of total hip replacement, dislocation. Stability is a crucial factor in the success of an implant and metal-on-metal bearings can play an important role in improving joint stability.

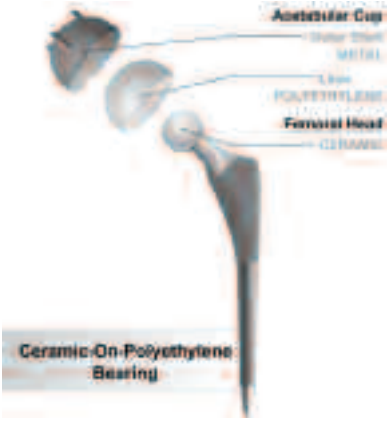
Due to the strength of metal-on-metal bearings, smaller acetabular shells can be used with larger femoral heads. This allows the surgeon to remove less healthy bone from the acetabulum (socket) to implant the smaller shell, which preserves healthy bone. This can be an important issue for younger, more active patients since no implant is as strong as natural, healthy bone.

Inform your doctor if you have metal sensitivity, such as an irritation or rash from metallic jewelry. There are many technical differences among metal-on-metal bearings. Material selection, manufacturing controls and methods play an important role in the durability and life of a metal-on-metal bearing.

Ultamet™ Metal-on-Metal bearings from DePuy have over five years of successful clinical history.

Ceramic Bearings

Another approach to reducing wear is to utilize components made from medical grade ceramic. Ceramic bearings are available in two configurations; a ceramic femoral head (ball) with a *polyethylene liner* or a ceramic femoral head (ball) with a *ceramic liner.*



Ceramic on Polyethylene Bearings

Traditionally, balls have been made of metal. As an alternative, heads made of alumina ceramic and alumina/zirconia composites are now

manufactured. The ceramic heads are harder than metal and with proper polishing, they can be smoother than metal heads. Ceramic heads are very difficult to scratch. The hard, scratch-resistant, ultra-smooth surface can greatly reduce the wear rate on the polyethylene bearing.[3]

One property of ceramic is that when it wears, it does so in "grains," not the "peaks and valleys" that result when metal scratches. The grains may be less likely to make the polyethylene liner wear down. In addition, ceramic is "water-friendly." Doctors refer to this as being hydrophilic. The benefit is a hydrophilic material will lubricate the surface more easily with reduced friction. Some surgeons see this as an advantage over metal.

DePuy has introduced the BIOLOX®*delta* ceramic femoral heads. With more than four years clinical success in Europe, BIOLOX®*delta* ceramic heads provide new treatment options for younger, more active patients.

BIOLOX®*delta* ceramic heads are made of zirconia-toughened, platelet-reinforced alumina ceramic (ZPTA), designed to incorporate the wear properties and stability of current alumina ceramics with vastly improved strength and toughness. Laboratory tests have demonstrated that BIOLOX®*delta* ceramic heads are 98% tougher than conventional alumina ceramic

BIOLOX®*delta* *is a trademark of CeramTec*

materials.[4] Ceramic materials with high ceramic toughness are less likely to break or deform under load, which is a critical factor for younger, more active patients.

Ceramic on Ceramic Bearings

Ceramic wears at a very low rate compared to polyethylene and metal.[5] While ceramic is ultra-hard and scratch-resistant, one disadvantage of alumina ceramic is its tendency to be more brittle than other surfaces. This makes it more prone to fracture, which can have serious consequences.

Another limitation of alumina ceramic, compared to polyethylene or metal, is ceramic can be less forgiving when doing a surgery. Precise insertion can pose some technical challenges in the surgeon's technique. There are also some limitations in the available sizes of ceramic femoral heads. Size limitations may require the surgeon to remove excess healthy bone to accommodate a larger cup or implant a smaller diameter femoral head, which may reduce range of motion and joint stability. Ceramic on ceramic bearings are typically the most expensive bearing option.

The Surgeon's Decision

Surgeons choose a bearing based on durability, level of performance, wear resistance, their experience and your personal needs.

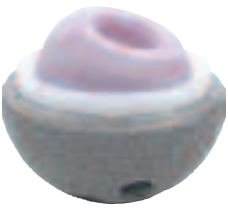
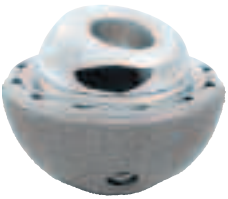
No one material is right for every patient. Only your surgeon can determine what's right for you. And what's right for you may not be right for the next patient!

About DePuy

DePuy Orthopaedics, Inc. is a leading designer, manufacturer and distributor of orthopaedic devices and supplies including hip and knee replacements and operating room products. DePuy has long been regarded as an innovator in new product development. DePuy researchers were on the forefront of the total hip replacement concept introduced in the early 1960s.

DePuy continues to invest millions in research to continually improve the bearing choices available to surgeons. To learn more about DePuy products, please visit www.hipreplacement.com.

Understanding Hip Implant Options

Product	Range of Motion	Stability	Wear
 **Metal on Cross-linked Polyethylene**	**Good: Up to 142°** Good range of motion to help restore proper biomechanics to reduce the risk of dislocation	**Excellent Stability** Marathon cross-linked Polyethylene is available in multiple liner configurations to improve joint stability and help restore proper hip biomechanics[6]	**Modest Wear Reduction** Marathon cross-linked Polyethylene from DePuy wears 85 percent less than traditional polyethylene materials while maintaining key mechanical properties essential for total hip replacement
 **Ceramic Femoral Head on Cross-linked Polyethylene**	**Good: Up to 142°** Good range of motion to help restore proper biomechanics to reduce the risk of dislocation	**Excellent Stability** BIOLOX *delta* femoral heads in cross-linked polyethylene liners provide multiple liner and femoral head options to enhance joint stability and restore proper biomechanics[7]	**Excellent Wear Reduction** BIOLOX *delta* Ceramic Femoral Heads and Marathon Cross-Linked Polyethylene from DePuy combine the wear reduction of Marathon with the enhanced toughness of BIOLOX *delta* ceramic to provide excellent wear reduction and improved functional performance
 **Alumina Ceramic on Ceramic***	**Good: Up to 142°** Good range of motion to help restore proper biomechanics to reduce the risk of dislocation	**Good Stability** Alumina ceramics are available in a limited size range and may require larger diameter acetabular shells which may require the removal of more healthy bone or the use of smaller diameter femoral heads.	**Excellent Wear Reduction** Alumina ceramic components exhibit low wear rates in hip simulator studies[8]
 **Metal-on-Metal**	**Excellent: Up to 151** Excellent range of motion restores biomechanics and provides enhanced functional performance	**Excellent Stability** Due to the high strength of metal-on-metal implants, larger femoral heads are available which provide excellent joint stability while preserving healthy acetabular bone[9]	**Excellent Wear Reduction** Ultamet metal-on-metal components from DePuy are extremely durable and wear 100 times less than traditional polyethylene

*Actual product shown not currently available in the United States, however, other ceramic-on-ceramic implants are available.

REFERENCES

1. McKellop et al. *Clinical Orthopaedics and Related Research* 369:73-82, 1999 and *American Journal of Orthopaedics* 17:157-167, 1999.
2. Anissian, H., et al. "Metal-on-metal bearing in hip prosthesis generates 100-fold less wear debris than metal-on-polyethylene." *Acta Orthopaedica Scandanavica* 70 (6), 1999:578-82. Goldsmith, A., et al. "A comparative joint simulator study of the wear of metal-on-metal and alternative material combinations in hip replacements." Institution of Mechanical Engineers, *Journal of Engineering in Medicine* 214, 2000:39-47.
3. Saikko,V.O. "Wear of the polyethylene acetabular cup: the effect of head material, head diameter, and cup thickness studied with a hip simulator."*Acta Orthopaedica Scandanavica* 66:501-6, 1995.
4. Data on file DePuy Orthopaedics, Rack, R. and H.G. Pfaff. "A new ceramic material for orthopaedics." Proceedings of the 5th International CeramTec Symposium, G. Thieme Verlag, Stuttgart, 2000: 141-145.
5. Ceramic-on-Polyethylene: Analysis of Results to Date. *Seminars in Arthroplasty*, Vol. 14, No. 2 (April), 2003: pp 86-88.
6. Collier, J.P., et al. "Comparison of Cross-Linked Polyethylene Materials." *Clinical Orthopaedics and Related Research* Vol. 414 Sept. 2003: 289-304.
7. Wroblewski, B.M., et al. "Low-friction arthroplasty of the hip using alumina ceramic and cross-linked polyethylene: A Ten-Year Follow-up Report." *The Journal of Bone and Joint Surgery* (Br) Vol. 81-B, No.1, Jan. 1999: 54-55.
8. Sodha, S., et al. "Concepts of the Modern Ceramic on Ceramic Total Hip Arthroplasty and Early Results." *University of Pennsylvania Orthopaedic Journal* Vol. 14, Spring 2001: 1-4.
9. Chan, F. "The Award Papers/The Otto Aufranc Award." *Clinical Orthopaedics and Related Research* Vol. 369 Dec. 1999: 10-24.

For more information on hip replacement surgery, visit **www.jointreplacement.com.**

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