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Metal-on-Metal Hip Implants

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Information for Patients Who Have Metal-on-Metal Hip Implants

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How do I know if I have a metal-on-metal hip implant?

Patients are usually told about the type of implant they are receiving prior to the surgery. If you are uncertain about which type you have, you should contact the orthopaedic surgeon who performed your procedure.

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How often should I follow-up with my orthopaedic surgeon?

You should follow-up with your orthopaedic surgeon as recommended. There are some cases where your orthopaedic surgeon may recommend more frequent follow-up based on the type of hip implant, the outcome of the surgery and your recovery and the results of blood tests or imaging procedures.

If you develop new or significantly worsening symptoms or problems with your hip including pain, swelling, numbness, noise (popping, grinding, clicking or squeaking of your hip), and/or a change in ability to walk, contact your orthopaedic surgeon right away.

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What should I discuss with my orthopaedic surgeon at each follow-up appointment?

It is critical that you talk to your surgeon about any new or worsening symptoms related to your hip, groin or legs since your last visit. This may include pain, swelling, numbness, noise, and/or change in ability to walk. It is also

important that you discuss:

- Changes in your general health.
- Whether you are being seen or treated by another physician for a new condition since receiving your metal-on-metal hip implant.

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What symptoms might a metal-on-metal hip implant cause?

Symptoms may include hip/groin pain, local swelling, numbness, or changes in your ability to walk. There are many reasons a patient with a metal-on-metal hip implant may experience such symptoms and it is important that you contact your surgeon to help determine why you are having them.

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Are there other medical effects that can occur with my metal-on-metal hip implant?

Metal-on-metal hip implants have the same adverse effects as other types of hip implants, including infection, loosening, bone loss, device or bone fracture, and joint dislocation.

In addition, metal particles from a metal-on-metal implant may cause a reaction around the joint, leading to deterioration of the tissue around the joint, loosening of the implant and failure of the device. Metal ions from a metal-on-metal implant will enter the bloodstream. There are case reports in which patients with metal-on-metal hip implants may have developed an adverse reaction to these metal ions and experienced medical problems that could have been related to their implants. These problems included:

- General hypersensitivity reaction (skin rash)
- Cardiomyopathy
- Neurological changes including sensory changes (auditory, or visual impairments)
- Psychological status change (including depression or cognitive impairment)
- Renal function impairment
- Thyroid dysfunction (including neck discomfort, fatigue, weight gain or feeling cold)

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What are my chances of developing a reaction to my metal-on-metal hip implant and having these types of medical problems?

The FDA does not know at this time how often adverse local tissue reactions occur in patients with metal-on-metal hip implants.

Part of the difficulty in answering this question is that individuals vary in how they react to metal ions in their bodies. For example, one patient may develop a reaction in response to a very small amount of metal ions in their body, whereas a different patient may have a much larger amount of metal ions in their bodies before they develop a reaction. Certain patients may have an increased risk of device wear or adverse local tissue reaction (ALTR) and should follow-up with their surgeon more frequently. They include:

- Patients with bilateral implants (hip replacements on both the right and left sides)
- Patients with resurfacing systems with small femoral heads (device sizes less than or equal to 44mm)
- Female patients
- Patients receiving high doses of corticosteroids
- Patients with evidence of renal insufficiency (kidney problems)
- Patients with suppressed immune systems
- Patients with suboptimal alignment of device components (device components not placed in the ideal positions)
- Patients with suspected metal sensitivity (e.g. cobalt, chromium, nickel)
- Patients who are severely overweight
- Patients with high levels of physical activity

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What should I do if I am experiencing adverse events associated with my metal-on-metal hip implant?

1. If you are experiencing hip/groin pain, noise, difficulty walking or a worsening of your previous symptoms, you should make an appointment to see your orthopaedic surgeon for further evaluation of your implant. Your orthopaedic surgeon may wish to perform a physical exam and other evaluations based on your symptoms.
2. If you experience any new symptoms or medical conditions in your body **other than at** your hip, you should report these to your primary physician and remind them that you have a metal-on-metal hip implant during their evaluation.

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What should I do if I am not experiencing adverse events associated with my metal-on-metal hip implant?

If you are not having any symptoms and your orthopaedic surgeon believes the metal-on-metal hip implant is functioning appropriately, there is no evidence to support the need for additional tests. You should continue to routinely follow-up with your orthopaedic surgeon every 1 to 2 years.

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What should I discuss with my other health care providers including my general internist or family practice doctor?

There are case reports of patients with metal-on-metal hip implants who experienced medical problems in areas of the body away from their hip implant. It is possible that these [problems](#) may be related to the metal ions released by the metal-on-metal hip implant.

If you see a health care provider for the evaluation of any new or worsening symptoms outside the hip/groin area, including the symptoms related to your skin, heart, nervous system, kidneys, or thyroid gland, it is important that you tell that clinician that you have a metal-on-metal hip implant. This information may affect the types of tests that are ordered to further evaluate the cause of your symptoms.

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When would a hip revision surgery be needed?

There are multiple reasons why a surgeon may recommend a device revision (a surgical procedure where your implant is removed and another is put in its place). Many of these reasons, including infection, dislocation, loosening, and device fracture, apply to any type of hip implant. Your surgeon might also consider revision if you develop evidence of local or systemic [reactions](#) to the metal from your hip implant. In that case, the surgeon will take several factors into account in considering if and when revision surgery is advisable.

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What are the risks of revision surgery?

Any surgical procedure, including revision surgery, has risks associated with it, including reaction to the anesthesia, infection, bleeding, and blood clots. The revision surgery may be more difficult if you had a local reaction to the implant that may have affected your soft tissue and/or bone quality.

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If I have a revision, what happens to the original implant?

In a revision surgery, your existing hip implant is removed and replaced with another device. Your surgeon may ask you to allow that the implant that was removed to be sent back to the manufacturer for analysis. If you agree, the manufacturer will perform a thorough examination and analysis of the device to better understand how the

implant worked and why it may have failed. The analysis is particularly informative in cases where there is no obvious cause of implant failure. Analysis can often lead manufacturers to improve an implant's design and update device labeling for future patients.

In addition to sending the implant, your surgeon will also provide non-personal information about you, the date of the procedure, observations from the revision surgery, and any reports or analysis on the tissue collected during surgery to the hospital pathologist.

There is typically no cost to you for this analysis and you will not be compensated for returning your implant. You may not be notified of the results of the analysis. If you do not want the implant returned to the manufacturer, you may decide what happens to the device.

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What does it mean when I see that a hip implant has been "recalled?"

A hip implant may be recalled by the manufacturer for a number of reasons. If your device is recalled, this does not necessarily mean that the device needs to be removed and replaced. In some cases the recall recommends different or more frequent monitoring. It is important to discuss the reason for the recall with your surgeon to determine the most appropriate course of action. If you are unsure if your hip implant was recalled, consult with your orthopaedic surgeon. Additional information on the recall can be obtained from the manufacturer or from:

[FDA: Medical Device Recalls](#)

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Where can I get additional information regarding metal-on-metal hip implants?

- [NIH Senior Health: Hip Replacement](#)
- [American Academy of Orthopaedic Surgeons: Questions and Answers about Metal-on-Metal Hip Implants](#)
- [American Academy of Orthopaedic Surgeons: Hip Implants](#)
- [American Association of Hip and Knee Surgeons: Information about hip and knee replacement for patients](#)
- [American Association of Hip and Knee Surgeons: Pre Op Surgery Center Patient Education: Hip Replacement Surgery](#)

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