# Plain Language Statement

Centre for Health, Exercise and Sports Medicine

Physiotherapy, Melbourne School of Health Sciences

## Knee Bracing and Footwear for Medial Arthritis of the Knee

### Research Team Contacts


Dr Michelle Hall (Principal Investigator)
Phone: +61 432128223
Email: halm@unimelb.edu.au

Dr David John Saxby
Phone: +61 7 5552 8917
Email: d.saxby@griffith.edu.au

Dr Kade Paterson
Phone: +61 3 8344 0425
Email: kade.paterson@unimelb.edu.au

Mr Scott Starkey (Student Investigator)
Phone: +61 439702870
Email: sstarkey@student.unimelb.edu.au

Prof. Rana Hinman
Phone: +61 3 8344 3223
Email: ranash@unimelb.edu.au


---

### Introduction

Thank you for your interest in participating in this research project. The following pages will provide you with further information about the project, so that you can decide if you would like to take part in this research.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can stop at any time.

### What is this research about?

Knee osteoarthritis (OA) is a very common joint disease that has a substantial burden on individuals and the greater society. The development and progression of knee OA is believed to be caused by inappropriate loading of the knee joint during walking. As such, there is a strong need for non-surgical methods to reduce knee loading. One such management strategy is to use knee braces that are designed to provide support and alleviate symptoms. Another strategy is to use specific footwear types that are known to be beneficial in those with knee OA.

The aim of this research is to evaluate the effects of one such knee brace, Ossür's Unloader One©, and two different types of off-the-shelf footwear on knee joint loading. We hope to gain a better understanding of the effects of knee bracing and footwear types in order to inform best care for people with knee OA.

You are invited to participate in this research project, which is being conducted by Dr Michelle Hall, Prof. Rana Hinman, Dr Kade Paterson, Dr David Saxby and Mr Scott Starkey.

### Why have I been invited to participate in this research?

You can participate in the study if you:

- Are aged 50 years or older;
- Have mild to severe knee osteoarthritis on x-ray (in the inner knee compartment) and outward

knee alignment;

- Currently have knee pain on most days;
- Willing to wear a knee brace during daily activities, every day for 8 weeks;
- Wear an Australian shoe size 6-11 (US size 6-11) for females or 7-12 (US size 8-13) for males;
- Able to fit into shoes of normal width (all shoes in this study are of normal width);
- Able to travel to undergo x-ray (if required)/magnetic resonance imaging and;
- Able to attend the Centre for Health, Exercise and Sports Medicine (CHESM) human movement lab at the University of Melbourne for testing;

You are not eligible if you

- Have had a knee or hip replacement on the affected side or knee realignment surgery;
- Have had any other knee surgery including arthroscopes in the past 6 months;
- Have a body mass index ≥ 36 kg/m$^2$;
- Awaiting or planning any back or lower-limb surgery within the next 3 months;
- Have plans to see an orthopaedic surgeon about your knee in the next 3 months;
- Current or past (within 3 months) oral corticosteroid use or corticosteroid injections in the knee joint;
- You have a systemic arthritic condition;
- You have work restrictions or other commitments that would stop you wearing a knee brace during daily activities;
- You have current (or within past 6 months) muscular, joint or neurological condition;
- Current (or within past 6 months), or intention to use with the next 3 months, a knee brace, walking stick or gait aid or;
- Are deemed unsuitable to undergo magnetic resonance imaging.

If you are a staff or a student of the University, your decision about whether or not to participate will not affect your relationship with the University or your grades in any way.

## What does the participation in the research involve?

The study involves two steps to confirm your suitability: (1) initial screening over the internet and/or phone (which you may have already completed) and (2) x-ray screening. If you pass the initial screening, you will be asked to sign the Consent Form (either on paper or online). You will then receive an x-ray of your knee. If you pass x-ray screening, you will be invited to take part in the 8-week study.

When you attend the initial assessment, you will be fitted with an appropriately sized Ossür Unloader One knee brace for you to wear over the 8-week period. During this assessment, we will also conduct short walking trials of you wearing two different types of footwear commonly used in day-to-day living. As we are also interested in knowing the short term (8-week) effect of the brace on your knee loading, we would like to ask you to commit to the research until your 8-week follow-up assessment is completed. It is very important for the research that information is collected at 8 weeks so that we can analyse your data as part of the project.

## X-ray screening

If you have not had an x-ray of your knees in the past 12 months, you will be asked to attend a radiology centre for a knee x-ray to determine your eligibility for the study. These centres are located at: Bridge Road Imaging-Richmond, Blackburn South Radiology and Brunswick Diagnostic Imaging. You may attend the centre that is easiest for you. The x-ray will take around 15 minutes and involves a small amount of radiation. There is no cost to you for this x-ray.

If you have a suitable x-ray of your knee taken within the past 12 months, you will not need an x-ray. We will send you a stamped addressed envelope to send the x-rays in to the University for assessment. Once this has been done, we will send the x-rays back to you.

## Magnetic resonance imaging

Our research requires high resolution images of your knee in order to best understand how the knee brace and footwear effects your individual knee. Therefore, we will ask you to attend the Royal Children's Hospital to undergo magnetic resonance imaging (MRI) of your knee. This process is completely safe and involves no harmful radiation whatsoever. These scans will take about 30 minutes and are explained in detail within the attached information leaflet.

## Laboratory assessment

We will call you when we have the x-ray results. If the x-ray shows you have knee OA that is mostly on the inner side of your knee and enough outward knee alignment, you will be eligible to take part in the study. If you are deemed suitable to take part, you will attend the CHESM laboratory at Melbourne University to undergo the baseline assessment, which will take about 2 hours. This will involve completing a set of questions that ask about your personal details, knee pain and function, medication usage, previous knee treatments and physical activity levels. You will then perform a series of strength tests and walking tests as described below.

## Walking assessments

At the CHESM Laboratory the function of your knee and muscles surrounding your knee will be assessed during walking. Initially, you will be prepared for the assessment with the application of skin-surface electrodes on the main muscles of one of your lower-limbs. You will then be asked to perform some short muscle contraction tasks of your leg muscles. These tasks will involve pushing and pulling with maximum effort against resistance. Afterwards, reflective markers will be applied to your body. You will then be asked to walk over ground at your preferred pace. Once familiar with the task, we will outfit you with a suitably sized pair of shoes and collect a further 6 short walking trials. You will then repeat this process with a different shoe type. We will then remove these shoes and collect a further 6 walking trials barefoot. As part of the barefoot walking trials, we will also ask you to perform short functional tasks such as squatting and step-ups. We will then outfit you with a suitably sized Ossür Unloader One knee brace and collect another 6 walking trials. Lastly, you will conduct another 6 walking trials for each of the two shoe conditions and with the brace on.

## Knee brace

After assessment is complete, you will then be asked to wear your knee brace during all daily activities (i.e. whenever you are on your feet) every day for 8 weeks. For the first day, we encourage you to wear the brace for two hours and increase by two hours every day. By the end of the first week, you should be able to wear your brace comfortably all the time. The student researcher is trained in fitting of the knee brace and will provide you with instructions on how to put the brace on and off whilst at home.

## Log-books

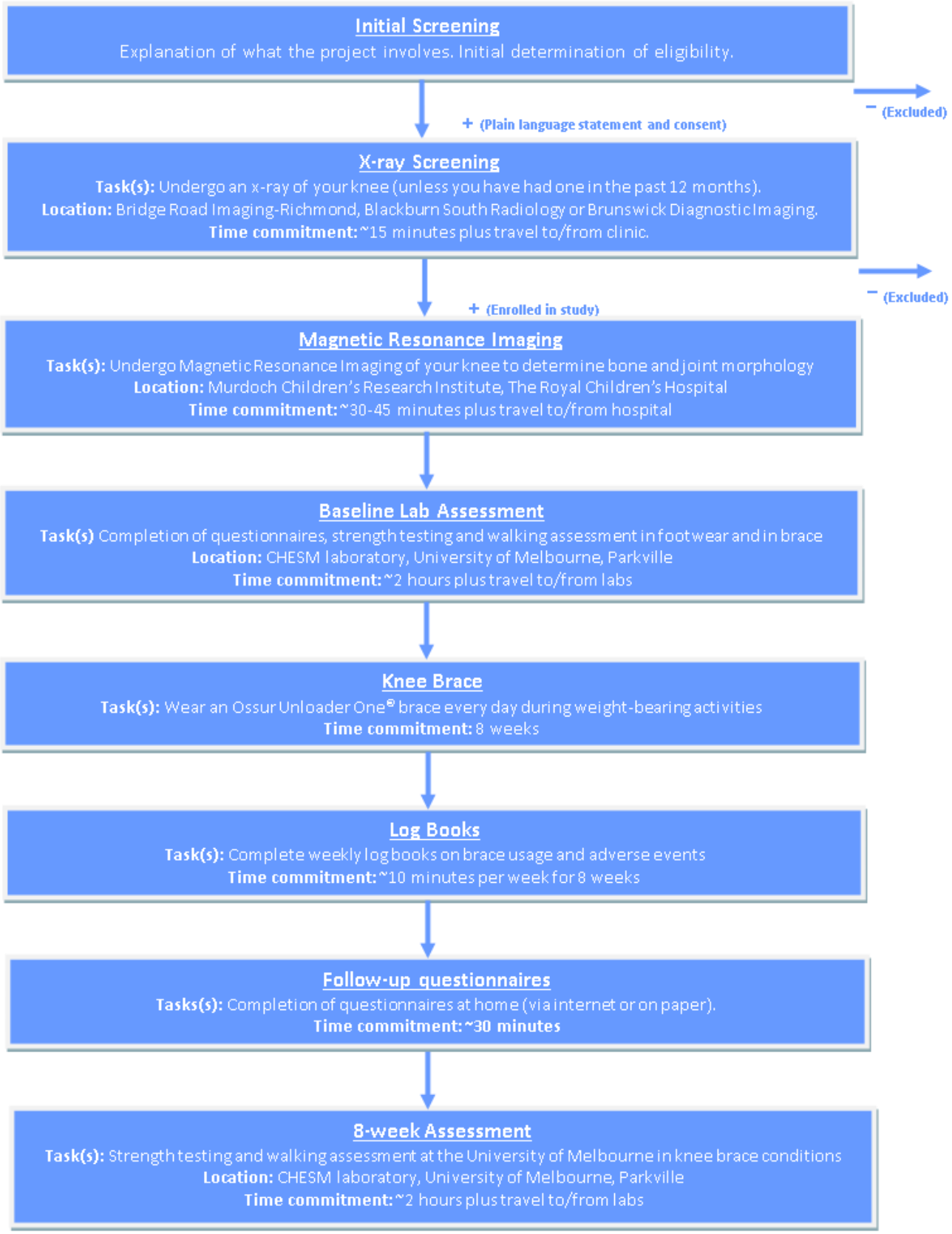
Over the 8 weeks, you will be asked to complete a short log book for every week. In the log book you will indicate how many hours you wore the brace for each day of that week. In this log book we will also ask you to report any problems from wearing the knee brace and your comfort and confidence levels. The log books will be provided with a stamped addressed envelope to return them in the mail, or you can bring them with you to your follow-up assessment.

## Follow-up

Eight weeks after being given your brace, you will be sent a follow-up question booklet to complete at home. You can complete this online or on paper where we will provide a stamped addressed envelope. These

questions will be similar to those completed at baseline. You will also answer questions about any adverse effects you had if not reported in your log-book. You will then be invited to attend your follow-up assessment at the CHESM laboratory. Here you will undergo the same walking testing with the brace as your initial assessment. However, you will not need to complete the walking trials in the different footwear types. It is estimated that the follow-up session will take approximately 1.5-2 hours.

## Study timeline



## Reimbursement for participation

To compensate you for your time and effort in wearing the knee brace and completing our questions and log-books, you will receive your fitted Ossür Unloader One knee brace to wear after completion of the study.

## Are there any costs for me?

The knee x-ray, MRI, brace and shoes are provided at no cost to yourself. We will also pay for your parking at the University to attend the lab assessments and to attend the Children's Hospital for your MRI. However, your travel or other costs to attend the x-ray appointment and the University are your own responsibility.

## What are the possible benefits?

The main benefit expected from this research is to understand how the knee brace changes knee joint loading. This is relevant because the brace is known to reduce symptoms and pain in people suffering from knee OA, but how it does this is not known. Similarly, we know that different footwear types are good for knee OA, however the way in which this occurs is unclear. Understanding whether and in what way people modify knee joint loading with the brace or certain footwear types will inform clinical decision making. It may also provide possible design improvements or personalisation of bracing and footwear to the individual. Therefore, by participating you will be providing valuable assistance to research that could benefit many others or even yourself in the future.

## What are the possible risks?

No measures taken or exercises performed will place you at any more risk than would be encountered during routine clinical tests, normal day-to-day living and sporting activities. However, it is possible you may experience muscle soreness due to the muscle contraction tasks, but this should subside in a few days. It is possible that you may experience increased knee pain while wearing the brace at home. To reduce this, the student investigator trained by the manufacturing company will demonstrate how to correctly fit your knee brace. We will provide you with the contact details of the student researcher and encourage you to contact him if you experience any side effects whilst wearing the brace.

**X-rays:** Participation in this trial involves exposure to a small amount of radiation if you need to obtain a knee x-ray as part of the screening process. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisievert (mSv) each year. The additional effective dose you will receive from entering this trial is about 0.04 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. Studies suggest any risk is minimal.

**Magnetic Resonance Imaging (MRI):** If operator, safety procedures and eligibility requirements are met, MRI is considered a very safe imaging technique. As part of the induction procedures, we will determine your suitability to receive an MRI. You will also undergo further safety screening at The Royal Children's Hospital before your scan. An information leaflet on how to prepare for your MRI exam is provided at the end of this document.

## Can I withdraw from the study if I wish?

Your participation in this study is voluntary. If you do not wish to take part, you are under no obligation to do so. Also, if you decide to take part but later change your mind, you are free to withdraw from the project at any

stage. You may also withdraw any information previously supplied by you. Your decision about whether or not to participate or to continue in the study will not affect your future medical care in any way. If you decide to withdraw after attending the initial lab assessment, you will be entitled to keep the knee brace provided to you without further participation in the study. If you withdraw prior to the initial laboratory assessment, you will not be entitled to receive the knee brace.

## Will I hear about the results of this project?

Once we have completed testing all the participants and analysed the data, we can send you a summary of the overall study results, if you wish. You will be offered the opportunity to receive a lay-written summary of the study findings by ticking the appropriate box on the consent form. This will occur about 2 years after conclusion of the study. Findings of the study will be presented academically at conferences and published in a yet to be determined peer reviewed journal.

## Will my details be kept confidential?

The anonymity of your participation is assured by our procedure, in which a code number and not your name will identify you. The motion analysis system used to record your movement only tracks the markers on your skin. Therefore it is not possible to visually identify you from the recordings. The de-identified data may be used for other research purposes in the future. No findings that could identify you will be published and access to individual results is limited to the investigators. Coded data will be stored for 15 years. All data and results will be handled in a strictly confidential manner, under guidelines set out by the National Health and Medical Research Council. The Principal Investigator is responsible for maintaining this confidentiality. This project is subject to the requirements of the Human Research Ethics Committee of the University of Melbourne. However, you must be aware that there are legal limitations to data confidentiality.

## Who is funding this project?

This project is funded by a Commonwealth Innovation Connection Grant & Industry-partner Ossür. These study sponsors will not play any role in the collection, analysis or interpretation of data, writing of the manuscript, or decision to submit the manuscript for publication.

## Where can I get further information?

You should ask for any information you want. If you would like more information about the study, or if there is any matter about it that concerns you, either now or in the future, do not hesitate to ask one of the researchers. Before deciding whether to take part you may wish to discuss the matter with a relative or friend or with your local doctor. You should feel free to do this. If you would like more information about the project, please contact our student researcher; Scott Starkey on 0439 702 870 or email sstarkey@student.unimelb.edu.au.

## Who can I contact if I have any concerns about the project?

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: HumanEthics-complaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project. The Principal Investigator will be available throughout the study if you have any questions. This project has been approved by the Radiation Safety Program of the Victorian Government Department of Human Services.

## About the researchers:

**Dr Michelle Hall** is a post-doctoral research fellow at the Centre for Health, Exercise and Sports Medicine at The University of Melbourne. Dr Hall has extensive experience in biomechanics research, running several randomised control trials investigating the effects of non-surgical interventions on joint health in clinical populations. She is also the lead contact with our industry partner Ossür and principal investigator of the study.

**Professor Rana Hinman** is a research physiotherapist at the Centre for Health, Exercise and Sports Medicine at The University of Melbourne. She has conducted 20 randomised controlled trials in musculoskeletal conditions, most in knee osteoarthritis.

**Dr Kade Paterson** is a podiatrist and musculoskeletal researcher at the Department of Physiotherapy at the University of Melbourne.

**Dr David Saxby** is a faculty member of the School of Allied Health Science at Griffith University. Both his MSc and PhD were in biomechanics, and he has >500 hours of in-laboratory training and experience in biomechanics research.

**Mr Scott Starkey** is a physiotherapist and PhD student at the Department of Physiotherapy at the University of Melbourne. He has clinical experience in managing patients with osteoarthritis and in biomechanics.

PATIENT FACTSHEET

Imaging @ Olympic Park

# MRI Scan

3.0 Tesla Magnetic Imaging (MRI) uses a very powerful magnetic field, radio waves and a computer to produce detailed images of almost every internal part of the body. The images from the scan can then be examined on a computer screen or a printout. This process is completely safe and involves no harmful radiation whatsoever.

MRI scans can be taken from almost any angle and are generally more detailed and thorough than any other type of scan. With our latest Philips 3.0 Tesla scanner we can perform Hi Resolution scans in minutes unlike open scanners and there is no need for oral sedation.

## Preparation

Before your Magnetic Resonance Imaging scan, you will be able to eat, drink and take any medication as normal. The only exception to this is if you are having an abdominal scan which means you will have to fast prior to the examination.

It's best to wear comfortable clothes and if possible without metal, this way you may not require to get changed. Otherwise we supply patient gowns and robes.

## Procedure

As you will be entering a very strong magnetic field as soon as you walk into the scanner room, all people enteringthe room must fill in a safety questionnaire to ensure
that there are no conditions that might make having an MRI scan unsafe for them. This includes questions aboutprevious surgery, implanted devices such as pacemakersor surgery leading to joint replacement etc.

Lockers are provided for the safe keeping of valuables,which are not allowed into the scan room. The MRI scanusually lasts between 10 and 45 minutes, depending onthe area of the body that is being scanned. Pieces ofequipment (coils) are placed around or strapped to parts of the body to gather images.

During the scan it is vital to remain as still as possible, asmotion will lead to the images being blurred and having tobe repeated. During the scan we will be in contact with youvia an intercom system and if you are concerned for anyreason you can contact us by using a panic button. Whenthe images are being taken, the scanner will make loud banging noises. To protect you from this noise, you will be provided with earphones or disposable earplugs, and your choice of music to listen to (CD's, MP3 players, phones etc).

Sometimes an injection of contrast media (dye) will be used to highlight areas within the body. This should not cause any discomfort or side-effects, however, if you haveany known kidney disease this may affect the decision touse the contrast agent.

## Remember

To bring any previous imaging and your music.

AAMI Park
60 Olympic Boulevard
Melbourne VIC 3004
www.iop.net.au

P 03 9420 1700
F 03 9420 1777
E info@iop.net.au

# Knee Bracing and Footwear for Medial Arthritis of the Knee

THE UNIVERSITY OF MELBOURNE

**How should I prepare for my MRI exam?**

If necessary, you may receive a gown to wear during your MRI examination. Before entering the MR system room, you will be asked questions (i.e., using a screening form) regarding the presence of contra-indications to MRI and will be instructed to remove all metal objects from pockets and hair. If you have any additional questions or concerns, discuss them with the MRI technologist or radiologist.

Items that may create a health hazard or other problem during an MRI exam may include:

- Cardiac pacemaker or implantable defibrillator
- A ferromagnetic metal vascular clip placed to prevent bleeding in the brain
- An implanted or external medication pump (such as that used to deliver insulin or a pain-relieving drug)
- A cochlear (inner ear) implant
- A neurostimulation system

**Note:** *Some items, including certain cardiac pacemakers, neurostimulation systems and medication pumps are acceptable for MRI. However, the MRI technologist and radiologist must know the exact type that you have in order to follow special procedures to ensure your safety.*

Items that need to be removed by patients and individuals before entering the MR system room include:

- Purse, wallet, money clip, credit cards, cards with magnetic strips
- Electronic devices such as beepers or cell phones
- Hearing aids
- Metal jewellery, watches
- Pens, paper clips, keys, coins
- Hair barrettes, hairpins
- Any article of clothing that has a metal zipper, buttons, snaps, hooks, underwire, or metallic threads
- Shoes, belt buckles, safety pins

Objects that may interfere with image quality if close to the area being scanned include:

- Metallic spinal rod
- Plates, pins, screws, or metal mesh used to repair a bone or joint
- Joint replacement or prosthesis
- Metallic jewellery including those used for body piercing
- Some tattoos or tattooed eyeliner (these alter MR images, and there is a chance of skin irritation or swelling; black and blue pigments are the most troublesome)
- Makeup, nail polish or other cosmetic that contains metal
- Bullet, shrapnel, or other type of metal fragment
- Metallic foreign body within or near the eye (such an object generally can be seen on an x-ray; metal workers are most likely to have this problem)
- Dental fillings (while usually unaffected by the magnetic field, they may distort images of the facial area or brain; the same is true for orthodontic braces and retainer