

COMPLICATIONS OF DEVICES, IMPLANTS & GRAFTS

Devices, implants, and grafts are materials that are surgically placed into the body to correct or repair a problem. Some examples include pacemakers for irregular heart rhythms, surgical mesh for hernia repairs, or skin grafts for burns. These materials can be natural, synthetic or a mix of the two. Sometimes, complications can occur due to these foreign materials being present in the body (U.S. Food and Drug Administration [FDA], 2015).

Grafts (Merriam-Webster, 2015)

Grafts can be natural, meaning that they come from a living donor, or synthetic, meaning they are made from artificial materials. Natural grafts are tissues such as skin or bone that are removed from one area of the body and are then transplanted. For example, a bone graft could be made of actual bone from the patient themselves or from a donor, or it could be made of a synthetic calcium phosphate ceramic-like substance. Skin grafting is one common form of grafting. This is often used in the treatment of burns or wounds that have left the patient without enough healthy skin. The skin grafting procedure helps speed up recovery and improves the function and appearance of the wound.

Devices and Implants (Merriam-Webster, 2015)

Most implants and devices that are used in the body are synthetically created, and are usually made from metal, ceramic and plastic materials. Examples include knee and hip prostheses, which are used in knee and hip replacement surgeries for weakened joints. In some cases, implants may contain electronics, such as an artificial pacemaker. Surgical implants can also be seen in surgeries such as breast augmentation.

Even though surgeries that involve grafts, devices, and implants are used to benefit patients, complications can occasionally happen, even when all preventative measures have been taken. Some complications include the following (FDA, 2000):

- ◆ Immune system response, possibly leading to rejection
- ◆ Infection
- ◆ Device failure
- ◆ Device breakdown or over-use
- ◆ Migration of the device
- ◆ Metal sensitivity
- ◆ Bleeding

- ◆ Blood clots
- ◆ Nerve damage

Complications depend on the type of surgery, the location in the body, the overall health and immune response of the patient, and the healthcare team involved. Technological advancements have greatly increased the number of surgeries involving grafts, implants and devices, but patients' bodies do not always accept them. Complications can occur immediately after surgery, or up to several years after. It is crucial that you note any unexpected changes after undergoing surgery involving a graft, implant, or medical device. Be sure to ask your healthcare provider the best way to monitor your health and keep him or her updated with any changes (FDA, 2000).



Risk factors (FDA, 2000)

There are specific conditions or factors that may make certain individuals more prone to implant complications. Such conditions or factors include:

- ◆ Sex
- ◆ Age
- ◆ Type of procedure
- ◆ Health of the individual before the procedure
- ◆ Reason for needing the implant
- ◆ Type of device that is being implanted
- ◆ Improper antibiotic choice or absence of antibiotics
- ◆ Number of procedures performed by the medical team

Signs & Symptoms (CDC, 2012)

Given that the range of complications and types of surgeries vary so greatly, the symptoms vary as well. The most common symptoms include:

- ◆ Bleeding
- ◆ Redness and swelling around the surgical site
- ◆ Pain
- ◆ Fever
- ◆ Little improvement of the initial condition.

If you are experiencing any of these symptoms after your procedure, contact your healthcare provider.

Diagnosis & Tests (CDC, 2012)

If a problem arises, your physician will first conduct a physical examination. If signs of a complication are present, diagnostic tests will be performed. These tests may include X-rays, blood tests, CT scans, diagnostic ultrasound, or an MRI.

Treatment (FDA, 2015)

Due to the large variety of possible complications, treatment is varied and depends on the type of complication and the type of implant, graft or device used. Treatment for these complications can range from surgery to antibiotics and/or analgesic pain medications to removal of the device. Regardless of your method of treatment, it is essential to follow your care plan exactly.

Prevention (FDA, 2015)

Preventing complications is not always possible, but following these methods can increase your chances of a successful surgery. Some methods of prevention include the following:

- ◆ Evaluate risks of undergoing an implantation surgery
- ◆ Ask your doctor questions before and after surgery so that you fully understand the procedure
- ◆ Avoid unnecessary exposure to germs and keep your surgical site clean to help prevent infection
- ◆ Research surgeons and procedures before you commit to the surgery
- ◆ Follow all instructions given to you by your medical staff

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REFERENCES

1. U.S. Food and Drug Administration (2015). Implants and Prosthetics. Retrieved July 14, 2015, from <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/>
2. U.S. Food and Drug Administration (2000). Medical device Use-Safety: Incorporating Human Factors Engineering into Risk management. Retrieved July 15, 2015, from <http://www.fda.gov/downloads/MedicalDevices/.../ucm094461.pdf>
3. Centers for Disease Control and Prevention (2012, May 17). Surgical Site Infection (SSI). Retrieved July 15, 2015, from <http://www.cdc.gov/HAI/ssi/ssi.html>
4. Merriam-Webster (2015) Medical Grafts. Retrieved July 15, 2015, from <http://www.merriam-webster.com/medical/graft>
5. Merriam-Webster (2015) Medical Grafts. Retrieved July 15, 2015, from <http://www.merriam-webster.com/medical/devices>