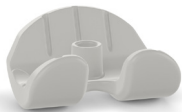


REMEDY® STEMMED KNEE SPACER**1**

Overview

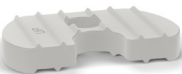
The REMEDY® Stemmed Knee Spacer is part of the treatment in a two-stage procedure performed if you have a permanent prosthesis infection. The REMEDY® Stemmed Knee Spacer implant is intended for temporary use only (180 days or less). It allows basic joint mobility and releases antibiotic into the joint area and adjacent to the device to protect the implant from bacterial colonization. A second surgery will be required at a later date to remove the REMEDY® Stemmed Knee Spacer and replace it with a permanent knee joint implant.



REMEDY®
Femoral Component



REMEDY®
Tibial Component



REMEDY®
Tibial Insert Wedge



REMEDY®
Stem Component

Materials

The PMMA implant is made of acrylic bone cement containing antibiotic gentamicin or the Poly+Plus Tibia is made out of Ultra-high molecular weight polyethylene (UHMWPE) crosslinked with vitamin E. The REMEDY® Stem Extension Component contains a metallic inner core. The gentamicin antibiotics in the PMMA components protect the implant from bacterial colonization (bacteria attaching to the implant).

Contraindications

Your surgeon will determine if you are a suitable candidate for the REMEDY® Stemmed Knee Spacer implant. Some of the common reasons not to use this product include:

- poor muscle or bone quality
- low immune system
- inadequate circulation in the affected leg
- inability to remove the original knee replacement parts
- infection cannot be confirmed or treated by gentamicin

- patient hypersensitivity (allergy) to gentamicin, aminoglycosides, PMMA, UHMWPE
- a secondary infection besides the infection in the knee
- infection is not caused by a total knee replacement
- your weight, age or activity level could cause problems with the REMEDY® Stemmed Knee Spacer

Potential Surgical Side Effects

The problems common to all surgeries could also occur during a REMEDY® Stemmed Knee Spacer surgery. Common potential side effects include, but are not limited to:

- blood loss
- heart problems
- damage to the nerves
- blood pressure problems
- reaction to the anesthesia
- delayed wound healing
- discomfort or pain
- infection

Potential Implant Side Effects

There are other problems that might happen due to the REMEDY® Stemmed Knee Spacer implant. These include, but are not limited to, the following:

- damage to the knee joint (bone, muscles, nerves)
- shortening of the leg
- hypersensitivity (allergic) reactions to the implant materials
- implant damage or breakage
- possible nephrotoxic (kidney) and ototoxic (ear) effect (during the first days of implantation of the spacer) if used in conjunction with the systemic administration of aminoglycosides, glycopeptides or other nephrotoxic and/or ototoxic drugs
- difficulty removing the infected implants making it impossible to implant the REMEDY® Stemmed Knee Spacer

NOTE: There is also a possibility of having a reaction to the gentamicin antibiotic in the REMEDY® Stemmed Knee Spacer. If this happens, early removal of the REMEDY® Stemmed Knee Spacer may be required.

Benefits

The REMEDY® Stemmed Knee Spacer allows limited mobility while systemic antibiotics are received to treat the infection in your joint. You must use some form of mechanical assistance to walk (i.e., cane, crutches, walker, etc.).

Before Surgery

- Talk with your doctor to understand what you will be expected to do after surgery.
- Ask your surgeon to explain all the possible problems of the REMEDY® Stemmed Knee Spacer implant.
- Tell your doctor about all physical or mental conditions. Your doctor will need to have complete and accurate information on your health status in order to decide whether the REMEDY® Stemmed Knee Spacer would be right for you.
- Ask your doctor to explain any other treatment options so you will have an understanding of other ways your infection could be treated. It is important that you understand the benefits and possible complications of each treatment option.

During Surgery

All previous implants and damaged bones and tissues are removed. The joint area is cleaned, then the surgeon determines the proper size implant and the REMEDY® Stemmed Knee Spacer is implanted. The surgeon checks the range of motion of your knee joint and closes the surgical site.

Post Surgery

After surgery, your doctor will instruct you on how to properly take care of your REMEDY® Stemmed Knee Spacer implant. This involves restricting certain activities and limiting the amount of weight you place on your knee. You should follow your doctor's instructions closely to protect the REMEDY® Stemmed Knee Spacer from damage. If the REMEDY® Stemmed Knee Spacer is damaged, it may have to be removed earlier than planned. This could mean additional surgeries and add to your overall recovery time.

Your doctor will schedule regular checkups including x-rays and/or removal of fluid from your knee joint to ensure the infection is healing. The checkups may also include drug monitoring tests to make sure the level of drugs in your system is correct. After the infection is healed, you will need to have a second surgery to remove the REMEDY® Stemmed Knee Spacer and implant a permanent knee joint implant.

Important Cautions

- Report any unusual pain or discomfort to your doctor immediately
- Report any problems with your hearing and/or balance to your doctor immediately
- Do not walk without crutches, a cane, a walker or another form of assistance
- Do not take part in any sporting activities
- Try not to gain weight during this temporary period
- Do not use alcohol or drugs that could interfere with your coordination and balance
- Do not go places where you could easily fall

Note: The REMEDY® Stemmed Knee Spacer implant is only for temporary use. It should be removed within 180 days and replaced by a permanent knee prosthesis if your clinical situation allows for it. If a permanent knee prosthesis cannot be safely implanted, your surgeon may choose to perform another type of procedure.

Questions

For further product information, please contact Customer Service.

Caution

Federal law restricts this device to sale by or on the order of a physician.

For Internal Use



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