

## REMEDY® ACETABULAR CUP

1

## Overview

The REMEDY® & REMEDY SPECTRUM® GV Hip Spacer are temporary hip implants that are used as part of a two-stage procedure. If you are receiving the REMEDY® or REMEDY SPECTRUM® GV Hip Spacer, your surgeon has recommended a two-stage procedure for you because of an infected hip implant. In the first stage, the REMEDY® or REMEDY SPECTRUM® GV Hip Spacer will be surgically implanted in your hip. The REMEDY® and REMEDY SPECTRUM® GV Hip Spacer are intended for temporary use only (180 days or less). It allows basic joint mobility and releases antibiotic into the joint area to protect the implant from bacterial colonization.



REMEDY® or REMEDY SPECTRUM® GV Hip Spacer can be used in conjunction with the REMEDY® Acetabular Cup. Your surgeon will decide whether you should receive the REMEDY® Acetabular Cup, as well as the hip spacer. A second surgery will be required at a later date to remove the REMEDY® or REMEDY SPECTRUM® GV Hip Spacer and Acetabular Cup, and to replace it with a permanent hip joint implant.

## **Materials**

The femoral implant has a metal supporting structure and is made with an outer covering of acrylic bone cement containing the antibiotic gentamicin or gentamicin and vancomycin. The antibiotics protect the implant from bacterial colonization (bacteria attaching to the implant). The acetabular cup is also made of acrylic bone cement containing the antibiotic gentamicin.

## **Contraindications**

Your surgeon will determine if you are an appropriate candidate for the REMEDY® or REMEDY SPECTRUM® GV Hip 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 hip replacement parts
- infection cannot be confirmed or treated by gentamicin or vancomycin
- patient hypersensitivity (allergy) to gentamicin, vancomycin, aminoglycosides or PMMA
- a secondary infection besides the infection in the hip
- infection is not caused by a total hip replacement
- patient's weight, age or activity level could cause problems with the REMEDY® or REMEDY SPECTRUM® GV Hip Spacer

### **Potential Surgical Side Effects**

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

- blood loss
- heart problems
- damage to the nerves
- 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® or REMEDY SPECTRUM® GV Hip Spacer implant. These include, but are not limited to, the following:

- damage to the hip joint (bone, muscles, nerves)
- changes in leg length
- 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

*NOTE: There is also a possibility of having a reaction to the gentamicin or vancomycin antibiotics in the REMEDY® or REMEDY SPECTRUM® GV Hip Spacer. If this happens, early removal of the REMEDY® or REMEDY SPECTRUM® GV Hip Spacer may be required.*

## Benefits

The REMEDY® and REMEDY SPECTRUM® GV Hip 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 surgeon to understand what you will be expected to do after surgery.
- Ask your surgeon to explain all the possible problems of the REMEDY® and REMEDY SPECTRUM® GV Hip Spacer implant.
- Tell your surgeon about all physical or mental conditions. Your surgeon will need to have complete and accurate information on your health status in order to decide whether the REMEDY® or REMEDY SPECTRUM® GV Hip 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® or REMEDY SPECTRUM® GV Hip Spacer is implanted. The surgeon checks the range of motion of your hip joint and closes the surgical site.

## **Post Surgery**

After surgery, your doctor will instruct you on how to properly take care of your REMEDY® or REMEDY SPECTRUM® GV Hip Spacer implant. This involves restricting certain activities and limiting the amount of weight you place on your hip. You should follow your doctor's instructions closely to protect the REMEDY® or REMEDY SPECTRUM® GV Hip Spacer from damage. If the REMEDY® or REMEDY SPECTRUM® GV Hip 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 hip joint to ensure the infection is resolving. The checkups may also include drug monitoring tests to make sure the level of drugs in your system is correct. After the infection is resolved, you will need to have a second surgery to remove the REMEDY® or REMEDY SPECTRUM® GV Hip Spacer and implant a permanent hip 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 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® or REMEDY SPECTRUM® GV Hip Spacer implant is only for temporary use. It should be removed within 180 days and replaced by a permanent hip prosthesis. If a permanent hip 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



6800 Poplar Avenue | Suite 120 | Memphis, TN 38138

901.453.3141 | [info@OsteoRemedies.com](mailto:info@OsteoRemedies.com) | [OsteoRemedies.com](http://OsteoRemedies.com)

OsteoRemedies, REMEDY and the corporate mark are registered trademarks of OsteoRemedies, LLC  
REMEDY is manufactured by OsteoRemedies, LLC

©2019 • 10-19-V2