

REMEDY® SHOULDER SPACER**1****Overview**

The REMEDY® Shoulder Spacer is part of the treatment foreseen in a two-stage procedure performed in the event of permanent prosthesis infection. The REMEDY® Shoulder Spacer implant is 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. A second surgery will be required at a later date to remove the REMEDY® Shoulder Spacer and replace it with a permanent shoulder joint implant.

**REMEDY® Modular
Humeral Head****REMEDY®
Modular
Humeral Stem**

Materials

The implant has a metal supporting structure and is made with an outer covering of acrylic bone cement containing antibiotic gentamicin. The antibiotic gentamicin protects the implant from bacterial colonization (bacteria attaching to the implant).

Contraindications

Your surgeon will determine if you are a successful candidate for the REMEDY® Shoulder 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 limb
- inability to remove the original shoulder replacement parts
- infection cannot be confirmed or treated by gentamicin
- patient hypersensitivity (allergy) to gentamicin, aminoglycosides, PMMA
- a secondary infection besides the infection in the shoulder

- infection is not caused by a total shoulder replacement
- patient's weight, age or activity level could cause problems with the REMEDY® Shoulder Spacer

Potential Surgical Side Effects

The problems common to all surgeries could also occur during a REMEDY® Shoulder 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® Shoulder Spacer implant. These include, but are not limited to, the following:

- damage to the shoulder joint (bone, muscles, nerves)
- shortening of the arm
- 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® Shoulder Spacer

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

Benefits

The REMEDY® Shoulder Spacer allows limited mobility while systemic antibiotics are received to treat the infection in your joint.

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® Shoulder 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® Shoulder 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® Shoulder Spacer is implanted. The surgeon checks the range of motion of your shoulder joint and closes the surgical site.

Post Surgery

After surgery, your doctor will instruct you on how to properly take care of your REMEDY® Shoulder Spacer implant. This involves restricting certain activities and limiting the movement range of your shoulder, eventually avoiding the lift of any load with the prosthetic limb. You should follow your doctor's instructions closely to protect the REMEDY® Shoulder Spacer from damage. If the REMEDY® Shoulder 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 shoulder 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® Shoulder Spacer and implant a permanent shoulder 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
- Use mobility assist devices (e.g. brace) during the implantation period as prescribed by the surgeon
- Do not take part in sporting activities
- Try not to gain weight during this temporary period
- Avoid any condition that tends to impose severe loading on the REMEDY® Shoulder Spacer
- 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® Shoulder Spacer implant is only for temporary use. It should be removed within 180 days and replaced by a permanent shoulder prosthesis if your clinical situation allows for it. If a permanent shoulder 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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