INTERSPACE® GV HIP SPACER

OVERVIEW

The INTERSPACE® GV Hip Spacer is part of the treatment foreseen in a two-stage procedure performed in the event of permanent prosthesis infection. The INTERSPACE® GV Hip Spacer is intended for temporary use only (180 days or less). The spacer allows basic joint mobility and releases antibiotics into the joint area to protect the implant from bacterial colonization. A second surgery will be required at a later date to remove the

MATERIALS

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

CONTRAINDICATIONS

Your surgeon will determine if you are a successful candidate for the INTERSPACE® GV Hip Spacer. 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 and vancomycin
- patient hypersensitivity (allergy) to gentamicin, aminoglycosides, vancomycin, glycopeptides and 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 INTERSPACE® GV Hip Spacer.

POTENTIAL SURGICAL SIDE EFFECTS

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

- damage to the hip 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 ainoglycosides, glycopeptides or other nephrotoxic and/or ototoxic drugs
- difficulty removing the infected implants making it impossible to implant the INTERSPACE® GV Hip Spacer.

Note: There is also a possibility of having a reaction to the gentamicin and vancomycin. If this happens, early removal of the INTERSPACE® GV Hip Spacer may be required.

BENEFITS

The INTERSPACE® 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 doctor to understand what you will be expected to do after surgery.
- Ask your surgeon to explain all the possible problems of the INTERSPACE® GV Hip Spacer implants.
- 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 INTERSPACE® GV Hip Spacer are right for you.
- Ask your doctor to explain any other treatment options so you will have an under standing of other ways your infection could be treated. It is important that you under stand 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 INTERSPACE® 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 INTERSPACE® GV Hip Spacer. 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 INTERSPACE® GV Hip Spacer from damage. If the INTERSPACE® 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 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 INTERSPACE® 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 INTERSPACE® GV Hip Spacer implants are only for temporary use. The spacer should be removed within 180 days and replaced by a permanent hip prosthesis if your clinical situation allows for it. 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.

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InterSpace® is manufactured by Tecres® S.p.A.
Via A. Doria, 6 - 37066 Sommacampagna - Verona, ITALY
and is distributed in North America by OsteoRemedies®

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OST314 Rev 00 07-2026