OSTEOPAL® G
Radiopaque bone cement containing Gentamicin for filling and stabilising vertebral bodies
OSTEOPAL® G

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Properties and composition

OSTEOPAL®G is a radiopaque PMMA cement for vertebral surgery with the X-ray contrast medium zirconium dioxide.

OSTEOPAL®G contains gentamicin sulphate as an antibiotic for infection prophylaxis.

One package of OSTEOPAL®G contains a sachet with cement powder including antibiotic and an ampoule with monomer liquid. The packaging for the cement powder is sterile. The outer, non-sterile aluminium protective bag contains a polyethylene-paper pouch, which is sterile on the inside. This pouch contains an additional sterile PE-paper bag that contains the cement powder.

The brown glass ampoule containing the sterile-filtered monomer liquid is also sterile packed in an ethylene oxide sterilised individual blister pack.

Constituents of the monomer liquid:

- 10 ml OSTEOPAL®G monomer liquid contains:
  - Methyl methacrylate, N,N-dimethyl-p-toluidine, hydroquinone and chlorophyll E141 (green dye).

Constituents of the polymer powder:

- 26.53 g OSTEOPAL®G cement powder contains:
  - Gentamicin 0.325 g (as gentamicin sulphate)
  - Other components: Poly (methyl methacrylate / methylacrylate), zirconium dioxide, benzoyl peroxide and chlorophyll E141 (green dye).

Intended use

OSTEOPAL®G is a radiopaque, self-hardening PMMA cement for the augmentation and stabilisation of vertebral bodies. OSTEOPAL®G is dyed with E141 green in order to make the cement clearly visible in the operating field.

Indications

OSTEOPAL®G is indicated for augmentation and stabilization of vertebral bodies in percutaneous vertebroplasty, balloon kyphoplasty,

- for painful compression fractures of the vertebral body,
- for painful tumours in the vertebral body (metastatic carcinomas or myelomas)
- for symptomatic vertebral hemangiomas.

Percutaneous vertebroplasty and balloon kyphoplasty are only palliative treatments for stabilizing the vertebral bodies. They do not treat the underlying illness, like osteoporosis and cancer.

Contraindications

OSTEOPAL®G must not be used in patients with known hypersensitivity to gentamicin or other constituents of bone cement.

OSTEOPAL®G must not be used in patients with severe renal insufficiency.

OSTEOPAL®G must not be used in patients with an active or incompletely treated infection.

OSEMPAL®G must not be used for the fixation of artificial joints (e.g. hip, knee and shoulder).

OSTEOPAL®G must not be used in patients with hemorrhagic diathesis.

Lesions of the vertebral body with epidural extension are relative contraindications due to the danger of spinal cord compression.

Side-effects

Due to the gentamicin contained in OSTEOPAL®G, side-effects that are typical for gentamicin can occur:

- Damage to auditory and vestibular nerves
- Renal toxicity
- Neuromuscular blockade (see interactions)
- Rare cases of paresthesia, tetany and amyasthenia
- Rare cases of allergic reactions (exanthema, urtikaria, anaphylactic reactions)

An overdose of gentamicin is not to be expected because when using OSTEOPAL®G the desired high local concentrations only result in temporary, transient serum concentrations during the first few hours after surgery. Therefore, the occurrence of the afore-mentioned side-effects is highly unlikely. Allergic reactions can occur, independent of the dosage.

In the case of PMMA bone cements, there are frequent reports about a temporary blood pressure decrease directly after implantation of the cement. Rare cases of hypotonia accompanied by anaphylaxia, including anaphylactic shock, cardiac arrest and sudden death have been reported.

These cardiovascular and respiratory side-effects, also known as implantation syndrome or bone cement syndrome, stem from an influx of bone marrow components into the venous vascular system. In the event of pulmonary, cardiovascular complications, monitoring and possibly an increase of the blood volume is required. In the presence of acute respiratory insufficiency, anesthesiological measures must be taken.

In addition, paravertebral structures may be damaged by cement escaping. Complications such as spinal cord compression, intercostal neuralgia, cement escaping into the intervertebral space, perivertebral filling of veins and arteries (danger of embolism), infections and post-procedural pain are possible.

To prevent cement escape and in order to detect unwanted occurrences in good time, application must be performed using imaging techniques (real time display). Immediate surgical intervention may also be necessary to counteract the described complications. Prior to surgery, a careful radiological investigation must be performed to assess possible risks (e.g. vertebral body lesions, vascular supply of the vertebral body or oedema). Incomplete filling of the vertebral body with bone cement may result in an insufficient reduction in acute pain and reduced long-term stability of the treated vertebral body.

Interactions

Owing to the administration of muscle relaxants and ether the neuromuscular blocking properties of gentamicin may be intensified. However, in view of the very low serum levels
this is relatively unlikely in patients with healthy kidneys. The probability of interactions occurring increases in proportion to the serum levels of gentamicin, e.g. in patients with impaired renal function.

Warnings and precautions
Prior to using OSTEOPAL®G, the surgeon should be very familiar with its properties, handling and application during use. It is recommended for surgeons to practice the entire procedure of mixing, handling and application prior to the use. Precise knowledge is also required if mixing systems and application systems are used for the application of the cement. The monomer liquid is highly volatile and flammable. Therefore, suitable precautions should be taken, in particular when using the product in the operating room. The monomer liquid is also a powerful lipid solvent and should not come into direct contact with the body. When working with the monomer or the cement, gloves must be worn to ensure adequate protection against penetration of the liquid (main component: methyl methacrylate). Gloves made up of three layers, polyethylene, ethylene vinyl alcohol copolymer, polyethylene and Viton® / Butyl, have proved to provide good protection over an extended period. Putting on two pairs of gloves, polyethylene surgical gloves over an inner pair of latex standard surgical gloves has also proved to offer adequate protection. The use of latex or poly (styrene-co-butadiene) gloves alone must be avoided. Please request the confirmation of your glove supplier whether their respective gloves are suitable for use with OSTEOPAL®G.

The liquid vapors may irritate the respiratory tract and the eyes and possibly damage the liver. Skin irritations have been reported which must be attributed to contact with the liquid.

Manufacturers of soft contact lenses recommend the removal of the lenses in the presence of harmful or irritating vapors. Since soft contact lenses are permeable to liquids and gases, they should not be worn in the operating room if PMMA monomer liquid is used.

Use in patients
Blood pressure, pulse and respiration must be carefully monitored during and immediately after implantation of the cement. Every significant change of these vital signs must be immediately eliminated with the corresponding measures. If pulmonary, cardiovascular complications arise, monitoring and possibly increasing the blood volume may be required.

In cases of acute respiratory insufficiency, anaesthesiological measures should be taken.

Gentamicin is active against many aerobic gram-negative and several gram-positive bacteria. Gentamicin is not effective against most anaerobic bacteria, fungi and viruses. Gentamicin is only minimally effective against streptococci. Resistances against gentamicin may occur both with gram-negative and gram-positive bacteria. Although only very low gentamicin concentrations are expected in the serum, superinfections with non-sensitive germs cannot be categorically excluded. Always when clinically indicated additional systemic antibiotics are administered in combination with PMMA cement that contains gentamicin, the safety aspects of the additional antibiotic should be carefully reviewed.

Pregnancy
Insufficient data is available regarding the use of gentamicin in pregnant women in order to assess a possible health risk. Aminoglycosides pass through the placental barrier. Ototoxicity in the foetus cannot be excluded. Cases of irreversible, bilateral, congenital hearing loss have been reported in children after prenatal exposure to streptomycin. Hearing loss has also been reported for several other aminoglycosides. In view of the concentration of gentamicin in the foetal kidneys, nephrotoxicity is a potential risk. Animal studies have proven ototoxicity and nephrotoxicity after prenatal exposure with gentamicin / aminoglycosides. For this reason, use of OSTEOPAL®G during pregnancy is not recommended. That is, unless the benefit to the mother outweighs the potential risk to the child.

Nursing
Gentamicin is excreted in small quantities in breast milk. Due to the increased intestinal permeability in newborns, accumulation and ototoxicity cannot be excluded. For this reason, the benefits to the mother should be weighed against the potential risk to the child before using OSTEOPAL®G in women who are nursing.

Incompatibilities
Additives (e.g. antibiotic powder or X-ray contrast media) or liquid solutions (e.g. antibiotic solutions) must not be added because they could negatively impact the mechanical stability and the processing properties of the cement.

Dosing
A single dose is made by mixing the entire contents of the powder sachet with the entire contents of the liquid ampoule. The required amount of cement depends on the respective anatomical conditions. No information is available on the maximum quantity of PMMA cement that can be applied. There is also no information about the maximum number of vertebral bodies that can be treated during one vertebroplasty or kyphoplasty procedure. At least one additional package of OSTEOPAL®G should be available before the start of the operation. Each package is mixed separately.

Preparation
Before opening the non-sterile aluminium protective sachet, the contents should be moved down to the bottom of the sachet by shaking or tapping it so that the contents are not damaged. The polyethylene paper sachet and the ampoule may only be opened under sterile conditions. The sterile components (inner polyethylene paper sachet and glass ampoule) are provided in sterile format.

Opening under sterile conditions
The outer polyethylene paper sachet is opened under sterile conditions and at the intended location so that the inner polyethylene paper sachet can be removed in sterile fashion. The blister packaging is also opened under sterile conditions and at the intended location so that the glass ampoule can be removed in sterile fashion. Before opening the inner polyethylene paper sachet, the contents should be moved down to the bottom of the sachet by shaking or tapping it in order to ensure that no powder is lost when cutting the sachet open at the top.
To facilitate opening of the glass ampoule, it should be equipped with a preset breaking point at the crossover to the tip of the ampoule. A breaking tool (tube) is attached to the glass ampoule to facilitate opening of the ampoule. Instead of the ampoule tip, the attached breaking tool is grasped and the ampoule tip is broken off through the breaking tool. The broken-off ampoule tip remains in the tube.

Mixing
The fluid from the ampoule is placed in a sterile mixing bowl. Then the powder is added from the open inner sachet. The mixture is stirred with a sterile spatula or spoon until a homogeneous mixture is created. The mixture should be stirred for 30 seconds independent of the ambient temperature. Strict compliance with the mixing instructions for the powder and liquid components can minimise the frequency of complications. The cement components can also be mixed in a mixing system with or without vacuum. The mixing times for mixing with or without vacuum are also 30 seconds, independent of the ambient temperature. Please refer to the user manuals of the mixing systems for details about the mixing systems. The processing time and polymerisation is greatly dependent on the temperature of the components and the environment. Higher temperatures accelerate and lower temperatures slow down the hardening time.

Processing
The viscosity increases with progressing polymerisation, i.e. with progression of the processing phase. The cement mass should be placed in an application system immediately after mixing as it still has low viscosity and is easy to aspirate at this point in time. To prevent vascular cement leakage, the cement should be applied when it is a paste like consistency. OSTEOPAL®G can be inserted into the vertebral body with the help of an application system that has been approved for percutaneous vertebroplasty or kyphoplasty, which enables constant, controlled injection. Please see the manufacturer’s user manual for instructions on how to handle the application system. During intravertebral application, consistent fluoroscopy (lateral-lateral) in real-time representation is necessary. In the event of paravertebral cement leakage, cement injection must be immediately stopped and can be continued after the cement’s viscosity has been increased. If the vertebral filling is not sufficient, additional contralateral access is viable. After augmentation, a mandrin should be inserted into the hypodermic needle so that no cement remnants remain in the soft tissue after removal of the hypodermic needle.

The mixing, processing and curing times of OSTEOPAL®G are shown in the diagram at the end of these instructions. The values apply to using bone fillers with a diameter of 3.5 mm (MAXXSPINE Ltd, 65307 Bad Schwalbach, Germany). The cement can still be removed from the bone fillers at the end of the processing period, but no longer binds free from creases. Therefore, the end of the processing time refers to the state of the cement, not to the possible end time for removing cement from the bone fillers.

Specifications relate to 26 g of cement powder compound and 1 ampoule of 10 ml monomer fluid.

Factors affecting the length of working phases:
- Ambient temperature: an increase in ambient temperature shortens waiting phase, application phase and hardening phase
- Temperature of the mixing and the delivery equipment: an increase in temperature of the mixing and the delivery equipment shortens waiting phase, application phase and hardening phase
- Use of fine needles will decrease the length of application phase and of hardening phase

There may be changes in the processing for other application systems. Needles with a diameter of less than 1.8 mm (13G) should not be used. The patient must remain immobilised until the cement has fully hardened.

Storage
The cement must be stored unopened and protected from light at a maximum temperature of 25°C (77°F) in a dry, clean place in the original packaging.

Shelf life / sterility
The expiration date is printed on the folding box, the protective aluminium sachet and the inner sachet. OSTEOPAL®G must not be used after the indicated expiration date. The contents of unused, yet opened or damaged packages must not be resterilised and must therefore be discarded. OSTEOPAL®G is sterilized by gassing with ethylene oxide and must not be resterilised. Do not use if the polymer powder has a yellow tint to it.
Processing times for OSTEOPAL®G [A]

Test conditions: 55% humidity. [B]
**OSTEOPAL®G**

特性与组成部分

OSTEOPAL®G 是一种不透X射线的低粘性 PMMA 骨水泥，添加二氧化锆作为 X 射线造影剂，用于脊柱外科手术。OSTEOPAL®G 添加硫酸庆大霉素，作为预防感染庆大霉素敏感菌的抗生素。

一包 OSTEOPAL®G 包括一袋含抗生素的骨水泥粉末以及一安瓿单体液体。骨水泥粉末采用无菌包装。铝箔外层无菌保护袋包括一个从内部灭菌的聚乙烯纸袋。同时，还包括一个装有骨水泥粉末的无菌聚乙烯纸袋。装有无菌过滤单体液体的棕色玻璃安瓿同样以无菌方式包装在环氧乙烷无菌单泡罩内。

**成分**

聚合物粉末成分

26.53 g OSTEOPAL®G 骨水泥粉末包含：
0.325 g 庆大霉素
其他成分：
聚（丙烯酸甲酯、甲基丙烯酸甲酯）、二氧化锆、过氧化苯甲酰和叶绿素铜 E 141。

单体液体成分

10 ml OSTEOPAL®G 单体液体包含：
甲基丙烯酸甲酯、N,N-二甲基对甲苯胺、对苯二酚和叶绿素铜 E 141。

用途

OSTEOPAL®G 是一种不透射线的低粘性 PMMA 骨水泥，用于扩大和稳固椎体。OSTEOPAL®G 添加叶绿素铜 E 141 染成绿色，以便在手术区清晰查看骨水泥。

适应症

OSTEOPAL®G 适用于经皮椎体成形术和球囊椎体后凸成形术填充和稳定椎体

- 缓解和消除椎体压缩骨折的疼痛
- 缓解和消除椎体瘤(转移癌或骨髓瘤)的疼痛
- 疼痛性椎体血管瘤

可防止移植物或相邻组织上感染庆大霉素敏感性微生物。

本产品里面团期使用。

原则上，经皮椎体成形术和球囊椎体后凸成形术仅起到止痛的椎体稳定治疗作用。无法治疗基础性病症（例如骨质疏松症、肿瘤病）。

禁忌症

已知对庆大霉素或其他骨水泥成分过敏时，禁止使用 OSTEOPAL®G。不得用于孕期或哺乳期妇女。

严重肾功能不全时，禁止使用 OSTEOPAL®G。

存在活性感染或感染治疗不彻底时，禁止使用 OSTEOPAL®G。

OSTEOPAL®G 禁止用于固定人工关节（例如髋、膝、肩）。存在出血素质时，禁止使用 OSTEOPAL®G。

由于存在压迫脊髓的危险，伴随硬膜外扩张的椎体损伤为相对禁忌症。

副作用

由于 OSTEOPAL®G 内含有庆大霉素，因此可能出现典型的庆大霉素副作用：

- 损伤听觉和前庭神经
- 肾毒性
- 神经肌肉阻滞（参见相互作用）
- 少数情况会出现感觉异常、肌肉痉挛和肌肉无力
- 少数情况会出现过敏反应（皮疹、荨麻疹、过敏反应）

### 附录

<table>
<thead>
<tr>
<th>成分</th>
<th>规格型号</th>
<th>OSTEOPAL®G 1x20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1x20</td>
<td>OSTEOPAL®G 1x20</td>
</tr>
<tr>
<td></td>
<td>1x20</td>
<td>每小袋中的 26.53 g 粉中含有</td>
</tr>
<tr>
<td>聚（丙烯酸甲酯、甲基丙烯酸甲酯）</td>
<td>13.92 g</td>
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</tr>
<tr>
<td>二氧化锆</td>
<td>11.94 g</td>
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</tr>
<tr>
<td>过氧化苯甲酰</td>
<td>0.13 g</td>
<td></td>
</tr>
<tr>
<td>硫酸庆大霉素</td>
<td>0.54 g</td>
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<tr>
<td></td>
<td>1x20</td>
<td>每安瓿瓶中的 10 ml 液体中含有</td>
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<tr>
<td>甲基丙烯酸甲酯</td>
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<tr>
<td>N，N-二甲基对甲苯胺</td>
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</tr>
<tr>
<td>其他成分</td>
<td></td>
<td>在粉中：叶绿素铜 (E141) 2 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>在液体中：叶绿素铜 (E141) ~20 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>对苯二酚 32 ppm</td>
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预计不会出现庆大霉素过量，因为使用OSTEOPAL®时所需的局部高浓度仅会造成术后几小时内暂时出现血清浓度。因此，出现上述副作用的可能性较低。

可能出现与剂量无关的过敏反应。使用PMMA骨水泥时，经常出现报告血压在植入水泥后临时降低的情况。极少数情况下会出现伴随过敏反应的低血压，包括过敏性休克、心衰、心排血量下降。

上述心血管和呼吸系统的副作用（亦被称为植入综合症或骨水泥综合症）是由于骨髓成分进入静脉系统造成的。如果出现肺部或心血管并发症，则必须进行监控并尽可能提高血容量。出现呼吸系统机能不全时，应采取麻醉措施。

另外，骨水泥渗漏也会损伤静脉旁的结构。可能会发生脊髓压迫症、肋间神经痛、骨水泥渗漏到椎间隙、椎周填充静脉和动脉（栓塞风险）、感染和术后疼痛等并发症。

上述心血管和呼吸系统的副作用（亦被称为植入综合症或骨水泥综合症）是由于骨髓成分进入静脉系统造成的。如果出现肺部或心血管并发症，则必须进行监控并尽可能提高血容量。出现呼吸系统机能不全时，应采取麻醉措施。

为了避免骨水泥渗漏或及时辨别意外事件，必须采用成像方法（实时显示）进行应用。此外，还必须能够立即进行手术干预，以便通过外科手术排除所并并发症。手前，必须进行仔细的放射学检查，以排除可能的风险（例如椎体血管化而损伤椎体或水肿）。使用骨水泥填充椎体不完整时，可能造成急性疼痛镇痛不足以及治疗的椎体稳定性降低。

相互作用
由于使用了肌肉松弛剂和乙醚有可能强化庆大霉素的神经肌肉阻滞特性。但如果血清抗生素水平不高，则出现此类情况的可能性相对较小，尤其是针对肾脏功能健全的患者。

警告提示和预防措施
使用OSTEOPAL®前，外科医生必须全面了解使用时的特性、操作及应用。建议外科医生在使用前接受与混合、使用及置入相关的指导培训。同时需要掌握骨水泥混合和应用系统的技术知识。单体液体极易挥发和易燃。因此，在手术室使用时应采取适当的预防措施。单体液体是一种烈性脂质溶剂，不得直接与身体接触。处理单体或骨水泥时必须佩戴手套，避免液体（主要成分：甲基丙烯酸甲酯）渗入皮肤。

服用前必须确保粉末未与液体接触。三层聚乙烯、乙烯—乙烯醇共聚物材质的手套及Viton®/丁基橡胶手套可长期提供良好保护。同时佩戴两副手套，比如在已佩戴的乳胶标准外科手套上再套一副聚乙烯外科手套亦可提供同样的保护作用。避免单独使用乳胶或聚苯乙烯丁二烯手套。请与您的供应商确认，手套是否适合使用OSTEOPAL®。液体蒸汽会刺激呼吸道和眼睛，并可能损伤肝脏。如果接触皮肤则可能引起刺激皮肤。

柔韧型隐形眼镜制造商建议，存在有害或刺激性蒸气时须摘除此类镜片。由于柔韧型隐形眼镜可渗透液体及气体（例如抗生素溶液），其可能对机械强度和骨水泥操作特性产生不利影响。

剂量和制备
通过混合粉末包的全部粉末与整个安瓿内的液体获得单剂量。骨水泥的所需用量取决于相应的结构条件。对于PMMA骨水泥的最大可用量尚无相关数据。对于可采用椎体成形术或椎体后凸成形术治疗的椎体最大数量尚无相关数据。在无菌条件下打开外部聚乙烯袋前在无菌条件下以及规定位置打开，从而确保可以以无菌方式取出无菌粉末及粉末容器。

用于患者
必须在植入骨水泥期间及完成植入后立即仔细监控血压、脉搏和呼吸。如果上述生命体征出现明显变化，则必须立即采取相应措施。如果出现肺部或心血管并发症，则必须进行监控并尽可能提高血容量。出现呼吸系统机能不全时，应采取麻醉措施。庆大霉素可有效对抗多种需氧革兰氏阴性细菌和部分革兰氏阳性细菌。庆大霉素对多数厌氧菌、真菌和病毒无对抗效用。庆大霉素对链球菌状皮炎菌仅有些许对抗效用。革兰氏阴性细菌和革兰氏阳性细菌可对庆大霉素产生耐药性。

妊娠
妊娠期妇女使用庆大霉素潜在健康风险评定相关的资料尚不充足。氨基糖苷类抗生素可渗透胎盘。无法排除对胎儿造成耳毒性的影响。有产前使用链霉素，导致儿童出现不可逆的双耳先天性损失的报告。对于其他的氨基糖苷类抗生素已观察到听觉损害。考虑到胎儿肾脏内的庆大霉素浓度，肾毒性是潜在风险。动物研究显示在产前暴露于庆大霉素/氨基糖苷类抗生素后，会有耳毒性。因此，妊娠期不建议使用OSTEOPAL®。除对孕妇的益处外对胎儿的潜在危害外，无需指征。

哺乳期间
庆大霉素会少量随乳汁分泌出。由于新生儿的肠道渗透性增强，无法排除对胎儿造成耳毒性的影响。因此，在哺乳期间使用OSTEOPAL®前必须权衡对胎儿的益处与对婴儿的潜在危害。

不相容性
禁止添加添加剂例如抗生素粉末或X射线造影剂或水溶液（例如抗生素溶液），其可能对机械强度和骨水泥操作特性产生不利影响。

准备
打开无菌包装前在无菌条件下打开。无菌组件（内部聚乙烯纸袋和玻璃安瓿）必须采取无菌方式操作。在无菌条件下打开。外部聚乙烯包装在无菌条件下以及规定位置打开，从而确保可以以无菌方式取出无菌粉末及粉末容器。其可能对机械强度和骨水泥操作特性产生不利影响。打开内部聚乙烯包装前，通过摇晃或敲击将内含物挤至下部。确保在剪开上部边缘时粉末不会丢落。在使用PMMA单体液体时切勿在手术室内佩戴隐形眼镜。由于柔韧型隐形眼镜可渗透液体及气体（例如抗生素溶液），其可能对机械强度和骨水泥操作特性产生不利影响。

在无菌条件下打开。外部聚乙烯包装在无菌条件下以及规定位置打开，从而确保可以以无菌方式取出无菌粉末及粉末容器。其可能对机械强度和骨水泥操作特性产生不利影响。打开内部聚乙烯包装前，通过摇晃或敲击将内含物挤至下部。确保在剪开上部边缘时粉末不会丢落。在使用PMMA单体液体时切勿在手术室内佩戴隐形眼镜。由于柔韧型隐形眼镜可渗透液体及气体（例如抗生素溶液），其可能对机械强度和骨水泥操作特性产生不利影响。
混合
将安瓿中的液体倒入无菌混合容器内。然后加入已打开内装中的粉末。使用无菌铲子或勺子搅拌混合，直至形成均匀的混合物。无论环境温度如何，都应搅拌混合 30 秒。严格遵守粉末和液态成分混合说明可以最大程度地降低并发症发生率。
骨水泥成分可以在有或无真空的混合系统内混合。无论是不是有真空，混合时间均为 30 秒，且不受环境温度影响。混合系统的详情参见混合系统使用说明书。
操作时间和聚合作用尤其取决于成分和环境温度。较高的温度可以加快固化，而较低的温度则会延长固化时间。

处理
黏度随着聚合作用而增加，即随着处理阶段的推进而增加。骨水泥搅拌后应立刻置放于使用工具，因为此时骨水泥黏度较低，容易纳入。为了避免骨水泥渗透于血液循环系统，应使用糊状的骨水泥。OSTEOPAL®G 可以用于经皮椎体成形术或椎体后凸成形术的应用系统（该系统可以控制注入量）置入椎体内。应用系统的使用参见制造商使用说明书。
在灌注椎体期间，需要持续进行 X 光透视（侧方）实时显示。若骨水泥渗漏椎体旁，必须立即中断骨水泥注入，待骨水泥黏度增加后继续注入。OSTEOPAL®G 的混合、处理和固化时间可以参见使用说明书的图表。参数在使用直径为 3.5 mm 的骨水泥注入设备时有效 (MAXXSPINE Ltd, 65307 Bad Schwalbach, Deutschland)。
骨水泥还可以在处理时间结束后从骨水泥注入设备中提取出来，但无法实现无折痕的连接。因此处理时间的结束应以骨水泥的状态为准，而非骨水泥注入设备结束骨水泥灌注为准。
规格适用于 26 克的骨水泥粉末和 10 ml 的单体安瓶。

下列因素会影响工作阶段持续时间：
- 环境温度：环境温度升高时，等待时间、操作时间和固化时间都会缩短
- 搅拌和分配时的温度：搅拌和分配温度升高时，等待时间、操作时间和固化的时间都会缩短
- 使用较细的针管会缩短操作时间和固化时间

若使用其他系统，骨水泥处理可能会有变化。不应使用直径小于 1.8 mm（13G）的针管。

存放
骨水泥必须置于原始包装内，在最高 25 °C (77 °F) 的温度下存放于干燥洁净处，不得开封且须避光。

有效期/无菌性
失效日期印于折叠盒、铝保护袋和内袋上。说明日期到期后，禁止使用 OSTEOPAL®G。即使内含物未使用，但已打开或损坏的包装禁止重新灭菌，必须丢弃。
OSTEOPAL®G 使用环氧乙烷气体灭菌，禁止重复灭菌。聚合物粉末变黄时，不得使用。产品灭菌有效期限 3 年。
OSTEOPAL®G 的加工时间

测试条件：55％空气湿度。
SYMBOLS / 符号

⚠️ Manufacturer/生产厂商

стерильная септическая обработкой

стерильная посредством эфирного оксида

Consult instructions for use/参考使用说明书

Keep away from sunlight/避免光照

Keep dry/保持干燥

Do not store above 25 °C (77 °F)/请勿储存于25摄氏度(77华氏度)以上的环境

Do not re-use/请勿二次使用

Do not re-sterilize/请勿二次灭菌

Catalogue number/产品编号

Use by date/有效期

Batch code/批号

Flammable liquid – Flashpoint 10 °C/易燃液体-闪点10摄氏度

Causes skin irritation/刺激皮肤

Do not use if the product sterilization barrier or its packaging is compromised/若发现无菌环境遭破坏或包装破损则禁止使用