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

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(Revision status: 2018-07)

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加工时间 10
(修订状态: 2018 年 07 月)
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.

Components

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 / methyl-acrylate), zirconium dioxide, benzoyl peroxide and chlorophyll E141 (green dye).

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).

Intended use

OSTEOPAL®G is intended for augmentation and stabilisation of vertebral bodies in percutaneous Vertebroplasty and Balloon Kyphoplasty.

Indications

Percutaneous Vertebroplasty and Balloon Kyphoplasty are indicated for
• Painful compression fractures of the vertebral body caused by osteoporosis
• Palliative stabilisation of vertebral bodies in patients with painful tumors in the vertebral body or symptomatic vertebral haemangioma

Percutaneous Vertebroplasty and Balloon Kyphoplasty are indicated when conservative treatment options have failed.

Contraindications

Absolute Contraindications
• Septicemia
• Active osteomyelitis of the target vertebra
• Uncorrectable coagulopathy
• Allergy to bone cement or opacification agent

OSTEOPAL®G must not be used
• in patients with known hypersensitivity to gentamicin or other constituents of bone cement
• in patients with severe renal insufficiency
• in patients with an active or incompletely treated infection
• for the fixation of artificial joints (e.g. Hip, knee and shoulder)
• used in patients with hemorrhagic diathesis

Relative Contraindications
• Lesions of the vertebral body with epidural extension due to the danger of spinal cord compression
• Radiculopathy in excess of local vertebral pain, caused by a compressive syndrome unrelated to vertebral collapse
• Occasionally preoperative Vertebroplasty can be performed before a spinal decompressive procedure
• Retropulsion of a fracture fragment causing severe spinal canal compromise
• Epidural tumor extension with significant encroachment on the spinal canal
• Ongoing systemic infection
• Patient improving on medical therapy
• Prophylaxis in osteoporotic patients
• Myelopathy originating at the fracture level

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 hypotonic accompanied by anaphylaxia, including anaphylactic shock, cardiac arrest and sudden death have been reported. These cardiovascular and respiratory side-effects, also known as an influx of bone marrow components into the venous vascular system. In the event of pulmonary, cardio-vascular complications, monitoring and possibly an increase of the blood volume is required. In the presence of acute respiratory insufficiency, anesthesiological measures must be taken.

Potential procedural complications vertebroplasty and kyphoplasty:
• cement leak (asymptomatic or symptomatic)
• spinal compression
• cement pulmonary embolism (asymptomatic or symptomatic)
• bleeding/hematoma
• infection
• neurological deficit
• adjacent fractures

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 (latero-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.

Disposal
Single components of the bone cement, cured solid material as well as (uncleaned) packaging material must be disposed by following the regulations of the local authorities.
### Processing times for OSTEOPAL®G

<table>
<thead>
<tr>
<th>Room temperature (°C)</th>
<th>Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>1</td>
</tr>
<tr>
<td>22</td>
<td>2</td>
</tr>
<tr>
<td>21</td>
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<tr>
<td>18</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td></td>
</tr>
</tbody>
</table>

Test conditions: 55% humidity.
特性和组成部分
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，用于骨科外科手术。
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 OSTOEPAL®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
26.53g OSTOEPAL®G 骨水泥粉末包含：
0.325g 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 OSTOEPAL®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
OSTOEPAL®G 用于在经皮椎体成形术和球囊后凸成形术中扩增和稳定椎体。

适应症
经皮椎体成形术和球囊后凸成形术适用于
- 由骨质疏松引起的椎体疼痛性压迫性骨折
- 在椎体疼痛性肿瘤或症状性椎体血管瘤患者中椎体的姑息性稳定
保守治疗选项无效后适用经皮椎体成形术和球囊后凸成形术。

禁忌症
绝对禁忌症
- 败血症
- 手术椎体骨髓炎
- 由与压缩性骨折无关的压迫综合征引起的、不只是局部椎体疼痛的神经根病
- 骨折片段后退导致严重椎管损害

相对禁忌症
- 延伸到硬膜外的椎体受损导致脊髓压迫危险
- 脊椎后凸成形术
- 骨髓炎或感染未治愈的患者
- 用于人工关节(例如髋、膝和肩关节)的固定
- 其它出血因素的患者

OSTOEPAL®G 不得用于
- 已知对庆大霉素或其他骨水泥成分过敏的患者
- 严重肾功能不全患者
- 骨髓炎或感染未治愈的患者
- 用于人工关节（例如髋、膝和肩关节）的固定
- 其它出血因素的患者

成分
规格型号
OSTOEPAL® G 1x20
每小袋中的 26.53g 粉中含有一下

<table>
<thead>
<tr>
<th>成分</th>
<th>规格型号</th>
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<tbody>
<tr>
<td>聚（丙烯酸甲酯、甲基丙烯酸甲酯）</td>
<td>13.92g</td>
</tr>
<tr>
<td>二氧化锆</td>
<td>11.94g</td>
</tr>
<tr>
<td>过氧化苯甲酰</td>
<td>0.13g</td>
</tr>
<tr>
<td>硫酸庆大霉素</td>
<td>0.54g</td>
</tr>
</tbody>
</table>

每安瓿瓶中的 10ml 液体中含有

<table>
<thead>
<tr>
<th>成分</th>
<th>规格型号</th>
</tr>
</thead>
<tbody>
<tr>
<td>甲基丙烯酸甲酯</td>
<td>9.8ml</td>
</tr>
<tr>
<td>N, N-二甲基对甲苯胺</td>
<td>0.2ml</td>
</tr>
<tr>
<td>其他成分 在粉中：叶绿素铜(E141)</td>
<td>2 ppm</td>
</tr>
<tr>
<td>其他成分 在粉中：叶绿素铜(E141)</td>
<td>~20 ppm</td>
</tr>
<tr>
<td>其他成分 在粉中：叶绿素铜(E141)</td>
<td>32 ppm</td>
</tr>
</tbody>
</table>
对椎管有明显侵入的硬膜外肿瘤扩张
进行中的全身性感染
预防治疗中的骨质疏松症
源于骨折椎体的骨髓病
副作用
其中 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：
• 损伤听说和前庭神经
• 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）
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预计不会出现庆大霉素过量，因为使用 OSTEOPAL®G 时，所需的局部高浓度仅会造成术后数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。

使用 PMMA 骨水泥时，经常会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，包括过低性休克、心脏骤停和猝死。

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。

椎体成形术和后凸成形术的潜在手术并发症：
• 水泥渗漏（无症状或症状性）
• 脊柱压迫
• 水泥肺栓塞（无症状或症状性）
• 出血/血肿
• 感染
• 神经功能缺损
• 相邻骨折

另外，骨水泥渗漏也会损伤静脉及结构。可能发生脊髓压迫症、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。

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，则必须及时采取相应措施解决。如果出现腹部或心肺并发症，则进行监测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细菌、真菌和病毒无效。庆大霉素对链锁状球菌仅有些许对抗作用。庆大霉素在骨髓中浓度尤其在骨水泥中浓度可达到一定水平。

妊娠
妊娠期间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，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力损伤。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，会有耳毒性及肾脏毒性。因此，妊娠期间不建议使用 OSTEOPAL®G。除非对孕妇的益处超过对胎儿的潜在危害时。

哺乳期间
庆大霉素会有少量随乳汁分泌出。由于新生儿的肠道渗透性增强，无法排出乳汁中含有的庆大霉素。因此，哺乳期间使用 OSTEOPAL®G 前必须权衡对孕妇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。

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信息。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信息。手术开始前，应至少准备一包额外的 OSTEOPAL®G。每包需单独混合。
准备
打开无菌铝制保护袋前，通过摇晃或敲击将内含物挤至下部。避免在打开时损坏内含物。聚乙烯纸袋和安瓿仅可在无菌条件下打开。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
外部聚乙烯纸袋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内部聚乙烯纸袋。泡罩包装同样在无菌条件下以及规定位置打开。向外部聚乙烯纸袋内插入无菌安瓿，通过无菌方式取出安瓿。

打开内部聚乙烯纸袋前，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尘不会丢落。

混合
将安瓿中的液体倒入无菌混合容器内。然后加入已打开内袋中的粉末。使用无菌铲子或勺子搅拌混合，直至形成均匀的混合物。如果环境温度过高，应将混合物加入到无菌混合容器中，保持混合温度在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
骨水泥黏度增加后继续注入。如果骨水泥填充不足，则须继续进行对侧填充。完成灌注后，应将芯子插入注射针管内。骨水泥可以向注射针管内继续注入，从而避免在取出注射针管后骨水泥残留在软组织内。

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3.5mm的骨水泥注入设备时有效。

骨水泥成分可以在有或无真空的混合系统内混合。无论是不随混合，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。

规格适用于26克的骨水泥粉末和10ml的单体安瓿。

处理各组分、硬化骨水泥以及（未清洁的）包装材料时，必须根据当地的规范性规定废弃处理骨水泥各组分、硬化骨水泥以及（未清洁的）包装材料。
OSTEOPAL®G 的加工时间

![时间 (分钟) vs. 室内温度 (°C) 图](image)

- 搅拌 [1]
- 粘丝期 [2]
- 面团期 [3]
- 固化 [4]

测试条件：55％空气湿度。
SYMBOLS / 符号

Manufacturers / 生产厂商

Sterilized using aseptic processing techniques / 无菌处理

Sterilized using ethylene oxide / 环氧乙烷灭菌

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 resterilize / 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 sterile barrier system or its packaging is compromised / 如果产品无菌屏障系统或其包装已受损，请不要使用