R.T.R. Granules

CE 0459

R.T.R. (Resorbable Tissue Replacement)
β tricalcium phosphate sterile resorbable bone substitute

DESCRIPTION
R.T.R. is made of β tricalcium phosphate granules of synthetic origin.
R.T.R. calcium phosphates are manufactured using the latest technologies, which guarantees that our products will have an extremely high level of purity.

PROPERTIES
R.T.R. is available as granules, with a size ranging between 500 µm and 1 mm.
The size of macropores varies from 100 *µ*m to 400 µm and micropores are less than 10 µm in diameter. These specific structural properties allows the colonization of macropores by newly formed bone.
R.T.R. is gradually resorbable.

INDICATIONS
R.T.R. is designed for the filling and reconstruction of bone defects in maxillofacial and dental surgery.

CONTRAINDICATIONS
- Acute osteomyelitis or necrosis of the recipient site.
- Bone degeneration.
- Known active infection.
- Known allergy to any constituent of the bone substitute.

WARNINGS AND PRECAUTIONS FOR USE
The manufacturer of R.T.R. guarantees material and manufacture quality.
Several criteria are of crucial importance for the operation with R.T.R. to be successful:
- appropriate selection of the patient who will undergo the operation,
- rigorous asepsis.
The practitioner is responsible for any complication which may result from improper use, faulty operative technique or lack of asepsis. These complications cannot be attributed to the manufacturer.

Underlying oral pathologies such as infections should be treated and ruled out before applying R.T.R.
Avoid saliva contamination.

The bone site which will be in contact with R.T.R. should be debrided and, if possible, well vascularised, so as to create a high quality recipient bed.

Any non-used part of R.T.R. should be systematically disposed of since the product is no longer sterile.

Check the packaging integrity before use.

Do not use if packaging has been damaged or opened before first use.

RESTERILISATION AND REUSE
The resterilisation and/or reuse of the R.T.R. bone substitutes is strictly prohibited, as it could expose the patient concerned to contamination and a subsequent risk of infection. Reusing a R.T.R. bone substitute would reduce its efficiency, namely a reduced strength (fracture risk) and a phenomenon of incomplete bone remodelling. There is also a significant risk of inflammatory reaction (for example, a host response against the graft before it has been implanted).

INSTRUCTIONS FOR USE
There are several possible methods of application for R.T.R.

- If using R.T.R Syringe, the granules may be packed directly into the bone cavity before closing the soft tissues.
  To do so, take some blood or saline solution through the filter tip of the syringe by pulling the plunger up until all the granules are soaked. The excess liquid can be easily released by pushing the plunger down. Remove the tip and inject the mixture into the surgical site by pushing the plunger down.
  The granules can also be mixed with the patient's blood or with saline solution in a sterile Dappen dish before being placed onto the operative site using a dental spatula.
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In any case, the operative site will have to be closed by joining together the wound edges (coaptation) with suture stitches.

EXPECTED PERFORMANCE
As their chemical composition is very close to that of natural mineral bone, calcium phosphates – and particularly β-tricalcium phosphate – play an important role in the biological processes governing the stability and regeneration of bone tissue. Accordingly, the role of R.T.R. bone substitutes is to temporarily replace bone tissue in the event of major tissue deficiency caused by trauma or a physiological problem. Thus these devices enable initiation of the bone remodelling phenomenon whilst facilitating their replacement with newly formed natural bone.

STORAGE
Keep only in the original container.

EXPIRY DATE
Do not use after the expiry date mentioned on the outer package.

PRESENTATION
- 0.8 cm^3 curved syringe in single-unit package sterilised by gamma radiation (minimal dose: 25 kGy).
- 2 cm^3 bottle in single-unit package sterilised by gamma radiation (minimal dose: 25 kGy).

For professional dental use only

SEPTODONT
58, rue du Pont de Créteil
94100 Saint-Maur-des-Fossés - France

09/14
C 05 74 303 21 00

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R.T.R. (Resorbable Tissue Replacement)
无菌可吸收β磷酸三钙

说明
R.T.R.磷酸钙采用了最新的技术，可以保证产品极高的纯度。
R.T.R.由β磷酸三钙颗粒组成。

属性
R.T.R.可用的粒径范围是500微米至1毫米。大孔孔径从100-400微米,小孔孔径小于10微米.这种特殊的结构属性使新形成骨可能在大孔中定植。
R.T.R.被逐渐吸收。

适应症
R.T.R.目的是用于代替骨损失，用患者的血液或生理溶液浸渍后，进行牙科治疗，如充填牙槽窝。

禁忌症
-急性骨髓炎或受区坏死。
-骨变性
-已知的急性感染。
-已知的对β磷酸三钙成分过敏。

使用的注意事项和预防措施
R.T.R.制造商保证材料和产品的质量。
手术中成功的应用R.T.R.有一些致关重要的标准：
-对患者的选择
-严格的无菌。
由于不适当的使用，错误的手术操作或者缺乏无菌条件，可能造成并发症，医生应当为此负责。这些并发症不能归因于制造商。
在使用R.T.R.之前，应当先治疗感染等基本口腔疾病。
避免唾液污染。
在R.T.R.与骨接触的部位应该严格清创，如果可能，良好的血管化有利于创造一个高质量的种植床。
任何未使用完的R.T.R.必须妥善扔弃，因为它们已被污染。
不再灭菌。
在使用之前检查包装的完整性。
如果有包装受损或开放，请不要使用。

使用说明
R.T.R. 可用于以下操作：
-在缝合软组织前，术者应当使用预填充的注射器，将R.T.R.颗粒 直接注入骨腔。
取患者的血液或生理溶液，通过注射器的过滤端混合注射器内容物，拉动注射器的柱塞上升直到所有颗粒都浸润。推动活塞下降，去除多余的液体。卸下过滤尖端，向下推活塞，把混合物注入手术部位。
-R.T.R. 也可以在无菌的牙科调药盘内，用牙科调拌刀与患者的血液或生理溶液相混合，然后再植入手术部位。
在这两类手术过程中，术者应该拉拢创口边缘，用缝合针缝合手术部位。

贮藏
原包装保存。

保质期
请在外包装说明的保质期内使用。产品有效期为5年。

包装规格
0.8cm^3 单独包装，经伽马辐射消毒（最小剂量：25kGy）
2.0cm^{3+}瓶装，经伽马辐射消毒（最小剂量：25kGy）

仅供口腔医生专业使用。
生产单位：SEPTODONT
生产单位地址：58 rue du pont de Créteil - 94100 Saint-Maur-des-Fossés - France
售后服务提供商名称：赛谱敦（上海）贸易有限公司
售后服务提供商地址：上海市长宁区天山路30号甲1206、1207室
售后服务提供商电话：021-62591002
售后服务提供商传真：021-62591002
标准编号：YZB/FRA 2097-2012
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SEPTODONT
58, rue du Pont de Créteil
94100 Saint-Maur-des-Fossés - France