# 4SEAL® Hemostatic Powder 1g, 3g, 5g
# Instructions for use

**Ref. no.: 1203-HP001, 1203-HP003, 1203-HP005.**

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**Important:**

This instruction cannot be used as a manual for surgical techniques used during the work with hemostatic products. To learn adequate knowledge about surgical technique it is necessary to contact our company or authorized distributor and to acquaint with appropriate technical instructions, professional medical literature and graduate proper training under supervision of a surgeon experienced in hemostatic techniques. Before use we recommend reading precisely all information included in this manual. Not being obedient to these information may lead to serious surgical consequences.

**Indications:**

4SEAL® Hemostatic Powder is indicated for use in surgical procedures or injuries as an adjunct hemostat when control of bleeding with capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. For adhesion prevention 4SEAL® Hemostatic Powder is indicated when the formation of post-operative adhesion is to be prevented after surgical interventions in cavities covered by mesothelium.

**Contraindications:**

DO NOT use 4SEAL® Hemostatic Powder as a primary treatment for coagulation disorders.
DO NOT use 4SEAL® Hemostatic Powder if the patient has intolerance to starch or products that contain starch.
DO NOT apply 4SEAL® Hemostatic Powder directly into blood vessels.
DO NOT apply 4SEAL® Hemostatic Powder directly to the eyes.
DO NOT apply 4SEAL® Hemostatic Powder directly into the the bladder or the urethra.
DO NOT use 4SEAL® Hemostatic Powder for controlling post-partum bleeding or menorrhagia.

**Description of the device:**

4SEAL® Hemostatic Powder is a sterile, hemostatic medical device composed of absorbable modified polymers and powder delivery applicator. Absorbable modified polymers are biocompatible, hydrophilic, non-pyrogenic and derived from purified plant starch. 4SEAL® Hemostatic Powder contains no animal or human-derived materials.

**Mechanism of action:**

4SEAL® Hemostatic Powder particles absorb rapidly water from the blood. This dehydration process increases the concentration of platelets, red blood cells and coagulation proteins at the bleeding site and thus accelerates the natural blood clothing process. After 4SEAL® Hemostatic Powder has been applied to the bleeding, the powder forms a gel-like mass. This creates a mechanical barrier to futher blood loss and is formed regardless of the patient coagulation status. The concentration of clotting factors and platelets in the gel-like mass serves to enhance normal clotting reactions and creates stable hemostatic plugs.
For adhesion prevention 4SEAL® Hemostatic Powder is applied to surgically traumatized mesothelial surfaces and transforms into a gel-like mass after the powder has been moistened with saline solution or sterile water. The gel forms a temporary mechanical barrier that separates the traumatized mesothelial tissue.
The absorption process begins immediately and is dependent on several factors, including the amount applied and the site of use. The product is completely degraded by an amylase and a glucoamylase in 3-5 days.

**Instructions for use:**

**Device preparation:**

1. Before opening and using the product, please check the packaging and its contents for any defects or damage. If any damage or defects are found, do not use this item.
2. After removing the second aluminium bag under sterile conditions from the first Tyvek peelable bag, open the aluminium bag and remove the applicator from the package.
3. By swinging movements break the cap off and remove it from the applicator to expose the tip. 4SEAL® Hemostatic Powder is now ready to use.
4. If 4SEAL Hemostatic Powder is to be used in an endoscopic procedure or in the areas with difficult access dedicated extended applicator (delivered separately) should be attached to the exposed tip. Compatible are extended powder applicators with a hub that fits conical tip 4,5 ±0,2 mm distal diameter and 5,5 ±0,2 mm diameter measured 30 mm from the tip.

**Application technique for hemostatic effect:**

1. Remove all excess blood by suctioning, wiping or dabbing to maximaze the hemostatic performance as it allows absorbable modified polymers direct contact with the site and source of active bleeding.
2. Immediately apply a liberal amount of 4SEAL® Hemostatic Powder to the source of bleeding. Throughly cover the bleeding wound with hemostatic powder. When treating deep-lying sources of bleeding, the applicator tip must be as close as possible to the source of bleeding. Use caution to avoid contacting the tip of the applicator with blood as this may occlude the applicator.
3. For severe bleeding, apply direct pressure to the wound for several minutes following 4SEAL® Hemostatic Powder application. The use of non-adhering substrate to apply pressure is recommended. If bleeding continues, remove excess particles and

repeat the procedure.

4. Excess 4SEAL® Hemostatic Powder should be removed from the site of application by suction and rinsing with saline solution after adequate hemostasis is attained.

**Application technique for adhesion prevention:**

1. In terms of adhesion prevention, 4SEAL® Hemostatic Powder may be applied in a dry state or as paste- or gel-like structure by previous mixing the product with sterile 0,9% saline.
2. To apply in a dry state cover entire mesothelial defect and wound surface with 4SEAL® Hemostatic Powder. Moisten the powder with sterile 0,9% saline or water for injection until 4SEAL® Hemostatic Powder is completely converted into paste- or gel-like structure.
3. To apply as paste or gel mix 4SEAL® Hemostatic Powder with 0,9% saline in a sterile bowl. Depending on the amount of liquid added, the mixture will take the form of a paste (to be applied with a spatula) or a thin gel (to be applied with a syringe or directly from the bowl).
4. The following proportions of powder / 0,9% saline are suggested for reference only. It is not necessary to strictly adhere to the given proportions. When mixing 4SEAL® Hemostatic Powder with the liquid, the amount of liquid should be selected in such a way as to achieve the consistency of the mix required by the surgeon.

| Required consistency | 4SEAL® Hemostatic powder weight | Volume of 0,9% saline | 4SEAL® Hemostatic powder weight | Volume of 0,9% saline |
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| Paste (to be applied with a spatula) | 5 g | 60 ml | 20 g | 240 ml |
| | 10 g | 120 ml | 25 g | 300 ml |
| | 15 g | 180 ml | 30 g | 360 ml |
| Gel (to be applied with a syringe or directly from the bowl) | 5 g | 80 ml | 20 g | 320 ml |
| | 10 g | 160 ml | 25 g | 400 ml |
| | 15 g | 240 ml | 30 g | 480 ml |

5. Apply mixture with a spatula, or syringe, or directly from the bowl depending on the consistency.

**Warnings and precautions measures:**

1. 4SEAL® Hemostatic Powder should only be used by physician or other licensed practitioners. The surgeon or medical staff takes full responsibility for its use.
2. 4SEAL® Hemostatic Powder it is not intended as a substitute for good surgical practice and proper use of conventional procedures (ligature) for hemostasis.
3. The best hemostatic properties are obtained when 4SEAL® Hemostatic Powder is used in a dry state. Contact with the liquid prior to application reduces hemostatic properties while maintaining antiadhesion activity.
4. 4SEAL® Hemostatic Powder is a sterile, single use product and must not be re-sterilised. Do not use products that have not been used but have already been opened.
5. Do not apply more than 50 g 4SEAL® Hemostatic Powder in diabetic patients, amount greater than 50 g could affect the glucose load.
6. In case of using 4SEAL® Hemostatic Powder in the nasal cavity and laryngopharyngeal, 4SEAL® Hemostatic Powder should be used with caution to avoid the dry particles being drawn into the trachea or bronchi.
7. It is not recommended to use of 4SEAL® Hemostatic Powder when the infection is suspected. 4SEAL® Hemostatic Powder should be used with caution in contaminates areas.
8. 4SEAL® Hemostatic Powder has not been investigated in children or pregnant women. In newborns up to ten months of age, amylase activity may be diminished, so that the absorption rate of products such as 4SEAL® Hemostatic Powder can be reduced.
9. In case of using 4SEAL® Hemostatic Powder in operations involving the spinal cord, bone foramina or optic nerves the excess of product must be deactivated and removed. 4SEAL® Hemostatic Powder swells when it comes into contact with blood or liquids, which can result in compression of the surrounding tissue.
10. 4SEAL® Hemostatic Powder should not be left in bladder, ureteral lumen or renal pelvis to eliminate the potential foci for calculus formation.
11. 4SEAL® Hemostatic Powder must be removed completely from the surface of the bone before the methylmethacrylate or other acrylic adhesives are applied to avoid any impairment of the bonding and binding of any product or device with the bone.
12. In cases where surgery is carried out using an extracorporeal circulation system (heart-lung machine) or autotransfusion devices, extra care must be taken to prevent 4SEAL® Hemostatic Powder particles from entering the bloodstream. The use of a 40µ cardiotomy reservoir, cell washing, and a 40µ transfusion filter, for example, is necessary in this case.
13. The use of 4SEAL® Hemostatic Powder in combination with other hemostatic agents has not been clinically tested.
14. The safety and effectiveness of 4SEAL® Hemostatic Powder in combination with other medical products for adhesion prophylaxis has not been tested. Post-operative adhesions may occur even if 4SEAL® Hemostatic Powder is used. Possible causes may be insufficient hemostasis or improper use.
15. Dispose of all opened products no matter if the hemostatic powder was used or not.
16. Use immediately after opening.
17. The product requires appropriate disposal after use in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and the environment.
18. This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
19. Product is intended to be used exclusively by qualified medical staff.

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| Keep dry | Consult electronic instructions for use | Manufacturer | Do not re-use |
| Caution, consult accompanying documents | Do not resterilize | Do not use if package is damaged and consult instructions for use | Use-by date |
| Authorized representative in the European Community | Catalogue number | Batch code | Quantity in package |
| Sterilized using irradiation | Double sterile barrier system | Medical device | Date of manufacture |

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*If you require a hard copy of IFU in other language, you can contact Grena Ltd.*
*at **ifu@grena.co.uk** or **44 115 9704 800**.*

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