4SEAL® Hemostatic Powder
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.
Patient target group – adult and young patients, males and females.
Intended users: product is intended to be used exclusively by qualified medical staff.

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 due to the risk of embolism.
DO NOT apply 4SEAL® Hemostatic Powder directly to the eyes as it can cause irritation or damage.
DO NOT apply 4SEAL® Hemostatic Powder directly into the bladder, the ureter or the urethra as it may cause obstruction of urinary tract.
DO NOT use 4SEAL® Hemostatic Powder for controlling post-partum bleeding or menorrhagia due to lack of sufficient data on efficacy and safety in these conditions.

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 process of degradation by amylase and glucoamylase and subsequent absorption begins immediately and lasts 24-48 hours when using 4SEAL for hemostasis and 3 to 8 days when used as adhesion prophylaxis. Differences in actual absorption time result from different amounts of powder and thickness of the layer applied.

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 as it may be contaminated what could cause infection.
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 by pressing bottom of the bellow bottle few times. 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. Excess powder left behind may complicate subsequent steps of the procedure.

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 or water for injection.
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 or water for injection 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). It is recommended to use 12 to 16 ml of liquid for each 1g of powder. 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.
4. 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 to avoid use of contaminated product.
5. 4SEAL® Hemostatic Powder is made of starch and does require quantitative restrictions on dosage, however caution is recommended when dosing 4SEAL® Hemostatic Powder in diabetic patients. Surgeon must take into account the type and severity of the disease as greater amounts of 4SEAL® 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 as they could cause airway obstruction or irritation.
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 contaminated areas as the product may not be effective and might interfere with infection control measures.
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 to prevent accidental use of a contaminated product.
16. Use immediately after opening. Storage of the device after package opening leads to its contamination and creates a risk of an infection to the patient.
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. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Keep dry	Consult electronic instructions for use	Manufacturer	Do not re-use
Caution	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

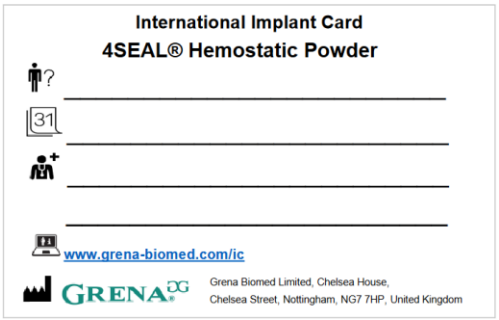
The hard copies of instructions for use delivered with Grena products are always in English language.
If you require a hard copy of IFU in other language, you can contact Grena Ltd.
*at **ifu@grena.co.uk** or **44 115 9704 800**.*

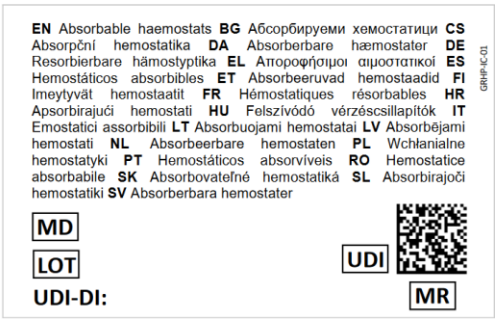
Please scan the below QR code with the appropriate application.
It will connect you with Grena Ltd. website where you can choose eIFU in your preferable language.

*You can enter the website directly by typing in **www.grena.co.uk/IFU** in your browser.*

Make sure that paper version of IFU in your possession is in the latest revision prior to use of the device.
Always use the IFU in the latest revision.

IMPLANT CARD INFORMATION





Implant card (IC) is delivered with the product, one IC for each device.
Implant card is supposed to be completed by a implanting healthcare institution or healthcare provider and should be handed over to the patient who has been implanted.
The instructions on how to complete the implant card (IC) in your preferable language you can find on our website
www.grena-biomed.com/ic