PlantTec Medical
MEDICAL SOLUTIONS INSPIRED BY NATURE

4DryField® PH

PROVIDES HEMOSTASIS – PREVENTS ADHESIONS

Instructions for use

4DryField® PH

EXPLANATION OF SYMBOLS

Manufacturer

Manufacturing date

Use by year and month

Reference number

Batch number

Sterilization method: Radiation

Do not re-sterilize

Do not use if package is damaged

Protect from sunlight

Store dry

Do not reuse

Observe the directions for use

Attention, see instruction for use

Medical device

Applicator (content)

Box (with applicators)

CE Mark

en | Instructions for Use

4DryField® PH

Hemostasis – Adhesion Prevention

Description

4DryField® PHis a sterile medical device, a disposable resorbable starch-based powder to be used by physicians or medical professionals for hemostasis and adhesion prevention.

4DryField® PH consists of hydrophilic, microporous particles produced from processed plant starch using the special SAFE™[1] technology. Due to its fluidity, 4DryField® PH can be applied easily and safely during surgical procedures or in case of surgical injuries.

4DryField® PH does not contain any components of human and/or animal origin. Due to its excellent tolerability, up to 1 g of 4DryField® PH can be administered per 1 kg body weight[2] [1]. 4DryField® PH is a fine, dry, biocompatible and pyrogen-free powder, which is usually resorbed within seven days [1]. 4DryField® PH is mainly degraded by amylase and glucoamylase. Duration of degradation depends upon several factors, including application technique, amount and where applied.

Performance characteristics of the product

*For **hemostasis**:*

Due to its molecular structure, 4DryField® PH extracts water from the blood and, therefore, the cellular blood components (e.g., erythrocytes, platelets) as well as blood proteins (e.g., fibrinogen, thrombin) are concentrated. As a result, cellular hemostasis and the coagulation cascade are accelerated and a stable clot is formed from 4DryField® PH and blood.

The conglomerate of 4DryField® PH and blood seals the bleeding source and stops any further bleeding. Disadvantages of a dilutional coagulopathy can be compensated by the effect of 4DryField® PH [2].

*For **adhesion prevention**:*

Due to the special molecular structure of 4DryField® PH, the hydrophilic, microporous particles form a gel through absorption of liquid. To prevent post-operative adhesions, 4DryField® PH is transformed into a gel with sterile solution.

This gel acts as a temporary, mechanical barrier separating traumatized mesothelial (or mesothelial-like) surfaces (risk zones for the formation of adhesions) during the post-operative healing phase [3-5].

Indications

*For **hemostasis**:*

4DryField® PH is indicated if pressure, ligatures, or other conventional measures are not effective or impractical to control bleeding from arterioles, capillaries, or veins during surgery or surgical injury.

*For **adhesion prevention**:*

4DryField® PH is also indicated to prevent the formation of post-operative adhesions following surgery or surgical injuries in peritoneal and pericardial cavities.

Patient groups

4DryField® PH can be used in all patient groups according to the indications.

4DryField® PH has not been systematically tested in pregnant and breast-feeding women or in patients with diabetes.

1 Starch-based Agent Functionally Engineered
2 Tested in animals

Application

4DryField® PH is intended for use by physicians and medical/technical professionals only. The following instructions for use provide an overview of the recommended use of 4DryField® PH. The procedures described do not represent all possible clinical procedures. This Instructions for Use is therefore not a substitute for product training, medical experience and judgment in the treatment of certain clinical situations.

Preparation:

1. Before using 4DryField® PH, check the integrity of the sterile barrier system. If the sterile barrier system is damaged, do not use 4DryField® PH. The local distributor must be contacted in this case.

2. Remove the bellows bottle from the sterile barrier system.

3. Remove the cap of the bellows bottle using a slight bending and rotating movement. 4DryField® PH is ready to use.

*Clinical application for **hemostasis**:*

1. Best possible cleaning and drying (e.g. suction, standard gauze) of the bleeding surfaces (see Figure 1). Excess blood should be removed. 4DryField® PH has its best effect when applied as directly as possible to the source of the bleeding.

2. Apply 4DryField® PH until complete **hemostasis** is achieved (see Figure 2). The entire wound area should be covered by 4DryField® PH. Avoid contact of the tip of the bellows bottle with blood, moisture, tissue or organs if possible to prevent clogging of the bellows bottle.

3. Whenever necessary, apply appropriate, even pressure to the bleeding surface (e.g. via standard gauze) until **hemostasis** is achieved (see Figure 3). The duration and strength of the pressure depend on the treated organ, the strength of the bleeding and the size of the wound area. Before removing the standard gauze, soak it with sterile solution to prevent it from sticking to the formed clot (if necessary). Pressure may not be necessary if bleeding persists.

4. If bleeding persists, remove the excess 4DryField® PH powder, then repeat the application of 4DryField® PH.

5. 4DryField® PH swells to its maximum volume within minutes after contact with blood or other fluids. Excess 4DryField® PH powder should be removed or soaked with sterile solution after achieving hemostasis (see Figure 4).

Fig. 1: Clean and dry the bleeding surfaces.

Fig. 2: Apply 4DryField® PH until hemostasis is achieved.

Fig. 3: Whenever necessary, apply pressure to the bleeding.

Fig. 4: Before removing a gauze, soak with saline solution.

If 4DryField® PH is also to be used for **adhesion prevention**, 4DryField® PH is applied as powder using one of the following instructions for use either on traumatized, mesothelial (or mesothelial-like) surfaces (risk zones for the formation of adhesion) and transformed into a gel that is as free of blood as possible, or first converted into a gel and then applied.

If the gel is locally penetrated by blood, the effect of 4DryField® PH for **adhesion prevention** may be reduced there.

*Clinical application for **adhesion prevention**:*

An important prerequisite for successful **adhesion prevention** is effective **hemostasis**. In many cases, 4DryField® PH can be used for this purpose as described in the above instructions for use.

For **adhesion prevention**, 4DryField® PH can be used according to one of the following two instructions for use (depending on

the clinical situation) on mesothelial (or mesothelial-like)-covered cavities (abdominal cavity, pericardium).

1. **Adhesion prevention** with 4DryField® PH as in-situ transformed gel:

1.1. Best possible cleaning (e.g. suction, standard gauze) and rinsing of the surfaces to be treated.

1.2. Apply 4DryField® PH in sufficient quantity until the entire defect is completely covered by 4DryField® PH (see Figure 5). This also applies to large wound areas (e.g. pelvic exenteration, large peritoneal, pericardial defects). 4DryField® PH that is applied to non-traumatized mesothelial (or mesothelial-like) surfaces, has no negative effects [1]. Care should be taken to ensure that the top of the powder layer is as free of blood as possible. Avoid contact of the tip of the bellows bottle with blood, moisture, tissue or organs if possible, to prevent clogging of the bellows bottle.

1.3. After applying 4DryField® PH as a powder, it is soaked in sterile solution (see Figure 6) until no white 4DryField® PH powder is visible anymore and a gel completely covers the surfaces to be treated (see Figure 7). When closing a body cavity, make sure that there are no compression effects caused by 4DryField® PH gel.

Fig. 5: Administer 4DryField® PH until the entire defect is covered.

Fig. 6: Soak the powder in sterile solution.

Fig. 7: ... until no white 4DryField® PH powder is visible and a gel covers the surface.

2. **Adhesion prevention** with 4DryField® PH as extracorporeal premixed gel:

2.1. Add 4DryField® PH powder in a suitable, clean, sterile vessel (e.g. mix or kidney dish) (see Figure 8). Depending upon the required viscosity, add approximately 10 ml[3] of sterile solution per 1g of powder [6-8] (see Figure 9). Mix 4DryField® PH and sterile solution to a homogeneous gel using an appropriate instrument (see Figure 10). Always follow the Instructions for Use for the respective vessels and instruments used.

2.2. Best possible cleaning (e.g. suction, standard gauze) and rinsing of the surfaces to be treated.

2.3. Then transfer the gel into a syringe of a suitable volume (see Figure 11) and apply it to the surfaces to be treated for **adhesion prevention** (see Figure 12). Always follow the instructions for use for the respective syringe.

OR

Apply the gel from the mixing vessel directly to the surfaces to be treated for **adhesion prevention** (see Figure 13).

Fig. 8: Place 4DryField® PH as powder into a suitable vessel.

Fig. 9: Depending upon the required viscosity, add saline solution to the powder[4].

Fig. 10: Mix 4DryField® PH and saline solution into a homogeneous gel.

3 Mixtures between 8 and 14 ml of isotonic saline solution per 1 g of 4DryField® PH powder have been clinically investigated [6-8]

4 For a firm gel, add 8 to 10 ml, for a more fluid gel, 10 to 14 ml of isotonic saline solution per 1 g of powder.

Fig. 11: Transfer gel into a syringe with suitable volume.

Fig. 12: Apply the gel from the syringe to the surface to be treated.

Fig. 13: Apply the gel directly from the mixing vessel.

f 4DryField® PH is used in conjunction with extracorporeal cardiopulmonary circulation (heart-lung machine) or an autologous ***cell saving*** (blood processing) system, use 40 µm filters and/or ***cell washing***.

If 4DryField® PH is to be applied to difficult-to-access, indicated areas using 4DFLap™ applicators, or used endoscopically or laparoscopically (minimally invasive surgery), always follow the instructions for use for the specific applicators used. The following applicators are recommended for use with 4DryField® PH:

LA0014-EU: 4DFLap™ applicator with 14 cm long application cannula
LA0038-EU: 4DFLap™ applicator with 38 cm long application cannula

It is not recommended to use other application aids.

Instructions for use for endoscopic or laparoscopic surgery

The above instructions for use for the treatment of the defined indications **hemostasis** and /or **adhesion prevention** must be followed. In addition, the following steps must be performed:

1. Necessary trocars must be installed correctly before using 4DryField® PH and 4DFLap™ applicator [23, 24]. Always follow the instructions for use for the respective trocar used to ensure proper application of 4DryField® PH to indicated areas.

Keep an eye on the tip of the 4DFLap™ applicator at all times during application to minimize the risk of accidental contact of 4DFLap™ with blood, moisture, tissue or organs and the possibility of clogging the tip of the applicator.

2. If the 4DFLap™ applicator gets clogged during use, replace it with a new 4DFLap™ applicator.

3. After use, carefully remove the 4DFLap™ applicator from the trocar.

See the 4DFLap™ instructions for use for complete information on 4DFLap™ when administering 4DryField® PH.

Fig. 14: LA0014-EU with a 14 cm long flexible application cannula extends the reach of 4DryField® PH.

Fig. 15: LA0038-EU with a 38 cm long flexible application cannula enables the application of 4DryField® PH through a trocar.

Product Training

For optimal application of 4DryField® PH, participation in product trainings or similar by the manufacturer's or distributor's product specialists is recommended prior to first use.

Contraindications

DryField® PH must not to be administered intravascularly, as this may cause embolization and in extreme cases death!

4DryField® PH is contraindicated for known hypersensitivity to starch or starch-containing substances.

Avoid application of 4DryField® PH into the bladder and ureter, as 4DryField® PH binds fluid and subsequently swells.

4DryField® PH is not indicated for adhesion prevention in the pleural cavity as use in pleural cavity has not been systematically investigated.

4DryField® PH is not indicated for the primary treatment of coagulation disorders.

4DryField® PH is contraindicated in the event of complete failure of one or more coagulation factors.

Warnings

WARNING

The safety and effectiveness of 4DryField® PH in combination with other medical devices for hemostasis and/or for adhesion prevention or adhesive agents have not been systematically investigated.

4DryField® PH has not been systematically investigated in **neurosurgery**, applied in the cranial cavity, it must be considered that 4DryField® PH swells due to the absorption of fluid.

Special care should be taken when using 4DryField® PH in conjunction with **cardiopulmonary circulation** or autologous ***cell-saving*** systems. The penetration of particles is prevented by the use of 40 µm filters and ***cell washing***. It is essential to follow the filter manufacturer's instructions for correct use.

4DryField® PH does not replace a careful surgical technique of hemostasis with ligatures or other conventional measures. When 4DryField® PH is used in the area around the osseous **foramina of the skull**, in the area of the **spinal column**, the **spinal cord** or in the area of **nerves** where nerve compression may occur (e.g. *Nervus opticus*, *Chiasma opticum*), remove excess 4DryField® PH. In particular, any remaining white 4DryField® PH should be removed. Removing the excess reduces the likelihood of disturbances of normal functions or the development of compression necrosis induced by the pressure of swelled 4DryField® PH.

When 4DryField® PH is used for hemostasis and/or adhesion prevention in the area of the right atrium of the **heart**, it is necessary to ensure that no compression can occur.

When 4DryField® PH is applied for hemostasis within the **respiratory tract**, remove any white 4DryField® PH powder after hemostasis is achieved and superficially soak the remaining 4DryField® PH with sterile solution. Removal and soaking strongly reduces the likelihood of 4DryField® PH blocking the airway.

4DryField® PH can theoretically mask tissue or vascular perforations due to its physical properties. It is therefore necessary to ensure that there is no persistent bleeding before the end of the operation.

If bleeding persists, remove the excess powder of 4DryField® PH, then repeat the application of 4DryField® PH.

After a surgery on the **heart**, it is recommended that either a drainage is inserted in the pericardium or that the pericardium is not completely closed.

4DryField® PH is a single-use product and must not be reused.

4DryField® PH is not to be used after the expiry date as indicated on the sterile barrier system and on the packaging.

Precautions

CAUTION

When used in **neurosurgery**, 4DryField® PH is not suitable for treating CSF leakage, as cerebrospinal fluid (CSF) is not a coagulable fluid.

When using 4DryField® PH on **bone surfaces** where prosthetic material is to be attached by means of adhesives or bone cement, any excess particles must be completely rinsed from the bone surfaces to be treated.

4DryField® PH should not be used if an infection is suspected. If there are signs of an infection or abscess in an area where 4DryField® PH has been applied, an additional surgery to insert a drainage may be necessary.

In **neonates** up to ten months of age, amylase activity may be reduced, which may reduce the degradation rate of products such as 4DryField® PH. No problem caused by this possible effect has been reported to date.

Hematoma may be formed after hemostasis. Drainage due to the use of 4DryField® PH for hemostasis is recommended, although clinical data show that 4DryField® PH can significantly reduce the formation of postoperative hematomas [9].

4DryField® PH can only develop its hemostatic effect in a dry state. Contact with saline solution or other fluids (e.g. antibiotics or Ringer's solution, cerebrospinal fluid, urine) can reduce the hemostatic potential.

In **urological procedures**, 4DryField® PH should not enter the renal pelvis to excude the potential for kidney stone formation.

The use of 4DryField® PH in ophthalmological procedures has not been systematically investigated.

For **diabetics**, it should be noted that 1 g of completely degraded 4DryField® PH corresponds to approximately 4 mmol glucose and would result in an increase of 0.8 mmol glucose per liter in 5 L of blood (about the average value for adults). However, since degradation takes place over days, the real values are much lower and consequently no problematic increase in glucose is to be expected even with unusually high doses.

Abdominal discomfort after surgery is a relatively common symptom, which can have a variety of causes. A causal relationship between treatment with 4DryField® PH and the onset of symptoms has not been examined.

Post-operative adhesions may occur despite the use of 4DryField® PH. Possible causes include insufficient hemostasis, a blood-infused gel, or improper use.

NOTICE

4DryField® PH is only intended for use by physicians and medical/technical professionals.

In the case of active bleedings (e.g. in the **spinal canal**), other measures may be necessary to achieve hemostasis.

4DryField® PH should not be used to control **postpartum bleedings** or **menorrhagia**.

Polysaccharides such as 4DryField® PH may interfere with the adhesion of acrylic-based adhesives.

In rare cases, 4DryField® PH degradation may be delayed or severely delayed. This can occur when large amounts of powder remain in the body without subsequent transformation into a gel. Abscesses, inflammatory reactions, encapsulation or similar consequences of delayed degradation have not been reported to date. For this reason, care should be taken to ensure that all excess powder is rinsed with sterile solution at the end of the treatment.

Side Effects

In rare cases, a selective increase of the **C-reactive protein (CRP)** concentration was reported in the first days after 4DryField® PH administration , which spontaneously returned to normal levels within a few days [25]. This increase, which may be induced by starch degradation, is not usually associated with an increase in other inflammatory parameters (e.g. body temperature, leucocy-

tes). If other inflammatory parameters are increased in addition to CRP concentration, an infection that requires treatment may be present, regardless of 4DryField® PH. In this case, appropriate measures must be taken.

Experimental Data

Due to its excellent tolerability, up to 1 g of 4DryField® PH can be administered per 1 kg body weight [1].

In an ***in vitro*** study, no significantly better growth of ***Escherichia coli*** in medium with 4DryField® PH compared to a control group (without 4DryField® PH) was demonstrated. This indicates that 4DryField® PH does not promote wound infection [10].

Furthermore, it was shown that the insertion of hernia nets combined with 4DryField® PH gel can significantly reduce adhesions [11, 12].

Clinical Data

4DryField® PH for hemostasis, especially for diffuse bleedings, has been shown to be safe and effective in clinical studies in general surgery [13, 26], gynecology [6, 14-18], plastic surgery [19], trauma surgery [9] and urology [20].

Safety and high efficacy concerning adhesion prevention were demonstrated in clinical studies including second-look surgeries in general surgery [7, 8], cardiac surgery [21] and gynecology [6, 14, 15, 17, 18, 22]. A significant reduction in the severity and extent of adhesions was confirmed [8, 17, 21, 22]. In addition, it has been shown that 4DryField® PH can be used safely and effectively for adhesion prevention, both as a powder with subsequent soaking with saline solution and in the form of an extracorporeally premixed gel in different viscosities [6].

In addition, the excellent tolerability was confirmed in an adhesion prevention study in pediatric heart surgery. Up to 2 g 4DryField® PH was used as a gel per 1 kg body weight without any degradation or tolerability problems [21].

Clinical studies in general surgery [13] and urology [20] showed that 4DryField® PH was effective in lymphostasis and in the treatment of seromas. In addition, 4DryField® PH reduced postoperative lymphocele and hematoma formation [9, 20].

Dosage forms

4DryField® PH can be supplied in 1 g, 3 g, 5 g and 9 g bellows bottles:

SK0001-EU: 4DryField® PH with 1 g filling quantity
SK0003-EU: 4DryField® PH with 3 g filling quantity
SK0005-EU: 4DryField® PH with 5 g filling quantity
SK0009-EU: 4DryField® PH with 9 g filling quantity

SK0001-AS: 4DryField® PH with 1 g filling quantity
SK0003-AS: 4DryField® PH with 3 g filling quantity
SK0005-AS: 4DryField® PH with 5 g filling quantity
SK0009-AS: 4DryField® PH with 9 g filling quantity

Depending on the registration not all variants (-EU/ -AS) are available in every country.

Storage

4DryField® PH should be stored at room temperature, protected from prolonged expose to direct sunlight. There are no other storage restrictions known beyond the conditions of normal hospital storage.

If stored properly, this product will remain fully ready for use for 5 years.

After Opening

Once the 4DryField® PH packaging has been opened, the sterile barrier is broken and there is a risk of contamination. It is recommended to use 4DryField® PH immediately after opening. Used and unused parts must be disposed of.

Note

All incidents in connection with 4DryField® PH must be reported to PlantTec Medical GmbH and the competent authority of the country in which the user and/or patient is established:

Tel.: +49 (0) 4131 394 23-60
Fax: +49 (0) 4131 394 23-8887
Email: vigilance@planttec-medical.de

Summary of safety and clinical performance

The Summary of Safety and Clinical Performance can be found after the launch of the corresponding module of the European Medical Devices Database (EUDAMED) at the following address: https://ec.europa.eu/tools/eudamed.

Disposal

Disposal of 4DryField® PH should be made in accordance with the applicable legal requirements and local regulations for the disposal of medical devices.

4DryField® PH

PROVIDES HEMOSTASIS – PREVENTS ADHESIONS

SIMPLE

Ready to use
Easy application
No special storage conditions
Simple and fast laparoscopic application with the **4DFLap™ applicator**

SAFE

Purely plant-based
- No human or animal components
- No risk of disease transmission

Excellent tolerability[1]
- Not cytotoxic
- Up to 1 g/kg body weight is well tolerated
- Does not enhance viability of tumor cells
- Promotes recovery

Free of pyrogens[2]
Resorption within 7 days[1]
No documentation requirement as per German transfusion law

EFFECTIVE

Immediate hemostasis[3-10]
Highly effective adhesion prevention[5-17]
1 g of 4DryField® PH is enough for ~25 cm^2

CE 0482

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PlantTec Medical
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PlantTec Medical GmbH
Dorette-von-Stern-Str. 10
21337 Lüneburg
Germany
Tel.: +49 4131 394 23 60
Fax: +49 4131 394 23 8887
eMail: info@planttec-medical.de

For further information and videos, please visit
www.planttec-medical.de

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