PlantTec Medical
MEDICAL SOLUTIONS INSPIRED BY NATURE

4DryField® PH

zh 使用說明書
en INSTRUCTIONS FOR USE

Instructions for use

4DryField® PH

“普蘭堤” 可吸收性止血劑及敷料

衛部醫輸字第031099號

使用前請務必詳閱原廠使用說明書並遵照指示使用

產品敘述:

本產品為可吸收性澱粉粉末,供醫師使用。

本產品由植物來源純化澱粉所產生的親水性微粒構成。流動性使本產品可在手術中簡單、安全的運用。本產品不含任何動物或人類來源成分。本產品經滅菌、不含熱原且具生物相容性、通常在7天內降解。本產品降解主要藉由澱粉酶和葡萄糖澱粉酶進行、降解所需時間取決於多個因素、包括使用方式、劑量和使用部位。

作用原理:

止血

由於本產品分子結構能夠吸取從傷口滲出之血液中的水分。血液中的細胞成分(紅血球、血小板)和蛋白質(纖維蛋白原、凝血酶)被濃縮、因此可加速凝血機制。

本產品和血液形成的止血凝塊(hemostatic plug)可阻止血液進一步滲漏。

防沾黏

由於本產品親水微粒吸收液體後會形成凝膠。為防止沾黏、可通過噴灑等滲透壓食鹽水將本產品轉化為凝膠。凝膠可作為暫時機械性屏障來將手術創傷的間皮(mesothelial)(或類間皮(mesothelial-like))表面(有可能形成沾黏的區域)分開。

適應症:

止血

本產品適用於手術中或創傷無法以加壓、結紮等常規方式控制的小動脈、微血管或靜脈出血。

防沾黏

有限的臨床證據顯示、在有間皮(mesothelial)(或類間皮(mesothelial like)的體腔內(例如:腹腔、胸腔)使用本產品、可產生防止沾黏效果。

目前無臨床結果證實本產品可使用在腹部整形手術(abdominoplasty)後預防出血之適應症。

禁忌症:

在已知對澱粉或含澱粉物質不耐受的情況下、禁止使用本產品。

注意:本產品不可使用在血管內、可能導致栓塞、在極端病例下會導致死亡!

應避免讓本產品進入泌尿系統或呼吸道、因為本產品會結合液體並膨脹。

使用方式:

應始終使用無菌技術。以下使用說明概述本產品的建議使用方式、然並不代表所有可能的臨床使用。因此、下列說明無法替代培訓課程、也無法替代臨床治療時的醫學經驗和判斷。

準備:

1. 使用本產品前、請確認包裝的完整性。如果包裝損壞不可使用、並請聯繫當地經銷商。

2. 從包裝中取出波紋噴瓶器。

3. 以輕微的彎曲和轉動取下瓶蓋、即可立即使用本產品。

止血臨床使用:

1. 盡可能徹底清潔和擦乾出血表面(利用幫浦、紗布)(見圖1)。應清除多餘血液、若將本產品盡可能直接應用在出血點可提供最佳效果。

2. 施用適量的本產品直到止血(見圖2)、應使本產品覆蓋整個傷口表面。應盡可能避免波紋噴瓶器與血液、水分、組織或器官接觸、以防止堵塞。

3. 必要時、對出血點施加適當均勻的壓力(利用紗布)直到止血(見圖3)。壓力的持續時間和大小取決於需治療的器官、出血的嚴重程度和傷口的大小。在取下標準紗布前、可視情況用生理食鹽水溶液徹底浸泡。滲血可能無須加壓。

4. 若血液持續滲出、請再次使用本產品。

5. 與血液或其他液體接觸、本產品會在幾分鐘內膨脹至最大體積。應去除過量產品或用生理食鹽水溶液浸泡(見圖4)。

圖1:清潔並擦乾出血區域 圖2:施用本產品直到止血 圖3:若有必要、加壓出血點 圖4:在取下紗布前、先用生理食鹽水浸泡

若同時將本產品用於防沾黏、可根據以下兩個說明之一將粉末施用在有間皮(或類間皮)表面(有形成沾黏風險的區域)並在盡可能避開血液下轉化為凝膠或先轉化為凝膠後使用。

若凝膠局部被血液滲透、則本產品的防沾黏效果可能會下降。

防沾黏臨床使用:

成功防止沾黏的前提是有效止血。在許多情況下、本產品可按上述說明使用。為防止沾黏、本產品可根據以下兩個說明之一用於有間皮(或類間皮)的體腔內(例如:腹腔、胸腔)。

1. 使用本產品原位轉化凝膠防沾黏:

1.1. 盡可能徹底清潔(利用幫浦、紗布)並沖洗待處理表面。

1.2. 使用適量的本產品、直到整個傷口被完全覆蓋(見圖5)。這同樣適用大傷口表面(即骨盆腔臟器切除手術、腹膜、胸膜缺損)。本產品用於非創傷性間皮(或類間皮)表面無負面影響。應注意盡可能避免血液混入粉末層、避免波紋噴瓶器與血液、水分、組織或器官接觸、以防止堵塞。

1.3. 在施用粉末後、將其用生理食鹽水溶液浸泡(見圖6)、直到看不見白色粉末且凝膠完全覆蓋處理區域(見圖7)。體腔縫合時、應注意確保本產品凝膠不會造成擠壓。

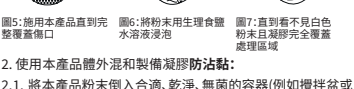


圖5:施用本產品直到完整覆蓋傷口 圖6:將粉末用生理食鹽水溶液浸泡 圖7:直到看不見白色粉末且凝膠完全覆蓋處理區域

2. 使用本產品體外混和製備凝膠**防沾黏:**

2.1. 將本產品粉末倒入合適、乾淨、無菌的容器(例如攪拌盆或腎形盤)中(見圖8)。依據所需要的黏稠度、每1 g粉末添加約10 ml生理食鹽水溶液(見圖9)。用合適的無菌器械將本產品和生理食鹽水混和成均勻的凝膠(見圖10)。必須遵守所用容器和器械的使用說明。

2.2. 盡可能徹底清潔(利用幫浦、紗布)並沖洗待處理表面。

2.3. 然後將凝膠放入適當體積的無菌注射器中(見圖11)、塗抹在待處理表面上以**防止沾黏**(見圖12)。必須遵守所用注射器的使用說明。

或

將混和容器中的凝膠直接塗抹在待處理表面上以**防止沾黏**(見圖13)。

圖8:將本產品粉末倒入合適的容器中

圖9:依據所需要的黏稠度,在粉末中添加生理食鹽水溶液

圖10:將本產品和生理食鹽水溶液混和成均勻的凝膠

圖11:將凝膠放入適當體積的無菌注射器中

圖12:以注射器將凝膠施用在待處理區域

圖13:直接從混和容器中施用凝膠

如果本產品將搭配延伸注入器施用在難以接近的指定位置或用於內視鏡、腹腔鏡(微創手術)、則必須遵守延伸注入器的使用說明、以確保本產品適用於該指定部位。建議可搭配以下延伸注入器:

LA0038-EU: 含38 cm長延伸套管的注入器

尚未確認其他注入器的效能。因此、嚴禁使用。

內視鏡或腹腔鏡手術使用說明

必須完全遵守上述止血和/或防沾黏的使用說明。此外、還須採取以下步驟:

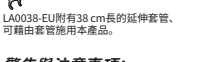
1. 要使用本產品搭配4DFlap延伸注入器前、必須正確安裝套管。必須完全遵守所使用套管的使用說明、以確保將本產品適當的施用在指定的區域。

2. 始終注視4DFlap注入器的前端、以最大程度減少可能導致注入器前端阻塞的血液、水分、組織或器官的意外接觸風險。

3. 若4DFlap注入器在使用過程中發生阻塞、應更換新的注入器。

4. 使用後、小心的從套管上取下4DFlap注入器。

有關4DFlap搭配本產品的完整訊息、請參考4DFlap使用說明。



LA0038-EU附有38 cm長的延伸套管、可藉由套管施用本產品。

警告與注意事項:

警告

- ***本產品僅供醫師使用。本產品不需使用結紮線或其他措施以替代精細止血手術。***
- ***即使使用本產品、也可能發生術後沾黏。原因可能是止血不足、凝膠被血液滲透或使用不當。***
- ***本產品尚未在神經外科中進行系統性研究。如果用於顱腔、必須考慮到產品由於吸收液體而膨脹。本產品不適用於治療腦脊液排出、因為腦脊液不是可凝固的液體。***
- ***在顱骨骨質區域、脊柱區域、脊髓區域或可能發生壓迫神經的區域(例如視神經、視交叉神經)完成止血後、需移除過量的粉末。特別是、還維持白色的粉末應移除。除去過量粉末可降低因本產品膨脹造成正常功能紊亂或發展出壓迫性壞死的機率。***
- ***本產品在眼科手術中的安全和有效性尚未得到系統性的研究。***
- ***本產品不應用於活動性出血的情況下(例如、椎管處)。可能需要採取其他措施來止血。***
- ***當使用在右心房區域時應確保不會造成擠壓。***
- ***如果本產品在手術過程中接觸到膀胱或尿道、需要注意本產品在接觸液體後會膨脹、影響尿道的通暢。***
- ***本產品不應用於疑似感染的部位。若本產品使用部位出現感染跡象可能需要重新操作置入引流管。***
- ***本產品尚未研究使用在幼兒或孕婦的狀況。在十個月大的新生兒中、澱粉酶活性可能降低、使本產品的吸收速率下降。***
- ***本產品不應用於控制產後出血或經血過多的情形。***
- ***尚未有本產品與其他止血或黏合劑搭配的研究報告。目前僅證實本產品與膠原或纖維素基質的產品搭配沒有問題。***
- ***多醣體(Polysaccharides)(如本產品)會削弱含丙烯酸黏合劑(Acrylic-containing adhesives)的黏附。***
- ***尚未有本產品與其他醫療設備搭配以防止沾黏的安全性及有效性研究報告。***
- ***成人之使用上限劑量為<0.12 g/kg (體重)。***

注意事項

- ***本產品不適合用於凝血障礙的初步治療。***
- ***止血後會自然形成血腫。儲管臨床數據顯示本產品可顯著減少術後血腫的形成、但不建議因使用本產品而取消插入引流管。未引流的血腫所引發的纖維蛋白溶解可能導致傷口深處再次出血。***
- ***本產品只有在乾燥狀態下可達到止血效果、與食鹽水或其他液體(例如抗生素或林格式液、腦脊液、尿液)接觸會降低止血效果。***
- ***使用本產品進行子宮內治療後、建議在第一個月經週期內避免受孕。***
- ***在泌尿外科手術中、本產品不應進入腎盂或輸尿管、以避免造成腎結石。***
- ***理論上來說、使用本產品塗抹一層可覆蓋像是組織或血管穿孔。不論是否使用本產品、都建議在手術結束前仔細檢視手術區域。***
- ***本產品以無菌產品(輻射滅菌)提供、因會降低效能而不可重複滅菌、也因此不可重複使用。***
- ***為避免汙染、不可重複使用本產品。未使用的部分應被丟棄。***
- ***請勿在超過包裝註明有效期限後使用本產品。***

副作用:

在極少數情況下、發現使用本產品後幾天內C反應蛋白(CRP)的選擇性增加、而在幾天後下降到正常範圍的水平。這可能是因澱粉降解所引起的、不會與其他發炎指數(例如體溫、白血球)一起發生。如果除了CRP外、其他發炎指數也在上升、可能存在與本產品無關但需要治療的感染。在此情形下、須採取適當的措施。

在極少數情況下、本產品的降解可能會延遲或非常緩慢。當大量粉末留在體內而沒有逐漸轉化為凝膠時、就會發生這種情況。然而、目前為止沒有因延遲降解而出現的膿腫、發炎反應、組織包膜或類似情形。

在10個月大的新生兒中、澱粉酶活性可能會降低、因此會降低本產品的降解速度。目前為止沒有因這種效應引發的問題。

儲存環境:

本產品不應曝露在極端溫度和陽光直射下。拆封後有汙染風險、建議在打開波紋噴瓶器後、未使用的部分應丟棄以避免汙染。

產品規格:

本產品可供應包含波紋噴瓶器的1 g、3 g、5 g或9 g的包裝:

SK0001-EU:5 x 1 g 4DryField PH、1 x 使用說明書、1 x紙盒
SK0003-EU:3 x 3 g 4DryField PH、1 x 使用說明書、1 x紙盒
SK0005-EU:3 x 5 g 4DryField PH、1 x 使用說明書、1 x紙盒
SK0009-EU:3 x 9 g 4DryField PH、1 x 使用說明書、1 x紙盒

LA0038-EU：18 x 38 cm 4DryField PH Applicator、1 x 使用說明書、1 x紙盒

產品效期：

5年(25°C以下)

製造業者名稱/地址：Manufactured by bmp, bulk medicines & pharmaceuticals production GmbH (Address: Neuhofer Weiche 48, D-19370 Parchim, Germany) for PlantTec Medical GmbH (Address: Dorette-von-Stern-Straβe 10, D-21337 Lüneburg, Germany)

醫療器材商名稱：埃默高有限公司

醫療器材商地址：依所轄衛生局最新核定之醫療器材商地址內容刊載

(市售品須刊載實際地址)

4DryField® PH

"PlantTec" Absorbable hemostatic agent and dressing

TFDA License Number : 031099

Please read carefully and follow the manufacturer IFU before use.

Description

4DryField® PH is a medical device, a resorbable starch powder, for application by physicians or medical-technical professionals.

4DryField® PH consists of hydrophilic, microporous particles manufactured from processed starch of plant-based origin. The free-flowing properties

of 4DryField® PH permit simple and safe application during surgical interventions or to injuries.

4DryField® PH does not contain any components of human or animal origin.

4DryField® PH is a fine, dry powder, which is biocompatible, free of pyrogens, sterile, and is usually resorbed within seven days. Degradation of 4DryField® PH mainly takes place via amylase and glucoamylase. Duration of degradation depends upon several factors, including application technique, amount and where applied.

Mode of Action

*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 consequence, cellular hemostasis and plasmatic hemostasis (coagulation) accelerate and a stable hemostatic plug is formed from 4DryField® PH and blood.

The clot formed from 4DryField® PH and blood closes the bleeding source and stops further blood leakage.

*For **adhesion prevention**:*

The hydrophilic, microporous particles form a gel when fluid is absorbed due to the particular molecular structure of 4DryField® PH. For prevention of postoperative adhesions, 4DryField® PH is transformed into a gel with isotonic saline solution.

This gel functions as a temporary mechanical barrier that separates traumatized mesothelial (or mesothelial-like) surfaces (areas that are at risk of the formation of adhesions) during postoperative healing.

Indications

*For **hemostasis**:*

4DryField® PH is indicated in cases in which bleeding from arterioles, capillaries, or veins during surgical interventions or in the case of injuries cannot or cannot effectively be controlled by pressure, ligatures, or other conventional measures.

*For **adhesion prevention**:*

4DryField® PH is also indicated when the formation of postoperative adhesions is to be prevented following surgical interventions or in the case of injuries in cavities with a mesothelial (or mesothelial-like) lining.

There are no clinical data proving that 4DryField® PH can be used to prevent bleeding after abdominoplasty.

Contraindications

4DryField® PH is contraindicated in the presence of known hypersensitivity to starch or starch-containing substances.

CAUTION: 4DryField® PH must not be administered intravascularly, because this can lead to embolization and, in extreme cases, to death!

Administration of 4DryField® PH into the ureter is to be avoided, because 4DryField® PH binds fluids and swells.

Directions for Use

Aseptic techniques should always be used. 4DryField® PH isonly intended for use by physicians and medical-technical professionals. The following directions for use provides an

overview of the recommended use of 4DryField® PH. The described procedures do not represent all possible clinical procedures. Therefore, this instructions for use can neither replace product training nor medical experience and judgement in the treatment of certain clinical situations.

Preparation:

1. Check the integrity of the packaging before using 4DryField® PH. 4DryField® PH must not be used if the packaging is damaged. If this is the case, contact your local distributor.

2. Remove bellows bottle applicator from the packaging.

3. Remove bellows bottle applicator cap with a slight bending and turning movement. 4DryField® PH is immediately ready for use.

*Clinical application for **hemostasis**:*

1. Clean and dry the bleeding surfaces as thoroughly as possible (e.g., suction, standard gauze) (see Figure 1). Excess blood should be removed. 4DryField® PH displays its optimum effect if it is applied as directly as possible to the source of bleeding.

2. Administer 4DryField® PH in sufficient quantity until hemostasis has occurred (see Figure 2). The entire wound surfaces should be covered with 4DryField® PH. Wherever possible, contact of the bellows bottle applicator with blood, moisture, tissue or organs is to be avoided in order to prevent blocking of the bellows bottle applicator.

3. Whenever necessary, apply appropriate even pressure to the bleeding (e.g., with standard gauze) until hemostasis is achieved (see Figure 3). Duration and magnitude of the pressure

depend upon the organ being treated, the severity of bleeding, and the size of the wound surface. Before removing the standard gauze, if appropriate, soak it thoroughly with isotonic saline solution. Bloody oozing may not require application of pressure.

4. If bloody oozing persists, re-administer 4DryField® PH.

5. After contact with blood or other fluids, 4DryField® PH swells within minutes to reach its maximum volume. Excess 4DryField® PH should be removed or soaked with isotonic saline solution after hemostasis is achieved (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 according to one of the two following directions for use either on traumatized mesothelial (or mesothelial-like) surfaces (areas that are at risk of the formation of adhesions) and transformed into a gel that is as free 4DryField® PH of blood as possible or fi rst transformed into the gel form 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 according to the above directions for use.

For **adhesion prevention**, 4DryField® PH can be employed in cavities with a mesothelial (or mesothelial-like) lining (e.g., abdominal cavity, chest cavity) according to one of the two following directions for use.

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

1.1. Clean as thoroughly as possible (e.g., suction, standard gauze) and rinse the surfaces to be treated.

1.2. Administer 4DryField® PH in sufficient quantity until the entire defect is completely covered by 4DryField® PH (see Figure 5). This also applies to large wound surfaces (i.e., pelvic exenteration, large peritoneal, pleural). 4DryField® PH that is administered to non-traumatized mesothelial (or mesothelial- like) surfaces has no negative effects [1]. Care should be taken to achieve a powder layer that is as free of blood as possible. Wherever possible, contact of the bellows bottle applicator with blood, moisture, tissue or organs is to be avoided in order to prevent blocking of the bellows bottle applicator.

1.3. Following application of 4DryField® PH as powder, this is soaked with isotonic saline solution (see Figure 6) until no white 4DryField® PH is visible and a gel completely covers the surfaces to be treated (see Figure 7). Care should be taken to ensure that there is no compression effect by 4DryField® PH as gel when body cavities are closed.

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

Fig. 6: The powder is soaked with saline 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 pre-mixed gel:

2.1. Place 4DryField® PH as powder into a suitable, clean, sterile vessel (e.g., mixing bowl or kidney dish) (see Figure 8). Depending upon the required viscosity, add about 10 mL3 isotonic saline solution per 1 g of powder [6-8] (see Figure 9). Mix 4DryField® PH and isotonic saline solution with a suitable, sterile instrument into a homogeneous gel (see Figure 10). The instructions for use for the respective vessels and instruments used must always be followed.

2.2. Clean as thoroughly as possible (e.g., suction, standard gauze) and rinse the surfaces to be treated.

2.3. Then either place the gel either into a sterile syringe of suitable volume (see Figure 11) and apply to the surfaces to be treated for **adhesion prevention** (see Figure 12). The instructions for use for the respective syringe used must always be followed.

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.

OR

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

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.

If 4DryField® PH is to be administered with the aid of additional applicators to indicated surfaces diffi cult-to-access or to be used endoscopically or laparoscopically (minimally invasive procedure), the instructions for use for the respective applicators used must always be followed to ensure a suitable application of 4DryField® PH to indicated surfaces. The following applicators are recommended for use with 4DryField® PH:

LA0038-EU: 18 x 4DFLap™ applicator with 38 cm long application cannula, 1 x instruction for use, 1 x carton

The use of other applicators has not been investigated. Therefore, it is advised against strictly.

Directions for Use for Endoscopic or Laparoscopic Surgery

The above directions for use for application for **hemostasis** and/or **adhesion prevention** must completely be followed, in addition, the following steps should be taken:

1. Necessary trocars must be installed correctly before using 4DryField® PH and 4DFLap™ applicator. The instructions for use for the respective trocar used must always be followed to ensure a suitable application of 4DryField® PH to indicated surfaces.

2. Maintain a direct view on the 4DFLap™ applicatior tip at all times in order to minimize the risk of inadvertent contact with blood, moisture, tissue, or organs that could result in blocking of the applicator tip.

3. If 4DFLap™ applicator does become blocked during use, it should be replaced with a new 4DFLap™ applicator

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

Complete information on 4DFLap™ for administration of 4DryField® PH are given in the instructions for use of 4DFLap™.

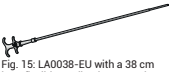


Fig. 15: LA0038-EU with a 38 cm long flexible application cannula enables the application of 4DryField® PH through a trocar.

Warnings

4DryField® PH is only suitable for use by physicians or medical- technical professionals. 4DryField® PH does not replace a careful surgical technique for hemostasis with ligatures or other conventional measures.

Postoperative adhesions may occur even if 4DryField® PH is used. Possible causes may be insufficient hemostasis, a gel penetrated by blood or improper use.

4DryField® PH has not been systematically investigated in neurosurgery. If applied in the cranial cavity, it must be taken into account that 4DryField® PH swells due to the absorption of fluid. 4DryField® PH is not suitable for treating the discharge of cerebrospinal fluid, since cerebrospinal fluid is not a coagulable fluid.

Excess 4DryField® PH is to be removed when 4DryField® PH is used in the area around the osseous foramina of the skull, in the area of the spinal column, of the spinal cord, or in the area of nerves in which nerve compression can occur (e.g., Nervus opticus, Chiasma opticum). In particular, 4DryField® PH that is still white should be removed. The likelihood of disturbances to normal functions or development of compression necroses brought on by swelling of 4DryField® PH is reduced upon removal of the excess.

The safety and effectiveness of 4DryField® PH in ophthalmological procedures have not yet been systematically investigated.

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

Care should be taken to ensure that no compression can be triggered when used for hemostasis and/or adhesion prevention in the area of the right atrium of the heart.

If 4DryField® PH comes into contact with the bladder or the urethra during the operation, it should be noted that 4DryField® PH swells after contact with fluid and can affect the patency of the urethra.

4DryField® PH should be used with caution in contaminated areas. 4DryField® PH should not be used if infections are suspected. Signs of infection or abscess in an area in which 4DryField® PH was administered may require re-operation for insertion of a drainage.

4DryField® PH has not been investigated in pregnant women. In new-borns up to ten months of age, amylase activity may be diminished, so that the degradation rate of products such as

4DryField® PH can be reduced.

4DryField® PH should not be used for control of postpartum bleeding or in the case of menorrhagia.

Combination of 4DryField® PH with other hemostats or adhesives has not been 4DryField® investigated. There were no problems with previously known applications of 4DryField® PH with, e.g., collagen- or cellulose-based products.

Polysaccharides such as 4DryField® PH can impair adhesion of acryl-containing adhesives.

The safety and effectiveness of 4DryField® PH in combination with other medical devices for adhesion prevention has not been systematically investigated.

The maximum dosage for adult is <0.12 g/kg (body weight).

Precautions

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

After hemostasis, the formation of a hematoma can naturally occur. Although clinical data show that 4DryField® PH can significantly reduce the formation of postoperative hematomas [9], it is not recommended to avoid the insertion of a drainage due to the use of 4DryField® PH. Fibrinolysis triggered by non-drained hematoma can theoretically lead to renewed bleeding in the depth of the wound.

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

After intrauterine treatment with 4DryField® PH, it is recommended to avoid conception during the first menstrual cycle.

In urological procedures, 4DryField® PH should not enter the renal pelvis or the ureter in order to exclude the potential for the formation of kidney stone.

It is theoretically conceivable that a layer of 4DryField® PH can mask, e.g., tissue or vascular perforations. Regardless of the use of 4DryField® PH, a careful monitoring of the surgical area before ending the surgery is strongly recommended.

4DryField® PH is supplied as a sterile product (using irradiation), cannot be re-sterilized because of loss of efficacy and, thus, cannot be re-used.

4DryField® PH is a disposable product. So as to avoid contamination, do not re-use a unit of 4DryField® PH multiple times. Unused portions are to be disposed of.

Do not use 4DryField® PH after the expiry date indicated on the packaging.

Side Effects

In rare cases, a selective increase in the concentration of the C-reactive protein (CRP) was reported during the first few days after the application of 4DryField® PH, which spontaneously returned to values in the normal range within a few days. This increase, possibly induced by starch degradation, does not usually occur together with an increase in other inflammatory parameters (e.g., body temperature, leukocytes). If further inflammatory parameters in addition to the CRP concentration are also increased, an infection requiring treatment may be present, independent of 4DryField® PH. In this case, appropriate measures must be taken.

In rare cases, the degradation of 4DryField® PH can be delayed or very delayed. This can occur when large amounts of powder remain in the body without subsequent transformation into a gel. However, abscesses, inflammatory reactions, tissue-encapsulations, or similar following delayed degradation have not been reported to date.

In new-borns up to ten months of age, amylase activity may be diminished, so that the degradation rate of products such as 4DryField® PH can be reduced. A problem caused by this effect has not been reported to date.

Storage

4DryField® PH should not be exposed to extreme temperatures and direct light irradiation. After the packaging of 4DryField® PH has been opened, there is a risk of contamination. It is recommended to use 4DryField® PH up after opening the bellows bottle applicator. Unused portions are to be discarded in order to avoid contamination.

How Supplied

4DryField® PH can be supplied in bellows bottle applicators containing 1 g, 3 g, 5 g, or 9 g:

SK0001-EU: 5 x 1 g 4DryField® PH, 1 x instruction for use, 1 x carton
SK0003-EU: 3 x 3 g 4DryField® PH, 1 x instruction for use, 1 x carton
SK0005-EU: 3 x 5 g 4DryField® PH, 1 x instruction for use, 1 x carton
SK0009-EU: 3 x 9 g 4DryField® PH, 1 x instruction for use, 1 x carton

LA0038-EU 18 x 38 cm 4DryField PH Applicator,
1 x instruction for use, 1 x carton.

Shelf Life

5 years (not over 25°C).

Reporting Note

All incidents that have occurred in a contributory cause with 4DryField® PH must be reported to PlantTec Medical GmbH and the national 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

Disposal

4DryField® PH is to be disposed according to the applicable legal regulations for disposal of medical products.

Unused portions of 4DryField® PH as well as used bellows bottle applicators and, if applicable, 4DFLap™ are to be disposed of as regular waste, which has no special requirements regarding the collection and disposal from an infection prevention point of view.

There are no special requirements for packaging made of plastic, metal, and cardboard from an infection prevention and environmental hygiene point of view.

Manufacturer Name / Address: Manugactured by bmp, bulk medicines & pharmaceuticals production GmbH (Address: Neuhofer Weiche 48 D-19370 Parchim, Germany) for PlantTec Medical GmbH (Address: Dorette-von-Stern-Straße 10, D-21337 Lüneburg, Germany)

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EXPLANATION OF SYMBOLS

	Manufacturer
	Date of manufacture
	Use-by year and month
LOT	Lot number
REF	Reference number
STERILE R	Method of sterilization: using irradiation
	Do not resterilize
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Do not re-use
	Consult instruction for use
	Attention, see instruction for use
MD	Medical device
	Applicator (content)
	Box (with applicators)
CE	CE-marking
UA.TR.120	National conformity mark (Ukraine technical regulations)

4DryField® PH

PlantTec Medical
MEDICAL SOLUTIONS INSPIRED BY NATURE

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