



### Kanamayı Durdurmaya Yardımcı Emilebilen Tampon

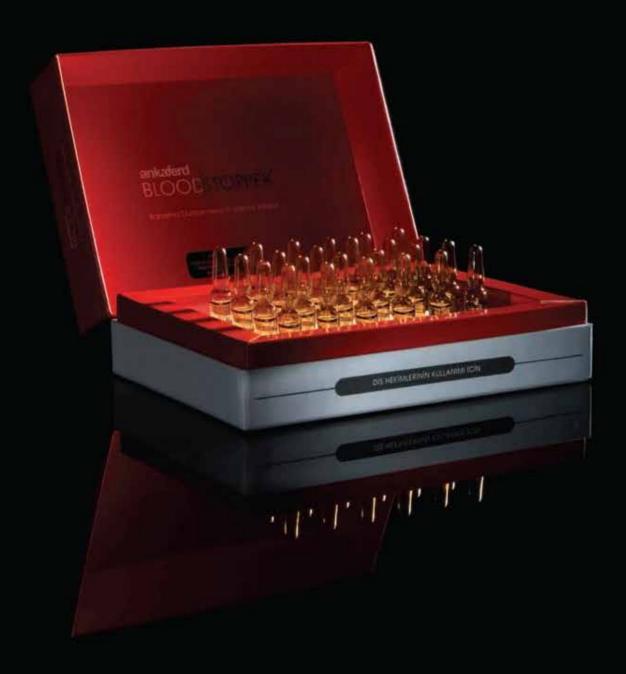


• EMİLEBİLEN ISLAK TAMPON 1Adet - 1Kutu





### Kanamayı Durdurmaya Yardımcı Ampul



• AMPUL 24 adet - 1 kutu





Diş Hekimleri neden Ankaferd BloodStopper (ABS) kullanmayı tercih ederler? Kanama kontrolünde yüz yılın ürünü olarak kabul edilen Ankaferd BloodStopper, kontrol altına alınamayan kanamalarda dahi kısa sürede kanama kontrolü sağlayarak hekime büyük kolaylık sağlar. Bu durum hekime müdahale rahatlığı sağlarken hastanın da konforunu arttırır.

#### Dental Girişimlerde Gelişen Kanamaların Kontrolünde Ankaferd BloodStopper Uygulamaları

Cerrahi girişim sonrasında oluşan kanamalı bölgeye dental anestezi için kullandığınız enjektör yardımıyla kuvvetlice püskürtün. 'İLK' püskürtmenin kuvveti ve bu ilk püskürtme ile doku hasarının oluştuğu kanama bölgesi kaplanır. Canlı şekilli kan elemanlarından ve ABS'den oluşan ağ (network) ilgili bölgeyi kaplar. Kanamanın olduğu bölge, tek püskürtme ile kaplanamayacak kadar büyükse aynı biçimde diğer bölgelere de püskürtmeler yapılabilir. ABS, püskürtme gerçekleştirilen kanama alanlarında oluturduğu ağ çerçevesinde canlı eritrosit aggregasyonu ve fizyolojik hemostaz regülasyonu yaparak kanamayı kontrol altına alacaktır. Bu süreci olumsuz etkileyecek tarzda etkin bir ilk püskürtmeyi takiben aynı alana ardı ardına püskürtmeler yapılması, gelişen fizyolojik ağı olumsuz etkileyebilir. Bu nedenle aynı alana tekrar püskürtme yapma ihtiyacı hissedilirse ilk püskürtmenin etkinliğine izin verecek tarzda 45 saniye kadar beklenmesi yararlı olur.İlk püskürtmenin kuvvetli ve kaplayıcı etkinliğinin olmadığı düşünülüyorsa kanamalı bölgeye dental enjektör ile kuvvetlice tekrar 'İLK' püşkürtme kabul edecek tarzda uygulama mümkündür. Uygulamaların bilinen herhangi bir yan etkisi yoktur. Ancak diş beyazlatma girişimleri sırasında tekrarlayan püskürtmeler yapıldığında ürünün bitkisel içeriği bu işlemde kullanılan kimyasal maddelerle etkileşerek patolojik önemi olmayan diş yüzeylerinde fırçalama ile çıkabilen renklenmelere yol açabilir. Bu nedenle izole olarak diş beyazlatma girişimi yapılacak hastalarda kontrolsüz kanama beklenmiyorsa standart kan durdurucu yöntemler tercih edilebilir.

### **Dental Girişimlerde Kullanım Alanları**

- Komplikasyonlu ya da normal diş çekimi operasyonlarında
- Süt dişlerinde, kron pulpa amputasyonunu takiben oluşan kanamalarda
- Detartraj ve küretaj işlemleri sonrası oluşan diş eti kanamalarında
- Diş eti flap operasyonları sonrasında
- İmplantasyon işlemleri sırasında ve sonrasında oluşan kanamalarda
- Perimplantitis tedavisinde
- Sistemik medikal sorunlu dental hastalıklarda; ilgili tıbbi branşın konsültasyonuyla, hemorajik komplikasyon riskli diş ve diş eti hastalıklarına kanama kontrol amaçlı lokal dental girişimlerde
- Yara iyileşmesinin gecikeceğinin düşünüldüğü sistemik hastalıkları bulunan hastalarda iyilesmeyi hızlandırmak amacıyla
- Kanama problemi oluşturacak hemofili gibi bir hastalığı olan hastalarda kullanılan faktör miktarını azaltmak amacıyla
- Antikuagülan tedavi altında bulunan ve çeşitli nedenlerle ilaç tedavisi kesilemeyen hastalarda kanama kontrolü amacıyla







Ampulü OPC işaretli yerinden kırınız



Enjektöre çekiniz. Lütfen dental enjektör kullanınız.



Kanamalı bölge



Kanamalı bölgeye damlatarak veya püskürterek uygulayınız. Kesinlikle enjekte edilmez



Etkisini gösterip kanamayı durdurana kadar uygulamayı sürdürünüz

#### Birim Formülü:

1 ml'lik ürün içerisinde; Urtica dioica (kurutulmuş kök ekstresi) 0.06 mg, Vitis vinifera (kurutulmuş yaprak ekstresi) 0.08 mg, Glycyrrhiza glabra (kurutulmuş yaprak ekstresi) 0.09 mg, Alpinia officinarum (kurutulmuş yaprak ekstresi) 0.07 mg, Thymus vulgaris (kurutulmuş toprak üstü ekstresi) 0.05 mg bulunmaktadır.

#### Tıbbi Özellikleri:

"Ankaferd BloodStopper Ampul"; plazma ve serum içerisinde kısa sürede hemostazı fizyolojik olarak yönlendiren özgül bir eritrosit-protein ağı oluşturur. Kan durdurulması işlemi temel olarak doku onarıcı bu ağ üzerinden yürütülmektedir. "Ankaferd BloodStopper Ampul" hem normal hemostatik değerlere sahip bireylerde hem de birincil ya da ikincil hemostaz bozukluğu olan hemorajik diyatezli hastalarda, örneğin hemofili hastalarında, kanamayı durdurmaya yardımcıdır. İn vitro çalışmalarda çok sayıda bakterilere (A.baumannii, E.coli, K.pneumonia, P.aeruginosa, Enterobacter spp., Stenotrophomonas maltophilia, Metisilin dirençli Staph. aureus (MRSA), Metisilin dirençli coagulase negatif Staphylococcus, ve vankomisin-rezistan enterokok (VRE) gibi) ve mantarlara (Zygosaccharomyces bailii, Candida albicans, Mucor rouxii, Mucor brunnea, Aspergillus flavus, Aspergillus parasiticus gibi) karşı etkili olduğu gösterilmiştir. Bu nedenle infekte hemorajik dokularda tedaviye yardımcı kullanımı yararlı olabilir.

"Ankaferd BloodStopper Ampul" kanamayı durdurucu ürün olarak; spontan, travmatik ve-veya cerrahiye sekonder yoğun dış kanamaların durdurulmasında yardımcıdır. "Ankaferd BloodStopper Ampul" damar içine ya da kan dolaşım sistemine yerleştirilmemelidir.

• Hemofili, diabetes mellitus ve hipertansiyon hastalarında hekim gözetiminde güvenle kullanılabilir.

#### Önerilen Kullanım Yeri:

Diş tedavisi ve diş operasyonları sonrası oluşabilecek dış kanamalarda ve cerrahi sekonder dış kanamalarda kanamayı durdurmaya yardımcı olarak kullanılır.





Aktas, Alper Er, Nuray Kiris, Serkan Koseoglu, Osman T. Haznedaroglu, Ibrahim C.

The Efficiency of Ankaferd Blood Stopper During the Dental Surgery in Hemorrhagic Diathesis: Case Series

UHOD-ULUSLARARASI HEMATOLOJI-ONKOLOJI DERGISI

24,1,60,6410.4999/uhod.12046,2014

Dental surgery in patients with hemorrhagic diathesis represents a great clinical challenge regarding the bleeding and complicated infections. There are various methods and materials for haemostasis of these patients. One of them is ABS (Ankaferd Blood Stopper), which has been approved for the clinical management of external post-surgical and dental surgery bleedings in Turkey. ABS could be effectively used both in individuals with normal haemostatic parameters and in patients with deficient primary hemostasis and/or secondary hemostasis. In this case series, total 11 patients who have various illnesses especially hemorrhagic diathesis are presented. ABS application demonstrated successful clinical management of the patients with various types of hemorrhagic diathesis.

Aktop, Sertac Emekli-Alturfan, Ebru Ozer, Cuneyt Gonul, Onur Garip, Hasan Yarat, Aysen Goker, Kamil

Effects of Ankaferd Blood Stopper and Celox on the Tissue Factor Activities of Warfarin-Treated Rats

**CLINICAL AND APPLIED THROMBOSIS-HEMOSTASIS** 

20,1,16,2110.1177/1076029613490254

AB The aim of this study is to evaluate the effect of these new generation hemostatic agents on early-stage soft tissue healing of warfarin-treated rats by measuring the tissue factor (TF) activities. Rats in the warfarin group were treated intraperitonally with 0.1 mg/kg warfarin, and rats in the control group were treated with 1 mL/kg saline. All rats had 3 incisions on dorsal dermal tissue applied Celox, Ankaferd Blood Stopper (ABS), or no hemostatic agent. Six rats from each group were killed on day 4, and the other 6 were killed on day 8. Prothrombin time (PT) and TF activities were evaluated, respectively. Both the hemostatic agents positively affected the hemostasis. Warfarin treatment increased the PT levels as expected. Celox-treated dermal tissues had higher TF activity when compared to ABS-treated ones. The ABS affected the early-stage healing positively in clinical aspect, whereas Celox was more effective on hemostasis by means of increasing TF activities.

Kazancioglu, Hakki Oguz Cakir, Onur Ak, Gulsum Zulfikar, Bulent

The Effectiveness of a New Hemostatic Agent (Ankaferd Blood Stopper) for the Control of Bleeding following Tooth



Extraction in Hemophilia: A Controlled Clinical Trial

TURKISH JOURNAL OF HEMATOLOGY

30, 1, 19, 2410.4274/tjh.2012.0036

Objective: To assess the hemostatic efficacy of a new local hemostatic agent, Ankaferd Blood Stopper (ABS), for the control of bleeding following tooth extraction in hemophiliacs.

Materials and Methods: Simple tooth extractions were performed in 27 hemophilia A patients. In the treatment group (n=17) local hemostasis was achieved via application of ABS to the extraction sockets, whereas in the control group (n=10) local hemostasis was achieved via direct packing with gauze. Results: In all, 57 (21 primary and 36 permanent) teeth extractions were performed in 27 hemophilia A patients. There were no significant differences in age or factor VIII level distribution between the 2

groups (p>0.05). The most significant clinical difference between the

groups was associated with the use of ABS; those in the treatment group had significantly shorter duration of bleeding (p=0.002). Conclusion: This is the first study to evaluate the efficacy of ABS for the control of bleeding following tooth extraction in hemophiliacs. ABS can be considered an alternative local hemostatic agent for reducing clotting factor concentrates in hemophilia patients.

Cakarer, Sirmahan Eyupoglu, Esra Gunes, Cigdem Ozcamur Kuseoglu, Banu Gurkan Berberoglu, Hulya Kocak Keskin, Cengizhan

Evaluation of the Hemostatic Effects of Ankaferd Blood Stopper During Dental Extractions in Patients on Antithrombotic Therapy

CLINICAL AND APPLIED THROMBOSIS-HEMOSTASIS

19. 1. 96. 9910.1177/1076029611435836

This study evaluated the early hemostatic effects of a novel hemostatic agent (Ankaferd blood stopper [ABS]) during dental extractions in

patients on antithrombotic therapy, without interruption or diminution of the medication. In total, 25 patients, who are on antithrombotic therapy and in need of simple dental extractions, were randomized into 2 groups. In group I (control group), which consisted of 10 patients, local hemostasis was achieved with direct packing with gauze. In group II, which consisted of 15 patients, local hemostasis was achieved by the local application of ABS on the extraction sockets. The bleeding time was compared between 2 groups following the tooth extraction. The bleeding time in the dental sockets treated with ABS was statistically lower compared to the sockets of the control group (p = 0.0001). It is concluded that the dental extractions could be performed without interruption of the medication in patients on antithrombotic therapy. The ABS appears to be sufficient as an alternative hemostatic agent.

Balcik, Oziem S. Koroglu, Mustafa Cipil, Handan Kaftan, Osman Maral, Senem Gurel, Ayse Goker, Hakan Haznedaroglu, Ibrahim C. Kosar, Ali

A Placebo-Controlled, Randomized, Double-Blinded, Cross-Over Phase-I Clinical Study Indicating the Safety of Topical Ankaferd Hemostat in Healthy Volunteers

UHOD-ULUSLARARASI HEMATOLOJI-ONKOLOJI DERGISI

ankaferd



#### 22, 4, 267, 27410.4999/uhod.10124

Ankaferd is a folkloric medicinal plant extract which has historically been used as an hemostatic agent in traditional Turkish medicine. Ankaferd Hemostat (ABS, Ankaferd BloodStopper (R)) includes the plants of Thymus vulgaris, Glycyrrhiza glabra, Vitis vinifera, Alpinia officinarum and Urtica dioica. The hemostatic effects of ABS have been established in the in vitro and in vivo studies in the Literature. The basic mechanism of action for ABS is the formation of an encapsulated protein network representing the focal points for the vital erythroid aggregation. The topical usage of ABS as a hemostatic agent in clinical hemorrhages and during dental interventions provided the first clues about the safety and efficacy of ABS in humans. The aim of this study is to search topical safety of ABS in a phase I randomized, double-blinded,cross-over, placebo controlled clinical study in healthy volunteers. Twenty-four healthy volunteers (11 males and 13 females, aged 18-44years) compatible with the study protocol were enrolled into the study. In this study, topical ABS application for 120 minutes is not different from the placebo, in terms of both the local skin findings and systemic laboratory tests. Based on those data, it is concluded that topical application of ABS is safe and tolerable in humans.

Aktas, Alper Er, Nuray Onur, Mehmet A. Tan, Gamze Hayran, Mutlu

Effects of Ankaferd Blood Stopper on Nerve Conductance: An Experimental Study on the Rat Sciatic Nerve

UHOD-ULUSLARARASI HEMATOLOJI-ONKOLOJI DERGISI

22, 1, 9, 1410.4999/uhod.10112

The aim of this study was to evaluate the effect of AnkaferdBloodStopper(R) (ABS) on nerve conductance. ABS consists of traditional haemstatic ingredients, and has been officially approved for topical use in the management of external hemorrhage and dental surgical procedures. The basic mechanism of action for ABS is the formation of an encapsulated protein network that provides focal points for vital erythrocyte aggregation. Total of 6 albino rats were used for nerve conduction experiments. Isolated rat sciatic nerves were placed in two suction electrodes in a pyrex bath containing a tyrode solution. Concentration-dependent evoked compound action potentials (CAP) of the nerves were recorded for 60 minutes within the ABS solution. The readings were conducted for 60 more minutes after washing the nerves. A significant reduction cAP voltage in 1000 mu I test groups was recorded. The pairwise comparisons showed that the only significant differences were between 1000 mu I and the rest of the solutions, but this effect was totally reversible after washing with tyrode solution at 120 min readings. No significant difference exists among groups for any other parameters. Observation of recovery of the cAPs on washed specimens, demonstrating that ABS has a reversible adverse effect on nerve conductance irrespective of the concentration applied.

Yilmaz, Erkan Gulec, Sukru Torun, Didem Haznedaroglu, Ibrahim Celalettin Akar, Nejat

The effects of Ankaferd (R) Blood Stopper on transcription factors in HUVEC and the erythrocyte protein profile

TURKISH JOURNAL OF HEMATOLOGY

28, 4, 276, 28510.5152/tjh.2011.39

Objective: Ankaferd (R) Blood Stopper (ABS) is an herbal extract that has historically been used as a hemostatic agent in traditional Turkish medicine. ABS is comprised of a standardized herbal mixture of T vulgaris, G. glabra, V vinifera, A. officinarum, and U. dioica. ABS's basic mechanism of action is the formation of an encapsulated protein web, which represents the focal point for vital erythrocyte masses. The hemostatic effects of ABS have been observed in vitro and in vivo. ABS was registered as a hemostatic agent for external hemorrhages and dental bleeding following phase I randomized, double-blind crossover placebo-controlled clinical research, and safety and efficacy reports. In terms of the potential use of ABS, transcription factors may be novel factors that play a role in the hemostatic and other pleiotropic effects of ABS. Materials and Methods: Hence, the present study aimed to investigate the effects of ABS on endothelium, and possible transcription factor changes in HUVEC (human umbilical vein endothelial cells) and the erythrocyte membrane profile. ABS (5 mu L and 50 mu L) was administered to HUVEC (in 75 cm(2); similar to 75% fullness) for 5 min and 15 min. Results: ABS caused significant increases in the level of activation of the following transcription factors; AP2, AR, CRE/ATF1, CREB, E2F1-5, E2F6, EGR, GATA, HNF-1, ISRE, Myc-Max, NF-1, NFkB, p53, PPAR, SMAD 2/3, SP1, TRE/AP1, and YY1, Following erythrocyte



membrane isolation, protein complexes were undissolved, but denatured. The protein complex formed was resistant to heat and detergent. Trypsin and sonication were used in order to break this complex; the complex dissolved and erythrocyte membrane proteins were released in SDS-PAGE. Conclusion: ABS established a very fast and solid protein web, and increased the level of transcription factor activation. Therefore the cellular effects of ABS could be related to different intracellular biological pathways. (Turk J Hematol 2011; 28: 276-85)

Odabas, M. E. Cinar, C. Tulunoglu, O. Isik, B.

A New Haemostatic Agent's Effect on the Success of Calcium Hydroxide Pulpotomy in Primary Molars

PEDIATRIC DENTISTRY

33, 7, 529, 534

Purpose: The purpose of this study was to evaluate the effect of the application of a new hemostatic agent, Ankaferd Blood Stopper (ABS), on the clinical and radiographic success of calcium hydroxide (CH) pulpotomies in primary molars. Methods: Patients with bilateral vital mandibular primary molar teeth that required pulpotomies, because of pulpal exposure to caries, were selected for this study After initial hemorrhage control, complete hemostasis into the canal orifice was achieved by: (1) applying a solution of ABS for 10 to 15 seconds; or (2) placing sterile, saline-wetted cotton pellets. Forty teeth in 2 groups were followed up clinically and radiographic at 1, 3, 6, 9, and 12 months. Results: CH group teeth had a total success rate of 90% at 12 months. There were no statistically significant differences between CH and CH+ABS group regarding both clinical and radiographic success rates. Conclusion: Ankoferd Blood Stopper may be a useful product in the management of pulpal bleeding during a calcium hydroxide pulpotomy. (Pediatr Dent 2011;33:529-34) Received April 7 2010 vertical bar Last Revision August 7, 2010 vertical bar Accepted August 8, 2010

Ciftci, Sevgi Keskin, Fahriye Ozcan, Sema Keceli Erdem, Mehmet Ali Cankaya, Burak Bingol, Recep Kasapoglu, Cetin

In Vitro Antifungal Activity of Ankaferd Blood Stopper Against Candida Albicans

CURRENT THERAPEUTIC RESEARCH-CLINICAL AND EXPERIMENTAL

72, 3, 120, 12610.1016/j.curtheres.2011.04.003

BACKGROUND: Candida albicans is a memeber of the oral flora that can lead to various complications in immunosupresive patients after oral surgery processes. Ankaferd Blood Stopper (R) (ABS) is a medical plant extract that is safe to use in patients with dental surgery bleedings in Turkey.

OBJECTIVE: The study evaluated the antifungal activity of ABS medicinal plant extract against C albicans using the agar diffusion and broth microdilution methods.

METHODS: The plant extract antifungal activity was assessed in vitro either by applying the ABS extract directly and by applying different concentrations of ABS onto Candida culture. For these experiments, an agar diffusion method was used. To determine the minimum inhibitory

concentration (MIC), a broth microdilution method was used.

RESULTS: Different volumes of the active substance (10, 20, 30, and 40 pi) were applied onto Candida (0.5 McFarland solution) cultivated plate; Candida growth was inhibited in accordance with the volumes of ABS. However, when various dilutions of ABS (1:2, 1:20, 1:40, and 1:80) were added as drops containing 20 mu L, no antifungal effects were found. No MIC values were identified using broth microdilution. When differen dilutions of ABS containing 100 mu A of 0.5 McFarland solution of C albicans were cultured depending on the time (10, 20, 30, and 40 minutes), the effect of the duration was not significant.

CONCLUSION: The various tests were carried out to investigate antifungal effects of ABS on Candida, but none were found. (Curr Ther Res Clin Exp. 2011;72: 120-126) (C) 2011 Elsevier HS Journals, Inc. All rights reserved.



Yasar, Husamettin Ozkul, Haluk

HAEMOSTATIC EFFECT OF ANKAFERD BLOOD STOPPER (R) SEEN DURING ADENOIDECTOMY

AFRICAN JOURNAL OF TRADITIONAL COMPLEMENTARY AND ALTERNATIVE MEDICINES

8, 4, 444, 44610.4314/ajtcam.v8i4.16

In Turkey, Ankaferd Blood Stopper (R) (ABS) has been approved for the management of external haemorrhages and bleedings occurring during dental surgeries (Goker et al., 2008). Ankaferd comprises a standardized mixture of plants, including Thymus vulgaris, Glycyrrhiza glabra, Vitis vinifera, Alpinia officinarum, and Urtica diodica. This study aimed to evaluate the efficacy of ABS tamponade in the control of intra-operativebleeding occurring during adenoidectomy performed in children under the age of 12. Sixty children were randomized to receive 1 to 5 minute-tamponade with either ABS or topical gauze sponges soaked in saline solution (SS) during their adenoidectomy. Time-to-haemostasis and the number of packs required were recorded. A visual analog scale was used by the operating surgeon to record subjective data, including the rate of bleeding following the first adenoid pack removal (0=none, 3=brisk). Compared to the children in the SS group (n=30), time-to-haemostasis seen in ABS patients (n=30) was significantly shorter (mean +/-standard deviation, 1.93 +/- 1.39 min vs 3.20 +/- 1.50 min; p<0.0001); they required a lower number of packs (mean, 1.93 vs. 3.20), and appeared to bleed less (53.3% vs 6.7%; p=0.0001). ABS aids in the control of intra-operative bleeding and reduces the number of packs required to achieve haemostasis, so that it can be recommended for tamponades performed during paediatric adenoidectomies.

Turgut, Mehmet Tutkun, Ferda Celebi, Nukhet Muglali, Mehtap Haznedaroglu, Ibrahim C. Goker, Hakan

Topical Ankaferd Bloodstopper in the Management of Critical Bleedings due to Hemorrhagic Diathesis

UHOD-ULUSLARARASI HEMATOLOJI-ONKOLOJI DERGISI

21, 3, 160, 16510.4999/uhod.09104

Ankaferd BloodStopper (R) (ABS) is an herbal extract which has been used historically as a haemostatic agent in traditional Turkish medicine. ABS comprises of standardized mixture of herbs Thymus vulgaris, Glycyrrhiza glabra, Vitis vinifera, Alpinia officinarum and Unica dioica. Basic effect mechanism of ABS is the formation of an encapsulated protein web which represents the focus points for the vital erythrocyte masses. The haemostatic effects have been demonstrated by in vitro and in vivo studies. The usage of ABS as a hemostatic agent in external hemorrhages and in dental treatment in humans constitutes the first hints on ABS's safety and efficacy in humans. A phase I randomized, double-blinded, cross-over, placebo controlled clinical study in healthy volunteers indicated the safety of ABS. The aim of this report is to depict hemostatic effects of ABS in critical bleedings due to hemorrhagic diathesis, refractory to conventional measures in distinct clinical settings.

Okten, S. Kurt, M. Onal, I. K. Haznedaroglu, I. C.

Use of Ankaferd Blood Stopper for controlling actively bleeding fundal Varices

SINGAPORE MEDICAL JOURNAL

52, 1, E10, E11

Variceal bleeding is one of the most important and life-threatening complications of portal hypertension. Although less common than oesophageal varices that have a lower frequency of bleeding, gastric varices tend to result in more severe and mortal bleeding. The AnkaferBlood Stopper (ABS) has been used with varying success in recent years for the management of bleeding from skin lesions and after dental surgery, and in other clinical conditions in which conventional haemostatic measures have proved to be deficient. In serious bleeding gastric fundal varices, ABS can also act as a bridge in the absence or unavailability of definitive therapies.



Turhan, Nesrin Bilgili, Hasan Captug, Ozge Kurt, Mevlut Shorbagi, Ali Beyazit, Yavuz Kurt, Ozlem Kar Kosar, Ali Haznedaroglu, Ibrahim Celalettin

**EVALUATION OF A HAEMOSTATIC AGENT IN RABBITS** 

#### AFRICAN JOURNAL OF TRADITIONAL COMPLEMENTARY AND ALTERNATIVE MEDICINES

8, 1, 61, 65

Topical hemostatic agents are applied locally to areas of injured vascular endothelium to control local bleeding. Ankaferd Blood Stopper (ABS) has gained approval in Turkey and Bosnia-Herzegovina as a topical haemostatic agent for external post-surgical and post-dental surgery bleeding. The safety of topical use of ABS has been demonstrated in numerous in vitro and in vivo animal models, as well as in a clinical Phase I trial in humans. ABS, besides its haemostatic activity, also has in vitro anti-infectious and anti-neoplastic effects. To assess potential detrimental effects of intravenous administration of ABS into intact systemic circulation in a rabbit experimental model, one milliliter of ABS was administered intravenously into the systemic circulation of twelve rabbits which were included in the study via the marginal ear vein. Animals were observed for 1 hr before euthanasia was performed by administering 40 mg of intracardiac suxamethonium chloride. In the event of death (cardiopulmonary arrest) before the end of the planned observation period of 60 minutes, time of death was recorded and histopathological examination of the liver and spleen was commenced. Ten rabbits were alive by the end of the planned observation period, without showing any clear signs of discomfort, whereas two animals died within five minutes after systemic administration of intravenous ABS. Postmortem histopathological examination of the livers and spleens of all animals' revealed findings consistent with hepatic venous outflow obstruction. Systemic intravascular administration of ABS into intact vascular endothelium should never be performed in any setting. Further experimental and clinical studies on this liquid hemostatic agent should proceed by accepting ABS as purely a topical haemostatic agent, to be applied solely to areas of injured vascular endothelium.

Haznedaroglu, Berat Z.
Haznedaroglu, Ibrahim C.
Walker, Sharon L.
Bilgili, Hasan
Goker, Hakan
Kosar, Ali
Aktas, Alper
Captug, Ozge
Kurt, Mevlut
Oezdemir, Oktay
Kirazli, Serafettin

Ultrastructural and Morphological Analyses of the In Vitro and In Vivo Hemostatic Effects of Ankaferd Blood Stopper

CLINICAL AND APPLIED THROMBOSIS-HEMOSTASIS

16, 4, 446, 45310.1177/1076029609343706

Ultrastructural and morphological analyses of a novel hemostatic agent, Ankaferd Blood Stopper (ABS), in comparison to its in vitro and in vivo hemostatic effects were investigated. High-resolution scanning electron microscopy (SEM) images accompanied with morphological analysis after topical application of ABS revealed a very rapid (<1 second) protein network formation within concurrent vital erythroid aggregation covering the classical coagulation cascade. Histopathological examinatio revealed similar in vivo ABS-induced hemostatic network at the porcine hepatic tissue injury model. Instantaneous control of bleeding was achieved in human surgery-induced dental tissue injury associated with primary and secondary hemostatic abnormalities. Ankaferd Blood Stopper could hold a great premise for clinical management of surgery bleedings as well as immediate cessation of bleeding on external injuries based on upcoming clinical trials.



Tokgoz, Husnu Karakaya, Kemal Hanci, Volkan Abdusoglu, Mustafa Erol, Buelent Turksoy, Ozlem Akduman, Buelent Mungan, Necmettin Aydin

Protective Value of a Folkloric Medicinal Plant Extract Against Mortality and Hemorrhage in a Life-threatening Renal Trauma Model UROLOGY

75, 6, 1515.e910.1016/j.urology.2009.12.016

OBJECTIVES To compare the efficacy of a folkloric medicinal plant extract (Ankaferd Blood Stopper [ABS]) with that of oxidized cellulose (Surgicel) in a life-threatening renal injury model. ABS is a mixture of 5 plants that has historically been used in Turkish traditional medicine. It has been approved by the Ministry of Health to manage external hemorrhage and dental surgery bleeding in Turkey. METHODS Twenty-two Wistar albino rats underwent partial nephrectomy after intravenous heparin anticoagulation (2000 U/kg). The cut surface received 1 of 3 therapies, namely no treatment, Surgicel (Johnson & Johnson, New Brunswick, NJ) or ABS (Trend Teknoloji I. la AS,, Istanbul, Turkey). Blood pressure was continually monitored. Survival time, total blood loss, and mean arterial pressure were recorded for 60 minute or until death. Rats that were alive (mean arterial pressure >= 20 mm Hg) at the end of 60 minutes were sacrificed with blood withdrawal with the help of catheters.

RESULTS All animals that received no treatment died within 60 minutes of follow-up. One of 7 in the Surgicel group, and 5 of 7 animals in the ABS group, survived. Mean survival times for the Surgicel and ABS groups were 42.7 and 53.4 minutes, respectively. Rats in the ABS and Surgicel groups survived significantly longer than rats in the control group (P < .05). There were no significant differences between the ABS and the Surgicel groups in survival (P = .128).

CONCLUSIONS ABS is as effective as Surgicel in achieving hemostasis and lengthening survival time following partial nephrectomy in an experimental rat model. UROLOGY 75: 1515.e9-1515.e14, 2010. (c) 2010 Elsevier Inc.

Ercetin, Sevil
Haznedaroglu, Ibrahim C.
Kurt, Mevlut
Onal, Ibrahim K.
Aktas, Alper
Kurt, Ozlem K.
Goker, Hakan
Ozdemir, Oktay
Kirazli, Serafettin

Safety and Efficacy of Ankaferd Blood Stopper in Dental Surgery

UHOD-ULUSLARARASI HEMATOLOJI-ONKOLOJI DERGISI

20, 1, 1, 5

The aim of this study was to assess retrospectively the hemostatic efficacy and safety of the topical use of Ankaferd Blood Stopper (ABS) in the setting of dental surgery. ABS was topically applied by homogeneously spraying to the 25 patients during dental interventions. Based on this retrospective evaluation; Tissue healing was evaluated at the 48th hour. The patients received 1 to 5 mL of ABS; the median dose was 2 mL. Bleeding stopped in median 1.8 seconds (1 to 3 seconds) in the first ABS application in 20 patients. Five patients needed a second dose of ABS; four of them were given 5 mL ABS totally. No patient had wound infection and the healing process appeared to be normal. ABS is useful for the local hemostasis and wound healing in periodontal surgeries.



Germiyanoglu, Cankon Huri, Emre Akgul, Turgay Ayyildiz, Ali Ustun, Huseyin

Invivo Hemostatic Effect of Ankaferd Blood Stopper in Rat Major Renal Trauma Model: Controlled Trial of Novel Hemostatic Agent

UHOD-ULUSLARARASI HEMATOLOJI-ONKOLOJI DERGISI

20, 4, 206, 211

Ankaferd Bloodstopper (ABS) which is a medicinal product has been approved in the control of hemorrhage externally, dental surgery bleedings in Turkey to control the bleeding in renal trauma model was evaluated. Twelve Wistar rats were divided into two groups. Group (GI), control, Group II (GII), study group. One cm(2) tissue was resected. ABS solution was applied to resected area in study group. Standard suture was applied to control group. Bleeding time, number of ABS, live condition were evaluated. Histopathologic evaluations were completed. Mean time of bleeding control was 3.2 (2.4-3.6) min in GII, no difference with CI (p > 0.05). In GII, active hemostasis was provided. Mean number of ABS gout was 6.0 (5-8). Glomerular necrosis was detected with higher rate in GI compared with GII. Erythrocyte aggregation was confirmed in GII. Calcification was formed significantly in GI compared GII (p<0.05). ABS could be an effective agent to stop active major bleeding in renal trauma model.

Huri, Emre Akgul, Turgay Ayyildiz, Ali Germiyanoglu, Cankon

HEMOSTASIS IN RETROPUBIC RADICAL PROSTATECTOMY WITH ANKAFERD BLOODSTOPPER (R): A CASE REPORT

KAOHSJUNG JOURNAL OF MEDICAL SCIENCES

25, 8, 445, 447

Ankaferd BloodStopper (R) (ABS) is a licensed medicinal plant product that provides active hemostasis in external, postsurgical and dental

bleeding, and is approved in Turkey by the Ministry of Health. The use of ABS for internal organ hemorrhage is under investigation. Our clinic is one of the certified centers conducting a phase II trial investigating the effects and reliability of ABS in urogenital surgery. We have used ABS to stop bleeding during radical retropubic prostatectomy in one patient, presented here as a case report.

Kurt, Mevlut Oztas, Erkin Kuran, Sedef Onal, Ibrahim K. Kekilli, Murat Haznedaroglu, Ibrahim C.

Tandem oral, rectal, and nasal administrations of Ankaferd Blood Stopper to control profuse bleeding leading to hemodynamic instability

AMERICAN JOURNAL OF EMERGENCY MEDICINE

27, 5, 631.e1,10.1016/j.ajem.2008.09.003

Ankaferd Blood Stopper (ABS) (Ankaferd Health Products Ltd., Istanbul, Turkey) is a standardized unique combined medicinal plant extract, which has been approved in the management of postsurgery dental bleeding and external hemorrhage in Turkey [1]. ABS induces a very rapid formation (<1 second) of a specific hemostatic protein network within vital erythroid aggregation in the injured vascular area [1]. The data on the efficacy of ABS in gastrointestinal (GI) system bleeding is limited to case reports only [2-4]. Here, we present a patient with a severe GI mucosal bleeding and nasal hemorrhage leading to hemodynamic instability, which was successfully controlled via the topical application of high-dose ABS.



Huri, Emre Akguel, Turgay Ayyildiz, Ali Uestuen, Hueseyin Germiyanoglu, Cankon

Hemostatic Role of a Folkloric Medicinal Plant Extract in a Rat Partial Nephrectomy Model: Controlled Experimental Trial

JOURNAL OF UROLOGY

181, 5, 2349, 2354, 10.1016/j.juro.2009.01.016

Purpose: Ankaferd BloodStopper (R) is a mixture of 5 plants used in traditional Turkish medicine as hemostatic agent for external traumatic, postoperative and dental bleeding. We investigated the hemostatic efficacy of Ankaferd BloodStopper for partial nephrectomy. Materials and Methods: A total of 24 Wistar rats were divided into 4 groups of 6 each. Group I underwent partial nephrectomy with hilar control as the conventional technique. Group 2 underwent the conventional technique with hemostatic agent application. Group 3 underwent hemostatic agent application to the renal parenchyma. In Group 4 partial nephrectomy was performed and the hemostatic agent was used without hilar control. Warm ischemia and partial nephrectomy times, and the number of hemostatic agent applications were recorded. Histopathological evaluations were completed. The Fisher, Kruskal-Wallis and Mann-Whitney U tests were used for statistical analysis. Results: Mean kidney size was 2 x 2.5 x 0.05 cm. Mean partial nephrectomy time was 3.7, 2.7, 1.8 and 3.2 minutes in groups 1 to 4, respectively, which was significantly different between groups 1 and 3 (p = 0.007). Warm ischemia time in group 3 was less than in group 1 (p = 0.011). The number of hemostatic agent applications was higher in groups 3 and 4 compared to those in group 2 (p = 0.003). Glomerular necrosis was detected at a higher rate in group 1 compared to that in groups 3 and 4 (p = 0.015). Calcification formed significantly more in group 1 than in groups 2 to 4 (p < 0.05). Erythrocyte aggregation was greater in groups 2 to 4 than in group 1 (p = 0.015). Giant cell reaction, fibrosis, inflammation and microvascular proliferation were not statistically different among the groups (p > 0.05).

Conclusions: Ankaferd BloodStopper decreases partial nephrectomy and warm ischemia times, and provides hemostasis. Erythrocyte aggregation confirmed the hemostatic action of the agent, while the absence of glomerular necrosis and calcification may have positive relevance.

Kosar, Ali
Cipil, Handan S.
Kaya, Arif
Uz, Burak
Haznedaroglu, Ibrahim C.
Goker, Hakan
Ozdemir, Oktay
Ercetin, Sevil
Kirazli, Serafettin
Firat, Huseyin Cahit

The efficacy of Ankaferd Blood Stopper in antithrombotic drug-induced primary and secondary hemostatic abnormalities of a rat-bleeding model

**BLOOD COAGULATION & FIBRINOLYSIS** 

20, 3, 185, 190, 10.1097/MBC.0b013e32831c4cb0

Ankaferd comprises a standardized mixture of plants Thymus vulgaris, Glycyrrhiza glabra, Vitis vinifera, Alpinia officinarum and Urtica dioica. Ankaferd Blood Stopper (ABS) as a medicinal product has been approved in the management of external hemorrhage and dental surgery bleedings in Turkey. This study aimed to evaluate the in-vivo hemostatic effect of ABS in rats pretreated with acetylsalicylic acid or enoxaparin. Wistar rats (210-270 g) of both sexes were used in this study. The animals were pretreated with acetylsalicylic acid (10 mg/kg) orally for 4 days or enoxaparin sodium (8 mg/kg) subcutaneously for 3 days or did not receive any anticoagulant before tail cut at 4th day. ABS was administered topically [a total of 4 ml (1 ml/puff x 4)] to the cut tail in the studied animals. The duration of bleeding and the amount of bleeding were measured in order to evaluate the hemostatic effect of ABS. In acetylsalicylic acid-treated animals, topical ABS reduced both the duration and also the amount of bleeding volume by 68.4 and 54.6%, respectively. It was also effective in shortening the duration of bleeding (30.6%) and decreasing the amount of bleeding (32.8%) in enoxaparin-treated animals. ABS, a traditional folkloric medicinal plant extract, has in-vivo hemostatic actions, which may provide a therapeutic potential for the management of patients with deficient hemostasis in the clinical medicine. Blood Coagul Fibrinolysis 20:185-190 2009 Wolters Kluwer Health vertical bar Lippincott Williams & Wilkins.





Germiyanoglu, Cankon Huri, Emre Akgul, Turgay Ayyildiz, Ali Ustun, Huseyin

Invivo Hemostatic Effect of Ankaferd Blood Stopper in Rat Major Renal Trauma Model: Controlled Trial of Novel Hemostatic Agent

UHOD-ULUSLARARASI HEMATOLOJI-ONKOLOJI DERGISI

20, 4, 206, 211

Ankaferd Bloodstopper (ABS) which is a medicinal product has been approved in the control of hemorrhage externally, dental surgery bleedings in Turkey to control the bleeding in renal trauma model was evaluated. Twelve Wistar rats were divided into two groups. Group (GI), control, Group II (GII), study group. One cm(2) tissue was resected. ABS solution was applied to resected area in study group. Standard suture was applied to control group. Bleeding time, number of ABS, live condition were evaluated. Histopathologic evaluations were completed. Mean time of bleeding control was 3.2 (2.4-3.6) min in GII, no difference with CI (p > 0.05). In GII, active hemostasis was provided. Mean number of ABS gout was 6.0 (5-8). Glomerular necrosis was detected with higher rate in GI compared with GII. Erythrocyte aggregation was confirmed in GII. Calcification was formed significantly in GI compared GII (p<0.05). ABS could be an effective agent to stop active major bleeding in renal trauma model.

Huri, Emre Akgul, Turgay Ayyildiz, Ali Germiyanoglu, Cankon

HEMOSTASIS IN RETROPUBIC RADICAL PROSTATECTOMY WITH ANKAFERD BLOODSTOPPER (R): A CASE REPORT

KAOHSJUNG JOURNAL OF MEDICAL SCIENCES

25, 8, 445, 447

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bleeding, and is approved in Turkey by the Ministry of Health. The use of ABS for internal organ hemorrhage is under investigation. Our clinic is one of the certified centers conducting a phase II trial investigating the effects and reliability of ABS in urogenital surgery. We have used ABS to stop bleeding during radical retropubic prostatectomy in one patient, presented here as a case report.

Kurt, Mevlut Oztas, Erkin Kuran, Sedef Onal, Ibrahim K. Kekilli, Murat Haznedaroglu, Ibrahim C.

Tandem oral, rectal, and nasal administrations of Ankaferd Blood Stopper to control profuse bleeding leading to hemodynamic instability

#### **AMERICAN JOURNAL OF EMERGENCY MEDICINE**

27, 5, 631.e1,10.1016/j.ajem.2008.09.003

Ankaferd Blood Stopper (ABS) (Ankaferd Health Products Ltd., Istanbul, Turkey) is a standardized unique combined medicinal plant extract, which has been approved in the management of postsurgery dental bleeding and external hemorrhage in Turkey [1]. ABS induces a very rapid formation (<1 second) of a specific hemostatic protein network within vital erythroid aggregation in the injured vascular area [1]. The data on the efficacy of ABS in gastrointestinal (GI) system bleeding is limited to case reports only [2-4]. Here, we present a patient with a severe GI mucosal bleeding and nasal hemorrhage leading to hemodynamic instability, which was successfully controlled via the topical application of high-dose ABS.





## **Full Quality Assurance Certificate**

### Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Notified Body Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara

Türkiye (NB 1783)

Company Name : İMMÜN GIDA İLAÇ KOZMETİK SAN. VE TİC. LTD. ŞTİ.

Company Address : KİREÇBURNU MAH. KİREÇBURNU CD. RAİFBEY SOK. NO:8/A

SARIYER/ISTANBUL TURKEY

Manufacturing Site : MAHMUTBEY MAH. HACI BOSTAN CAD. ERBAY CENTRE NO.4 KAT

1 BAĞCILAR/İSTANBUL TURKEY

BİKAR İLAÇ SAN. ve TİC. LTD. ŞTİ.

GÜLLÜBAĞLAR MAH. ANKARA CAD. ŞİRİN SOKAK. NO:14

PENDIK/ISTANBUL TURKEY

FERHATPAŞA MAH. YEDİTEPE CAD. 14.SOKAK NO:11-13

ATAŞEHİR/İSTANBUL TURKEY

Scope : BLOOD STOPPER PUSH & STOP TAMPON

(ABS-ANKAFERD BLOOD STOPPER®)

**GMDN** Code : 38771

Classification Rule : Rule 4 and 13, Class III

Inspection Report Number : 1039-MDD-054/2018-01

First Issue Date : 22.05.2019

Validity Date : 22.05.2024

The manufacturer's quality system is inspected in accordance with Annex II of the Medical Device Directive and the quality system meets the requirements of Medical Device Directive Annex II. The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5. For Class III products covered by this certificate, a EC Design Examination Certificate issued in accordance with Medical Device Directive Annex II Section 4 is also required.

Certificate No: 1783- MDD-122

Firat HACIOĞLU

Deputy Director of Directives ANKARA Rev 02, 25/05/2021



## **Full Quality Assurance Certificate**

### Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Notified Body : Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara

Türkiye (NB 1783)

Company Name : İMMÜN GIDA İLAÇ KOZMETİK SAN. VE TİC. LTD. ŞTİ.

Company Address : KİREÇBURNU MAH. KİREÇBURNU CD. RAİFBEY SOK. NO:8/A

SARIYER/İSTANBUL TURKEY

Manufacturing Site : BİKAR İLAÇ SAN. ve TİC. LTD. ŞTİ.

GÜLLÜBAĞLAR MAH. ANKARA CAD. ŞİRİN SOKAK. NO:14

PENDİK/İSTANBUL TURKEY

FERHATPAŞA MAH. YEDİTEPE CAD. 14.SOKAK NO:11-13

ATAŞEHİR/İSTANBUL TURKEY

Scope : BLOOD STOPPER WET TAMPON and WET TAMPON (FOAM)

(ABS-ANKAFERD BLOOD STOPPER®)

GMDN Code : 38771

Classification Rule : Rule 4 and 13, Class III

Inspection Report Number : 394-MDD-002/2018-01

First Issue Date : 26.10.2017

Validity Date : 26.10.2022

The manufacturer's quality system is inspected in accordance with Annex II of the Medical Device Directive and the quality system meets the requirements of Medical Device Directive Annex II. The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5. For Class III products covered by this certificate, a EC Design Examination Certificate issued in accordance with Medical Device Directive Annex II Section 4 is also required.

Certificate No: 1783- MDD-003



Fırat HACIOĞLU

Deputy Director of Directives ANKARA Rev 07, 25/05/2021

### **Full Quality Assurance Certificate**

### Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Notified Body

Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara

Turkey (NB 1783)

Company Name

: İMMÜN GIDA İLAÇ KOZMETİK SAN. VE TİC. LTD. STİ.

Company Address

: KİREÇBURNU MAH. KİREÇBURNU CD. RAİFBEY SOK. NO:8/A

SARIYER/İSTANBUL TÜRKEY

Manufacturing Site

: BİKAR İLAÇ SAN. ve TİC. LTD. ŞTİ.

GÜLLÜBAĞLAR MAH. ANKARA CAD. SİRİN SOKAK. NO:14

PENDÍK/ÍSTANBUL TURKEY

FERHATPAŞA MAH. YEDİTEPE CAD. 14.SOKAK NO:11-13

ATAŞEHİR/İSTANBUL TURKEY

Scope

: ABSORBABLE BLOOD STOPPER WET TAMPON

(ABS-ANKAFERD BLOOD STOPPER®)

**GMDN** Code

: 38771

Classification Rule

: Rule 8 and 13, Class III

Inspection Report Number

: 1478-MDD-103/2018-01

First Issue Date

: 02.07.2019

Validity Date

: 26.05.2024

The manufacturer's quality system is inspected in accordance with Annex II of the Medical Device Directive and the quality system meets the requirements of Medical Device Directive Annex II. The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5. For Class III products covered by this certificate, a EC Design Examination Certificate issued in accordance with Medical Device Directive Annex II Section 4 is also required.

Certificate No: 1783- MDD-130



Deputy Director of Directives ANKARA Rev 01, 25/05/2021



### **EC Design-Examination Certificate**

### Directive 93/42/EEC on Medical Devices, Annex II (4) (Devices in Class III)

Notified Body : Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara

Türkiye (NB 1783)

Company Name : ÎMMÛN GIDA ÎLAÇ KOZMETÎK SAN. VE TÎC. LTD. ŞTÎ.

Company Address : KİREÇBURNU MAH. KİREÇBURNU CD. RAİFBEY SOK. NO:8/A

SARIYER/İSTANBUL TURKEY

Manufacturing Site : MAHMUTBEY MAH. HACI BOSTAN CAD. ERBAY CENTRE NO.4 KAT

1 BAĞCILAR/İSTANBUL TÜRKEY

BİKAR İLAÇ SAN. VE TİC. LTD. ŞTİ. GÜLLÜBAĞLAR MAH. ANKARA

CAD. ŞİRİN SOKAK. NO:14 PENDİK/İSTANBUL TURKEY

FERHATPAŞA MAH. YEDİTEPE CAD. 14.SOKAK NO:11-13

ATAŞEHİR/İSTANBUL TURKEY

Scope : BLOOD STOPPER PUSH & STOP TAMPON

(ABS-ANKAFERD BLOOD STOPPER®)

GMDN Code : 38771

Classification Rule : Rule 4 and 13, Class III

Inspection Report Number : 1039-MDD-054/2018-01

First Issue Date : 22.05.2019

Validity Date : 22.05.2024

Full Quality Assurance Certificate Number: 1783-MDD-122

Above scope has been examined and certified according to the requirements of 93/42 / EC - Medical Device Directive Annex-II Section 4. This certificate is valid with its annexes. It is totally 2 pages, including this page. The products included in the scope mentioned above must also have a certificate of Full Quality Assurance (Annex II excluding Section 4). The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5.

Certificate No: 1783- MDD-123



Direktifler Müdürü V.

Firat HACIOĞLU

ANKARA Rev02, 25/05/2021



### **EC Design-Examination Certificate**

### Directive 93/42/EEC on Medical Devices, Annex II (4) (Devices in Class III)

Notified Body

Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara

Türkiye (NB 1783)

Company Name

: İMMÜN GIDA İLAÇ KOZMETİK SAN. VE TİC. LTD. ŞTİ.

Company Address

: KÎREÇBURNU MAH. KÎREÇBURNU CD. RAÎFBEY SOK. NO:8/A

SARIYER/İSTANBUL TURKEY

Manufacturing Site

: BİKAR İLAÇ SAN. ve TİC. LTD. STİ.

GÜLLÜBAĞLAR MAH. ANKARA CAD. ŞİRİN SOKAK. NO:14

PENDIK/ISTANBUL TURKEY

FERHATPAŞA MAH. YEDİTEPE CAD. 14.SOKAK NO:11-13

ATAŞEHİR/İSTANBUL TURKEY

Scope

: BLOOD STOPPER WET TAMPON and WET TAMPON (FOAM)

(ABS-ANKAFERD BLOOD STOPPER®)

GMDN Code

: 38771

Classification Rule

: Rule 4 and 13, Class III

Inspection Report Number

: 394-MDD-002/2018-01

First Issue Date

: 26.10.2017

Validity Date

: 26.10.2022

Full Quality Assurance Certificate Number: 1783-MDD-003

Above scope has been examined and certified according to the requirements of 93/42 / EC - Medical Device Directive Annex-II Section 4. This certificate is valid with its annexes. It is totally 3 pages, including this page. The products included in the scope mentioned above must also have a certificate of Full Quality Assurance (Annex II excluding Section 4). The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5.

Certificate No: 1783- MDD-004



Fırat HACIOĞLU

Deputy Director of Directives ANKARA Rev 07, 25/05/2021



### **EC Design-Examination Certificate**

#### Directive 93/42/EEC on Medical Devices, Annex II (4) (Devices in Class III)

Notified Body : Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara

Turkey (NB 1783)

Company Name : İMMÜN GIDA İLAÇ KOZMETİK SAN. VE TİC. LTD. ŞTİ.

Company Address : KİREÇBURNU MAH. KİREÇBURNU CD. RAİFBEY SOK. NO:8/A

SARIYER/İSTANBUL TURKEY

Manufacturing Site : BİKAR İLAÇ SAN, ve TİC, LTD, ŞTİ,

GÜLLÜBAĞLAR MAH. ANKARA CAD. ŞİRİN SOKAK. NO:14

PENDÍK/İSTANBUL TURKEY

FERHATPAŞA MAH. YEDİTEPE CAD. 14.SOKAK NO:11-13

ATAŞEHİR/İSTANBUL TURKEY

Scope : ABSORBABLE BLOOD STOPPER WET TAMPON

(ABS-ANKAFERD BLOOD STOPPER®)

GMDN Code : 38771

Classification Rule : Rule 8 and 13, Class III

Inspection Report Number : 1478-MDD-103/2018-01

First Issue Date : 02.07.2019

Validity Date : 26.05.2024

Full Quality Assurance Certificate Number: 1783-MDD-130

Above scope has been examined and certified according to the requirements of 93/42 / EC - Medical Device Directive Annex-II Section 4. This certificate is valid with its annexes. It is totally 3 pages, including this page. The products included in the scope mentioned above must also have a certificate of Full Quality Assurance (Annex II excluding Section 4). The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5.

Certificate No: 1783- MDD-131

Marat HACIOGLU

Deputy Director of Directives ANKARA Rev 01, 25/05/2021

#### **ANKAFERD-WEB OF SCIENCE YAZILARI (OCAK 2015)**

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