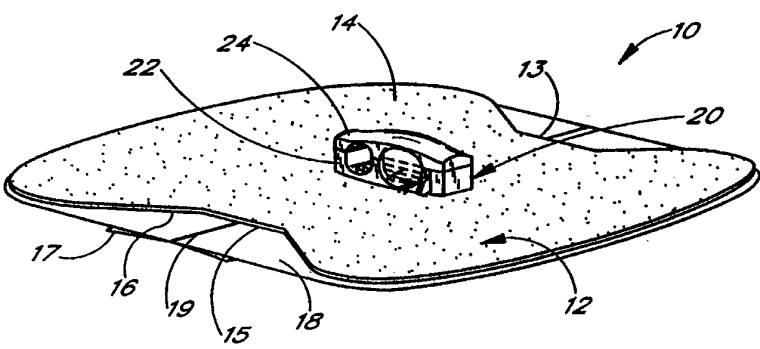


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<p>(21) International Application Number: PCT/US98/21962 (22) International Filing Date: 16 October 1998 (16.10.98) (30) Priority Data: 60/062,323 17 October 1997 (17.10.97) US 09/049,825 27 March 1998 (27.03.98) US (71) Applicant: VENETEC INTERNATIONAL, INC. [US/US]; Suite 260, 27405 Puerta Real, Mission Viejo, CA 92691 (US). (72) Inventor: BIERMAN, Steven, F.; 143 Eighth Street, Del Mar, CA 92014 (US). (74) Agent: ALTMAN, Daniel, E.; Knobbe, Martens, Olson and Bear, LLP, 16th floor, 620 Newport Center Drive, Newport Beach, CA 92660 (US).</p>	<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	
<p>(54) Title: ANCHORING SYSTEM FOR A MEDICAL ARTICLE</p>		
		
<p>(57) Abstract</p> <p>An anchoring system secures a catheter to the body of a patient and arrests axial movement of the catheter without meaningfully impairing fluid flow through the catheter. The anchoring system includes an anchor pad that adheres to the patient's skin and supports a retainer. The retainer releasably receives a portion of the catheter and includes one or more retention mechanisms. The retention mechanisms inhibit axial movement of the catheter relative to the retainer when the catheter is secured therein. In one mode, the retention mechanism is positioned within a channel of the retainer and includes at least first and second members that project from opposite sides of the channel. The members are arranged to cooperate with one another when the cover is closed so as to capture a structural portion of the catheter between the first and second members without substantially occluding an inner lumen of the catheter.</p>		

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**ANCHORING SYSTEM FOR A MEDICAL ARTICLE**Background of the InventionField on the Invention

5 The present invention relates to an anchoring system for securing a medical article to a patient to inhibit movement or migration of the medical article relative to the patient.

Description of Related Art

10 Hospitalized patients often have limited mobility due either to their condition or to doctor's orders. Such patients must lie in bed and not move about their hospital room, even to urinate. As such, a Foley catheter is often used with the bed-confined patient to drain urine from the patient's bladder. Use of a Foley catheter thus eliminates toilet trips as well as reduces bedpan use.

15 A Foley catheter typically includes two coaxial lumens: a drainage lumen and an inflation lumen. The inflation lumen communicates with an inflation balloon located at the tip of the catheter (i.e., the catheter proximal end). The proximal end of the drainage lumen includes one or more influent openings to receive urine from the bladder. The lumens usually diverge in a Y-type pattern at the distal end of the catheter to form an effluent port and an inflation port.

20 In use, a healthcare provider inserts the Foley catheter through the urinary tract of the patient to locate the tip of the catheter within the patient's bladder. Although the catheter usually includes a siliconized outer coating as provided by the manufacturer, healthcare providers often apply further lubricant, such as, for example, water-based jelly. The provider then inflates the balloon by attaching the inflation port to a source of pressurized working fluid (e.g., saline solution). Once inflated, a valve, which is located at the inflation port, inhibits the flow of fluid from the inflation lumen and the balloon to keep the balloon inflated. The inflated balloon prevents the catheter from unintentionally dislodging from the bladder. The healthcare provider then connects the distal end of the drainage lumen (i.e., its effluent port) to a drainage tube leading to a collection container.

25 The healthcare provider usually secures the distal end of the Foley catheter to the patient using tape. That is, the healthcare provider commonly places long pieces of tape across the distal end of the catheter in a crisscross pattern to secure the catheter distal end to the inner thigh of the patient. This securement inhibits disconnection between the catheter and the drainage tube, as well as prevents the catheter or drainage tube from snagging on the bed rail or other object.

30 Taped connections, however, often collect contaminants and dirt. Normal protocol therefore requires periodic (e.g., daily) tape changes in order to inhibit bacteria and germ growth at the securement site. Frequent tape changes though lead to another problem: excoriation of the patient's skin. In addition, valuable time is spent applying and reapplying the tape to secure the catheter. And healthcare providers often remove their gloves when taping because most find the taping procedure difficult and cumbersome when wearing gloves. Not only does this further lengthen the procedure, but it also subjects the healthcare provider to possible infection.

35 A number of catheter securement devices have been developed to obviate the need for frequent application of tape. U.S. Patent Nos. 5,304,146 and 5,342,317 disclose several examples of such devices. Although these

devices hold the catheter to the patient, they fail to arrest longitudinal movement of the catheter. These devices rely upon friction between the catheter and a band wrapped over the catheter to prevent axial movement. Such contact between the catheter and the securement device, however, often fails to arrest axial movement of the catheter, especially when used with a lubricated catheter (e.g., a Foley catheter).

5 Other securement devices have attempted to improve the securement of Foley catheters. One such securement device is disclosed in U.S. Patent No. 4,397,647. The approach taught by this patent, however, at least partially occludes the catheter and prevents the free flow of urine through the catheter. Improper drainage of the bladder consequently may occur, leading to patient discomfort and possible medical complications (e.g., infection).

10 A need therefore exists for a simply-structured anchoring system that secures a catheter to a patient, without occluding or otherwise restricting fluid flow through the catheter.

#### Summary of the Invention

One aspect of the present invention thus involves an anchoring system for securing a medical article to the body of a patient. The system comprises an anchor pad having an upper surface and a lower surface. The lower surface has an adhesive layer which adheres to the body of a patient. A retainer is mounted onto the upper surface of the anchor pad and receives a portion of the medical article. The retainer is formed by a base and a cover. The base has a first side and a second, opposite side. The base also includes a groove having a curvilinear cross-sectional shape. The cover is formed in a similar manner as the base. The first side of the cover attaches to the first side of the base and the second side of the cover is moveable between a closed position, in which the second side of the cover lies generally above the second side of the base, and an open position, in which the second side of the cover is spaced apart from the second side of the base so as to expose the groove in the base. When the cover is closed, the grooves in the base and cover define a channel having a curvilinear cross-sectional shape. The cross-sectional area of the channel varies over the length of the channel. Also, a latching mechanism, which is operable between the base and the cover, releasably secures the second side of the cover to the second side of the base.

25 Another aspect of the present invention involves an anchoring system including an anchor pad with an upper surface and a lower surface. At least a portion of the lower surface is formed with an adhesive layer for attachment to the patient's skin. A retainer is permanently affixed to the upper surface of the anchor pad and comprises a base and a cover. The base has a first groove to receive at least a portion of an elongated medical article. The cover is pivotally coupled to the base and moveable between an open position and a closed position. In the open position, the groove is exposed, and in the closed position, the groove is covered. The cover also includes a second groove that cooperates with the first groove when the cover is in the closed position to define a channel. The channel is configured to support the portion of the medical article received by the retainer on at least diametrically opposed sides thereof along the entire length of the received portion of the medical article. At least one retention member projects into the channel and is arranged to engage a portion of the medical article to inhibit longitudinal movement of the medical article through the channel. Interengaging structure also cooperates between the base and cover to releasably secure the cover to the base.

In accordance with an additional aspect of the present invention, the anchoring system comprises an anchor pad with upper and lower surfaces. At least a portion of the lower surface is formed by an adhesive layer. A retainer is affixed to the upper surface of the anchor pad and comprises a base and a cover. The base has a first groove to receive at least a portion of the elongated medical article. The cover is pivotally coupled to the base and is moveable between an open position and a closed position. The cover also includes a second groove that cooperates with the first groove when the cover is in the closed position to define a channel. The channel is configured to accept a portion of the medical article received by the base. The base and cover include interengaging structure which releasably secures together the base and the cover in the closed position. At least one retention mechanism is positioned within the channel and includes at least first and second members that are arranged to cooperate with one another when the cover is closed to hold a structural portion of the medical article between the first and second members without substantially occluding the inner lumen of the medical article.

Further aspects, features and advantages of the present invention will become apparent from the detailed description of the preferred embodiment that follows.

#### Brief Description of the Drawings

The above mentioned and other features of the invention will now be described with reference to the drawings of a preferred embodiment of the present anchoring system. The illustrated embodiment of the anchoring system is intended to illustrate, but not to limit the invention. The drawings contain the following figures:

Figure 1 is a perspective view of an anchoring system in accordance with a preferred embodiment of the present invention and illustrates the anchoring system from a proximal end;

Figure 2 is a perspective view of the anchoring system of Figure 1 from a distal end;

Figure 3 is a bottom view of the anchoring system of Figure 1;

Figure 4 is an elongated perspective view of a retainer of the anchoring system of Figure 2 with a cover of the retainer in an open position;

Figure 5a is a perspective view of the retainer illustrated in Figure 2 with the cover in a closed position;

Figure 5b is an elevational view of a distal end of the retainer of Figure 5a;

Figure 6 is a top plan view of the retainer of Figure 4 with the cover in a fully open position;

Figure 7 is a cross-sectional view of the retainer of Figure 5a, taken along the line 7-7;

Figure 8 is a cross-sectional view of a latch receptacle of the retainer illustrated in Figure 6, taken along the line 8-8;

Figure 9 is a cross-sectional view of the retainer of Figure 5a, taken along the line 9-9;

Figure 10 is a partial side elevational view of the retainer of Figure 6 as viewed in the direction of line 10-10, and illustrates the cover and an associated latch mechanism of the retainer;

Figure 11 is a perspective view of the anchoring system of Figure 1, and illustrates the cover in an open position and a catheter aligned above the anchoring system for insertion therein;

Figure 12 is a perspective view of the anchoring system of Figure 1, and illustrates the cover in a partially closed position with a channel formed by the cover and base of the anchoring system receiving the catheter; and

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