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(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | |
|-----------|---|--------|---------------|
| 722,943 | A | 3/1903 | Chappell |
| 732,662 | A | 6/1903 | Smith |
| 1,678,991 | A | 7/1928 | Marschalek |
| 1,970,631 | A | 8/1934 | Sherman |
| 2,186,888 | A | 1/1940 | Tullar et al. |

(Continued)

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FOREIGN PATENT DOCUMENTS

| | | |
|----|--------------|--------|
| DE | 202008018507 | 2/2015 |
| EP | 0148116 | 7/1985 |

(Continued)

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OTHER PUBLICATIONS

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B65D 51/24 (2006.01)

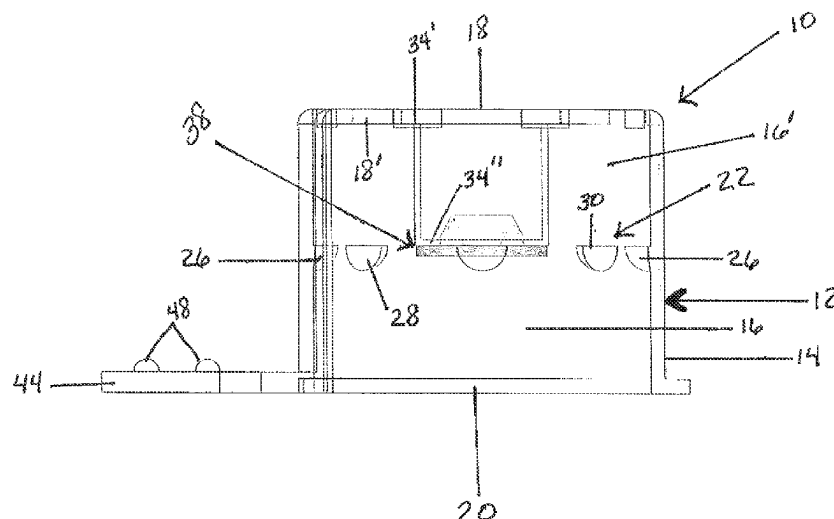
(57) **ABSTRACT**

A tamper evident seal structure for a vial septum or other cover having a housing including a sidewall terminating in oppositely disposed open and closed ends. A retainer is fixedly disposed within the housing and structured for retaining engagement with a portion of a vial, substantially adjacent the vial cover. The housing also includes a pressure member disposed within an interior thereof in attached, relation to the closed-end. The pressure member and the retainer are cooperatively disposed and structured to respectively exert pressure on the vial cover concurrent to retaining engagement with the vial. Tamper evident capabilities are at least partially defined by a detachment of a removable sidewall section from a remainder of said sidewall.

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(56)

References Cited

U.S. PATENT DOCUMENTS

| | | | | | | | |
|-----------|---|---------|------------------|-----------|---|---------|----------------------|
| 2,277,936 | A | 3/1942 | Rosenblatt | 4,842,592 | A | 6/1989 | Caggiani et al. |
| 2,459,304 | A | 1/1949 | Blank | 4,844,906 | A | 7/1989 | Hermelin et al. |
| 2,477,598 | A | 8/1949 | Hain | 4,863,451 | A | 9/1989 | Marder |
| 2,734,665 | A | 2/1956 | Flamm | 4,906,231 | A | 3/1990 | Young |
| 2,739,590 | A | 3/1956 | Yochem | 4,919,285 | A | 4/1990 | Roof et al. |
| 2,811,283 | A | 10/1957 | Bowen | 4,936,445 | A | 6/1990 | Grabenkort |
| 2,823,674 | A | 2/1958 | Yochem | 5,007,535 | A | 4/1991 | Meseke et al. |
| 2,834,346 | A | 5/1958 | Adams | 5,009,323 | A | 4/1991 | Montgomery et al. |
| 2,875,761 | A | 3/1959 | Helmer et al. | 5,024,323 | A | 6/1991 | Bolton |
| 2,888,015 | A | 5/1959 | Hunt | 5,049,129 | A | 9/1991 | Zdeb et al. |
| 2,952,255 | A | 9/1960 | Hein, Jr. | 5,057,093 | A | 10/1991 | Clegg et al. |
| 3,122,280 | A | 2/1964 | Goda | D323,392 | S | 1/1992 | Bryne |
| 3,180,532 | A | 4/1965 | Michel | 5,078,696 | A | 1/1992 | Nedbaluk |
| 3,245,567 | A | 4/1966 | Knight | 5,085,332 | A | 2/1992 | Gettig et al. |
| 3,323,798 | A | 6/1967 | Miller | 5,090,564 | A | 2/1992 | Chimienti |
| 3,364,890 | A | 1/1968 | Andersen | 5,119,975 | A | 6/1992 | Jemielita |
| 3,368,673 | A | 2/1968 | Johnson | 5,133,454 | A | 7/1992 | Hammer |
| 3,489,268 | A | 1/1970 | Meierhoefer | 5,135,496 | A | 8/1992 | Vetter et al. |
| 3,568,673 | A | 3/1971 | Cowley | 5,148,652 | A | 9/1992 | Herzog |
| 3,574,306 | A | 4/1971 | Alden | 5,163,922 | A | 11/1992 | McElveen, Jr. et al. |
| 3,598,120 | A | 8/1971 | Mass | 5,165,560 | A | 11/1992 | Ennis, III et al. |
| 3,610,241 | A | 10/1971 | LeMarie | 5,230,429 | A | 7/1993 | Etheredge, III |
| 3,674,181 | A | 7/1972 | Marks et al. | 5,267,983 | A | 12/1993 | Oilschlager et al. |
| 3,700,215 | A | 10/1972 | Hardman et al. | 5,292,308 | A | 3/1994 | Ryan |
| 3,706,307 | A | 12/1972 | Hasson | 5,293,993 | A | 3/1994 | Yates, Jr. et al. |
| 3,712,749 | A | 1/1973 | Roberts | 5,295,599 | A | 3/1994 | Smith |
| 3,726,445 | A | 4/1973 | Ostrowsky et al. | 5,312,367 | A | 5/1994 | Nathan |
| 3,747,751 | A | 7/1973 | Miller et al. | 5,312,368 | A | 5/1994 | Haynes |
| 3,850,329 | A | 11/1974 | Robinson | 5,316,163 | A | 5/1994 | von Schuckmann |
| 3,872,867 | A | 3/1975 | Killinger | 5,328,466 | A | 7/1994 | Denmark |
| 3,904,033 | A | 9/1975 | Haerr | 5,328,474 | A | 7/1994 | Raines |
| 3,905,375 | A | 9/1975 | Toyama | 5,332,113 | A | 7/1994 | Kusler, III et al. |
| 3,937,211 | A | 2/1976 | Merten | 5,356,380 | A | 10/1994 | Hoekwater et al. |
| 3,987,930 | A | 10/1976 | Fuson | 5,370,226 | A | 12/1994 | Gollobin et al. |
| 4,005,739 | A | 2/1977 | Winchell | 5,380,295 | A | 1/1995 | Vacca |
| 4,043,334 | A | 8/1977 | Brown et al. | 5,402,887 | A | 4/1995 | Shillington |
| 4,046,145 | A | 9/1977 | Choksi et al. | 5,405,339 | A | 4/1995 | Kohnen et al. |
| 4,068,696 | A | 1/1978 | Winchell | 5,456,668 | A | 10/1995 | Ogle, II |
| 4,085,845 | A | 4/1978 | Perfect | 5,458,580 | A | 10/1995 | Hajishoreh |
| 4,106,621 | A | 8/1978 | Sorenson | 5,468,224 | A | 11/1995 | Souryal |
| 4,216,585 | A | 8/1980 | Hatter | 5,474,178 | A | 12/1995 | DiViesti et al. |
| 4,216,872 | A | 8/1980 | Bean | 5,505,705 | A | 4/1996 | Galpin et al. |
| 4,244,366 | A | 1/1981 | Raines | 5,531,695 | A | 7/1996 | Swisher |
| 4,252,122 | A | 2/1981 | Halvorsen | 5,540,324 | A | 7/1996 | Knapp |
| 4,271,972 | A | 6/1981 | Thor | 5,540,666 | A | 7/1996 | Barta et al. |
| 4,286,591 | A | 9/1981 | Raines | 5,549,571 | A | 8/1996 | Sak |
| 4,286,640 | A | 9/1981 | Knox et al. | 5,558,648 | A | 9/1996 | Shields |
| 4,313,539 | A | 2/1982 | Raines | 5,584,817 | A | 12/1996 | van den Haak |
| 4,369,781 | A | 1/1983 | Gilson et al. | 5,588,239 | A | 12/1996 | Anderson |
| 4,420,085 | A | 12/1983 | Wilson et al. | 5,611,445 | A | 3/1997 | Kano et al. |
| 4,430,077 | A | 2/1984 | Mittleman et al. | 5,617,954 | A | 4/1997 | Kato et al. |
| 4,433,790 | A | 2/1984 | Gibson | 5,624,402 | A | 4/1997 | Imbert |
| 4,457,445 | A | 7/1984 | Hanks et al. | 5,662,233 | A | 9/1997 | Reid |
| 4,482,071 | A | 11/1984 | Ishiwatari | 5,674,209 | A | 10/1997 | Yarger |
| D277,783 | S | 2/1985 | Beck | 5,695,470 | A | 12/1997 | Roussigne et al. |
| 4,520,942 | A | 6/1985 | Dwinell | 5,699,913 | A | 12/1997 | Richardson |
| 4,521,237 | A | 6/1985 | Logothetis | 5,700,247 | A | 12/1997 | Grimard et al. |
| 4,530,697 | A | 7/1985 | Kuhlemann et al. | 5,702,374 | A | 12/1997 | Johnson |
| 4,558,554 | A | 12/1985 | Herbert | 5,706,985 | A | 1/1998 | Feer |
| 4,571,242 | A | 2/1986 | Klien et al. | 5,713,485 | A | 2/1998 | Liff et al. |
| 4,589,171 | A | 5/1986 | McGill | 5,776,124 | A | 7/1998 | Wald |
| 4,664,259 | A | 5/1987 | Landis | 5,785,691 | A | 7/1998 | Vetter et al. |
| 4,667,837 | A | 5/1987 | Vitello et al. | 5,797,885 | A | 8/1998 | Rubin |
| 4,676,530 | A | 6/1987 | Nordgren et al. | 5,807,343 | A | 9/1998 | Tucker et al. |
| 4,693,707 | A | 9/1987 | Dye | 5,829,589 | A | 11/1998 | Nguyen et al. |
| 4,726,483 | A | 2/1988 | Droz | D402,766 | S | 12/1998 | Smith et al. |
| 4,735,617 | A | 4/1988 | Nelson et al. | 5,842,567 | A | 12/1998 | Rowe et al. |
| 4,742,910 | A | 5/1988 | Staebler | 5,876,381 | A | 3/1999 | Pond et al. |
| 4,743,229 | A | 5/1988 | Chu | 5,883,806 | A | 3/1999 | Meador et al. |
| 4,743,231 | A | 5/1988 | Kay et al. | 5,884,457 | A | 3/1999 | Ortiz et al. |
| 4,753,345 | A | 6/1988 | Goodsir et al. | 5,901,866 | A | 5/1999 | Storar |
| 4,760,847 | A | 8/1988 | Vaillancourt | 5,902,269 | A | 5/1999 | Jentzen |
| 4,813,564 | A | 3/1989 | Cooper et al. | 5,926,922 | A | 7/1999 | Stottle |
| 4,832,695 | A | 5/1989 | Rosenberg et al. | 5,951,522 | A | 9/1999 | Rosato et al. |
| 4,834,706 | A | 5/1989 | Beck et al. | 5,951,525 | A | 9/1999 | Thorne et al. |
| | | | | 5,954,203 | A | 9/1999 | Marconi |
| | | | | 5,954,657 | A | 9/1999 | Rados |
| | | | | 5,957,166 | A | 9/1999 | Safabash |
| | | | | 5,957,314 | A | 9/1999 | Nishida et al. |

(56)

References Cited

U.S. PATENT DOCUMENTS

| | | | | | | | |
|-----------|----|---------|--------------------|-----------|----|---------|-------------------|
| 5,963,136 | A | 10/1999 | O'Brien | 7,608,057 | B2 | 10/2009 | Woehr et al. |
| 5,983,596 | A | 11/1999 | Corniani et al. | 7,611,487 | B2 | 11/2009 | Woehr et al. |
| 5,989,227 | A | 11/1999 | Vetter et al. | 7,632,244 | B2 | 12/2009 | Buehler et al. |
| 5,993,437 | A | 11/1999 | Raoz | D608,900 | S | 1/2010 | Giraud et al. |
| 6,000,548 | A | 12/1999 | Tsals | 7,641,636 | B2 | 1/2010 | Moesli et al. |
| D419,671 | S | 1/2000 | Jansen | D612,939 | S | 3/2010 | Boone, III et al. |
| 6,021,824 | A | 2/2000 | Larsen et al. | 7,681,606 | B2 | 3/2010 | Khan et al. |
| 6,027,482 | A | 2/2000 | Imbert | 7,698,180 | B2 | 4/2010 | Fago et al. |
| 6,068,614 | A | 5/2000 | Kimber et al. | 7,708,035 | B2 | 5/2010 | Windmiller |
| D430,293 | S | 8/2000 | Jansen | 7,735,664 | B1 | 6/2010 | Peters et al. |
| 6,112,951 | A | 9/2000 | Mueller | 7,748,892 | B2 | 7/2010 | McCoy |
| D431,864 | S | 10/2000 | Jansen | 7,762,988 | B1 | 7/2010 | Vitello |
| 6,126,640 | A | 10/2000 | Tucker et al. | 7,766,919 | B2 | 8/2010 | Delmotte |
| 6,190,364 | B1 | 2/2001 | Imbert | 7,802,313 | B2 | 9/2010 | Czajka |
| 6,193,688 | B1 | 2/2001 | Balestracci et al. | 7,886,908 | B2 | 2/2011 | Farrar et al. |
| 6,196,593 | B1 | 3/2001 | Petrack et al. | 7,918,830 | B2 | 4/2011 | Langan et al. |
| 6,196,998 | B1 | 3/2001 | Jansen et al. | 7,922,213 | B2 | 4/2011 | Werth |
| 6,216,885 | B1 | 4/2001 | Guillaume | 7,988,004 | B1 | 8/2011 | Marret et al. |
| 6,235,376 | B1 | 5/2001 | Miyazaki et al. | 8,034,041 | B2 | 10/2011 | Domkowski et al. |
| 6,279,746 | B1 | 8/2001 | Hussaini et al. | 8,079,518 | B2 | 12/2011 | Turner et al. |
| 6,280,418 | B1 | 8/2001 | Reinhard et al. | 8,091,727 | B2 | 1/2012 | Domkowwksi |
| 6,287,671 | B1 | 9/2001 | Bright et al. | 8,118,788 | B2 | 2/2012 | Frezza |
| 6,322,543 | B1 | 11/2001 | Singh et al. | 8,120,484 | B2 | 2/2012 | Chisholm |
| 6,338,200 | B1 | 1/2002 | Baxa et al. | 8,137,324 | B2 | 3/2012 | Bobst |
| 6,358,241 | B1 | 3/2002 | Shapeton et al. | 8,140,349 | B2 | 3/2012 | Hanson et al. |
| 6,375,640 | B1 | 4/2002 | Teraoka | 8,252,247 | B2 | 8/2012 | Ferlic |
| 6,394,983 | B1 | 5/2002 | Mayoral et al. | 8,257,286 | B2 | 9/2012 | Meyer et al. |
| 6,439,276 | B1 | 8/2002 | Wood et al. | 8,328,082 | B1 | 12/2012 | Bochenko et al. |
| 6,485,460 | B2 | 11/2002 | Eakins et al. | 8,348,895 | B1 | 1/2013 | Vitello |
| 6,488,666 | B1 | 12/2002 | Geist | 8,353,869 | B2 | 1/2013 | Ranalletta et al. |
| 6,491,665 | B1 | 12/2002 | Vetter et al. | 8,413,410 | B2 | 4/2013 | Ulm et al. |
| 6,500,155 | B2 | 12/2002 | Sasso | 8,413,811 | B1 | 4/2013 | Arendt |
| 6,520,935 | B1 | 2/2003 | Jansen et al. | 8,443,999 | B1 | 5/2013 | Reinders |
| 6,540,697 | B2 | 4/2003 | Chen | D684,057 | S | 6/2013 | Kwon |
| 6,565,529 | B1 | 5/2003 | Kimber et al. | 8,512,277 | B2 | 8/2013 | Del Vecchio |
| 6,581,792 | B1 | 6/2003 | Limanjaya | 8,528,757 | B2 | 9/2013 | Bisio |
| 6,585,691 | B1 | 7/2003 | Vitello | 8,556,074 | B2 | 10/2013 | Turner et al. |
| 6,592,251 | B2 | 7/2003 | Edwards et al. | 8,579,116 | B2 | 11/2013 | Pether et al. |
| 6,666,852 | B2 | 12/2003 | Niedospial, Jr. | 8,591,462 | B1 | 11/2013 | Vitello |
| 6,682,798 | B1 | 1/2004 | Kiraly | 8,597,255 | B2 | 12/2013 | Emmott et al. |
| 6,726,652 | B2 | 4/2004 | Eakins et al. | 8,597,271 | B2 | 12/2013 | Langan et al. |
| 6,726,672 | B1 | 4/2004 | Hanly et al. | 8,616,413 | B2 | 12/2013 | Koyama |
| 6,764,469 | B2 | 7/2004 | Broselow | D701,304 | S | 3/2014 | Lair et al. |
| 6,796,586 | B2 | 9/2004 | Werth | 8,672,902 | B2 | 3/2014 | Ruan et al. |
| 6,821,268 | B2 | 11/2004 | Balestracci | 8,702,674 | B2 | 4/2014 | Bochenko |
| D501,549 | S | 2/2005 | McAllister et al. | 8,777,910 | B2 | 7/2014 | Bauss et al. |
| 6,921,383 | B2 | 7/2005 | Vitello | 8,777,930 | B2 | 7/2014 | Swisher et al. |
| 6,935,560 | B2 | 8/2005 | Andreasson et al. | 8,852,561 | B2 | 10/2014 | Wagner et al. |
| 6,942,643 | B2 | 9/2005 | Eakins et al. | 8,864,021 | B1 | 10/2014 | Vitello |
| 6,991,126 | B2 | 1/2006 | Jackel | 8,864,707 | B1 | 10/2014 | Vitello |
| 7,036,661 | B2 | 5/2006 | Anthony et al. | 8,864,708 | B1 | 10/2014 | Vitello |
| 7,055,273 | B2 | 6/2006 | Roshkoff | 8,911,424 | B2 | 12/2014 | Weadock et al. |
| 7,100,771 | B2 | 9/2006 | Massengale et al. | 8,945,082 | B2 | 2/2015 | Geiger et al. |
| 7,125,397 | B2 | 10/2006 | Woehr et al. | 8,978,909 | B2 | 3/2015 | Kakutani et al. |
| 7,141,286 | B1 | 11/2006 | Kessler et al. | 9,016,473 | B2 | 4/2015 | Tamarindo |
| 7,175,081 | B2 | 2/2007 | Andreasson et al. | 9,027,769 | B2 | 5/2015 | Willows et al. |
| 7,182,256 | B2 | 2/2007 | Andreasson et al. | 9,082,157 | B2 | 7/2015 | Gibson |
| 7,232,066 | B2 | 6/2007 | Andreasson et al. | 9,101,534 | B2 | 8/2015 | Bochenko |
| 7,240,926 | B2 | 7/2007 | Dalle et al. | D738,495 | S | 9/2015 | Strong et al. |
| 7,299,981 | B2 | 11/2007 | Hickle et al. | 9,125,976 | B2 | 9/2015 | Uber, III et al. |
| 7,374,555 | B2 | 5/2008 | Heinz et al. | D743,019 | S | 11/2015 | Schultz |
| 7,404,500 | B2 | 7/2008 | Marteau et al. | 9,192,443 | B2 | 11/2015 | Tennican |
| 7,410,803 | B2 | 8/2008 | Nollert et al. | 9,199,042 | B2 | 12/2015 | Farrar et al. |
| 7,425,208 | B1 | 9/2008 | Vitello | 9,199,749 | B1 | 12/2015 | Vitello et al. |
| 7,437,972 | B2 | 10/2008 | Yeager | 9,220,486 | B2 | 12/2015 | Schweiss et al. |
| 7,438,704 | B1 | 10/2008 | Kawashima et al. | 9,220,577 | B2 | 12/2015 | Jessop et al. |
| D581,046 | S | 11/2008 | Sudo | 9,227,019 | B2 | 1/2016 | Swift et al. |
| D581,047 | S | 11/2008 | Koshidaka | D750,228 | S | 2/2016 | Strong et al. |
| D581,049 | S | 11/2008 | Sudo | 9,272,099 | B2 | 3/2016 | Limaye et al. |
| 7,482,166 | B2 | 1/2009 | Nollert et al. | 9,311,592 | B1 | 4/2016 | Vitello et al. |
| D589,612 | S | 3/2009 | Sudo | D756,777 | S | 5/2016 | Berge et al. |
| 7,497,330 | B2 | 3/2009 | Anthony et al. | 9,336,669 | B2 | 5/2016 | Bowden et al. |
| 7,503,453 | B2 | 3/2009 | Cronin et al. | D759,486 | S | 6/2016 | Ingram et al. |
| 7,588,563 | B2 | 9/2009 | Guala | D760,384 | S | 6/2016 | Niunoya et al. |
| 7,594,681 | B2 | 9/2009 | DeCarlo | D760,902 | S | 7/2016 | Persson |
| | | | | 9,402,967 | B1 | 8/2016 | Vitello |
| | | | | 9,427,715 | B2 | 8/2016 | Palazzolo et al. |
| | | | | 9,433,768 | B2 | 9/2016 | Tekeste et al. |
| | | | | 9,463,310 | B1 | 10/2016 | Vitello |

(56)

References Cited

U.S. PATENT DOCUMENTS

| | | | | | | | |
|--------------|-----|---------|------------------------|--------------|-----|---------|---------------------------------|
| D773,043 | S | 11/2016 | Ingram et al. | 2002/0046962 | A1 | 4/2002 | Vallans et al. |
| D777,903 | S | 1/2017 | Schultz | 2002/0079281 | A1 | 6/2002 | Hierzer et al. |
| 9,662,456 | B2 | 5/2017 | Woehr | 2002/0097396 | A1 | 7/2002 | Schafer |
| D789,529 | S | 6/2017 | Davis et al. | 2002/0099334 | A1 | 7/2002 | Hanson et al. |
| 9,687,249 | B2 | 6/2017 | Hanlon et al. | 2002/0101656 | A1 | 8/2002 | Blumenthal et al. |
| 9,694,948 | B1 | 7/2017 | Pakhomov et al. | 2002/0104770 | A1 | 8/2002 | Shapeton et al. |
| 9,744,304 | B2 | 8/2017 | Swift et al. | 2002/0133119 | A1 | 9/2002 | Eakins et al. |
| D797,928 | S | 9/2017 | Davis et al. | 2003/0041560 | A1 | 3/2003 | Kemnitz |
| D797,929 | S | 9/2017 | Davis et al. | 2003/0055685 | A1 | 3/2003 | Cobb et al. |
| 9,764,098 | B2 | 9/2017 | Hund et al. | 2003/0146617 | A1 | 8/2003 | Franko, Sr. |
| 9,821,152 | B1 | 11/2017 | Vitello et al. | 2003/0183547 | A1 | 10/2003 | Heyman |
| D806,241 | S | 12/2017 | Swinney et al. | 2003/0187403 | A1 | 10/2003 | Balestracci |
| D807,503 | S | 1/2018 | Davis et al. | 2004/0008123 | A1 | 1/2004 | Carrender et al. |
| 9,855,191 | B1 | 1/2018 | Vitello et al. | 2004/0064095 | A1 | 4/2004 | Vitello |
| D815,945 | S | 4/2018 | Fischer | 2004/0116858 | A1 | 6/2004 | Heinz et al. |
| 9,987,438 | B2 | 6/2018 | Stillson | 2004/0129738 | A1 | 7/2004 | Stukas |
| D825,746 | S | 8/2018 | Davis et al. | 2004/0173563 | A1* | 9/2004 | Kim B65D 41/48 215/254 |
| 10,039,913 | B2 | 8/2018 | Yeh et al. | 2004/0186437 | A1 | 9/2004 | Frenette et al. |
| D831,201 | S | 10/2018 | Holtz et al. | 2004/0225258 | A1 | 11/2004 | Balestracci |
| D834,187 | S | 11/2018 | Ryan | 2005/0146081 | A1 | 7/2005 | MacLean et al. |
| 10,124,122 | B2 | 11/2018 | Zenker | 2005/0148941 | A1 | 7/2005 | Farrar et al. |
| 10,166,343 | B1 | 1/2019 | Hunt et al. | 2005/0209555 | A1 | 9/2005 | Middleton et al. |
| 10,166,347 | B1 | 1/2019 | Vitello | 2006/0049948 | A1 | 3/2006 | Chen et al. |
| 10,183,129 | B1 | 1/2019 | Vitello | 2006/0084925 | A1 | 4/2006 | Ramsahoye |
| 10,207,099 | B1 | 2/2019 | Vitello | 2006/0089601 | A1 | 4/2006 | Dionigi |
| D842,464 | S | 3/2019 | Davis et al. | 2006/0169611 | A1 | 8/2006 | Prindle |
| D847,373 | S | 4/2019 | Hurwit et al. | 2006/0173415 | A1 | 8/2006 | Cummins |
| 10,293,987 | B2 | 5/2019 | Sattig et al. | 2006/0189933 | A1 | 8/2006 | Alheidt et al. |
| 10,300,263 | B1 | 5/2019 | Hunt | 2007/0060898 | A1 | 3/2007 | Shaughnessy et al. |
| 10,307,548 | B1 | 6/2019 | Hunt et al. | 2007/0106234 | A1 | 5/2007 | Klein |
| 10,315,024 | B1 | 6/2019 | Vitello et al. | 2007/0142786 | A1 | 6/2007 | Lampropoulos et al. |
| 10,315,808 | B2 | 6/2019 | Taylor et al. | 2007/0191690 | A1 | 8/2007 | Hasse et al. |
| 10,376,655 | B2 | 8/2019 | Pupke et al. | 2007/0219503 | A1 | 9/2007 | Loop et al. |
| D859,125 | S | 9/2019 | Weagle et al. | 2007/0257111 | A1 | 11/2007 | Ortenzi |
| 10,478,262 | B2 | 11/2019 | Niese et al. | 2008/0068178 | A1 | 3/2008 | Meyer |
| 10,555,872 | B1 | 2/2020 | Thorne | 2008/0078146 | A1 | 4/2008 | Cirio |
| 10,695,490 | B2 | 6/2020 | Perazzo et al. | 2008/0097310 | A1 | 4/2008 | Buehler et al. |
| 10,758,684 | B1 | 9/2020 | Vitello et al. | 2008/0106388 | A1 | 5/2008 | Knight |
| 10,773,067 | B2 | 9/2020 | Davis et al. | 2008/0140020 | A1 | 6/2008 | Shirley |
| 10,800,556 | B2 | 10/2020 | Thorne et al. | 2008/0243088 | A1 | 10/2008 | Evans |
| D903,865 | S | 12/2020 | Banik et al. | 2008/0302711 | A1 | 12/2008 | Windmiller |
| 10,888,672 | B1 | 1/2021 | Vitello | 2008/0303267 | A1 | 12/2008 | Schnell et al. |
| 10,898,659 | B1 | 1/2021 | Vitello et al. | 2008/0306443 | A1 | 12/2008 | Neer |
| 10,912,898 | B1 | 2/2021 | Vitello et al. | 2009/0008356 | A1 | 1/2009 | Gadzic et al. |
| 10,933,202 | B1 | 3/2021 | Banik | 2009/0084804 | A1 | 4/2009 | Caspary et al. |
| 10,940,087 | B2 | 3/2021 | Thorne et al. | 2009/0099552 | A1 | 4/2009 | Levy et al. |
| 10,953,162 | B1 | 3/2021 | Hunt et al. | 2009/0149815 | A1 | 6/2009 | Kiel et al. |
| 11,040,149 | B1 | 6/2021 | Banik | 2009/0166311 | A1 | 7/2009 | Claessens |
| 11,040,154 | B1 | 6/2021 | Vitello et al. | 2009/0212954 | A1 | 8/2009 | Adstedt et al. |
| 11,097,071 | B1 | 8/2021 | Hunt et al. | 2009/0326481 | A1 | 12/2009 | Swisher et al. |
| 11,278,681 | B1 | 3/2022 | Banik et al. | 2010/0050351 | A1 | 3/2010 | Colantonio et al. |
| D948,713 | S | 4/2022 | Banik | 2010/0051491 | A1 | 3/2010 | Lampropoulos et al. |
| 11,357,588 | B1 | 6/2022 | Vitello et al. | 2010/0084403 | A1 | 4/2010 | Popish et al. |
| 11,413,406 | B1 | 8/2022 | Vitello et al. | 2010/0089862 | A1 | 4/2010 | Schmitt |
| 11,426,328 | B1 | 8/2022 | Ollmann et al. | 2010/0126894 | A1 | 5/2010 | Koukol et al. |
| 11,471,610 | B1* | 10/2022 | Banik A61M 39/20 | 2010/0179822 | A1 | 7/2010 | Reppas |
| 11,523,970 | B1 | 12/2022 | Vitello et al. | 2010/0211016 | A1 | 8/2010 | Palmer-Felgate |
| 11,541,180 | B1 | 1/2023 | Vitello et al. | 2010/0228226 | A1 | 9/2010 | Nielsen |
| 11,690,994 | B1 | 7/2023 | Banik et al. | 2010/0252564 | A1 | 10/2010 | Martinez et al. |
| 11,697,527 | B1 | 7/2023 | Hendren et al. | 2010/0283238 | A1 | 11/2010 | Deighan et al. |
| 11,779,520 | B1 | 10/2023 | Vitello | 2010/0307108 | A1 | 12/2010 | Sink et al. |
| 11,793,987 | B1 | 10/2023 | Vitello et al. | 2011/0009836 | A1 | 1/2011 | Chebli et al. |
| 11,857,751 | B1 | 1/2024 | Vitello | 2011/0044850 | A1 | 2/2011 | Solomon et al. |
| 11,872,187 | B1 | 1/2024 | Vitello et al. | 2011/0046550 | A1 | 2/2011 | Schiller et al. |
| 11,904,149 | B1 | 2/2024 | Vitello et al. | 2011/0046603 | A1 | 2/2011 | Felsovalyi et al. |
| 11,911,339 | B1 | 2/2024 | Lehel et al. | 2012/0064515 | A2 | 3/2012 | Knapp et al. |
| 12,070,591 | B1 | 8/2024 | Vitello | 2012/0096957 | A1 | 4/2012 | Ochman |
| 12,172,803 | B1 | 12/2024 | Vitello et al. | 2012/0110950 | A1 | 5/2012 | Schraudolph |
| 12,195,241 | B1 | 1/2025 | Vitello et al. | 2013/0018356 | A1 | 1/2013 | Prince et al. |
| 12,201,230 | B2 | 1/2025 | Bell | 2013/0018536 | A1 | 1/2013 | Prince et al. |
| 2001/0003150 | A1 | 6/2001 | Imbert | 2013/0056130 | A1 | 3/2013 | Alpert et al. |
| 2001/0034506 | A1 | 10/2001 | Hirschman et al. | 2013/0088354 | A1 | 4/2013 | Thomas |
| 2001/0056258 | A1 | 12/2001 | Evans | 2013/0145725 | A1 | 6/2013 | Bianco et al. |
| 2002/0007147 | A1 | 1/2002 | Capes et al. | 2013/0237949 | A1 | 9/2013 | Miller |
| 2002/0023409 | A1 | 2/2002 | Py | 2013/0269592 | A1 | 10/2013 | Heacock et al. |
| | | | | 2014/0000781 | A1 | 1/2014 | Franko, Jr. |
| | | | | 2014/0034536 | A1 | 2/2014 | Reinhardt et al. |
| | | | | 2014/0069202 | A1 | 3/2014 | Fisk |

US 12,383,463 B1

Page 5

(56)

References Cited

U.S. PATENT DOCUMENTS

| | | | | |
|--------------|------|---------|---------------------|------------------------|
| 2014/0069829 | A1 | 3/2014 | Evans | |
| 2014/0076840 | A1 * | 3/2014 | Graux | B65D 41/465 215/341 |
| 2014/0135738 | A1 | 5/2014 | Panian | |
| 2014/0155868 | A1 | 6/2014 | Nelson et al. | |
| 2014/0163465 | A1 | 6/2014 | Bartlett, II et al. | |
| 2014/0257843 | A1 | 9/2014 | Adler et al. | |
| 2014/0319141 | A1 | 10/2014 | Stratis et al. | |
| 2014/0326727 | A1 | 11/2014 | Jouin et al. | |
| 2014/0353196 | A1 | 12/2014 | Key | |
| 2015/0013811 | A1 * | 1/2015 | Carrel | A61J 1/1425 137/798 |
| 2015/0048045 | A1 | 2/2015 | Miceli et al. | |
| 2015/0112296 | A1 * | 4/2015 | Ishiwata | A61J 1/1425 604/406 |
| 2015/0136632 | A1 | 5/2015 | Moir et al. | |
| 2015/0182686 | A1 | 7/2015 | Okihara | |
| 2015/0191633 | A1 | 7/2015 | De Boer et al. | |
| 2015/0246185 | A1 | 9/2015 | Heinz | |
| 2015/0251820 | A1 | 9/2015 | Glaser et al. | |
| 2015/0302232 | A1 | 10/2015 | Strassburger et al. | |
| 2015/0305982 | A1 | 10/2015 | Bochenko | |
| 2015/0310771 | A1 | 10/2015 | Atkinson et al. | |
| 2016/0067144 | A1 | 3/2016 | Chang | |
| 2016/0067422 | A1 * | 3/2016 | Davis | A61M 5/3134 604/192 |
| 2016/0090456 | A1 | 3/2016 | Ishimaru et al. | |
| 2016/0136352 | A1 | 5/2016 | Smith et al. | |
| 2016/0144119 | A1 | 5/2016 | Limaye et al. | |
| 2016/0158110 | A1 | 6/2016 | Swisher et al. | |
| 2016/0158449 | A1 | 6/2016 | Limaye et al. | |
| 2016/0176550 | A1 | 6/2016 | Viitello et al. | |
| 2016/0194121 | A1 * | 7/2016 | Ogawa | A61J 1/05 215/249 |
| 2016/0250420 | A1 | 9/2016 | Maritan et al. | |
| 2016/0279032 | A1 | 9/2016 | Davis | |
| 2016/0328586 | A1 | 11/2016 | Bowden et al. | |

| | | | | |
|--------------|------|---------|---------------------|-------------|
| 2016/0361235 | A1 | 12/2016 | Swisher | |
| 2016/0367439 | A1 | 12/2016 | Davis et al. | |
| 2017/0007771 | A1 | 1/2017 | Duinat et al. | |
| 2017/0014310 | A1 | 1/2017 | Hyun et al. | |
| 2017/0124289 | A1 | 5/2017 | Hasan et al. | |
| 2017/0173321 | A1 | 6/2017 | Davis et al. | |
| 2017/0203086 | A1 | 7/2017 | Davis | |
| 2017/0225843 | A1 | 8/2017 | Glaser et al. | |
| 2017/0239141 | A1 | 8/2017 | Davis et al. | |
| 2017/0297781 | A1 * | 10/2017 | Kawamura | B65D 51/18 |
| 2017/0319438 | A1 | 11/2017 | Davis et al. | |
| 2017/0328758 | A1 | 11/2017 | Fuchs | |
| 2017/0349335 | A1 * | 12/2017 | Sattig | B65B 55/10 |
| 2017/0354792 | A1 | 12/2017 | Ward | |
| 2018/0001540 | A1 | 1/2018 | Byun | |
| 2018/0014998 | A1 | 1/2018 | Yuki et al. | |
| 2018/0064604 | A1 | 3/2018 | Drmanovic | |
| 2018/0078684 | A1 | 3/2018 | Peng et al. | |
| 2018/0089593 | A1 | 3/2018 | Patel et al. | |
| 2018/0098915 | A1 | 4/2018 | Rajagopal et al. | |
| 2018/0147115 | A1 * | 5/2018 | Nishioka | A61J 1/1425 |
| 2018/0312305 | A1 | 11/2018 | Rognard | |
| 2019/0308006 | A1 | 10/2019 | Erekovcanski et al. | |
| 2019/0388626 | A1 | 12/2019 | Okihara | |
| 2022/0008645 | A1 | 1/2022 | Ukai et al. | |
| 2022/0024630 | A1 | 1/2022 | Bohamed | |
| 2022/0339067 | A1 * | 10/2022 | Christie | B65B 7/2821 |

FOREIGN PATENT DOCUMENTS

| | | |
|----|--------------|---------|
| EP | 269920 | 6/1988 |
| EP | 571980 | 12/1993 |
| EP | 2724977 | 4/2014 |
| GB | 486367 | 6/1938 |
| JP | 08002544 | 1/1996 |
| KR | 101159987 | 6/2012 |
| WO | WO2008000279 | 1/2008 |
| WO | WO2017086607 | 5/2015 |

* cited by examiner

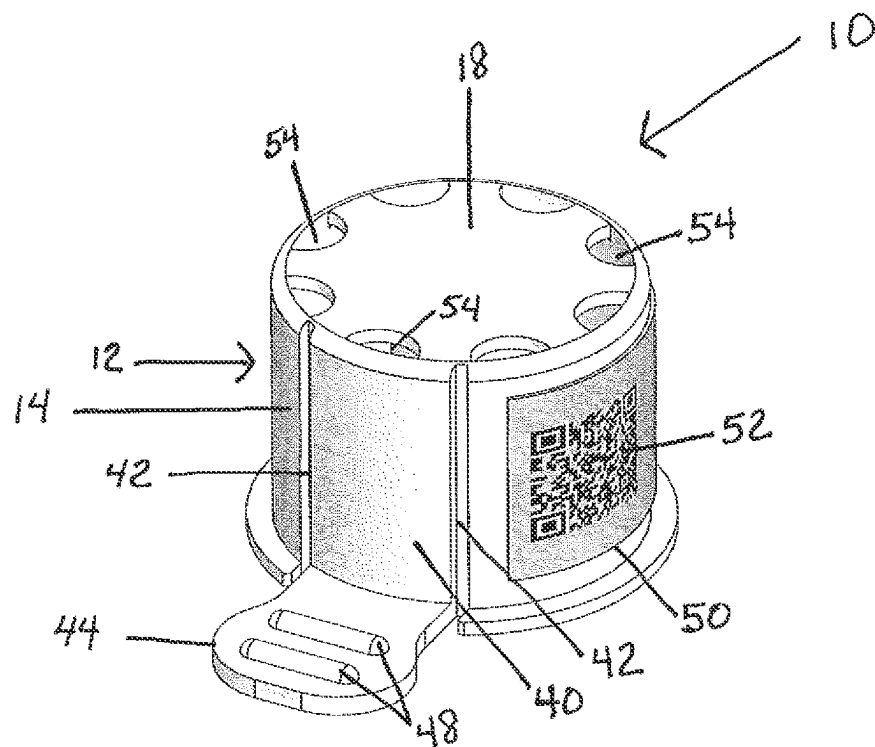


Figure 1:

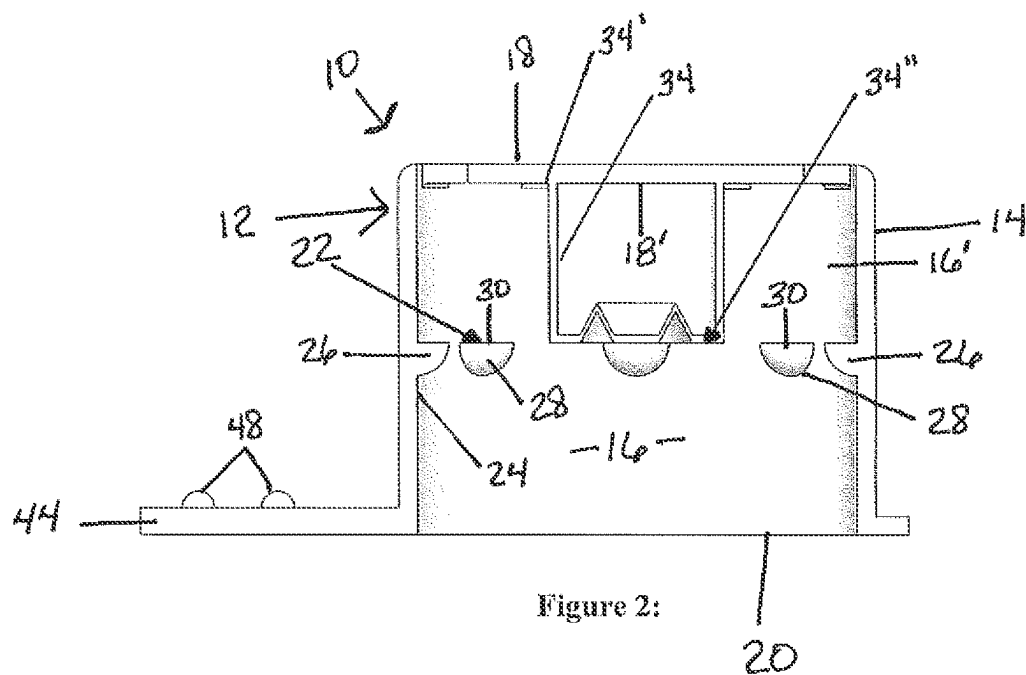
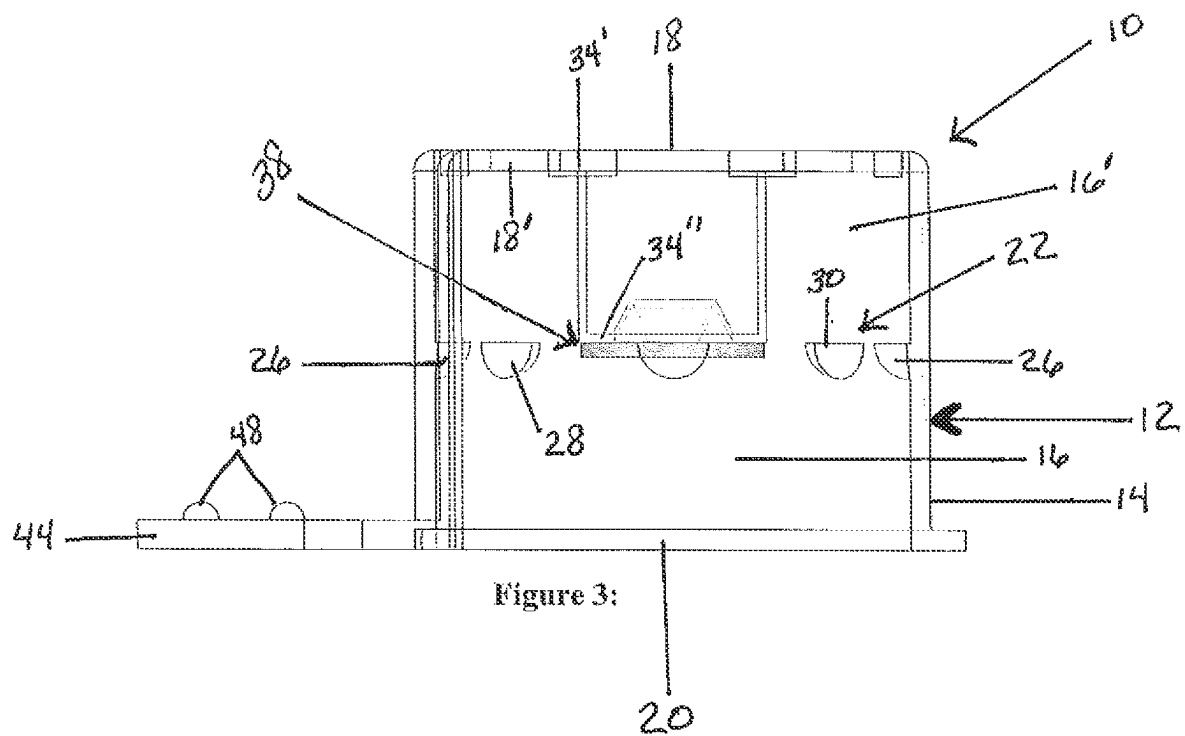


Figure 2:



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TAMPER EVIDENT SEAL FOR A VIAL COVER

The present application is a Continuation Patent Application of and claims priority to a previously filed U.S. Non-Provisional patent application, namely, that having Ser. No. 17/563,371 and a filing date of Dec. 28, 2021, which is set to mature into U.S. Pat. No. 11,872,187, on Jan. 16, 2024, and further claims priority under 35 U.S.C. Section 119(e) to a U.S. Provisional patent application, namely, that having Ser. No. 63/131,124 and a filing date of Dec. 28, 2020, with the contents of both prior applications being incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

Field of the Invention

This invention is directed to a closure or cover type of seal structure for a septum or other cover for a vial including a housing disposable in enclosing, retaining engagement with the upper end of the vial and the septum or cover attached thereto. The housing further includes tamper evident capabilities, which prevent reattachment or reuse of the housing in the intended manner.

DESCRIPTION OF THE RELATED ART

In the medical field, it is relatively common procedure to administer fluids to a patient by syringes, intravenous infusion (IV), etc. Such administration devices or assemblies are useful in the treatment of a number of medical conditions because a variety of fluids and/or medications can be administered to a patient utilizing such assemblies. By way of example, it is common for medical personnel to order that a patient be given a medication by injection. However, there are a number of safety issues associated with administering injections. One concern relates to avoiding contamination by bacteria, germs, or other harmful organisms. Because of this, and also due to the potential for theft of the medication and/or tampering in order to access the medication, one important concern relates to minimizing the number of people handling syringes. This concern is perhaps even more pronounced with regard to pre-filled syringes.

More specifically it is relatively common in a number of hospital settings for a number of syringes to be pre-loaded or pre-filled with certain medications by pharmacists or other authorized personnel, at an appropriate location, for subsequent dispensing of such prefilled syringes to one or more nursing stations or distribution areas and then, subsequently to the patient for direct use. The pharmacy or location where syringes are filled are often located in a remote part of the health facility relative to the location of the patient and the site of administration of the injection. From the foregoing, it may be understood that during the course of loading a syringe with a drug, and also afterwards when a prefilled syringe is delivered to a nurse's station, the syringe can easily be handled by a number of different individuals. This, in turn, increases the chance for the syringe to become contaminated which in turn, could possibly result in introduction of a contaminated substance into the body tissues of a patient. Consequently, a high level of importance is associated with maintaining the sterility of a syringe, from the time of it being filled to the time of injection administration.

Also, in the case of a very expensive drug or addictive drug such as, but not limited to, morphine, there is some

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danger that a prefilled syringe will be tampered with by person seeking to improperly gain access to the drug. A resulting danger also exists in the possibility of a saline solution or other substance being substituted for a dose of the medication intended to be administered. This could have extremely serious consequences to the patient, possibly including death. Therefore, the growing use of prefilled syringes raises problems relating to the determination of whether a prefilled syringe has been tampered with and and/or exposed to contamination. In order to address such problems, there is a need in the medical field for closures for syringes and/or other medical containers or administering devices, which maintain sterility while providing sufficient assurances that the contents of the syringe, medical container, administering devices, etc. have not been compromised.

Accordingly, tamper evident capabilities and/or structures associated with medical closures, covers, caps, etc. are important to protect the integrity of prefilled syringes, as well as other types of medical containers. Thus, and as a further example, vials are often filled with a previously prepared medication and are utilized in combination with a syringe. In use, the needle of the syringe penetrates and passes through a septum and into the interior of vial to establish access to the medication contained therein. As is well recognized in the medical profession, vials are medical containers recognized by appropriate governmental bodies and/or legislation (e.g., 503b) and hospital pharmacies for the containment of medications such as, but not limited to, medication prepared for the distribution of vaccines. As such, the open-end or access opening of the vial include a lid crimped or otherwise secured to the open end of the vial, wherein a penetrable septum may be structured as part of the vial lid.

In many cases, vials contain more than one dose of the contained medication or drug. After the first use, medical personnel commonly use tape placed over the septum and other portions of the vial lid to protect the contents of the vial. In other instances, and by way of example, a vial lid can also be utilized with a chemo vent needle, which is used to reconstitute medication at the hospital pharmacy. More specifically, vials used for chemotherapy drugs may contain a powder material. In order to accomplish conversion to a final drug it must be reconstituted, which in turn may involve breaking the original vial lid. To practice the aforementioned procedure, needles are required to prevent any toxic fumes escaping during the preparation and/or conversion. Once preparation is complete, an additional closure, cover, seal, etc. can be applied to the fully converted or prepared medication.

In order to address the problems and disadvantages of the type set forth above, especially with regard to protecting the contents of a vial containing one or more doses and/or the aforementioned chemotherapy medication, there is a need in the medical profession and related supply industries for a cover type seal structured to be secured to the vial and/or lid or cover of the vial in a manner which closes or seals the septum associated with the vial lid or cover. In addition, if any such proposed seal structure were developed, it would preferably also include tamper evident capabilities and/or structure which provides clear evidence that authorized or unauthorized prior access to the vial has been attempted.

SUMMARY OF THE INVENTION

The present invention is directed to a cover or closure type seal structure for a vial and/or vial cover including a

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housing. The housing includes a sidewall surrounding and at least partially defining the boundaries of the interior of the housing, wherein the interior of the housing is at least partially hollow. In addition, the sidewall terminates in a closed-end and an open-end which are substantially, oppositely disposed to one another. As will be explained in greater detail hereinafter, the open-end is dimensioned and configured to facilitate passage therethrough of the vial and a vial cover or lid, secured to the open-end or access opening of the vial.

Additional features of the seal structure include a retainer disposed within the interior of the housing. In at least one embodiment, the retainer is fixedly or integrally secured to the interior surface of the housing and more specifically, to the interior surface of the sidewall. Also, the retainer extends therefrom, inwardly towards the center of the open or hollow interior of the housing. In the one or more preferred embodiments of the retainer, as explained in greater detail hereinafter, it is disposed and structured for retaining engagement with the vial and/or the vial cover or lid.

It is emphasized that the term "vial", as used herein, is meant to include the vial itself as well as the cover or lid secured in overlying relation to the open end thereof. Moreover, as typically structured, the vial cover or lid may include a septum formed of a penetrable material which facilitates passage of a needle of a syringe or other medical device to pass therethrough into direct contact and/or communication with the medication contained within the vial. Accordingly, when describing the retainer being disposed in retaining engagement with the vial it is to be recognized that the actual "retaining engagement" may comprise the retainer being disposed, in whole or in part, in operative engagement with the vial itself or in the alternative with the vial cover and more specifically the periphery thereof, as will be described in greater detail hereinafter.

One or more embodiments of the retainer include it being at least partially defined by a plurality of retainer segments disposed in spaced, substantially coplanar relation to one another and collectively having an annular or circular configuration. As indicated, each of the retainer segments may be fixedly or integrally secured to the interior surface of the sidewall and extend inwardly, substantially towards the center of the hollow interior of the housing. The plurality of retainer segments are cooperatively disposed and structured to establish the aforementioned "retaining engagement" of the retainer with the vial and/or more specifically with an under portion of the outer periphery of the vial cover or lid.

The plurality of retainer segments may vary in size and configuration, and may be collectively dimensioned with a remainder of the housing to accommodate a vial and/or vial cover or lid of different sizes. Further, in order to establish the intended "retaining engagement" with the vial each or at least a majority of the retainer segments have a cooperative configuration. In more specific terms, the undersurface portion of each of the retainer segments has a curved or beveled configuration which facilitates a sliding engagement of the vial and/or vial cover or lid with such beveled undersurface. In addition, the sidewall of the housing is structured to include at least a minimal degree of outward flexure. As a result, as the vial and/or vial cover or lid enter through the open end of the housing, they will be forced into the aforementioned sliding engagement with the beveled or curved undersurface portions of each or at least a majority of the plurality of retainer segments. Such forced, sliding engagement will cause at least a minimal outward flexure of the housing, which in turn will allow passage of at least a portion of the vial, such as the vial cover or lid to pass

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through the retainer and/or plurality of retainer segments and be operatively disposed between the retainer and the inner surface of the closed-end.

The aforementioned retaining engagement is further facilitated by the upper surface of each or at least a majority of the retainer segments being configured to establish an abutting, "removal preventing" engagement with the vial and/or vial cover or lid. More specifically, the upper surface of the one or more retainer segments may be substantially flat or planar and be operatively disposed immediately beneath and in engagement with the under portion of the neck of the vial and/or most probably the undersurface of the outer periphery of the vial cover and/or lid. It is to be noted that both the undersurface and upper surface of the plurality of retainer segments may vary in configuration from that specifically described herein. However, the configurations of the undersurface and the upper surface of the plurality of retainer segments should be sufficient to respectively facilitate the aforementioned sliding engagement of the undersurface of the retainer segments with the vial and the removal preventing engagement of the upper surface.

In addition, and in cooperation with the retainer, one or more preferred embodiments of the seal structure of the present invention further includes a pressure member. The pressure member has an at least minimally elongated configuration fixedly secured to the interior surface of the housing. As such, the pressure member includes a proximal end fixedly or integrally secured to the interior surface of the closed-end and extending downwardly or inwardly therefrom and in depending relation thereto. Moreover, the pressure member includes a distal end substantially oppositely located to the proximal end and in outwardly spaced relation from the interior surface of the closed-end of the housing. The dimension and configuration of the pressure member is cooperatively determined relative to the location and structure of the retainer. Therefore, the distal end of the pressure member is disposed in substantially aligned relation to the retainer and/or plurality of retainer segments so as to be substantially coplanar or minimally spaced out of such a coplanar relation with the retainer.

Accordingly, the pressure member is disposed, configured and structured such that the aforementioned distal end thereof is disposed in a pressure exerting engagement with the vial cover or lid and more specifically with the septum of the vial. Due to the cooperative configurations and dispositions of the retainer and the pressure member, specifically including the distal end of the pressure member, the distal end will be disposed in the aforementioned pressure exerting, at least partially sealing engagement with the vial cover or lid and even more specifically the septum associated with the vial cover or lid. Concurrently the retainer, including the plurality of retainer segments, will be disposed in the retaining engagement comprising the engaging relation with an under portion of the outer periphery of the vial cover or lid. As a result, the vial and more specifically the vial cover or lid will be securely retained on the interior of the housing by virtue of a substantially clamping action and engagement between the retainer and/or plurality of retainer segments and the pressure member and/or distal end thereof exerting pressure on the septum or other portion of the vial cover or lid. Such clamping action will result in a sealing engagement and or action of the vial cover and in particular the sealing, pressure exerting engagement of the distal end of the pressure member with the septum.

With further reference to the pressure member, at least one embodiment includes the provision of an antiseptic or disinfected connected to, mounted on or otherwise opera-

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tively associated with the distal end. Moreover, the antiseptic, disinfectant or like composition may be on or within a pad, wherein the pad is fixedly secured to the distal end at a location which facilitates its direct engagement with the exterior surface of the septum, during the pressure exerting engagement of the pressure member/distal end with the vial cover. The aforementioned antiseptic, etc. pad may be made of a foam or other appropriate cushion-like material in order to engage the septum of the vial cover or lid without causing damage thereto.

As emphasized herein, the seal structure of the present invention includes tamper evident capabilities and/or structure. In at least one embodiment the tamper evident capability or structure includes a removable sidewall section initially integral with a remainder of the sidewall. Further, the removable sidewall section includes a detachable connection to the remainder of the sidewall. Such a detachable connection may comprise at least one, but preferably two elongated weakened seam lines each disposed on a different opposite side of the removable section and extending along a length thereof from the open end to the closed-end of the housing. The weakened seam lines are structured such that exertion of a pulling or other appropriately directed force on the removable section will cause a breakage, disconnection and/or separation of one or both of the weakened seam lines from the remainder of the sidewall, due to at least in part to reduction in the thickness of the sidewall along and entirety or at least a portion of the length of the weakened seam lines. In addition, the aforementioned pulling or other appropriately directed force exerted on the removable sidewall section may be facilitated by the inclusion of a pull tab secured to the removable section preferably at one end thereof coincident with the open end of the housing. The pull tab will extend outwardly from the exterior surface of the sidewall and otherwise be structured to facilitate the gripping or securement thereof by the hand or fingers of a user.

As should be apparent, partial or complete removal of the removable sidewall section will result in an inability to reconnect the replaceable sidewall section with remainder of the housing. As a result, the housing will not be able to be reconnected in its original operative configuration. In turn, the retainer and the pressure member will not be able to be disposed in retaining, clamping, sealing engagement with the vial and/or the vial cover. Clear evidence of authorized or unauthorized prior attempted access to or tampering with the vial will thereby be apparent.

Yet additional features of one or more embodiments of the seal structure of the present invention may include the dimensioning and configuring of the sidewall to include a display field disposed on the exterior surface of the sidewall. In addition, a machine-readable code will be disposed on the display field. The machine-readable code may take a variety of different code configurations or structures including conventional barcode, quick response code (QR), RFID tag, etc. As a result, the code may be an operative part of a tracking system or tracking capabilities associated with the seal structure of the present invention. Such a tracking system or tracking capability may be operative to facilitate the tracking of each such seal structure along a "path of distribution" from an initial point of manufacture, assembly, distribution, etc. to an endpoint such as a location of authorized use. Such a machine-readable code may be on or at least partially within the display field and include visually observable coded indicia providing adequate information or data regarding the origin, structure, utilization, etc. of the seal structure.

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These and other objects, features and advantages of the present invention will become clearer when the drawings as well as the detailed description are taken into consideration.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature of the present invention, reference should be had to the following detailed description taken in connection with the accompanying drawings in which:

FIG. 1 is a perspective view of a tamper evident seal structure for a vial cover of the present invention.

FIG. 2 is an interior sectional view of the embodiment of FIG. 1.

FIG. 3 is an interior sectional view of another preferred embodiment of the present invention including an antiseptic component.

Like reference numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention will now be described more fully herein-after with reference to the accompanying drawings in which illustrative embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

The present invention is directed to a cover or closure type seal structure generally indicated as **10** for a vial and/or vial cover (not shown in FIG. 1). The seal structure **10** includes a housing generally indicated as **12** having a sidewall **14** surrounding and at least partially defining the boundaries of the interior **16** of the housing **12**. The interior **16** of the housing **12** is at least partially hollow, as represented in at least FIGS. 2 and 3. In addition, the sidewall **14** terminates in a closed-end **18** and an open-end **20** which are substantially oppositely disposed to one another. Further, the open-end **20** is dimensioned and configured to facilitate passage therethrough of the vial and a vial cover or lid secured to the open-end or access opening of the vial.

Additional features of the seal structure **10** include a retainer generally indicated as **22** disposed within the interior **16** of the housing **12**. In at least one embodiment, the retainer **22** is fixedly or integrally secured to the interior surface **24** of the sidewall and extends therefrom inwardly towards the center of the hollow interior **16** of the housing **12**. In one or more embodiments and as will be explained in greater detail hereinafter, the retainer **22** is disposed and structured for retaining engagement with the vial and/or the vial cover or lid.

It is emphasized that the term "vial" as used herein is meant to include the vial itself as well as the cover or lid crimped or otherwise secured in overlying, covering relation to the open end thereof. Moreover, as typically structured, the vial cover or lid may include a septum formed of a penetrable material which facilitates passage of a needle of a syringe or other medical device to pass therethrough into direct contact, access and/or communication with the medication contained within the vial. Accordingly, when describing the retainer **22** being disposed in retaining engagement with the vial, it is to be recognized that the actual "retaining engagement" may comprise the retainer **22** being disposed,

in whole or in part, in operative engagement with the vial cover or lid and more specifically the periphery thereof, as described hereinafter.

One or more additional embodiments of the retainer 22 include it being at least partially defined by a plurality of retainer segments 26 disposed in spaced relation to one another and collectively having an annular or circular configuration, as represented in FIGS. 2 and 3. As indicated, each of the retainer segments 26 may be fixedly or integrally secured to the interior surface 24 of the sidewall and extend inwardly, substantially towards the center of the hollow interior 16 of the housing 12. The plurality of retainer segments 26 are cooperatively disposed and structured to establish the aforementioned "retaining engagement" of the retainer 22 with the vial and/or more specifically with an under portion of the outer periphery of the vial cover or lid.

The plurality of retainer segments 26 may vary in size and configuration and may be collectively dimensioned with a remainder of the housing 12 to accommodate a vial and/or vial cover or lid of different sizes. Further, in order to establish the intended "retaining engagement" with the vial, each or at least a majority of the retainer segments have a cooperative configuration. In more specific terms, the undersurface portion 28 of each of the retainer segments 26 has a curved or beveled configuration, as represented in FIGS. 2 and 3, which facilitates a sliding engagement of the vial and/or vial cover or lid with such beveled undersurface 28. In addition, the sidewall 14 of the housing is structured to include at least a minimal degree of flexibility in order to facilitate an outward flexure. As a result, as the vial and/or vial cover or lid enter through the open end 20 of the housing 12, it will be forced into the aforementioned sliding engagement with the beveled or curved undersurface portion 28 of each or at least a majority of the plurality of retainer segments 26. Such forced, sliding engagement will cause at least a minimal outward flexure of the sidewall 14 and/or the housing 12, which in turn will allow passage of at least a portion of the vial, such as the vial cover or lid to pass through and beyond the plurality of retainer segments 26 and be operatively disposed with in an interior portion 16' of the housing 12, located between the retainer 22 and the inner surface of the closed-end 18'.

The aforementioned retaining engagement is further facilitated by the upper surface of each or at least a majority of the retainer segments 26 being configured to establish an abutting, "removal preventing" engagement with the vial and/or vial cover or lid. More specifically, the upper surface 30 of the one or more retainer segments 26 may be substantially flat or planar and be operatively disposed immediately beneath and in engagement with the under portion of the neck of the vial and/or most probably the undersurface of the outer periphery of the vial cover and/or lid. It is to be noted that both the undersurface portion 28 and upper surface portion 30 of the plurality of retainer segments 26 may vary in configuration from that specifically described herein. However, the configurations of the undersurface 28 and the upper surface 30 of the plurality of retainer segments 26 should be sufficient to respectively facilitate the aforementioned sliding engagement of the undersurface 28 of the retainer segments 26 with the vial and the removal preventing, abutting engagement of the upper surface 30.

In addition, and in cooperation with the retainer 22, one or more preferred embodiments of the seal structure 10 of the present invention further includes a pressure member 34. The pressure member 34 has an at least minimally elongated configuration fixedly secured to the interior surface of the housing 12. As such, the pressure member 34 includes a

proximal end 34' fixedly or integrally or fixedly secured to the interior surface 18' of the closed-end 18 and extending downwardly or inwardly therefrom and in depending relation thereto. Moreover, the pressure member 34 includes a distal end 34" substantially oppositely located to the proximal end 34' and in outwardly spaced relation from the interior surface 18' of the closed-end 18 of the housing 12. The dimension and configuration of the pressure member 34 is cooperatively determined relative to the location and structure of the retainer 22. Therefore, the distal end 34" of the pressure member 34 is disposed in substantially aligned relation to the retainer 22 and/or plurality of retainer segments 26 so as to be substantially coplanar or minimally spaced out of such a coplanar relation with the retainer 22.

Accordingly, the pressure member 34 is disposed, configured and structured such that the aforementioned distal end 34" thereof is disposed in a pressure exerting engagement with the vial cover or lid and more specifically with the septum of the vial lid. Due to the cooperative configurations and dispositions of the retainer 22 and the pressure member 34, specifically including the distal end 34" of the pressure member 34, the distal end 34" will be disposed in the aforementioned pressure exerting, at least partially sealing engagement with the vial cover or lid and the septum associated therewith. Concurrently, the retainer 22, including the plurality of retainer segments 26 will be disposed in the retaining engagement, which comprises the engaging relation of the upper surfaces 30 with an under portion of the outer periphery of the vial cover or lid. As a result, the vial and the vial cover or lid will be securely retained on the interior 16 of the housing 12 by virtue of a substantially clamping action and engagement between the retainer 22 and plurality of retainer segments 26 and the pressure member 34 and distal end 34" thereof exerting pressure on the septum or other portion of the vial cover or lid. Such clamping action will result in a sealing engagement and or action of the vial cover and in particular the sealing, pressure exerting engagement of the distal end 34" of the pressure member 34 with the septum.

With further reference to the pressure member 34 and as represented in FIG. 3, at least one embodiment includes the provision of an antiseptic or disinfectant composition and/or solution operatively associated with the distal end 34". Moreover, the antiseptic, disinfectant or like composition/solution may be on or within a pad 38 which is fixedly secured to the distal end 34" at a location which facilitates the direct engagement of the pad 38 with the exterior surface of the septum, during the pressure exerting engagement of the pressure member 34 or more specifically the distal end 34" with the vial cover.

As emphasized herein, the seal structure 10 of the present invention includes tamper evident capabilities and/or structure. Therefore, in at least one embodiment the tamper evident capability or structure includes a removable sidewall section 40 initially integral with a remainder of the sidewall 14. Further, the removable sidewall section 40 includes a detachable connection to the remainder of the sidewall 14. Such a detachable connection may be defined by and/or comprise at least one but preferably two elongated weakened seam lines 42 each disposed on a different opposite side of the removable section 40 and extending along a length thereof from the open end to the closed-end 18 of the housing 12. The weakened seam lines 42 are structured such that exertion of a pulling or other appropriately directed force on the removable section 40 will cause a breakage, disconnection and/or separation of one or both of the weakened seam lines 42 from the remainder of the sidewall 14,

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due to at least in part to a reduction in the thickness of the sidewall 14 along and entirety or at least a portion of the length of the weakened seam lines 42. In addition, the aforementioned pulling or other appropriately directed force exerted on the removable sidewall section 40 may be facilitated by the inclusion of a pull tab 44 secured to the removable section 40 preferably at one end thereof which is aligned and/or coincident with the open end 20 of the housing 12. The pull tab 44 is fixedly secured to the removable sidewall section 40 and movable/removable there with as the removable section 40 breaks away from the remainder of the sidewall 14. As represented throughout the Figures, the pull tab 44 will extend outwardly from the exterior surface of the sidewall. To facilitate gripping of the pull tab 44, the exterior surface or other portion of the full tab 44 may be raised, roughened or otherwise structured, as at 48, to facilitate the gripping or securement thereof by the hand or fingers of a user.

As should be apparent, partial or complete removal of the removable sidewall section 40 will result in an inability to reconnect the replaceable sidewall section 40 with remainder of the sidewall 14 or housing 12. As a result, the housing 12 and/or sidewall 14 will not be able to be "closed" or reconnected in its original operative configuration, as represented in at least FIG. 1. In turn, the retainer 22 and the pressure member 34 will not be able to be disposed in retaining, clamping, sealing engagement with the vial and/or the vial cover, as described herein. Clear evidence of authorized or unauthorized prior attempted access to or tampering with the vial will thereby be apparent.

Yet additional features of one or more embodiments of the seal structure of the present invention may include the dimensioning and configuring of the sidewall 14 to include a display field 50 disposed on the exterior surface of the sidewall 14, as clearly represented in FIG. 1. In addition, a machine-readable code 52 will be disposed on or within the display field 50. The machine-readable code 52 may take a variety of different code configurations or structures including a conventional barcode, a quick response code (QR), an RFID tag, etc. As a result, the code 52 may be an operative part of a tracking system or tracking capabilities associated with the seal structure 10 of the present invention.

Yet another structural and operative feature which may be included in at least one embodiment of the seal structure 10 is represented in FIG. 1 and includes at least one but preferably a plurality of openings 54 formed in the closed-end 18 and disposed in communicating relation with the interior 16 and/or 16' of the housing 12.

Since many modifications, variations and changes in detail can be made to the described preferred embodiment of the invention, it is intended that all matters in the foregoing description and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense. Thus, the scope of the invention should be determined by the appended claims and their legal equivalents.

What is claimed is:

1. A seal structure for a vial cover, said seal structure comprising:

- a housing including a sidewall disposed in surrounding relation to an interior of said housing,
- said housing including an open-end and a closed-end oppositely disposed to one another,
- a retainer fixedly disposed to the interior of said housing and structured for retaining engagement with a vial,
- a pressure member disposed within said housing in attached relation to said closed-end,

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said pressure member dimensioned and disposed in pressure exerting relation to the vial cover concurrent to said retaining engagement of said retainer with the vial cover, and

said pressure member including a distal end, said distal end disposed in substantially aligned relation with said retainer, concurrent to pressure exerting engagement with the vial cover.

2. The seal structure as recited in claim 1 wherein said retainer is fixedly secured to an inner surface of said housing and extends inwardly therefrom in substantially surrounding relation to said pressure member.

3. The seal structure as recited in claim 2 wherein said retainer comprises a plurality of retainer segments disposed in spaced relation to one another and collectively disposed in substantially surrounding relation to said pressure member.

4. The seal structure as recited in claim 3 wherein each of said plurality of retainer segments includes a substantially beveled undersurface portion, said beveled undersurface portions collectively configured to facilitate sliding engagement of the vial through said retainer, into said retaining engagement.

5. The seal structure as recited in claim 4 wherein each of said plurality of retainer segments include an upper surface configured to prevent passage of the vial out of said retaining engagement and through said open-end.

6. The seal structure as recited in claim 3 wherein each of said plurality of retainer segments include an upper surface configured to prevent passage of the vial out of said with retaining engagement.

7. The seal structure as recited in claim 1 wherein said sidewall comprises a removable section, said removable section including a detachable connection to a remainder of said sidewall.

8. The seal structure as recited in claim 7 wherein said removable connection comprises weakened seam lines disposed on opposite sides of and extending along a length of said removable section, from said open-end to said closed-end.

9. The seal structure as recited in claim 7 further comprising a pull tab, said pull tab fixedly connected to said removable section and removable there with upon detachment of said removable section from a remainder of said sidewall.

10. The seal structure as recited in claim 9 wherein said pull tab is fixedly connected to said removable section at one end thereof adjacent said open-end; said pull tab extending transversely outward from said removable section.

11. The seal structure as recited in claim 9 wherein said detachment of said removable section and said pull tab at least partially defines a tamper evident structure.

12. The seal structure as recited in claim 7 further comprising tamper evident capabilities at least partially defined by a detachment of said removable section from a remainder of said sidewall.

13. The seal structure as recited in claim 1 wherein said sidewall comprises a display field at least partially disposed on an exterior surface thereof, said display field including a machine-readable code.

14. The seal structure as recited in claim 1 wherein said pressure member includes a proximal end fixedly connected to an interior surface of said closed-end and wherein said distal end is disposed into said interior of said housing, in spaced, depending relation to said closed-end.

15. The seal structure as recited in claim 1 further comprising an antiseptic composition disposed on said pressure

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member in engaging relation to the vial cover, concurrent to said retaining engagement of said retainer with said vial.

16. The seal structure as recited in claim **15** said antiseptic composition disposed on said distal end, in engaging relation to the vial cover.

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17. The seal structure as recited in claim **15** wherein said antiseptic composition comprises an antiseptic composition disposed in a pad, said pad connected to a distal end of said pressure member and disposed in engageable relation to the vial cover.

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