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Access sheath with valve assembly

Abstract

An access sheath and method of assembling the access sheath. The access sheath includes a hub, a cartridge carried by the hub, the cartridge having a first valve, a second valve spaced from the first valve along a central axis, and a spacer disposed between the first valve and the second valve, wherein the first valve and the second valve each have at least two slits that extend along, and twist about, the central axis, and a shaft assembly having a shaft hub and a shaft that extends from the shaft hub in the distal direction. The access sheath provides a liquid-tight seal when receiving the introducer and other devices to prevent leakage and blood loss and to decrease device insertion forces.

Inventors: **Arnold; Donald Richard (Montrose, PA), Maor; Nathaniel Haim (Chester Springs, PA)**

Applicant: **Teleflex Life Sciences LLC** (Wilmington, DE)

Family ID: **1000008765528**

Assignee: **Teleflex Life Sciences LLC (Wilmington, DE)**

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References Cited

U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
3125095	12/1963	Kaufman et al.	N/A	N/A
4665918	12/1986	Garza et al.	N/A	N/A
4760847	12/1987	Vaillancourt	N/A	N/A
4798594	12/1988	Hillstead	604/167.04	A61M 39/0606
4890612	12/1989	Kensey	N/A	N/A
4895346	12/1989	Steigerwald	604/167.04	F16K 7/20
4895565	12/1989	Hillstead	N/A	N/A
4990151	12/1990	Wallsten	N/A	N/A
5021059	12/1990	Kensey et al.	N/A	N/A
5026377	12/1990	Burton et al.	N/A	N/A
5041095	12/1990	Littrell	N/A	N/A
5059183	12/1990	Semrad	N/A	N/A
5222974	12/1992	Kensey et al.	N/A	N/A
5282827	12/1993	Kensey et al.	N/A	N/A
5292309	12/1993	Tassel et al.	N/A	N/A
5306254	12/1993	Nash et al.	N/A	N/A
5322508	12/1993	Viera	N/A	N/A
5324306	12/1993	Makower et al.	N/A	N/A
5360414	12/1993	Yarger	N/A	N/A
5363847	12/1993	Viera	N/A	N/A
5411520	12/1994	Nash et al.	N/A	N/A
5531759	12/1995	Kensey et al.	N/A	N/A
5545178	12/1995	Kensey	606/232	A61B 17/0057
5643318	12/1996	Tsukernik et al.	N/A	N/A
5662681	12/1996	Nash et al.	N/A	N/A
5700277	12/1996	Nash et al.	N/A	N/A
5702421	12/1996	Schneidt	N/A	N/A
5843124	12/1997	Hammerslag	N/A	N/A
6010520	12/1999	Pattison	N/A	N/A
6056768	12/1999	Cates et al.	N/A	N/A
6090130	12/1999	Nash et al.	N/A	N/A
6107004	12/1999	Donadio, III	N/A	N/A
6179863	12/2000	Kensey et al.	N/A	N/A
6245054	12/2000	Fuimaono et al.	N/A	N/A
6425911	12/2001	Akerfeldt et al.	N/A	N/A
6440151	12/2001	Cragg et al.	N/A	N/A

6440153	12/2001	Cragg et al.	N/A	N/A
6447534	12/2001	Cragg et al.	N/A	N/A
6494848	12/2001	Sommercorn et al.	N/A	N/A
6682489	12/2003	Tenerz	606/213	A61B 17/0057
6860895	12/2004	Akerfeldt et al.	N/A	N/A
7037322	12/2005	Sing et al.	N/A	N/A
7044916	12/2005	Tenerz et al.	N/A	N/A
7073509	12/2005	Tenerz et al.	N/A	N/A
7094209	12/2005	Egnelöv et al.	N/A	N/A
7285097	12/2006	Tenerz et al.	N/A	N/A
7316704	12/2007	Bagaoisan et al.	N/A	N/A
7597705	12/2008	Forsberg et al.	N/A	N/A
7618436	12/2008	Forsberg	N/A	N/A
7648493	12/2009	Forsberg et al.	N/A	N/A
7695493	12/2009	Saadat et al.	N/A	N/A
7850654	12/2009	Belhe et al.	N/A	N/A
7905902	12/2010	Huitema et al.	N/A	N/A
8002749	12/2010	Macatangay	604/167.03	A61M 39/0613
8029533	12/2010	Bagaoisan et al.	N/A	N/A
8097007	12/2011	Evans et al.	N/A	N/A
8137321	12/2011	Argentine	604/167.06	A61M 25/0097
8273094	12/2011	Belhe et al.	N/A	N/A
8337522	12/2011	Ditter	N/A	N/A
8382793	12/2012	Egnelöv et al.	N/A	N/A
8435256	12/2012	Lehe et al.	N/A	N/A
8444673	12/2012	Thielen et al.	N/A	N/A
8540750	12/2012	Tegels	N/A	N/A
8685059	12/2013	Walters	N/A	N/A
8870917	12/2013	Walters	N/A	N/A
8926564	12/2014	King	604/167.03	A61M 25/0668
8974476	12/2014	Tegels	N/A	N/A
9089363	12/2014	Dooney, Jr.	N/A	A61B 17/3423
9675371	12/2016	Shimon	N/A	N/A
9757104	12/2016	Walters et al.	N/A	N/A
10154835	12/2017	Walters et al.	N/A	N/A
10383611	12/2018	Walters et al.	N/A	N/A
10390810	12/2018	Walters et al.	N/A	N/A
10448937	12/2018	Walters et al.	N/A	N/A
10485524	12/2018	Walters et al.	N/A	N/A
10555727	12/2019	Walters et al.	N/A	N/A
10639019	12/2019	Walters	N/A	N/A
10668253	12/2019	Jacobs	N/A	N/A
10682128	12/2019	Walters et al.	N/A	N/A
11020224	12/2020	Jacobs	N/A	N/A

11123053	12/2020	Walters et al.	N/A	N/A
11419592	12/2021	Walters et al.	N/A	N/A
11576663	12/2022	Walters et al.	N/A	N/A
11589855	12/2022	Walters et al.	N/A	N/A
11779320	12/2022	Walters et al.	N/A	N/A
2001/0003158	12/2000	Kensey et al.	N/A	N/A
2001/0044639	12/2000	Levinson	N/A	N/A
2002/0022822	12/2001	Cragg et al.	N/A	N/A
2003/0078616	12/2002	Ginn et al.	N/A	N/A
2004/0138674	12/2003	Egnelov et al.	N/A	N/A
2004/0147950	12/2003	Mueller et al.	N/A	N/A
2004/0204741	12/2003	Egnelov et al.	N/A	N/A
2004/0267308	12/2003	Bagaoisan et al.	N/A	N/A
2005/0085856	12/2004	Ginn	N/A	N/A
2005/0107820	12/2004	Forsberg et al.	N/A	N/A
2005/0107826	12/2004	Zhu et al.	N/A	N/A
2005/0107827	12/2004	Paprocki	N/A	N/A
2005/0125030	12/2004	Forsberg et al.	N/A	N/A
2005/0277961	12/2004	Stone et al.	N/A	N/A
2006/0058844	12/2005	White et al.	N/A	N/A
2006/0217664	12/2005	Hattler et al.	N/A	N/A
2006/0229673	12/2005	Forsberg	N/A	N/A
2007/0123936	12/2006	Goldin et al.	N/A	N/A
2007/0282373	12/2006	Ashby et al.	N/A	N/A
2008/0082123	12/2007	Forsberg et al.	N/A	N/A
2008/0157017	12/2007	Macatangay et al.	N/A	N/A
2008/0306509	12/2007	Osborne	N/A	N/A
2009/0054926	12/2008	Pipenhagen et al.	N/A	N/A
2009/0088793	12/2008	Bagaoisan et al.	N/A	N/A
2009/0099598	12/2008	McDevitt et al.	N/A	N/A
2009/0137870	12/2008	Bakos et al.	N/A	N/A
2009/0171387	12/2008	Pipenhagen et al.	N/A	N/A
2009/0248064	12/2008	Preinitz	N/A	N/A
2009/0312790	12/2008	Forsberg et al.	N/A	N/A
2009/0318894	12/2008	Lafitte et al.	N/A	N/A
2010/0016887	12/2009	Inderbitzi	N/A	N/A
2010/0168789	12/2009	Bagaoisan et al.	N/A	N/A
2010/0179589	12/2009	Roorda et al.	N/A	N/A
2010/0185216	12/2009	Garrison et al.	N/A	N/A
2011/0004162	12/2010	Tal	N/A	N/A
2011/0046665	12/2010	Green et al.	N/A	N/A
2011/0054456	12/2010	Thompson et al.	N/A	N/A
2011/0160765	12/2010	Melmed et al.	N/A	N/A
2011/0208222	12/2010	Ljahnicky et al.	N/A	N/A
2011/0213414	12/2010	McGuckin, Jr. et al.	N/A	N/A
2011/0213415	12/2010	McGuckin, Jr. et al.	N/A	N/A
2011/0301619	12/2010	Walters	N/A	N/A
2012/0010634	12/2011	Crabb et al.	N/A	N/A

2012/0022585	12/2011	Atanasoska et al.	N/A	N/A
2012/0065668	12/2011	Ginn et al.	N/A	N/A
2012/0071919	12/2011	Pipenhagen et al.	N/A	N/A
2012/0083829	12/2011	Ginn et al.	N/A	N/A
2012/0101525	12/2011	Jenson et al.	N/A	N/A
2012/0109192	12/2011	Egneloev et al.	N/A	N/A
2012/0116446	12/2011	Green et al.	N/A	N/A
2012/0143244	12/2011	Hill et al.	N/A	N/A
2012/0143245	12/2011	Tegels	N/A	N/A
2012/0143249	12/2011	Jenson et al.	N/A	N/A
2012/0158044	12/2011	Jenson et al.	N/A	N/A
2012/0165854	12/2011	Pipenhagen et al.	N/A	N/A
2012/0245517	12/2011	Tegels	N/A	N/A
2012/0245597	12/2011	Tegels	N/A	N/A
2012/0245624	12/2011	Glazier et al.	N/A	N/A
2012/0283770	12/2011	Kramer et al.	N/A	N/A
2012/0296275	12/2011	Martin et al.	N/A	N/A
2013/0006297	12/2012	Drasler	N/A	N/A
2013/0006298	12/2012	Terwey	N/A	N/A
2013/0025588	12/2012	Bosel	N/A	N/A
2013/0035719	12/2012	Hill et al.	N/A	N/A
2013/0072949	12/2012	Halac et al.	N/A	N/A
2013/0079802	12/2012	Halac et al.	N/A	N/A
2013/0103077	12/2012	Ditter et al.	N/A	N/A
2013/0131718	12/2012	Jenson et al.	N/A	N/A
2013/0144316	12/2012	Mccrea et al.	N/A	N/A
2013/0150884	12/2012	Belhe et al.	N/A	N/A
2013/0178895	12/2012	Walters et al.	N/A	N/A
2013/0226227	12/2012	Terwey	N/A	N/A
2014/0039264	12/2013	Heiman	N/A	N/A
2014/0046217	12/2013	Lim et al.	N/A	N/A
2014/0046220	12/2013	Nelson et al.	N/A	N/A
2014/0094846	12/2013	Lim et al.	N/A	N/A
2014/0188160	12/2013	Tegels et al.	N/A	N/A
2014/0200611	12/2013	Walters	N/A	N/A
2014/0222064	12/2013	Tegels	N/A	N/A
2014/0236088	12/2013	Al-Rashdan et al.	N/A	N/A
2014/0309686	12/2013	Ginn et al.	N/A	N/A
2014/0364899	12/2013	Ginn et al.	N/A	N/A
2015/0068009	12/2014	Walters	N/A	N/A
2015/0100083	12/2014	Walters et al.	N/A	N/A
2015/0173794	12/2014	Kurth et al.	N/A	N/A
2016/0228109	12/2015	Jacobs et al.	N/A	N/A
2017/0135725	12/2016	Tegels	N/A	N/A
2017/0333015	12/2016	Walters et al.	N/A	N/A
2019/0015204	12/2018	Jacobs	N/A	N/A
2019/0015637	12/2018	Jacobs	N/A	N/A
2019/0110781	12/2018	Walters et al.	N/A	N/A
2019/0336116	12/2018	Walters et al.	N/A	N/A
2020/0000448	12/2019	Walters et al.	N/A	N/A

2020/0146661	12/2019	Walters et al.	N/A	N/A
2020/0289101	12/2019	Walters	N/A	N/A
2022/0273277	12/2021	Walters et al.	N/A	N/A
2022/0338852	12/2021	Walters	N/A	N/A
2024/0325011	12/2023	Walters et al.	N/A	N/A

FOREIGN PATENT DOCUMENTS

Patent No.	**Application Date**	**Country**	**CPC**
0474752	12/1994	EP	N/A
0766947	12/1996	EP	N/A
0797953	12/1996	EP	N/A
1163020	12/2000	EP	N/A
1169968	12/2001	EP	N/A
1222896	12/2001	EP	N/A
1254634	12/2001	EP	N/A
0664687	12/2002	EP	N/A
1371333	12/2002	EP	N/A
1413255	12/2003	EP	N/A
1440661	12/2003	EP	N/A
1532929	12/2004	EP	N/A
1658811	12/2005	EP	N/A
1695667	12/2005	EP	N/A
1836967	12/2006	EP	N/A
1836968	12/2006	EP	N/A
2055236	12/2008	EP	N/A
2064999	12/2008	EP	N/A
2213247	12/2009	EP	N/A
2215974	12/2009	EP	N/A
1919367	12/2010	EP	N/A
1874195	12/2011	EP	N/A
1893100	12/2011	EP	N/A
2227148	12/2011	EP	N/A
1893099	12/2011	EP	N/A
1893098	12/2013	EP	N/A
2611366	12/2013	EP	N/A
2605707	12/2013	EP	N/A
1773438	12/2016	EP	N/A
1989011301	12/1988	WO	N/A
1990014796	12/1989	WO	N/A
1992014396	12/1991	WO	N/A
1993008743	12/1992	WO	N/A
1993008746	12/1992	WO	N/A
1994007421	12/1993	WO	N/A
1998005259	12/1997	WO	N/A
1999022646	12/1998	WO	N/A
2000078226	12/1999	WO	N/A
2003094740	12/2002	WO	N/A
2004096056	12/2003	WO	N/A
2005002451	12/2004	WO	N/A

2005039387	12/2004	WO	N/A
2005060514	12/2004	WO	N/A
2006075228	12/2005	WO	N/A
2006110615	12/2005	WO	N/A
2007035187	12/2006	WO	N/A
2008036634	12/2007	WO	N/A
2009005722	12/2008	WO	N/A
2009025836	12/2008	WO	N/A
2009029914	12/2008	WO	N/A
2009035921	12/2008	WO	N/A
2009088440	12/2008	WO	N/A
2009088441	12/2008	WO	N/A
2009112930	12/2008	WO	N/A
2010129042	12/2009	WO	N/A
2011014244	12/2010	WO	N/A
2011019374	12/2010	WO	N/A
2011025529	12/2010	WO	N/A
2011025543	12/2010	WO	N/A
2011037635	12/2010	WO	N/A
2011146729	12/2010	WO	N/A
2011156498	12/2010	WO	N/A
2012009007	12/2011	WO	N/A
2012012641	12/2011	WO	N/A
2012045356	12/2011	WO	N/A
2012061486	12/2011	WO	N/A
2012064888	12/2011	WO	N/A
2012083045	12/2011	WO	N/A
2012145356	12/2011	WO	N/A
2012145362	12/2011	WO	N/A
2012148745	12/2011	WO	N/A
2012148747	12/2011	WO	N/A
2012158662	12/2011	WO	N/A
2012158737	12/2011	WO	N/A
2012158738	12/2011	WO	N/A
2012158740	12/2011	WO	N/A
2012158931	12/2011	WO	N/A
2013063227	12/2012	WO	N/A
2013081659	12/2012	WO	N/A
2014150154	12/2013	WO	N/A
2015099977	12/2014	WO	N/A
2017123853	12/2016	WO	N/A

OTHER PUBLICATIONS

PCT International Search Report mailed Oct. 22, 2021 in PCT/US2021/041730. cited by applicant
PCT Written Opinion mailed Oct. 22, 2021 in PCT/US2021/041730. cited by applicant
Extended European Search Report and Opinion mailed Jun. 16, 2021 in EP Application No. 21163623.8. cited by applicant
International Search Report and Written Opinion for International Application No. PCT/US2012/061855 dated Jan. 22, 2013 (21 pages). cited by applicant
Koh, Wui-Jin et al. “Femoral vessel depth and the implications for groin node radiation,” 1993,

International Journal of Radiation Oncology 'Biology' Physics, vol. 27, p. 969-974. cited by applicant
Officer Gunter Held, International Search Report and the Written Opinion, International Patent Application PCT/US2017/013314, dated Apr. 18, 2017, 11 pp. cited by applicant
PCT International Preliminary Report on Patentability, PCT/US2014/068694, Jun. 28, 2016, 11 pp. cited by applicant
PCT International Search Report and the Written Opinion, PCT/US2014/068694, Mar. 17, 2015, 17 pp. cited by applicant
Badawi et al, “A Simple Percutaneous Technique for Hemostasis and Closure after Transcatheter Aortic Valve Implantation”, Catheterization and Cardiovascular Interventions, Jan. 1, 2012, 79(1), 152-155. cited by applicant
Bui et al, “Double-Wire Angio-Seal Closure Technique after Balloon Aortic Valvuloplasty”, Catheterization and Cardiovascular Interventions, 2010, 75, 488-492. cited by applicant
Extended European Search Report mailed Sep. 6, 2021 in EP Application No. 21166157.4. cited by applicant
European Search Report and Search Opinion mailed May 10, 2023, in EP Patent Application No. 23153276.3. cited by applicant
Extended European Search Report and Opinion mailed Jul. 24, 2024 in EP Application No. 24160990.8. cited by applicant

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Primary Examiner: Kamikawa; Tracy L

Attorney, Agent or Firm: Dorsey & Whitney LLP

Background/Summary

TECHNICAL FIELD
(1) The present disclosure relates to an access sheath for device introduction and exchange in a vessel.
BACKGROUND
(2) Percutaneous procedures often involve accessing vasculature with elongated instruments, e.g., catheters, deployed in an ordered sequence. During an interventional cardiovascular procedure access to the cardiovascular system may be obtained via an artery or vein in situations where an artery is not a suitable approach path. In one example, a vascular closure system may include a sheath introducer and a delivery system having a sealing unit designed to seal a puncture in a vessel. Such systems and related devices may function to exchange a procedure access sheath used to guide a catheter (or other medical device) into the vessel, e.g. the femoral artery or the aorta, with an access sheath for use with a device. The access sheath may have a valve that is designed to minimize blood loss during device insertion into the access sheath. Current valves, however, present leakage issues as well as high device introduction forces. In order to accommodate larger diameters, the valves stretch beyond their tear limits. The tear reduces the likelihood of the valve being able to seal around a guidewire prior to introduction of the delivery system or during catheter exchange. Leakage may occur during the exchange between catheters, such as between the sheath introducer and the delivery system, resulting in blood loss. In addition, existing efforts to improve leakage can increase insertion forces, as the delivery system requires more force to pierce through the valve.
SUMMARY
(3) An embodiment of the present disclosure is an access sheath configured to be disposed along a

guidewire into a puncture of a vessel. The access sheath includes a hub having a proximal end and a distal end spaced from the proximal end. The access sheath further includes a cartridge carried by the hub, the cartridge having a first valve, a second valve spaced from the first valve along central axis, and a spacer disposed between the first valve and the second valve. The first valve and the second valve each have at least two slits that extend through first valve and the second valve, respectively, along the central axis. The access sheath further includes a shaft assembly having a shaft hub coupled to hub disposed relative the cartridge in a distal direction along the central axis, and a shaft that extends from the shaft hub in the distal direction.

(4) Another embodiment of the present disclosure is an access sheath. The access sheath is configured to be disposed along a guidewire into a puncture of a vessel. The access sheath includes a hub having a proximal end and a distal end spaced from the proximal end. The access sheath further includes a cartridge carried by the hub. The cartridge has a first valve, a second valve spaced from the first valve along a central axis, and a spacer disposed between the first valve and the second valve. The first valve and the second valve each have at least two slits that extend along, and twist about, the central axis. The access sheath further includes a shaft assembly having a shaft hub coupled to the hub and disposed relative to the cartridge in a distal direction along the central axis, and a shaft that extends from the shaft hub in the distal direction.

(5) A further embodiment of the present disclosure is a vascular closure system. The vascular closure system includes an access sheath configured to be inserted into the vessel. The access sheath has a proximal end and a distal end spaced from the proximal end along a central axis. The access sheath further includes a hub, a cartridge carried by the hub, the cartridge having a first valve, a second valve spaced from the first valve along the central axis, and a spacer disposed between the first valve and the second valve. The first valve and the second valve each have at least two slits that extend along the central axis. The access sheath further includes a shaft assembly having a shaft hub coupled to hub and disposed relative to the cartridge in a distal direction along the central axis, and a shaft that extends from the shaft hub in the distal direction to define the distal end of the access sheath. The access sheath further includes an access channel that extends from the proximal end at the hub to the distal end along the central axis. The vascular closure system further includes a deployment assembly having a sealing element configured to seal the puncture in the vessel. The deployment assembly is insertable into the access channel and into engagement with the first valve and the second valve such that the first valve and second valve stretch around the deployment assembly.

(6) Another embodiment of the present disclosure is a method. The method includes placing a first valve inside a sheath hub of a shaft assembly, the shaft assembly including an elongated shaft that extends from the sheath hub. The method further includes coupling the sheath hub to a cartridge with a tool. The method further includes placing a second valve in the cartridge adjacent a spacer such that second valve is spaced apart and aligned with the first valve, wherein the first valve and the second valve each have at least two slits. The method further includes inserting an assembly of the cartridge and sheath hub to a hub to form an access sheath.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) The foregoing summary, as well as the following detailed description, will be better understood when read in conjunction with the appended drawings. The drawings show illustrative embodiments of the disclosure. It should be understood, however, that the application is not limited to the precise arrangements and instrumentalities shown.

(2) FIG. **1** is a perspective view of an access sheath according to an embodiment of the present disclosure;

(3) FIG. **2** is an exploded view of the access sheath shown in FIG. **1**;
(4) FIG. **3**A is a side sectional view of the access sheath shown in FIGS. **1** and **2**;
(5) FIG. **3**B is a side sectional view of the access sheath shown in FIG. **3**A;
(6) FIG. **4**A is a perspective view of the valve shown in FIG. **2**;
(7) FIG. **4**B is a perspective cross-sectional view of the valve shown in FIG. **4**A;
(8) FIG. **5** is a perspective view of a vascular closure system according to an embodiment of the present disclosure;
(9) FIG. **6**A is a perspective view of an introducer and an access sheath of the system shown in FIG. **1**;
(10) FIG. **6**B is a perspective view of the vascular closure device and access sheath of the system shown in FIG. **1**;
(11) FIG. **7**A is a perspective view of a vascular closure device in accordance with an embodiment of the present disclosure;
(12) FIG. **7**B is a perspective view of a sealing device associated with the vascular closure device in FIG. **3**A;
(13) FIG. **7**C is a side sectional view of a distal portion of the vascular closure device;
(14) FIG. **8** is a process flow diagram illustrating a method for assembling the access sheath.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

(15) Certain terminology is used in the following description for convenience only and is not limiting. The words “right”, “left”, “lower” and “upper” designate directions in the drawings to which reference is made. The words “proximally” and “distally” refer to directions toward and away from, respectively, the individual operating the system. The terminology includes the above-listed words, derivatives thereof and words of similar import.

(16) Referring to FIGS. **1** and **2**, an access sheath **23** is configured to be inserted into a vessel of a patient for sheath introduction or exchange in a vessel. The access sheath **23** has a front end **21***f*, a rear end **21***r* opposite to the front end **21***f*, and a lumen (not numbered) that extends from the front end **21***f* to the rear end **21***r*. The access sheath **23** includes a hub **21***b*, a shaft assembly **21***d* that extends from the hub **21***b* in the distal direction **2**, and a valve assembly **41**. The rear end **21***r* of the access sheath includes the hub **21***b* that is configured to be coupled to the deployment assembly **14** during a closure procedure. The shaft assembly **21***d* includes a shaft hub **25** coupled to the valve assembly **41** and a shaft **27** that extends from the shaft hub **25** in the distal direction **2**. When the access sheath **23** is coupled to the deployment assembly **14**, the shaft assembly **21***d* extends along the release component **22** and delivery component **26** in the distal direction **2**. The shaft **27** includes at least one marker **130**. Thus, there may be a single marker **130** or a plurality of markers **130**. In the illustrated embodiment, the markers **130** are evenly spaced along the shaft **27** and can be positioned to aid in identifying the location of the shaft assembly **21***d* in the vessel. The marker **130** is one of a laser etch, radio opaque band, a radio opaque ink, or a radio opaque paint. The shaft **27** includes an outer diameter DS. In one embodiment, the outer diameter DS of the shaft **27** may be 14 F. In another embodiment, the outer diameter of the shaft may be 18 F. Other sizes are contemplated. In one example, the shaft length may vary as needed.

(17) Referring to FIGS. **3**A and **3**B, the valve assembly **41** carries the valves **44***a*, **44***b*. As shown, the valve assembly **41** is coupled to the shaft assembly **21***d* and the hub **21***b*. The valve assembly **41** includes a cartridge **48** that carries a first valve **44***a* and a second valve **44***b*. The first and second valves **44***a*, **44***b* may be hemostasis valves and are configured to minimize the loss of blood during insertion of the deployment assembly **14** into the access sheath **23**.

(18) The cartridge **48** includes a cartridge body **47** that is configured to house and hold the first and second valves **44***a*, **44***b*. As shown the cartridge body **47** has a first end **68** and a second end **72** opposite the first end along the central axis A. The cartridge body **47** has an outer diameter OD that extends through and intersects the central axis A. The cartridge body **47** further defines an internal surface **76**, which in turn, defines a spacer **51** that extends inwardly toward the central axis A. The

spacer **51** is configured to separate the first valve **44***a* and the second valve **44***b*. The cartridge body **47** further defines one or more grooves **49** disposed on either end of the cartridge **48**. In the illustrated embodiment, the cartridge **48** has an outer diameter of approximately 19 mm. The outer diameter OD can range between 15 mm and 30 mm as needed. The cartridge **48** may be formed from any polymeric material. It should be appreciated, however, that the cartridge **48** can be made of other materials and can have other configurations.

(19) The first and second valves **44***a*, **44***b* include a body **50** having a proximal surface **52** and a distal surface **56** opposite the proximal surface **52** along the central axis A. The valve body **50** can further define a thickness T that extends from the proximal surface **52** to the distal surface **56** in a direction that is parallel to the central axis A. In the illustrated embodiment, the thickness of the first and second valves **44***a*, **44***b* is approximately 3 mm. However, the thickness T may range between 2 mm and 5 mm or higher as needed. Furthermore, each valve body has a circular cross-sectional shape to fit with the cartridge. As shown, each valve has a diameter D that intersects and is perpendicular to the central axis A. In one example, the diameter D of the first and second valves **44***a*, **44***b* is approximately 15 mm. The diameter D may range between 8 mm and 20 mm, as needed. This size permits the deployment assembly **14** to pass through the slits as explained further below. The first and second valves **44***a*, **44***b* may be made of silicone. It should be appreciated, however, that the first and second valves **44***a*, **44***b* can be made of other materials and can have other configurations.

(20) The first and second valves **44***a* includes a set of tabs **64** disposed on the distal surface **56** of the body **50**. The tabs **64** of the first valve **44***a* are configured to couple the first valve **44***a* to the shaft hub **25** of the shaft assembly **21***d* via the cartridge **48**. The tabs **64** of the second valve **44***b* are configured to couple the second valve **44***b* to the hub **21***b* via the cartridge **48**. The grooves **49** of the cartridge **48** with the tabs **64** of the first and second valves **44***a*, **44***b*, couple the first and second valves **44***a*, **44***b* to the shaft assembly **21***d* and hub **21***b*, respectively. This configuration further enhances sealing within the access sheath **23**.

(21) Referring to FIGS. **4**A and **4**B, the first and second valves **44***a*, **44***b* include at least two slits **60**. As shown, the valves **44***a*, **44***b* include three slits **60***a*, **60***b*, **60***c* that extend along and spiral about the central axis A. In the illustrated embodiments, the valves **44***a*, **44***b* include a minimum of two slits. In alternative embodiments, the valves **44***a*, **44***b* may include more than three slits. The slits **60***a*, **60***b*, **60***c* extend diametrically across a portion of the body **47**. The slits **60***a*, **60***b*, **60***c* bisect each other at the center axis A. In this manner, the three slits form six identically sized flap portions with a 60 degree rotation on the body **50**. The slits **60***a*, **60***b*, **60***c* extend in a spiral form about the central axis A from the distal surface **56** to the proximal surface **52**. The slits **60***a*, **60***b*, **60***c* allow for the guidewire and the deployment assembly **14** to pass through the valve assembly **41** and the shaft assembly **21***d* of the access sheath **23** while still providing a seal to inhibit leakage and blood flow and loss. In the illustrated embodiments, the slits **60***a*, **60***b*, **60***c* are equal in size. In alternative embodiments, the slits **60***a*, **60***b*, **60***c* may vary in size. The first and second valves **44***a*, **44***b* are configured to stretch to accept the insertion of introducers (as needed) and in particular for insertion of the deployment assembly **14**. The first and second valves **44***a*, **44***b* are configured to stretch around the deployment assembly **14** to minimize leakage/flow around a and the deployment assembly **14** is advanced.

(22) The first valve **44***a* is positioned within the access sheath **23** such that the distal surface **56** of the first valve **44***a* is firmly seated against the shaft hub **25** while the proximal surface **52** of the first valve **44***a* abuts the spacer **51** of the cartridge **48**. Engagement between the shaft hub **25** and the distal surface **56** of the first valve **44***a* and between the proximal surface **52** and the cartridge **48** creates a fluid-tight seal therebetween to prevent leakage and blood loss. Similarly, the second valve **44***b* is positioned within the access sheath **23** such that the proximal surface **52** of the second valve **44***b* is firmly seated against the hub **21***b* while the distal surface **56** of the second valve **44***b* abuts the spacer **51** of the cartridge **48**. Engagement between the hub **21***b* and the proximal surface

52 of the second valve **44***b* and between the distal surface **56** and the cartridge **48** creates a fluid-tight seal therebetween to further prevent leakage and blood loss.

(23) Referring to FIGS. **5**-**7**C, in the illustrated embodiment, the valve assembly described herein is used in connection with a vascular closure system **10** for sheath introduction and exchange during vascular closure procedures. In alternative embodiments, the valve assembly described herein may be used for any sheath introduction or exchange in a vessel. Continuing with FIGS. **5**-**6**B, the vascular closure system **10** includes an introducer **100** and a closure device **12** that is configured to seal a puncture in a vessel wall. The introducer **100** is configured to facilitate placement of the closure device **12** into the desired position within a puncture site of a vessel wall following a surgical procedure. The closure device **12** includes a deployment assembly **14** and an access sheath **23**. The access sheath **23** can be inserted into the vessel and the deployment assembly **14** can be inserted into the access sheath **23** to position a sealing unit **18** (FIG. **5**C) into the vessel. The access sheath **23** and introducer **100** can be referred to as insertion assembly **15**.

(24) Referring to FIGS. **7**A and **7**B, a vascular closure device **12** includes a sealing unit **18** at least partially disposed within a deployment assembly **14**. The vascular closure device **12** can be configured such that after a distal portion of deployment assembly **14** is inserted through a puncture site of the vessel, the sealing unit **18** is deployed to thereby seal or otherwise close the puncture site of the vessel. The deployment assembly **14** is configured to control orientation of a toggle **40** of the sealing unit **18** in an easier and more efficient manner during deployment of the sealing unit **18**. Furthermore, the deployment assembly **14** is configured to reduce forces required to deploy the sealing unit **18** and seal the puncture.

(25) In accordance with the illustrated embodiment, the deployment assembly **14** includes a release component **22** that restrains the toggle **40**, a delivery component **26** (See FIG. **2**B) that contains at least a portion of the toggle **40** and a suture **43** of the sealing unit **18**, a guide member **35**, and one or more actuators **38** coupled to the release component **22**. The deployment assembly **14** may also include a tamper **70**, in the form a tube, that extends along the suture **43** and is located in a proximal direction relative to the locking member **230** (See FIG. **3**C). The guide member **35** extends through the sealing unit **18** and is configured to receive a guidewire as will be discussed below. In another example, the deployment assembly **14** can be configured so that the guidewire extends along the side of the toggle **40**. The release component **22** is operatively associated with the suture **43** such that actuation of the actuator **38** causes the release component **22** to 1) release the toggle **40**, and 2) apply tension to the suture **43**, which urges the toggle **40** against the delivery component **26** and orients the toggle **40** in the sealing position. The guide member **35** is configured to be removed from at least the sealing unit **18** prior the sealing unit **18** sealing the puncture.

(26) Turning to FIG. **7**C, the sealing unit **18** includes the toggle **40** connected to the suture **43**, a plug **88** coupled to the suture **43** and spaced from the toggle **40** in a proximal direction **4**, and a locking member **230** proximal to the plug **88**. The toggle **40** includes a distal end **45** *d* and a proximal end **41** *p* opposite to the proximal end **41** *p*, and a plurality of apertures (not numbered) extending therethrough. The suture **43** extends through the apertures as illustrated such that an end of the suture **43** is formed into a slidable knot **232**. The knot **232** is slidable along the suture **43** between the plug **88** and the locking member **230**. In an implanted state, the toggle **40** is adjacent to an inner surface of the vessel and the locking member **230** squeezes the toggle **40** and the plug **88** against the vessel to seal the puncture.

(27) The sealing unit **18** is formed with materials suitable for surgical procedures such as any biocompatible material. It should be appreciated, however, that the toggle **40** can be made of other materials and can have other configurations so long as it can be seated inside the vessel against the vessel wall. The plug **88** can comprise a strip of compressible, resorbable, collagen foam and can be made of a fibrous collagen mix of insoluble and soluble collagen that is cross linked for strength. It should be appreciated, however, that the plug member **88** can have any configuration as desired and can be made from any material as desired. The suture **43** can be any elongate member,

such as, for example a filament, thread, or braid.

(28) Now referring to FIG. **8**, a method **800** for assembling the access sheath **23** shown in FIGS. **1**-**6**B will be described. It should be appreciated that the access sheath **23** can be assembled during manufacture or at the surgical site prior to its use as described above. In step **804**, the first valve **44***a* is placed inside the shaft hub **25** of the shaft assembly **21***d*. In step **808**, the shaft hub **25** is coupled to the cartridge **48**. In step **812**, the second valve **44***b* is placed in the cartridge **48** adjacent the spacer **51** such that second valve **44***b* is spaced apart and aligned with the first valve **44***a*. In step **816**, the assembly of the cartridge **48** and the shaft hub **25** is inserted into the hub **21***b*, forming the access sheath **23**. The second valve **44***b* may be inserted such that the tabs **64** of the second valve **44***b* are configured to mate with the grooves of the hub **21***b*.

(29) The systems and devices as described herein may be used to seal punctures in a femoral artery. In particular, the valve assembly **41** may be utilized with a vascular closure system to seal so-called large bore punctures, such as 10 F French, 12 French, 14 French or larger sized bore. Such a system is typically used to seal a puncture in vessel within a patient's limb. In addition, the method may be used to seal a puncture in a so-called trans-caval procedure. In alternative embodiments, the valve assembly **41** may be utilized to allow sheath introduction and exchange in the vessel for any procedure.

(30) While the foregoing description and drawings represent the preferred embodiment of the present invention, it will be understood that various additions, modifications, combinations and/or substitutions may be made therein without departing from the spirit and scope of the present disclosure as defined in the accompanying claims. In particular, it will be clear to those skilled in the art that the present disclosure may be embodied in other specific forms, structures, arrangements, proportions, and with other elements, materials, and components, without departing from the spirit or essential characteristics thereof. One skilled in the art will appreciate that the present disclosure may be used with many modifications of structure, arrangement, proportions, materials, and components, which are particularly adapted to specific environments and operative requirements without departing from the principles of the present disclosure. In addition, features described herein may be used singularly or in combination with other features. For example, features described in connection with one component may be used and/or interchanged with features described in another component. The presently disclosed embodiment is therefore to be considered in all respects as illustrative and not restrictive, the scope of the present disclosure being indicated by the appended claims, and not limited to the foregoing description. It will be appreciated by those skilled in the art that various modifications and alterations of the present disclosure can be made without departing from the broad scope of the appended claims. Some of these have been discussed above and others will be apparent to those skilled in the art.

Claims

1. An access sheath configured to be disposed along a guidewire into a puncture of a vessel, the access sheath comprising: a hub having a proximal end and a distal end spaced from the proximal end; a cartridge carried by the hub, the cartridge including: a first valve, a second valve spaced from the first valve along a central axis, and a cartridge body defining an internal surface and defining a spacer extending inwardly from the internal surface, the spacer disposed between the first valve and the second valve, wherein: the first valve includes a valve body having a first slit and a second slit that intersect each other and twist about the central axis, the second valve includes a valve body having a first slit and a second slit that intersect each other and twist about the central axis, the first slit of the valve body of the first valve and the first slit of the valve body of the second valve are oriented in substantially the same direction diametrically across the respective valve body, the second slit of the valve body of the first valve and the second slit of the valve body of the second valve are oriented in substantially the same direction diametrically across the

respective valve body, and the cartridge body is open at longitudinal ends so that the first valve is inserted into a first longitudinal end of the cartridge body distal to the spacer, and the second valve is inserted into a second longitudinal end of the cartridge body proximal to the spacer; and a shaft assembly having a shaft hub coupled to the hub, and a shaft that extends from the shaft hub in a distal direction; wherein the first valve and the second valve include at least one set of tabs disposed on a distal surface of each valve body and configured to couple the first valve to the shaft hub and the second valve to the hub, respectively.

2. The access sheath of claim 1, wherein the first valve and the second valve are hemostasis valves.

3. The access sheath of claim 1, wherein the valve body of each of the first and second valves includes a third slit, such that the three slits of each valve body spiral about the central axis.

4. The access sheath of claim 1, wherein: the valve body of the first valve has a proximal surface spaced from the respective distal surface along the central axis, wherein the first and second slits of the valve body of the first valve extend from the proximal surface to the distal surface of the valve body of the first valve, and the valve body of the second valve has a proximal surface spaced from the respective distal surface of the valve body of the second valve along the central axis, wherein the first and second slits of the valve body of the second valve extend from the proximal surface to the distal surface of the valve body of the second valve.

5. The access sheath of claim 4, wherein the first valve is seated against the shaft hub while the proximal surface of the valve body of the first valve abuts the spacer.

6. The access sheath of claim 4, wherein the second valve is firmly seated against the hub while the distal surface of the valve body of the second valve abuts the spacer.

7. The access sheath of claim 4, wherein the valve body of each of the first and second valves includes a third slit, wherein the three slits of each valve body bisect each other at the central axis.

8. The access sheath of claim 7, wherein the three slits of the valve body of the first valve extend in a spiral about the central axis from the proximal surface of the valve body of the first valve to the distal surface of the valve body of the first valve.

9. The access sheath of claim 7, wherein the three slits of the valve body of the second valve extend in a spiral about the central axis from the proximal surface of the valve body of the second valve to the distal surface of the valve body of the second valve.

10. An access sheath configured to be disposed along a guidewire into a puncture of a vessel, the access sheath comprising: a hub having a proximal end and a distal end spaced from the proximal end; a cartridge carried by the hub, the cartridge including: a first valve that includes a distal surface and at least one tab extending distally from the distal surface, a second valve that includes a distal surface, and a cartridge body defining an internal surface and defining a spacer extending inwardly from the internal surface, the spacer positioned between the first valve and the second vale so that the first valve and the second valve are spaced apart with respect to each other along a central axis, wherein; each of the first valve and the second valve has a valve body and at least two slits that extend partially across the respective valve and twist about the central axis as they extend through the valve body such that the at least two slits of the first valve and the at least two slits of the second valve are oriented in substantially the same directions diametrically across a portion of the respective valve body, and the cartridge body is open at longitudinal ends so that the first valve is inserted into a first longitudinal end of the cartridge body distal to the spacer, and the second valve is inserted into a second longitudinal end of the cartridge body proximal to the spacer; and a shaft assembly having a shaft hub coupled to the hub and the at least one tab of the first valve, and a shaft that extends from the shaft hub in a distal direction.

11. The access sheath of claim 10, wherein the first valve and the second valve are hemostasis valves.

12. The access sheath of claim 10, wherein the at least two slits of each of the first and second valves are three slits that twist about the central axis.

13. The access sheath of claim 10, wherein the valve bodies of the first valve and the second valve

each have a proximal surface spaced from the respective distal surface along the central axis, and wherein the at least two slits extend from the respective proximal surface to the respective distal surface.
14. The access sheath of claim 13, wherein the distal surface of the valve body of the first valve is seated against the shaft hub while the proximal surface of the valve body of the first valve abuts the spacer.
15. The access sheath of claim 13, wherein the second valve is firmly seated against the hub while the distal surface of the valve body of the second valve abuts the spacer.
16. The access sheath of claim 13, wherein the at least two slits of each of the first and second valves are three slits, and wherein the three slits of each of the first and second valves bisect each other at the central axis.
17. The access sheath of claim 16, wherein the three slits of the first valve extend in a spiral about the central axis from the proximal surface of the valve body of the first valve to the distal surface of the valve body of the first valve.
18. The access sheath of claim 16, wherein the three slits of the second valve extend in a spiral about the central axis from the proximal surface of the valve body of the second valve to the distal surface of the valve body of the second valve.
19. A vascular closure system configured to seal a puncture in a vessel, the vascular closure system comprising: an access sheath configured to be inserted into the vessel, the access sheath having a proximal end and a distal end spaced from the proximal end along a central axis, the access sheath further including a hub; a cartridge carried by the hub, the cartridge having a first valve, a second valve spaced from the first valve along the central axis, and a spacer defined by and extending from an internal surface of the cartridge between the first valve and the second valve, wherein: the first valve and the second valve each having at least two slits that extend partially across the first valve and the second valve, respectively, and spiral about the central axis such that the at least two slits of the first valve and the at least two slits of the second valve are oriented in substantially the same directions diametrically across a portion of the respective valve, the first valve and the second valve each further comprises a proximal surface and a distal surface, the respective distal surfaces each including one or more distally extending tabs, and the cartridge is open at longitudinal ends so that the first valve is inserted into a first longitudinal end of the cartridge distal to the spacer, and the second valve is inserted into a second longitudinal end of the cartridge proximal to the spacer; a shaft assembly having a shaft hub coupled to the hub, and a shaft that extends from the shaft hub in a distal direction to define the distal end of the access sheath; and an access channel that extends from the proximal end at the hub to the distal end along the central axis; and a deployment assembly having a sealing element configured to seal the puncture in the vessel, wherein the deployment assembly is insertable into the access channel and into engagement with the first valve and the second valve such that the first valve and the second valve stretch around the deployment assembly.
20. The vascular closure system of claim 19, wherein the first valve and the second valve are hemostasis valves.
21. The vascular closure system of claim 19, wherein the at least two slits of each of the first and second valves are three slits that spiral about the central axis.
22. The vascular closure system of claim 19, wherein the at least two slits extend from the respective proximal surface to the respective distal surface of each of the first valve and the second valve.
23. The vascular closure system of claim 22, wherein the first valve is seated against the shaft hub while the proximal surface of the first valve abuts the spacer.
24. The vascular closure system of claim 22, wherein the second valve is firmly seated against the hub while the distal surface of the second valve abuts the spacer.
25. The vascular closure system of claim 22, wherein the at least two slits of each of the first and

second valves are three slits, wherein the three slits of each of the first and second valves bisect each other at the central axis.
26. The vascular closure system of claim 25, wherein the three slits of the first valve extend in a spiral about the central axis from the proximal surface of the first valve to the distal surface of the first valve.
27. The vascular closure system of claim 25, wherein the three slits of the second valve extend in a spiral about the central axis from the proximal surface of the second valve to the distal surface of the second valve.
28. The vascular closure system of claim 19, wherein the first valve and the second valve are configured to inhibit blood flow along an outer surface of the deployment assembly when 1) the deployment assembly is engaged with the first valve and the second valve and 2) a distal end of the deployment assembly is placed inside the vessel.
29. The vascular closure system of claim 19, wherein the first valve and the second valve are configured to transition from an unstretched state into a stretched state when the deployment assembly is inserted therein.
30. A method, comprising: providing a first valve and a shaft assembly having a shaft hub and an elongated shaft that extends from the shaft hub in a distal direction; coupling the shaft hub to a cartridge with a tool, the cartridge including: a cartridge body defining an internal surface and defining a spacer extending inwardly from the internal surface, the cartridge body is open at longitudinal ends so that the first valve is inserted into a first longitudinal end of the cartridge body distal to the spacer: placing a second valve in the cartridge by inserting into a second longitudinal end of the cartridge body proximal to and adjacent the spacer such that the second valve is spaced apart from and aligned with the first valve along a central axis and the spacer is disposed between the first valve and the second valve, wherein: the first valve includes a valve body having a first slit and a second slit that intersect each other and twist about the central axis, the second valve includes a valve body having a first slit and a second slit that intersect each other and twist about the central axis, the first slit of the valve body of the first valve and the first slit of the valve body of the second valve are oriented in substantially the same direction diametrically across the respective valve body; the second slit of the valve body of the first valve and the second slit of the valve body of the second valve are oriented in substantially the same direction diametrically across the respective valve body, and the first valve and the second valve include at least one set of tabs disposed on a distal surface of each valve body and configured to couple the first valve to the shaft hub and the second valve to a hub; and inserting an assembly of the cartridge and the shaft hub to the hub to a hub to form an access sheath.
31. The method of claim 30, wherein the twist of the first slit and the second slit of the first valve, and the first slit and second slit of the second valve, each are spirals about the central axis.
32. The method of claim 31, wherein; the first valve includes a third slit, the second valve includes a third slit, the first slit, the second slit, and the third slit of the first valve bisect each other at the central axis, and the first slit, the second slit, and the third slit of the second valve bisect each other at the central axis.
33. The method of claim 32, wherein; the first valve and the second valve have a proximal surface, and the distal surface is spaced from the proximal surface along the central axis, the first slit and the second slit of the first valve extend from the proximal surface to the distal surface, and the first slit and second slit of the second valve extend from the proximal surface to the distal surface.
34. The method of claim 33, wherein the first slit, the second slit, and the third slit of the first valve extend in a spiral about the central axis from the proximal surface of the first valve to the distal surface of the first valve.
35. The method of claim 33, wherein the first slit, the second slit, and the third slit of the of the second valve extend in a spiral about the central axis from the proximal surface of the second valve to the distal surface of the second valve.