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Bülach, February 2013

Urgent Field Safety Notice

Product: Pharos Vitesse Neurovascular Stent System

Dear Customer,

BIOTRONIK AG is issuing this communication to inform you about the clarification for the current indications for the use of the Pharos Vitesse Neurovascular Stent System.

Description of the problem:

Published results from the SAMMPRIS trial (Wingspan stent) and early analysis of preliminary data of the VISSIT trial (Pharos Vitesse stent) led BIOTRONIK AG to carefully re-evaluate the appropriate use of intracranial stenting for the treatment of intracranial atherosclerotic disease (ICAD). As a result of our internal review, we believe it is necessary to reiterate and clarify the current Pharos-Vitesse indications for use to ensure that only the most appropriate patients are treated with this device. Pharos-Vitesse is indicated only for **patients who are refractory to medical therapy**. This term should be understood to signify patients who continue to have recurrent stroke (and not only recurrent transient ischemic attacks) despite the most aggressive effective medical treatment option(s) deemed appropriate for individual patients.

Peri-procedural complications that may accompany stenting for ICAD have become well known, and therefore, Pharos-Vitesse should only be used in patients that present with a potentially favorable risk-benefit ratio of treatment with stenting over continued failing medical management.

BIOTRONIK AG will inform the appropriate Competent Authorities of this Voluntary Field Safety Action.

Details on affected devices:

This Field Safety Action pertains to the entire product range and all Lots of Pharos Vitesse. See Attachment 1 for the list of product codes

Advice on action to be taken by the customer:

Our records indicate that you have received Pharos Vitesse Neurovascular Stent Systems and we are asking for your cooperation in our efforts to complete this Voluntary Field Safety Action. Therefore, please follow the instructions outlined below.

1. Please complete and sign the Customer Acknowledgement Form enclosed to this Field Safety Notice to acknowledge the receipt and to confirm that you have read and understood the clarification detailed in this Field Safety Notice.
2. Please bring this Field Safety Notice to the attention of any health care professional in your organisation that needs to be aware.
3. Please send the completed and signed Customer Acknowledgement Form to the following fax number or e-mail address:
Fax: 0041 44 864 5181
E-Mail: cnf.vi@biotronik.com

We apologize for any inconvenience this action may cause. We appreciate your cooperation in this matter and are committed to maintaining your confidence in the quality of our products.

If you have further questions or need assistance with this Voluntary Field Safety Action, please do not hesitate to contact us on +41 44 864 5525/ -5526.

Respectfully,



Marcel Schäfer
Director Regulatory Affairs

Attachment 1
Product Codes Associated with Field Safety Notice for PHAROS Vitesse Stent Products

Pos	Description	Catalogue Number (Ref. No.)	Stent Diameter [mm]	Stent length [mm]	Usable length [cm]
1	PHAROS Vitesse 2.0/8/147	360560	2	8	147
2	PHAROS Vitesse 2.25/8/147	360561	2.25	8	147
3	PHAROS Vitesse 2.5/8/147	360562	2.5	8	147
4	PHAROS Vitesse 2.75/8/147	360563	2.75	8	147
5	PHAROS Vitesse 3.0/8/147	360564	3	8	147
6	PHAROS Vitesse 3.5/8/147	360565	3.5	8	147
7	PHAROS Vitesse 4.0/8/147	360566	4	8	147
8	PHAROS Vitesse 2.0/10/147	360567	2	10	147
9	PHAROS Vitesse 2.25/10/147	360568	2.25	10	147
10	PHAROS Vitesse 2.5/10/147	360569	2.5	10	147
11	PHAROS Vitesse 2.75/10/147	360570	2.75	10	147
12	PHAROS Vitesse 3.0/10/147	360571	3	10	147
13	PHAROS Vitesse 3.5/10/147	360572	3.5	10	147
14	PHAROS Vitesse 4.0/10/147	360573	4	10	147
15	PHAROS Vitesse 2.0/13/147	360574	2	13	147
16	PHAROS Vitesse 2.25/13/147	360575	2.25	13	147
17	PHAROS Vitesse 2.5/13/147	360576	2.5	13	147
18	PHAROS Vitesse 2.75/13/147	360577	2.75	13	147
19	PHAROS Vitesse 3.0/13/147	360578	3	13	147
20	PHAROS Vitesse 3.5/13/147	360579	3.5	13	147
21	PHAROS Vitesse 4.0/13/147	360580	4	13	147
22	PHAROS Vitesse 4.5/13/147	360581	4.5	13	147
23	PHAROS Vitesse 5.0/13/147	360582	5	13	147
24	PHAROS Vitesse 2.0/15/147	360583	2	15	147
25	PHAROS Vitesse 2.25/15/147	360584	2.25	15	147
26	PHAROS Vitesse 2.5/15/147	360585	2.5	15	147
27	PHAROS Vitesse 2.75/15/147	360586	2.75	15	147
28	PHAROS Vitesse 3.0/15/147	360587	3	15	147
29	PHAROS Vitesse 3.5/15/147	360588	3.5	15	147
30	PHAROS Vitesse 4.0/15/147	360589	4	15	147
31	PHAROS Vitesse 4.5/15/147	360590	4.5	15	147
32	PHAROS Vitesse 5.0/15/147	360591	5	15	147
33	PHAROS Vitesse 2.0/18/147	360592	2	18	147
34	PHAROS Vitesse 2.25/18/147	360593	2.25	18	147
35	PHAROS Vitesse 2.5/18/147	360594	2.5	18	147
36	PHAROS Vitesse 2.75/18/147	360595	2.75	18	147
37	PHAROS Vitesse 3.0/18/147	360596	3	18	147
38	PHAROS Vitesse 3.5/18/147	360597	3.5	18	147
39	PHAROS Vitesse 4.0/18/147	360598	4	18	147
40	PHAROS Vitesse 4.5/18/147	360599	4.5	18	147
41	PHAROS Vitesse 5.0/18/147	360600	5	18	147
42	PHAROS Vitesse 2.0/20/147	360601	2	20	147
43	PHAROS Vitesse 2.25/20/147	360602	2.25	20	147
44	PHAROS Vitesse 2.5/20/147	360603	2.5	20	147
45	PHAROS Vitesse 2.75/20/147	360604	2.75	20	147
46	PHAROS Vitesse 3.0/20/147	360605	3	20	147

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Product Codes Associated with Field Safety Notice for PHAROS Vitesse Stent Products

Pos	Description	Catalogue Number (Ref. No.)	Stent Diameter [mm]	Stent length [mm]	Usable length [cm]
47	PHAROS Vitesse 3.5/20/147	360606	3.5	20	147
48	PHAROS Vitesse 4.0/20/147	360607	4	20	147
49	PHAROS Vitesse 4.5/20/147	360608	4.5	20	147
50	PHAROS Vitesse 5.0/20/147	360609	5	20	147
51	PHAROS Vitesse 2.25/22/147	360610	2.25	22	147
52	PHAROS Vitesse 2.5/22/147	360611	2.5	22	147
53	PHAROS Vitesse 2.75/22/147	360612	2.75	22	147
54	PHAROS Vitesse 3.0/22/147	360613	3.0	22	147
55	PHAROS Vitesse 3.5/22/147	360614	3.5	22	147
56	PHAROS Vitesse 4.0/22/147	360615	4.0	22	147
57	PHAROS Vitesse 3.0/26/147	360616	3.0	26	147
58	PHAROS Vitesse 3.5/26/147	360617	3.5	26	147
59	PHAROS Vitesse 4.0/26/147	360618	4.0	26	147
60	PHAROS Vitesse 4.5/26/147	360619	4.5	26	147
61	PHAROS Vitesse 5.0/26/147	360620	5.0	26	147
62	PHAROS Vitesse 3.0/30/147	360621	3.0	30	147
63	PHAROS Vitesse 3.5/30/147	360622	3.5	30	147
64	PHAROS Vitesse 4.0/30/147	360623	4.0	30	147
65	PHAROS Vitesse 4.5/30/147	360624	4.5	30	147
66	PHAROS Vitesse 5.0/30/147	360625	5.0	30	147
67	PHAROS Vitesse 4.5/35/147	360626	4.5	35	147
68	PHAROS Vitesse 5.0/35/147	360627	5.0	35	147
69	PHAROS Vitesse 4.5/40/147	360628	4.5	40	147
70	PHAROS Vitesse 5.0/40/147	360629	5.0	40	147