

22.12.2025

Urgent safety notice for customers in the field

Batch recall: Tentos 4F

Due to multiple cases of internal catheter breakage

For Attention of:
Physicians, users and/or staff in the field of vascular surgery

Contact details of local representative

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Stensgårdsvej 47
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Fig.1: Tentos 4F

Information on affected devices				
1. device type(s)				
Tentos 4F				
2. trade name(s)				
Tentos 4F				
3. Unique Device Identifier(s) (UDI-DI)				
Article numbers		UDI-DI	Article numbers	
7603-6020	4047199168568		7606-6120	4047199169046
7603-6030	4047199168575		7606-6150	4047199169053
7603-6040	4047199168582		7606-6170	4047199169060
7603-6060	4047199168599		7606-7020	4047199169077
7603-6080	4047199168605		7606-7030	4047199169084
7603-6100	4047199168612		7606-7040	4047199169091
7603-7020	4047199168629		7606-7060	4047199169107
7603-7030	4047199168636		7606-7080	4047199169114
7603-7040	4047199168643		7606-7100	4047199169121
7603-7060	4047199168650		7606-7120	4047199169138
7603-7080	4047199168667		7606-7150	4047199169145
7603-7100	4047199168674		7606-7170	4047199169152
7604-6020	4047199168681		7607-6020	4047199169169
7604-6030	4047199168698		7607-6030	4047199169176
7604-6040	4047199168704		7607-6040	4047199169183

7604-6060	4047199168711	7607-6060	4047199169190
7604-6080	4047199168728	7607-6080	4047199169206
7604-6100	4047199168735	7607-6100	4047199169213
7604-7020	4047199168742	7607-6120	4047199169220
7604-7030	4047199168759	7607-6150	4047199169237
7604-7040	4047199168766	7607-6170	4047199169244
7604-7060	4047199168773	7607-7020	4047199169251
7604-7080	4047199168780	7607-7030	4047199169268
7604-7100	4047199168797	7607-7040	4047199169275
7605-6020	4047199168803	7607-7060	4047199169282
7605-6030	4047199168810	7607-7080	4047199169299
7605-6040	4047199168827	7607-7100	4047199169305
7605-6060	4047199168834	7607-7120	4047199169312
7605-6080	4047199168841	7607-7150	4047199169329
7605-6100	4047199168858	7607-7170	4047199169336
7605-6120	4047199168865	7608-6020	4047199169343
7605-6150	4047199168872	7608-6030	4047199169350
7605-6170	4047199168889	7608-6040	4047199169367
7605-7020	4047199168896	7608-6060	4047199169374
7605-7030	4047199168902	7608-6080	4047199169381
7605-7040	4047199168919	7608-6100	4047199169398
7605-7060	4047199168926	7608-6120	4047199169404
7605-7080	4047199168933	7608-6150	4047199169411
7605-7100	4047199168940	7608-6170	4047199169428
7605-7120	4047199168957	7608-7020	4047199169435
7605-7150	4047199168964	7608-7030	4047199169442
7605-7170	4047199168971	7608-7040	4047199169459
7606-6020	4047199168988	7608-7060	4047199169466
7606-6030	4047199168995	7608-7080	4047199169473
7606-6040	4047199169008	7608-7100	4047199169480
7606-6060	4047199169015	7608-7120	4047199169497
7606-6080	4047199169022	7608-7150	4047199169503
7606-6100	4047199169039	7608-7170	4047199169510

4. Primary clinical purpose of the device(s)

The Tentos 4F stent system is used to insert a self-expanding Nitinol stent into the arterial vascular system in the pelvic/leg area using the application system. The stent itself is designed to improve the lumen diameter of the target vessel and blood flow.

5. Device model/catalogue/part number(s)

Article numbers

7603-6020	7605-6020	7606-6120	7607-7060
7603-6030	7605-6030	7606-6150	7607-7080
7603-6040	7605-6040	7606-6170	7607-7100
7603-6060	7605-6060	7606-7020	7607-7120
7603-6080	7605-6080	7606-7030	7607-7150
7603-6100	7605-6100	7606-7040	7607-7170
7603-7020	7605-6120	7606-7060	7608-6020

7603-7030	7605-6150	7606-7080	7608-6030
7603-7040	7605-6170	7606-7100	7608-6040
7603-7060	7605-7020	7606-7120	7608-6060
7603-7080	7605-7030	7606-7150	7608-6080
7603-7100	7605-7040	7606-7170	7608-6100
7604-6020	7605-7060	7607-6020	7608-6120
7604-6030	7605-7080	7607-6030	7608-6150
7604-6040	7605-7100	7607-6040	7608-6170
7604-6060	7605-7120	7607-6060	7608-7020
7604-6080	7605-7150	7607-6080	7608-7030
7604-6100	7605-7170	7607-6100	7608-7040
7604-7020	7606-6020	7607-6120	7608-7060
7604-7030	7606-6030	7607-6150	7608-7080
7604-7040	7606-6040	7607-6170	7608-7100
7604-7060	7606-6060	7607-7020	7608-7120
7604-7080	7606-6080	7607-7030	7608-7150
7604-7100	7606-6100	7607-7040	7608-7170

6. Software version

n/z

7. Affected serial or batch numbers

Article number	Lot	Article number	Lot
7603-6020	6000233341	7606-6040	6000259618
7603-6020	6000240751	7606-6040	6000261520
7603-6020	6000245183	7606-6040	6000261882
7603-6020	6000245726	7606-6040	6000264942
7603-6020	6000249425	7606-6040	6000266265
7603-6020	6000255909	7606-6040	6000267752
7603-6020	6000258939	7606-6060	6000240786
7603-6020	6000260754	7606-6060	6000242343
7603-6020	6000261938	7606-6060	6000244337
7603-6020	6000263351	7606-6060	6000245367
7603-6030	6000240752	7606-6060	6000246403
7603-6030	6000245237	7606-6060	6000251534
7603-6030	6000251529	7606-6060	6000253455
7603-6030	6000251782	7606-6060	6000255696
7603-6030	6000255910	7606-6060	6000256561
7603-6030	6000259787	7606-6060	6000256572
7603-6030	6000263057	7606-6060	6000262083
7603-6030	6000266262	7606-6060	6000264455
7603-6030	6000269503	7606-6060	6000266007
7603-6040	6000236522	7606-6060	6000266684
7603-6040	6000240753	7606-6060	6000269131
7603-6040	6000241401	7606-6080	6000240905
7603-6040	6000243583	7606-6080	6000242556
7603-6040	6000248776	7606-6080	6000244338
7603-6040	6000251530	7606-6080	6000244691
7603-6040	6000258450	7606-6080	6000255152
7603-6040	6000263527	7606-6080	6000256298
7603-6040	6000265119	7606-6080	6000256571
7603-6040	6000269855	7606-6080	6000259619
7603-6060	6000233343	7606-6080	6000261522
7603-6060	6000240754	7606-6080	6000262683
7603-6060	6000241402	7606-6080	6000265421

7603-6060	6000245239	7606-6080	6000266765
7603-6060	6000250400	7606-6100	6000240823
7603-6060	6000254232	7606-6100	6000241403
7603-6080	6000240755	7606-6100	6000241404
7603-6080	6000255911	7606-6100	6000242377
7603-6080	6000263056	7606-6100	6000244339
7603-6100	6000233344	7606-6100	6000244695
7603-6100	6000240756	7606-6100	6000253700
7603-6100	6000247984	7606-6100	6000256445
7603-6100	6000251531	7606-6100	6000256570
7603-7020	6000233345	7606-6100	6000260216
7603-7020	6000240757	7606-6100	6000264862
7603-7020	6000242770	7606-6100	6000265422
7603-7020	6000244014	7606-6120	6000240824
7603-7020	6000244677	7606-6120	6000242533
7603-7020	6000249327	7606-6120	6000244697
7603-7020	6000250119	7606-6120	6000245369
7603-7020	6000252388	7606-6120	6000256210
7603-7020	6000263773	7606-6120	6000256568
7603-7020	6000266261	7606-6120	6000256825
7603-7030	6000232994	7606-6120	6000257860
7603-7030	6000233533	7606-6120	6000260073
7603-7030	6000244678	7606-6120	6000264056
7603-7030	6000250120	7606-6150	6000235843
7603-7030	6000252149	7606-6150	6000240825
7603-7030	6000253786	7606-6150	6000242611
7603-7030	6000253910	7606-6150	6000244698
7603-7030	6000257424	7606-6150	6000246447
7603-7030	6000258972	7606-6150	6000248046
7603-7030	6000261939	7606-6150	6000260148
7603-7030	6000266681	7606-6170	6000240826
7603-7030	6000268842	7606-6170	6000244724
7603-7040	6000232995	7606-7020	6000251135
7603-7040	6000233535	7606-7020	6000263749
7603-7040	6000234408	7606-7020	6000269132
7603-7040	6000242513	7606-7030	6000244348
7603-7040	6000246080	7606-7030	6000245366
7603-7040	6000250121	7606-7030	6000253443
7603-7040	6000251866	7606-7030	6000255009
7603-7040	6000254259	7606-7040	6000240827
7603-7040	6000255264	7606-7040	6000244336
7603-7040	6000258678	7606-7040	6000247815
7603-7040	6000258786	7606-7040	6000247895
7603-7040	6000259990	7606-7040	6000248628
7603-7040	6000261515	7606-7040	6000250339
7603-7040	6000261516	7606-7040	6000252729
7603-7040	6000265171	7606-7040	6000253699
7603-7040	6000267444	7606-7040	6000254929
7603-7040	6000269504	7606-7040	6000259617
7603-7060	6000232996	7606-7040	6000262480
7603-7060	6000241139	7606-7040	6000263112
7603-7060	6000244679	7606-7040	6000264567
7603-7060	6000248254	7606-7040	6000266266
7603-7060	6000251868	7606-7040	6000268414
7603-7060	6000254487	7606-7040	6000270020
7603-7060	6000254979	7606-7060	6000233544

7603-7060	6000257376	7606-7060	6000233888
7603-7060	6000259528	7606-7060	6000240906
7603-7060	6000259941	7606-7060	6000243393
7603-7060	6000263320	7606-7060	6000244688
7603-7060	6000265393	7606-7060	6000248536
7603-7060	6000267232	7606-7060	6000251536
7603-7060	6000268062	7606-7060	6000253114
7603-7080	6000232997	7606-7060	6000255151
7603-7080	6000241140	7606-7060	6000263321
7603-7080	6000244680	7606-7060	6000265529
7603-7080	6000246082	7606-7060	6000266624
7603-7080	6000254550	7606-7060	6000269389
7603-7080	6000257377	7606-7080	6000233000
7603-7080	6000259615	7606-7080	6000233536
7603-7080	6000262058	7606-7080	6000240877
7603-7080	6000262059	7606-7080	6000243859
7603-7080	6000264699	7606-7080	6000245368
7603-7080	6000267200	7606-7080	6000248574
7603-7080	6000267566	7606-7080	6000248662
7603-7100	6000234409	7606-7080	6000251066
7603-7100	6000240758	7606-7080	6000252996
7603-7100	6000243002	7606-7080	6000253206
7603-7100	6000245727	7606-7080	6000256182
7603-7100	6000248045	7606-7080	6000259620
7603-7100	6000248513	7606-7080	6000262503
7603-7100	6000251051	7606-7080	6000264460
7603-7100	6000253105	7606-7080	6000265742
7603-7100	6000254590	7606-7080	6000268934
7603-7100	6000257330	7606-7100	6000233496
7603-7100	6000259586	7606-7100	6000233537
7603-7100	6000261081	7606-7100	6000240830
7603-7100	6000261511	7606-7100	6000244693
7603-7100	6000262063	7606-7100	6000251537
7603-7100	6000262801	7606-7100	6000255153
7603-7100	6000264444	7606-7100	6000264462
7603-7100	6000267198	7606-7100	6000266556
7603-7100	6000267332	7606-7100	6000267233
7603-7100	6000267494	7606-7100	6000268181
7603-7100	6000269125	7606-7100	6000269632
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7604-6020	6000240759	7606-7120	6000242752
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7604-6020	6000256978	7606-7120	6000248511
7604-6020	6000258802	7606-7120	6000251449
7604-6020	6000263110	7606-7120	6000257861
7604-6020	6000266263	7606-7120	6000262889
7604-6030	6000235827	7606-7120	6000267333
7604-6030	6000240760	7606-7150	6000235852
7604-6030	6000245241	7606-7150	6000236356
7604-6030	6000253446	7606-7150	6000240833
7604-6030	6000257575	7606-7150	6000240835
7604-6030	6000258971	7606-7150	6000241016
7604-6030	6000261379	7606-7150	6000243049
7604-6030	6000262416	7606-7150	6000250340
7604-6030	6000263491	7606-7150	6000251450

7604-6030	6000267339	7606-7150	6000254347
7604-6040	6000240761	7606-7150	6000254425
7604-6040	6000241551	7606-7150	6000256830
7604-6040	6000245242	7606-7150	6000257752
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7604-6040	6000248658	7606-7150	6000259464
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7604-6040	6000256297	7606-7150	6000265743
7604-6040	6000256564	7606-7170	6000235853
7604-6040	6000256569	7606-7170	6000240836
7604-6040	6000269126	7606-7170	6000240879
7604-6040	6000269856	7606-7170	6000243578
7604-6060	6000240762	7606-7170	6000246817
7604-6060	6000241770	7606-7170	6000247839
7604-6060	6000245244	7606-7170	6000248947
7604-6060	6000262979	7606-7170	6000250668
7604-6060	6000270407	7606-7170	6000251337
7604-6080	6000240763	7606-7170	6000252731
7604-6080	6000241811	7606-7170	6000254426
7604-6080	6000246353	7606-7170	6000255019
7604-6080	6000256566	7606-7170	6000256818
7604-6100	6000240764	7606-7170	6000258975
7604-6100	6000242514	7606-7170	6000267157
7604-6100	6000244681	7606-7170	6000268845
7604-7020	6000233349	7607-6020	6000240837
7604-7020	6000235828	7607-6020	6000266656
7604-7020	6000240765	7607-6020	6000267507
7604-7020	6000242769	7607-6030	6000235854
7604-7020	6000244682	7607-6030	6000240838
7604-7020	6000255210	7607-6030	6000254295
7604-7030	6000240904	7607-6030	6000262504
7604-7030	6000244683	7607-6030	6000263923
7604-7030	6000251712	7607-6040	6000240840
7604-7030	6000251769	7607-6040	6000241400
7604-7030	6000252150	7607-6040	6000242089
7604-7030	6000253453	7607-6040	6000246367
7604-7030	6000254980	7607-6040	6000248372
7604-7030	6000259616	7607-6040	6000252765
7604-7030	6000262084	7607-6040	6000254021
7604-7030	6000263111	7607-6040	6000256975
7604-7030	6000264307	7607-6040	6000258976
7604-7030	6000265781	7607-6040	6000262597
7604-7030	6000266628	7607-6040	6000263055
7604-7030	6000268004	7607-6040	6000265507
7604-7030	6000269958	7607-6040	6000265782
7604-7040	6000232998	7607-6060	6000235858
7604-7040	6000241476	7607-6060	6000240841
7604-7040	6000244684	7607-6060	6000241516
7604-7040	6000245365	7607-6060	6000246368
7604-7040	6000248660	7607-6060	6000255241
7604-7040	6000253454	7607-6080	6000235859
7604-7040	6000254020	7607-6080	6000240842
7604-7040	6000257637	7607-6080	6000241517
7604-7040	6000259621	7607-6080	6000245854
7604-7040	6000262501	7607-6080	6000246369
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7604-7040	6000264728	7607-6080	6000256976
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7604-7040	6000266629	7607-6100	6000232578
7604-7040	6000268060	7607-6100	6000235860
7604-7040	6000269506	7607-6100	6000242379
7604-7060	6000232999	7607-6100	6000243205
7604-7060	6000240766	7607-6100	6000256282
7604-7060	6000244685	7607-6100	6000256573
7604-7060	6000248461	7607-6120	6000233495
7604-7060	6000248946	7607-6120	6000235861
7604-7060	6000255942	7607-6120	6000240336
7604-7060	6000258447	7607-6120	6000240844
7604-7060	6000258973	7607-6120	6000240880
7604-7060	6000259991	7607-6120	6000243206
7604-7060	6000261517	7607-6120	6000256280
7604-7060	6000263600	7607-6150	6000240845
7604-7060	6000263604	7607-6170	6000240846
7604-7060	6000264291	7607-7020	6000251136
7604-7060	6000264809	7607-7020	6000252393
7604-7060	6000266093	7607-7020	6000267964
7604-7060	6000267446	7607-7030	6000233924
7604-7060	6000269416	7607-7030	6000236058
7604-7080	6000234116	7607-7030	6000236358
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7604-7080	6000258878	7607-7030	6000247267
7604-7080	6000266630	7607-7030	6000248537
7604-7080	6000269607	7607-7030	6000251144
7604-7100	6000240767	7607-7030	6000252394
7604-7100	6000243199	7607-7030	6000254823
7604-7100	6000252662	7607-7030	6000264308
7604-7100	6000254042	7607-7030	6000266046
7604-7100	6000256959	7607-7030	6000269809
7604-7100	6000259637	7607-7040	6000233001
7604-7100	6000264502	7607-7040	6000233539
7604-7100	6000267197	7607-7040	6000240849
7604-7100	6000269507	7607-7040	6000247814
7605-6020	6000235819	7607-7040	6000251488
7605-6020	6000240870	7607-7040	6000251538
7605-6020	6000242071	7607-7040	6000252685
7605-6020	6000243584	7607-7040	6000257206
7605-6020	6000247184	7607-7040	6000262360
7605-6020	6000253138	7607-7040	6000267334
7605-6020	6000269456	7607-7040	6000268904
7605-6030	6000240769	7607-7060	6000233002
7605-6030	6000244343	7607-7060	6000240884
7605-6030	6000245855	7607-7060	6000240907
7605-6030	6000256977	7607-7060	6000242772
7605-6030	6000267979	7607-7060	6000245025
7605-6030	6000268843	7607-7060	6000247985
7605-6040	6000235821	7607-7060	6000248575
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7605-6040	6000241873	7607-7060	6000254043
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7605-6040	6000255251	7607-7060	6000262778
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7605-6040	6000261877	7607-7060	6000264810
7605-6040	6000264330	7607-7060	6000268003
7605-6040	6000269212	7607-7060	6000270204
7605-6060	6000235823	7607-7080	6000242925
7605-6060	6000240771	7607-7080	6000243204
7605-6060	6000242515	7607-7080	6000248663
7605-6060	6000243169	7607-7080	6000251298
7605-6060	6000246212	7607-7080	6000252395
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7605-6080	6000245852	7607-7080	6000266625
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7605-7030	6000244687	7607-7170	6000244810
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7605-7040	6000234410	7607-7170	6000259468
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7605-7040	6000252053	7608-6020	6000256281
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7605-7040	6000254235	7608-6020	6000261164
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7605-7080	6000240872	7608-6060	6000242369
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7605-7080	6000252302	7608-6060	6000246087
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7605-7080	6000253842	7608-6080	6000230381
7605-7080	6000256936	7608-6080	6000235877
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7605-7100	6000240873	7608-7020	6000261148
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7605-7100	6000252389	7608-7030	6000261080
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7605-7150	6000244616	7608-7060	6000247987
7605-7150	6000249580	7608-7060	6000251104
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7605-7150	6000264466	7608-7060	6000259992
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7605-7170	6000252391	7608-7080	6000251068
7605-7170	6000254457	7608-7080	6000251437
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7606-6020	6000240876	7608-7080	6000259635
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7606-6020	6000252392	7608-7100	6000251486
7606-6020	6000259208	7608-7100	6000252016
7606-6020	6000263748	7608-7100	6000254048
7606-6030	6000240784	7608-7100	6000259519
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7606-6040	6000240785	7608-7150	6000258135
7606-6040	6000241621	7608-7150	6000259472
7606-6040	6000243203	7608-7150	6000259473
7606-6040	6000243858	7608-7170	6000251069
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7606-6040	6000251533	7608-7170	6000258472
7606-6040	6000254478	7608-7170	6000259756
7606-6040	6000256629	7608-7170	6000260149
7606-6040	6000258851	7608-7170	6000268159

8. Assigned devices

n/z

Reason for the field safety corrective action (FSCA)

1. description of the product problem

Danger due to loosening of the polyimide inner catheter proximal to the crown marker of the TENTOS 4F stent system.

2. Hazard that leads to FSCA

Due to insufficient elasticity of the polyimide inner catheter, there is a risk of failure at the transition from the proximal crown marker to the filler material. After release of the stent, this can lead to loosening of the inner structure distal to the transition from the crown marker to the filler material. The possible consequence is that this inner structure detaches and remains in the vessel, which could cause complications.

Based on investigations of the inner catheter raw material and the inner structure of the application system, it was possible to identify the raw material batches that, due to their low elongation at break, could potentially lead to the above-described failure of the inner structure.

The raw material batches with the lowest values also lead to the most frequent complaints.

3. Probability of occurrence of the problem

Potentially possible at any time

4. Expected risk for patients/users

May lead to loss of product components

5. Further information on the characterisation of the problem

n/z

6. Background to the problem

Customer complaint

7. Other information relevant to the FSCA

n/z

Type of risk mitigation measure	
1. Measure to be taken by the user	
☐ Identify device ☒ Return device ☐ On-site modification/inspection of the device ☐ Follow recommendations for patient treatment ☐ Observe changes/reinforcements to the instructions for use (IFU) ☐ Other ☐ Quarantine the device ☐ Destroy device ☐ None	
Comment:	
2. By when should the measure be completed?	31.01.2026
3. Special considerations for	n/z
4. Is patient follow-up or a review of patient outcomes to date recommended?	
no	
5. Is feedback from the customer required?	yes
6. (If yes, please attach a form stating the return deadline)	
6. Measure taken by the manufacturer	
☒ Product return ☐ Software upgrade ☐ Other ☐ On-site modification/inspection of the device ☐ Change in instructions for use or labelling ☐ None	
7. When should the measure be completed?	31.03.2026
8. Must the FSN be communicated to the patient/non-professional user?	No
9. If yes, has the manufacturer provided additional information suitable for the patient/non-professional user in an information letter/sheet?	
n/z	

General information	
1. FSN-Type	New
2. For updated FSN, reference number and date of the previous FSN	n/z
3. For updated FSN, significant new information as follows	
n/z	
4. Further advice or information that is already expected in the subsequent FSN?	No
5. If a subsequent FSN is expected, what further advice is it expected to relate to?	
n/z	
6. Expected timeframe for the subsequent FSN	n/z
7. Manufacturer information (For contact information of the local representative, see page 1 of this FSN)	
a. Company name	Optimed Medizinische Instrumente GmbH
b. Address	Ferdinand-Porsche-Str. 11, 76275 Ettlingen, Deutschland
c. Website	www.optimed.com

FSN Ref: RE-25-021

FSCA Ref: RE-25-021

8. n/z	
9. List of annexes/inserts	n/z
10. name/signature	 22.12.'25 On behalf of and on the instructions of Dr. Ralf Smounig PRRC

Transmission of this field safety notice

This notice must be shared with everyone in your organization who needs to be informed, or with any organization to which the potentially affected products have been transferred (if applicable).

Please forward this notice to other organizations affected by this action (if applicable).

Please keep this notice and the resulting action under review for an appropriate period of time to ensure the effectiveness of the corrective action.

Please report any product-related incidents to the manufacturer, distributor, or local representative, as well as the national competent authority, if applicable, as this provides important feedback."