

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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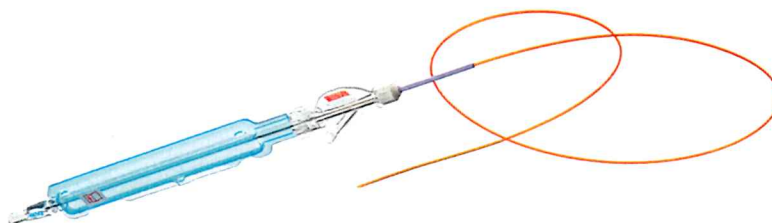


Fig.1: Tentos 4F

Information on affected devices				
1. device type(s)				
Tentos 4F				
2. trade name(s)				
Tentos 4F				
3. Unique Device Identifier(s) (UDI-DI)				
	Article number	UDI-DI	Article numbers	UDI-DI
	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
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7606-6030	4047199168995	7608-7080	4047199169473
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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
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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
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7604-6080	6000241811	7606-7170	6000254426
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7605-7030	6000244687	7607-7170	6000244810
7605-7030	6000253444	7607-7170	6000250623
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7605-7040	6000242922	7607-7170	6000260179
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7605-7040	6000252053	7608-6020	6000256281
7605-7040	6000252726	7608-6020	6000259587
7605-7040	6000254235	7608-6020	6000261164
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7605-7060	6000256181	7608-6040	6000258488
7605-7060	6000262502	7608-6040	6000261878
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7605-7060	6000264565	7608-6060	6000230388
7605-7060	6000269130	7608-6060	6000235876
7605-7060	6000270668	7608-6060	6000241297
7605-7080	6000240872	7608-6060	6000242369
7605-7080	6000242748	7608-6060	6000243207
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7605-7080	6000253842	7608-6080	6000230381
7605-7080	6000256936	7608-6080	6000235877
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7605-7150	6000235837	7608-7040	6000266626
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7605-7150	6000243977	7608-7060	6000240865
7605-7150	6000244616	7608-7060	6000247987
7605-7150	6000249580	7608-7060	6000251104
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7605-7150	6000259462	7608-7060	6000253707
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7605-7150	6000264466	7608-7060	6000259992
7605-7170	6000235838	7608-7060	6000265627
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7605-7170	6000242751	7608-7060	6000268434
7605-7170	6000244286	7608-7080	6000232898
7605-7170	6000245705	7608-7080	6000240866
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7605-7170	6000252391	7608-7080	6000251068
7605-7170	6000254457	7608-7080	6000251437
7605-7170	6000259463	7608-7080	6000254047
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7606-6030	6000262676	7608-7120	6000258134
7606-6030	6000266045	7608-7150	6000240869
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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
7606-6040	6000244699	7608-7170	6000258136
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	
<input type="checkbox"/> Identify device <input checked="" type="checkbox"/> Return device <input type="checkbox"/> On-site modification/inspection of the device <input type="checkbox"/> Follow recommendations for patient treatment <input type="checkbox"/> Observe changes/reinforcements to the instructions for use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> Quarantine the device <input type="checkbox"/> Destroy device <input type="checkbox"/> 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	
<input checked="" type="checkbox"/> Product return <input type="checkbox"/> Software upgrade <input type="checkbox"/> Other <input type="checkbox"/> On-site modification/inspection of the device <input type="checkbox"/> Change in instructions for use or labelling <input type="checkbox"/> 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

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

Transmission of this field safety notice
<p>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).</p> <p>Please forward this notice to other organizations affected by this action (if applicable).</p> <p>Please keep this notice and the resulting action under review for an appropriate period of time to ensure the effectiveness of the corrective action.</p> <p>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."</p>