Rev 1: 23.Jun.2025
FSN Ref: RE-25-005 FSCA Ref: RE-25-005

Date: 23. Jun.2025

Urgent Field Safety Notice and changes to the IFU Tentos 4F

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

Contact details of local representative
BMEDIC ApS
Stensgårdsvej 47
7000 Fredericia
Denmark
+45 30552500
pb@bmedic.dk

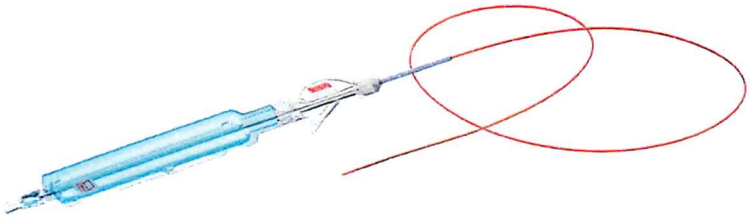

Fig.1: Tentos 4F

Information on affected devices			
1. device type(s)			
Tentos 4F			
2. trade name(s)			
Tentos 4F			
3. Unique Device Identifier(s) (UDI-DI)			
Artikelnummer	**UDI-DI**	**Artikelnummer**	**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
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 introduce a self-expanding nitinol stent into the arterial vascular system of the pelvis/lower extremities using the application device. The stent itself has the purpose of increasing the lumen diameter of the target vessel and improving 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

n/z

8. Assigned devices

n/z

Reason for the field safety corrective action (FSCA)

1. description of the product problem

Risk of damage to the TENTOS 4F due to unauthorised folding or bending during unpacking or preparation.

2. Hazard that leads to FSCA

Recent investigation of customer complaints about the TENTOS 4F breaking at the proximal mark before, during or after release of the stent led to the conclusion that extensive kinking/bending must have occurred during unpacking and/or preparation of the delivery device prior to implantation.

It follows that the kink/bend must have occurred during preparation of the delivery device when the guidewire is inserted through the inner catheter of the delivery device. As a standard procedure in the over-the-wire configuration, the user advances the guidewire with one hand and holds the delivery device with the other hand. During this procedure, inserting the guidewire and pushing it through the inner catheter or the delivery system can lead to an offset between the guidewire and the delivery system and thus to excessive kinking/bending if the user does not follow the instructions for use (IFU).

The current instructions for use state that the user must ensure that the application device is not kinked during preparation. However, due to recent incidents, this wording was found to be confusing and is now updated to state that the application device must not be kinked before or during use.

The more comprehensible wording is expected to raise awareness of the risk of kinking and thus prevent errors.

3. Probability of occurrence of the problem

Potentially possible at any time

4. Expected risk for patients/users

Can lead to loss of body parts and a serious accident

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

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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 Comment:		☐ Quarantine the device ☐ Destroy device ☐ None
2. By when should the measure be completed?	15.10.2025	
3. Special considerations for	n/zt	
4. Is patient follow-up or a review of patient outcomes to date recommended?		
no		
5. Is feedback from the customer required? 6. (If yes, please attach a form stating the return deadline)	yes	
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?	n/z	
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	**Tobias Lang** **PRRC** 15.08.2025

Transmission of this field safety notice
This notification must be forwarded to everyone who needs to be informed in your organisation or to any organisation to which the potentially affected devices have been transferred (if applicable). Please forward this notice to other organisations that are impacted by this action (if applicable). Please keep track of this notification and the resulting action for an appropriate period of time to ensure the effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative and the national competent authority, if applicable, as this will provide important feedback.