

My No: MSD/SCU(S)/Cir/2025
Medical Supplies Division,
357, Ven. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.
Tel: (011)2694114/13
03 -05-2026

Circular No: **MSD/Q/S/2026/6**

To :
DDG/NHSL – Colombo,
DDG/NH – Kandy,
DDG/NH – Galle,
All Provincial Directors of Health Services,
All Regional Directors of Health Services,
All Directors of Teaching Hospitals,
All Directors of Specialized Campaigns,
Director, N.I.H.S Kalutara,
All MOIC/MOH- Institutions,
MOIC/Medical Institutions of Line Ministry.

REPORT ON FAILING SAMPLE – Angiographic Catheter, TIG, size 5F, 110cm (approximately.)

MSD Order List No : 2021/SPC/N/C/S/00141 PA Order No: DHS/SUS/WW/269/579DP/2021

Re-above, details of the letter NMRA/MD/QF/20/2025 dated 27th April 2026 received from CEO/NMRA are circulated herewith for your information and necessary action, please (NMRA correspondence was received by MSD on 04.05.2026, and the SWASTHA System notification was shared on the same day)

1.1) Name of the product/ Item : **Angiographic Catheter, TIG, size 5F, 110cm (approximately.)
Angiographic catheter, 5F, (Angiodyn)**

SR : **13509606**

1.2) Manufacturer : **PendraCare International B.V., Van der waalspark 22, 9351 VC Leek,
Netherland**

1.3) Batch Details :

Batch No	Date of Manufacture	Date of Expiry
2307-0076	24.07.2023	30.06.2026

1.4) Reference of NMRA : **To the decision of the 103rd Medical Device Evaluation Committee (MDEC)**

1.5) Nature of Defects : **Following issues observed while using this catheter by clinicians,**

- Poor torque control
- Difficulty in maneuvering
- Challenge in engaging the right coronary artery reliably
- A tendency for the catheter to engage too deeply (“deep throating”), raising potential safety concerns during coronary angiography

2. CEO-NMRA Instruction : **To withdraw the above mentioned batch from use Immediately**


3. Considering above facts, you are requested the following

3.1) **To withdraw the above mentioned batch (as detailed 1.1-1.3 above) from use immediately**

4. Please note: It would be your responsibility, in addition to point 3,
- 4.1) To follow the instructions given by Secretary of Health, under the circular No: 01/2021 dated 08.12.2021.
5. 5.1) Please bring the contents of this circular to all concerned in your Province/ Region/ Institution.
- 5.2) Please Note: It is the responsibility of all RDHS to ensure that the copies of this circular is circulated among all the heads of the institutions under your purview.

6. Previous Circulars

Circular No	Batch	Decision
MSD/Q/S/2026/4	2307-0076	Withhold


Dr. DEDUNU DIAS
 Director - (Acting)
 Medical Supplies Division
 Rev. Baddegama Wimalawansa Thero Mw.
 Colombo 10.
 Director,
 Medical Supplies Division,

Cc:

- | | | |
|---|---|--------------------|
| 1. Auditor General - f.i. | 2.DGHS-f.i. | 3. DDG(M/S) - f.i. |
| 4. Chairman/SPC – f.i. & n.a. | | |
| 5.CEO/NMRA – f.i. | 6. DD/MSD - f.i. & n.a | |
| 7. D/NMQAL – f.i. | | |
| 8. Chief Internal Auditor/ MOH-f.i. | 9.D/(Stock Verific.)/MOH - f.i. | |
| 10. Chief Accountant (Finance) / MSD – To make arrangements to recover the relevant charges | | |
| 11. Chief Accountant (Supply) / MSD – To make arrangements to recover the relevant charges | | |
| 12. AD/ICT Unit – To publish in MSD web site | | |
| 13. AD(S)/MSD – f.i. & n.a. | | |
| 14. AD (M&C) – f.i. | | |
| 15. AD (Stores)/MSD - f.i. | 16. AD(Dispatch)/MSD – f.i. | |
| 17. Secretary / MDEC- f.i. | | |
| 18. All DP/DPDHS - f.i. & n.a. | 19. SP / MSD - f.i. | |
| 20. HSCO (S) - f.i. & n.a. | | |
| 21. SCO (S/WH 23) – f.i. & n.a. | | |
| 22. SCO (D/WH 23)- f.i & n.a. | 23.MSA-WH (23)/MSD - f.i. & n.a. | |
| 24. MO (Technical unit)/MOH- f.i & n.a. | 25. H/Destruction Unit (MSD) - f.i & n.a. | |