# Medical Devices Safety Notice

**The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:**

| Device Details | |
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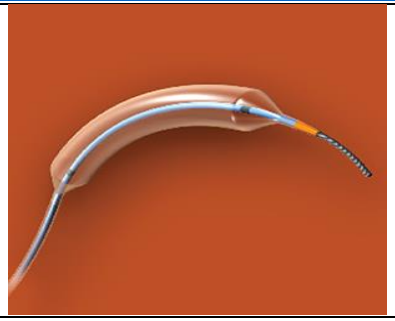
| **Device Name** | Coronary Dilatation Catheter (NC Trek RX; NC Traveler RX) |
| **Device Details** | NC TREK 4.00X8MM - PN# 1012453-08 - LOT# 90928G1<br>NC TREK 4.00X12MM - PN# 1012453-12 - LOT# 90927G1<br>NC TREK 4.00X15MM - PN# 1012453-15 - LOT# 90815G1<br>NC TREK 4.50X12MM - PN# 1012454-12 - LOT# 90731G1 |
| **Manufacturer** | ABBOTT VASCULAR |
| **Country of Origin** | Netherlands |
| **Reference** | https://www.fda.gov/medical-devices/medical-device-recalls/abbott-vascular-recalls-nc-trek-rx-and-nc-traveler-rx-coronary-dilatation-catheters-due-failure |
| **Device picture** |  |
| **Reason of Recall** | NHRA initiates this FSN because the balloons from the impacted lots may not deflate as intended. This issue is due to weaker material close to the balloon bond resulting from excessive exposure to heat during manufacturing. Use of these devices may cause serious adverse health consequences, such as prolonged cardiac ischemia (reduced blow flow to the |

**For more information please contact Medical_Devices@nhra.bh**

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| | heart), air embolism, thrombosis (clot in the artery), myocardial infarction (heart attack), and additional surgery that could lead to post-operative complications, including death. |
| **Action should be taken** | In case of having the above defected medical device, please stop using it and contact your Authorized representative **Wael Pharmacy** at vincent@waelpharmacy.com to take the necessary action. |

**Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.**

**For more information please contact Medical_Devices@nhra.bh**