



Circular No. 27 / 2023

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29 -01-2023

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Field Safety Notice of NovaStar plus and Nova Star TS from Draeger Medical Systems Inc

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=18423
Product	NovaStar plus and Nova Star TS
Description	Surgical equipment/ Anaesthesia - anaesthesia and medical gas supply
Manufacturer	Draeger Medical Systems Inc
Local Agent	Waleed Pharmacy & Stores LLC.
The affected products	NovaStar TS and NovaStar plus (Attached – annex1).
Reason	Magnet in the swivel frame/tube set and the headgear clips might impact medical devices (implanted as well as not-implanted) and metallic implants.
Action	1. Apart from the contraindication, you can continue to use NovaStar plus masks, if you ensure that the magnets are kept at least 15 cm (approx. 6 inches) away from any other medical implants or medical devices that can be impacted by the magnetic fields. 2. Contact the local agent for remedial action.
Product Image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General





To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 27 dated 29/1/2023 Regarding NCMDR FSN of NovaStar plus and Nova Star TS from (mfr: Draeger Medical Systems Inc).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

Medical Devices Sector

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NCMDR


National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

BfArM Recall

Reference Number: mdprc 014 01 23 000

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Date submitted: 1/24/2023

Manufacturer:	Draeger Medical Systems Inc
Device Type:	NovaStar plus and Nova Star TS
Description:	Surgical equipment/ Anaesthesia - anaesthesia and medical gas supply
Medical Device Identifier:	NovaStar TS and NovaStar plus
Reason of Field Safety Corrective Action:	Magnet in the swivel frame/tube set and the headgear clips might impact medical devices (implanted as well as not-implanted) and metallic implants.
Remedy Action:	Apart from the contraindication, you can continue to use NovaStar plus masks, if you ensure that the magnets are kept at least 15 cm (approx. 6 inches) away from any other medical implants or medical devices that can be impacted by the magnetic fields.
Athorized Representative/Importer/Distributor:	Draeger Arabia Co. Ltd.
Report Source:	BfArM
Source Ref. Number:	00953/23
SFDA Comments:	SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company.
Attachments:	 Draeger.pdf

[View History](#)

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To our customers of
*NovaStar TS and NovaStar plus NIV oronasal
mask*

January 2023

Important Safety Notice

Magnets of NovaStar masks might impact implants or implanted medical devices.

Only the following products are affected:

Annex I – Overview of NovaStar TS and NovaStar plus

Dear Sir or Madam,

During the course of our global market surveillance activities, we have become aware that other manufacturers of masks similar to our NovaStar TS and NovaStar plus have received complaints indicating that the magnets used in the swivel frame/tube set and the headgear clips might impact medical devices (implanted as well as not-implanted) and metallic implants. Dräger is not aware of any similar event related to NovaStar TS and NovaStar plus masks. However, NovaStar TS and NovaStar plus also features a magnet in the swivel frame/tube set and the headgear clips.

In case the magnets of the NovaStar TS and NovaStar plus are positioned near medical devices (implanted as well as not-implanted) and metallic implants the magnetic field might impact the implants or devices and cause serious injury.

The magnetic field strength of the NovaStar TS and NovaStar plus magnets is 380mT. Tests have shown that no magnetic field was measured at a distance of at least 15cm from the magnet.

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Swift-Code: NOLADE21SPL

Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 7903 HL
Komplementär: Drägerwerk Verwaltungs AG
Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 7395 HL

Vorsitzender des Aufsichtsrats der
Drägerwerk AG & Co. KGaA und
Drägerwerk Verwaltungs AG:
Stefan Lauer
Vorstand:
Stefan Dräger (Vorsitzender)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Axel Schaffner

Actions to be taken:

Use of the mask is contraindicated for patients and other persons in close vicinity to patients using the masks, that have implanted devices that may be affected by magnets, including but not limited to:

- Pacemakers
- Implantable cardioverter defibrillators (ICD)
- Neurostimulators
- Magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher (i.e., neck and head)
- Cerebral spinal fluid (CSF) shunts (e.g., ventriculo peritoneal (VP) shunt)
- Aneurysm clips
- Embolic coils
- Intracranial aneurysm intravascular flow disruption devices
- Metallic cranial plates, screws, burr hole covers, and bone substitute devices
- Metallic splinters in the eye
- Ocular implants (e.g., glaucoma implants, retinal implants)
- Certain contact lenses with metal
- Implants to restore hearing or balance that have an implanted magnet (such as cochlear implants, implanted bone conduction hearing devices, and auditory brainstem implants)
- Magnetic denture attachments
- Metallic gastrointestinal clips
- Metallic stents (e.g., aneurysm, coronary, tracheobronchial, biliary)
- Implantable ports and pumps (e.g., insulin pumps)
- Hypoglossal nerve stimulators
- Devices labeled as MR (Magnetic Resonance) unsafe

- Magnetic metallic implants not labeled for MR or not evaluated for safety in a magnetic field

Apart from the contraindication, you can continue to use NovaStar plus masks, if you ensure that the magnets are kept at least 15 cm (approx. 6 inches) away from any other medical implants or medical devices that can be impacted by the magnetic fields.

Please add a copy of this Important Safety Notice to every box of masks you have in your facility and ensure that all users of the above-mentioned products and other persons within your organization are made aware it.

If you have provided the products to third parties, please forward a copy of this information.

Dräger will be updating the NovaStar Instructions for Use accordingly. Until the updated version of the Instructions for Use is available, we will be adding this Important Safety Notice to each box of masks.

Please keep this information at least until the measure has been completed.

The responsible authorities have been notified of this action.

Identification of the affected medical devices:

According to our records, you have received NovaStar TS and/ or NovaStar plus masks manufactured by Drägerwerk AG & Co. KGaA (see attached list) that are affected by this issue.

Contact:

If you have any questions, please do not hesitate to contact your local Dräger representative.

We apologize for any inconvenience caused by this measure.

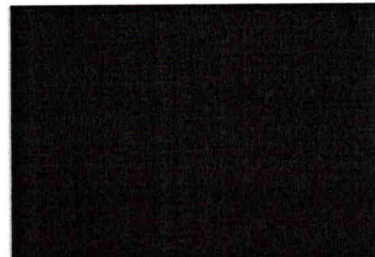
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We thank you for your support.

With kind regards



BU Hospital Consumables & Accessories
Medical Division
Drägerwerk AG & Co. KGaA



Quality & Regulatory Affairs
Medical Division
Drägerwerk AG & Co. KGaA

Attachment:

- List of affected NovaStar TS and NovaStar plus part numbers

Annex I – Affected NovaStar TS and NovaStar plus

Material	Description
MP01564	NovaStar SE VPack S,3xMP01579
MP01565	NovaStar SE VPack M,3xMP01580
MP01566	NovaStar SE VPack L,3xMP01581
MP01569	NovaStar AAV VPack L,3xMP01578
MP01576	NovaStar® TS NIV-Mask,AAV,S
MP01577	NovaStar® TS NIV-Mask,AAV,M
MP01578	NovaStar® TS NIV-Mask,AAV,L
MP01579	NovaStar® TS NIV-Mask,SE,S
MP01580	NovaStar® TS NIV-Mask,SE,M
MP01581	NovaStar® TS NIV-Mask,SE,L
MP01585	NovaStar TS Headgear Clips,4pc
MP04701	NovaStar® TS NIV-Mask,AAVNV,S
MP04702	NovaStar® TS NIV-Mask,AAVNV,M
MP04703	NovaStar® TS NIV-Mask,AAVNV,L
MP04704	NovaStar®TS NIV-Mask,AAVNV,XL
MP04705	NovaStar® TS NIV-Mask,SE,XL
MP04706	NovaStar® TS NIV-Mask,AAV,XL
MP05051	NovaStar plus, NIVmask, SE, S
MP05052	NovaStar plus, NIVmask, SE, M
MP05053	NovaStar plus NIVmask, SE, L
MP05054	NovaStar plus NIVmask, SE, XL
MP05061	NovaStar plus, NIVmask, AAV, S

Material	Description
MP05062	NovaStar plus, NIVmask, AAV, M
MP05063	NovaStar plus, NIVmask, AAV, L
MP05064	NovaStar plus, NIVmask, AAV, XL
MP05071	NovaStar plus, NIVmask, AAVnV, S
MP05072	NovaStar plus, NIVmask, AAVnV, M
MP05073	NovaStar plus, NIVmask, AAVnV, L
MP05074	NovaStar plus, NIVmask, AAVnV, XL
MP05080	NovaStar® plus Headgear