

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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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
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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 |