Medtronic

Medtronic Australasia Pty Ltd

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February 2020

Dear Valued Customer,

To comply with the European Union Medical Device Regulation (MDR) requirements, the following changes will come into effect after May 2020 on the Guedel Airways (sterile and non-sterile) products.

Changes to Guedel Cannula

1. Designated size and color codes of the Guedel cannula insert are as follows:

Code	Previous size	Length	Previous color code		New size/ length	New color code/ ISO 5364:2016
287/7843	6	11 cm	Light blue		11 cm	**Orange**
287/7631	5	10 cm	Red		10 cm	Red
287/7632	4	9 cm	Yellow		9 cm	Yellow
287/7633	3	8 cm	Green		8 cm	Green
287/7634	2	7 cm	White		7 cm	White
287/7635	1	6 cm	Violet		6 cm	**Black**
287/7636	0	5 cm	Blue		5 cm	Blue
287/7838	00	4 cm	Orange		4 cm	**Pink**
287/7839	000	3 cm	Pink		3 cm	**Lilac**
287P7843SP	6	11 cm	Light Blue		11 cm	**Orange**
287P7631SP	5	10 cm	Red		10 cm	Red
287P7632SP	4	9 cm	Yellow		9 cm	Yellow
287P7633SP	3	8 cm	Green		8 cm	Green
287P7634SP	2	7 cm	White		7 cm	White
287P7635SP	1	6 cm	Violet		6 cm	**Black**
287P7636SP	0	5 cm	Blue		5 cm	Blue
287P7838SP	00	4 cm	Orange		4 cm	**Pink**
287P7839SP	000	3 cm	Pink		3 cm	**Lilac**

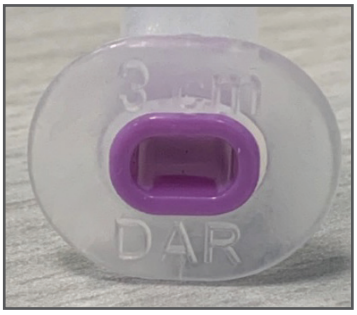
2. New GTIN material numbers will be created.

3. Flanged end of Guedel Airway products:

There has been a change in font, an addition of bold type, the protrusion height from the flange has been increased, and the manufacturer name has moved to the bottom of flange. The old sizing has been removed from the flange.

OLD

NEW



4. Instructions for use

To comply with MDR requirements, the current insert will be revised to meet instruction for use requirements: to specify/clarify intended purpose/use/indications, contraindications, adverse events, and warnings. This change will not affect the safety or effectiveness of the Guedel Airways products and are added for improved clarity in order to meet European regulation and requirements of ISO 5364:2016.

5. Labelling change - Addition/update in packaging label are mentioned below:

- Addition of the Medical Device symbol on the outer box label.
- New EC representative i.e., Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, the Netherlands.
- Addition of the Single Sterile Barrier symbol for sterile device.
- Addition of the MR Safe symbol.
- Addition of the Consult Instruction for Use symbol.
- Addition of Date of Manufacture on the primary unit pack for the sterile device.
- Update in Not made with DEHP symbol.
- Size of the CE mark increased.
- Addition of languages on the label.
- Removal of Temperature Limit symbol from outer carton label.

We apologise for the inconvenience caused.

If you have any questions, please contact your local Medtronic representative.

Yours sincerely,

James Woodin - Product Manager ANZ – Respiratory Interventions

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