



12th January 2026

Dear Valued Customer,

We would like to inform you of an important update to our catheter labelling, implemented as part of EU MDR 2017/745 and UK MDR 2002,618 remediation to comply with ISO 20696 requirements.

What has changed

- The inflation volume (e.g., 10 mL) has been moved outside the balloon image, with an arrow pointing inward.
- This change eliminates confusion and clearly indicates the amount of water required to inflate the balloon.

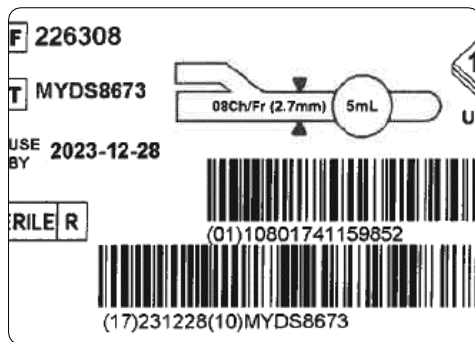
The adjustment addresses three key points:

- Correct balloon size
- Correct balloon fill volume
- Compliance with ISO 20696 and MDR requirements

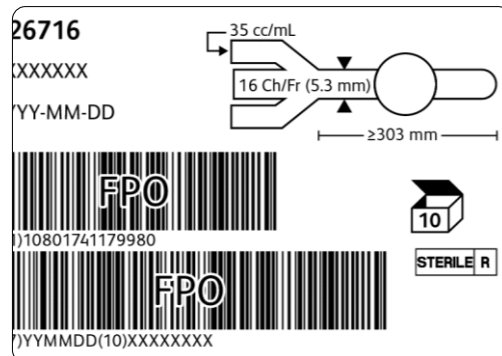
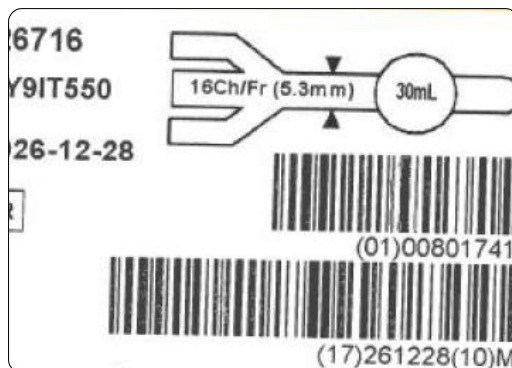
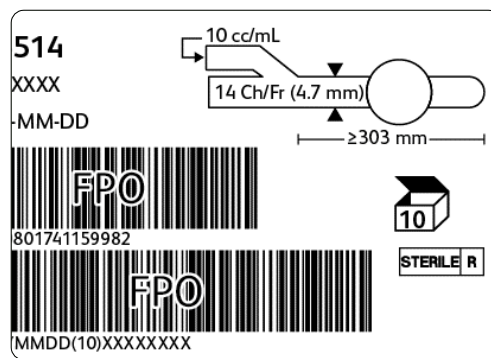
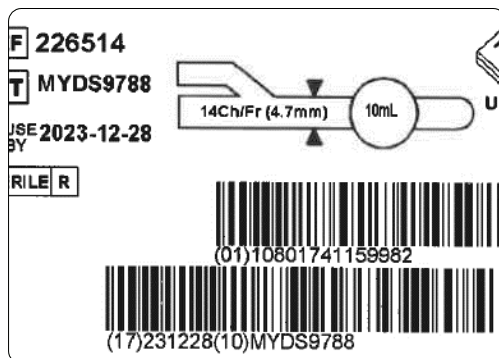
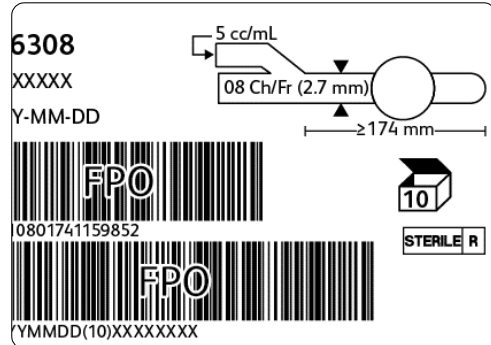
Clarifying Balloon Size vs. Inflation Volume

- “5 mL” refers to the balloon size only.
- “10 mL” refers to the inflation volume needed to fill the balloon (including the inflation valve, arm, and inner lumen).
- Inflating beyond the standard size creates the necessary tension for secure placement.

Previous Label:



Current Label:



Please note: This is a labeling update only, the clinical practice remains unchanged.

To help clarify, this table was also added to the IFU:

d. Inflation Volume (A) incorporates the volume required to pass through lumen and fully inflate the specific Balloon Size (B).

	Inflation Volume (A)	Balloon Size (B)
	10 mL	5 mL
	35 mL	30 mL

Note: Drawing may not display actual shape of catheter tip or presence of additional lumen(s).

To best serve you, all inquiries and requests should be directed through your local sales representatives or by contacting BD's Customer Service. Thank you for your continued trust and partnership.

Sincerely,
Deborah Hetherington
UK Urology Marketing Manager

Please consult product labels and instruction for use for indications, contraindications, hazards, warnings and precautions.

BD-168292