

Product Notification:

# Phasing out of Releen® InLine Foley catheter and introduction of new Releen® InLine 2.0 Foley catheter

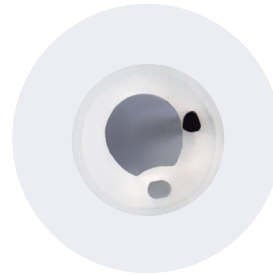
Dear Healthcare Professional / Valued Customer,

Medical device regulations in Europe are undergoing transition to replace the existing Medical Devices Directive (93/42/EEC) (MDD) with the new Medical Devices Regulation (2017/745/ EU) (MDR). The MDR was published in May 2017 and has been transitioning over a period of time. From the 26th of May 2024 our existing Releen® InLine MDD certification expires and in order to maintain supply of this unique product, we have needed to transition to the new MDR certified Releen® InLine 2.0 Foley catheter.

Below outlines the changes between the Releen® InLine & Releen® InLine 2.0 Foley catheters.

### What remains the same?

- Integrated balloon
- 100% soft Silicone
- Short bullet tip & smooth eyelets
- Box Quantity
- Price



### What is changing?

	Current Releen® InLine Foley Catheters	NEW Releen® InLine 2.0 Foley Catheters
<b>Packaging / Labels</b>		
<b>Indication</b>	Suprapubic and Urethral	Urethral Only
<b>Indwell time (days)</b>	Up to 12 weeks	Up to 30 days
<b>Product codes (refer to table on reverse)</b>	5-digit item code	same 5-digit code with '1' suffix
<b>WAND Number</b>	180129-WAND-6PP9K8 Suprapubic 180129-WAND-6PP9NE Urethral	240212-WAND-72TWDT - Urethral
<b>ARTG Number</b>	107139 & 107138	432170

## Coloplast Releen® InLine Foley catheters to Releen® InLine 2.0 Foley catheters codes

Current Releen® InLine Foley Catheters			NEW Releen® InLine 2.0 Foley Catheters		
Item Number	Description	UoM	Item Number	Description	UoM
28762	Releen Inline CH12 Male	5	287621	Releen Inline 2.0 CH12 Male	5
28764	Releen Inline CH14 Male	5	287641	Releen Inline 2.0 CH14 Male	5
28766	Releen Inline CH16 Male	5	287661	Releen Inline 2.0 CH16 Male	5
28768	Releen Inline CH18 Male	5	287681	Releen Inline 2.0 CH18 Male	5
28770	Releen Inline CH20 Male	5	287701	Releen Inline 2.0 CH20 Male	5
28772	Releen Inline CH22 Male	5	287721	Releen Inline 2.0 CH22 Male	5
28774	Releen Inline CH24 Male	5	287741	Releen Inline 2.0 CH24 Male	5
28776	Releen Inline CH26 Male	5	287761	Releen Inline 2.0 CH26 Male	5
28782	Releen Inline CH12 Female	5	287821	Releen Inline 2.0 CH12 Female	5
28784	Releen Inline CH14 Female	5	287841	Releen Inline 2.0 CH14 Female	5
28786	Releen Inline CH16 Female	5	287861	Releen Inline 2.0 CH16 Female	5
28788	Releen Inline CH18 Female	5	287881	Releen Inline 2.0 CH18 Female	5
28790	Releen Inline CH20 Female	5	287901	Releen Inline 2.0 CH20 Female	5

Over the coming months you will begin to see a phasing out of the current Releen® InLine and transition to the new Releen® InLine 2.0 Foley catheter. Orders placed using the new item numbers will be supplied stock of either the existing or new product based on availability. We anticipate that the phasing out will be complete in May 2024.

Please consult the Instructions for Use for further information.

Coloplast will continue to support our clinicians and patients throughout this transition. If you have questions or concerns, please contact us at **\*1800 170 009\*** fl\* - US **0800 270 502** in NZ or via email [aureleen@coloplast.com](mailto:aureleen@coloplast.com)

Sincerely,



Michael Joseph  
Business Unit Manager  
Coloplast Interventional Urology