Urgent Field Safety Notice

Attention:
To: The European Authorized Representative (Caretechion GmbH), TÜV Rheinland, the BfArM, German distributors, and hospitals within the distributors' sales network.
Issue: Fracture of the reset button resulting in failure to open the jaws.

Details on affected devices:
Product Name:EndoBule Endoscopic Staper
Product Model:The product specification in this manual applies to all models (regardless of batch).
CE certificate:SX 2090547-1
Intended Use:Suitable for tissue resection, transection and anastomosis in endoscopic surgery of abdominal surgery, gynecology, pediatrics and thoracic surgery.

Description of the problem:
During lung surgery, the operator selected the TCZNXK-45B for stapling and transecting pulmonary vessels. The stapling and cutting procedure proceeded smoothly. However, when retracting the release button, the operator used a one-sided pulling method, causing the button to fracture. As a result, the cartridge unit's jaws failed to open.

Advise on action to be taken by the user:
1.When pull back the reset button to open the jaws, both the left and right sides of the reset button must be pulled simultaneously to the initial position, otherwise there is a chance of the reset button breaking or falling off, potentially resulting in a surgical safety risk.
2.If cutting and stapling of lung tissue is required, cartridges with the staple height of no less than 2.5 mm shall be selected. If cutting and stapling of pulmonary vessels is required, the use of Model B or Model H cartridges is recommended. But during the operation, please be careful to avoid the lung tissue surrounding the vessels which will increase tissue height, and the selection of cartridges must strictly comply with IFU.

Transmission of this Field Safety Notice:
This notice will be forwarded to the EU Authorized Representative (Caretechion GmbH),BfArM, and German distributors(Rivolution GmbH) by e-mail, hospitals within the distributors' sales network will receive the relevant notification within one month after the distributors' receipt of this notice.
We will continue to closely monitor this incident to ensure effectiveness of the corrective action.

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The undersign confirms that this notice has been notified the appropriate Regulatory Agency

(Closing paragraph)

Signatur

Date August 21,2025