

14 Gojeong-ro, Woltgot-myeon,
Gimpo-si, Gyeonggi-do,
KOREA 10022

URGENT: MEDICAL DEVICE RECALL

Niti-S Tracheobronchial Uncovered Stent

Type of Action	Recall Notice
Product Name	Niti-S Tracheobronchial Uncovered Stent
Article Number	BRxxxxW
Model Numbers	All Models within expiration date (3 years from manufacturing date)
Lot Identification	All Lots within expiration date (3 years from manufacturing date) Attachment 1.

March 14, 2024

Taewoong Medical Reference: R2024-02

Dear Device Customer,

This notification is to inform you that Taewoong Medical has initiated a voluntary recall of our manufactured devices. Performance test by Batch has confirmed that the some of the specifications for the Niti-S Tracheobronchial Uncovered Stent (BRxxxxW) do not meet the company's standards due to design defects. There is a possibility that some of the Niti-S Tracheobronchial Uncovered Stents (BRxxxxW) within the expiration date (3 years from manufacturing date) may not perform as intended due to the underperformance of expansion and compression. Taewoong Medical request to immediately stop the use of the device, and isolate and return all affected Niti-S Tracheobronchial Uncovered Stents (BRxxxxW).

Health Risk Assessment and Affected Devices:

Taewoong Medical has not been notified of any patient injuries related to this issue. This issue only affects Niti-S Tracheobronchial Uncovered Stent (BRxxxxW).

Sincerely yours,



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URGENT: PROMPT RESPONSE REQUIRED

Acknowledgement and Receipt Form

You are required to fill out and return this form.
Please return it within 10 business days of receipt.

Name	
Title	
Company / Hospital	
Location	
Contact (Email and/or Phone)	
Date	
Signature	

I have read and understand the recall instructions provided in the letter dated March 14, 2024.

I have shared the letter "URGENT: MEDICAL DEVICE RECALL" with appropriate personnel within your organization or with any organization where the affected product(s) have been transferred.

Affected Product Information

Return

Affected Lot Number	Model / Size	Quantity to be returned

Used

Affected Lot Number	Model / Size	Quantity to Used

14 Gojeong-ro, Woltgot-myeon,
Gimpo-si, Gyeonggi-do,
KOREA 415871

Returning this form and affected product(s)

- Upon completion of this form, please return it to the Taewoong Medical Customer Support Team via email.

Email: customersupport@stent.net

- Should you have any questions regarding the recall, please contact the Customer Support Team at Taewoong Medical. Please use customersupport@stent.net, or call us +82 31 996 0641(Ext 212). Monday through Friday, 9:00A M to 6:00PM, Korea Standard Time.

- Return affected product(s) and send this form to this address:

Taewoong Medical

ATTN: CS Team Voluntary Recall

14 Gojeong-ro, Woltgot-myeon,

Gimpo-si, Gyeonggi-do,

KOREA 10022

- To report adverse events, contact Taewoong Medical Customer Support Team at customersupport@stent.net, or call us +82 31 996 0641(Ext 212). Monday through Friday, 9:00A M to 6:00PM, Korea Standard Time.