



URGENT PRODUCT SAFETY NOTICE

Stille Medstone, specific models

IMMEDIATE ACTION REQUIRED

Purchasing Agent: Our records indicate you are the distributor of a table included in an urgent product safety notice. We have taken measures to contact your customer, however, please ensure this notice is forwarded **immediately** to all users of Stille Medstone table with the following serial number:
18-4051 & 19-4412,

Dear Healthcare Provider:

This safety notice involves specific versions of Stille Medstone Table models sold with the bariatric tops part 505-1104 and 505-1105. We have identified your facility owning one of the serial numbers mentioned above.

Stille has determined a potential malfunction may exist with the 500-1001, 500-1002 & 500-1003 if equipped with the bariatric top 505-1104 & 505-1105. And models 500-1031 & 500-1037 that have the bariatric top as standard.

With the full maximum load of 340kg, a motor bracket might bend.

There have been no reported incidents or malfunctions of this part in the field. The potential malfunction was discovered during the normal production tests, but, as Stille always puts the greater good of our users and their patients first, we issue this warning. Stille will develop a replacement part and will voluntarily correct all tables affected without any cost for you as a customer.

IMMEDIATE ACTION REQUIRED BY YOU

In accordance with this safety notice, please:

- 1. Do not use the table with patients who exceed 227 kg.**
- 2. If you are in doubt about using the table: IMMEDIATELY STOP USING THE TABLE and contact: Stille AB**

Ralph Tamm
Stille AB, Ekbacken 11
S-644 30 Torshälla, Sweden

Mail: ralph.tamm@stille.se
Tel +46-8-588 58 000
Fax +46-8-588 58 005

- 1. If the table at any point before has been used for a patient with the higher weight of 340kg, or if you feel uncertain in any ways,: IMMEDIATELY STOP USING THE TABLE AND CONTACT: STILLE AB – Stille will send out a technician free of charge to inspect your table to ensure it is safe to use for the lower weight limit.**
- 2. BEFORE EVERY USE OF THE TABLE, INSPECT THE MOTOR BRACKET ACCORDING TO THE ATTACHED INSTRUCTIONS. IF YOU SEE A CHANGE IN**



THIS BRACKET, IMMEDIATELY STOP USING THE TABLE AND CONTACT: STILLE AB

- 3. WE ARE IN THE PROCESS OF CONTACTING YOUR FACILITY TO SCHEDULE A TECHNICIAN TO INSPECT YOUR TABLE. IF YOU HAVE IMMEDIATE CONCERNS BEFORE EVERY USE OF THE DEVICE, THE MOTOR BRACKET MUST BE INSPECTED PER THE ATTACHED INSTRUCTIONS. IF YOU SEE A CHANGE IN THIS BRACKET: IMMEDIATELY STOP USING THE TABLE AND CONTACT: STILLE INC AT ANY OF THE NUMBERS PROVIDED ABOVE.**

4. Complete the enclosed acknowledgement card and return it by FAX to Stille AB at +46-8-588 58 005 or by email to QA@stille.se. We would appreciate your confirmation as soon as possible and no later than March 10, 2020.

IMPORTANT: IT IS IMPERATIVE THAT YOU RETURN THIS ACKNOWLEDGEMENT CARD EVEN IF YOU DO NOT HAVE THE CONCERNED PRODUCT. Your return of the acknowledgement card is critical in our ability to track the receipt of this Safety Notification.

If you have further distributed the product, please contact your customers immediately; advise them of the product correction and have them ~~to~~ confirm to Stille AB that they have the table.

This safety notice has been sent and the malfunctioning will be registered in FDA MAUDE database, LMV's and FSN.

See next page for acknowledgment form.

Should you have any questions about this safety notice, please contact STILLE at: +46-8-588 58 000. We appreciate your assistance with this matter and regret any inconvenience this may have caused you or your patients. We are committed to providing you with the highest quality products, services and ongoing support as you care for your patients. If you have any questions or comments, please contact your local Stille representative.

Sincerely,





URGENT SAFETY NOTICE

Stille Medstone

FAX or EMAIL FORM

To be sent by fax to STILLE AB, at fax number +46-8-588 58 005, or by email to QA@stille.se, as soon as possible and not later than March 10, 2020.

I confirm that I have received and understood the information in this product correction about the Stille Medstone Table field correction program. I would like to have the table(s) indicated below serviced as soon as possible.

PLEASE USE BLOCK LETTERS

Stille Medstone table, Serial number: _____

Hospital/User Premise _____

Name: _____

Address: _____

Phone: _____

E-mail: _____

Signature: _____ Date: _____