July 27, 2017

To: Risk Managers
CC: Chairman Medical Board and relevant Head of Departments

Subject: **URGENT MEDICAL DEVICE CORRECTION**

Affected Product: A.T.S® 2200TS and A.T.S® 4000TS

Zimmer Biomet Surgical is initiating a Medical Device Correction for the A.T.S® 2200TS and A.T.S® 4000TS to provide an on-device label and 3 pages of an updated Operator/Service Manual.

In a typical OR setting, Zimmer Biomet originally recommended a minimum separation distance of 3.8 meters (m) between RF communication equipment to mitigate the potential for electromagnetic interference and to achieve optimal performance of the tourniquet machines. RF equipment consists of, but is not limited to, electrosurgical equipment, including any consoles, wiring, and pencil units. This distance recommendation originates from IEC 60601-1-2.As a result of customer feedback, additional internal testing was performed to see if this distance could be shortened, and it was determined that 1.0 meter provided adequate distance to avoid interference. Notably, this newly established 1.0m separation distance is a *reduction* from the previously recommended 3.8m distance and therefore does not contradict or nullify previous revisions of product Operator/Service Manuals.

Zimmer Biomet is now communicating this newly shortened separation distance of 1.0m between RF communication equipment to mitigate the potential for electromagnetic interference and achieve optimal performance of the tourniquet machines. We are providing an on-device label and updated Operator/Service Manual pages to notify our customers of this newly established separation distance to allow for a smaller distance between equipment, suitable for smaller OR settings. The proper on-device label placement is to have the label placed directly above the IV Pole label on the side of the device, as shown below on Figure 1.

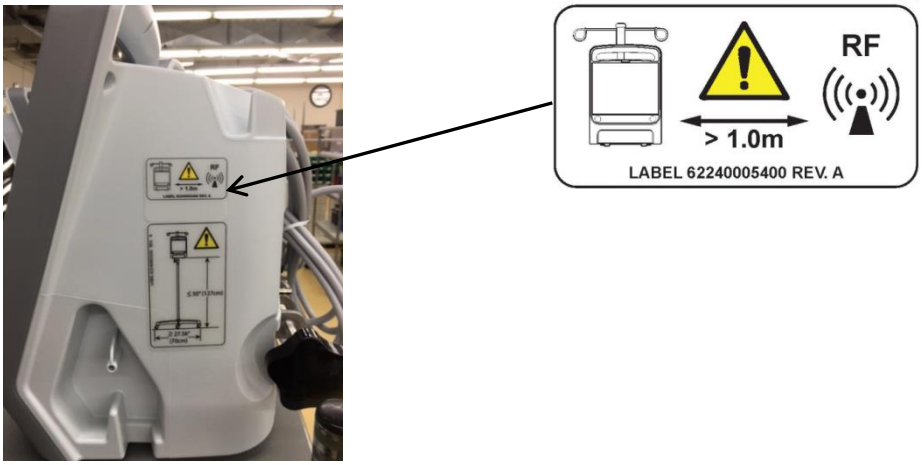

Figure 1. Proper on-device label placement

<2015-01>

If the user does not comply with the recommended separation distance of either 3.8m or 1.0m and experiences an event, the likelihood of injury is 'Less than remote," with the most likely outcome being a spontaneous inflation event resulting a delay in surgery of less than 30 minutes. Further, cuff inflation will trigger an inflation timer on the ATS which is set to a default of 60 minutes. The ATS will monitor the elapsed time of inflation and alarm when the timer expires, mitigating an unnoticed spontaneous cuff inflation.

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of January 2014 and June 2017 and have serial numbers that begin with the prefixes shown in attachment 2.

Risk Manager Responsibilities:

1. Review the notification and ensure affected personnel are aware of the contents.
2. Confirm that you have received the on-device label and 3 pages of the updated Operator/Service Manual, included in this package.
3. Place the label on the device in the location specified in Figure 1 above.
4. Replace the 3 pages of the Operator/Service Manual with the updated pages.
5. Email a completed copy of the Attachment 1 form to Corporatequality.postmarket@zimmerbiomet.com to confirm that you have placed the label in the specified location on the device and replaced the 3 pages of the Operator/Service Manual with the updated pages.
6. If after reviewing this notification you have further questions or concerns please call +1(330) 364-0989 between 8:00 am and 5:00 pm EST, or contact your Zimmer Biomet Sales Representative.

Other Information

This medical device correction was reported to the U.S. Food and Drug Administration, and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the even. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing SurgicalRegulatoryReporting@zimmerbiomet.com

Please be aware that the names of user facilities notified are routinely provided to the Regulatory Authorities for audit purposes. Your urgent cooperation is needed.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your cooperation in advance and regret any inconveniences caused by this medical device correction.

Sincerely,

_____

Kevin W. Escapule, Post Market Surveillance & Regulatory Compliance Director

<2015-01>

ATTACHMENT 1
Certificate of Acknowledgement

By signing below, I acknowledge that the required actions have been taken in accordance with the Medical Device Correction Notice.

[ ] **Hospital Facility**

Please confirm the following by checking the boxes:

1. ☐ I fixed the new label to the device(s) as instructed.
2. ☐ I replaced 3 pages of the IFU with the current copies.

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) ____-_____ **Date:**____/____/____

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: corporatequality.postmarket@zimmerbiomet.com

ATTACHMENT 2
Affected Product List

Item Number	Serial Number prefix	Item Description
60220030101	2214	ATS2200TS WITH HOSES-ZH S
60220030103	2214-2216	ATS2200TS WITH HOSES-DA
60220030104	2214-2216	ATS2200TS WITH HOSES-NL
60220030105	2214-2216	ATS2200TS WITH HOSES-FI
60220030106	2214-2216	ATS2200TS WITH HOSES-FR
60220030107	2214-2216	ATS2200TS WITH HOSES-DE
60220030108	2214-2216	ATS2200TS WITH HOSES-IT
60220030110	2214-2216	ATS2200TS WITH HOSES-KO
60220030112	2214-2216	ATS2200TS WITH HOSES-ES
60220030113	2214-2216	ATS2200TS WITH HOSES-SV
60400030101	4014-4016	ATS4000TS WITH HOSES-ZH S
60400030103	4014-4016	ATS4000TS WITH HOSES-DA
60400030104	4014-4016	ATS4000TS WITH HOSES-NL
60400030105	4014-4016	ATS4000TS WITH HOSES-FI
60400030106	4014-4016	ATS4000TS WITH HOSES-FR
60400030107	4014-4016	ATS4000TS WITH HOSES-DE
60400030108	4014-4016	ATS4000TS WITH HOSES-IT
60400030109	4015-4016	ATS4000TS WITH HOSES-JA
60400030110	4014-4016	ATS4000TS WITH HOSES-KO
60400030111	4015	ATS4000TS WITH HOSES-PT
60400030112	4014-4016	ATS4000TS WITH HOSES-ES
60400030113	4014-4016	ATS4000TS WITH HOSES-SV