

CH-3110 Münsingen, September 28, 2018

FIELD SAFETY NOTICE

Please forward this information to all your relevant staff and potential users of the Schaerer Axis Surgical tables.

PREVENTIVE CORRECTIVE ACTION CONCERNING SCHAERER SHOULDER ARTHROSCOPY PLATE, REF. NO. 90568 (25mm side rails) and 90569 (30mm side rails)

Dear Customer

With this letter, we inform you about a potential issue concerning the Shoulder Arthroscopy Plate 90568 and 90569.



Description of the problem

Based on long term experience and reported product complaints, Schaerer Medical declares a general useful life of its operating tables and accessories of 10 years, provided that the annual maintenance is performed by a factory trained service engineer and the daily cleaning and maintenance is done according to the user manual.

As part of our Post Market Surveillance we became aware that some Schaerer Shoulder Arthroscopy plates, which have exceeded the 10 years life span, may be affected by corrosion around the holding plugs, which are the interface between the Shoulder Plate and the Surgical Table.

Thus far, one broken plug in a 13 year old plate was reported. The surgeon and the OR staff have managed the incident and the procedure could be completed. The Shoulder Arthroscopy Plate was subsequently taken out of service.

Identification of the affected Schaerer Shoulder Arthroscopy Plates

All Shoulder Arthroscopy plates which have been shipped between May 2002 and May 2018.

Which measures are to be taken by the end user and the authorized Schaerer distributor ?

Our sales records show that one or more Shoulder Arthroscopy Plate REF NO. 90568 or 90569 was shipped to your organization during the last 16 years.

The following measures have to be taken:

Plates shipped before May 2008:

These plates must be taken out of service and replaced by a new model. The local Schaerer Representative will contact you accordingly. Schaerer Medical declines its responsibility for any claims resulting of the further use of these old plates.

Plates shipped between June 2008 and May 2018:

Schaerer Medical AG is reducing the patient weight capacity of these plates to 100kg and makes clarifications for the use and maintenance in the user manual. A new label and a revised user manual will be provided.

Furthermore, these plates have to be checked for corrosion and micro cracks of the plugs and the surrounding areas.

A Schaerer service representative will contact you in order to coordinate the next steps.

Which measures have to be taken by authorized Schaerer distributors ?

Please ensure that your local medical device authority is informed by you.

Please ensure that all customers and persons and functions within your organization who use the above mentioned Shoulder Arthroscopy Plate receive and understand this field safety notice.

Schaerer Medical will provide labels, a revised user manual and instructions for the customers.

Please contact the customers according to the shipment dates and ensure the information and action in due course.

If you have passed the product on to third parties, please forward a copy of this notice or inform Schaerer Medical contacts persons.

Please keep this notice at least until the corrective measure has been performed.

Contact Person

For further inquiries, please do not hesitate to contact Schaerer Medical AG or your local Schaerer representative.

For quality and regulatory inquiries, please contact Mr. Ansgar Kluemper, ak@schaerermedical.ch

For service and logistic support, please contact Customer Service: service@schaerermedical.ch

We apologize for any inconvenience, however, safety comes first and therefore, consider this action as a preventive measure to increase the safety of our products.

Sincerely yours,

Schaerer Medical AG



Theodor Grob
CEO



Ansgar Klümper
Product Manager

