

h/p/cosmos sports & medical gmbh

Am Sportplatz 8  
DE 83365 Nussdorf-Traunstein / Germany  
phone +49 86 69 86 42 0  
fax +49 86 69 86 42 49  
safety@h-p-cosmos.com  
[www.h-p-cosmos.com](http://www.h-p-cosmos.com)

February 20, 2016



## **Field safety notice to buckle (fastener) of h/p/cosmos safety harness chest belt**

### **Addressee:**

Users and operators of h/p/cosmos safety harnesses, used as fall prevention in combination with the safety arch.

### **Identification of concerned medical devices and equipment:**

All h/p/cosmos safety harnesses with article number cos14903-xx manufactured January 2006 till February 2016.

chest belt system XXS for safety arch harness	chest belt system M for safety arch harness
chest belt system XS for safety arch harness	chest belt system L for safety arch harness
chest belt system S for safety arch harness	chest belt system XL for safety arch harness

### **Description of the problem including the determined cause:**

Our buckle/fastener supplier informed us recently about a field safety notice concerning the COBRA® buckles. It is possible that the rivets of the buckles have not been press fixed.

The probability of this error is very small (approx. 1 case among 2 million pieces).

h/p/cosmos installs these buckles into the safety harnesses used for the treadmills as a fall prevention.

In case of an incorrect affixation of the rivets, the buckles would show malfunctions.

### **Risk assessment:**

h/p/cosmos has been using and checking the COBRA® buckles for more than 10 years.

Within the incoming and outgoing inspections h/p/cosmos has been performing a functional and safety inspection. At h/p/cosmos there has never been any malfunction of a COBRA® buckles so far.

Within each annually required maintenance and safety checks, an authorized service technician checks all safety- related functions of your device. All consumables (also textile parts like the safety harness) are checked as well. If needed they are replaced.

According to our instructions for use, also the user has to perform a daily preventive maintenance and visual inspection. This preventive maintenance includes safety checks and monitoring work of safety equipment and basic functions. See PDF: <https://www.h-p-cosmos.com/en/contact-support/media-downloads/manuals>

See also German medical device operator regulations „Medizinprodukte-Betreiberverordnung – MPBetreibV“

Source: <http://www.gesetze-im-internet.de/bundesrecht/mpbetreibv/gesamt.pdf>

**Thereby, the probability to detect a malfunction of the COBRA® buckle is considered to be very high.**

For medical applications and also whenever falling of the subject would result in serious injury, treadmill application without fall prevention is prohibited. Examples for fall prevention are the safety arch with harness and chest belt or a body weight support device.

The correctly applied safety harness protects the subject from falling onto the treadmill. Even in case a fall occurred, only the feet/legs would touch the running surface. Whenever a load of more than approx. 8 kg is applied to the rope of the safety arch harness, the emergency stop is activated and the running belt of the h/p/cosmos treadmill stops immediately. Fall prevention and the emergency stop can prevent from serious injury.

As an immediate reaction to the described safety notice, h/p/cosmos performed a fall simulation with a defective (artificially manipulated) buckle. The simulation showed, that even in case of a defective buckle, the subject would only slip a little within the correctly applied safety harness chest belt. In worst case the subject's knees would touch the running belt.

Conclusion: Even in case of a defective buckle, the subject does not fall onto the treadmill and the emergency stop terminates the rotation of the running belt immediately.

**In case of a defective buckle, the probability as well as the severity of an injury are only slightly higher than in case of a non-defective buckle.**

**The safety of all users and operators, ensured by 100% function, performance, quality and safety of our products, is our top priority.**

**For this reason we forward this safety information to our customers, although the probability of a defect and the severity of a possible injury are extremely low.**

#### **What measures does the operator have to take?**

1. Please perform a visual inspection and functional control of the h/p/cosmos safety harness chest belt according to the illustrations below.
2. The rivet should show an embossing in the form of a ring on the front and back.
3. In case the rivet does not show an embossing in the form of a ring, the defect described above is indicated.
4. Perform a functional check. Opening and closing should be performed easily. When closing the buckle, a click-sound occurs. Pulling on both ends must not cause opening of the buckle.
5. In case the rivets have not been press fixed or in case of any other doubts, stop the use of the product immediately. Exclude the use of the device through other persons until the problem is solved.

**In case of any detected or assumed malfunction, please inform us immediately via email to [safety@h-p-cosmos.com](mailto:safety@h-p-cosmos.com) or call us on +49 86 69 86 42 0. Indicate also the serial number of the treadmill. In case of any doubts we suggest taking a high resolution photo of the buckle and the rivet and sending the photo to h/p/cosmos. We look forward to helping you.**

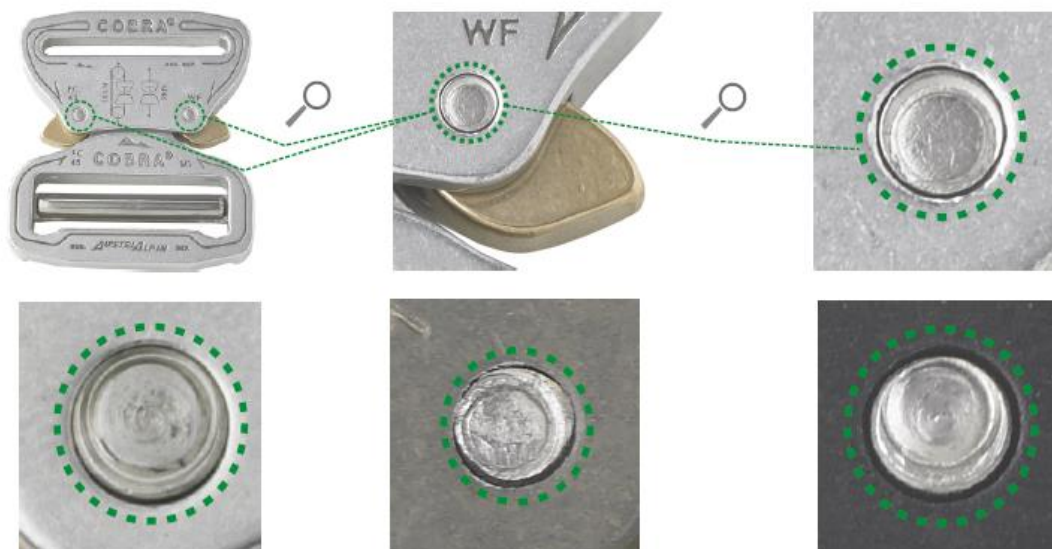
#### **Publication of the information described in this statement:**

Please make sure that all users of the aforementioned products and other relevant person within your organization will be aware of this **field safety notice**. If you have passed the products to third parties, please forward a copy of this information or inform the below mentioned contact person.

Please keep this information at least until the action has been completed.

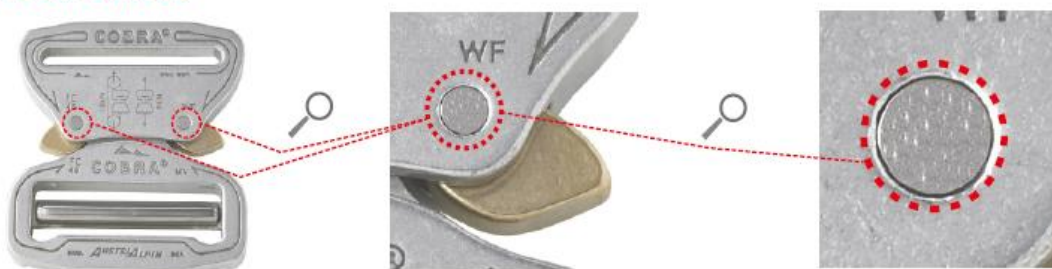
The responsible German government authorities „Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)“ have a copy of this field safety notice.

## Correct



The rivet shows an embossing in the form of a ring on both the front and back sides of the rivet. Do not manipulate the rivets by mechanical action.

## NOT Correct



The rivet does not show any circular embossing.

### Contact person:

**Michael Hesel, Safety officer for medical devices**

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Nussdorf-Traunstein, 20.02.2016

**Franz Harrer**  
President & CEO / R & D Manager

**Michael Hesel**  
Safety officer for medical devices  
German Medical Devices Act §30

## ANNEX 1

### REPLY FORM

#### IMPORTANT INFORMATION ABOUT SAFETY RELEVANT CORRECTIVE MEASURE

Product name: **COBRA®-buckle on safety harness chest belt for fall prevention**  
FSCA-reference: **ref160215-47760**  
Date: **February 20, 2016**  
Kind of measure: **recommendation for action**

#### Instructions:

1. In case your product is affected by this malfunction, **contact the h/p/cosmos service department** by telephone: +49 86 69 86 42 0
2. Whether or not your product is affected, fill out this form and send it via email to [safety@h-p-cosmos.com](mailto:safety@h-p-cosmos.com) or via fax to +49 86 69 86 42 49

Filling out this reply form, I confirm that I read and understood the above mentioned safety information concerning the COBRA® buckle and performed the measures described.

The malfunction described was detected:  yes /  no (mark with a cross where applicable)

Name of institution: \_\_\_\_\_

Name of contact person in block letters: \_\_\_\_\_

Signature and stamp if available: \_\_\_\_\_

phone: \_\_\_\_\_ email: \_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_\_\_

Please fill out and reply via fax or email until **31.03.2016** to:

**Fax - +49 86 69 86 42 49, E-Mail - [safety@h-p-cosmos.com](mailto:safety@h-p-cosmos.com)**