OSYPKA
Technology for an active life
A company of the Peter Osypka Foundation

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Urgent Safety Information

Recall of VACS II / VACS III – Valvuloplasty Catheters

03.04.2014

Receiver:
User, provider and distributor of said product

Identification of concerned Medical Devices:
This Safety Information concerns Valvuloplasty Catheters:

VACS II 24 x 60 mm	**Catalogue number (REF): YA0057**
VACS III 23 x 40 mm	**Catalogue number (REF): YA32340**

Exclusively the following production charge numbers (lots) are concerned:

P286679-00
P286673-01

Problem description:

The concerned products are incorrectly labeled. Due to inobservance during packaging of the medical devices, the concerned catheter types have been mixed-up.

During appliance of operating pressure, which lies between the nominal and rated burst pressure that are mentioned on the label, the balloon segment of the mistaken catheters can rupture. The immediate consequence is the release of the contrast fluid into the bloodstream. Owing to circumstances a hindered removability of the Valvuloplasty catheter through the introducer can occur.

Action taken by Receiver:

We kindly ask the user to **return the concerned product immediately**:

1. Please verify if products of the concerned lot number are in your inventory.
2. **Do not use these products for medical purposes.**
3. Please clearly mark the concerned product „defect / recall!“ to avoid accidental usage until the goods are returned.

OSYPKA AG
Medizintechnik
Earl-H.-Wood-Strasse 1
79618 Rheinfelden, Germany
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Registergericht: Freiburg, HRB 705638
Vorsitzender des Aufsichtsrates:
Prof. Dr.-Ing. Dr.-Ing. E.h. Peter Osypka Senator h.c.
Vorstand: Dr. Nicola Osypka, Achim Kitschmann
Bank: Commerzbank AG Lörrach
Kto-Nr.: 6 557 600 00 (BLZ 680 800 30)
IBAN: DE61 6808 0030 0655 7600 00
SWIFT-BIC: DRES DE FF 680

4. Please return the concerned products to:

Osypka AG
Sales Department
Earl-H.-Wood-Straße 1
79618 Rheinfelden
Germany

If you no longer have any of the concerned products in your inventory, we will need proof of receipt of this *Urgent Safety Information*. Please **return the attached response form** within a week of receipt of this information by fax to **Fax-No. +49 7623 7405-213.**

Action taken by Manufacturer:
This *Safety Information* will be send to all concerned customers until 03.06.2014.
Organizational measurements have been taken by OSYPKA AG to further avoid the likeliness of commutation during packaging for the concerned product types and variations.
The relevant national authority (BfArM – Bundesinstitut für Arzneimittel und Medizinprodukte) has been informed about this *Urgent Safety Information*.

Contact person:

Mr. Benjamin Lehmann
Product Management
Tel: +49 7623 7405 – 208
Email: b.lehmann@osypka.de

We deeply regret any inconveniences caused by the incorrect labeling of our products.

Rheinfelden, 03.04.2014
Osypka AG

_____
i.V. Benjamin Lehmann
Product Management

TELEFAX

To: **Osypka AG** **Priority: High**
[redacted]
Marketing and Sales Assistant

Fax #: **+49 7623 7405 - 213**

By: **PLATZHALTER ADRESSAT**
PLATZHALTER ADRESSAT

Fax #: ……

Subject: **Notice *Important Safety Information***
regarding Valvuloplasty Catheter VACS II / III dated 04.03.2014

We hereby confirm the receipt and attention of the important Safety Information dated 04.03.2014, regarding the call-back of OSYPKA Valvuloplasty Catheters of type VACS II and VACS III catalogue numbers YA0057 and YA32340.

☐ **we confirm, we no longer have products of the concerned lot numbers in stock.**

☐ **we confirm, all products of the concerned lot numbers in our stock have been returned to OSYPKA AG.**

☐ **We require further information. Please call us at Tel. no.** …… **.**

Date, Place	Name:	Signature/Company Stamp:
	Function:	