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Date:
1. September
2006

Urgent Recall for Medical Product Group "sinus-Carotid-RX-System"

(Product: sinus-Carotid-Conical-RX Stent / sinus-Carotid-RX Stent)

Dear Ladies and Gentlemen,

OptiMed Medizinische Instrumente GmbH is hereby conducting a voluntary recall of the OptiMed- Products with the Name "sinus-Carotid-Conical-RX Stent" and "sinus-Carotid-RX Stent".
The only products that are affected are from the Product Group "sinus-Carotid-RX-System" with the abbreviated symbol "RX" on the Label.

OptiMed GmbH has received two complaints to date. It was reported that during specific anatomical conditions of the patient the stent from this Product Group was difficult or not able to be released.

In each of these cases no complications or patient injury occurred. The potential clinical effects of this situation are a delay or extended procedure time and/or the possibility of some neurological event.

Our records show that you have received products from the effected Product Group and as seen in the attachment, please find the Answer Letter that indicates which Products have been sent, including the Article Number and LOT number.

This recall is related to the risk, that might exist, when releasing the stent (during this action). Already implanted Stents are not effected. Therefore it is not necessary to examine patients, which have been treated successfully.

Please be aware that only the Products listed on the Answer Letter are affected by this voluntary recall.

Because of this situation we ask for your cooperation.

To proceed correctly, please read the following instructions.

PROCEDURE:

1. **Remove from your inventory all affected Products and preserve in separate area. These products cannot come into clinical use.**

2. **Advise OptiMed in the Answer Letter how many from the affected Products will be sent back and how many have already been used.**

3. **Fill out and sign the Answer Letter, also when no units of the affected Product will be returned.**

4. **Send the completed Answer Letter by Fax or Post to OptiMed by the 18th of August 2006.**

5. **Send only affected Product to the OptiMed address listed on the Answer Letter. For all sterile Product returned, a Credit Note will be issued.**

The responsible Authorities are informed by Opti*Med*.

We apologize for any inconvenience this has caused and thank you for your understanding.

For further questions to this recall, our Quality Management Department is available under the telephone number:
+49 7243 7633 43.

For further details to your return of affected products and the issue of a Credit Note, please contact our Customer Service: +49 7243 76 33 20.

Thank you in advance for your cooperation.

Best regards,
Opti*Med* GmbH

[redacted]
Security Delegate for Medical Products
Quality Management

PLEASE RESPOND by 18. August 2006 PER FAX to +49 7243/ 76 33 584
Or by Post to: *OptiMed Medizinische Instrumente GmbH, Ferdinand-Porsche-Str. 11, D- 76275 Ettlingen, Germany*

Urgent Answer:
Voluntary Recall of "sinus-Carotid-RX-System"

Customer:
Address:

Past shipments of affected Product:

For the Return of affected Product, please note the quantities of Product used and number of Systems being returned.

Please fill out for eventual questions:

Contact partner: .....
Telephone Number:.....
Date: .....

Signature:.....