Urgent Field Safety Notice
Written follow-up to phone call dated dd-mm-yyyy

Commercial Name :***80372SV4 TempImplant , ø 2.0mm, L 12.0mm, Ti lot VK308***
FSCA identifier: ***ER19-0096***
Type of Action: ***(Return / exchange)***

Dear Customer (insert name)

Please find enclosed the Field Safety Notice associated with the **Straumann® TempImplants *80372SV4 TempImplant , ø 2.0mm, L 12.0mm, Ti lot VK308*** which are used for immediate implant fixed restorations during the healing phase of the permanent dental implants, thus preventing premature loading of the permanent implants. They must be removed again at the conclusion of the healing phase of the permanent dental implants or after 6 months at the latest. The **Straumann® TempImplants** are supplied sterile.

Description of Problem
In the course of routine quality testing, Straumann has identified irregularities in the blister pack seal of a small quantity of the individual blister packages of the Straumann® TempImplants 80372SV4 TempImplant , ø 2.0mm, L 12.0mm, Ti lot VK308. The seal around the blister pack provides a sterility barrier. If it is impaired, the sterility of the product may be compromized. This could result in infection in a patient if the implant is used.
This issue is limited to the above listed article and lot only and not all units are affected.
There have been no incidents reported to Straumann which could be associated with the above issue.

Institut Strauman has decided to voluntarily initiate a Field Safety Corrective Action. .

According to our records you have received xx (enter quantity) pieces of ***80372SV4 TempImplant , ø 2.0mm, L 12.0mm, Ti lot VK308***

Action to be taken:

1. Identify all units of ***80372SV4 TempImplant , ø 2.0mm, L 12.0mm, Ti lot VK308)*** in your inventory.
2. Stop use / distribution of the product immediately and quarantine / segregate physically
3. Return your stock of ***80372SV4 TempImplant , ø 2.0mm, L 12.0mm, Ti lot VK308 to the attention of ?*** insert employee's name) for credit
    a. ***Please inform us if you have a planned surgery using the TempImplant 80372SV4***.
4. If you have used the***(80372SV4 TempImplant , ø 2.0mm, L 12.0mm, Ti lot VK308*****, no action is necessary in addition to your already defined patient**

follow-up plan. However, please inform us of any issues that are detected during these follow-up appointments.

5. In all cases complete and return the enclosed **Customer Confirmation Form to *(insert contact details)***

Transmission of the Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the affected devices have been transferred.

The competent authority of your country has been informed about this Field Safety Corrective Action.

We apologize for any inconvenience that this may cause.

Kind regards,

(insert name)