

**Re: Customer information to Injectomat syringe 50 ml with
Cannula (Ref.No.: 9000701) and Injectomat syringe 50 ml
(Ref.No. 9000711)**

We have received information from customers, that the Injectomat syringes 50ml with the reference numbers (see above) could lead to the administration of a microbolus when administered as infusion together with a corresponding syringe pump.

Immediate internal investigations showed that the concerned syringes could show in the combination with a low flow rate of 2ml/hour a uneven slip behavior. This means that a pressure is built up and after release it could cause a microbolus of the infusion. This behavior could lead to microboli of max. 0.07 ml which is within the specified limit of the used syringe pumps.

The microbolus of max. 0.07 ml as mentioned above is not considered as a clinical relevant risk during administration of drugs with the exception of the administration of especially adrenaline and noradrenalin in a dilution ratio of 1:1 in patients in extreme unstable cardiovascular status or during/after cardiac surgery. In such cases we recommend the user to define application regimes which exclude a possible risk (microbolus). This could be applied for example through higher flow rates with lower dilution ratio or smaller syringe volumes (e.g. 10 ml, 20 ml).

Despite the fact that product features and function are within the acceptable limit we are optimising the products. By end of July / beginning of August 2008 we should have products with better slip properties. As soon as the products are available we will inform you.

For further information and clarification please contact one of the following persons:

-Your local sales Representative

-Your distributor

We apologize for any inconvenience caused.

Kind regards,

Liste der betroffenen Chargen

| 2007 | |
|------------------------------------|--------|
| 50ml Injectomat with cannula | lot |
| 9000701 | C03620 |
| 9000701 | C03629 |
| 9000701 | C0362B |
| 9000701 | C0362C |
| 9000701 | C03641 |
| 9000701 | C03642 |
| 9000701 | C03643 |
| 9000701 | C0364C |
| 9000701 | C0364D |
| 9000701 | C03667 |
| 9000701 | C03678 |
| 9000701 | C03679 |
| 9000701 | C03688 |
| 9000701 | C03689 |
| 9000701 | C0369B |
| 9000701 | C0369D |
| 9000701 | C0369E |
| 9000701 | C036B0 |
| 9000701 | C036B1 |
| 9000701 | C036B2 |
| 9000701 | C036CF |
| 9000701 | C036D0 |
| 9000701 | C036D1 |
| 9000701 | C036D2 |
| 9000701 | C036EF |
| 9000701 | C036F0 |
| 9000701 | C036F1 |
| 9000701 | C036F2 |
| 9000701 | C03724 |
| 9000701 | C03725 |
| 9000701 | C03726 |
| 9000701 | C03727 |
| 9000701 | C03748 |
| 9000701 | C03749 |
| 9000701 | C0374A |
| 9000701 | C03768 |
| 9000701 | C03769 |
| 9000701 | C0376A |
| 9000701 | C03774 |
| 9000701 | C03775 |
| 9000701 | C03776 |
| 9000701 | C03777 |
| 9000701 | C03791 |
| 9000701 | C03792 |
| 9000701 | C03793 |
| 9000701 | C03794 |
| 9000701 | C037AE |
| 9000701 | C037AF |
| 9000701 | C037B0 |
| 9000701 | C037AD |
| 9000701 | C037C7 |

| 2007 | |
|------------------------------------|--------|
| 50ml Injectomat without cannula | lot |
| 9000711 | C03657 |
| 9000711 | C03658 |
| 9000711 | C03603 |
| 9000711 | C036D3 |

| 2008 | | 2008 | |
|----------------------------------|-----------|--------------------------------|-----------|
| 50ml Injectomat mit Kanüle | Charge | 50ml Injectomat ohne Kanüle | Charge |
| 9000701 | C037E7 | 9000711 | C037F2 |
| 9000701 | C037E6 | 9000711 | C037F3 |
| 9000701 | C037E5 | 9000711 | 30 C038E5 |
| 9000701 | 30 C0389D | 9000711 | 30 C03952 |
| 9000701 | 30 C039AA | 9000711 | C037F1 |
| 9000701 | 30 C03973 | 9000711 | 30C038E4 |
| 9000701 | 30 C03947 | 9000711 | 30C038E6 |
| 9000701 | 30 C03946 | 9000711 | 30C03953 |
| 9000701 | 30 C03945 | | |
| 9000701 | 30 C03901 | | |
| 9000701 | 30 C03900 | | |
| 9000701 | 30 C038F2 | | |
| 9000701 | 30 C038CB | | |
| 9000701 | 30 C0389E | | |
| 9000701 | 30 C0387C | | |
| 9000701 | 30 C03867 | | |
| 9000701 | 30 C03867 | | |
| 9000701 | 30 C03866 | | |
| 9000701 | 30 C03850 | | |
| 9000701 | 30 C0384F | | |
| 9000701 | 30 C0384E | | |
| 9000701 | 30 C0384D | | |
| 9000701 | 30 C0383F | | |
| 9000701 | 30 C0383B | | |
| 9000701 | 30 C03813 | | |
| 9000701 | 30 C03812 | | |
| 9000701 | 30C0387D | | |
| 9000701 | 30C0387E | | |
| 9000701 | 30C0389B | | |
| 9000701 | 30C0387F | | |
| 9000701 | 30C0389C | | |
| 9000701 | 30C038B3 | | |
| 9000701 | 30C039A0 | | |
| 9000701 | 30C03985 | | |
| 9000701 | 30C03984 | | |
| 9000701 | 30C03975 | | |
| 9000701 | 30C03974 | | |
| 9000701 | 30C03986 | | |
| 9000701 | 30C0399B | | |