

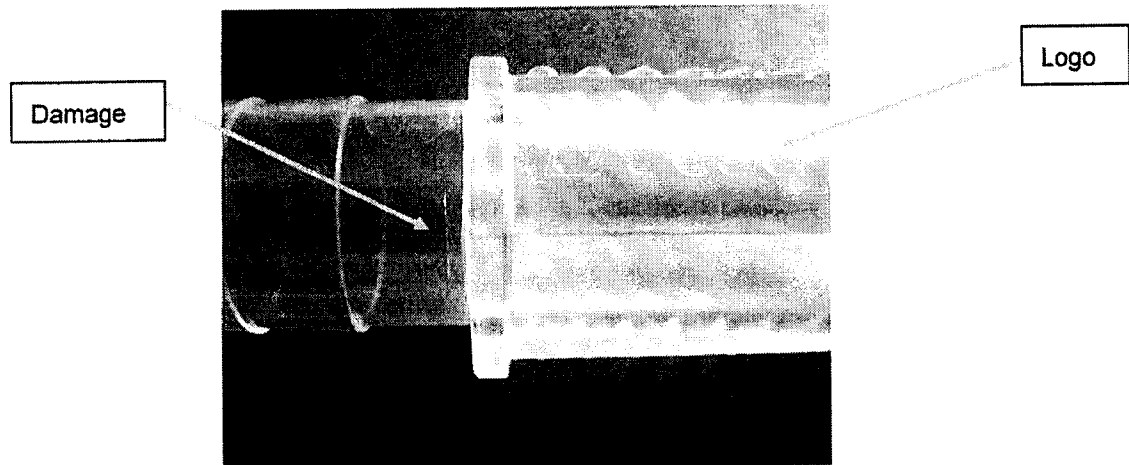
Hirrlingen, 27.08.10

**Field Safety Corrective Action – Connector Ref #0286 (1/2"x1/2")**

Dear Business Partner,

We hereby inform you of a possible problem concerning the connector ref #0286 (1/2"x1/2"). One case was reported where a leak was found at the shank during priming before perfusion (see picture). No patient injury is reported.

Despite this fact and according to our company guidelines we want to inform you of this situation in order to avoid any potential risk and to guarantee the highest level of quality. The result of our internal investigation shows that the malfunction can be limited to specific production lot numbers.



We have reviewed the situation with our supplier and defined the necessary corrective actions. As a result the mentioned malfunction is eliminated for all new delivered products.

MAQUET Cardiopulmonary AG  
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MEMBER OF THE GETINGE GROUP

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Registergericht: Amtsgericht Stuttgart HRB 390389  
Ust.-IdNr. DE 182935498  
Vorstandsvorsitzender: Josef Bogenschütz  
Vorstand: Gerhard Mayer, Manfred Engler  
Aufsichtsratsvorsitzender: Dr. Heribert Balhaus  
Commerzbank AG Balingen (BLZ 653 412 04) 127605400  
SWIFT-Code: COBADEFF665  
IBAN: DE58 6534 1204 0127 6054 00  
BIC: COBADEFFXXX

Different procedures have to be followed for specific products:

1) **Single connectors**

Do not use any of the single connectors and return them to your local MAQUET representative. You will receive new connectors from MAQUET.

2) **Tubing sets with not pre-connected connectors**

The affected tubing sets can be used by following this procedure. You will receive new connectors from MAQUET. Please use these new connectors and replace the connectors in the set before use. As an alternative adequate connectors from other manufacturers can be used.

3) **Tubing sets with pre-connected connectors**

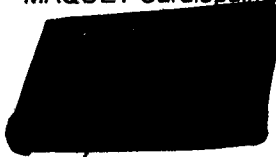
The affected connectors are preconnected in specific lines in the tubing set. We produce these specific lines separately and provide them for you. Before use the affected lines have to be replaced by the new ones. Alternatively the affected tubing sets can be returned to MAQUET for re-work.

All affected products with its lot numbers are listed in the attachment. Please check the list and send the confirmation letter immediately and the completed list latest until 03.09.2010 to your local representative. Please do not hesitate to contact your local MAQUET representative regarding the handling or in case of questions regarding replacement.

We apologize for any inconveniences caused. Nevertheless we hope you understand this procedure and we thank you for your cooperation.

Best regards

MAQUET Cardiopulmonary AG



Vice President Sales



Director  
Quality Assurance & Regulatory Affairs

Attachment:

List of products

Confirmation letter

Hirrlingen, 02.09.2010

**Field Safety Corrective Action – Connector Ref #0286 (1/2"x1/2")**

Dear Business Partner,

In addition to the Field Safety Corrective Action of the connector ref #0286 (1/2"x1/2") dated 27.08.2010 we want to clarify procedure no. 3.

Description in the letter dated 27.08.2010:

3) Tubing sets with pre-connected connectors

The affected connectors are pre-connected in specific lines in the tubing set. We produce these specific lines separately and provide them to you. Before use, the affected lines have to be replaced by the new ones. Alternatively the affected tubing sets can be returned to MAQUET.

Additional information:

In case that the affected connector is pre-connected, but only used during priming before perfusion and cut out before starts perfusion there is no risk for the patient. The affected products can be used. In conclusion there is no need to return the products or to replace the affected lines.

Because of regulatory issues we ask you to confirm that the procedure mentioned in the additional information will be followed for the products marked in the list of the products.

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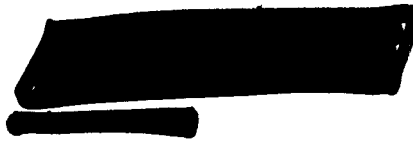
Please do not hesitate to contact your local MAQUET representative regarding the handling or in case of questions regarding replacement.

Best regards

MAQUET Cardiopulmonary AG



Vice President Sales



Director  
Quality Assurance & Regulatory Affairs

Attachment:  
Confirmation letter

To MAQUET Cardiopulmonary AG  
[REDACTED]  
Quality Assurance Manager  
Hechinger Straße 38  
72145 Hirrlingen  
Germany  
Phone: +49 (0) 7478 921-[REDACTED]  
Fax: +49 (0) 7478 921-8222

From

Date

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**Confirmation of receipt**

Dear Mr. Maurer,

I have received the second letter dated 02.09.2010 regarding the Field Safety Notice from MAQUET Cardiopulmonary AG concerning the Connector ref #0286 (1/2"x1/2") and I confirm that I will follow the procedure defined for preconnected connectors.

Best regards

Dealer /Customer

Name  
Function

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