

REPUBLIQUE LIBANAISE

MINISTÈRE DE LA SANTÉ PUBLIQUE

LE DIRECTEUR GÉNÉRAL



الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٢٧/٢٥
رقم الصادر: ١٢/١١٦٨٤١
بيروت، في: ١٥ تشرين الأول ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعنى بالمتابعة:

- Infusion & transfusion, blood bags, blood bag collection set, whole blood collection set
- Trade Mark: Macopharma
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل في تصنيع الصنف المذكور

أعلاه ، نرجو منكم تعميم هذه النشرة على جميع بنوك الدم في المستشفيات.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- الموقع الإلكتروني لوزارة الصحة
- المستشفيات الحكومية
- المحفوظات

وثيقة مصدقة للأجهزة
بيروت في ١٢ تشرين الأول ٢٠١٢ مدير عام الصحة
د. وليد عثمان
عناية غصن



URGENT: Field Safety Notice

Absence of Giving Ports on Final Red Cell Pack (MacoPharma REF: 1201.123)

Background

Our FQE6280LB Whole Blood set is manufactured using 4 separate packs. Two transfer packs that contain giving ports and two solution packs that do not contain ports. These are for the CPD anticoagulant and the SAG-M additive solution.

We have detected some systems where the CPD pack in the system has been inverted with the final red cell pack. This has led to the final red cell pack (issue pack) containing no ports. During manufacture this occurs as an operator has not correctly followed our assembly SOP in production. This occurs at an incidence of less than 0.00007% and is less than one pack affected in over 1.5million systems manufactured every month.

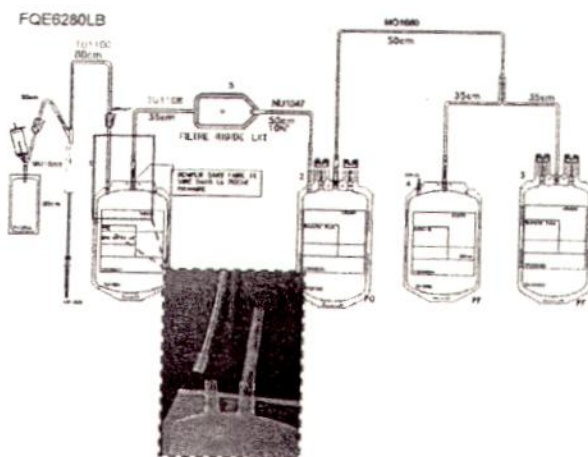
These packs tend not to be detected and can end up being issued which can lead to delays in transfusion and the loss of a blood product.

Corrective Actions

To combat the occurrence of this issue we have implemented a number of corrective actions which has lowered the rate at which this defect occurs however has not prevented its occurrence.

This started in April 2010 with the implementation of the pick-to-light system on our production lines. This is a computer monitoring system that uses sensors to detect that the operator is picking up the packs in the correct order; it alarms and shuts down the system if the incorrect bag is picked. This worked in preventing any large scale incidents from occurring however after a few months we found that some operators were tricking the system after accidentally picking up more than one bag.

We initiated retraining of all operators at this point and started work on an engineered solution to remove the possibility of this defect occurring. Our engineered solution involves the use of a ring joint which is present in some of our more complex systems. This modifies the external diameter of a joint ensuring that the pack will only attach to the corresponding tube within the system. This removes the chance of an inversion occurring. The diagram below shows the location and form of the new ring joint.



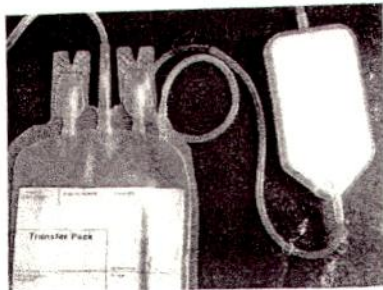
This modification has completed its internal sign off and has passed out internal validation carried out by our materiovigilance department. We are currently awaiting notification from our customers as to whether or not they see a validation being required; and if required how many samples would be needed.

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Interim Phase

During this transition phase we ask that our customers remain vigilant and implement additional checks to ensure the final red cell pack contains ports. We see this as a temporary measure until our engineered solution has passed our customer validations at which point we will be able to provide the first LOT numbers of products containing the modified joint.

One quick check that could be added to the pre-use inspection is a check that the post filtration pack contains ports as shown below. This is the pack directly after the filter that will go on to become the final red cell pack.



**CORRECT
CONFIGURATION**



**INCORRECT
CONFIGURATION**

A second visual check in issue to ensure the final pack has ports could also be implemented as a final check before the product is sent out to the hospitals. We will be providing a FSN to be forwarded to your customers recommending a check on receipt of units.

As a final note we should state that if a pack that contains no ports has been bled into; transferring product via a sterile connection to a pack with ports is acceptable in our eyes. This is because although the pack has been incorrectly configured during production there is no risk to integrity of the unit and all sterilization procedures would have been carried out on the pack.