

Date: 20th July 2016

MacoPharma REF: 1604 71*

ANSM REF: Awaiting Reference

MHRA REF: 2016/006/030/291/004

HPRA REF: V27997

URGENT FIELD SAFETY NOTICE (FSN)

Missing cuts in lateral weld (CV1014)

Introduction

Side slits and hanging holes have been reported missing on the final red cell pack of some bottom and top (BAT) systems. This was initially reported by a French customer (REF: EFS PM 2016-134).

Affected Products

See attached list for product codes and LOTs.

Description of Issue

The side slits and hanging loop is cut into the pack in the final stages of the welding process on our automatic bag welding machines (Automates). They are cut into the positions shown below:



MacoPharma, MacoProduction 1, 200 Chaussée Fernand Forrest, Tourcoing, 59 200, FRANCE

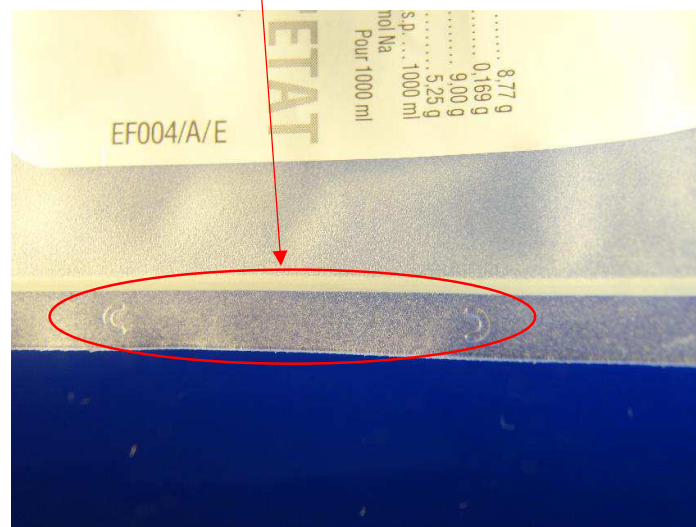
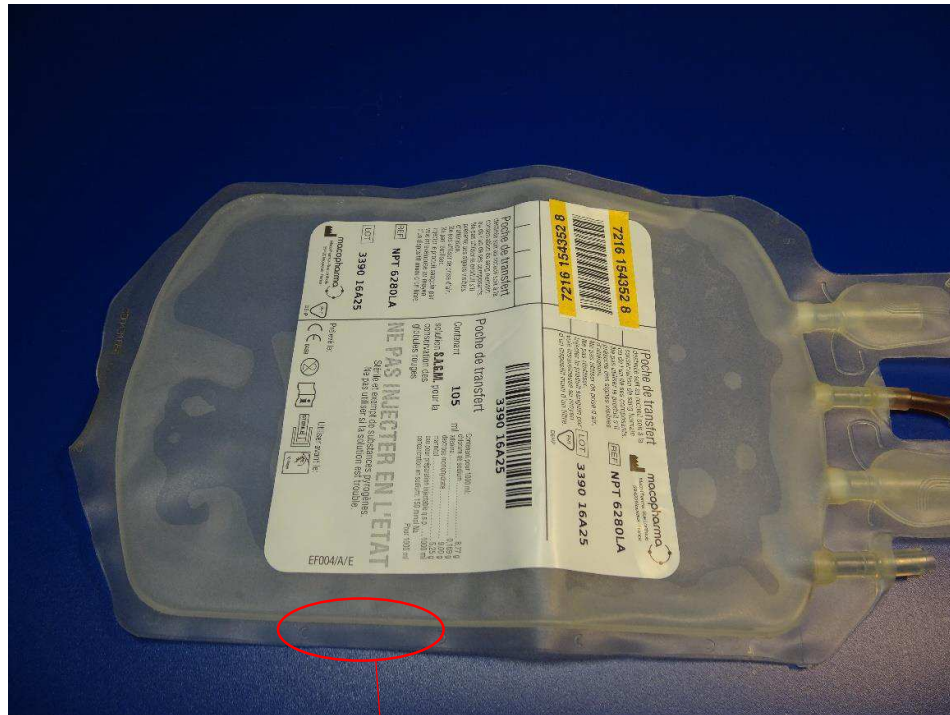
WEB: www.Macopharma.com

The hanging loop is used during the inversion of the pack to run additive into the concentrate red cells. This is a recommended production step so would be identifiable here.

The slits cut into the CV1014 pack are used to store the crossmatch line 'pig-tails' giving us a second line of detection prior to issue.

With this we can say that it is highly unlikely that the product can make it out to the hospital.

The absence of these of these cuts is easily detectable, a pack with missing side slits and hanging loop is shown below:

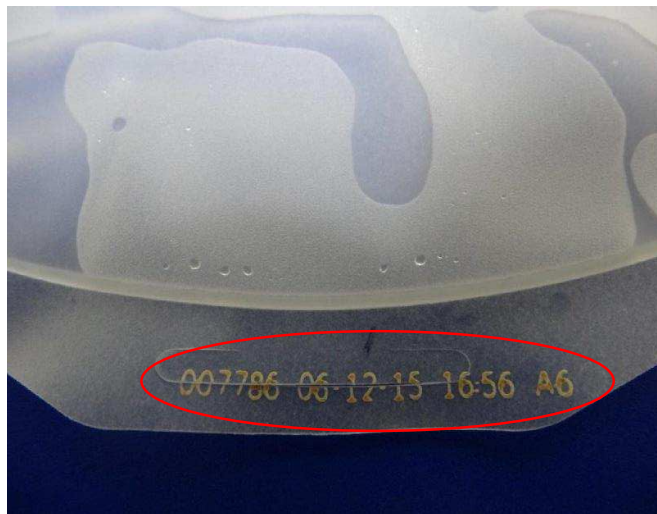


Recommendations for Early Identification

The CV1014 bag is present at the rear of the system for our final packing. It is therefore our recommendation that the first step of the pre-use inspection is to remove the system from the overwrap and lay it label side down on the bench. The pack at the top of the system is the CV1014 pack type. A simple check for the side slits and hanging loop can be carried out at this point prior to a donation being collected.

Closing Comments

Systems that are found to be absent of side slits and hanging loops should not be used. We ask that a note of the pack traceability is reported to us so we can add it to our investigation file when samples cannot be returned. This is present at the base of the CV1014 pack and will be structured like below:



Pack Traceability Mark : 007786 06.12.15 16:56 A6

If you require further assistance please do not hesitate to contact your local MacoPharma Quality Representative.

29/06/2016

Potential batches with missing side slits on the final bag (CV1014)

REFERENCE	BATCH	Qty	COUNTRY
DDG6501LW	0384516B12	504	To be assigned
KSV0001XQ	0403716B04	120	To be assigned
KSV0003XN	369916A18	3852	Greece
KSV0003XP	0352516A11	10008	Pologne
LPB6285LQ	417816C24	2040	Serbia
LPB6289LC	0370516A21	11772	Austria
LPB6289LC	0415916C14	6000	Austria
LPB6289LC	0433416D19	5988	Austria
LPT6285LU	0361816A15	6732	Turkey
LPT6285LU	0409116C21	11976	Albania/Mexico
LPT6285LU	0409216C24	10092	Turkey
LPT6285LU	0417916C23	10260	Turkey/Serbia
LPT6286LR	0392716C08	14796	Italy
LPT6286LR	0424816C29	14880	Italy
LQE6285LL	0372616C14	1992	Portugal
LQE6285LN	384816A30	4008	Greece
LQT614B	11163421BM	72	To be assigned
LQT6230LU	0369016A28	3372	Singapour
LQT6280LU	0382816A28	14652	Spain
LQT6281FC	370616A26	1344	Germany
LQT6281FC	392816B12	3360	Germany
LQT6281FC	392916D04	3360	Germany
LQT6281LR	0386316A20		To be assigned
LQT6281LR	0370316C09	15456	Italy
LQT6282LE	0129916D30	4500	Sweden
LQT6282LS	0371116A13	2508	Chili
LQT6283LB	0371615L18	9216	EBA PRODUCT (Australia / Belgium / Danemark / Scotland / England / Ireland / New Zealand)
LQT6283LB	0374116A11	12264	
LQT6283LB	0374216A12	12228	
LQT6283LB	0374316A14	9552	
LQT6283LB	0374716A12	12144	
LQT6283LB	0375016A18	12023	
LQT6283LB	0376416C11	12024	
LQT6283LB	0376616C07	12230	
LQT6283LB	0376716D26	15288	
LQT6283LB	0376816B27	12132	
LQT6283LB	0376916D15	12230	
LQT6283LB	0377016B16	12132	
LQT6283LB	0377116D12	12192	
LQT6283LB	0377216A25	12060	
LQT6283LB	0377316C01	12120	
LQT6283LB	0434416D27	15288	
LQT6283LB	0379216C02	12230	
LQT6283LB	0377916B01	11964	
LQT6283LB	0412516C31	15240	
LQT6283LB	0378016B08	12204	
LQT6283LB	0412616D04	15252	
LQT6283LB	0412016C17	15276	
LQT6283LB	0378616B18	12024	
LQT6283LB	0378216B09	12192	
LQT6283LB	0430816D06	12228	
LQT6283LB	0378916C04	12144	
LQT6283LB	0432916D16	15288	
LQT6283LB	0411416C21	12216	

LQT6283LB	0411516C25	6115	EBA PRODUCT (Australia / Belgium / Danemark / Scotland / England / Ireland / New Zealand)	
LQT6283LB	0374816A20	12120		
LQT6283LB	0433016D18	15288		
LQT6283LB	0379016B19	11964		
LQT6283LB	0440816E04	11940		
LQT6283LB	0377416A29	12012		
LQT6283LB	0374916A22	12084		
LQT6283LB	0377516A26	12216		
LQT6283LB	0411616C11	12012		
LQT6283LB	0412716D08	15216		
LQT6283LB	0417316D08	15288		
LQT6283LB	0375116A21	12132		
LQT6283LB	0377616A26	12204		
LQT6283LB	0378316B10	12230		
LQT6283LB	0431516D12	15288		
LQT6283LB	0378116B03	12216		
LQT6283LB	0378716B19	12144		
LQT6283LB	0379316C05	12108		
LQT6283LB	0433116D19	15288		
LQT6283LB	0377716A27	12168		
LQT6283LB	0431616D13	15288		
LQT6283LB	0377816B05	12192		
LQT6283LB	0431716D14	15288		
LQT6283LB	0378816B25	12192		
LQT6283LB	0378416B24	12096		
LQT6283LB	0431816D15	15288		
LQT6283LB	0378516B12	12204		
LQT6283LB	0427516D08	156		
LQT6284LE	0383116A27	14796		Norway
LQT6284LE	0393416C01	14964		Norway
LQT6284LE	0396616C07	14484		Norway
LQT6284LE	0406416C15	12000		Norway
LQT6284LE	0406616D08	10000		Norway
LQT6287LU	0368616A15	15192		Turkey
LQT6287LU	0368716A16	15060		Turkey
LQT6287LU	0371716A18	15144		Turkey
LQT7242FC	410016C03	4032		Germany
LQT7242FC	410116C18	4032		Germany
LQT7247LC	341316A19	10008	Germany	
LQT7247LC	372616B03	10008	Germany	
LQT7247LC	430916D06	15000	Germany	
LQT7247LC	431016D07	15000	Germany	
LQT7247LC	431116D07	10032	Germany	
LQT7247LC	416216C18	10008	Germany	
LQT7247LC	341916A20	9972	Germany	
LQT7247LC	372716B03	10080	Germany	
LQT7247LC	372916B04	10080	Germany	
LQT7247LC	372816B04	9972	Germany	
LQT7248LC	329816A19	10692	Germany	
LQT7248LC	393216C02	9984	Germany	
LQT7248LC	393316C03	10008	Germany	
LQT7291FC	394916C14	3100	Germany	
LQT7294FC	383416A26	3900	Germany	
LQT7294LC	322416B09	1992	Germany	
LQT7294LC	432016D14	4080	Germany	
LQT7296LC	363816A20	10080	Germany	
LQT7296LC	408716C23	12000	Germany	
LQT7297LC	341816B01	3324	Germany	

MSE0100Q	389016D07	765	To be assigned
MSH6201Q	366716C10	5000	To be assigned
NPT614B	11163420BM	72	To be assigned
NPT6280LA	338315L16	15336	France
NPT6280LA	338516A04	15384	France
NPT6280LA	338616A11	15432	France
NPT6280LA	338716A14	15360	France
NPT6280LA	338916A18	15336	France
NPT6280LA	338816A21	15288	France
NPT6280LA	338916A18	15288	France
NPT6280LA	339016A25	15288	France
NPT6280LA	339116A29	11664	France
NPT6280LA	339216B02	15072	France
NPT6280LA	339316B10	10008	France
NPT6280LA	339416B09	5280	France
NPT6280LA	339516B15	15288	France
NPT6280LA	339616B18	15204	France
NPT6280LA	389616B24	15288	France
NPT6280LA	389716B29	15288	France
NPT6280LA	389916C03	11100	France
NPT6280LA	390016C16	15288	France
NPT6280LA	390416C18	15288	France
NPT6280LA	390516C23	14155	France
NPT6280LA	390716C31	15288	France
NPT6280LA	390816D19	15288	France
NPT6280LA	391016D26	15288	France
NPT6280LA	406316B12	7620	France
NPT6280LE	0217616A08	12192	Sweden
NPT6280LE	0412816C22	15144	To be assigned
NPT6280LE	0432116D11	15264	To be assigned
NPT6283LB	0374416B04	12180	England