HAEMONETICS®
THE Blood Management Company

Haemonetics S.A.
Signy Centre
P.O. Box 262
1274 Signy-Centre, Suisse
Tel: +41.22.363.9011

Urgent Field Safety Notice

Blood collection sets: Please see the attached list on affected products
FSCA-identifier No 0687-FY13-POR
Type of action: Advice regarding the use of the device

December, 2012

Dear Chief Medical Director and Site Director:

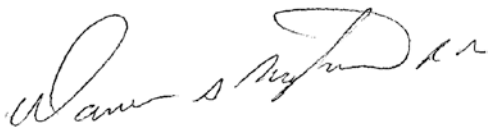
Description of problem:
The purpose of this letter is to inform you that due to a manufacturing defect, there is the potential for a leak to occur, at a very low frequency, in the flexible Y connector of the donor line in some Whole Blood Collection Sets shipped to you. This defect could potentially affect the whole blood as well as the resulting blood components. Haemonetics has determined that all product lots for the product codes identified in the attached Protocol require examination. ***Note: Because of the recent acquisition from Pall Corporation, all of these lots are labeled as being manufactured by Pall Medical, A Subsidiary of Pall Europe Ltd.***

We are requesting that during pre-phlebotomy, post-phlebotomy and post-collection users conduct an examination of the collection sets as listed in the attached protocol, and you especially examine the Y connectors. As noted in the protocol, if a defect is detected before collection, the set must not be used. If a defect is detected during collection, the collection must be halted and any collected blood must be discarded, and if a defect is detected after collection, the blood must be discarded. In all cases please ensure sets are retained for evaluation as per local protocol.

We regret any inconvenience the examination process may cause, but trust that these added steps will continue to assure you of our commitment to provide you with products that meet your needs. We encourage you to report any product issues, including patient infections, through your normal reporting procedures. Additionally, please report issues to Haemonetics and if necessary to appropriate regulatory authorities.

Should you have any questions regarding the above, please contact your local Haemonetics representative.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.



Warren Nighan, RN
Vice President of Worldwide QA/RA

Protocol for Examining Flexible Y Connector in Whole Blood Collection Sets

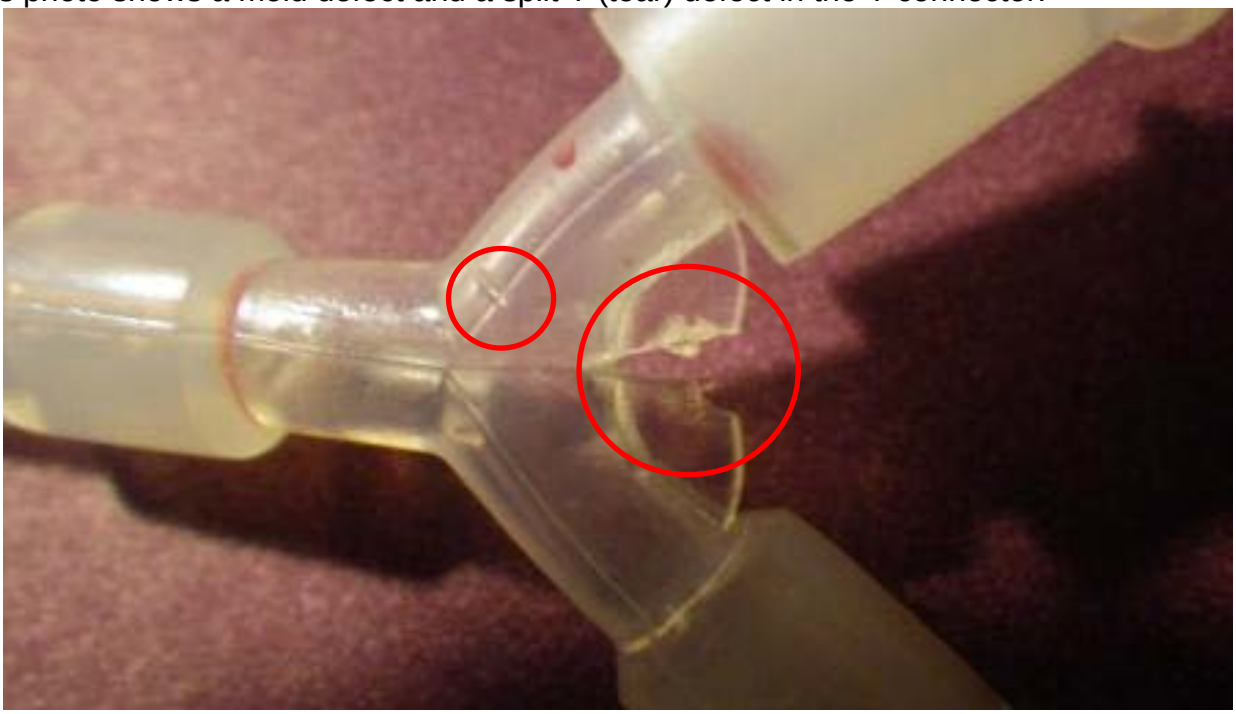
Pre-Phlebotomy Examination

Prior to phlebotomy please examine the flexible Y connector in the donor line to look for the presence of a mold defect, a pin hole, or a split Y. The following shows a normal Y connector:

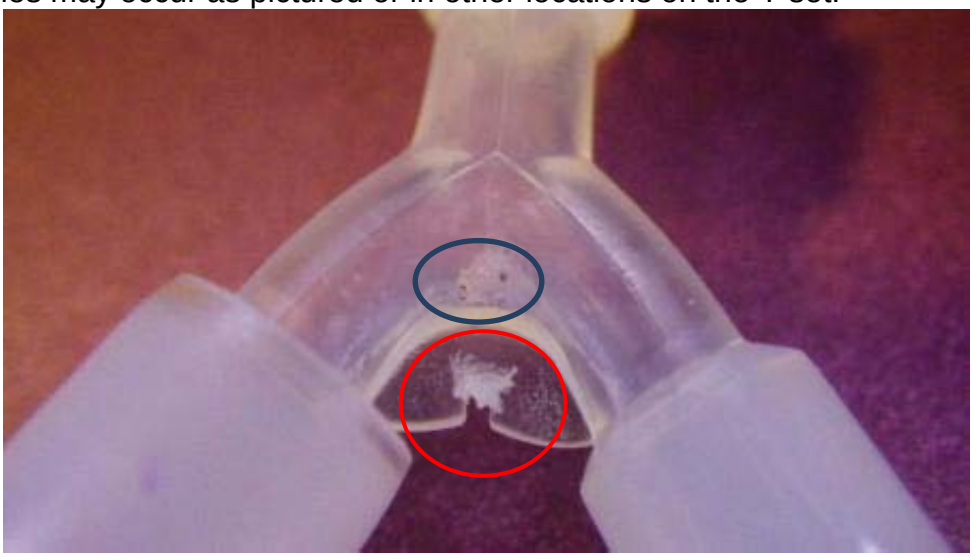
Normal (Good) Flexible Y Connector:

The following photos show Y connectors with defects or potential defects:

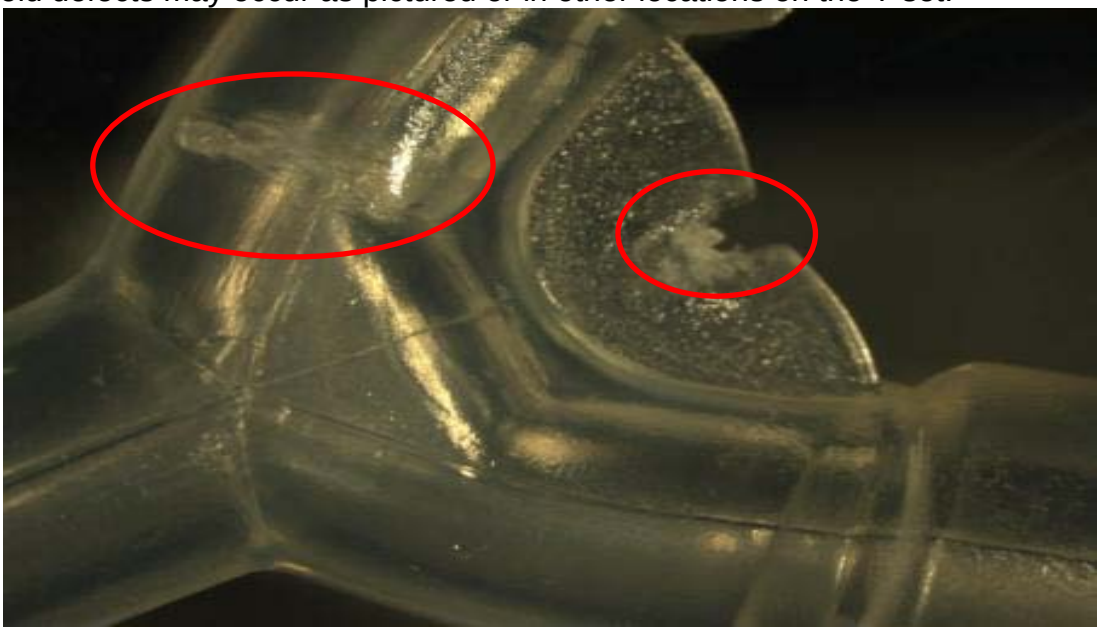
This photo shows a mold defect and a split Y (tear) defect in the Y connector:



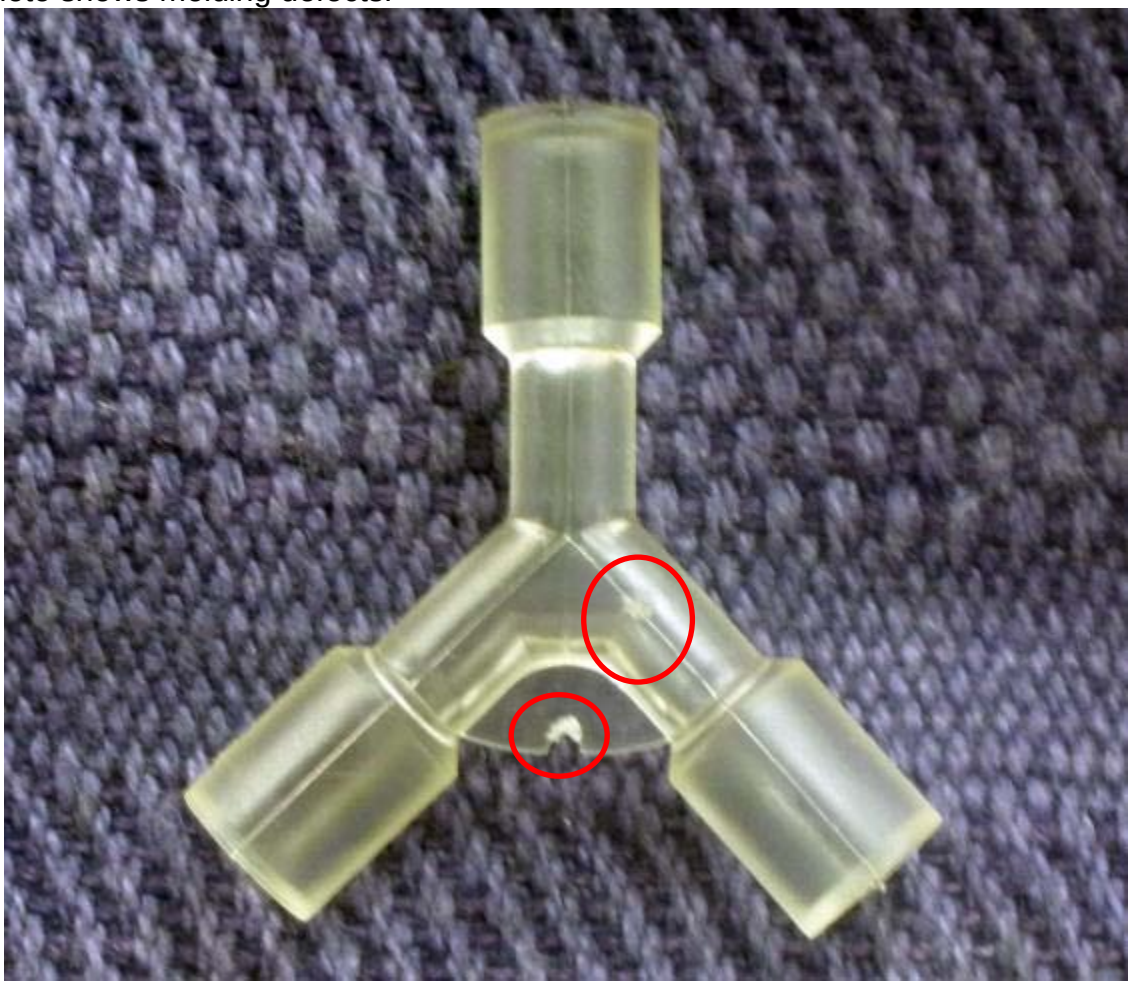
This photo shows a pin hole (blue circle) and molding defect (red circle)
Note: Pin holes may occur as pictured or in other locations on the Y set:



This photo shows molding defects
Note: Mold defects may occur as pictured or in other locations on the Y set:



This photo shows molding defects:



This photo shows a molding defect:

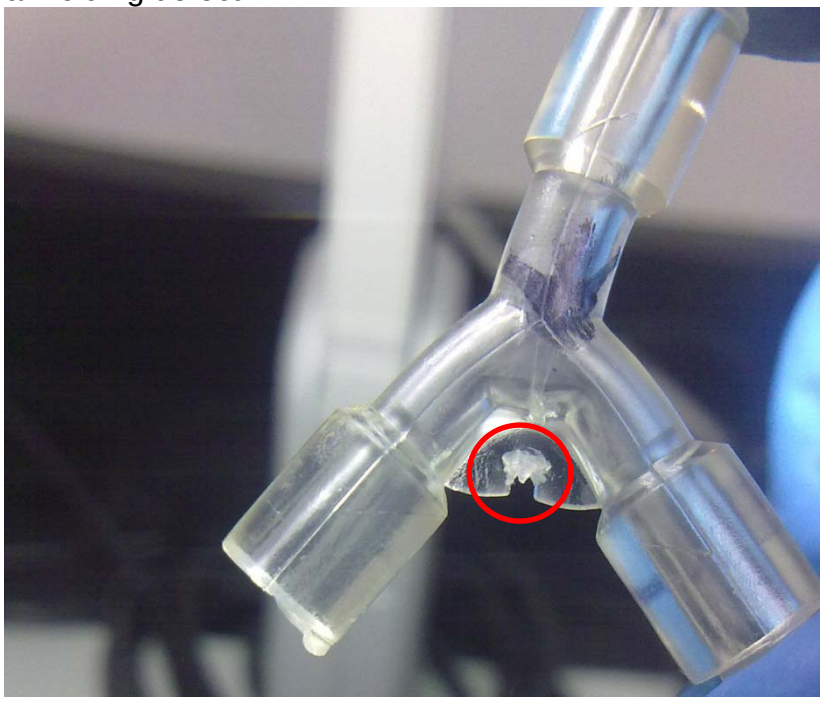
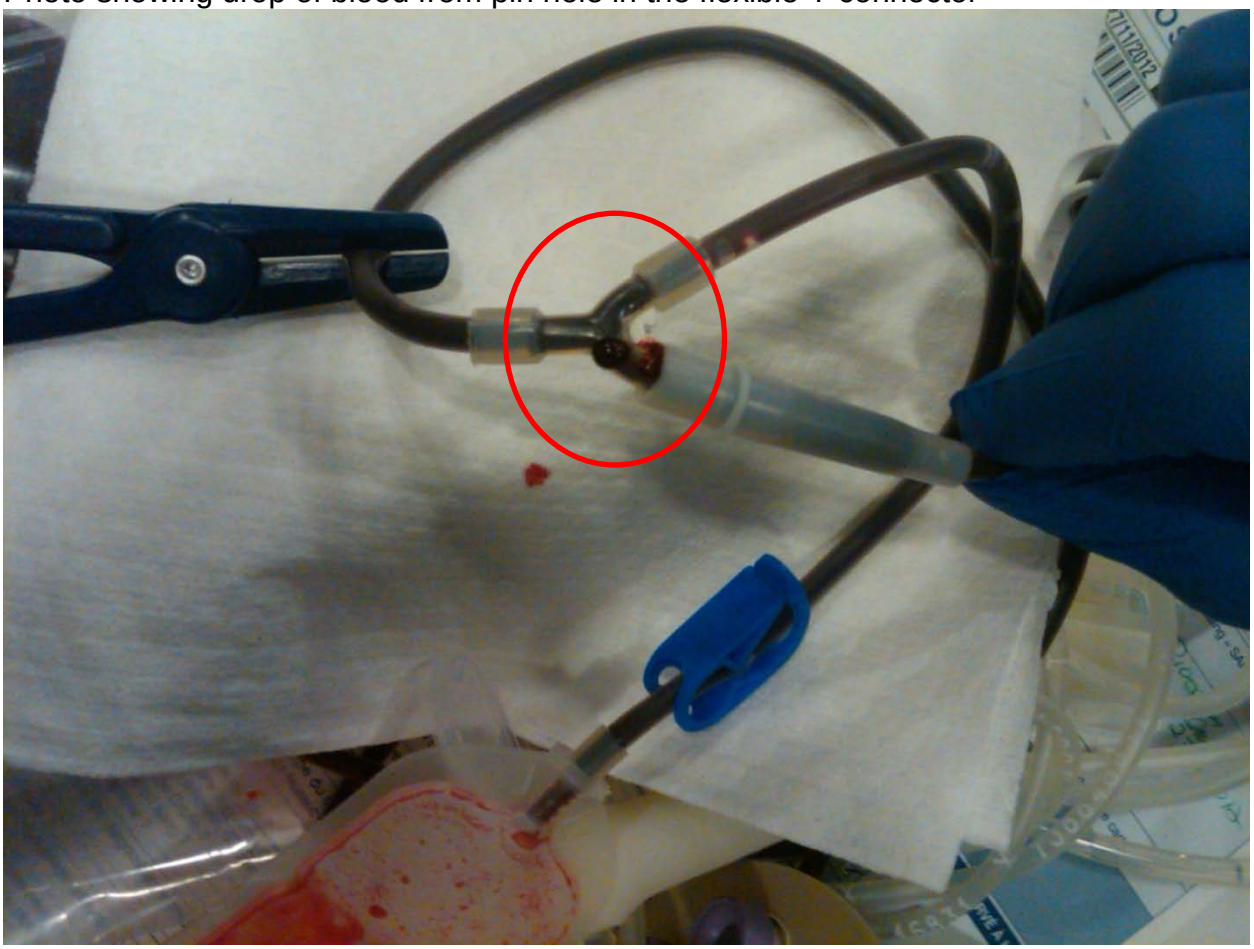


Photo showing drop of blood from pin hole in the flexible Y connector



If a defect is detected before collection, the set should not be used. If a defect is detected during collection the collection should be aborted and any collected blood must be discarded. If a defect is detected after collection the blood must be discarded.

Please report any observed defects via normal local reporting routes. Additionally, please complete the attached form to document the defect. Any defects should be reported to us immediately via email at msnudden@haemonetics.com *or* fax at +41-22-594-8410 by using the attached form.

Advice on action to be taken by the user

Post-Phlebotomy Examination

After phlebotomy and transfer of blood to the Sample Diversion Pouch, please close the blue clamp and then re-examine the flexible Y connector to verify that there has been no blood leak, prior to opening the Breakaway Closure (BAC) or clamp to initiate collection of the unit. The user should then wipe the Y connector with gauze (or other absorbent material) to help determine if a leak has occurred (see the photo above). If no leak is observed, open the BAC and collect the unit.

Post-Collection Examination

After collection of the units, please re-examine the Y connector as described above to verify no blood leak has occurred.
If a blood leak is observed before or after collecting the unit, please report through normal local reporting routes and additionally complete the attached form to document the defect.
Please report to the relevant authorities any infections in patients transfused with blood collected with the affected whole blood collection sets, and inform Haemonetics as well.

Please report any defects to us immediately via fax at +41-22-594-8410 or by email at msnudden@haemonetics.com using the attached “Flexible Y Connector Defect Form” .
A letter confirming receipt of the flexible Y connector defect complaint and containing the assigned POR complaint number will be provided to you by Haemonetics Quality Assurance department.

Please complete and return the enclosed “Acknowledgement of Receipt Form” related to the receipt of this field safety notice as soon as possible as indicated in this form.

If you have any additional questions or concerns, please do not hesitate to contact your local Haemonetics representative.

Flexible Y Connector Defect Form

Fax to +41-22-594-8410/msnudden@haemonetics.com

Person Reporting Difficulty: _____
Customer Name: _____
Address: _____
Phone Number: _____
Reorder Code of Product: _____
Set Lot Number of Product: _____
Nature of Difficulty (indicate with "X"): _____ Defect in Flexible Y; _____ Leak in Flexible Y
Process Step when difficulty occurred (indicate with "X"):
_____ Found prior to use of the set
_____ After phlebotomy but before opening breakaway closure
_____ During or after collection of the unit
_____ Other (explain) _____

Date of Occurrence: _____
Number of Implicated Products: _____
Best Time And Telephone Number To Be Reached For Additional Information (if needed) for investigation: _____
Additional Comments:
Form Completed By:_____Date: _____

Scope: This action covers the following lot numbers of Whole Blood Collection Sets identified by the Product Codes as listed below:

Type	List Number	Item description	Batch
Blood collection sets - Non filter systems	NFB334CL	T&B 3 bag CPD/SAGM 450ml	1210230
Blood collection sets - Red cell filtration	RCB434CEL	RCT&B4PVCBAG63MLCPD/100MLSAG-M	1207146
	RCB434CEL3	T&B QUAD RC CPD/SAG-M 450 ML	1206125
			1210238
	RCB436CCU	T&B QUAD RC CPD/SAG-M 450	1256128
			1256129
			1256217
			1256218
	RCB436KCE	T&B QUAD RC CPD/SAG-M 475 ML	1256098
	RCB438DCGS	T&B QUAD RCS CPD/SAG-M 500 ML	1256542
	RCT434CCL	T&T QUAD RC CPD/SAG-M 450ML	1256145
	RCT434CEL	T&T QUAD RC CPD/SAG-M 450ML	1205103
			1207145
			1207157
Blood collection sets - Red cells, platelets, plasma	RPT434CCL	T&T QUAD RCPL CPD/SAG-M 450ML	1256162
	RPT434CEL	T&T QUAD RCPL CPD/SAG-M 450ML	1207156
			1209213
Blood collection sets - Whole blood filtration	WBT428GG	T&T Quad WB CPD/PAGGSM-M 450ML	1205118
	WBT434CC	T & T QUAD WB CPD/SAG-M 450ML	1205121
			1206141
			1206142
			1207149
			1207151
			1210225
			1210247
	WBT434CCL	T&T Quad WB CPD/SAG-M 450ML	1256163
			1256197
			1256260
			1256261
	WBT434CEL	T&T Quad WB CPD/SAG-M 450ML	1204100
			1210232
	WBT434CUP	WBT&T4PVCBAGSCPD/SAG-M63/100ML	1205119
	WBT434GB	T&T Quad WB CPD/PAGGSM-M 450ML	1209215
	WBT436CCU	T & T QUAD WB CPD/SAG-M 450ML	1256479
			1256480

Type	List Number	Item description	Batch
Blood collection sets - Whole blood filtration	WBT436CEA	T & T QUAD WB CPD/SAG-M 450ML	1209210
	WBT436CEU	T & T QUAD WB CPD/SAG-M 450ML	1205124
			1206128
			1206129
			1206130
			1206132
			1206133
			1206134
			1206135
			1207153
			1207154
			1207155
			1207159
			1207160
			1207161
			1210233
			1210234
			1211252
	WBT436KCE	T&T QUAD WB CPD/SAG-M 475 ML	1256097
			1256203
	WBT438DCG	T&T QUAD WB CPD/SAG-M 500 ML	1256125
			1256161
			1256233
			1256243
			1256255
			1256411
			1256417
			1256430
			1256431
			1256504

Acknowledgment of Receipt Form

In order for Haemonetics to advise the relevant Competent Authorities about the receipt of this Field Safety Notice, you are requested to complete and return this form promptly.

Customer Information:
Customer Name _____

Institution _____

Street Address _____

City, Zip Code, Country _____

Regarding: Field Safety Notice for Examination of Flexible Y Connectors
I have read and understand the instructions provided in the letter. Yes____ No____
Signature of Receipt: _____
Date:_____

Name/Title	
Telephone	
Email Address	

PLEASE EMAIL COMPLETED RESPONSE FORM TO: yconnect@haemonetics.ch
or FAX TO +41-22-594-8410
or MAIL TO: Ms. Hilde van Mechelen
QA Department
P.O. Box 262
Rue des Fléchères
1274 SIGNY Centre
Switzerland