



ALCIS SARL



Urgent Field Safety Notice

This Field Safety Notice follows the one sent you on 02 Feb. 2016

Date: 22 February 2016

For the attention of: Healthcare Professionals and Distributors

Commercial name of the affected product: **HQS**, valve introducer catheter

Manufacturer: Alcis

Alcis Reference Number: RC 16/007

Type of action: Recall

Details on affected products:

Device	Commercial Reference	Lot Number	Device	Commercial Reference	Lot Number																																					
HQS - valve introducer catheter	2064-HQS-10F-100	14/751	HQS - valve introducer catheter	2064-HQS-20F-140	11/326																																					
		14/638			2064-HQS-16F-140	14/300	2064-HQS-20F-200	15/114	13/418	2064-HQS-20F-300	11/327	13/417	11/117	13/147	11/114	2064-HQS-16F-300	14/726	2064-HQS-22F-140	12/148		11/325	2064-HQS-22F-300	14/611	12/425	14/505	11/426	14/168	11/118	12/149	2064-HQS-18F-200	15/115		11/425	2064-HQS-18F-300	12/424	2064-HQS-24F-140	13/427	11/429	2064-HQS-26F-140	11/084		
	2064-HQS-16F-140	14/300		2064-HQS-20F-200		15/114																																				
		13/418				2064-HQS-20F-300		11/327																																		
		13/417						11/117																																		
		13/147						11/114																																		
		2064-HQS-16F-300			14/726	2064-HQS-22F-140	12/148																																			
		11/325		2064-HQS-22F-300	14/611																																					
		12/425			14/505																																					
		11/426			14/168																																					
		11/118			12/149																																					
	2064-HQS-18F-200	15/115			11/425																																					
	2064-HQS-18F-300	12/424		2064-HQS-24F-140	13/427																																					
		11/429		2064-HQS-26F-140	11/084																																					
			12/583																																							

Les hauts du Chazal - Témis Santé
2 rue Paul MILLERET- Bât. BIOPARC
25000 BESANCON
France

ALCIS

SARL au capital de 48 000 €
Siret 423 808 914 00042 - APE 3250A
Code TVA : FR30423808914

ALSEAL

SAS au capital de 210 000 €
Siret 517 993 176 00026 - APE 3250A
TVA intracom : FR 30 517 993 176

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Description of the problem:

Following the field safety notice sent on 02 February 2016 asking for quarantine potentially affected products, we proceed to the **recall** of affected products.


We were informed of breakage of HQS introducers extremity during use. We observed that some batches of our HQS introducers present a risk of partial break of the end of sheath tubing.

Adverse events can occur following the partial break of this extremity, such as a medical intervention to retrieve a loose segment or complications due to the loose end occluding blood flow towards the irrigated organs. To our knowledge there is no report nor any description of illness or injury linked to this potential hazardous situation. We did not identify any additional risk for the patient, for whom an HQS introducer has been used without incident with the sheath extremity.

An extended light exposure of these sheath tubings (stored before manufacturing) is at the origin of this risk.

This risk is significantly increased in case an effort is required during the insertion, the endovascular tool passage or the removal of our HQS introducer sheath.

Following the decision of quarantine potentially affected products, Alcis is conducting a **recall** of the batch of HQS products affected. For that purpose you will find attached to this mail the list of products concerned by this recall.

All the tests performed after real time ageing of products in their original packing have been successfully passed. Then, we do underline the importance of storing the HQS products shielded from the light, as illustrated by the logo found on label. 

Advice on action to be taken by the user:

1. Please review the attached list of affected products and lot numbers and quarantine any affected product that remains unused.

Pay particular attention to the following batches which were not mentioned in our previous communication:


- 2064-HQS-22F-300, batch 11/425
- 2064-HQS-26F-140, batch 12/583


Please note that the following batches have been removed from the list as they have been identified compliant or they have reached their expiry date on January 2016:

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- 2064-HQS-20F-140, batch 11/079
- 2064-HQS-22F-140, batches 11/082 and 11/078
- 2064-HQS-22F-300, batch 11/077

2. Immediately collect and return all unused affected products to Alcis.

Send the removed products to the manufacturer:

Alcis
Les hauts du Chazal - Témis Santé
2 rue Paul Milleret– Bat. BIOPARC
25000 BESANCON
France

Please contact our customer service to define pick up arrangement
(commercial@alcis.net - +33 (0)3.81.61.69.93).

Returned products will be exchanged as soon as possible.

3. Please complete the enclosed form acknowledging of the receipt of this field safety notice by sending it back by email to regulatory@alcis.net or by fax +33 (0)3.81.53.47.65

Transmission of the field safety notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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Contact reference person:

Jean-François Delforge – CEO
or
Alexandra Bouland – Regulatory Affairs Manager

Alcis
Les hauts du Chazal - Témis Santé
2 rue Paul Milleret – Bat. BIOPARC
25000 BESANCON
France

Should you have any question, please feel free to contact us for further information
(email: regulatory@alcis.net, phone: +33 (0)3.81.61.69.93)

We confirm that this notice has been notified to the appropriate competent authorities.

Jean-François Delforge
ALCIS CEO / ALSEAL President

Annex: Acknowledgment form

Les hauts du Chazal - Témis Santé
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Acknowledgement receipt of this field safety notice referred RC 16/007

Please complete and return this form to:
email: regulatory@alcis.net or fax: +33 (0)3.81.53.47.65

Please tick off the boxes accordingly:

We hereby confirm that we are aware of this field safety notice concerning the HQS product. The field safety notice was communicated within our organization, and if required, to any other organization having affected products

In our facility, we do not have any of the affected products in stock

Or

We have quarantined and will return the following products:

Device	Commercial Reference	Lot Number	Quantity to be returned
HQS - valve introducer catheter	2064-HQS-10F-100	14/751	
		14/638	
	2064-HQS-16F-140	14/300	
		13/418	
		13/417	
		13/147	
	2064-HQS-16F-300	14/726	
	2064-HQS-18F-140	15/392	
		11/427	
		11/325	
		12/425	
		11/426	
		11/118	

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Device	Commercial Reference	Lot Number	Quantity to be returned
	2064-HQS-18F-200	15/115	
	2064-HQS-18F-300	12/424	
		11/429	
	2064-HQS-20F-140	11/326	
	2064-HQS-20F-200	15/114	
	2064-HQS-20F-300	11/327	
		11/117	
		11/114	
	2064-HQS-22F-140	12/148	
	2064-HQS-22F-300	14/611	
		14/505	
		14/168	
		12/149	
		11/425	
	2064-HQS-24F-140	13/427	
	2064-HQS-26F-140	11/084	
		12/583	

Institution (name and address):

Phone:

Name:

Date / Signature:

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