



ALCIS SARL



Urgent Field Safety Notice

Date : 02 February 2016

For the attention of: Healthcare Professionals

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

Manufacturer: Alcis

Alcis Reference Number: RC 16/007

Type of action: Quarantine of devices

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			11/079	
	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	
	2064-HQS-18F-140	15/392			11/082	
		11/427		11/078		
		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		11/077		
	2064-HQS-18F-300	12/424		2064-HQS-24F-140	13/427	
		11/429		2064-HQS-26F-140	11/084	

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

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ALSEAL

SAS au capital de 210 000 €
Siret 517 993 176 00026 - APE 3250A
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Description of the problem:

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.

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

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.
This list has been established with the potentially affected products identified in your stock, according to our internal records.
Please also ensure that you do not have products identified in the exhaustive list of products present in the section "Description of concerned devices".
2. 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


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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.

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 potentially affected products

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

Or

We have quarantined the following products:

Device	Commercial Reference	Lot Number	Quantity Received	Quantity in stock and quarantine
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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		11/082		
		11/078		
	2064-HQS-22F-300	14/611		
		14/505		
		14/168		
		12/149		
		11/077		
	2064-HQS-24F-140	13/427		
	2064-HQS-26F-140	11/084		

Institution (name and address):

Phone:

Name:

Date / Signature:

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