Saint Priest, 07 février 2018

Customer

Adress

SAFETY CORRECTIVE ACTION / RECALL – MEDICAL DEVICE	
Name of medical device:	ODALYS STERILE – Curved rod Ø6 L35 à L75 ODALYS STERILE – Cross link 37-49 et 49-73
Type of action :	Recall of products

Addressees: Director of healthcare facility, Local vigilance correspondent, services and healthcare facilities concerned

Reference and lot number of products concerned:

Reference	Description	Lot
10BR0010	Curved rod Ø6 L35	**140428 ; 150429 ; 150769 ; 150846**
10BR0020	Curved rod Ø6 L40	**140221 ; 140396 ; 140397 ; 140398 ; 140430 ; 150431 ; 150629 ; 150630 ; 150631 ; 150632 ; 150770 ; 150847**
10BR0030	Curved rod Ø6 L45	**140222 ; 140399 ; 140400 ; 140401 ; 140432 ; 150433 ; 150633 ; 150634 ; 150771 ; 150772 ; 150848**
10BR0040	Curved rod Ø6 L50	**140223 ; 140402 ; 140403 ; 140404 ; 140434 ; 150435 ; 150773 ; 150774 ; 150849**
10BR0050	Curved rod Ø6 L55	**140436 ; 150437 ; 150775**
10BR0060	Curved rod Ø6 L65	**140224 ; 140405 ; 140406 ; 140438 ; 150776**
10BR0070	Curved rod Ø6 L75	**140440 ; 150441 ; 150635 ; 150777 ; 150778 ; 150850**
10CL0010	Cross link 37-49	**150584 ; 150625 ; 150779 ; 150851 ; 150866**
10CL0020	Cross link 49-73	**150585 ; 150780 ; 150852**

Intended use of the device:

The ODALYS system allows posterior thoraco-lumbar osteosynthesis.

Context and purpose of the information:

The sterile barrier system of ODALYS Ø6 curved rods and cross link consists of a PETPE / Tyvek pouch (first sterile barrier) and a PETG / Tyvek blister pack (second sterile barrier).
The medical device is initially packaged in the PETPE / Tyvek pouch and then the set (device + pouch) is packaged in the PETG / Tyvek blister pack.
Finally the blister is placed in a cardboard box to protect it from shocks, light and dust.




In 2016, during the accelerated validation of the sterile barrier system for a period of 5 years, KISCO International detected a failure on the integrity of the seal of the PETPE / Tyvek pouch constituting the first sterile barrier of the device.
At this time, the risk that the device could be contaminated was considered zero because the PETG / Tyvek blister constituting the second sterile barrier had no failure and guaranteed the sterility of the device over a period of 5 years.
Corrective action was taken and consisted of the validation of a new sterile barrier system made of 2 PA / PE pouches. No new batch of devices has since been manufactured with this new sterile barrier system.
Following the conclusions of an internal audit of the validation process carried out in December 2017, we decided to reconsider the assessment of the potential risk on the contamination of the devices concerned.

Evaluation of potentiel risk:

The PETPE / Tyvek pouch no longer ensuring its microbial barrier function, the sterility of the medical device is only guaranteed by the PETG / Tyvek blister pack.
The sterility of the medical device may no longer be ensured if the device in its PETPE / Tyvek pouch is deposited in a non-sterile operative field after the blister is opened by the user.

Corrective action implemented:

Validation of a new sterile barrier system made of 2 PA / PE pouches

Actions required by users:

Our records indicate that we have made available to your healthcare facility devices affected by this safety corrective action.
KISCO International thanks you kindly:
- Identify and isolate all devices concerned within your facility
- Return to KISCO International the devices with a copy of the attached customer response form.

Diffusion and taking into account of this safety corrective action:

We would like to ask you to :

- Transmit this information to everyone involved in your establishment,
- Keep a copy of this information and ensure its regular diffusion to ensure the effectiveness of the safety corrective action

For any additional questions, our quality department is at your disposal by phone at +33 (0) 4 69 84 23 38 or by email: isabelle.broca@kisco.fr

We apologize for the inconvenience and thank you for your understanding and cooperation.

Please accept, Sir, Madam, to express our sincere greetings

Isabelle BROCA

Quality manager

Answer form : *Name of establisment*

SAFETY CORRECTIVE ACTION / RECALL – MEDICAL DEVICE
ODALYS STERILE – Curved rod Ø6 L35 à L75 ODALYS STERILE – Cross link 37-49 et 49-73

We kindly ask you to complete this answer form and return it to us within 7 days:
KISCO International, Quality Service
By email: isabelle.broca@kisco.fr

I attest:
- Having received safety corrective action from KISCO International
- Have transmitted this information to the people concerned

I return the references, lot numbers and quantities listed below

Reference	Lot number	Quantity

Etablissement :	
Name :	
Function :	
Date :	
Visa :	