SurgiPro PRIVATE LIMITED
Co. Reg. No.: 199506597D
✓Ophthalmic ✓ ENT ✓ General ✓ Operating Theatre Equipment ✓ Physio & Rehab Equipment ✓ Maintenance & Services
CERTIFICATION INTERNATIONAL HSA TS-01:GDPMDS Cert. No: CIS / 8412G
實際寶 私人有限公司

16 December 2015

Urgent Field Safety Notice

Affected Product : ARCOTANE

FSCA reference: 091215-749

FSCA action: recall of certain lots

[redacted]

Dear [redacted]

ARCADOPHTA has been notified of 3 cases of inexplicable severe vision loss after uneventful retinal detachment surgery during which our Perfloro-n-octane ARCOTANE device has been used.

Those 3 cases occurred in the same hospital with the same surgeon and were confirmed after gas tamponade dissipation.

As of today ARCADOPHTA has no evidence whether the product ARCOTANE is potentially the cause of the unfortunate vision loss in the 3 cases reported.

As a conservative measure and in light of the current materiovigilance context regarding pefluoro-n-octane based products, ARCADOPHTA has decided to perform a recall of all the lots that are potentially linked to these 3 cases.

SurgiPro is implementing this recall on behalf of ARCADOPHTA in Singapore territory, therefore

You are requested to please

1. to quarantine your current inventory of the below lots
2. to contact your sales person who will organize the sending back to SurgiPro all units belonging to these lots
3. please take action immediately and forward this information to the concerned personnel within your organization

23 WOODLANDS INDUSTRIAL PARK E1 #03-05
SINGAPORE 757741
TEL : +65 6894 6038
FAX : +65 6894 6036

Lots concerned by this FSCA recall:

Product presentation	Lot #
ARCOTANE 5 ml	9432774
	9433347
	9433706
ARCOTANE 7 ml	9433348

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience this action may cause you. We expect that this action demonstrates SurgiPro commitment to safety and quality of care for its customers and patients.

[redacted]

The Management of SurgiPro

We hereby acknowledged receipt of your Field Safety Notice and have ceased further use of the affected lot of the mentioned devices.

Acknowledged By :

Date :

Endorsement Stamp :