

URGENT FIELD SAFETY NOTICE

Disposable devices and accessories for Hyperthermic Perfusion treatments for use with PERFOMER HT and PERFORMER LRT equipment

FSCA – Rand ref. FSCA-SM02-21

PRODUCT REMOVAL

Date: 14/04/2021

Description of the problem:

Our sterilization contractor informed us about a quality issue possibly affecting the sterilization process of a certain number of RAND products, thus leading us to open an immediate investigation.

Although during our investigation of the issue the risk of having non-sterile products on the market was considered quite low, as a precaution we have decided to remove the product batches listed below from the market.

Details on affected devices:

Ref. code	Device description	Affected LOT numbers
R9900033	HIPP (F) line set	F180216 F180272
R9900067	HANG&GO HT – Kit for hyperthermic perfusion	F180194 F180198 F180209 F180212 F180262 F180271 F180301 F180302 F180308 F180316 F180322 F180323 F180360 F180386 F190206

INNOVATION IN MEDICAL TECHNOLOGY

Ref. code	Device description	Affected LOT numbers
		F190233 F190260 F190317 F190547 F200017 F200018 F200019 F200020
R9900071	CH24 Round silicone catheter	F180180 F180191 F180193 F180221 F180243 F180249 F180313 F190150 F190116 F190234 F190240 F200014
R9900086	ILP HT – Lines set for organ or limb perfusion	F180127 F180238 F200004
R9900088	HANG&GO HT Basic – kit for hyperthermic perfusion	F180197 F180210 F180219 F180250 F180259 F180270 F180300 F180327 F180370 F190105 F190236 F190241 F190242 F190289
R9900089	HYPER Protect-OR	F180283 F190213 F200015

INNOVATION IN MEDICAL TECHNOLOGY

Ref. code	Device description	Affected LOT numbers
R9900093	HIPP (FO) accessories kit	F190561
R9900101	Flow Reverse – Accessory for hyperthermic perfusion	F180115 F180235 F190235
R9900110	HANG&GO HT FR – kit for hyperthermic perfusion	F200047 F200060
R9900119	HANG&GO basic HV – Lines set for hyperthermic perfusion	F180321 F190278 F190468
R9900127	HANG&GO HT BASIC FR - kit for hyperthermic perfusion	F180265 F180275 F180369 F180402 F190197 F190288 F190523
R9900129	ILP HT LF accessory	F180256 F200016

Clinical impact:

The exposure to non-sterile products may result in an increased risk of patient infection. However we have not received any adverse event report regarding patient infection events associated with this field safety notice, so far. No specific follow up activities are required if the products have already been used.

Advise on action to be taken by the user:

Please proceed as follows:

1. Please check if you still have in your stock non-expired products belonging to the lot numbers above.
2. **If yes, please stop using them and put these products in quarantine. Please be sure that they are properly and clearly identified as “on-hold” to prevent their unintentional use.**
3. Please fill in the form in the last page and return it to cristina.vaccari@rand-biotech.com as soon as possible, **but in any case no later than May 30, 2021**. The form must be completed and returned also if involved products are no longer present in your stock.

Follow-up:

If any non-conforming products are present in your stock you will receive instructions on what to do with them (return them to RAND or destroy them).

INNOVATION IN MEDICAL TECHNOLOGY

Transmission of this Field Safety Notice:

Please forward this notice to those in your organization who need to be aware or to any organization where the potentially affected devices have been transferred.

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

Contact reference persons:

If you have any questions or concerns regarding this notification, do not hesitate to contact us at the following addresses:

For quality/regulatory questions:

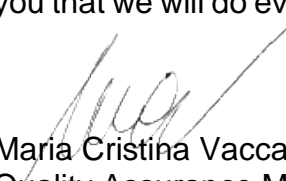
cristina.vaccari@rand-biotech.com – telephone +39 0535 49283

For commercial issues (product returns/replacement, etc):

cristiana.bellini@rand-biotech.com – telephone +39 0535 49283

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

We sincerely apologize for the inconvenience that this situation may cause and we assure you that we will do everything possible to mitigate its effects. Thank you for your cooperation.



Maria Cristina Vaccari
Quality Assurance Manager
RAND S.p.A.

URGENT FIELD SAFETY NOTICE – FEEDBACK FORM

Please, fill this form and return it to cristina.vaccari@rand-biotech.com.

- ☐ We have no stock of the listed lots
- ☐ We have stock of the listed lots and we have put them in quarantine. These are the pieces we have put in quarantine:

Ref. code	Device description	LOT number	Quantity

Hospital / City:

Name: Role:

Telephone: Email:

Date: