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INNOVATION IN MEDICAL TECHNOLOGY

URGENT FIELD SAFETY NOTICE

Disposable devices for Hyperthermie Perfusion treatments:

- **HIPP(F)**
- **All Hang&Go models**

FSCA-RanD ref. IROl/17
Additional advice on the use of the device

Date: 13 April 2017

Details on affected devices:

Ref. code	Device description	Affected LOT numbers
R9900088	Hang&Go HT Basic	F160257
		F170024
		F170053
R9900067	Hang&GoHT	F160258
		Fl70030
		F170039
		F170042
		F170067
R9900119	Hang&Go Basic HV	F170054
R9900120	Hang&GO kit	F170029
R9900033	HIPP(F)	F160243

Description of the problem:
RanD has become aware of an issue with regard to the above mentioned devices.
Specifically, one of the two lines of the table pack set included in each of the above mentioned codes has a female quick connector and a white protection cap inside the connector, as in picture below:

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It has come to our attention that sometimes this cap is a little loose and it might unintentionally fall off. Handling the table pack lines too close to the surgical wound (which is not an optimal practice) might result in the remote event of the cap falling into the body cavity. A potential risk is associated to this event, but the probability that this happens is very unlikely. However, if the product is c01Tectly handled, there is no potential risk to Patient's safety. So far, we received one report of caps disconnection but we never received reports concerning the caps falling into the patient laparotomy.

Advise on action to be taken by the user:
The product can be safely used by following the precautions below:

1. Unpack and unroll the table pack lines at an appropriate distance from the Patient cavity.
2. Remove the cap from the female connector and proceed as usual.

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation 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 conective action.

Contact reference person:
If you have any questions or concerns regarding this notification, please contact directly RanD or your local Service Representative. A contact list is attached hereto.

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

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RECEIPT INFORMATION

Please fill in this form and return it to:

RanD S.r.l.
Via Statale 12; 62
41036 Medolla (MO)
Italy
mailto: cristina.vaccari@rand-biotech.com
Fax: +39 0535 660636

as prove of good reception of the field safety notice (IROl/17).

Form completed and returned from:

Name of the institution/hospital: _____

Name of the contact person: _____

Function: _____

Signature: _____ Date: _____

TÜV SÜD ISO 13485:2003