

Type of Customer Information Bulletin: **ADVICE ONLY**

Dear Customer,

Rocket Medical understands that you have received the affected product referenced below. This Customer Information Bulletin is being published to make you aware of a potential issue that has recently been reported to us and to offer clinical advice in the event you experience this issue.

Background

In December 2020, Rocket Medical changed the material of the IPC catheter from a peroxide cured to a platinum cured material. This change provided an improved and more consistent mechanical catheter performance. The first supplied product containing the new material: R54400-16-PT Lot 492222.

Reported Issue

Post Market feedback, received in January 2022, has highlighted potential difficulty viewing the IPC catheter during post insertion x-ray in patients with high volumes of fluid.

Investigation

It has been confirmed that although the white x-ray stripe of the IPC Catheter does contain barium it is at a reduced level as compared to the original material.

Rocket Medical Action

We are currently investigating the possibility of increasing the level of barium contained in the x-ray stripe. When these actions are complete, an updated Customer Information Bulletin will be published on the Rocket Medical Website:

<https://sales.rocketmedical.com/regulatory-policies/customer-information-bulletins>

Following discussion with clinical experts and review of the recommended clinical paper (Lenaeus et al, 2018)¹, The following advice is offered:

- **If the IPC is working and draining, no X-ray is required.**
- **If you have performed a post insertion X-ray and cannot view the catheter, perform a drainage check as above.**
- **If X-ray is required, invert image to improve the contrast.**
- **The IPC can be seen under ultrasound and CT scan if required.**

For and behalf of Rocket Medical,



Richard Varey
Product Manager

If you have any questions, please forward an e-mail to pncf@rocketmedical.com

¹Lenaeus, Shepherd and White. Routine Chest Radiographs after Uncomplicated Thoracentesis. 2018, Journal of Hospital Medicine

**ROCKET MEDICAL IPC
AFFECTED CODES**

R51400-16-00 - From Lot 495192

R54400-16-MI - From Lot 492643

R54400-16-MT - From Lot 492222

R54400-MINI - From Lot 492335