NIPRO
Live Longer. Live Better.

Urgent Field Safety Notice

Magnet Gear Pump Replacement Action

NIPRO CORPORATION
- FSCA number: FSCA 2025/07/16
- Product: SurdialX Dialysis Machine
- Type of Action: Replacement of Magnet Gear Pump and Cut Filter

Dear Valued Customer,

As you know, NIPRO Corporation is committed to patient safety. This is demonstrated by our continuous monitoring of product performance and our readiness to take action when receiving complaints — all to ensure the highest standards of patient safety and customer satisfaction.

We always strive for product excellence and therefore would like to provide you with this important update regarding a potential safety concern for patients.

BACKGROUND & IDENTIFIED ISSUE
NIPRO Corporation became aware of an issue affecting Surdial X machines equipped with Type 2 or Type 3 Magnet Gear Pump P1 (Model Reference FG309XB0PX80814), following a number of complaints reporting dialysate flow errors and discoloration of the cut filter.

After thorough investigation, these cases were linked to the same root cause: progressive mechanical degradation of the pump motor. Over time, this may lead to the introduction of fine particles or residues into the dialysate, which are typically retained by the cut filter — resulting in visible discoloration.

While the machine's safety systems and cut filter(s) are effective, in-depth worst-case testing showed a potential patient safety risk. To date, there have been no reports of adverse health effects. However, we aim to prevent any potential long-term exposure risks to unintended constituents and therefore, in line with our commitment to patient safety, we are initiating a Field Safety Corrective Action.

Although further technical review shows that the potential risk is limited to Pump P1, due to its direct role in the dialysate circuit, we will replace both pumps P1 and P2 to exclude any further patient safety risk.

NEXT STEPS AND SUPPORT FROM NIPRO
Where possible it is advised to continue dialysis treatment on not impacted dialysis machines. In case these are not available, the affected Surdial X machines may continue to be used for dialysis treatment. As there is a potential increase in nickel released by the pump, we advise you not to

NIPRO CORPORATION
3-26 Senriokashinmachi, Settsu-shi, Osaka 566-8510, JAPAN
T: +81-6-6310-6770 • www.nipro.co.jp

NIPRO
Live Longer. Live Better.

treat patients with a known nickel allergy on these machines. Built-in safety systems remain active and will notify users of any issues related to dialysate flow. In addition, the cut filter will continue to serve its purpose by capturing particles and protecting the patient from potential contaminants such as endotoxins and bacteria.

To address the issue NIPRO Medical Europe will contact your facility to schedule the replacement of the affected Magnet Gear Pumps (Type 2 or Type 3), along with the cut filter. Replacements will be planned as soon as possible/at your earliest convenience and based on the age and operating hours of the installed pumps, starting with the oldest units.

If Preventive Maintenance is already scheduled for your machines, the Type 1 pump and cut filter shall be ordered and used for that activity. Likewise, if a service intervention is required due to pump-related issues, the updated pump version shall be ordered and installed at that time.

Please note that all Surdial X machines manufactured by NIPRO Medical Europe since 28 April 2025 already include the updated pump version and are not affected by this action.

IDENTIFYING IMPACTED DEVICES
The Surdial X machines impacted by this action can be identified by their serial numbers. The following serial number ranges correspond to devices delivered with the affected Type 2 or Type 3 Magnet Gear Pump P1:

- **Surdial X Type A**: 23DN1722 ~ 25DN2116
- **Surdial X Type B**: 23DR0969 ~ 25DR1436
- **Surdial X Type C**: 23DS11092 ~ 25DS15360
- **Surdial X Type D**: 23EJ3361 ~ 25EJ5025

In addition, Surdial X machines that underwent maintenance or repair from 2023 onwards and received replacement parts using the order codes listed below are also considered impacted.

SPARE PART	NIPRO ORDER CODE
MAGNET GEAR PUMP UPDATE KIT	0-704-349
MAGNET GEAR PUMP ASSEMBLY	0-704-343
MAGNET GEAR PUMP	0-704-341
PUMP BODY SET	0-704-335

FOR YOUR ATTENTION AND AWARENESS
We kindly ask that this notice be shared with both the technical manager and the nurse manager of your facility. Their awareness is essential to monitor for dialysate flow error messages and cut filter discoloration, which may indicate pump-related degradation.

Live Longer. Live Better.

The additional maintenance actions need to be planned as part of your operational scheduling. NIPRO Medical Europe will contact you to initiate and coordinate the intervention.

YOUR RESPONSE HELPS US CARE BETTER

To support the effective implementation of this Field Safety Corrective Action, we kindly ask you to complete and return the attached FSN Response Letter to NIPRO Medical Europe at quality@nipro-europe.com within 10 working days, and no later than 10 August 2025.

If you have any questions regarding this action, please contact our team using the email address above. We understand that this corrective action may require additional coordination at your site, and we appreciate your support in ensuring it is implemented as smoothly as possible.

We thank you for your collaboration and continued trust in our ongoing efforts to uphold the highest standards of patient safety.

Sincerely,

Toyoshi Yoshida
Director QA and Regulatory Compliance Headquarters
NIPRO CORPORATION

NIPRO CORPORATION
3-26 Senriokashinmachi, Settsu-shi, Osaka 566-8510, JAPAN
T: +81-6-6310-6770 • www.nipro.co.jp

NIPRO
Live Longer. Live Better.

Urgent Field Safety Notice

Magnet Gear Pump Replacement Action

NIPRO CORPORATION
- FSCA number: FSCA 2025/07/16
- Product: Surdial 55Plus Dialysis Machine
- Type of Action: Replacement of Magnet Gear Pump and Cut Filter

Dear Valued Customer,

As you know, NIPRO Corporation is committed to patient safety. This is demonstrated by our continuous monitoring of product performance and our readiness to take action when receiving complaints — all to ensure the highest standards of patient safety and customer satisfaction.

We always strive for product excellence and therefore would like to provide you with this important update regarding a potential safety concern for patients.

BACKGROUND & IDENTIFIED ISSUE
NIPRO Corporation became aware of an issue affecting Surdial 55Plus machines equipped with Type 2 or Type 3 Magnet Gear Pump P1 (Model Reference FG309XB0PX80814), following a number of complaints reporting dialysate flow errors and discoloration of the cut filter.

After thorough investigation, these cases were linked to the same root cause: progressive mechanical degradation of the pump motor. Over time, this may lead to the introduction of fine particles or residues into the dialysate, which are typically retained by the cut filter — resulting in visible discoloration.

While the machine's safety systems and cut filter(s) are effective, in-depth worst-case testing showed a potential patient safety risk. To date, there have been no reports of adverse health effects. However, we aim to prevent any potential long-term exposure risks to unintended constituents and therefore, in line with our commitment to patient safety, we are initiating a Field Safety Corrective Action.

Although further technical review shows that the potential risk is limited to Pump P1, due to its direct role in the dialysate circuit, we will replace both pumps P1 and P2 to exclude any further patient safety risk.

NEXT STEPS AND SUPPORT FROM NIPRO
Where possible it is advised to continue dialysis treatment on not impacted dialysis machines. In case these are not available, the affected Surdial 55Plus machines may continue to be used for dialysis treatment. As there is a potential increase in nickel released by the pump, we advise you

NIPRO CORPORATION
3-26 Senriokashinmachi, Settsu-shi, Osaka 566-8510, JAPAN
T: +81-6-6310-6770 • www.nipro.co.jp

not to treat patients with a known nickel allergy on these machines. Built-in safety systems remain active and will notify users of any issues related to dialysate flow. In addition, the cut filter will continue to serve its purpose by capturing particles and protecting the patient from potential contaminants such as endotoxins and bacteria.

To address the issue NIPRO Medical Europe will contact your facility to schedule the replacement of the affected Magnet Gear Pumps (Type 2 or Type 3), along with the cut filter. Replacements will be planned as soon as possible/at your earliest convenience and based on the age and operating hours of the installed pumps, starting with the oldest units.

If Preventive Maintenance is already scheduled for your machines, the Type 1 pump and cut filter shall be ordered and used for that activity. Likewise, if a service intervention is required due to pump-related issues, the updated pump version shall be ordered and installed at that time.

Please note that all Surdial 55Plus machines manufactured by NIPRO since 28 April 2025 already include the updated pump version and are not affected by this action.

IDENTIFYING IMPACTED DEVICES

The Surdial 55Plus machines impacted by this action can be identified by their serial numbers:

- **Surdial 55Plus Type 2**: 23CX30481 ~ 25CX38704

In addition, Surdial 55Plus machines that underwent maintenance or repair from 2023 onwards and received replacement parts using the order codes listed below are also

SPARE PART	NIPRO ORDER CODE
MAGNET GEAR PUMP UPDATE KIT	0-504-248
MAGNET GEAR PUMP ASSEMBLY	0-704-343
MAGNET GEAR PUMP	0-704-341
PUMP BODY SET	0-704-335

FOR YOUR ATTENTION AND AWARENESS

We kindly ask that this notice be shared with both the technical manager and the nurse manager of your facility. Their awareness is essential to monitor for dialysate flow error messages and cut filter discoloration, which may indicate pump-related degradation.

The additional maintenance actions need to be planned as part of your operational scheduling. NIPRO Medical Europe will contact you to initiate and coordinate the intervention.

YOUR RESPONSE HELPS US CARE BETTER

To support the effective implementation of this Field Safety Corrective Action, we kindly ask you to complete and return the attached FSN Response Letter to NIPRO Medical Europe at quality@nipro-europe.com within 10 working days, and no later than 18 August 2025.

If you have any questions regarding this action, please contact our team using the email address above. We understand that this corrective action may require additional coordination at your site, and we appreciate your support in ensuring it is implemented as smoothly as possible.

NIPRO CORPORATION
3-26 Senriokashinmachi, Settsu-shi, Osaka 566-8510, JAPAN
T: +81-6-6310-6770 • www.nipro.co.jp

NIPRO
Live Longer. Live Better.

We thank you for your collaboration and continued trust in our ongoing efforts to uphold the highest standards of patient safety.

Sincerely,

Toyoshi Yoshida
Director QA and Regulatory Compliance Headquarters
NIPRO CORPORATION