

## Notice of Voluntary Recall for the HF-II Instrument

April 17<sup>th</sup>, 2025

TO:            Sysmex Asia Pacific Pte Ltd.  
                   Sysmex (Malaysia) Sdn Bhd.  
                   Medicaroid Asia Pacific Pte. Ltd.

From:         Medicaroid Corporation  
                   Legal Manufacturer

Dear Authorized representative, Device Distributors,

This is to inform you of a voluntary product recall involving the “HF-II Series Instrument” products used in conjunction with the hinotori™ Surgical Robot System, as identified below. This voluntary recall has been initiated due to the finding that there is a risk of some parts detaching and falling off.

We apologize for the great inconvenience and concern this may cause you. We would greatly appreciate your kind understanding and cooperation.

■ **Product Name and Affected Serial No.**

Product Name	Product code	Affected Serial No.
HF-II Series Bipolar Instrument - Bipolar Fenestrated Forceps	BQ119474	As per the attached sheet
HF-II Series Bipolar Instrument - Bipolar Maryland Forceps	AU959241	
HF-II Series Instrument - Needle Holder	BB112269	
HF-II Series Instrument - Wide Needle Holder	CQ896890	

■ **Reason for the Voluntary Recall**

As a result of a careful investigation into the device failure where pulleys, the parts that drive the instrument’s wire, detached and fell off, it was found that the diameter of the flange around the pin that supports the pulleys was smaller than the specified diameter. The flange acts as a stopper at the tip of the pin, preventing pulleys from slipping off the pin. The flange diameter is one of the in-process quality inspection items during manufacturing. Pass/fail was determined based on the flange diameter measured by automatically detecting the circumference of the flange top using image processing. However, the circumference was not precisely detected, and we found cases where the measured flange diameter was larger than the actual diameter. After the review of the measurement method and reevaluation of measurements based on image files, we have decided to initiate a voluntarily recall of products with specific serial numbers.

The affected products to be recalled include those other than the “HF-II Series - Bipolar Instrument” forceps. This is because we have decided to also recall products for which conformity could not be substantiated with sufficient evidence during reevaluation due to issues with image files.

■ Specific Health Risks of Concern

The raw material of these parts is stainless steel that meets an official standard with a track record of use in orthopedic surgical implants, such as intramedullary nails for internal fixation. Based on this fact as well as the size and shape of the parts, we do not believe that these parts lead to any serious health risk even if the parts (pulleys) fall off and remain inside a patient's body, as the risk of them causing injury to other organs is low. There has been no report of an adverse health impact from the parts remaining inside the bodies.

■ Compensation for the Recalled Products

We will proceed with the recall of the affected products above and provide a full refund. However, those instruments that have already reached the maximum usage counts will be excluded from a refund. We would appreciate your understanding.

■ Request

We respectfully request that you refrain from using any of the products with the serial numbers listed on the attached sheet.

\*\*\* End \*\*\*

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**Contact Information**

RA CA Dept. GVP Section

Medicaroid Corporation

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## 【Attachment】 Affected Serial Numbers

- HF-II Series Bipolar Instrument - Bipolar Fenestrated Forceps

Product code: BQ119474

No. of affected instruments: 14

Serial Numbers:

100249011, 100250011, 100251011, 100252011, 100253011, 100254011, 100393011, 100394011, 100395011, 100396011, 100397011, 100398011, 100451011, 100452011

- HF-II Series Bipolar Instrument - Bipolar Maryland Forceps

Product code: AU959241

No. of affected instruments: 17

Serial Numbers:

100168011, 100169011, 100170011, 100171011, 100172011, 100173011, 100273011, 100274011, 100275011, 100276011, 100277011, 100278011, 100371011, 100372011, 100373011, 100374011, 100375011

- HF-II Series Instrument - Needle Holder

Product code: BB112269

No. of affected instruments: 8

Serial Numbers:

100034011, 100035011, 100036011, 100038011, 100039011, 100040011, 100041011, 100042011

- HF-II Series Instrument - Wide Needle Holder

Product code: CQ896890

No. of affected instruments: 2

Serial Numbers:

100001011, 100002011

\*\*\* End \*\*\*