Summary of Technical Documents

Summary of:	TDF_IVD_05_Rev.10
Summarized on:	September 20, 2024

Category	Pathological instruments
Product group	Blade Handles
Product name	FEATHER TRIMMING KNIFE HANDLE FEATHER SAFETY TRIMMING KNIFE HANDLE
GMDN codes	Histology/pathology tissue knife handle IVD, 65558
Contents of technical documentation	
Product Description	- General description of the devices - Intended purpose of use - Operation - Manufacturing process - Classification
Technical requirements	- Identification of technical requirement - Annex I checklist - Common specifications
Design	- Risk analysis - Labeling / IFU - Product life - Drawings
Change records	
Declaration of conformity	F_Dec._IVD_07, F_Dec._IVD_11

Approved by; Executive Director, PRRC SATOSHI MITSUISHI Signature	Author; Quality Control Dept. DAISUKE SUEMATSU Signature

Product Description	
General description of the devices	< FEATHER TRIMMING KNIFE HANDLE > F-130WP/F-260WP  F-80WP 

Components	Raw materials
BLADE HOLDER	Stainless Steel
HANDLE	Polysulfone resin
Sales unit package	Paper box

F-80mini



F-80HL

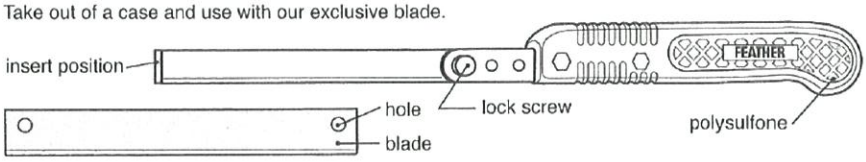


Components	Raw materials
HANDLE	POM resin
Sales unit package	Paper box

FEATHER SAFETY TRIMMING KNIFE HANDLE F-1326WP



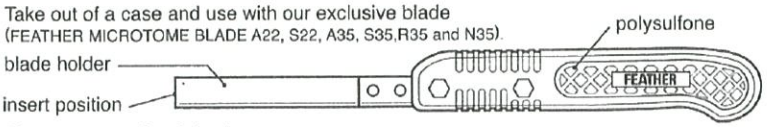
Components	Raw materials
BLADE HOLDER	Stainless Steel
HANDLE	Polysulfone resin
Sales unit package	Paper box

Intended purpose of use	**The devices are intended to be attached to the dedicated autopsy blade and to dissect tissues or test specimen.**
Operation	**F-130WP, F-260WP** **Instructions for use** Take out of a case and use with our exclusive blade.  **How to set the blade** ❶ Slacken a lock screw and insert the blade from the insert position with care. ❷ After confirming the hole of the blade connect to lock screw, tighten lock screw. ※Always check the lock screw is connecting to the hole of the replacement blade before use. ※Do in reverse order when detaching the blade **Caution** ●Make sure the blade is fixed on the handle before use. ●Use only as a trimming instrument. ●Do not use when there is something wrong with the product. ●For prevention of contamination, dispose properly after use. **Resterilization Instruction** **General Information** The handles are supplied non-sterile. The instructions provided assists in obtaining the highest quality performance. **Each handle can be autoclaved and reused on responsibility of the user. The number of cases per instrument depends on how the handles are used.** Effective cleaning/disinfection is the indispensable prerequisite for effective resterilization of the products. Please ensure that only adequately validated device and product-specific processes are used for cleaning/ disinfection and sterilization and that the validated parameters are adhered to in each cycle. In addition, **please observe the statutory regulations in your country as well as the rules of hygiene of the hospital or clinic.** **Cleaning and disinfection** **Caution : Remove the blade form handle before cleaning. Do not clean the handle with blade. When cleaning, do not use any organic solvents such as xylene or thinners.** **Manual cleaning** ❶ Clean the handle with distilled or sterile water immediately after use. ❷ Remove all dirt and pollution including protein by using cleaning solution in accordance with each institution's instruction. ❸ Rinse cleaning solution well by using distilled or sterile water. ❹ Dry thoroughly. **Mechanically cleaning** ❶ If available, mechanically clean/disinfect the handle using alkaline solution (pH>10,minimum55°C or 131°F) or alternatively clean the handle in an ultrasonic bath. ❷ Dry thoroughly. **Resterilization** ※Resterilize the handle using autoclave (Temperature: at 134°C or 273°F, Minimum exposure time: 5 minutes for products mechanically clean with alkaline solution or 18 minutes if notcleaned with alkaline solution) ※The manufacturer will accept no responsibility should other sterilization processes (e.g.,hot-air, ethylene oxide, formaldehyde,radiation or low-temperature plasma sterilization) be used. ***Attention*** ***Prior to reuse, visually inspect the handle. Do not use if product is damaged.*** GB FEATHER SAFETY RAZOR CO., LTD. 3-70, OHYODO-MINAMI 3-CHOME, KITA-KU, OSAKA 531-0075, JAPAN *http://www.feather.co.jp/* MADE IN JAPAN

Operation	F-80WP

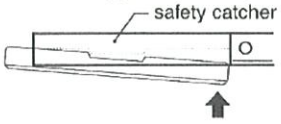
Instructions for use

Take out of a case and use with our exclusive blade
(FEATHER MICROTOME BLADE A22, S22, A35, S35,R35 and N35).



How to set the blade

❶ Insert the blade from the insert position with care.
❷ Make sure the blade is set horizontally because there is a safety catcher in the blade holder.
※Always check the blade is fixed correctly before use.



How to detach the blade

❶ Sligtly push down the end of the blade and check the blade separate from the safety catcher,and then detach the blade slowly.



Caution ●Make sure the blade is fixed on the handle before use. ●Use only as a trimming instrument. ●Do not use when there is something wrong with the product. ●For prevention of contamination, dispose properly after use.

Resterilization Instruction

General Information

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Cleaning and disinfection

Caution : Remove the blade form handle before cleaning. Do not clean the handle with blade. When cleaning, do not use any organic solvents such as xylene or thinners.

Manual cleaning

❶ Clean the handle with distilled or sterile water immediately after use. ❷ Remove all dirt and pollution including protein by using cleaning solution in accordance with each institution's instruction. ❸ Rinse cleaning solution well by using distilled or sterile water. ❹ Dry thoroughly.

Mechanically cleaning

❶ If available, mechanically clean/disinfect the handle using alkaline solution (pH>10,minimum55°C or 131°F) or alternatively clean the handle in an ultrasonic bath. ❷ Dry thoroughly.

Resterilization

※Resterilize the handle using autoclave (Temperature: at 134°C or 273°F, Minimum exposure time: 5 minutes for products mechanically clean with alkaline solution or 18 minutes if notcleaned with alkaline solution)
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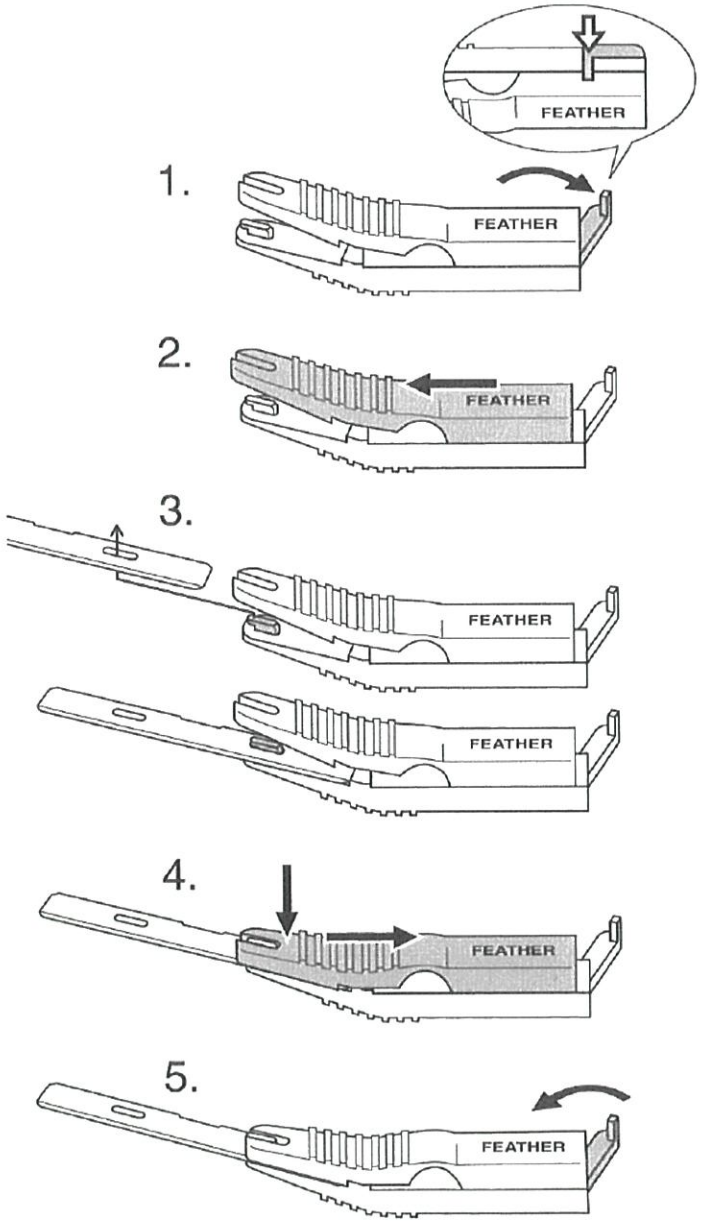
Attention ***Prior to reuse, visually inspect the handle. Do not use if product is damaged.*** GB

FEATHER SAFETY RAZOR CO.,LTD.
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MADE IN JAPAN

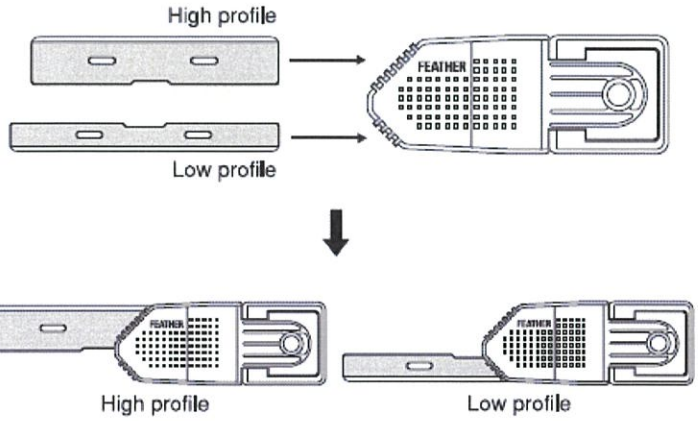
Operation	F-80mini

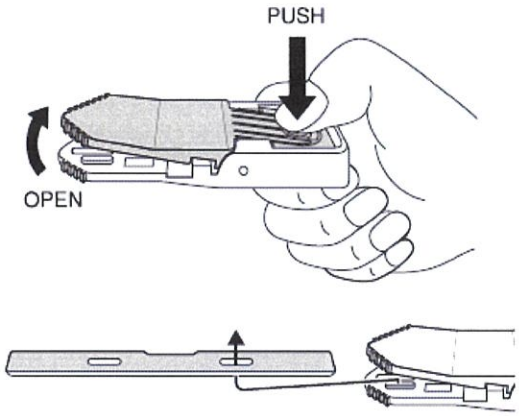
- ご使用方法
- Handling instruction
- Gebrauchsanweisung
- Mode d'emploi
- Manual de instrucciones
- Istruzioni per l'uso
- Instruções de utilização
- Gebruiksaanwijzing

- ご使用の際は刃先にご注意ください。
- Use care when handling blades.
- Vorsicht beim Umgang mit den Klingen.
- Utiliser les lames avec précaution.
- Usar las cuchillas con cuidado.
- Maneggiare le lame con cura.
- Ter todo o cuidado ao manusear lâminas.
- Voorzichtig bij het gebruik van de messen.

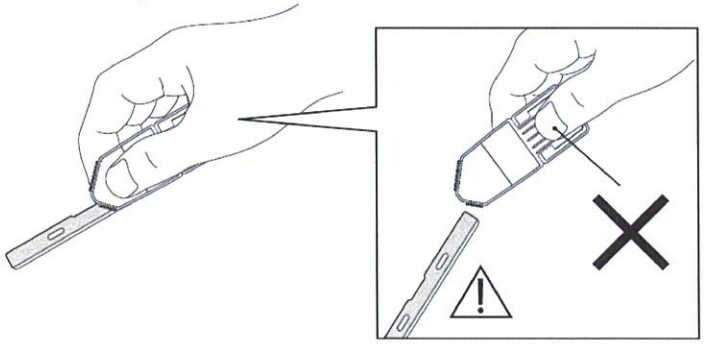


Operation	F-80HL





Caution ●Make sure the blade is fixed on the handle before use. ●Use only as a trimming instrument. ●Do not use when there is something wrong with the product. ●For prevention of contamination, dispose properly after use. ●Do not autoclave. ●Use care when handling blades.



Cleaning and disinfection

Caution : Remove the blade from the handle before cleaning. Do not clean the handle with blade. When cleaning, do not use any organic solvents such as xylene or thinners.

Manual cleaning

1. Clean the handle with distilled or sterile water immediately after use. 2. Remove all dirt and pollution including protein by using cleaning solution in accordance with each institution's instruction. 3. Rinse cleaning solution well by using distilled or sterile water. 4. Dry thoroughly.

Attention ***Prior to reuse, visually inspect the handle. Do not use if product is damaged.*** GB

Operation	F-1326WP

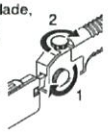
Instructions for use

Fitting the safety trimming blade

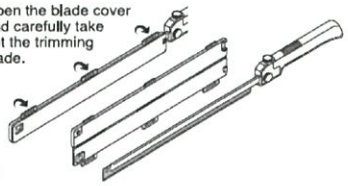
Ⓐ Make sure the top and side screws are loose. With its blade cover on, insert the trimming blade into the handle slot as far as it will go.



Ⓑ To secure the trimming blade, tighten the side screw first, and then the top screw.



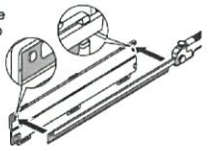
Ⓒ Open the blade cover and carefully take out the trimming blade.



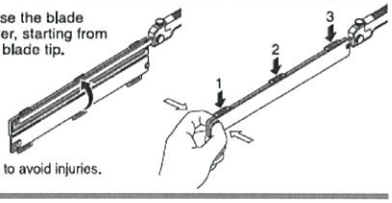
※To change the trimming blade again, carry out these steps in reverse order.

Securing the blade cover

Ⓓ Place the trimming blade in the blade cover. To do this, insert the opening on the tip of the trimming blade into the corresponding groove in the blade cover.



Ⓔ Close the blade cover, starting from the blade tip.



※After use, put the blade cover on the trimming blade and store it safely in order to avoid injuries.

Opening and cleaning the safety trimming handle

Caution: before taking the handle apart, carefully remove the blade.

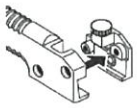
Ⓕ Tighten the top screw.



Ⓖ Unscrew and remove the two side screws.



Ⓗ It is now possible to remove the metal side cover.



※To assemble, carry out these steps in reverse order. ※Take care not to lose any of the screws.

Caution •Make sure the blade is fixed on the handle before use. •Use only as a trimming instrument. •Do not use when there is something wrong with the product. •For prevention of contamination, dispose properly after use.

Resterilization Instruction

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Caution: Remove the blade form handle before cleaning. Do not clean the handle with blade. When cleaning, do not use any organic solvents such as xylene or thinners.

Manual Cleaning

❶ Clean the handle with distilled or sterile water immediately after use. ❷ Remove all dirt and pollution including protein by using cleaning solution in accordance with each institution's instruction. ❸ Rinse cleaning solution well by using distilled or sterile water. ❹ Dry thoroughly.

Mechanically cleaning

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Resterilization

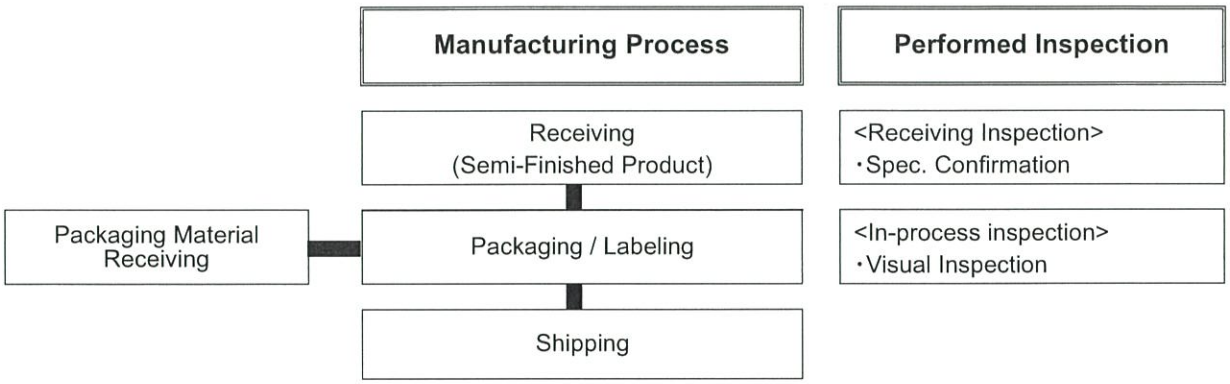
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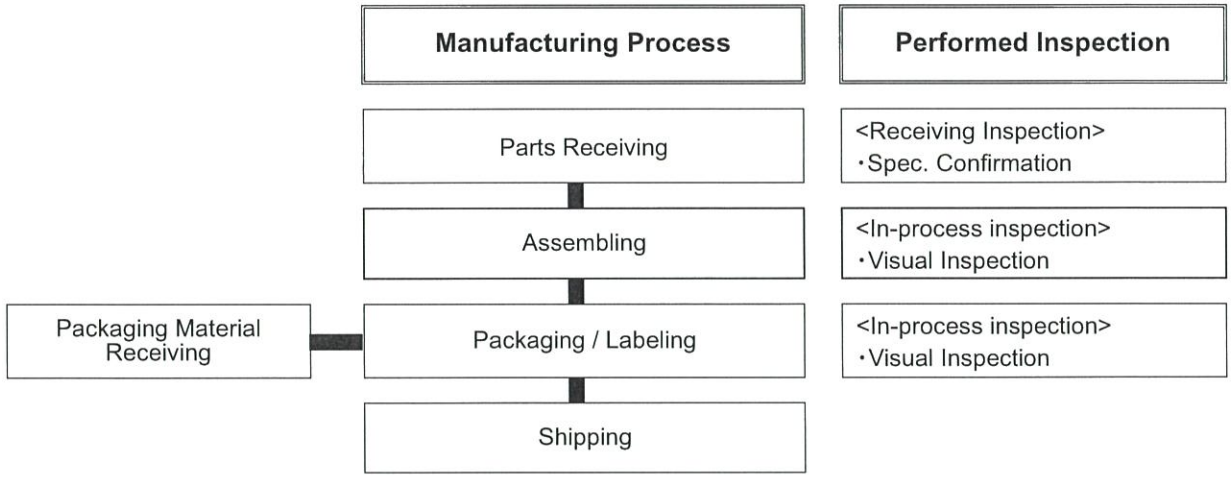
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Manufacturing process

130WP / 260WP / 80WP



F80mini / F-80HL / F1326WP



Classification	**Class A** **Rule 5 of Annex VIII.**

Technical requirements	
Identification of technical requirement	**Regulation (EU) 2017/746** **Annex I General Safety and Performance Requirements (GSPR)**
Annex I checklist	**FEATHER TRIMMING KNIFE HANDLE** **FEATHER SAFETY TRIMMING KNIFE HANDLE** *See attachment*
Common specifications	**N/A**

Design		
Risk analysis	Risk management report FEATHER TRIMMING KNIFE HANDLE FEATHER SAFETY TRIMMING KNIFE HANDLE *See attachment*	
Labelling / IFU	- Sales unit package *See attachment*	
Product life	NA	
Drawings:		Adaptive Blades
F-80mini	Drawing No.8920000	FEATHER MICROTOME BLADE S35, R35, A22, A35, N35, N35H, S22
F-80WP	Drawing No.8910011	
F-130WP	Drawing No.8930011	FEATHER TRIMMING BLADE No.130, No.130R, No.260
F-260WP	Drawing No.8900011	
F-1326WP	Drawing No.8931011	FEATHER SAFETY TRIMMING KNIFE BLADE No.M130RC, No.M260RC
F-80HL	Drawing No.8921001	FEATHER MICROTOME BLADE S35, R35, A22, A35, N35, N35H, S22, High-profile

Legal Manufacturer **FEATHER SAFETY RAZOR CO., LTD.** **Sales** **FEATHER SAFETY RAZOR CO., LTD.** **OVERSEAS TRADE DIVISION**	**Address** **3-70, Ohyodo-Minami 3-chome, Kita-ku, Osaka, 531-0075 JAPAN**
Manufacturing facility **FEATHER SAFETY RAZOR CO., LTD.** **MINO SITE**	**Address** **600-1, Matsumori, Mino-City, Gifu, 501-3753 JAPAN**
Design facility **FEATHER SAFETY RAZOR CO., LTD.** **RESEARCH & DEVELOPMENT CENTER**	**Address** **1-17, Hinode-machi, Seki-City, Gifu, 501-3873 JAPAN**
EC-representatives **pfm medical gmbh**	**Address** **Wankelstraße 60, 50996 Cologne, Germany**

Change records

Date	Contents/details	Documentations	Contact to Notified body
9th edition January 24, 2024	Update on Authorized representative name.		
10th edition September 20, 2024	Replacement of product types. Minor correction on manufacturer's address.		