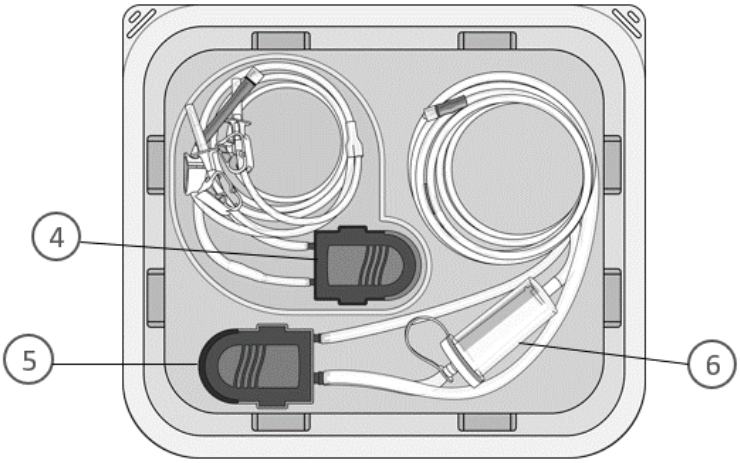
HOLOGIC®

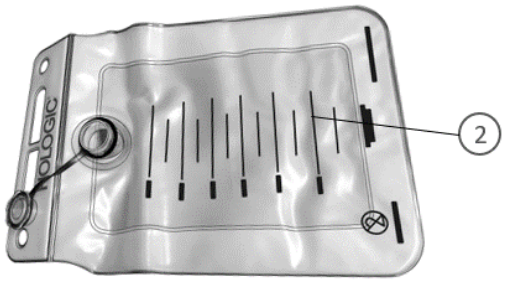
Fluent® Pro

Fluid Management System

Procedure Kit Operator's Manual

Refer to the Fluent Pro System IFU for instructions for use of the entire system.





DEVICE DESCRIPTION

The Fluent Pro Procedure Kit consists of a sterile Fluent Pro In-FloPak™, a sterile Fluent Pro Out-FloPak™ with inline tissue trap, and non-sterile, single use Waste Bag. This single-use procedure kit is intended to be used with the Fluent Pro Fluid Management System.

Fluent Pro Procedure Kit Components		
1	Procedure Kit Tray	Thermoform tray containing the Sterile In-FloPak and Out-FloPak components.
2	Waste Bag	The non-sterile Waste Bag is designed to capture waste fluid from hysteroscopic procedures. The Waste Bag hangs on the Waste Bag Hooks at the bottom of the Fluent Pro fluid management system. Hang only a single Waste Bag on the Waste Bag Hooks at a time. Hanging more than one bag may impact fluid deficit accuracy. The Waste Bag includes an attached cap. If an accurate manual deficit assessment is required, pour fluid into calibrated container. The markings on the Waste Bag are not intended as a volumetric measuring device and are only for general reference.
3	Procedure Kit Carton	Carton containing the Procedure Kit Tray and Waste Bag.

Fluent Pro Procedure Kit Components		
4	In-FloPak	The In-FloPak pulls clean fluid from the Fluid Bag. It contains the Fluid Bag Tube and the hysteroscope Inflow Tube. It fits securely into the blue Fluent Pro In-FloPak receptacle on the front left side of the fluid management system. These connections allow the transfer of distension fluid from a Fluid Bag to the hysteroscope inflow channel. The flow of fluid is monitored and controlled using the Touchscreen to maintain the pressure at a specified setting.
5	Out-FloPak	The Out-FloPak drains waste fluid from the hysteroscope Outflow Channel, the MyoSure® Tissue Removal Device (TRD) tube, and the Under-Buttocks Drape (UBD) Tube into the Waste Bag. It fits securely into the yellow Fluent Pro Out-FloPak receptacle on the front right side of the fluid management system. These connections allow the transfer of fluid from the hysteroscope Outflow Channel, the MyoSure Tissue Removal Device (TRD), and the Under-Buttocks Drape (UBD) Port to the Waste Bag.
6	Tissue Trap	The Tissue Trap is designed to capture resected tissue throughout the procedure to allow the tissue to be sent to pathology. The Tissue Trap Canister contains the Tissue Trap that captures the resected tissue. Please monitor the Tissue Trap so it does not overfill.

INDICATIONS FOR USE

The Fluent Pro fluid management system is intended to provide liquid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation liquid flowing into and out of the uterus while providing drive, control, and suction for hysteroscopic morcellators.

The Fluent Pro Procedure Kit should only be used with the Fluent Pro fluid management system.

INTENDED USERS

The gynecologist should be trained in diagnostic and therapeutic hysteroscopy, resection, and removal of gynecological tissue.

INTENDED USE ENVIRONMENT

The Fluent Pro fluid management system is designed to be used in operating rooms, ambulatory surgical centers, and physician's office environments.

PATIENT TARGET GROUP

The intended patient population for the Fluent Pro fluid management system is dependent on the Indications for Use and Contraindications; it is not limited by age, weight, or other health conditions unrelated to hysteroscopic contraindications.

CONTRAINDICATIONS

The system may not be used to introduce fluids into the uterus when hysteroscopy is contraindicated. See the operator's manual of your hysteroscope for absolute and relative contraindications.

The Fluent Pro fluid management system should not be used to remove pathologies from pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

⚠WARNING!

Fluent Pro Procedure Kits are single use disposables. Do not re-use or reprocess any of the components contained within the single-use Fluent Pro Procedure Kit.

⚠WARNING!

For your own safety and that of your patient, use only Fluent Pro accessories.

See the Fluent Pro System IFU for additional warnings and precautions.

PROCEDURE STEPS

Refer to the Fluent Pro IFU for full instructions regarding installation, use, and replacement of the Fluent Pro Procedure Kit.

HANG FLUID BAG

1. Hang a Fluid Bag containing distension media appropriate for the procedure on the Fluid Bag Hook. Hang only a single Fluid Bag on the Fluid Bag Hooks at a time. The Fluid Bag size should not exceed 3L for each hook.

   ⚠WARNING!
   The Fluid Bag size should not exceed 3L per hook. Doing so may impact fluid deficit accuracy.

2. The Fluent Pro fluid management system does not need to be powered on to hang the Fluid Bags. If the system is on, then follow the prompts. The system will detect and display a '⊘DETECTED' icon on the Setup screen when the Fluid Bag has been properly installed.

UNPACK THE FLUENT PRO PROCEDURE KIT

3. Open the Fluent Pro Procedure Kit carton.

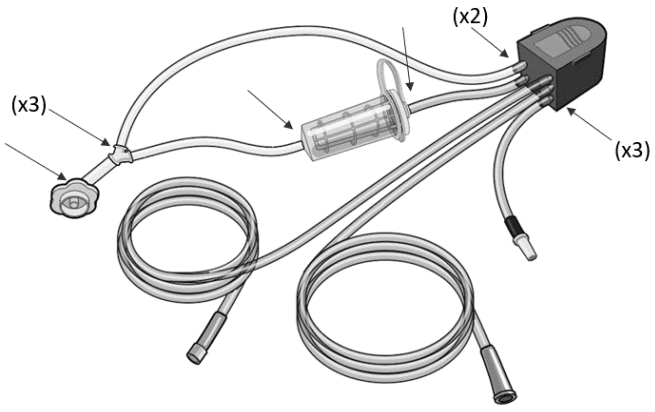
4. Set the non-sterile Waste Bag aside.

5. Peel back the sterile cover of the Fluent Pro Procedure Kit.

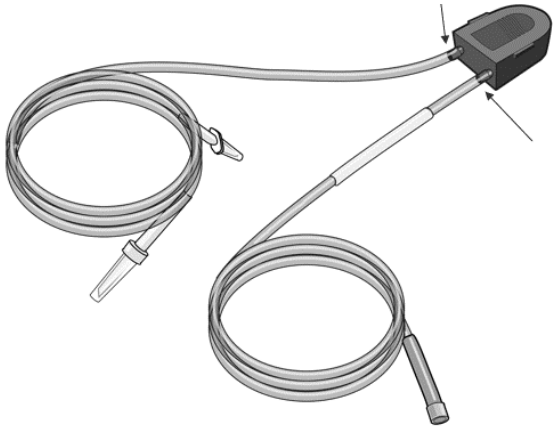
6. While maintaining sterile technique, place the In-FloPak and Out-FloPak onto a sterile surface.

7. Prior to use, ensure that all FloPak tubing connections are intact.

Out-FloPak connections



In-FloPak connections



HANG WASTE BAG

8. Hang the new Waste Bag evenly on the Waste Bag Hooks to begin any new procedure. The system will detect and display a '⊘DETECTED' icon on the Setup screen when the Waste Bag has been properly installed.

   ⚠WARNING!

   Hang only a single Waste Bag on the Waste Bag Hooks at a time. Hanging more than one bag may impact fluid deficit accuracy.

INSTALL IN-FLOPAK

9. Depress the In-FloPak Lever and slide the In-FloPak over the triangular shaft. While releasing the Lever, ensure the In-FloPak is flush with front of the console. The system will detect and display a '⊘DETECTED' icon on the Setup screen when the In-FloPak has been properly installed.

10. Clamp the tubing and spike the Fluid Bag.

11. Connect the blue inflow luer connector to the hysteroscope inflow channel.

INSTALL OUT-FLOPAK

12. Depress the Out-FloPak Lever and slide the Out-FloPak over the triangular shaft. While releasing the Lever, ensure the Out-FloPak is will detect and display a '⊘DETECTED' icon on properly installed.

13. Connect the yellow outflow luer connector to the hysteroscope Outflow Channel.

14. Connect the yellow suction connector onto the Under-Buttocks Drape (UBD) Port.

15. Secure the Out-FloPak Waste Bag Connector onto the Waste Bag by rotating clockwise.

16. Connect the light cord and the camera to the hysteroscope.

17. Confirm all tubing is properly connected, inflow channel is open, and outflow channel is closed. To continue touch 'NEXT'.

18. The displayed steps will not be automatically detected and will need to be manually confirmed by touching the blue 'CONFIRM' icon in any order. Actions can be confirmed simultaneously by selecting the 'CONFIRM ALL' icon. To continue touch 'NEXT'.

REPLACING THE WASTE BAG

19. Replace the Waste Bag when the Waste Bag is almost full or when the system alerts you. The system will pause when approximately 6000mL of fluid is in the Waste Bag.

20. If the system is running, touch the 'PAUSE' icon to pause the system.

21. Remove the Waste Bag Connector from the Waste Bag by rotating the Connector counterclockwise.

22. Screw the Waste Bag cap onto the Waste Bag by rotating the cap clockwise.

23. Remove the full Waste Bag from the Waste Bag Hooks and discard the Waste Bag according to facility protocols.

24. Hang a new Waste Bag onto the Waste Bag Hooks.

25. Attach the Out-FloPak Waste Bag Connector onto the Waste Bag by rotating the connector clockwise.

26. If 'Missing Waste Bag' error is displayed, ensure the Waste Bag is installed properly on the Hooks, touch the 'CLEAR' icon and continue with the procedure.

REPLACING THE TISSUE TRAP

27. If the tissue trap appears to be full, by expanding outside of the internal basket, the tissue trap is near capacity and must be changed.

28. Touch the 'PAUSE' icon to pause the system.

29. Open the lid of the Tissue Trap Canister.

30. Remove the Tissue Trap from the Canister (leaving the basket behind) and place into a specimen container.

31. Place a new Tissue Trap into the Tissue Trap Canister.

32. Close the Tissue Trap Lid securely.

Refer to the Fluent Pro System IFU for additional instructions on operating the system, including how to disconnect the FloPaks at the end of a procedure.

FLUENT PRO PROCEDURE KIT AND ACCESSORIES

Item	Order Number
Package of Six (6) Fluent Pro Procedure Kits (In-FloPak, Out-FloPak, Tissue Trap and Waste Bag)	FLT-212
Fluent Pro Disposable Pack - Single	FLT-212S
Fluent Pro Waste Bag - Five Pack	FLT-205
Fluent Pro Tissue Trap - Ten Pack	FLT-210

STORAGE

The Fluent Pro Procedure Kit should be stored at room temperature away from moisture and direct heat. Do not use after expiration date.

DISPOSAL

The used disposable device must be treated as biohazardous waste and disposed of according to standard practices of the hospital or clinical where the procedure took place.

STERILITY

The FloPaks and Tissue Traps included in the Fluent Pro Procedure Kit are ETO sterilized. Do not use if the package is damaged. **DO NOT RE-STERILIZE. DO NOT REUSE**. The Waste Bag is non-sterile.

TECHNICAL SUPPORT & PRODUCT RETURN INFORMATION

Contact Hologic Technical Support for proper disposal of any part if the Fluent Pro Procedure Kit fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and biohazard kit if applicable. Return Fluent Pro Procedure Kit according to the instructions provided by Technical Support.

CONTACTING HOLOGIC TECHNICAL SUPPORT

For Technical Support or reorder information in the United States, please contact:

HOLOGIC, INC.

250 Campus Drive,

Marlborough, MA

01752 USA

1.800.442.9892 (US Toll Free)

www.hologic.com

WARRANTY

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ('Warranty Period'); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13- 24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products.

These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or 'as-is' basis.

SYMBOLS GLOSSARY

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	EN ISO 15223-1, 5.1.5 ISO 7000, 2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	EN ISO 15223-1, 5.1.6 ISO 7000, 2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	EN ISO 15223-1, 5.4.4 ISO 7000, 0434A IEC 60601-1, Table D.1, 10	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	EN ISO 15223-1, 5.4.3 ISO 7000, 1641 IEC 60601-1, Table D.1, 11	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	EN ISO 15223-1, 5.1.7 ISO 7000, 3082	Manufacturer	Indicates the medical device manufacturer
	ISO/DIS 15223-1, 5.7.11. ISO 7000, 6049	Country of Manufacture	To identify the country of manufacture of products
	EN ISO 15223-1, 5.1.3 ISO 7000, 2497	Date of manufacture	Indicates the date when the medical device was manufactured.
	EN ISO 15223-1, 5.1.4 ISO 7000-2607	Use-by date	Indicates the date after which the medical device is not to be used.
	EN 15986 4.2, Annex A and Annex B ISO 7000-2725	Does not contain phthalates (DEHP)	Indicates patient contact parts do not contain the presence phthalates.
	EN ISO 15223-1, 5.2.6 ISO 7000, 2608	Do not resterilize	Indicates a medical device that is not to be resterilized.

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	EN ISO 15223-1, 5.4.2 ISO 7000, 1051 IEC 60601-1, Table D.1, 28	Do not re-use	Indicates a medical device that is intended for one single use only.
	EN ISO 15223-1, 5.2.8 ISO 7000-2606	Do not use if package is damaged	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	EN ISO 15223-1, 5.1.7 ISO 7000-3082	Manufacturer	Indicates the medical device manufacturer
	ISO/DIS 15223-1, 5.7.7	Medical device	Indicates the item is a medical device.
	ISO 7000-2794	Packaging unit	To indicate the number of pieces in the package.
	FDA 21 CFR 801	Prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician
	ISO/DIS 15223-1, 5.7.10.	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.
	EN ISO 15223-1 5.2.11	Single sterile barrier system	Indicates a single sterile barrier system
	EN ISO 15223-1 5.4.5 and Annex B ISO 7000-2725	Product is not made from natural rubber latex	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.

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