INTRAN® PLUS

Instructions for Use

Description

These instructions are intended for the Disposable Intrauterine Pressure Monitoring System, INTRAN® Plus, developed, manufactured and marketed by Utah Medical Products, Inc.

This product is sterile, single patient use device that does not require fluid filling. It is designed with a pressure transducer tip for continuous, accurate measurement of intrauterine pressures. Although the catheter is designed to be inserted with or without the use of an introducer, a simple and safe introducer for the insertion of INTRAN Plus is enclosed. Additionally, an Amnio Port has been incorporated into the design of INTRAN Plus to allow open communication into the amniotic sac while simultaneously monitoring continuous, accurate uterine pressure. The INTRAN Plus cable connector interfaces with a reusable cable that is specifically designed for the type of monitor being used.

INTRAN Plus does not require "levelling" the transducer at a particular anatomical landmark when zeroing the system since the pressure is measured at the catheter tip. INTRAN Plus provides a convenient method of zeroing the monitor while in situ. Models IUP-4xx or IUP-5xx have the zero slide switch located on the catheter cable connector. Models IUP-6xx or IUP-7xx have the zero button located on the reusable cable which connects the catheter to the monitor.

Model	Zero Switch on catheter	Zero Button on reusable cable	View Port
IUP-400 and IUP-450	X		
IUP-500 and IUP-550	X		X
IUP-600 and IUP-650		X	
IUP-700 and IUP-750		X	X

Reuse. Reuse of this sterile device poses a significant risk of cross contamination and sepsis and/or dependence on an unvalidated process.

This device is not structurally designed or validated for reuse.

Indications and Intended Use

The INTRAN Plus intrauterine pressure monitoring catheter is for use in patients requiring close monitoring of contraction intensities and/or amnioinfusion during active labor.

Precautions

Insertion of the catheter should be performed carefully and gently, using aseptic technique. If any resistance is encountered, determine alternate area for insertion. Any cervical quadrant may be used. Forced insertion may result in malfunction of the system, patient discomfort, or maternal or fetal trauma.

Warning

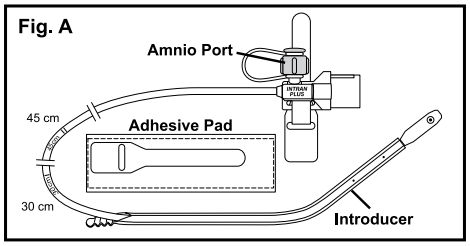
Amniotic membranes must be ruptured and the cervix adequately dilated prior to insertion of INTRAN Plus. Do not insert the introducer beyond the cervical os. Do not advance catheter into placenta.

Contraindications

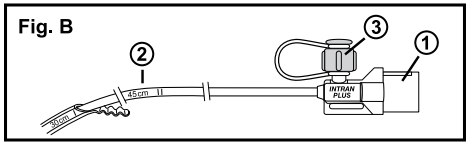
Do not use INTRAN Plus if there is uterine bleeding of undetermined origin, or if placenta previa is diagnosed or suspected.

Catheter Preparation
(Recommended: monitor zeroed prior to catheter insertion into the womb.)

1. Gather necessary supplies: INTRAN Plus (see Figure A), reusable cable which connects the INTRAN Plus to the fetal monitor, infusion fluid with IV tubing if amniofusion is to be performed, and sterile gloves.

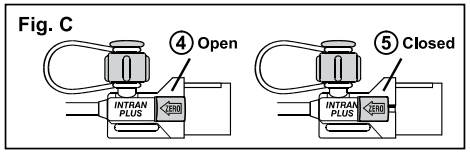


2. Turn the monitor ON.
3. Plug the reusable interface cable into the fetal monitor outlet designated UA or UC.
4. Open the pre-sterilized INTRAN Plus Package.
5. Connect the reusable cable to the INTRAN Plus connection site (see Figure B, number 1)

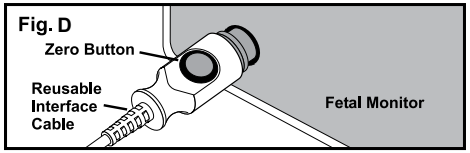


6. **Zero the Monitor -** By zeroing prior to insertion, atmospheric pressure becomes the zero reference point. This zeroing procedure establishes a "zero" reference for the catheter system.

Slide Switch (IUP-4xx and IUP-5xx) - Maintain the zero slide switch in the "open" or monitoring position (Figure C, number 4) prior to IUPC insertion and zero the monitor as per the monitor manufacturer's instructions.



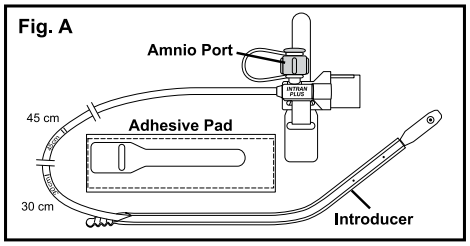
Button (IUP-6xx and IUP-7xx) - WITHOUT depressing the zero button (Figure D) in the reusable cable, zero the monitor as per the monitor manufacturer's instructions.



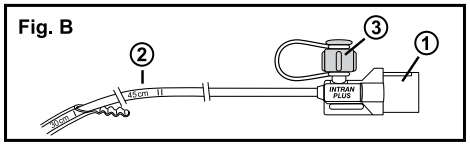
7. Using aseptic technique, remove the INTRAN Plus catheter from the package. If amnioinfusion may be performed, prime the Amnio Lumen with infusion solution prior to insertion. Insert catheter into uterus following the "Catheter Insertion" instructions below.

Catheter Preparation
(Alternative: monitor zeroed after catheter insertion)

1. Gather necessary supplies: INTRAN Plus (see Figure A), reusable cable which connects the INTRAN Plus to the fetal monitor, infusion fluid with IV tubing if amniofusion is to be performed, and sterile gloves.

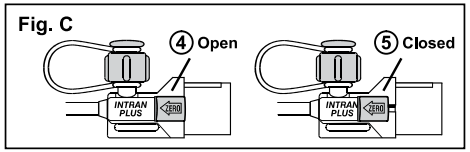


2. Turn the monitor ON.
3. Plug the reusable interface cable into the fetal monitor outlet designated UA or UC.
4. Open the pre-sterilized INTRAN Plus Package.
5. Using aseptic technique, remove the INTRAN Plus catheter from the package. If amnioinfusion may be performed, prime the Amnio Port and lumen with infusion solution prior to insertion. Insert catheter into uterus following the " Catheter Insertion" instructions below.
6. Connect the reusable cable to the INTRAN Plus connection site (see Figure B, number 1).

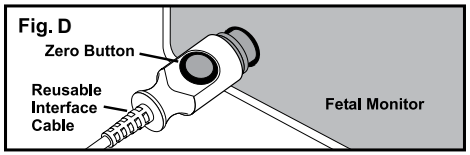


7. **Zero the Monitor after insertion -** This procedure "zeros" the monitor exclusive of the catheter tip while in utero.

Slide Switch (IUP-4xx and IUP-5xx) - Slide the zero slide switch to the "closed" or forward position (Figure C, number 5) and zero the monitor as per the monitor manufacturer's instructions. Return the zero slide switch to the "open" or monitoring position.

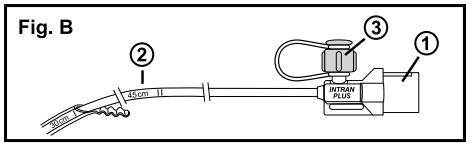


Button (IUP-6xx and IUP-7xx) - Depress and hold the zero button in the reusable interface cable (Figure D), while zeroing the monitor as per the monitor manufacturer's instructions. After the monitor has been zeroed, release the zero button on the reusable cable.

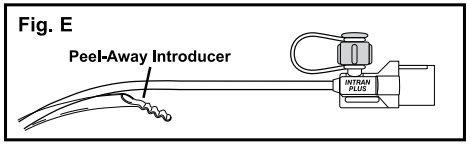


Catheter Insertion

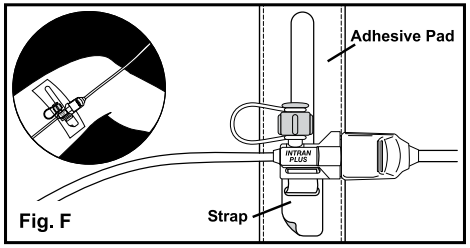
8. Confirm the amniotic membranes are ruptured and the cervix is adequately dilated for insertion of INTRAN Plus.
9. Perform vaginal exam and with the index finger of the examining hand, palpate the fetal presenting part to determine the optimal position for catheter placement.
10. Insert the introducer and the catheter through the vagina into the cervical os. Secure the introducer between the examining fingers and adjacent to the fetal presenting part. Do not extend the introducer beyond fingertips.
11. Advance INTRAN Plus until the second mark, the 45 cm marking (see Figure B, number 2), is at the introitus. This marking indicates that the tip of the catheter has progressed 30-35 cm into the uterus and should be positioned at the fundus of the uterus. If catheter placement does not proceed easily,
    a. alter catheter direction by slightly changing the angle of the introducer, or
    b. determine alternate position for catheter placement and proceed with catheter insertion.



12. Following insertion of INTRAN Plus, carefully slide the introducer back along the catheter. Holding the serrated tab of the introducer in one hand, lift the catheter out of the introducer with the other hand, thus peeling the catheter away from the introducer (see Figure E).



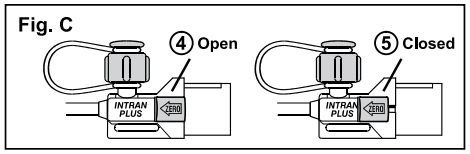
13. To secure the INTRAN Plus, remove the paper from the adhesive pad which is located in the recessed compartment of the product tray. Adhere the pad to the patient's thigh or abdomen, whichever is more comfortable. Secure the strap attached to INTRAN Plus to the adhesive pad. Adjust the strap as desired (see Figure F).



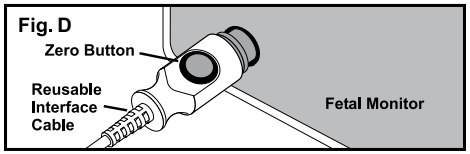
14. Document the insertion in the medical record. Record the time of insertion on the electronic fetal monitor strip (if not done automatically by the electronic fetal monitor). Observe the contraction waveform. Encourage the patient to cough, and watch the recording to observe a spike to confirm optimal placement and function of INTRAN Plus. Follow hospital protocol for making initial notation of hydrostatic pressure.

Rezeroing Procedure - Zero Slide (After insertion of INTRAN Plus, following a monitor change)

1. Zero the monitor by moving the zero slide switch to the forward or "closed" position (Figure C, number 5), and zero the monitor as per the monitor manufacturer's instructions.
2. Return the zero slide switch to the monitoring or "open" position (Figure C, number 4) following completion of the zeroing procedure.

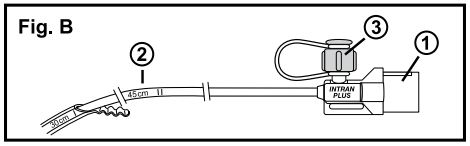


Rezeroing Procedure - Zero Button (After insertion of INTRAN Plus, following a monitor change) Depress and hold the zero button in the interface cable (Figure D), while zeroing the monitor as per the monitor manufacturer's instructions.



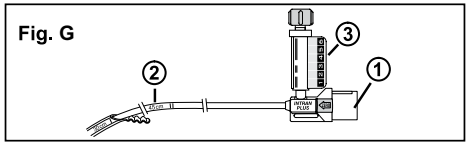
Amnio Port

The Amnio Port (Figure B, number 3) provides direct communication to the lumen openings which are approximately two inches from the distal tip, used for amnioinfusion. The Amnio Port should be accessed per established hospital protocol. To prevent fluid leakage, the end cap should be replaced when the Amnio Port is not in use.



Amnio View Port (models IUP-5xx and IUP-7xx)

Amniotic fluid may be visualized through the clear section of the Amnio/View Port (Figure G, number 3) by removing the end cap and drawing amniotic fluid through the View Port with a syringe per established hospital protocol. The color strip may be used as a reference for amniotic fluid color comparisons.



Amniotic Fluid Visualization

INTRAN Plus is provided with a clear covering over the Amniolumen for clinicians who may wish to assess fluid return upon catheter insertion. Remove the end cap from the proximal Amnio Port (Figure B, number 3) prior to catheter insertion to allow fluid to enter the Amniolumen. The end cap should be replaced following visualization until amnioinfusion or sampling of the fluid is indicated.

Disposal. Dispose of the used catheter with other medical waste per facility protocol for products contaminated with bodily fluids and tissue.

Advice to Patient. If the patient needs to ambulate, disconnect the catheter from the cable and advise the patient to not move the catheter. After reconnection to cable, rezeroing should not be necessary.

EU Notice. Any serious incident (as defined in EU MDR Ch. I, Article 2 (65)) that occurs in relation to this device should be reported to the manufacturer and the competent authority of the Member State where the incident occurs.

MD	Medical Device
℞ ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner
2	Do not re-use
2 STERILIZE	Do not resterilize
	Do not use if package is damaged
LATEX	Product is not manufactured with natural rubber latex
STERILE EO	Sterilized using ethylene oxide
CE 1639	This product fulfills the requirements of EU Medical Device Regulation
	Manufacturer
EC REP	Authorized representative in the European Community

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