Front Side:-

Instructions for Use
Disposable Pressure Transducer Kit
Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description:
A Disposable Pressure Transducer Kit is a sterile, single-use medical device designed to measure physiological fluid pressures through a fluid-filled catheter system. The device converts mechanical pressure into a proportional electrical signal, which is displayed on a compatible patient monitoring system.

Product Name:
Disposable Pressure Transducer Kit

Variants:
Abbott – Single/Double/Triple Lumen
Edwards – Single/Double/Triple Lumen

Intended Use:
A Disposable Pressure Transducer Kit is intended to convert physiological fluid pressure into an electrical signal for monitoring and diagnostic purposes.

Material of Construction:
DEHP Free PVC, ABS, PP, LDPE, PU& HDPE.

Indications for Use:
- Arterial blood pressure (invasive blood pressure monitoring – IBP).
- Central venous pressure (CVP).
- Intracardiac pressures.
- Other physiological pressures where invasive pressure monitoring is clinically required.

Contra-Indications:
- Local infection at the catheter insertion site.
- Vascular injury or anatomical abnormalities.

Intended Patient Population:
Adult, pediatric, and neonatal patients who require invasive monitoring of physiological fluid pressures.

Intended User:
Trained medical professionals, including doctors, nurses, and clinicians.

Use Environment:
Healthcare Setup

Instruction for Use:
- Inspect sterile packaging; do not use if damaged, opened, or expired.
- Verify model (single/double/triple channel), accessories, and monitor compatibility.
- Ensure all components (transducer(s), tubing, stopcocks, flush device) are present and intact.
- Close all stopcocks and clamps prior to setup.
- Prepare the flush solution (e.g., heparinized saline as per institutional protocol).
- Remove protective caps using aseptic technique.
- Spike the IV fluid container with the flush device spike using a twisting motion.
- Open stopcocks sequentially to allow fluid to fill the entire system (tubing, transducer dome).
- Flush each line using the flush device to remove all air bubbles completely.
- Gently tap components to dislodge microbubbles; ensure a continuous fluid column with no visible air.
- Re-close stopcocks to maintain a closed, air-free system.
- Connect the transducer cable(s) to the compatible patient monitor (Abbott/Edwards-type interface).
- Using aseptic technique, connect the patient catheter (arterial/venous) to the pressure line via luer lock.
- Open stopcocks to establish patient-to-transducer fluid continuity.
- Confirm appropriate waveform and numeric values.
- Continuously observe pressure waveform quality and numeric readings.
- Maintain continuous slow flush (via pressurized system) to prevent clot formation.
- Do not reuse or re-sterilize (single-use device).
- Disconnect and dispose of all components in accordance with hospital protocol and biomedical waste regulations.

Intended Clinical Benefits to the patients:
- Accurate real-time hemodynamic monitoring.
- Improved clinical decision-making.
- Early detection of hemodynamic instability.
- Enhanced patient safety during critical care and surgery.
- Reduced risk of cross-contamination.

Clinical Safety:
- Device Design and Material Safety.
- Biocompatible products.
- Our device is a single use device.
- Our product is non-toxic, sterile & non-pyrogenic.

Performance Characteristics:
- Provides accurate pressure measurements over the specified operating range with defined tolerance limits and linear response to applied pressure.
- Designed to accurately reproduce physiological pressure waveforms with appropriate natural frequency and damping coefficient, minimizing distortion or signal overshoot.
- Maintains a stable baseline (zero reference) with minimal drift over time, ensuring consistent and reliable readings during continuous monitoring.

Accessories which can be used with the device:
Compatible patient monitors, interface cables, IV Catheters & other infusion devices.

Warnings:
- The product should not be reprocessed.
- Improper transport and handling may cause structural and/or functional damage to device or packaging.
- Do not clean or resterilize.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packaging.

MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.

Cautions:
- Do not use if package is damaged.
- Discard after single use.

Limitations:
- Dependant on Compatible devices.
- Single Use Design

Back Side:-

Potential Side Effects:
- Infection
- Bleeding
- Hematoma
- Air Embolism
- Allergy respect to material

Disposable instructions:
Used Devices may be contaminated with infectious and/or other hazardous materials. Unused expired devices should be disposed of as per local regulations.

Duration of use:
Short-term duration (typically up to 72 hours)

Storage Conditions:
Store in Cool & Dry Place. Keep away from direct sunlight.

Shelf life:
5 Years.

Type of Sterilization:
This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened unused devices.

Notice to Users and/ or Patients:
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	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.)		Date of manufacture (Indicates the date when the medical device was manufactured)
STERILE EO	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)	LOT	Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)	REF	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
STERILE EO	Single sterile barrier system (Indicates a single sterile barrier system)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Keep dry (Indicates a medical device that needs to be protected from moisture)	DEHP	Free from DEHP (Indicates material used are free from DEHP)
UDI	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)	MD	Medical device (Indicates the item is a medical device)
IN	Country of manufacture (To identify the country of manufacture of products)		Non-pyrogenic (Indicates a medical device that is non- pyrogenic)
	This way up		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
525-P, Sector-37, Pace City-II,
Gurgaon, Haryana - 122001 (INDIA)
Mfg. Lic. No.:MFG/MD/2019/000037

REV.: 01_02.04.2026

REV BY	Q.A			
	Q.C			
	Pro.			
CHD BY	Mkt.			
DGN BY	Gopal Singh		DATE: 02.04.2026	
SCALE-N.T.S			TOLERANCE : ±2 mm	

MAIS INDIA MEDICAL DEVICES PVT. LTD.
525-P SECTOR-37, PACE CITY II,
GURGAON, HARYANA-122001 (INDIA)

TITLE : IFU of Disposable Pressure Transducer Kit

For Party Code 000

COLOR OF PRINT: Black

REVISION DETAILS:

SHEET No. 1/1

DRW. No.: I24100-IFU-000

REV.: 01

Size:- 225x130mm

APPROVED BY: