

INSTRUCTIONS FOR USE LEAFLET

INSTRUCTIONS FOR USE

Extension tubing with Three Way Stopcock

Mediflexo/Gloflexo/Aboval/Anina – (Lipid Resistant)

DEVICE DESCRIPTION:

Three-Way Stop cock with Extension tube is to be used with any of the various infusion or transfusion devices in order to allow for attachment with any special or general-purpose medical device, in order to improve ease of use also to provide an alternative channel for introduction of medicine to the patient.

MATERIAL:

High density polyethylene (HDPE), Lipid Resistant Polycarbonate (PC), Polypropylene (PP), Poly Vinyl chloride (PVC), Acrylonitrile butadiene styrene (ABS)

INTENDED PURPOSE:

It is intended for fluid flow, directional control, and for providing access port(s) for the administration of solutions.

INTENDED USER:

Use is restricted to qualified doctor or a paramedic.

INTENDED PATIENT POPULATION:

All patient population irrespective of age and gender.

INDICATIONS

- Infusion of I.V. solutions.
- Administration of highly viscous lipid fluids.
- Intermittent intravenous Drug Administration.

CONTRAINDICATIONS

- Use in patients allergic/hypersensitive to materials used in device.
- Blood transfusion.

INSTRUCTION FOR USE

- Verify the integrity of the sterile barrier packaging.
- Open the pack from the area of peel and uncoil it.
- Ensure that the tap is in close position to the main line.
- Unscrew the threaded stopper of the main line of three way stop cock.
- Close the clamp of administration set and connect the female connector of three way stop cock to the male connector of administration set.
- Remove the plain stopper from male connector and hold the tube in upright position (ensure that the threaded stopper of second line is closed).
- Open the clamp of administration set.
- Rotate the tap and open the main line of stop cock and displace the air.
- Rotate the tap again and close the tap. (After closing, care should be taken to hold the tube in upright position).
- Connect the male luer connector to the female luer of vascular

access device by applying a slight torque along with an axial force.

- Rotate the tap such that the ends with arrow mark face the lines which are to be open and end with no arrow mark faces the female end which is required to be close.
- Open the clamp of administration set and adjust the flow rate.
- Ensure that the stop cock is in close position for the second line.
- To use second line, remove the threaded stopper and connect female luer of the stop cock to the male luer of the second infusion line.
- Open the clamp of administration set and adjust the flow rate.
- To use only one infusion line at a time, close the clamp of other line.

- To disconnect the device, close the clamps of administration set and remove all the connections of the stop cock.

- Discard the device as per the instructions provided

To give intermittent medication –

- Rotate the tap and close the main line. Remove the threaded stopper from the stop cock.
- Take the pre-filled syringe and connect to the female luer port of the stop cock.
- Push the plunger and give the medication and close the threaded stopper.
- Open the main line by rotating the tap.

PRECAUTIONS:

- Open the sterile barrier pack only under aseptic conditions.
- Product should not be used with pressure more than 5 bar.
- Do not infuse lipids through plain variants.
- Close the threaded stopper of female luer port when not in use.
- The use of this product is restricted to a qualified doctor or a paramedic.
- Do not use if the sterile pack is opened or damaged.
- Dispose after single use.
- This product is for single use only; re-use could cause infection or cross-contamination.
- Store in a cool and dry place. Keep away from sunlight and rain.
- Exposure to elevated temperature and ultraviolet light to be avoided.

WARNINGS

- Do not use if protective caps are loose or missing.
- Read instructions before use.
- The product should be used according to the instructions for

use.

GLOBAL MEDIKIT LTD. DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE.

- The Product should not be reprocessed.
- Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/or functional damage to device or packaging.
- The product is guaranteed sterile if the package has not been opened or damaged.
- Do not clean or re-sterilize.
- The product should be used immediately after opening the packaging.

ADVERSE EFFECTS:

Some common minor complications known from long-standing device use include allergic reaction from hypersensitivity to materials used in the device, infection etc.

HAZARDS OF RE-USE:

Transmission of infection from one patient to another.

PACKAGING:

The device is packed in soft blister film sealed with medical grade paper are packed in inner carton i.e. duplex board & inner carton are packed in master carton i.e. Kraft pulp paper.

STERILIZATION:

Device is EO sterilized and sterilization is done by Global Medikit Limited.

STORAGE CONDITION:

Temperature Limit: 5°C to 25°C

DISPOSAL:

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

REPORTING OF ADVERSE EVENTS:

In case of any serious adverse event please report the same to info@globalmedikit.in or regulatory@obelis.net

Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established



	Manufacturer
	Authorised representative in the European Community
	Date of manufacture
	Use by / Expiry Date
	Batch code
	Catalogue number
	Sterilized using ethylene oxide
	Do not resterilize
	Temperature limit
	Do not reuse
	Consult instructions for use
	Do not use if package is damaged and consult instructions for use
	Caution
	Medical Device
	CE marking
	Unique Device Identifier
	Single sterile barrier system
	Non-Pyrogenic
	Keep Dry
	Keep Away from Sunlight

Global Medikit Limited

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E-mail: regulatory@obelis.net

Revision : 5 Date : 16/11/2022

IFU

Device Name : Extension tubing with Three Way Stopcock

Brand Name : Mediflexo/Gloflexo/Aboval/Anina – (Lipid Resistant)

Dimension : Length 203 x width 140mm

Colour : BLACK

Material : Chromo art paper 70gsm

Artwork No.: GML/IFU/21/002, Rev-05, Dated: 16-11-2022

INSTRUCTIONS FOR USE LEAFLET

INSTRUCTIONS FOR USE *Three Way Stopcock* Mediflex/Gloflex/Anina/Aboval - (Lipid Resistant)

DEVICE DESCRIPTION:

The Three-way stopcock is a multiple port and needleless access device that can be attached to other intravascular administration set devices by the user at the point of use during infusion or sampling. The single-use disposable device is intended for use on continuous intermittent fluid administration or withdrawal of fluids. An in-line access site can be connected to female luer adapters to allow needleless access to fluid or vascular fluid path. The user can control fluid flow by rotating flow control tap. The multiple access sites can be used for administration of drugs and solutions to common fluid path or patient vascular system through a needle or catheter inserted into a vein.

MATERIAL:

High density polyethylene (HDPE), Lipid Resistant Polycarbonate (PC), Polypropylene (PP)

INTENDED PURPOSE:

Three way stop cock is intended for fluid flow, directional control, and for providing access port(s) for the administration of solutions.

INTENDED USER:

Use is restricted to qualified doctor or a paramedic.

INTENDED PATIENT POPULATION:

All patient population irrespective of age and gender.

INDICATIONS

- Infusion of I.V. solutions.
- Administration of highly viscous lipid fluids.
- Intermittent intravenous drug administration.

CONTRAINDICATIONS

- Use in patients allergic/hypersensitive to materials used in device.
- Blood transfusion.

INSTRUCTIONS FOR USE

- Verify the integrity of the sterile barrier packaging.
- Open the pack from the area of peel and remove the device.
- Ensure that the tap is in close position to the main line.
- Unscrew the threaded stopper of the main line of three way stop cock.
- Close the clamp of administration set and connect the female connector of three way stop cock to the male connector of administration set.
- Remove the plain stopper from male connector and hold the device in upright position (Ensure that the threaded stopper of second line is closed).
- Open the clamp of administration set.

- Rotate the tap and open the main line of stop cock and displace the air.
- Rotate the tap again and close the tap. (After closing, care should be taken to hold the device in upright position).
- Connect the male luer connector to the female luer of vascular access device by applying a slight torque along with an axial force.
- Rotate the tap such that the ends with arrow mark face the lines which are to be open and end with no arrow mark faces the female end which is required to be close.
- Open the clamp of administration set and adjust the flow rate.
- Ensure that the stop cock is in close position for the second line.
- To use second line remove the threaded stopper and connect female luer of the stop cock to the male luer of the second infusion line.
- Open the clamp of administration set and adjust the flow rate.
- To use only one infusion line at a time, close the clamp of other line.
- To disconnect the device, close the clamps of administration set and remove all the connections of the stop cock.
- Discard the device as per the instructions provided.

To give intermittent medication –

- Rotate the tap and close the main line. Remove the threaded stopper from the stop cock.
- Take the prefilled syringe and connect to the female luer port of the stop cock.
- Push the plunger and give the medication and close the threaded stopper.
- Open the main line by rotating the tap.

PRECAUTIONS:

- Open the sterile barrier pack only under aseptic conditions.
- Product should not be used with pressure more than 5 bar.
- Do not infuse lipids through plain variants.
- Close the threaded stopper of female luer port when not in use.
- The use of this product is restricted to a qualified doctor or a paramedic.
- Do not use if the sterile pack is opened or damaged.
- Dispose after single use.
- This product is for single use only; re-use could cause infection or cross-contamination.
- Store in a cool and dry place. Keep away from sunlight and rain.
- Exposure to elevated temperature and ultraviolet light to be avoided.

WARNINGS

- Do not use if protective caps are loose or missing.
- Read instructions before use.
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- Do not clean or re-sterilise.
- The product should be used immediately after opening the packaging.

ADVERSE EFFECTS:

Some common minor complications known from long-standing device use include allergic reaction from hypersensitivity to materials used in the device, infection etc.

HAZARDS OF RE-USE:

Transmission of infection from one patient to another.

PACKAGING:

The device is packed in hard blister film sealed with medical grade paper or Tyvek paper, inner carton i.e. duplex board & such inner cartons are packed in master carton i.e. Kraft pulp paper.

STERILIZATION:

Device is EO sterilized and sterilization is done by Global Medikit Limited.

STORAGE CONDITION:

Temperature Limit: 5°C to 25°C

DISPOSAL:

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

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Revision : 6 Date : 16/11/2022



	Manufacturer
	Authorised representative in the European Community
	Date of manufacture
	Use by / Expiry Date
	Batch code
	Catalogue number
	Sterilized using ethylene oxide
	Do not resterilize
	Temperature limit
	Do not reuse
	Consult instructions for use
	Do not use if package is damaged and consult instructions for use
	Caution
	Medical Device
	CE marking
	Unique Device Identifier
	Single sterile barrier system
	Non-Pyrogenic
	Keep Dry
	Keep Away from Sunlight

Global Medikit Limited

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E-mail: regulatory@obelis.net

IFU

Device Name : Three Way Stop Cock

Brand Name : Mediflex/Gloflex/Anina/Aboval - (Lipid Resistant)

Dimension : Length 203 x width 140mm

Colour : BLACK

Material : Chromo art paper 70gsm

Artwork No.: GML/IFU/02/002, Rev-06, Dated: 16-11-2022