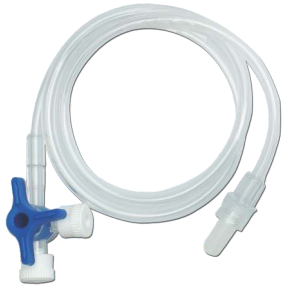
Gloflexo®

Extension tubing with 3 way Stop cock

Three-way stopcock with an integrated extension tubing for minimizing manipulation during intravenous administration of fluids/drugs through an I.V. Catheter.

- Minimizes chances of mechanical irritation and infection by taking.
- The administration site away from insertion site.
- The integrated three-way stopcock offers multiple infusion lines.
- Smooth internal surface to minimize turbulence.
- Disposable, sterile and non-pyrogenic.



Technical Specifications

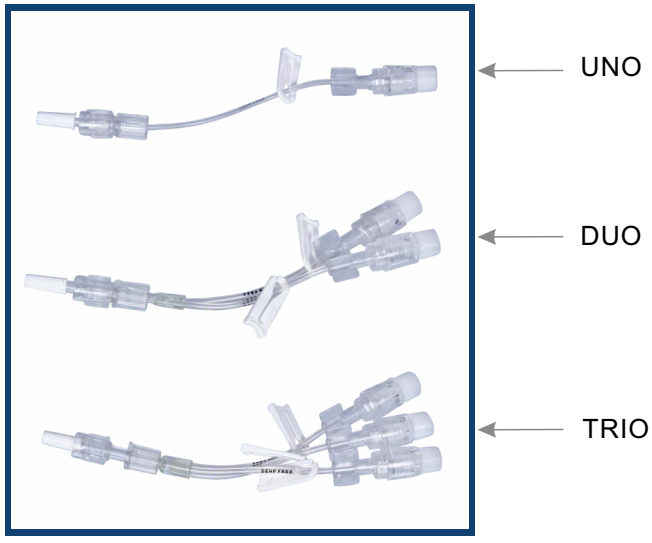
Soft Blister Pack			
Length (cm.)	Int.- Ext. Dia. (mm.)	Ref. No.	Qty. in carton Inner/ Outer
5	3.3-4.5	4270053G	30/180
7	3.3-4.5	4270073G	30/180
10	3.3-4.5	4270103G	30/180
25	3.3-4.5	4270253G	30/180
50	3.3-4.5	4270503G	30/180
75	3.3-4.5	4270753G	30/180
100	3.3-4.5	4271003G	30/180
125	3.3-4.5	4271253G	30/180
150	3.3-4.5	4271503G	30/180
200	3.3-4.5	4272003G	30/180
250	3.3-4.5	4272503G	30/180

Glolinn™

Extension line with needle free valve

FEATURES & BENEFITS:

- Small bore multiple extension sets.
- Needless luer access ports provides virtually zero residual volume and high flow rates.
- Glolinn™ is light weight with an easy rotating luer lock which reduces the chances of pulling and kinking.
- Designed for multiple drug delivery.
- Valve features a straight-through, minimal dead space.
- Use of Glolinn™ reduces the chances for catheter/cannula related complications and improves the patient comfort.
- Low priming volume enable small-volume infusions.
- Silicone sealing membrane with slide clamp.
- Available in uno, duo, trio.
- **DEHP free**.
- Latex free.



USAGE:
Glolinn™ is designed to meet the needs of general I.V. therapy.

The ability of needle free connector is to prevent contamination of fluid path.

Technical specifications

Valve	Total length of Set	Approx. Priming volume (ml)	Ref. No.	Qty. Inner / Outer
UNO (1 way)	15 cm	0.25 ml	4280101G	50 / 500
DUO (2 way)	15 cm	0.45 ml	4280103G	50 / 500
TRIO (3 way)	15 cm	0.80 ml	4280105G	50 / 500

Infusion

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 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.
- The product should be used according to the instructions for use.

GLOBAL MEDIKIT LTD. DISCLAIMS ANY RESONSIBILITY 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

Revision : 5 Date : 16/11/2022

MEDIKIT
The better life

	Manufacturer
EC REP	Authorised representative in the European Community
	Date of manufacture
	Use by / Expiry Date
LOT	Batch code
REF	Catalogue number
STERILE EO	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
MD	Medical Device
CE 0123	CE marking
UDI	Unique Device Identifier
SBS	Single sterile barrier system
	Non-Pyrogenic
	Keep Dry
	Keep Away from Sunlight

Global Medikit Limited

Khasra No. 323 (MI), Central Hope Town, Camp Road, Selaqui, Dehradun, Uttarakhand, India -248197
E-mail: info@globalmedikit.in
Web: www.globalmedikit.in

EC REP **Obelis s.a.**

Boulevard Général Wahis 53, 1030 Brussels, BELGIUM
Tel: +32 (2) 73 25 954 | Fax: +32 (2) 73 26 003
E-mail: regulatory@obelis.net

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

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Phone: +91 11 27662182
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Ref. No: TDS – 02B, Revision No - 05

TECHNICAL DATA SHEET

Gloflexo®

Extension Tubing with Integrated 3-Way Stop Cock

Global Medikit Limited
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GENERAL DESCRIPTION OF DEVICE

DEVICE BRAND NAME	**GLOFLEXO® (Non-Lipid / Lipid resistance)**
DEVICE MODEL	Extension Tubing with Integrated 3-Way Stop Cock
DEVICE DESCRIPTION	Extension Tubing with Integrated 3-Way Stop Cock is a device used as an accessory to direct the flow of fluid through an infusion system while allowing multiple fluids to be connected to the same input source. An exterior handle – called tap, allows the clinician to choose the specific fluid or medication to flow at a given point of time. Extension Tubing with Integrated 3-Way Stop Cock is available in lipid resistant (LR) and non-lipid resistant (Plain).
INTENDED USE	Extension Tubing with Integrated 3-Way Stop Cock is intended for fluid flow, directional control, and for providing access port(s) for the administration of solutions.
CLASSIFICATION	Extension Tubing with Integrated 3-Way Stop Cock is non-invasive, short term use device which is intended for channeling liquids for the purpose of eventual administration or introduction into the body and hence classified as Class IIa as per Rule 2 of Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR 2017/745).
SIZE AVAILABLE	5, 7, 10, 25, 50, 75, 100, 125, 150 and 200 cms
PATIENT POPULATION	Child, Adult

PRODUCT SPECIFICATIONS

❖ **Technical Specifications**

A	**3-way Stopcock**:	
	Base/Housing	Transparent
	Pressure stability (up to)	5 Bar
B	**Tubing:**	
	Material	PVC (Transparent, flexible)
	O.D.	4.5 mm ± 0.1 mm
	I.D.	3.3 mm ± 0.1 mm
C	**Luer lock connector at both end**	6% Taper as per ISO 594 -2.

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❖ Reference No

Length(cm.)	Int.- Ext. Dia.(mm.)	Ref. No.
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7	*3.3 – 4.5*	*4270073G*
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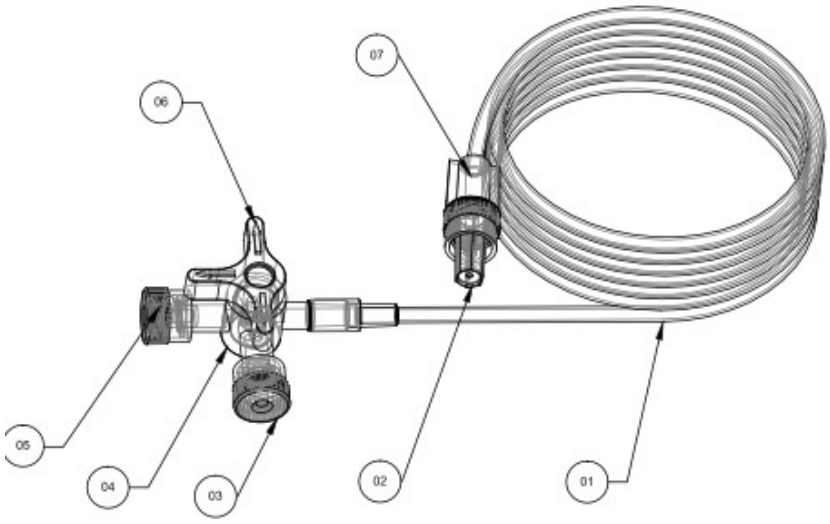
125	*3.3 – 4.5*	*4271253G*
150	*3.3 – 4.5*	*4271503G*
200	*3.3 – 4.5*	*4272003G*
250	*3.3 – 4.5*	*4272503G*

❖ *Features*:

- Extension Tubing with Integrated 3-Way Stop Cock for minimizing manipulation during intravenous administration of fluids/drugs through an I.V. Catheter.
- Minimizes chances of mechanical irritation and infection by taking.
- Tap turns 360° without limitation
- The integrated three-way stopcock offers multiple infusion lines.
- Smooth internal surface to minimize turbulence.
- Disposable, sterile and non-pyrogenic.

DEVICE DRAWING



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APPROVED MATERIAL OF CONSTRUCTION

Details of all components and its material are given in following table. The product and product packaging doesn't contain any constituent of animal origin

S. No.	Qty.	Part name	Material used
1	1	Tubing	Poly Vinyl Chloride (PVC) Soft
2	1	Protective Cap	Polypropylene (PP)
3	2	Threaded Stopper (Luer Lock)	High Density Poly Ethylene [HDPE]
4	1	Three Way Body/Housing	Poly Carbonate (PC)
5	1	Tap	High Density Poly Ethylene [HDPE]
6	1	Male Luer Lock	Poly vinyl chloride (PVC.) Hard

PACKING SPECIFICATION

The Device is individually packed in Soft/Hard Blister Film packs, sealed with medical grade Tyvek/60gsm paper, such 30 PCs. are packed in inner carton i.e. Kraft pull Paper & such 6 inner cartons are packed in master carton i.e. Kraft pull Paper.

Packing Details

Inner carton size	255 x 175 x 205 mm
No. Of blister packed pieces in inner carton	30 pcs
Master carton size	630 x 366 x 275 mm
No. Of inner cartons in master carton	6 nos
No. Of blister packed pieces in master carton	180 pcs

STERILIZATION

The device is sterilized by Ethylene Oxide (EtO), A Concentration of 20:80 (ETO: CO2).

STORAGE CONDITION

Stored in at 5°C to 25°C temperature, keep away from moisture, direct light and heat sources.

SHELF LIFE

Shelf life of the finished product 5 years from the date of sterilization.

STANDARDS COMPLIANCE

ISO 13485:2016	Medical devices – quality management systems – requirements for regulatory purposes

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ISO 14971:2019	Medical devices – application of risk management to medical devices
ISO 15223-1:2021	Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – part 1: general requirements
ISO 20417:2021	Information supplied by the manufacturer of medical devices
ISO 8536-9:2015	Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment
ISO 8536-10:2015	Infusion equipment for medical use – part 10: accessories for fluid lines for single use with pressure infusion equipment
ISO 80369-7: 2016	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
IEC 62366-1:2015	Medical devices - application of usability engineering to medical devices
ISO 11607-1:2019	Packaging for terminally sterilized medical devices – part 1: requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices – part 2: validation requirements for forming, sealing and assembly processes
ISO 10993-1:2018	Biological evaluation of medical devices – part 1: evaluation and testing within a risk management process
ISO 10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO 11135:2014	Sterilization of health care products – ethylene oxide – part 1: requirements for development, validation and routine control of a sterilization process for medical devices
ISO 14644-1:2015	Cleanrooms and associated controlled environments – part 1: classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
MEDDEV 2.7.1., Rev 4	Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2020	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
MDCG 2020-6	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC

Date: 21 February 2023

Samar Keshari Jena
Regulatory Affairs Manager
Global Medikit Limited