Glothin®

I.V. Catheter with Injection Valve and Wings

- A specially designed injection port cap which has a recessed plug and a protective skirt to minimize contamination.
- Disposable, sterile, non-pyrogenic.
- Sealed blister packing.

Technical Specifications

		Catheter				
Gauge	Colour Code	Ext. Dia. (mm.)	Length (mm.)	Flow Rate (ml./min.)	Ref. No. Clear	Qty. in carton Inner/ Outer
14	Orange	2.1	45	300	4100142G	100/1000
16	Grey	1.8	45	200	4100162G	100/1000
17	White	1.5	45	140	4100172G	100/1000
18	Green	1.3	45	90	4100182G	100/1000
20	Pink	1.1	33	61	4100202G	100/1000
22	Blue	0.9	25	36	4100222G	100/1000
24	Yellow	0.7	19	15	4100242G	100/1000
26	Purple	0.6	19	13	4100262G	100/1000

Glocath®

I.V. Catheter with an integrated three-way stopcock

Ports of the stopcock can be utilized for attaching additional stopcocks for multiple infusion therapy.

- Colour coded tap for easy identification.
- Flexible wings with suture holes for secure fixation.
- Luer lock stoppers to prevent contamination.
- 360° rotation of the tap without limitation.
- Rigid and sturdy design for longevity.
- Female luers with6% taper for compatibility with all standard devices.
- Disposable, sterile and non-pyrogenic.
- Sealed blister packing.

Technical Specifications

		Catheter				
Gauge	Colour Code	Ext. Dia. (mm.)	Length (mm.)	Flow Rate (ml./min.)	Ref. No. Radiopaque	Qty. in carton Inner/ Outer
16	Grey	1.8	45	200	40316BBC	50/500
18	Green	1.3	45	90	40318BBC	50/500
20	Pink	1.1	33	61	40320BBC	50/500
22	Blue	0.9	25	36	40322BBC	50/500

Gloflex®

Three-way stopcock

Three way stopcock made of polycarbonate

- Multiple channels for multiple infusion therapy.
- Designed to withstand pressure upto 5 bars.
- Smooth, fully rotatable tap.
- Stability tested pneumatically and hydrostatically.
- Tap turns every 360° without limitation.
- Flow shuts off every 90°.
- Minimal dead space in ports to ensure precise drug administration and maximum infusion flow. Continuous flow channels.
- Arrow indication marks on top to indicate direction of flow.
- Low profile for stable and safe positioning.
- Available in lipid resistant/non-lipid resistant varieties.
- Available with blue and red pegs for easier identification.
- Disposable, sterile and non-pyrogenic. Sealed blister packing.

Technical Specifications

Colour Code	Ref. No.		Qty. in carton Inner/ Outer
	Non- Lipid Resistant	Lipid Resistant	
Blue	4310012G	4320012G	50/500
White	4310022G	4320022G	50/500
Red	4310032G	4320032G	50/500

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 offluids. 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 acommon 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 connectorand 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.
- 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-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.

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 : 6 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

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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 : 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

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Ref. No: TDS – 02A, Revision No - 05

TECHNICAL DATA SHEET

GLOFLEX®

Three-way stopcock

Global Medikit Limited
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Phone: +91 11 27662182
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GENERAL DESCRIPTION OF DEVICE

DEVICE BRAND NAME	**GLOFLEX® (Non-Lipid / Lipid resistance)**
DEVICE MODEL	Three Way Stopcock
BASIC UDI-DI	8903545GMLSTC017P6
DEVICE DESCRIPTION	The Three 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. Three Way Stop Cock is available in lipid resistant (LR) and non-lipid resistant (Plain).
INTENDED USE	Three way stop cock is intended for fluid flow, directional control, and for providing access port(s) for the administration of solutions.
CLASSIFICATION	Three 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).
TAP COLOUR	Blue, White, Red
PATIENT POPULATION	Child, Adult

PRODUCT SPECIFICATIONS

❖ **Technical Specifications**

Parameter	Value
Base/Housing	Transparent
Flow Rate	500 ml/min. ± 10%
Pressure stability (up to)	5 Bar
Rotation	360° rotation tap
Priming Volume	0.20 ml (Approx.)
Connecting Ports: Transparent having 6% Taper with luer lock facility.	

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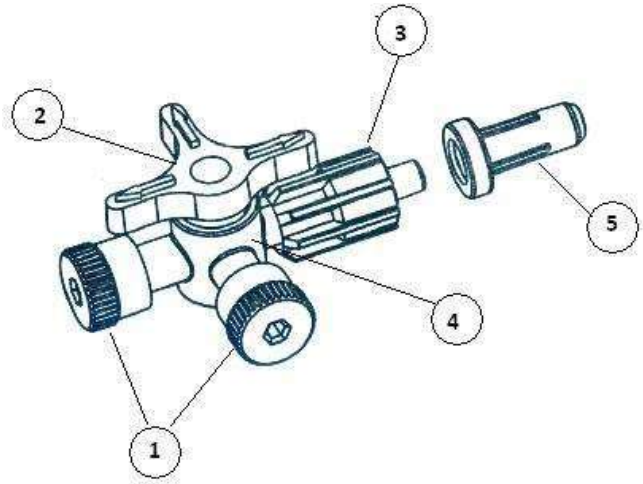
Reference No.

Colour Code		Ref. No.	
		Non-Lipid resistance	Lipid resistance
	Blue	4310012G	4320012G
	White	4310022G	4320022G
	Red	4310032G	4320032G

❖ Features

- Multiple channels for multiple infusion therapy.
- Designed to withstand pressure up to 5 bars.
- Smooth, fully rotatable tap.
- Tap turns 360° without limitation.
- Flow shuts off every 90°.
- Minimal dead space in ports to ensure precise drug administration and maximum infusion flow.
- Continuous flow channels.
- Arrow indication marks on top to indicate direction of flow.
- Low profile for stable and safe positioning.
- Available in lipid resistant/non-lipid resistant varieties.
- Sterile, non-pyrogenic, for single use.

DEVICE DRAWING



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.

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S.NO	PART NAME	MATERIAL
1	Threaded stopper	HDPE (High Density Polyethylene)
2	Tap	HDPE (High Density Polyethylene)
3	Rotator	PC (Poly Carbonate)
4	Body/housing	PC (Poly Carbonate)
5	Plain stopper	PP (Polypropylene)

PACKING SPECIFICATIONS

The Device is individually packed in PVC blister packs (Thickness 0.28 mm) sealed with Medical grade Tyvek/60gsm paper, such 50 PCs. are packed in inner carton i.e. Duplex Board & such 10 inner cartons are packed in master carton i.e. Kraft pull Paper.

Packing Details

Inner carton size	168 x 136 x 105 mm
No. Of blister packed pieces in inner carton	50 pcs
Master carton size	538 x 288 x 178 mm
No. Of inner cartons in master carton	10 nos
No. Of blister packed pieces in master carton	500 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
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

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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

Digitally signed by Dolgopol Iulian
Date: 2025.06.05 12:43:15 EEST
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