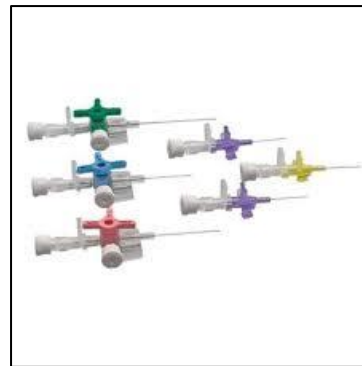
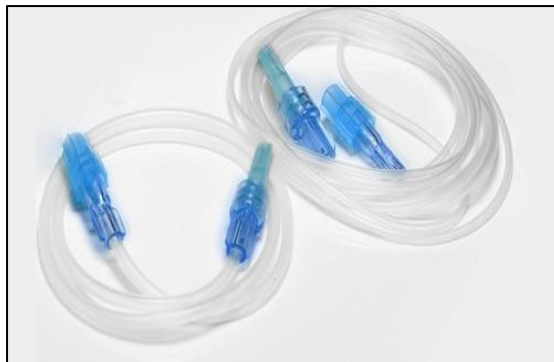
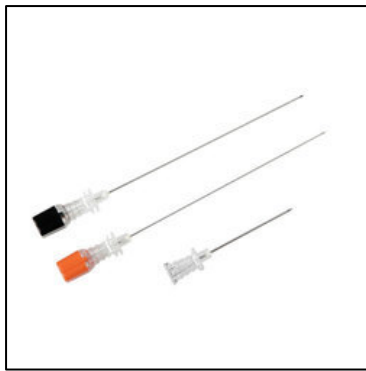




MECCA HEALTHCARE PRIVATE LIMITED



MEDICAL DISPOSABLES & CONSUMABLES FOR HOSPITALS

OUR MISSION

Our mission is to be an organization whose employees strive for growth and values the contribution made by its founding members, through always keeping in mind the health and safety of the users of its products and thus satisfying the growing needs of the healthcare industry and its customers.

OUR VISION

To be an organization whose people & products exude CARE, COMPASSION & TRUST towards its customers, business partners and the society at large.

A BRIEF NOTE ABOUT MECCA INDUSTRIES

"Mecca Group of Industries", is a company set up in the year 1977 catering to the healthcare industry. Mecca Industries is among the first Indian company to begin mfg. Intravenous Infusion Equipments.

Our organization has three state of the art mfg. plants located at Kalol Dist; Gandhinagar & Chhatral Dist. Mehsana in Gujarat and Boranada Dist; Jodhpur, in Rajasthan.

Today we are an CE MARKED PRODUCTS, ISO 13485:2016 and WHO GMP compliant concern supplying to varied sectors of the healthcare industry in India. Recently Mecca has started developing 510K approval US FDA facility at its Kalol plant and intends to procure the certification by 2025.

Our products on an annual rate contract basis are supplied to State Governments of Gujarat, Rajasthan, Madhya Pradesh, Maharashtra, Bihar, Orissa, Assam, Karnataka and Tamil Nadu in India.

Mecca group is also exporting its CE marked products to all the CIS countries, Middle Eastern Nations, South East Asian countries, African Nations and Latin American countries since 1991 through contract manufacturing and merchant exports.

We are also working on a loan license contract mfg. basis with Indian arms of two of the largest German companies of healthcare sector in the world, **M/s. B. Braun and M/s. Fresenius Kabi. Besides we are holding loan licence of Claris Otsuka Ltd (Formerly Core Parenterals associated since 1988) and Hetero Labs, Camber Pharmaceuticals USA & Hollister Inc. USA.**

In past our co. has worked with almost all the Intravenous Infusion mfg. cos in India prominent being Sarabhai Industries, Cadila Pharmaceuticals, Tide Pharmaceuticals (a unit of Torrent Pharma.), Wockhardt Pharma, Intas Pharmaceuticals, Cipla Limited, Albert David Ltd. et al.

To know more about our organization and its line of work we suggest you to visit.

www.mhplindia.com

www.mhplindia.in

www.acmevision.uk

Mecca Healthcare (P) Limited, INDIA

Plant Address;

UNIT - 1, 99 - 102, GIDC, KALOL (N.G.), Dist; Gandhinagar, Gujarat

UNIT - 2, L-1202, GIDC Chattral, Dist.; Mehsana, Gujarat

UNIT - 3, F-252, III Phase, Boranada, Jodhpur, Rajasthan

www.mhplindia.com

AN ISO 13485 : 2016 & ISO 9001 : 2015 CERTIFIED COMPANY

WHO GMP COMPLIANT MFG. PLANT

CE MARKED PRODUCTS

Intensive Care Products Detailer



1. Product Name: Needle free connector



Needle-less/Needle-free connectors (NCs/NFCs) as the name suggests, eliminates the need to use a needle, and are devices that attach to the end of vascular catheters to enable quick access for infusion, aspiration, or injection. NCs can be used with central, peripheral, and arterial catheters.

Advantages / Key Benefits of NCs:

1. **Protects Healthcare Workers** from needlestick injuries (and consequent infections), reduce the risk of accidental punctures and infections.
2. Act as a **microbial gatekeeper** for vascular catheters.

- Needle Free Connectors are Intravenous tubing or devices for connecting IV catheters, IV Administration Sets, Syringes, enabling intermittent catheter access for infusion or aspiration.
- Needle Free Connectors help to reduce the risk of needle-stick injuries.
- Needle Free Connectors minimize catheter occlusion risk.
- Helps in prohibiting microbial entry to the Intravenous Infusion Line.
- Protects against microbial growth and internal biofilm formation during an intravenous drugs administration process.
- Available with Positive, Negative & Neutral Pressure specification.
- GLOBAL Brand Names: Clave Connectors Mfg. by ICU Medical USA www.icumed.com / Ultrasite Mfg. by Bbraun Germany

types/variants of NCs/NFCs & difference:

- **POSITIVE Displacement NFCs**

Uses positive displacement technology to clear the catheter tip when disconnected, which can help reduce the risk of occlusions

- **NEUTRAL Displacement NFCs**

Can be used for three-second disinfection to help prepare for procedures

- **NEGATIVE Displacement NFCs**

Uses negative displacement technology to help achieve a small amount of blood being moved/pushed back into the catheters

DIFFERENCE BETWEEN POSITIVE, NEGATIVE & NEUTRAL Displacement NFCs

Positive fluid displacement forces a small amount of fluid into the catheter end to prevent occlusion from blood and conversely, negative displacement allows a small amount of blood to move back into the catheter. Neutral displacement indicates no movement of fluid back into the catheter after disconnection.

Needle Free Connectors

- Neutral displacement connector
- Needle free technology, designed to reduce the risk of bacterial contamination and improve patient outcome
- Split-septum technology
- Straight fluid path & minimal deadspace of 0.04 ml allows for lower flush volumes
- Swabable surface for ease of disinfection
- Allows saline flush option which eliminates the risk of Heparin Induced Thrombocytopenia (HIT)
- No latex or metal components, DEHP free, MRI compatible



- Negative displacement connector
- Needle free connector reduces risk of Catheter Related Blood Stream Infections (CRBSI)
- Needle free technology reduces the risk of bacterial contamination
- Suitable for all peripheral, arterial and central venous catheters for the administration of I.V. fluids or medication
- Flat smooth swabable surface for ease of disinfection
- Safe & secure connection to luers of other systems
- No latex or metal components, DEHP free, MRI compatible



Needle free technology, designed to reduce the risk of bacterial contamination and improve patient outcome. A complete line of Needle Free I.V. Connectors to help paramedicals meet needs to eliminate in-clinical infections.

2. Product Name: 3 way needle free connector with Multi-lumen port



- Three way connector with three needle free connector ports.
- Achieves 3 compatible fluids to be infused into a single lumen without mixing.
- For eg. In case of diabetic patients 1 for insulin, 1 for glucose, 1 for n/saline.
- Acts as a central or peripheral catheter.

Multiple Lumen Catheter

Usage: Hospital

Is It Sterilized: Sterilized

Disposables: Yes

Material PU

Size Fr12-Fr26 / 14 - 30 cm

Price: 1350-2000/pc

Description A multi-lumen catheter is a single catheter with more than one internal channel (called a lumen). A different intravenous infusion can be connected to each lumen, and the fluid will usually exit at a slightly different point along the catheter

Basic Set Contains (Seldinger technique Insertion set)

Radiopaque Polyurethane Catheter

Vessel Dilator

Y-shape Introducer Needle (18G x 7cm)

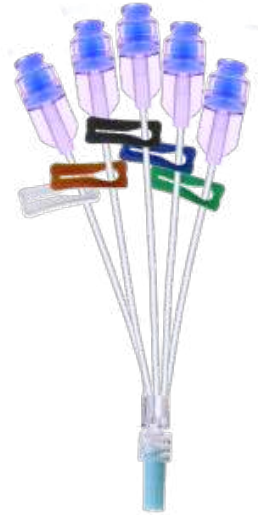
One Injection cap per lumen

Optional suture loop with box clamp

0.035" x 60cm guide wire with straight and J-

tip and guide wire insertion devices 5ml

syringe with 22g Needle.



Extension Lines with Needle Free Connector

- Neutral displacement connector
- Needle free technology, designed to reduce the risk of bacterial contamination and improve patient outcome
- Split-septum technology
- Straight fluid path & minimal deadspace of 0.04 ml allows for lower flush volumes
- Swabable surface for ease of disinfection
- Allows saline flush option which eliminates the risk of Heparin Induced Thrombocytopenia (HIT)
- No latex or metal components, DEHP free, MRI compatible



Mono



Duo



Trio

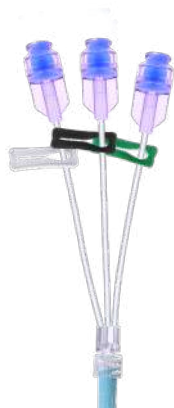
- Negative displacement connector
- Needle free connector reduces risk of Catheter Related Blood Stream Infections (CRBSI)
- Needle free technology reduces the risk of bacterial contamination
- Suitable for all peripheral, arterial and central venous catheters for the administration of I.V. fluids or medication
- Flat smooth swabable surface for ease of disinfection
- DEHP Free extension tubing
- Latex Free



Mono



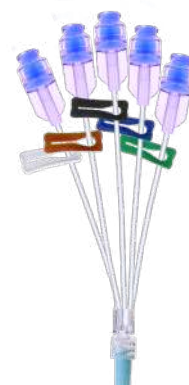
Duo



Trio



Quatro



Penta

Disinfecting Cap

A single-use device that contains foam impregnated with 70% isopropyl alcohol to act as an antiseptic.

It can be also referred to as a microbial gatekeeper.

Mitigates risks of Biofilm formation and entry of microorganisms into the vascular access catheters.

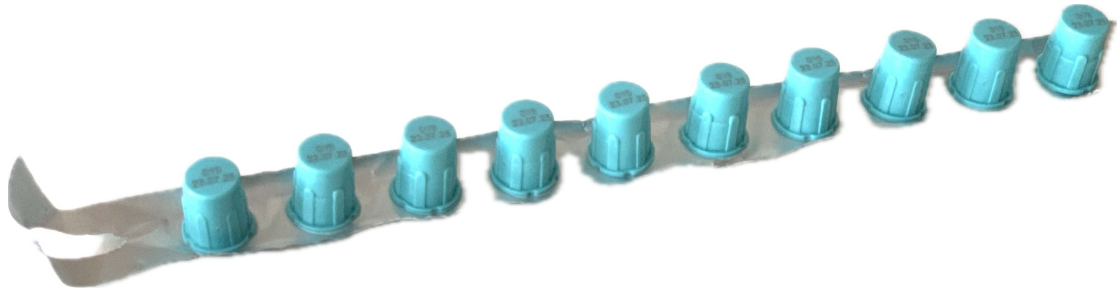
Helps achieving total protection through scrubbing of the TIP & THREADS of the NCs.

Total IV Device Disinfection



Disinfecting Cap

Luer Ports Disinfection Caps



Disinfecting Cap for swabable needle-free valves is a single-use disinfecting product that protects patients from infection.

The product is impregnated with a high liquid absorbent sponge saturated with 70% Isopropyl Alcohol (IPA).

- Provides instant active and efficient disinfection
- Compatible with all needle free and luer access systems
- Eliminates inter-personal variation in compliance of 'scrub the hub' method of disinfection and saves nursing time
- Ergonomic design for smooth usage
- PVC Free, Latex Free, DEHP Free
- Gamma Sterile
- Available in Single pack & Multi pack
- Provide active disinfection for 7 days if not removed
- **Options available :**
 - 70 % Isopropyl alcohol



3. Product Name: Medical Manifolds



- Suitable for use during angiography, angioplasty, intervention radiology & cardiology procedures.
- Used as delivery device of I.V. Fluids to patient's vascular system.
- Available with 2, 3, 4, 5 or 6 way configurations.

Pressure Manifolds Devices

- Suitable for intervention radiology and cardiology procedures
- Used as delivery device for I.V. fluids to the patient's vascular system
- Available with 2, 3, 4, 5 & 6 way channels
- Minimal residual & priming volume
- Lipid resistant



2 Ways



3 Ways



4 Ways



5 Ways



6 Ways



Manifolds

Usage/Application: Hospital
Material: Plastic, Polycarbonate
Is It Sterilized: Yes

Price Range: 180 to 240

Description: It provides 3-way flow (from inlet to outlet, inlet to side-port or side port to outlet) by use of the handle on the top of the stopcock to open and close lines. The device can also be used to reduce to lines down to one, for drugs/drug infusion purposes and for the attachment of extension lines

Additional Information:

Working Pressure: 250 psi, 500 psi, 800 psi

Sterilization: Ethylene Oxide

Port Size: 2 Port, 3 Port

Packaging Type: Packet

In addition, options include rotating luer and block body or half body styles.

Control Volume with large bore (.093"/.25cm) inner lumen throughout, including rotator

Control Ordering Option with 246 styles and pressure ratings of both 200 and 500 psi.

Control Operation with 6" (15.6cm) extended rotators.

Extension Sets

Usage/Application: Hospital

Material: Pvc

Is It Sterilized: Yes

Price Range: Rs 16- 40

Pack Type: poly pack/ box

Description: Extension sets are available with low pressure resistance designed for infusion bags and high pressure resistance designed for infusion pumps. The extension tubing prevents dislodgement of the catheter. It can be used to add length to existing tubing.

Additional Information:

Removable Sure-Lok® Needle-Free Connector

Pinch Clamp

Rotating Male Luer Lock

DEHP-free

Latex-free

Length: 8in

Priming Volume: 1.8mL



Needle free connector

Usage/Application: Hospital

Material: Polypropylene

Is It Sterilized: Yes

Price Range : 20 to 42

Description: Needleless connectors (NCs) are essential devices which connect to the end of vascular catheters and enable catheter access for infusion and aspiration.

Additional Description:

PVC Tube Length

10 - 300 Cm

Specifications and models - PV-I straight form structural composition - interface, a joint, a piston and a silicon spring

Type - Positive Pressure Type

Length of Extension Tube - 10-30cm

Usage - Blood Dialysis Treatment

Injection site: Silicone

All materials are latex-free and DEHP-free

4. Product Name: Extension Set for Intravenous Fluid Administration



DESCRIPTION : Extension sets are sterile devices for single use only. They are intended to be used as part of system for the infusion of fluids/ medications in medical applications.

S.N	Components
1	Needle free Connector
2	Female Port
3	Tube
4	C Clamp
5	Male Luer Lock

5. Product Name: Intramuscular Pressure Monitoring Catheter



DESCRIPTION

- Pressure Monitoring Catheters are sterile devices for single use only.
- They are intended to be used as a connection between syringe infusion pump and patient for the infusion of fluids/drugs medications in medical applications.
- Fitted with male luer locks to one end and female luer locks to other end they act as a tool to monitor pressure during medication.

Usage/Application: Hospital

Material: PVC, S.S, ABS, HDPE

Is It Sterilized: Yes

Length Available 10 cm 0.50 ml; 25 cm 1.40 ml; 50 cm 2.90 ml; 100 cm 5.90 ml; 150 cm 8.90 ml

Price Range: INR 12 - 23

Description: It monitors the fluent blood pressure accurately and used for the connection between patient and syringe infusion pump.

S.no	components
01	Transducer dome
02	I.V. SET
03	Pressure monitoring line
04	3-way stop cock
05	Male luer lock

Extension Lines



High Pressure Extension Line

- Suitable for high pressure monitoring
- Kink resistant PVC tubing
- For pressure up to 55 bar (800 psi)
- Priming volume : 0.8 ml/meter
- Tube dia : I Ø 1.0 mm & O Ø 3.0 mm
- Tube Length : 20, 25, 50, 60, 100, 150, 200, 300
- DEHP Free
- **Also available with photosensitive tubing**

Low Pressure Extension Line

- Extension line suitable for low pressure applications
- Kink resistant PVC tubing
- For pressure up to 4.5 bar (65 psi)
- Priming volume : 6.46 ml/meter
- Tube dia : I Ø 3.0 mm & O Ø 4.1 mm
- Tube Length : 25, 50, 100, 150 & 200
- DEHP Free



PVC Free High Pressure Extension Line (Straight)

- Kink resistant PE tubing
- For pressure up to 55 bar (800 psi)
- Tube dia : I Ø 1.0 mm & O Ø 2.0 mm
- Tube length : 10, 25, 30, 50, 85, 100, 120, 150, 200, 300, 400
- Priming volume 0.84 ml/meter



PVC Free High Pressure Extension Line (Coiled)

- Kink resistant PE tubing
- For pressure up to 55 bar (800 psi)
- Tube length : 200 cm, 300 cm & 400 cm
- Tube dia : I Ø 1.0 mm & O Ø 2.0 mm
- Priming volume 0.84 ml/meter

T-Type Extension Set

- Extension Tube T-Type
- Tube Length : 15 cm
- **Also available with Luer lock & Luer slip**



3way stopcock as an accessory to perfusion sets.

Usage Clinical, Hospital
Use Single Use Only
Color Red, White, Blue
Price: Rs 11

Product Specifications
Manufactured from transparent polycarbonate/PE.
Inside is completely smooth & available with moulded luer lock.
Manufactured from non-toxic medical grade material.
E. T. O. Sterile and pyrogen free.
Color : Red/Blue/White



- For multiple infusions
- 360° rotation
- Rotating male luer and two female luer connectors

6. Product Name: Three Way Stop Cock

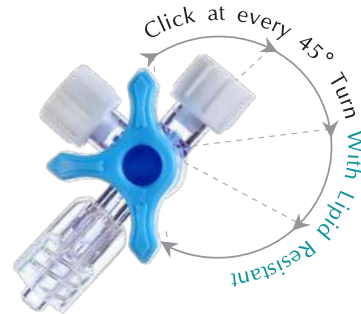


- It provides 3-way flow (from inlet to outlet, inlet to side-port or side port to outlet) by use of the handle on the top of the stopcock to open and close IV Fluid lines.
- The device can also be used to reduce two lines down to one, for drugs/drug infusion purposes and for the attachment of extension lines.
- A blood sample can also be taken via the injection port.
- Key Areas it is used are: ICU, High Dependency Units, Operation Theatre, All wards area generally.
- Device has 3 ports; 2 female ports and 1 male port which are covered with cap. On top a handle is fitted which is used for change-over of flow between each 3 ports individually.

Three Way Stop Cocks Lipid Resistant



Three Way Stop Cock Lipid resistant with 45° Click



Common features

- For multiple infusions
- 360° rotation
- For pressure up to 5.5 bar

Three Way Stop Cock with Extension Tube

- Soft, frosted & kink resistant DEHP free PVC tubing provides uninterrupted fluid movement
- Tube length : 7, 10, 15, 20, 25, 30, 50, 80, 100, 150 & 200 cm
- Tube dia : I (Ø 3 mm) & O (Ø 4.1 mm)
- **Available with rotating Luer Lock**

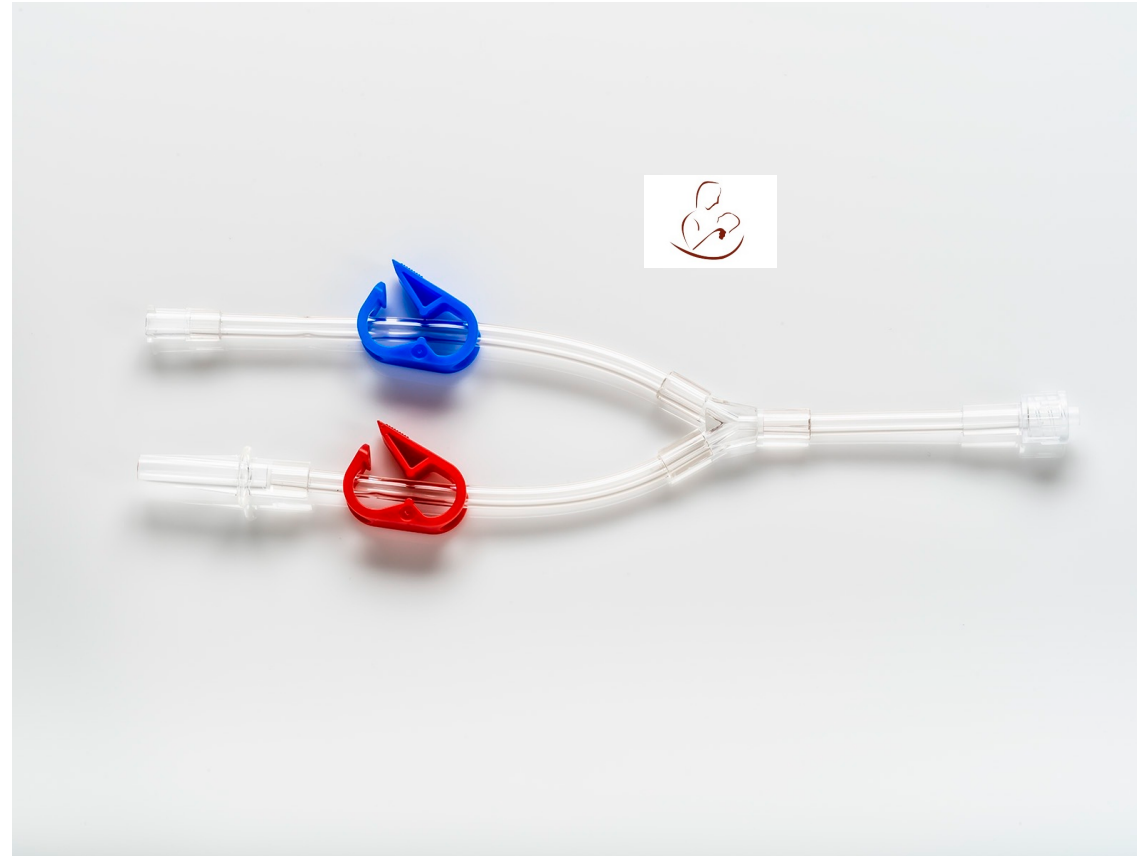


Common features

- Crystal clear transparent channel
- Minimum priming volume required for accurate drug administration
- Rotating male luer and two female luer connectors
- Arrow indication on the handle to indicate the direction of flow
- Connection meets 6% taper requirement to ensure leakage free fitment

7. Product Name: Y-Connector as an accessory to Perfusion Sets

S.N	Components
1	Y Connector
2	Female Port
3	Tube
4	C Clamp
5	Male Luer Lock



Y connector as an accessory to perfusion sets

Usage: Hospital/ Clinical

Material: Polycarbonate

Description: Y-connector. a device in the shape of the letter Y that connects the end of one piece of tubing to two outlets

Color Transparent

Extension Tube: 20 cm

Price Range: 35 - 250

flow rate from 5ml / hr - 250 ml / hr manually.

Built-on "Y" Connector Injection site for extra Medication

Provision of male and female luer lock makes it compatible with other devices.

Available with DEHP Free Material.

Sterile / Disposable / Individually Packed.



WE SPECIALIZE IN

MECCA INFUSION DEVICES

Lightproof Photosensitive IV Administration Infusion Set (Micro Infusion Set)

Product Specifications

- This Infusion set is prepared from Lightproof / Photosensitive polymer materials. Angioplast provides this Photosensitive sets available in Yellow and Brown color and are obtainable with or without Precision Flow Controller [Dial Type] 5 ml to 250 ml/hrs.



Features of our Lightproof Photosensitive Infusion Set:-

- Latex Free.
- Soft, Clear and Flexible Tubing.
- Sterile, Non-Toxic and Pyrogen-Free.
- Sterilized by E.O. (Ethylene Oxide)



- 88" IV Administration Set Vented, Vented Spike 20 Drops-ml with Guard/Brown Color Drip Chamber 60mm/Fluid Filter 15 Micron/ Flow Regulator/Precision Flow Controller 5-250ml-hr. /Latex Free 'Y'-Site/Rotating Luer Lock Male Adaptor with Cap/3.0 x 4.1mm PVC Tubing Brown Colour Length 30+140+30cm/Sterile/Paper Poly Pack/ Quantities per Carton = 300 pcs



- 88" IV Administration Set Vented, Vented Spike 20 Drops-ml with Guard/Yellow Color Drip Chamber 60mm/Fluid Filter 15 Micron/ Flow Regulator/Latex Free Flash Bulb/Rotating Luer Lock Male Adaptor with Cap/ 3.0 x 4.1mm Yellow Color PVC Tubing Length 30+140+30cm/Sterile/Paper Poly Pack/ Quantities per Carton = 300

DCS



- 84" IV Administration Set Vented, Vented Spike 20 drops-ml with Guard/Drip Chamber 70mm/Fluid Filter 15 micron/Flow Regulator/ Dial Flow Regulator/ Latex Free 'Y'-Site/0.2 Micron Filter/Rotating Luer Lock Male Adaptor with Cap/ 3.0mm x4.1mm PVC Tubing-Length 60+50+30+15cm/EO Sterile/Paper Poly Pack / Quantities per Carton = 300 pcs



- it-01a1 82" IV Administration Set Non-Vented, Non-Vented Spike 10 drops-ml with Guard/Drip Chamber 70mm/Flow Regulator/Latex Free 'Y' Site/0.2 Micron Filter/Rotating Luer Lock Male Adaptor with Cap/3.0mm x4.1mm PVC Tubing-Length 115+30+15cm/EO Sterile/Paper Poly Pack / Quantities per Carton = 300 pcs



- 82" IV Administration Set Vented, Vented Spike 20 drops-ml with Guard/Drip Chamber 70mm/Fluid Filter - -15 micron/Flow Regulator/Latex Free 'Y'- Site/0.2 Micron Filter/Rotating Luer Lock Male Adaptor with Cap/ 3.0mm x 4.1mm PVC Tubing-Length 115+30+15cm/EO Sterile/Paper Poly Pack / Quantities per Carton = 300 pcs



- 12" Standard Bore Extension Set, Female Luer with Cap/0.2 Micron Filter/Slide Clamp/Latex Free 'Y'- Site/Rotating Luer Lock Male Adaptor with Cap/3.0mm x4.1mm PVC Tubing-Length 10+10+10cm/EO Sterile/ Paper Poly Pack / Quantities per Carton = 400 pcs



- 12" Standard Bore Extension Set, Female Luer with Cap/1.2 Micron Filter/Slide Clamp/Latex Free 'Y' Site/Rotating Luer Lock Male Adaptor with Cap/3.0mm x4.1mm PVC Tubing-Length 10+10+10cm/EO Sterile/ Paper Poly Pack / Quantities per Carton = 400 pcs

0.2 micron in-line filter fitted Infusion Set



INNOVATIVE "AIR STOP" FEATURE KEY BENEFITS

1. Avoids "Air Infusion" when IV Bottle gets empty & maintains a constant fluid level inside Infusion line so no air can get inside the patient body.
2. Unique Technology "Precision-Filter" acts as a barrier for particulate matter 15 microns & below.
3. Offers "No-Hassle", "Risk-Free" & "Smooth Switch-Over" to next IV Bottle.

INNOVATIVE "PRIME STOP" FEATURE KEY BENEFITS

1. "Auto Fill" of Infusion Set with "No Dripping" of IV Fluid on hands, floors & bedding at time of IV Infusion.
2. Offers ease in Multiple Solution preparations and saves time.
3. Maintains a closed system before the commencement of IV Therapy to a patient.

- * Fitted with Safety Roller Controller offering secure disposal of IV Set after use.
- * Fitted with Rotating Luer Lock for easy fitment to an IV Catheter.
- * Fitted with a Slip Clamp offering ease in temporary stop-over of IV Therapy.
- * Fitted with a Y-Site for Extra Medication

KEY BENEFITS

	Mecca IV Set	Normal IV Set
Air Embolism Risk Free	Yes	No
Time and Energy Savings in Multiple Solution Preparation	Yes	No
Prevention of Infusion Line getting Dry	Yes	No
Smooth Switch Over to next IV Bottle	Yes	No
Maintenance of a closed system before IV Therapy	Yes	No

A Technical Collaboration with ACME UK Inc. Limited, London, Great Britain

Manufactured At: 99, GIDC, Kalol, Gandhinagar, Gujarat, India, Pin: 382721

Contact for a Demo: +91 999 869 9090



CONTACT US

Corporate Office

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Opposite ITC Narmada, Judges Bungalow Road,
Near Mansi Crossroads, Vastrapur,
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Tel; +91 79 4800 5989

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Gujarat, India,
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Tel; +91 2764 221020

UNIT 2 ADDRESS

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Rajasthan, India, Pincode: 342012
Tel; +91 8320107430

Branch Office

L-1202, GIDC Chattral, Dist.
Mehsana, Gujarat India

REGD. OFFICE

408, Spectrum, Near G.P.O., Relief
Road, Ahmedabad-01, Gujarat
India

OUR UK REPRESENTATIVE'S ADDRESS

ACME UK INC LTD

25 Leeming Road, Borehamwood,
Hertfordshire WD64EB
United Kingdom

Website: www.acmevision.com

CERTIFICATIONS



Certificate

No. Q6 104986 0001 Rev. 00

Holder of Certificate: **Mecca Industries**
99-102, G.I.D.C
District-Gandhinagar
Kalol (N.G.), Gujarat 382725
INDIA

Facility(ies): Mecca Industries
99-102, G.I.D.C, District-Gandhinagar, Kalol (N.G.), Gujarat
382725, INDIA

Certification Mark:



Scope of Certificate: Manufacturing and Distribution of Sterile Medical Devices for Infusion /Perfusion/Transfusion & Urology Procedure like IV Set without Needle and Urine Collection Bag.

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: IND2019052
Valid from: 2020-04-30
Valid until: 2023-04-29

Date, 2020-04-30

Christoph Dicks
Head of Certification/Notified Body



EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)
No. G2S 104986 0002 Rev. 00

Manufacturer **Mecca Industries**
99-102, G.I.D.C
District-Gandhinagar
Kalol (N.G.), Gujarat 382725
INDIA

Product **IV Set without Needle and Urine Collection Bag**
Category(ies):

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: IND2019052

Valid from: 2020-04-30
Valid until: 2024-05-26

Date, 2020-04-30

Christoph Dicks
Head of Certification/Notified Body