

# Ami Polymer

"Sealing Expert in Silicone"



TUBING | HOSES | SINGLE USE ASSEMBLIES | BAGS | GASKETS & BELLOWS | INFLATABLE SEALS

## PP BAGS

Solution to IV Infusion



### Certification and Compliance

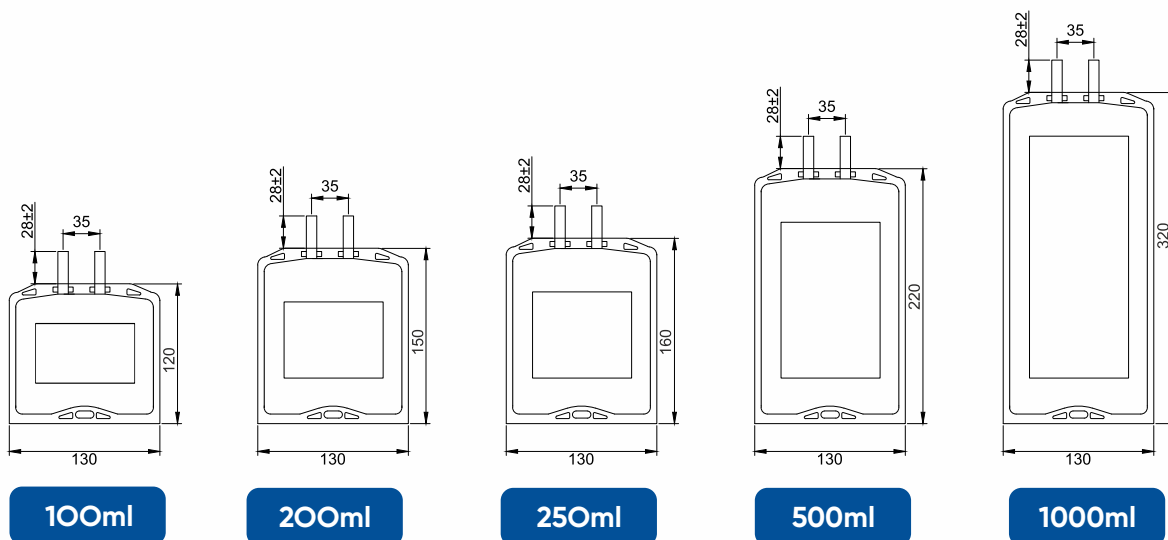




# PP BAGS

## Solutions to IV Infusion

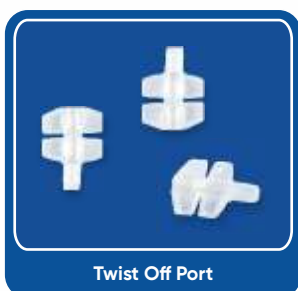
The Ima-I Bag is a single-use, needle-free container designed for intravenous solution administration using an intravascular administration set. Medication transfer in and out of the bag is conducted with aseptic techniques. The Needle-Free Valve facilitates filling the bag with IV solutions, allows for disinfection, and enables access for adding medications. By eliminating needles, our system significantly reduces the risk of needlestick injuries, a leading cause of occupational infections among healthcare workers.



## CHARACTERISTICS

- Clean room facility and documentation is designed to meet ISO 15747 compliance
- Clear polypropylene container allows for optimal visual inspection
- Bag is designed to help minimize medicine waste
- Empty & ready to be filled with custom medications
- Tube port compatible with needleless syringes
- Offered with twist-off or spike ports
- Steam Sterilizable at 121°C
- PVC & DEHP free
- Closed system for administration and delivery
- Elemental impurity Declaration as per ICH Q3D guideline
- IR graph report along with all the supplied batches
- Validation pack available upon request
- Custom printing available upon request

## MISC. COMPONENTS OF IV BAGS





## KEY FEATURES

FILM TYPE	3 Layer PP Film
MANUFACTURING ENVIRONMENT	cGMP Compliant Clean room of class 10000
EXTRACTABLE STUDY REQUIREMENTS	Tested according to PQRI guidelines from USFDA approved laboratory
BIOCOMPATIBILITY CERTIFICATIONS	Compliant with <ul style="list-style-type: none"><li>• USP Class &lt;87&gt;</li><li>• USP Class &lt;88&gt;</li><li>• ISO 10993 standards</li></ul>
MISC. DECLARATIONS	Following declarations available <ul style="list-style-type: none"><li>• TSE/ BSE &amp; Latex free requirements</li><li>• Food grade requirements</li><li>TOTM (TRI OCTYL TRIMELLITATE) declarations</li><li>• Nitrosamine impurities free declaration</li></ul>
REGULATORY FILING STATUS	Registered for DMF type-3 in USFDA, LOA available on request

## APPLICATIONS

- Primary packaging for IV solutions (IV bags)
- Packaging of antibiotics, biotechnology and oncology treatment drugs.
- Packaging of premix injectables
- Suitable for the reconstitution of special pharmaceutical powders or freeze-dried products.
- Packaging of nutraceutical and electrolyte products.

## SIZES AVAILABLE

Catalogue no.	Volume	Tubes or boat port	Connectors	Dimensions(mm)
PP-0100-001	100 ml	2	As per the requirement	120X 130
PP-0200-001	200 ml	2	As per the requirement	150X 130
PP-0250-001	250 ml	2	As per the requirement	160X 130
PP-0500-001	500 ml	2	As per the requirement	220X 130
PP-1000-001	1000 ml	2	As per the requirement	320X 130



## Our Presence In World



## Our Branches in India

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### MANUFACTURING UNIT- II

Survey No. 106/2/1, 106/2/2, 113/3/P1, Opp. Guarniflon India Pvt. Ltd, Karajgam Road, Village Kala, Khanvel, UT of Dadra & Nagar Haveli and Daman & Diu, India 396230



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