

Ami Polymer

"Sealing Expert in Silicone"



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

PP FILMS & BAGS

Solution to IV Infusion



Certification and Compliance



The Company believes in "Be in business with ethics" and assure Quick Development, Fastest Delivery, Ultimate Quality and also very Competitive Rates.



About Us

Since 1998, APPL is in the business of Silicone Elastomeric product and also, other Polymeric components which ultimately provide solutions to Fluid Transfers, Sealing and Contamination controls for Biopharma, Pharma, Medical, Laboratory, Food, Beverages, and Engineering sectors worldwide.

Our Strength

New manufacturing facility with a total area 3,50,000 sq. ft. in Kala, Dadra Nagar Haveli & Daman and Diu, including a 1,00,000 sq. ft. clean room. We supply to 25+ brands with a global presence in 50+ countries and employee over 700 skilled professionals. Our world-class capabilities include extrusion, molding, tooling, and laser-controlled systems. We offer rapid development of customized single-use manifolds and assemblies, supported by a cutting-edge research lab and hose crimping facility.

Accolades include the Asia-Pacific Bioprocessing Excellence Award for Best Bioprocessing Supplier (Single-Use Consumables) and various USFDA Drug Master Files. Our certifications include Clean Room Class 10000, NSF-51, BPOG standardized extractables tests, and TUV Nord IMS (ISO 9001, 14001, 45001, 27001, 13485). We have a high performance credit rating and a track record of developing 5000+ customized products for over 3000 global customers.

Company Overview

45+
Rubber Technologist

Annual Turnover
USD 25 million

700+
Employees

Exporting to **50+**
Countries

Audited by **150+**
Companies

ISO 13485 & BPOG

ISO Class **7 & 8**
Cleanroom

FDA Approved

New Facility of
3,50,000 sq.ft Area

In House Tool
Designing and R&D Labs

Awards & Recognitions



Best Bio-Processing Supplier for Single-Use Systems, awarded by Biopharma Excellence Award by IMAPAC 2024



Exceptional Partnership recognition from Biocon Biologics at the Supplier Conclave 2023.



Asia Pacific Bioprocessing **Excellence Awards 2023** hosted by IMAPAC



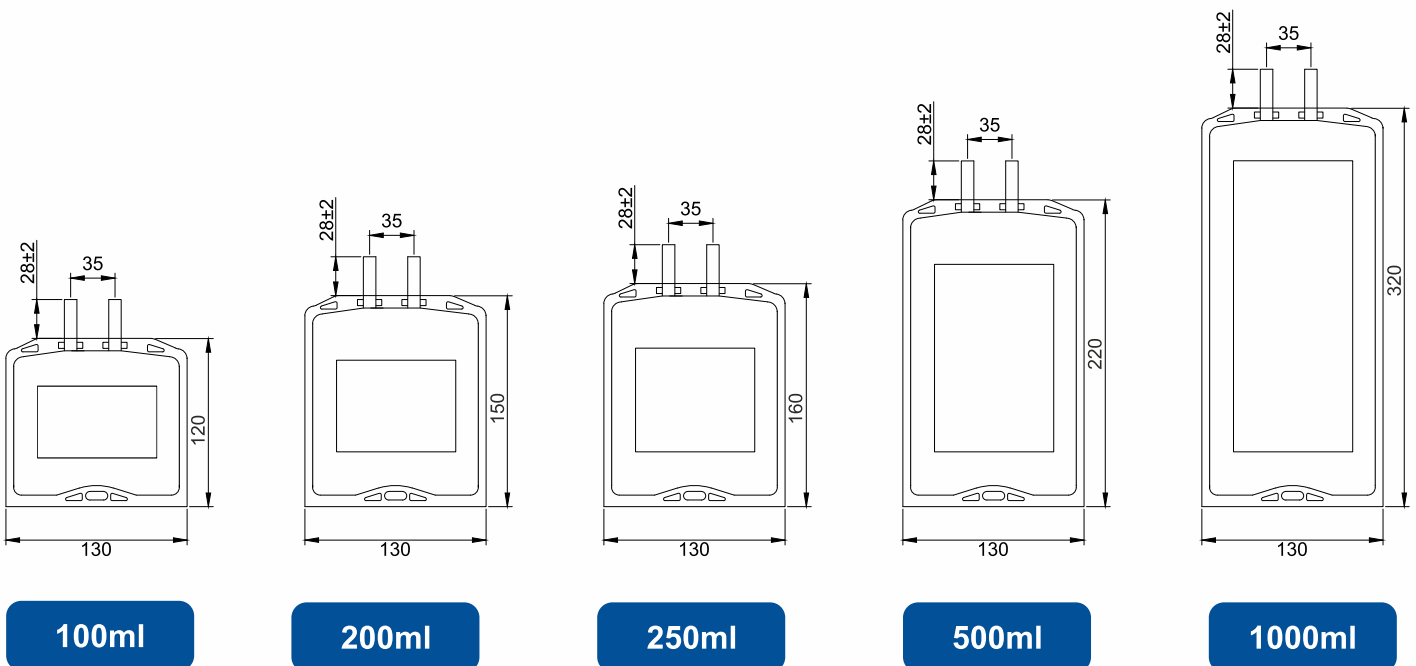
Proud Top Supplier to Vikram Sarabhai Space Centre, Honored to received award by ISRO Chairman Mr. S Somanath at HEMCE 2024!"



PP BAGS

Solutions to IV Infusion

It is 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 needle stick 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

KEY FEATURES

FILM TYPE	3 Layer PP Film (Imaflexell™ 301)
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">• USP Class <87>• USP class <88>• ISO 10993 standards
MISC. DECLARATIONS	Following declarations available <ul style="list-style-type: none">• TSE/BSE & Latex free requirements• Food grade requirements• TOTM (TRI OCTYL TRIMELLITATE) declarations• Nitrosamine impurities free declaration
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.

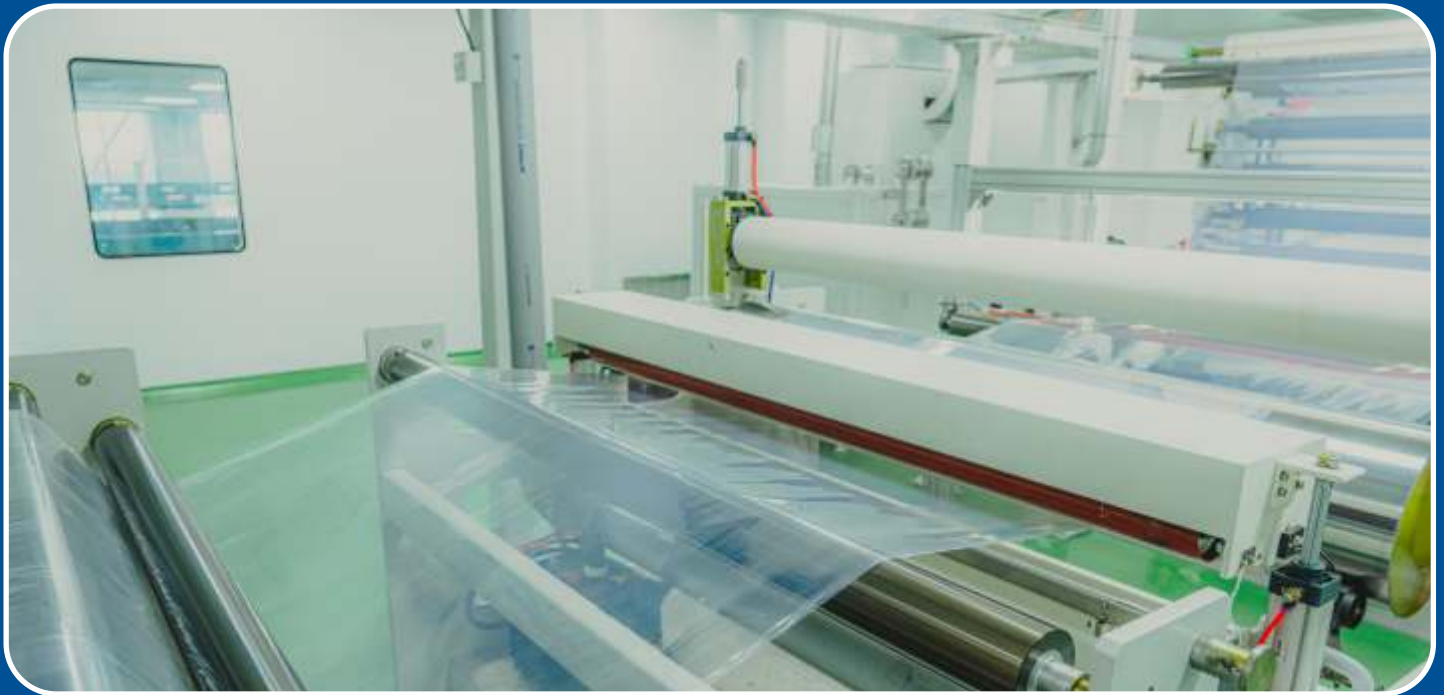
SIZES AVAILABLE

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

Imaflexell™ 301

Primary Films for IV solutions

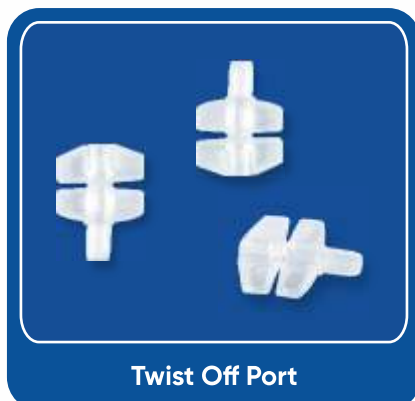
Imaflexell™ 301 is a specially formulated 3 layer coextruded PP film designed to meet critical requirements of IV primary packaging. It is supplied in double wound flat film with customized widths as per client's requirement. It most reliable and cost effective material for IV bags which can be used on the highly efficient fully automated heat seal machines.



CHARACTERISTICS

- Manufactured and packaged in cGMP compliant clean room class 10000 facility
- Medical grade RM granules ensures contamination free product
- IR graph report along with all the supplied batches
- Excellent compatibility with the IV solution
- Good sealing properties supports high quality leak proof bag manufacturing
- Sterilization temperature up to 121 °C
- Compliant with USP Class < 87>, USP class <88>, ISO 10993
- DMF Filing (type-3) (Application filed)
- Extractable study report available upon request
- Elemental impurity Declaration as per ICH Q3D guideline
- Complies to TSE/BSE & Latex free requirements
- Validation report available upon request

MISC. COMPONENTS OF IV BAGS



Twist Off Port



Spike Port



PP Tubing



Our Presence In World



Our Branches in India

BADDI (H.P.)

+91 9816 595 011/+91 9218 595 011
baddi@amipolymer.com

BENGALURU

+91 8123 023 922
support1@amipolymer.com

CHENNAI

+91 7738 788 877
chennai@amipolymer.com

DELHI

+91 9977 600 935
harsh.s@amipolymer.com

GOA

+91 9223 290 943 / +91 9223 290 940
goa@amipolymer.com

AHMEDABAD

+91 9152 032 305/ +91 9712 588 819
guj@amipolymer.com

HYDERABAD

+91 7700 908 414/ +91 9515 113 662
hybd@amipolymer.com

INDORE

+91 9712 588 819 / +91 9512 273 730
sanjay.p@amipolymer.com

MUMBAI

+91 9223 290 943 / +91 9512 283 830
mumbai@amipolymer.com

HARIDWAR

+91 9977 600 935/+91 7718 888 743
roorkee@amipolymer.com

SIKKIM

+91 9512 274 748
sikkim@amipolymer.com

VIZAG

+91 7700 908 414/ +91 9515 113 662
hybd@amipolymer.com

PUNE

+91 9512 298 787
hrishikesh.g@amipolymer.com

SILVASSA

+91 9223 290 934 / +91 9512 235 354
rohit.s@amipolymer.com

ROI

+91 9223 290 936
info@amipolymer.com

CORPORATE OFFICE

Office No. 6 & 7, Upper Basement, Western Edge II, Behind Metro Stores, W.E. Highway, Borivali, Mumbai, Maharashtra - 400066
Cell: +91 9081 488 825/ +91 9223 290 943

USA OFFICE

800 West Cummings Park, Suite 3325 | Woburn, Massachusetts 01801
Cell: +1 (978) 482-5400/+1 (267) 810-3834 | Email: usa@amipolymer.com

MANUFACTURING UNIT- I

Plot No. 66-D/E, Govt. Industrial Estate, Near Beekaylon Factory, Masat, Silvassa, UT of Dadra & Nagar Haveli and Daman & Diu, India 396230

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