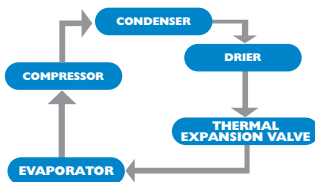


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# Yantra

Yantra is an ancient Sanskrit word for any kind of device designed to perform a particular action

## 25 years of Customer Service



C Balagopal  
Managing Director

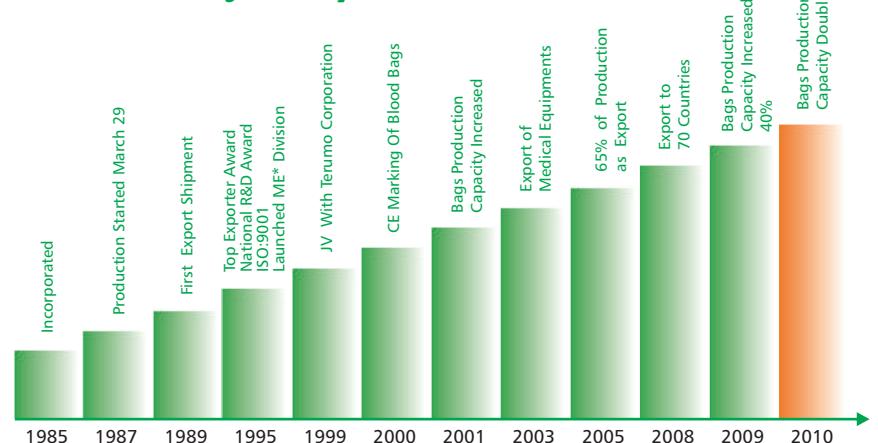
Terumo Penpol Limited will enter the 25th year of operations in April 2010. It is proposed to conduct various programs during the coming financial year to celebrate this important landmark.

During this time, TPL has grown from a small beginning to become the leading manufacturer of products used in the Blood Transfusion sector in India as well as in many important export markets.

TPL today produce a wide range of blood bag systems including the advanced sets equipped with safety features. Blood bag systems equipped with inline filters will shortly be supplied to key markets. TPL produces a wide range of equipment used in modern blood centers to collect, store, and process blood and components. TPL has truly become a total solutions provider for the Blood Transfusion sector.

The commitment of TPL to a high level of customer service will continue, and the company will seek new ways of engaging with customers to enable their processes and outcomes to meet high standards of safety and quality.

### Journey of TERUMO PENPOL



\* ME - Medical Equipments

### Whats ahead ?

Emphasis on special projects for the local community as part of Terumo Penpol's silver jubilee year.

Yantra is an ancient Sanskrit word for any kind of device designed to perform a particular action

2 | 10 Jan-Mar 2010

Bulletin of  
Terumo Penpol Limited  
For Internal Circulation



**Standardisation of Medical Systems Group's quality certification by TUV Rheinland Cert GmbH as part of Terumo Penpol's corporate quality policy.**

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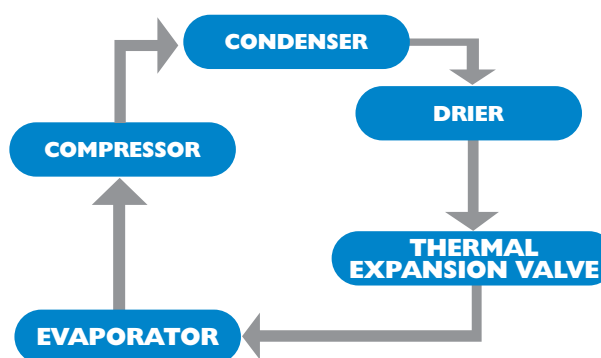
## TECHNOLOGY

# Ultra Low Freezing

Ultra low freezing is essential for the safe storage of plasma. Depending on the requirement of plasma products, temperature from  $-25^{\circ}\text{C}$  to  $-86^{\circ}\text{C}$  is used for storage. Among the different technologies for producing and maintaining ultra low temperatures like Liquid Nitrogen,  $\text{CO}_2$ , Compressor Refrigeration etc, the most viable method of refrigeration is by the use of Compressors.

In Compressor based systems, depending on the requirement of temperatures, different systems are used for attaining low temperatures. For up to  $-40^{\circ}\text{C}$ , single stage refrigeration system is adequate, but for temperatures below  $-40^{\circ}\text{C}$ , multiple stages of refrigeration are required. Multiple stage refrigeration system is also known as cascade refrigeration system.

### SIMPLE BLOCK DIAGRAM OF A SINGLE STAGE REFRIGERATION SYSTEM



- Once the compressor starts, the Low pressure vapour refrigerant is compressed and discharged out of the compressor as a high temperature, high pressure, "superheated" vapour.
- The condenser changes this high pressure refrigerant from a high temperature vapour to a low temperature liquid and this leaves through the "Liquid Line". This is where the actual cooling takes place.
- The high pressure refrigerant then flows through a filter dryer to the Thermal Expansion valve which meters the correct amount of liquid refrigerant into the evaporator. Here the high pressure liquid refrigerant changes to a low pressure, low temperature, saturated liquid/vapour.
- This saturated liquid/ vapour enters the evaporator and is changed to a low pressure, dry vapour which returns to the compressor through the "Suction line".

**Cascade Refrigeration systems:** Deep temperatures below  $-40^{\circ}\text{C}$  can be achieved by cascading of refrigeration system. This arrangement makes use of two refrigeration systems with two different refrigerants. Even though there are two separate systems, the "Condensor" of second system is placed in the "Evaporator" of first system. This is placed in a closed chamber called the "Heat Exchanger", where as the name indicates, the effective heat transfer from the first stage to second stage takes place. When first stage condensor generates extremely cold (around  $-40^{\circ}\text{C}$ ) temperatures, second stage can generate further low temperatures, which results in attaining ultra low temperatures of  $-80^{\circ}\text{C}$ .

## CUSTOMER SPEAK

# Terumo Penpol helps to provide safe blood



All India Institute of Medical Sciences, a premier medical institute, in India are pioneers in blood banking practices. AIIMS blood bank has been using leuko-depletion and buffy coat method to serve the patients with high quality blood products aimed to have better recovery with no side effects due to leukocytes.

Dr. Kabitha Chatterjee, AIIMS who is a regular user of TERUMO's IMUGARD® III filters says "The primary Goal of every Blood Transfusion Service is to provide patients with the safest possible Blood products.

Terumo Penpol helps us to give the Right Blood to the Right Patient at the Right time.

Terumo Penpol has come out with filters for Leuko reduction-both standalone labside/bedside filters and Inline RC filters. Primarily the effect of Leukocyte reduction can be summarized as Reduction of :

- FNHTRs (Febrile Non-Hemolytic Transfusion Reaction) due to non leuko depleted RBC
- Human Leukocyte Antigen (HLA) allo-immunization
- Transmission of Leukotropic viruses (HTLV-1, CMV)
- Immuno modulation

# Blood Bag Manufacturing

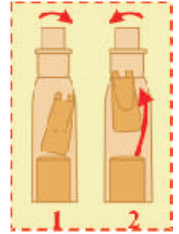
## Process Improvements

- Sterilization validations are carried over as per International Standard – ISO 17665-1, which deals with Requirements for the development, validation and routine control of a sterilization process for medical devices.
- Introduced conveyor system online production for standardization of primary packing of products.
- Introduced completely automatic Double nozzle Filling system for anticoagulant and additive solutions.
- Complying with safety standards for online production and Quality Control.

## Product Quality Improvements

- Extrusion of High molecular weight sheet with imported PVC pellets.
- Imported click tip assembly, which facilitates easy breakability and smooth flow of components.
- Incorporating symbols on labels as per International standard requirements for medical devices, ISO-15223-1.
- Introduced bar coding system on product labels for domestic market.

### Click Tip Assembly



Facilitate easy and smooth flow of blood by break opening in either direction.

## ALTERNATE APPLICATION

# Deep Freezer -80 in Tissue Banking

Deep freezers, as the name indicates, are generally used for long term preservation of materials in frozen condition at recommended temperatures. Terumo Penpol manufactures Deep Freezers primarily for storage of Plasma in a Blood Bank.

**The bone allografts can be stored upto 3 years at -80°C.**



In recent years, it is being widely used in Hospitals & Laboratories too. Bone bank, Microbiology, Pathology, Biotechnology, Virology, Gastroenterology, Neonatology, Endocrinology are a few locations for alternate usage of Deep Freezers.

Deep Freezer is an imperative storage device in bone banking. TERUMO PENPOL had supplied its Deep Freezer -80 (DF 80U) to Ganga Hospital Tissue bank (Bone bank), Coimbatore for storage of Gamma irradiated bone allograft in frozen conditions.

The bank is currently using well processed and gamma irradiated cortico cancellous bone allografts from tibial slices

and femoral heads, bones from amputated stumps in various clinical conditions like comminuted fractures and non-unions with bone loss of both upper & lower limbs, revision joint replacement surgeries and spinal fusion surgeries.

A Tissue bank is a facility that is capable of providing a complete spectrum of human tissues that have clinical usefulness as Fresh or Preserved allografts (grafts between different individuals of the same species).

The bone allografts can be stored upto 3 years at -80°C.

In a Bone bank, before storing the bones in the deep freezer, it has to undergo the following procedures.

1. Sterile procurement of bone  
Sterilization at 60°C
2. Pasteurization  
Placed in a shaker with water
3. Ultrasonic therapy  
Remove fat
4. Alcohol therapy  
Wash with alcohol
5. Lyophilization  
Vaccumisation using an equipment (The bones will be placed in vaccumizing equipment)
6. Sterile packing  
Placed in Laminar airflow and packed.
7. Gamma irradiation  
To kill microorganisms- Gamma irradiation is used.
8. Store at -80 degree in Deepfreezer

Bone allograft under room temperature can be later incorporated in human body, based on clinical requirement.

# Sampling Bag

The sampling bag was developed based on customer requirements from Terumo branch in Europe, and their intent was for a system for sampling, during storage of blood components.

Sampling bag is a device that provides a system for collecting blood samples. This can be used at the time of collection or storage. In a way this can be used in closed multiple blood bag system environments, which assures accurate cross matching and typing of cellular blood components prior to transfusion.

If sampling is required before transfusion and is not done in a closed system, then there is a probability for the system to be potentially open to bacteria and other contamination. Also there is an adverse effect on the maximum available

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storage periods of the components. The advantage of a closed system of sampling is that blood components may be stored to the limit of their viability.

This device consists of a flexible PVC bag of 50 ml capacity and a sampling arm, with luer adaptor and holder to enable multiple sampling. The tubing of the blood collection and/or storage container

is connected to the tube of the sampling bag using sterile connecting device. The tube is sealed at the desired position after transfer of the required volume of blood to the sampling bag. The vacuum tubes are then inserted firmly into the tube holder to collect the sample thus maintaining a functionally closed system.



**ISO 3826-3:2006(E) which deals with Plastic and collapsible containers for human blood and blood components, has clause 5.2 that specifies requirement for Pre- donation sampling device. Terumo Penpol sampling bag is designed based on this requirement.**

## INITIATIVE

# “GEMBA JISSHU” Training at Work-spot

As part of customer support initiatives, Terumo Penpol associates visited Terumo Branches and Blood Centres for promoting Terumo Penpol Medical Equipment and for providing technical support during January 2010.

Mr. Shinu Nair, Asst. Manager (Development) and Mr. S. Vinod Kumar, Asst. Manager (Export) visited major Blood Centers in China & Hong Kong in order to understand the requirement of the customers and actual usage of Terumo Penpol Medical Equipment by each Blood center. The visit was well appreciated by technicians of major blood centers in China and Hongkong.

In order to enhance product knowledge, a training program was conducted at Terumo Corporation, Malaysia, during the period from 18th to 19th January 2010. The twenty participants mainly included Terumo associates and major distributors. There was good amount of interaction among the participants and various

questions were raised during the program. The training mainly focused on giving the introduction, product features and maintenance procedures of Terumo Penpol equipment. The program was well structured and gave assurance to the participants that Terumo Penpol is a Customer focused Company and always prioritized to meet the customer requirement.

