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INTRA UTERINE DEVICE - COPPER T

Plastics play an important role in the bio-medical applications. Due to their inert properties and the required flexibility, plastics parts can be implanted inside the human body to perform the designed task.

One of such applications is for a device used for family planning activity.

Govt. of India has taken several initiatives for the family welfare programme to curtail rapid population growth. Introduction of various contraceptive choices is one among them.

The National Welfare Programme offers the following :

1. Natural Methods
2. Barrier Methods
3. Spacing Methods
4. Terminating Methods

Of these, Spacing Method, using Intra Uterine Devices (IUD) is widely popular.

These IUD's are classified into 2 categories :

1. Un - Medicated
2. Medicated - that is copper or hormone releasing

In the 60's and 70's, Lipper Loop and Margulies Spiral were widely used. These were made of Low Density Polyethylene, compounded with Magnesium Sulphate (MgSO₄). These devices were implanted within the body and were easily removable by medical doctors.

Mechanical design of the device is of extreme importance, though the plastic material per se causes no harm to body function.

After the initial feedback of higher expulsion rate, subsequent research enabled the addition of pure copper to the Plastic 'T' - frames, increasing the effectiveness of the device and reduction in expulsion rate.

The full set of Copper-T - device comprises of :

T- frame

Low Density Polyethylene
Compounded with Barium
Sulphate

Pure Copper Wire

Pure Copper (99.9% purity)

A Thread

High Density Polyethylene

Insertion Tube

High Density Polyethylene

Flange (Cervical Stop)

Polyvinyl Chloride

Displacement Rod (Solid Rod, Plunger)

Polypropylene

A Pouch (for packaging)

Spunbonded Polyethylene Sheet
(Ethylene Oxide Permeable)

Except the Pure Copper Wire, all other parts are made of different Plastics materials, emphasizing the utility, safety and versatility of plastics.

Description of a Cu-T Device :

The Intra-Uterine Contraceptive Device is a mechanical device for insertion into the uterus to prevent pregnancy. The T-device consists of Low Density Polyethylene, compounded with barium sulphate, with a thread of High Density Polyethylene at its base and high purity copper wire wound around the stem of the T. The device is supplied along with insertion tube made of High Density Polyethylene, a solid rod, made of Polypropylene, containing a pinch of titanium dioxide



and a flange made of Polyvinyl Chloride pigmented with a blue dye.

The Copper-T frame has a ball at the tip of the stem. All the components are packed in plastic pouches, which are sterilized and stored for long-term, upto 4 years. The Copper-T and the thread, both of which are made of Plastics, and the copper wire have to remain inside the body for a period of about four years. Therefore, these are considered critical components. Hence, long term toxicity, degradation, sterilization and stability are some of the important characteristics, which are studied thoroughly for these components.

Whereas displacement rod, insertion tube and flange - all of which are plastic components, help to place the device in uterine cavity and thus have short term contact with inner body parts, and hence are considered semi-critical devices.

Among the plastics components used for complete Copper-T device, the material used for making the 'T-Frame' is extremely critical.

The specification for 'Copper-T' has been described in the Indian Standard, IS: 124 18 Part 4, which is similar to that followed in the USA.

Main Tests conducted on the Copper-T are:

FLEXIBILITY TEST:

Horizontal arm of T provides structures to the device and exerts mechanical forces on the uterine cavity that takes the shape of the uterine cavity on implantation. Flexibility plays an important role to have effective forces on the wall and needs to be kept in specified limits. Clinically it has been observed that lesser or greater values of flexibility contribute to pain and bleeding on account of alteration in the mechanical forces.

The flexibility test is extremely critical, as per the standard. The frames are sterilized by Gamma Ray at 2.5 and 5.0 mega rad. The flexibility values are maintained after the sterilization also.

MEMORY TEST:

The memory is the ability of the device to get back to its original shape after distention within a short span of time. Memory is measured in terms of recovery after acute flexion. Clinically in memory deficient 'T', expulsion and perforation of the uterine cavity have been observed.

STERILITY TEST:

The "Copper-T's", after moulding, are subjected to Gamma Radiation and sterility is tested under sterile condition as per requirements listed in Indian Pharmacopoeia.

FOURIER TRANSFORM INFRA RED SPECTROSCOPY:

The raw materials as well as the blends are analysed with the help of Fourier Transform Infra-red Spectroscopy.

The spectra gives the infra red absorption bands corresponding to C-H stretching, C-H bending of CH₂ groups and CH₃ and CH₂ rocking of sequences of methylene groups.

This is done to compare the raw material and its blend's properties with that of an earlier accepted sample.

DIFFERENTIAL SCANNING CALORIMETER (DSC) AND THERMAL GRAVIMETRIC ANALYSIS (TGA):

Thermal analysis of polymers done by DSC and TGA give the information regarding the characteristic changes in the material with respect to degradation, crystallization, annealing and their chemical changes with increasing temperature. These are necessary tests for identifying and characterizing the purity of the raw material.

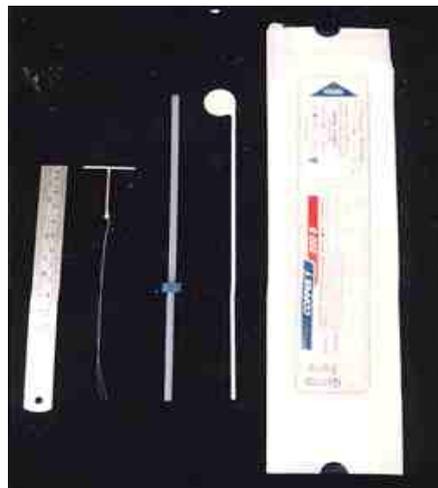
Other tests which are carried out are:

EXTRACTIBLE TEST:

Pre-determined quantity of the material to be tested is mixed with vegetable oil and heated at a standard temperature for 24 hours. Then the mixture is brought to room temperature.

Rabbits are injected with the extract. Side by side, tests are conducted with known negative control sample also.

Any change in behaviour of the animal is observed.



IMPLANTATION TEST:

This test method is used to provide information on the effects of the direct contact of a Copper-T material with the living tissues when implanted into the para-vertebral muscle of the rat/rabbit for a certain period. This test is intended for long term use of the IUD's within the uterine cavity.

All the components, originally of imported source, and later on INDIGENISED, passed these critical tests, and were approved for use as implanted device.

The information is a summary of the theoretical points of a report submitted by National Centre for Technological Evaluation of IUDs and Tubal Rings, Centre for Biomedical Engineering, Indian Institute of Technology (Delhi) and All India Institute of Medical Sciences, New Delhi.

Others associated in the project were :

DST : Department of Science and Technology
DRDO : Defence Research and Development Organisation
ICMR : Indian Council of Medical Research
DMRL : Defence Metallurgical Research Lab
IPCL : Indian Petrochemical Corporation Ltd.
HLL : Hindustan Latex Ltd., and other processors of 'Copper T'

ICPE Initiative

Plastic Industry Announces the 'Clean Mahabaleshwar' Programme

The Indian Centre for Plastics in the Environment (ICPE) and the Maharashtra Plastics Manufacture Association (MPMA) partnered with Mahabaleshwar Giristan Parishad and Bisleri to launch the "Clean Mahabaleshwar" programme on September 19, 2003. The programme was launched by Mr K.G. Ramanathan, President, Governing Council, ICPE.

Mahabaleshwar, the Queen of all Hill Stations, situated at an altitude of 1,372m in the heart of Sahyadri Hills, Maharashtra has been a major tourist attraction over the past many years. However, irresponsible littering and garbage disposal has led to a mounting garbage problem. The "Clean Mahabaleshwar" programme is a collaborative effort between the plastics industry, local government, local businesses in Mahabaleshwar and corporates to manage the issue of garbage disposal and littering. Mr Gopal Rathi, President of MPMA and Mr Mahesh Komti, Vice President, Mahabaleshwar Giristan Parishad were also present during the launch of the programme.

The Mahabaleshwar Giristan Parishad has allocated space where dry waste collected from hotels, shops, markets and other points would be dumped and segregated. ICPE will provide 2 representatives to segregate the waste that will be sent to the recycler. In addition, MPMA, Bisleri and ICPE will also donate hoardings with bins to be installed in appropriate public locations like the market, lake, bus stand etc. These will generate awareness among tourists on responsible disposal of waste. Speaking on the occasion, Mr K.G. Ramanathan, President, Governing Council, ICPE said, "With this initiative, the plastic industry continues with its efforts to promote the responsible disposal of garbage and overall waste management. ICPE implemented a similar programme in Matheran and met with tremendous success. We now hope to preserve and clean up Mahabaleshwar. Ultimately, it is a joint effort between tourists, residents, hotels, shops, regulatory authorities and the industry."

ICPE aims at improving the knowledge and understanding of the environmental benefits of the responsible use and disposal of plastics. It represents the industries efforts to encourage, promote and support upgradation of plastic waste management in India. One of their key activities is to develop and implement waste management programmes, and generate awareness and educate people on littering and responsible disposal of waste.

DID YOU KNOW?
**In Europe and U.S.A.,
plastic waste
makes up only 8% of
the total municipal
solid waste**





PAHAL SCHOOL PROGRAMME

Pahal 'Paryavaran' an Environmental Initiative

Introduction

Education in India has so far focused mainly on the academic aspect of the students. Schools are unable to give children the experiences, which will help students to be competent and skilled to enter the world of work and participate actively in decision-making as well as in the cultural and political affairs of the community of which they are a part. An attempt was made by the government to expand the role of the schools by encouraging school community partnership under the Total Literacy Campaign.

Under this campaign:

- Students participated in the teaching-learning process organized for the illiterates
- Teachers and students helped in community mobilization on a large scale
- Community residents interacted actively with school authorities

Based on the success of the Literacy Campaign in Mumbai, the Paryavaran (Environment) Project was initiated by PAHAL in December 2000. PAHAL was an informal group consisting of five non-governmental and governmental organizations and five secondary schools of Bhandup. Their objective was to come together and make interventions in crucial

areas of school education. It was at the behest of PAHAL that the Environment Initiative (Pahal Paryavaran) was started in Bhandup by five secondary schools of Bhandup, an eastern suburb of Mumbai with financial support from MMRDA (Mumbai Metropolitan Regional Development Authority). The five schools adopted 5 slum areas in close proximity to their schools with the specific objective of creating awareness among the community residents about issues relating to the environment

Why Environment - Rapid urbanization in the last century has resulted in considerable degradation of the urban environment that has upset the development - environment equation and has posed a severe threat to the very survival of the cities.

The indifference of the civic authorities as well as the citizens to the issues aggravates the problem. An initiative towards the goal of sustainable development must start with the education of the stakeholders about the subject.

One of the most important and lasting efforts to educate the citizens on social and civic issues is to focus on the school going children. An exposure to the children at this formative stage helps them to internalize the

environmental issues and thus it becomes a part of their social and public behavior.

The Pahal Paryavaran Initiative (environmental initiative) was started with the specific objective of creating awareness among the students and teachers and through them in the adopted community, on issues relating to environmental degradation, on an experimental basis for a period of one year.

Results of the Paryavaran Initiative

The evaluation of the project after a year of implementation showed the following results:

- Awareness about broad environmental issues was created e.g. the depletion of tree cover
- On the problem of rampant use of plastics, and their effect on health and living conditions of human beings, greater awareness was created among the stake-holders (1000 adopted families, 500 school students and 25 teachers)
- Interface was facilitated between the community residents, schools, municipal and government authorities: by organizing municipal authorities meetings and cleanliness programmes by the community based organizations
- School children learnt the art of communication and gained self-confidence, as they were actively

DID YOU KNOW?

Polyethylene nursery bags are used for growing seedlings for plantation crops all over the world

involved in survey, organizing community meetings, awareness programmes etc

- The teachers were able to mobilize community support on a large-scale, this was especially visible when local residents came forward to help the school authorities in organizing meetings, rallies, cleanliness drives, survey etc.
- The civic and the local people's representatives also gave their full support to the programme

The Present Project

The present project focuses on creating awareness about solid waste disposal and slum sanitation. The problem is caused by the inefficient management of the solid waste by the civic authorities as well as indiscriminate disposal of the waste by the citizens. This gets very serious in the slums, where the civic authorities do not provide the regular conservancy services. Social mobilization on this issue is therefore of utmost significance.

Objectives of the Project

The objective of the project is to focus on slum sanitation, segregation of garbage and its proper disposal and thereby create awareness about the Slum Adoption Scheme.

Beneficiaries

It is proposed to involve at least 100 students of standard eight who will



adopt at least 2000 families from the adopted slums thus covering a population of 10,000. These students will create awareness and monitor the Slum Adoption Scheme. The project also proposes the active involvement of the municipal authorities, and the local community based organizations (CBOs) in the actual implementation of the programme.

Project Schedule and Activities

The project will be implemented on pilot basis for a period of six months from August '03 to January '04.

*First Phase: - Planning
(August 20 to September 20, 2003)*

This phase will involve

- Identification of the areas for study and adoption by the Community Based Organizations for undertaking the implementation of the programme, development of the training module for students, teachers, CBOs.

*Second Phase: - Implementation
(September - December '03)*

The phase will include

- Shramdaan by the students, teachers, CBOs, officials, etc for cleaning the area.
- Tree planting, health camps, visits to vermiculture plants, etc.
- Constant monitoring of the Slum Adoption Scheme and mid term evaluation.

*Third Phase: - Final Phase
(December '03 - January '04)*

This phase will involve

- Students showcasing project work done by them.
- Evaluation of the project (methodology of monitoring and evaluation-Annexure C).

Expected Outcomes of the Programme

This programme will result in an increased school and community interaction

- the students will learn about the working of the municipality and the different schemes floated by it
- the implementation and success of the SAS will have greater importance for the community
- convergence of local needs and civic decision making
- local representatives will be involved actively in the programme
- identification of felt community needs with convergence of MCCB and CBO at planning phase; at final phase this will have been achieved.

The project will be implemented on a pilot basis. It will be so devised that it can be replicated in other schools also and thus become part of the school curriculum.

(Estimates of expenditure on the project - Annexure 'D')





Plastics in Healthcare Help Save Lives

*By Prof. A.K. Ghosh of IIT, New Delhi, and
Dr R.S. Dhaliwal, Indian Council of Medical Research, New Delhi*

Imagine healthcare without plastics today! For more than 40 years, plastic medical products from disposable syringes to intravenous fluid and blood bags to heart valves have helped doctors and nurses save innumerable lives. It is plastics-based technology that has made life-saving and life-enhancing surgery possible, like heart valves and hip joint replacement.

Plastics are used for making sutures - the threads that are used to stitch tissues like muscles and skin. Doctors use polyglycolic acid for stitches which get absorbed, and nylon or polyamide for stitches that are not absorbable. Stents - tubes which keep internal structures like blood vessels and gall bladder ducts open - are also made of plastic.

These days surgeries are usually done with flexible cameras called scopes - like laparoscope for surgery in the abdomen, arthroscope for joint surgery. These scopes too are made up of various plastics and plastic materials with metal reinforcement, to strengthen them. A mesh of polypropylene is used in surgical fields to augment body tissues in the repair of hernias. Even fundamental medical care involves plastics in the form of blood bags, disposables, hygienic medical instruments, safer

spectacles, contact lenses and gradual delivery of medicines via capsules and patches. All of these make better and longer lives a reality for the rich and the poor in developed and developing nations.

Plastics offer a very wide variety of materials ranging from soft rubbers to hard tough plastics, as well as bio-stable and biodegradable materials. They are an ideal class of materials for use in health and healthcare due to their lightweight and bio-compatibility. Plastics are non-corrosive in nature, chemically inert, low in cost and have comparable densities with human organs. In some cases, they may contain additives or reinforcing agents to modify or enhance properties.

There are two types of uses of plastics in healthcare - 1) those used inside the human body or in contact with tissue, blood and/or biological fluids and 2) those used in medical-related applications like packaging, hearing aids, low vision aids and artificial limbs.

The second category covers a wide spectrum and includes dentistry, contact lenses, blood bags, artificial organs, sutures, catheters, syringes, surgical drapes and equipment housing. The biggest potential for growth in the future is in the

development of new plastic systems for implantation in the human body. Some examples of implants include orthopaedic implants, cardiac valves, pacemakers, tracheometry tubes, intraocular lenses, sheet implants and breast implants. The knee replacement surgery of Prime Minister Atal Bihari Vajpayee was done with a durable and mouldable bio-inert plastic - Ultra High Density Polyethylene (UHDP).

These plastics have to adhere to very stringent standards and must be non-toxic, non-carcinogenic, bio-compatible, and in no way injurious in the biological environment. Traditional materials like glass and metal have various disadvantages including packaging problems, fragility and weight, non-flexibility, high co-efficient of friction to withstand fluid flow and high cost. This is where plastics score.

Described as one of the greatest inventions of the modern age, plastics offer a wide range of benefits to society at large. They occupy a unique position in the kaleidoscopic world of materials. Some of the greatest technological developments in the 20th century have been made possible to a great extent by the phenomenal contribution of plastics.

(This article is extracted from the book "Plastics for Environment & Sustainable Development" published by the Indian Centre for Plastics in the Environment (ICPE) and Central Institute of Plastics Engineering and Technology, Chennai)



INDIA

Kanchi villages to have plastic-mix roads

Kancheepuram: In an integrated approach, bringing holistic health and development to the rural areas, the Kancheepuram district administration has evolved a novel scheme of laying recycled plastic-mixed roads in the panchayat areas.

A one-km road has been laid at Kattavakkam to Chettiyarpet on the Grand West Trunk Road connecting the two rural areas. A 10 per cent saving was effected on this by mixing the plastic waste. The total cost of this road of 1.16 km length comes to Rs 7 lakh. Health and clean environment for panchayats also envisages a pollution-free environment and effective eco-friendly waste management, the district collector Venkatesan told journalists here today. Plastic waste segregated

from waste is recycled and then added to the tar and this road is least vulnerable to rain's battering and erosions, he said. Not only sanitation and prevention of disease but also such methods help to keep the air clean, as waste is otherwise burnt and leads to lung diseases. A total of 19 km of link roads are planned to be laid in panchayats this year, Venkatesan added.

<http://in.news.yahoo.com/031021/54/28o5b.html>

INTERNATIONAL

Plastic ring may rival the Pill

A new contraceptive device, a soft plastic ring put inside the vagina is being tested in Brisbane. Family Planning Queensland medical director Dr Caroline Harvey said the ring contained the same hormones as the combined contraceptive pill. The ring, already available in the US and other countries, is worn for three out of four weeks. Dr Harvey said there

were several benefits to using the ring, which was similar to using a low-dose contraceptive pill.

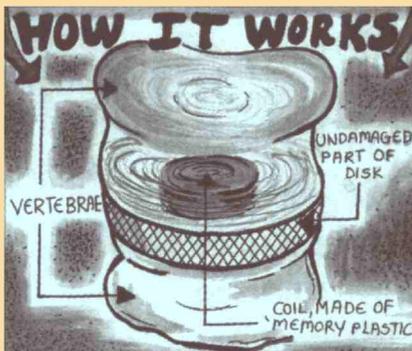
She said instead of having to remember to take a pill every day, women just had to remember to insert the ring every four weeks. "You have a period as you would get while taking sugar pills in a contraceptive packet. With the ring, it simply goes back in after your period," Dr Harvey said.

"The level of hormones in the ring is equivalent to the lowest-dose pills available, and because the hormones don't have to go through the stomach, side-effects such as nausea are less common." She said having sex should not be affected by use of the ring. The device is being tested in 30 sites around Australia through FPQ services, GPs and specialists. A six-month supply of the device will be supplied to participants free of charge. Dr Harvey said further studies were necessary before it could be made available in Australia.

http://www.theaustralian.news.com.au/common/story_page/0,5744,7574378%255e421,00.html

Plastic that cures back pain

A MEMORY plastic has been used for the first time in treating back pain. French and Swiss specialists developed the strip of plastic that can change its shape when implanted in the back. It has been programmed to wind itself into a coil and plug up the space left in the spine, after a surgery, like a disc operation.



It has been designed to replace the inner material of a disc, which comprises two parts. These are the

inner, jelly-like portion, and the outer harder surface. At times, disc operations cause leg and back pain, when the tissue inside them bulges and compresses the nerves. This usually sorts itself out. If not, a discectomy is required to remove this tissue. The 'memory plastic' is then used to replace this material. It functions as a shock absorber to keep the back flexible and provide pain relief. Tests have shown that it is highly resistant to pressure, tear resistant and that it can be compressed several million times as required.

Results from the first trials on patients - men and women aged 24 to 52 - has shown that pain levels were reduced in all those who took part. Functioning of the back also improved, and all but one of the patients have since returned to work.

The specialists who carried out the study say the results show the spiral can restore both the loss in disc height after discectomy and normal working of the spine. An international study assessing the spiral is now underway, and the new implant could soon be used by thousands of patients with a variety of back problems. - Daily Mail, London

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