

IUDs - Development and challenges

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IUDs - Development and challenges

- IUDs –Widely used Non systemic contraceptive
- Long term and short term applications
- Public health programme generic and branded products
- Reversible
- Cost of pregnancy prevention
- Stand alone contraceptive, drug delivery system

Evolution - basic model

- Variants – Design – ‘T’, sleeves, copper content
- ISO 7439 – Generic,
- WHO UNFPA Technical Specification – specific to TCu380 A
– based on the model clinically proven and procured by UNFPA supported programmes
- Other variants also widely used in public health programmes.
- Design specificity and need for innovation and development

Current challenges:

- Design limitations – clinical evaluation
- Limited sources of key components - LDPE for ‘T’ frame, barium sulphate, Copper wire and sleeve – supply and logistics constraints
- Validation of alternate sources/ materials
- Flange – use of PVC
- Need for alternate polymers for insertion rod and tube.
- Setting up Post market surveillance programmes as per requirements of Medical Devices Regulations

Potential areas of development:

- Specifications – pharmacopeia based and evaluated by ISO 10993 – on Chemical characterization
- Need for alternate biocompatibility evaluations based on invitro cell cultures and Chemical characterization - moving away from animal based testing
- Use of packing materials and Films to newer materials complying with ISO 11607 – 2.
- Replacing the printed label inserts with printing on packaging materials with appropriate ink

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Potential areas of development:

- Introduction of barcode and Track and Trace systems
- Design for post partum IUDs and their validation
- Recycled materials for secondary and tertiary packing materials
- Guidance on processing additives used in molding and the removal of residues

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Potential areas of development:

- Sustainable development – support
- Volumes involved
- Provision of resources
- Regulatory requirements
- Time frame involved

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Thank you