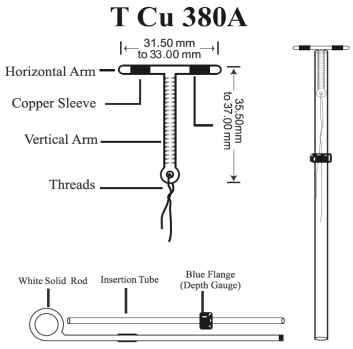
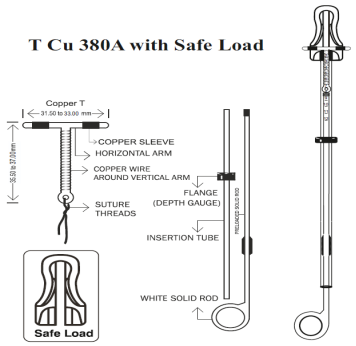
Summary of Safety and Clinical Performance

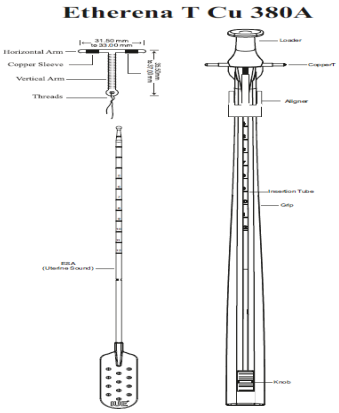
Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound



TCu380A and its Components



TCu380A with Safeload and its Components



Etherena TCu380A and its Components

PREGNA INTERNATIONAL LTD.
Plot No. 219, Survey No. 168,
Dabhel Co. Op. Ind. Soc. Ltd.,
Dabhel, Daman (U.T.)- 396210, India
Phone : +(91)-(260)-3206372/3207093.
Fax : +(91)-(22)-23513484.
www.pregna.com

1. Introduction

The Regulation (EU) 2017/745 on medical devices requires that the manufacturer shall draw up a summary of safety and clinical performance (SSCP) for implantable devices and for class III devices, other than custom-made or investigational devices. The SSCP shall be validated by a notified body (NB) and made available to the public via the European database on medical devices (Eudamed).

The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the medical device. The SSCP will be an important source of information for intended users – both healthcare professionals and if relevant for patients. It is one of several means intended to fulfil the objectives of the Medical Device Regulation (MDR) to enhance transparency and provide adequate access to information.

Conformity assessment is performed according to Annex IX in the MDR.

The SSCP is not intended to:

- Give general advice on the diagnosis or treatment of particular medical conditions, nor
- Replace the instructions for use (IFU) as the main document that will be provided to ensure the safe use of a particular device, nor
- Replace the mandatory information on implant cards or in any other mandatory documents.

The main purpose of this document is to guide the presentation, content and validation of the SSCP. The word “shall” is used when there is a corresponding “shall” in the MDR, otherwise “should” or “recommended” etc. is used to indicate the interpretation of the MDR.

2. Device identification and general information

2.1	Device trade name(s)	Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound
		• Pregna Model T Cu 380A • Securit T IUD Model T Cu 380A • MyChoice IUD Model T Cu 380A • Althea T Cu 380A • Longact T Cu 380A • Pregna+ T-Kare Model T Cu 380A • Pregna+ T Cu 380A • Andalan T Cu 380A • OK IUCD T Cu 380A • Lydia Copper T Cu 380A

		• Heer T Cu 380A Plus • Pregna Standard T Cu 380A • Pregna T Care T Cu 380A • Opset Model Copper T 380A • Trust Copper T Cu 380A • Andalan Classic Cu 380 Dispositivo Intrauterino • New Choice Model T Cu 380° • Elenora + T Cu 380A • Lana T T Cu 380A • Lana T Plus T Cu 380A • Copper T 380A with Safeload • Pregna Model T Cu 380A with Safeload • Safeload T Cu 380A • Andalan Safeload T Cu 380A • Etherena T Cu 380A • Heer T Cu 380A Safeload • Lydia T Cu 380A Safeload • Pregna Safeload T Cu 380A • Pregna Feminin Safeload T Cu 380A • Trust T Cu 380A Safeload • Freedom 10 Copper T 380A with Safeload • Aleze Safeload TCu380A • Elenora Safeload T Cu 380 A • Andalan Classic Cu 380 Dispositivo Intrauterino Safeload • Lana TS T Cu 380A with safeload • Etherena T Cu 380A with Disposable Uterine Sound
2.2	Manufacturer's name and address	PREGNA INTERNATIONAL LTD. Plot No. 219, Survey No. 168, Dabhel Co. Op. Ind. Soc. Ltd., Dabhel, Daman (U.T.)- 396210, India Phone : +(91)-(260)-3206372/3207093. Fax : +(91)-(22)-23513484. www.pregna.com
2.3	Manufacturer's single registration number (SRN)	IN-MF-000010389
2.4	Basic UDI-DI	
i.	T Cu 380 A	89040453pregnaTCu380A00LY
ii.	T Cu 380 A with Safe Load	

iii.	Etherena T Cu 380A with Disposable Uterine Sound	
2.5	Medical device nomenclature description / text	Copper T 380 A was introduced by The Population Council, New York. The specifications laid down by The Population Council as updated from time to time are followed by Pregna International Ltd. and users of these devices, even today. Copper T consists of T shaped body made up of polyethylene compounded with barium sulphate. The body bears the coil of copper wire on its vertical arm. In case of Copper T 380 A, copper sleeves are added on the horizontal arm in order to increase copper content. A monofilament suture thread made up of high density polyethylene is tied to the ball of T Frame at the bottom of vertical arm. This suture thread facilitates periodic checking by the user and also removal of device. Copper T is packed in individual sterile pouches. Each pouch contains one unit of Copper T380 A, Copper T380 A with Safe Load and Etherena along with other components like insertion tube, solid rod flange and safe Load (used for insertion purpose) and label insert. All the components are packed in a Film/Film pouch. Etherena is packed in film/film and or blister pouch. The pouch and or blister are then gamma sterilized and can be stored for up to seven years.
i.	EMDN Code:	U110201 - Intrauterine coils
ii.	MDA/MDN Code:	MDN 1104.2
iii.	MDS & MDT Codes:	MDS 1001, MDS 1005 MDT 2001, MDT 2002, MDT 2008, MDT 2011
2.6	Class of device	Class III, Rule 14 as per Annex VIII of MDR 2017/745
2.7	Year when the first certificate (CE) was issued covering the device	2006
2.8	Authorized representative if applicable; name and the SRN	Medical Technology Promedt Consulting GmbH Address: Ernst-Heckel-Straße 7, 66386 St. Ingbert,Germany Phone: +49 6894 581020 Email: ear@mt-procons.com Website: https://www.mt-procons.com/ SRN: DE-AR-00000008

2.9	NB's name (the NB that will validate the SSCP) and the NB's single identification number	DNV Product Assurance AS Veritasveien 3, 1363 Høvik, Norway www.dnv.com Notified Body No: 2460

3. Intended use of the device

3.1 Intended purpose

Copper T380 A, Copper T380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound offer almost complete protection against pregnancy having shelf life 7 years and it remains effective for period of 10 years.

3.2 Indication(s) and target population(s)

i. Medical Indications

Intrauterine contraceptive devices are indicated for use in women of child bearing age.It is used for contraception in female which is reversible means fertility (Pregnancy) can be achieved by removing Copper T380 A, Copper T380 A with Safe Load.

ii. Target Population

Adolescence and Adult female of any age above 10 years.

3.3 User Qualification

The device will be inserted by Trained Medical Professionals

3.4 Contraindications and/or limitations

Contraindication (Absolute)

- Malignant diseases of the genital tract
- Undiagnosed vaginal bleeding
- Pregnancy
- History of ectopic pregnancy or predisposing factors.
- Infections of the genital tract
- Sexually transmitted diseases during the last 12 months (except bacterial vaginitis,
- repeated herpes infection, Hepatitis B)
- Abortion with infection during the last 3 months, pelvic inflammatory disease
- Uterine malformations (congenital or acquired)

- Allergy to copper

Contraindication (Relative) -

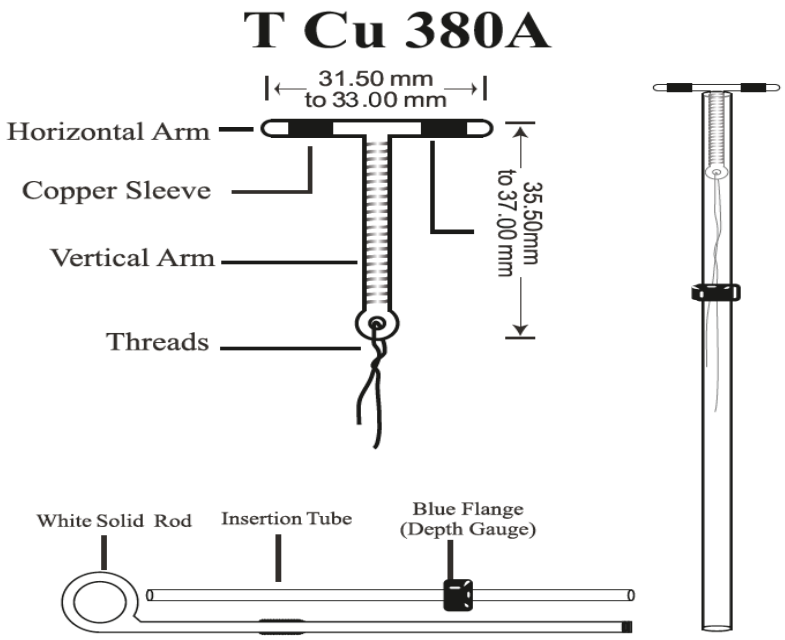
- Anemia
- Valvular heart disease
- Coagulation disorders
- Anti-inflammatory treatment
- Wilson's disease
- Multiple exposures to different sexual partners

4. Device description

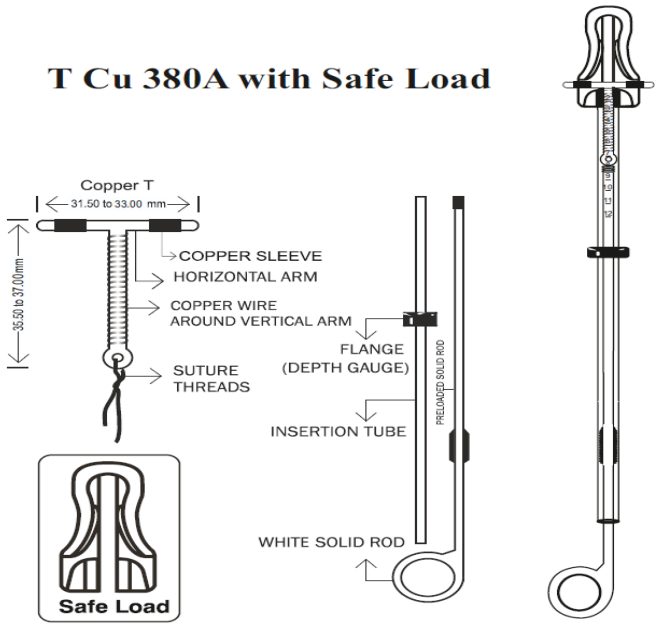
4.1 Description of the device

Copper T 380 A was introduced by The Population Council, New York. The specifications laid down by The Population Council as updated from time to time are followed by Pregna International Ltd. and users of these devices, even today.

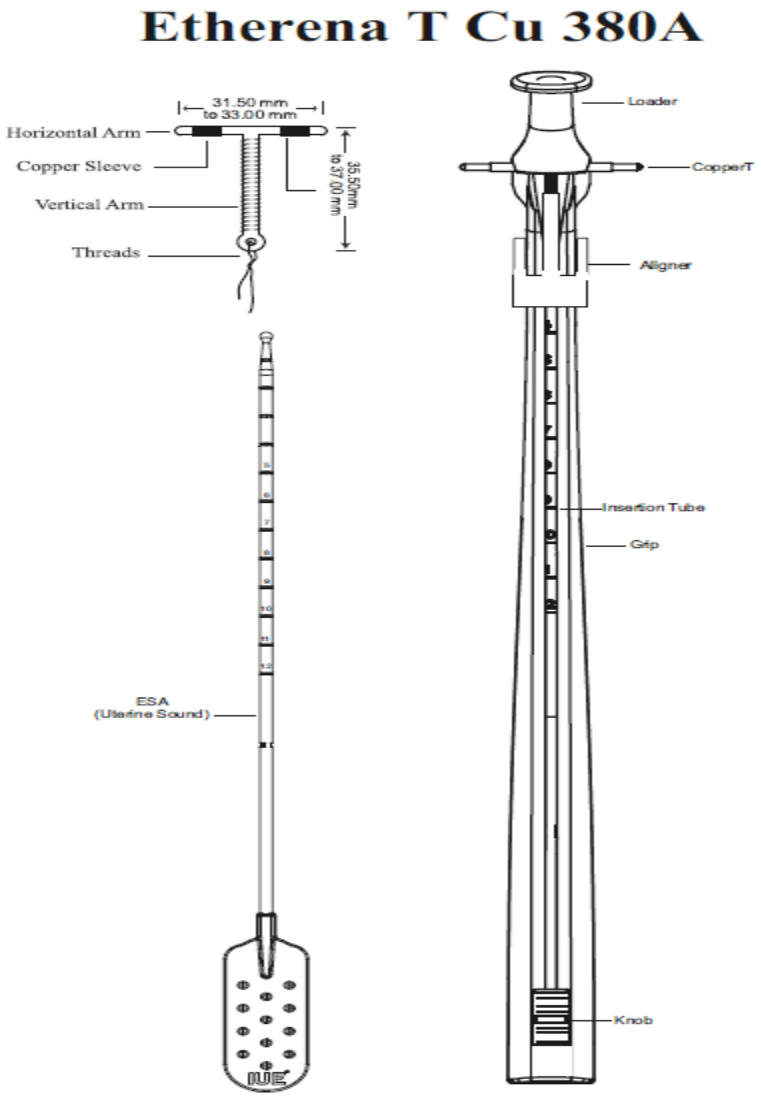
Copper T consists of T shaped body made up of polyethylene compounded with barium sulphate. The body bears the coil of copper wire on its vertical arm. In case of Copper T 380 A, copper sleeves are added on the horizontal arm in order to increase copper content. A monofilament suture thread made up of high density polyethylene is tied to the ball of T Frame at the bottom of vertical arm. This suture thread facilitates periodic checking by the user and also removal of device.



TCu380A and its Components



TCu380A with Safeload and its Components



Etherena TCu380A and its Components

Copper T is packed in individual sterile pouches. Each pouch contains one unit of Copper T380 A, Copper T380 A with Safe Load and Etherena along with other components like insertion tube, solid rod flange and safe Load (used for insertion purpose) and label insert. All the components are packed in a Film/Film pouch. Etherena is packed in film/film and or blister pouch. The pouch and or blister are then gamma sterilized and can be stored for up to seven years.

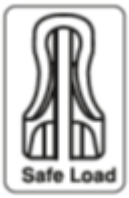
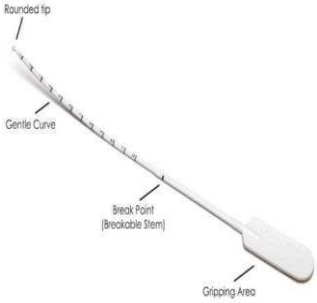
4.1.1 Information about the constituents should be provided, as required for the IFU, if the device incorporates a medicinal substance (including a human blood or plasma derivative)

Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound incorporates Copper substances which is considered ancillary medicinal substance.

4.2 A reference to the previous generation(s) or variants if such exist, and a description of the differences

#	Variant Name	Variant Details
1.	T Cu 380A	Pregna Model T Cu 380A, Securit T IUD Model T Cu 380A, MyChoice IUD Model T Cu 380A, Althea T Cu 380A, Longact T Cu 380A, Pregna+ T-Kare Model T Cu 380A, Pregna+ T Cu 380A, Andalan T Cu 380A, OK IUCD T Cu 380A, Lydia Copper T Cu 380A, Heer T Cu 380A Plus, Pregna Standard T Cu 380A, Pregna T Care T Cu 380A, Opset Model Copper T 380A, Trust Copper T Cu 380A, Andalan Classic Cu 380 Dispositivo Intrauterino,New Choice Model T Cu 380°, Elenora + T Cu 380A, Lana T T Cu 380A, Lana T Plus T Cu 380A
2.	T Cu380A with Safeload	Pregna Model T Cu 380A with Safeload,Safeload T Cu 380A, Andalan Safeload T Cu 380A, Heer T Cu 380A Safeload, Lydia T Cu 380A Safeload, Pregna Safeload T Cu 380A, Pregna Feminin Safeload T Cu 380A, Trust T Cu 380A Safeload, Freedom 10 Copper T 380A with Safeload, Aleze Safeload TCu380A, Elenora Safeload T Cu 380 A, Andalan Classic Cu 380 Dispositivo Intrauterino Safeload, Lana TS T Cu 380A with safeload
3.	Etherena T Cu 380 A	Etherena T Cu 380A, Etherena T Cu 380A with Disposable Uterine Sound

4.3 Description of any accessories which are intended to be used in combination with the device

S. No	Accessory Name	Image	Intended purpose
1.	Safe Load		Safeload is use to load the IUD in to the insertion tube.
2.	Disposable uterine sound		It is intended for probing a woman's uterus through the cervix, to measure the length and direction of the cervical canal and uterus
3.	Insertion tube along with Flange		Insertion tube is use for loading and insertion of IUD through uterine cavity. Flange is use for adjusting the measured uterine depth on the insertion tube.
4.	Solid rod		Solid rod is use for pushing the loaded IUD to release the arm of IUD in the uterine cavity.

4.4 Description of any other devices and products which are intended to be used in combination with the device

Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound is not intended to be used in combination with the device.

5. Risks and warnings

5.1 Risk Estimations

As per our Risk Management process, we estimated the risks for each hazardous situation. The risk estimation incorporates an analysis of the probability of the occurrence and level of severity to the end user. The possible consequences are listed for the use of risk evaluation and risk control.

Probability of Occurrence (per use):

Sales Data is considered for cumulative for all 03 variants.

Year	Total	Complaints
2018	3717071	00
2019	5930136	01
2020	4560885	00
2021	4977655	01
2022	5600838	00
Total	**24786585**	**02**
Annual Average	**4957317**	**0.4**

Annual average sales considered as closet round down figure as 49,00,000.

Annual Average Complaints considered as 01.

Probability of improbable event occurrence = Annual avg. complaints / Annual avg sales = 1/49,00,000

We have identified 5 probability levels from Improbable (O1) TO Frequent (O5). These probability levels are exponentiated by 0.5 or multiples of annual average sales volume.

Definition	Probability	Description	Value
Frequent	$\geq$ 1/490	Will undoubtedly happen or recur, possibly frequently	O5
Probable	< 1/4900	Will probably happen or recur, but it is not a persisting issue / circumstance	O4
Occasional	< 1/49000	Might happen or recur occasionally	O3

Definition	Probability	Description	Value
Remote	< 1/490000	Do not expect it to happen or recur but it is possible it may do so	O2
Improbable	<1/4900000	This will probably never happen or recur	O1

Severity:

When estimating severity for harms of each hazardous situation, we have leveraged the objective evidence to support our estimates. Objective evidence include:

- Similar products performance
- Regulatory data (such as adverse events reported to FDA, MAUDE, MHRA database)
- Scientific white papers published in relation with the device and harms
- Applicable standards
- End-user expertise and feedback
- Pre-clinical test data

We have identified 5 severity levels from Catastrophic (S5) to Negligible (S1). The worst-case harm is "Uterus Perforation" are identified based on the harms that may result from Intrauterine Contraceptive Device – T Cu 380A, T Cu 380A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound. The further severity level is estimated from the hazardous situation.

Rating	Definition	Harm	Value
Catastrophic	Results in life-threatening and/or reversible injury which require professional medical intervention	Uterus Perforation	S5
Critical	Results in prolonged discomfort which may lead to Major injury, which require professional medical intervention	Pelvic inflammatory Disease, Ectopic pregnancy	S4
Serious	Minor Injury which requires professional medical intervention	Menstrual cramps, Menstrual Bleeding, Ovarian cysts, misplacement of the device	S3
Minor	Temporary discomfort result which requires professional medical intervention	Infection within the 3 weeks of IUD implantation, Irregular or heavy periods, spotting periods, expulsion, Allergic reactions, Bleeding, Unwanted Pregnancy, Difficulty in placing the IUD	S2
Negligible	Inconvenience & temporary discomfort does not require	Pain, Itching, User inconvenience to perform implantation, Burning & Irritation, Lost Strings, Delay in	S1

Rating	Definition	Harm	Value
	professional medical intervention	procedure, Smelly discharge, Patient discomfort	

5.2 Residual risks and undesirable effect

5.2.1 Residual risks:

#	Residual Risk	Total Hazards	Leading Hazardous Situation	Hazard ID Details	Status
1.	Uterus Perforation	04	• Improper IUD implantation	D80, D87, D88, D89	Conditionally Accepted based on the RBA through Medical & Clinical Benefits
2.	Pelvic inflammatory Disease	14	• Inadequate pre-patient evaluation • Microbial Contamination • Contamination	D22, D43, D81, D82, D84, D86, D93, D100, D101, D102, D105, D106, D108, D110	Conditionally Accepted based on the RBA through Medical & Clinical Benefits
3.	Allergic reactions, Menstrual Bleeding Menstrual Cramps	13	• Misplacement of the device • Device Embedded in tissue • Inadequate pre-patient evaluation	D90, D91, D92, D94, D96, D97, D98, D99, D103, D104, D107, D114, D115	Conditionally Accepted based on the RBA through Medical & Clinical Benefits
4.	Unwanted Pregnancy	09	• Product Structure deformity • Product degradation • Device Migration	D78, D79, D83, D85, D95, D109, D111, D112, D113	Conditionally Accepted based on the RBA through Medical & Clinical Benefits

5.2.2 Side effects

There is no evidence of side effects/ adverse events such as:

- IUD Expulsion
- Pain and excessive bleeding during periods
- Positive Pregnancy test
- Dislocation of IUD

- Migration of IUD
- Anemia
- Back ache
- Vaginal inflammation
- Pain during sex
- Uterine perforation

5.3 Warnings and precautions

- Prior to use inspect the package for any visible damage or defect.
- Do not re-sterilize, re-sterilization can lead to product degradation which can result in unwanted pregnancy
- Ectopic pregnancy: If a woman gets pregnant with IUD in place, there is a chance of having an extra uterine pregnancy which should be evaluated.
- Pelvic infection: IUD's may be associated with an increased relative risk of Pelvic Inflammatory Disease (PID) compared to other forms of contraception.
- Expulsion: Sometimes an IUD is pushed out of the uterus into the vagina during heavy flow of menses as uterus remains slightly open during the menstrual period.
- Perforation: Partial or total perforation of the uterine wall or cervix may occur rarely during placement, though it may be detected later

5.4 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable.

FSCA Related to – Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound

FSCA during the PSUR reporting period and the status of the FSCA

Type of action	Starting date	Status of the FSCA	Mnfr. Reference number	Rationale and description of action taken	Impacted regions
NA	NA	NA	NA	NA	NA

Actions are taken for safety reasons outside the FSCA

Type of action	Starting date	Status of the action	Rationale and description of action taken	Impacted regions
NA	NA	NA	NA	NA

6. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

6.1 Summary of clinical data related to a similar device, if applicable

The Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound

belongs to the "Intrauterine Device" group. In the present market there are many similar devices and/or benchmark devices available with same intended purpose and are having the same generally acknowledged state-of-the-art.

These similar devices fall under "Well-Established Technology". Data from similar devices is considered for the conformation of conformity to the Intrauterine Contraceptive Device - Copper T380 A, Copper T380 A with Safe Load relevant general safety and performance requirements. The similar device data is used to demonstrate ubiquity of design, lack of novelty, known safety and performance profile of a generic group of devices, etc.

The below mentioned similar devices data is used to evaluate the Intrauterine Contraceptive Device - Copper T380 A, Copper T380 A with Safe Load relevant general safety and performance requirements as part of literature review. These similar devices contain the same Raw materials and same intended purpose, but due to insufficient information availability the full assessment of equivalence is not possible. Therefore, these similar devices are used for the same clinical intended purposes as the Intrauterine Contraceptive Device - Copper T380 A, Copper T380 A with Safe Load and are considered to be similar but non-equivalent devices.

#	Device Name	Brand Name	Manufacturer Name & Country	Image	Intended Use
1	Intrauterine Contraceptive device	MONA LISA® Cu T 380A	Mona Lisa N.V.		T Cu 380 A offer almost complete protection against pregnancy.

6.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Not Applicable

6.3 Summary of clinical data from other sources, if applicable

The below mentioned are literatures selected for detailed review for:

- Evaluation of state of the art
- Evaluation of clinical data from similar devices

#	ID#	Source Link	Literature Title
1.	L1	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4717389/	Intrauterine contraception in nulliparous women: a prospective survey
2.	L2	https://pubmed.ncbi.nlm.nih.gov/22763376/	Intrauterine contraception: incidence and factors associated with uterine perforation—a population-based study
3.	L4	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3655294/	Magnetic Field Interactions of Copper-Containing Intrauterine Devices in 3.0-Tesla Magnetic Resonance Imaging: In Vivo Study
4.	L5	https://pubmed.ncbi.nlm.nih.gov/26294910/	Practical Advice for Emergency IUD Contraception in Young Women
5.	L7	https://pubmed.ncbi.nlm.nih.gov/27771475/	The safety of intrauterine devices among young women: a systematic review
6.	L8	https://pubmed.ncbi.nlm.nih.gov/27421765/	The safety of intrauterine devices in breastfeeding women: A systematic review
7.	L10	https://pubmed.ncbi.nlm.nih.gov/28146650/	Long-acting reversible contraception
8.	L11	https://pubmed.ncbi.nlm.nih.gov/23945595/	Copper T380 intrauterine device for emergency contraception: highly effective at any time in the menstrual cycle
9.	L13	https://pubmed.ncbi.nlm.nih.gov/24679478/	Extended use of the intrauterine device: a literature review and recommendations for clinical practice
10.	L14	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683138/	Five-year review of copper T intrauterine device use at the University of Calabar Teaching Hospital, Calabar
11.	L16	https://obgyn.onlinelibrary.wiley.com/doi/abs/10.1576/toag.2002.4.1.37	Intrauterine devices update on clinical performance
12.	L17	https://pubmed.ncbi.nlm.nih.gov/15006311/	FFPRHC Guidance (January 2004). The copper intrauterine device as long-term contraception
13.	L19	https://pubmed.ncbi.nlm.nih.gov/17943851/#:~:text=Authors'%20conclusions%3A%20TCu380A%20or%	Copper containing, framed intra-uterine devices for contraception

		20TCu380S,who%20have%20not%20had%20children.	
14.	L20	https://www.glowm.com/section_view/heading/intrauterine-contraceptives/item/393	Intrauterine Contraceptives
15.	L22	https://pubmed.ncbi.nlm.nih.gov/31306443/	Intrauterine contraceptive device training and outcomes for healthcare providers in developed countries: A systematic review
16.	L23	https://pubmed.ncbi.nlm.nih.gov/15033401/#:~:text=Among%20IUD%20acceptors%2C%2074%25%20of,after%20postplacental%20insertion%20of%20IUD.	Clinical outcomes of early postplacental insertion of intrauterine contraceptive devices
17.	L25	https://pubmed.ncbi.nlm.nih.gov/21072313/	Long-term safety, efficacy, and patient acceptability of the intrauterine Copper T-380A contraceptive device
18.	L26	https://www.researchgate.net/publication/313089408_Acceptance_perception_experience_and_satisfaction_of_the_couple_with_postpartum_intrauterine_contraceptive_devices_PPIUCD_insertion	Acceptance, perception, experience and satisfaction of the couple with postpartum intrauterine contraceptive devices (PPIUCD) insertion.
19.	L28	https://www.sciencedirect.com/science/article/abs/pii/S0010782419300563	Safety of levonorgestrel 52 mg intrauterine system compared to copper intrauterine device: a population-based cohort study
20.	L29	https://journals.ekb.eg/article_212588.html	Role Of Ultrasound Technique In Woman Satisfaction During Placement Of Intrauterine Contraception (A Randomized Clinical Trial)
21.	L30	https://www.sciencedirect.com/science/article/pii/S1110569010001822	Comparison between Cupper T380 IUD and Multiload 375 IUD in early postpartum insertion
22.	L31	https://www.contraceptionjournal.org/article/S0010-7824(21)00467-4/fulltext	"I never went to see that doctor again": A qualitative study examining Australian women's experiences requesting removal of LARC within 12 months of insertion
23.	L32	https://www.contraceptionjournal.org/article/S0010-7824(21)00003-2/fulltext	Debunking myths about contraceptive safety among women in Kingston, Jamaica: Pilot randomized controlled trial

24.	L33	https://www.contraceptionjournal.org/article/S0010-7824(21)00415-7/fulltext	Society of Family Planning Committee statement on IUD nomenclature
25.	L34	https://pubmed.ncbi.nlm.nih.gov/34566304/	Clinical Outcome of Cu-T 375 PPIUCD by Novel Dedicated Inserter Technique
26.	L35	https://www.ijhcr.com/index.php/ijhcr/article/view/3465	Comparative feedback between traditional Copper-T 380 A and Etherena T Cu 380 A a Innovative loading and inserting device to provide a safe and convenient method of IUD insertion
27.	L36	MOH of Vietnam	Brief Report on Clinical Trial of two types T Cu 380A intrauterine Device: from Famy Care of India (FaI) And Finishing Enterprise Intrauterine (FEI - USA).

6.4 An overall summary of the clinical performance and safety

Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound comply with all the Safety and Performance requirements with respect to the intended use of the device from the Clinical Evaluation study. The clinical evaluation is complete and conforms to the essential requirements. The Clinical evidence is demonstrated with the relevant essential requirements as per Annex I of MDR. Risk Mitigation has been established as per the guidelines of EN ISO 14971:2019.

6.5 Ongoing or planned post-market clinical follow-up.

Post market clinical follow-up activities for Intrauterine Contraceptive Device- Copper T380 A with Safe Load & Etherena T Cu 380A with Disposable Uterine Sound are ongoing from 2022-2027.

The study will be Single arm, Multicentric, open-label, observational, prospective clinical study

- Subjects will be fully explained about the study and signed informed consent will be taken. The subjects who met the inclusion criteria will be enrolled for the study.
- The rates of uterine perforation during insertion, the efficacy in preventing pregnancy and other complications related to IUD will be assessed through Case Report Forms.
- There will be six follow up visits after the insertion of IUD after one month, 1st year, 2nd year, 3rd year, 4th year and 5th year.
- During the follow up visit of one year, second year, third year, fourth year and fifth year the reversible fertility condition also will be verified in those subjects who had removed the IUD's during these years.

- At every follow up visit the Investigator will examine the subject and position of IUD and overall well-being of the subject. The investigator will be evaluating the subjects for the product performance, safety, benefits, risks, satisfaction, any side effects, and adverse device effect. The results will be update in the corresponding case report form.

Once all subjects complete the follow up visit, the final data analysis will be done and the outcome of each product will be reported in PMCF report. The Interim data analysis will be performed after every year and an interim report will be prepared based on the outcome.

Retrospective PMCF study had conducted for Copper T380 A, the study was conducted as per guidelines of ISO 14155:2020 - Clinical investigation of medical devices for human subjects - Good clinical practice, MDR 2017/745, ANNEX XIV, Part B PMCF - A guide for Manufacturers and Notified bodies and MDCG 2020-8- Post-market clinical follow-up (PMCF) Plan A guide for manufacturers and notified bodies. This study was Retrospective, observational and multi-center study. The study is conducted as per the PMCF protocol –PMCF-PROTOCOL/IUD/2022/001, Rev -01 dated 02.09.2022.

According to PMCF, CRFs were collected for 72 subjects who are using Copper T380 A from the year April 2019 onwards to get complete protection against pregnancy.

6.5.1 Intended use summary

T Cu 380 A offer almost complete protection against pregnancy having shelf life 7 years and it remains effective for period of 10 years.

The intended use, which was one of the primary objectives of this study is evaluated by using questionnaire, which is been answered by the Co-Investigator on behalf of subject.

All the 72 subjects who have been on Copper T 380A did not conceive during these years. Hence it is proven that the IUD has met the intended use of complete protection against pregnancy.

Meets the Intended Use

6.5.2 Summary of Clinical safety and efficacy

Safety Parameters evaluated for Cu 375 IUD

Clinical Safety parameters evaluated	Results
Currently using IUD	All subjects have their IUD from the time of implantation day onwards
Having regular periods	All the 72 subjects except 1 subject had regular periods after using IUD
Having heavy menstrual bleeding	Out of 72 subjects,6 subjects (8%) had observed with heavy menstrual bleeding
Experienced any of the below events • **Abnormal Spotting or very less bleeding during periods** • **Abdominal pain/pain during intercourse** • **Severe back pain during periods** • **Infection or vaginal discharge** • **Excessive cramping during periods**	In 89% of subjects, none of these events were observed. In 11% of the subjects have reported abdominal pain, vaginal infection and excessive cramps
Removed the IUD because of any complications	None of the subjects removed IUD
Switched to any other alternative contraceptive methods	None of the Subjects Switched to any other alternative contraceptive methods
Any pregnancy/ ectopic pregnancy	No pregnancy/ ectopic pregnancy observed after having IUD implantation
Able to locate the IUD's string throughout this period	All the subjects are able to locate the IUD's string throughout the period
Able to feel the IUD thread/strings	All the subjects are able to feel the IUD thread/strings
After IUD implantation any sudden weight gain	Only 1 subject out of 72 observed sudden weight gain after IUD implantation

Clinical implementation of Copper T 380 A IUD exhibits significant benefit in all the subjects, showing high safety and efficacy of the product and clinically proven

6.5.3 Summary on Performance

The clinical Performance of the product is evaluated by taking the post T Cu 380 A IUD implantation results from the subjects. Performance parameters are given below in the table.

Sl no:	Performance attribute	Rating given by Co I	Overall Rating
1.	Effectiveness of preventing pregnancy	5	**4.4**
2.	Unintended pregnancy	5	
3.	Ease of use	4.3	
4.	Comfort to the end user	3.7	
5.	Long term efficacy	3.8	

The overall rating given for 72 subjects is 4.4 which are good as per the definition

6.5.4 Overall Results from the PMCF study of Copper T 380 A

Parameter	Study Results
Subjects	Total 72 subjects participated in the study among which 50 subjects (69%) were in age between 25-35yrs and 22 subjects (31%) were in age between 36 to 45 yrs.
Gender	72 Adult Females
Target Users	Gynecologist
Study Site	Sri Clinic, Multispeciality Clinic LIG 233 &234, S.R Residency, 7th Phase, KPBH Colony, Kukatpally, Hyderabad, Telegana-500 072
Clinical Safety	All the subjects considered for PMCF study benefitted out of using the Copper T 380 A which shows the safety of using our device on subject with better efficacy and were proven clinically.
Clinical Performance	The average rating for the performance attributes of Copper T 380 AIUD is 4.3 which are Good as per the definition in CRF.
Complications & other Pathologies	Co-I had observed vaginal infection for 2 subjects (3%) and smelly vaginal discharge for 5 subjects (7%) who had undergone the IUD implantation using Copper T 380 A.

	However, these complication are already identified in risk management file (RMF/CopperT380A/D) and had taken risk mitigation action 90% of the subjects had not observed with any of these complications It proves Copper T 380 A IUD is safe and effective
Possible misuse and off label use	In none of the CRFs the CO I had reported any possible misuse of off label use scenarios
Overall Product satisfaction from CO I	The overall product satisfaction of Copper T 380 A from PI is 3.8 which is neutral as per definition in CRF
Comment from CO I	The Co I had commented that in 8 subjects(11%) Copper T 380A helped in prevention of Asherman syndrome. The IUD prevented the uterine wall adhesion.
Overall Product satisfaction from Subject	The overall product satisfaction of Copper T 380 A from subject is 3.9 which is neutral as per definition in CRF

7. Possible diagnostic or therapeutic alternatives

Other methods of contraception include:

- Oral contraceptives
- Condoms
- Progestin implants
- Progestin shots
- Vaginal rings
- Cervical caps
- Hormonal patches
- Diaphragms
- Sponges
- Abstinence
- Fertility awareness
- Permanent sterilization

8. Suggested profile and training for users

The device will be inserted by Trained Medical Professionals. Mandatory training is necessary to perform the procedure.

9. Reference to any harmonized standards and CS applied

9.1 List of Harmonized Standards

#	Standard ID	Current Issue	Title
1.	EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
2.	EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices
3.	EN ISO 20417	2021	Information supplied by the Manufacture of Medical devices
4.	EN ISO 15223-1	2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
5.	EN 62366-1	2015+AC:2015+ AC:2016+A1:2020	Medical devices - Application of usability engineering to medical devices
6.	EN ISO 7439	2023	Copper-bearing contraceptive intrauterine devices — Requirements and tests
7.	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
8.	EN ISO 10993-3	2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
9.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
10.	EN ISO 10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
11.	EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
12.	EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
13.	EN ISO 11737-1	2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products

14.	EN ISO 11737-2	2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
15.	EN ISO 11137-1	2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
16.	EN ISO 11137-2	2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
17.	EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
18.	EN ISO 11607-2	2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
19.	BS EN 556-1	2001/AC:2016	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.
20.	BS EN 556-2	2015	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" Requirements for aseptically processed medical devices

9.2 List of Other Applicable Standards

#	Standard ID	Current Issue	Title
1.	ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2.	ISO 14971	2019	Medical devices - Application of risk management to medical devices
3.	ISO 15223-1	2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
4.	ISO 14630	2012	Non-active surgical implants - General requirements
5.	IEC 62366-1	2015/AMD 1:2020	Medical devices – Part 1: Application of usability engineering to medical devices

6.	ASTM D4169-22	2022	Standard Practice for Performance Testing of Shipping Containers and Systems
7.	ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
8.	ISO 10993-5	2009/AMD 1:2019	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
9.	ISO 10993-3	2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
10.	ISO 10993-10	2021	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
11.	ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
12.	ISO 11737-1	2018/AMD 1: 2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
13.	ISO 11737-2	2019	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
14.	ISO 11607-1	2019/CD AMD 1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
15.	ISO 11607-2	2019/CD AMD 1	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
16.	ISO 7439	2015	Copper-bearing contraceptive intrauterine devices — Requirements and tests
17.	ISO 14644-1	2015	Cleanrooms and associated controlled environments —Part 1: Classification of air cleanliness by particle concentration
18.	ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice
19.	ISO/TR 20416	2020	Medical devices — Post-market surveillance for manufacturers

9.3 Guidelines

#	Guideline	Current Issue	Title
1.	MEDDEV 2.7.1 Rev. 4	June 2016	Clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
2.	MEDDEV 2.5/5 Rev. 3	February 1998	Evaluation of clinical data: A guide for manufacturers and notified bodies
3.	MEDDEV 2.12-1 Rev. 8	January 2013	Vigilance system for medical devices
4.	MEDDEV 2.12/2 Rev. 2	January 2012	Post-market clinical follow-up studies: A guide for manufacturers and notified bodies
5.	NB-MED 2.12/Rec. 1	July 2019	Post Market surveillance
6.	MDCG 2021-24	Oct 2021	Guidance on classification of medical devices
7.	MDCG 2020-6	2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC.
8.	MDCG 2018-1 Rev.4	April 2021	Guidance on BASIC UDI-DI and changes to UDI-DI
9.	MDCG 2020-7	April 2020	Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies
10.	MDCG 2020-8	April 2020	Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies
11.	MDCG 2022-21	December 2022	Guidance On Periodic Safety Update Report (PSUR) According to Regulation (EU) 2017/745 (MDR
12.	MDR 2017/745 Annex XIV, Part A & B	August 2019	Medical Devices Regulation Annex XIV - Clinical evaluation and post-market clinical follow-up
13.	MDCG 2019-9 Rev.1	March 2022	Summary of safety and clinical performance A guide for manufacturers and notified bodies

9.4 Regulations

#	Regulation	Title
1.	EU MDR 2017 /745	European Union Medical Device Regulation

Summary of Safety and Clinical Performance Intended for Patient

Introduction

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions for Use to provide information on the safe use of the device.

1. Device identification and general information

1.1	Device trade name(s)	Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound • Pregna Model T Cu 380A • Securit T IUD Model T Cu 380A • MyChoice IUD Model T Cu 380A • Althea T Cu 380A • Longact T Cu 380A • Pregna+ T-Kare Model T Cu 380A • Pregna+ T Cu 380A • Andalan T Cu 380A • OK IUCD T Cu 380A • Lydia Copper T Cu 380A • Heer T Cu 380A Plus • Pregna Standard T Cu 380A • Pregna T Care T Cu 380A • Opset Model Copper T 380A • Trust Copper T Cu 380A • Andalan Classic Cu 380 Dispositivo Intrauterino • New Choice Model T Cu 380° • Elenora + T Cu 380A • Lana T T Cu 380A • Lana T Plus T Cu 380A • Copper T 380A with Safeload

		• Pregna Model T Cu 380A with Safeload • Safeload T Cu 380A • Andalan Safeload T Cu 380A • Etherena T Cu 380A • Heer T Cu 380A Safeload • Lydia T Cu 380A Safeload • Pregna Safeload T Cu 380A • Pregna Feminin Safeload T Cu 380A • Trust T Cu 380A Safeload • Freedom 10 Copper T 380A with Safeload • Aleze Safeload TCu380A • Elenora Safeload T Cu 380 A • Andalan Classic Cu 380 Dispositivo Intrauterino Safeload • Lana TS T Cu 380A with safeload • Etherena T Cu 380A with Disposable Uterine Sound
1.2	Manufacturer's name and address	PREGNA INTERNATIONAL LTD. Plot No. 219, Survey No. 168, Dabhel Co. Op. Ind. Soc. Ltd., Dabhel, Daman (U.T.)- 396210, India Phone : +(91)-(260)-3206372/3207093. Fax : +(91)-(22)-23513484. www.pregna.com
1.3	Basic UDI-DI	
i.	T Cu 380 A	89040453pregnaTCu380A00LY
ii.	T Cu 380 A with Safe Load	
iii.	Etherena T Cu 380A with Disposable Uterine Sound	
1.4	Year when the device was first CE-marked	2006

2. Intended use of the Device

2.1 Intended purpose

Copper T380 A, Copper T380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound offer almost complete protection against pregnancy having shelf life 7 years and it remains effective for period of 10 years.

2.2 Indication(s) and target population(s)

Medical Indications: Intrauterine contraceptive devices are indicated for use in women of child bearing age.It is used for contraception in female which is reversible means fertility (Pregnancy) can be achieved by removing Copper T380 A, Copper T380 A with Safe Load.

Target Population: Adolescence and Adult female of any age above 10 years.

2.3 Contraindications and/or limitations

Contraindication (Absolute)

- Malignant diseases of the genital tract
- Undiagnosed vaginal bleeding
- Pregnancy
- History of ectopic pregnancy or predisposing factors.
- Infections of the genital tract
- Sexually transmitted diseases during the last 12 months (except bacterial vaginitis,
- repeated herpes infection, Hepatitis B)
- Abortion with infection during the last 3 months, pelvic inflammatory disease
- Uterine malformations (congenital or acquired)
- Allergy to copper

Contraindication (Relative) -

- Anemia
- Valvular heart disease
- Coagulation disorders
- Anti-inflammatory treatment
- Wilson's disease
- Multiple exposures to different sexual partners

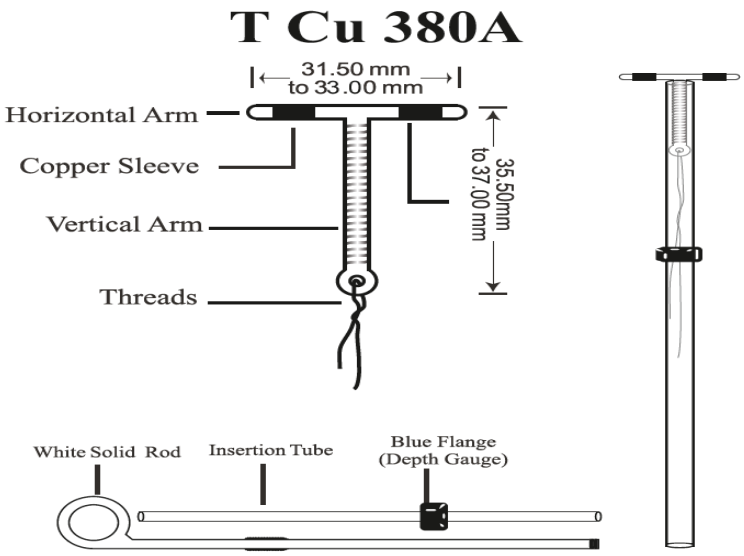
3. Device Description

3.1 Device description

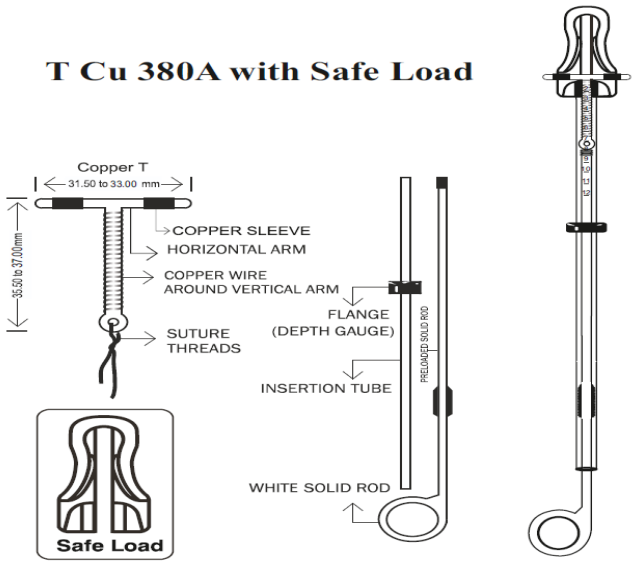
Copper T 380 A was introduced by The Population Council, New York. The specifications laid down by The Population Council as updated from time to time are followed by Pregna International Ltd. and users of these devices, even today.

Copper T consists of T shaped body made up of polyethylene compounded with barium sulphate. The body bears the coil of copper wire on its vertical arm. In case of Copper T 380 A, copper sleeves are added on the horizontal arm in order to increase copper content. A monofilament suture thread made up of high

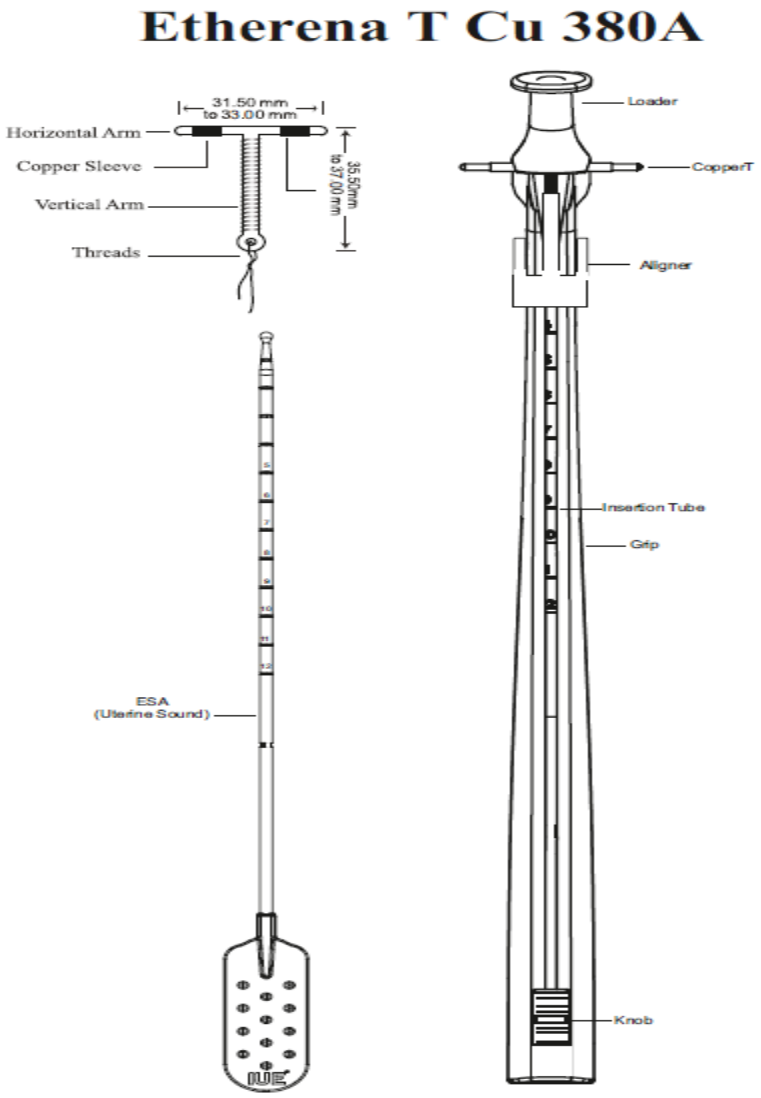
density polyethylene is tied to the ball of T Frame at the bottom of vertical arm. This suture thread facilitates periodic checking by the user and also removal of device.



TCu380A and its Components



TCu380A with Safeload and its Components



Etherena TCu380A and its Components

Copper T is packed in individual sterile pouches. Each pouch contains one unit of Copper T380 A, Copper T380 A with Safe Load and Etherena along with other components like insertion tube, solid rod flange and safe Load (used for insertion purpose) and label insert. All the components are packed in a Film/Film pouch. Etherena is packed in film/film and or blister pouch. The pouch and or blister are then gamma sterilized and can be stored for up to seven years.

3.2 Materials that come in contact with patient

Device Trade Name	Material that comes in contact with patient
T Cu 380 A	- T frame - Copper wire - Copper collar - Suture thread - Insertion tube - Flange - Solid rod
T Cu 380 with Safe Load	- T frame - Copper wire - Copper collar - Suture thread - Insertion tube - Flange - Solid rod - Safeload
Etherena T Cu 380A with Disposable Uterine Sound	- T frame - Copper wire - Copper collar - Suture thread - Insertion tube - Flange - Disposable Uterine Sound - Loader - Knob - Upper Grip/Top Grip - Bottom Grip - Aligner - Tyvek Tray (OHSL Pack)

3.3 Information about medicinal substances in the device, if any

Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound incorporates Copper substances which is considered ancillary medicinal substance.

3.4 Description of how the device is achieving its intended mode of action

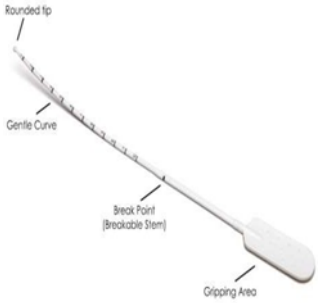
Intrauterine contraceptive devices (TCu380A) prevent pregnancy by interference with sperm transport (thus reducing the number and viability of sperm), ovum development or transport, fertilization and implantation. The copper acts as spermicidal adding to the contraceptive effect. Further the endometrium undergoes morphological and biochemical changes that make it unsuitable for implantation of zygote.

Copper T (TCu380A), once inserted remains effective for 5 to 10 years depending on the model inserted. In case further contraception is required, a new device can be inserted immediately after the old one is removed. Copper T, once inserted, does not require daily attention from the user and does not interfere with sexual activity. Because it contains no hormones, this device does not affect lactation. This is fully reversible method and protection is reversed on its removal.

In operation of T Cu 380 A, the user loads the IUD into the insertion tube by peeling the sealed pouch back half-way, complete the bending of horizontal arm of T frame by bringing the thumb and index finger together while using the other hand to maneuver the insertion tube to pick you the arm of T. Insert the folded arm of T in to the insertion tube and adjust the flange according to the depth of uterus. Gently introduce the loaded insertion assembly through the cervical canal and advanced upward until the T lies in contact with the fundus, and flange comes in contact with cervix. Holding solid the solid rod/plunger stationary by one hand withdraw the insertion tube and release the arm of T frame by pushing the solid rod. After fundal placement gently withdraw first the solid rod, and then the insertion tube from the cervical canal. Cut the suture thread so that they protrude only 3-4 cm in to the vagina. The T Cu 380A device is use for single use only.

In operation of T Cu 380A with Safeload, the user loads the IUD in to Insertion tube with help of Safeload device by peeling the sealed the pouch back half-way. Through the pouch, hold the Safeload by thumb and index finger. Use the other hand to push the insertion tube with T in to the Safeload. Ensure proper bending of horizontal arm of T in the designed profile of Safeload. Pull the insertion tube backwards till it comes out of the Safeload. Lift the insertion tube upward and push it towards the T. Both arm fit in to the insertion tube. Turn the insertion tube 90 degree and withdraw the insertion tube along with loaded T to remove it from Safeload. Gently introduce the loaded insertion assembly through the cervical canal and advanced upward until the T lies in contact with the fundus, and flange comes in contact with cervix. Holding solid the solid rod/plunger stationary by one hand withdraw the insertion tube and release the arm of T frame by pushing the solid rod. After fundal placement gently withdraw first the solid rod, and then the insertion tube from the cervical canal. Cut the suture thread so that they protrude only 3-4 cm in to the vagina. The T Cu 380A device is for single use only.

3.5 Description of accessories, if any

S.No	Accessory Name	Image	Intended purpose
1.	Safe Load		Safeload is use to load the IUD in to the insertion tube.
2.	Disposable uterine sound		It is intended for probing a woman's uterus through the cervix, to measure the length and direction of the cervical canal and uterus
3.	Insertion tube along with Flange		Insertion tube is use for loading and insertion of IUD through uterine cavity. Flange is use for adjusting the measured uterine depth on the insertion tube.
4.	Solid rod		Solid rod is use for pushing the loaded IUD to release the arm of IUD in the uterine cavity.

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1 How potential risks have been controlled or managed

We have established and are maintaining a strong quality management system and continuous process monitoring controls as per ISO 13485:2016 requirements. We have implemented all necessary risk control measures for each hazard that are appropriate for reducing the risks to an acceptable level in a reasonably practicable way. As per the risk management plan, we have identified the risk control options as mentioned below.

- Making the medical device design and the manufacturing process inherently safe.
- Taking protective measures in the medical device or in the manufacturing processes.
- Information for safety.

After all risk control measures implementation and verification, the overall residual risks are acceptable as per the defined risk acceptability criteria. The risk associated with the indented use is acceptable when weighed against benefit to the patient. As part of “Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound” risk assessment, the identified residual risks are analyzed through benefit-risk analysis.

The Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound medical benefits and residual risks are compared based on medical condition, literature data certainty, similar device data (benefits & residual risks) from the market, acknowledged state of the art. The defined residual risks are outweighed by the expected medical benefits when used as per the defined intended purpose of Intrauterine Contraceptive Device- T Cu 380 A, T Cu 380 A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound.

However, the residual risks are accepted as per the benefit-risk analysis with proper literature evidence and also by providing necessary information on safety to the end user’s awareness in the form of “Label’ and ‘Instructions for Use”.

4.2 Residual Risks

- Uterus Perforation

- Pelvic inflammatory Disease
- Allergic reactions, Menstrual Bleeding, Menstrual Cramps
- Unwanted pregnancy

4.3 Side effects

There is no evidence of side effects/ adverse events such as:

- IUD Expulsion
- Pain and excessive bleeding during periods
- Positive Pregnancy test
- Dislocation of IUD
- Migration of IUD
- Anemia
- Backache
- Vaginal inflammation
- Pain during sex
- Uterine perforation

4.4 Warnings and Precautions

- Prior to use inspect the package for any visible damage or defect.
- Do not re-sterilize, re-sterilization can lead to product degradation which can result in unwanted pregnancy
- Ectopic pregnancy: If a woman gets pregnant with IUD in place, there is a chance of having an extra uterine pregnancy which should be evaluated.
- Pelvic infection: IUD's may be associated with an increased relative risk of Pelvic Inflammatory Disease (PID) compared to other forms of contraception.
- Expulsion: Sometimes an IUD is pushed out of the uterus into the vagina during heavy flow of menses as uterus remains slightly open during the menstrual period.
- Perforation: Partial or total perforation of the uterine wall or cervix may occur rarely during placement, though it may be detected later

4.5 Summary of any field safety corrective action, (FSCA including FSN) if applicable

There were no identified and/or received reportable events that led to death, a serious deterioration in the state of health of the patient, user, or other person for Intrauterine Contraceptive Device – T Cu 380A, T Cu 380A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound. Hence FSCA or FSN is not applicable**.**

5. Summary of clinical evaluation and post-market clinical follow-up

5.1 Clinical background of the device

The Intrauterine Contraceptive Device – T Cu 380A, T Cu 380A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound is a designed and developed as per the latest and/or current technical, international and regulatory standards i.e., EN ISO 7439: 2023 & ISO 7439: 2023 and WHO UNFPA technical specification 2016. The Intrauterine Contraceptive Device – T Cu 380A, T Cu 380A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound performance complies all necessary requirements required for its intended purpose. The Intrauterine Contraceptive Device – T Cu 380A, T Cu 380A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound related all known foreseeable hazards are identified and associated risk are reduced as far as possible by implementing all necessary risk control measures as per the requirements of EN ISO 14971:2019/A11:2021. The Intrauterine Contraceptive Device – T Cu 380A, T Cu 380A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound is manufactured as per the defined standard operating procedures in controlled environments by training personnel and complies all necessary requirements of EN ISO 13485:2016/A11:2021.

5.2 The clinical evidence for the CE-marking

Intrauterine Contraceptive Device – T Cu 380A, T Cu 380A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound is having a CE certified medical device under EU MDD 93/42/EEC. Hence, the Intrauterine Contraceptive Device comply the definition as a legacy device as per the MDCG 2020-6:2020 – Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC.

Device Name:	Intrauterine contraceptive device
Models/Variants:	T Cu 380A, T Cu 380 A with Safe Load and Etherna T Cu 380 A with Disposable Uterine Sound and Etherena T Cu 380A with Disposable Uterine Sound
93/42/EEC (MDD) Cert. No.:	11233-2017-CE-IND-NA-PS Rev 7.0

Notified Body Details:	DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway

Similar Device Details:

The Intrauterine Contraceptive Device – T Cu 380A, T Cu 380A with Safe Load and Etherena T Cu 380A with Disposable Uterine Sound belongs to the "Intrauterine Device" group. In the present market there are many similar devices and/or benchmark devices available with same intended purpose and are having the same generally acknowledged state-of-the-art.

#	Device Name	Brand Name	Manufacturer Name & Country
1.	Intrauterine Contraceptive device	MONA LISA® Cu T 380A	Mona Lisa N.V., Belgium

5.3 Safety

We have reviewed and analysed all the residual risks and also identified the medical benefits of the intended use outweigh the overall residual risk. The literature evidence supports the conclusion that the medical benefits outweigh the overall residual risks, then the overall residual risk is judged acceptable. All the residual risks are acceptable by providing appropriate information to the end user's awareness in the form of "Label' and 'Instructions for Use".

Medical Benefits	
1. Uterus Perforation 2. Pelvic inflammatory Disease 3. Allergic reactions, Menstrual Bleeding, Menstrual Cramps 4. Unwanted pregnancy	Benefit related to Legacy Device: 1. Intrauterine contraception in women is safe, effective method when compared to other existing methods. 2. It can be used as emergency contraception device. 3. No unwanted pregnancy or ectopic pregnancy is identified. 4. Less infection rates. Benefits related to Similar Device from the market: 1. Low perforation rates 2. Lower expulsion rates 3. Ease of IUD insertion 4. Low risk of developing Pelvic inflammatory disease. 5. No cases of pelvic infections 6. Less Abdominal pain and vaginal discharge 7. Decreased rate of dysmenorrhea

	8. Provide the highest contraceptive efficacy and rates of satisfaction. 9. No IUD-related artifacts were found.

As part of our quality system, an appropriate post-market surveillance plan is a key to identifying and investigating Known and unknown residual risks associated with the use of Intrauterine Contraceptive Device (IUD) placed on the market. These residual risks shall be investigated and assessed in the post-market phase through systematic Post-Market Clinical Follow-up Feedback Survey.

While conducting PMCF we shall proactively collect feedback on the product safety and performance of Intrauterine Contraceptive Device (IUD). The product is placed on the market or put into service within its intended purpose with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

6. Possible diagnostic or therapeutic alternatives

Other methods of contraception include:

- Oral contraceptives
- Condoms
- Progestin implants
- Progestin shots
- Vaginal rings
- Cervical caps
- Hormonal patches
- Diaphragms
- Sponges
- Abstinence
- Fertility awareness
- Permanent sterilization

7. Suggested training for users

The device will be inserted by Trained Medical Professionals. Mandatory training is necessary to perform the procedure.

10.Revision history

Rev #	Date	Initiated By	Summary of Change (Amended / Updated)
00	14.09.2022	Mr. Ranjit Gaikwad	Initial Release
01	12.09.2024	Mr. Ranjit Gaikwad	Added Summary of safety and clinical performance intended for patient
02	10.03.2025	Mr. Ranjit Gaikwad	1. Medical device nomenclature description text (EMDN Code, MDA/MDN Code, MDS & MDT Codes) updated in section 2 subsection 2.5 (Summary of safety and clinical performance intended for users) 2. Conformity assessment procedure with annex number is updated in section 1 (Summary of safety and clinical performance intended for users) 3. Information about the constituents, as required by the IFU, if the device incorporates a medicinal substance (including a human blood or plasma derivatives) is updated in section 3.3 (Summary of safety and clinical performance intended for patient) 4. Warnings and precautions are updated in section 5.3 (Summary of safety and clinical performance intended for users) and in section 4.4 (Summary of safety and clinical performance intended for patient). 5. Literature details are added in section 6.3 (summary of clinical data from other sources)