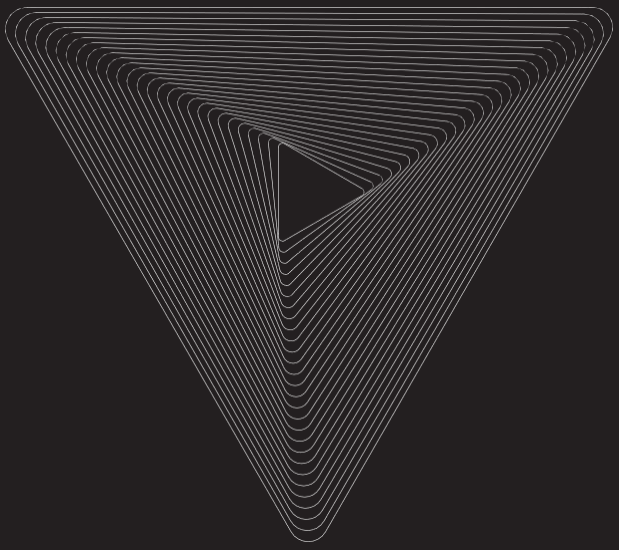
VERSO
BIOSENSE



IRIS KIT
PHYSICIAN INSTRUCTIONS FOR USE

CONTENTS

INTENDED USE

- The IRIS is intended to measure core body temperature (T) and dissolved oxygen (DO) in vivo for up to 7 days to support conception. The IRIS is intended to be used post-ovulation, during the embryo implantation window of the menstrual cycle. The data provided by the IRIS helps to plan for conception in subsequent menstrual cycles.

- The IRIS is indicated for adult women (≥ 18yrs) who are wanting to conceive and have not reached menopause (refer to contraindications).

- The IRIS is intended to be inserted by healthcare professionals who must be qualified to an appropriate level of competence in intrauterine techniques. The healthcare professional must also be trained by Verso Biosense Ltd prior to inserting the IRIS. The trained healthcare professional will ensure correct placement of the IRIS during insertion and correct operation prior to release of the patient from the clinic.

  Note: It is recommended that women who want to conceive, should have a BMI between 19-30.

CONTENTS

UDI: 5065013157009	IRIS KIT	VBS-0260	IRIS
		VBS-0233	Inserter Tube
		VBS-0235	Inserter Rod
		VBP-041	Hydration Saline
		VBS-0440	Hydration Pocket
		0300-IFU-02	Physician IFU

The IRIS Kit is intended to be used with the following products which are sold separately:

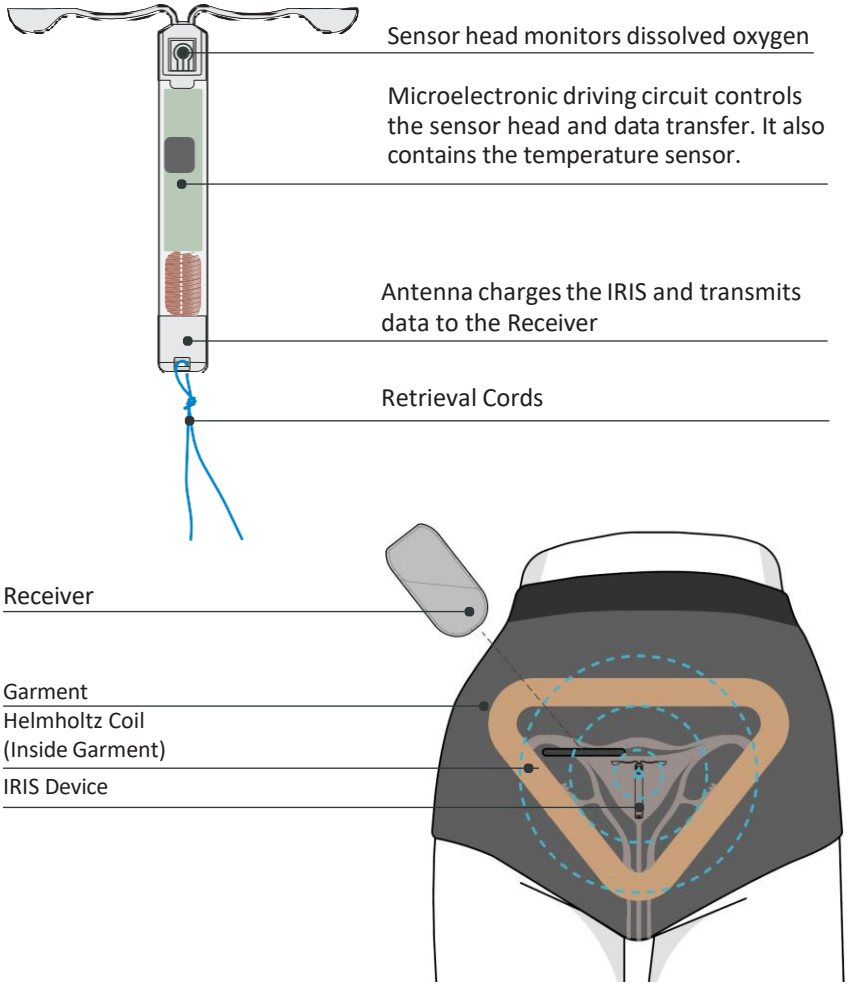
UDI: 5065013157016	RECEIVER KIT - SMALL	VBS-0254-Small	2x Garments
		VBS-0290	2x Receivers
		VBP-029	1x Charger
		0300-IFU-01	Patient IFU
UDI: 5065013157023	RECEIVER KIT - MEDIUM	VBS-0254-Medium	2x Garments
		VBS-0290	2x Receivers
		VBP-029	1x Charger
		0300-IFU-01	Patient IFU
UDI: 5065013157030	RECEIVER KIT - LARGE	VBS-0254-Large	2x Garments
		VBS-0290	2x Receivers
		VBP-029	1x Charger
		0300-IFU-01	Patient IFU

DESCRIPTION

The IRIS is a sensor device that is inserted into the uterus by an appropriately trained clinician at a clinic.

The IRIS monitors the core body temperature and dissolved oxygen in the uterus for up to 7 days and transmits the data to a Receiver via an aerial.

Data from the Receiver is retrieved for analysis post use.



CONTRAINDICATIONS

Pregnancy or suspicion of pregnancy

Abnormalities of the uterus resulting in distortion of the uterine cavity (including fibroids) or a uterine cavity length less than 6cm.

Presenting with or has a history of or has a current behaviour suggesting a high risk of any of the following conditions:

- Acute pelvic inflammatory disease (PID)
- Postpartum endometritis
- Post-abortal endometritis (in the past 3 months)
- Uterine or cervical malignancy
- Cervical neoplasia
- Mucopurulent cervicitis
- Vaginitis
- Bacterial vaginosis
- Sexually transmitted infection (STI)
- Urinary tract infection (UTI)
- Group A Streptococcus infection

Presenting with uterine or genital bleeding of unknown aetiology

Have a history of hypersensitivity or allergic reaction to any patient-contacting component of the IRIS, e.g. silicone or barium sulphate.

Has an IUD currently inserted.

The IRIS is not suitable for use, for a patient who is using a wearabale or implantable electrical medical device which is life sustaining, or providing treatment.

WARNINGS

NOTE
(Please discuss the warnings with the patient.)

- Vasovagal reaction, Bradycardia and Arrythmia

Over-stimulation of the cervix during insertion of an IUD may cause temporary clinical conditions such as fainting, dizziness or light-headedness (vasovagal reaction), slowness of heart rate (bradycardia) or abnormal heart rhythm (arrhythmia). In healthy women such incidents are usually resolved with simple resuscitation measures; rarely does bradycardia or arrythmia persist and require further treatment.

- Insertion pain

Insertion of an IRIS can cause pain or discomfort and is normally due to poor insertion technique. Insertion under ultrasound guidance will allow the healthcare professional to see where they are placing the device and avoid as far as possible any injury to the uterus. The pain and discomfort in most cases will be short lasting and the patient is normally prescribed pain medication prior to the insertion. Rarely, the pain may continue after insertion but in these instances, there is the option for the device to be removed early. There is also the option of having local anaesthetic in the cervix (neck of the womb) during insertion if the patient wishes to have it administered.

Components of the insertion procedure that may cause pain include the application of the tenaculum (if used) to the cervix to stabilize the uterus and provide traction for straightening the cervical canal, passing the uterine sound, advancing the inserter tube through the cervix, and irritation of the endometrial cavity when the device is deployed.

- Perforation and embedment

Perforation is a hole in the uterine wall which is the result of when the device has physically pierced it during insertion of an IRIS. Embedment is when the IRIS remains embedded in the uterine wall after having pierced it. Both are normally due to poor insertion technique. Insertion under ultrasound guidance will allow the gynaecologist to see where they are placing the device and avoid as far as possible any injury to the uterus.

WARNINGS CONT.

- Pelvic Infection

Pelvic inflammatory disease (PID) is an infection of the female reproductive system which includes the womb, fallopian tubes and ovaries. Most cases of PID are caused by a bacterial infection that's spread from the vagina or the cervix to the reproductive organs higher up. Many different types of bacteria can cause PID. In many cases, it's caused by a sexually transmitted infection (STI), such as chlamydia or gonorrhoea. In other cases, it's caused by bacteria that normally live in the vagina. In the case specific to IUDs, it is possible that an unsterile IRIS, unsterile insertion accessories or poorly controlled insertion technique, allows for an introduction of bacteria into the vagina or the uterus.

- Expulsion

Expulsion is defined as when the IRIS is ejected from the uterus of its own accord (after the patient has left the clinic with the device in situ).

- Adverse Tissue Reaction

Adverse tissue reaction may occur when local tissue is in contact with materials that are foreign to the human body. Materials such as polymers may contain chemical substances that are harmful and can cause local irritation, hypersensitivity or cytotoxicity (cell lysis).

WARNINGS CONT.

- Magnetic Resonance Imaging (MRI) scans and X-ray equipment

IRIS is not suitable for use during operation of MRI scans and X-ray equipment. Exposure to X-rays will damage the product electronics and prevent it from functioning as intended (there is no safety issue). The use of MRI is contra-indicated for people with inserted medical devices. These devices may be susceptible to overheating or dislocation when subjected to the magnetic field. The magnetic field associated with MRI is like the magnetic field that is used in the product to power the IRIS during normal use. The magnetic field generated by the product is approximately 190 microTesla. The magnetic field generated during an MRI scan is likely to be more than 1.5tesla. The larger magnetic field has the potential to damage the IRIS.

The effect of MRI scans or X-rays on the device have not been investigated. The IRIS can easily be removed without harm to the user should an MRI scan or X-ray be required.

- Radio Communications

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in incorrect operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from the IRIS receiver Otherwise, degradation of the performance of this equipment could result.

Use of the IRIS system in the vicinity of metals may result in a degradation of performance of the system.

- Contacting Electrical Connectors

Avoid touching the electrical connectors on the receiver, as this may damage it.

STORAGE CONDITIONS FOR THE IRIS

Store the IRIS in original sealed package, away from direct sunlight, between 5°C-40°C.

The Garment, receiver, and electrical accessories must be stored in a dry location.

GARMENT SIZING

To size the patient for the appropriate garment, using a measuring tape, measurements are taken across:

1. The waistline – measured at 71 cm from the gusset.
2. The hip line – measured at the widest part of the hips.

A reference table is provided to correctly identify which size both the hips and the waist measurements fall into. If the patient is between two sizes, the clinician should select the smaller size. This is because the garment is made from an elasticated material and can accommodate stretch in both the hips and the waist. The waist measurement is critical to keeping the garment in the correct position during use.

Garment Size	Waist Circumference	Hip Circumference
Small	69cm	89cm
Medium	72cm	95cm
Large	75cm	101cm

SCREENING FOR PATIENT SUITABILITY

- A full personal and family medical history should be taken (including recent unprotected vaginal sexual intercourse).

- A urinary pregnancy test will be conducted during the screening visit.

- An ultrasound and pelvic examination should be carried out to determine measurements of the uterus. The uterus should measure between 6 to 10 cm in length. Insertion of the Verso IRIS into a uterine cavity less than 6.0 cm may increase the incidence of expulsion, bleeding, pain, and perforation.

PREPARATION FOR INSERTION

The IRIS should be inserted by a trained health care provider. Health care providers are advised to become thoroughly familiar with the insertion instructions before attempting insertion of the IRIS.

Advise the patient to drink 2-3 cups of water 1-2 hours before the ultrasound scan and not empty their bladder before the procedure.

Observe strict asepsis during insertion. The presence of organisms capable of establishing PID cannot be determined by appearance, and IRIS insertion may be associated with introduction of vaginal bacteria into the uterus.

Fundal positioning of IRIS is important to prevent expulsion and maximize efficacy. Therefore, follow the instructions for the insertion carefully.

Pulse and blood pressure should be observed prior to insertion and pulse monitored during insertion and post procedure.

If the patient develops decreased pulse, perspiration, or pallor, have them remain supine until these signs resolve. Insertion may be associated with some pain and/or bleeding. Syncope, bradycardia, or other neurovascular episodes may occur during insertion of the IRIS, especially in patients with a predisposition to these conditions or cervical stenosis.

Ensure the IRIS has been hydrated and the pre-checks have been completed according to the IFUs:

- 0300-IFU-03 - IRIS Hydration Instructions
- 0300-IFU-04 - IRIS Performance Check Instructions

CAUTION !

Inserting the IRIS without hydrating,
may cause the device to not operate as intended.

PATIENT PREPARATION

Ensure that the patient understands the contents of the Patient Information Booklet and obtain consent. A consent form that includes the IRIS lot number is on the last page of the Patient Instructions for Use.

Confirm that there are no contraindications to the use of the IRIS system. Confirm that

at least one of the following is true:

- There has been no sexual intercourse since last menses.
- A reliable method of contraception has been correctly and consistently used since last menses.

A negative pregnancy test adds weight to the exclusion criteria but only if >3weeks since last episode of unprotected sexual intercourse.

With the patient comfortably in lithotomy position, gently insert a speculum to visualize the cervix and rule out genital contraindications to the use of the IRIS system.

Perform an abdominal ultrasound to establish the size and position of the uterus, to detect other genital contraindications, and to exclude pregnancy.

The uterus should measure between 6 to 10 cm in length. Insertion of the Verso IRIS into a uterine cavity less than 6.0 cm may increase the incidence of expulsion, bleeding, pain, and perforation.

Thoroughly cleanse the cervix and vagina with a suitable antiseptic solution. Perform

a paracervical block, if needed.

INSERTION OF THE IRIS

NOTE

Only healthcare professionals that hold the appropriate FSRH Letter of Competence in Intrauterine Techniques or have achieved equivalent recognised competencies and show evidence of recertification/ reaccreditation and have received training from Verso Biosense Limited are approved for the insertion and removal of IRIS.

Valid consent from the patient is required for the use of IRIS.
The offer of a chaperone should be made who will also monitor patient during the procedure and be available in an emergency.

Only use the insertion accessories provided.

CAUTION !

Insertion may be associated with some pain and/or bleeding or vasovagal reactions so should always be performed in a clinical environment with appropriate resuscitation equipment if required.

CAUTION !

No gels or lubricants must be used during the insertion process.
This may affect the performance of the device.

CAUTION !

Ensure that no hydration saline has leaked outside the hydration pocket.

CAUTION !

The device must be used within 24 hours of hydration, The risk of insertion with hydrating for longer than 24 hours may cause the device to not operate as intended

CAUTION !

Do not use the IRIS or insertion accessories if the pouch is damaged or unintentionally opened before use.

INSERTION OF THE IRIS CONT.

NOTE

The contents of the package are sterile.
Use sterile surgical gloves while handling the contents of the package.

The threads of the IRIS are threaded through the inserter tube.

Peel open the upper edges of the pouch far enough to allow access to the inserter tube

Grasping the inserter tube and the removal cord, remove the IRIS and the inserter tube from the sterile package.

Holding the inserter tube in one hand and the removal cords in the other, draw the IRIS into the inserter tube by pulling on the removal cord until the tips of the arms form a hemisphere at the end of the inserter tube. Ensure the hemisphere remains outside the inserter tube. (Figure 2).

Grasp the inserter tube (taking care not to dislodge the IRIS) in the hand you will use to guide the inserter tube into the uterus.

With your other hand, gently fold the threads of the IRIS back along the inserter tube and clasp under the thumb of the hand holding the inserter tube.

Insert the inserter rod into the open end of the inserter tube and push towards the back of the IRIS. Take care not to dislodge the IRIS from its position in the inserter tube.

The following steps shall be performed under ultrasound guidance: Continue to

hold the inserter tube and securing the thread with the thumb.

Grasp the tenaculum forceps (if required) with your other hand and apply gentle traction to align the cervical canal with the uterine cavity.

Ensuring that the sensor face on the IRIS is facing upward, gently introduce the inserter tube through the cervical canal and into the uterus. Visualise the progress of the IRIS using ultrasound. Insert until the leading edge of the inserter tube is about 2 cm from the fundus.

INSERTION OF THE IRIS CONT.

Check the positioning of the IRIS using ultrasound.

Stage 1: While visualising under ultrasound, hold the inserter rod steady and push the inserter rod forward until the arms of the IRIS are released from the inserter tube.

Wait approximately 10 seconds to allow the arms of the IRIS to fully open.

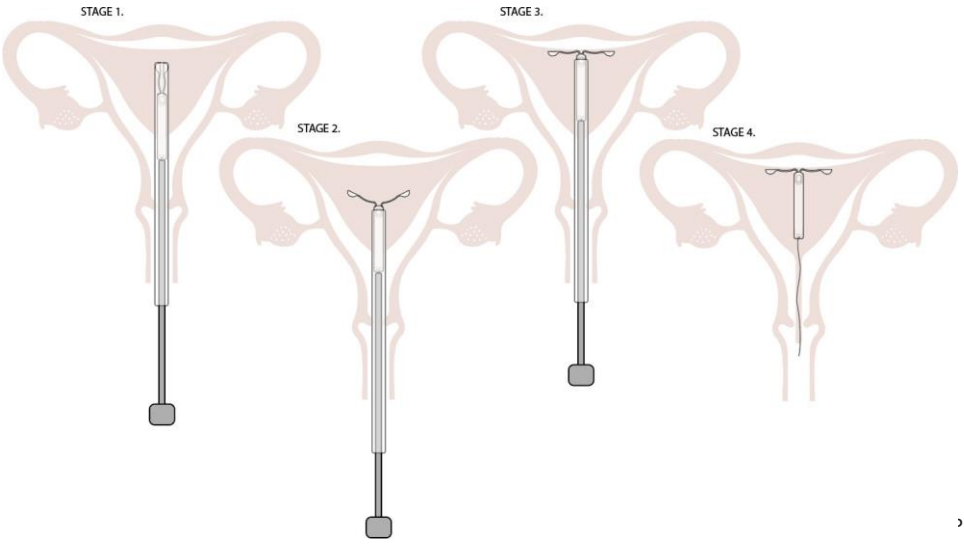
Stage 2: Gently advance the inserter tube and inserter rod together further into the uterine cavity. By visualising under ultrasound, advance the IRIS up to the fundus. Confirm by ultrasound that the IRIS is in the correct position and orientation.

Stage 3: Release the IRIS fully into the uterine cavity by keeping the inserter rod stationary and withdrawing the inserter tube until the free end of the tube meets the handle on the inserter rod.

Carefully withdraw the inserter rod from inside the inserter tube. Ensure the

thread is free to move into the inserter tube.

Stage 4: Carefully withdraw the inserter tube clear of the cervix.



INSERTION OF THE IRIS CONT.

Confirm by ultrasound the correct position and orientation of the IRIS inside the uterus.

Cut the device threads square at around 3 cm from the cervix. Do not apply tension or pull on the threads when cutting to prevent displacing the IRIS.

The LOT number of the IRIS should be recorded in the patient record. The lot number of the device can be found on the label applied on the outer packaging of the IRIS.

Retain the instructions for use after IRIS insertion.

CAUTION !

If you suspect that the IRIS is not in the correct position, remove the IRIS following the removal instructions in this IFU. A removed IRIS must not be reinserted.

If perforation or embedment of the uterine body or cervix is detected during physical examination or ultrasound remove the IRIS immediately.

Any case of uterine perforation and insertion difficulties must be recorded appropriately.

CONNECTING RECEIVERS WITH THE GARMENT

Direct the Patient to wear the garment over their underwear, ensuring the waistband of the garment is level front and back.

Check the fit of the garment. The garment should fit snugly but not be uncomfortably tight.

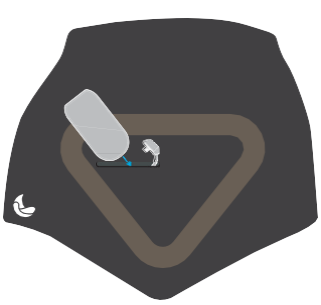
Locate the switch on the receiver and switch the receiver ON. The green LED on the receiver will flash continuously.

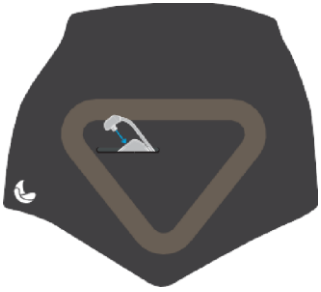
Place the receiver into the pocket on the front of the garment and attach the connector from the garment to the receiver.

The receiver will vibrate twice to confirm the receiver is connected to the garment.

Once the receiver is in place and connected, check for any red indicator lights on the receiver over the next 10 minutes.

If the receiver does not indicate a red light, the product is functioning correctly. If a red indicator light on the receiver comes on, refer to the troubleshooting section.





TROUBLESHOOTING

If the red indicator light on the receiver comes on, this will signify that the system has experienced a fault. Request that the patient replaces the garment with a new one and repeat the receiver connection steps with the second receiver. Switch on the second receiver. Place the receiver into the pocket on the front of the garment and attach the connector from the garment to the receiver. The receiver will vibrate twice to confirm receiver connected to the garment and observe the system for 10 minutes for the presence of a red light.

If the second receiver indicates a red light, the system has a significant fault, and the patient on boarding should be discontinued. Request that the patient remove the garment. Arrange for the IRIS to be removed as soon as possible. All the components of the product should be returned to Verso Biosense.

Please refer to the section on returning product.

PATIENT CARE

CAUTION !

Care should be taken to ensure that the patient is not experiencing any unreasonable discomfort following the IRIS insertion procedure. Advise on the use of over-the-counter analgesics if appropriate.

Cervical stimulation during the insertion of intrauterine methods can cause a vasovagal reaction, bradycardia, and other arrhythmias. In healthy women vasovagal incidents usually resolve with simple resuscitation measures; rarely bradycardia persists and requires treatment with intravenous or intramuscular atropine.

Guide the patient through the contents of the patient instructions for use (0300-IFU-01), provided within the receiver kit.

NOTE

The patient instructions for use includes information that is important for safeguarding the patient.

Guide the patient though the daily use of the product taking special care to mention the need for replacing and charging the receivers. Also, highlight the need for the garment to be replaced with the second garment three or four days into the 7-day monitoring period.

The patient should be instructed to call the technical support line with any questions regarding the use of the product and with any reports of alarms and alerts.

The patient should also be instructed that if the receiver overheats or emits a smell while in use, then they are to remove it immediately and call the technical support line.

The patient should also be instructed to contact the technical support line with any health concerns.

REMOVAL OF THE IRIS

NOTE

Only healthcare professionals that hold the appropriate FSRH Letter of Competence in Intrauterine Techniques or have achieved equivalent recognised competencies and show evidence of recertification/ reaccreditation and have received training from Verso Biosense Limited are approved for the insertion and removal of IRIS.

CAUTION!

Removal may be associated with some pain and/or bleeding or vasovagal reactions so should always be performed in a clinical environment with appropriate resuscitation equipment if required.

The IRIS must be removed within 7 to 10 days of it being inserted. Use

sterile surgical gloves throughout the removal of the IRIS.

Remove the IRIS by applying gentle traction on the threads with a pair of grasping forceps.

If no threads are seen, conduct a trans-abdominal ultrasound to determine if IRIS in the uterine cavity. If IRIS is in the uterine cavity, use a 'thread retriever' or narrow forceps, such as an alligator forceps to remove the IRIS. This may require dilation of the cervical canal and/or continuous ultrasound assessment to determine the position of the IRIS during removal.

If the threads are not available, the device will have to be retrieved in accordance with usual clinical practice.

After removal of IRIS, examine the IRIS to ensure that it is intact. Disintegration or breakage of the device must be reported accordingly, this information should also be shared with Verso Biosense.

If the device is seen to be disintegrated or broken, the remains of the device must be retrieved using hysteroscopy performed under general anaesthetics.

PRODUCT RETURN / DISPOSAL

The IRIS system which includes the IRIS, garments, receivers and charger must be returned to Verso Biosense Limited after use. Care must be taken to ensure that individual patients' systems are kept segregated from one another.

The IRIS must be handled in accordance with the hospital guidelines for the handling of biohazardous waste, stored in the storage container provided by Verso Biosense Limited and returned to Verso Biosense Limited.

The outer IRIS kit packaging can be handled as a household waste.

PATIENT FOLLOW-UP

The patient will be contacted by Verso Biosense within 2 days post insertion of the IRIS. Following the first post-insertion call, the patient will be contacted by Verso Biosense every 2 days until the day of IRIS removal.

The patient will be asked to report:

- Any pain or discomfort, especially any pelvic pain.
- Problematic bleeding
- Any rise in body temperature
- Unusual vaginal discharge
- If they can still feel the retrieval threads
- Problems with the product

The patient will also be contacted two days after removal to report:

- Any pain or discomfort, especially any pelvic pain.
- Problematic bleeding
- Any rise in body temperature
- Unusual vaginal discharge
- If they can still feel the retrieval threads
- Problems with the product

PATIENT REPORT

The patient will be provided with a report of their measurement data from Verso Biosense Limited. The patient should discuss these results with their physician before planning for conception.

LABELING SYMBOLS


Manufacturer Information


Date of manufacture

Do not re-sterilise

Non-Sterile


Consult instructions for use


Do not use if package is damaged

Single patient - Multiple uses


Type BF applied part


Keep dry Temperature


limits

Model Number

Unique Device identifier


Single Use Only

Lot Number

Medical Device


Fragile, Handle with care

Serial Number

CE


RF Electromagnetic Radiation


Use-By Date

European Authorised Representative

Single Sterile Barrier System - Sterilised by Ethylene Oxide

ELECTROMAGNETIC COMPATIBILITY AND RADIO SPECIFICATION

Emissions Test	Compliance	
CISPR B Emissions Classification	Group 1 Class B	
Harmonic Emissions IEC 61000- 3-2	Class A	
Immunity	**Immunity Test Levels**	
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8kV contact. +/- 15 kV air	
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz 3 V/m 2.7 to 6 GHz	
Proximity fields from RF Wireless communications Equipment IEC 61000-4-3	380 - 390 MHZ	27 V/m
	430 - 470 MHZ	28 V/m
	704 - 787 MHz	9 V/m
	800 - 960 MHZ	28 V/m
	1.7 - 1.99 GHz	28 V/m
	2.4 - 2.57 GHz	28 V/m
	5.1 - 5.8 GHz	27 V/m
Electrical fast transient burst IEC 61000-4-4	+/- 2kV at 100 KHz	
Surge IEC 61000-4-5	Line to Line: +/- 1KV	
Conducted RF IEC 61000-4-6	3Vrms 150KHz to 80 MHz, 6 Vrms ISM and amateur radio bands	
Voltage dips, short interruptions, and voltage variations on power IEC61000-4-11	0% Residual voltage for 0.5 cycle 0% Residual voltage for 1 cycle 70% Residual voltage for 30 cycles Voltage interruption: 0% residual voltage for 300 cycles	

Radio Specifications	
Frequency of operations	139.6KHz
Frequency band	119KHz to 140KHz
Modulation	Amplitude Modulation
Radiated H-Field	35.5 dBuA/m

TECHNICAL SPECIFICATIONS

IRIS	TECHNICAL SPECIFICATION
Temperature Sensor	34°C to 42°C +/- 0.1°C
Dissolved Oxygen Sensor	Lower Range 0 - 20 mmHg +/- 2 mmHg Middle Range 21 – 50 mmHg +/- 10% Upper Range 51 – 150 mmHg +/- 13%
IRIS Usage	Single Use for up to 7 days
Field Strength Requirements	<1mT
Overall dimensions	36mm x 32mm
Inserter Tube	222mm x 5mm

CONTACT DETAILS

All queries should be addressed to:

Verso Biosense Limited 115B
Innovation Drive Milton Park
Milton
Abingdon OX14
4RZ

T: +44(0) 2380 111 555
E: customercare@versobiosense.com
www.versobiosense.com

This IFU can also be found at:
https://versobiosense.com/product-docs/

Any serious incident that has occurred in relation to the IRIS must be reported to Verso Biosense Limited and your national Competent Authority.

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