

Wing Needle™ Instructions for Use

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These instructions are for use with the Wing needle™. Each needle is delivered in a single sterile pack and is for single use only.

Indications for Use

Only medical professionals who have experience of working with devices and needles within the uterine cavity should use this needle.

The Wing Needle™ is designed to deliver local anaesthesia safely into the uterine cavity through a minimum 5 French working channel of any standard operative hysteroscope. It allows the surgeon to perform various surgical procedures, safely and without the need for spinal or general anaesthesia.

CAUTION:

- This needle should only be used by clinicians with the appropriate training in use of needles under hysteroscopic guidance and who are familiar in the geography of the uterine cavity.
- If the packaging is open or damaged, the sterility of the product will be compromised and should not be used.

Description

The Wing Needle™ consists of a standard Luer connection with an outer 17 gauge Needle and inner 24 gauge needle bevelled upward. The needle is 36cm long with four 3mm placement markers positioned 5mm apart at its distal end. These are visible through the hysteroscope and aid with positioning the needle and the measurement of intrauterine pathology.

Contraindications

The Wing Needle™ is contraindicated for use in uteri in which the anatomy cannot be defined. Two tubal Ostia must be recognized in normal uteri, or one tubal ostium in unicornual uteri. Only in these situations can the location of the injections within the uterine wall be carried out safely.

Potential Adverse Events

The following adverse events are potentially associated with the Wing Needle™.

- Allergic reaction due to injection of local anaesthetics with or without adrenaline
- Perforation and damage to the surrounding organs in case the surgeon pushes the needle with more than usual force through the uterine wall, despite the safety feature of the needle.

Warnings

- The Wing Needle™ should be considered as contaminated medical waste after use.
- The product must not be used if the packaging has being compromised or contaminated.
- This device is intended for single use only.
- Do not reuse, re-sterilize or autoclave. Reuse of single use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient.

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- Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure. The manufacturer will not be responsible for any direct, incidental or consequential damages resulting from re-sterilization or reuse.
- Do not apply excessive force when advancing the needle since this can result in the risk of the needle tip bending or breaking.
- Do not use the Wing Needle™ after the expiry date.













Directions for Use

- The Wing Needle™ is supplied in a protective sleeve within a sterile pouch.
- Check expiry date. Do not use if the expiry date has passed.
- Peel open pouch at the end with the chevron seal to remove the needle using standard aseptic technique.
- Connect a syringe containing the anaesthesia to the female luer hub of the Wing Needle™ and prime the needle.
- The Wing Needle™ is designed to pass through a minimum 5 French working channel of any standard operative hysteroscope.
- After the hysteroscope is set up, insert the Needle through the working channel.
- Using the markings on the distal end of the Needle, manipulate the bevelled tip to the desired location for anaesthesia delivery.
- Press the tip gently into the wall of the Uterus and inject the anaesthesia.
- Remove the tip gently and continue to manipulate the needle to as many locations as required.
- Once the desired number of injections have being delivered, the needle should be removed and safely disposed of in accordance with local medical hazardous waste practices.


Storage Conditions

The product should be stored at room temperature while avoiding locations subject to high temperature and direct sunlight.

Symbols Used on Labelling

	Catalogue Number		Date of expiry
	Do not use if pack is opened or damaged		Avoid moisture
	Avoid direct sunlight		Do not re-sterilize
	Sterilized by steam or dry heat		Batch number
	Manufacturer		Single use only
	Consult instructions for use		CE Mark and Identification Number of Notified Body. Product conforms to the essential requirements of the Medical Devices Directive 93/42/EEC.



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