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SUMMARY OF SAFETY AND EFFECTIVENESS WALLACE ARTIFICIAL INSEMINATION CATHETERS

The Summary of Safety and Effectiveness on Artificial Insemination Catheters reflects data available and resented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Intended Use

The Family of Wallace Artificial Insemination Catheter are sterile single-use device intended for insertion of catheters and introduction of washed spermatozoa into the uterine cavity.

Indications

The ability of the Family of Wallace Artificial Insemination Catheter to meet its intended function includes the finely smoothed tip and constant internal lumen to prevent embryo damage and ensure atraumatic technique.

Contraindications

The Wallace Artificial Insemination Catheters are not intended for intrafallopian tube procedures.

Caution

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Substantial Equivalency Information

The Wallace Artificial Insemination Catheter are similar to the Edwards-Wallace Catheters currently offered by Marlow Surgical Technologies, Inc.

	Edwards-Wallace Catheters	AIC Catheters
Materials	Polypropylene Fluorethylenepropylene Polyurethane	Polypropylene Fluorethylenepropylene Polyurethane
Sterilization	EO SAL 10 ⁻⁶	EO SAL 10 ⁻⁶

The intended use and technological characteristics of these devices do not vary significantly. The safety and effectiveness of the Wallace Artificial Insemination Catheter are comparable to that of the other catheters.