

# ELECTRONIC INSTRUCTIONS FOR USE

Part: E-Ray Detectable Devices

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# ORS<sup>®</sup>

## X-RAY DETECTABLE DEVICES

by **fabco**<sup>®</sup>

**fabco**<sup>®</sup>

Manufactured for:

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1391-00000-00174 Rev. Issue [ENG]

## FABCO<sup>®</sup> ORS<sup>®</sup> X-RAY DETECTABLE DEVICES

(Please Read Prior to Use)

### DESCRIPTION

FABCO<sup>®</sup> ORS<sup>®</sup> X-RAY DETECTABLE DEVICES are made with an x-ray detectable marker that is affixed or embedded into the device.

### INSTRUCTIONS FOR USE

- Step 1.** Verify count and integrity of devices when package is opened.
- Step 2.** Use device for medical and/or surgical procedures, as intended.
- Step 3.** Verify count of devices after withdrawal from the patient.

### PRECAUTIONS AND WARNINGS

- Surgical and/or medical procedures should be performed only by physicians having adequate training and familiarity with surgical techniques. A thorough understanding of operating principles, risks versus benefits, and the hazards involved in utilizing medical devices is essential to avoid the potential for injury to the patient and/or user.
- Do not use if individual packaging is damaged or open due to risk of contamination. Product expiration/"Use By" dates for both non-sterile and sterile products should be considered compromised if packaging is damaged or open (as applicable). Use proper aseptic technique in all phases of handling.
- This product is for single use only; do not re-sterilize. Re-use can result in microbial contamination causing subsequent health deterioration of patient. Devices contain absorbent materials that cannot be cleaned. FABCO will not be responsible for any product that has been re-sterilized and/or reused.
- Count all devices before and after the procedure prior to surgical closure. In the event a device cannot be located, an x-ray can be used to locate the devices. Failure to perform count and verification may result in additional procedures and/or extended surgery.
- Used devices should be considered as bio waste and be disposed of in accordance with local regulations
- RADIOGRAPHY:** Devices may be obscured from x-ray when behind bone or in morbidly obese individuals. It is recommended that at least three views, using the optimal parameters for the imaging (x-ray) equipment, at a variety of angles (e.g., 45 degrees, 22.5 degrees, and 0 degree angles) for anterior and posterior, or the appropriate plane, be taken and examined for a missing device. If there are concerns regarding visualization, consult with your local imaging expert to establish the optimal radiographic parameters (e.g., kVp, mAs) for visualization with the imaging equipment.
- PHthalATES:** The X-ray detectable material in this device contains phthalates, specifically Diisononyl phthalate (DINP). The results of certain animal experiments have shown phthalates to be potentially toxic to reproduction. Proceeding from the present state of scientific knowledge, risks for male premature infants cannot be excluded in the case of long-term exposure or application. Medical products containing phthalates should be used only temporarily with pregnant women, nursing mothers, babies and infants.

### EXPLANATION OF SYMBOLS (as applicable)



1391-00000-00174 Rev. Issue [ENG]