



# Radiation Products Design, Inc.

**THIS PRODUCT IS NOT STERILE  
TO BE USED BY AUTHORIZED PERSONNEL ONLY**

RADIATION PRODUCTS DESIGN, INC. assumes no liability for consequential damages of any kind for this material when used or for any direct or indirect consequences of its use or misuse by their customer.

## **ABS OVOID CAPS WITH TUNGSTEN**

- Cleaning:** Use detergent similar to Klenzyme®, Manu-Klenz® or NpH-Klenz® and water.  
Ultrasound cleaner may be used.
- Sterilization:** Ethylene Oxide (ETO) **ONLY**. Temperature between 120 to 140 degrees Fahrenheit for 2-3 hours. Aerate for 8-12 hours.
- Warning:** The **ONLY** verified method for sterilization of shielded caps is Ethylene Oxide.  
**DO NOT use Sterrad**  
**DO NOT Autoclave**

## **NYLON AND DELRIN STERILIZATION TECHNIQUES**

- Cleaning:** Use detergent similar to Klenzyme®, Manu-Klenz® or NpH-Klenz® and water.  
Ultrasound cleaner may be used.
- Sterilization:** Sterrad, Steris, or Gas  
Temperature **must not** exceed 140°
- Warning:** **DO NOT steam autoclave**

## **ACRYLIC STERILIZATION TECHNIQUES**

- Cleaning:** Use detergent similar to Klenzyme®, Manu-Klenz® or NpH-Klenz® and water or vinegar and water
- Sterilization:** Sterrad, Steris, or Gas  
Temperature **must not** exceed 140°
- Warning:** DO NOT clean with alcohol as this may cause acrylic to fracture.  
**DO NOT steam autoclave**

## **STAINLESS STEEL AND ALUMINUM STERILIZATION TECHNIQUES**

- Cleaning:** Use detergent similar to Klenzyme®, Manu-Klenz® or NpH-Klenz® and water.  
Warning - DO NOT clean with hydrogen peroxide or glutaraldehyde (Cydex).
- Sterilization:** Sterrad: Temperature **must not** exceed 140° (Peroxide sterilization may take coloring out of aluminum)  
Steris: Temperature **must not** exceed 140°  
Gas: Temperature **must not** exceed 140°
- Warning:** DO NOT clean with ultrasound cleaner

## **STERILIZATION TRAY**

Use GAS (Ethylene Oxide) steam sterilization at normal cycle  
DO NOT Flash - flash steam sterilization may cause nylon coating to flake off.  
**Not certified for Sterrad.**

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### **GAS STERILIZATION PROCEDURE**

Warm up phase is one hour at 130°F. Conditioning phase at 130°F for 30 minutes. Inject gas, type 12% Ethylene Oxide and 88% Freon, and hold for 2 hours or type 100% Ethylene Oxide and hold for 225 minutes at 85°F or 62 minutes at 130°F. Mechanically aerate for 40 hours at 120°F or 20 hours at 130°F or 10 hours at 140°F or room aerate for 7 days.

**5218 Barthel Industrial Drive NE – Albertville, MN 55301**  
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### **CAUTION**

"The U.S. Food and Drug Administration (FDA) has received reports of eight incidents in which the closed end of the intrauterine colpostats of a Fletcher Suit applicator separated from the applicator and remained in the uterus after the applicator had been removed, necessitating an additional removal procedure. Clearly this can cause undesirable complications for patients and holds the potential for the loss of capsules of radium or related radioactive materials within the patients's uterus. The reason for these separations is unknown. However, cleaning the applicator with hydrogen peroxide or glutaraldehyde (Cydex) prior to autoclaving or cold sterilization can result in corrosion of the applicator's welds.

FDA is using this notice to alert users of Fletcher Suit applicators of this potential problem. FDA believes that all Fletcher Suit applicators should be inspected to determine whether or not the closed end of the colpostats or the colpostats themselves are adequately secured, and that any applicators that are questionable should not be used. Until recently, manufacturers' guidance on cleaning and sterilization may not have been clear. The applicators should be cleaned using ONLY a mild detergent and water, and then thoroughly rinsed with water before sterilization.

Although, to date, FDA has only received reports of problems with Fletcher Suit applicators, it is also recommending that all applicators of similar design be checked, and that the same cleaning instructions be followed."

The above article appears in the newsletter of the American Association of Physicists in Medicine. Volume 14 No. 3, May/June 1988, Pages 7 and 8.

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## TEST AND INSPECTION FOR FLETCHER-SUIT-DELCLOS APPLICATORS

Separate your Fletcher-Suit-Delclos Colpostat into two halves and conduct TESTS A, B and C on each half as follows:

**MECHANICAL TEST A** - Gently manipulate each ovoid with one hand while holding the ovoid handle with the other. Each ovoid should be solidly attached to the handle. If the ovoid is loose, Test A fails and no other tests need to be done. If Test A passes, continue to Test B.

**VISUAL TEST B** - Visually inspect each half of your FSD for hairline cracks at the top and bottom of ovoid and the ovoid handle joint. Inspect silver-brazed joints where center pivots and the locking brackets attach to the ovoid handles. If cracks are seen, Test B fails and no other tests need to be done. If Test B passes, continue to Test C.

**PRESSURE TEST C** - Conduct this test on each half of the FSD:

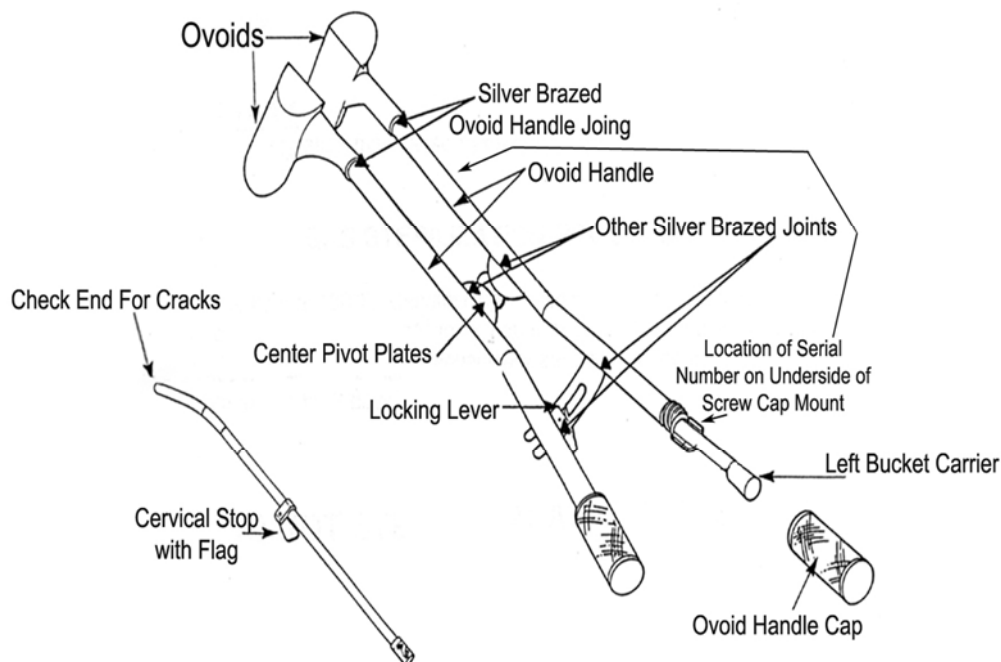
- 1) Remove the ovoid handle cap from the end of the ovoid handle.
- 2) Remove the bucket carrier.
- 3) Stand the colpostat in a beaker of water to a depth above the ovoid handle joint.
- 4) Apply slight air pressure on the open end of the FSD handle (using for example, a 10cc syringe connected to surgical tubing connected to the FSD handle), and look for air bubbles escaping from the ovoid or ovoid handle joint. If bubbles are seen, TEST C fails. If Test C passes, the ovoid is solidly attached to the ovoid handle and no immediate action is necessary.

**IF TEST A OR B OR C FAILS STOP USING THE FLETCHER-SUIT-DELCLOS FOR PATIENT THERAPY.**

Send complete units in for repair including bucket carriers, to Radiation Products Design, Inc.

The above tests can be conducted at Radiation Products Design, Inc. for a charge.

### FLETCHER-SUIT-DELCLOSAPPLICATOR



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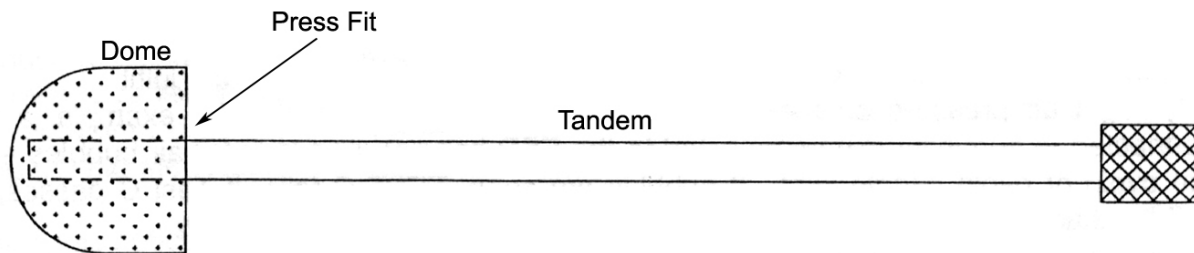
**Radiation Products Design, Inc.**

**TEST AND INSPECTION FOR DELCLOS UTERINE/VAGINAL  
AFTERLOADING APPLICATOR**

**MECHANICAL TEST FOR PRESS FIT DOME TANDEM ASSEMBLY** - With one hand grip Dome and with other hand grip Tandem then try pulling apart. If part pulls apart stop using unit for patient therapy.

**DO NOT AUTOCLAVE**

Replacement Parts can be purchased from Radiation Products Design, Inc.



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