

## **Radiation Products Design Inc**

## **INSTRUCTIONS**

# **RPD INFORMATION**

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# **RPD PRODUCT INFORMATION**

Item Number	HDR Simon-Heyman Disposable Applicator
903-0420	4 mm Diameter x 1.4 mm Wall x 20 mm Active Area
903-0430	4 mm Diameter x 1.4 mm Wall x 30 mm Active Area
903-0620	6 mm Diameter x 2.4 mm Wall x 20 mm Active Area
903-0630	6 mm Diameter x 2.4 mm Wall x 30 mm Active Area
903-06420	6.4 mm Diameter x 2.6 mm Wall x 20 mm Active Area
903-06430	6.4 mm Diameter x 2.6 mm Wall x 30 mm Active Area
903-0820	8 mm Diameter x 3.4 mm Wall x 20 mm Active Area
903-0830	8 mm Diameter x 3.4 mm Wall x 30 mm Active Area
903-1020	10 mm Diameter x 4.4 mm Wall x 20 mm Active Area
903-1030	10 mm Diameter x 4.4 mm Wall x 30 mm Active Area

#### **DISCLAIMER**

THESE PRODUCTS ARE NOT STERILE AND ARE TO BE USED BY AUTHORIZED PERSONNEL ONLY. USA FEDEARL LAW RESTRICTS THE SALE OF THIS DEVICE FOR USE ONLY BY (OR AT THE ORDER OF) A PHYSICIAN.

RADIATION PRODUCTS DESIGN INC assumes no liability for consequential damages of any kind for this material when used interchangeably with products of other manufacturers/suppliers or for any direct or indirect results and consequences of its use or misuse by the customer. Federal law (USA) restricts the sale of this device for use only by (or at the order of) a physician.

#### **INTRODUCTION**

These applicators are a disposable item and intended for single use only. Each applicator has a radio-opaque marker in the tip, a stainless steel obturator, and is individually numbered. There are 10 applicators in each package. Color variations for each capsule are due to the material.

There may be some scatter in CT from the stainless steel screw in the applicator tip. Remove obturator before CT.

# **SPECIFICATIONS**

15ga. Tubing

Source Depth Length is 250mm

Active Area in Nylon Buildup Cylinder is 20 mm or 30 mm

Wall Thickness: 1.4 mm, 2.4 mm, 2.6mm, 3.4 mm or 4.4 mm

Nylon Density 1.17 g/cm<sup>3</sup>

Stainless Steel Screw is in tip 1/8" deep

Stainless Steel Obturator included

#### **STERILIZATION**

# WARNING DO NOT AUTOCLAVE OR ULTRASONICALLY CLEAN

#### ETHYLENE OXIDE (EGO)

- Remove obturators/stylets from applicators.
- 2. Temperature during exposure and aeration must not exceed 140°F (60°C).
- Package relative humidity must be maintained between 50 and 90%.

Applicators and obturator/stylets must be exposed to at least 1500mg per liter-hour of EGO. Aeration time must be such that less than 250ppm ETO is being evolved from the applicators.

#### **COLD AQUEOUS SOLUTION**

Cidex, Zephiran, Sporicidin, etc. may be used. Assure that no fluid enters the afterloading tubes by not removing the metallic obturators/stylets until time of afterloading with radioactive source. Follow the solution manufacturer's instructions for soaking procedures and exposure times.

#### **PRECAUTION**

All units are checked for mechanical strength and resistance to leakage prior to shipment. However, we suggest the following precautions be taken after sterilization.

- Before inserting into patient, test tensile strength by pulling on capsule end while holding tubing end using amount of force required for removal from patient. Note: obturator/stylet should be in place for this test.
- Before insertion into patient, test shear strength by pushing on capsule end while holding tube close to capsule using amount of force required for insertion. Note: obturator/stylet should be in place for this test.
- Obturator/stylet must be left in applicator until time of afterloading, but must be removed for CT.
- 4. Obturator/stylet should be placed into applicator prior to removal from patient.

Note for dosimetric purposes, a radiopaque (stainless steel) marker has been placed into each capsule end. This marker indicates the position of the distal tip of the radioactive source assembly, not the active length (see source manufacturer's specification sheet).

#### **End of Document**