



Expect Service

Radiation Products Design Inc

INSTRUCTIONS

RPD INFORMATION

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RPD PRODUCT INFORMATION

Item Number	PEEK Dome Needle/Cylinder Applicator
977-6820	20mm Diameter x 180 mm Long
977-6825	25mm Diameter x 180 mm Long, 6 needles on 21mm diameter, 2 mm BU
977-6830	30mm Diameter x 180 mm Long
977-6835	35mm Diameter x 180 mm Long
977-6840	40mm Diameter x 180 mm Long



DISCLAIMER

SHIPPED NON-STERILE

These products are not shipped sterile but should be cleaned, disinfected and sterilized before each use by authorized personnel.

RX ONLY

Federal law (USA) restricts the sale of these devices for use only by (or at the order of) a physician.

LIABILITY

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.

INSPECTION

Before each use and prior to sterilizing, examine the device for burrs or rough edges, which could have occurred through normal use.

INDICATIONS FOR USEThe PEEK Dome Needle/Cylinder Applicator will be inserted into the vaginal area to treat a tumor mass in the frontal area with HDR.

PRODUCT DESCRIPTION

This PEEK Dome Needle/Cylinder Applicator type is used to treat a tumor mass in the vaginal frontal area with HDR. The applicator is available in a variety of outside diameters and features multiple needle slots in a diameter with easy locking needle collets. The needle slot allows access for steam sterilization. The tandem is held in place with a collet and nut assembly when used or a threaded Delrin plug can be screwed into the frontal end when not used. A Collar Clamp (See Chart) is used to support the cylinder during **Treatment, MR or CT** using the Titanium Flex Arm System (Item # 978-60517) or with Radiation Implant Briefs (See Chart) and Velcro®.

**Includes**

Qty. 1 Needle Cylinder

Qty. 1 Tandem Collet

Qty. 1 Nut, for Tandem Collet

Qty. 6 15ga. Needle Collets

Qty. 1 Needle Collet Wrench

Qty. 1 Clamping Collar (Sized per applicator diameter)

Order Needles Separately

SPECIFICATIONS

FDA Compliant Material - PEEK

Density: 1.31 g/cm³

Max Temperature Rating: 250° C, (482° F)

Steam Autoclave, Using Open Slots for Sterilization

Finish: Smooth

Tandem Hole Diameter: 6.63 mm (.261")

Tandem Hole Plug: Delrin, Item 977-070, Steam Autoclave 3 or 4 Minute cycles

Needle Collets 15ga.: Aluminum Anodized, Steam Autoclave 3 or 4 Minute cycles

Tandem Collet: Titanium, Steam Autoclave 3 or 4 Minute cycles

Tandem Collet Nut: Aluminum Anodized, Steam Autoclave 3 or 4 Minute cycles

Collar Clamp: Ertalyte (PET-P) (See Chart), Steam Autoclave 3 or 4 Minute cycles

MR Conditional: Product contains Aluminum and Titanium

SIZING

Sizing can be done using are Nylon Dilators with rounded and elliptical ends and a Depth Collar. Order Dilator and Depth Collar the same size as your applicator diameter. See Chart.

Sizing Chart

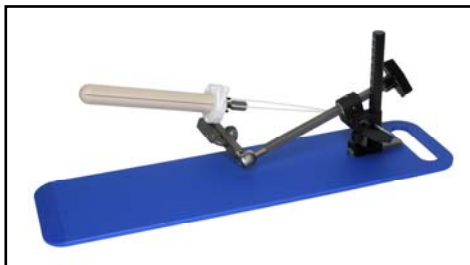
Applicator Cylinder Diameter	Nylon Dilator or Sizing Diameter	Depth Collar
10 mm	970-656-10	970-6210
15 mm	970-656-15	970-6215
16 mm	970-656-16	970-6216
20 mm	970-656-20	970-6220
23 mm	970-656-23	970-6223
25 mm	970-656-25	970-6225
26 mm	970-656-26	970-6226
30 mm	970-656-30	970-6230
35 mm	970-656-35	970-6235
40 mm	970-656-40	970-6240
45 mm	970-656-45	970-6245
50 mm	970-656-50	970-6250

INSTRUCTIONS FOR USE

This PEEK Dome Needle/Cylinder Applicator will be inserted into the vaginal area for treatment of a frontal tumor mass with HDR. Insert needles using a Mandrin (Obturator).

The cylinder can be held in place by:

A. Using a Collar Clamp (See Chart) that fits your applicator diameter which has a 12mm diameter stud on the bottom allowing the "MR/CT Conditional Titanium Flex Arm System" Item 978-60517 to attach and hold applicator in position during **Treatment, CT or MR.**

Item # 977- 6225 MR/CT MULTIPURPOSE COLLAR CLAMP**Item # 978-60517 MR/CT TITANIUM FLEX ARM SYSTEM
Sold Separately**

B. Use patient Radiation Implant Briefs (See Chart) and a Collar Clamp (See Chart) that fits your applicator diameter. Velcro is used to secure Briefs to the Collar Clamp thru a slot, which is attached to the applicator holding it in position during **Treatment, CT or MR.**



CLEANING

- Devices must be thoroughly cleaned before being disinfected or sterilized.
- The presence of organic matter can protect bacteria from the action of the disinfectant or sterilant, or react with the agent and make it ineffective.
- Cleaning can be done either with a mixture of soap and water (or detergent) or with water and detergent and disinfectant.
- Cleaning with a disinfectant reduces the risk of contamination to the cleaning staff, but does not eliminate them completely.
- Be sure to rinse thoroughly with water to remove all soap or detergent and/or disinfectant residue from the device.

DISINFECT

CIDEX OPA DISINFECTANT

If applicable, separate parts prior to disinfection. Remove gross filth and heavy soil loads. Wash with water and soap or detergent and disinfectant. Soak in Cidex OPA for 12 minutes. Then rinse in three different batches of sterile water to remove all traces of Cidex OPA. **Restrictions on use:** For Professional and Hospital Use. Wear Barrier protection: protective gloves, gowns, masks and eye coverings.

Note: This product does not require **ACTIVATION**.

CAVICIDE DISINFECTANT

A. Remove gross filth and heavy soil loads.

For use as a precleaning decontaminant immersion solution: Place instruments in a container with a sufficient amount of CaviCide so as to allow for complete submersion, cover and allow to soak for 10 minutes at room temperature (69°F/20°C). Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Discard solution after each use.

Restrictions on use: For Professional and Hospital Use. Wear Barrier protection: protective gloves, gowns, masks and eye coverings.

B. For use as an ultrasonic precleaning solution: Thoroughly rinse instruments under running water to remove visible gross debris. Add 1 ounce CaviCide per liter of water to ultrasonic unit. Immerse instruments in solution and activate ultrasonic unit for 5 minutes or longer, if necessary. Remove and rinse instruments. Follow with appropriate cleaning and disinfection process. Discard solution after each use.

Restrictions on use: For Professional and Hospital Use. Wear Barrier protection: protective gloves, gowns, masks and eye coverings.

CAVICIDE DISINFECTION

Instruments must be thoroughly cleaned to remove excess organic debris, rinsed and dried. Thoroughly clean and rinse lumens of hollow instruments. Using either a tray or an ultrasonic unit, immerse instruments in CaviCide for 3 minutes at room temperature (68°F/20°C). Remove and rinse instruments. Wipe dry prior to sterilization. Discard Solution after each use. Device must be sterilized prior to use. **Restrictions on use:** For Professional and Hospital Use. Wear Barrier protection: protective gloves, gowns, masks and eye coverings.

REPROCESSING DISCLAIMER

This information is not a guarantee and does not relieve the user from the responsibility of the proper and safe use of cleaning agents. The use of certain agents can be harmful on the surface appearance. **Restrictions on use:** For Professional and Hospital Use. Wear Barrier protection: protective gloves, gowns, masks and eye coverings.

Radiation Products Design, Inc. assumes no responsibility resulting from the use of such cleaning agents to the Product.

STERILIZATION

Separate all parts prior to sterilization.

Peek Dome Cylinder/Needles Applicators, Metal Collets and Nut Sterilization Chart

Nonporous and Porous Items with Lumens

Sterilization Method	Temperature	Pressure	Time	Dry Time
Steam Autoclave	121°C (250°F)	15 psi	15 Min.	30-40 Min.
Steam Autoclave (Gravity Displacement)	121°C (250°F)	15 psi	15 Min.	30-40 Min.

Steam Autoclave (prevacuum)				
Unwrapped Items	121°C (250°F)	30 psi	3 Min.	30-40 Min.
Unwrapped Items	132°C (270°F)	30 psi	3 Min.	30-40 Min.
Lightly Wrapped Items	132°C (270°F)	30 psi	4 Min.	30-40 Min.
Medium Wrapped Items	132°C (270°F)	30 psi	8 Min.	30-40 Min.
Heavily Wrapped Items	132°C (270°F)	30 psi	10 Min.	30-40 Min.
Steam Flush Pressure-Pulse	132°C (270°F)	N/A	4 Min.	30-40 Min.

psi = Pounds Per Square Inch

Collar Clamp: Ertalyte (PET-P)**Tandem Hole Plug:** Delrin**Ertalyte and Delrin Sterilization Chart**

Steam Autoclave (prevacuum)	Temperature	Pressure	Time	Dry Time
Unwrapped Items	121°C (250°F)	30 psi	3 Min.	30-40 Min.
Unwrapped Items	132°C (270°F)	30 psi	3 Min.	30-40 Min.
Lightly Wrapped Items	132°C (270°F)	30 psi	4 Min.	30-40 Min.
Steam Flush Pressure-pulse	132°C (270°F)	N/A	4 Min.	30-40 Min.

ACCESSORIES

Item #	Description
466-401	Cidex OPA, 1 gal.
466-403	Cidex OPA Solution Test Stripes, 60 Strips/bottle
466-332	CaviCide Disinfectant, 24 oz. spray bottle
977-7040	Needle Plastic 15 ga. x 40 cm Long Qty. 10 in Sterile Package Uses same HDR connector as used on Prostate 15 ga. Needles
977-7140	Mandrin (Obturator) 40.2 cm Long: for 15ga Needle
946-004	Slessinger Board MR Conditional
946-05304	Titanium Flex Arm Support for Slessinger Board: MR Conditional
978-60504	Titanium Flex Arm Support Board: MR Conditional
182-300	Bed, Manual, MR/TBI/HDR with 0-60° Fowler Positioning, MR Conditional

Order from Varian@:

Plastic Needle 15ga. x 320 mm with Collet & Mandrin (Obterator)
GM11011180

Plastic Needle 15ga. x 200 mm with Collet & Mandrin (Obterator)
GM11011110

Collar Clamps

Applicator Cylinder Diameter	Collar Clamp
10 mm	970-6210
15 mm	970-6215
16 mm	970-6216
20 mm	970-6220
23 mm	970-6223
25 mm	970-6225
26 mm	970-6226
30 mm	970-6230
35 mm	970-6235
40 mm	970-6240
45 mm	970-6245
50 mm	970-6250

Radiation Implant Briefs

Item #	Size/US	Measurement
970-050	S / 5	36-38" Hips
970-051	M / 6	39-41" Hips
970-052	L / 7	42-44" Hips
970-053	XL / 8	45-47" Hips
970-054	1X / 9	48-50" Hips
970-055	2X / 10	51-53" Hips
970-056	3X / 11	54-56" Hips
970-057	4X / 12	57-59" Hips
970-058	5X / 13	60-62" Hips

977-600 White Velcro® Strapping (3/8"x 25 yds.)

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