

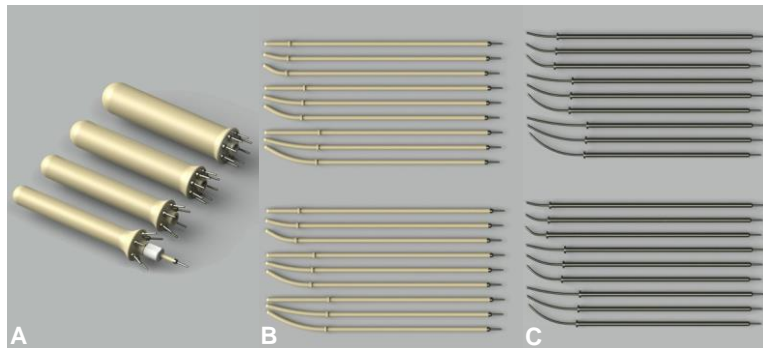
# Instructions for Use



Universal Multi-channel Cylinder Set, GM11011400

Universal Cervix Probe Sets, GM11011500–1700

Universal Titanium Cervix Probe Sets, GM11013100–3200



A: Universal Multi-channel Cylinder Set; B: Universal Cervix Probe Sets; C: Universal Titanium Cervix Probe Sets

## Key to Symbols

MR Safe:		Caution:	
MR Conditional:		Warning:	
MR Unsafe:		Note:	

A complete list of symbols is included in the Symbol Definition Sheet (AL25220000).

**Table 1.0: Component List**  
Universal Multi-channel Cylinder Set  
GM11011400

Description	Qty.	Product #	Material	Reusable	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Universal multi-channel cylinder, ø 25 mm	1	GM11011410	PEEK/ Titanium	✓	100	100	✓	✓	
Universal multi-channel cylinder, ø 30 mm	1	GM11011420	PEEK/ Titanium	✓	100	100	✓	✓	
Universal multi-channel cylinder, ø 35 mm	1	GM11011430	PEEK/ Titanium	✓	100	100	✓	✓	
Universal multi-channel cylinder, ø 40 mm	1	GM11011440	PEEK/ Titanium	✓	100	100	✓	✓	
Rigid guide tube, 250 mm length	1	GM11011180	PEEK/ Titanium	✓	500	500	✓	✓	
Clamping segment	1	GM11005180	PPSU	✓	500	500	✓	✓	
Cleaning caps, dark blue (pack of 25)	4	GM11010770	Silicone	-	1	1	✓	✓	

**Note:** For Tables 1.0 – 3.0, numbers in the Manual and Machine Cleaning columns indicate the maximum number of reprocessing and/ or use cycles. Enter the completed cycles in the Sterilization Tracking System. Refer to the “Cleaning, Disinfecting and Sterilization” and “Storage and Repeated Use” sections for more information.

**Note:** In the Bravos control software, it is necessary to set the “Applicator type” to “Rigid” for the channel tests. Refer to the Bravos afterloader Instructions for Use for more information on channel tests.

# Instructions for Use



## Universal Multi-channel Cylinder Set

## Universal Cervix Probe Sets

## Universal Titanium Cervix Probe Sets

Table 1.1: Component List Universal Cervix Probe Set GM11011700 (even lengths)				Reusable	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Description	Qty.	Product #	Material						
Applicator probe, ø 6.3 mm x 320 mm, straight, 40 mm	1	GM11011540	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, curved 15°, 40 mm	1	GM11011550	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, curved 30°, 40 mm	1	GM11011560	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, straight, 60 mm	1	GM11011600	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, curved 15°, 60 mm	1	GM11011610	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, curved 30°, 60 mm	1	GM11011620	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, straight, 80 mm	1	GM11011660	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, curved 15°, 80 mm	1	GM11011670	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, curved 30°, 80 mm	1	GM11011680	PEEK/ FEP Titanium	-	1	500	✓	✓	
Cleaning caps, dark blue (pack of 25)	4	GM11010770	Silicone			1	✓	✓	

Table 1.2: Component List Universal Cervix Probe Set GM11011500 (odd lengths)				Reusable	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Description	Qty.	Product #	Material						
Applicator probe, ø 6.3 mm x 320 mm, straight, 30 mm	1	GM11011510	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, curved 15°, 30 mm	1	GM11011520	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, curved 30°, 30 mm	1	GM11011530	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, straight, 50 mm	1	GM11011570	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, curved 15°, 50 mm	1	GM11011580	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, ø 6.3 mm x 320 mm, curved 30°, 50 mm	1	GM11011590	PEEK/ FEP Titanium	✓	500	500	✓	✓	

# Instructions for Use



## Universal Multi-channel Cylinder Set

## Universal Cervix Probe Sets

## Universal Titanium Cervix Probe Sets

Table 1.2: Component List (continued) Universal Cervix Probe Set GM11011500 (odd lengths)				Reusable	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Description	Qty.	Product #	Material						
Applicator probe, $\varnothing$ 6.3 mm x 320 mm, straight, 70 mm	1	GM11011630	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, $\varnothing$ 6.3 mm x 320 mm, curved 15°, 70 mm	1	GM11011640	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Applicator probe, $\varnothing$ 6.3 mm x 320 mm, curved 30°, 70 mm	1	GM11011650	PEEK/ FEP Titanium	✓	500	500	✓	✓	
Cleaning caps, dark blue (pack of 25)	4	GM11010770	Silicone	-	1	1	✓	✓	

Table 1.3: Component List Universal Titanium Cervix Probe Set GM11013100 (even lengths)				Reusable	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Description	Qty.	Product #	Material						
Titanium applicator probe, $\varnothing$ 3 mm x 320 mm, curved 15°, 40 mm	1	GM11013110	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, $\varnothing$ 3 mm x 320 mm, curved 30°, 40 mm	1	GM11013120	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, $\varnothing$ 3 mm x 320 mm, curved 45°, 40 mm	1	GM11013130	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, $\varnothing$ 3 mm x 320 mm, curved 15°, 60 mm	1	GM11013140	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, $\varnothing$ 3 mm x 320 mm, curved 30°, 60 mm	1	GM11013150	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, $\varnothing$ 3 mm x 320 mm, curved 45°, 60 mm	1	GM11013160	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, $\varnothing$ 3 mm x 320 mm, curved 15°, 80 mm	1	GM11013170	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, $\varnothing$ 3 mm x 320 mm, curved 30°, 80 mm	1	GM11013180	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, $\varnothing$ 3 mm x 320 mm, curved 45°, 80 mm	1	GM11013190	Titanium	✓	500	500	✓	✓	
Cleaning caps, dark blue (pack of 25)	4	GM11010770	Silicone	-	1	1	✓	✓	

# Instructions for Use



## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets

**Table 1.4: Component List**  
Universal Titanium Cervix Probe Set  
GM11013200 (odd lengths)

Description	Qty.	Product #	Material	Reusable	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Titanium applicator probe, ø 3 mm x 320 mm, curved 15°, 30 mm	1	GM11013210	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, ø 3 mm x 320 mm, curved 30°, 30 mm	1	GM11013220	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, ø 3 mm x 320 mm, curved 45°, 30 mm	1	GM11013230	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, ø 3 mm x 320 mm, curved 15°, 50 mm	1	GM11013240	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, ø 3 mm x 320 mm, curved 30°, 50 mm	1	GM11013250	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, ø 3 mm x 320 mm, curved 45°, 50 mm	1	GM11013260	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, ø 3 mm x 320 mm, curved 15°, 70 mm	1	GM11013270	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, ø 3 mm x 320 mm, curved 30°, 70 mm	1	GM11013280	Titanium	✓	500	500	✓	✓	
Titanium applicator probe, ø 3 mm x 320 mm, curved 45°, 70 mm	1	GM11013290	Titanium	✓	500	500	✓	✓	
Cleaning caps, dark blue (pack of 25)	4	GM11010770	Silicone	-	1	1	✓	✓	

## Cautions and Warnings



**CAUTION:** Each physician is responsible for using the appropriate technique and deciding on the indication for use of the applicator set based on his own experience, training and medical judgment. The physician must be trained in the proper use of the Varian afterloader.



**CAUTION:** There is no limitation to patient population. Limitations are on the maximal radiation dose applicable to the individual organs.



**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.



**CAUTION:** If a ClickFit™ connector becomes contaminated during a treatment, clean the connector surfaces by wiping with hospital wipes soaked in detergent solution until contamination is removed, followed by wiping with a hospital wipe soaked in purified water. Allow the connector to dry and place a cleaning cap on it before manual or machine cleaning.

# Instructions for Use



## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets



**CAUTION:** Cleaning caps and leak stop buttons are single use devices that must be disposed of after use. A reused cleaning cap or leak stop button might not securely protect the connector of the source or transfer guide tube, so liquid could enter and this could lead to malfunction of or damage to the Varian afterloader.



**WARNING:** Failure to use leak stop buttons may lead to contamination of the applicator or source/ transfer guide tubes, which could lead to patient infection. Cleaning caps must be used when instruments are immersed for manual and machine cleaning or disinfection. Cleaning caps must be removed before sterilization so that the inside of the applicator can be sterilized.



**WARNING:** The Universal Multi-channel Cylinder Set (GM11011400), the Universal Cervix Probe Sets (GM11011500–1700) and the Universal Titanium Cervix Probe Sets (GM11013100–3200) were designed solely for use with Varian afterloaders. The manufacturer does not accept responsibility if an afterloader device from another manufacturer is used.

MRI Safety Information
<p>Non-clinical testing and MRI simulations were performed to evaluate the Universal Multi-channel Cylinder Set and the Universal Cervix Probe Sets. Non-clinical testing demonstrated that the Universal Multi-channel Cylinder Set and the Universal Cervix Probe Sets (excluding the cleaning caps) are MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:</p> <ul style="list-style-type: none"><li>• Static magnetic field of 1.5 Tesla or 3 Tesla</li><li>• Maximum spatial gradient magnetic field of 3000 Gauss/cm or less</li><li>• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg in the Normal Operating Mode of operation for the MR system</li><li>• All stainless steel parts (such as marker wires, length gauges, etc.) must be removed prior to entering the MR environment.</li></ul>
<h3>MRI Related Heating</h3>
<p>Under the scan conditions defined, the Universal Multi-channel Cylinder Set and the Universal Cervix Probe Sets are expected to produce a maximum temperature rise of less than 2° C after 15 minutes of continuous scanning.</p>
<h3>Artifact Information</h3>
<p>In non-clinical testing, the image artifact caused by the Universal Multi-channel Cylinder Set and the Universal Cervix Probe Sets extends approximately 20 mm from this device when imaged using a gradient echo pulse sequence and a 3 Tesla MR system.</p>

# Instructions for Use



## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets

MRI Safety Information (continued)
The cleaning caps and leak stop buttons are MR Safe and marked with the MR Safe symbol in Tables 1.0 - 3.0.
The titanium applicator probes (of the Universal Titanium Cervix Probe Sets) and cervical stops are MR Unsafe and marked with the MR Unsafe symbol in Tables 1.0 - 3.0.
MR Unsafe components are made from or are partially made from magnetic or conductive materials. Such components should not be brought into the MRI environment.

### Intended Use

The Universal Multi-channel Cylinder Set and the Universal Cervix Probe Sets are intended for use when performing HDR or PDR brachytherapy within a CT and MRI environment. The Universal Titanium Cervix Probe Sets are intended for use when performing HDR or PDR brachytherapy within a CT environment.

### Intended Users

The Universal Multi-channel Cylinder Set, the Universal Cervix Probe Sets and the Universal Titanium Cervix Probe Sets are primarily intended for use by the physician responsible for the radiation treatment of the patient. This may be a radiation oncologist or other qualified physician. The physician may supervise technicians or other medical personnel who assist or carry out procedures associated with the radiation treatments.

### Indications for Use

The Universal Multi-channel Cylinder Set is indicated for use for cancer treatment of the vagina, vaginal stump, cervix, uterus, endometrium and rectum using HDR or PDR brachytherapy.

The Universal Cervix Probe Sets in combination with the Universal Multi-channel Cylinder Set are indicated for use for cancer treatment of the vagina, cervix, uterus and endometrium using HDR or PDR brachytherapy.

The Universal Titanium Cervix Probe Sets in combination with the Universal Multi-channel Cylinder Set are indicated for use for cancer treatment of the vagina, cervix, uterus and endometrium using HDR or PDR brachytherapy.

# Instructions for Use



## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets

### General Information

Carefully follow this Instructions for Use.

All of the applicator sets in this Instructions for Use are CT compatible. The Universal Multi-channel Cylinder Set (GM11011400) and the Universal Cervix Probe Sets (GM11011500–1700) are MR conditional. The Universal Titanium Cervix Probe Sets (GM11013100–3200) are MR Unsafe.

The cylinders are built on a rigid guide tube for vagina-only or rectal treatments or a cervix probe to allow intrauterine access to the source. The standard rigid guide tube is 250 mm in length. All cervix probes are 320 mm in length.

The Universal Multi-channel Cylinder Set, Universal Cervix Probe Sets and Universal Titanium Cervix Probe Sets are intended for use for less than 30 days of contact with patients.

**The Universal Multi-channel Cylinder Set, Universal Cervix Probe Sets and Universal Titanium Cervix Probe Sets are compatible with all Varian afterloaders (Bravos, GammaMed*plus* series and VariSource series).** Use only Varian source or transfer guide tubes to connect the applicator to the afterloader.

Set components are listed in Tables 1.0 – 1.4. Tables 2.1 – 2.3 contain the accessories required to use the applicator sets with the Bravos afterloader, the GammaMed*plus* series and VariSource series afterloaders, and to take radiographs. Use the appropriate Varian X-ray markers for taking radiographs. Optional components and accessories available for the sets are listed in Table 3.0.

Table 2.1: Required for Bravos Afterloader				Reusable	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Description	Qty.	Product #	Material						
Transfer guide tube for 200 mm applicators	*	GM11010850	Data available in individual Instructions for Use.						
Transfer guide tube for 250 mm applicators	1	GM11010860							
Transfer guide tube for 320 mm applicators	1	GM11010800							
Transfer guide tube, 1000 mm length for applicators	*	GM11010870							
Length assessment device	1	GM11011800							
X-ray marker BV, up to 320 mm applicators, uncoded	1	GM11009600							
Leak stop button (pack of 50), non-sterile	1	GM11003810		Silicone	-	25	25	✓	✓

**Note:** \* One transfer guide tube is necessary per peripheral channel.

# Instructions for Use



## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets

**Note:** When the transfer guide tube for applicators (GM11010870) is connected to an applicator, the combination length is 1000 mm plus the length (mm) of the attached applicator (e.g., GM11010870 connected to an applicator with a 320 mm length has a combination length of 1320 mm).

Table 2.2: Required for GammaMedplus Series				Reusable	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Description	Qty.	Product #	Material						
Length gauge, GammaMedplus	1	GM11000330	Data available in individual Instructions for Use.						
Source guide tube with locking mechanism for 200 mm needles	*	GM11000320							
Source guide tube with locking mechanism for 250 mm needles	1	GM11008960							
Source guide tube with locking mechanism for 320 mm applicators	1	GM11000340							
X-ray marker BV, up to 320 mm applicators, uncoded	1	GM11009600							
Leak stop button (pack of 50), non-sterile	1	GM11003810	Silicone	-	25	25	✓	✓	MR

**Note:** \* One source guide tube is necessary per peripheral channel.

Table 2.3: Required for VariSource Series				Reusable	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Description	Qty.	Product #	Material						
ClickFit™ transfer guide tube, set of 4 for VariSource 200	1	GM19001000	Data available in individual Instructions for Use.						
Needle ClickFit™ transfer guide tube set, channels 1-10 (200 Series)	1	GM19002000							
Measurement marker clip	1	AL13119000							
Measurement marker wire	1	AL13154000							
Measurement ruler	1	AL13169000							
X-ray marker BV, up to 320 mm applicators, uncoded	1	GM11009600							
Leak stop button (pack of 50), non-sterile	1	GM11003810	Silicone	-	25	25	✓	✓	MR



# Instructions for Use



## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets

**Table 3.0: Optional Components & Accessories**

Description	Qty.	Product #	Material	Reusable	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Cervical stop	1	GM11000670 *	PEEK/ Titanium	✓	100	100	✓	✓	
Cervical stop	1	GM11011710 **	PEEK/ Titanium	✓	100	100	✓	✓	
Titanium cervical stop	1	AL07344000	Data available in Titanium Fletcher-Suit-Delclos-style (AL13030001) Instructions for Use.						
Flexible fixation device for gynecological applicators	1	GM11001960	Data available in individual Instructions for Use.						
Basic accessory kit for intracavitary/ GYN applicators, GammaMed <i>plus</i>	1	GM11008210							
Basic accessory kit for intracavitary/ GYN applicators, VariSource	1	GM11008740							
Cervical sleeve, 3 mm aperture, 20 mm length, single use	1	AL13142000							
Cervical sleeve, 3 mm aperture, 40 mm length, single use	1	AL13142001							
Cervical sleeve, 3 mm aperture, 60 mm length, single use	1	AL13142002							
Cervical sleeve, 3 mm aperture, 80 mm length, single use	1	AL13142003							
Kelowna GYN Template for 2.0 mm needles, including locking collets (pack of 25) and needle collet wrench	1	GM11012200 ***							
Kelowna GYN Template for 16 gauge (1.65 mm) needles, including locking collets (pack of 25) and needle collet wrench	1	GM11012210 ***							
Kelowna GYN Template for 17 gauge (1.47 mm) needles, including locking collets (pack of 25) and needle collet	1	GM11012220 ***							
Source guide tube support	1	GM11001390	Refer to the manufacturer's instructions on the label.						
Titanium allen wrench, autoclavable	1	AL07342000							
Allen key ø 2.5 mm, autoclavable	1	GM11002370							
Universal applicator clamping device	1	GM11008700							
Universal sterilization box	1	GM11010340	Aluminum/ Silicone	✓	-	-	500	-	-

**Note:** \* Compatible with the Universal Titanium Cervix Probe Sets (GM11013100 and GM11013200).

**Note:** \*\* Compatible with the Universal Cervix Probe Sets (GM11011700 and GM11011500).

# Instructions for Use

varian

## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets



**Note: \*\*\*** Compatible with the Universal Multi-channel Cylinder  $\varnothing$  25 mm (GM11011410) only.

### Delivery Condition

Each set is carefully packaged and in a clean but non-sterile condition. The packaging must be unopened and undamaged upon receipt. Remove the components from the packaging in an environment with clean and disinfected surfaces. These reusable applicators must be handled carefully to avoid damage. Prior to each treatment, the user must ensure that the applicator is undamaged and still meets specifications.

### Pre-Treatment Testing



**WARNING:** Do not use an intrauterine probe if its curvature has been changed from the manufacturer's specifications. Treatment planning programs assume the curvatures as given. Deviation will lead to incorrect patient treatment.

After connecting the source guide tube, use the length gauge (GM11000330) for the GammaMed*plus* to check the correct source guide tube/ applicator combination length. For the VariSource afterloader, this test should be performed using the measurement ruler, marker wire and marker clip (AL13169000, AL13154000, AL13119000) to check the correct transfer guide tube/ applicator combination length.



**WARNING:** An incorrect source or transfer guide tube/ applicator combination length can lead to incorrect treatment of the patient through underexposure or overexposure. Verify the correct source or transfer guide tube/ applicator combination length.



**Note:** The rigid guide tube is 250 mm in length. This is 70 mm shorter than the historic GYN applicator length of 320 mm. When used with the VariSource afterloader and connected with a ClickFit™ transfer guide tube (GM19001000), the measured length should be 114.4 cm and the BrachyVision planning length should be 113.0 cm.



**Note:** For the Bravos afterloader, when an applicator is connected to a transfer guide tube meant for a specific length applicator (e.g., transfer guide tube for 250 mm applicators, GM11010860), the standard treatment length is 1500 mm. When an applicator is connected to a 1000 mm length transfer guide tube (e.g., transfer guide tube, 1000 mm length for applicators, GM11010870), the treatment length is 1000 mm plus the lumen length of the applicator. The Bravos afterloader performs a channel length measurement to determine the end point of each channel. In cases where the transfer guide tube/ applicator combination length is not known (e.g., a catheter cut to a random length), use the Length Assessment Device (GM11011800) to determine this length after connecting the transfer guide tube to the applicator.

## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets

### Assembly and Use – Vagina-only or Rectal Treatments



**CAUTION:** Liquid or other kinds of contamination entering the applicator or rigid guide tube can lead to malfunction of or damage to the Varian afterloader.



**WARNING:** Using a damaged applicator can lead to incorrect treatment of the patient and may cause radiation hazards to patients and medical staff.

Prior to each use (including the first use), clean, disinfect and sterilize the applicator and accessories carefully according to the supplied instructions. Use cleaning caps during the procedure, and when components are immersed in cleaning, disinfection and rinse solutions.



**Note:** New, sterilized cleaning caps can be placed onto applicators during patient insertion if this is desired.

1. Select the universal multi-channel cylinder in the diameter required for the patient anatomy.
2. Insert the rigid guide tube into the selected cylinder.
3. Slide the clamping segment over the rigid guide tube (thinner part first) and push it into the cylinder.
4. Hold the applicator vertically with the distal end pointing up. While holding onto the cylinder, turn the clamping segment clockwise until tight.
5. To verify if the attachment and the rigid guide tube are securely fastened:
  - Pull the clamping segment while holding onto the cylinder (use adequate force).
  - Push the rigid guide tube while holding onto the cylinder (use adequate force without applying a torque).



**Note:** The rigid guide tube needs to stay in place. If necessary, adjust the fastening of the clamping segment and repeat the check.

- Be sure the cylinder is still in the most forward position.
  - Measure the length of rigid guide tube protruding from the clamping segment.
6. Insert the complete applicator into the vagina or rectum of the patient. Do not use the rigid guide tube as a pushing device.
  7. Check that the amount of rigid guide tube protruding from the clamping segment has not changed from before insertion.
  8. Immobilize the applicator with the universal applicator clamping device (GM11008700) or the flexible fixation device for gynecological applicators (GM11001960).



**Note:** The universal applicator clamping device should not be used in the vicinity of an MR scanner.

9. To take radiographs, remove the cleaning caps and insert the X-ray marker into the desired channel(s).

# Instructions for Use

varian

## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets

10. Connect the correct source or transfer guide tube to the corresponding channel of the indexer/ turret according to the treatment plan. Use only channels 1 through 19 for GammaMed units. For more information, refer to the source or transfer guide tube Instructions for Use.



**WARNING:** Interchanging the source or transfer guide tube connections will lead to incorrect treatment of the patient.

11. Remove the X-ray marker (if used) and push leak stop buttons (GM11003810) onto the rigid guide tube and peripheral channels.



**CAUTION:** Blood or liquid entering the source or transfer guide tube connector can cause the connector to malfunction. Use the leak stop button (GM11003810) or sufficient pads to protect the connector.

12. Connect the source or transfer guide tube to the rigid guide tube and peripheral channels.
13. Ensure that there is no tension or tight curve in the source or transfer guide tubes. For support, use the source guide tube support (GM11001390).
14. Before starting the treatment, as necessary, inform the patient about appropriate behavior during the treatment.



**WARNING:** The patient must be advised about avoiding any movements that might change the position of the applicator. If necessary, the patient must contact the treatment staff immediately by intercom or viewing equipment. A shift in position of the applicator could lead to misadministration of the treatment.

15. The patient can now be treated according to the user manual for the Varian afterloader.

## Assembly and Use – Intrauterine Treatments



**CAUTION:** Liquid or other kinds of contamination entering the applicator or cervix probe can lead to malfunction of or damage to the Varian afterloader.



**WARNING:** Using a damaged applicator can lead to incorrect treatment of the patient and may cause radiation hazards to patients and medical staff.

Prior to each use (including the first use), clean, disinfect and sterilize the applicator and accessories carefully according to the supplied instructions. Use cleaning caps during the procedure, and when components are immersed in cleaning, disinfection and rinse solutions.



**Note:** New, sterilized cleaning caps can be placed onto applicators during patient insertion if this is desired.

### Pre-assembly Instructions (outside of the patient)

1. Select the required length and angle cervix probe.

## Universal Multi-channel Cylinder Set

## Universal Cervix Probe Sets

## Universal Titanium Cervix Probe Sets

2. If desired, place an optional cervical stop on the probe from the distal end and slide it down to the integral cylinder stop. Tighten the screw of the cervical stop to fix its position on the cervix probe.
3. Select the universal multi-channel cylinder in the diameter required for the patient anatomy and slide it onto the cervix probe.
4. Slide the clamping segment over the cervix probe (thinner part first) and push it into the cylinder.
5. Turn the clamping segment clockwise until tight while holding onto the cylinder.
6. Measure the length of cervix probe protruding from the clamping segment.

### Assembly Instructions (inside the patient)

1. Disassemble the applicator and using standard techniques, place the cervix probe through the cervical os into the intrauterine canal.
2. Visually verify that the integral cylinder stop or the optional cervical stop is placed against the cervical os.
3. Slide the universal multi-channel cylinder onto the cervix probe into the vagina, taking care not to displace the cervix probe.
4. Slide the clamping segment over the cervix probe (thinner part first) and push it into the cylinder.
5. Turn the clamping segment clockwise until tight while holding onto the cylinder.
6. Check that the amount of cervix probe protruding from the clamping segment is the same as during the pre-assembly outside of the patient.
7. To verify if the attachment and the cervix probe are securely fastened:
  - Pull the clamping segment while holding onto the cylinder (use adequate force).
  - Pull back on the cylinder while holding onto the cervix probe (use adequate force without applying a torque).



**Note:** The cervix probe needs to stay in place. If necessary, adjust the fastening of the clamping segment and repeat the check.

8. Immobilize the applicator with the universal applicator clamping device (GM11008700) or the flexible fixation device for gynecological applicators (GM11001960).



**Note:** The universal applicator clamping device should not be used in the vicinity of an MR scanner.

9. To take radiographs, remove the cleaning caps and insert the X-ray marker into the desired channel(s).
10. Connect the correct source or transfer guide tubes to the corresponding channels of the indexer/ turret according to the treatment plan. Use only channels 1 through 19 for GammaMed units. For more information, refer to the source or transfer guide tube Instructions for Use.



**WARNING:** Interchanging the source or transfer guide tube connections will lead to incorrect treatment of the patient.

# Instructions for Use

varian

## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets

11. Remove the X-ray marker (if used) and push leak stop buttons (GM11003810) onto the cervix probe and peripheral channels.



**CAUTION:** Blood or liquid entering the source or transfer guide tube connector can cause the connector to malfunction. Use the leak stop button (GM11003810) or sufficient pads to protect the connector.

12. Connect the source or transfer guide tubes to the cervix probe and peripheral channels.
13. Ensure that there is no tension or tight curve in the source or transfer guide tubes. For support, use the source guide tube support (GM11001390).
14. Before starting the treatment, as necessary, inform the patient about appropriate behavior during the treatment.



**WARNING:** The patient must be advised about avoiding any movements that might change the position of the applicator. If necessary, the patient must contact the treatment staff immediately by intercom or viewing equipment. A shift in position of the applicator could lead to misadministration of the treatment.

15. The patient can now be treated according to the user manual for the Varian afterloader.

## Removal and Disassembly – Vagina-only or Rectal Treatments

1. Remove the source or transfer guide tubes from the applicator.
2. Remove the leak stop buttons from the rigid guide tube and peripheral channels.
3. Inspect ClickFit™ connectors for contamination.
4. Remove the cleaning caps from the ClickFit™ connectors.
5. If contaminated, wipe the ClickFit™ connector surfaces with a hospital wipe soaked in enzymatic cleaner followed by wiping with a hospital wipe soaked in purified water.
6. Place cleaning caps on the ClickFit™ connectors before fully cleaning the component.
7. Remove the applicator fixation (if used).
8. Withdraw the complete applicator.
9. Hold on to the cylinder while turning the clamping segment counterclockwise to loosen it.
10. Remove the clamping segment and cylinder from the rigid guide tube.

## Removal and Disassembly – Intrauterine Treatments

1. Remove the source or transfer guide tubes from the applicator.
2. Remove the leak stop buttons from the cervix probe and peripheral channels.
3. Inspect ClickFit™ connectors for contamination.
4. Remove the cleaning caps from the ClickFit™ connectors.

# Instructions for Use

varian

## Universal Multi-channel Cylinder Set

## Universal Cervix Probe Sets

## Universal Titanium Cervix Probe Sets

5. If contaminated, wipe the ClickFit™ connector surfaces with a hospital wipe soaked in enzymatic cleaner followed by wiping with a hospital wipe soaked in purified water.
6. Place cleaning caps on the ClickFit™ connectors before fully cleaning the component.
7. Remove the applicator fixation (if used).
8. Hold on to the cylinder while turning the clamping segment counterclockwise to loosen it.
9. Remove the clamping segment and cylinder from the cervix probe.
10. Remove the cervix probe from the patient.
11. If used, loosen the screw in the cervical stop and remove the cervical stop from the cervix probe.

## Cleaning, Disinfecting and Sterilization

All parts of the Universal Multi-channel Cylinder Set, the Universal Cervix Probe Sets and the Universal Titanium Cervix Probe Sets are reusable. Before the first use, and after each use, clean, disinfect and sterilize all parts of the Universal Multi-channel Cylinder Set, the Universal Cervix Probe Sets and the Universal Titanium Cervix Probe Sets according to the Applicators and Accessories Reprocessing Instructions (GM11011300).



**Note:** Leak stop buttons (GM11003810) are intended for single use; however, unused leak stop buttons can be reprocessed up to 25 times.



**Note:** A slight color change may appear on PEEK parts over the course of cleaning, disinfecting and sterilization reprocessing. This color change does not affect the clinical use of the product.

## Storage and Repeated Use

Store the applicator so it will not be damaged. We suggest storing all parts in a suitable sterilization box. Close the opening of the rigid guide tube or cervix probe and the peripheral channels with cleaning caps to avoid contamination while stored without being packed in a sterilization box.

The applicator sets are designed for repeated use. Use cycles for individual components are indicated in Tables 1.0 – 3.0. After this period of use, dispose of the applicator parts according to local rules.

Prior to each use, it is the sole responsibility of the user to thoroughly check all applicator parts and accessories for any damage and to ensure that the applicator and/ or accessory meets factory specifications according to the Instructions for Use. For storage instructions for accessories, refer to the corresponding Instructions for Use.

If the proper condition of a part is in question, that part must not be used. The part must be returned immediately for inspection by the manufacturer. If damage to a part is obvious, please contact the manufacturer for a replacement part.

# Instructions for Use

## Universal Multi-channel Cylinder Set Universal Cervix Probe Sets Universal Titanium Cervix Probe Sets

The manufacturer is not responsible for the use of damaged parts or the use of parts that do not meet factory specification.

### Material Thickness

Tip thickness for all angles and lengths:	
Rigid Guide Tube (GM11011180)	3.0 mm
Cervix Probe (GM11011510 - GM11011680)	2.2 mm
Titanium Cervix Probe (GM11013100 - 3290)	0.65 mm
Universal Multi-channel Cylinder Set (GM11011400)	2.25 – 3.43 mm

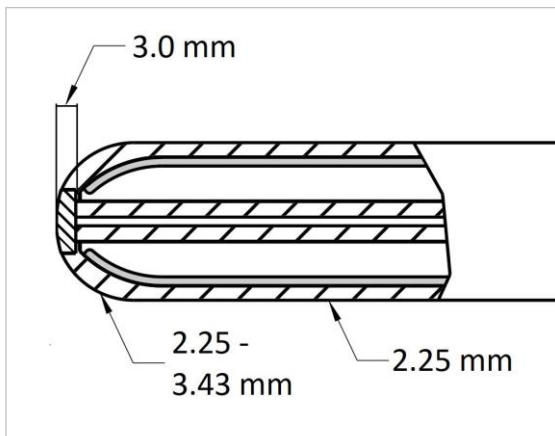


Figure 1 Rigid Guide Tube

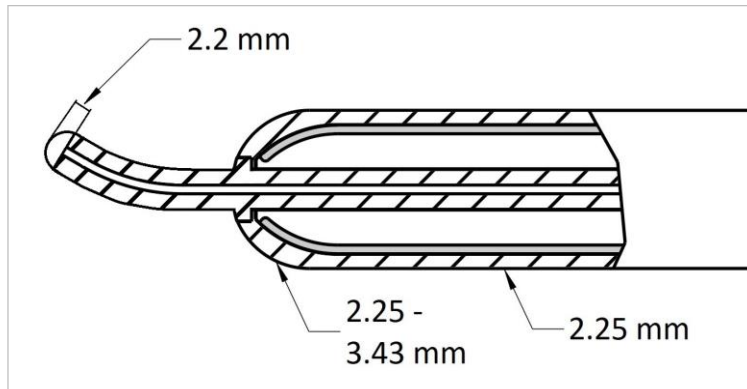


Figure 2 Cervix Probe



# Instructions for Use



Universal Multi-channel Cylinder Set  
Universal Cervix Probe Sets  
Universal Titanium Cervix Probe Sets

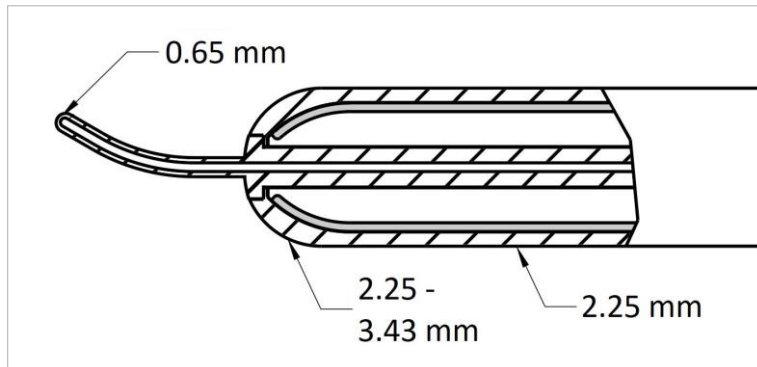


Figure 3 Titanium Cervix Probe and Universal Multi-channel Cylinder Set

## Report Serious Incident

Any serious incident that has occurred in relation to the Universal Multi-channel Cylinder Set, the Universal Cervix Probe Sets and the Universal Titanium Cervix Probe Sets should be reported to the manufacturer and the competent authority of the Member State in which the user or patient is established.

## Varian Customer Support

For technical questions relating to this product, contact Varian Customer Support. Refer to the Varian Customer Support Contacts sheet (AL25509000) for contact information.

## Location of Instructions for Use

The Instructions for Use for the Universal Multi-channel Cylinder Set, the Universal Cervix Probe Sets and the Universal Titanium Cervix Probe Sets are located on the Varian Applicators and Accessories Instructions for Use DVD (GM11010400). Soft copy versions of the Instructions for Use may also be found online at [www.MyVarian.com](http://www.MyVarian.com).

## Office Locations

Authorized Representative in the EU	Legal Manufacturer
Varian Medical Systems Nederland B.V. Kokermolen 2 3994 DH Houten The Netherlands	Varian Medical Systems, Inc. 3100 Hansen Way Palo Alto, CA 94304-1038 United States of America



## Document Signing Page

**This document has been reviewed and electronically signed by the following people:**

Workflow ID: 128106679, Doc Title: Universal Multi-Channel Cylinder Set GM11011400 2019-09-10 EN.pdf, Doc No:2019-09-10, Approver: David Harrington (dharring), Title: Product Manager, Applicators and Accessories, Date: Tuesday, 09/10/2019 01:07 PM Pacific Daylight Time, Meaning: I acknowledge my electronic signature carries the same meaning as a handwritten signature

Workflow ID: 128106679, Doc Title: Universal Multi-Channel Cylinder Set GM11011400 2019-09-10 EN.pdf, Doc No:2019-09-10, Approver: Lisa-Marie Kuchinke (dps4833), Title: Mechanical Design Engineer, Date: Tuesday, 09/10/2019 11:06 PM Pacific Daylight Time, Meaning: I acknowledge my electronic signature carries the same meaning as a handwritten signature

Workflow ID: 128106679, Doc Title: Universal Multi-Channel Cylinder Set GM11011400 2019-09-10 EN.pdf, Doc No:2019-09-10, Approver: Tommi Kaehkoenen (djn3053), Title: Manager Applicator Engineering, Date: Tuesday, 09/10/2019 11:11 PM Pacific Daylight Time, Meaning: I acknowledge my electronic signature carries the same meaning as a handwritten signature

Workflow ID: 128106679, Doc Title: Universal Multi-Channel Cylinder Set GM11011400 2019-09-10 EN.pdf, Doc No:2019-09-10, Approver: Christian Gerber (cgerber), Title: Sr. Manager Test Engineering, Date: Tuesday, 09/10/2019 11:14 PM Pacific Daylight Time, Meaning: I acknowledge my electronic signature carries the same meaning as a handwritten signature

Workflow ID: 128106679, Doc Title: Universal Multi-Channel Cylinder Set GM11011400 2019-09-10 EN.pdf, Doc No:2019-09-10, Approver: Christian Gerber (cgerber), Title: Sr. Manager Test Engineering, Date: Tuesday, 09/10/2019 11:16 PM Pacific Daylight Time, Meaning: I acknowledge my electronic signature carries the same meaning as a handwritten signature

Workflow ID: 128106679, Doc Title: Universal Multi-Channel Cylinder Set GM11011400 2019-09-10 EN.pdf, Doc No:2019-09-10, Approver: Katja Strehle (kstrehle), Title: Sr. Mechanical Engineer/Risk Management, Date: Tuesday, 09/10/2019 11:47 PM Pacific Daylight Time, Meaning: I acknowledge my electronic signature carries the same meaning as a handwritten signature

Workflow ID: 128106679, Doc Title: Universal Multi-Channel Cylinder Set GM11011400 2019-09-10 EN.pdf, Doc No:2019-09-10, Approver: Judith Jaensch (jjaensch), Title: Director Brachy Engineering, Date: Wednesday, 09/11/2019 05:04 AM Pacific Daylight Time, Meaning: I acknowledge my electronic signature carries the same meaning as a handwritten signature

Workflow ID: 128106679, Doc Title: Universal Multi-Channel Cylinder Set GM11011400 2019-09-10 EN.pdf, Doc No:2019-09-10, Approver: Juergen Handke (jhandke), Title: Sr. QA/RA Manager, Date: Wednesday, 09/11/2019 08:14 AM Pacific Daylight Time, Meaning: I acknowledge my electronic signature carries the same meaning as a handwritten signature



## **Document Audit Page**

**This document has been approved by delegated or proxy approvers below:**

Christian Gerber(cgerber) signed as a proxy approver for Ruth Deselaers (bhq7865) on Tue Sep 10 23:16:10 UTC+0200 2019