Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Sealed Source
(Amended in its Entirety)

NO.: NR-1235-S-102-S DATE: **February 6, 2013**
(Supersedes TX-1153-S-102-S)

SOURCE TYPE: Medical Reference Source

MODEL:
BM06E Series
BM06S Series
BM06V5 Series
BM06V10 Series
BM06V20 Series

MANUFACTURER/DISTRIBUTOR:
International Isotopes Idaho, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

ISOTOPE:	MAXIMUM ACTIVITY:	
Cobalt-60	0.1 mCi	(3.7 MBq)
Barium-133	0.5 mCi	(18.5 MBq)
Cesium-137	0.5 mCi	(18.5 MBq)
Sodium-22 (NARM/NORM)	0.5 mCi	(18.5 MBq)
Cobalt-57 (NARM/NORM)	15 mCi	(555 MBq)
Germanium-68 (NARM/NORM)	1.2 mCi	(44.4 MBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (X) Medical Reference Sources

CUSTOM SOURCE: _____ Yes __X__ No

SOURCE TYPE: Medical Reference Source

DESCRIPTION:

The Model BM06 Series sealed sources are intended for use as reference standards to check the response of dose calibrators used to measure research, diagnostic, and therapeutic radiopharmaceuticals. The BM06 Series offers these reference standards in **five** differing geometries. The first of these is the 30 ml vial geometry referred to as the BM06E. The second geometry is the 5 cc syringe geometry referred to as the BM06S. **Geometries 3, 4, and 5 simulate 5 cc, 10 cc, and 20 cc serum vials and are referred to as the BM06V5, BM06V10, and the BM06V20 Series, respectively. All of these source geometries** consist of a radioisotope in a chloride or nitrate complex uniformly dispersed in high impact epoxy casting resin (Emerson & Cuming Stycast 1264 or equivalent) color coded to visually differentiate the radioisotopes, which is then cured in either a 30 ml dose calibrator vial **(BM06E)**, a facsimile of a 5 cc syringe **(BM06S)**, **or in 5 cc, 10 cc, or 20 cc serum vials** (**BM06V5, BM06V10, and BM06V20, respectively)**.

The BM06E epoxy containing the dispersed radioactivity is sandwiched between two layers of epoxy which does not contain radioactive material. A rubber septum or equivalent material is chemically welded into the neck of the vial and a color coded (to visually differentiate the radioisotopes) screw top cap is chemically welded onto the vial so that disassembly without destruction of the vial is not possible.

The **BM06S** syringe geometry consists of a body and cap manufactured with a translucent **or color coded** acrylic. The body is filled with a layer of epoxy containing dispersed radioactivity which is sealed beneath a layer of epoxy containing no radioactive material. A screw type acrylic cap, color coded to match the epoxy matrix is chemically welded into the body of the syringe so that disassembly without destruction of the syringe is not possible.

SOURCE TYPE: Medical Reference Source

The BM06V geometries consist of break-resistant plastic, type PETG (glycol-modified polyethylene terephthalate) with a 20 mm septum cap and aluminum crimp seal. The body is filled with a layer of epoxy containing dispersed radioactivity which is sealed beneath a layer of epoxy containing no radioactive material. The septum cap is set in place and crimped onto the vial with an aluminum crimp top. The non-radiological epoxy layer provides a barrier to the radioactive epoxy matrix should the end-user remove the crimp top and septum. Access to the radioactive epoxy matrix is not possible without destruction of the vial.

Each source is supplied to the customer in a shielded storage pig.

The BM06 Series **can be provided in 30 configurations** encompassing **five geometries** and six isotopes.

The following table delineates the isotope **and geometry** differences between the BM06 models:

Model Number	Isotope	Geometry
BM06E-33	Barium-133	30 ml vial
BM06E-37	Cesium-137	30 ml vial
BM06E-60	Cobalt-60	30 ml vial
BM06E-22	Sodium-22	30 ml vial
BM06E-57	Cobalt-57	30 ml vial
BM06E-68	Germanium-68	30 ml vial
BM06S-33	Barium-133	5 cc syringe
BM06S-37	Cesium-137	5 cc syringe
BM06S-60	Cobalt-60	5 cc syringe
BM06S-22	Sodium-22	5 cc syringe
BM06S-57	Cobalt-57	5 cc syringe
BM06S-68	Germanium-68	5 cc syringe

SOURCE TYPE: Medical Reference Source

DESCRIPTION (Cont.):

Model Number	Isotope	Geometry
BM06V5-33	Barium-133	5 cc serum vial
BM06V5-37	Cesium-137	5 cc serum vial
BM06V5-60	Cobalt-60	5 cc serum vial
BM06V5-22	Sodium-22	5 cc serum vial
BM06V5-57	Cobalt-57	5 cc serum vial
BM06V5-68	Germanium-68	10 cc serum vial
BM06V10-33	Barium-133	10 cc serum vial
BM06V10-37	Cesium-137	10 cc serum vial
BM06V10-60	Cobalt-60	10 cc serum vial
BM06V10-22	Sodium-22	10 cc serum vial
BM06V10-57	Cobalt-57	10 cc serum vial
BM06V10-68	Germanium-68	10 cc serum vial
BM06V20-33	Barium-133	20 cc serum vial
BM06V20-37	Cesium-137	20 cc serum vial
BM06V20-60	Cobalt-60	20 cc serum vial
BM06V20-22	Sodium-22	20 cc serum vial
BM06V20-57	Cobalt-57	20 cc serum vial
BM06V20-68	Germanium-68	20 cc serum vial

Models of the BM06V Series

LABELING:

Each source and storage pig is conspicuously labeled with the source isotope and activity and bears the warning "CAUTION: RADIOACTIVE MATERIAL" as well as the trefoil radiation symbol in magenta on a yellow background, the designer's name and the name of the manufacturer. Each label also contains the source model number, serial number and a reference date for the source activity. The label will be affixed to the exterior of the source and will be laminated to prevent wear as a result of use.

SOURCE TYPE: Medical Reference Source

DIAGRAM:

See Attachments 1 **through 4**.

CONDITIONS OF NORMAL USE:

The sources are designed for use in a medical or commercial pharmacy environment and are not expected to experience extreme environmental factors. The sources are intended for use as reference standards to check the response of dose calibrators used to measure research, diagnostic, and therapeutic radiopharmaceuticals. The expected useful life of the Co-57 and Ge-68 sources will be approximately 2 years. The manufacturer expects that the working life of the Cs-137, Ba-133, Na-22 and Co-60 sources will be at least 5 years.

PROTOTYPE TESTING:

A prototype vial and syringe source, containing Co-57, designated as Models BM06E-57 and BM06S-57, were constructed and tested in accordance with ANSI N43.6-1997 and achieved a sealed source classification of ANSI 97C22312. Only a prototype BM06E-57 and BM06S-57 were tested because the maximum activity of this model was significantly higher than the other models and a failure of the source that would release radioactive material would be more readily detected. There is no difference in the construction materials or assembly methods for the different models in the BM06E Series and no difference in the construction materials or assembly methods for the different models in the BM06S Series.

A total of six Model BM06V Series prototype sources were tested (two for each geometry) containing Ge-68 at activity levels ranging from 55.4 µCi to 220 µCi. The manufacturing method for the BM06V Series serum source geometries is similar to the BM06E and BM06S Series. All of the prototype sources were made from the same batch of epoxy mixed with Ge-68. The range of activity corresponds with the active volume area of the source geometries.

SOURCE TYPE: Medical Reference Source

PROTOTYPE TESTING (Cont.):

Each prototype source was uniquely identified as indicated in the table below:

Prototype	Activity[1]
BM06V5-1	55.4 µCi
BM06V5-2	57.7 µCi
BM06V10-1	109.7 µCi
BM06V10-2	110.4 µCi
BM06V20-1	220.0 µCi
BM06V20-2	220.0 µCi
[1]Reference date of 04/16/2012 12:25	

The level of activity of the prototype sources was considered sufficient to readily identify leakage through dry wipe testing and was low enough to minimize personnel exposure during the tests.

Slight deformation of serum vial body as a result of the high temperature test did not result in a breach of source or leakage of radioactive material from the source. All of the prototype sources were successfully tested in accordance with ANSI N43.6-2007 and achieved a sealed source classification of ANSI 07C22312.

SOURCE TYPE: Medical Reference Source

EXTERNAL RADIATION LEVELS:

Maximum radiation levels for these sources are as follows:

Model	Contact Dose	Dose at 5 cm	Dose at 30 cm	Dose at 100 cm
BM06E-33	39	10	1.4	0.1
BM06E-37	45	12	1.6	0.1
BM06E-60	160	30	1.0	0.2
BM06E-22	470	78	6.0	0.6
BM06E-57	293	68	5.9	1.2
BM06E-68	526	89	7.2	1.0
BM06S-33	456	49	1.7	0.2
BM06S-37	558	60	2.1	0.2
BM06S-60	352	38	1.4	0.1
BM06S-22	891	95	3.4	0.3
BM06S-57	1382	158	12	2.4
BM06S-68	905	96	3.4	0.2
BM06V5-33	**864**	**38**	**1.6**	**0.2**
BM06V5-37	**937.5**	**40**	**1.75**	**0.25**
BM06V5-60	**740**	**32**	**1.4**	**0.2**
BM06V5-22	**3405**	**147.5**	**6**	**0.5**
BM06V5-57	**5580**	**240**	**9.8**	**0.9**
BM06V5-68	**3787.2**	**163.2**	**6.7**	**0.7**
BM06V10-33	**696**	**36**	**1.6**	**0.2**
BM06V10-37	**752.5**	**40**	**1.25**	**0.25**
BM06V10-60	**594**	**32**	**1.4**	**0.2**
BM06V10-22	**2737.5**	**142.5**	**6**	**0.5**
BM06V10-57	**4562**	**234**	**9.8**	**0.9**
BM06V10-68	**3045.6**	**158.4**	**6.7**	**0.7**
BM06V20-33	**506**	**32**	**1.4**	**0.2**
BM06V20-37	**555**	**35**	**1.5**	**0.25**
BM06V20-60	**436**	**28**	**1.2**	**0.2**
BM06V20-22	**2015**	**130**	**5.75**	**0.5**
BM06V20-57	**3445**	**221**	**9.9**	**1**
BM06V20-68	**2246.4**	**146.4**	**6.5**	**0.7**

External Radiation Levels in mrem/hr

SOURCE TYPE: Medical Reference Source

EXTERNAL RADIATION LEVELS (Cont.):

Note: Dose rates for Models BM06E-57, BM06E-68 and BM06S-57 were measured on prototype sources manufactured by International Isotopes Idaho, Inc., and corrected to the maximum activities for these sources. Dose rates for Models BM06E-33, 37, 22 and 60 measured on NIST traceable sources of similar construction and geometry and corrected to the maximum activities for these sources. Dose rates for Models BM06S-33, 37, 60, 22 and 68 were calculated using MicroShield.

Dose rates for Models BM06V5, BM06V10, and BM06V20 were calculated using MicroShield. Radiation measurements were obtained on the prototype sources, corrected to the maximum activity levels and found to be within ±25% of the modeled results at the 30 cm and 100 cm distances.

Modeled results are significantly higher than measured results at the contact and 5 cm distances, this is due, in part, to MicroShield overestimation of exposure rate at very close distances to the radiation source and that the actual radiation detector is located approximately 0.25 inches inside the body of the instrument.

QUALITY ASSURANCE AND CONTROL:

International Isotopes Idaho, Inc. maintains a quality assurance and quality control program which has been deemed acceptable for licensing purposes by the Nuclear Regulatory Commission. Periodic audits by International Isotopes Idaho, Inc. Quality Assurance staff will ensure that the program continues to perform at an acceptable level.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall be distributed to persons specifically licensed by the NRC, an Agreement State or a Licensing State.

SOURCE TYPE: Medical Reference Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont.):

- Handling, storage, use, transfer and disposal to be determined by the licensing authority but should be, at a minimum, in accordance with the product information pamphlet provided by the distributor.

- The sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.

- The sources shall not be subjected to conditions that exceed their ANSI/HPS N43.6-1997 classification of 97C22312.

- The sources should be stored and transported in the manufacturer's shielded case.

- This registration sheet and the information contained within the references shall not be changed without the written consent of the U.S. Nuclear Regulatory Commission.

- International Isotopes Idaho, Inc. provides for design control, procurement control, process quality control and final quality assurance pertaining to the manufacture of these sources. Distribution will be directly from the manufacturer's facility to the customer.

- Licensees in possession of sources that have decayed below their useful range of activities may contact International Isotopes Idaho, Inc. for instructions regarding return to the manufacturer.

SOURCE TYPE: Medical Reference Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont.):

- Reviewer's Note: the sources had been previously registered by the State of Texas under registration No. TX-1153-S-102-S, which also included the following sources with NARM/NORM materials: BM06-22 (Sodium-22, 0.5 mCi), BM06-57 (Cobalt-57, 15 mCi), and BM06-68 (Germanium-68, 0.5 mCi). Registration No. TX-1153-S-102-S was reissued by NRC as NR-1235-S-102-S under the licensee's address in Idaho.

- Reviewer's Note: The effective date for distribution of the BM06E-68 and BM06S-68 sources up to 1.2 mCi each is October 1, 2010. Also, the color coding for these sources found in Attachment 2 changed from white to purple.

The Energy Policy Act of 2005 gave authority to the NRC to regulate NARM/NORM. The State of Idaho does not have a state licensing program nor regulations for NARM or NORM materials. Therefore, the NRC included NARM/NORM on this certificate, accepting the review performed by the State of Texas under Registration No. TX-1153-S-102-S for the NARM/NORM sources.

SOURCE TYPE: Medical Reference Source

SAFETY ANALYSIS SUMMARY:

The BM06E, BM06S, **BM06V5, BM06V10, and BM06V20** Series sources are intended for use as quality control and reference sources for dose calibrators and are expected to maintain their integrity for normal conditions of use and likely accidental conditions. Rupture of the encapsulating material would not reasonably be expected to allow dispersion of radioactive material due to the epoxy matrix with which the radioactive material is mixed.

The most severe accident scenario involving these sources would be a fire, and would most likely result in a release of radioactive material. Temperatures exceeding 200 degrees C would result in combustion of the resin in which the radioisotope is dispersed, as well as the plastic which constitutes the vial.

Based on review of the information and test data submitted for the BM06E, BM06S, **BM06V5, BM06V10, and BM06V20** Series sources and the references cited below, we conclude the these sources are acceptable for licensing purposes as described within this certificate.

REFERENCES:

The following supporting documents for International Isotopes Idaho, Inc. Model BM06E, BM06S, **BM06V5, BM06V10, and BM06V20** Series reference sources are hereby incorporated by reference and are made a part of this registry document.

- International Isotopes application dated July 12, 2002, sent to Texas Department of Health, with enclosures thereto.

- International Isotopes letters dated September 18, 2002, October 16, 2002, August 20, 2003, and November 27, 2003, sent to Texas Department of Health, with enclosures thereto.

SOURCE TYPE: Medical Reference Source

REFERENCES (Cont.):

- International Isotopes letter dated March 31, 2005, to Texas Department of Health, requesting transfer of certificate to NRC.
- Texas Department of Health letter dated April 27, 2005, transferring International Isotopes Model BM-06 Series file to NRC.
- Texas Department of Health email dated June 13, 2005.
- State of Idaho, INL Oversight and Radiation Control Division, email dated October 28, 2005.
- International Isotopes letters dated November 16, 2006, and January 3, 2007, with enclosures thereto.
- International Isotopes letters dated August 9, 2010 and September 20, 2010, with enclosures thereto.
- **International Isotopes letters dated August 24, 2012 and December 31, 2012, with enclosures thereto.**
- **International Isotopes emails dated January 29, 2013, with enclosures thereto.**

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: February 6, 2013 Reviewer: **/RA/**
Stephen Poy

Date: February 6, 2013 Concurrence: **/RA/**
John P. Jankovich

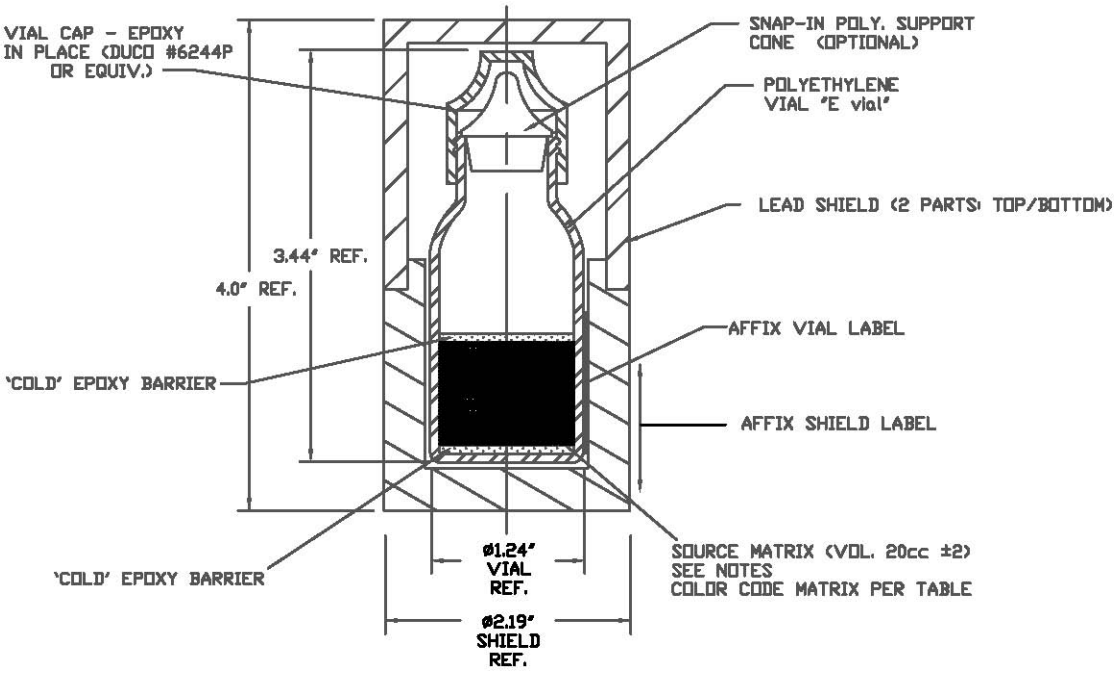
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1235-S-102-S DATE: **February 6, 2013** ATTACHMENT 1 OF 4

Source Label Example

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1235-S-102-S DATE: **February 6, 2013** ATTACHMENT 2 OF 4

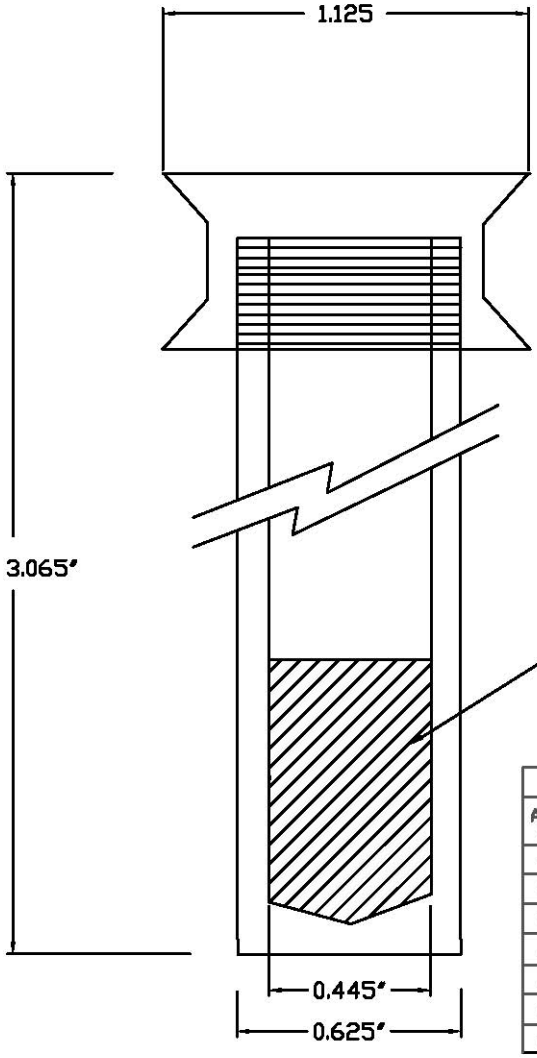


STANDARD MODEL TABLE				
ASS'Y. P/N	MODEL NO.	NUCLIDE	NOMINAL ACTIVITY	COLOR CODE
-01	BM06E-22	NA-22	0.20 MCI	YELLOW
-02	BM06E-60	CO-60	0.05 MCI	BLUE
-03	BM06E-37	CS-137	0.20 MCI	GREEN
-04	BM06E-33	BA-133	0.25 MCI	BLK/GRY
-05	BM06E-57	Co-57	5.0 MCI	RED
-06	BM06E-68	GE-68	1.20 MCI	PURPLE
-07	BM06E-157	CO-57	10.0 MCI	RED

Model BM06E - Vial

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1235-S-102-S DATE: **February 6, 2013** ATTACHMENT 3 OF 4

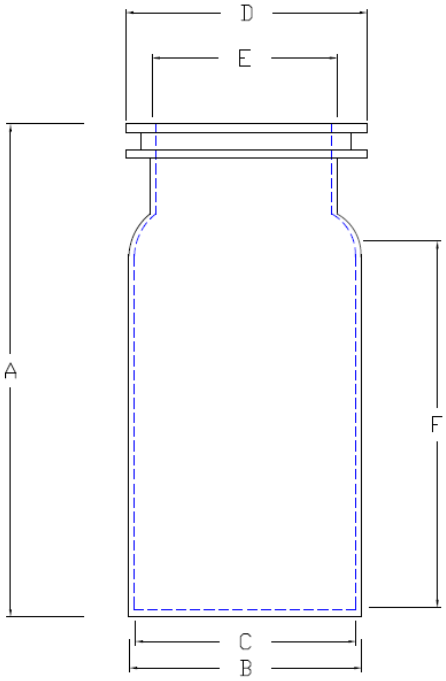


STANDARD MODEL TABLE				
ASS'Y. P/N	MODEL NO.	NUCLIDE	NOMINAL ACTIVITY	COLOR CODE
-01	BM06S-22	NA-22	0.20 MCI	YELLOW
-02	BM06S-60	CO-60	0.05 MCI	BLUE
-03	BM06S-37	CS-137	0.20 MCI	GREEN
-04	BM06S-33	BA-133	0.25 MCI	BLK/GRY
-05	BM06S-57	Co-57	5.0 MCI	RED
-06	BM06S-68	GE-68	1.20 MCI	PURPLE
-07	BM06S-157	CO-57	10.0 MCI	RED

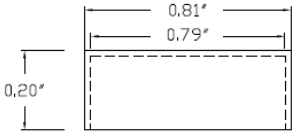
Model BM06S - Syringe

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1235-S-102-S DATE: **February 6, 2013** ATTACHMENT 4 OF 4

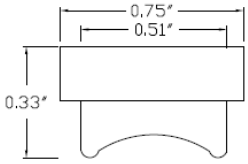


	DIMENSIONS IN INCHES (REFERENCE ONLY)					
	A	B	C	D	E	F
5 CC	1.56	0.88	0.79	0.79	0.50	0.96
10 CC	1.97	0.94	0.85	0.79	0.50	1.42
20 CC	2.30	1.17	1.07	0.79	0.50	1.63



AL CRIMP SEAL

VIALS/SEPTA/CRIMP SEAL VOIGT GLOBAL DISRIBUTION INC,



SILICONE SEPTA

Models BM06V5, BM06V10, and BM06V20 - Serum Vials