INSTRUCTIONS

RPD INFORMATION

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Phone	763-497-2071 or 800-497-2071
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RPD PRODUCT INFORMATION

RPD is an authorized distributor

Item Number	Description
244-400	SecureVac Cushion, 50cm x 20cm, 2.25L Fill
244-402	SecureVac Cushion, Head & Shoulder, 65x67 cm, 10L Fill
244-404	SecureVac Cushion, 70cm x 50cm, 15L Fill
244-406	SecureVac Cushion, 70cm x 70cm, 20L Fill
244-410	SecureVac Cushion, 100cm x 70cm, 35L Fill
244-412	SecureVac Cushion, 100cm x 100cm, 50L Fill
244-414	SecureVac Cushion, Whole Body -150cm x 70cm, 55L Fill
244-416	SecureVac Cushion, 150cm x 100cm, 80L Fill
244-418	SecureVac Cushion w/ Pelvic Portal, 100cm x 70cm, 35
244-420	SecureVac Tri-Vac, 3 Chambered Cushion
244-422	SecureVac T-Vac, 2-Chambered Cushion
244-424	SecureVac Tri-Vac, 3-Chambered Cushion
244-426	SecureVac VersaCushion, 35 x 15 x 9 cm, 2 L Fill

SecureVac™ Cushions Instructions for Use

Caution: Federal Law restricts this device to sale by or on the order of a licensed Physician or Radiation Therapist.

DEVICE DESCRIPTION

Bionix Radiation Therapy SecureVac™ cushions are reusable, customizable devices intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

INDICATIONS

The Bionix Radiation Therapy SecureVac™ cushions are intended to be used for the positioning and repositioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

CONTRAINDICATIONS

No contraindications have been identified for the use of SecureVac cushions.

STORAGE

Store in a cool, dry environment with cushions slightly evacuated.

ADVERSE REACTIONS

No adverse reactions have been identified for the use of SecureVac cushions.

WARNINGS

- Do NOT use SecureVac cushions if the package is damaged or open.
- Inspect the SecureVac cushions before each use.
- Do NOT attempt to sterilize the SecureVac Cushion. Attempts to sterilize the SecureVac Cushion may result in product damage and / or patient injury.

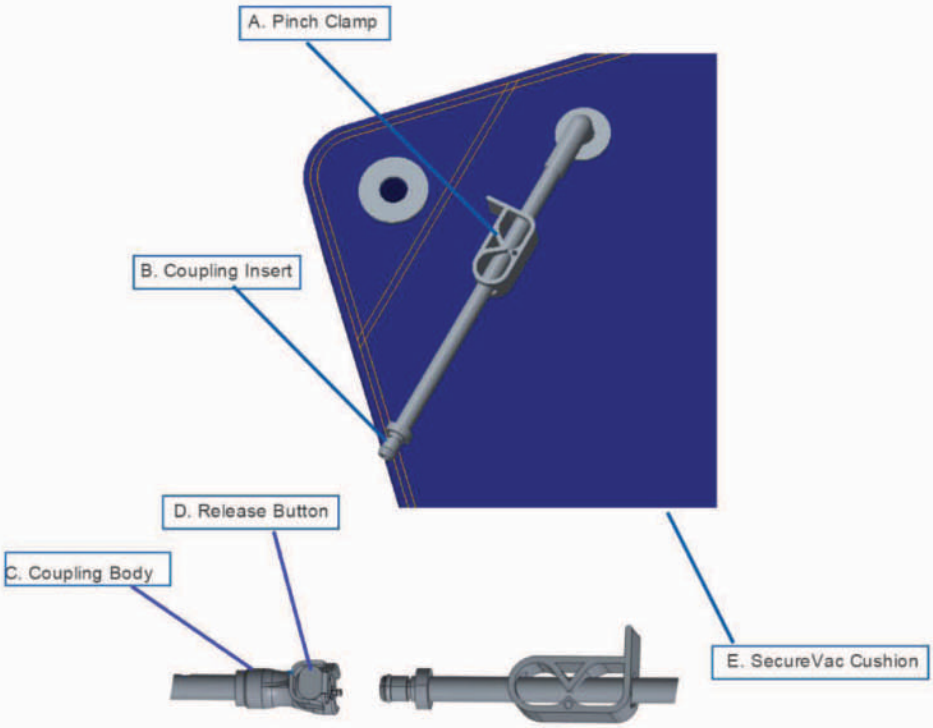
CLEANING INSTRUCTIONS

Note: It is the user's responsibility to clean products per hospital protocol / local regulations. Do not use alcohol-based cleaners on this product. Recommended cleaning procedures include:

1. Wipe thoroughly with water-based antiseptic cleaner or foam.
2. Allow to dry before next patient use.

Note: When using the SecureVac cushion(s), it may be necessary to use a lockdown adapter to prevent movement. See accessory items below.

Figure 1.



INFLATION

1. Release the pinch clamp (A) on the tubing leading to the Bionix Radiation Therapy SecureVac Cushion (E).
2. Insert the coupling insert (B) (the end of the tube protruding from the Bionix Radiation Therapy SecureVac Cushion) into the coupling body (C) (on the end of the tube attached to the Bionix Radiation SecureVac Pump or other approved vacuum/pressure system) until you hear a click, as shown in Figure 1.
3. To inflate the cushion, apply pressure from the Bionix Radiation Therapy SecureVac Pump or other approved vacuum/pressure system.
   Warning: Over inflation of the cushion can cause it to burst.

DEFLATION

1. To deflate the SecureVac Cushion, apply the vacuum from the Bionix Radiation Therapy SecureVac Pump or other approved vacuum/pressure system.
2. Once your SecureVac Cushion is inflated or deflated to the desired firmness, tighten pinch clamp (A), and disconnect the coupling body (C) from the coupling insert (B) by pressing the release button, as shown in Figure 1.
3. Replace the red cap.

DISPOSAL INSTRUCTIONS

Dispose of properly in accordance with local regulations and standard hospital or clinic procedures.

Note: See the table below for additional accessories:

REF	Description	Quantity
SVRT-7120	Rolling Storage Cart	1
SVRT-7101	Dual Action Vacuum Pump	1
SVRT-7106	SecureVac Hose Adapter	1
SVRT-5014	SecureVac Box Adapter	1
SVRT-7121	S-Hooks	5
SVRT-7710	SecureVac Cushion Repair Kit	1
SVRT-7011	Mold Care Alignment Device	1
RM60-0021	Replacement Male End O-Rings	1

Additional SecureVac Part Numbers and Sizes:

REF	Description
SVRT-7130	150 x 70cm, 50L Fill
SVRT-7136	Extremities Cushion, 2.5L Fill
SVRT-7140	Pelvic Portal Cushion 100 x 70cm, 35L Fill
SVRT-7380-A	100 x 150, 80L Fill
SVRT-7702	50 x 25cm 2.25L Fill
SVRT-7815-A	70 x 70cm 15L Fill
SVRT-7915	70 x 50cm, 15L Fill
SVRT-7820-A	70 x 70cm, 20L Fill
SVRT-7535-A	100 x 70cm, 35L Fill
SVRT-7450-A	100 x 100cm, 50L Fill
SVRT-7135	VersaCushion 32 x 15 x 9cm, 2L Fill
SVRT-7715	Head & Shoulder Cushion
SVRT-7140	Pelvis Portal Cushion 100 x 70cm, 25 x 25 cm Portal, 35L Fill
SVRT-9450	100 x 100cm, 50L Fill
SVRT-9530	100 x 70cm, 30L Fill
SVRT-9535	100 x 70cm, 35L Fill
SVRT-9820	70 x 70cm, 20L Fill
SVRT-7600	Upper: 60 x 100cm, 28L Fill Middle: 65 x 70cm, 20L Fill, Lower: 90 x 70cm, 35L Fill
SVRT-7625	Upper: 100 x 60cm, 28L Fill Lower: 70 x 100cm, 24L Fill
SVRT-7650	Upper: 60 x 100cm, 28L Fill Middle: 65 x 70cm, 20L Fill, 90 x 70cm, 28L Fill Built in Wedge 6" x 18"

Label Symbol Glossary (Note: not all symbols may be applicable to this product)

Symbol	Title of Symbol	Description of Symbol	Symbol Designation Number	Title of Symbol Standard Development Org. Standard
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1	ISO 15223-2012
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	5.1.2	ISO 15223-2012
	Date of manufacture	Indicates the date when the medical device was manufactured.	5.1.3	ISO 15223-2012
	Use-By Date	Indicates the date after which the medical device is not to be used.	5.1.4	ISO 15223-2012
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	ISO 15223-2012
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.	5.1.6	ISO 15223-2012
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	5.1.7	ISO 15223-2012
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3	ISO 15223-2012
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4	ISO 15223-2012
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.	5.2.6	ISO 15223-2012
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7	ISO 15223-2012
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8	ISO 15223-2012
	Biological Risks	Indicates that there are potential biological risks associated with the medical device.	5.4.1	ISO 15223-2012
	Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2	ISO 15223-2012
	Consult Instructions For Use	Indicates the need for the user to consult the instructions for use.	5.4.3	ISO 15223-2012
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4	ISO 15223-2012
CE 0459	European Conformity	EC Declaration of Conformity by Notified Body	Annex XII	MDD 93/42/EEC:2007
CE	European Conformity	European Conformity	Annex XII	MDD 93/42/EEC:2007
℞ Only	By Prescription Only	Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.	N/A	FDA 81 Federal Register pg. 38911-38931

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