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ALVUE™ BALLOON DILATION SYSTEM

04/2019

IMPORTANT INFORMATION ON THE ALVUE™ BALLOON DILATION SYSTEM

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WITHIN THE UNITED STATES ONLY

ENGLISH

IMPORTANT INFORMATION ON THE ALVUE™ BALLOON DILATION SYSTEM

DESCRIPTION
The ALVUE™ Balloon Dilation System is a surgical instrument that consists of an inflatable nylon balloon attached to the distal end of a dilator. ALVUE™ is used to dilate soft tissue to gain access to the surgical site and is available in a variety of sizes to accommodate the anatomical needs of the patient. The system includes accessories for inflation. ALVUE™ is a sterile single use device.

INDICATIONS
The ALVUE™ Balloon Dilation System is indicated for patients undergoing surgical procedures requiring tissue retraction including the following procedures: endoscopic; laparoscopic; general surgery; plastic and reconstructive surgery; spine surgery; orthopedic surgery; thoracoscopic surgery; and procedures in the extraperitoneal space. The system is intended to create an operative space by dissecting layers of connective tissue along natural tissue planes of separation of the extraperitoneal, subcutaneous extremity, or thoracic space.

WARNINGS
Potential risks which may require additional surgery include:

- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae;
- Rupture with fragmentation of the inflatable portion of the Balloon Dilation System resulting in retention of a fragment within the body;
- Rupture of the balloon causing contrast medium exposure, possibility resulting in an allergic reaction or anaphylaxis or tissue necrosis due to contrast medium exposure;
- Damage to the balloon dilator may result in retention of a foreign body in the patient;
- Complications that may occur during a parapedicular approach include pneumothorax and bleeding;
- The balloon component of the system may fail due to surgical tool contact;
- Do not inflate the balloon until it has been fully inserted in the retraction space. Inflating the balloon prior to full deployment may result in balloon failure;
- Do not use this product after the expiration date printed on the package. The device may not be safe or effective beyond its expiration date.

Inflating the ALVUE™ Balloon Dilation System beyond the recommended inflation volume may cause the balloon to rupture during operation.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic instruments. General surgical risks should be explained to the patient prior to surgery.

Use this device as supplied and in accordance with the handling and use information provided below.

PRECAUTIONS
- Use of the ALVUE™ Balloon Dilation System should be performed only by experienced surgeons with specific training in the use of this system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered prior to performing surgery.
- Never use any gaseous medium to inflate the balloon dilator.
- Follow manufacturer's instructions for contrast medium indications and usage. Unintended contrast medium exposure to the patient may occur in the use of this system.
- The device is not intended for continuous insufflation.
- The device is intended for single use only. Do not re-sterilize or reuse.

CONTRAINDICATIONS
Use of the ALVUE™ Balloon Dilation System is contraindicated in patients if the adjacent anatomy dimensions do not allow safe placement and inflation of balloon.

INSTRUCTIONS FOR USE
An Inflation Kit containing a syringe, inflation hose, and a one-way valve is provided with the ALVUE™ Balloon Dilation System. The kit is not intended for use with any other device.

1. Select the appropriate size ALVUE™ balloon dilator and inflation kit.
2. Fill the injection syringe with saline or a mixture of contrast medium and saline.
3. Draw the appropriate volume of contrast mixture into the injection syringe based on the chosen dilator size (see chart below).
4. Assemble the inflation construct:
   a. Attach the female luer of the one-way valve to the male luer of the inflation hose, if desired. The one-way valve is optional.
   b. Attach the female luer of the inflation hose to the male luer of the injection syringe. Remove all air bubbles from the construct.
5. Ensure that the occlusion switch is in the open position.
6. Make an incision in the skin over the target area using a scalpel.
7. Place the dilator through the soft tissue to the selected target, using fluoroscopy as necessary.
8. Dock the tip of dilator into the target site. If the dilator is cannulated, a k-wire may be advanced to secure dilator placement.
9. Connect the inflation construct by attaching the male luer of the one-way valve to the female luer at the proximal end of the dilator.
10. Holding the dilator firmly in place, inflate the balloon to the desired volume to dilate soft tissue with the injection syringe.
11. For the 22x60mm size dilator, repeat steps 2-10 to fill the remaining inflation volume of the dilator.
12. Move the occlusion switch to the "CLOSE" position to seal off the fluid pathway, and disconnect the inflation construct from the Luer valve.
13. The appropriate size retractor or port may be passed over the dilator to gain access and the dilator may be removed.

INFLATION TABLE
ALVUE™ Balloon Dilator Inflation Volumes

Expansion Range: diameter x length (mm)	13x40	13x60	13x120	17x40	17x60	19x40	19x60	22x40	22x60
Inflation Volume (cc)	6.0	8.5	15.5	11.0	15.0	13.5	19.0	18.0	26.0

PACKAGING
These instruments are supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

CONTACT INFORMATION
Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION
The ALVUE™ Balloon Dilation System and components are sterilized by gamma radiation to ensure a Sterility Assurance Level (SAL) of 10^{-6}. The expiration date is provided on the package label. Do not use if expired. These components are considered sterile unless the packaging has been opened or damaged.

STORAGE
The ALVUE™ Balloon Dilation System should be stored in its original shipping materials. Proper care should be taken to ensure that the balloon dilator will not be damaged. Store the balloon dilator in a cool, dry place at 10°C - 40°C (50°F - 104°F).

CAUTION: Federal (U.S.A.) Law Restricts this Device to Sale by or on the Order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY	Rx ONLY	PRESCRIPTION USE ONLY