Transcatheter Closure of ASDs

An overview of therapeutic options for atrial septal defect closure.

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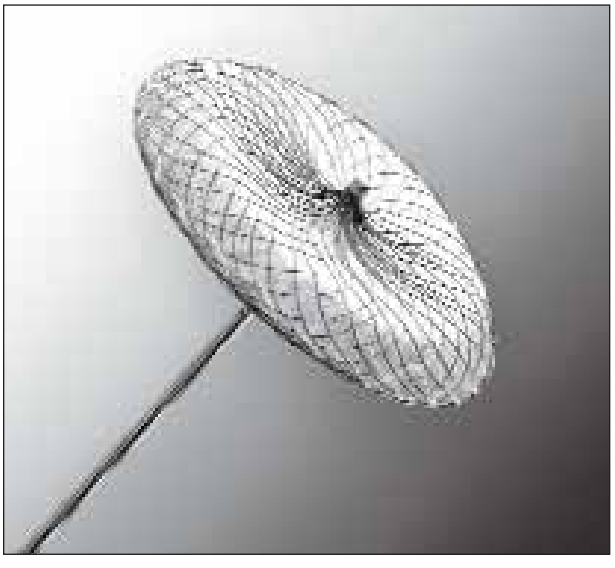
Transcatheter therapy, whether palliative or corrective in nature, has evolved as an accepted therapy for many congenital cardiac defects. Percutaneous closure of atrial septal defects (ASDs) is a perfect example of this shift in treatment strategies. Although "open heart" surgical closure was performed until the late 1990s in the majority of patients, transcatheter therapy has since become the method of choice for closing these defects. Today, in larger centers, more than 90% of patients are treated percutaneously, and surgical therapy is usually reserved for rare defects that are unsuitable for transcatheter closure. This progress has been achieved through the introduction of a large variety of newer devices that were specifically developed for individual congenital cardiac lesions over the last several years, thereby enabling many procedures to be safely performed in a much wider range of clinical centers. Because it is virtually impossible to present a complete summary of all available and investigative devices, the authors have tried to discuss devices available for closure of ASDs that have found the most widespread use within the US.

HISTORY AND DEVICES

The pioneering work by King and Mills, who in 1976 were the first to describe the closure of ASDs in the catheterization laboratory, set the stage for the subsequent acceleration in device development that has occurred during the past decade.[1] In 1987, Dr. James Lock described the clamshell device to occlude a ventricular septal defect (VSD) using a percutaneous approach.[2] This device was further modified, and its successors include the CardioSeal ASD occlusion device (NMT Medical, Boston, MA) as well as the StarFlex Occluder, which is a self-centering modification of the CardioSeal device. In 2001, the Amplatzer Septal Occluder (AGA Medical Corporation, Golden Valley, MN) (Figure 1) gained FDA approval for occlusion of secundum ASDs, which has resulted in a significant increase in percutaneous closure of ASDs performed within the US. It is presently the most frequently used transcatheter device for occlusion of ASDs. A modification of its principle design to accommodate the specific characteristics of multifenestrated ASDs has since been approved (Amplatzer Cribriform Septal Occluder, AGA Medical Corporation). Another device that has recently acquired FDA premarket approval for the occlusion of ASDs is the Helex Septal Occluder (Gore & Associates, Flagstaff, AZ),[3] and its recent modification of the delivery system has made it a welcome alternative for small- to medium-sized ASDs. Devices that have been used outside the US include the Sideris buttoned device (Pediatric Cardiology Custom Medical Devices, Athens, Greece),[4,5] the Das-Angel Wings (ev3 Inc., Plymouth, MN),[6] the PFO-Star (Cardia, Inc., Burnsville, MI), as well as the ASDOS (Osypka, GmbH; Grenzach-Wyhlen, Germany).[7]

Although many devices have been used for closure of ASDs on an off-label basis, the only two devices that are specifically approved for closure of ASDs within the US are the Amplatzer Septal Occluder and its modification, the Cribriform Septal Occluder, as well as the Helex Septal Occluder. This article mainly focuses on describing the



(Courtesy of AGA Medical Corporation.)

Figure 1. Amplatzer Septal Occluder.

Amplatzer Septal Occluder and the specific techniques that can be employed to occlude the technically more challenging ASDs.

CLOSURE OF ASDs USING THE AMPLATZER SEPTAL OCCLUDER

The Amplatzer Septal Occluder, which was first described in 1997,[8,9] is a double-disc device formed of .005-inch nitinol mesh, with the two disks being linked to each other through a central connecting waist that has a length of 3 to 4 mm. Dacron fabric is incorporated into each disc, as well as the connecting waist. The device size is defined by the diameter of the connecting waist and is available from 4 to 38 mm (up to 40 mm outside the US). The diameter of the left atrial disc exceeds the connecting waist by 12 to 16 mm.

Closure can be performed under general anesthesia, which is usually preferred when transesophageal echocardiography (TEE) is used as guidance for device deployment and delivery. However, intracardiac echocardiography (ICE) is equally suitable to monitor device deployment, thereby allowing these procedures to be performed under conscious or deep sedation in older children and adults.[10,11] It also has the additional advantage of allowing the operator to better visualize the inferoposterior rim, which can be difficult to visualize using TEE alone. Echocardiographic assessment should include the ASD dimension and septal rims in at least three different echocardiographic planes (four-chamber view, short-axis view, and bicaval view), pulmonary venous drainage, as well as evaluation for the presence of pre-existing atrioventricular valve regurgitation. The retroaortic rim is deficient in more than 50% of ASDs, and multiple rim deficiencies clearly increase the demands on the operator's technical skill, although studies have documented that closure of ASDs even with multiple septal rim deficiencies is feasible.[12,13]

Vascular access is usually obtained in the (right) femoral vein, placing an additional arterial monitoring cannula in the right femoral artery with additional femoral venous access being required for intracardiac echocardiography. ASD closure can also be performed using transhepatic access (Figure 2),[14] whereas internal jugular venous access is unsuitable for this procedure. All procedures are performed using therapeutic heparinization with activated clotting time maintained at >200 seconds. A standard hemodynamic evaluation should include an assessment of left-to-right shunt, pulmonary artery pressures, pulmonary vascular resistance, as well as left ventricular end-diastolic pressure (LVEDP). In older patients with a degree of left ventricular diastolic dysfunction, pretreatment with diuretics and afterload-reducing agents may be required before ASD closure.[15] A full hemodynamic evaluation does require test occlusion of the ASD before definitive closure in these patients. If an increase

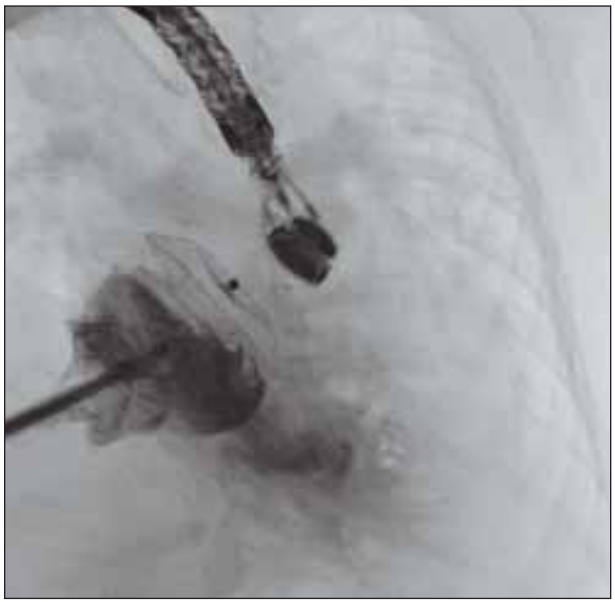


Figure 2. Transhepatic ASD closure. A 5.5-kg patient with recurrent respiratory tract infections and failure to thrive, as well as an interrupted inferior vena cava. Transhepatic deployment of an Amplatzer Septal Occluder.

of mean left atrial pressure to more than 20 to 25 mm Hg is observed, the patient may require implantation of a fenestrated device.[16] Angiography performed in the right upper pulmonary vein (RUPV) in the left anterior oblique (LAO) and cranial angulation facilitates a more accurate assessment of the atrial septal length *en face* and provides a perfect road map for subsequent device deployment. The exact degree of LAO and cranial angulation varies from patient to patient, and incremental injections will allow the operator to adjust the cameras appropriately.

In small children in whom the ASD dimensions in the various echocardiographic planes are consistent, balloon sizing may not always be necessary, and adding 20% to 25% to the average two-dimensional diameter may serve as a good estimate for the appropriate device size. Balloon sizing, however, is frequently beneficial in larger ASDs in adults, as well as ASDs that appear oval or irregularly shaped based on echocardiographic assessment. For this purpose, the LUPV is entered, and an exchange length, extra-stiff, J-tipped wire is advanced, which can be used for balloon sizing as well as positioning of the delivery sheath. Static Doppler stop-flow balloon sizing under echocardiographic guidance can be performed using an Amplatzer Sizing Balloon II (AGA Medical Corporation) or a NuMED PTS Sizing Balloon Catheter (NuMED, Hopkinton, NY). When no waist is visible on cine recording, the echocardiographic stretched diameter is frequently more reliable than cine recording because the angle of the atrial septum in relation to the sizing bal-

loon may vary. When balloon sizing is used, the device size chosen should be equal to or not larger than 1 to 2 mm larger than the maximum stretched diameter. When determining the device size in the presence of larger ASDs in small children, the interventionist has to be sure that the total length of the chosen device (12 to 14 mm, plus the size of the device) does not exceed the total septal length.

Once the device size has been determined, the appropriate delivery sheath (such as the Amplatzer TorqVue Delivery System, AGA Medical Corporation) is advanced over the guidewire toward the mouth of the LUPV. The dilator and wire are then gently removed, taking care to avoid inadvertent air embolism. The prepared device is advanced through the sheath under fluoroscopic and echocardiographic guidance, using the same projections as during the initial angiographic assessment. Once the device is at the tip of the delivery sheath, the whole assembly is pulled back until the tip of the delivery sheath exits the mouth of the pulmonary vein, at which stage the left atrial disc is deployed gradually. If the device is oriented appropriately, it is pulled back gradually toward the septum with the central waist being deployed just a little before the left atrial disk reaches the septum, thereby allowing self-centering of the device within the ASD. Occasionally, a gentle rotation of the sheath may aid a better device alignment. This is followed by deployment of the right atrial disc once the connecting waist stents the defect itself. If the device pulls through the septum, the device is recaptured, the delivery sheath repositioned, and the deployment process is started again. Device position is carefully evaluated using echocardiography, and

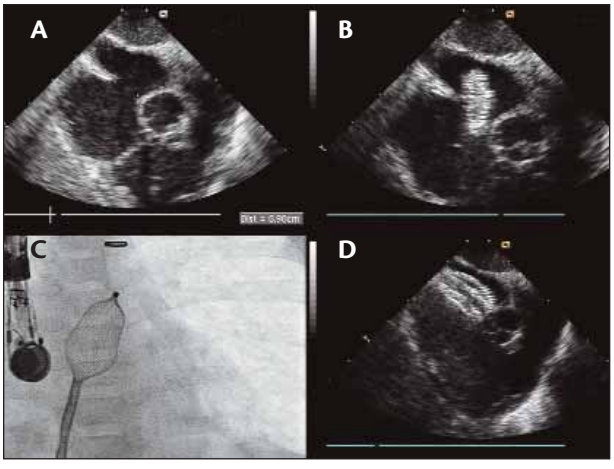


Figure 3. Pulmonary device venous deployment. A 6.5-kg, expremature, ventilator-dependant infant with bronchopulmonary dysplasia and a moderate secundum ASD with deficient retroaortic rim (A). Standard deployment technique was unsuccessful in aligning the device with the atrial septum (B). Left upper pulmonary venous deployment technique (C). Device alignment and position after release (D).

the interventionist should be able to document clear separation of the two discs by varying the fluoroscopic projection. A gentle push-pull motion on the delivery cable may facilitate better disk separation and aid the echocardiographic assessment to confirm that all rims have been captured. Color-flow mapping may show some residual flow between the two disks but should never show residual flow around the two disks. Once a satisfactory position has been confirmed, the device is released, and it usually reorients itself into a more appropriate position once the tension of the delivery cable has been removed. A final echocardiographic assessment is performed after release of the device.

THE DIFFICULT ASD

The aforementioned technique works very well for approximately 75% of ASDs, but what distinguishes a center of excellence is the ability to achieve successful closure of ASDs even in cases in which the standard technique fails. The biggest challenge in large defects and/or small children with (multiple) rim deficiencies is to achieve appropriate alignment of the device with the atrial septum. It is common for the device to pull through at a deficient anterior retroaortic rim using the standard delivery technique. In small children, a positioned TEE probe can frequently distort device alignment and, therefore, the deployment should be performed using the angiographic road maps with the TEE probe being pulled up throughout the deployment process. A number of additional techniques can be used to aid device alignment. The use of a specialized S-curved delivery sheath (Hausdorf sheath, Cook Medical, Bloomington, IN) can be extremely helpful and frequently aligns a device exactly parallel to the atrial septum. Again, the angiographic landmark is often more important as a road map than TEE guidance itself, which can distort device orientation. Deploying the left atrial disk in the LUPV allows deployment of the right atrial disk before the left atrial disk gradually milks out of the pulmonary venous ostium (Figure 2). This technique has to be performed quickly, but once the right atrial trial disk is positioned appropriately, the left atrial disk usually does not pull through the septum. Similarly, deployment in the RUPV allows the device to be dragged along the superior rim, which at that angle frequently prevents the left atrial disk from pulling through the atrial septum. Having a wire next to the delivery cable and through the device itself (mesh and polyester fabric) positioned in the LUPV during delivery may serve as a railroad and provide additional stability during device deployment. Once the device is appropriately deployed, the wire can be removed before release of the device. Finally, occasionally, a dilator can be advanced through additional venous access to prevent the device from pulling through the defect, and in other

patients, a Judkins right coronary guide catheter may be used for deployment of smaller devices.[13,17,18] In small children with large defects, device deployment may be especially cumbersome, and sometimes the transhepatic route may offer better device alignment when compared to femoral venous access (Figure 3). On occasion, right atrial angiography through the delivery sheath may be helpful to unmask inappropriate device position. The angiogram has to be evaluated carefully to see whether contrast is confined solely to the right atrial disk on right atrial injection (Figure 3) and whether it solely fills the left atrial disk on levophase. Filling of both disks would be suspicious for inaccurate device placement.

Closure of multifenestrated and multiple ASDs is of considerable challenge to the operator. Available options include the use of a larger single device, use of multiple devices, or use of the Amplatzer Cribriform Septal Occluder. A larger single device is usually most suitable when a large ASD is in very close proximity to a smaller second ASD. In this case, a larger device is deployed through the larger of the two defects, and careful evaluation is performed to determine whether the single device occludes both defects appropriately. If two defects are a little more separated from each other, each defect is crossed separately, and a guidewire is positioned through each of the two defects. It is frequently easier crossing the second defect while balloon occluding the first defect. Once guidewires are placed through both defects, balloon sizing of the two defects is performed. Device deployment is often performed so that the smaller of the two devices is deployed first, with the larger of the two devices sandwiching it in between its two disks, although the sandwiching can also be performed the opposite way (Figure 4). Alternatively, the two devices overlap each other. Whenever there are more than two to three defects, the use of the Amplatzer Cribriform Septal Occluder may be more appropriate. The device was introduced in 2003 and has gained FDA premarket approval in 2007.[19] The device is very similar to the Amplatzer Septal Occluder but has two equally sized disks with a very small pin-like central connecting waist. The device is available in sizes of 18, 25, and 35 mm in diameter. The thin central connecting waist allows a much larger area of the device to be available to cover the atrial septum when compared to the Amplatzer Septal Occluder, while at the same time avoiding any septal distortion through the central connecting waist. To close multifenestrated defects, it is essential to position a wire through the most central of the defects. The length of the device is determined by assessing the distance from the central defect to the other defects and choosing a device that is long enough to cover all defects while being positioned in the central defect.

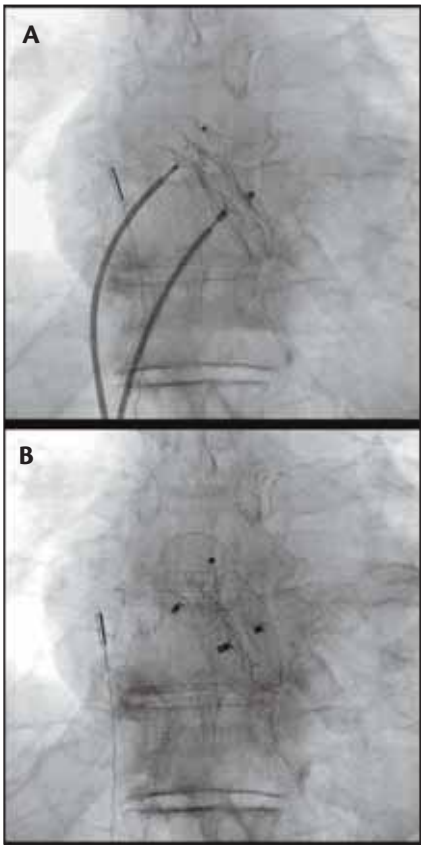


Figure 4. Closure of two secundum ASDs in an adult using two Amplatzer Septal Occluders. Two devices deployed but not released, and the larger device is sandwiched within the smaller device (A). Both devices after release (B).

RESULTS AND ADVERSE EVENTS

Although adverse events after ASD device closure are extremely rare, the procedure is not completely without risks. One of the most worrisome complications after ASD closure is erosion of the device into the aortic root, which is observed after approximately .1% of procedures and may be related to oversizing of devices and deficiency of the retroaortic rim.[20] However, the exact etiology is not yet fully understood, and as such, any patient with chest pain after ASD closure should be evaluated using transthoracic echocardiography, with or without additional CT imaging, to delineate the position of the device in relation to the aortic root and the potential presence of a pericardial effusion.

Because of this rare complication, operators recently tended to be more conservative when choosing the appropriate device size. This potentially increases the risk of device embolization that usually occurs during the procedure or within the first 24 hours after the procedure and has been described at an incidence of .5%, especially when attempting to close very large defects with deficient rims.[21] Although device migration during the procedure is usually obvious, signs may be more subtle during recovery on the inpatient floor and, therefore, any rhythm abnormality on telemetry, especially new-onset ventricular ectopy, or symptoms of prolonged palpitations necessitate a transthoracic echocardiographic evaluation. Any physician attempting to

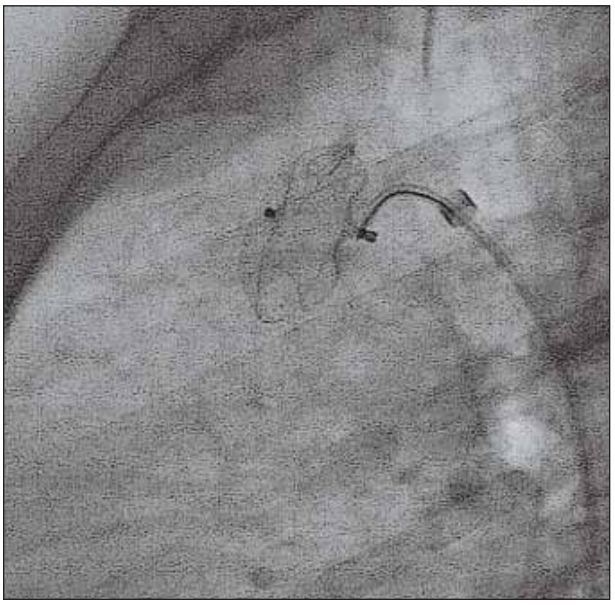


Figure 5. Retrieval of an embolized Amplatzer Septal Occluder from the ascending aorta using a Gooseneck snare in an adult patient.

close larger ASDs should be sufficiently trained and skilled in device retrieval using a delivery sheath sized 4 F larger than required for device deployment, as well as for a Gooseneck snare to engage the microscrew (ev3 Inc.). Usually, devices can be successfully retrieved from positions within the left or right atrium, pulmonary artery, or aorta (Figure 5), but transcatheter retrieval should not be attempted if the device is lodged within the left or right ventricle; in such cases, surgical retrieval is indicated.

Electrophysiological abnormalities are common within the first 24 hours after ASD device closure,[22] but most of these are subclinical and resolve quickly, and persistent rhythm or conductance disturbances 1 year after device closure are extremely rare.[23] However, very occasionally, the device can cause second- or third-degree heart block. This is usually obvious during device deployment itself with temporary episodes of heart block but can also occur after a completely unremarkable deployment process. It is therefore very important to carefully evaluate the telemetry, as well as the surface EKG, the day after device closure for the presence of rhythm but more importantly for conduction abnormalities. If heart block is present, temporary observation may be sufficient because most cases resolve spontaneously. Occasionally, a short course of steroids may aid in recovery of this abnormality.

Even though a release of nickel from the device has been described,[24] its clinical significance is questionable, and reports of clinically significant allergic reactions to nickel after device implantation are rare.[25]

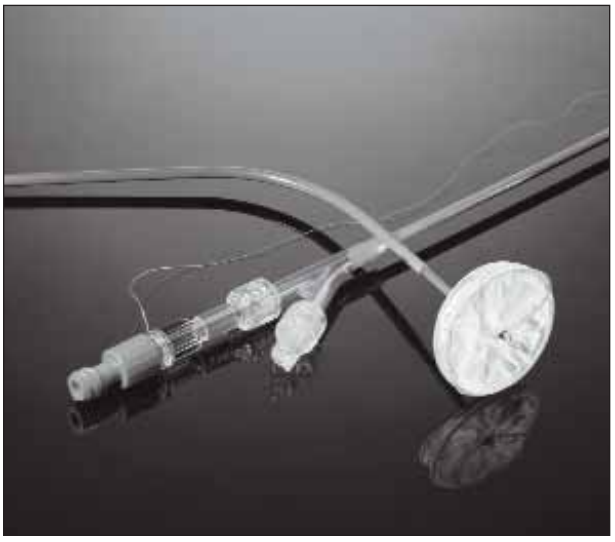
Closure rates are excellent, and residual shunts are <5% at 1-year follow-up,[9,13,26,27] most of which are of trivial degree and do not necessitate any repeat intervention. Right ventricular end-diastolic diameter usually decreases after ASD closure.[28] Although ASD closure in small children can be challenging, a small size should not defer from closure of an ASD that is clinically indicated. Holzer and colleagues reported on 26 patients weighing <10 kg (range, 2.4 to 10 kg) in whom ASD closure was attempted, with an overall procedural success rate of 95%.[29]

CLOSURE OF ASDs USING THE HELEX SEPTAL OCCLUDER

The Helex Septal Occluder recently gained FDA premarket approval within the US and was first described by Zahn and colleagues in 2001.[3] The Helex Septal Occluder consists of a nitinol wire with an attached polytetrafluoroethylene membrane (Figure 6). When deployed, the device forms two circular discs that are created by the spiraling nitinol wire with its attached polytetrafluoroethylene membrane. The device is available in sizes ranging from 15 to 35 mm (diameter of discs), in 5-mm increments. A device-to-defect ratio of 1.7 to 2:1 is recommended. The device comes prepared with its own 9-F delivery catheter that can be advanced directly through the ASD, or can be advanced over a wire, similar to a Multi-Track Angiographic catheter (NuMed). The device itself is deployed using a repetitive "push-pin-pull" action. It can be recaptured easily, and when compared to the Amplatzer Septal Occluder, the device has a lower profile, has a more atraumatic contour, and creates less distortion of the atrial septum before its release. When used for small- to medium-sized ASDs, closure rates have been reported to be approximately 85% at 6 months, with residual shunts usually being hemodynamically insignificant.[30] Serious complications have not yet been described and, if embolized, the device can usually be easily retrieved using a transcatheter approach. With its low-profile design characteristics and its newly modified delivery system, the Helex Septal Occluder may provide a suitable alternative for occlusion of small- to medium-sized ASDs.

CONCLUSION

Transcatheter device closure has become standard therapy for ASDs and can be performed safely with excellent short- and medium-term results. Although only the Amplatzer Septal Occluder and the Helex Septal Occluder have gained FDA premarket approval in the US for this specific indication, a variety of different devices are used on- and off-label worldwide. However, although closure of these defects has become a routine procedure in most centers, it should be emphasized that the rare



(Courtesy of Gore & Associates.)

Figure 6. Helex Septal Occluder, including delivery catheter.

challenging defects require a significant amount of operator skill, as does the ability to deal with potential complications such as device embolization or device malposition. For this matter, not every center and cardiologist should offer this therapeutic catheterization procedure. Difficult ASDs cannot always be predicted purely based on a surface echocardiography, and exposing a patient to open heart surgery as a result of failure of transcatheter closure that could have been avoided with a more experienced operator is not in the best interest of the patient. ■

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