FlexiPort™ Blood Pressure Cuffs
Frequently Asked Question

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How can hospitals use FlexiPort Cuffs?

Option	Explanation	How Cuff is Connected	Benefit	Disadvantage
Fully Configured	**Customers buy fully configured cuffs with tubes attached**	**Using the standard fittings at the end of the cuff tube**	**Easy Transition since very little change is required**	**Does not reduce inventory or cost significantly**
Fully Configured to Raw Cuffs	**Customers buy fully configured cuffs with tubes attached to stock inventory, but then they buy Raw cuff replacement**	**Can be connected at the FlexiPort on the cuff or at the traditional cuff tubing connectors**	**Can be a good first step to transition customers to the Raw cuff concept**	**May be confusing having two connection points. Practitioners could loose tubing since it can be removed from the cuff and device simultaneously.**
Raw Cuffs	**All blood pressure devices at the facility are equipped with FlexiPort fittings (1 or 2 tube) and customer buys only Raw cuffs.**	**Cuff is connected using the FlexiPort allowing the cuff to connect to all devices.**	**The cuff becomes universal and is the only true standardization available on the market.**	**Requires that all devices are equipped with the FlexiPort fittings. This requires some initial effort.**

How can a hospital save money using the FlexiPort?

- **Inventory Reduction –** Fewer SKU's lead to lower inventory requirements since the cuffs work universally. Streamlined inventory starts at the point of care since one cuff style will work with all blood pressure devices eliminating the need for inventory of multiple types of cuffs.
- **Part Number Reduction –** Typical hospitals can reduce blood pressure cuff part numbers by 60%.

Why do some patients bruise when they have their blood pressure taken?

From a clinical perspective, in patients with "normal" blood clotting and "normal" skin, the cuff will usually not cause bruising. With multiple readings, it is possible to observe striations on the arm where the cuff was placed. They are usually temporary and will disappear within several hours. These striations appear more commonly on cuffs with an integrated (one-piece) bladder as opposed to the two-piece cuffs which have a separate bladder.

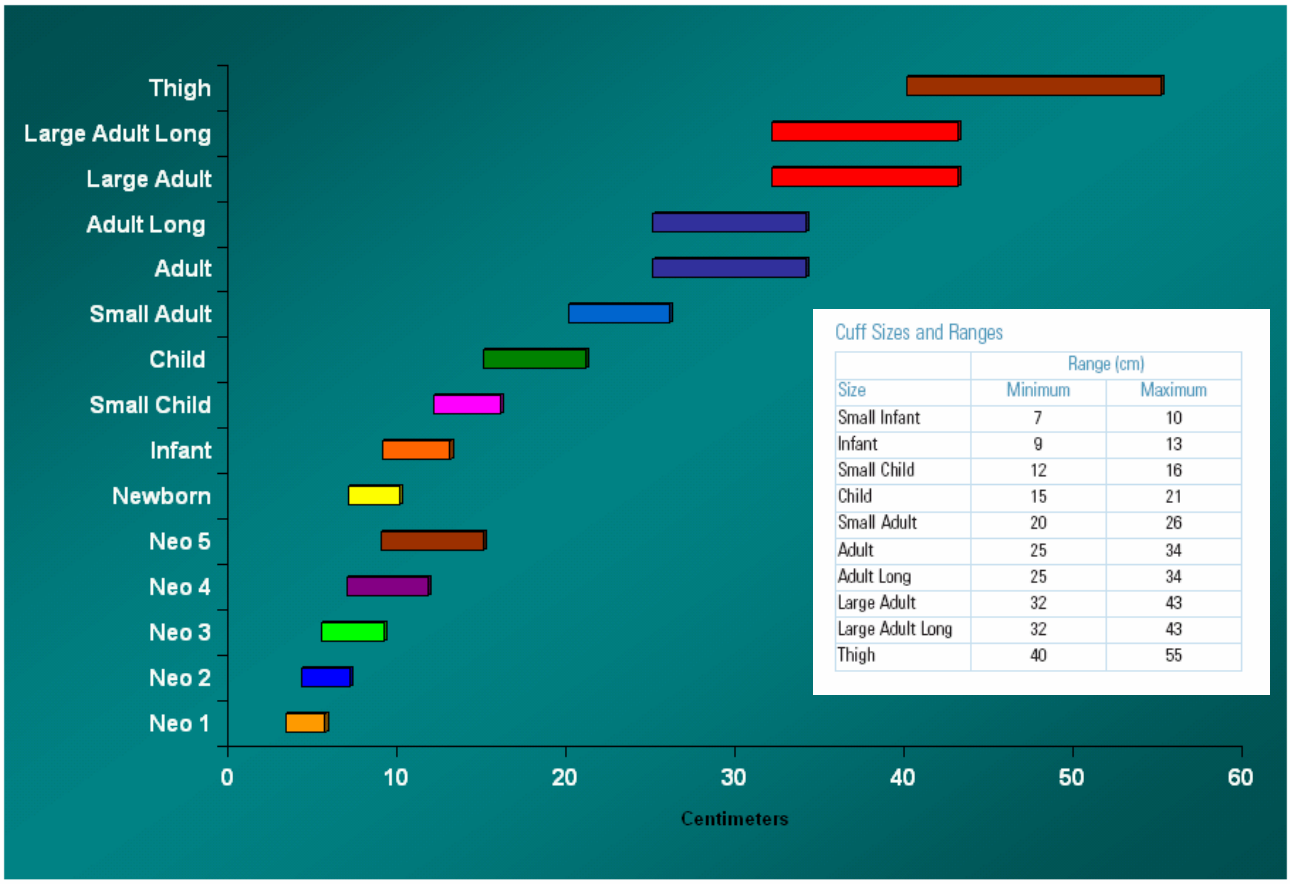
Some elderly people have very fragile skin and this may make them more prone to excessive bruising. It is not necessarily a reflection of the cuff or device but only that they bruise much more easily due to frail skin and tissue.

The other scenario that may physically make the patient more prone to bruising is if the patient is on anticoagulant (anti-clotting) therapy. In some patients who are at a high risk for blood clots, they are placed on oral or intravenous therapy to prevent blood clots from forming. A side effect of the therapy is that they are much more prone to bruising.

It is difficult to make an assessment without complete information about the bruising that was observed and the patient's condition, medications, frequency of vital, etc. Therefore, if bruising does not go away within a couple of hours after the last reading and the patient is not on anticoagulant therapy, an official complaint should be opened.

How long will the Antimicrobial last on the reusable cuffs?
The antimicrobial coating on the Welch Allyn blood pressure cuffs is designed to last the life of the cuff. Welch Allyn warranties the reusable cuffs for 3-year.

What are the cuff ranges?



Cuff Sizes and Ranges

	Range (cm)	
Size	Minimum	Maximum
Small Infant	7	10
Infant	9	13
Small Child	12	16
Child	15	21
Small Adult	20	26
Adult	25	34
Adult Long	25	34
Large Adult	32	43
Large Adult Long	32	43
Thigh	40	55

How are the cuff dimensions and ranges established?
Welch Allyn FlexiPort cuffs are designed to meet the sizing requirements of the Association for the Advancement of Medical Instrumentation (AAMI).

AAMI's most recent requirements are outlined in the standard ANSI/AAMI SP-10: 2002. The standard stipulates two dimensional requirements for blood pressure cuffs. The first dimension pertains to the length of the inflatable portion (bladder) of the cuff. According to the standard, the bladder length should be approximately 0.80 times the circumference of the limb at the midpoint of the intended range of the cuff. The second dimension relates to the width of the cuff bladder. The width should be optimally 0.40 times the circumference of the limb at the midpoint of the intended range of the cuff.

AAMI standards help manufactures develop safe and effective devices that are used in the indirect measurement of blood pressure. These devices include, but are not limited to, mechanical and electronic blood pressure gauges/monitors and cuffs. Welch Allyn One-Piece Blood Pressure Cuffs adhere to these standards to help ensure they will function properly on Welch Allyn and competitor's devices.

Welch Allyn has conducted several studies to validate the accuracy of the Welch Allyn One-Piece Blood Pressure Cuffs on Welch Allyn blood pressure monitors. Additionally, Welch Allyn has conducted functional equivalent testing on competitive blood pressure devices. These tests statistically show that Welch Allyn cuffs do not affect the accuracy of the blood pressure readings when used on these devices.

Why do the long cuffs have the same range as the non-long versions?
The "long' cuffs have the same intended range as the non-long versions. This is due to the Association for the Advancement of Medical Instrumentation's (AAMI) guidelines related to cuff width to length ratios. As a manufacturer, we adhere to these guidelines. However, long cuffs are intended to fill a gap between traditional cuff sizes on patients with short (from the elbow to the armpit), stocky arms. For these patients, many practitioners feel that the best solution is to use these special long cuffs outside the intended range since no other cuff will fit. Long cuffs have extra material to allow user to use the cuffs in this manner if they have no other option.

Do the FlexiPort cuffs meet AAMI and AHA specifications?
Yes, the FlexiPort cuffs meet the AAMI and AHA specifications.

How do you apply the cuff correctly?

- Select the cuff size appropriate for the arm. Always use the largest, most appropriately sized cuff.
- The artery index marker line on the cuff should fall within the range indicated. If the index line falls short of the range, a larger cuff should be used to ensure accurate results. If the index line is past the range, a smaller cuff should be used to ensure accurate results. Using the cuff outside the range markings may result in erroneous blood pressure readings.
- Wrap the cuff around the arm with the "artery" arrow located over the brachial artery and with lower border about 2.5 cm above the bend in the elbow.

Why are there no newborn FlexiPort cuffs?
The Food and Drug Administration (FDA) does not consider differences between newborn and neonatal patients. However, neonatal blood pressure cuffs are intended for use with electronic neonatal blood pressure monitors exclusively. Welch Allyn's traditional Newborn blood pressure cuffs were designed to work with manual sphygmomanometers and non-neonatal electronic blood pressure devices. Traditional Newborn cuffs are not intended to be used with neonatal monitors. Therefore, to eliminate confusion, Welch Allyn changed the name of the "Newborn" cuffs to "Small Infant".

Why don't the neonatal cuffs have the FlexiPort?
Following are three reasons why Welch Allyn did not add the FlexiPort feature to neonatal blood pressure cuffs.

1. Neonatal Cuffs are too small to allow the FlexiPort fitting.
2. Neonatal cuffs are almost always equipped with luer slip fittings. The FlexiPort would eliminate the need for one and two tube neonatal cuffs. However, most areas where neonatal cuffs are used do not have a mixture of one and two tube neonatal devices. Therefore, there are not major benefits for having the FlexiPort on neonatal cuffs.
3. Another important reason the FlexiPort is not used on neonatal cuffs is that Welch Allyn wanted to help prevent accidental connection of neonatal cuffs to devices that are not in neonatal mode. Many monitors go into a special neonatal mode (with lower pressure presets) when a neonatal tube is connected to the device. If the FlexiPort was interchangeable with neonatal and non-neonatal cuffs, it would be easier for practitioners to inadvertently leave the monitor in adult or child mode when taking blood pressure on neonatal patients resulting in potential harm/discomfort to the patient.

Why is the FlexiPort cuff different to apply than other blood pressure cuffs?
The FlexiPort blood pressure cuff is designed in an upside-down manner relative to traditional Welch Allyn One-Piece cuffs. This is done to position the FlexiPort and cuff tubing on top of the bicep when the cuff is applied correctly to the left arm. With traditional cuffs, the tubing is located in the armpit when the cuff is applied correctly. This could cause interference with the patient and it would make accessing and using the FlexiPort fittings more difficult. Therefore, Welch Allyn designed the FlexiPort cuff in an upside-down manner to improve the ergonomics for the patient and practitioner.

Why are my left and right arm systolic blood pressure readings often different?
Left-arm and right-arm (interarm) blood pressure differences are common. Blood pressure may be slightly higher in your dominant arm. For example, if you're left-handed, your left arm may have a slightly higher reading than your right arm. Several studies have been done to determine 'normal' variation between right and left arm readings. In general, any difference of 10 mm Hg or less is considered normal and not a cause for concern.

Since some studies showed that the average interarm systolic blood pressure difference was significantly greater in patients with known coronary artery disease, it's a good idea to discuss differences higher than 10 mm Hg with a doctor.

Many factors affect blood pressure. To detect a difference in blood pressure between your arms, your doctor may take alternate-arm blood pressure readings or even measure your blood pressure in both arms at the same time with two blood pressure gauges and two observers. The fact that there are differences in right and left arm readings emphasizes the importance of measuring blood pressure in both arms initially to prevent the misdiagnosis of high blood pressure. If one arm has higher blood pressure than the other, then that arm should be used to determine if you have hypertension. (American Heart Association, 2007)

What are the long cuffs used for?
Long cuffs are designed to allow practitioners to take blood pressure readings on patients who have short and stocky arms. These patients have arms that are large in circumference, but that are too short (from the elbow to the armpit) to allow the use of cuffs with traditional dimensions. For these patients, long cuffs may be the best solution for obtaining blood pressure readings since they are not wider than the non-long versions. These long cuffs are longer. However, the intended range of the long cuffs is the same as the non-long version. Some practitioners decide to use the long cuffs outside of the intended range since no other acceptable alternative exists.

How can you take blood pressure readings on bariatric patients?
The obese population presents one of the greatest challenges for measuring blood pressure both from a clinical and manufacturing perspective. There are a number of variables that can bias the measurement of BP in this population.
The most important factor for measuring BP in the obese comes from choosing the right cuff width for the patient's arm circumference (CW/AC) ratio. This will have the greatest impact in reducing the risk of either overestimating or underestimating the patient's BP. Some facilities use the forearm for measuring BP in the obese, but it is not a reliable site.

Welch Allyn does not have a cuff that is specifically labeled a "Bariatric Cuff". However, Welch Allyn cuffs range from the small neonatal cuffs for arms as small as 3.3 cm to the thigh cuff that will work on a limb that is up to 55 cm in circumference. There are no gaps between cuff sizes since the ranges overlap from one size to the next. Many people use the thigh cuff on obese patients' arms. If this cuff is too wide (to fit between the elbow and the armpit) they will often use the large adult long cuff.

The American Heart Association (AHA) and the Association for the Advancement of Medical Instrumentation (AAMI) have guidelines for cuff length to width ratios. This causes cuffs to increase in width as they get longer. If there is a cuff on the market that is long, but not wide, it is likely not compliant with AHA and AAMI standards and the accuracy of the reading could be effected.

What is the difference between single patient use and disposable cuffs?
Single Patient and regular Disposable Cuffs are virtually identical. In fact, Single Patient cuffs are actually a form of disposable cuffs. However, the intended use is slightly more restrictive. Single Patient Use Cuffs are intended to be used on one patient and then discarded. These cuffs may be used on the patient for extended periods of time and the cuffs typically stay with the patient during the patient's entire stay at the facility. Regular disposable cuffs do not have this restriction and can be used on multiple patients. These cuffs are typically discarded when they wear out or become dirty.

Can disposable cuffs be reprocessed?
The Association of Disposable Device Manufacturers (ADDM) and the Association for the Advancement of Medical Instrumentation (AAMI) have urged FDA officials to announce policy enforcing premarket submission requirements on reprocessors of used disposable devices.

The ADDM has voiced its concerns for patient safety resulting from poor cleaning and impaired functionality of reprocessed single-use devices.

The ADDM says that the intended function of single-use devices, coupled with the fundamental fairness requirements of the Administrative Procedure Act and the pre-market review procedure established by the Medical Device Amendments of 1976, mandate that 510(k) clearance or PMA approval for multiple use be obtained prior to use of the devices on a second patient. There are also concerns regarding the ability to trace infections back to reprocessed devices, and changes in critical functionality of the reprocessed devices.

Also, says the ADDM, many patients are not informed that reprocessed disposable devices are being used in their procedures. The group says enforcement of premarket submission requirements would ensure that patients exposed to reprocessed disposable devices are at no increased risk as opposed to patients exposed to new disposable devices. *(Health Industry Today, June 1999)*

Do the FlexiPort cuffs contain latex?
No, all of the FlexiPort cuff materials including fabric, inks, hook, loop, gauge tabs, tubing, connectors, ports, and even packaging are latex free.

Do the cuffs contain DEHP?
No, all of the FlexiPort cuff materials including fabric, inks, hook, loop, gauge tabs, tubing, connectors, and ports are DEHP free.

How do you know the FlexiPort cuff materials are safe?
All of the FlexiPort cuff materials have been biocompatibility tested. The materials passed all biocompatibility tests for Cytotoxicity, Sensitization and Irritation.

How can you use on cuff on one- and two- tube devices?
FlexiPort blood pressure cuff have a unique and patented connector that allows the tubes to be easily removed and attached from the blood pressure cuff. There are two different types of fittings that can be used on the FlexiPort cuffs. One fitting version has a single hose barb and the other version has dual hose barbs. Both fittings attach and detach in the same manner. The single barb version has one airway channel that leads into the cuff and is used on devices that utilize one tube (single lumen). The dual barb fitting has two channels that are separated until the air enters the cuff. This air separation prevents disruption of the blood pressure signal and allows the FlexiPort cuff to work with two-tube (dual lumen) blood pressure devices. Some two tube devices on the market require air separation until the air enters the cuff. Therefore, other Y-tubes that funnel the air channels into one air stream prior to the air entering the cuff can impact the device reading.

What are the risks associated with Luer Lock connections?
Luer fittings, connectors, and locks are small, inexpensive, and convenient. They're commonly used to connect many medical devices, components, and accessories. Unfortunately, because they're so easy to use, and since their use is widespread, health care personnel may mistakenly connect the wrong devices. The main risk associated with this involves the potential for

delivering a substance or air through the wrong route. These kinds of errors can cause serious injury or even death.

There have been reported incidences involving blood pressure monitors mistakenly connected to patients' IV lines, causing fatal air emboli. In another case, an air supply hose from a pneumatic compression device was inadvertently hooked up to a needleless IV tubing port.

An FDA article in the journal Nursing2005 reports on these and other types of misconnections between devices with luer connectors. In one case, while a patient was being repositioned, his I.V. tubing became disconnected. It was inadvertently reconnected to the inflation port of his tracheal cuff. The I.V. fluid infused into the cuff, causing an acute airway obstruction, and the patient suffered respiratory arrest and died.

In another example, a ventilator-dependent patient was receiving enteral nutrition after an aortic aneurysm repair. The enteral nutrition tubing was inadvertently connected to the patient's central line after a diagnostic test was performed. The patient received about 45 ml of enteral feeding solution intravenously.
(Source: The Food and Drug Administration Patient Safety News Website, Show # 46 December 2005, www.fda.gov/psn)

The FlexiPort connector and fittings are not compatible with luer fittings. Therefore, the risk associated with luer fittings can be eliminated from blood pressure connectors when FlexiPort cuffs are used.

What can be done to prevent accidental misconnection of luer fittings?
According to the FDA the following precautions can help prevent dangerous luer connection mix-ups.

• First, teach staff to carefully inspect and then follow the proper connector sequence when connecting tubing and device components.

• Read and follow the equipment manufacturers' recommendations and precautions, especially about compatibility with other devices.

• Don't modify I.V. or feeding devices because doing so may compromise the safety features built into their design

• Consider using devices that are specifically designed for safety, to reduce the risk of misconnections.

• And tell patients and family members that they must ask clinical staff for help when they need to disconnect and reconnect equipment because they could easily connect the wrong device.
(Source: The Food and Drug Administration Patient Safety News Website, Show # 46 December 2005, www.fda.gov/psn)

What Welch Allyn Blood Pressure Devices use Luer Lock connectors?

With the exception of neonate monitors, no Welch Allyn automated blood pressure device currently ships with a luer connection.

Neonate monitors are equipped with female luer lock adaptors that will not mate with the patient side of an intravenous line -- that also use female luer-lock connections.

The last time a non-neonate Welch Allyn automated blood pressure device shipped with a luer connection was July, 2000.

Some Welch Allyn manual sphygmomanometer models are equipped with a male luer-lock connection. There are several Welch Allyn manual sphygmomanometer models has a non-luer substitute available -- Welch Allyn DS58 Platinum-Series Classic Aneroid -- that was introduced in September 2005.

What does Welch Allyn do to make sure the cuffs last?

Welch Allyn does extensive lifecycle testing to reusable and disposable cuffs to ensure they will meet the demanding environment in which they are used. The cuff materials have been selected based on strength and patient comfort. In general, the hook and loop (Velcro) is typically the first component of a cuff that will fail. Every time the hook and loop (Velcro) is engaged and disengaged, it deteriorates slightly. Over time, the slight tears caused by disengagement will cause the loop to fray. Eventually, this fraying will prevent the hooks from penetrating and grabbing the loop and the cuff will no longer work properly. Welch Allyn has optimized the hook and loop closure and only Velcro branded hook and loop materials are used on Welch Allyn FlexiPort blood pressure cuffs.

To test the Velcro life, Welch Allyn applies the cuffs to a mandrel to simulate a patient arm, inflates the cuff to 300 mmHg, deflates the pressure to 0 mmHg, and disengages the Velcro. This entire process is considered on cycle. The reusable cuffs are tested to over 30,000 cycles at various pressures. The disposable cuffs are tested to 1,000 cycles.

The Association for the Advancement for Medical Instrumentation only has one specification for reusable cuff life. They stipulate that a reusable cuff must last for 10,000 cycles. Welch Allyn cuffs exceed this requirement by a factor of more than 3.

What is the warranty on the cuffs?

Durable One-Piece Cuffs have a Three-year warranty against original defects in material or workmanship. This warranty does not cover breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping. The warranty is void if the blood pressure cuff is not used in accordance with manufacturer's recommendations or if repaired or serviced by other than Welch Allyn or a Welch Allyn authorized representative. Welch Allyn Inc. will repair or replace, free of charge, any Welch Allyn Single-Patient Blood Pressure Cuff proven to be defective through causes other than misuse, neglect, damage in shipment, or normal wear.

How can you tell when the cuff was made?

Every Welch Allyn FlexiPort cuff has a date code imprinted on the cuff.

What does the term "One-Piece" Cuff refer to?
For years, blood pressure cuffs consisted of rubber bladder and an outer fabric shell. These two pieces provided an inflatable area (bladder) and a means to attach the bladder to the patient since the outer shell contained fasteners. As technology evolved, manufactures were able to integrate the bladder into the cuff shell eliminating the need for two separate components. As a result, Cuffs with this integrated bladder are called One-Piece cuffs.

One and Two Piece cuffs are currently available in the market. However, many practitioners prefer a one-piece cuff due to the ease of use and since the bladder does not need to be removed during cleaning.

How can the cuffs be cleaned?
Refer to Instruction Sheet that ships with cuffs for specifications.

Why use disposable cuffs?
See Infection Control Articles
Refer to Instruction Sheet that ships with cuffs for specifications.

Are the FlexiPort Cuffs Color Coded by Size?
The FlexiPort Disposable blood pressure cuffs are color coded by size.

		What is Color Coded	
Size	**Color**	**Disposable**	**Reusable**
Small Infant	Yellow	Cuff Artwork	No Color Coding
Infant	Rust	Cuff Artwork	No Color Coding
Small Child	Violet	Cuff Artwork	No Color Coding
Child	Green	Cuff Artwork	Cuff Material
Small Adult	Light Blue	Cuff Artwork	Cuff Material
Adult	Navy Blue	Cuff Artwork	Cuff Material
Adult Long	Navy Blue	Cuff Artwork	Cuff Material
Large Adult	Maroon	Cuff Artwork	Cuff Material
Large Adult Long	Maroon	Cuff Artwork	Cuff Material
Thigh	Brown	Cuff Artwork	No Color Coding

What are the little molded spikes on the underside of the FlexiPort Fitting?
These molded spikes are particle filters that are designed to prevent lint and debris from entering the device tubing.

How do I prevent dirt and debris from entering the FlexiPort?
When the FlexiPort fitting is attached to the cuff, the cuff port is closed. However, when the FlexiPort is detached the port is open and could potentially allow foreign particles to enter the cuff. Welch Allyn has conducted testing to show that these particles will not affect the blood pressure reading. However, if the FlexiPort cuffs are used in areas containing a high level of dust, dirt or debris, Welch Allyn recommends the use of an accessory port plug (part number 5082-189). This plug seals the port hole when applied and conveniently remains tethered to the cuff when it is not in use.

Where are FlexiPort cuffs made?
FlexiPort cuffs are manufactured in the United States and in Mexico. All cuffs ship from Mexico and are transported across the Mexico-USA boarder for domestic and International shipment.

Can the FlexiPort Tubing assemblies be ordered separately?
The FlexiPort Tubing assemblies can be ordered as accessories. Following are part numbers and descriptions:

How do the FlexiPort cuffs compare to the previous Welch Allyn one-piece cuffs?
Welch Allyn conducted clinical testing to verify that the FlexiPort cuffs were functional equivalent to the previous one-piece Welch Allyn cuffs. This testing was conducted on Reusable, Soft, and Vinyl cuffs. During these tests, the following devices were used: Spot, Spot LXi, VSM 300, Propaq, PIC 50.

Can FlexiPort Cuffs be used in an MRI environment?
FlexiPort Reusable and Disposable Blood Pressure Cuffs and FlexiPort Fittings do not contain metal. Therefore, these components are 100% MRI compatible. There are some tubing assembly fittings (inflation bulb valves) that contain metal and should not be used during an MRI procedure.