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Instructions for Use
VersaCross® Steerable Access Solution

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English

Carefully read all instructions prior to use. Observe all warnings and precautions noted in these instructions. Failure to do so may result in patient complications.
Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the procedure.
CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the procedure.

DEVICE DESCRIPTION
The VersaCross® Steerable Access Solution consists of five components: the VersaCross Steerable Sheath kit (VersaCross Steerable Sheath, VersaCross Transseptal Dilator, 0.035" J-tipped guidewire), VersaCross RF Wire and a Baylis single-use Connector Cable.
The VersaCross Steerable Sheath is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The sheath provides superior torque control and is flexible. The VersaCross Transseptal Dilator provides support for the sheath, features a tapered tip and a shaft that can be reshaped manually. Radiopaque tips maximize visualization of the sheath and dilator during manipulation.
The VersaCross RF Wire is packaged with a single-use VersaCross RF Wire and a Baylis single-use Connector Cable (Connector Cable) The VersaCross RF Wire must be used with an approved Baylis RFP-100A Radiofrequency Puncture Generator (Baylis RF Generator) and the Connector Cable.
The VersaCross RF Wire delivers radiofrequency (RF) power in a monopolar mode between its distal electrode and a commercially available external Disposable Indifferent (Dispersive) Patch (DIP) Electrode, which is in compliance with current IEC 60601-2-2 requirements. The Connector Cable connects the Baylis RF Generator to the VersaCross RF Wire. This Connector Cable enables RF power to be delivered from the Baylis RF Generator to the VersaCross RF Wire. Detailed information concerning the Baylis RF Generator is contained in a separate manual that accompanies the equipment (entitled "Baylis Medical Company Radiofrequency Puncture Generator Instructions for Use").
The dimensions of the VersaCross RF Wire and the Connector Cable can be found on the device labels. The insulation on the body of the VersaCross RF Wire facilitates smooth advancement of the device and provides electrical insulation. The floppy distal portion of the VersaCross RF Wire has a curve and the active tip is rounded to be atraumatic to cardiac tissue unless RF energy is applied. A radiopaque and echogenic marker coil is positioned on the distal section for visualization during manipulation. The main body of the VersaCross RF Wire provides a stiff rail for advancing ancillary devices into the left atrium following the creation of an atrial septal defect. The VersaCross RF Wire features visible markers along its length to assist with aligning the wire tip in a compatible transseptal sheath and dilator assembly (e.g., the VersaCross Transseptal Sheath kit). The proximal end of the VersaCross RF Wire is bare metal to connect only with the provided Connector Cable and not with electrocautery or electrosurgery devices. The other end of the Connector Cable connects to the Baylis RF Generator.

The J-tipped guidewire, hereafter referred to as the "guidewire", is comprised of a stainless-steel core with a flexible, spiral shaped PTFE coated steel coil along the full length of this device. The sheath shaft and guidewire are in their entirety coated with hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for these coatings.

INDICATIONS FOR USE
The VersaCross Steerable Access Solution is indicated for creation of an atrial septal defect in the heart and for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum

CONTRAINDICATIONS
The included VersaCross RF Wire is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other Baylis RF Generator or any other device.

WARNINGS
- Only physicians with a thorough understanding of angiography, aseptic technique and percutaneous interventional procedures should use this device. It is recommended that physicians avail themselves of pre-clinical training, a review of pertinent literature and other appropriate education before attempting new interventional procedures.
- RF puncture procedures should be performed only by physicians thoroughly trained in the techniques of RF-powered puncture in a fully equipped catheterization laboratory.
- Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.
- The VersaCross Steerable Access Solution is intended for single patient use only. Do not attempt to sterilize and reuse any component of the VersaCross Steerable Access Solution. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another.
- The VersaCross Steerable Access Solution is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged.
- The sheath shaft is coated with a hydrophobic lubricious coating for smoother device manipulation. The following warnings must be considered:
    - Use with sheaths smaller than the size listed in the section below may result in a tight fit that affects device performance, including coating integrity.
    - Excessive wiping and/or wiping with a dry gauze may damage the coating.
    - Manual shaping of the dilator distal curve shall be done with smooth motions along the curve without applying excessive force and/ or pressure. Excessive manual bending and/or shaping of the shaft may affect the coating integrity.
- The guidewire is coated with a lubricious coating. The following warnings must be considered:
    - Use with incompatible introducers or dilators may affect device performance and integrity, including coating integrity
    - Excessive manual bending and/or shaping of the device may affect the coating integrity.
- The VersaCross RF Wire must be used with the Connector Cable provided. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.
- Do not use the VersaCross RF Wire or mechanical guidewire with electrocautery or electrosurgery generators, connector cables or accessories as attempted use can result in patient and/or operator injury.
- The Connector Cable must only be used with the RFP-100A Baylis RF Generator and the included VersaCross RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator.
- The VersaCross RF Wire must be used with 0.035" compatible transseptal sheath and dilator devices. Use of incompatible accessory devices may damage the integrity of the VersaCross RF Wire or accessory devices and may cause patient injury.
- The VersaCross RF Wire has only been validated for transseptal puncture use through VersaCross dilators which have been demonstrated to provide the required support for optimal function.
- The active tip and distal curve of the VersaCross RF Wire are fragile. Be careful not to damage the tip or the distal curve while handling the VersaCross RF Wire. If the tip or the distal curve becomes damaged at any time during its use, discard the VersaCross RF Wire immediately. Do not attempt to straighten the active tip if bent. Damage to device can lead to patient injury.
- The VersaCross RF Wire is not intended for use with neonatal patients (i.e. less than one month of age). Do not attempt to treat neonatal patients with the VersaCross RF Wire.
- Do not attempt to insert or retract the VersaCross RF wire or mechanical guidewire through a metal cannula or a percutaneous needle, which may damage the device and may cause patient injury.
- Care should be taken to ensure that all air is removed from the sheath before infusing through the side port

- Care should be taken when removing the dilator and catheters from the sheath
- Care should be taken when inserting or removing accessory devices from the sheath. For example, if removing the dilator, any devices through the dilator shall be removed as well.
- Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury.
- Damage to guidewire may result if withdrawn through a metal needle cannula.
- Maintain continuous hemodynamic monitoring throughout procedure"
- Provide continuous heparinized saline infusion while the introducer remains in vessel.
- To minimize vacuum effects during withdrawal of sheath/dilator, remove components/aspirate slowly. Refrain from aspiration if a wire is directly through the valve.
- Avoid contact with liquids other than blood, isopropyl alcohol, contrast solution or saline.
- Prior to steerable sheath's delivery and removal, ensure distal section is as straight as possible.
- Do not kink, stretch or severely bend steerable sheath.
- Do not use surgical instruments to handle sheath.

PRECAUTIONS

- Do not attempt to use the VersaCross Steerable Access Solution before thoroughly reading the accompanying Instructions for Use.
- The sterile packaging and all components should be visually inspected prior to use. Do not use if the device, packaging or sterile barrier have been compromised or damaged.
- Careful manipulation must be performed to avoid cardiac damage, tamponade or vessel trauma. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the VersaCross RF Wire or sheath and dilator assembly. Excessive force may lead to bending or kinking of the VersaCross RF Wire limiting advancement and retraction of sheath and dilator device.
- Do not use the VersaCross Steerable Access Solution after its "Use By" date.
- Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur.
- The VersaCross Steerable Access Solution is compatible with introducer sheaths 12.5Fr or larger.
- Note that a compatible access introducer sheath may be used at the venous cutaneous puncture site if desired. Refer to the compatible introducer sheath's Instructions for Use for details and directions.
- The VersaCross Transseptal Sheath and Dilator are compatible with transseptal devices and guidewires .035" or smaller.
- The VersaCross Steerable Access Solution is not compatible with transseptal needles such as the "NRG Transseptal Needle".
- Monitor the location of the radiopaque tip of the sheath and dilator frequently under fluoroscopy. Echocardiographic guidance is also recommended.
- Visually inspect the VersaCross RF Wire and Connector Cable prior to use to ensure there are no cracks or damage to the insulating material. Do not use the wire or the cable if there is any damage.
- The VersaCross RF Wire and Connector Cable are intended for use with only those devices listed in **Equipment Required**.
- Read and follow the manufacturer's Instructions For Use for the DIP electrode (not included). Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements.
- Placement of the DIP electrode on the thigh could be associated with higher impedance.
- In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application.
- Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Baylis RF Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Baylis RF Generator.
- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications.
- Do not attempt to insert and use the proximal end of the VersaCross RF Wire as the active tip.
- Do not bend the VersaCross RF Wire or the Connector Cable. Excessive bending or kinking of the wire shaft, distal curve of the wire and/ or the Connector Cable may damage the integrity of the device components and may cause patient injury. Care must be taken when handling the VersaCross RF Wire and Connector Cable.
- VersaCross RF Wire and ancillary sheath and dilator assembly advancement should be done under imaging guidance. The use of visible markers on the wire body are only an approximate guide for positioning the wire tip with the distal end of the dilator.
- Do not attempt to deliver RF energy until the active tip of the VersaCross RF Wire is confirmed to be in good contact with the target tissue.
- Avoid RF energy delivery of the VersaCross RF Wire with incompatible dilator or cannula devices, which may lead to patient burns, ineffective puncture or failure to puncture.
- It is recommended not to exceed five (5) RF power applications per VersaCross RF Wire.
- Never disconnect the Connector Cable from the Baylis RF Generator while RF power is being delivered.
- Never disconnect the Connector Cable from the Baylis RF Generator by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable.
- Do not twist the Connector Cable while inserting or removing it from the Isolated Patient Connector on the Baylis RF Generator. Twisting the cable may result in damage to the pin connectors.
- The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the VersaCross RF Wire and/or DIP electrode, particularly when operating the device.
- During power delivery, the patient should not be allowed to come in contact with ground metal surfaces.
- Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the active tip of the VersaCross RF Wire against the atrial septum. Only increase the power if low power output persists.
- If using electroanatomical mapping guidance, it is recommended to use it along with alternative imaging modality in the event there is loss of visibility of the device.
- Use compatible tip straightener with mechanical guidewire
- Do not reshape distal tip or curve of mechanical guidewire. Excessive bending or kinking of the distal curve may damage integrity of the wire or coating and lead to patient injury
- Do not attempt to insert proximal end of mechanical guidewire as distal end
- Individual patient anatomy and physician technique may require procedural variations.
- Confirm ancillary devices are compatible with the dilator and guidewire diameters before use. The steerable sheath must only be used with the dilator included in the kit
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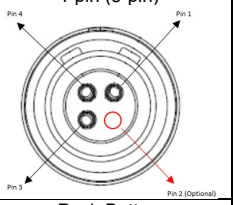
SPECIAL STORAGE AND/OR HANDLING INSTRUCTIONS

Keep away from sunlight.

PRODUCT SPECIFICATIONS

Product	**VersaCross RF Wire**	**Product**	**RFP 100A Connector Cable**
Length	180 or 230cm	**Useable Length**	10 feet/3m
Wire Diameter	0.035" / 0.89mm	**Generator Connector**	4-pin (3-pin) 
Curve Diameter	9 mm J-tip or 24 mm Pigtail	**Device Connector**	Push Button

ADVERSE EVENTS

Adverse events that may occur while using the VersaCross Steerable Access Solution include:

Perforation and/or tamponade	Sepsis/Infection
Hemorrhage	Hematoma
Vessel spasm	Vessel perforation
Vessel/Vascular trauma	AV fistula formation
Pericardial/pleural effusion	Pseudoaneurysm
Thromboembolic episodes	Vascular thrombosis
Air embolus	Arrhythmias
Atrial Flutter	Tachycardia
Atrial Fibrillation	Sustained arrhythmias
Ventricular Tachycardia	Vasovagal reaction
Atrial septal defect	Aortic puncture
Pulmonary edema	Dissection
Pain and Tenderness	Myocardial Infarction
Valve damage	Catheter entrapment
Additional Surgical procedure	Wire entrapment/entanglement
Stroke	Allergic reaction
Local nerve damage	Coronary artery spasm and/or damage
Foreign body/wire fracture	Perforation of the myocardium

Embolic events

PREPARATION FOR USE

Prior to use of the VersaCross Steerable Access Solution, the individual components should be carefully examined for damage or defects, as should all equipment used in the procedure. Do not use defective equipment. Do not reuse the devices.

EQUIPMENT REQUIRED

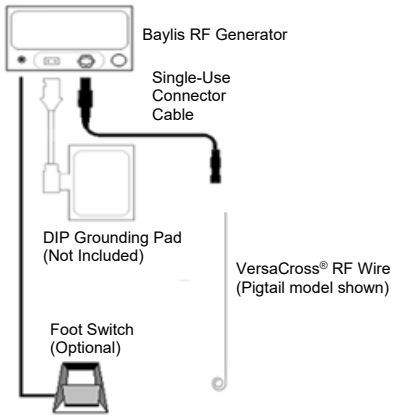
RF transseptal procedures should be performed in a specialized clinical setting equipped with appropriate imaging equipment and compatible examination table, echocardiography imaging, physiologic recorder, emergency equipment and instrumentation for gaining vascular access. Ancillary materials required to perform this procedure include:

- RFP-100A Baylis RF Generator
- 0.035" compatible transseptal sheath and dilator devices
- DIP electrode, meeting or exceeding IEC 60601-2-2 requirements for electrosurgical electrodes (not included)
- DuoMode Cable™ for use with electroanatomic mapping systems

SUGGESTED DIRECTIONS FOR USE

- Carefully read all instructions prior to use. Failure to do so may result in complications.
- The VersaCross Steerable Access Solution is supplied sterile. Use aseptic technique when opening the packaging and handling the products in the sterile field.
- Connect the generator connector end of the Connector Cable to the isolated patient connector port on the Baylis RF Generator as per the Baylis RF Generator Instructions for Use. Gently line up the connector pins with the socket and push in until the connector fits firmly into the socket. Any attempt to connect the cable otherwise will damage the pins on the connector.
- Do not use excessive force in connecting the Connector Cable to the Baylis RF Generator. Use of excessive force may result in damage to the connector pins.
- Verify proper deflection of steerable sheath by using knob.
- Insert steerable sheath only when distal end is completely straight.
- Thoroughly flush the sheath, guidewire and dilator with heparinized saline solution prior to use.
- Perform a standard vein puncture at the desired access site using an access needle (not supplied).
- Introduce the guidewire through the vasculature access point and advance to required depth (the VersaCross RF Wire may be used). If resistance is encountered, DO NOT use excessive force to advance or withdraw the guidewire. Determine the cause of resistance before proceeding.
- Enlarge the cutaneous puncture site as necessary.
- Assemble the dilator and sheath until the dilator hub locks into the sheath hub. The sideport of the sheath and curve indicator of the dilator should be in the same orientation.
- The distal curvature of the dilator may be adjusted manually if desired. Manually adjust dilator curvature when assembled in the sheath. Do not use excessive force when reshaping.
- Thread the dilator/sheath assembly over the guidewire using a slight twisting motion under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the dilator/sheath assembly over the guidewire. Determine the cause of resistance before proceeding.
- Use standard technique to position the sheath/dilator assembly into the desired heart chamber.
- Turn steerable sheath knob in direction of desired distal deflection. Sheath stays in desired position until sheath handle is turned again.
- If resistance is encountered, DO NOT use excessive force to deflect the sheath.
- If the VersaCross RF Wire was not used to advance the sheath to the SVC, remove the guidewire and exchange for the VersaCross RF Wire with the provided tip straightener.
- Advance the VersaCross RF Wire through the sheath and dilator assembly until the wire tip is just within the dilator tip. The visible markers on the wire body can be used to assist with the positioning of the wire tip with the distal end of the dilator.
- Firmly grasp the catheter connector end of the Connector Cable in one hand. Using your thumb, depress the red button on the top of the connector. Slowly insert the proximal end of the VersaCross RF Wire into the opening of the catheter connector. Once the exposed portion of the proximal end of the device is no longer visible, release the red button on the connector. Gently tug on the device to ensure that you have a secure connection.
- Position the tip of the transseptal assembly (RF wire, sheath, dilator) in the right atrium against the fossa ovalis under appropriate imaging guidance including but not limited to fluoroscopic, echocardiographic and/or electroanatomic mapping guidance using standard technique.
- NOTE: If using electroanaotmical mapping guidance, it is recommended to confirm tip placement and septal tenting with echocardiographic imaging or another imaging modality.
- Apply pressure to the dilator to tent the septum at the fossa ovalis.
- Advance the VersaCross RF Wire so that the active tip is engaging the septum at the fossa ovalis but still within the dilator.
- Once appropriate positioning has been achieved, deliver RF power via the Baylis RF Generator to the active tip. This results in puncture of the targeted cardiac tissue. Please refer to the Baylis RF Generator Instructions For Use for the correct operation of the generator.
- Apply firm pressure to the VersaCross RF Wire during the application of RF energy to successfully advance the VersaCross RF Wire through the tissue.
- NOTE: Use the lowest appropriate RF settings to achieve the desired puncture.
    - For RFP-100A: An initial RF setting between one (1) second on "PULSE" mode to two (2) seconds on "CONSTANT" mode has been shown to be sufficient for successful puncture.
- RF power delivery can be terminated by pressing the RF ON/OFF button on the Baylis RF Generator if the timer has not expired.
- Entry into the left atrium can be confirmed by monitoring the VersaCross RF Wire under appropriate imaging guidance. Echocardiographic guidance is also recommended.
- If septal puncture is not successful after five (5) RF power applications, it is advised that the user utilize an alternate method for the procedure.
- Once the puncture is successfully completed, the VersaCross RF Wire should be mechanically advanced without any RF power. Positioning in the left atrium is sufficient when the full distal curve and floppy section have crossed the septum and are observed in the left atrium. Echocardiographic guidance is also recommended.
- The dilator can then be advanced over the VersaCross RF Wire to enlarge the puncture.
- To disconnect the VersaCross RF Wire from the Connector Cable, depress the red button on the catheter connector and gently remove the proximal end of the VersaCross RF Wire from the Connector Cable.
- To disconnect the Connector Cable from the Baylis RF Generator, grasp the connector firmly and gently pull it straight out of the socket.
- Retract the VersaCross RF Wire slowly through the transseptal sheath and dilator assembly.
- Ensure the sheath is clear of air. To aspirate blood, use the sheath side port.
- Monitor the location of the radiopaque tip frequently under fluoroscopy.
- Deliver a continuous heparinized solution infusion or aspirate periodically. This may help reduce the risk of thromboembolic complications due to thrombus formation, as there may be a possibility of thrombus development at the distal sheath tip or inside the sheath lumen. Also aspirate when removing the transseptal device or dilator.
- Straighten distal end of sheath as much as possible prior to removal.
- After removal of the sheath, use standard technique to achieve hemostasis.
- Discard all kit equipment after removal from body.

Connections



CLEANING AND STERILIZATION INSTRUCTIONS

Do not clean or re-sterilize the VersaCross Steerable Access Solution. The VersaCross Steerable Access Solution is intended for single use only.

TROUBLESHOOTING

The following table is provided to assist the user in diagnosing potential problems.

PROBLEM	COMMENTS	TROUBLESHOOTING
Connector Cable does not fit into the Isolated Patient Connector on the front panel of the generator	The connectors are designed to connect in a specific way for safety reasons. If the connector "keys" are out of line, the connectors won't fit together.	Check that the connector keys are lined up in the proper orientation.
Generator Error Messages	In order to successfully perforate tissue using RF energy, all devices must be properly connected and in good working order.	Ensure that all connections are made i.e.: - VersaCross RF Wire to Connector Cable - Connector Cable to Baylis RF Generator - Baylis RF Generator to power outlet - Baylis RF Generator to grounding pad (not included) Visually inspect the VersaCross RF Wire and Connector Cable for damage.

		Immediately discard any damaged devices. If problem persists, discontinue use. For error messages encountered while attempting RF puncture, refer to the Instructions for Use that accompanies the Baylis RF Generator.
Wire breaks or kinks	Breaks and kinks in the VersaCross RF Wire are a potential cause of patient injury.	Discard immediately.

DISPOSAL OF WASTE
Treat the used device(s) as biohazardous waste and dispose of in compliance with standard hospital procedures.

CUSTOMER SERVICE AND PRODUCT RETURN INFORMATION
If you have any problems with or questions about Baylis Medical Equipment contact our technical support personnel.

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NOTES:
1. In order to return products you must have a return authorization number before shipping the products back to Baylis Medical Company. Product Return Instructions will be provided to you at this time.
2. Ensure that any product being returned to Baylis Medical has been cleaned, decontaminated and/or sterilized as indicated in the Product Return Instruction before returning it for warrantied service. Baylis Medical will not accept any piece of used equipment that has not been properly cleaned or decontaminated as per the Product Return Instructions.

LABELING AND SYMBOLS

	Manufacturer		Do Not Resterilize
STERILE EO	Sterile using ethylene oxide		Single Use – Do not reuse
	Use-By Date	LOT	Lot Number
	Caution		Do Not Use if Packaging is Damaged
REF	Catalogue number		Keep Away from Sunlight
Rx ONLY	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.		Non-Pyrogenic: The RF wire, sheath, dilator and guidewire are non-pyrogenic unless packaging is opened or damaged.
Max Guidewire O.D.	Maximum guidewire outside diameter that can be used with this device		Follow Instructions for Use

LIMITED WARRANTIES
Baylis Medical Company Inc. (BMC) warrants its Disposable and Accessory products against defects in materials and workmanship. BMC warrants that sterile products will remain sterile for a period of time as shown on the label, as long as the original package remains intact. Under this Limited Warranty, if any covered product is proved to be defective in materials or workmanship, BMC will replace or repair, in its absolute and sole discretion, any such product, less any charges to BMC for transportation and labor costs incidental to inspection, removal or restocking of product. The length of the warranty is: (i) for the Disposable products, the shelf life of the product, and (ii) for the Accessory products, 90 days from shipment date.

This limited warranty applies only to new original factory delivered products that have been used for their normal and intended uses. BMC's Limited Warranty shall not apply to BMC products which have been resterilized, repaired, altered, or modified in any way and shall not apply to BMC products which have been improperly stored or improperly cleaned, installed, operated or maintained contrary to BMC's instructions.

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No agent, employee or representative of Baylis Medical has the authority to bind the Company to any other warranty, affirmation or representation concerning the product.
This warranty is valid only to the original purchaser of Baylis Medical products directly from a Baylis Medical authorized agent. The original purchaser cannot transfer the warranty.
Use of any BMC product shall be deemed acceptance of the terms and conditions herein.

The warranty periods for Baylis Medical products are as follows:

Disposable Products	The shelf life of the product
Accessory Products	90 days from the shipment date