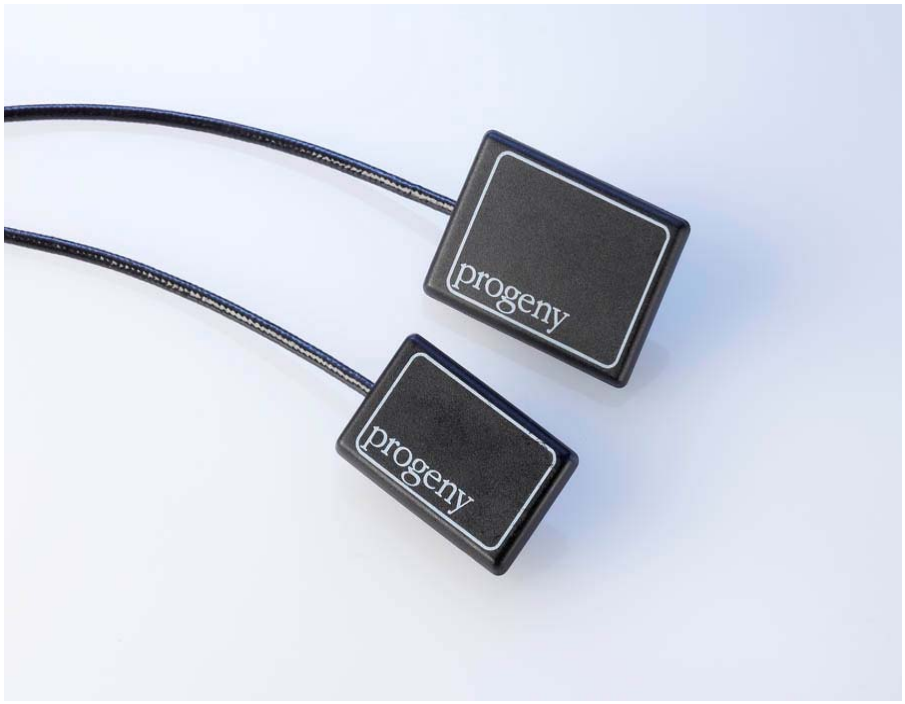
progeny™ DENTAL

VISION DX

Digital Sensor System



User Guide

PN 00-02-1594
ECN P1713
Rev. B

Vision DX Digital Sensor System

User Guide

00-02-1594

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General Information

Intended Use

- Vision DX is intended to be used as an intraoral receiver of x-rays for dental radiography.

Product Description

Progeny VisionDX USB Sensor is a state of the art intraoral system intended for digital imaging of teeth and the oral cavity. The system provides:

- Immediate production of an image
- Digital image storage and management
- Efficient archiving and recall of images
- Reduction of the x-ray dose to patient
- Elimination of film processing

The components of the VisionDX USB Sensor system are the Digital Sensor, the USB Module, the USB Cable, and the Sensor Calibration Files disk. An optional component is the USB Dual-Host Switch.

Digital Sensor	The Digital Sensor is designed to transform a two dimensional X-Ray picture into an electrical signal. The structure of the sensor is assembled with a first layer of phosphor atoms (scintillator) which, when triggered by incident X-Rays, emits a luminous radiation. This light is then transferred to the photo sensitive elements of the Digital Sensor where it is transformed to electrical potential. The electrical signal is sent to the USB Module for processing.
USB Module	The USB Module processes the image and sends it as a digital signal to the software.
USB Cable	Connects the USB Module (standalone configuration) or the Bus-powered USB Hub (Preva Plus integrated configuration) and the computer's USB 2.0 port. The total cable length may not exceed 5 m (15 ft).
Sensor Calibration Files Disk	During installation of the VisionDX USB Sensor System, files specific to the sensor serial number are stored on each computer where the sensor will be used. For more details, refer to the VisionDX USB Sensor Installation Guide.
Software	Provides the user interface to acquire, store, retrieve, transmit, review and post process images acquired by the VisionDX USB Sensor system. For more details refer to the VisionDX USB Installation Guide or the specific software user guide.
USB Dual-Host Switch	The USB Dual-Host Switch is an option that allows two separate computers to connect to one VisionDX USB Sensor when the VisionDX USB Sensor is installed in the Preva Plus integrated configuration.

Installation Configurations

The VisionDX USB Sensor can be installed with the Preva Plus Dental X-Ray System or it can be used as a standalone sensor. These configurations are shown in Figures 1 and 2. With the addition of the optional USB Dual-Host Switch, the VisionDX USB Sensor integrated with the Preva Plus can be shared by two computers. This setup, shown in Figure 3, might be desired when the Preva Plus is mounted in a pass-through cabinet between two operatories.

Figure 1: Preva Plus-- VisionDX Integrated USB Sensor

Figure 2: VisionDX USB Sensor (Standalone)

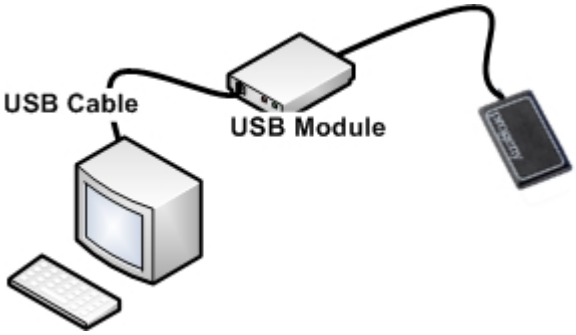

Figure 3: Preva Plus--VisionDX Integrated USB Sensor with Optional USB Dual-Host Switch

Compliance with Applicable Standards

The following regulatory documents apply:

General	EEC 93/42 Medical Device Directive ISO 13485 EN 46001
EMI/EMC	IEC 60601-1-2
General Safety	EC 60601-1, 2nd Ed. IEC 60601-1, 2nd Ed.
IEC 60601-1 Classifications	Protection Against Electrical Shock: Class II Degree of Protection Against Electrical Shock: Type BF Applied Part Degree of Protection Against Ingress of Water: IPX0 (Ordinary) Not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

EC Declaration of Conformity

Product Name and Description	Progeny VisionDX USB Intraoral Dental X-Ray Sensor
Catalog Part Number	Sensors 600-301 Size 1 sensor integrated cable 600-302 Size 2 sensor integrated cable 600-303 Size 1 sensor long cable 600-304 Size 2 sensor long cable Sensor Systems 600-401 Integrated system with size 1 sensor 600-402 Integrated system with size 2 sensor 600-403 Integrated system with size 1 and size 2 sensor 600-404 Integrated system without sensors. 600-405 Standalone system without sensors 600-406 Standalone system with size 1 sensor 600-407 Standalone system with size 2 sensor 600-408 Standalone system with size 1 and size 2 sensor
Class (93/42/EEC)	1
Reference Documents	IEC60601-1 (1988) 2nd edition with Amendments No.1 (1991) and No. 2 (1995) IEC60601-1-1, Ed. 2 (2000) EN60601-1-2 (Cispr 11) B level radiated emissions EN60601-1-2 (Cispr 11) B level conducted emissions
Declaration	Progeny, Inc. declares that the products described herein meet all the applicable Essential Requirements of the EC Medical Device Directive 93/42/EEC in Annex VII. For Class I products described herein, the product is manufactured, inspected, tested and released in accordance with the approved quality assurance system established in accordance with ISO 13485 and Annex II of the EC Medical Device Directive under the Supervision of the SGS United Kingdom Ltd., a Notified Body.

Contact	Technical Support +1 (888) 924 3800

Authorized Representatives

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Safety

Radiation Safety

Only qualified and authorized personnel may operate this equipment observing all laws and regulations concerning radiation protection.

- The operator at all times must remain at least 2m (6ft.) from the focal spot and the X-ray beam for operator protection.
- Full use must be made of all radiation safety features on the X-Ray equipment.
- Full use must be made of all radiation protection devices, accessories and procedures available to protect the patient and operator from x-ray radiation.

Electrical Safety

- The VisionDX USB sensor cable should be handled with care. Do not kink or crimp the sensor cable. Doing so could permanently damage the sensor.
- Only qualified and authorized service personnel should remove covers on the equipment.
- This equipment must only be used in rooms or areas that comply with all applicable laws and recommendations concerning electrical safety in rooms used for medical purposes, e.g., IEC, US National Electrical code, or VDE standards.
- Before cleaning or disinfecting, this equipment must always be disconnected from the main electrical supply.
- The VisionDX USB Intraoral Dental X-Ray Sensor is ordinary type medical equipment without protection against ingress of liquids. To protect against short-circuit and corrosion, no water or any other liquid should be allowed to leak inside the equipment.

Patient Safety

- Prior to use **always** cover the sensor with a disposable hygienic protective cover. A new cover must be used for each patient.
- The VisionDX USB, USB Module, Computer, and provided cables comprise a Medical Electrical System. The Computer and USB Module are not intended to be located in the patient environment (within a 1.5 m radius of the patient).
- System installation shall be in accordance with the requirements of IEC 60601-1, the Standard for Safety Requirements of Medical Electrical Systems
- Patients should only be connected to applied parts of equipment complying with IEC 60601-1. The computer and USB Module used for connection to the VisionDX USB shall comply with the standard for Information Technology Equipment, IEC 60950-1.

Explanation of Symbols on Technical Labels

	Type BF: Protection against electric shock (IEC 60601-1)
	Class II: Double Isolation to protect against electric shock (IEC 60601-1)
	Consult written instructions in User's Manual.
	CE Mark

Obtaining Technical Support

Contact	PROGENY, INC. 675 Heathrow Blvd. Lincolnshire, IL 60069 Phone: +1 (847) 415-9800 Toll free (888) 924-3800 Fax: +1 (847) 415-9801

Operating the VisionDX USB

Acquiring Images

Prerequisites

- Install the imaging software following the installation guide provided with the product.
- Connect and calibrate the VisionDX USB as described in the VisionDX USB Installation Guide.

Connect the Sensor

1. Place the VisionDX USB in the operating environment.
2. Connect the VisionDX USB X-Ray Sensor to the USB Module (standalone configuration) or to the USB Interface Module (VisionDX Integrated USB configuration) by inserting the round connector into the receptacle on the front of the USB Module or USB Interface Module. The sensor connector will only fit one way.
3. If you are sharing the VisionDX Integrated USB X-Ray Sensor between operatories using the optional USB Dual-Host Switch, be sure that the switch is set to your operatory.

Taking images

1. Refer to the specific imaging software manual for patient selection and X-Ray image acquisition.
2. Verify that the X-Ray system exposure parameters are adequate to the desired imaging procedure.
3. Insert the X-Ray Sensor into a sensor sheath and position the sensor inside the patient's mouth in the desired position.
4. Position the tube head of the X-Ray system to the patient, using standard accepted positioning procedures.
5. Activate the VisionDX USB via the specific software (refer to imaging software guide).
6. Repeat steps 1-5 for additional images

Using the Sensor Sheaths (PN 500-430/500-431)

Prior to using the VisionDX USB Sensor **always** cover the X-Ray Sensor with a disposable hygienic protective cover (Sanitary Sensor Sheaths). Follow the procedure below.

Figure 4:
Using a protective sensor sheet

1. Hold sheath and insert sensor into opening between the white tab and the paper.
2. Gently slide the sensor into the sheath until it reaches the tip of the sheath. Do not force it.
3. Peel back the protective cover.
4. Peel away the paper backing. The sensor is now protected and ready for normal use.

Using a Sensor Positioning System

To facilitate positioning of the X-Ray Sensor in the patient's mouth, an optional plastic holder can be used. The pictures below illustrate the most common procedures.

Figure 5:
Bitewing Positioning

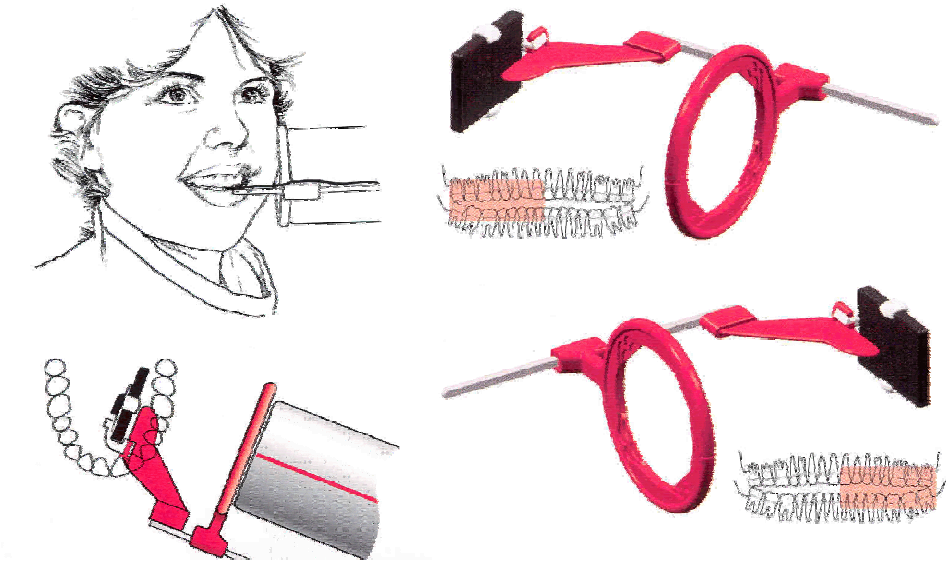


Figure 6:
Endodontic Positioning

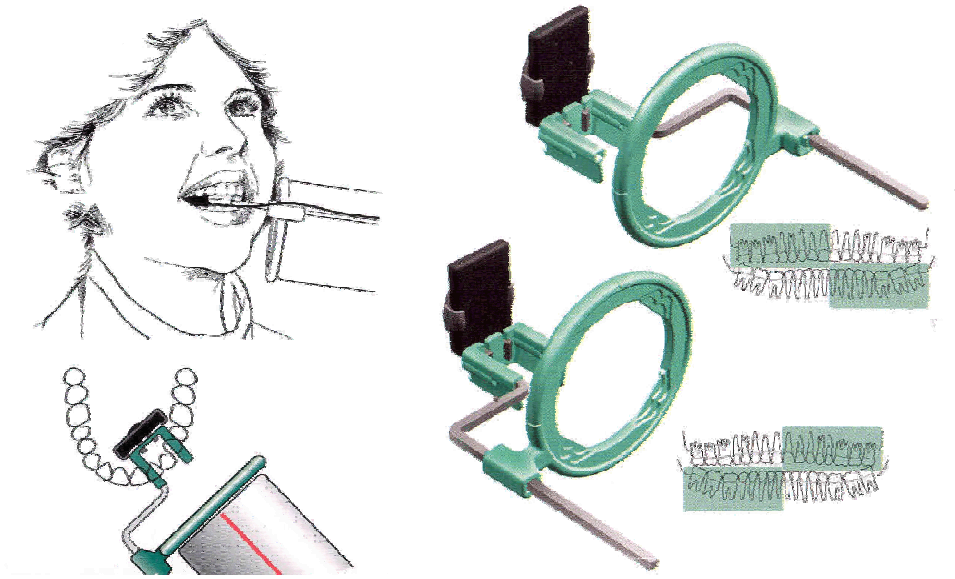


Figure 7:
Posterior Positioning

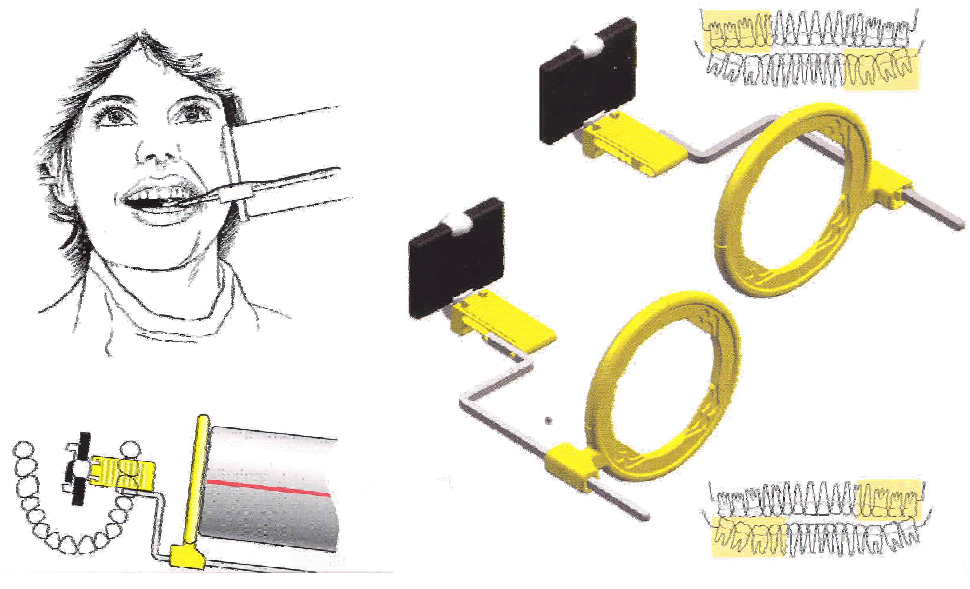
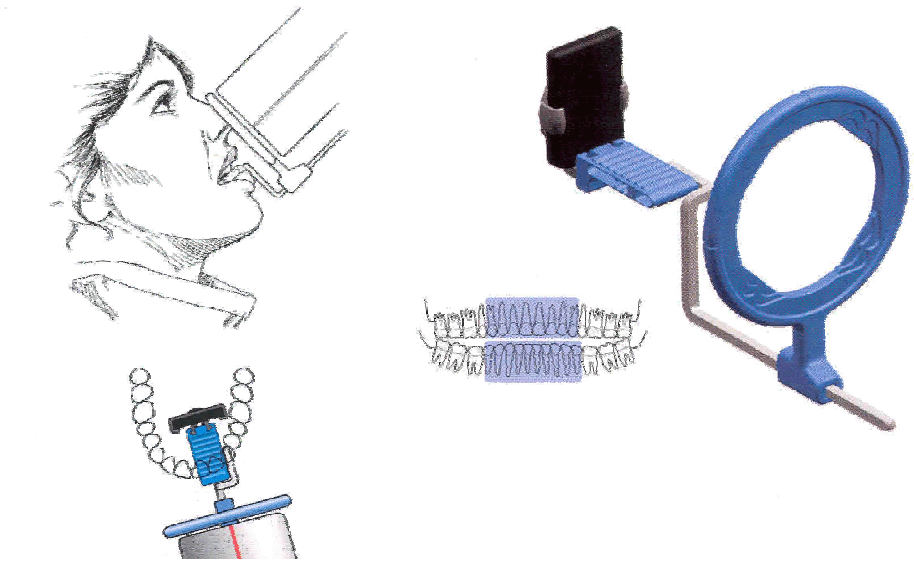


Figure 8:
Anterior Positioning



Maintenance

Recommended Maintenance

In the interest of equipment safety, a regular maintenance program must be established. This maintenance program should consist of cleaning and disinfecting as well as annual system function checking. It is the owner's responsibility to arrange for this service and to assure that the personnel performing these steps are fully qualified and authorized to service Progeny Dental x-ray equipment.

Cleaning and Disinfecting

Sensor must always be used with sanitary sheaths. The sheath must be changed after use on every patient.

Any part of VisionDX USB system should be cleaned by the following procedure:

1. The VisionDX USB Sensor, USB Module, and cables may be disinfected by wiping with an EPA approved hospital grade surface disinfectant as per manufacturer's directions (USA and Canada).
2. To clean the X-Ray Sensor, first wipe off gross debris with water or ethyl alcohol, then wipe with gauze or sleeve soaked with the following solutions:

   Ethyl alcohol (Ethanol)
   2% aqueous glutaraldehyde
   2% aqueous sodium hypochlorite solution.

WARNING:

Do not use disinfectants with ethanol and phenol combinations (such as Lysol, Procide or Decident). Use only glutaraldehyde-based solutions such as Cidex or Banicide.

WARNING:

Do not heat sterilize or autoclave the sensor, cable, or control unit, as this will damage the electronics, carbon case and enclosure and void the warranty. Do not submerge the sensor in any liquids. Do not spray any aerosol or non-aerosol sprays into the control module.

NOTICE:

PROPER DISINFECTION AND STERILIZATION IS THE SOLE RESPONSIBILITY OF THE USER ACCORDING TO THEIR PRACTICE PROTOCOL AND THE INSTRUCTIONS, REQUIREMENTS AND LIMITATIONS OF THE STERILIZING/DISINFECTING AGENT/DEVICE BEING USED, AS PER THE MANUFACTURER OF THE AGENT/DEVICE.

Specifications

X-Ray Sensor

Film Size equivalent	Size 1 Size 2
Active Area	33 x 20 mm (Size 1) 36 x 27 mm (Size 2)
Number of Pixels	1.3 million Pixels (Size 1) 1.9 million Pixels (Size 2)
Pixel Size	22 µm x 22 µm
Theoretical Resolution	22 lp/mm
Dynamic Range	>72 dB
Sensor Cable	2.5 m, Shielded
Connection type	LEMO FGG 1B.314, 14 Pins

Control Module

Power Supply	+5V/ 0.5 mA supplied by the USB port on the computer
Signal-to-Noise Ratio	70 dB
Levels of gray	4096

Environmental

Operating Temperature	+10 ºC/+35 ºC (+50 ºF/+95 ºF)

Storage Temperature	-25 ºC/+66 ºC (-13 ºF/+150 ºF)
Relative Humidity	10 – 80 %, non-condensing

Terms

Film Size Equivalent	The size of the X-Ray Sensor active area in relation to traditional film based x-ray systems available to the dentistry profession.
Active Area	The equivalent sensor area used to produce an image, measured in square millimeters (mm^2). The larger the number the larger the active area.
Number of Pixels	The total number of pixels in the sensor active area. It has no unit value; however, a larger number results in a finer image.
Pixel Size	The size of the smallest discrete picture element used in the process of image acquisition, measured in micrometers (µm). The smaller the pixel size the finer the image.
Theoretical Resolution	Measures the maximum level of detail that the sensor system is capable of acquiring, measured in line-pairs per millimeter (lp/mm). The larger the number the finer the image.
Dynamic Range	Represents the largest output of the device as a ratio to the smallest output, measured in decibels (dB). A larger number shows a greater X-Ray exposure range in which the X-Ray sensor system can produce an image without degradation.
Sensor Cable	Identifies the type and length of the sensor cable.
Connection Type	Specifies the connection type used to attach the sensor system to the computer.
Power Supply	Specifies the power supply source used to power the sensor system.
Signal to Noise Ratio	A logarithmic ratio between output generated by the X-Ray exposure and the output generated by the inherent system noise, expressed in decibels (db). The larger the number, the better the image quality.
Levels of gray	Measures the maximum number of X-Ray intensity steps used to represent the image in levels of gray. It has no unit value; however, a larger number results in a finer image.

Accessories and Part Numbers

A variety of accessories and replacement parts are available from Progeny, Inc. for the VisionDX USB System. Please contact us or your dealer for pricing and ordering details.

PART NUMBER	ITEM DESCRIPTION
600-401	VisionDX System, Integrated with Sensor #1
600-402	VisionDX System, Integrated with Sensor #2
600-403	VisionDX System, Integrated with Sensors #1 and #2
600-404	VisionDX System, Integrated without Sensor
600-406	VisionDX System, Non-Integrated with Sensor #1
600-407	VisionDX System, Non-Integrated with Sensor #2
600-408	VisionDX System, Non-Integrated with Sensors #1 and #2
600-301	X-Ray Sensor Size 1
600-302	X-Ray Sensor Size 2
E1-13047	USB Cable
600-305	USB Module
45-P0002	Sensor Storage Holder
500-430	Sanitary Sensor Sheaths – Size 1
500-431	Sanitary Sensor Sheaths – Size 2
30-08137	Switch
600-100	Cable Extender Kit
260-008	Extended Warranty Plan

Warranty and Service

Warranty:

A separate Limited Warranty card has been included with your system. Please complete and return the warranty registration card immediately to validate your warranty and receive technical support. **Progeny cannot offer technical support or assistance unless your product has been registered.**

Extended Warranty Options are available. For more details, contact Progeny Dental or your dealer.

Service:

In the event you should require factory service, please follow these instructions:

Call +1.888.924.3800 and request a Return Authorization Number. Be sure to have the model number, serial number, nature of the problem, and a major credit card readily available for our customer service representative. Please mark the RA number clearly on the **OUTSIDE** of the shipping box and packing slip. If the RA# is not readily in sight, our receiving clerk is not authorized to accept the package. **Progeny Dental cannot accept responsibility for merchandise returned without a Return Authorization Number.**

Returns:

Please review your dealer's return policy if you purchased this product from an authorized Progeny dealer.

Progeny Return Policy: Returns are not accepted without prior written approval of Progeny, Inc. Defective products will be repaired or replaced per Progeny warranty program. No returns are accepted more than 30 days after the order date. Sterile sheaths are considered perishable items and are not returnable under any circumstances unless defective. Progeny cannot be responsible for any missing items unless contacted within 72 hours of shipment receipt by the customer. Any verbal representations are superseded by this written document. Progeny representatives may not modify any of the above terms and conditions without Progeny management's written approval.

IMPORTANT:
SAVE ALL BOXES AND PACKING MATERIALS. ALWAYS SHIP THE SYSTEM IN THE ORIGINAL BOXES TO PREVENT DAMAGE. FAILURE TO RETURN THE SYSTEM IN ITS ORIGINAL PACKAGING MAY VOID YOUR WARRANTY.

