

CAUTIONS:

FEDERAL LAW (U.S.) RESTRICTS THIS DEVICE TO THE SALE, DISTRIBUTION, AND USE BY OR ON THE ORDER OF A PHYSICIAN. THE USE OF THE EXTRACT UNIVERSAL EXTRACTION SYSTEM IS NOT RECOMMENDED WITHOUT THE INSTRUCTION OF A SURGEON THAT IS EXPERIENCED HANDLING THESE INSTRUMENTS.

SYSTEM DESCRIPTION

The Extract Universal Extraction System is for locking onto screws, pins, wires and other metallic fragments for removal. All collets, trephine bits, gouge chisel tips, and guide pins are intended for single use only.

SYSTEM CONTENTS

See page 3 for details.

MATERIAL COMPOSITION

The elements in the Extract Universal Extraction System are made of several materials including: Collets are manufactured from stainless steel. Handles are manufactured from stainless steel and aluminum, and Guide pins are manufactured from stainless steel.

INDICATION FOR USE

The Extract Universal Extraction System set is used to explant commonly used screws, pins, and wires. The Extract Removal System can also remove other metallic fragments if they are within the size parameters of the device.

CONTRAINDICATIONS

The system should not be used to grasp pins, wires, screws, or other metallic fragments outside the size parameters of the system (0.9mm to 8mm). Patients should be warned of the following contraindications. Possible adverse effects include but are not limited to the following:

- Infection
- Access site complications
- Inadequate skin, bone, or neurovascular status.

INSTRUCTIONS FOR USE

- 1 Prepare surgical site using preferred sterile technique.
- 2 Utilize the fluoroscopy unit to locate and mark the appropriate incision point.
- 3 Incise skin and dissect soft tissue to bone with care to preserve and protect vascular and neurological structures.
- 4 A guide wire may be placed through the cannulation of the Extract Universal Extraction System or used alone to probe and mark the center of the screw or pin to be removed.
- 5 Choose the appropriate size and style of collet tip based on surgical need.
- 6 Insert collet into extractor handle.
- 7 Rotate collet until it seats into the shaft.
- 8 Turn the knob at the top of the handle clockwise to engage the collet and continue until it is secure within the handle.
- 9 Place the entire instrument over the guide wire and advance to the hardware to be removed.
- 10 Insert the collet over and above the broken fragment.
- 11 Turn the device clockwise with light pressure toward the hardware in order to auger around the pin or screw.
- 12 At this point you may elect to utilize the fluoroscope to visualize placement around the pin or screw or simply engage the lever to compress the hardware. The knob can be turned clockwise to tighten or counter clockwise to loosen grip to obtain the appropriate collet pressure.
- 13 Once proper grip has been obtained on the hardware piece to be removed, rotate the instrument counterclockwise to remove the entire construct.
- 14 Dispose of used collet.

CLEANING AND STERILIZATION

All products associated with the Extract Universal Extraction System are provided non-sterile. The following instructions describe how to clean and sterilize the system components.

All handle attachments (standard collets, deep retrieval collets, k-wire collets, gouge chisels, and trephine bits) and guide pins in the Extract Universal Extraction System are single use devices. Single use devices may be sterilized multiple times; however, single use devices should not be reprocessed if they have been contaminated with blood, any body fluid or debris. Possible risks associated with reprocessing of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

Prior to each use, the following instructions should be used to clean and sterilize the Extract Universal Extraction System components. All components should be removed from the packaging and shipping material prior to cleaning and sterilization. Prior to sterilization, the parts should be thoroughly cleaned. Any collets should be disassembled from the handle before cleaning. Components should be manually cleaned using lukewarm water (between 27°C and 44°C) with an appropriate detergent that is labeled as safe for use on the materials in the Extract Universal Extraction System (stainless steel and aluminum). An enzyme detergent may be used for heavy organic soil. Follow the manufacturer instructions as provided on the detergent labeling. All parts can be wiped or brushed with a soft cleaning cloth or brush. The lumens in the handles should be cleaned with an appropriate sized cleaning brush and flushed. Any movable parts should be actuated as they are flushed, cleaned and rinsed.

After cleaning, the parts should be thoroughly rinsed to remove debris and detergent residue, including rinsing of all lumens. A final rinse with treated water (i.e. de-ionized, distilled or reverse osmosis water) is recommended. Dry the instruments with a clean, disposable, absorbent cloth. For reusable instruments that have been contaminated with blood, the parts should be pre-soaked in cold water. If contamination is found on the reusable instruments, remove

it by rinsing with cold water, wiping and/or brushing. All Extract Universal Extraction System components are fully submersible. The parts should be visually inspected (internal and external) to ensure cleanliness. If necessary, the steps above should be repeated until the part is visibly clean.

The following steps should be used to sterilize the Extract Universal Extraction System components. Populate the tray with the appropriate Extract Universal Extraction System components only. The system tray is not a sterile barrier and must be wrapped. The system may be steam sterilized in its tray using a pre-vacuum cycle at 132°C (270°F) for 4 minutes followed by 30 minutes drying time.

At any time, if any component appears to have any pitting, corrosion or other signs of degradation, the implant should be disposed of or returned to the manufacturer and a new component should be used. If alternative cleaning and/or sterilization methods are used, it is the user's responsibility to qualify these methods in conjunction with the Extract Universal Extraction System.

STORAGE CONDITIONS

Instruments must be stored in a clean, dry environment and be protected from sunlight and extreme temperatures.

SYSTEM CONTENTS

PART NUMBER	COMPONENT	INSIDE DIAMETER	OUTSIDE DIAMETER	CUTTING DEPTH	LENGTH
01-004-1000	Short driver	-	-	-	75mm Shaft
01-004-1500	Long driver	-	-	-	140mm Shaft
01-010-1001	Guide pin	-	0.9mm	-	250mm
01-010-1002	Guide pin	-	1.1mm	-	250mm
01-010-1003	Guide pin	-	1.6mm	-	250mm
01-005-1001	K Wire Collet	0.9mm	-	-	-
01-005-1002	K Wire Collet	1.1mm	-	-	-
01-005-1003	K Wire Collet	1.6mm	-	-	-
01-009-1001	Gouge Chisel	-	3.0mm	-	-
01-009-1002	Gouge Chisel	-	5.0mm	-	-
01-008-1001	Trephine	3.0mm	4.5mm	50mm	-
01-008-1002	Trephine	3.8mm	5.5mm	50mm	-
01-008-1003	Trephine	4.9mm	6.5mm	50mm	-
01-007-1001	Deep Retrieval	3.0mm	5.0mm	8.1mm	-
01-007-1002	Deep Retrieval	4.0mm	6.0mm	8.7mm	-
01-007-1003	Deep Retrieval	5.0mm	7.0mm	8.7mm	-
01-007-1004	Deep Retrieval	6.0mm	8.0mm	9.1mm	-
01-007-1005	Deep Retrieval	7.0mm	9.0mm	9.3mm	-
01-006-1001	Standard Collet	2.0mm	4.0mm	7.3mm	-
01-006-1002	Standard Collet	2.7mm	4.5mm	7.3mm	-
01-006-1003	Standard Collet	3.0mm	5.0mm	7.3mm	-
01-006-1004	Standard Collet	3.5mm	5.5mm	7.3mm	-
01-006-1005	Standard Collet	4.0mm	6.0mm	7.3mm	-
01-006-1006	Standard Collet	4.5mm	6.5mm	7.3mm	-
01-006-1007	Standard Collet	5.0mm	7.0mm	7.3mm	-
01-006-1008	Standard Collet	5.5mm	7.5mm	7.3mm	-
01-006-1009	Standard Collet	6.0mm	8.0mm	7.3mm	-
01-006-1010	Standard Collet	6.5mm	8.5mm	7.3mm	-
01-006-1011	Standard Collet	7.0mm	9.0mm	7.3mm	-
01-006-1012	Standard Collet	7.5mm	9.5mm	9.5mm	-
01-006-1013	Standard Collet	8.0mm	10.0mm	9.5mm	-

MANUFACTURER



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WARRANTY:

Ap-Med provides this limited warranty that the product has been manufactured and released for use in accordance with its specifications and tested using its established test methods. Ap-Med makes no other express or implied warranties, including the implied warranties of merchantability and fitness for a particular purpose. Ap-Med specifically does not make any representation or warranty about the use or performance of this device used in conjunction with any other devices. Handling, storage, cleaning and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Ap-Med control may directly affect the device and the results obtained from its use. Ap-Med makes no warranty, expressed or implied, including but not limited to the warranties of merchantability or fitness for a particular use with respect to collets reused, reprocessed or re-sterilized.