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MELT
LOOSE
REMOVE

Pressure-free
Technique of Cement Removal

AXIOM™
ULTRASONIC BONE CEMENT REMOVAL SYSTEM

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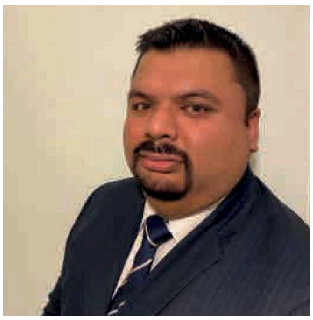
- Axiom- Surgeons Reviews
- United Kingdom
- NHS Hospitals

Surgeon Review
Surgeon: Mr Henry Atkinson
Hospital: North Middlesex University Hospital NHS Trust
Comments
I really like using this device, AXIOM with its novel non-pressure cement extraction and sonic pulses provides a safer way of extracting Cement.

Surgeon Review
Surgeon: Mr Shahnawaz Khan
Hospital: North Middlesex University Hospital NHS Trust
Revie Comments
The AXIOM system has significant advantages in cement removal with several versatile attachments combined with a novel use of sonic pulses to break through cement with preservation of bone stock, preventing canal perforation and thermal injury.



Surgeon Review
Surgeon: Mr Zuhair Nawaz
Hospital: Frimley Park NHS Foundation Trust
Review Comments
liked using the AXIOM cement removal system it has significant advantages in cement removal with novel use of non-pressure sonic pulses to break through cement and with preservation of bone stock and power celebration preventing canal perforation.

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ULTRASONIC BONE CEMENT REMOVAL SYSTEM

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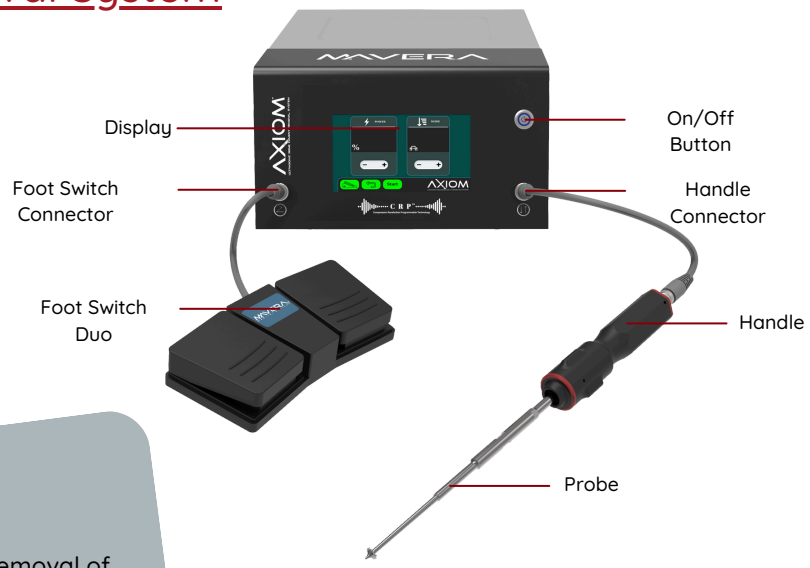
"A superior arthroplasthy revision method going beyond just 'removing' the bone cement."

Axiom™ Ultrasonic Cement Removal System

A Visionary Device Offering Better Results

- Selectively remove cement
- Preserving host bone

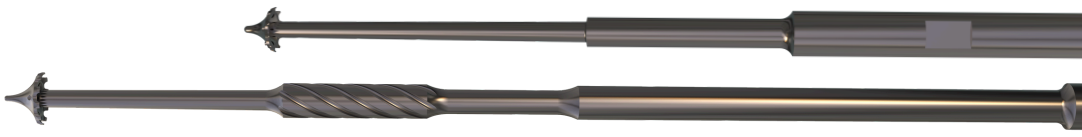


Mechanism of Action

Axiom™ Ultrasonic Cement Removal System is used in the removal of synthetic materials like polymethylmethacrylate bone cement (PMMA) in large joint revision procedures. The ultrasonic vibration at the tip of probe softens the cement around the implant.
The system is designed and developed to facilitate the removal of bone cement during revision arthroplasty whilst controlling bleeding.
The softened material is then scrabbed from the host tissue.

The Axiom™ Cement Removal System & Accessories may be used as an adjunct to or substitute for manually done PMMA removal procedure in orthopedic surgeries such as hip joint shoulder arthroplasty revision surgeries.

Vibration-generated temperature increase at the tip can transform PMMA from a rigid material to fluffy malleable form which in turn beefs up the removal process of PMMA from the contact circumference. Technically speaking, the phenomenon of glass transition temperature is realized in changing the form of material by upcoming micro movement and resulting in changing elasticity modules, heat conduction and thermal expansion.



Principle of Operation

Cement Removal System is realized between 25-30 kHz.. In principle, the outlet voltage is supplied at 50 to 60 hertz. The generator boosts this frequency to 25-30 kHz. The resulting ultrasonic frequency is delivered into the hand-piece and amplified to the motion. After activation, the handle probe can vibrate 25-30.000 strokes per second and result in cavitation at the surgical site. The system uses this cavitation to soften the cement holding the implant in place.

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Axiom™ Ultrasonic Cement Removal System should be used by the surgeons who have received the appropriate training.

RIGID » FLUFFY

1) Selectively remove cement

Axiom™ Ultrasonic Cement Removal System removes cement selectively during revision arthroplasty.Bone cement has a high capacity for absorbing energy and low thermal conductivity. The substantial temperature increase of the system protects the surrounding tissue during the removal of cement.[1]

2) Preserving host bone

Axiom™ Ultrasonic Cement Removal System preserves host bone. Ultrasound affects cancellous bone and it is removed when subjected to energy levels applied while removal of cement. Whereas due to design of the probe and levels of energy that are used, cortical bone is not affected. Ultrasound could not be absorbed by bone just as readily as cement and due to both audible and tactile mechanism of the system, probe position within the bone could be detected by surgeons.[2] [3]

Indications

The Axiom™ Cement Removal System & Accessories are indicated for removal of PMMA in arthroplasty revision surgeries and to be used to scrab, debride, fragment, aspirate and remove undesired and unwanted hard and soft tissue.

Axiom™ Ultrasonic Cement Removal System is intended to be used in selectively fragmentation,resection,emulsufication, irrigation and/or aspiration of synthetic materials (e.g.polymethylmethacrylate (PMMA) bone cement) during revision surgeries.It can also be used to scrape,debride,fragment, aspirate and remove undesired and unwanted hard and soft tissue. Indications, contraindications and instructions for use can be found on the product labeling supplied with each device.

AXIOM ULTRASONIC BONE CEMENT REMOVAL SYSTEM

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SHOULDER & ELBOW

PRODUCT DEFINITION	REFERENCE		LENGTH	ACTIVE	KHz	O.D
Cement Removal Probe CPXLV	AXM-CPXLV		103.37mm	15.93mm	26 khz	6mm
Cement Removal Probe CPXLVI	AXM-CPXLVI		100.4mm	17.31mm	26 khz	6mm
Cement Removal Probe CPXLVII	AXM-CPXLVII		194.2mm	69.09mm	26 khz	6mm
Cement Removal Probe CPXLVIII	AXM-CPXLVIII		189.8mm	69.47mm	26 khz	6mm
Cement Removal Probe CPXLIX	AXM-CPXLIX		101.61mm	17.91mm	26 khz	8mm
Cement Removal Probe CPL	AXM-CPL		102.96mm	18.52mm	26 khz	8mm
Cement Removal Probe CPLI	AXM-CPLI		191.41mm	71.21mm	26 khz	8mm
Cement Removal Probe CPLII	AXM-CPLII		190.96mm	71.12mm	26 khz	8mm

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ULTRASONIC BONE CEMENT REMOVAL SYSTEM

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KNEE

PRODUCT DEFINITION	REFERENCE		LENGTH	ACTIVE	KHz	O.D
Cement Removal Probe CPXLV	AXM-CPXLV		103.37mm	15.93mm	26 khz	6mm
Cement Removal Probe CPXLVI	AXM-CPXLVI		100.4mm	17.31mm	26 khz	6mm
Cement Removal Probe CPXLVII	AXM-CPXLVII		194.2mm	69.09mm	26 khz	6mm
Cement Removal Probe CPXLVIII	AXM-CPXLVIII		189.8mm	69.47mm	26 khz	6mm
Cement Removal Probe CPXLIX	AXM-CPXLIX		101.61mm	17.91mm	26 khz	8mm
Cement Removal Probe CPL	AXM-CPL		102.96mm	18.52mm	26 khz	8mm
Cement Removal Probe CPLI	AXM-CPLI		191.41mm	71.21mm	26 khz	8mm
Cement Removal Probe CPLII	AXM-CPLII		190.96mm	71.12mm	26 khz	8mm

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ULTRASONIC BONE CEMENT REMOVAL SYSTEM

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KNEE

PRODUCT DEFINITION	REFERENCE		LENGTH	ACTIVE	KHz	O.D
Cement Removal Probe CPLIII	AXM-CPLIII		102.93mm	18.49mm	26 khz	10mm
Cement Removal Probe CPLIV	AXM-CPLIV		110mm	18.52mm	26 khz	10mm
Cement Removal Probe CPLV	AXM-CPLV		102.96mm	18.52mm	26 khz	10mm
Cement Removal Probe CPLVII	AXM-CPLVII		192.72mm	75.01mm	26 khz	10mm
Cement Removal Probe CPLVIII	AXM-CPLVIII		194.39mm	84.54mm	26 khz	10mm

AXIOM™
ULTRASONIC BONE CEMENT REMOVAL SYSTEM

References
[1]Schultz JM, editor. Treatise on materials science and technology. New York: Academic Press; 1977. materials. Properties of solid polymetric p602. [2]Klapper RC, Caillouette JT, Callaghan JJ, Hozack WJ. Ultrasonic technology in revision joint arthroplasty. Clin Orthop. 1992; 285:147- 54. [3]Brooks AT, Nelson CL, Hofmann OE. Minimal femoral cortical thickness necessary to prevent perforation by ultrasonic tools in joint revision surgery. J Arthroplasty. 1995; 10:359-62

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HIP

PRODUCT DEFINITION	REFERENCE		LENGTH	ACTIVE	KHz	O.D
Cement Removal Probe CPXLV	AXM-CPXLV		103.37mm	15.93mm	26 khz	6mm
Cement Removal Probe CPXLVI	AXM-CPXLVI		100.4mm	17.31mm	26 khz	6mm
Cement Removal Probe CPXLVII	AXM-CPXLVII		194.2mm	69.09mm	26 khz	6mm
Cement Removal Probe CPXLVIII	AXM-CPXLVIII		189.8mm	69.47mm	26 khz	6mm
Cement Removal Probe CPXLIX	AXM-CPXLIX		101.61mm	17.91mm	26 khz	8mm
Cement Removal Probe CPL	AXM-CPL		102.96mm	18.52mm	26 khz	8mm
Cement Removal Probe CPLI	AXM-CPLI		191.41mm	71.21mm	26 khz	8mm
Cement Removal Probe CPLII	AXM-CPLII		190.96mm	71.12mm	26 khz	8mm

AXIOM™

ULTRASONIC BONE CEMENT REMOVAL SYSTEM

References

[1]Schultz JM, editor. Treatise on materials science and technology. New York: Academic Press; 1977. materials. Properties of solid polymetric p602. [2]Klapper RC, Caillouette JT, Callaghan JJ, Hozack WJ. Ultrasonic technology in revision joint arthroplasty. Clin Orthop. 1992; 285:147- 54. [3]Brooks AT, Nelson CL, Hofmann OE. Minimal femoral cortical thickness necessary to prevent perforation by ultrasonic tools in joint revision surgery. J Arthroplasty. 1995; 10:359-62

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HIP

PRODUCT DEFINITION	REFERENCE		LENGTH	ACTIVE	KHz	O.D
Cement Removal Probe CPLIII	AXM-CPLIII		102.93mm	18.49mm	26 khz	10mm
Cement Removal Probe CPLIV	AXM-CPLIV		110mm	18.52mm	26 khz	10mm
Cement Removal Probe CPLV	AXM-CPLV		102.96mm	18.52mm	26 khz	10mm
Cement Removal Probe CPLVI	AXM-CPLVI		105mm	32.25mm	26 khz	5.5mm
Cement Removal Probe CPLVII	AXM-CPLVII		192.72mm	75.01mm	26 khz	10mm
Cement Removal Probe CPLVIII	AXM-CPLVIII		194.39mm	84.54mm	26 khz	10mm
Cement Removal Probe CPLIX	AXM-CPLIX		299.25mm	40.41mm	26 khz	10mm
Cement Removal Probe CPLX	AXM-CPLX		298.98mm	50.57mm	26 khz	10mm

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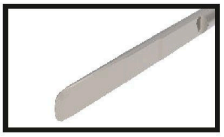
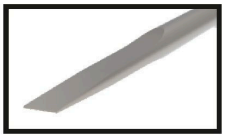
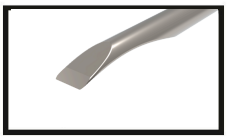
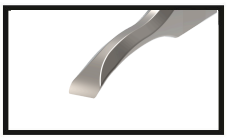
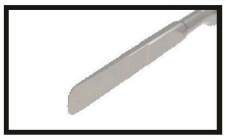
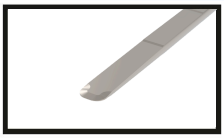
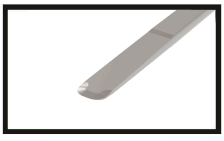
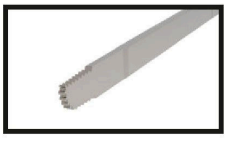
HIP

PRODUCT DEFINITION	REFERENCE		LENGTH	ACTIVE	KHz	O.D
Cement Removal Probe CPLXIII	AXM-CPLXIII		105.1mm	28.8mm	26 khz	6mm
Cement Removal Probe CPLXIV	AXM-CPLXIV		105.1mm	28.8mm	26 khz	6mm
Cement Removal Probe CPLXI Acetabular Cup Removal	AXM-CPLXI		102mm	38.96mm	26 khz	6mm
Cement Removal Probe CPLXII Acetabular Cup Removal	AXM-CPLXII		120.96mm	38.96mm	26 khz	6mm

Probes for Uncemented Revisions

			LENGTH	ACTIVE	KHz	O.D
Uncemented Removal Probe CPLXV	AXM-CPLXV		105.1mm	28.8mm	26 khz	6mm
Uncemented Removal Probe CPLXVll	AXM-CPLXVII		215.35mm	23.5mm	26 khz	5mm
Uncemented Removal Probe CPLXVIII	AXM-CPLXVIII		298.35mm	127.5mm	26 khz	5mm
Uncemented Removal Probe CPLXIX	AXM-CPLXIX		192.05mm	118.36mm	26 khz	5mm

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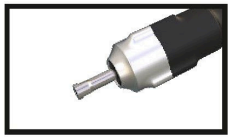
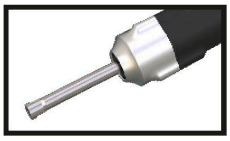
	PRODUCT DEFINITION	REFERENCE		LENGTH	ACTIVE	KHz	O.D
HIP	*Cement Removal Probe CPLXVI*  Acetabular Cup Removal	AXM-CPLXVI		110.96mm	45.79mm	26 khz	16mm
EXTENDER	*Extender EXTIII* 	AXM-EXTIII-N		110mm	–	26 khz	–
	Extender EXTV 	AXM-EXTV-N		100mm	–	26 khz	–
	Extender EXTVI 	AXM-EXTVI-N		90mm	–	26 khz	–
handles & generator	*Ultrasonic Handle HL02* 	AXM-HL02-N		203.8mm	–	26 khz	–
	Ultrasonic Handle HL01 	AXM-HL01-N		223.3mm	–	26 khz	–
	Ultrasonic Generator GN02 	AXM-GN02-N		–	–	26 khz	–

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References
[1]Schultz JM, editor. Treatise on materials science and technology. New York: Academic Press; 1977. materials. Properties of solid polymetric p602. [2]Klapper RC, Caillouette JT, Callaghan JJ, Hozack WJ. Ultrasonic technology in revision joint arthroplasty. Clin Orthop. 1992; 285:147- 54. [3]Brooks AT, Nelson CL, Hofmann OE. Minimal femoral cortical thickness necessary to prevent perforation by ultrasonic tools in joint revision surgery. J Arthroplasty. 1995; 10:359-62

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AXM-HL01-N

Compatible with

- AXM-CPLVII
- AXM-CPLXIII
- AXM-CPLXV

AXM-HL02-N

Compatible with

- AXM-CPXLV
- AXM-CPXLVI
- AXM-CPXLVII
- AXM-CPXLVIII
- AXM-CPLX
- AXM-CPLXII
- AXM-CPXLIX
- AXM-CPLI
- AXM-CPLI
- AXM-CPLII
- AXM-CPLIX
- AXM-CPLXIV
- AXM-CPLIII
- AXM-CPLIV
- AXM-CPLV
- AXM-CPLVI
- AXM-CPLVIII

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Mavera Medical Devices Inc. guarantees that the products are designed, manufactured and packaged on application of the EN ISO 13485 certified quality management with all possible care, using the most suitable state-of-the-art processes and applying the principle of integrating safety into its design and manufacture. This system is designed to guarantee the safe use of device when it is employed under condition and tor the purposes tor which it Is intended, in accordance with precautions described in the operator's manual and/or instructions for use and to minimize the risks associated with the use of the device as far as possible although they cannot be totally eliminated. The device must only be used under the responsibility of specialist medical personnel, taking account of the unavoidable risks and the possible side effects and complications of the treatment for which, it is designed, including those referred to in other sections of these instructions for use

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