



OSCAR™ 3

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OSCAR has been designed and built in accordance with ISO 13485:2003 Quality Assurance standard for medical devices and Part 820 of the Title 21 of the Code of Federal Regulations of the USA. CE conformance has been certified and the equipment complies with BSEN60601-1.

OVERVIEW

- OSCAR 3 is a tool for cutting and removing of acrylic bone cement in cemented arthroplasty revision;
- It can also be used for cutting and removing bone in cementless press-fit arthroplasty revision;
- Energy from ultrasound waves (above 16 kHz) are transferred and concentrated at the implant interface;
- Bespoke probes are deployed in sequence to collect and remove the softened cement from the host bone or cut through cortical or cancellous bone.

BENEFITS

- Reduces ambiguity by differentiating between cement and bone easily;
- Reduces the likelihood of fracture or perforation of the host's bone;
- Reduces the degree of manual force required;
- Protects cortical bone due to predefined wave length (energy level) setting;
- Provides audible and tactile feedback during surgery;

EQUIPMENT

- Portable generator with two output channels, which can drive either:
 - OSCAR cement removal handset; or,
 - OSCAR osteotome handset.
- Handsets are connected via a silicone rubber cable and activated by an air footswitch or switches on the individual handsets.
- Extensive portfolio of single-use sterile probes for cement removal and bone cutting.



Generator

- Portable, mains powered generator (240V ac);
- Size: 475mm (width) x 140mm (height) x 355 (depth);
- Weight 7.5kg (15kg including transport case);
- Each output channel is controlled by a microprocessor, producing ultrasonic energy at the resonant frequency of the attached handset;
- Frequency range in 27.9 to 28.5 kilohertz;
- Energy delivery to the handsets increase in response to load at the head of the probe- up to 150-watt output
- The front panel has two output channels, two air nozzles sockets and LCD;
- The back panel has mains power connection, an ON/OFF switch and Equipotential connection.

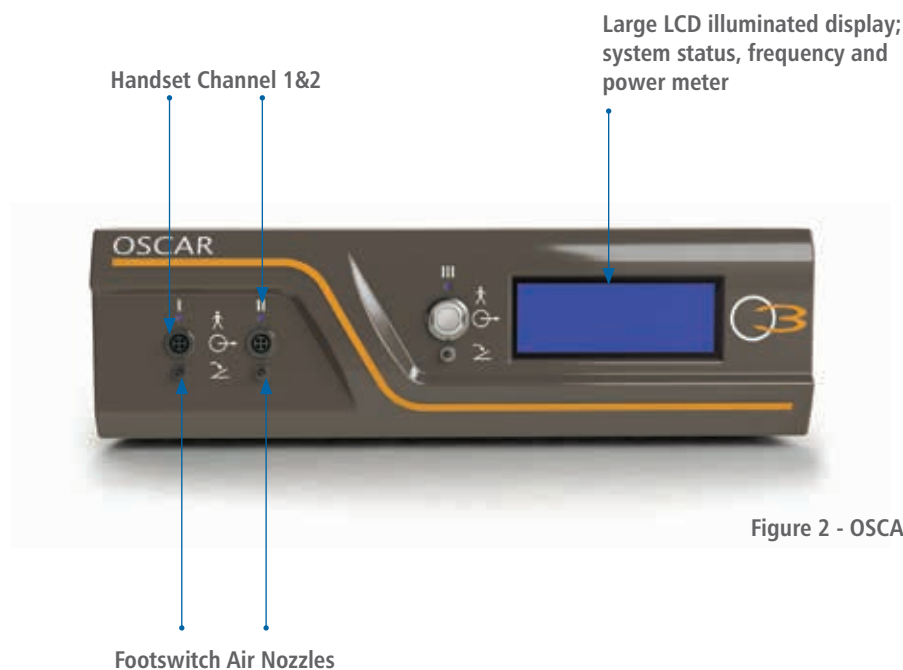
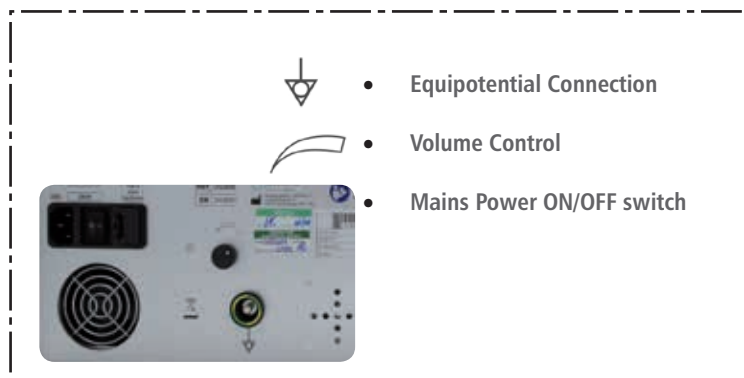


Figure 2 - OSCAR 3 Front panel

Back Panel



Cables

- Silicone rubber cables (with screened conduction wires) connect Generator with Handsets;
- They contain two separate ground leads*;
- Cables must be sterilised and connect at either end of Handset Channels 1&2 on the front to the Generator**;
- **Red Dots** are aligned, pressed together until an audible click is heard.



* Patient will be grounded; turn off diathermy during OSCAR use

**Cables are interchangeable

Footswitch

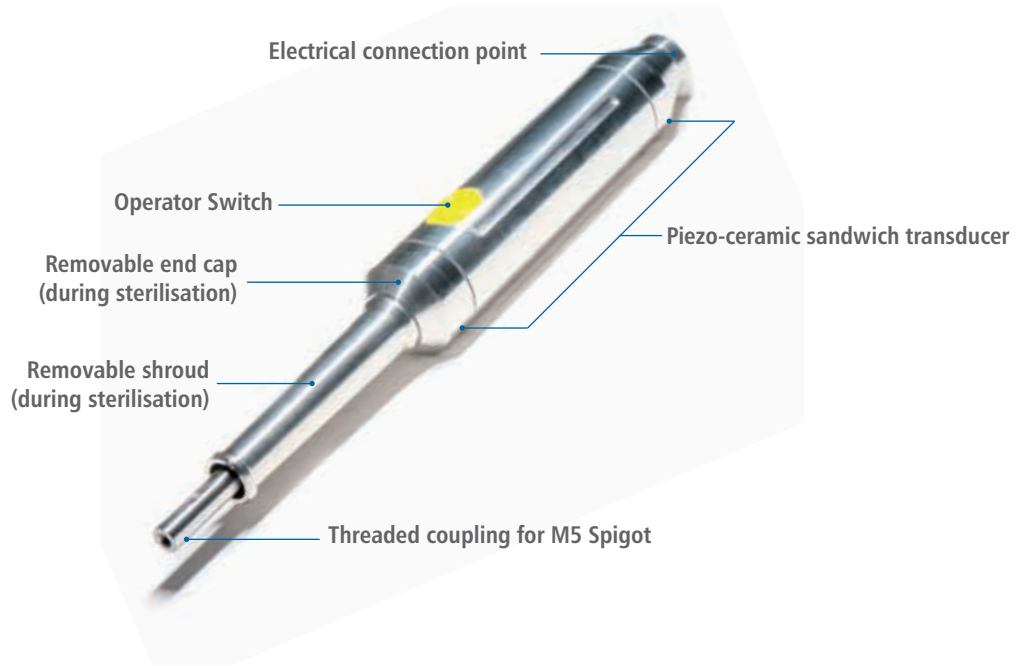
- Double air footswitch connects in air nozzles directly under Channel 1&2 on the Generator;
- Non-sterile;
- Can select or operate either Channel or Handset.



Handsets - Cement Removal ONLY

- Contains a piezo-ceramic sandwich transducer;
- Mechanical focusing Device (the Horn) with M5 threaded spigot coupling for probe attachment;
- Operator switch;
- Water and pressure sealed in stainless steel casing;
- Generator induces crystals inside the Handset to vibrate and produce Ultrasonic energy;
- Energy propagated along the length of the probes and concentrated at the head- causing vibration between 27.9 and 28.5 kilohertz;
- Rapid oscillation produces heat when in contact with bone cement.

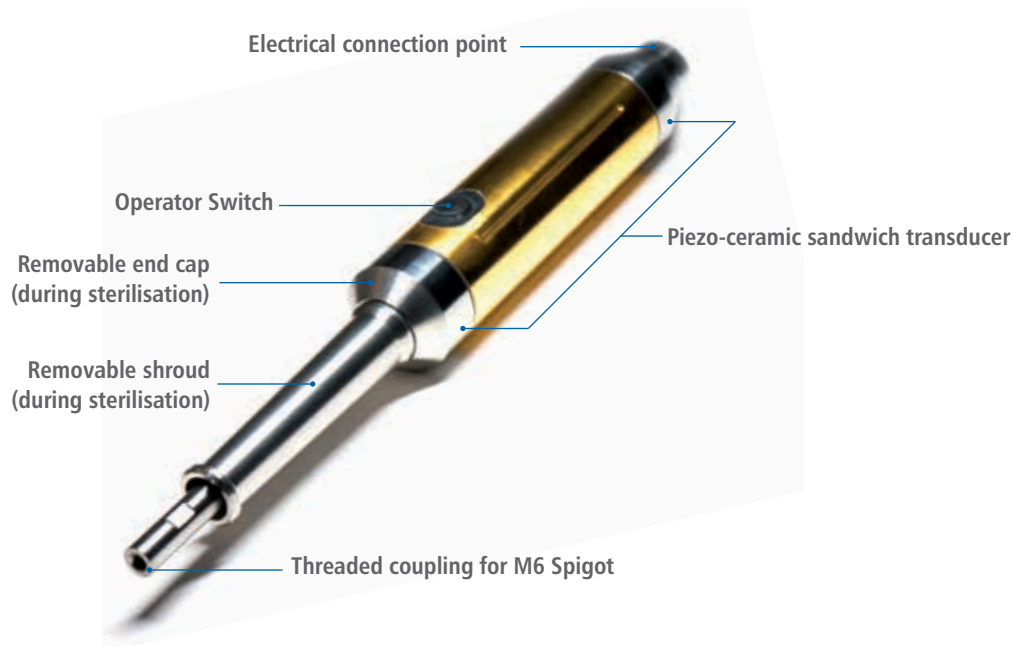
POLISHED STAINLESS STEEL HANDSET ONLY



Handsets - Bone Cutting ONLY

- Contains a piezo-ceramic sandwich transducer;
- Mechanical focusing Device (the Horn) with M6 threaded spigot coupling for probe attachment;
- Operator switch;
- Water and pressure sealed in stainless steel casing;
- Generator induces crystals inside the Handset to vibrate and produce Ultrasonic energy;
- Axial vibration has been modified so the output impedance is comparable with bone;
- This reduces the displacement amplitude in order to withstand higher distal load.

GOLD SLEEVED HANDSET ONLY



Probes - Cement Removal ONLY

- Multiple variations designed to;
 - Piercer or create channels
 - Scrape
 - Cut
- Single-Use ONLY;
- **Cannot** cut through cortical bone;
- M5 spigot to coupling to Polished Stainless Steel Handset- ONLY;
- Require the use of extension bars.

POLISHED STAINLESS STEEL HANDSET ONLY



Probe ID	Probe Name	Use with Extension/Reduce Bars.				
		OHR2000 Reducer Bar	OHRE2000SU OHRE2002SU Short Extension Bar	OHRE2001SU OHRE2003SU Long Extension Bar	Use without Extension/reducer Bar	OHE2000 Standard Extension Bar
OHP218FSU	8mm Flat Piercer	YES	NO	NO	NO	NO
OHP2080SU	8mm Piercer	NO	YES	YES	NO	NO
OHS2080SU	8mm Scraper	NO	YES	YES	NO	NO
OHP2062SU	Slim 6mm Piercer	NO	NO	NO	YES	NO
OHP2100SU	10mm Piercer	NO	YES	YES	NO	NO
OHS2100SU	10mm Scraper	NO	YES	YES	NO	NO
OHS2062SU	Slim 6mm Scraper	NO	NO	NO	YES	NO
OHA2030SU	Acetabular Probe	NO	NO	NO	YES	YES (Optional)
OHH2062SU	6mm hoe Probe	NO	NO	NO	YES	NO
OHH2081SU	8mm Hoe Probe	NO	NO	NO	YES	NO
EXP2681SU	Extraction Probe	NO	NO	NO	YES	YES (Optional)

Probes- Bone Cutting ONLY

- Three osteotome variations;
 - Flat Serrated
 - Flat Non-Serrated
 - Curved Serrated
- Single-Use ONLY
- Can cut through cancellous;
- M6 spigot to coupling to Gold Sleeved Handset- ONLY; and,
- **Do not** require the use of an extension bar.



INDICATIONS FOR USE (IFU)

- "OSCAR 3 is intended to be used for cutting and removal of bone and acrylic bone cement in orthopaedic applications."
- For detailed safety and precautionary warning and instruction please see full IFU by following the link below:
- http://abs.orthofix.it/db/resources/PQ_OSC.pdf

BUSINESS MODELS

- Capital Sales
 - Direct to the customer
 - Lease agreement*
- Hire*
- Warranty
- Repair

**in Orthofix subsidiaries only*

PRODUCT REGISTRATION

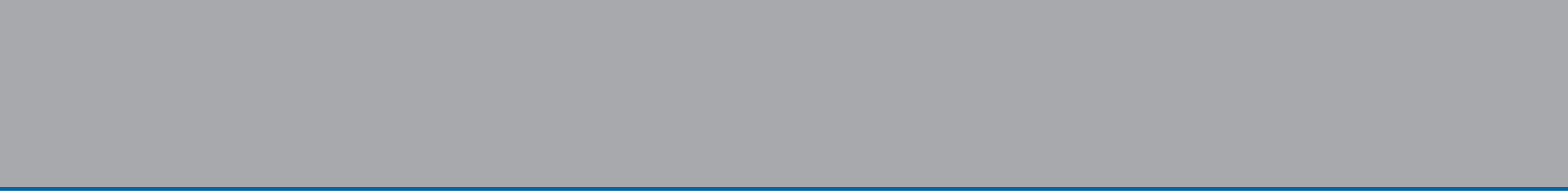
OSCAR 3 is registered in the following countries and can be sold without any regulatory restrictions:

- Australia
- **CE mark:**
 - Austria, Chile, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Italy, Hong Kong, Israel, Luxembourg, Libya, Lebanon, Malta, Netherlands, Norway, Oman, Qatar, Poland, Slovenia, South Africa, Sweden, Honk Kong, Trinidad Tobago, Switzerland, United Kingdom.
- Israel
- New Zealand
- Puerto Rico
- Russia
- Saudi Arabia
- USA

SUMMARY

- Ultrasonic arthroplasty revision system
- Indicated for prosthesis extraction in:
 - Cemented;
 - Cementless; and,
 - Hybrid Revision Arthroplasty
- Usable in the Hip, Knee, Elbow and Shoulder







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CE 0123

Distributed by:



Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Proper surgical procedure is the responsibility of the medical professional. Operative techniques are
furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique
based on his or her personal medical credentials and experience. Please refer to the "Instructions
for Use" supplied with the product for specific information on indications for use, contraindications,
warnings, precautions, adverse reactions and sterilization.

www.orthofix.com

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