

OSCAR PRO™ is an ultrasonically powered surgical system intended to reduce the challenges associated with revision arthroplasty surgery





#### **EFFICIENT**

Specific probes are utilised in a sequence to soften and remove cement from the bone. The technique reduces manual force to a minimum, resulting in low risk of bone fracture and perforation.



#### SAFE

All probes are designed to preserve the bone quality and the soft tissue. The system is designed with specific audible and visual feedback to provide the user a safe and efficient operating environment for their patients.



#### **VERSATILE**

Single use probes have been designed for providing high quality performance for every case with safety in mind. The vast range of probes are designed to

provide an optimal choice for a number of different revision surgeries.

## **GENERATOR**

- 7-inch touch screen
- Multi-language
- Audible feedback
- Visual notifications
- Integrated Wi-Fi
- Data log



# UNIVERSAL HANDSET



# SINGLE USE PROBES

- Extended range of probes
- No extension bar needed
- Single use
- M6 connection (reduces the probability of breaking)
- Easy probe coupling



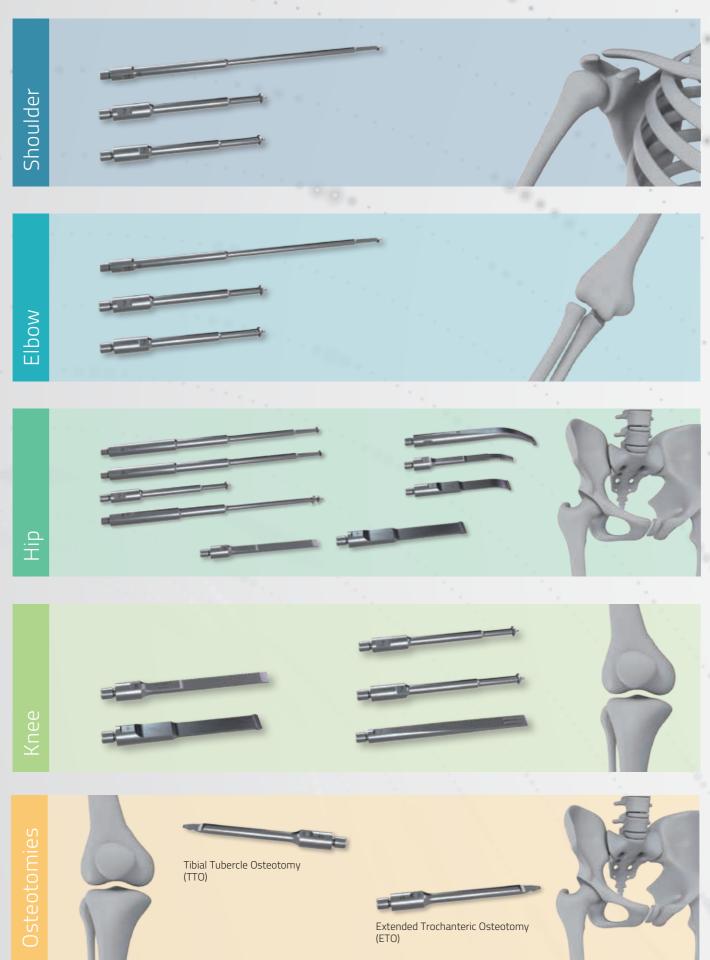
# CEMENTLESS PROSTHESIS REMOVAL

- Designed to remove osseointegrated prostheses
- Probes can advance through the cancellous bone prosthesis interface
- The curved probe is advanced in line with the curvature of acetabular cup circumferentially around the acetabulum





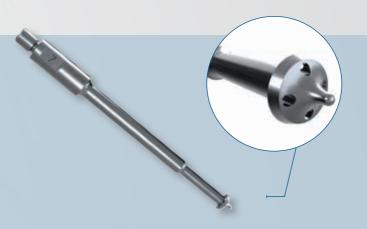
# USE OF PROBES

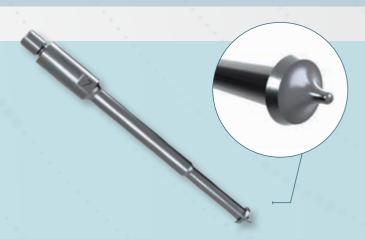


## CEMENT REMOVAL PROBES

### Piercer

- Designed to create clear channels in the cement following a straight line movement
- Molten excess cement is cleared through the perforations in the head of the probe





### Scraper

- Designed to clear channels of undesired cement
- The probe is advanced down a channel and drawn smoothly backwards, collecting excess cement in the recess between the probe's head and the stem

### Hoe

- Designed to remove cement in narrow canals, such as the ulnar and the humerus
- The probe is advanced down a channel and drawn smoothly backwards, collecting excess cement in the recess between the probe head and the stem





#### Acetabular

- Designed to create channels in cement bonding of the acetabular component
- The probe is advanced in line
   with the curvature of acetabular cup
   circumferentially around the acetabulum

## SALES CONFIGURATION

#### SINGLE USE STERILE ITEMS

The following items codes and description of probes are provided in single, sterile packaging configuration. The packaging consists of double pouch inner packaging with a cardboard FSC outer box.

Part #	Description - Single use probes
99-04SL09D06	OSCAR PRO TITANIUM CEMENT SCRAPER L90MM D6MM STERILE
99-04SL18D06	OSCAR PRO TITANIUM CEMENT SCRAPER L180MM D6MM STERILE
99-04SL09D08	OSCAR PRO TITANIUM CEMENT SCRAPER L90MM D8MM STERILE
99-04SL18D08	OSCAR PRO TITANIUM CEMENT SCRAPER L180MM D8MM STERILE
99-04SL27D08	OSCAR PRO TITANIUM CEMENT SCRAPER L270MM D8MM STERILE
99-04SL09D10	OSCAR PRO TITANIUM CEMENT SCRAPER L90MM D10MM STERILE
99-04SL18D10	OSCAR PRO TITANIUM CEMENT SCRAPER L180MM D10MM STERILE
99-04PL09D06	OSCAR PRO TITANIUM CEMENT PIERCER L90MM D6MM STERILE
99-04PL18D06	OSCAR PRO TITANIUM CEMENT PIERCER L180MM D6MM STERILE
99-O4PL09D08	OSCAR PRO TITANIUM CEMENT PIERCER L90MM D8MM STERILE
99-O4PL18D08	OSCAR PRO TITANIUM CEMENT PIERCER L180MM D8MM STERILE
99-04PL27D08	OSCAR PRO TITANIUM CEMENT PIERCER L270MM D8MM STERILE
99-04PL09D10	OSCAR PRO TITANIUM CEMENT PIERCER L90MM D10MM STERILE
99-04PL18D10	OSCAR PRO TITANIUM CEMENT PIERCER L180MM D10MM STERILE
99-04HL18D06	OSCAR PRO TITANIUM CEMENT HOE L180MM D6MM STERILE
99-04HL18D08	OSCAR PRO TITANIUM CEMENT HOE L180MM D8MM STERILE
99-O4EXP	OSCAR PRO TITANIUM CEMENT PLUG EXTRACTOR L180MM STERILE
99-04AL09DNA	OSCAR PRO TITANIUM CURVED CEMENT PIERCER L90MM STERILE
99-O4PSFB8	OSCAR PRO TITANIUM FLAT CEMENT PIERCER L90MM STERILE
99-O4OL09B10	OSCAR PRO TITANIUM FLAT BLADE SMOOTH L90MM W10MM STERILE
99-O4CL09B10	OSCAR PRO TITANIUM CURVED BLADE SMOOTH L90MM W10MM STERILE
99-04FL08B06	OSCAR PRO TITANIUM FLAT BLADE SMOOTH L80MM W6MM STERILE
99-04SCL08B04	OSCAR PRO TITANIUM CURVED BLADE SERRATED L80MM W4MM STERILE
99-O4EL09B06	OSCAR PRO TITANIUM OSTEOTOME WEDGE TIP L90MM W6MM STERILE

The following item is referred to the Irrigation Kit (irrigation tube + nozzle) provided in single, sterile packaging configuration. The packaging consists of a double pouch inner packaging with a cardboard FSC outer box. The following two codes are:

#### MANUFACTURER BY:



**EMOTEC S.R.L.** - VIA MAESTRI DEL LAVORO, 5 — 41036 MEDOLLA (MO) ITALY C.F. E P. IVA 02578710366 - TEL.: +39 0535 / 53060 - FAX: +39 0535 / 52629 - E-MAIL: EMOTEC@ EMOTEC.IT



**ORTHOFIX**\* Orthofix Srl - Via delle Nazioni 9 - 37012 Bussolengo (VR) Italy
Telephone +39 045 671 9000 - Fax +39 045 671 9380

IRRIGATION KIT		
Part #	Description	
2000972	STERILE KIT FOR PERISTALTIC PUMP	
8000001	STERILE KIT FOR PERISTALTIC PUMP US	

#### **MULTIPLE USE, NON STERILE ITEMS**

The following items are sold individually packed.

Part #	Description
O4HAND*	OSCAR PRO UNIVERSAL HANDSET
O4UHH	OSCAR PRO UNIVERSAL HANDSET HANDLE
O4HOLD	OSCAR PRO HANDSET HOLDER
O4IPL200	OSCAR PRO SLAP HAMMER
SPAN7MM	SPANNER 7 MM
SPAN8/9MM	SPANNER 8/9MM
O4CABLE*	OSCAR PRO UNIVERSAL HANDSET CABLE
04F00T-U*	OSCAR PRO FOOTSWITCH FOR ULTRASOUND
O4FOOT-W*	OSCAR PRO FOOTSWITCH FOR IRRIGATION
OSCAR PRO Main le	ad:
O4POWEU	OSCAR PRO MAIN LEAD EU
or	
O4POWUS	OSCAR PRO MAIN LEAD US
or	
O4POWUK	OSCAR PRO MAIN LEAD UK

A sterilization tray is available to sterilize multiple use.

#### **04TRAY - OSCAR PRO INSTRUMENT TRAY EMPTY**

The tray can accommodate reusable and re-processable instruments, as per the following configuration:

-	as per and removing serving and an arrangement of the period of the peri		
Q.ty	Part #	Description	
2	O4UHH	OSCAR PRO UNIVERSAL HANDSET HANDLE	
2	O4HOLD	OSCAR PRO HANDSET HOLDER	
1	O4IPL200	OSCAR PRO SLAP HAMMER	
2	SPAN7MM	SPANNER 7MM	
2	SPAN8/9MM	SPANNER 8/9MM	
2	O4CABLE	OSCAR PRO UNIVERSAL HANDSET CABLE	
OSCAR PRO Instrument Tray spare part:			
04T	RAY-01	OSCAR PRO Base tray	
04T	RAY-02	OSCAR PRO Lid tray	

A dedicated flight case for the instrument tray is available and sold separately; the flight case includes a custom foam in a non-sterile configuration.

#### **OINSTFLY1 - OSCAR INSTRUMENT FLIGHT CASE**

The OSCAR PRO generator is provided within a dedicated flight case, including also one water bag holder.

OS4	OS4000* - OSCAR PRO GENERATOR		
Q.ty	Part #	Description	
1		OSCAR PRO GENERATOR	
1	OGENFLY2	OSCAR PRO GENERATOR FLIGHT CASE	
1	O4BEAM	OSCAR PRO HOLDER FOR WATER BAG L459MM	

The OGENFLY2 flight case is designed to accommodate also the following items, as per below configuration:

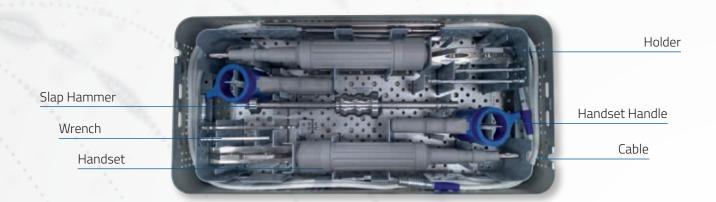
OGENFLY2 - OSCAR PRO GENERATOR FLIGHT CASE		
Q.ty	Part #	Description
1		OSCAR PRO main lead:
	O4POWEU	OSCAR PRO MAIN LEAD EU
	O4POWUS	OSCAR PRO MAIN LEAD US
	O4POWUK	OSCAR PRO MAIN LEAD UK
1	O4FOOT-U	OSCAR PRO FOOTSWITCH FOR ULTRASOUND
1	O4FOOT-W	OSCAR PRO FOOTSWITCH FOR IRRIGATION

OSCAR PRO Generator spare parts:		
Part #	Description	
OGENFLY2	OSCAR PRO GENERATOR FLIGHT CASE	
O4BEAM	OSCAR PRO HOLDER FOR WATER BAG L459MM	

<sup>\*</sup> Component of the device: OSCARPRO – ULTRASOUND MEDICAL SYSTEM

# FOCUSED INSTRUMENTATION

- Handset handle for enhanced maneuverability and grip
- Handset holder to stabilise universal handset and protect probe while not in use
- New tray design allowing an easy probe assembly inside the sterile field
- Labelled instrumentation for easy identification of corresponding parts



## REFERENCES

- "The OSCAR 3 Ultrasonic arthroplasty revision instrument for removing bone cement during prosthetic joint revision", NICE National Institute for Health and Care Excellence, Medtech innovation briefing [MIB13].
- "Scanning electron microscopy investigation of PMMA removal by laser irradiation (Er: YAG) in comparison with an ultrasonic system and curettage in hip joint revision arthroplasty, Birnbaum, K. and Gutknecht, N., 2010. Lasers in medical science, 25(4), pp.595–603.
- "Safe Removal of Massive Intrapelvic Cement Using Ultrasonic Instruments", Smith, P.N. and Eyres, K.S., 1999. The Journal of arthroplasty, 14(2), pp. 235–238.
- "Ultrasonically driven instruments in the transfemoral approach—an aid to preservation of bone stock and reduction of implant length", Fletcher,
   M., Jennings, G.J. and Warren, P.J., 2000. Archives of orthopaedic and trauma surgery, 120(10), pp.559-561.
- "Thermal Tissue Damage Caused by Ultrasonic Cement Removal from the Humerus", Goldberg, S.H., Cohen, M.S., Young, M. and Bradnock, B., 2005.JBJS, 87(3), pp.583-591.
- "Gas chromatography-mass spectroscopy analysis of emissions from cement when using ultrasonically driven tools", Shewale, S.B. and Briggs, R.D., 2005. Acta orthopaedica, 76(5), pp.647-650.



Manufactured by: ORTHOFIX Srl Via Delle Nazioni 9, 37012 Bussolengo (Verona), Italy Telephone +39 045 6719000, Fax +39 045 6719380





#### Distributed by:



Instructions for Use: See actual package insert for Instructions for Use

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.

