Oscar Pro™

System
Surgical Technique

ORTHOFIX®

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please kindly refer to the product IFU PQOPM, PQPRO, PQOHC and PQOPI that contain instructions for use of the product.

INTRODUCTION

The task of removing PMMA bone cement during revision arthroplasty has always posed a challenge to the surgical team. Difficulty in visualization, ambiguity in discriminating between cement and bone, and unpredictable scheduling can result in unnecessary complications. The worst cases present severely compromised bone stock and the need for expensive prostheses and other reconstructive materials.

Removing these unpredictable problems requires a device that can be relied upon to restore a planned schedule and outcome. Ultrasound, when applied correctly, can make the cement removal part of the operation predictable, safer and by definition more efficient and precise.

PMMA bone cement responds instantly to a vibrating wave-guide. The putty-like consistency of the cement is then easily removed from the endosteum through novel design of the wave-guides (probes). Cortical bone is not affected by the wave guide to the same extent as the cement due to the probe design and the energy levels used. It does not absorb ultrasound as readily as the cement and therefore the surgeon will have awareness of the position of the probe within the bone through both audible and tactile feedback. It is important to refer to the operating techniques discussed later in this manual, because any tool is potentially dangerous if used contrary to the controlled methods described. As technology has advanced, control of the production of ultrasound, its delivery and monitoring are now fully under digital circuitry.

Ultrasound and the Removal of Bone Cement

Ultrasound is the name given to high frequency vibrations (above 16 kHz) that travel through air, liquid or solid media as pressure and displacement waves. In a bounded system, standing waves may be established, which produce a much greater concentration of acoustic energy and scope for rapid local heating at absorption sites. Bone cement is remarkable in that it can maintain a temperature gradient of 200° over a distance of 1mm. Using a series of specially designed handsets and probes in conjunction with a portable ultrasonic generator like the OSCAR PRO™ System, molten cement can be removed rapidly while, the residual cement hardly increases in temperature thus minimizing damage to adjacent bone.

Cement removal using this technique is precise and safe. The risk of bone perforation or fracture is negligible when the OSCAR PRO™ System is used, as the probes are designed to emit a characteristic sound the moment they come into contact with the bone surface. The equipment is simple to operate, and both efficient and predictable in its performance.

Cementless Prosthesis Revision

Over the last 15 years, total joint surgery has moved away from cemented fixation to the use of press-fit prostheses. These are normally either porous or hydroxyapatite coated stems and acetabular shells, which encourage bony in-growth to provide fixation and stability. Inevitably, a percentage of these will require revision and the specific task of separating the implant from the bone will require osteotomes and burrs, leading to a complex and potentially damaging procedure. Precedents exist for the use of ultrasound powered osteotomes and adding this function to the OSCAR PRO™ System was a natural extension to cater to the changing needs in arthroplasty revision surgery. Ultrasound is one of the most effective and safe energy forms available for powering surgical instruments. By careful design of the oscillatory system, collateral damage due to local heating can be minimized to levels significantly below that associated with high-speed burrs and oscillating saws. Low force cutting coupled with precise control of energy delivery to the operating site ensure that ultrasonically powered osteotomes will answer surgical needs in the growing demand for revision arthroplasty.

GENERAL DESCRIPTION

OSCAR PRO™ System is an ultrasonically powered surgical system intended to reduce the challenges associated with revision arthroplasty surgery. The system consists of:

- A mains-powered, portable generator and control unit with a large touch screen display.
- A universal handset connected via a cable encased in silicone rubber to the generator, integrated peristaltic water pump and footswitches.
- A range of single-use probes for cement removal, cementless prosthesis removal and for select osteotomies.

The OSCAR PRO™ System converts electrical energy into mechanical energy in the form of ultrasound waves within a frequency range of 20-100 kHz. The ultrasonic energy is guided along the uniquely engineered metallic probes and concentrated at the head of the probe, causing it to oscillate. Friction is created as the oscillating probe head makes contact with the substrate.

Bone cement preferentially absorbs heat energy caused by the friction at the specific frequency range of 28.0 – 30.0 kHz. On absorbing the heat energy, the physical state of the bone cement changes from a solid to a molten consistency, removing it from the bone interface.

The OSCAR PRO™ technology can also be used to cut through the bone implant interface during cementless revision arthroplasty procedures. The system works using the same technical principles as the cement removal function, however the specific probe shapes separate the implant from its bond with the bone interface. The osteotomy probes are specifically designed to cut through both cancellous and cortical bone.

ADDITIONAL CONTENTS (USER MANUAL)

A full description of the OSCAR PRO™ System is provided within the User Manual (PQOPM) that includes the following additional contents:

- IMPORTANT INFORMATION UPON DELIVERY
- FIRST POWER ON
- CLINICAL INFORMATION
- PRODUCT DESCRIPTION
- SYSTEM SETUP
- OSCAR PRO™ GENERATOR MENU FUNCTIONS MAP
- SYSTEM & MAINTENANCE AREA
- CONNECTION AREA
- AUDIBLE AND VISIBLE FEEDBACK SUMMARY
- INSTRUCTIONS FOR PROCESSING AND REPROCESSING
- TROUBLESHOOTING
- SERVICE & REPAIR
- GENERAL SAFETY STATEMENTS
- DISPOSAL

WARNING: Careful consideration should be given to patients who have pacemakers or other active implanted devices. Interference produced can cause pacemaker or other active implantable device to malfunction, enter an unsafe mode, or cause permanent damage to the device. Consult the pacemaker or other active device manufacturer for specific info.

PROBES

OSCAR PRO™ System includes an extensive portfolio of single use sterile probes made of a titanium alloy, with a broad variety of shapes, sizes and lengths, which can separate and remove bone cement or cut cortical and cancellous bone.

Each probe is attached to the handset via a screw threaded connection and possesses a unique ultrasonic signature, which causes a specific power output relative to probe shape and material properties it comes into contact with. Once connected correctly, the probe acts as a waveguide, focusing and directing the ultrasound energy generated within the handset to the probe tip or blade, enabling the handset to remove bone cement or cut bone.

To mount a probe on the handset within the sterile field, proceed as follows:

1. Detach the handset cable from the bottom of the handset to deactivate the channel.
2. Place the handset horn on the handset holder **(Fig. 1)**.

Code	Description
O4HOLD	OSCAR PRO HANDSET HOLDER

PRECAUTION: In order to avoid excessive torque transmission while coupling/uncoupling the probe to/from the handset, ensure that the handset horn is correctly inserted in the handset holder leaning on a table. Excessive torque may damage probe and/or the handset.

3. Select the appropriate sterile probe according to the surgical procedure to be performed.
4. Couple the selected sterile probe with the handset by hand **(Fig. 2)**.

NOTE: The probe horn is marked with the number of the appropriate wrench to be used for the final tightening.

5. Hold the handset by the shroud with one hand, perform final tightening (clockwise) with the appropriate wrench by the other hand **(Fig. 3)**.
6. Connect the handset cable to the handset.
7. Select the desired surgical function, activate the appropriate channel, and perform the probe scan via the handset button.

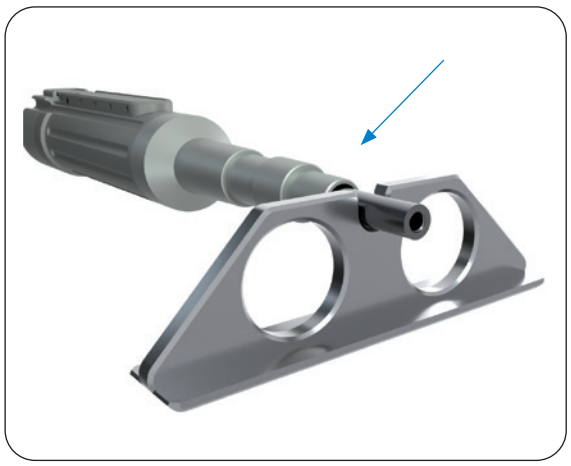

Fig. 1 Handset holder and Horn positioning

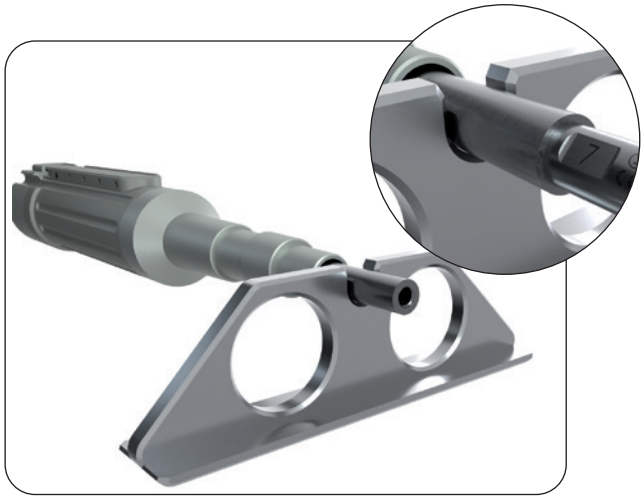

Fig. 2 Probe coupling

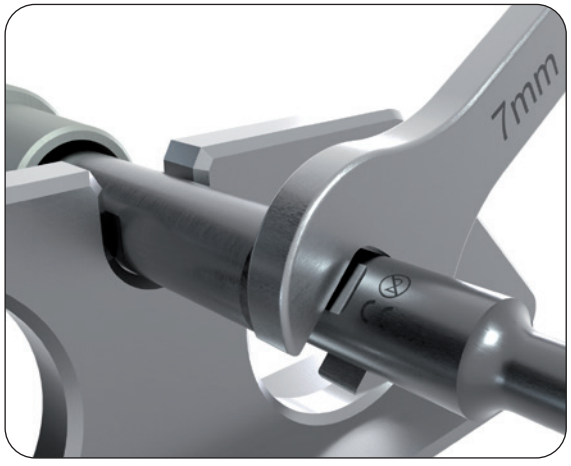

Fig. 3 Final tightening

SURGICAL PROCEDURES

Before starting surgical procedure with OSCAR PRO™ the following WARNINGS and PRECAUTIONS shall be taken into account.

WARNINGS: During use, warning messages may be displayed on the screen in relation to a specific event or machine status. Refer to section Troubleshooting of the user manual (PQOPM) for the meaning of each message.

In case of excessive load, the OSCAR PRO™ warns the user with specific luminous and acoustic signals. See sections “Audible and Visible Feedback” and “Troubleshooting” section within the User Manual (PQOPM).

The probe may be damaged if it touches a metal surface while activated. If this happens, remove the probe and replace it with a new one.

Sparks may be produced if the probes touch anything metal while activated. This equipment is not to be used in the presence of flammable gases and liquids nor in an oxygen rich environment to prevent fire ignition.

Ultrasonic probes can break under excessive use in extreme conditions, e.g. when excessive load is applied. The probe could break into two or more fragments with the main fragment remaining attached to the handset. All fragments must be retrieved immediately from the surgical site. The fragments should be checked to ensure that no further pieces are missing. It is possible that a fragment is propelled outside of the surgical cavity. Diagnostic imaging, such as X-ray, must be used if a fragment cannot be found to confirm that the broken piece is outside of the surgical cavity.

PRECAUTIONS: OSCAR PRO™ must not be used adjacent to or stacked with other electrical equipment that may interfere with its normal functionality or decrease its immunity. Minimum distances to other electrical medical devices or electrical appliances are stated in the EMC information provided in OSCAR PRO™ User Manual (PQOPM). If adjacent or stacked use is necessary, the generator should be observed to verify normal operation.

Ensure that the software status bar, positioned in the right corner of the header, is continuously blinking as this means that Graphic User Interface is operational.

In case of high loads and prolonged use, in exceptional cases beyond the recommended 10s duty cycle, the handset may accumulate heat up to 45°C. Overheating might affect the user and may reduce the handset transducer’s life. Audible and visible alarms inform the user when the system is approaching this condition. Proceed by changing the handset in use or by reducing the active time of the duty cycle in favour of the cooling time, until the temperature limit returns within the acceptable range.
Do not use probes if packaging is open or damaged.
Avoid contact between the energized probe and metal surfaces. The contact in non-visible areas can be easily detected by the high pitch noise that occurs at the contact with a metal surface.
Do not allow the probe to come into firm contact with soft tissue, as this will cause a friction burn in case the probe is energized.

PRECAUTIONS: Extra care should be taken when operating the energized probe in the vicinity of nerves.

If a probe becomes damaged during a procedure or its performance significantly decreases, it must be replaced with a new one.
Do not allow blood or any form of contamination on the mating surfaces, as this will cause erosion and materially affect the ultrasonic conduction of the waveguide, making it less efficient.

The probe may become hot during use. Do not allow the probe to come into contact with soft tissue after its usage.

Irrigation, either manual or assisted by the OSCAR PRO™ irrigation function, must be used whenever temperature control is deemed necessary to limit overheating effects.

Refer to section 5.6 of OSCAR PRO™ User Manual (PQOPM) for additional details.

Cement Removal

OSCAR PRO™ System facilitates the removal of bone cement during revision arthroplasty procedures using ultrasound to soften the cement shell holding the implant in place. Specific probes are deployed in sequence to collect and remove the softened cement from the host bone. This technique reduces the need to use manual force and minimizes the risk of bone fracture and perforation.

PROBE SELECTION

Probes have different designs to perform cement removal. The probes designed to cut through regions of compact cement have heads incorporating two or more perforations or grooves. Friction between the bone cement and the high velocity tip surface of the ultrasonic probe causes rapid heating at points of contact. A small volume of cement melts, and under the advancing impetus of the probe tip this molten cement is forced through the ports in the head, or the grooves in the body, solidifying behind it when the ultrasonic energy is turned off. Probes designed solely for scraping material from the endosteal surface of the bone are not equipped with perforations in the probe head. Once broken up, the cement can readily be removed, either by withdrawing the probe with adhering cement or using conventional instruments.

Descriptions of individual probe designs follow.

Piercers

The Piercer is a round, spear shaped device with 4 perforations in the head **(Fig. 4)**. A short Piercer with a small tip diameter (i.e. 6MM) is primarily used to create longitudinal channels in the proximal cement mantle to weaken the integral cement mass and permit segmental removal with conventional instruments. Longer Piercers with larger tip diameters are subsequently used for fenestrating the distal plug of cement to provide a clear channel, which can then be enlarged using the long Scraper.

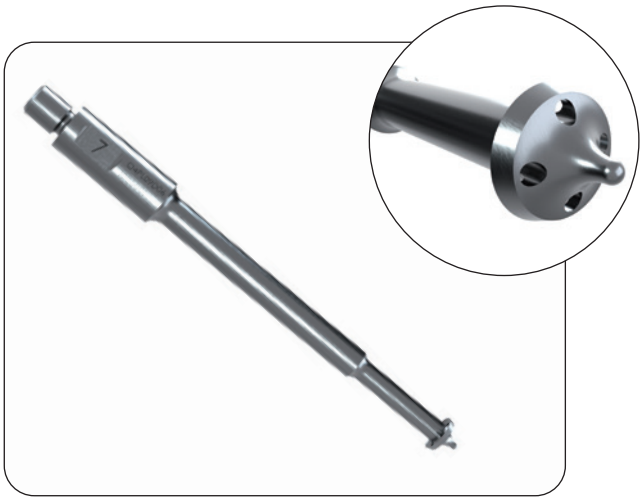

Fig. 4 Example of Piercer probe for cement removal

The Piercer will detune when it is in contact with bone, unless it is circumferentially compressed by bone, in which case detuning will not occur but there will be physical resistance. When the Piercer strikes cortical bone there is a high pitched audible squeaking noise and resistance is felt.

The Piercer is supplied in different tip diameters and different lengths **(Table 1)**.

Code	Description
99-O4PL09D06	OSCAR PRO TITANIUM CEMENT PIERCER L90MM D6MM STERILE
99-O4PL18D06	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-O4PL27D08	OSCAR PRO TITANIUM CEMENT PIERCER L270MM D8MM STERILE
99-O4PL09D10	OSCAR PRO TITANIUM CEMENT PIERCER L90MM D10MM STERILE
99-O4PL18D10	OSCAR PRO TITANIUM CEMENT PIERCER L180MM D10MM STERILE
99-O4PL27D10	OSCAR PRO TITANIUM CEMENT PIERCER L270MM D10MM STERILE

Curved Piercer

The Curved Piercer **(Fig. 5)** is designed to assist in the removal of the cemented acetabular cup.

The Scraper is supplied in one tip diameter and length **(Table 2)**.

Code	Description
99-O4AL09DNA	OSCAR PRO TITANIUM CURVED CEMENT PIERCER L90MM STERILE

Flat Piercer

The flat Piercer **(Fig. 6)** is designed to assist in the removal of the tibial component of the cemented knee prosthesis.

The Scraper is supplied in one tip diameter and length **(Table 3)**.

Code	Description
99-O4PSFB8	OSCAR PRO TITANIUM FLAT CEMENT PIERCER L90MM STERILE

Fig. 5 Curved Piercer probe for cemented acetabular cup

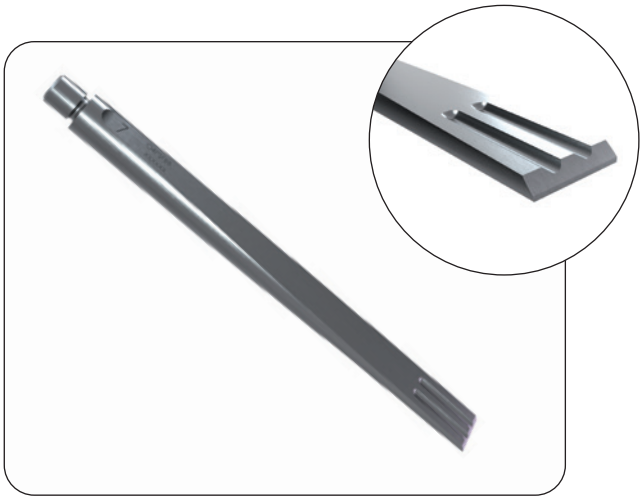

Fig. 6 Flat Piercer probe for cemented knee prosthesis

Scrapers

The Scraper is a spear shaped device with no perforations within the head **(Fig. 7)**. The cutting edge of the Scraper is machined at an angle of 20 degrees to the axis of the probe, and it is used for removing well bonded proximal or distal cement and membrane from the endosteal surface by applying a reverse scraping action.

The Scraper is supplied in different tip diameters and different lengths **(Table 4)**.

Code	Description
99-O4SL09D06	OSCAR PRO TITANIUM CEMENT SCRAPER L90MM D6MM STERILE
99-O4SL18D06	OSCAR PRO TITANIUM CEMENT SCRAPER L180MM D6MM STERILE
99-O4SL09D08	OSCAR PRO TITANIUM CEMENT SCRAPER L90MM D8MM STERILE
99-O4SL18D08	OSCAR PRO TITANIUM CEMENT SCRAPER L180MM D8MM STERILE
99-O4SL27D08	OSCAR PRO TITANIUM CEMENT SCRAPER L270MM D8MM STERILE
99-O4SL09D10	OSCAR PRO TITANIUM CEMENT SCRAPER L90MM D10MM STERILE
99-O4SL18D10	OSCAR PRO TITANIUM CEMENT SCRAPER L180MM D10MM STERILE
99-O4SL27D10	OSCAR PRO TITANIUM CEMENT SCRAPER L270MM D10MM STERILE

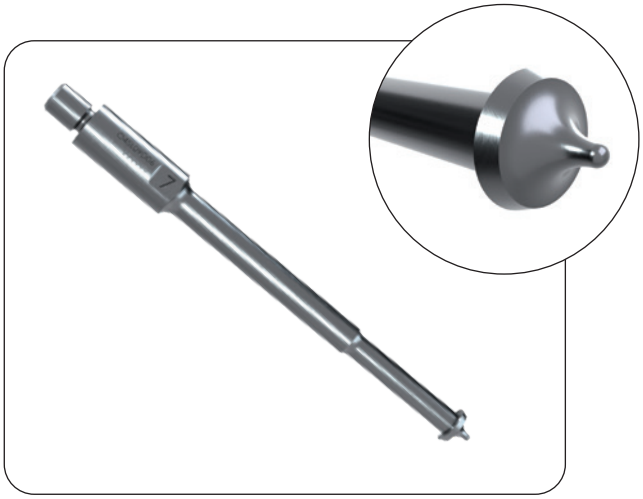

Fig. 7 Example of Scraper probe for cement removal

Hoes

The Hoe is designed to remove small pieces of cement during upper extremity revisions. Similar to the reverse Scraper, the Hoe probe is used in a back scraping motion to remove cement from thinner cortices and in narrow canals **(Fig. 8)**.

The Hoe is supplied in two different tip diameters and one length **(Table 5)**.

Code	Description
99-O4HL18D06	OSCAR PRO TITANIUM CEMENT HOE L180MM D6MM STERILE
99-O4HL18D08	OSCAR PRO TITANIUM CEMENT HOE L180MM D8MM STERILE

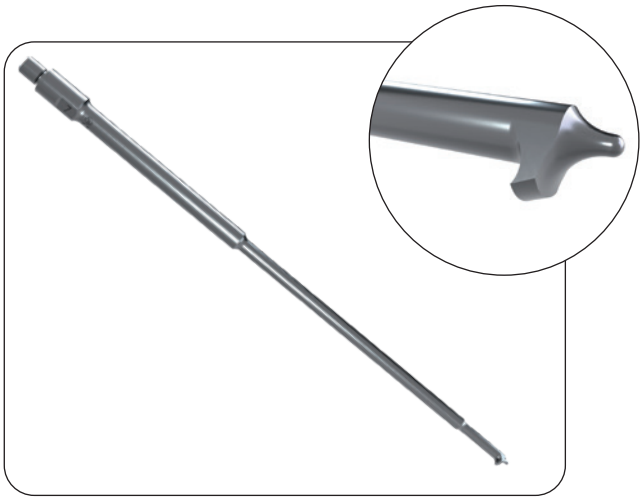

Fig. 8 Example of Hoe probe for cement removal

Cement Plug Extractor

The Cement Plug Extractor Probe **(Fig. 9)** is designed to penetrate the cement in a forward motion and, connected to the slap hammer **(Fig. 10)**, allows the user to remove larger pieces of cement and the cement plug. The technique relies on the probe being embedded in cement, which is allowed to solidify. Instructions for use are provided in the surgical steps of this Operative Technique.

The Cement Plug Extractor is supplied in one tip diameter and length **(Table 6)**.

Code	Description
99-O4EXP	OSCAR PRO TITANIUM CEMENT PLUG EXTRACTOR L180MM STERILE
O4IPL200	OSCAR PRO SLAP HAMMER
99-O4EXP27	OSCAR PRO TITANIUM CEMENT PLUG EXTRACTOR L270MM STERILE

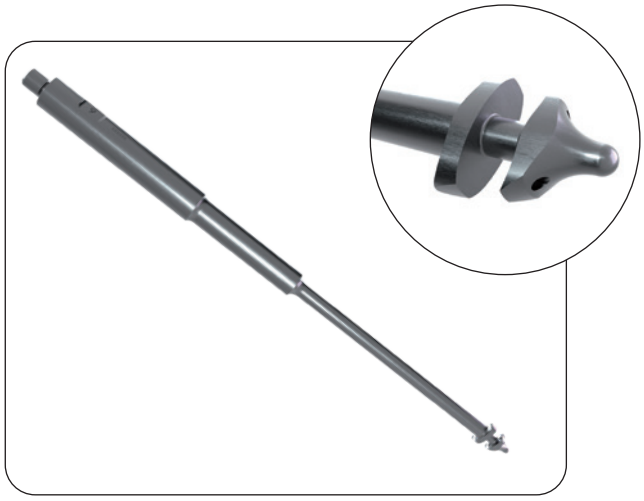

Fig. 9 Cement Plug Extractor

Fig. 10 Slap hammer

SURGICAL STEPS

NOTE: The following description relates to hip surgery but is equally applicable to other forms of revision arthroplasty in which cement removal is necessary.

To facilitate cement removal the patient should be positioned appropriately to allow the femur to be visualized safely through the surgeon's preferred approach. Following removal of the femoral component it is important to have adequate access to the cement. Remove bone from the upper part of the greater trochanter, if necessary, to allow straight access to cement within the femoral canal.

Removal of the Proximal Cement Mantle

The proximal cement in the upper third of the shaft is often loose, with a membrane between it and the bone. This cement can be removed simply, using short Piercer with a small tip diameter to cut longitudinal channels through it **(Fig. 11-A)**. When the cutting edge of the Piercer is placed in contact with the cement, the friction generated by the ultrasonic beam will heat up the cement, which softens and extrudes through the holes in the side flanges. The Piercer is then pushed gently down the femoral canal in contact with bone to remove a trough of cement.

This trough can be extended within the femoral canal **(Fig. 11-B)**. It is common to make 3 longitudinal troughs within the cement at approximately 120-degree intervals. The amount of force required is similar to that needed to push a knife through hard butter.

PRECAUTION: Continuous probe motion is recommended in order to minimize contact duration with the ultrasonic tip and minimize heat build-up. In this instance a more frequent intermittent use must be applied.

NOTE: When using ultrasound to remove cement, irrigation should be carried out between operating cycles of cement softening rather than during to prevent progressive heat gain of the bone cavity and remove, with suction, all of the cement fragments. This is particularly true when the cortex is thin, and in the humerus because of the proximity to the radial nerve.

PRECAUTION: During use, the probe for cement removal may reach a temperature up to 120°C, depending on the use. Irrigation, either manual or assisted by the OSCAR PRO™ irrigation function, must be used whenever temperature control is deemed necessary to limit overheating effects such as bone necrosis around the cemented area.

According to user's preference, irrigation can be delivered manually or by the interconnected water pump of the OSCAR PRO™ System (in this case, before starting the surgical procedure, ensure the irrigation kit is set up as described in section 4.3 "System Set-Up for Use" of the User Manual - PQOPM).

Fig. 11-A Femoral canal entry

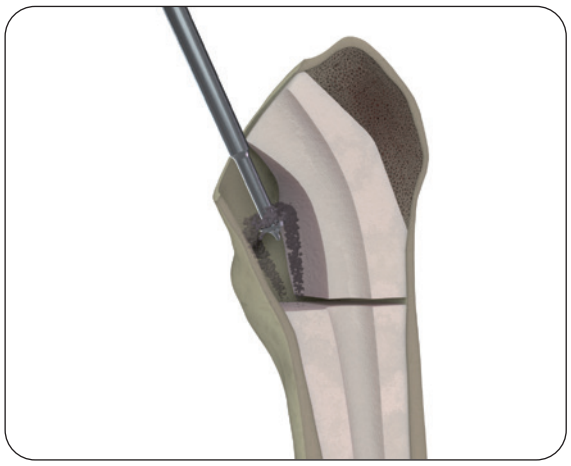

Fig. 11-B Proximal longitudinal channel

Once the 3 longitudinal grooves have been made, it is necessary to make circumferential grooves at approximately 1.5 to 2 cm intervals down the cement mantle. This can be done using either the Piercer or a Scraper **(Fig. 11-C)**. The fragments of bone cement can then be folded into the canal and removed with forceps. The proximal cement is removed incrementally, using this technique, down to the level of the well fixed cement by using subsequent longer probes.

Fig. 11-C Circumferential groove

Removal of the Well Bonded Cement and Residual Membrane

Any residual well bonded cement that remains after removal of the proximal cement mantle, and the fibrous membrane that is usually adherent to the endosteal surface, may be removed using the Scraper that cuts by focusing ultrasonic energy on the retroverted cutting edge at the back of its spear shaped tip.

The cutting edge is put into contact with the cement or the membrane and withdrawn with a moderate amount of force for removing cement, or just gentle pressure for removing the membrane **(Fig. 12)**.

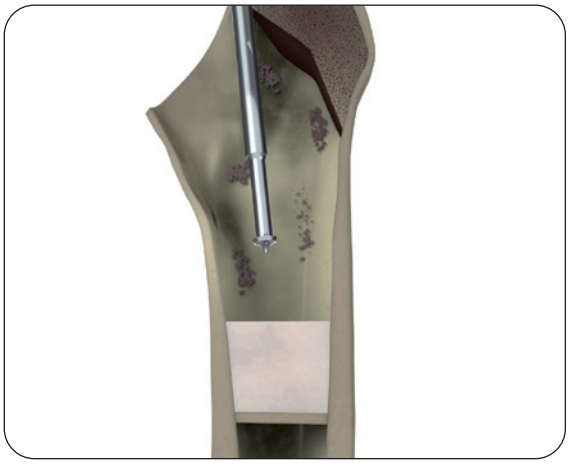

Fig. 12 Well bonded cement removal

Removal of the Distal Cement Mantle and Cement Restrictor

Removal of the cement plug is performed using the Piercer. The Piercer focuses ultrasound to the very tip of its spear shaped head causing the cement to liquefy at the point of contact. The liquid cement then flows backwards through the perforations in the head and solidifies behind it.

The Piercer is gently pushed into the cement plug and advances between 1.5 and 2 cm until the plug has been perforated **(Fig.13)**. The switch on the handset is released and the handset can be removed a few seconds later; this short period of time allows the cement to re-solidify behind the flange for most efficient removal.

Fig. 13 Plug perforation

If the Piercer is pushed with too much force, the energy at the tip will reduce and the system will work less efficiently. An audible alarm on the OSCAR PRO™ System will alert the surgeon of this eventuality.

Once the plug has been perforated, it is necessary to remove the cement that is in contact with the femoral diaphysis. This can be done either with a long Scraper or, if the femur is too narrow, with a long Piercer with a small tip diameter **(Fig. 14)**.

There is sometimes a polythene cement restrictor distal to the cement plug. The ultrasonic device will cut through polythene, but it does so at a slower rate than when cutting through bone cement. In these circumstances it is necessary to wait for a few seconds before advancing the probe, as polyethylene absorbs more ultrasonic energy than polymethylmethacrylate.

Fig. 14 Distal cement removal

Use of the Extraction Probe

For rapid removal of the cement plug and under certain conditions, the OSCAR PRO™ System incorporates a Cement Plug Extractor probe and a slap hammer. The Cement Plug Extractor, like the Piercer, is designed to penetrate the cement in a forward motion.

The surgeon sinks the Cement Plug Extractor into the cement plug up to a reasonable depth and then immediately rotates the probe and handset 90 degrees **(Fig 15)**.

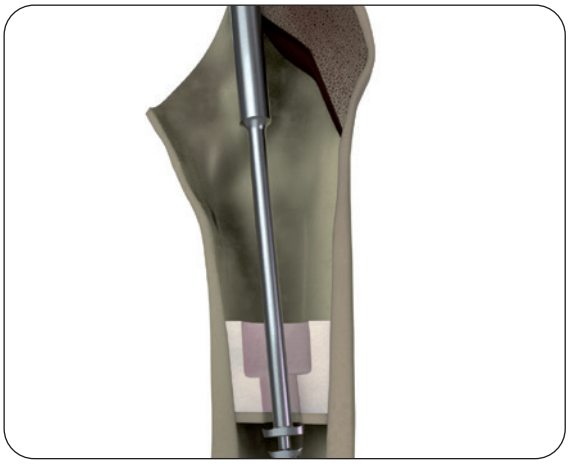

Fig. 15 Plug perforation

By removing the power cable and holding the probe in situ in the canal for 30 seconds, the cement re-hardens around the probe. The handset can then be detached and the slap hammer connected and used to remove the distal cement plug en-mass **(Fig 16)**.

X-rays will give good indication of when the extraction probe can be used. Ensure that there is good bone stock, delamination of the cement, an even tapered canal, and the cement lies above the isthmus.Incorrect positioning of the probe can easily lead to fracture.

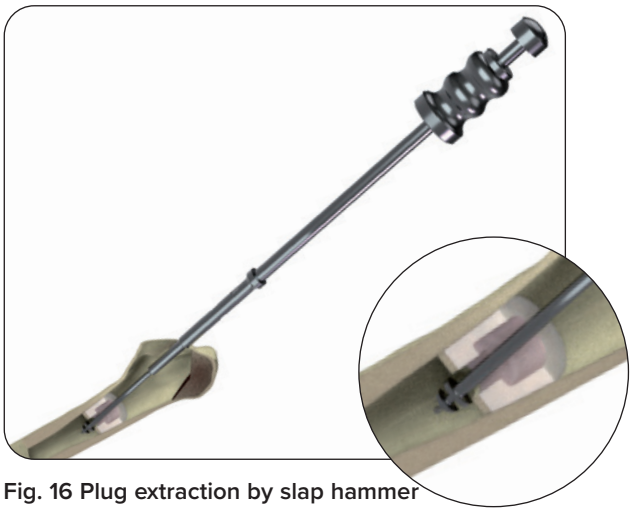

Fig. 16 Plug extraction by slap hammer

Remove Cement From Acetabular Cup

When using OSCAR PRO™ System, the operating physician/surgeon must minimize the contact between the activated probe and metal components, especially when considering its application to the acetabular cup.

PRECAUTION: Avoid contact between the energized probe and metal surfaces. The contact in non-visible areas can be easily detected thanks to the high pitch noise that occurs at the contact with the metal surface.

By reference to the x-rays, identify and locate all metallic parts associated with the prosthesis. The Curved Piercer can be used to remove cement posterior to the cup by making a series of curved slots extending from the exposed circular profile towards the center of the cemented hemispherical surface **(Fig. 17)**. Four or five slots should be sufficient to loosen the acetabular component, which may then be removed by careful use of a cement chisel.

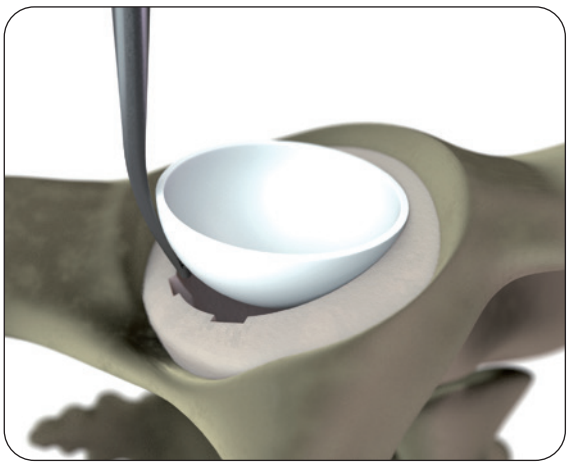

Fig. 17 Cemented acetabular cup removal

Cementless Prosthesis Removal

Ultrasound remains a safe and efficient energy form used for cementless prosthesis revision. When revision of a cementless prosthesis is necessary, the implant is removed by cutting through the interface between the bone and the implant.

Information reported in the Paragraph below as well as Figure 18 and 19 refer only to product with software version 1.1.

Selectable power levels are provided in order to accommodate surgical needs. Once the system is ready the power level is set to 1 and it is then possible to increase it during the Surgical procedure if deemed necessary by the surgeon. In order to move on to “high power levels” 5 and 6 a confirmation on the pop-up massage is necessary. Irrigation level suggested “3 or higher” in the message is to be considered as a general guideline and should be adjusted based on surgeon’s expertise, pathology and anatomy of the patient. A table with percentage power provided by each level is reported.

Tissue removal rate ranges from the lowest (level 1) to the highest (level 6).

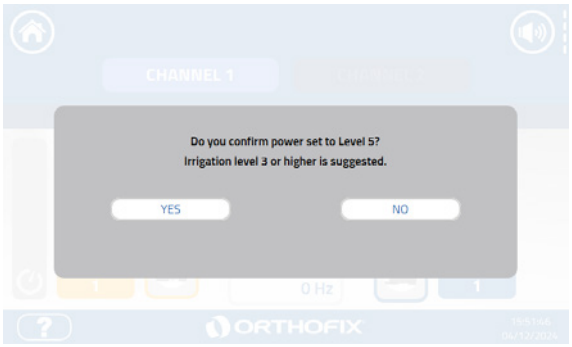

Fig.18 Pop-up message

Power level	Percentage Power
6	100%
5	92%
4	84%
3	76%
2	68%
1	60%

Fig.19 Power level to Percentage Power table

Irrigation is mandatory while removing cementless prosthesis.

According to user’s preference, irrigation can be delivered manually or by the interconnected water pump of the OSCAR PRO™ System (in this case, before starting the surgical procedure, ensure the irrigation kit is set up as described in section 4.3 “System Set-Up for Use” of the User Manual - PQOPM).

PRECAUTIONS: When inserting the irrigation line in the pump, make sure that the intended flow direction matches the indication arrow on the pump cover.

When enabling the irrigation function, verify that spillage is not occurring along the line from water bag to handset. DO NOT operate pump with pump cover in raised position. Rollers might pinch loose clothing or fingers, resulting in personal injuries.

NOTE: It is important to maintain a steady flow of saline around the prosthetic stem during insertion of osteotomes so metal on metal interface is kept cool while the active edges of the osteotome are cutting bone.

NOTE: To minimize the risk of thermal damage to the cut interface between the bone and the implant, within the 30 seconds maximum operation period, intermittent energised sequences limited to 5 seconds are strongly recommended. In case of an exceptional clinical need to exceed this timing recommendation, the probe contact point must be changed frequently.

PRECAUTIONS: During bone cutting, bone necrosis may result if the probe is not moved relative to bone. A continuous probe motion is recommended to minimize contact duration with the ultrasonic tip and heat build-up. In this instance a more frequent intermittent use must be applied.

To ensure effective cooling, the irrigation flow shall be directed on the tip of the probe by adjusting the direction of the dedicated irrigation nozzle **(Fig. 20)**.

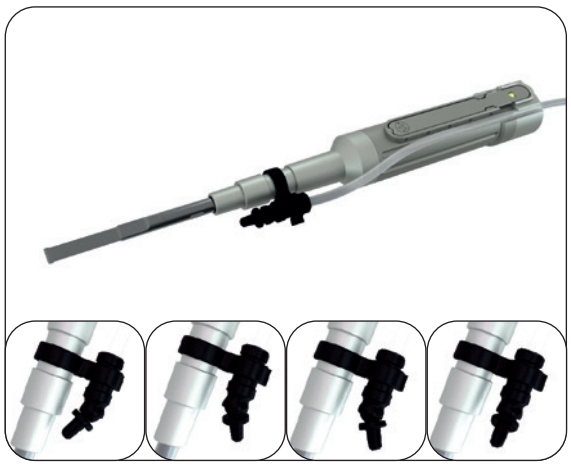

Fig. 20 Irrigation nozzle

PRECAUTIONS: Precaution applicable only to product with software version 1.1. During osteotomy and cementless prosthesis removal procedures, power levels 5-6 may cause increased probe wear and breakage. To minimize these risks, always use irrigation and suction tools, and exercise extra caution when applying force to the probe.

Probe Selection

When cementless revision is performed, the implant is removed by cutting through what is a substantial area of cancellous bone interface surrounding the stem. This is performed using a variety of flat or curved and smooth or serrated osteotomes **(Fig. 21-22-23-24-25)** coupled to the handset.

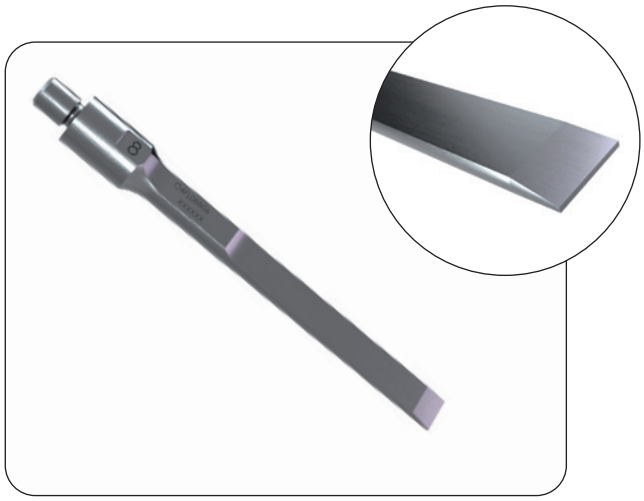

Fig. 21 Flat and smooth blade osteotome

NOTE: A high-pitched noise will be created when the active probe being is in contact with the prosthesis.

PRECAUTIONS: During cementless prosthesis removal, if a deep cut is required and probe 99-O4OL18B10 is to be used, first use shorter probes or other available tools to initiate the cut and create a pilot hole. Only then should probe 99-O4OL18B10 be used to complete the procedure.

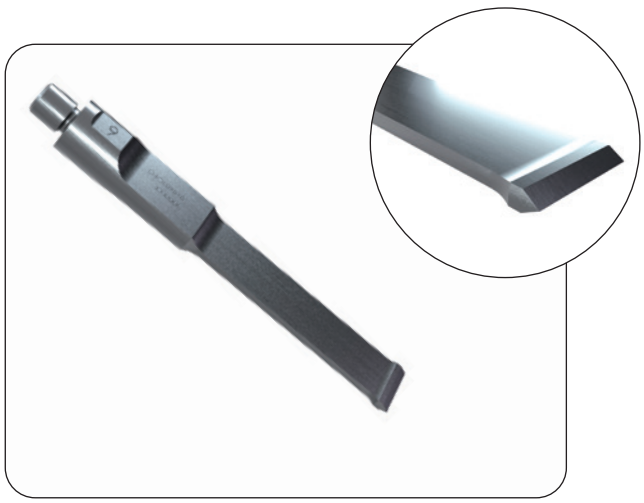

Fig. 22 Example of Flat and smooth blade probe

Code	Description
99-O4FL08B06	OSCAR PRO TITANIUM FLAT BLADE SMOOTH L80MM W6MM STERILE

Code	Description
99-O4OL09B10	OSCAR PRO TITANIUM FLAT BLADE SMOOTH L90MM W10MM STERILE

Code	Description
99-O4OL18B10	OSCAR PRO TITANIUM FLAT BLADE SMOOTH L180MM W10MM STERILE

Code	Description
99-O4CL09B10	OSCAR PRO TITANIUM CURVED BLADE SMOOTH L90MM W10MM STERILE

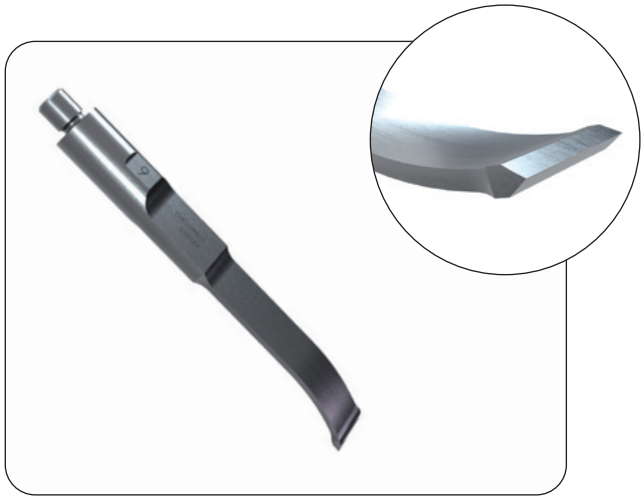

Fig. 23 Curved and smooth blade osteotome

Code	Description
99-O4SCL08B04	OSCAR PRO TITANIUM CURVED BLADE SERRATED L80MM W4MM STERILE

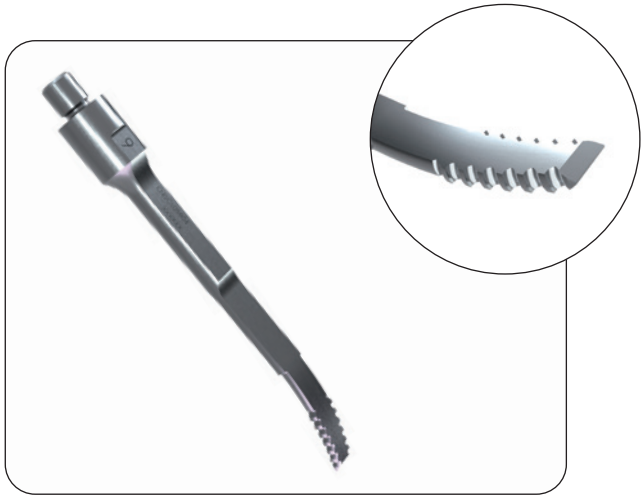

Fig. 24 Curved and serrated blade osteotome

SURGICAL STEPS

Cementless revision is performed by introducing the osteotome beside the prosthesis stem to form a series of extended slots that effectively isolate the implant from the host bone. In some cases it may be necessary to cut into cortical bone when the depth of cancellous bone is limited.

Acetabular Cup Removal

The curved smooth or serrated osteotome probe is first used to create slots around the circumference of the cup **(Fig. 25)**.

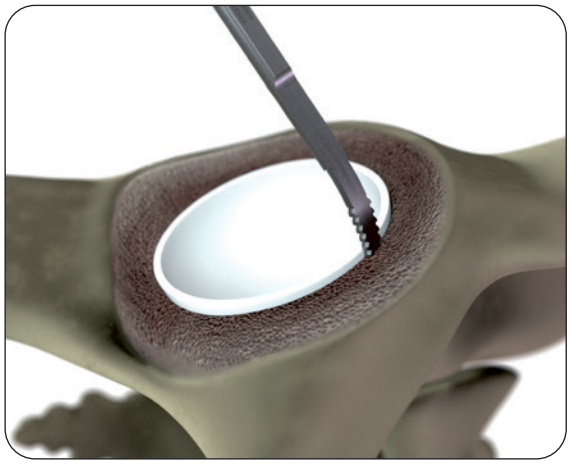

Fig. 25 Slots creation

Once the slots are created, the curved serrated probe can be used in a lateral motion to cut the remaining bony ingrowth interface **(Fig. 26)**.

NOTE: It is important to remember to activate the probe before advancing into a previously created slot and to not create manual pressure before activating the probe. Doing so may lead to the probe improperly tuning and possibly breaking during use.

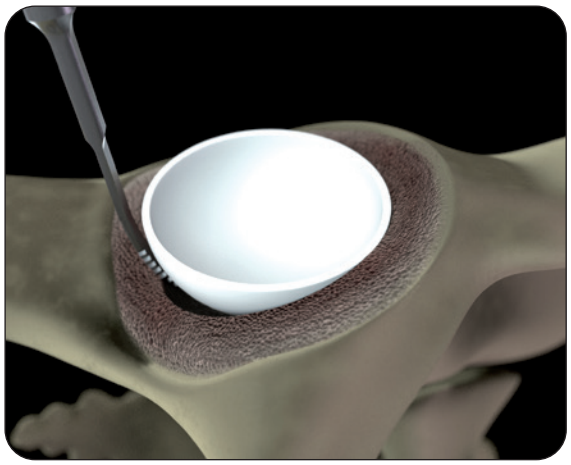

Fig. 26 Cup removal

Stem Extraction from Femur

A flat and smooth blade osteotome probe is used to create slots in the cancellous bone interface surrounding the stem **(Fig. 27)**.

Fig. 27 Slots creation

The same probe, or the curved and smooth blade osteotome, can then be used to break the remaining bond between bone and prosthesis **(Fig. 28)**.

Fig. 28 Remaining bond breakage

Tibial and Femoral Component Extraction

The steps in removing the knee components with the OSCAR PRO™ bone cutting probes are similar to the stem extraction steps in hip revisions. A flat and smooth blade osteotome probe is used to penetrate the interface and create slots under the prosthesis **(Fig. 29)**.

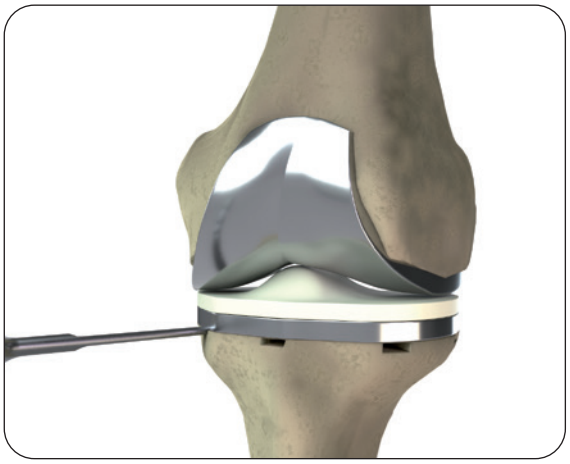

Fig. 29 Slots creation

The curved serrated probe can then be used laterally to break the remaining bond between bone and prosthesis **(Fig. 30)**.

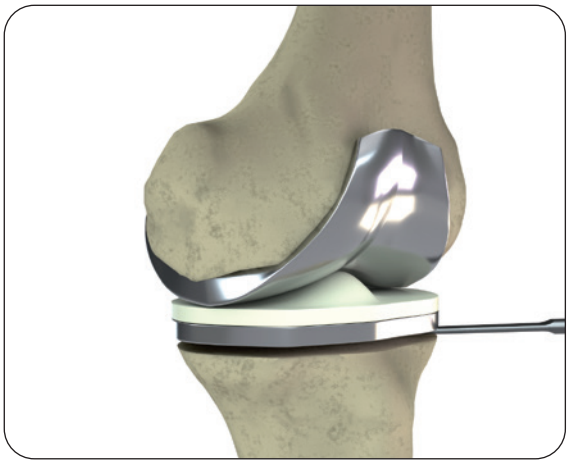

Fig. 30 Remaining bond breakage

Osteotomies

The portfolio of probes designed to perform cementless revision procedures expands the possibilities of the OSCAR PRO™ System to enable select osteotomies. Osteotomy blades vary in their geometry and length in order to meet different clinical and user needs, allowing precise and controlled bone cutting.

Information reported in the Paragraph below as well as Figure 31 and 32 refer only to product with software version 1.1.

Selectable power levels are provided in order to accommodate surgical needs. Once the system is ready the power level is set to 1 and it is then possible to increase it during the Surgical procedure if deemed necessary by the surgeon. In order to move on to “high power levels” 5 and 6 a confirmation on the pop-up massage is necessary. Irrigation level suggested “3 or higher” in the message is to be considered as a general guideline and should be adjusted based on surgeon’s expertise, pathology and anatomy of the patient. A table with percentage power provided by each level is reported.

Tissue removal rate ranges from the lowest (level 1) to the highest (level 6).

NOTE: Irrigation is mandatory while performing osteotomies.

Irrigation is mandatory while performing osteotomies.

According to user’s preference, irrigation can be delivered manually or by the interconnected water pump of the OSCAR PRO™ System (in this case, before starting the surgical procedure, ensure the irrigation kit is set up as described in section 4.3 “System Set-Up for Use” of the User Manual - PQOPM).

NOTE: It is important to maintain a steady flow of saline around the bone during insertion of osteotomes so the bone is kept cool and lubricated while the active edges of the osteotome are cutting. Limit intermittent energized sequences to 5 seconds to minimize damage to the cut bone.

PRECAUTIONS: During bone cutting, bone necrosis may result if the probe is not moved relative to bone. A continuous probe motion is recommended in order to minimize contact duration with the ultrasonic tip and minimize heat build-up. When motion is slow, proceed cutting the bone in more instances between pauses.

To ensure effective cooling, direct the irrigation flow on the tip of the probe by adjusting the direction of the dedicated irrigation nozzle (Fig. 33).

PRECAUTIONS: Precaution applicable only to product with software version 1.1.

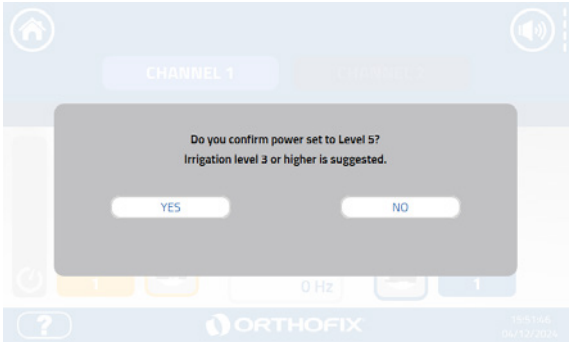

Fig.31 Pop-up message

Power level	Percentage Power
6	100%
5	92%
4	84%
3	76%
2	68%
1	60%

Fig.32 Power level to Percentage Power table

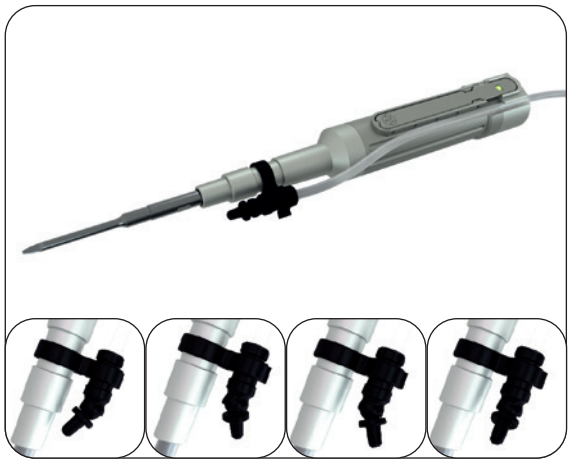

Fig. 33 Irrigation nozzle

During osteotomy and cementless prosthesis removal procedures, power levels 5-6 may cause increased probe wear and breakage. To minimize these risks, always use irrigation and suction tools, and exercise extra caution when applying force to the probe.

NOTE: To reduce the risk of thermal damage to the bone undergoing the osteotomy, within the 30 seconds maximum operation period, intermittent energized sequences limited to 5 seconds are strongly recommended. In case of an exceptional clinical need to exceed this timing recommendation, the probe contact point must be changed frequently.

The wedge tip osteotome **(Ref. Figure 34)** is the appropriate probe to cut the first cortex and perform procedures such as the Extended Trochanteric Osteotomy (ETO) and the Tibial Tubercle Osteotomy (TTO).

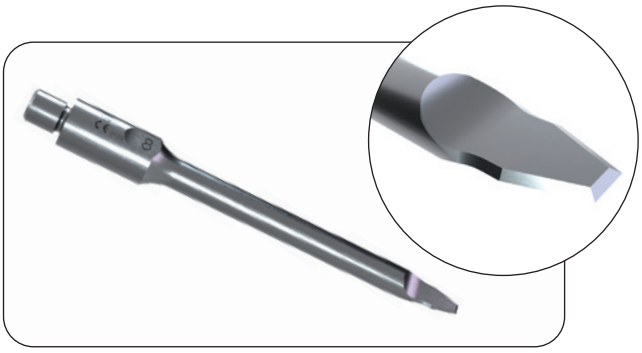

Fig. 34 Wedge osteotome

Code	Description
99-O4EL09B06	OSCAR PRO TITANIUM OSTEOTOME WEDGE TIP L90MM W6MM STERILE

ETO

Performing an ETO

The first decision in performing an ETO is the length of the osteotomy required, which is determined by the amount of exposure required. In general, 12-15 cm is adequate to allow sufficient exposure to greatly aid stem or cement extraction. In the case of long fully coated cementless stems, a much longer osteotomy may be required.

A posterolateral approach to the femur is preferred, through the posterior margin of vastus lateralis. Care should be taken to not damage the gluteus medius or vastus lateralis tendons on the greater trochanter. Using a ruler, the length of the osteotomy should be measured and marked. The starting point should be posterior to the greater trochanter. The osteotomy is marked out in pen along the posterior border of the femur to the length required **(Fig. 35)**. Care must be taken to ensure adequate bone is left posteriorly to prevent inadvertent fracture.

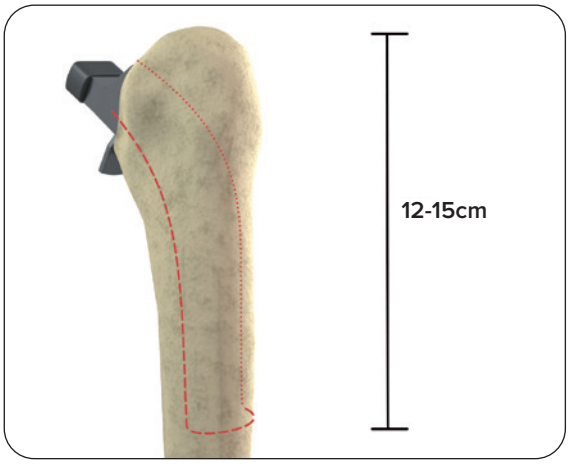

Fig. 35 ETO marked out

The osteotomy is made in a sequential manner from proximal to distal using the OSCAR PRO™ wedge tip osteotome (CODE 99-O4EL09B06). Once the required length is reached the anterior extension of the osteotomy is made. Care must be taken to ensure the wedge tip osteotome has passed through the full thickness of the cortex at all points to ensure the osteotomy opens safely.

Osteotomes are placed along the length of the osteotomy and lifted together to open the femur anteriorly. The anteromedial cortex will fracture in a controlled manner allowing the osteotomy to open.

If a stem is in situ, the osteotomes should be directed anteriorly to lift the anterior femur off the stem, taking care not to lever on the posterior bone. Once opened, the osteotomy can be retracted anteriorly, maintaining the anteromedial soft tissue hinge **(Fig. 36)**.

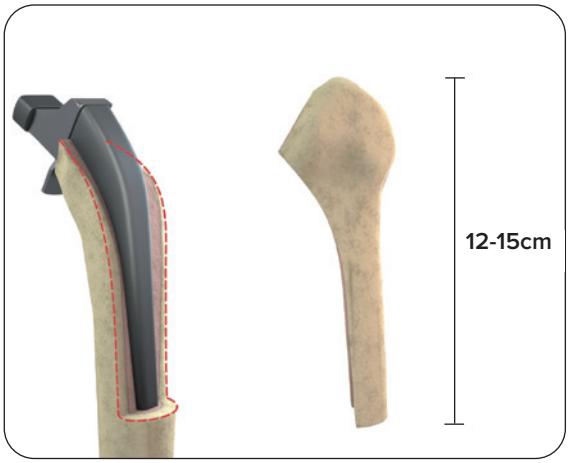

Fig. 36 ETO opened, allowing easy access to the proximal femur

Once stem or cement removal has been performed the osteotomy can be closed. This should be anatomical, taking care to not allow the anterior femur to migrate proximally. Closure can be via cerclage wires or cables.

Extension of an ETO

If further length is needed, for example if a long cementless stem is still well fixed, then the above technique can be repeated for a further distance, usually to the end of the stem. If the proximal femur has a significant varus deformity, which is often seen in loosening of stems after many years, the deformity can be corrected by performing an additional osteotomy on the posterior portion of the proximal femur. The osteotomy should be performed greater than 1 cm proximal to the anterior osteotomy to ensure there is a step rather than a complete transverse osteotomy at one level.

TTO

Use the standard skin incision for the parapatellar approach, but extend this approximately 12 - 20 cm below the joint line. Use the ruler and skin marker pen to plan and mark the proposed osteotomy site, which should be perpendicular to the long axis of the tibia **(Fig. 37)**.

This should be 8 -10 cm in length, 1 cm thick and 2 cm wide (but individual patient sizes should be taken into consideration). Ensure that the TTO includes the entire length of the patella tendon insertion. The distal limb is tapered obliquely to minimize a stress riser.

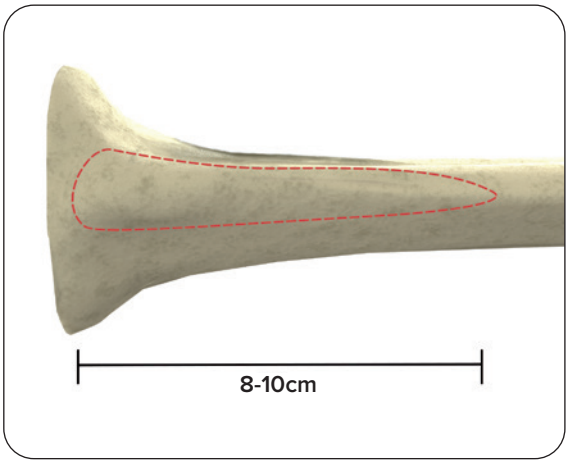

Fig. 37 TTO marked out

Use the OSCAR PRO™ wedge tip osteotome (CODE 99-O4EL09B06) to make osteotomy from medial to lateral direction while remaining perpendicular to the long axis of the tibia. Cut through the medial cortex and partially through the lateral cortical bone. Ensure that the lateral periosteal hinge is left intact to prevent proximal migration of the TTO and serve as a blood supply to it. Side-by-side osteotomes placed in the osteotomy site are then used to lever the TTO anteriorly en mass and expose the proximal tibia and medullary canal **(Fig. 38)**.

The prosthetic components and any cement within the tibial canal can then be removed with the aid of the OSCAR PRO™ cement removal device.

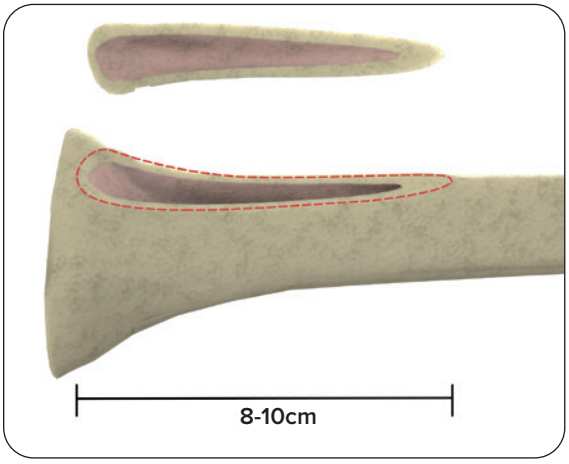

Fig. 38 Exposed TTO site with an intact lateral periosteal sleeve

TROUBLESHOOTING

Probe Stuck in Cement

The probe getting stuck in the cement is most likely to occur when a Piercer is being used. If the tip of the Piercer is pushed too deeply into the cement and allowed to remain in situ, then the cement behind the tip is liable to solidify and trap the probe. If this happens, the load on the probe may be excessive, preventing normal resonance because the mass of cement is now attached to the probe. An error message will appear on the generator screen warning the user about probe in 'stuck in cement' mode.

In order to remove the probe from cement, energize the handset but do not apply any pressure on the handset for the first 2 seconds of use (this gives the channel a better chance to find a resonant feature). The generator will perform repeated scans of the handset, sounding a double beep as it does so. While this occurs, gently remove the probe from the cement. When free from cement, the channel mode will return to normal operation.

This procedure may lead to an OVER-TEMPERATURE message on the screen. Allow the channel to cool for several minutes or switch channels. When the channel resets, attempt removal again. This process may take a couple of attempts, depending how deeply the probe is stuck in the cement.

NOTE: For additional troubleshooting refer to Chapter 10 of OSCAR PRO™ User Manual (PQOPM).

Oscar Pro™

System

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.

Electronic Instructions For Use available at the website http://ifu.orthofix.it

Electronic Instructions For Use - Minimum requirements for consultation:
- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):
tel +39 045 6719301, fax +39 045 6719370,
e-mail: customerservice@orthofix.it

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.

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