Records processed under FOIA Request 2014-8215; Released 11/5/14

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(jsh)
FOLDER:	K961725 - 377 pages
COMPANY:	C.L. MCINTOSH & ASSOC., INC. (CLMCIN)
PRODUCT:	INSTRUMENT, SURGICAL, SONIC AND ACCESSORY/ATTACHMENT (JDX)
SUMMARY:	Product: OSCAR ORTHOSONICS SYSTEM FOR CEMENTED ARTHROPLASTY REVISION
DATE REQUESTED:	Oct 24, 2014
DATE PRINTED:	Oct 24, 2014

Note: Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K961725

AUG - 1 1996

AUG - 2 1996

510(k) Summary

OSCAR ORTHOSONICS SYSTEM FOR CEMENTED ARTHROPLASTY REVISION

Common/Classification Name: Sonic surgical instrument, 21 CFR 888.4580

Sponsor: Orthosonics, Ltd.
Bremridge Farm
Ashburton
Devon TQ137JX
UK
+44-1364-652426
+44-1364-653589

Contact: Dr. Michael J. R. Young

Prepared: May 1, 1996

A. LEGALLY MARKETED PREDICATE DEVICES

The **OSCAR Orthosonics Ultrasonics Cement Removal System** is substantially equivalent to the Advanced Osseous Technologies System 10 Model 100 Surgical System (K900003), and is similar to the Cooper Lasersonics CUSA System 200M (K864983).

B. DEVICE DESCRIPTION

The **OSCAR Orthosonics Ultrasonic Cement Removal System** consists of a power module which generates the ultrasonic energy and provides overall control of the device, a handpiece, a set of cement removal probes, and an ultrasonic cleaning system for part of the reprocessing procedures for reuse of the probes. Three independent power modules are included in each device and these are mounted in a cart for ease of use.

C. INTENDED USE

The **OSCAR Orthosonics System for Cemented Arthroplasty Revision** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision.

D. TECHNOLOGICAL CHARACTERISTICS

The **OSCAR Orthosonics Ultrasonic Cement Removal System** has the same technological characteristics as the predicate device. The energy

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source is ultrasonic for both, and both have probes made of the titanium alloy Ti-6Al-4V.

E. TESTING

Orthosonics carried out testing to address the following issues:

(1) temperature rise in bone during OSCAR procedures,

(2) damage to bone from direct contact,

(3) clinical experience,

(4) reprocessing probes for use on the next patient,

(5) electromagnetic compatibility,

(6) electrical safety, and

(7) validation of sterilization recommendations.

The results from all of these tests supported the safety and effectiveness of the Orthosonics OSCAR device and demonstrate that the Orthosonics OSCAR is substantially equivalent to the predicate devices.

F. CONCLUSIONS

The Orthosonics OSCAR device has the *same* intended use and target population as the predicate devices. Orthosonics has demonstrated through its performance tests on the OSCAR device and its comparison of OSCAR characteristics with those of the predicate device that the OSCAR device is substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1996

Mr. Robert L. Sheridan
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K961725
Trade Name: OSCAR Orthosonics System for Cemented Arthroplasty Revision
Regulatory Class: II
Product Code: LZV
Dated: May 3, 1996
Received: May 3, 1996

Dear Mr. Sheridan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under

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sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K961725

Device Name: **Orthosonics OSCAR System for Cemented Arthroplasty Revision**

Indications For Use:

The **Orthosonics OSCAR System for Cemented Arthroplasty Revision** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision.

[redacted] K961725

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(K) ROUTE SLIP

510(k) NUMBER K961725 PANEL OR DIVISION DGRD BRANCH

TRADE NAME OSCAR ORTHOSONICS SYSTEM FOR CEMENTED ARTHROPLASTY REVISION

COMMON NAME

PRODUCT CODE 50X

II

APPLICANT C.L. MCINTOSH & ASSOCIATES, INC.
SHORT NAME CLMCIN
CONTACT ROBERT L SHERIDAN
DIVISION MEDICAL AND REGULATORY AFFAIRS SERVICES
ADDRESS 12300 TWINBROOK PARKWAY
SUITE 625
ROCKVILLE, MD 20852
PHONE NO. (301) 770-9590 FAX NO. (301) 770-9584

MANUFACTURER ORTHOSONICS, LTD. REGISTRATION NO. 9681503

DATE ON SUBMISSION 03-MAY-96 DATE DUE TO 510(K) STAFF 17-JUL-96

DATE RECEIVED IN ODE 03-MAY-96 DATE DECISION DUE 01-AUG-96

DECISION __ DECISION DATE _____

Is this 510(k) identified as a Class III device ____YES ✓ NO

AUG 1 1996

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date:

From: Reviewer(s) - Name(s) Harry W Newman

Subject: 510(k) Number K961725

To: The Record - It is my recommendation that the subject 510(k) Notification:

- [x] Is substantially equivalent to marketed devices. K-1
- [ ] Requires premarket approval. NOT substantially equivalent to marketed devices.
- [ ] Requires more data.
- [ ] Accepted for review _____ (date)
- [ ] Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☐ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☒ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: Class II : 87 LZY

Additional Product Code(s) with panel (optional):

Review: HWD Team Leader Mark N. Melkerson (Branch Chief) ORDB (Branch Code) 7/30/96 (Date)

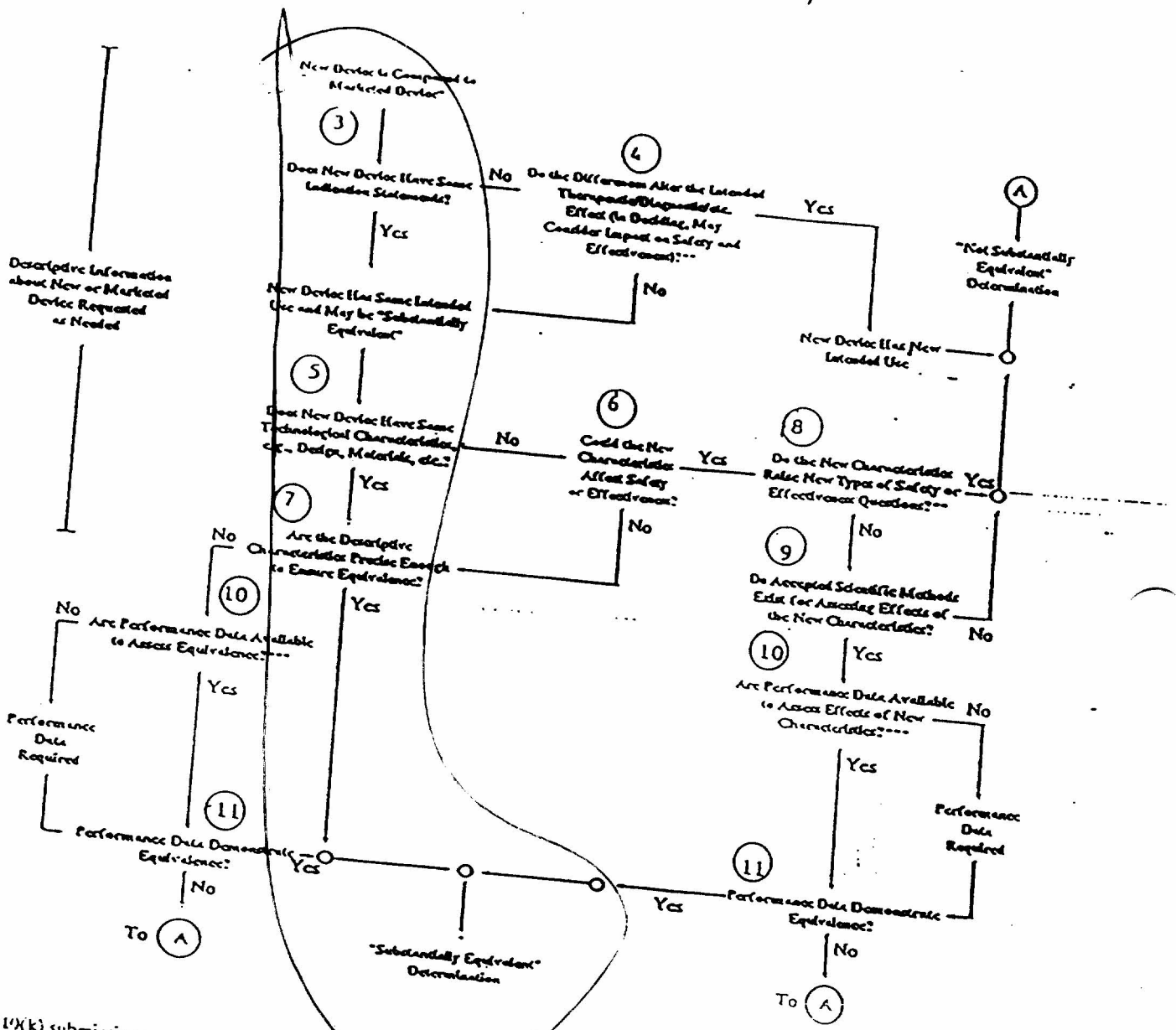
Final Review: _____ (Division Director) _____ (Date)

004

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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PREMARKET NOTIFICATION - 510(K)

HWD
Team Leader 7/29/96

Date: 7/26/96
TO: File
FROM: **HANY W. DEMIAN, BIOENGINEER, M.S.** HWD
DGRD/Orthopedic Devices Branch

SUBJECT: Orthosonics OSCAR System for Cemented Arthroplasty Revision
Document Number: K961725
Date Received: May 03, 1996
Review initiated: June 28, 1996
Point of Contact: **Robert Sheridan (C.L. McIntosh consultants for Orthosonics, Inc)**

Product Codes: Class II: 87 LZV (cement removal/extraction system)

Reviewer's Decision:

Based on the intended use, design, and materials, I recommend that the OSCAR System be found substantially equivalent to legally marketed devices (e.g., Biomet's Ultra Drive System K90003).

Review:

The sponsor has provided all administrative requirements.

Intended use:

The OSCAR System for Cemented Arthroplasty Revision is indicated for removal of the old PMMA cement during revision total hip arthroplasty.

Device Description:

The Orthosonic OSCAR Ultrasonic Cement Removal System consist of a power module which generates the ultrasonic energy and provides overall control of the device, a handpiece, a set of cement removal probes, and an ultrasonic cleaning system for part of the reprocessing procedures for reuse of the probes.

Standards:

The OSCAR system is designed to meet IEC 601 part 1, and has received full type test approval to this standard.

Electrical Safety -- The OSCAR system meets the applicable requirements of DIN VDE 0750 part 1/12.91- EN 60601

Electromagnetic Compatibility -- The equipment has been approved to EN 60601-1-2 and CISPR 11.

Power Modules:

The power modules are microprocessor controlled and are designed to produce continuous wave ultrasonic energy at the resonant frequency of the attached handset within a range of (b)(4). The resonant frequency, at which the maximum output is attained, depends on the load impedance.

The RF generator power output ranges from (b)(4). The power at the probe tip depends on the load impedance, but varies from (b)(4) in air and (b)(4) in the cement. The surgeon is able to determine whether the probe is in air,

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cement, or bone by the pitch of the sound emanating from the probe.

So a high-pitched, audible noise comes from the probe when it contacts bone, warning the user.

Probes:

Probes are made of titanium and screw into the distal part of the handset. There are three different probes: 1) the groover; 2) the axisymmetric reverse scraper; and 3) the piercer.

Groover - flattened spear-shaped head with one hole on either side and a forward cutting blade at the lateral aspect of the device

Reverse Scraper - spear-shaped with no perforations within the head. The groover is used to cut longitudinal channels in the proximal or distal cement and membrane from the endosteal surface: the user applies a reverse scraping action

Piercer - spear-shaped device with 4 perforations in the head designed to place holes in the distal plug of the cement so that a larger groover can then break up distal cement mantle. The piercer is supplied with two tip diameters, 6 and 8 mm. A slight bend is designed so that if the piercer hits bone it can be redirected

Acetabular - (optional) looks like a pointed tip that has been curled under at the end of the tip

Cables:

Silicone rubber insulated cables with screened conduction wires are supplied. The cable has a sterile section (connected to the handset prior to sterilization) and a non-sterile section (2 meters in length) joined at a locking ring.

Accessories:

Acetabular Probe; extension cable, module blanking plate; and additional Ultrasonic cleaning cells

Material Identification:

The probes are made from (b)(4)

Cleaning and Sterilization:

The Oscar system is provided to the user in non-sterile condition (see section VI of operative manual). The handsets and the short steam sterilization cycles: 10 minutes, 132-136°C Vacuum or gravity cycle. The recommended sterilization procedures are currently being validated by an independent laboratory. The protocol for this validation is included in exhibit 6. Orthosonics will not market the OSCAR device in the U.S. until the validation of the sterilization recommendations has been completed.

Performance Testing:

The performance testing that the Orthosonics has performed address the following issues: temperature rise in the bone during use; damage to the bone from direct contact; clinical experience; reprocessing probes for use; electromagnetic compatibility; and electrical safety.

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Temperature During Use:

(b)(4)

Damage to Bone From Direct Contact:

(b)(4)

Clinical Experience:

(b)(4)

Software Development Manual:

The sponsor has provide adequate hazard analysis (exhibit 13), software documentation (exhibit 14, 15) and verification, validation and testing (exhibit 16) for the Oscar system.

Labeling Information:
The sponsor has provide the proposed labeling for the device and the accessories which included the company name, address, product name, caution statement, and read instruction before use statement.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Material provided by sponsor in support of SE:

As required by 21 CFR 807.87 (f), the device under review in this 510(K) is compared for substantial equivalence to a legally marketed predicate device.

The following, table I, was constructed for comparison of the cement removal systems.

Bone Cement Removal Device	Oscar K961725	Biomet K90003
Intended Use	removal of old PMMA during revision	same
energy Source	(b)(4)	
Output Power		
Irrigation	Ordinary hand-held saline	Built-in irrigation
Cement Plug Removal	by using the piercer	plug puller
Probe material	(b)(4)	(b)(4)

Discussion:

Both systems use ultrasound energy transferred from tip to cement. The energy stimulates the molecules in the cement causing it to soften. Irrigation is used to resolidfy softened cement around the tip and slide hammer is used to extract the cement. The main difference is that the subject device does not have built in irrigation/aspiration system like the predicate device. However, this can be done manually by the surgeon.

Summary of Safety and Effectiveness:

The sponsor has provided a summary of SSE.

Telephone Communications:

On July 1, 1996, I spoke with Bob Sheridan regarding the potential for probe tips to break off during use and potentially becoming stuck in the cement. Dr. Sheridan informed me that there is a start up procedure for all handsets and probes that involves a full computer-controlled tuning cycle. Any weakness due to fatigue cracking would manifest itself as a failure to tune correctly. On July 8, 1996 I received the hard copy regarding this concern.

This adequately addressed my concerns.

HANY W DEMIAN
BIOMEDICAL ENGINEER, M.S.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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C.L. McIntosh
& ASSOCIATES, INC
Medical and Regulatory Affairs Services

12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852
Tel: (301) 770-9590
Fax: (301) 770-9584

K961725/A1

RECEIVED
8 JUL 96 13 54
FDA/CDRH/ODE/DMC

June 28, 1996

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: K961725
Orthosonics, Ltd.
Orthosonics OSCAR System for Cemented Arthroplasty Revision

ATTN: Hany Demian (HFZ-410)

Dear Mr. Demian:

We are submitting this amendment to K961725 on behalf of Orthosonics, Ltd. in response to your request for more information in our telephone conversation of today.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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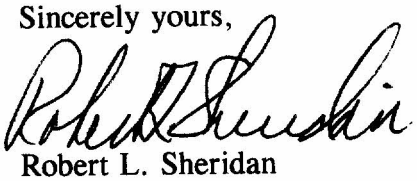
I hope that this information has addressed your concerns. Thank you for your consideration in this matter. If you require any additional information or clarification, please call me at (301) 770-9590.

Sincerely yours,



Robert L. Sheridan
Vice President for Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-8215; Released 11/5/14

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K961725

Device Name: **Orthosonics OSCAR System for Cemented Arthroplasty Revision**

Indications For Use:

The **Orthosonics OSCAR System for Cemented Arthroplasty Revision** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-8215; Released 11/5/14

DUPLICATE

K961725/A1

C.L. McIntosh
& ASSOCIATES, INC.
Medical and Regulatory Affairs Services

12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Tel: (301) 770-9590
Fax: (301) 770-9584

July 1, 1996

RECEIVED
8 JUL 96 13 54
FDA/CDRH/ODE/DMC

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: K961725
Orthosonics, Ltd.
Orthosonics OSCAR System for Cemented Arthroplasty Revision

ATTN: Hany Demian (HFZ-410)

Dear Mr. Demian:

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

I hope that this information has addressed your concerns. Thank you for your consideration in this matter. If you require any additional information or clarification, please call me at (301) 770-9590.

Sincerely yours,

Robert L. Sheridan
Vice President for Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISED:01/22/96

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

K 961725 Device Name Cement orthosonics

Division/Branch DGRD / OR

Administrative Reviewer Signature Michael Cowley Date 5/7/96

Supervisory Signature _____ Date _____

Did the firm request expedited review? _____ Yes ✓ No

Did we grant expedited review? _____ Yes ✓ No

Truthful and accurate statement enclosed? ✓ Yes _____ No
(If Not Enclosed, Must Be A Refuse To Accept Letter)
Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed? ✓ YES _____ No
(Required for Original 510(k)s received 1/1/96 and after -- must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? _____ Yes ✓ No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If so, a new ODE review is not required, please forward to POS.

_____ Yes ✓ No

✓
Accepted

_____
Refuse To Accept

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	☐	☐
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	☐	☐
C. Is Device Subject To Review By CDRH?	☐	☐
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision?	☐	☐
(ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	☐	☐
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer.	☐	☐
(ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	☐	☐
F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	☐	☐
1. Device Trade Or Proprietary Name	☐	☐
2. Device Common Or Usual Name Or Classification Name	☐	☐
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	☐	☐
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	☐	☐
5. Classification Panel	☐	☐
6. Action Taken To Comply With Section 514 Of The Act	☐	☐
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	☐	☐
9. For Class III Devices Only, A Class III Certification And A Class III Summary	☐	☐
10. Photographs Of The Device	☐	☐
11. Engineering Drawings For The Device With Dimensions And Tolerances	☐	☐
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	☐	☐
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	☐	☐
14. Data To Show Consequences And Effects Of A Modified Device(s)	☐	☐
15. Truthful And Accurate Statement	☐	☐
II. Additional Information That Is Necessary Under 21 CFR 807.87(h):	☐	☐
A. Submitter's Name And Address	☐	☐
B. Contact Person, Telephone Number And Fax Number	☐	☐
C. Representative/Consultant If Applicable	☐	☐
D. Table Of Contents With Pagination	☐	☐
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	☐	☐
III. Additional Information That May Be Necessary Under 21 CFR 807.87(h):	☐	☐
A. Comparison Table Of The New Device To The Marketed Device(s)	☐	☐
B. Action Taken To Comply With Voluntary Standards	☐	☐
C. Performance Data	☐	☐
MARKETED DEVICE:	☐	☐
Bench Testing	☐	☐
Animal Testing	☐	☐
Clinical Data	☐	☐
NEW DEVICE:	☐	☐
Bench Testing	☐	☐
Animal Testing	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clinical Data	☐	☐
D. Sterilization Information	☐	☐
E. Software Information	☐	☐
F. Hardware Information	☐	☐
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	☐	☐
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	☐	☐
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	☐	☐
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	☐	☐
I. Other (Specify)	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics ar not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 03, 1996

C.L. MCINTOSH & ASSOCIATES, INC.
MEDICAL AND REGULATORY AFFAIRS SERV
12300 TWINBROOK PARKWAY
SUITE 625
ROCKVILLE, MD 20852
ATTN: ROBERT L. SHERIDAN

510(k) Number: K961725
Received: 03-MAY-96
Product: OSCAR ORTHOSONICS SYSTEM FOR CEMENTED ARTHROPLASTY REVISION

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522 (a) (1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance at the number below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

If you have procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or call me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-8215; Released 11/5/14

C.L. McIntosh
& ASSOCIATES, INC.
Medical and Regulatory Affairs Services

12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Tel: (301) 770-9590
Fax: (301) 770-9584

K961725

May 3, 1996

Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center
9200 Corporate Blvd
Rockville, MD 20850

ATTN: Orthopedic Devices Branch, HFZ-410
Division of Restorative and General Devices

Re: 510(k) Premarket Notification
OSCAR Orthosonics System for Cemented Arthroplasty Revision

RECEIVED
2 MAY 96 16 19
FDA/CDRH/OCE/DMC

Dear Sir or Madam:

We are submitting this document on behalf of our client, Orthosonics Ltd, of Ashburton, Devon, UK, in order to demonstrate that a new product, the **OSCAR Orthosonics System for Cemented Arthroplasty Revision**, is substantially equivalent to similar ultrasonic surgical instruments presently cleared for marketing.

The indications for use and target population for the **OSCAR Orthosonics System for Cemented Arthroplasty Revision** are the same as for the predicate devices, and the performance of the Orthosonics device is the same as or better than the predicate devices.

Device Name

The classification name of the of the device that Orthosonics intends to introduce is **sonic surgical instrument (and accessories/attachments)**. The trade name for this device is the **OSCAR Orthosonics System for Cemented Arthroplasty Revision**.

Establishment Registration

The Establishment Registration number for Orthosonics, Ltd. is 9681503.

OR
II

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Classification

21 CFR 888.4580
Class II
87JDX
Orthopedic Devices Panel

Performance Standards

To date, to the best of our knowledge, no Section 514 Performance Standards have been established for this device.

Substantial Equivalence

The **OSCAR Orthosonics System for Cemented Arthroplasty Revision** is similar in design and function to the System 10 Model 100 ("UltraDrive") Surgical System made by Advanced Osseous Technologies (K900003).

For your convenience the "Premarket Submission Cover Sheet" immediately follows this cover letter.

We believe that the enclosed information meets all the Food and Drug Administration's requirements for a premarket notification. To assist you in coming to the same conclusion, we have provided a completed "Premarket Notification 510(k) Checklist for Acceptance Decision," which follows this cover letter.

Contact Person

The contact person for all questions regarding this document is the undersigned.

"510(k) Summary"

In response to the requirements addressed by the SMDA of 1990, we have enclosed a summary of the safety and effectiveness information upon which the substantial equivalence[1] determination is based. This 510(k) Summary contains the information described in 21 CFR 807.92, and is provided in **Section VII**.

---

[1] The terms "substantial equivalence" and "substantially equivalent" are used in this letter and the enclosed 510(k) as they are defined in the Federal Food, Drug, and Cosmetic Act.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Premarket Notification Truthful and Accurate Statement

We have also enclosed the Premarket Notification Truthful and Accurate Statement Certification as required by 21 CFR 807.87(j) in **Section VIII**.

Statement of Indications for Use

In response to the requirement that a 510(k) contain a statement of indications for use on a separate labeled page, we have included such a statement as the last page of **Section I**.

Confidentiality

We request, in accordance with 21 CFR 807.95(b), that FDA hold confidential the information in this premarket notification as it relates to our intention to market this product in the U.S. Further, some of the information in this application may be trade secret or commercial/financial information that is privileged or confidential. This confidential information is nondisclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with us, as provided for in 21 CFR 20.45, should you have any question whether requested information is confidential. Each page of this document containing "Confidential" information has been clearly identified.

This submission provides the premarket notification required by Section 510(k) of the FD&C Act and 21 CFR 807.87. Based on the information submitted herein, Orthosonics requests clearance to market this product as soon as possible.

Thank you for your consideration of this matter. If you require any additional information or clarification, please call the undersigned or Dr. T. Whit Athey at 301-770-9590.

Sincerely yours,

Robert L. Sheridan
Vice President
Device Evaluation

Enclosures: 510(k) Cover Sheet
510(k) Checklist
510(k) Premarket Notification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cover Sheet Checklist

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: FDA Document Number:

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement -Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission - 510(k)s Only

- ☒ New device
- ☐ Additional or expanded indications
- ☐ Change in technology, design, materials, or manufacturing process
- ☐ Other reason (specify):

Section B2 — Reason for Submission - PMAs Only

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
- ☐ Amendment

Section B3 — Reason for Submission - IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Protocol - feasibility
  - ☐ Protocol - other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Document Number:

Section C — Product Classification

Product code: **87JDX**

CFR Section: **CFR 888.4580**

Device class:

☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Classification panel: **Orthopedics**

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 **JDX**	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 **K900003**	1 **System 10, Model 100 Surgical System**	1 **Advanced Osseous Technologies (AOT)**
2 **K864983**	2 **CUSA System 200M**	2 **Cooper Lasersonics**
3	3	3
4	4	4
5	5	5
6	8	8

Section E — Product Information - Applicable to All Applications

Common or usual name or classification name: **System, Cement Removal Extraction**

Trade or proprietary or model name	Model number
1 **Oscar Orthosonics System for Cemented Arthroplasty Revision**	1 **None**
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 **N/A**	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory testing ☒ Animal trials ☐ Human trials

Indications (from labeling):
For removal of bone cement during cemented arthroplasty revision

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		FDA Document Number:	
Section F		**Manufacturing / Packaging / Sterilization Sites**	
☒ Original ☐ Add ☐ Delete	FDA establishment registration number: **9681503**	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: **Orthosonics, Ltd**			
Division name (if applicable):			Phone number (include area code): **+44-1364-652426**
Street address: **Bremridge House**			FAX number (include area code): **+44-1364-653589**
City: **Ashburton**	State / Province: **Devon**	Country: **UK**	ZIP / Postal Code: **TQ137JX**
Contact name: **Dr. Michael Young**			
Contact title: **Managing Director**			
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:			
Division name (if applicable):			Phone number (include area code):
Street address:			FAX number (include area code):
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-8215; Released 11/5/14

	FDA Document Number:		
Section G	**Applicant or Sponsor**		
Company / Institution name: **Orthosonics, Ltd**			FDA establishment registration number: **9681503**
Division name (if applicable):			Phone number (include area code): **+44 1364 652426**
Street address: **Bremridge House**			FAX number (include area code): **+44 1364 653589**
City: **Ashburton**	State/Province **Devon**	Country: **UK**	ZIP / Postal Code: **TQ137JX**
Signature:			
Name: **Michael J. R. Young**			
Title: **Managing Director, Orthosonics Ltd.**			
Section H	**Submission correspondent (if different from above)**		
Company / Institution name: C. L. McIntosh & Associates			
Division name (if applicable):			Phone number (include area code): 301-770-9590
Street address: 12300 Twinbrook Parkway, Suite 625			FAX number (include area code): 301-770-9584
City: Rockville	State / Province MD	Country:	ZIP / Postal Code: 20852
Contact name: Robert L. Sheridan	OR	T. Whit Athey	
Contact title: Vice President, Device Evaluation		Senior Consultant	

Your volunatry completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The informaiton you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a quesiton concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2014-8215; Released 11/5/14

	FDA Document Number:

Section G — Applicant or Sponsor

Company / Institution name: **Orthosonics, Ltd**			FDA establishment registration number: **9681503**
Division name (if applicable):			Phone number (include area code): **+44 1364 652426**
Street address: **Bremridge House**			FAX number (include area code): **+44 1364 653589**
City: **Ashburton**	State/Province **Devon**	Country: **UK**	ZIP / Postal Code: **TQ137JX**
Signature:			
Name: **Michael J. R. Young**			
Title: **Managing Director, Orthosonics Ltd.**			

Section H — Submission correspondent (if different from above)

Company / Institution name:			
Division name (if applicable):			Phone number (include area code):
Street address:			FAX number (include area code):
City:	State / Province	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

Your volunatry completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The informaiton you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a quesiton concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

K _____ **DATE DMC RECEIVED:** _____

DEVICE TRADE NAME: Oscar Orthosonics System for Cemented Arthroplasty Revision

REASON FOR 510(K): The applicant, Orthosonics Ltd, is expressing its intention to introduce the device into commerce, and this application is submitted as required by regulation

(21 CFR 807.81(a)(2)).

DIVISION/BRANCH: Division of General and Restorative Devices
Orthopedic Devices Branch

ADMINISTRATIVE REVIEWER SIGNATURE:

_____ **DATE:** _____

SUPERVISORY SIGNATURE:

_____ **DATE:** _____

I. Critical Elements:

A. Is the product a device?

The applicant believes the product to be a device based upon definition in the law and claimed equivalence to classified devices.

B. Is the device exempt from 510(k) by regulation or policy?

The applicant does not believe that the device is exempt from 510(k) requirements by regulation or policy.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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C. Is device subject to review by CDRH?

The applicant believes that the device is subject to review by CDRH. The device is not a combination product and does not achieve its intended effect by metabolism, etc.

D. (i) Are you aware that this device has been the subject of a previous NSE decision?

The device has not been the subject of a previous NSE decision.

(ii) If yes, does the new 510(k) address the NSE issue(s) (e.g., performance data)?

Not applicable.

E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer.

The submitter has not been the subject of an integrity investigation.

(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)

F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?

- **Device trade or proprietary name.**

  The **Cover Letter** and **Overview** identify the proprietary name as **Oscar Orthosonics System for Cemented Arthroplasty Revision**

- **Device common or usual name or classification name.**

  The classification name and regulation number are identified in the **Cover Letter** as:

  21 CFR 888.4580 Sonic surgical instrument and accessories/attachments

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- **Establishment registration number (only applicable if establishment is registered).**

- **Class into which the device is classified under (21 CFR Parts 862 to 892).**

  The **Cover Letter** includes the device classification: the **Oscar Orthosonics System for Cemented Arthroplasty Revision** is a Class II device.

- **Classification Panel.**

  The cover letter states that the device would be reviewed by the Orthopedic Devices Panel.

- **Action taken to comply with Section 514 of the Act.**

  The applicant is not aware of any requirements of Section 514 that apply to the device.

- **Proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1).**

  Proposed labeling and package labels are discussed in **Section IV**, and copies are included in the application in **Section VI**.

- **A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request.**

  A 510(k) Summary of safety and effectiveness is included with the application **Section VII**.

- **Action taken to comply with 21 CFR 807.87(j)**

  A Premarket Notification "Truthful and Accurate" Statement is included in **Section VIII**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- **For Class III devices only, a Class III Certification and a Class III Summary.**

  The device has not been classified as a class III device.

- **Photographs of the device.**

  Photographs of the device and accessories are enclosed with the application in **Section II**.

- **Engineering drawings for the device with dimensions and tolerances.**

  Engineering drawing of the device and accessories are provided in **Section II**.

- **The marketed device(s) to which equivalence is claimed including labeling and description of the device(s).**

  The marketed devices are identified in **Section IV** with premarket notification numbers of specific predicate devices. Discriptions and labeling are also included in the application for one of the predicate devices.

- **Statement of similarities and/or differences with marketed devices.**

  Similarities to and/or differences from marketed devices are discussed in **Section IV** of the application.

- **Data to show consequences and effects of a modified device.**

  (Not a modified device)

II. Additional information that <u>is</u> necessary under 21 CFR 807.87(h):

A. Submitter's name and address.

The applicant's name and business address is provided in the **Cover Letter**

B. Contact person, telephone number and fax number.

The contact person is identified in the **Cover Letter** along with his address, and telephone and fax numbers.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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C. Representative/Consultant if applicable.

C.L. McIntosh & Associates, Inc. has been consulted in the preparation of this application. The firm's address and telephone and fax numbers are listed below.

C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20850
ATTN: T. Whit Athey
Telephone: (301) 770-9590
Fax: (301) 770-9584

D. Table of Contents with pagination.

The **Table of Contents** with pagination is included in the application.

E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s).

The address of the manufacturing facility is given in the **Overview Section**.

Sterilization Site: Not Applicable

III. Additional information that <u>may be</u> necessary under 21 CFR 807.87(h):

A. Comparison table of the new device to marketed device(s).

A table comparing the attributes of the **Oscar Orthosonics System for Cemented Arthroplasty Revision** with the legally marketed predicate devices is included in **Section IV** of the application.

B. Action to comply with voluntary standards.

Information on certifications by standards organizations is included in **Section III**.

C. Performance data.

Marketed (Predicate) Device(s):

Bench testing - None
Animal testing - None
Clinical data - None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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New Device:

Bench testing - **Section III** contains data from bench testing.

Animal testing - **Section III** contains data from animal testing.

Clinical data - A paper describing the clinical experience with the device is included in **Exhibit 5.**

D. Sterilization information.

Section II has recommended sterilization procedures. Validation of the sterilization procedures is reported in **Section III.**

E. Software information.

Software validation and documentation procedures and results are contained in **Section VI.**

F. Hardware information.

Section II contains a complete device description.

G. Is this device subject to issues that have been addressed in specific guidance documents?

No

If yes, continue review with checklist from any appropriate guidance documents.

N/A

If no, is 510(k) sufficiently complete to allow substantive review?

The applicant believes that this premarket notification is complete in all of its particulars and should be filed for review.

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SECTION I

510(k) OVERVIEW

A. INTENDED USE

The **Orthosonics OSCAR System for Cemented Arthroplasty Revision** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision. The required statement of intended use is included as the last page of this section.

B. DEVICE DESCRIPTION OVERVIEW

Section II of this submission contains a detailed description of the **Orthosonics OSCAR Ultrasonic Cement Removal System**. This section is intended as a brief introduction to the device.

The **Orthosonics OSCAR Ultrasonic Cement Removal System** consists of a power module which generates the ultrasonic energy and provides overall control of the device, a handpiece, a set of cement removal probes, and an ultrasonic cleaning system for part of the reprocessing procedures for reuse of the probes.

TABLE 1

510(k) Review Issues	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device implanted (short-term or long-term)?		X	
Does the device use software?	X		
Is the device shipped sterile?		X	
Is the device single use?		X	
Is the device home use?		X	
Is the device for prescription only?	X		
Does the device contain a drug or biological product as a component?		X	
Is this device a kit?		X	

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C. PERFORMANCE TESTING

Section III contains a complete description and discussion of performance testing on the **Orthosonics OSCAR Ultrasonic Cement Removal System.** This testing addressed the following issues: temperature rise in bone during OSCAR procedures, damage to bone from direct contact, clinical experience, reprocessing probes for use on the next patient, electromagnetic compatability, and electrical safety.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

1. Predicate Devices

The **Orthosonics OSCAR Ultrasonic Cement Removal System** is substantially equivalent to the Advanced Osseous Technologies System 10 Model 100 "UltraDrive" Surgical System (K900003), and is similar to the Cooper Lasersonics CUSA System 200M (K864983). **Section IV** contains a detailed comparison of the **Orthosonics OSCAR Ultrasonics Cement Removal System** with the predicate devices.

2. Substantial Equivalence Algorithm

Figure 1 illustrates the flow chart for a decision of substantial equivalence for the **Orthosonics OSCAR Ultrasonic Cement Removal System.** The path to substantial equivalence for the **Orthosonics OSCAR Ultrasonic Cement Removal System** is highlighted on the chart, and an explanation for the decision points follows.

The **Orthosonics OSCAR Ultrasonic Cement Removal System** is a medical device, and it has the same indications for use and the same target population as the legally marketed predicate devices, so the first few decision points in Figure 1 are clear.

The **Orthosonics OSCAR Ultrasonic Cement Removal System** has similar technological characteristics as the predicate devices.

The decision flow chart shows that the **Orthosonics OSCAR Ultrasonic Cement Removal System** is substantially equivalent to the predicate devices.

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3. Summary

This pre-market submission will demonstrate Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

E. SOFTWARE

The software for the OSCAR device has only limited functions: it drives the display, adjusts the frequency (over a limited range) for best match, and monitors timers and a few sensors. An argument could be made that the software represents a "minor level of concern;" however since the software monitors the time of continuous operation and the temperature of a critical component, the sponsor has chosen to treat the software as representing a "moderate level of concern."

Section V contains complete information on software validation and testing, satisfying the requirements discussed in FDA's "Reviewer Guidance for Computer Controlled Medical Devices." The software certification is also included in this section.

F. LABELING OVERVIEW

1. Claims

Orthosonics makes the following claims for OSCAR:

(a) The **Orthosonics OSCAR System for Cemented Arthroplasty Revision** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision.

(b) arthroplasty revision with the OSCAR device is significantly faster than revisions which employ mechanical instruments; and

(c) arthroplasty revisions using OSCAR result in significantly fewer complications than with traditional mechanical instruments.

Section VI reviews the evidence for these claims.

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2. Labeling

Instructions for use, package/face-plate labeling, and promotional literature are contained in **Section VI** of this submission. A comparison of this labeling with that of the predicate devices is contained in **Section IV.B.3**.

G. 510(k) SUMMARY

In accordance with the Safe Medical Devices Act of 1990 and the final rule concerning 510(k) Summaries published in the Federal Register on December 14, 1995, page 64287 (Vol. 59, No. 239), with an effective date of March 14, 1995, Orthosonics has prepared a 510(k) Summary which is included as **Section VII**.

H. INTEGRITY STATEMENT

Also required by the Federal Register final rule (807.87(j)) is a statement certifying that the information contained in a 510(k) notification is truthful and accurate. This statement is included as **Section VIII**.

I. REGULATORY HISTORY

The **Orthosonics OSCAR Ultrasonic Cement Removal System** has been marketed in Europe since 1994. Orthosonics is now seeking to enter the United States market, and is therefore, submitting a new 510(k) to FDA for clearance.

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STATEMENT OF INDICATIONS FOR USE

The **Orthosonics OSCAR System for Cemented Arthroplasty Revision** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision.

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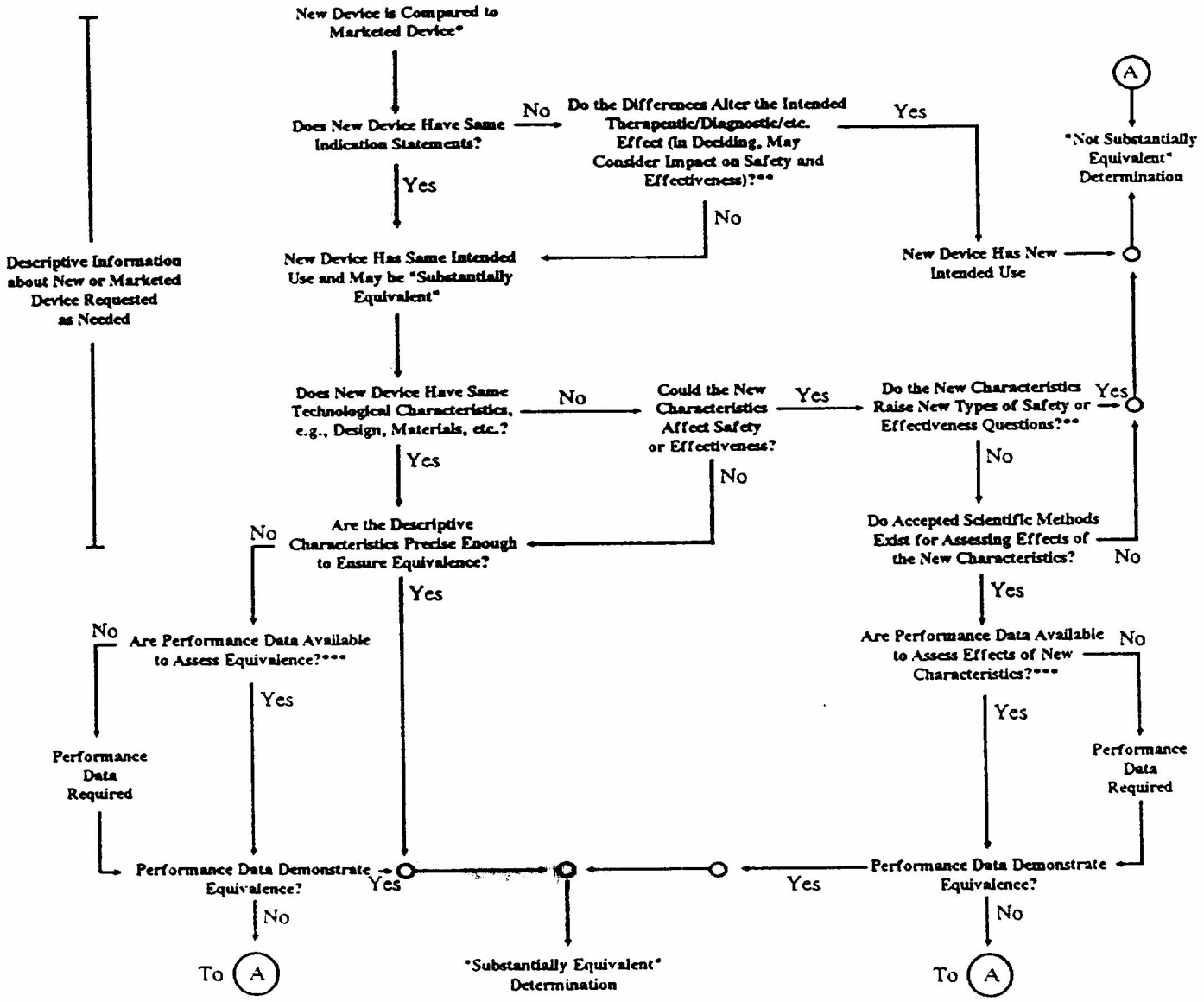
A3 - 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Figure 1. Substantial Equivalence Decision-Making Process

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II

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SECTION II

DEVICE DESCRIPTION

A. INTRODUCTION

The **OSCAR Orthosonics System for Cemented Arthroplasty Revision** is a device for removing the old cement from a bone during arthroplasty revision.

The system is comprised of a portable housing unit with up to three ultrasound power modules (see Figure 2), interchangeable handsets with probes and associated cables, and a separate dedicated ultrasonic cleaning system. The operation of any one of the ultrasound power modules does not affect the operation of the others, so in the unlikely event that one of the modules should fail, the cable can be quickly shifted to another module, or the module itself can be replaced if a spare is available.

B. STANDARDS

The OSCAR system is designed to meet IEC 601 part 1, and has received full type test approval to this standard; no part 2 is available for this type of equipment.

Electrical Safety -- The OSCAR system meets the applicable requirements of DIN VDE 0750 part 1/12.91 - EN 60601 (see **Exhibit 9** for test report).

Electromagnetic Compatibility -- The equipment has been approved to EN 60601-1-2 (see **Exhibit 7** for test report) and CISPR 11 (see **Exhibit 8** for test report).

C. POWER MODULES

The power modules are microprocessor controlled and are designed to produce continuous wave ultrasonic energy at the resonant frequency of the attached handset within a range of (b)(4) The resonant frequency, at which the maximum output power is attained, depends on the load impedance. The resonant frequency is determined by hardware and software tuning procedures at startup and at any time that the retune procedure is initiated (by pressing the handset button twice). Failure in any part of this tuning process simply means that less than the

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maximum power will be transmitted.

The RF generator power output ranges from (b)(4). The power at the probe tip depends on the load impedance, but varies from (b)(4) (b) in air and (b)(4) in cement.

A high-pitched, audible noise comes from the probe when it contacts bone, warning the user. This tone is not an "alarm" requiring a detection scheme, but a mechanical effect which occurs simply because of passive mechanical phenomena.

D. PROBES

Probes for the **OSCAR Orthosonics System for Cemented Arthroplasty Revision** are made of titanium and screw into the distal part of the handset. There are three different probes supplied with each OSCAR system, the groover, the axisymmetric reverse scraper, and the piercer.

The groover (see Figure 3) has a flattened spear-shaped head with one hole on either side and a forward cutting blade at the most lateral aspect of the device. The groover is used primarily to cut longitudinal channels in the proximal cement mantle, in order to weaken the integral cement mass and permit segmental removal with conventional instruments.

The axisymmetric reverse scraper (Figure 4) is spear-shaped with no perforations within the head. A long (8 mm diameter) and a short (10 mm diameter) version are supplied. The cutting edge is machined at an angle of 20° to the axis of the probe, and it is designed for removing well-bonded proximal or distal cement and membrane from the endosteal surface: the user applies a reverse scraping action. It may also be used to cut circumferential channels in the cement mantle to break the shell and aid its removal with minimal force.

The piercer (Figure 5) is a spear-shaped device with four perforations in the head and is used for fenestrating the distal plug of cement to provide a clear channel, which can then be enlarged using the long scraper. The piercer is supplied with two tip diameters, 6 mm and 8 mm. A slight bend has been engineered in this series of probes so that if the piercer comes into contact with bone it can be redirected by rotating the handset through 90°, thus allowing the piercer to find a fresh route through the cement.

The acetabular probe (optional) is used to assist in the removal of the acetabular cup. It is diagrammed in Figure 10 of the Operator's Manual.

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E. CABLES

Silicone rubber insulated cables with screened conduction wires are supplied with the equipment. Each cable contains two separate grounding wires for safety. The device will not work unless both grounding wires are functional.

The cable is comprised of two sections, a sterile section (connected to the handset prior to sterilization) and a non-sterile section. Each section is two meters in length. The connector which joins the two sections has a locking ring.

F. CLEANING AND STERILIZATION

OSCAR Orthosonics System for Cemented Arthroplasty Revision is provided to the user in non-sterile condition. To ensure the safety of the system in the high-risk hospital environment, Orthosonics recommends reprocessing and sterilization procedures in the labeling (see **Section VI, Operative Manual**):

Reprocessing the probes for use with the next patient requires three steps. First the probe is cleaned in a standard hospital washer or is hand washed with soap and water to remove all loose debris and soil. Second, the probe is cleaned in the ultrasonic cleaner (supplied with the system). Finally the probe, handset, and cable are sterilized in a hospital steam sterilizer.

The ultrasonic cleaning system consists of a small, trolley-mounted enclosure (see Figure 6) containing an ultrasound generator with timing control and a disposable cleaning cell. Each handset with its contaminated probe is connected via a standard connecting cable to the socket at the rear of the enclosure. The probe is then inserted into the cleaning cell where it is automatically energized. Two cycles, long (25 sec) and short (15 sec), are available. If any trace of cement or soil remain after the cycle, the operation may be repeated until visual inspection assures that cleaning is complete. The cleaning cells are discarded after several uses. Replacement cells are supplied with sealed ends, and the seals are broken as the first probe is inserted.

The handsets and the short cable which attaches directly to the handset are sterilized in a hospital steam sterilizer.

Recommended Hospital Steam Sterilization Cycles:

10 minutes, 132-136 °C Vacuum or Gravity Cycle

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The recommended sterilization procedures are currently being validated by an independent laboratory. The protocol for this validation is included in **Exhibit 6**. Orthosonics will not market the OSCAR device in the U.S. until the validation of the sterilization recommendations has been completed.

G. ACCESSORIES

Appendix 2 of the Operator's Manual (included in **Section VI** on Labeling) contains a table which shows the items provided with each OSCAR system and the items which are optional. The optional accessories are described above:

(1) Acetabular Probe;

(2) Extension Cable;

(3) Module Blanking Plate; and

(4) Additional Ultrasonic Cleaning Cells

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Section III
Performance Tests

III

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SECTION III

PERFORMANCE TESTING

This section summarizes the performance testing that Orthosonics carried out on the **OSCAR Orthosonics System for Cemented Arthroplasty Revision.** This testing addressed the following issues:

(1) temperature rise in bone during OSCAR procedures,

(2) damage to bone from direct contact,

(3) clinical experience,

(4) reprocessing probes for use on the next patient,

(5) electromagnetic compatibility

(6) electrical safety

A. TEMPERATURE RISE DURING OSCAR PROCEDURE

(b)(4)

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(b)(4)

B. DAMAGE TO BONE FROM DIRECT CONTACT

(b)(4)

C. CLINICAL EXPERIENCE

(b)(4)

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(b)(4)

D. CLEANING AND STERILIZATION

Orthosonics recommends a three-stage reprocessing procedure for probes and handsets. Validation studies for these recommendations are under way and will be successfully completed showing an SAL of 10^{-6} prior to marketing of the OSCAR system in the U.S. The protocol for validating the sterilization recommendations is included in **Exhibit 6**.

1. The first stage in the recommended reprocessing procedure is the removal of loose soil and debris with soap and water. The handsets, cables, and probes are disassembled and the shrouds are removed. This stage can be carried out in a commercial hospital washer where available, or in hand washing where such equipment is not available. At this stage it is not necessary that all adhering particles be removed--only those that are easily removable. After the parts are thoroughly dry, they are reassembled.

2. The second stage involves washing in the ultrasonic washer provided with the Oscar system. A cleaning cell is inserted in the Oscar cleaning equipment and the probes are inserted and cleaned. If there are any remaining particles or soil visible, the cycle is repeated. After cleaning, the cables, handsets, and probes are again disassembled and sent for sterilization.

3. The parts are CV wrapped and placed in a tray as complete sets. A steam sterilization instrument cycle is recommended:

   gravity or vacuum cycle at 132-136 °C for 10 minutes

E. ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility tests were carried out on an Oscar unit by an independent testing laboratory, Radio Frequency Investigation, Ltd. Testing was conducted to determine compliance with EN 60601-1-2 May 1993, and with CISPR 11: 1990 Group 1 Class B specifications. The device was found to satisfy the requirements. Copies of the lab reports are included in **Exhibits 7 and 8**.

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F. ELECTRICAL SAFETY

The OSCAR device was tested for electrical safety according to DIN VDE 0750 part 1/12.91 of EN 60601. The device passes all of the applicable requirements of the standard. A copy of the test report is included as **Exhibit 9.**

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SECTION IV

SUBSTANTIAL EQUIVALENCE

A. INTRODUCTION

The **OSCAR Orthosonics System for Cemented Arthroplasty Revision** is substantially equivalent to the Advanced Osseous Technologies (AOT) System 10 Model 100 ("UltraDrive") Surgical System (K900003), and is similar to the Cooper Lasersonics CUSA System 200M (K864983). These devices are described in 21 CFR 888.4580 (87JDX), Sonic Surgical Instrument and Accessories/Attachments, and are under the responsibility of the Orthopedic Devices Panel.

TABLE 2
Side-by-Side Comparison with Predicate Devices

Characteristic	OSCAR	AOT Ultradrive
Intended Use	Removal of bone cement from bone	Removal of bone cement from bone
Patient Population	Patients undergoing arthroplasty revision	Patients undergoing arthroplasty revision
Energy source	(b)(4)	
Output Power		
Output Channels	3 independent power channels	1 channel, which can power two handsets through a switch
Frequency Control	Fully automatic with PLL and microprocessor tuning	PLL frequency control which is dependent on accurately tuned mechanical wave guides

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TABLE 2
Side-by-Side Comparison with Predicate Devices

Characteristic	OSCAR	AOT Ultradrive
Function Control	Entirely in handset, except for on/off and full reset switches which are on panel	Foot switch, machine front panel for power selection
Instrument Choice	Three basic instruments are available for random order insertion, re-tuning is automatic in a few seconds	Several instruments available
Irrigation	Ordinary hand-held saline irrigation device is adequate (not provided)	Built-in irrigation channel directs water against the energized probe
Fume Removal	Ordinary hand-held suction is adequate in the short cycle procedure employed	Built-in suction provided to remove fumes during lengthy extraction procedure
Cement Plug Removal	By using piercer probe--plug puller not required	Plug puller is recommended
Sterilization	Three-stage process: 1. Cleaning 2. Ultrasonic cleaning 3. Sterilization	Hand units and accessory tools (no reuse of probes) are recommended for sterilization "in a steam autoclave" (no details given)
Probe Material	Ti-6Al-4V	Ti-6Al-4V

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B. DISCUSSION OF SIMILARITIES AND DIFFERENCES

The **OSCAR Orthosonics System for Cemented Arthroplasty Revision** has the same intended use as the AOT System 10, Model 100, and an intended use similar to that of the Cooper Lasersonics CUSA System 200.

The AOT System 10, Model 100 ("Ultradrive") is an ultrasound-powered device intended for cement removal. The OSCAR system differs from the AOT device in the way the frequency and power are selected. In the OSCAR system these functions are selected by pressing one button. The frequency is tuned (within 2 kHz) to provide the maximum output for the particular probe being used. In the AOT device the power is manually set at one of three selectable levels.

The Cooper Lasersonics CUSA System 200 was cleared for general surgery applications, specifically including orthopedic applications, where tissue is removed by ultrasonic fragmentation and aspiration. In the OSCAR system it is orthopedic cement which is being removed from a bone, rather than removal of part of the bone itself, but the applications are very similar and would presumably be covered under "general surgery (orthopedic)" applications.

The OSCAR system does not incorporate an integral irrigation/aspiration device, but relies on the user to provide for irrigation and aspiration through independent devices (not supplied). The Cooper device uses an integrated irrigation/aspiration channel to remove the material loosened by ultrasound. The UltraDrive system also has an integral irrigation/aspiration system built into the hand set, and it directs water directly at the tip of the energized probe. Orthosonics believes that directing water directly at the energized handset represents a potential hazard to the user because of the risk of generating an aerosol of blood and water if the handset is accidently activated when in air (when in cement, the tip motion is damped, so generation of an aerosol is less likely). In addition, Orthosonics believes that the UltraDrive irrigation system, while directed toward the site of melting cement, the interface where the highest temperatures are obtained is not touched by the water. See **Exhibit 10** for a more detailed discussion of this issue.

There are other devices cleared under product code LZV which have the same intended use as the OSCAR system--removal of bone cement. However, most of these devices are manual instruments. The Origin Medsystems Prosthetic Cement Remover is such a device. Other devices in this category are pneumatically powered rotary burrs, drills and reamers, the use of which involves high risk of bone injury from direct mechanical damage or excess heating.

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C. ADVANTAGES OF OSCAR ORTHOSONICS SYSTEM FOR CEMENTED ARTHROPLASTY REVISION OVER THE PREDICATE DEVICES

The main advantages that the **OSCAR Orthosonics System for Cemented Arthroplasty Revision** enjoys over the other types of devices available for cement removal are safety and speed.

The main concern for all cement removal techniques is bone perforation or fracture, the consequence of which can be greatly increased post-operative recovery times. High speed burrs can cause femoral necrosis. If the OSCAR system is used according to recommended procedures, the probe will never touch the bone. If the probe does touch the bone momentarily, it would not cause any significant damage. A high-pitched audible noise comes from the probe when it contacts bone, warning the user. Performance testing reported in **Section III** showed that in an animal model, even 10 seconds of direct contact with live bone caused cell death only to a local depth of 50 microns--much less that the 500 micron depth of cell death due just to the curing of the (regular) PMMA cement.

The OSCAR system is much faster and safer than manual or powered mechanical cement removal systems. Where hammers and chisels are used, just the cement removal can take up to two hours, and femoral perforation or fracture occurs in a substantial proportion of cases[1]. High-speed drills may reduce the time for cement removal, but the potential for femoral damage is increased. If a fracture occurs and cement leaks out between the fractured bone ends, there is no possibility of bone healing since the cement will cause a mechanical obstruction.

In many instances where mechanical tools are used, surgeons elect to make a window in the femur at the level of the distal plug to allow removal of the plug under direct visualization. When this is done, the cement used to bond a replacement prosthesis in place cannot be pressurized effectively and the resultant cement-bone bond is weaker than would have been obtained had the window not been made. This window is not necessary with the OSCAR device.

Cement removal using OSCAR can normally be accomplished in 25 minutes or less. The risk of bone perforation or fracture is negligible when OSCAR is used. In the clinical study reported in **Exhibit 5**, the complication rate fell from 9.1% to zero in the first year after changing

---

1 According to the recent article by Brooks [*J Arthroplasty*, 8:517-521 (1993)], "The usual method of cement removal involves the use of chisels, saws, high-speed drills, burrs, osteotimes, and mallets, all of which have been associated with femoral fracture and perforation of bone in as many as 13% of revision surgeries."

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from manual tools to OSCAR.

Orthosonics recommends a cleaning and sterilization procedure for its probes, whereas the UltraDrive User Manual (see **Exhibit 11**) recommends no reuse. In practice, the users *do* reuse UltraDrive probes because it is too costly to discard them after one use. However, UltraDrive users have no validated procedures to follow for reuse of probes.

D. BIOCOMPATIBILITY

The OSCAR probes are made of a (b)(4) which is commonly used in dental and orthopedic implants. The short time of exposure of the patient to the probe, and the good reports of biocompatibility with long-term implants made of the same alloy, assure that employing the probes for their intended use raise no biocompatibility issues.

E. SUMMARY

Orthosonics has demonstrated through its performance tests on the OSCAR device and its comparison of OSCAR characteristics with those of the predicate devices that the OSCAR device is substantially equivalent to the predicate devices.

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SECTION V

SOFTWARE

A. LEVEL OF CONCERN

For the purposes of this 510(k) submission, Orthosonics has chosen to treat its software as representing a **moderate level of concern**, even though Orthosonics believes that a case could probably be made that the software represents only a minor level of concern.

B. SOFTWARE DEVELOPMENT AND TESTING

Orthosonics' software development and testing procedures are described on the following pages and in **Exhibits 12-16**.

C. SOFTWARE CERTIFICATION

I hereby certify that the software development process described herein was followed, that quality assurance procedures were adhered to, and that testing demonstrates that the functional requirements were met and that system specifications were fulfilled. Future revisions of this software will also be developed following this process.

Michael J. R. Young

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D. SOFTWARE DEVELOPMENT MANUAL

The Orthosonics Software Development Manual, Version 1.2, is included in **Exhibit 12**. This manual describes the overall approach to software development and testing at Orthosonics. The responsible persons for development activities and final approval are named.

The Software Development Manual specifies that development follow the steps recommended in the FDA Guidance:

(1) System and Software Requirements and Design

(2) Hazard Analysis

(3) Development and Testing

(4) Authorization

(5) Documentation

(6) Revision Procedures

E. HAZARD ANALYSIS

The Hazard Analysis for the OSCAR device may be found in **Exhibit 13**. Potential problems which might harm the hardware or the patient are discussed along with the consequences of each.

F. OSCAR SYSTEM AND SOFTWARE REQUIREMENTS AND DESIGN

The requirements document for the OSCAR device may be found in **Exhibit 14**. The software for the OSCAR device only has a small number of functions or requirements, and these are discussed.

G. OSCAR SOFTWARE DESCRIPTION

The Software Description document for the OSCAR device is in **Exhibit 15**. The functions of the various modules are described, as are the subroutines which comprise each module. A chart showing the relationship of all the functional components is included, along with flow charts of the individual subroutines.

H. OSCAR VERIFICATION, VALIDATION, AND TESTING

The OSCAR test procedures are described in **Exhibit 16**. The test procedures include initial testing on an emulator, through device testing. Sample software test and authorization forms are also included.

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SECTION VI

LABELING

This section contains the product labeling: claims, instructions for use, and promotional literature.

A. CLAIMS

Orthosonics makes the following claims for the OSCAR system:

(1) The **OSCAR Orthosonics System for Cemented Arthroplasty Revision** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision.

(2) Arthroplasty revision with the OSCAR device is significantly faster than revisions which employ mechanical instruments.

The study carried out at the Leicester Hospital (see **Exhibit 5**) found that revisions using OSCAR took a total of 2.75 hours, versus 3.5 hours using traditional instruments, or a 21% reduction in total time. The cement-removal step represents only a part of the total time for revision, so the reduction in cement removal time is much larger than 21%--clearly a significant reduction.

(3) Arthroplasty revision with the OSCAR device results in significantly fewer complications than revisions with mechanical instruments.

The study carried out at the Leicester Hospital (see **Exhibit 5**) found that revisions using OSCAR had no complications in 53 cases, while there were 6 complications in 66 cases (9.1% complication rate) using traditional instruments.

B. INSTRUCTIONS FOR USE

Orthosonics's draft Operator's Manual for the OSCAR device is included in this section.

C. FACE-PLATE AND PACKAGE LABELING

The labels affixed to the OSCAR front and back panels are illustrated in Appendix 1 of the Operator's Manual.

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The following information will be printed on a label which will be affixed to the housing for the power modules:

- Orthosonics identification, address, and logo
- OSCAR Orthosonics System for Cemented Arthroplasty Revision
- See Instructions prior to use
- Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

The following information will be printed on a label which will be affixed to the package containing the probes:

- Orthosonics identification, address, and logo
- OSCAR Orthosonics System for Cemented Arthroplasty Revision
- Part identification
- NON-STERILE
- See Instructions for Cleaning and Sterilization prior to use.
- Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

D. PROMOTIONAL MATERIALS

Following the Operator's Manual in this section, promotional literature used with the OSCAR device is presented.

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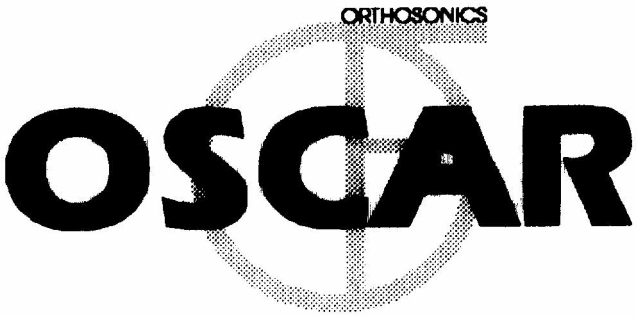

Orthosonics System for Cemented Arthroplasty Revision

OPERATIVE MANUAL

version 1.5

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page	subject
1	Introduction
4	The Equipment
11	Cleaning and Sterilising OSCAR system
14	Safety Precautions and Equipment Care
16	Operative Technique
21	Problems and Solutions
24	Appendices:

i. Markings on OSCAR front and rear panels
ii. List of Parts
iii. Technical Information
iv. Bibliography

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INTRODUCTION

The introduction of acrylic cement, (polymethylmethacrylate, PMMA, bone cement) as a space filling fixation material by Charnley in 1960, was a major breakthrough in joint replacement surgery. With increasing numbers of patients undergoing total hip replacement, and the fact that the cement-bone interlock weakens after several years, the number of patients requiring revision hip surgery is also increasing. At the present time approximately 60,000 cemented hip replacements are performed annually in the U.K., and 139,000 in the United States. The revision rate is currently about 8% per annum.

While a prosthesis is in place, the femur is stress-protected by the metal and cement. As a result of this, the cortex of the bone becomes thinner, and eventually, regional osteoporosis develops. At revision, therefore, removal of the well-bonded brittle cement from within a tube of fragile bone, presents a formidable challenge to the orthopaedic surgeon and carries with it a considerable risk to the patient.

Until now, available techniques have been tedious and time-consuming. Where hammers and cement chisels are used, cement removal can take up to two hours, and femoral perforation or fracture can occur in a substantial proportion of cases. High speed drills may reduce the time for cement removal but the potential for femoral damage is increased If a fracture occurs and cement leaks out between the fractured bone ends, there is no prospect of the bone healing as the cement will cause a mechanical obstruction.

In many instances surgeons elect to make a window in the femur at the level of the distal plug to allow removal of the plug under direct visualisation. When this is done, the cement used to bond a replacement prosthesis in place cannot be pressurised effectively and the resultant cement-bone bond is weaker than would have been obtained had the window not been made. Furthermore, where a window is made in the femur, it is necessary to employ a long-stemmed femoral component. This has the effect of producing more stress protection within the femur and osteoporosis will occur over a longer length of bone. This can produce a stress raiser at the tip of the prosthesis, and in some cases patients develop supracondylar fractures.

Where the femur fractures during revision surgery, it is necessary for the patient to remain partially weightbearing for a period of up to 3 months, and this in itself can prolong hospitalisation, as elderly people find it difficult to learn to walk safely with crutches.

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Ultrasound and the removal of bone cement:

Ultrasound is the name given to high frequency vibrations (above 16 kHz) which 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. Attempts were made at the Endo Clinic in Hamburg in the early 1970's to remove bone cement by melting it with ultrasound. Bone cement is remarkable in that it can maintain a temperature gradient of 200°C over a distance of 1mm. This means that if molten cement can be removed rapidly, the residual cement hardly increases in temperature, thus minimising damage to adjacent bone. In the initial studies in Hamburg, however, it was found difficult to remove the molten cement.

The technology is now available to do this, using a series of specially designed handsets and probes in conjunction with a portable ultrasonic generator ("OSCAR" - Orthosonics System for Cemented Arthroplasty Revision). Animal studies have demonstrated that when the tip of the probe is in contact with the endosteal bone surface for a period of 10 seconds, cell death to a depth of only 50 microns occurs. This contrasts with cell death to a depth of 500 microns which occurs when conventional PMMA is applied to the endosteal surface.

Cement removal using this technique is extremely rapid, and can normally be accomplished in 25 minutes or less. The risk of bone perforation or fracture is negligible when OSCAR 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. It has been designed with surgeons, scrub nurses, technicians and hospital engineers in mind and its use permits the accurate scheduling of theatre lists.

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The Benefits of OSCAR:

Rapid - Cement liquifies on contact with probe enabling complete removal in 2.5 to 25 minutes.

Low risk of femoral damage - The equipment will give an auditory warning when the probe touches bone.

Efficient - Speedy and complete cement removal with low risk of femoral fracture means predictable operating time and more efficient planning of theatre lists.

Short Learning Curve - Easy to use; fingertip control for the surgeon.

Removes the need to make femoral windows - No stress raisers produced, and the ability to pressurise cement is not compromised giving better cement-bone interlock.
No need for image intensification - Reduced radiation in the theatre environment.

Completely portable, lightweight apparatus - Easy transport between theatres and hospitals.

Modular generator design - Back up units available; units can be individually serviced.

Re-usable probes - Economical

Autoclavable - can be used for several procedures in a single day.

Liquid Crystal Display - Continuous information on functional status of the equipment.

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THE EQUIPMENT

This comprises a portable generator with three modules; three interchangeable handsets and associated cables, and a dedicated cleaning system.

The Generator

The generator, which is mains powered and completely portable, is made up of 3 identical modules which operate independently of one another, each driving a handset with a different probe attached. A block diagram of the electrical system is shown in Figure 1.

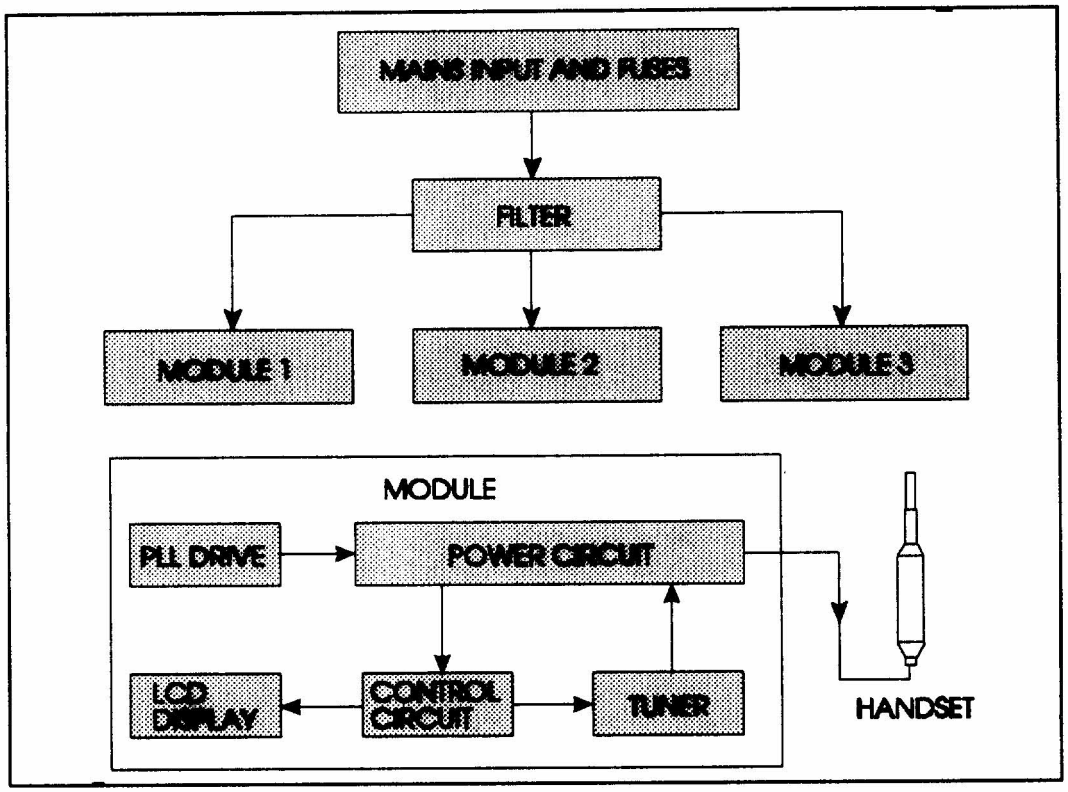

Figure 1

The modules are microprocessor controlled and are designed to produce ultrasonic energy at the resonant frequency of the attached handset within a range of 27.5 to 29.5 kilohertz. Careful control of the generator output ensures that the energy delivered to the probes increases automatically in response to the increased load; in effect, as the probe is pushed into the bone cement more energy is supplied to the handset - ranging from a few watts to a 200 watt output. In practice the peak loads do not exceed 130 Watts when piercing solid cement.

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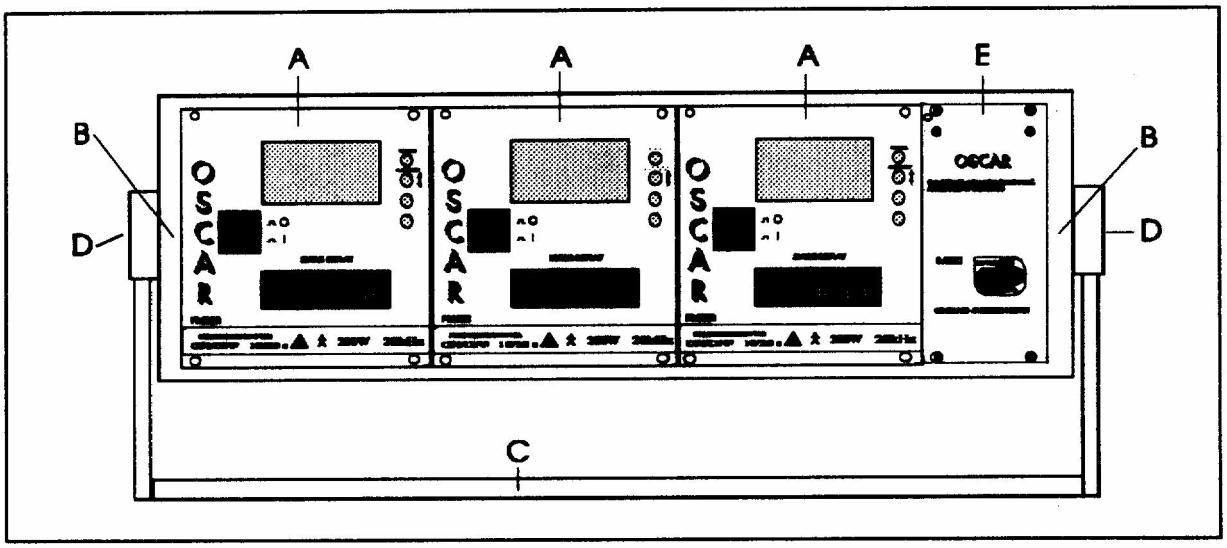

Figure 2

Once connected to the mains supply, the generator (Figure 2) is activated by the ON/OFF switch at the back. The individual power modules (A) are protected by a splash-proof screen which can be unlocked using keys, on either side (B). The generator has a carrying handle which doubles as a stand (C). It is adjusted for this purpose by depressing the centre of the hinge, on either side of the generator (D) and rotating the handle inferiorly to the front of the module. This improves visibility of the module displays. The small module located to the right of the three power modules is the mains power conditioning module (E).

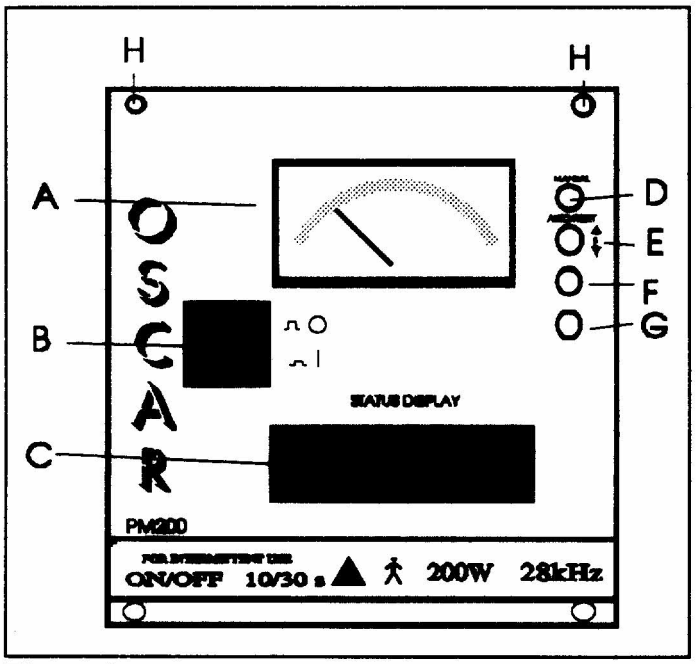

Figure 3

On the power modules themselves (Figure 3), an analogue meter (A) gives an indication of the mechanical load on the system, and shows when the handset is correctly tuned and working optimally. The meter needle should remain within the green band when initially tuned in the unloaded condition. As the activated probe is pushed into the cement the increased load causes the needle to deflect into the yellow band.

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If the indicator needle is in the yellow band when unloaded, the handset will require to be re-tuned. The surgeons can do this automatically by pressing the button on the handset twice, holding it down firmly on the second press and waiting for the module to complete its tuning cycle. Should this fail to re-tune the handset, the Reset button (see Fig 3[D]). should be depressed and released. This will instigate a full tuning cycle. The tuning cycle is accompanied by a series of audible tones, and should be allowed to continue until the tones cease.

The power switch (B), can be used to disable a module prior to its removal from the generator caseframe.

The Liquid Crystal Display or LCD (C) indicates the current status of the handset by displaying a series of messages and system readings.

The top switch (D) is marked "MANUAL" & "AUTO/RESET".
This switch should always be left in the central (AUTO) position. The up (MANUAL) position is for system diagnostic purposes only. Pressing the switch down and then releasing will reset the microprocessor. This may be necessary during the course of an operation. The lower switch (E) and apertures (F) and (G) are for servicing purposes only.

Should an individual module fail for any reason, the remaining modules will remain operational. In these circumstances the module in question can easily be removed for servicing by Orthosonics engineers by loosening the screws in the top corner of the front plate (H), and pulling the unit forwards.

The Handsets

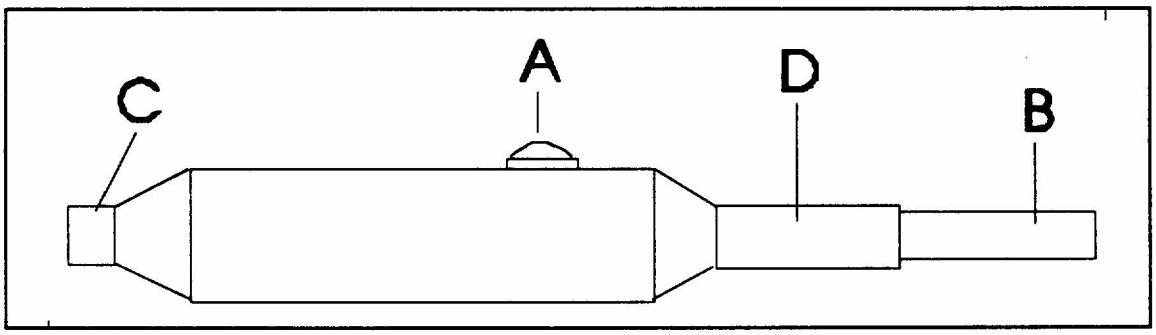

Figure 4

Three handsets are supplied with the instrument (Fig 4). Each handset contains a Piezo-ceramic sandwich transducer (the ultrasonic "motor") and a mechanical focusing device, the "horn" [B]. These are enclosed in a water and pressure tight stainless steel casing which incorporates a small hand operated switch [A]. This switch if depressed once and held will operate the handset; if depressed twice, and held down, it will retune the handset. The electrical connection is at the rear end of the handset [C]. The shroud [D] is removed from the handset prior to autoclaving.

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A variety of probes may be fitted to the output end of the horn via a screwed coupling, and these permit the surgeon to carry out a range of procedures with maximum efficiency. Each probe consists of a wave-guide which is an integral number of half-wave lengths long, its shape and overall length being chosen to suit a particular case.

The signal from the generator induces the crystals within the handset to vibrate, producing ultrasonic energy. This energy is focused along the wave-guide to the tip of the probe, which will vibrate at approximately 28.5 KHz. The rapid oscillatory movement produces heat when the tip of the probe is in contact with bone cement, causing the cement to liquefy for a fraction of a second.

The Probes

There are three different probe designs. All probes are made of titanium, and screw into the distal part of the horn. They are tightened using a 9mm spanner. Each probe is designed to perform a different function, grooving, scraping or piercing. Those probes designed to cut through regions of compact cement have heads incorporating two or more perforations. 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, solidifying behind it when the ultrasonic energy is turned off.

Smoke is generated during the procedure. The dominant components are methylmethacrylate, benzine and styrene. All concentrations produced are well below OES/MEL values. (OES = occupational exposure standards, MEL = maximum exposure limits).

Once broken up in this way, the fragments of cement can readily be removed, either by withdrawing the probe, or using conventional instruments.

Probes designed solely for scraping material from the endosteal surface of the bone are not equipped with perforations in the probe head. A description of individual probe designs follows:

Do not allow any probe to come into contact with a metal surface whilst active, as this will cause damage to the probe.

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The Groover

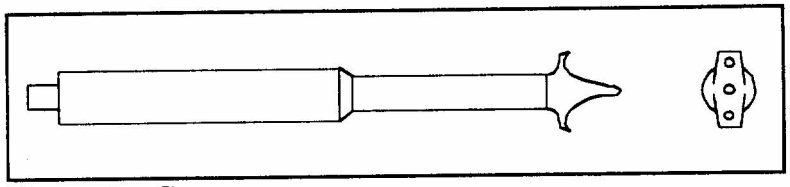

Figure 5: Groover

The groover (Figure 5) has a flattened spear-shaped head with one hole on either side and a forward cutting blade at the most lateral aspect of the device.

The groover is used primarily, to cut longitudinal channels in the proximal cement mantle, in order to weaken the integral cement mass and permit segmental removal with conventional instruments. When the groover comes into contact with bone, a high-pitched squeaking noise is heard, and resistance encountered.

The Axisymmetric Reverse Scraper

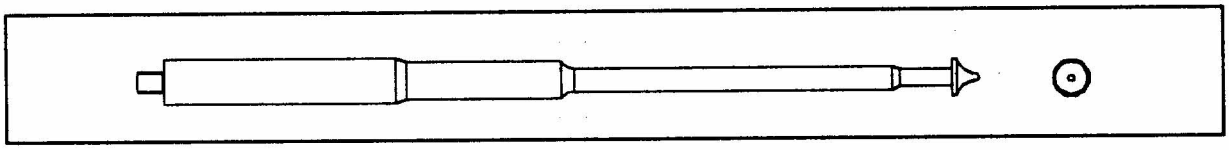

Figure 6: 8mm scraper

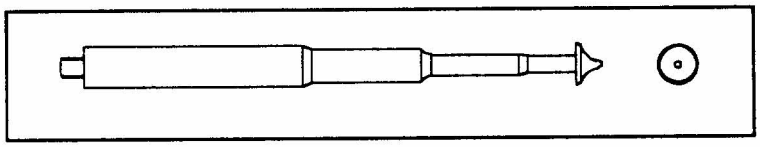

Figure 7: 10mm scraper

The scraper is spear-shaped, with no perforations within the head and is supplied with two tip diameters, 8mm (Figure 6) and 10mm (Figure 7). Note: the the 10mm scraper has a short wave guide. The cutting edge 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. It may also be used to cut circumferential channels in the cement mantle to break the shell and aid its removal with minimal force.

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The Piercer

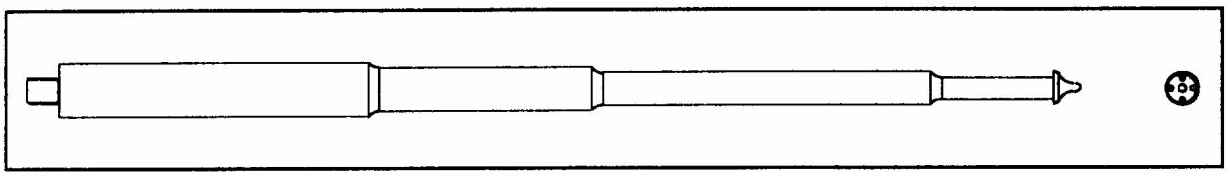

Figure 8: 6mm Piercer

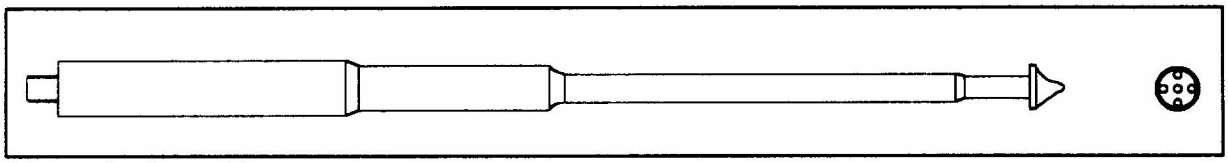

Figure 9: 8mm Piercer

The piercer is a round, spear-shaped device with 4 perforations in the head and it used for fenestrating the distal plug of cement to provide a clear channel, which can then be enlarged using the long scraper. The piercer is supplied with two tip diameters 6mm (Figure 8) and 8mm (Figure 9). A slight bend has been engineered in the wave guide deliberately so that when the piercer comes into contact with bone it can be redirected by rotating the handset through 90 degrees, thus allowing the piercer to find a fresh route through the cement. When the piercer strikes bone there is a high pitched audible squeaking noise and resistance is felt, even if the bone if wafer thin.

It should be noted that the piercer will de-tune when it is in contact with bone, unless it is circumferentially compressed by bone, when de-tuning will not occur but resistance will be felt and no smoke will be generated.

The Acetabular Probe

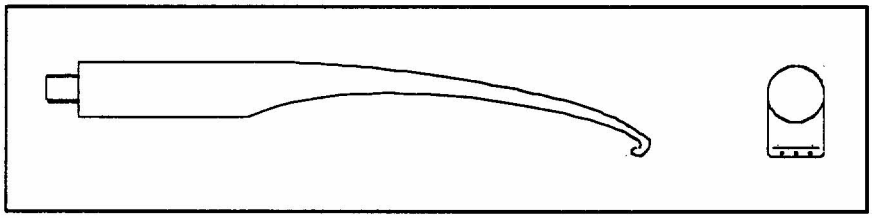

Figure 10: Acetabular Probe

The Acetabular (Figure 10) probe is used to assist in the removal of the acetabular cup. It is important to remember that when using OSCAR, none of the activated instruments should be allowed to make contact with metallic components; this is particularly relevant when considering its application to the acetabular cup.

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The Cables

Silicone rubber cables with screened conduction wires are supplied with the equipment to connect the handsets to the generator. Each cable contains 2 separate ground leads for safety reasons and the device will not work if either of these leads should become detached. This means in effect, that the patient will be grounded when in contact with the device and this may cause hospital diathermy equipment to cease functioning as this apparatus will not work when the patient is grounded.

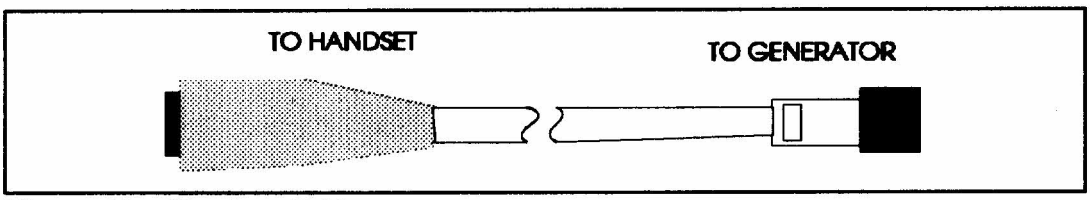

Figure 11: Handset Cable

The sterile cable (Figure 11) is connected to the rear of the generator by inserting the single way connector appropriately and tightening up a locking ring. The same procedure is used to connect the cable to the handset. The cable should then be secured to the trolley top drape using a towel clip, care being taken not to perforate the cable.

An additional non-sterile cable (Figure 12) can be supplied upon request. This enables the handset to be operated at a greater distance from the generator. This cable is first attached to the back of the generator and it is then connected to the sterile cable which has already been attached to the trolley top drape using a towel clip, care being taken not to perforate the cable.

Do not attempt to autoclave the non-sterile cable as this can lead to serious equipment damage.

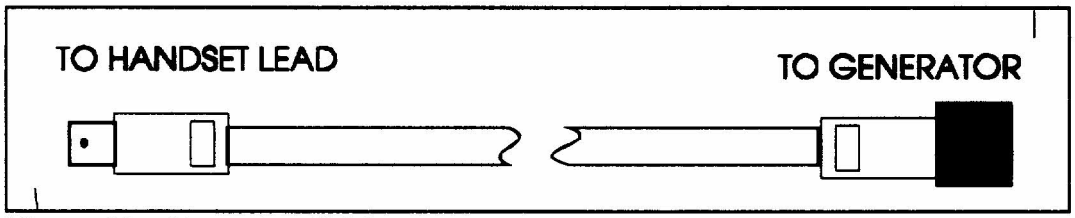

Figure 12: Extension Cable

Module Blanking Plate

If a power module needs to be removed for repair and no spare module is available then the exposed aperture should be covered with a module blanking plate and secured by the screws at each corner.

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CLEANING AND STERILISING OSCAR SYSTEM

PREFERRED METHOD:
- Washing Machine
- OSCAR probe cleaning instrument
- Autoclaving

1. Washing Machine:

After use, separate handsets, cables and probes and remove shroud (see Fig 4[D]) from each handset.

The handsets should be positioned so that their switches are not depressed.

The cables should not be kinked.

Place cables, handsets and probes in the washing machine and complete cycle.

Allow them to air dry and cool, for 30 minutes.

2. OSCAR probe cleaning instrument:

After surgical use it is necessary to remove all traces of PMMA from each instrument head prior to sterilisation. This avoids the risk of contamination from small traces of tissue which might be trapped under the cement. The cleaning system (Figure 13) is designed for use in the "sluice" room and consists of a small trolley-mounted enclosure containing an ultrasound generator with timing control circuit and a cleaning cell.

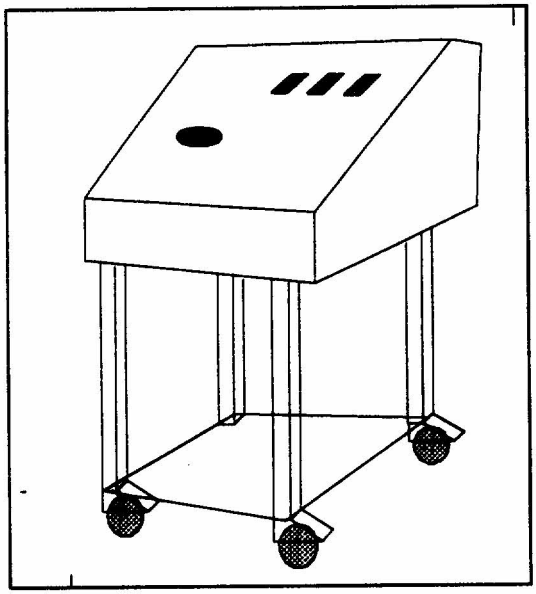

Figure 13

Ensure that all pins and sockets on ends of handsets and cables are dry then re-assemble the cables, shrouds and each contaminated probe. Insert a new cleaning cell in the OSCAR cleaning equipment and clean each probe. Each handset with its contaminated probe is connected via the connecting cable to the socket at the rear of the enclosure.

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The probe is then inserted into the cleaning cell when it is automatically energised by special circuitry incorporated in the apparatus. It is held in place in this way until the cleaning cycle is complete. A short cycle, (15 secs) and long cycle, (30 secs) are selectable to provide optimum cleaning conditions. Should traces of cement remain after removal from the cell, the operation may be repeated until visual inspection of the cement removal head indicates that cleaning is complete.

The cleaning cells (Figure 14) are designed to be discarded after use due to contamination build up, and it is recommended that this be done daily following one or more revision procedures.

Replacement cells are supplied with sealed ends; the seals are broken as the first revision instrument is inserted.

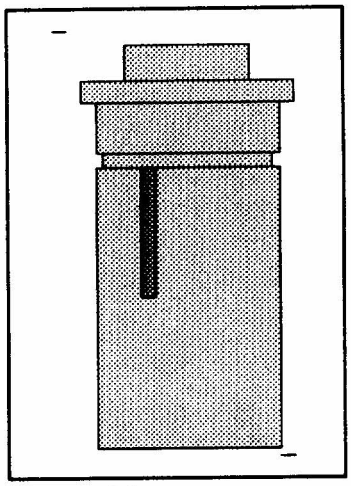

Figure 14

3. Autoclaving

Wrap instruments
Use a gravity or vacuum cycle autoclave; cycle 132°C -136°C; 10min.

Ensure that the electrical connectors are completely dry before connecting the handsets to the generator or cleaning system.

4. After Autoclaving:
The handsets should be allowed to cool for at least 45 minutes.

N.B. ALL PARTS SHOULD BE PLACED ON ONE TRAY AND RETURNED TO THEATRES AS A FULL SET.

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IF NO WASHING MACHINE IS AVAILABLE

After washing the dismantled equipment by hand it is imperative not to carry out the OSCAR cleaning system stage until the handset and cable pins and sockets are thoroughly dry.

Notes on Autoclaving:

The following items are autoclavable at a temperature not exceeding 136°C:

Handsets
Cables which attach directly to the handset, (**NOT** the extension cables)
All probes
Spanners

During autoclaving the cable **MUST NOT** be connected to the handset. Care should also be taken to ensure that the cables are not kinked during sterilisation as this can produce cracks in the cable and reduce cable life.

The handsets must be positioned in the autoclave such that their switches are not depressed during sterilisation as this can also cause damage.

Should the handset have recently been removed from the steriliser and be warm, it will require to be cooled prior to use for at least 45 minutes. Faster cooling can be accomplished by immersing it in cold saline, with the cable connected, or by wrapping saline-soaked swabs around the handset. **It is always best to begin with the equipment at room temperature.**

IMPORTANT: WHEN THE HANDSETS HAVE BECOME HOT DURING USE OR AFTER CLEANING, THEY CAN RETAIN A SMALL STATIC CHARGE WHICH CAN BE DISCHARGED THROUGH THE PINS AT THE BACK OF THE HANDSET. AVOID TOUCHING THESE PINS, IF A CHARGE IS EXPERIENCED THIS WILL BE LIKE A CHARGE FROM A CAR ON A WARM DRY DAY. THE CHARGE IS DISPERSED WHEN HANDSETS ARE ATTACHED TO THE GENERATOR.

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SAFETY PRECAUTIONS AND EQUIPMENT CARE

Before Use:

Before use it is recommended that the probes are inspected for cracking or other damage and the cables for damaged insulation.

In Use:

Do not operate OSCAR in a potentially explosive or flammable area.

It is recommended that OSCAR is not used in cases where a patient or an operator of the unit has been fitted with a cardiac pacemaker.

Please take care of the handsets, probes and cables as rough treatment may affect the safety and performance of the unit.

The use of handsets or probes not supplied as part of the OSCAR system may damage the generator and create a safety hazard for the operator and patient.

Avoid allowing an energised probe coming into contact with any metal surface.

Where possible, avoid allowing probes to become stuck in cement as this may cause the generator thermal trip to operate.

Do not allow an energised probe to come into firm contact with skin or muscle as this will cause a friction burn.

Do not overtighten the probes to the handsets.

Storage of Equipment between cases:

It is recommended that the handsets and cables are stored, between cases, in a large autoclave tray and again, care should be taken to ensure that the cable is not kinked close to the connector. In this situation it is much easier to coil the cable when the handset is disconnected.

Maintenance

There are no user-serviceable parts in OSCAR. However, since OSCAR consists of three independent and identical generator/handset systems it is usually possible to determine which component is faulty. See Problems and Solutions section of this manual.

Warning:

Should a module be removed from the generator case for repair or upgrading, the resulting aperture in the front panel will allow access to live parts if the unit is subsequently switched on. **ALWAYS** replace the missing module with a spare module or a blanking plate (see parts list).

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Precautions During Surgical Procedure:

The handset instruments are machined from a special titanium alloy and the profile of each instrument is carefully controlled to minimise the likelihood of metal fatigue and to ensure that it functions correctly throughout its expected life of six to nine months (30-50 operations). It is important to ensure that the instrument tip does not touch any metal component whilst the handset is engaged. Even a brief contact with a screw, retractor, or part of the prosthesis can result in serious damage and impair the performance of the instrument. Sparks may sometimes be seen if the probe tip comes into contact with metal.

The back scraper will lose its sharp cutting edge if it is in contact with hard cortical bone. Cracks in the piercer head will reduce its cutting efficiency, although it will still function.

If a probe becomes damaged during a procedure it is possible to replace it by unscrewing it from the distal part of the horn using a 9mm spanner. While replacing a probe in this way it is most important not to get talcum powder, blood or any form of contamination on the mating surfaces as this will cause them to become eroded and materially affect the ultrasonic conduction of the wave guide, making it less efficient. Cables should not be compressed during cement removal as this can cause fracture of the components of the cable.

Any damage to the probes or cables should be notified and the components returned to Orthosonics for repair or replacement at the earliest opportunity.

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OPERATIVE TECHNIQUE

The following description relates to hip surgery but is equally applicable to other forms of revision Arthroplasty. It is essential that the patient is placed on his/her side to facilitate cement removal. Following removal of the femoral component it is important to have adequate access to the cement. To this end it is worthwhile removing bone from the upper portion of the greater trochanter to allow straight access to the cement within the femoral canal.

Setting up:

Before starting, each of the three handsets bearing its probe should be attached to a different module within the generator unit. The generator outputs are marked with the handset symbol (Fig 15) and a number corresponding to its generator module.

Figure 15

First ensure that the device is plugged into mains voltage and that the switch on the back of the machine is in the 'ON' position. The individual switches (see Fig 3[B]) behind the splashproof screen should all be depressed and will light up when properly connected.

Tuning

When the machine is switched on for the first time with handsets attached it will go through an automatic full tuning cycle as each handset button is depressed.

A quick tuning cycle may be activated when the switch on the handset is pressed twice and held down; the tuning function is separate for each handset. Audible bleeps will be heard while the tuning cycle is in progress, and tuning is complete when the bleeping stops. The handset is activated only when the switch is depressed.

The full tuning cycle can be activated only by pressing the reset button on the power module (see Figure 3[D]), or by switching the module off and on (see Figure 3[B]).

The handsets will feel satiny when light pressure is applied to the wave guide. It is most important not to squeeze the probe as this will cause a friction burn to the tissues. It is equally important not to allow the wave guide to come into firm contact with the patient's skin or muscle during operation.

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Removal of the Proximal Cement Mantle:

The proximal cement in the upper third of the shaft is usually loose, with a membrane between it and the bone. This cement can be removed simply, using the groover to cut longitudinal channels through it. When the cutting edge of the groover 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. (Fig 16).

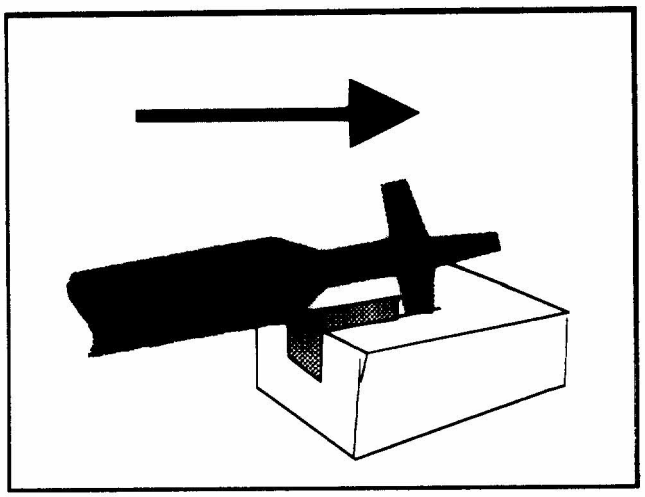

Figure 16

The groover 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 as far as the groover can go.

It is usual to make 3 longitudinal troughs within the cement at approximately 120 degree intervals. (Fig 17). The amount of force required is similar to that needed to push an apple core through hard butter.

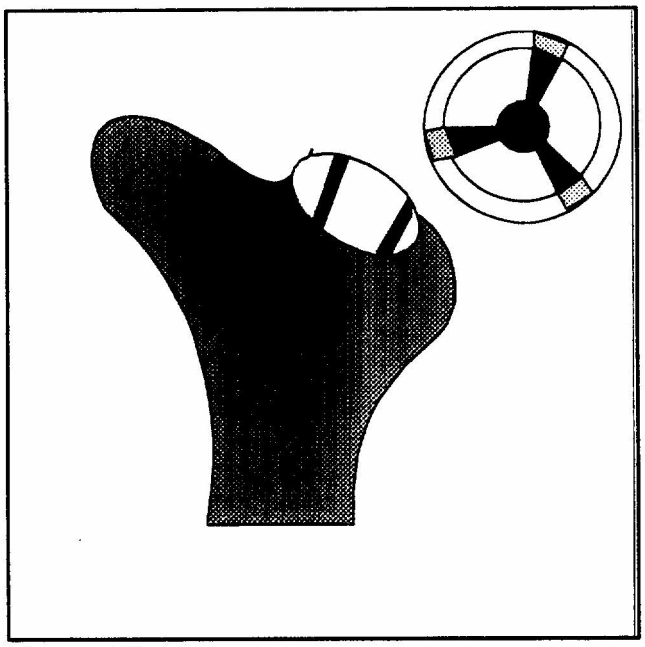

Figure 17

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 groover or a back scraper. The fragments of bone cement can then be folded into the medulla and removed with forceps.

The proximal cement is removed incrementally, using this technique, down to the level of the cement plug.

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Removal of Well-Bonded Cement and Residual Membrane:

Any residual well-bonded cement which remains after removal of the proximal cement mantle, and the fibrous membrane which is usually adherent to the endosteal surface, may be removed using the Axisymmetric reverse scraper (back scraper).

The back scraper cuts by focusing ultrasonic energy on to the retroverted cutting edge at the back of its spear shaped tip.

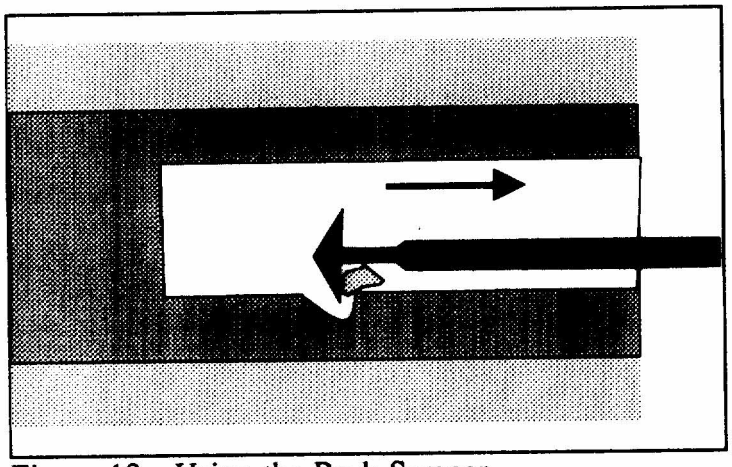

Figure 18: Using the Back Scraper

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. The membrane will peel off in strips (Fig 18) leaving a raw cancellous surface which is ideal for bone grafting should this be required.

Removal of the Cement Plug:

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 after advancing it for between 1.5 and 2 cm the switch on the handset is released and the handset is removed 1 or 2 seconds later. This short period of time allows the cement to solidify behind the flange for most efficient removal. (Fig 19). If the piercer is pushed with too much force, the energy at the tip will reduce and the system will work less efficiently.

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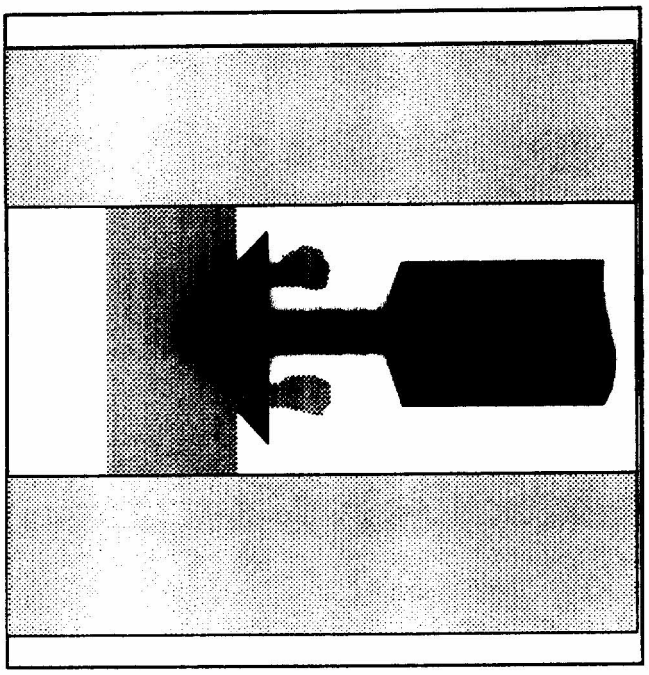

Figure 19

The cement removed using the piercer can be simply wiped from the wave guide using a wet swab, after each application. Should the tip of the piercer come in contact with bone, the wave guide will de-tune slightly and produce an audible high pitched squeaking noise. Resistance will be felt and the volume of smoke generated will diminish. Should this occur, all that is required is to rotate the handset through 90 degrees and the piercer will find a fresh path through the cement.

This is made possible by the fact that there is a very slight bend in the wave guide of the piercer. The piercer is used in this fashion 3 or 4 times to perforate the plug.

Removal of the Cement from the Distal Femur:

Once the plug has been perforated, it is necessary to remove the cement that is in contact with the distal femur and this can be done either with the groover or, if the femur is too narrow, with a long back scraper. (Fig 20)

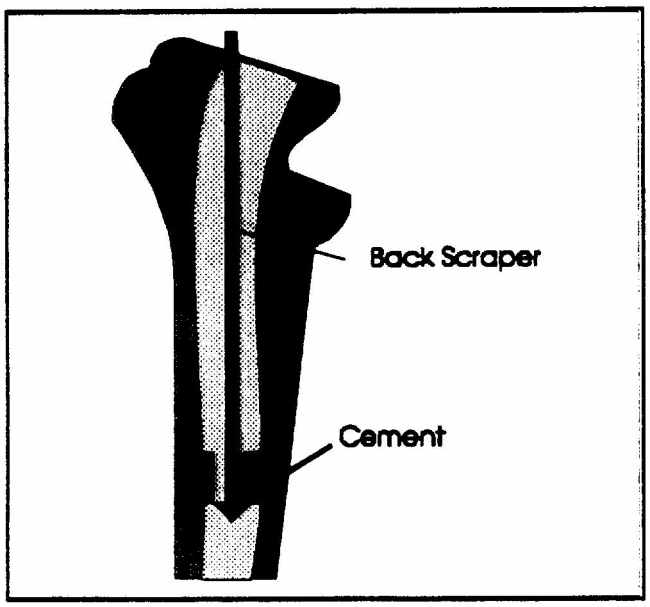

Figure 20

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.

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Removal of cement from the Acetabular cup

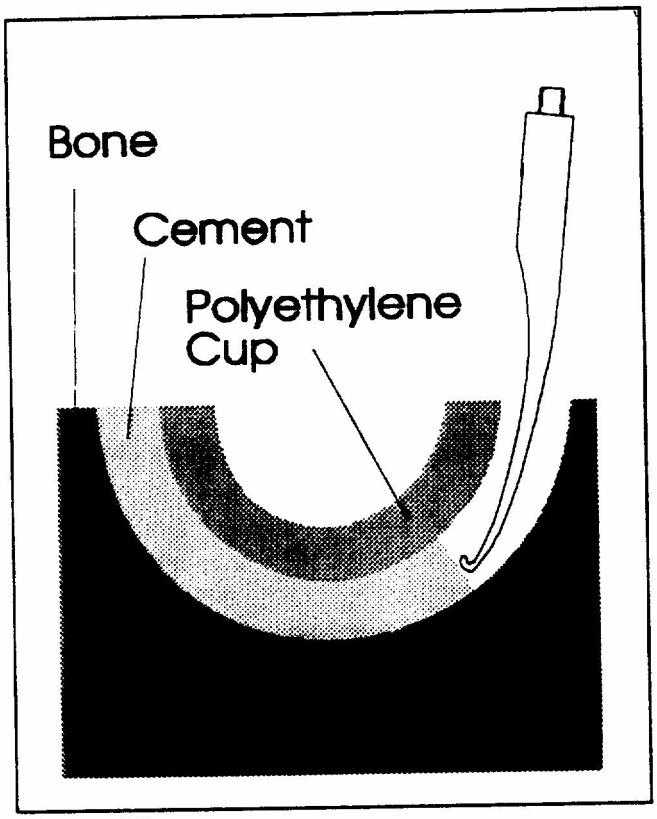

Figure 22

It is important to remember that when using OSCAR, none of the activated instruments should be allowed to make contact with metallic components; this is particularly relevant when considering its application to the acetabular cup. By reference to the X-Rays, identify and locate all metallic parts associated with the prosthesis; the acetabular probe 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 centre of the cemented hemispherical surface (Fig 22). Four or five slots should be sufficient to loosen the acetabular component which may then be removed by careful use of a cement chisel.

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PROBLEM & SOLUTIONS

1. Probe Stuck in cement:

This is most likely to occur when a piercer is being used. If the tip of the piercer is pushed too deeply into the cement, then the cement behind the tip is liable to solidify and trap the probe. If this happens, the normal tuning cycle may not be able to achieve resonance because of the mass of cement now attached to the probe.
To free the probe:

i. Press the RESET switch (Figure 3, D).

ii. Allow the tuning cycle to finish whilst gently rotating the probe (if possible).

iii. Repeat i. and ii. until the cement around the tip has softened sufficiently to allow a normal resonance be found.

iv. When the probe is resonating correctly it can be gently pulled from the cement.

Note: This procedure is likely to cause a thermal trip if repeated many times. If this occurs transfer the handset and lead to another module and continue the above procedure.

2. Metal fatigue:

This can occur if the probe comes into contact with metal and becomes scratched, causing a stress riser to appear. When this happens, fragments of the probe will fall off during operation.

Solution: Change the probe and replace at the earliest opportunity.

3. Intermittent power during operation:

If the handset/probe suffers from intermittent power and a clicking noise, caused by the tripping of relays, comes from the generator, then the cable connecting the handset to the generator will have fractured.

Solution: Change the cable associated with the defective system.

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4. Low power during operation:

i. The probe will appear to be working inefficiently if it is pressed too hard into the cement.

Solution: To enable the probe to work at maximum efficiency always press the tip gently into the cement. **Avoid excessive force at all times.**

ii. Lack of power during cutting can be due to the interface between the probe and the handset being slack.

Solution: Tighten the connection using the 9mm spanner provided. The power level can also be diminished if this interface is not clean and has been damaged due to the presence of particles. Should this occur, it is necessary to re-surface the interface. This can be done by the manufacturer.
Should the stud attached to the probe become loose, it must be returned to the manufacturer for repair.

iii. Loss of power when cutting cement can also be due to the crystals overheating. The crystals will heat up if the wave guide is working inefficiently and this occurs when it is inadequately tuned. The handset will become perceptively warm, and the energy required to drive the crystals will require to be adjusted.

Solution: Re-tune the handset to the new resonant frequency by double clicking the button on the handset and holding it depressed on the second click until the tuning cycle is complete.

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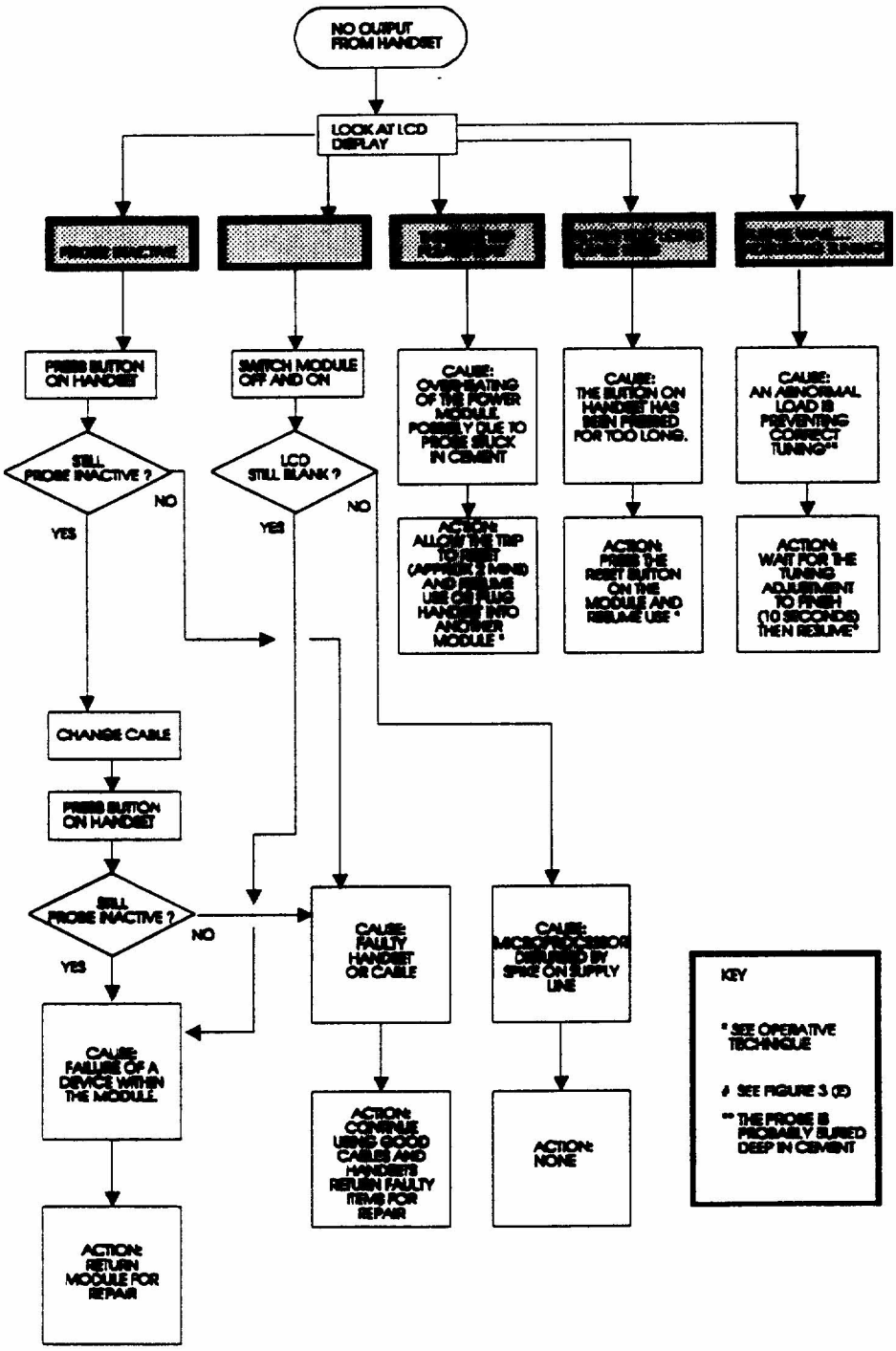
4. Loss of Power During Use.

Use the flowchart below:



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Appendix 1

Markings on the OSCAR front and back panels

⚠	ATTENTION: Consult accompanying documents before use
🚶	Type B equipment
○	Mains power off
|	Mains power on
~	Alternating voltage
T5A	Fuse rated at 5 Amps (antisurge)
FOR INTERMITTENT USE ON/OFF 10/30 s	Activate the handset for no more than 10 seconds in any 40 second period
28kHz	Approximate output frequency
200W	Approximate output power
	Handset

000065

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Markings on the OSCAR front and back panels (continued)

DOM

Date Of Manufacture (month year)

Tested to IEC601 by TUV

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Appendix 2

OSCAR Parts List

ITEM	Quantity *	see Fig.	Product Code
Ultrasonic Generator	1	2	OG2000
Power Module	(3)	3	PM200
Handset	3	4	OH200
Groover	1	5	OHG2020
Scraper 8mm	1	6	OHS2081
Scraper 10mm	1	7	OHS2100
Piercer 6mm	1	8	OHP2061
Piercer 8mm	1	9	OHP2081
Acetabular Probe	OPTION	10	OHA2030
Handset switch cover	3	4	OHC201
Handset Cable	3	10	CH200
Extension Cable	OPTION	11	CE200
Instrument Cleaner	1	12	OC200
Cleaning Cell	6	13	OC201
Module Blanking Plate	OPTION	-	BP200
Spanner	2	-	OSSP9

* SUPPLIED AS STANDARD

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Appendix 3

Technical Information

Generator:

Dimensions		52cm x 18cm x 40cm (width x height x depth) (excludes handle)
Weight	case	13.2 kg
	handset	1.1 kg
Operating frequency		28.5 kHz
Input voltage		120V ac or 230V ac
Input frequency		50 Hz - 60 Hz
Power consumption		600 watts max.
Modular system		3 modules (removable for maintenance).
Classification		Class 1 insulation, Type B

NOTE Patient applied parts are at ground potential.

Handset:

Stainless steel and titanium construction with sealed switch and cable connector, suitable for autoclave sterilisation. Connecting cable provided with grounded screen.

If the unit requires repair please contact:

Orthosonics Ltd.
Bremridge House
Bremridge
Ashburton
S. Devon
TQ13 7JX
UK

Tel: 01364 652426
Fax: 01364 653589

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Orthosonics Ltd is a member of the Orthofix group of Companies.

Appendix 4

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How did we get cement from a bone as delicate as this without breaking it?

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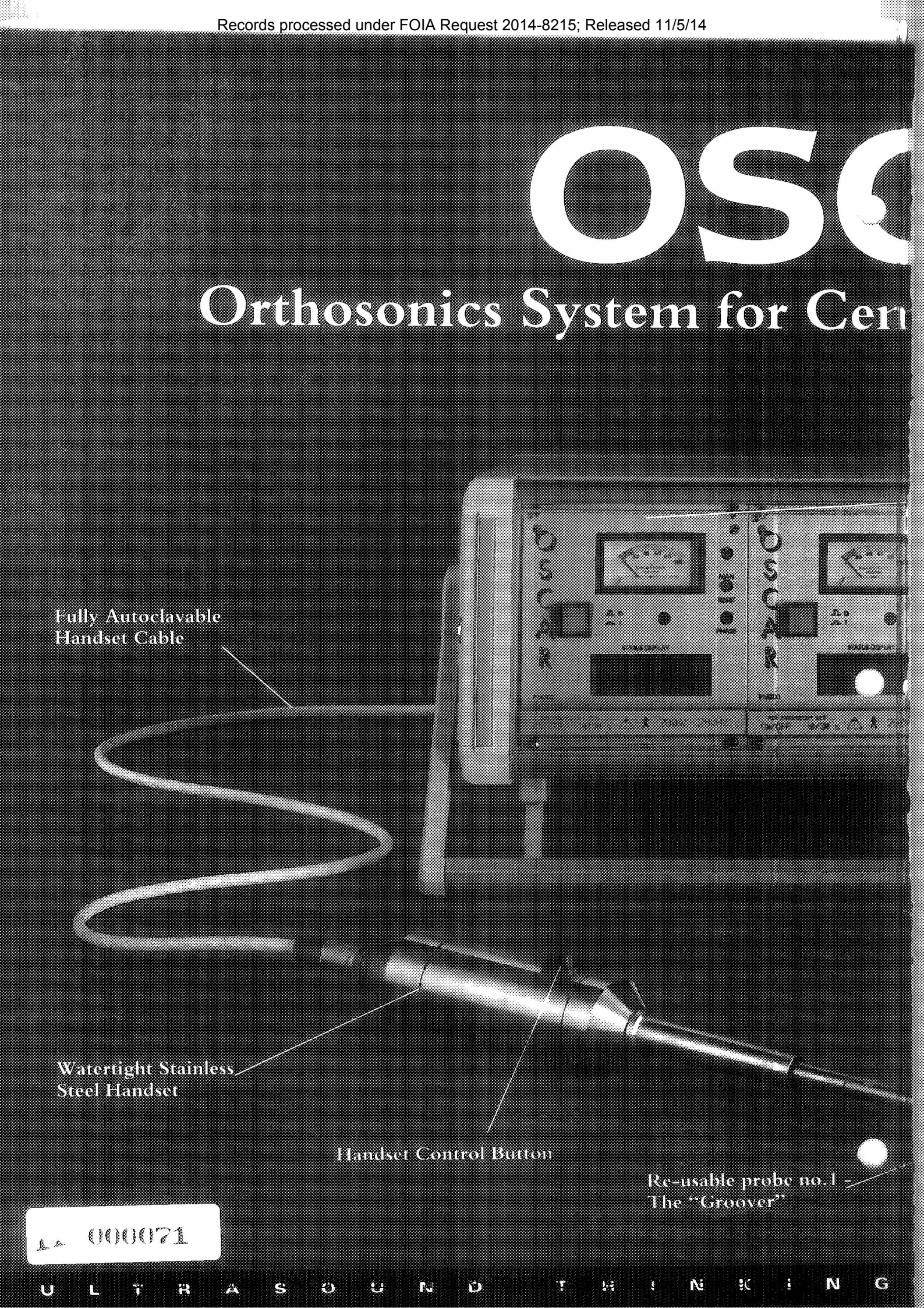
OSC

Orthosonics System for Cer



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U L T R A S O U N D T H I N K I N G

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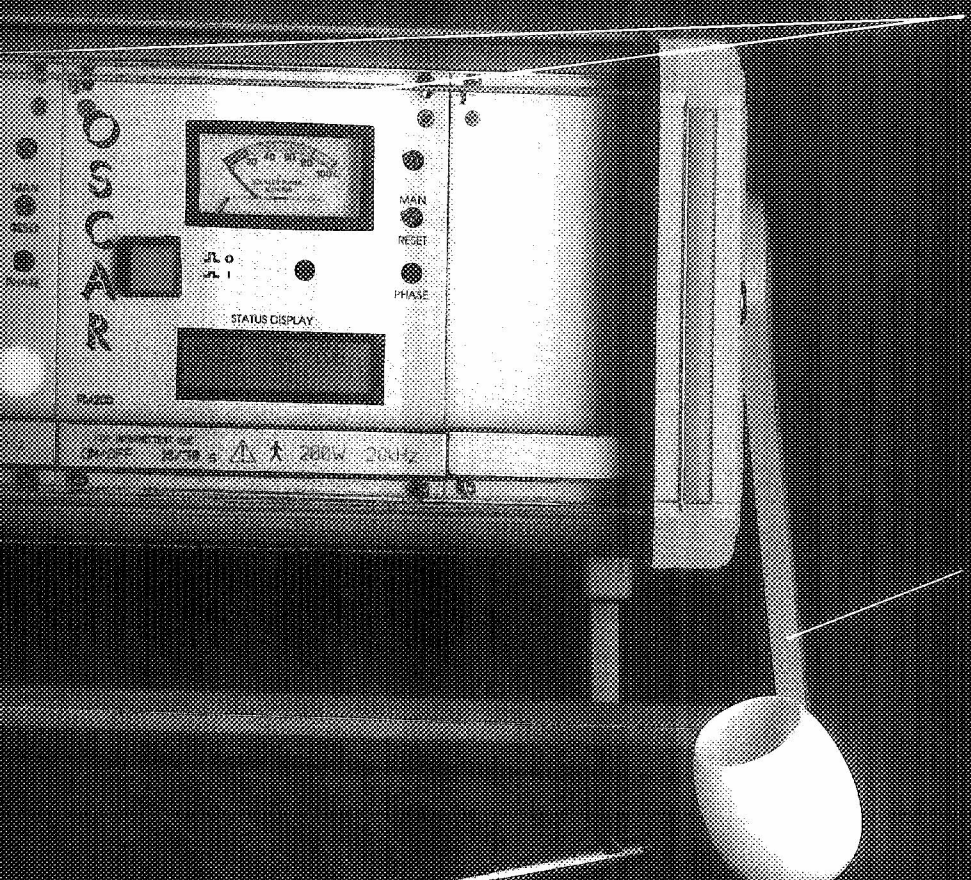
ented Arthroplasty Revision



Independent Power Modules

Stand/Carrying Handle

Re-usable probe no.2 - The "Scraper"

Re-usable probe no.3 - The "Piercer"

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I N R E V I S I O N S U R G E R Y

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With OSCAR you ca
in less than half the time, wi

Less theatre time

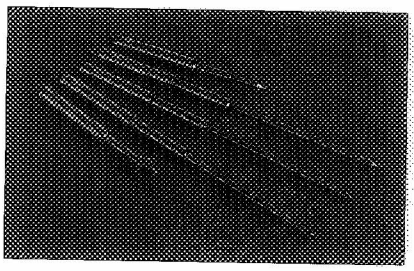
- Using conventional techniques it can take up to 2 hours to remove well bonded cement in revision arthroplasty

- With **OSCAR** it normally takes less than 25 minutes[1] - so operation time is more predictable allowing more efficient planning of theatre lists

Less trauma

- **OSCAR** uses ultrasonic waves to momentarily liquefy cement in the femoral canal - making removal easy with the help of specially designed re-usable probes

- **OSCAR** eliminates the need to create a "window" in the femur



- no stress raiser is produced, so there is minimal risk of fracture
- cement pressurisation is not compromised, so that a better cement-bone interlock is possible

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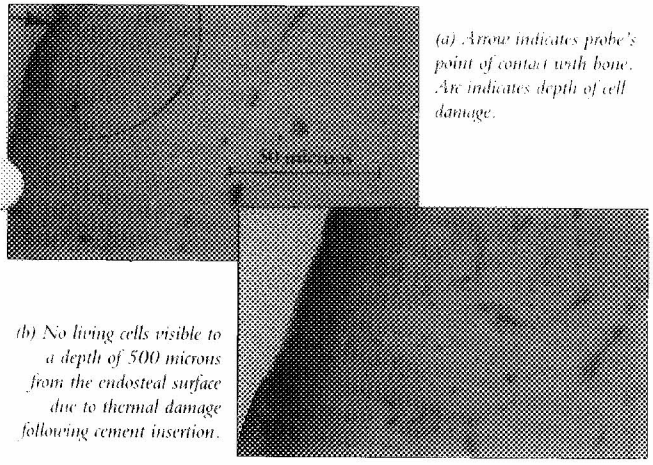
n do revision surgery
t. less than half the trouble.

Less damage to bone tissue

- When **OSCAR** was in direct contact with ovine bone for 10 seconds, cell damage to a depth of only 50 microns (0.05mm) (Fig a) occurred - this compares very favourably with the 500 microns (Fig b) of cell damage caused by the high temperatures associated with cement insertion[2]



(a) Arrow indicates probe's point of contact with bone. Arc indicates depth of cell damage.

(b) No living cells visible to a depth of 500 microns from the endosteal surface due to thermal damage following cement insertion.

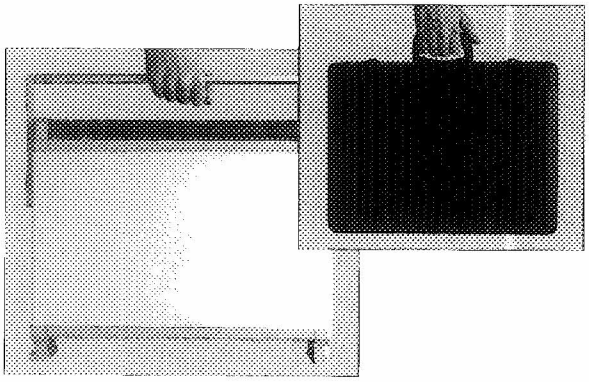
- **OSCAR** produces auditory feedback to discriminate between bone and cement further minimising the risk of trauma

Less stress for you

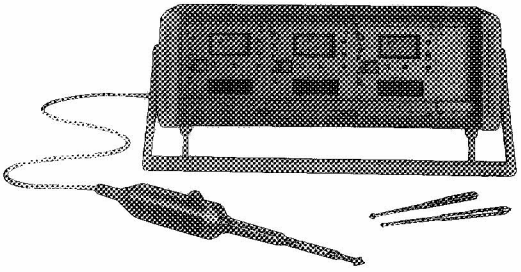
- Shorter, more predictable procedure
- Less physical exertion - no need to use excessive force to remove hardened cement
- Less mental exertion - **OSCAR** is simple to operate and the technique is easy to learn

Less cumbersome

- **OSCAR** is compact, unobtrusive and easily portable



Less is more



- **OSCAR** reduces theatre time, reduces the likelihood of bone trauma, and reduces stress for you, the surgeon - making revision surgery more predictable and more satisfying.

ORTHOSONICS

OSCAR

Orthosonics System for Cemented Arthroplasty R

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I N R E V I S I O N S U R G E R Y

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With OSCAR you ca
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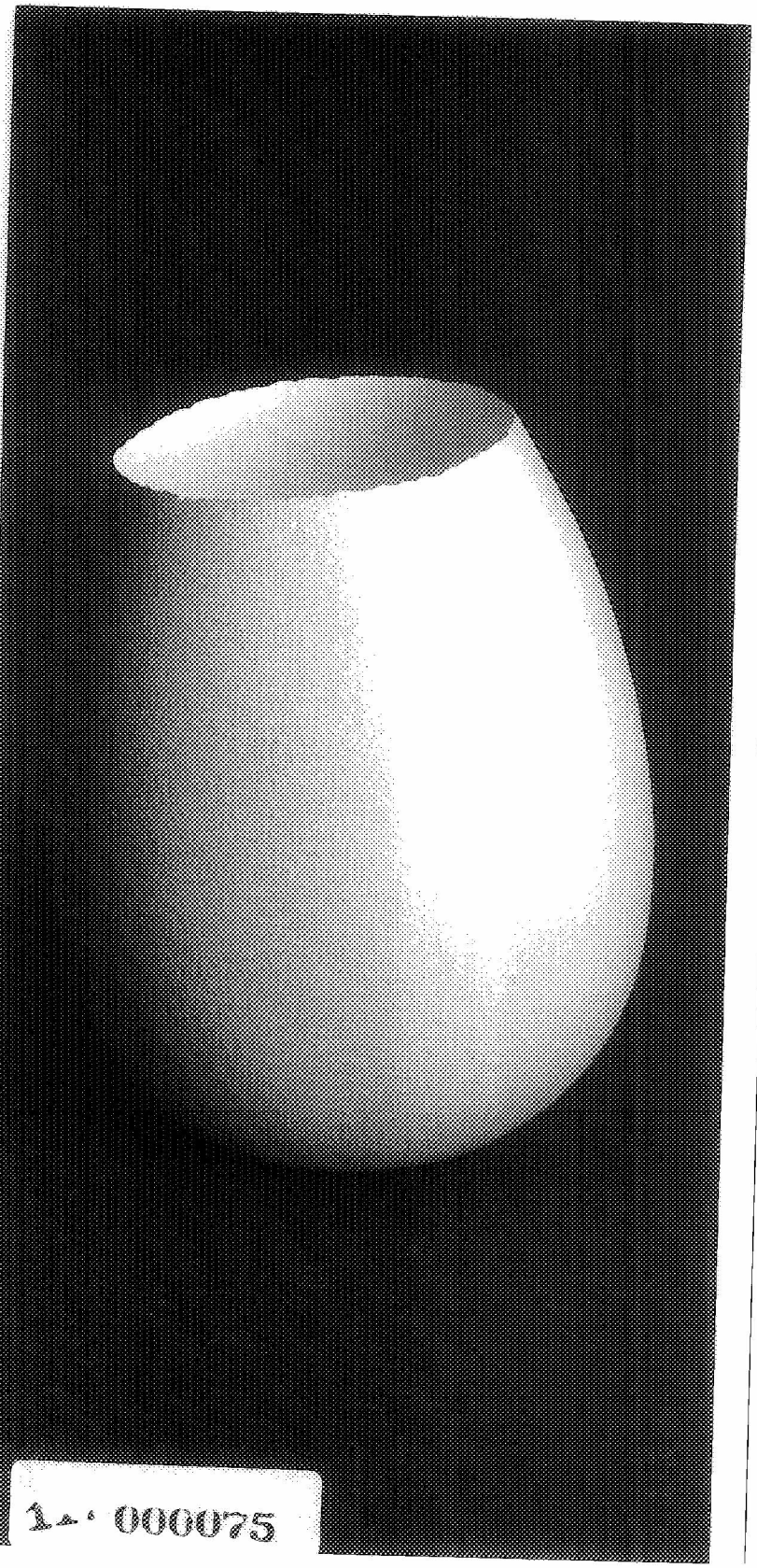
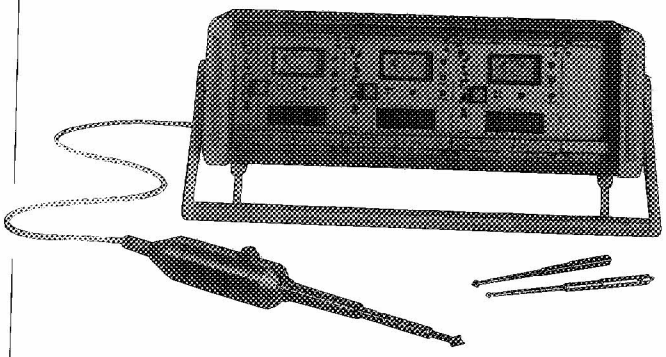


OSCAR helps you cut theatre costs

- With traditional techniques it can take up to 2 hours to remove cement from the femoral canal



- With **OSCAR** it can take from 2.5 to 25 minutes - which can mean substantial savings in terms of theatre time

OSCAR helps you cut aftercare costs

- **OSCAR** is associated with significantly less trauma and bone damage than traditional techniques - which can substantially reduce costly post-operative hospitalisation

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U L T R A S O U N D T H I N K I N G

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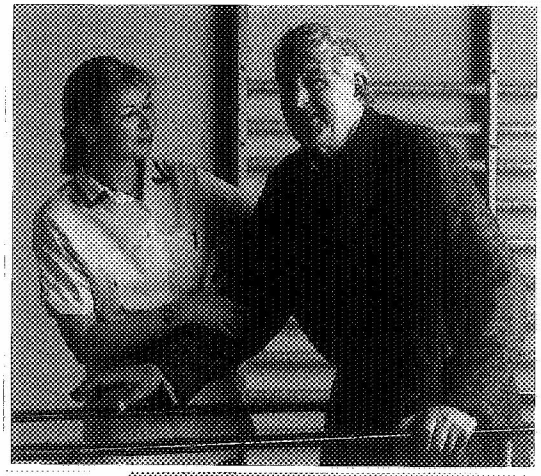
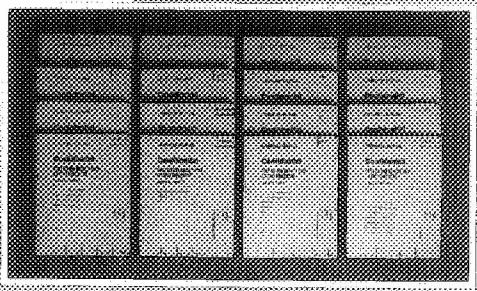
n get cement from a
nout breaking your budget



- OSCAR is likely to be associated with lower infection rates due to reduced operating time

OSCAR helps you cut waiting lists

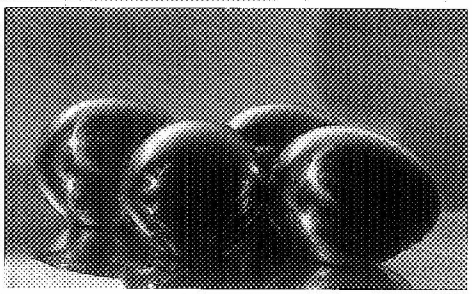


- Faster and more efficient procedure, less trauma and reduced pressure on bed space combine to help cut waiting lists

OSCAR helps you make more of your budget

- Faster, more predictable operating time allows cost-efficient planning of theatre lists
- The money and resources saved with OSCAR can be redeployed where most needed

OSCAR can help you generate revenue



- OSCAR facilitates faster patient turnover – which could mean additional revenue for your hospital

ORTHOSONICS

OSCAR

Orthosonics System for Cemented Arthroplasty Revision

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I N R E V I S I O N S U R G E R Y

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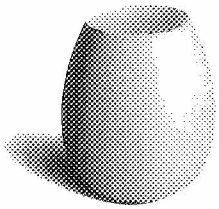

About Orthosonics Ltd

An Orthofix Company

Established in 1990 Orthosonics Ltd is a company that brings together the experience and vision of a practising orthopaedic surgeon and the technical know-how of a specialist in the design of high intensity ultrasound systems.

This unique fusion of knowledge has been coupled with the innovative expertise of Orthofix to develop, assess and refine ultrasonically energised instruments in the field of orthopaedics.

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Sound ideas worth thinking about

For all enquiries in the UK please contact:

Colgate Medical

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Colgate Medical, 1 Shirley Avenue, Windsor, Berks SL4 5LH.
Tel: 0753 860378 Fax 0753 831137.

1190077

References: Bradnock B. & Young M. *The removal of bone cement in* [illegible] *years.* Presented at British Orthopaedic Association Spring Meeting. [illegible]

2. Bradnock B. & Young M. *Ultrasonic removal of bone cement.* Pres. at the Ital. Soc. of Orthopaedic Associations Spring Meeting. [illegible]

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VII

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510(k) Summary

OSCAR ORTHOSONICS SYSTEM FOR CEMENTED ARTHROPLASTY REVISION

Common/Classification Name: Sonic surgical instrument, 21 CFR 888.4580

Sponsor: Orthosonics, Ltd.
Bremridge Farm
Ashburton
Devon TQ137JX
UK
+44-1364-652426
+44-1364-653589

Contact: Dr. Michael J. R. Young

Prepared: May 1, 1996

A. LEGALLY MARKETED PREDICATE DEVICES

The **OSCAR Orthosonics Ultrasonics Cement Removal System** is substantially equivalent to the Advanced Osseous Technologies System 10 Model 100 Surgical System (K900003), and is similar to the Cooper Lasersonics CUSA System 200M (K864983).

B. DEVICE DESCRIPTION

The **OSCAR Orthosonics Ultrasonic Cement Removal System** consists of a power module which generates the ultrasonic energy and provides overall control of the device, a handpiece, a set of cement removal probes, and an ultrasonic cleaning system for part of the reprocessing procedures for reuse of the probes. Three independent power modules are included in each device and these are mounted in a cart for ease of use.

C. INTENDED USE

The **OSCAR Orthosonics System for Cemented Arthroplasty Revision** is intended to assist in the removal of polymethylmethacrylate (PMMA) bone cement during arthroplasty revision.

D. TECHNOLOGICAL CHARACTERISTICS

The **OSCAR Orthosonics Ultrasonic Cement Removal System** has the same technological characteristics as the predicate device. The energy

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source is ultrasonic for both, and both have probes made of the titanium alloy Ti-6Al-4V.

E. TESTING

Orthosonics carried out testing to address the following issues:

(1) temperature rise in bone during OSCAR procedures,

(2) damage to bone from direct contact,

(3) clinical experience,

(4) reprocessing probes for use on the next patient,

(5) electromagnetic compatibility,

(6) electrical safety, and

(7) validation of sterilization recommendations.

The results from all of these tests supported the safety and effectiveness of the Orthosonics OSCAR device and demonstrate that the Orthosonics OSCAR is substantially equivalent to the predicate devices.

F. CONCLUSIONS

The Orthosonics OSCAR device has the *same* intended use and target population as the predicate devices. Orthosonics has demonstrated through its performance tests on the OSCAR device and its comparison of OSCAR characteristics with those of the predicate device that the OSCAR device is substantially equivalent to the predicate device.

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VIII

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ORTHOSONICS LTD

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87(j))

I certify that, in my capacity as Director of Orthosonics Ltd, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Michael J.R.Young, Ph.D., for
Orthosonics Ltd.

29/2/96

Date

Bremridge House, Bremridge, Ashburton, Devon, TQ13 7JX
Tel: (01364) 652426 Fax: (01364) 653589

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Cement/Bone interface temperature on polymerisation and ultrasonic cement removal.

Summary

(b)(4)

Experimental method

(b)(4)

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(b)(4)

Results.

(b)(4)

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Equipment Summary:

(b)(4)

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Figure 5 b

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Figure 5 c

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Figure 5 d

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Figure 5 e

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Figure 6 a

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Figure 6 b

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Figure 6 c

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(b)(4),Test Data

Figure 6 d

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Figure 6 e

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2

Exhibit 2

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Thermal Injury to Bone

Following the introduction of polymethylmethacrylate in orthopaedic surgery there have been many publications criticising its use on the grounds of the damaging effects of the heat produced by polymerisation.(ref 1,2,3). Meyer,(see enclosed reference page 151) a surgeon from Chicago, states that the maximum temperature recorded at the cement bone interface during human total hip replacement surgery was seventy degrees centigrade. He also stated that irrigation of the surface of the bone and prosthesis had no significant effect on the maximum temperature. Under more controlled conditions as suggested in ISO 5833 (enclosed ref 5) Table 1 on page 2 indicates that temperatures around 90 degrees centigrade occur during polymerisation.

Surgeons in Pennsylvania (enclosed Ref 6) have shown using a rabbit model that temperatures of 70 degrees centigrade for a period of one minute caused bone necrosis to consistently occur. Temperatures of 85 degreees centigrade caused bone damage to a depth of 1.5mm. (see page 289 Ref 6).

Huiskes (ref 7 enclosed) has compiled the definitive text on the subject of thermal injury to bone. He quotes work from Lundskog, 1972 and Moritz and Henriques 1947 (see pages 52-53) which show that **thermal injury is dependant upon two variables: time and temperature.** These results are further substantiated in an elaborate mathematical model utilising finite element analysis (see chapter 6 pages 70-76) By utilising computer simulation isotherms can be produced (see page 96) and consequently the depth of cell death can be calculated mathematically. (see fig 8.7 page 97)

Mjoberg in a further supplement to the Acta Orthopaedica Scandinavica No 221 entitled Loosening of the cemented hip prosthesis *The importance of Heat injury*, supports Huiskes and discusses a method of analysing migration of prosthetic components using tantalum beads and RSA (Roentgen Stereophotogrammetric Analysis) (ref 8 enclosed) By producing a lower viscosity cement , composed of polymethylmethacrylate, by the introduction of a bimodal distribution of particle size to produce a better packing fraction (see page 21) he also reduces the exotherm per unit volume to the point were thrmal injury to bone is not apparent. (see page 22)

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1/ Andersson,G.B.J., Freeman,M.A.R., and Swanson,S.A.V. 1972 Loosening of the cemented acetabular cup in total hip replacement. Journal of Bone and Joint Surgery 54 B 590-599

2/ Miller,A.J. 1972 Late fracture of the acetabulum after total hip replacement, Journal of Bone and Joint Surgery 54 B 600-606

3/ Homsy,C.A., Tullos, H.S., Anderson, M.S., et al1972 Some physiological aspects of prosthetic stabilisation with acrylic polymer. Clinical Orthopaedics and Related Research, 83, 317-328.

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On the Setting Properties of Acrylic Bone Cement

BY P. R. MEYER, JR., M.D.*, E. P. LAUTENSCHLAGER, PH.D.†, AND B. K. MOORE, PH.D.†,
CHICAGO, ILLINOIS
From Northwestern University, Chicago

ABSTRACT: In the one batch of methylmethacrylate tested the surface of the setting cement never exceeded 70 degrees centigrade while the setting time was prolonged by lowering the ambient temperature, decreasing the powder to liquid ratio, and increasing the mass of cement. Working time, that is, the interval between the dough stage and setting, did not change as the powder-liquid ratio varied but decreased with rises in ambient temperature and mass. Batch to batch variation should be expected, and even greater variation will occur with minor variations in composition of cement.

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Questions? C

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The Journal of Arthroplasty Vol. 8 No. 4 1993

Effect of an Ultrasonic Device on Temperatures Generated in Bone and on Bone–Cement Structure

Andrew T. Brooks, MD, Carl L. Nelson, MD, Charles L. Stewart, BS, Robert A. Skinner, BS, and Martin L. Siems, BS

Abstract: Cement removal during revision arthroplasty can be a tedious, time-consuming process. The usual methods of removing cement include high-speed drills, chisels, saws and reamers, which are often associated with fracture and/or perforation of the femoral shaft. Ultrasound has been used in dentistry to remove plaque and in ophthalmology to remove cataracts and is now applied to cement removal in orthopaedic surgery. There is little data available on the effect of ultrasound on temperatures generated in bone and on its effects on the structure of bone–cement. A cement mantle was constructed in the intramedullary canal in each of six 10 cm lengths of human cadaver femora. A temperature probe was then inserted into predrilled holes and temperatures generated by the ultrasonic device were recorded under a variety of conditions. In addition, a cement cylinder was microscopically evaluated after an ultrasonic tool had been inserted. Temperatures generated by the ultrasonic tool in cadaver bone were no higher than previously reported temperatures of 140°C generated by high-speed drills. Furthermore, temperatures at the bone–cement interface never exceeded 60°C when saline irrigation was used in conjunction with the ultrasonic tools, [illegible] were below 40°C 1 minute after deactivation of the device. Microscopic examination shows that ultrasound produced local changes in the structure of bone–cement converting it from a microscopically spherical interlocked material to one that appears homogeneous and granular. **Key words:** ultrasound, revision arthroplasty, bone–cement, temperature.

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Assessment of Possible Ultrasonic Injury to Bone

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Animal Model

(b)(4)

Results

(b)(4)

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Conclusion

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THE IMPLICATIONS OF THE INTRODUCTION OF NEW TECHNOLOGY IN REVISION HIP SURGERY : A COSTED EVALUATION.

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OSCAR Validation Procedure:

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* **Test details**

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OSCAR

Orthosonics System for Cemented Arthroplasty Revision

(b)(4)

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[Translation]

Ultra-Drive™

Bone-cement removal instrument

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Summary

Why a new cement removal system?

The cement removal techniques currently used in arthroplasty revisions, utilise manual and electrically-driven tools. Manual tools, such as e.g. of the Moreland type, are well constructed and relatively non-traumatic, but do not allow the surgeon to distinguish between cement and bone. Hence, it is not unusual to have endosteal bone fractures caused by the surgeon. Electrically driven tools, such as e.g. the Midas-Rex or Anspach ones, also do not permit differentiation and may perforate the femur distally. Turner et al report femoral perforation in 16% of revision cases (1). An intra-surgical x-ray is sensible in cases involving the removal of distal cement, so as to allow precise working with a high-speed drill, but this again is laborious and time-consuming.

Criteria for a new cement-removal system

1. **Sensitivity** – non-traumatic, tactile and audible feedback which permits the surgeon to distinguish between cement and bone and thus to remove the cement without damaging the bone.

2. **Control** – reducing the occurence of perforations and/or fractures.

3. **Speed** – reducing operating theatre time.

4. **Safety** – no adverse effects on patient tissue.

How are these requirements fulfilled by ultrasound?

First, let's discuss the piezo-electric effect again. This effect occurs when a crystal is polarised so that positive electric charges are present on one side, and negative on the other. If a voltage is applied to the crystal, oscillations will take place – the oscillation frequency will be in the range of 20 000 to 100000 Hertz. This is the effect exploited in ultrasound-driven tools: the tools oscillate or pulse at certain frequencies, depending on their characteristics. This vibration is transmitted to the tool longitudinally, so that its tip travels a microscopic distance at very high speed. This movement is very powerful but physically not discernible, so that the surgeon can steer the tool precisely, and in addition can work with a sensitivity which is not made possible by any other tool, whether manual or electric. In this way the surgeon can remove distal cement safely and effectively, without the need for an intra-surgical x-ray.

What happens to the cement?

The tool transfers energy to the PMMA, whereby friction is created between the molecules; this causes the cement to change its state so that it is no longer stone-hard, but as soft as wax.

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Ultrasound energy is tried and tested in medical applications

The Ultra-Drive utilises a technology which has proved itself well in conventional medical applications. Ultrasound-driven tools have been in existence for over 40 years. The first application was the plaque-remover – a tool used by the dentist to remove glass-like plaque from the back of the teeth without damaging the teeth themselves. The precisely-controlled frequency and the tactile feedback allow the dentist to penetrate between plaque and tooth, and to break the plaque away without attacking the tooth (2). It is precisely this principle which we use for removing cement during revisions.

The Phacom-Emulgator was developed in the Seventies for cataract surgery. this ultrasound-driven tool allows ophthalmologists to remove hardened cataract material from inside the eye, without damaging surrounding ocular tissue. Currently, the Phacom-Emulgator represents the state of the art in this demanding and difficult procedure. The CUSA, developed at the same time as the Phacom-Emulgator, is an ultrasound-driven tool used in neurosurgery which permits safe removal of tumors at awkward sites, close to critical nerves and vascular structures. The precisely-controlled frequency and the tactile feedback allow the surgeon to perform previously impossible operations.

Similarly, the Ultra-Drive is tuned so as to cut very efficiently through bone cement, but very inefficiently through cortical bone. This leads to less traumatic removal of cement and prosthetics than with previously-available tools.

What is the effect of ultrasound on bone?

Many studies have been carried out by Dr James Caillouette et al. One of the first was concerned with the generation of heat in the removal of cement and fixed prosthetics. In this study, sensors were fitted to seven locations on the endosteal surface of freshly frozen human femurs. The prosthetics were cemented in place and later removed by direct coupling to the ultrasound converter, and the temperature measured. The highest temperature measured during ultrasound coupling was 38.9°C. In contrast, the cement is cured at temperatures of up to 40 °C, and according to reports, temperatures exceeding 100°C are generated during drilling with high-speed drills (4). Small necrotic bone sites were observed in several cases where the ultrasound tool was applied to the bone for a long period. Unpublished studies, and the experience gained by surgeons and Ultra-Drive users, have both shown that the necrotising degree is very local (less than 1mm) and these sites can easily be removed with a curette or similar tool. The heat signatures caused by the Ultra-Drive are significantly less than those created by high-speed drills. These results show that there are no adverse biological, physiological or clinical effects. Clinical application will continue to be monitored in order further to underpin these findings.

Conclusion: ultrasound tools elevate bone-temperature very much less than do the curing of cement or high-speed drills.

Bone strength remains unaffected

Dr John Callahan and his team at Duke University have undertaken a comparative analysis of the effect of mechanical and ultrasound methods of cement removal on total bone strength. Pairs of rabbit femurs were filled with cement. The cement was removed in all cases by the same surgeon, using mechanical or ultrasound techniques. The torsional stress-resistance was measured in all the tests; it appeared that as far as the effect on total bone strength was concerned, both techniques were

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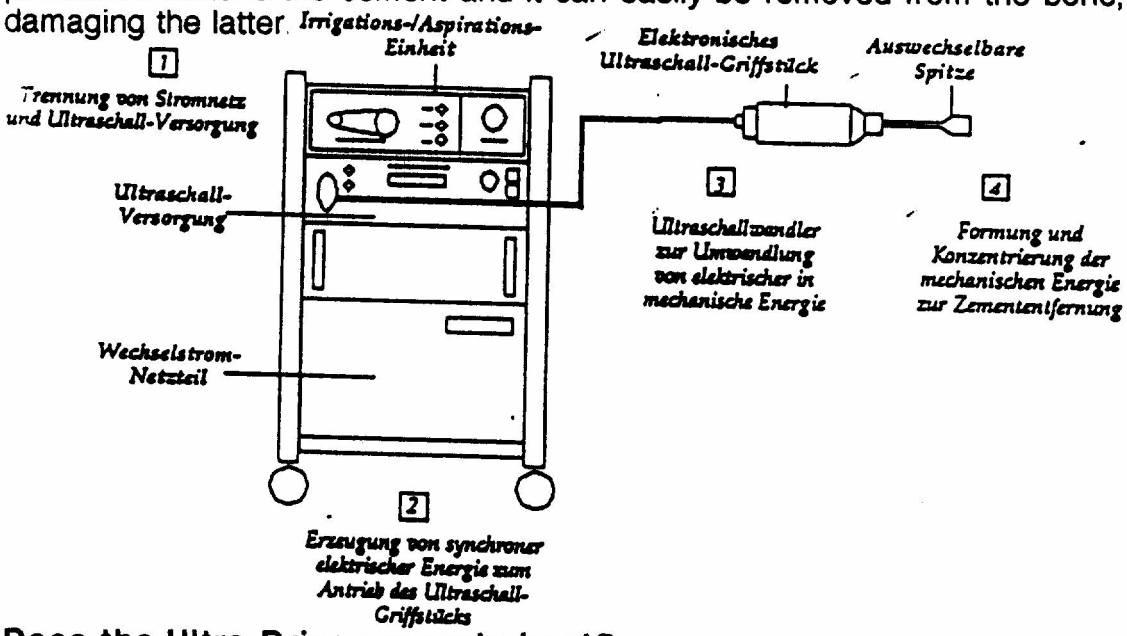
statistically identical. The only difference consisted of the mean length of time needed to remove the cement: mechanical removal lasted on average 277 minutes, removal with ultrasound tools required 40 minutes (3).

Conclusion: ultrasound tools produce no harmful effects on bone strength compared with other investigated methods, but significantly reduce the time needed for cement removal.

How does the ultrasound technique work?

No ultrasound waves are transmitted deep into the bone or into the cement, but rather the ultrasound energy is converted to mechanical energy which affects the bone cement via a series of specially-constructed instrument tips. The energy reaches the tip in the form of an acoustic wave, which causes it to oscillate at a high frequency. This leads to the cement being fragmented in three ways: first, by the transition between the cement and the tool being "locally" heated through the effect of the ultrasound energy on the cement; secondly, by the creation of "excited surface molecules" and "frictional heat" through the friction of instrument tip with the cement surface; and thirdly, through mechanical cutting and fragmenting of the cement by the sharp tool edge. The entire system and the instrument tips are so designed that the cement is easily penetrated, but the bone remains relatively unaffected. This procedure softens the cement and it can easily be removed from the bone, without damaging the latter.



PTO

Does the Ultra-Drive generate heat?

During the surgical procedure, the surgeon will notice that a certain amount of heat is given off by the bone cement. The tip of the ultrasound tool does not itself produce heat, but the cement touched by the tip gives off heat as it softens, hence the tip can also heat up through conduction. This is why irrigation is necessary when the Ultra-Drive is being used. Should the ultrasound tool be activated in the air and the tip touched immediately after it is switched off, it will feel cold to the touch. Please note that the tip must never be touched when it is switched on, as this may lead to distinct "local" thermal effects. We emphasise these are "local", since independent unpublished studies have shown that the maximum thermal depth of penetration is less than 1mm (5). The ultrasound energy is not transmitted deep into the tissues, and therefore does not give rise to thermal effects in interior tissue or bones.

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Conclusion: ultrasound tools produce no harmful effects on bone strength compared with other investigated methods, but significantly reduce the time needed for cement removal.

The bone's growth potential is not adversely affected

Studies in dogs, using pairs of femurs, were carried out in order to determine the effect of ultrasound cement removal on bone growth. Two sites in each femur were filled with methyl metacrylate cement. The cement was removed from one site with an ultrasound tool, the other was left unchanged for comparison. Cement removal in the other femur was carried out using a high-speed drill. Three weeks later, formation of new bone started at the site where cement had been removed by ultrasound.

Conclusion: the ultrasound tool has no discernible effect on the formation of new bone following cement removal.

Are the vapours harmful?

The results of bio-toxicological tests show that the gaseous and fluid samples examined, have no toxic properties in concentrations which may be considered a health risk. For further information on the toxicological test results, please contact Randy Hulse at Biomet Co. for a copy of the toxicological report.

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ULTRA-DRIVE™

System Description

Feature	Advantages
Simple, easy-to-understand attachments and controls.	Operating the system can be learned easily in a single session. The system can be assembled and used by the surgical team without extensive training; no conversion is necessary.
Built-in irrigation unit.	In complicated revision surgery, both hands are kept free for other work.
Operation of the ultrasound supply and irrigation unit via a foot-switch.	Simple and precise control of the Ultra-Drive.
A range of clinically-tested tips.	These allow the surgeon to work with precision and remove cement from the entire femoral canal, from proximal to the end of the bone. The selection permits the choice of the most suitable tip for each patient and for each part of the bone. The special construction of the hand-unit allows quick replacement of the ultrasound instrument tip.
A selection of numerous tip extensions.	These make it possible to reach efficiently the cement in the entire canal.
Instrument tips tuned for ultrasound.	This permits the surgeon really to feel the difference between cutting bone cement and contact with cortical bone. Precise tuning of the tip allows bone cement to be cut very efficiently and cortical bone very inefficiently, which conserves patient anatomy and significantly reduces the risk of cortical perforation.
Robust and reliable ultrasound hand-unit.	Designed for straightforward and reliable operation. Can be sterilised quickly.
Acoustic signal when the ultrasound supply is switched on.	The surgeon is immediately aware of system status.
Tactile feedback.	Resistance is felt on contact between tip and bone.

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Ultra-Drive ™

80-4238-00	**Ultra-Drive ~ Gerät bestehend aus einer**				
	Ultraschall Energiequelle				Pleskig
	Stromversorgungseinheit				
	Kühlpumpe für die Instrumente				
80-4238-02	Fußpedal	X1	19,919	49.000,00	19919
80-4238-03	**Ultra-Drive ~ Handinstrument 40 kHz**	X3	19,830	17.000,00	6,910
80-4238-10	**Zubehör-Paket bestehend aus:**				
80-4238-12	Handinstrumente Container				
80-4238-13	Instrumentensieb				
80-4238-14	Verlängerung Handinstrument				
80-4238-16	Schraubenschlüssel 7/32				
80-4238-17	Schraubenschlüssel 3/8				
	Stromadapter (Ist ab Werk integriert für D)				
80-4238-18	Ausschlagvorrichtung				
80-4238-44	Instrumentenkühlung		1,504	3.700,00	1,504
80-4238-35	**Grundausstattung Handinstrumente**				
80-4238-19	Fluggewicht				
80-4238-36	Instrumentenverlängerung 60 mm MF				
80-4238-38	120 mm MF				
80-4238-40	180 mm MF				
80-4238-42	240 mm MF		1,129	2.900,00	1,179
80-4238-55	**Einweginstrumente Anfangsset**				
80-4238-56	65 MM X 85° Acetabulum Löffel			298,00	121
80-4238-59	Retrohobel			520,00	211
80-4238-64	5,0 mm Querosteom			400,00	163
80-4238-68	6,0 mm Zementstopfenzieher			437,00	178
80-4238-71	Spaghetti-Bohrer 7,0 mm			500,00	203
80-4238-72	9,5 mm			500,00	203
80-4238-73	11,0 mm			500,00	203
80-4238-74	13,0 mm			500,00	203
80-4238-76	8,0 mm Halbrohrmeißel			420,00	171
80-4238-80	9,5 mm Osteotom kurz			485,00	197
80-4238-81	9,5 mm Knie-Osteotom			485,00	197
80-4238-83	6,5 mm Knie-Osteotom			440,00	179
80-4238-90	6,0 mm Osteotom lang, gerade			540,00	220
80-4238-92	6,0 mm Osteotom lang, gebogen			440,00	179
80-4238-94	7,0 mm Osteotom viertelrohr			420,00	171
	Gesamtpreis bei Erstbestellung		5,300	5.300,00 (6885)	(2799)
	Einwegzubehör 10er Packung				
80-4238-22	Kühlpumpen-Schläuche			490,00	199
80-4238-52	Instrumenten-Lampe			530,00	221

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Implantate zur rekonstruktiven Chirurgie

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Acoustic feedback as soon as the tip comes into contact with cortical bone.	Allows the surgeon to note immediately when the cement layer has been separated.
Attachments for two ultrasound hand-units.	Permits a second hand-unit to be permanently kept ready, which saves time in replacing the tips at the various stages of cement removal.
Specially constructed basic instrument.	The top surface of the instrument serves as a table for tools and hand-units. The basic instrument can be extended for future applications and thus will not become obsolete in the foreseeable future.
Disposable items in sterile packing.	Sterility is assured.
Practical trays for storage and sterilisation of all parts.	Makes possible a logical and correct working procedure.
Practical drawer.	Allows storage of all parts in the basic instrument.
Stable, lockable wheels.	Allows easy transport of the instrument and securing it in situ.
Technical help available via a 0130 number.	Allows immediate access to technical advice and assistance, should queries concerning the Ultra-Drive occur during surgery.
One year warranty for the basic instrument, six months for the hand-units.	Ensures safety and reliability during constant use of the Ultra-Drive.
Despatch of spare parts within 24 hours.	Ensures that the Ultra-Drive is always ready for use.
Construction in modular plug-in units.	Allows simple disconnection for servicing.
Optional extended guarantee.	An economical service contract is available for long-term reliability and servicablity.
UL544/IEC 601	The system conforms to the UL544 and IEC 601 standards.

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ULTRA-DRIVE™

Product summary

IMPORTANT: A COMPLETE SYSTEM DESCRIPTION IS CONTAINED IN THE OPERATING INSTRUCTIONS. IT IS IMPORTANT TO READ CAREFULLY THROUGH THE INSTRUCTIONS, IN ORDER TO BECOME FAMILIAR WITH THE SYSTEM FUNCTIONS.

The basic instrument

The basic instrument consists of three basic building blocks: the irrigation/aspiration unit, the ultrasound power supply and the AC mains unit. It also contains a drawer for keeping the sterilisation tray.

The controls on the front of the instrument are clearly marked and easy to understand.

The AC mains unit supplies the Ultra-Drive with mains power.

The ultrasound power supply contains all controls, displays and attachments relating to the ultrasound hand-units.

The irrigation/aspiration unit consists of two parts, one for irrigation and the other for aspiration. The irrigation section permits pump-irrigation via the hand-unit and is operated through a foot switch. The aspiration section contains a vacuum regulator for aspiration control. Thus the surgeon has cooling irrigation available during surgery, and the bone can simultaneously be cleaned of fluids and bone cement, without a further pair of hands being needed at the incision.

Accessories

Hand-unit: the 40 kHz hand-units need neither be assembled nor disassembled, but only need to have small disposable tubes, extensions and tips fitted to them. Ultrasound energy is converted in the hand-unit to mechanical energy, which causes the tip to vibrate and thus fragment the cement.

Extensions

Three different extensions are available, in lengths of 60 mm, 120 mm and 180mm. This ensures that the correct size of tip can be used even in complicated cases. Extensions can be sterilised by autoclave and re-used, however they should be disposed of when visibly used or when assembly becomes difficult.

Spanners

The spanners are used for attaching extensions and tips; this achieves ultrasound-proof locking.

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Adapter for plug puller

This adapter is used in conjunction with the plug puller tip, to allow extraction of the bone plug with the slide hammer.

Slide hammer

Works in conjunction with the plug puller adapter to remove the bone plug.

Assembly tray

For sterilisation, storage and assembly of the hand-units, designed to be set up on the basic instrument.

Sterilisation tray

For efficient storage and for sterilisation of extensions, spanners etc, designed to be set up on the basic instrument.

Cable holder

For safe storage of the foot switch when the instrument is not in use.

Irrigation accesories

A carton with 10 sets of tubing and pads is supplied with each Ultra-Drive basic instrument. In addition, a separate irrigation set is a component of the accessories set.

Disposable items

Note: all disposable articles are supplied in sterile packing.
The instrument tips are designed for single use. The different tips are designed for removing cement from all the different sites in the femoral canal – you will find a description of the tips and their use in the part list.

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ULTRA-DRIVE™

Clinical advantages

- The system permits a significant reduction in surgery time in difficult revision cases.
- Substantial reduction in risk of cortical bone damage or perforation.
- Improves the surgeon's sensitivity and ability to distinguish between bone and cement through the creation of a tactile and audible feedback, when the surgeon meets cortical bone through the cement.
- In contrast to high-speed drills, no high temperatures are generated during contact with cortical bone.
- All parts of the femoral canal are reached more easily.
- Less stressful, both for the surgeon and the patient.
- The system makes possible faster recuperation and hence shorter hospitalisation.

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ULTRA-DRIVE™

Surgical technique

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▼ INTRODUCTION

The ULTRA-DRIVE surgical system is an orthopaedic instrument system for joint revisions. It is designed to be used in procedures, where simultaneous modification and irrigation of tissue or bone cement (polymethyl metacrylate, PMMA) are required. Two major objectives affected system development: allowing the surgeon greater control and flexibility, and making surgery simpler, faster and less traumatic.

Arthroplastic hip revision can last three to five hours, and the largest fraction of this time is used for implant and bone cement removal. Manual tools lack precision; their use can lead to unintentional femoral fractures, perforations, excessive loss of cancellous bone and the creation of sites of increased stress along the entire endosteal bone surface.

The Ultra-Drive system is a safe and effective approach to non-traumatic cement removal. Using ultrasonic tools, the surgeon can distinguish between cortical bone and bone cement, and thus significantly reduce the possibility of inadvertent bone trauma. In this way, ULTRA-DRIVE protects bone material and at the same time reduces the length of the operation and blood loss.

These surgical technique instructions are written as your introduction to the ULTRA-DRIVE system. Separate operating instructions describe in full detail the ULTRA-DRIVE system's components, its control and maintenance.

Should you have any questions or require further information, please refer them to your Biomet representative or direct to

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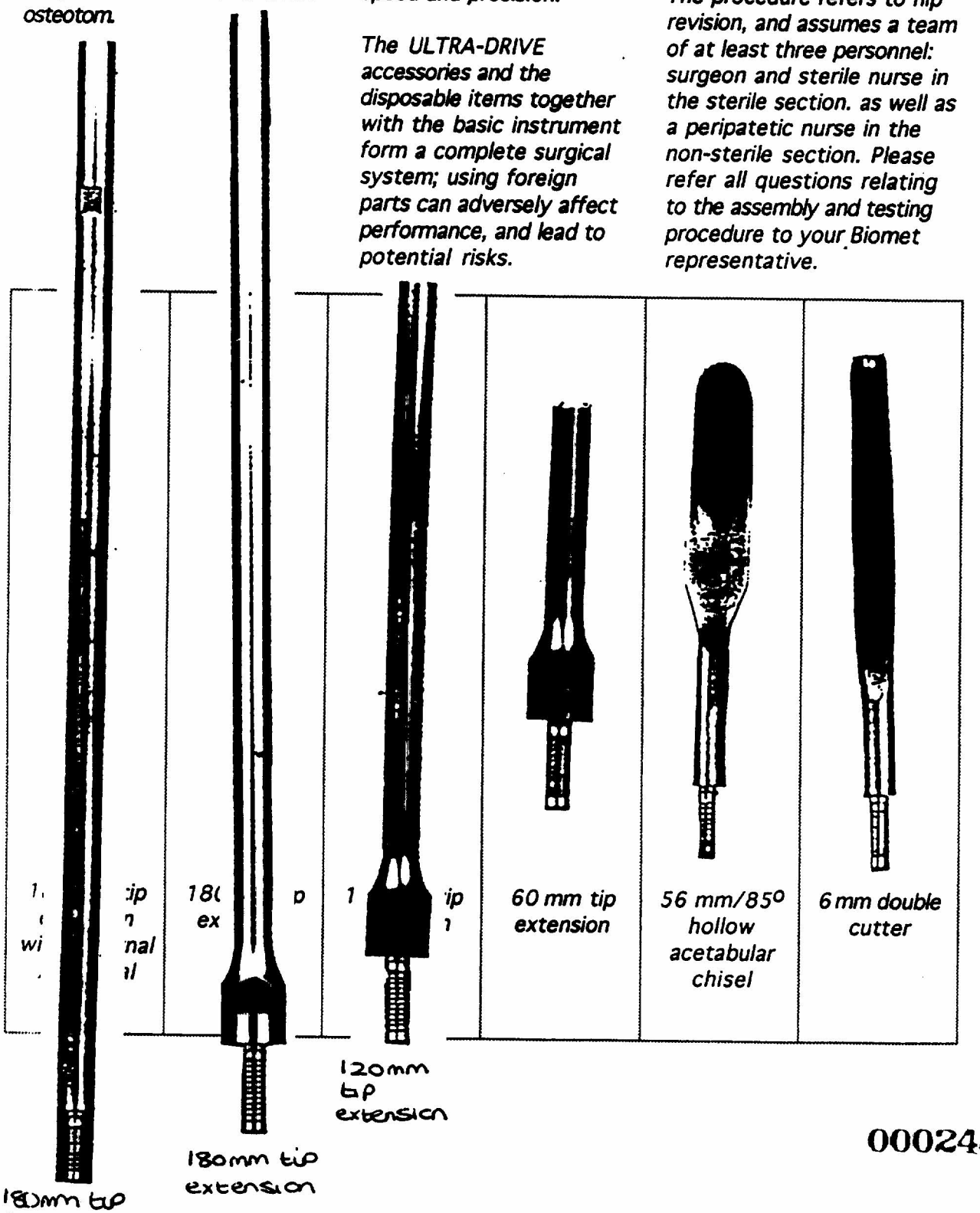
The basic set of instruments consists of three each of the following items: hollow acetabular chisel, double cutter, hook, plug puller, disc drill, hollow chisel and short osteotom.

The ultrasound instrument tips are designed for single use only. Repeated use of the tips reduces the cutting effectiveness and hence speed and precision.

The ULTRA-DRIVE accessories and the disposable items together with the basic instrument form a complete surgical system; using foreign parts can adversely affect performance, and lead to potential risks.

The recommended procedure for assembling and testing the ULTRA-DRIVE system's functions are described in the operating instructions. The procedure refers to hip revision, and assumes a team of at least three personnel: surgeon and sterile nurse in the sterile section. as well as a peripatetic nurse in the non-sterile section. Please refer all questions relating to the assembly and testing procedure to your Biomet representative.



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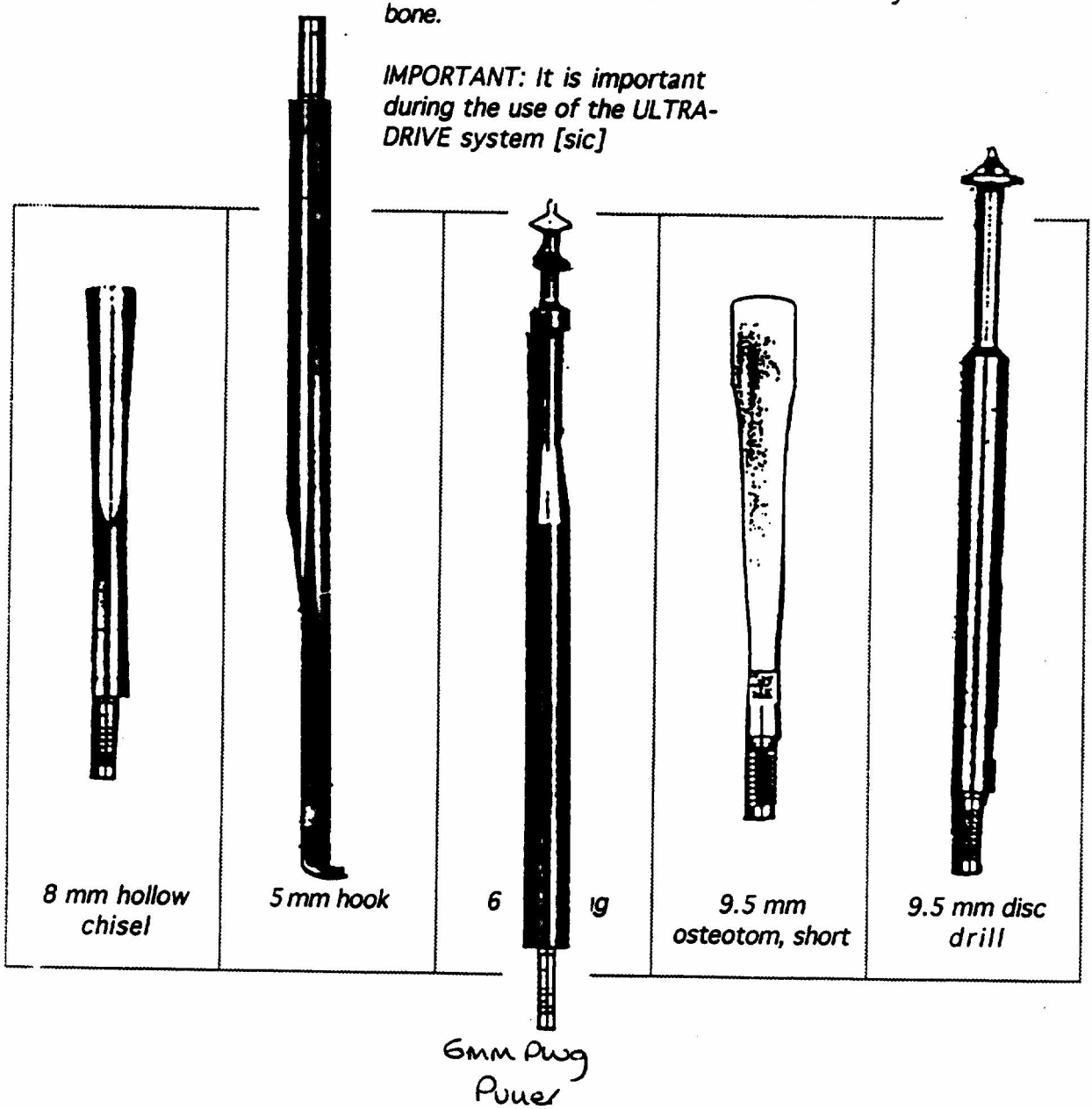
Assessing cement layer thickness takes place during pre-surgery planning. If the layer is thicker than 3 mm, this should be reduced to 2 - 3 mm with a hollow chisel, trowel or double cutter.

The instrument tips can be efficiently moved through the cement by applying light pressure (ca. 3 kp). The tool should always be steered, not pushed hard. If you feel resistance, do not increase the pressure – you have probably reached cortical bone.

IMPORTANT: It is important during the use of the ULTRA-DRIVE system [sic]

NOTE: The tools and extensions forming part of the ULTRA-DRIVE system are specially designed for ultrasound operation and should not be used manually, as the results of manual operation would be quite unsatisfactory.



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▼ PREPARATION OF THE CEMENT LAYER

The cement in the femoral canal can be fragmented with the 8 mm hollow chisel, the trowel or the double cutter. The latter can also cut backwards, when moved distally/ proximally in the canal; it can also be used effectively for cleaning.

8 mm hollow chisel

6 mm double cutter

9.5 mm osteotom, short

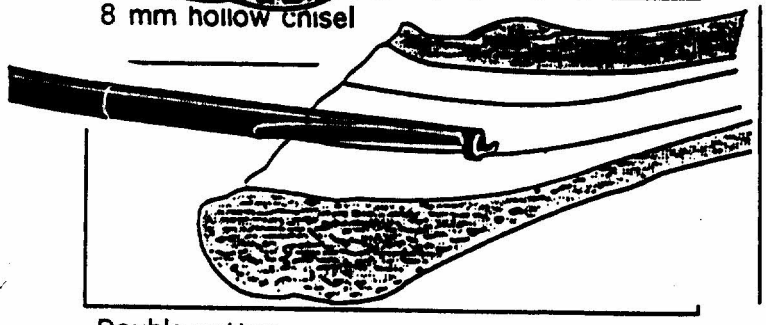
Using the short (9.5 mm) ultrasound osteotom, make three or four longitudinal slits over the entire length of the cement layer, so that it is divided into roughly equal segments (see diagram).

In order to produce the slits, move the tool sideways back and forth to widen the slit, whilst pushing it forward distally. Carry out the same motion during proximal removal of the osteotom.

NOTE: If the slit is insufficiently widened, soft cement will flow back into the slit and effectively block the forward movement. The thicker the cement layer, the wider the slit needs to be.

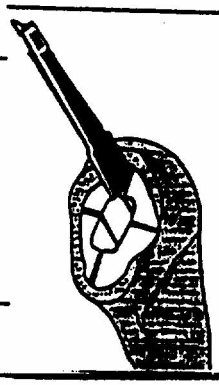
NOTE: It is important to ensure constant irrigation and to move the osteotom forward and backward, to prevent it being stuck in the cement.

8 mm hollow chisel

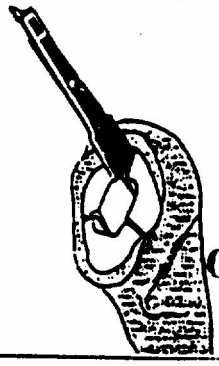


Double cutter

Slit locations



Four slits



Three slits

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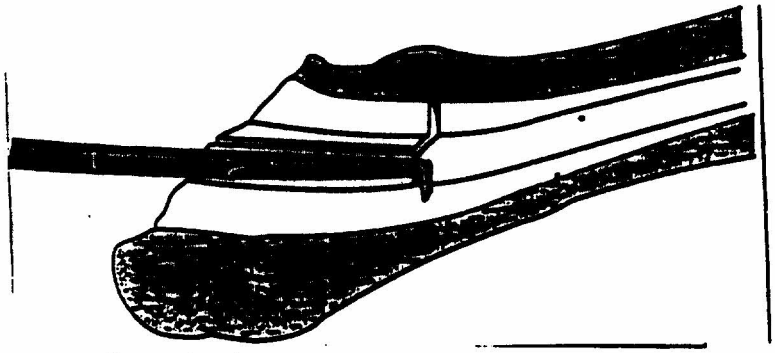
In a few cases it may be simpler to section the cement transversally for easier removal. The tip of the hook is angled so as to cut the cement vertically to the femoral shaft.

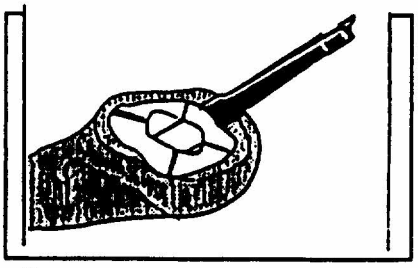
5 mm hook



5 mm hook

Move along the contact surface between cement and bone with the short osteotom or the short hollow chisel, once again under irrigation and with a back-and-forth movement, in order to facilitate penetration of the saline solution between bone and cement.

As soon as a first path is created using the short ultrasonic osteotom, insert a manual osteotom between bone and cement in order gently to separate larger cement fragments. Remove these fragments carefully from the medular canal. Cement fragments may be gripped and removed with rectal biobsy forceps or a pituitary scraper.



Short osteotom

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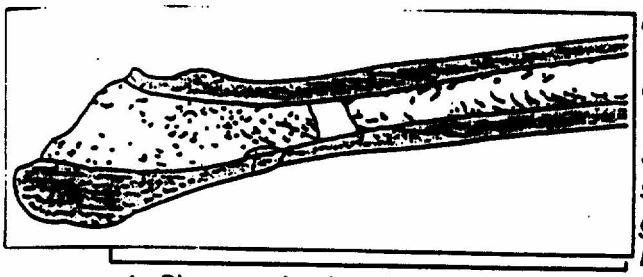
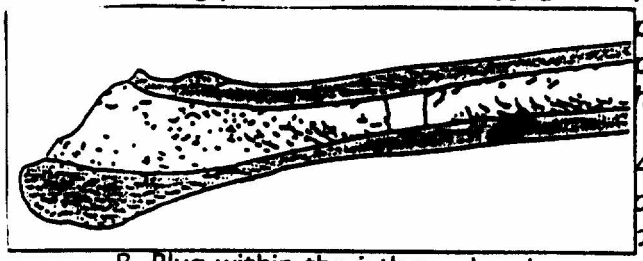
▼ PLUG ASSESSMENT

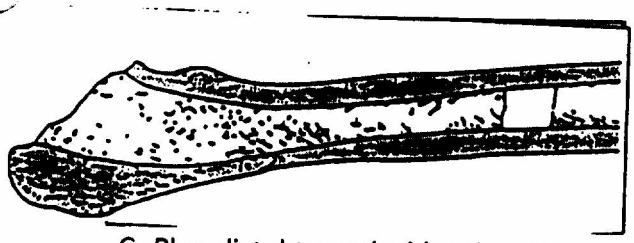
Assess plug position and attachment according to the following classification:



A. Plug proximal to isthmus bend



B. Plug within the isthmus bend, or a type A plug which cannot be pulled



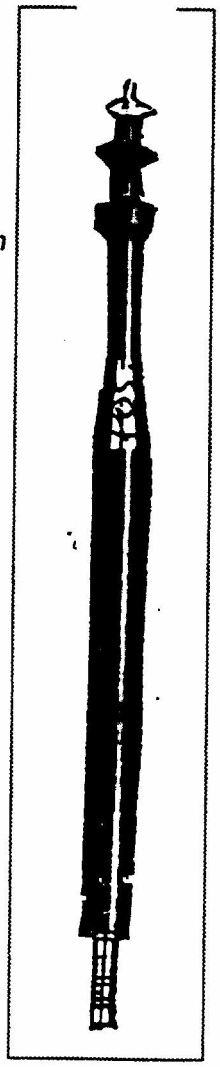
C. Plug distal to and wider than the isthmus bend

▼ PLUG REMOVAL (TYPE A)

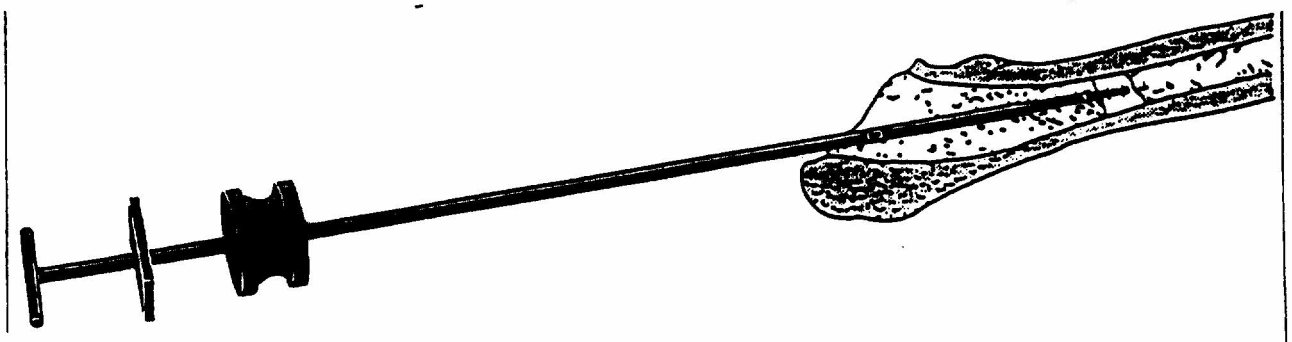
For type A plug removal, assemble together the short extension, the extension with internal and external thread and the plug puller. With ULTRA-DRIVE switched on, fully push the tip of the plug puller into the plug, until only the collar margin remains proximally visible.

Switch off the ultrasound power and simultaneously turn the hand-unit gently by 90° clockwise. Keep the hand-unit still until the cement has re-set (15 seconds). The tip of the plug puller should now be securely positioned in the plug. Remove the hand-unit and the short extension.

Attach the slide hammer to the plug puller adapter. Securely attach the plug puller adapter to the extension with internal and external thread, and carefully tap out the plug. If the plug does not separate, do not apply ever more force - remove the plug puller adapter and the slide hammer, reassemble the short extension and the hand-unit and remove the plug puller with ultrasound. Proceed as for the removal of type B plug.



6 mm plug puller



Plug puller-adapter/slide hammer/extension with internal and external thread/plug puller

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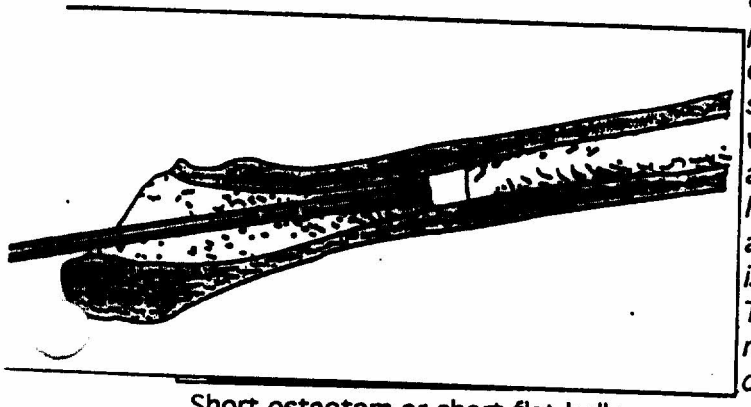
▼ PLUG REMOVAL (TYPE B)

Attach the short osteotom or the short flat hollow chisel to the hand-unit, using the appropriate extension. Proceed along the plug's periphery, using powerful irrigation and with a light dipping motion - this will help to detach the plug. Then proceed as for type A plug above.

If the plug fails to separate, proceed as for type C plug below.

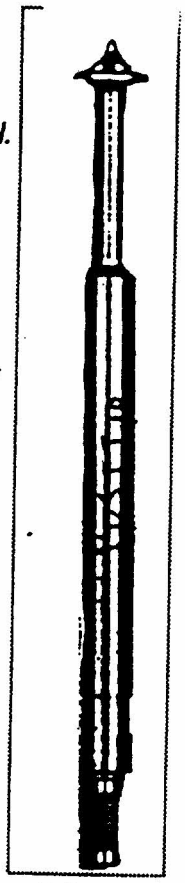


Short osteotom or short flat hollow chisel

▼ PLUG REMOVAL (TYPE C)

Plugs which are solidly stuck, and those that are located distally to the isthmus, must be drilled and made into hollow cylinders before removal. This is done by drilling through the plug, first with a disc drill and then widening the hole gradually with larger and larger disc drills.

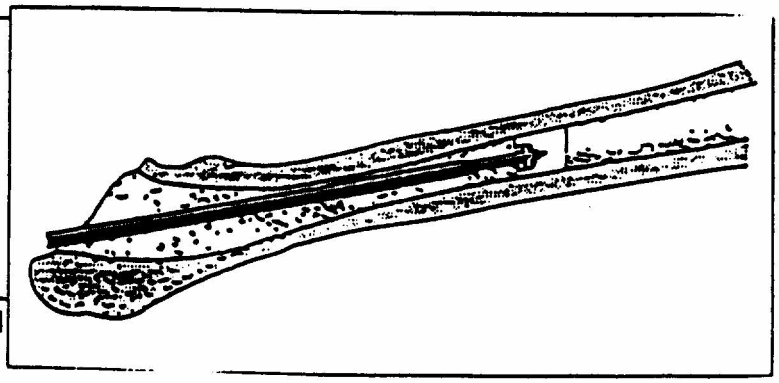
Drill ultrasonically into the plug, using powerful irrigation, until only the drill's hub is visible above the plug. The small holes in the drill ensure that the cement is extruded proximally. Keep pulling the drill out with the ultrasound switched on, so that the cement is extracted along with it. Wipe off residual cement and keep drilling until the plug is hollow. Continue with larger drills as described, until the cement layer is reduced to a thickness of 2 - 3 mm. This remaining cement layer can now be removed using the techniques described above.



9.5 mm disc drill

NOTE: The disc drill can also be used backwards, but less effectively.

FINAL CLEANING: The double cutter is well suited for cleaning. Position the double cutter distally to the plug, and pull it gently in the proximal direction. Using this procedure allows the surgeon to distinguish effectively between cortical bone and any remaining cement.



Disc drill

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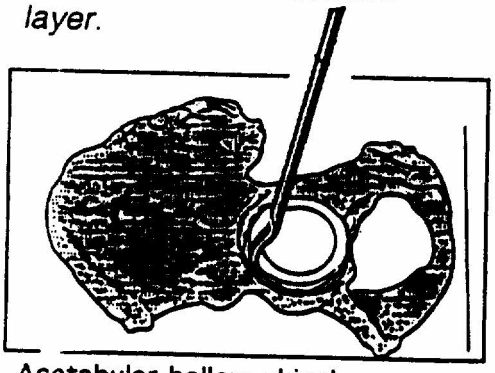
▼ REMOVAL OF THE ACETABULAR COMPONENTS

Apply the ultrasonic acetabular hollow chisel at the transition between acetabulum and socket cement.

IMPORTANT: to begin with, the hollow chisel must be positioned with the ultrasound switched off, in order to prevent knocking and possibly tip fracture. If the chisel fractures it becomes unusable and must be replaced.

After the tip is applied, switch on the ultrasound. Move the chisel carefully in an arc along the cement boundary, in line with the socket's shape. Steer the chisel in and out along the edge of the socket, so as to create a concentric hollow space behind the socket. The movement must be forward and backward under powerful irrigation, to prevent blocking the chisel with cement and to avoid excessive temperatures at the transition between tip and cement.

After the boundary between the cement and the acetabular socket has been broken up, the socket can be carefully removed from the cement layer.

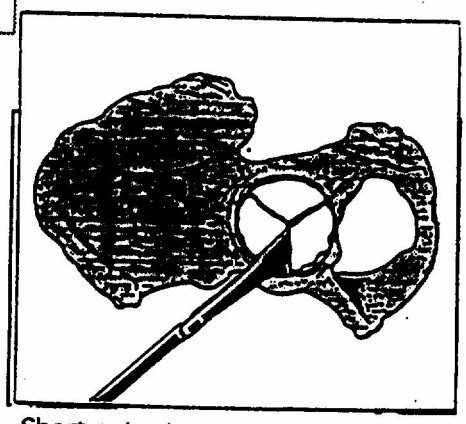


Acetabular hollow chisel

56 mm/85 ° acetabular hollow chisel

Attach the short osteotom to the hand-unit. Using a back-and-forth motion and with powerful irrigation, divide the cement into three sectors, radially from the apex to the edge of the cement-covered acetabulum. Carefully break off and extract the triangular pieces with a hand-chisel.

Proceed with extreme care, so that the ultrasonic tool does not come into contact either with cortical bone or with the metal acetabular socket. A characteristic sound and perceptible resistance will be noticed if the bone or acetabular components are touched. In such an event, pull the tool out of the cement layer and apply it at a different angle, in order to prevent contact with the bone or with the components.



Short osteotom

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[INFORMATION ??]

ULTRA-DRIVE SYSTEM

PART NO.	DESCRIPTION
423800	ULTRA-DRIVE basic instrument
423802	Bus switch
423803	Hand-unit (40 kHz)
423810	**Accessories pack** - contains one each of the following:
423811	cable holder
423812	Assembly tray
423813	Sterilisation tray
423814	Hand-unit extension
	Accessories
423816	7/32" spanner
423817	3/8" spanner
423818	Plug puller adapter
423819	Slide hammer
423835	**Accessories - basic selection -** contains two each of the following items:
423836	60 mm tip extension
423838	120 mm tip extension
423840	180 mm tip extension
423842	180 mm tip extension with internal/external thread
423844	Irrigation set
423855	**Disposable items - basic selection -** contains three each of the following:
423856	Acetabular hollow chisel 56 mm/85 o
423860	Double cutter 6 mm
423864	Hook 5 mm
423868	Plug puller 6 mm
423872	Disc drill 9.5 mm
423876	Hollow chisel 8 mm
423880	Short osteotom 9.5 mm
423874	trowel 8 mm
423875	trowel 9.5 mm
423877	Short flat hollow chisel 9.5 mm
423820	Tubing & pads set (10 pieces).

Ultra-Drive™

The ULTRA-DRIVE system is manufactured by Advanced Osseous Technologies (AOT) and exclusively distributed by Biomet.

[EFFNER?] BIOMET GmbH · Alt-Lankwitz 102 · D-12247 Berlin · Tel.030-77 00 92-0 · Fax 030-774 40 53

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ULTRA-DRIVE™

Operating instructions

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1 Introduction

The ULTRA-DRIVE system is a sophisticated ultrasonic instrument, designed to be used in orthopaedic surgery. It was developed and manufactured by Advanced Osseous Technologies (AOT), and is exclusively distributed by Biomet.

These instructions are your written introduction to the ULTRA-DRIVE system. Please read through the entire instructions carefully before operating any part of the system. The recommended settings are merely guide-lines, and should not be regarded as obligatory clinical boundary values.

It is important that you understand and observe the notes and warnings contained in these instructions; they are printed in bold throughout the text for emphasis, and are summarised once again in the chapter "Safety notes" on page 11.

When you receive your ULTRA-DRIVE system, please contact your Biomet representative who will arrange the unpacking, installation and training. Please allow four hours for training purposes.

Should you have any questions concerning the system and its use, or should you require further information, please refer to your Biomet representative or direct to:

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2 Technical data

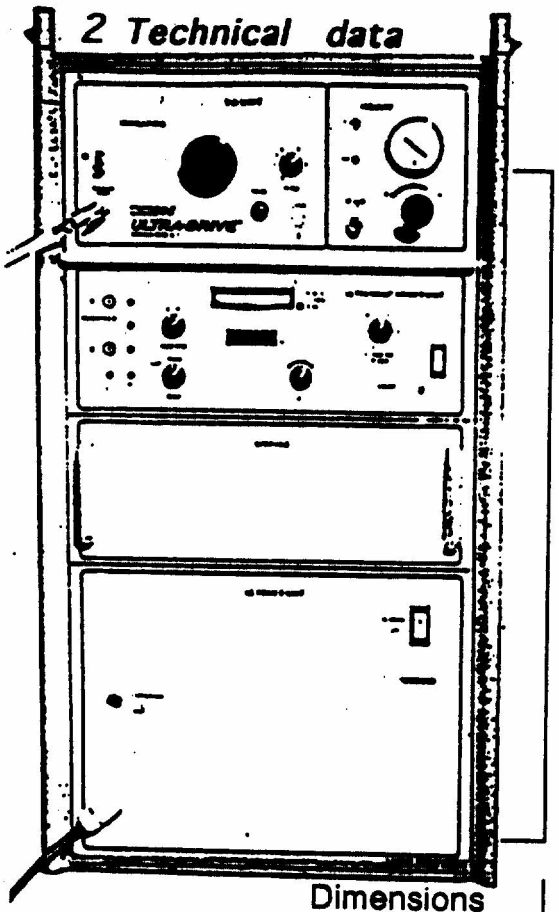

Illustration 1
ULTRA-DRIVE basic instrument

Dimensions	Height:	115 cm	
	Width:	56 cm	
	Depth:	62 cm	
Weight	without packaging:	98 kg	
	with packaging:	120 kg	
Environmental conditions		In operation	In storage
	Max. altitude:	3 000 m	12 000 m
	Temperature:	10° - 40° C	10° - 60° C
	Relative atm. humidity	15 - 95 % with no condensation	15 - 95 % with no condensation
Power supply	230 V nominal AC (207-252 V) 50/60 Hz nominal frequency 500 VA [sic] Also available in 115 V AC.		

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3 Description

The ULTRA-DRIVE surgical system is an orthopaedic joint revision instrument, designed to be used in procedures which require sectioning of bone cement (polymethyl metacrylate or PMMA). The R&D objective was to render the surgeon's work more precise and flexible, and simultaneously make surgery simpler, quicker and less traumatic.

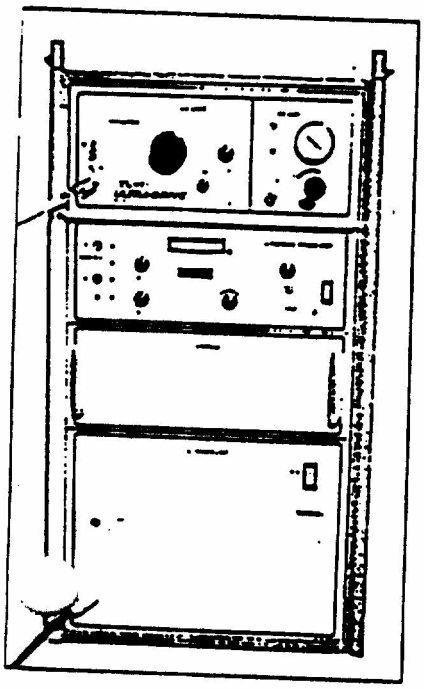

Illustration 2
ULTRA-DRIVE control panel

Characteristics

- Fluid supplied through disposable attachments
- Autoclave-compatible, air-cooled piezoelectric ultrasonic hand-units
- Ultrasound generator with automatic tuning
- Ultrasound control via foot-switch
- Irrigation control via foot-switch
- Low-pressure restriction setting is controlled by the user
- Audible warning when ultrasound is switched on

Special system features

Control panel

The control panel (illustration 2) contains all ULTRA-DRIVE controls, displays and connections. The control panel is divided into four sections (from top to bottom): the irrigation/ aspiration unit, the ultrasound power supply, the drawer and the AC mains section.

AC mains section

The mains unit contains the AC input (mains cable), the foot-switch socket, a timing counter and the mains switch.

Mains connection – mains power supply is provided through a mains cable permanently attached to the instrument, in accordance with clinical standards.

Foot-switch socket – the foot-switch through which the hand-unit's ultrasound supply can be switched on, is connected via this socket through a securable plug.

Mains switch – the green AC MAINS switch is both a mains switch and an automatic safety cut-out. The switch is lit when the mains supply is on.

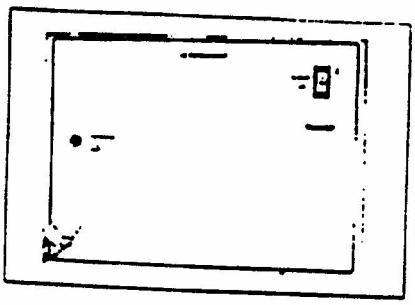

Illustration 3
Mains switch

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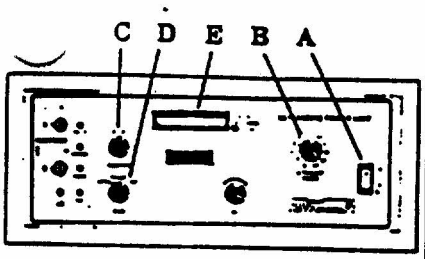

Illustration 4
Ultrasound supply unit

Drawer

The drawer serves for the efficient storage of the assembly tray (including two hand-units) and of the sterilisation tray with the spanners, extensions and other instruments in a single, easily accessible place.

Ultrasound supply unit

The ultrasound supply unit (illustration 4) contains all control elements, displays, lights and connections relating to the ultrasonically driven hand-units.

A On-off switch – the white illuminated switch, which is also an automaic safety cut-out, is located at bottom right of the ultrasound supply unit.

B Ultrasound level control – a rotary knob, located immediately to the left of the on-off switch, is used to set the level available at the hand-unit. The level can be selected in the range 0 to 100, according to application.

C Function selector – the FUNCTION switch determines which of the connected hand-units A or B, is on. Both hand-units can be permanently connected, for convenience. The switch controls which hand-unit, A or B, is supplied with ultrasound.

D Operating mode – the MODE rotary switch has three settings: STANDBY, OUTPUT and TEST.

- D STANDBY – this operating mode should be selected when the instrument is first switched on, or when it is momentarily not in use. In this setting, the ultrasound generator is electrically isolated from the hand-units, and simultaneously a calibration signal is sent to the hand-unit (A or B) selected via the FUNCTION switch.

- D OUTPUT – in this operating mode the ultrasound generator is connected to the hand-unit (A or B) selected via the FUNCTION switch. Activation is achieved via the foot switch.

- D TEST – in this operating mode, the foot switch is bypassed, and the hand-unit selected via the FUNCTION switch is directly supplied with ultrasound. This setting is used for testing purposes, when the foot switch cannot easily be reached. If the rotary switch is released whilst in the TEST position, it returns automatically to the STANDBY setting.

E Calibration – this function allows the user to test the calibration of each hand-unit with the attached extension and tool. This function is available in the STANDBY mode, and applies to the hand-unit selected via the FUNCTION switch.

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Calibration test for hand-units, extensions and tools:

1) Select STANDBY mode.
2) Selected the required hand-unit, A or B.
3) Using the frequency rotary switch (Hz), set the meter to maximum deflection – the figure should lie between 125 & 185, and the digital display should show ca. 40 000 (Hz).

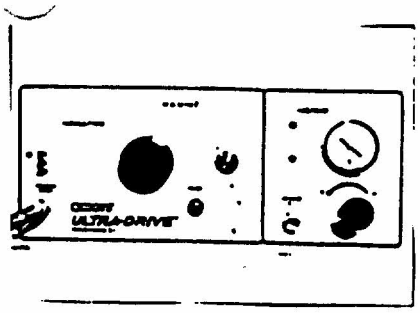

Illustration 5
Irrigation/ aspiration unit

Irrigation/aspiration unit (I/A unit)

The irrigation/aspiration unit (illustration 5) consists of two parts, one for irrigation and one for aspiration. The irrigation section uses a pump and is controlled through a foot-switch, and the aspiration section contains a vacuum control.

Irrigation

FLOW – this rotary switch is used to set the rate at which the pump supplies irrigation fluid to the surgery site: "0" is the 'Off' position, "10" – the maximum supply rate.

PRIME – when this button is pressed, the pump operates at its maximum level, so that the tubing can be rid of air without using the foot-switch.

Aspiration

Vacuum control – the large black rotary switch below the meter is used to set the vacuum: anti-clock-wise for stronger vacuum, clockwise for less. The meter above it displays the output vacuum in inches of mercury.

CB1 – this automatic safety device protects the DC circuits. A raised button shows that the safety cut-out has been tripped; in such an event refer to your Biomet representative.

DC POWER – this light indicates that the DC mains section is supplying the logic circuits in the irrigation/aspiration unit with voltage.

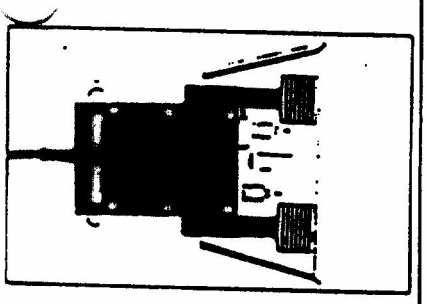

Illustration 6
Foot-switch

Operating modes, foot-switch functions

Table 1
Foot-switch control

	LEFT PEDAL		RIGHT PEDAL	
Operating mode	Normal	Pressed	Normal	Pressed
TEST	Ultrasound	Ultrasound	Ultrasound	Ultrasound
STANDBY	Standby	Standby	Standby	Standby
OUTPUT	Neutral	Irrigation	Neutral	Ultrasound and irrigation

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Displays and warning lights

OVERLOAD – this red overload warning light comes on when the frequency or the output level exceed the permitted values. If the frequency remains above 40 kHz, the warning light stays on until the overload is neutralised or the instrument is switched to STANDBY.

Ultrasound power supply meter – displays the power output in Watts.

Calibration display – when in standby mode, this shows the relative output level available in the selected hand-unit (A or B).

Vacuum display – shows the available vacuum in inches of mercury.

Timing counter – shows for how long the Ultra-Drive was switched on.

Control tone – a continuous tone is audible when the ultra-sound is activated. A discontinuous tone indicates a fault.

Fault – an illuminated red FAULT light indicates in which hand-unit (A or B) an earthing fault is present; the light stays on until the fault is rectified. The built-in safety switch disconnects the output. Reactivation is achieved by setting the MODE switch to STANDBY.

Overheating – the red TEMPERATURE light indicates in which hand-unit (A or B) a thermal overload is present. The light stays on until the hand-unit has cooled down.

Foot-switch – the red FOOTSWITCH light indicates that a foot-switch is connected.

Connections

VAC IN – quick-connection plug for standard hospital vacuum lines.

VAC OUT – quick-connection socket; the vacuum exit line fits a standard hospital aspiration vessel.

Foot-switch socket – connection for self-securing clinical standard plug with multiple earth.

Mains connection – fixed low-loss clinical standard mains supply cable.

Hand-unit socket A – connection for self-securing clinical standard plug with multiple earth.

Hand-unit socket B – connection for self-securing clinical standard plug with multiple earth.

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Safety cut-outs

In case of electrical overload, the automatic safety cut-out device switches off the ultrasound system's ultrasound mains section. If the cut-out trips, switch it back ON; if it trips again immediately, disconnect the system and contact the service department.

General

Drawer – the hand-units, assembly tray and accessories can be stored here.

Foot-switch holder – two hooks on the side-stand serve to store the foot-switch.

Cable holder – four attachments on the stand serve to store the foot-switch and mains cables.

Lockable wheels – all four wheels can be locked; two wheels should always be locked whenever the instrument is not being moved.

Assembly tray – a hardened stainless-steel assembly tray serves to hold the hand-units in position during the assembly of extensions.

Controls

Fluid control

Irrigation – the irrigation system consists of a peristaltic pump which provides fluid from the container to the hand-unit. The pump is turned off in the normal state; it is controlled through both pedals on the foot-switch. The flow-rate can be regulated via the FLOW controller on the irrigation unit's front panel.

Aspiration – the aspiration system is regulated through the vacuum controller on the front panel; settings range from 0 to maximum hospital vacuum (762 mm Hg) when fully open. The actual pressure can be read off the meter located above the button. The aspiration way runs from the aspiration hand-unit via the collecting vessels to the VAC OUT connection.

Ultrasound system

The ultrasound hand-unit permits the simultaneous use of ultrasound tools and of the irrigation system. The ultrasound converter is located in the middle of each hand-unit; this converter and the tools connected to it vibrate longitudinally ca. 40000 times per second, when the ultrasound is switched on. Ultrasound power is set via a rotary switch located on the right of the ultrasound supply unit's front panel.

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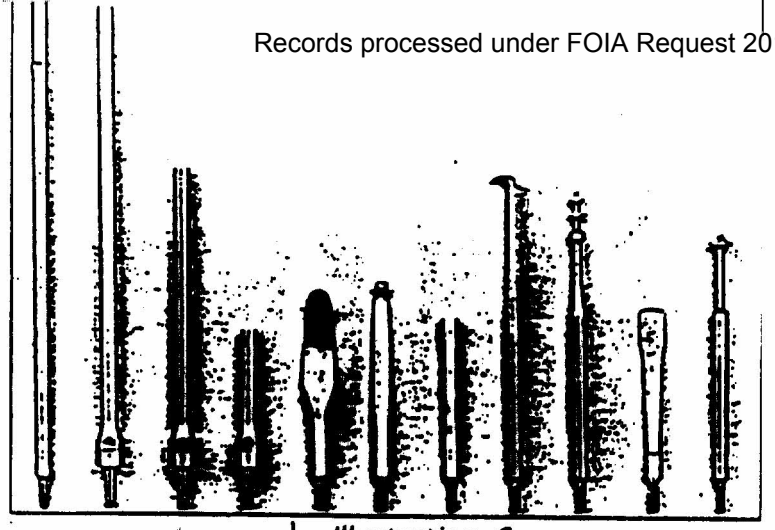

Illustration 6
Ultrasound tool sets

Disposable items

Instruments – the ultrasound tool sets are designed for single use. The ULTRA-DRIVE basic range of disposable items consists of three each of the following: acetabular hollow chisel, double cutter, hook, plug puller, disc drill, hollow chisel, short osteotom. Replacement tools can be ordered individually.

Irrigation set – a carton with ten tubing/pad units comes as standard with each ULTRA-DRIVE supplied.

Disposable items for the ULTRA-DRIVE system come in sterile packing, and are designed to be used once and then disposed of.

NOTE - PACKING LABELS: always read the notes on the packaging before use.

WARNING:

- Do not use disposable items whose packaging is damaged or whose sealing is faulty.
- **Disposable sterile medical articles should not be re-used!** These items were designed for a single application – **DO NOT RE-USE THEM** (cf. *The Joint Commission Standards for Hospitals: Accreditation Manual for Hospitals,* Chicago, IL, 1989).
- The ULTRA-DRIVE accessories and the disposable items together with the basic instrument, form a self-contained surgical system. Using components foreign to the system may adversely affect system performance and is potentially dangerous.
- The instructions for installation and operation of the instrument contained in this manual, must be thoroughly read and understood before any part of the ULTRA-DRIVE system is used.

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The ULTRA-DRIVE is controlled electronically and provides automatic tuning of the ultrasonic hand-unit.

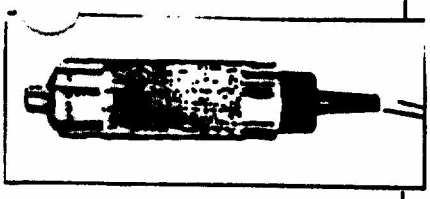

Illustration 7 Ultrasonic hand-unit

Additional equipment

Hand-units

The 40 kHz hand-units developed for the ULTRA-DRIVE have the following characteristics:

- Can be steam-treated in an autoclave
- Dimensions: 44 mm diameter, 135 length, 567 g weight
- Provide ultrasound cutting
- No assembly needed, other than the attachment of disposable tubes and extensions or tools

Assembly tray – a stainless steel sterilisation tray which serves both for sterilisation and for the changing of tools attached to the hand-units.

Sterilisation tray – a stainless steel tray, which serves for the sterilisation of ultrasound extensions and other tools.

Cable holder – located on the instrument's right-hand side; used to store the following:

- Foot-switch
- Mains cable
- Vacuum containers
- Irrigation containers

Accessories

The accessories can be re-used repeatedly, but should be replaced when signs of wear become apparent otherwise performance will suffer.

Extensions – extensions for the 40 kHz hand-units are available in three sizes: 60, 120 and 180 mm.

Spanners – four spanners are supplied as standard, two each in 7/32" and 3/8" sizes.

Plug puller adapter – accomodates the plug puller and is used with the slide hammer or the slit hammer.

Slide hammer – used in conjunction with the plug puller adapter. Weight ca. 450 g.

Irrigation set – a curved stainless-steel tube with clips for attachment to the hand-unit.

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4 Safety notes

Most of the safety notes in this chapter are repeated elsewhere in this manual. If you require further information, please contact your Biomet representative.

Hand-unit attachments

- Please ensure that all hand-unit attachments (extensions and tools) are properly fixed to the hand-unit. Tools incorrectly attached will suffer from poor tuning. However, do not over-tighten the tools as this can make removal difficult. Loose attachment and broken tools will usually squeak or cause the OVERLOAD warning light to come on, preceded by an audible clicking sound when the ultrasound supply is switched on.
- Keep the contact surfaces free of deposits.
- Spanners which are not part of the ULTRA-DRIVE system, may damage the instruments or the hand-unit.

Care of the hand-unit

- The ultrasound hand-unit is a surgical instrument and must be treated with care. Make sure that the plug connecting it with the instrument is completely dry before use.
- Thoroughly clean the hand-unit immediately after use. **DO NOT CLEAN THE HAND-UNIT IN AN ULTRASOUND CLEANING DEVICE**. Ultrasound cleaning of this hand-unit would cause irreparable damage. Please refer to the chapter-heading "Disassembly and cleaning" in this manual (page 15) for information on correct cleaning.
- **DO NOT IMMERSE THE HAND-UNIT'S PLUG IN LIQUIDS.**
- Do not allow the ultrasonic tool's cutting edges to come in contact with metallic objects while switched on, as this may cause the tool to break or blunt.
- Following treatment in a steam autoclave, allow the hand-units and accessories to cool down in the air for at least 30 minutes.

Manipulation of the hand-unit

- Do not touch the extensions or the tools at any point when switched on; only hold the ultrasound hand-unit by the ribbed surface.

Foot-switch

- Never lift or move the foot-switch by the cable, as this may damage it.

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Disposable items

- **Sterile disposable medical articles should not be re-used!** (cf. *The Joint Commission Standards for Hospitals: Accreditaion Manual for Hospitals,* Chicago, IL, 1989.
- The ULTRA-DRIVE accessories and the disposable items together with the basic instrument form a self-contained surgical system. Using components foreign to the system may adversely affect system performance, is potentially dangerous and may jeopardise the warranty.
- The instructions for installation and operation of the instrument contained in this manual, must be thoroughly read and understood before any part of the ULTRA-DRIVE system is used.
- Ensure that no tubes are bent or blocked during surgery.

Pre-surgery tests

Pre-surgery test should be carried out as described on pp. 13-15, in the section "Assembly and testing". In case of faults, refer to pp. 16-18, "Troubleshooting notes". If the problem cannot be rectified, DO NOT PROCEED. Switch off the instrument and inform your Biomet representative.

General safety notes

- Do not use the ULTRA–DRIVE system near flammable anaesthetics.
- The use of other ultrasound hand-units in lieu of those forming part of the ULTRA-DRIVE system may damage the ultrasound supply unit or adversely affect its performance.

5 Sterilisation

The following components of the ULTRA-DRIVE system may be sterilised in a (fast) steam autoclave, using your clinic's usual procedure:

- Ultrasonic hand-units with cables and plugs
- Hand-unit extensions
- Tool extensions
- Spanners
- Plug puller adapter
- Slide hammer
- Assembly and sterilisation trays

WARNING: After treatment in a (fast) steam autoclave, allow the hand-units and accessories to cool down in the air for at least 30 minutes.

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6 Assembly and testing

This section explains in detail the recommended procedure for the ULTRA-DRIVE system's assembly and functions testing. Assembly may be modified to suit your clinic's specific requirements, but the tests prescribed for the various stages of the assembly procedure must be carried out exactly as listed.

The procedure described here relates to hip revisions, and presupposes a team of at least three persons: surgeon and sterile nurse in the sterile area, as well as a peripatetic nurse in the non-sterile area.

Please refer all questions relating to the assembly and testing procedure to your Biomet representative.

SYSTEM ASSEMBLY

– CARRIED OUT WITH THE INSTRUMENT SWITCHED OFF –

Step	Carried out by
1. Place all parts to be sterilised on the assembly and sterilisation tray supplied with the ULTRA-DRIVE system.	Peripatetic
2. Sterilise the assembly and sterilisation tray, using the usual clinical method. NOTE: if a steam autoclave is used, allow the hand-units and accessories to cool down in the air for at least 30 minutes after treatment.	Peripatetic
3. Position the instrument as required by the surgeon, and lock the wheels.	Peripatetic
4. Remove the foot-switch from its holder at the side of the instrument, and connect it. Plug it into the mains socket, **but do not switch on the instrument yet**.	Peripatetic
5. Position the foot-switch so that it is easily accessible during surgery.	Peripatetic
6. Fold down the aspiration-vessel shelf, by pulling its attachment away from the instrument's side. Install one to three vessels. Connect the first vessel * to VAC OUT, using the aspiration connecting piece. Connect the other vessels in turn, in the usual way. Connect the VAC IN attachment directly to the clinic's vacuum line, not via other vessels.	Peripatetic
7. Open the sterile tubing/pad packing and transfer the contents aseptically to the sterile nurse. Proceed as specified on the packet.	Peripatetic

* NOTE: In order to protect the system regulator, the first vessel must have a built-in filter which can be switched off.

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FUNCTIONS TESTING

Step	Carried out by
1. Place the assembly and instrument trays on top of the covered instrument. Hand the 40 kHz hand-unit to the peripatetic nurse.	Sterile nurse
2. Connect the ultrasonic hand-unit to the required socket, A or B, on the instrument. Make the following settings: • Ultrasound level 20 • STANDBY mode • FUNCTION A • FLOW 5	Peripatetic
3. Fit the sterile irrigation tube to the hand-unit.	Sterile nurse
4. Arrange the irrigation and aspiration tubing sets in accordance with the instructions on the packet.	Sterile nurse
5. Hang up the packet containing the irrigation fluid.	Peripatetic
6. With hand-units attached, switch on the instrument and the ultrasound supply – the frequency calibration display lights up at this point.	Peripatetic
7. Remove the air from the tubes, in accordance with the instructions on the packing.	Peripatetic
8. Place the hand-unit in the assembly tray and attach the required tool and the extension, aligning the arrows on the parts to be connected. Always attach an internal to an external quick-fitting thread, and tighten the connection with the appropriate spanner by one quarter turn clockwise. **WARNING: Using hand-units, extensions or spanners which do not form part of the ULTRA-DRIVE system, may damage the tools or the hand-unit.**	sterile nurse
9. Test the hand-unit's operation, by holding it with the tool pointing up and activating the foot-switch's right pedal; the instrument must be set to OUTPUT. A warning tone is sounded, all warning lights are off, and the level indicator lies in the range 2 - 5. **WARNING: The hand-units must be at room temperature. Never immerse them in cooling liquids; after treatment in a steam autoclave, allow them to cool down in the air for at least 30 minutes.** WARNING: When the hand-unit is switched on, do not touch the extension or the tool.	Sterile nurse

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SETTINGS FOR SURGERY

Step	Carried out by
1. Set the FUNCTION switch to A or B, according to the hand-unit you wish to use.	Peripatetic
2. Set the MODE switch to STANDBY.	Peripatetic
3. Set the ultrasound level to 70%.	Peripatetic
4. Turn the VAC ADJ button to the fully open position.	Peripatetic

7 Settings during surgery

The following settings and tasks may be carried out during surgery:

- Increasing or decreasing the irrigation flow.
- Changing the hand-unit (switching over from A to B or vice versa)
- Testing frequency & condition of the hand-unit and attachments via the calibrator.
- Increasing or decreasing
  – ultrasound level
  – vacuum
  (in each case, refer to the relevant information on pp. 5 - 6).
- Changing extensions and tools.

8 Disassembly and cleaning

After use, proceed as follows:

1. Set the MODE switch to STANDBY.
2. Switch off the ultrasound supply and the mains switch.
3. Detach the irrigation and aspiration tubes from the hand-unit and empty the tubes.
4. Dispose of the remaining irrigation solution and of all single-use items.
5. Clean the hand-units – the entire cleaning procedure must follow immediately after every surgical use, as tissue residues and salt-containing irrigation solution collect in the hand-units and may cause long-term damage. Do not place the hand-units in the autoclave until all residues are removed.

   WARNING: NEVER CLEAN THE HAND-UNITS WITH AN ULTRASOUND CLEANING DEVICE, AS THIS MAY CAUSE IRREPARABLE DAMAGE.

   NOTE: NEVER USE WIRE, METALLIC OBJECTS OR WIRE BRUSHES TO CLEAN ANY PART OF THE HAND-UNITS.

6. Disconnect the foot-switch plug and the mains plugs and hang up the cables in the designated places on the holder.

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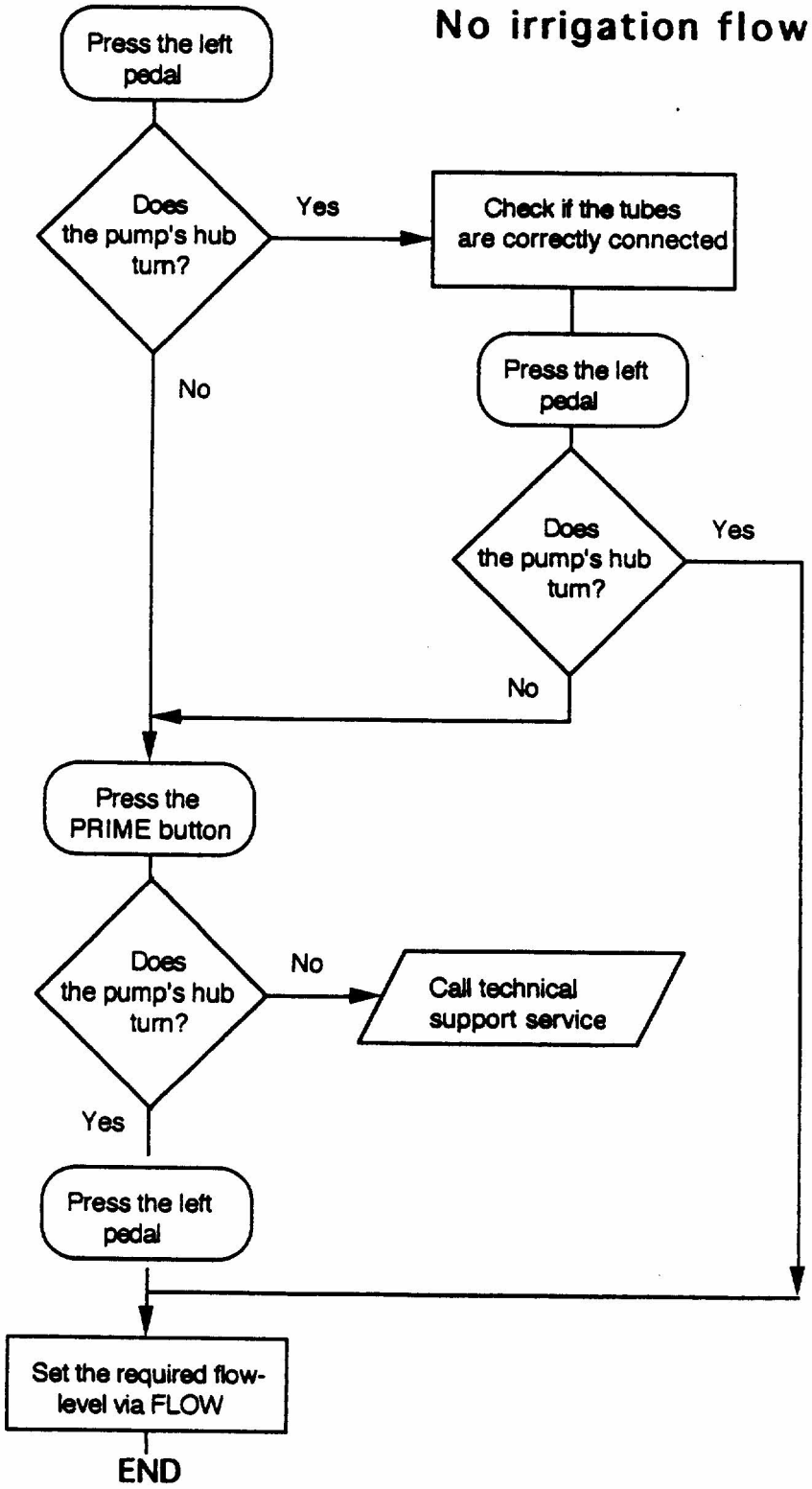
9 Troubleshooting notes

These diagrams are designed for quick pin-pointing of inoperative or faulty parts; they should not replace the usual methods of discovering the source of problems. Contact your Biomet representative if the steps described in the diagrams prove unsuccessful.

Taking normal care during troubleshooting is recommended, to avoid creating further problems.



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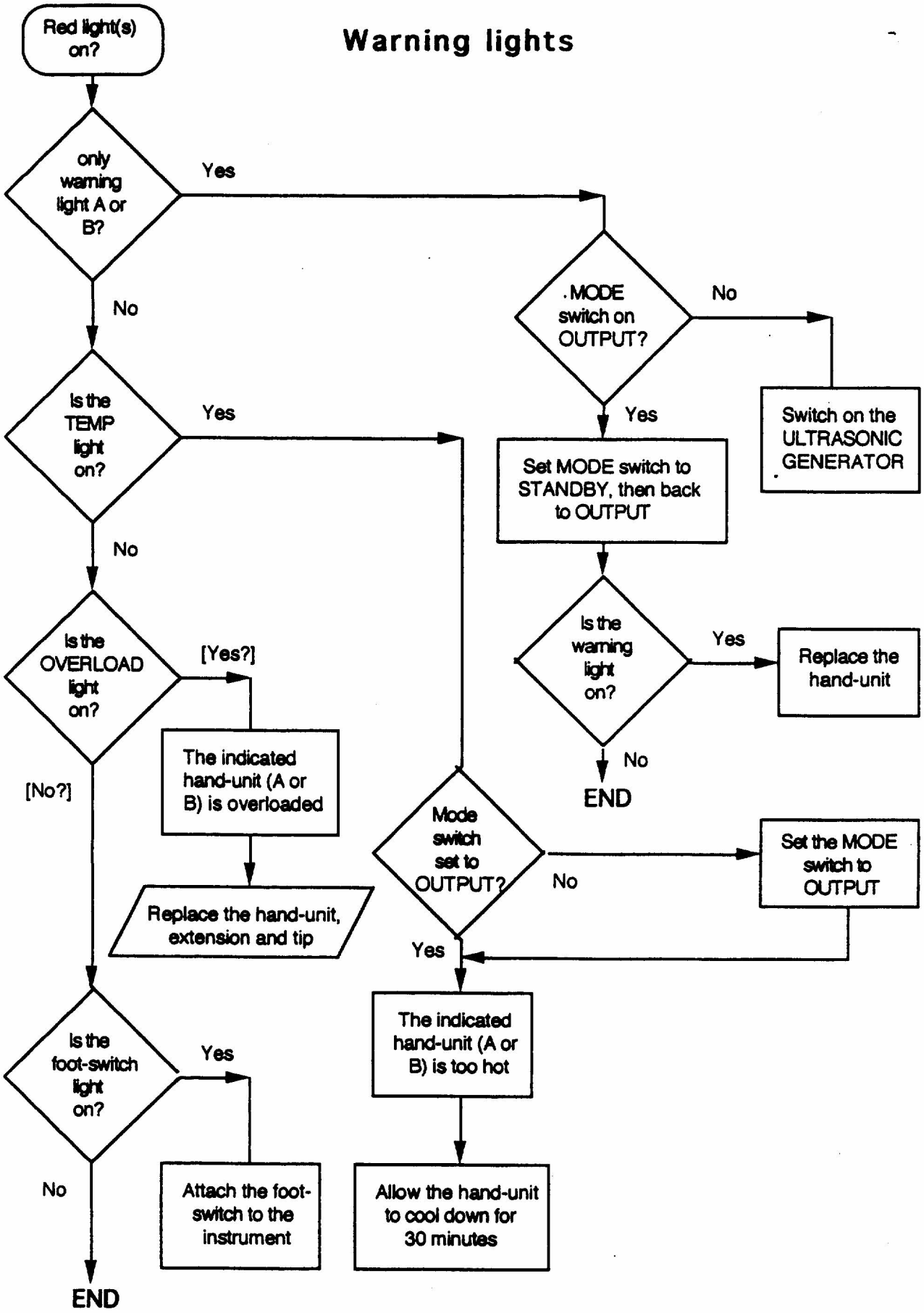
Warning lights



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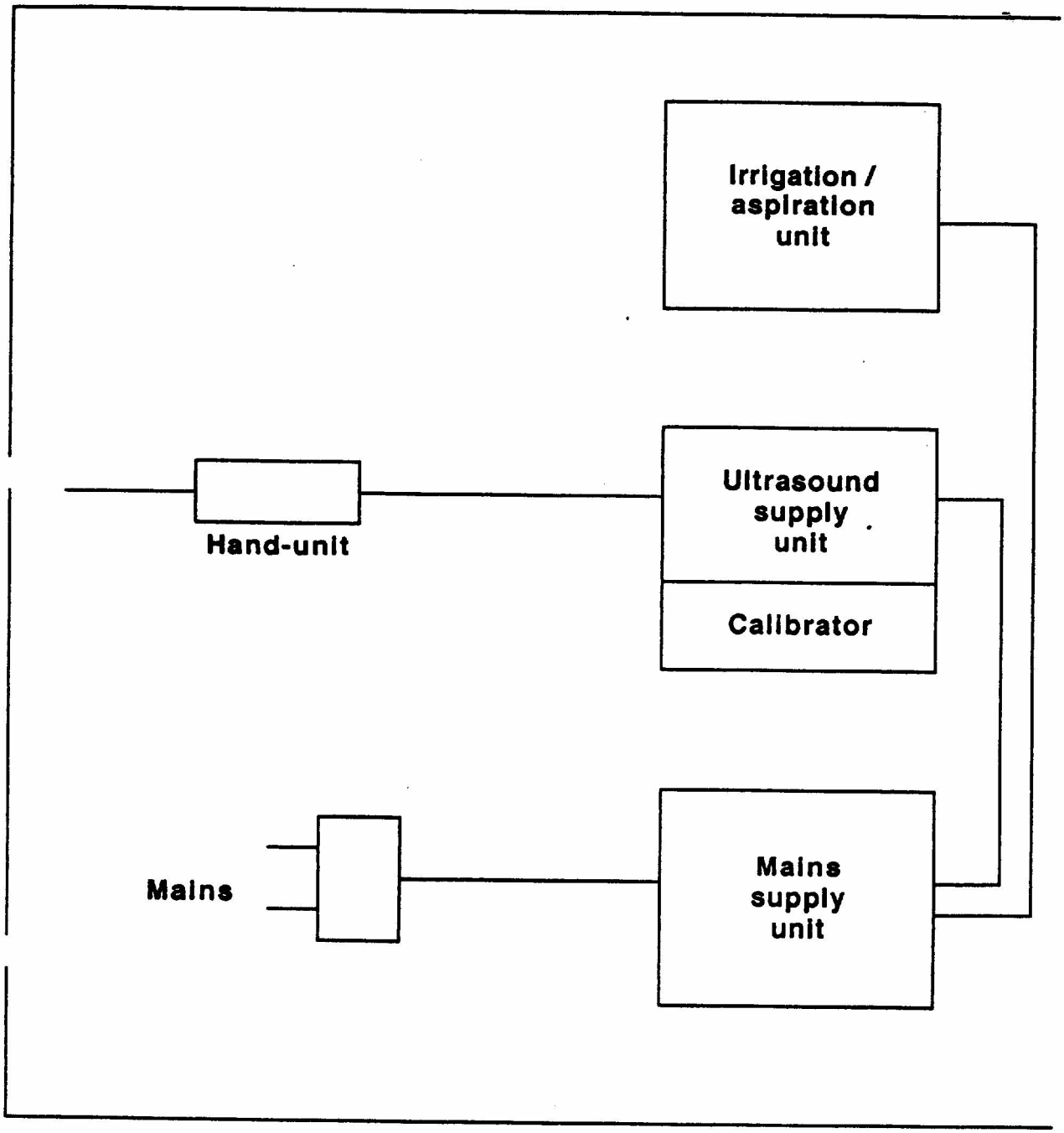

Illustration 9
ULTRA-DRIVE system
Circuit diagram

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10 Accessories and spare parts

Accessories and spare parts can be obtained from Biomet . . .

ULTRA-DRIVE system

Part No.	Description
423800	ULTRA-DRIVE basic instrument
423802	Foot-switch
423803	Hand-unit (40 kHz)
423810	**Accessories set** – contains one each of the following items: 423811 Cable holder 423812 Assembly tray 423813 Sterilisation tray 423814 Hand-unit extension
	ACCESSORIES
423816	7/32" spanner
423817	3/8" spanner
423818	Plug puller adapter
423819	Slide hammer
423844	Irrigation set
423835	**Accessories - basic selection -** contains two each of the following items: 423836 Tool-extension, 60 mm 423838 Tool-extension, 120 mm 423840 Tool-extension, 180 mm 423842 Extension with internal/external thread, 180 mm
423855	**Disposable items - basic selection -** contains three each of the following: 423856 Acetabular hollow chisel 56mm/85° 423860 Double cutter 6 mm 423864 Hook 5 mm 423868 Plug puller 6 mm 423872 Disc drill 9.5 mm 423876 Hollow chisel 8 mm 423880 Short osteotom 9.5 mm
423820	Tubing/pad set (10 pieces)

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Please note

The ULTRA-DRIVE system together with the accessories and the disposable items forms a self-contained surgical system; using components foreign to the system may adversely affect system performance, is potentially dangerous and may jeopardise the warranty

In order to avoid unnecessary transport of instruments or parts thereof, please contact Biomet before returning any such items. Biomet will assign a repair number if it considers that the return of any items is necessary; this number must be displayed on the outside of the packaging. The return address is:

...
...
...

Maintenance

Maintenance of the ULTRA-DRIVE system by the user is limited to that specified in the chapters "Assembly and testing" (pp. 13-15) and "Troubleshooting notes" (pp. 16-18). If the problem cannot be resolved by following those instructions, contact Biomet or your regional Biomet representative.

There are no user-servicable or user-replacable parts in the basic instrument.

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SOFTWARE DEVELOPMENT MANUAL

VERSION 1.2

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OSCAR HAZARD ANALYSIS

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OSCAR VERIFICATION, VALIDATION, AND TESTING

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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