DESCRIPTION
The Ultra-Drive™ System is used to aid in the removal of bone cement (PMMA) and non-cemented implants in conjunction with revision arthroplasty. The Ultra-Drive™ device converts standard electrical energy into mechanical energy, via an ultrasonic transducer in the Ultra-Drive™ handpiece. This energy is transmitted through individually tuned tool tips in acoustic waves, causing the tool tip to vibrate at a controlled high speed. This action breaks down bone cement and cuts through cancellous bone. Biomet manufactures a variety of Ultra-Drive™ Tool Tips to be used in these applications.

MATERIALS
Titanium Alloy

WARNINGS
1. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to performing surgery. The Ultra-Drive™ System is to be operated in accordance to the Operator’s Manual.
2. Do not force tool tips. Tools are to be guided, not forced. If the instrument meets resistance, do not force the tool, the tool may have contacted cortical bone. The application of force can cause damage to the cutting tip, the system and unnecessary damage to bone.
3. See product labels for recommended power settings.
4. Do not attempt removal of a bone plug with the Ultra-Drive™ handpiece. The jolting force often required for removal of a bone plug can cause unrepairable, permanent damage to the handpiece. Bone plugs are to be removed with the aid of the Slide Hammer (REF 423819) and Plug Puller Adapter(REF 423818).
5. The patient is to be made aware and warned of general surgical risks. The patient is to be warned that Ultra-Drive™ tool tips can break or otherwise fail during surgery, and that fragments of broken tool tips can remain at the surgical site after surgery.
6. Device is single use only. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard.

PRECAUTIONS
The Ultra-Drive™ System is designed to aid in the removal of bone cement (PMMA) or non-cemented implants in conjunction with revision arthroplasty. Intraoperative fracture or breakage of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

STERILITY
Ultra-Drive™ Tool Tips are sterilized by exposure to a minimum dose of 25kGy of gamma radiation. Single Use Only. Do not re-sterilize. Do not reuse. Do not use after expiration date.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968

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