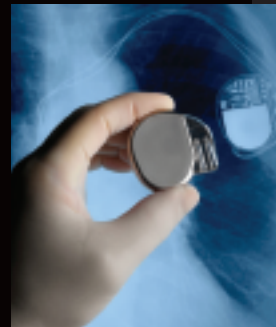
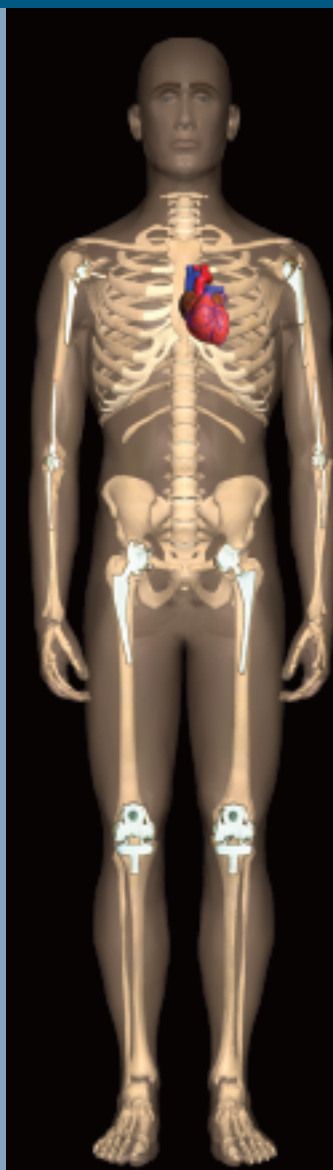


BUEHLER®

Comprehensive Solutions for Biomedical Science



- **Medical Metals & Devices**
- **Medical Electronics**
- **Biomedical Research**
- **Dental Research**
- **Medical Fiber Optics**



BUEHLER

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Buehler

As a world leader in specimen preparation equipment for the medical community, Buehler supports medical device manufacturers, medical material suppliers, biomedical and dental researchers and medical electronic manufacturers. Our products help to advance scientific knowledge which improves manufacturing and quality, while increasing enhanced understanding of the end results.

Buehler manufactures scientific equipment and consumables for use in materials analysis. Our products are used throughout the world for product development, manufacturing, academic research and maintaining quality control. Everything needed to equip or retrofit your laboratory for sectioning, mounting, grinding and polishing to final analysis with a complete line of microscopes and image analysis systems is available.

Our capabilities are broad, as we are able to offer proper equipment, consumables and methods for a wide variety of material applications. Medical device manufacturers face very stringent material properties that require extensive testing. These materials must be accepted by the human body and continue to function over a long period of time. Implantables and other orthopedic devices must resist wear in a highly corrosive environment. There is a growing trend toward smaller devices with increased mechanical performance. Whether you are preparing hip/knee implants or an apparatus as small as a drug-eluting stent, Buehler can provide a method which includes the best equipment and consumables for microscopic cross-sectional analysis.

This brochure outlines some challenges that the medical community faces when preparing specimens for analysis. Solutions are met in a variety of ways using Buehler expertise, specialty equipment, consumables and services in the medical electronics failure analysis, histology and fiber optics markets. Our educational programs offer in-depth knowledge, support and demonstration of equipment and consumables.



Sectioning of Medical Materials & Devices



MetAbras® Abrasive Cut-off Wheels



IsoMet® 5000 Linear Precision Saw.
Options include a Bone Chuck, Glass Slide Chuck and Irregular Specimen Chuck.



IsoCut® and IsoMet® Wafering Blades

Health related devices consist of a variety of materials with diverse properties. They include, but are not limited to metals, alloys, ceramics, polymers and carbonaceous materials. The main concern in cross-sectioning is to obtain a surface with minimal damage. Buehler offers a wide variety of abrasive cutters and precision saws for the medical industry.

Larger devices, such as hip or knee implants, require the use of abrasive cutters as the first step of metallographic preparation. These materials may also be coated to enhance their performance or biocompatibility. Porous metal or ceramic coatings deposited on implants are applied to facilitate bone ingrowth. The coatings must be protected to view the true microstructure. All of Buehler's abrasive cutters and MetAbras® Abrasive Cut-off Wheels are specially designed to produce minimum deformation without sacrificing cutting rates.

Specialized applications may arise in the study of histological specimen preparation. For example, when preparing a stent implantation, the metal and tissue interface must be prepared without distortion. Drug-eluting stents (Au sputter coated for drug protection) can be cross-sectioned without damaging the drug layer, so that the adhesion and uniformity of the drug can be viewed. The stent should be mounted in an epoxy, for ease of handling, before sectioning.

Buehler's abrasive and precision saws come with a variety of vises and fixtures which accommodate most of the medical industries needs. The largest abrasive saws can handle specimens up to 6" (170mm) in diameter. Any of Buehler's IsoMet® Precision Saws can easily resection a specimen, with minimal surface damage, when used with the IsoCut® and IsoMet® Wafering Blades. These proprietary blades were developed specifically to offer accurate sectioning.



Pryolitic heart valve cross-section.

Specimen Mounting



SimpliMet® 3000 Automatic Mounting Press has short heating and cooling times.



Cast N' Vac 1000 Vacuum Impregnation System for impregnation of porous specimens.



EpoHeat® Epoxy is excellent for vacuum impregnation. It is a fast, heat curing epoxy with low shrinkage & viscosity.

First, the specimen is sectioned to a workable size. Next, it is normally mounted for grinding and polishing. Finally, it is ready for microscopic examination. Depending on the type of specimen being prepared, mounting alternatives encompass three different methods.

Compression Mounting

This process is performed in a mounting press. Specimens are placed in the press chamber and a suitable resin is poured over the specimen. Presses, such as the SimpliMet® 1000 or 3000 Automatic Mounting Press, are quick and easy to use. They offer short heating and cooling times, and also provide excellent edge retention of a specimen when used with the proper mounting media. Importance here lies with edge microscopy analysis such as medical implants that have coatings to retain the edge in its original condition. However, compression mounting is not suitable for heat-or pressure-sensitive samples. A full list and description of mounting resins can be located in the Buehler Consumables Buyer's Guide.

Castable Mounting Compounds

With specimens that are sensitive to high pressures and temperatures, it is recommended to mount them using a castable epoxy resin. There are many options to consider when choosing a suitable epoxy. Variables include cure time, peak temperature during the curing cycle, hardness and level of edge protection. Other properties important to think about are viscosity for filling small voids, transparency and if the epoxy can be used under a vacuum. Use of the Cast N' Vac Impregnation Vacuum System can assist in filling small fragile pores without damaging them during the mounting process and enhance edge protection. An example of a specimen mounted with EpoHeat® Epoxy under a vacuum is shown below with this sectioned Acetabular Cup.

Specialty Castable Glass Slide Mounting

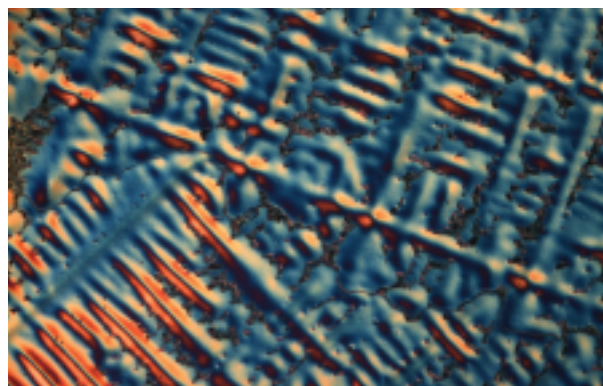
When evaluating tissue or bone response adjacent to the implanted biomaterial, it is important to maintain true architecture for histological examination. Buehler can assist the pathologist with proper cutting, grinding and polishing methods. Glass slide mounted specimens are typically thinned to 5-10 microns. Appropriate technique is essential when dissimilar materials, such as a hard implant, are in contact with a much softer bone or tissue. Embedding epoxy is commonly done in the preparation of specimens that will be analyzed using an electron microscope.



Acetabular Cup mounted in EpoHeat® Epoxy.



Microstructure of Acetabular Cup, Ti-6Al-4V Substrate with CP Ti Powder.



Cast dendritic microstructure of ASTM F75, Co-28% Cr-8% femoral knee implant.

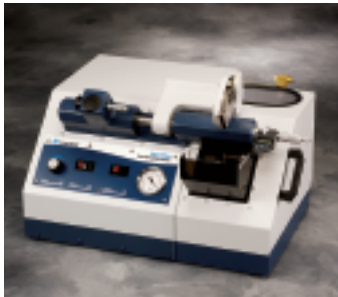
Grinding & Polishing



EcoMet® 250 Grinder-Polisher & AutoMet® 250 Power Head



Histologic Glass Slide Holder for controlled material removal.



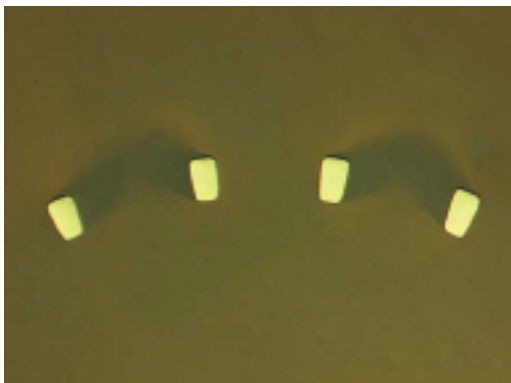
PetroThin® Thin Sectioning System for preparing glass slide mounted thin sections.

Buehler offers the medical industry a choice when selecting the right grinder-polisher. Our EcoMet® family is designed to meet their needs. This product line offers medical implant manufacturers options for preparing samples in single or central force modes when combined with an AutoMet® Power Head. Select a platen of 8" (200mm), 10" (250mm) or 12" (300mm) based on size and volume of specimens to be prepared each day. The EcoMet® Pro is controlled by a touch-screen and offers additional features including Zaxis, with Macro Material Removal System which allows the operator to remove material by depth in central force only. The EcoMet® family of grinder-polishers comes with a large variety of specimen holders for central and single force operations.

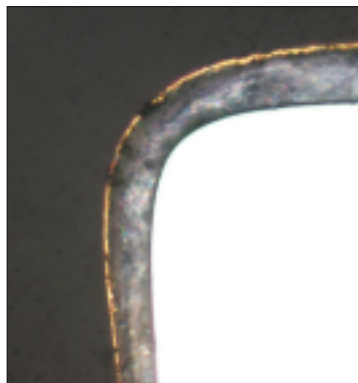
Specialty holders are also available for histological specimen preparation. For example, the Histologic Glass Slide Holder is used for thinning specimens mounted to glass slides. These can be used for hand polishing or can be mounted in a specimen holder and used semi-automatically with the EcoMet® 300 and the AutoMet® 300 which uses a 12" (305mm) diameter platen. Such holders provide controlled material removal by depth while retaining sample flatness because they grind only to the stop ring.

Preparation of Thin Sections

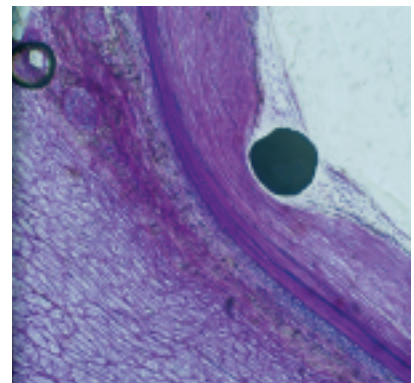
The PetroThin® Thin-Sectioning System is used for precision thinning of histological specimens. It is designed to cut and grind a specimen which is first mounted on a glass slide. By mounting a specimen on a glass slide, the same plane is maintained during preparation. However, it is recommended for medical applications that the specimens are cut with an IsoMet Precision Saw first, and then ground with the PetroThin. Buehler's IsoMet Precision Saws offer thinner blades (less kerf loss) that minimize tissue damage and preserves the specimen. Specimens prepared on the PetroThin can be thinned to 50-100 microns. Further thinning would then be performed using the Histologic Glass Slide Holders discussed previously.



Cross-section of drug coated stent, 4x.

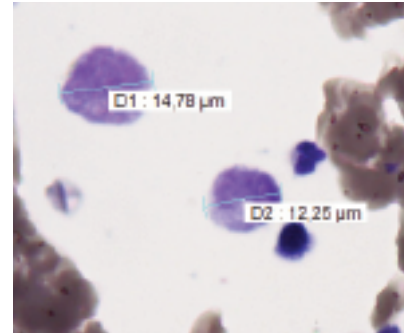
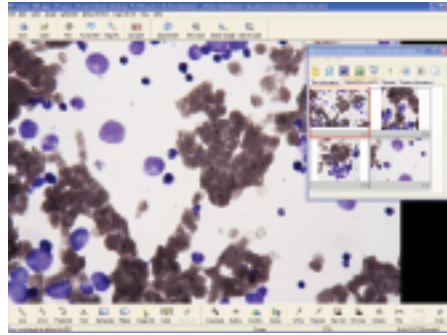
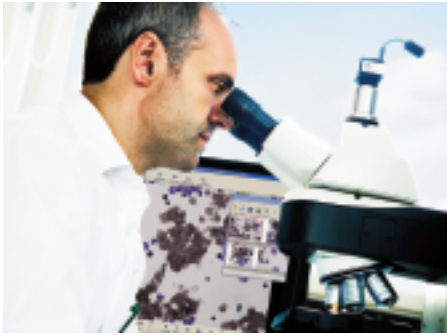


Cross-section of a drug coated stent, gold coated to protect the drug during preparation, 500x.

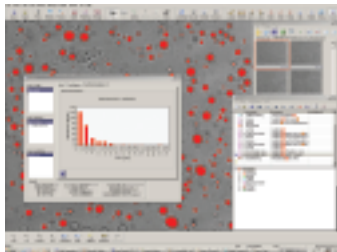


Thin section of a stented artery showing the tissue stent interface.

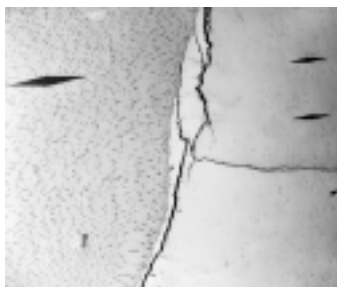
Image Analysis Software & Microindentation Hardness Testing



Skin lotion is being analyzed for the amount of quantification of fat cells in different sizes. The purple image shows bone marrow smear.



OmniMet® Modular Digital Imaging System Screenshot



Microhardness indentations in a tooth. The large indent shows that the dentine is much softer than the enamel (smaller indent).

Image Analysis Software

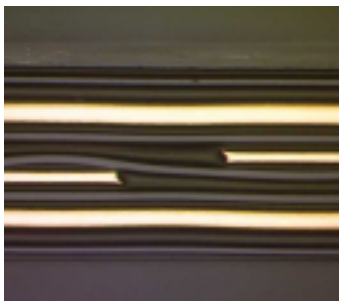
OmniMet® Modular Digital Imaging Systems cover the gamut from a simple image archiving and database management tool to a fully functional suite of applications for the medical industry. The OmniMet® Capture Advanced System incorporates database management tools, basic image processing and measurement functions (including feature classification and counting), as well as full reporting capabilities that will help support Part 11 of Title 21 Code of Federal Regulations (21CFR Part 11). These guidelines were prepared to meet FDA requirements for electronic records and electronic signatures. In addition, there are specific application modules for object measurement analysis, weld, hardness testing and grain size evaluation. Tubing made of high performance polymers and nitinol for making stents and catheters can easily be measured and documented using an OmniMet system. In using the secure OmniMet® Database, you can easily link all of your OmniMet® Software Systems together throughout the world. Sharing laboratory information has never been easier.

Microindentation Hardness Testing

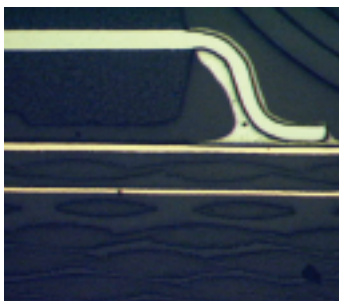
Microindentation hardness testing is used throughout the medical and dental industries. Applications include evaluating curing methods for dental resins, characterizing orthopaedic implant materials prior to fabrication, and determining coating hardness and component hardness profiles. Microhardness systems utilize Vickers or Knoop indenters at low test loads, from 0.5gf to 2000gf. The Vickers test uses a square diamond shaped indenter while the Knoop test uses an elongated diamond indenter. Knoop indents are shallower and can be placed closer together making them more suitable for determining the hardness of coatings and thin parts.

Buehler's OmniMet® MHT Fully Automated Microindentation Hardness Systems improve productivity and repeatability through automated profile placement, turret rotation, objective focusing, and indent measurement. See our Equipment Buyer's Guide for details on our system configurations and microhardness testers.

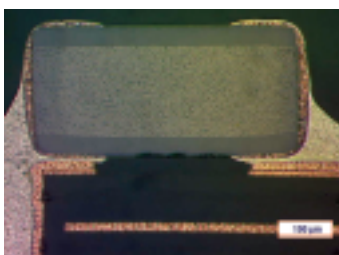
Medical Electronics Preparation for Failure Analysis



Multilayer flex circuit cross-section, as polished, at 100x.



Cross-section of soldered wire joint mounted on a printed circuit board, at 50x.



Cross-section of soldered capacitor, etched at 100x.

Throughout the healthcare sector, medical electronics plays an important role. Diagnostic imaging equipment, portable consumer medical products and implantables all require the highest quality and reliability. These products have to meet longer life cycles than typical consumer products and maintaining quality is of the utmost concern. Buehler has a long history of working with medical Original Equipment Manufacturers (OEM), and more recently, Electronic Manufacturing Services (EMS) providers, assisting them in specimen preparation for failure analysis.

Printed Wiring Boards

Buehler offers two printed wiring board through-hole cross-sectioning systems to assist bare board manufacturers in monitoring copper plated through-hole quality. The NelsonZimmer® 2000 and 3000 Printed Wiring Board Systems provide cross-sectional semi-automation, accuracy and high volume capabilities for preparing through-holes. Buehler's newest system, the NelsonZimmer 3000 High Volume Printed Wiring Board Preparation System, can target the center of plated through-holes down to 0.004" (0.10mm) in diameter. Combined with the PWB Router and Drill, suspected failure sites can be removed anywhere on a bare printed circuit board.

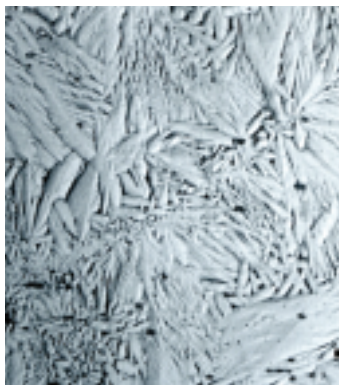
Microelectronic Components

Failure analysis is an important process in the effort to ensure reliability of electronic products and systems throughout their product life cycle. Significant improvements in the reliability of electronics can be achieved by retrieving fielded products and examining them to determine the root cause of any failure and the extent of degradation which has occurred over time. Cross-sectional analysis is a valuable tool for failure analysis of electronic devices, wafers, solid-state devices and components and a variety of mechanisms used in medical devices.

- | | | |
|-------------------|-------------------------|-------------------|
| ◇ BioMEMS | ◇ Miniature components | ◇ Packages |
| ◇ Flex circuits | ◇ Flip Chips | ◇ POP-Package-on- |
| ◇ Sensors | ◇ Electrical connectors | Package |
| ◇ Storage devices | ◇ Bare die | |

Targeting failure sites or specific points of interest in electronic circuits is accomplished with controlled material removal systems such as the MPC 2000 Cross-Sectioning and MPC 3000 Backside Grinding Systems. These systems grind and polish in the Z-axis and are micrometer controlled within \pm one micron of a desired feature. Combined with proper consumables, such as the UltraPrep® Diamond Lapping Films, these systems can easily grind and polish components of varying materials.

Customer Support & Education



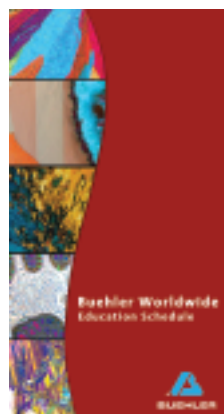
Nitinol martensitic structure after going through the shape memory effect at 1000x.

The medical industry can rely on Buehler for assistance preparing many different materials and devices under development or used in the market today. Our laboratories throughout the world are prepared to tackle your problems by developing a preferred method to reveal the true structure of your specimen. Send us your specimen to be prepared before making that final decision on what to buy. We will recommend the best approach, saving you time and money.

Buehler continues to be a leader in educational programs aimed at the medical industry. "Metallographic Techniques for Medical Devices," "Metallographic Interpretation" and "Advanced Metallographic Techniques" are just a few courses available worldwide. Visit the Buehler biomedical website at www.buehler.com/biomedical for additional information. Finally, join our free Buehler e-Club to access specimen preparation methods of medical materials. The Buehler e-Club also offers useful information on equipment and consumables.



Buehler biomedical website.
www.buehler.com/biomedical.htm.



Buehler Education Schedule.



Buehler Tech-Note, Volume 3 Issue 8, Specimen Preparation of Bones, Tissues and Other Similar Materials.

For additional selections of specimen holders, consumables and other accessories, refer to the Buehler Equipment Buyers Guide or Consumables Buyers Guide, or contact your local Buehler Sales Engineer. Buehler continuously makes product improvements; therefore, technical specifications are subject to change without notice.

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