University of Michigan Health System

Fact Finding: Ongoing Safety Review of Arthroscopic Shavers and Suction Tips

University of Michigan

Jahan Azizi, Clinical Engineer Risk Management Consultant

University of Michigan Health System

Arthroscopic Shaver

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Ongoing Safety Review of Arthroscopic Shavers

The FDA has become aware of events in which tissue has remained within certain arthroscopic shavers, even after the cleaning process was believed to have been completed according to the manufacturer's instructions.

Reports submitted to the FDA suggested that the tissue retained was not evident to the naked eye. Multiple manufacturers of these devices recently informed their customers of this situation and reiterated the importance of proper cleaning procedures.

Examples (include but not limited to)

- **Bioburden**:
  - Blood, Bone, Tissue

  ANSI/AAMI/ISO TIR11139:2006 as "population of viable microorganisms on or in product and/or sterile barrier system".
- **Foreign Bodies (debris)**:
  - Bone cement, artificial nails, Gelfoam™ and like products, ink pens/pencils, insects, Ioban ™, jewelry, knife blades, coins, rust, suture, unidentified material, bone wax

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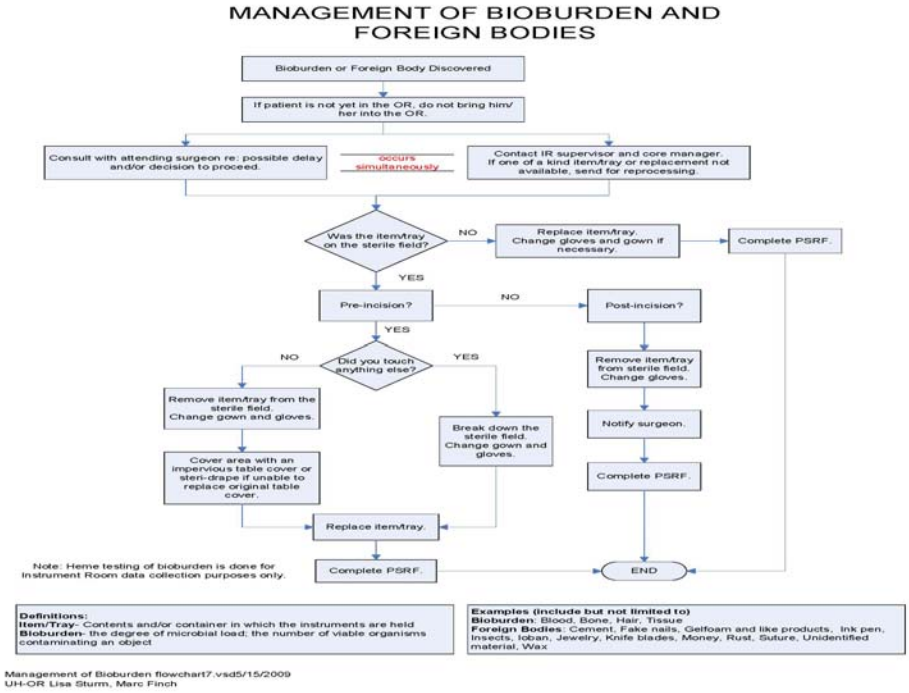

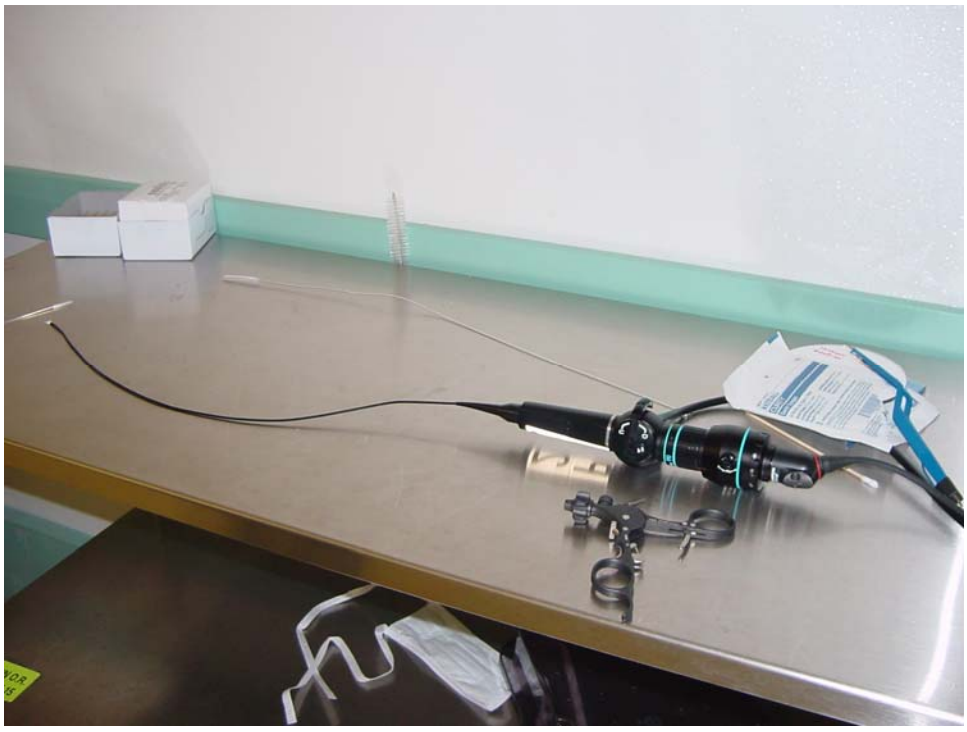

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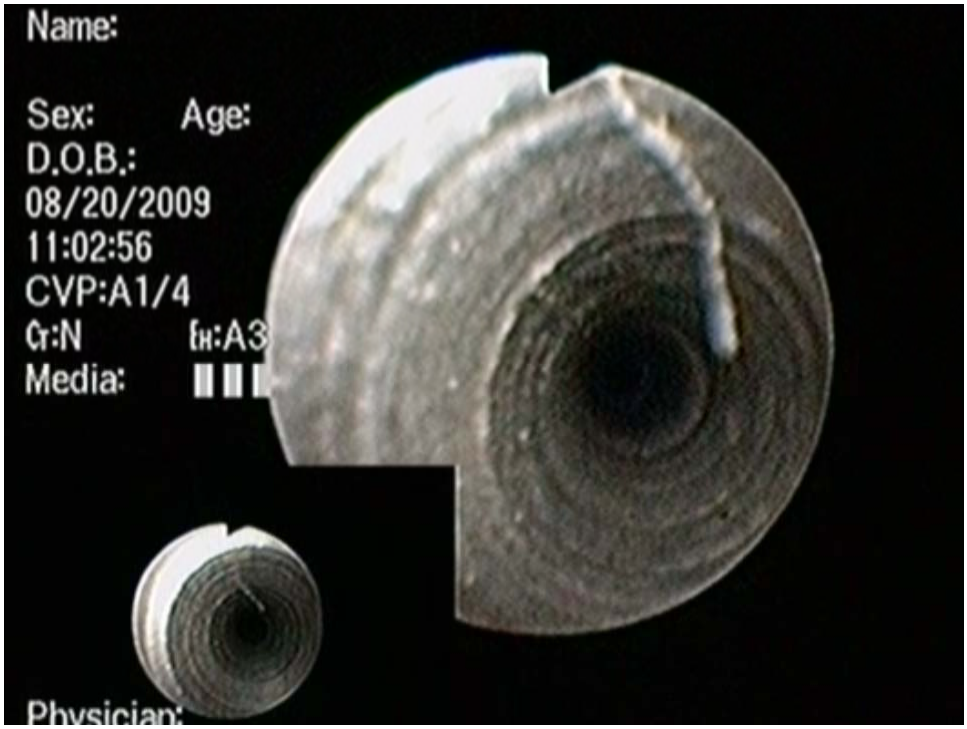

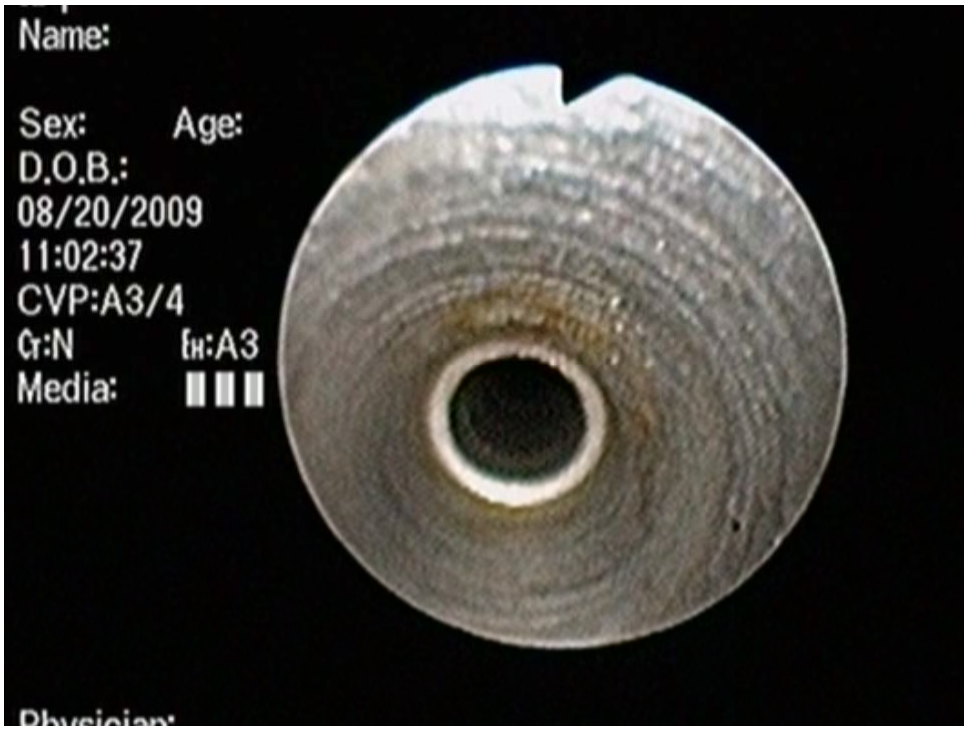

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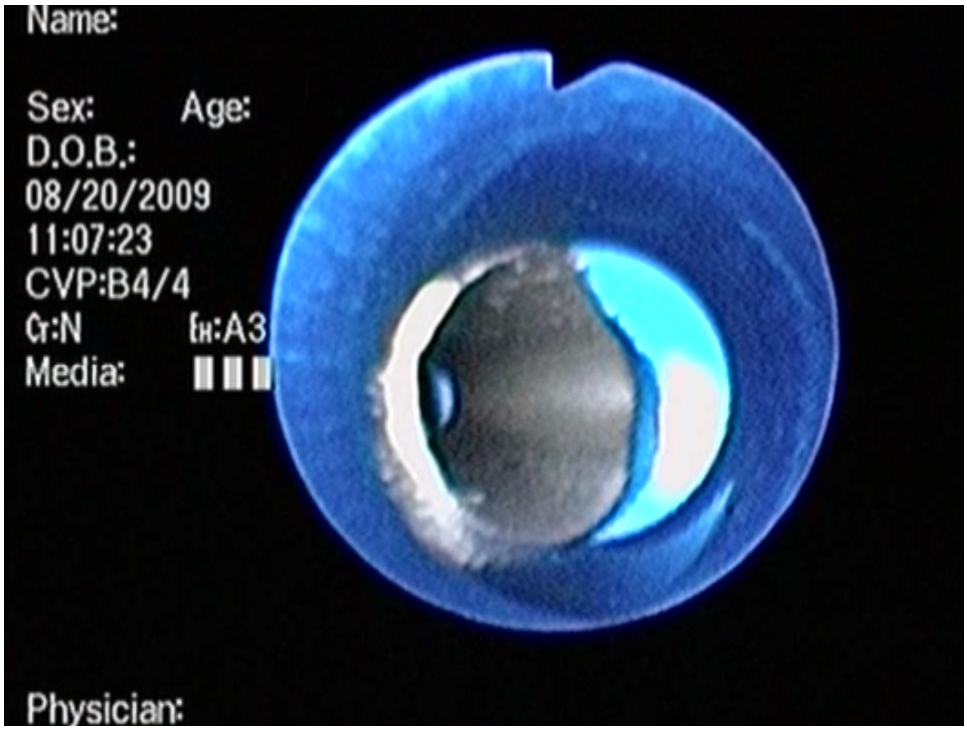

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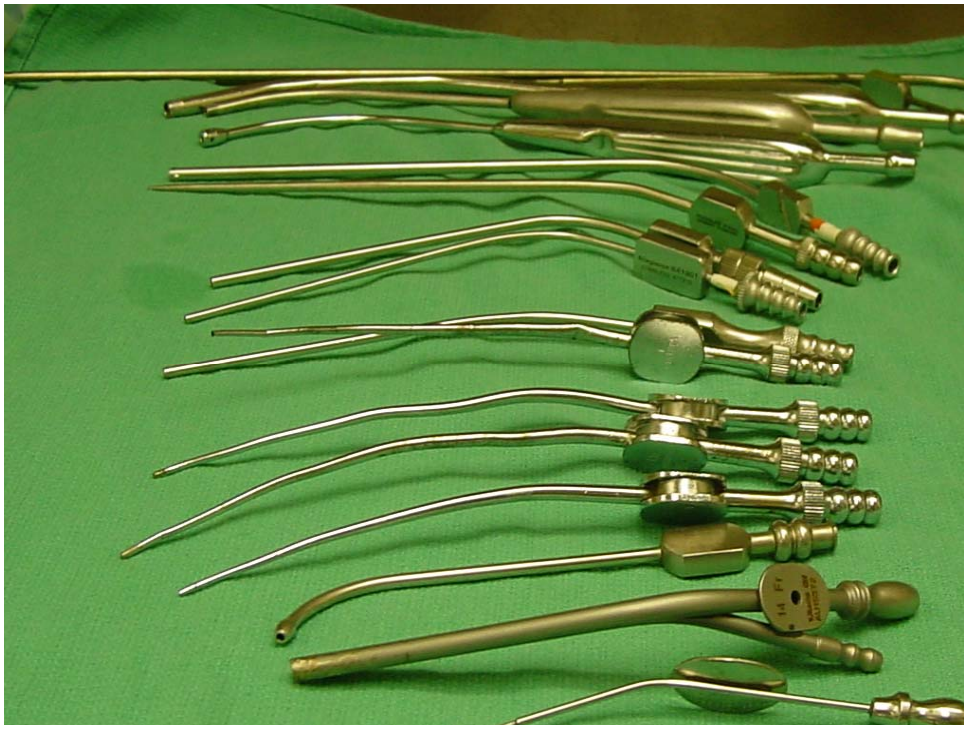

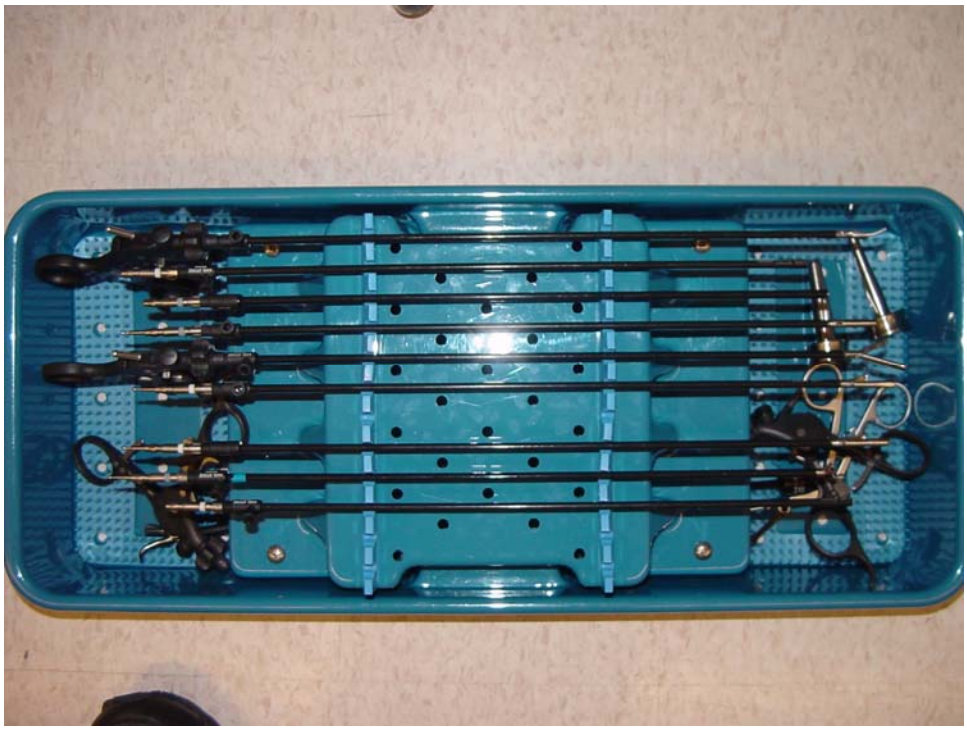

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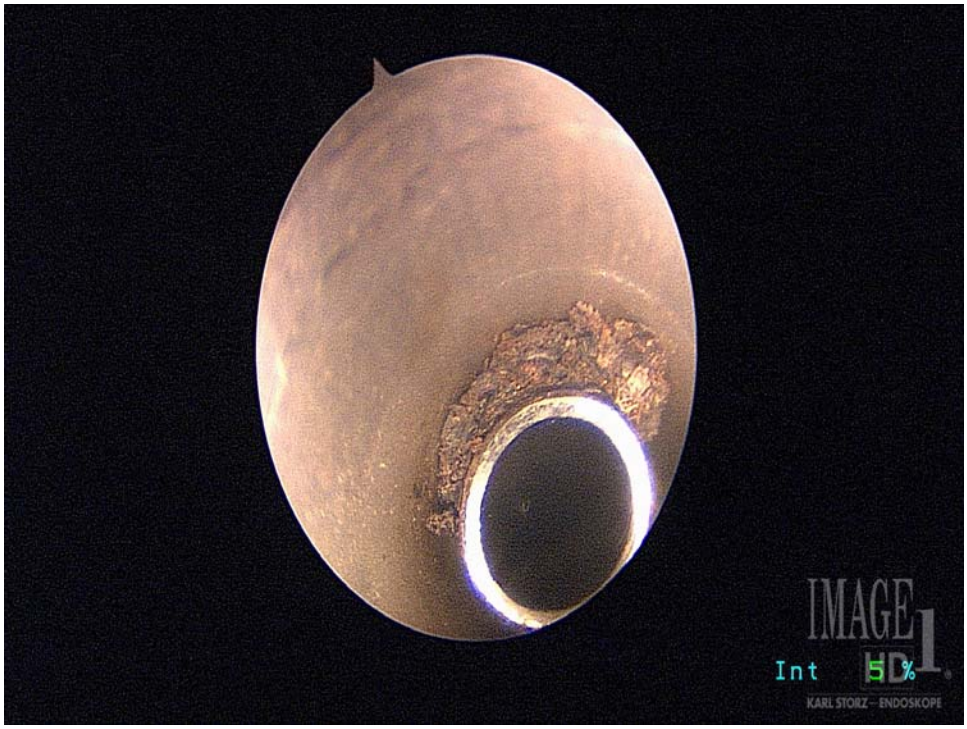

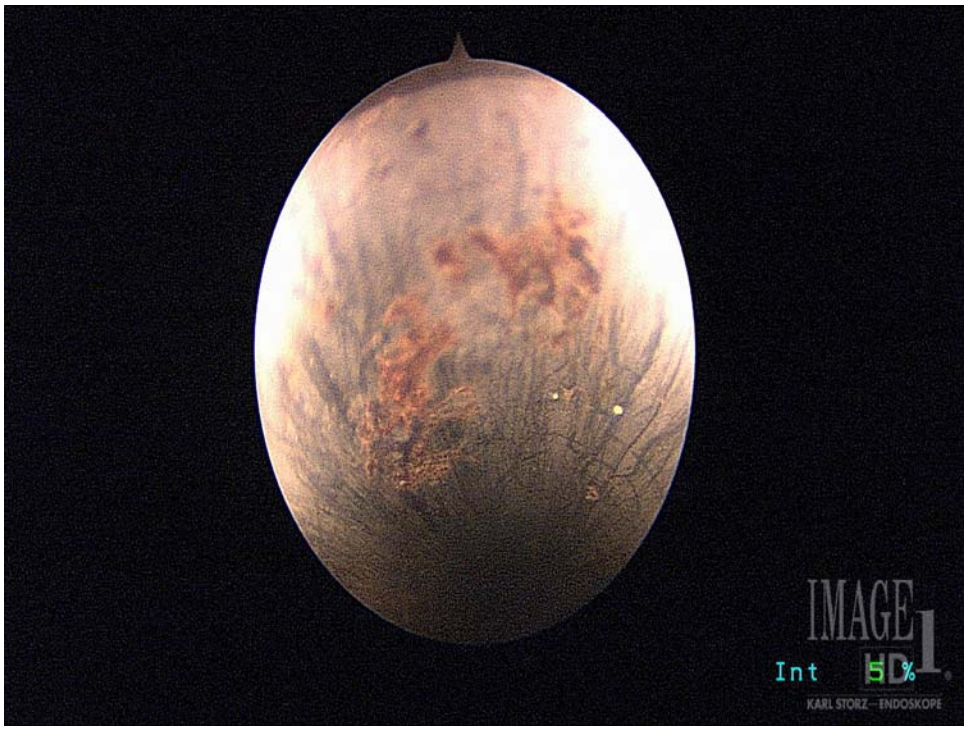

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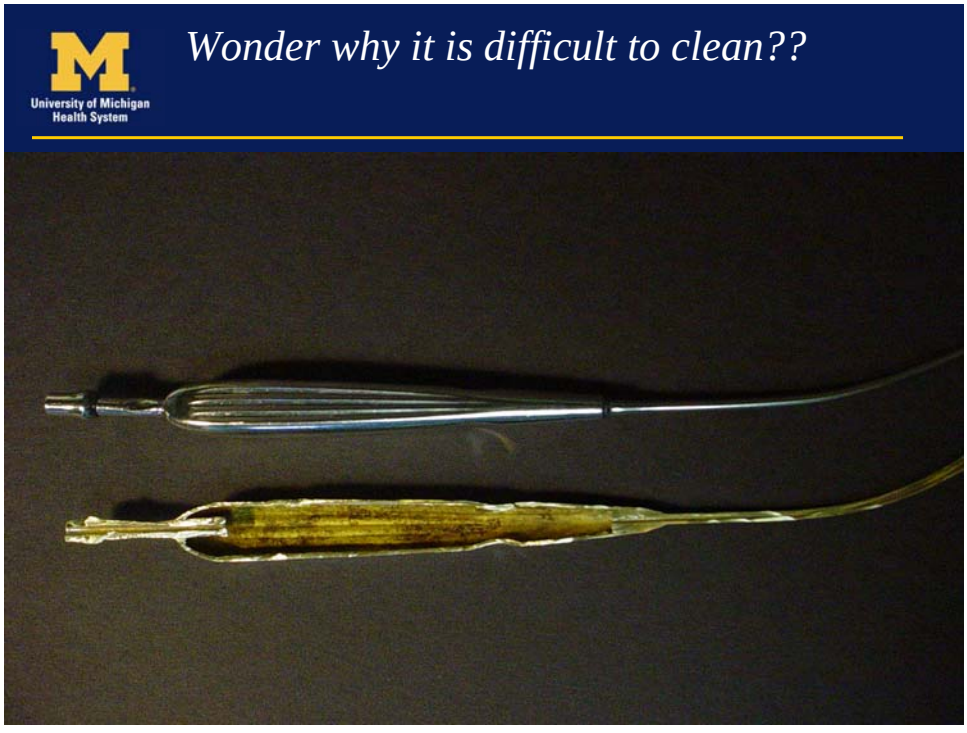

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Problematic Instrumentation

- Septorrhinoplasty set due to all the cannulas
- Coronary suctions due to the strange shape of the cannula
- All Ear trays, suctions and the very fine delicate instrments.
- Gastroscopes, Bronchoscopes, etc...
- Defribrillator. Paddles
- Lenses
- Trivex System
- Drills & saws
- Gamma nail sets
- Extract All set
- Kerrison Rongeurs
- Spring loaded drill guides
- flexible scopes
- Bipolar forceps with delicate tips
- Tympanomastoid set
- Kerrisons
- Orthopedic reamers

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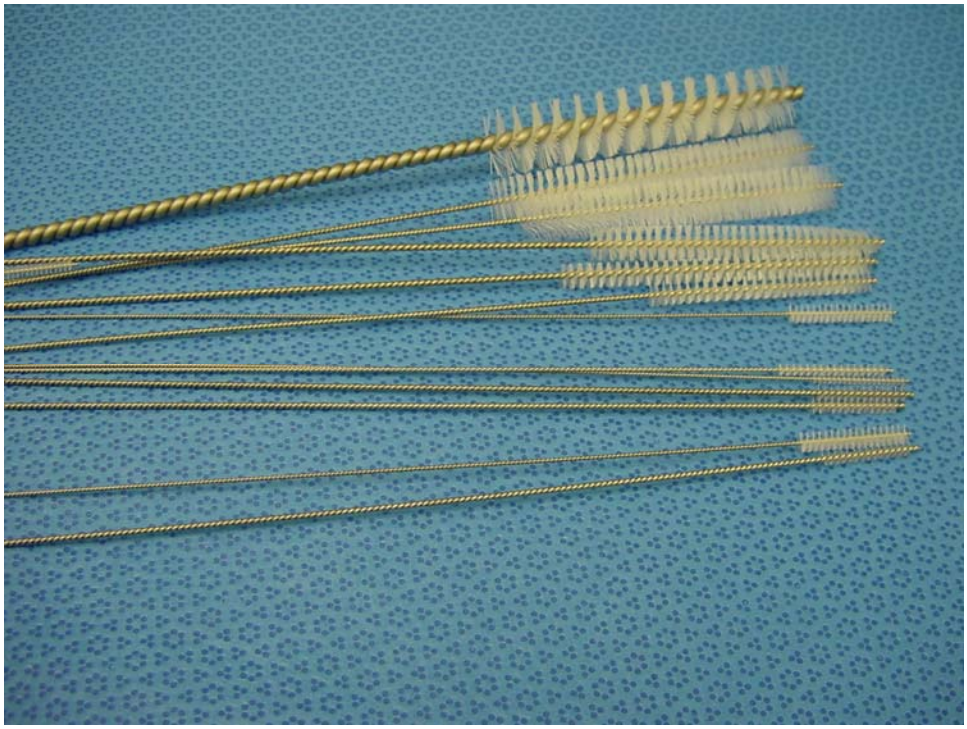

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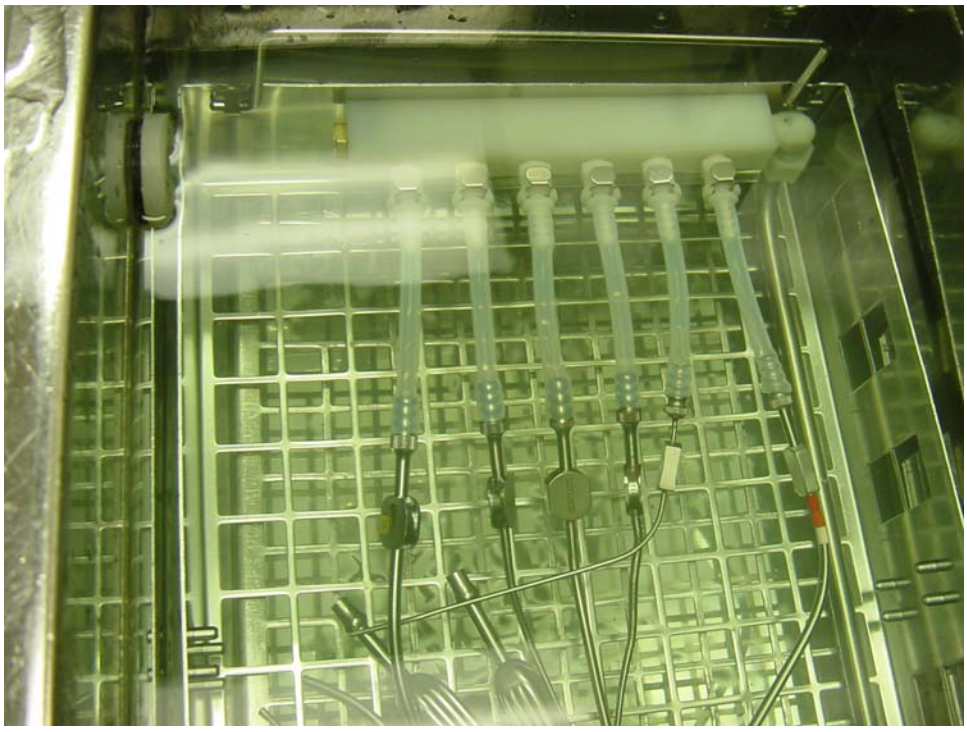

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Next Step

- The Tempest™ Surgical Instrument Washer is a fully automated, single operator cleaning system designed for the Central Processing Department of Hospitals.
- Industrial strength design
- A proven cleaning process developed from more than 30 years experience as a leader in the automotive and aerospace industries, the Tempest™ brings more horsepower to cleaning all surgical devices than any other system previously available to the market.

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Tempest Surgical Device Washer

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Developed for Automotive and Aerospace Industries.

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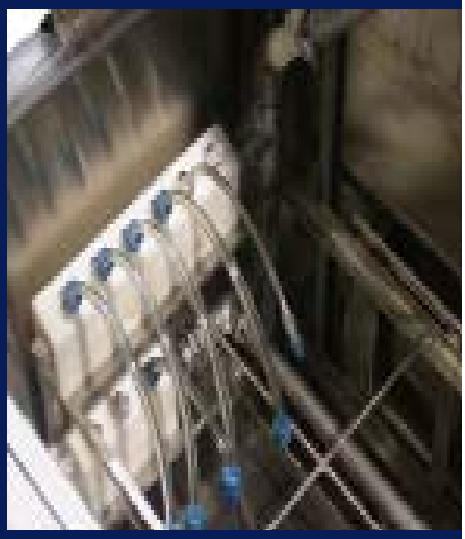
- High fluidheat agitated submersion
- Low flow, high pressure fluid stream
- Varying frequencies from digital ultrasonics



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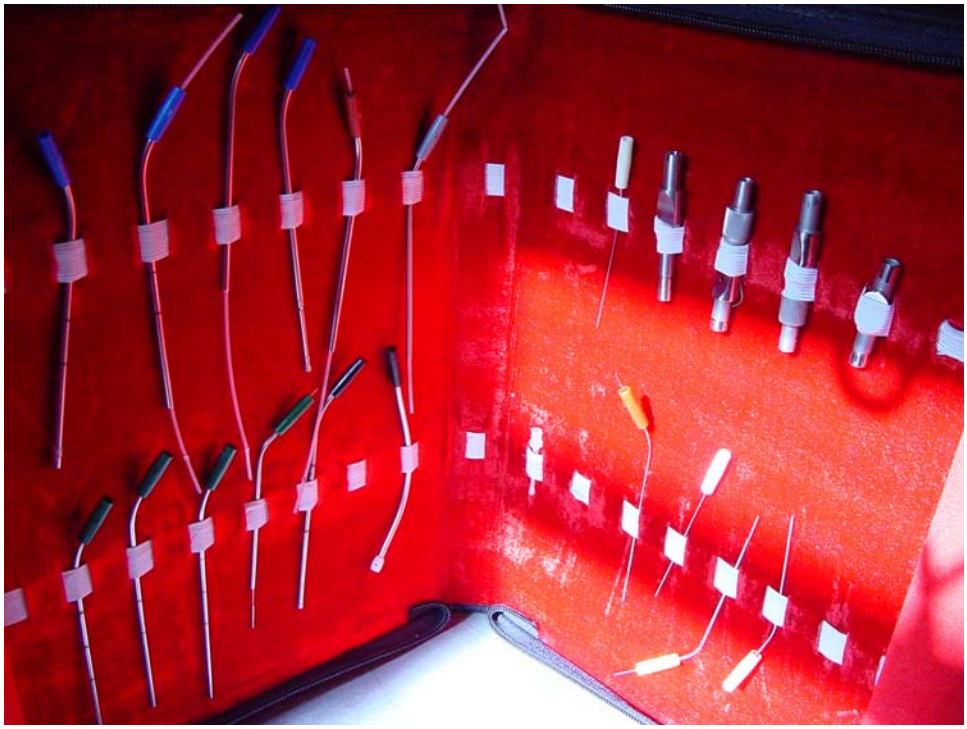

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Questions?

Jahan Azizi: azizi@umich.edu

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