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

University of Michigan

Jahan Azizi, Clinical Engineer Risk Management Consultant

Arthroscopic Shaver
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
MANAGEMENT OF BIOCUMBER AND FOREIGN BODIES

- Bioburden or Foreign Body Discovered
- Assessment is not yet in the OQ, do not bring harm to patient. Call

Consult with assisting surgeon on possible delay prior to decision be made.

Was the identification of the object correct?

NO

Yes

Pre-insertion?

NO

Yes

Inlaid the object?

NO

Yes

Replace Bioburden with an object of the same size. Change gown and gloves.

Complete PIRS.

END

Remove burden from the patient. Change gown and gloves.

Complete PIRS.

END

End point here. Do not touch object.

Break open the sterile field Change gown and gloves.

END

Note: Handling of Bioburden is done for instrument room data collection purposes only.

Definitions:
- Bioburden: A substance or container in which the instruments are held.
- Microbiologically, the number of viable organisms contaminating an object.

Examples: Bioburden but not isolated are:
- Blood, tissue, fluid, secretions, microorganisms and/or products, i.e., pus, tissue, blood, sputum, semen, urine, sweat, body fluids. Identify object, label.

Management of Bioburden: References: United States, Mexico, Canada, United Kingdom.
Workshop on Medical Device Cleanliness: How Clean is Clean Enough?
Sponsored by ASTM Committee F04 on Medical and Surgical Materials and Devices

Name:

Sex:   Age:
D.O.B.: 08/20/2009
11:02:56
CVP:A1/4
Q:N     I:N:A3
Media: 

Physician:

Name:

Sex:   Age:
D.O.B.: 08/20/2009
11:02:37
CVP:A3/4
Q:N     I:N:A3
Media: 

Physician:
Wonder why it is difficult to clean??

University of Michigan Health System
## Problematic Instrumentation

<table>
<thead>
<tr>
<th>Septorrhinoplasty set due to all the cannulas</th>
<th>Drills &amp; saws</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary suctions due to the strange shape of the cannula</td>
<td>Gamma nail sets</td>
</tr>
<tr>
<td>All Ear trays, suctions and the very fine delicate instruments.</td>
<td>Extract All set</td>
</tr>
<tr>
<td>Gastroscopes, Bronchoscopes, etc...</td>
<td>Kerrison Rongeurs</td>
</tr>
<tr>
<td>Defribrillator. Paddles</td>
<td>Spring loaded drill guides</td>
</tr>
<tr>
<td>Lenses</td>
<td>flexible scopes</td>
</tr>
<tr>
<td>Trivex System</td>
<td>Bipolar forceps with delicate tips</td>
</tr>
<tr>
<td></td>
<td>Tympanomastoid set</td>
</tr>
<tr>
<td></td>
<td>Kerrisons</td>
</tr>
<tr>
<td></td>
<td>Orthopedic reamers</td>
</tr>
</tbody>
</table>
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.
Tempest Surgical Device Washer

Developed for Automotive and Aerospace Industries.

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

Jahan Azizi: azizi@umich.edu