

Policy on Use of Glass (Hot) Bead Sterilizers and 'Tips Only' Technique

The policy below describes the use of glass bead ('hot bead') sterilizers and tips only technique in rodent and avian survival surgery. Glass bead sterilizers may not be used as a primary method of instrument sterilization for survival surgery; instruments used for survival surgery must be sterilized using another method before use of a hot bead sterilizer in a survival surgery session.*

CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (updated 2024) states, regarding the use of glass bead sterilizer units: "the FDA believes there is a risk of infection with this device because of potential failure to sterilize dental instruments and their use should be discontinued until the device has received FDA clearance." While units that have submitted premarket approval information to FDA continue to be manufactured and used, there is conflicting data regarding their effectiveness for true sterilization. This is due, in large part, to variable temperature within the well of glass beads.

Therefore, glass (hot) bead sterilizers may be used to re-sterilize instrument tips for batch** rodent and avian survival surgical procedures but are not acceptable as a primary method of sterilization. Glass bead sterilizers may also be used for survival surgeries that involve inadvertent or minor contamination but must not be used for batch surgeries involving gross contamination (e.g. gastrointestinal surgery). For the primary sterilization, all instruments must be sterilized by autoclaving, chemical or gas sterilization. Glass bead sterilizers may be used between animals when one set of primary sterilized instruments is used on a group of up to 5 animals, provided the instruments are cleaned thoroughly of debris prior to insertion in the glass bead well, and the instrument tips have not penetrated any possible contaminated organ (e.g. gastrointestinal tract).

Approval for the use of glass bead sterilization must be secured and the approved procedure must be described in full detail in the approved Animal Use Protocol and must describe use of tips only technique.

The general instructions below notwithstanding, each glass bead sterilizer must be used in accordance with the specific manufacturer's recommendations. This includes cleaning and/or replacement of the glass beads.

Glass bead sterilizer general instructions:

- Remove cover (if any) from well. Ensure that the glass beads level is within 2 mm of the top of the well.
- Turn on the unit and allow adequate time for the beads to heat (15-30 minutes, depending on the unit).
- Remove all debris from instruments prior to inserting into the glass beads. Care should be taken to remove debris from the grooves of forceps, the box locks of needle holders and the hinge area of scissors. Wipe or rinse instruments with alcohol and allow to air dry before insertion.
- Insert tips at least ½" below the surface of the beads.
- Allow contact time between 30-60 seconds. Larger instruments require more time to achieve sterilization (2-3 minutes). Note that longer contact times may damage instruments.
- Do not place more than 3-4 instruments in the well at a time. Do not overload well with instruments. Proper decontamination cannot be assured if the glass bead well is overloaded.
- Instrument tips become extremely hot and must be cooled before use. This will require a minimum of 15 seconds (possibly as long as 1 minute) before the instrument can be used.
- Before using instruments, check that no glass beads are adhered to their surface.

Notes:

- 1. If the instrument tips become contaminated by contact with a non-sterile surface or non-sterile portions of the body, the tips must be rinsed with alcohol and resterilized in the glass bead sterilizer.
- 2. If an instrument's tips become contaminated with the contents of the gastrointestinal tract, a new sterile (primary sterilization as described above) set of instruments must be used for subsequent surgeries.
- 3. Do not heat hollow instruments in a glass bead sterilizer. The inner surface will not be in contact with the heated beads and will not be properly decontaminated. In addition, high heat may cause such instruments to explode.
- 4. Glass beads must be cleaned and/or replaced in accordance with the manufacturer's recommendations.
- 5. All glass bead sterilizers must be checked semiannually to ensure that the equipment reaches the manufacturer's certified temperature range. The date a unit is checked should be kept either in a log available for review by the ACUC or on a label affixed to the unit.

Tips Only Technique

• A "tips-only" technique restricts the surgeon to using only the sterile working ends of the surgical instruments to manipulate the surgical field.

- The surgeon's non-sterile gloved hands and non-sterile sections of instruments must never touch the working end of the instruments, the suture, suture needle, wound clips, or any part of the aseptic surgical field.
- If the surgeon lays an instrument down, the sterile tips must only be placed on a sterile surface. The instrument handle must not come in contact with the sterile surface to avoid contamination of that surface.
- If the tip of a surgical instrument becomes contaminated (with the exception of entering the gastrointestinal tract), the tips may be re-sterilized by rinsing away blood or tissue using alcohol or sterile water and placing the tips in a hot bead sterilizer.

Any deviation from the above must be approved in advance by the ACUC; such approvals require scientific justification. The approved deviation must be described in the approved Animal Use Protocol.

*A survival surgery session includes only those survival surgeries performed on the same day. Non-survival and survival surgeries may not use the same instruments without undergoing a primary (non-hot bead sterilizer) method of sterilization before use in a survival surgery.

** Batch survival surgeries = consecutive surgeries on up to 5 adult animals of the same rodent or avian species performed in a single surgical session.

References

CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008; Update: May 2019 (accessed November 23, 2022)

Engelhardt JP, Grun L, Dahl HJ. Factors affecting sterilization in glass bead sterilizers. J Endod. 1984 Oct;10(10):465-70. doi: 10.1016/s0099-2399(84)80202-2. PMID: 6593409.

Federal Register Volume 62, Number 13 (Tuesday, January 21, 1997, Final Rule, Dental Devices; Endodontic Dry Heat Sterilizer (accessed November 23, 2022).

Holdridge JA, Nichols MS, Dupont WD, Jones CP, Shuster KA. The Effectiveness of Hot Bead Sterilization in Maintaining Sterile Surgical Instrument Tips across Sequential Mouse Surgeries. J Am Assoc Lab Anim Sci. 2021 Nov 1;60(6):700-708. doi: 10.30802/AALAS-JAALAS-21-000047. Epub 2021 Nov 8. PMID: 34749843; PMCID: PMC8628527.

Hoogstraten-Miller SL, Brown PA. Techniques in aseptic rodent surgery. Curr Protoc Immunol. 2008 Aug; Chapter 1: Unit 1.12.1-1.12-14. doi: 10.1002/0471142735.im0112s82. PMID: 18729061; PMCID: PMC2587003.

Sheth NC, Rathod YV, Shenoi PR, et al. Evaluation of new technique of sterilization using biological indicator. Journal of Conservative Dentistry: JCD. 2017 Sep-Oct;20(5):346-350. DOI: 10.4103/jcd.jcd_253_16. PMID: 29386784; PMCID: PMC5767831.

Skiles B, Johnston NA, Hendrix GK, Hickman DL. Effectiveness of the Glass Bead Sterilizer for Sterilizing Surgical Instruments. J Am Assoc Lab Anim Sci. 2022 May

1;61(3):252-255. doi: 10.30802/AALAS-JAALAS-21-000053. Epub 2022 Mar 21. PMID: 35314021; PMCID: PMC9137293.

Subbiah, Subba Rao C V, Balaji R G. Effect of disinfectants and glass bead size on efficacy of glass bead sterlizer. J Conserv Dent 2005;8:23-31

University of South Florida Standard Operating Procedure, GerminatorTM 500 Glass Bead Dry Sterilizer. (retrieved November 7, 2019)

Revision History

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