Frequently Asked Questions:

ASP STERRAD® CYCLESURE® 24 Biological Indicator (BI) (P/N 14324) Recall

1. **What is the STERRAD® CYCLESURE® 24 Biological Indicator (BI)? How is it used?**
   The STERRAD® CYCLESURE® 24 BI is used to provide evidence that proper sterilization conditions have been achieved in just 24 hours.

2. **Why did ASP initiate a voluntary recall for certain lots of STERRAD® CYCLESURE® 24 BI?**
   ASP recently determined that it does not have adequate data to support the entire duration of the product's labeled shelf-life. As a result, ASP has issued a global product recall to revise the expiration dates of STERRAD® CYCLESURE® 24 BI effective July 3, 2012.

3. **Is there a health and safety risk to patients?**
   Use of expired product may result in not being able to verify proper sterilization conditions. While the number of individual patients at risk for exposure to infections may be high, the risk of a life-threatening infection to an individual patient is very low, given that this biological indicator is only one of three sterilization system monitors and the window of possible exposure to the malfunctioning STERRAD® CYCLESURE® 24 BI is relatively short.

4. **Should I inform patients that were treated with an improperly sterilized medical device?**
   FDA has recommended that healthcare facilities follow their procedures. Also, a recent FDA Safety Communication stated that while the number of individual patients at risk for exposure to infections may be high, the risk of a life-threatening infection for an individual patient is very low, given that the STERRAD® CYCLESURE® 24 BI is only one of three sterilization system monitors part of STERRAD® Systems, and the window of possible exposure to malfunctioning product is relatively short.

5. **Where can I find the FDA Safety Communication?**
   The FDA Safety Communication, posted on July 3, 2012, can be accessed here: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm310549.htm.

6. **Should my healthcare facility re-sterilize medical devices that were sterilized with an expired STERRAD® CYCLESURE® 24 BI?**
   Yes. ASP is recommending that these devices be re-sterilized.

7. **What do I need to do now?**
   ASP is asking customers to take inventory of their STERRAD® CYCLESURE® 24 BI supply and review each case against the revised shelf-life for the product pursuant to the instructions set forth in the "What Action Is Required" section of the Customer Letter (CL107822_A). Customers should discontinue the use of product from certain lots of STERRAD® CYCLESURE® 24 BIs that exceed the newly determined expiration date and return it according to instructions in the customer letter for replacement product.

8. **What if I have a lot number that is not listed on the customer letter?**
   The recall of STERRAD® CYCLESURE® 24 BI affects only certain lots of product that were shipped beginning December 2011. Affected lots of STERRAD® CYCLESURE® 24 Biological Indicator (P/N

14324) product, which are also components of STERRAD® Test Packs (P/Ns 20123, 14325, 20239 and 20103), are listed on the customer letter that can be found on www.aspjj.com. If your lot number does not appear on the list provided with the customer letter, you may proceed to use the STERRAD® CYCLESURE® 24 Biological Indicator (P/N 14324) product in accordance with the provided instructions for use (IFU).

9. **How should I re-label the product with the newly calculated expiration date?**
   Please follow the instructions as set forth in the "What Action Is Required" section of the Customer Letter (CL-107822_A). ASP recommends that your facility manually re-label the non-expired product boxes with the newly calculated expiration date so that your inventory is correctly labeled for your use. Note, manually re-label the non-expired product boxes.

10. **I receive my product from a distributor or other third-party. Will they be responsible for manually re-labeling the product with the newly calculated expiration date?**
    ASP does not sell STERRAD® CYCLESURE® 24 Biological Indicator through distribution channels. Individual hospitals should follow the directions indicated in the "What Action Is Required" section of the Customer Letter (CL107822_A):
    - Provide the notice to anyone in their facility that needs to be informed
    - Maintain a copy of this notice with the affected product
    - If any of the STERRAD® CYCLESURE® 24 Biological Indicator (BI) product has been forwarded to another facility, contact that facility and arrange return
    - Maintain awareness of this notice until expired product listed above has been returned

11. **Will I receive replacement product?**
    Yes. Please follow the "Product Return Instructions" in the Customer Letter (CL107822_A) to receive replacement product.

12. **How will I be able to identify product with correctly-labeled expiration date?**
    Product with the correctly-labeled expiration date will be available beginning July 9, 2012 and will have an eight (8) character lot number, compared to the six (6) character lot number on current product. For example, product with the correctly-labeled expiration date will have a lot number containing eight (8) characters, e.g. 123456EE.

13. **Will the change to a lot number containing eight (8) characters be permanent?**
    Yes.

14. **What if I have limited inventory?**
    In extreme circumstances where you have limited supply, you have the option to take steps to help prevent depletion of your supply of STERRAD® CYCLESURE® 24 BIs:
    - Shift the per cycle use of STERRAD® CYCLESURE® 24 BIs to daily per cycle usage
    - Maximize loads, within the appropriate cycle claims, of devices processed in each STERRAD® System
    - Reduce the facilities' utilization of multiple STERRAD® Systems to using only one system per day

15. **What products does this recall affect?**
    - STERRAD® CYCLESURE® 24 BI (P/N 14324): Please see Addendum 1 to Customer Letter (CL-107822_A) for the list of lot numbers affected by this product recall.

    Be advised that STERRAD® CYCLESURE® 24 BI is a component of the kits listed below and are individually labeled:

    - STERRAD® CYCLESURE® 24 Test Pack (P/Ns 20123, 14325, 20239 and 20103)

16. **Will the recall impact new installations of STERRAD® Systems?**
    Once STERRAD® CYCLESURE® 24 BI product with labeling that indicates the new shelf-life becomes available on July 9, 2012, regular installations will resume on a limited basis.

17. **Is there an approved alternative to STERRAD® CYCLESURE® 24 BIs?**
    No. Only STERRAD® CYCLESURE® 24 BIs are validated by ASP for use in STERRAD® Systems in the United States.

18. **What if I run out of my STERRAD® CYCLESURE® 24 BI supply?**
    If you are out of stock or within 72 hours of depleting your supply, you can place an emergency order. In extreme situations where there could be patient safety implications, a very short-term recommendation can be to migrate sterilization to alternative methods in accordance with instrument IFUs.