FDA MISSION OF MERCY
A PROGRAM OF THE FLORIDA DENTAL ASSOCIATION

Sterilization Department Set Up and Protocol

ADCF employs 16 uniquely identified MIDMARK M-ll Ultraclave gravity displacement steam sterilizers in support of each free dental clinic.

Sterilizers are to be placed as directed by ADCF personnel and according to MIDMARK location requirements. Environmental requirements as identified by MIDMARK are also considered i.e. ambient temperature and area relative cleanliness. Once connected and running, the sterilizers cannot be turned off for the duration of the clinic including in evening and non-clinic hours. All Sterilizers must be grouped together and may not be placed in any location outside of the sterilization area. ADCF instruments may only be sterilized in ADCF MIDMARK M-11 sterilizers. No sterilization activity including scrubbing instruments, placing sterilizers in locations outside of the sterilization area or other such activities are permitted.

Electrical supply shall be reviewed with ADCF staff prior to powering up sterilizer units.

Sterilizers are then loaded with instruments and a test spore vial identified for the appropriate sterilizer. ADCF staff will test all sterilizers. Clinic volunteers will not be permitted to do so.

Test spore vials (Biological Indicators) are manufactured by 3M ESPE. #1261 is a 24 hour test vial, #1262 is a 48 hour test vial. While ADCF provides the #1262 vials, either is sufficient to prove sterilizer performance.

Once the testing cycle is completed, the vials are placed in incubators along with a control vial. The control vial will turn yellow indicating the presence of bacteria. The other individually marked vials will turn purple indicating that no bacteria is present in the vial and proving the operability of the specific sterilizers being tested.

ADCF's experience with over 1000 incubator tests is that the vials begin turning purple after 4 hours, indicating the absence of bacteria in the vial. The vials are read at 12 hours by ADCF staff to verify operability, read again at 18 hours and again at 24 hours for the #1261 vials. Using the #1262 the incubators will continue to be run for the entire 48 hours. Data from each of these tests are to be recorded in the Biological Monitoring Record which is included on each ADCF truck.

Once a vial indicates the lack of bacteria by turning purple, sterilizer operability has been validated. Although the vial is referred to as a 24 or 48 hour test vial, the vial actually turns either purple of yellow within 12 hours. ADCF has verified with 3M (test manufacturer) that the

presence or lack of bacteria can be verified before 24 hours with either vial. If a specific vial should turn yellow, a second test will be performed on that sterilizer to verify that human error was not a factor. If a second test is failed, that sterilizer will be pulled from service for that event and declared inoperable.

Sterilizers are to be used in **Pouches Mode** as recommended by MIDMARK for ADCF applications. In this mode, the sterilizer runs at 270 degrees F. for 5 minutes followed by a 30 minute drying time. Due to the extremely large number of instruments required to be repetitively sterilized at an event (over 5000), ADCF recommends letting the instruments cool for roughly 10 minutes. This allows both sterilizers and instruments to cool slightly before the next cycle is run. Instruments in paper sterilization pouches should be run to completion including the full drying cycle. Failure to do this can result in the paper bag tearing resulting in re-sterilization of the instruments. Paper pouches containing personal instruments shall be labeled with the Doctor's name. Appropriate writing utensils will be provided by ADCF.

In order to satisfy concerns with wicking, the process whereby air born particulates penetrate porous materials or wet paper pouches, ADCF uses all nylon pouches which are impervious to contamination from air born particulates. ADCF provides nylon pouches donated by Henry Schein Cares. Approximately 12,000 are used at each 100 operatory clinic. ADCF will also supply internal indicators that are to be placed in each bag. ADCF instruments are only to be sterilized using these nylon pouches.

Sterilizers are to be loaded, operated and unloaded in accordance with manufacturer's guidelines.

States should be aware of the Single Use Guidelines. If an item is marketed as single use it shall not be sterilized and reused. These items are usually confined to burs and endo files but when securing supply donations or purchases you should make sure of the product you are getting. The process of reusing an item that is labeled single use is against the law.

ADCF utilizes Zirc cassettes for standard instrument sets- PURPLE for dental hygiene, GREEN for restorative or general dentistry and BLUE for oral surgery. These as well as all other specialized instruments provided by ADCF come to the event pre-sterilized and ready for use.

Sterilization volunteers must inspect pouched instruments after set up to find punctured or unsealed pouches. Any compromised pouches must be re-sterilized.

Sterilization Set Up

The best set up for the sterilization area is to have an inner ring of tables with the 2 power stations inside the ring. Plywood is provided to place on top of the tables which hold the sterilizers. Areas must be set up to receive ADCF dirty instruments, personal dirty instruments,

handpiece station, clean ADCF instruments, clean personal instruments, sinks and ultrasonic cleaners. Please see attached diagram for more clarification.

All sterilization volunteers must wear appropriate PPE and must have a Hepatitis B vaccination.

No open toe shoes are allowed in the sterilization area. Gloves must be worn by all volunteers who touch dirty instruments and volunteers handling any contaminated instruments must wear heavy duty utility gloves.

Instruments are all banded to identify each type of instrument. Clean, pouched instruments are placed in bins which are labeled with the instrument name along with an identifying picture. Personal instruments should be kept separate from ADCF instruments so that personal instruments do not get put into ADCF bins.

Some volunteers should be designated as dirty instrument volunteers. These volunteers may, clean instruments, sort dirty instruments, check cassettes and bag dirty instruments. These volunteers may also place trays of dirty, bagged instruments into the sterilizers. Clean volunteers should start the sterilizers, remove clean instruments from sterilizers, and sort the instruments into the appropriate bins.

Steps for processing instruments:

1. Instruments are dropped off on at the designated “dirty” or “used” location. Instruments will then be briefly inspected to make sure there are no foreign objects i.e. teeth, sharps, gauze, cotton rolls or any other items that are not an instrument.
2. Instruments will then go into the ultra-sonic cleaners for the designated amount of time.
3. Upon completion of the ultra-sonic cycle, instruments are then transferred to the sinks for rinsing. At this time instruments will again be inspected and any stubborn blood or saliva can be lightly scrubbed and removed. Instruments should not be scrubbed with disinfecting wipes or gauze pads.
4. After rinsing, instruments are transferred to an area where they can be sorted and dried. This area will also be where instruments are bagged.
5. Instruments should be bagged individually unless they are in a cassette or they are a doctor’s personal instruments. An internal indicator strip will also be placed in each bag at this time. Instruments with a hinge should be placed in the sterilization bag with the hinge open. When bagging instruments, you should be aware of the proper manufacturer’s instructions which states that bags should be folded and sealed at the appropriate point. Bags folded in half are not considered by the manufacturer to be sterile. Check for a perforated line or a simple dotted line. This is where the bags are intended to be folded over and sealed.
6. After instruments are bagged appropriately and placed on trays they can be transferred to a sterilizer. All instruments will be run on the Pouches cycle. Please note it is very important that the trays are not overloaded trays with instruments. This may cause bags to stick together, cassettes to melt and/or over heating of the sterilizer. If you experience any of these upon the completion of the sterilization cycle please make note and correct those that may be overloading. If the sterilizer over heats, the cycle will not complete.

Instruments should be moved to another sterilizer and the overheated unit shall not be used until ADCF staff has had a chance to examine it.

7. Upon completion of the sterilization cycle, doors to the units will automatically open. Although we do not recommend the full dry cycle, it is recommended that instruments be allowed to dry for a short time before removing them from the sterilizers. This allows the instruments to cool slightly and it also allows the sterilizer to cool. With the frequency of use, if not allowed to cool down slightly between each load the sterilizer may over heat. Instruments and trays will be hot when removed so appropriate heat protection (pot holder) should be used. Any instruments that are sterilized in a half paper, half nylon bag should be allowed to dry for the full drying cycle. If manufacturer's directions are followed and a full drying cycle is not completed, the bags run the risk of tearing due to moisture and you will have to re-sterilize. Half paper/half nylon pouches should only be used for personal instruments.
8. Instruments are then transferred to an area designated as "clean" where they can be examined for tears or gaps in the seal one last time. Bags should be checked to determine that the bags are free of tears and instruments should be checked to ensure no debris is present. At this point instruments will be sorted and placed in their corresponding bins to be re-circulated back into the clinic for use.
9. Handpieces - When a handpiece is returned for processing it is to be wiped with alcohol to remove any debris. Disinfecting wipes are not to be used to wipe handpieces. Handpieces should not go through the ultra-sonic cleaner or be rinsed under water. They are then lubricated and bagged for sterilization. Handpieces can be processed with the other instruments and steps 5-8 apply when processing hand pieces.
10. If instruments are returned unused and still in their all nylon packaging, they shall be inspected for tears. If the sterilization bag has not been compromised the bag shall be wiped with the appropriate disinfecting wipe and then returned to its bin for redistribution. If the bag is partially made of paper the instrument must be re-bagged and re-sterilized.