Example Policy of the Humipak to Keep Instruments/Medical Devices Moist

NOTE: This document is an example of a policy that may be instituted in a healthcare facility for the use of the Humipak to keep instruments/medical devices moist after they have been used.

Subject: Using the Humipak to keep instruments/medical devices moist after they have been used

Department: Sterile Processing/Medical Device Reprocessing/Central Processing

Approved By: [Name of Dept Supervisor/Manager]

Effective: [Enter the date when this will take effect]

Revised: July 2021

Purpose: To provide guidance in using the Humipak product to keep surgical instruments/medical devices in a moist environment after their intended use until they can begin the cleaning process on instruments/device.

Policy: To keep instruments moist until they are properly cleaned

Rationale: Dried blood poses a significant challenge to the cleaning of patient used instruments as well as being highly corrosive. Lumened instruments are particularly troublesome due to the potential of biofilm formation. Thus, it is recommended that patient used instruments be cleaned immediately following a procedure. However, this is not always possible. In these cases, the standards recommend keeping them moist until the cleaning process can begin.

Reprocessing of instruments immediately after use to prevent the drying of contamination to their surfaces would be ideal but is not always practical within a busy surgical environment, distance from in-house, and outlining clinics. Studies have indicated drying times longer than 15 minutes significantly reduce the efficacy of subsequent treatments to remove proteins, including prions. Keeping surgical instruments in a moist environment (like humidity retention bags) directly after use greatly reduces protein/amyloid attachment and improves decontamination efficacy.¹

Any department that reprocesses surgical instruments must reduce the Decontamination Holding Time (DHT). DHT is the time from when the instrument is last used to when it is received in decontamination and the cleaning process begins. This can vary in length of time (i.e., a few minutes to hours or even days).

NOTE: It is important to follow the IFU's of the specific instrument(s) contained in the Humipak for precleaning and transportation to next stage of reprocessing (e.g., instruments in the open position)

Standards and Professional Society Recommendations:

"...Prior to transport, instruments should be prepared in such a way as to prevent organic soils from drying placing a towel moistened with water (not saline) over the instrument, placing items inside a package designed to maintain humid conditions, or applying a product designed for pre-treatment. Long delays in processing can result in the formation of tenacious and difficult-to-remove biofilm that will shield microorganisms from routine cleaning procedures and possibly interfere with disinfection or sterilization. ..."²

AORN also says the following regarding endoscope transportation for reprocessing:

"IV.b. Endoscopes and accessories should be kept wet or damp but not submerged in liquid during transport: High Evidence] Keeping the endoscope and accessories wet helps dilute, soften, and ease removal of organic soils. Allowing organic material to dry on the surface and in the channels of the endoscope makes the cleaning process difficult.

Submerging the endoscope in liquid during transport may increase the risk of spillage and could lead to fluid invasion if the endoscope has an unknown leak."³

Thus, instrument manufacturers, AAMI, AORN, and others generally recommend that cleaning of instruments begin as soon as possible so that organic soils, particularly blood, do not dry. But, again, often this is not possible. One solution is to extend the holding time of soiled instruments until they can be reprocessed by placing the instruments/medical devices into a Humipak.

The Humipak has been specifically designed to keep instruments moist that are unable to be cleaned quickly. The Humipak consists of a layer of highly absorbent material sandwiched between two layers of waterproof film. To use:

- 1. Place individual instruments, or an entire instrument tray inside the Humipak
- 2. Add the specified amount of water to the absorbent layer
- 3. Seal with the peel away adhesive strip
 - a. This creates a watertight, moist atmosphere that helps prevent organics from drying over an extended period of time
 - b. The transparent film allows observation of the contents
 - c. A list of contents and instructions can be written directly onto the film.

Testing has demonstrated items will remain moist for up to five days (depending upon the type of instruments and the exact composition of the residue⁴,³). It is not recommended to keep instruments in the Humipak for that long, but they can be based on this research The preferably choice is to begin the cleaning process as soon as possible.

The Humipak is a useful product shown to work in situations where clinics (medical facilities of all types) that are miles or hours away from the centralized reprocessing department are able to keep the instruments moist until processing can occur.⁴

Thus, placing surgical instruments and other medical devices (see IFU) into the Humipak after use will keep items moist longer delaying the drying of bio-contaminants before the cleaning process commences.⁵

Procedure:

Items placed in the Humipak should be cleaned as soon as possible. When opening the Humipak, use the correct PPE. To transport the items, they must be contained in a hospital approved container like the Healthmark SSTTM.

- 1. Follow all manufacturers' IFUs on precleaning before placing any instrument in the Humipak
- 2. Pick the correct Humipak pouch size (see IFU for the various sizes) for the items that are to be kept moist until reprocessing
- 3. Add the specified amount of water per the directions found on the Humipak pouch. Water will wick into and be absorbed throughout the Humipak pouch because of the special absorbent layer between the transparent films
- 4. Place items in the pouch
- 5. Peel off protective strip from adhesive band
- 6. Fold over the adhesive strip and press down firmly from the center outwards to ensure a watertight seal
- 7. Place Humipak in a hospital approved container for transportation (e.g., Healthmark SSTTM)
- 8. Send to the appropriate area for reprocessing as soon as possible
- 9. The Humipak is NOT a sharps container and is NOT puncture proof. Be sure to follow your facility's policy for handling contaminated reusable sharps in compliance with OSHA Guidelines for transporting

<u>Responsibility</u>:

The Sterile Processing manager (or their designee) is responsible for assuring training of staff, initiation, completion, documentation, and analysis of the Humipak policy.

Sample Competency for Using the Humipak:

Name:

Competency Statement: Complies with policy and procedure of the Humipak to keep instruments/medical devices moist.

Key

1 = Performs independently and consistently. Request assistance in new situations.

2 = Performs with minimal guidance and direction. Request assistance when necessary.

3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

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Comments:

Competency Achieved: _____ Date: _____

Evaluator: _____

Learner: _____

Critical Behavior	1	2	3
Review Hospital Policy on cleaning of items along with the IFU			
of the Humipak.			
Selects and wears the proper personal protective equipment			
(PPE).			
Pick the correct size of Humipak pouch for the items that are to			
be kept moist until reprocessing.			
Add the specified amount of water per the directions found on the			
Humipak pouch. Water will wick and be absorbed throughout the			
Humipak pouch because of the special items in the pouch.			
Place items in the pouch.			
Peel off the protective strip from the adhesive band.			
Fold over the adhesive strip and press down firmly from the			
center outward to ensure a watertight seal.			
Send to the appropriate area for reprocessing to begin as soon as			
possible.			
Cut open; preferable cutting along the side or end farthest away			
from the body to avoid direct contact with air expelled from the			
pouch.			
Ensure environmental conditions within the decontamination area			
are controlled to minimize the spread of airborne organisms.			
The Humipak is NOT a sharps container and is NOT puncture			
proof. Be sure to follow your facility's policy for handling			
contaminated reusable sharps in compliance with OSHA			
Guidelines.			

References:

- ¹Efficacy of humidity retention bags for the reduced adsorption and improved cleaning of tissue proteins including prion-associated amyloid to surgical stainless-steel surfaces; Biofouling, 2015;Vol. 36, No. 6, 535–541.
 <u>http://dx.doi.org/10.1080/08927014.2015.1067686</u>. T.J. Secker*, H.E. Pinchin, R.C. Hervé and C.W. Keevil
- ² © 2017 Association for the Advancement of Medical Instrumentation *ANSI/AAMI ST79:2017*. Section 6.3.5, page 35.
- ³ AORN GUIDELINE FOR PROCESSING FLEXIBLE ENDOSCOPES; Revised February 2019 for publication in Guidelines for Perioperative Practice, 2016 edition.
- ⁴ Inc., Healthmark Industries Company. (2011, March). HUMIPAK VERIFICATION TESTS SUMMARY. <u>https://www.healthmark.info</u>. <u>http://www.healthmark.info/InstrumentRetrieval/HumiPak/Humipak_Verification_Tests.</u> <u>pdf</u>.
- ⁵ Inc., Healthmark Industries Company, & MSmith. (2017, July 19). *Instructions for Use: Humipak* [™]. <u>http://www.healthmark.info</u>. <u>http://www.healthmark.info/InstrumentRetrieval/HumiPak/Humipak_IFU_2017-07-19.pdf</u>.