

Student Education Program – Training & Certification



Self-Paced, Industry Recognized

Whether you have used Alpha Cradle® brand foam and forms in the past, or are a new student to proton and radiation therapy, this course is for you. Smithers Medical Products is dedicated to your ongoing education. This **completely free, training and certification course** for radiation therapists and oncologists will increase your knowledge and help you stay current on radiation therapy treatment trends and the Alpha Cradle® system. This is one more way to show our commitment in working with you for total treatment success.

This course includes demo video-clips, an online test to quiz your knowledge of government regulations, OSHA, EPA and FDA requirements, and the correct use of our foams and forms. This program is designed to

teach you the safe and effective use of the **most successful immobilization and repositioning tool in the world.**

Learn about current FDA regulations as they relate to treatment devices, how to read MSDS sheets, and the potential toxicology of products you may already be using. At the end of the course, you will be given an online exam to test your knowledge. Participants will be emailed a printable certificate of completion.

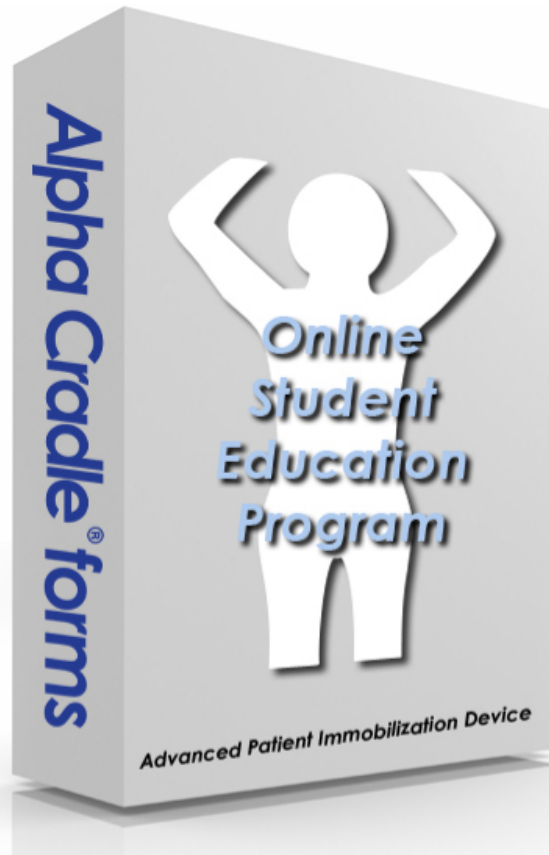
Free training supplies! Practical, hands-on learning for students who complete the quiz.

If you are an RTT educator, you can request **free samples of various Alpha Cradle® immobilization and repositioning forms for your immobilization labs.** You may also receive free copies of the Gunilla Bentel book, "Patient Positioning and Immobilization in Radiation Oncology."

Send us an email with: **name, facility, a line-by-line shipping address that accepts UPS shipments, the number of students you will have in class, and the date of your immobilization lab.** We will send materials to you in time for your class. You will receive one form for each pair of students in class. This allows one student to be the patient, and another student to make the form.

Online test: <https://smithersmedicalproducts.com/exam/>





Student Education Program Contents

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FDA Regulations: What do they have to do with treatment devices?

FDA's Center for Devices and Radiological Health is responsible for radiation therapy treatment aids

The FDA's (Food and Drug Administration's) Center for Devices and Radiological Health is responsible for regulating all companies that either manufacture, re-label, or import medical devices in the United States.



Medical Devices are classified into Class I, II, and III. The regulatory control increases as you progress from Class I to Class III.

The code of Federal Regulations Title 21, Part 807, 21 CFR Part 807, states that all manufacturers must register their establishments with the FDA, verifying all information annually, and must also list their devices with the FDA. Regulations cover everything from proper labeling, testing, pre-market notification and pre-market approval and a myriad of other regulations that cover the safe and effective use of products used on humans. Smithers Medical Products, Inc. has registered with the FDA and registered its products with the FDA. SMP has also had on-site inspections from the FDA and the FDA representative commended us on our facility and operations.

Different facilities sometimes go to hardware stores and purchase construction hardware supplies to create devices on humans, unaware of the physical dangers they place on their staff as well as their patients. Besides the inherent dangers in using these toxic chemicals indoors, it is a violation of federal law to use these chemicals which were never designed for use on

cancer patients in a hospital setting. It is a requirement to follow quality system regulations, 21 CFR Part 820, relating to methods used in manufacturing, designing, storing and installing and servicing medical devices.

Depend on quality companies that you can trust to provide you with tried, field tested and patented medical products for your patients. With SMP's Alpha Cradle® brand, this is exactly what you get. From our state of the art solid state dispensing equipment to our self-calibrating electronic scales that are accurate to the nearest tenth of a gram, SMP goes above and beyond to provide you with the highest quality product. We are also the only medical manufacturer in the world to use accordion-style bottles with our foaming agents—just one more level of safety built into every set of foam we provide.

What Is a Material Safety Data Sheet?

MSDS – Material Safety Data Sheet

Have you ever heard of the Right-To-Know-Law? It was mandated by OSHA, the Occupational Safety and Health Administration. In the United States, every



company that either manufactures or distributes hazardous chemicals must prepare a Material Safety Data Sheet (MSDS). This mandate can be found in OSHA's Hazard Communications Standard 29CFR 1910.1200, otherwise referred to as the Right-To-Know Law.

Its purpose is to ensure that the hazards of all chemicals either produced or imported in the United States are evaluated, and that information is transmitted to employers and employees. The transmission is accomplished by comprehensive hazard communications programs, which include container labeling and other forms of warning, Material Safety Data Sheets (MSDS) themselves, and employee training.

Additionally, other federal, state and local agencies also mandate content requirements of these sheets. Another law, the Community Right to Know Law (SARA Title III), falls under the domain of the Environmental Protection Agency (EPA). The best way to know which regulations apply to you is to contact both your state and federal OSHA offices.

A MSDS must provide different fundamental information about the chemical that allows the user to recognize and prepare for potential hazards with the chemical and prepare for potential emergency situations. A MSDS may be written in any format, but it must contain the information found in OSHA Form 174. MSDSs should be referred to in case of fire or explosion, before working with a chemical, in the event of a spill, and to prepare risk assessments. They can be complicated to the novice user. For example, Section (g)(2)(i)(C) of the OSHA standard 1920.1200 deals with MSDSs for mixtures. You should consult

a MSDS in case of fire or explosion, before working with a chemical, in the event of a spill, and to prepare risk assessments.

MSDS Sections – What are they and what do they mean for me?

Section I. Manufacturer's Name and Contact Information

Just above section I, you will see the chemical identity as it appears on the label. This is the title of the MSDS. Section I lists information on the manufacturer of the chemical. It provides the details about the manufacturer or supplier of the chemical. It will list the manufacturer's name, address, telephone number, emergency telephone numbers, and the date that the MSDS was prepared.

Section II. Hazardous Ingredients/Identity Information

This section provides the identities of the chemicals in the chemical or product. In this section, you will find the trade names, synonyms, Chemical Abstract Service (CAS) number, chemical family, molecular formula, and the molecular weight. If the chemical is a trade secret, the manufacturer does not have to list the exact chemical components. However, the manufacturer must provide regulatory exposure limits and related information on the chemical. This section will identify whether or not the chemical is a significant toxic hazard. It provides relevant regulatory exposure levels. This is where you may find the 8 hour average OSHA PEL (Permissible Exposure Limit). The lower the "safe" exposure limits are, the more toxic a chemical is. For example, a chemical with an exposure limit of 1 PPM (part per million) would be much more toxic than one with an exposure limit of 1,000 PPM. This section will also identify whether SARA Title III (the Community Right to Know Law) applies to the chemical.

Section III. Physical/Chemical Characteristics

This section provides fundamental information about the chemical, and how the conditions it is exposed to may affect it. These include appearance, odor, boiling point, specific gravity, vapor pressure (mm Hg), pH, melting point, vapor

density, evaporation rate and solubility in water. This information is important for your safety. For example, if you have an ignition source located on the floor, it's important to know the density of the flammable vapors. The boiling point or vapor pressure will let you know if it is safe to store the chemical in a non-air conditioned room. The pH will prevent you from mixing acids with bases.

Section IV. Fire and Explosion Hazard Data

In this section, you will find vital information about fire safety and explosion hazards of the chemical. It will list the applicable flash points, flammable limits and needed extinguishing media. It will also provide special fire fighting procedures, if needed, and list any unusual fire and explosion hazards. Some materials may give off toxic fumes when burned, or become explosive under certain conditions.

The flash point is the temperature, above which, the chemical will burn in air. If the chemical has a flash point that can be reached when exposed to heat or fire, you need to worry. A chemical may not ignite by itself, but it might be ignited if it is exposed to direct sunlight, a window, or by being placed too close to a heat source.

Some chemicals can burn or become combustible at normal temperatures, while others are only flammable within certain limits. Different chemicals can ignite at different percentages of volume in air. If you are working in a poorly ventilated environment, you may easily reach the flammable limit of an ordinarily common chemical. Please note that working in a large room does not always prevent reaching the flammability range. If heavier-than-air vapors collect along the floor, or lighter-than-air vapors collect towards the ceiling, you could easily reach a high enough concentration to combust.

Knowing the correct extinguishing media is vital. While your first instinct may be to douse a fire with water or a CO₂ extinguisher, certain chemicals actually react with these agents. Water or CO₂ added to a sodium metal fire would have the effect of tossing gasoline on the fire.

Section V. Reactivity Data

This section of the MSDS provides information on mixing or storing the chemical with another chemical. This section will list the reactivity hazards

with the chemical, storage or usage conditions to avoid, and warnings about incompatibilities with other chemicals. An example would be a MSDS for common bleach. Section V of the MSDS would warn about mixing this chemical with ammonia, and the potential deadly vapor created. This section also contains information about the stability of the chemical. Some chemicals actually break down into hazardous or explosive mixtures when exposed long-term to oxygen.

Section VI. Health Hazard Data

This section lists the routes of entry of the chemical. It may enter a person via inhalation, through the skin, by ingesting, or a combination of all of these. It will also list whether the chemical presents an acute or chronic health hazard. It will also list the carcinogenicity (NTP, IARC monographs, OSHA regulated) of the chemical. It will list the signs and symptoms of exposure, medical conditions aggravated by exposure, as well as emergency and first aid procedures. Because of this, it is vital if you or a coworker needs medical attention due to chemical exposure, you should always take a copy of the MSDS, or the label off the chemical container to the emergency room. The information on the MSDS will assist health professionals in the assessment and treatment of the possible chemical exposure.

Human and animal toxicity will be listed if it is available. If the chemical is known to cause cancer or other diseases, it will be listed here. Often, you may see LD50, which is the dose that causes death in 50% of the test subjects with acute, or short term exposure. This section will be replete with medical terminology and may require a medical dictionary to decipher.

All acute and chronic health effects associated with exposure must be listed in this section. This will include symptoms of exposure as well as medical conditions aggravated by exposure to the chemical. Emergency and first aid procedures must be listed separately for each different route of entry. It is common for reactions to skin exposure to really need 15+ minutes to be washed from body tissue. Always follow the instructions very carefully from this section. If you have a chemical spill, accident or exposure, always seek medical attention even if you feel fine after following first aid or emergency

procedures. Some chemicals, like hydrofluoric acid may not irritate the skin of the victim and they may feel fine. However, delayed effects can show up 24 hours later, at which point irreversible and painful bone damage or even death may occur. Therefore, never depend solely on how the victim of a potential chemical exposure feels. Always seek medical attention.

Section VII. Precautions for Safe Handling and Use

This section of the MSDS details the safe storage, use, and disposal of the chemical. It will also provide instructions on what to do in the event of a spill, or if the chemical is released into the environment, whether via air or water or ground spill. It is a good idea to have a response plan for these types of conditions before they occur.

Some of the information may seem to be repeated in the different sections. The reason for this is that an incident with a chemical may involve more than one section of the MSDS. A fire, for example, may release toxic materials that need to be cleaned up in a certain manner once the fire has been extinguished. Always review the entire MSDS as you do not know what section may contain vital information for the circumstances surrounding the specific use of the chemical at your facility.

Section VIII. Control Measures

The final section lists the safety or control measures to be used with the chemical. These include respiratory protection, ventilation (local, mechanical exhaust, special or other), protective gloves, eye protection, protective clothing, and any protective equipment needed. Work and hygienic procedures are also listed in this section. It is vital that all safety measures comply with all federal, state and local regulations. For example, just having a needed respirator is not sufficient according to OSHA. All involved personnel must be correctly fitted and trained in the use of respirators. These listed safety items may not just be “on hand” if needed, personnel must be trained in the effective use of such equipment.

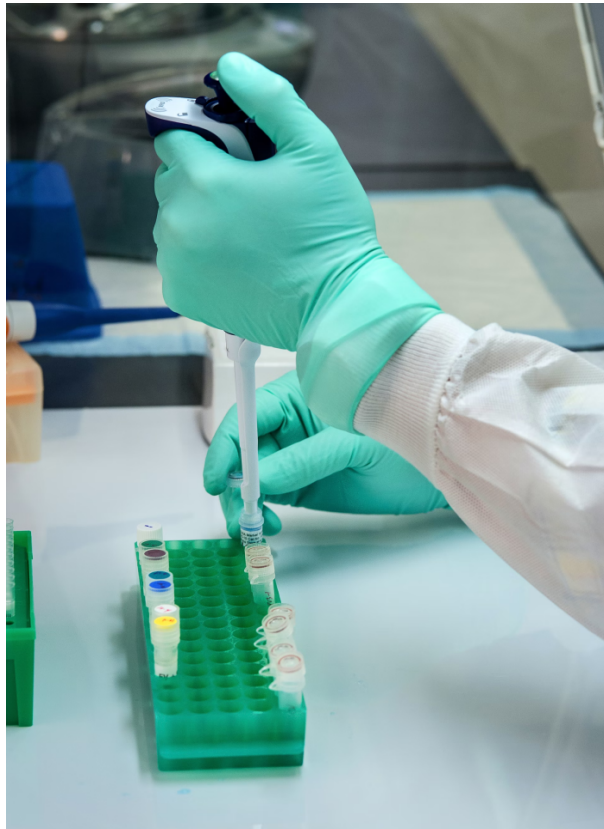
All ventilation must comply with all pertinent federal, state and local regulations. This is especially true regarding chemicals that are discharged into the air or water.

Toxicology—Are Alpha Cradle® Devices Safe?

What other harmful chemicals do I need to be aware of?

Only Alpha Cradle brand foaming agents offer you published toxicology results from an independent environmental consulting lab. SMP requested an industrial hygiene sampling of our proprietary foaming agents to be tested for determining exposure rates to MDI vapors.

On November 22nd, 1999, this independent agency collected samples for testing at the SMP production facility. Samples were analyzed by high pressure liquid chromatography in accordance with general procedures contained in OSHA Method 47.



While the current OSHA permissible exposure limit (PEL) for MDI is 0.02ppm, the measured airborne concentration of MDI for the SMP samples was less than the limit of detection for the sampling and analytical method of

0.0008ppm. That's less than 1 part per billion! Although foaming agents are designed to be used in closed polyol bags, we tested the foam to simulate a spill, or leak. The sample collected six inches above a box containing a reacting foaming agent mixture was expected to present a "worse case" exposure scenario with the foam open to the air.

The fact that no airborne MDI was detected under these conditions confirms the safety of Alpha Cradle brand foaming agents to radiation oncology employees who may be exposed frequently, and to the radiation therapy patients.

Only Alpha Cradle brand foaming agents have been tested for toxicology. **You will not find CFCs, TDI or formaldehyde gas given off in the foaming process.** If you use alternative chemicals to make polyurethane foam, *they must be registered with the FDA*, and should be tested for gases so that you know what you, your staff, and your patients are being subjected to. Always insist on the safest, most reliable foam specifically designed for use with your radiation therapy patient, and your oncology department staff.

Attenuation and Microwave Radiation

In 1987, an article was published in the Journal of the AAMD entitled, "Transmission and build-up characteristics of polyurethane-foam immobilization devices." This article was written by Peter Mondalek/Colin Orton, PhD.

This experiment was a test of the SMP Alpha Cradle® brand medical foam. Many in the field assume the same characteristics hold true for all other foams that have been introduced into the field over the years. Nothing could be further from the truth. Other foams are made from different compounds. The foam that has been tested is a proprietary formula owned by Smithers Medical Products, Inc. Other foam companies have introduced their cardboard box packaging foam as foam safe for use in radiation therapy. Many times the makers of these foams may not know a hospital or medical center is buying their commercial/industrial foam for use indoors for use on humans. Different foams have different densities and chemical compounds, not to mention different toxicology. Therefore the results provided below are for Alpha Cradle brand products only.

Our Alpha Cradle brand customized repositioning forms consist of a two-part foam system that creates a polyurethane foam. This foam is poured on top of a base piece of extruded polystyrene foam. Today, more than 40 years later, most forms made from our foam are made with the AC325 set of foam on the ACMMII. This means you are using the same two-part foam component, but no extruded polystyrene base! The original study on the attenuation of the foam was also based upon latex sheeting. The latex sheeting, 8 mils in thickness, was found to have a negligible affect on the transmission, but increased build up by approximately 1.0%. Today, latex sheeting has been replaced with very strong, yet thin PVC bags, averaging in thickness around 1.2 mils.

When you create the form today, you can measure temperatures of the rising foam on the skin surface measuring between 105-110 degrees F. This feels

comfortably warm, like a warm water bottle to most patients. Patients who may have had surgery in the area of the foam can place a piece of paper from an exam table to help offset the temperature difference. Although thin, by the time the heat transfers through the special paper, the temperature of the foam has already started to drop.

The data in the original article was obtained from Cobalt, 4, 10 and 15 MeV. Cobalt is rarely used today and new energy machines typically range from 6 MeV



to 25 MeV. Proton therapy utilizes protons, with typical energies ranging from 70 to 250 MeV. The point being there have been many changes in machines and energy since the early study. For all energies tested, transmission was affected very little by the foam. In the build up region, a significant decrease in skin sparing was observed due to the loss of build up, especially for the lower energy machines. At higher energies, the loss of skin sparing is considerably less.

Anytime skin sparing is clinically important and lower energies are being used, a simple port can be cut through the form without damage to the stability of the form. The foam has the consistency of dried toast, and ports can be cut easily with a serrated knife or a hack saw blade. Simply wipe the form clear of any tiny foam dust or particles and cover the exposed foam with tape.

Alpha Cradle foam was designed specifically for use in radiation therapy. Other foams on the marketplace may not be safe to use. Many foam compounds may contain TDI, formaldehyde gas, CFCs and other toxic gases that are given off in the formation process. Alpha Cradle brand foam contains NONE OF THESE TOXIC GASES.

Microwave Radiation

Another article, "Testing of patient immobilization foam subjected to microwave radiation," tested Alpha Cradle brand foam. A foam slab was subjected to microwave irradiation for one hour. The microwave applicator consisted of 915 MHz 10 x 10 applicator, a muscle equivalent phantom, and a 15 x 11 x 1.5 cm piece of Alpha Cradle brand foam, placed between the applicator and the phantom. Probes were attached to the bottom surface of the slab and the top surface of the slab, with one probe inserted inside the slab. Microwaves were radiated by the applicator and absorbed by the phantom. The bottom surface of the slab was maintained at the same high temperature, up to 50 degrees C, for one full hour, as was the phantom surface. After one hour, no signs of changes in its structure or burns were noticed. Heating of the slab was due to heat transfer and not to microwave power absorption.

Two conclusions were made by the study. The first conclusion showed that **Alpha Cradle brand foam doesn't absorb microwaves significantly**. The second conclusion showed that **irradiating the foam to the upper limit of hyperthermia temperature range for one hour does not change the mechanical properties of the foam**.

Only one brand of foam has gone through such rigorous testing. Only one company has spent so much time, money, and effort into creating, field testing, and providing you with the safest foaming agents on the market today. When lives count, insist on Alpha Cradle brand foaming agents and products for all of your immobilization and repositioning needs.

Making Alpha Cradle® brand Forms

The Modern Approach in Repositioning for Radiation Therapy



Showing Dignity and Increasing Comfort and Security

Cancer treatments can be scary, cold, and very uncomfortable. Make all of your patients, especially your palliative therapy patients, as comfortable as you can by using Alpha Cradle brand repositioning forms. They offer warmth, comfort and security, allowing your patient to relax while remaining immobilized during treatment.

Reduce Misalignments

Reducing rates of misalignments reduces the number of repeated port films, saving therapists and oncologists precious time. Therapists find it easier and faster to prepare for treatment, as each patient wiggles back into their form, until they are comfortable, in their original set-up position. Making patients comfortable encourages them to hold still while the form most accurately

immobilizes them. Comfortable patients can be treated in less time, with fewer treatment errors.

No noxious smells of TDI, CFCs or formaldehyde gas occur, as our medical foam contains none of these toxic chemicals. Precise accuracy is assured with pre-measured bottles, not chemicals you stir with a stick. *Our medical grade foam is measured on self-calibrating electronic scales that are accurate to within the nearest tenth of a gram!* Our foam is the only medical foam in the world that incorporates the use of accordion-style bottles for maximum safety during the mixing process.

Our proprietary foam has never been duplicated. It has been reformulated three times over the course of its history; each time being tested at a leading medical center after hundreds of tests at our testing facility. Additionally, for maximum safety, our foam was tested for toxicology at an outside, independent laboratory. MDI vapor concentrations, measured at the top of a lined container, simulating a worst case scenario—a spill—found levels barely detectable, and far, far below standards set for PEL by OSHA. No other company has gone to such extremes to create the safest, most reliable and tested foam on the market today.

Using our foam is easy. Each set comes with two pre-measured bottles of foam. Bottle #1, with a small mouth, is poured into Bottle #2 that has a large mouth. The mixture is recapped and shaken vigorously, for 10 timed seconds. This begins a chain reaction that creates an exothermic reaction expanding the foam's volume up to 40 times.

As the foam rises, the top layers act as an insulator, protecting your patient from internal heat temperatures which can reach 150 degrees Celsius. On the patient's skin, the temperature of the rising foam only reaches 115 degrees Fahrenheit, the temperature of a comfortably warm water bottle. This rising foam surrounds your patient in warmth and comfort, immobilizing them in an easily reproduced position.

At the School of Allied Health, Forsyth Technical Community College in Winston-Salem, North Carolina, one of the students, Brent

Woodall (RT)(T), demonstrated that a common item found in most treatment rooms, KY Jelly, can be used to clean up messes with the mixed foam. This safe, easy-to-use, and easily accessible product effectively cleans up any hardened foam; and it is safe for use on skin and hair. Our thanks to Brent for his tip.

Accordion-Style Bottles



From our smallest sizes of foaming agents up to the popular and most widely used AC325 (for most adult molds), the foam is poured into accordion-style bottles. These patented bottles are exclusively used by Smithers Medical Products, Inc. in the field of radiation therapy.

When ready to add the contents of bottle #1, you expand the middle portion of the collapsed ribs of the bottle, after removing the cap. Keep the top three ribs, marked with a red marker, collapsed. This is a safety feature to prevent an explosion of foam at your facility. If you shake the foam too long, the top three ribs will begin to expand. If you open the bottle at that point, the foam will shoot out of the bottle.

If you notice the three top ribs beginning to expand, immediately place the bottle, with cap on, in the provided bag. Wrap it in the bag and place in a lined

trash receptacle. When the lid blows off, it will harmlessly spread foam inside the bag. If this happens, call our office and we will replace the set of foam free of charge. Safety with each bottle is just one more feature that sets us apart from other device manufacturers.

Learn How the ACMMII (Alpha Cradle Mold Maker) and the Alpha Cradle Patient Repositioning System Make the Custom Forms You Need

Over the next two pages, you will learn how to use our two different systems for immobilizing and repositioning patients. Both systems work to provide comfort and security, while easily immobilizing your patient.

The ACMMII, a wooden slotted board with different size and shaped dividers, allow you to create the form you need, by first mixing the foam and pouring it into a bag. Next, the patient lies down on the bag and you place them in the desired set-up position. Using the dividers, maneuver the bag, holding it tightly against the patient as the foam rises and takes shape. When finished, you have a customized anatomical device that fits on top of a particular treatment aid you may be using, such as a head holder.

This system is more “hands on”, as you have to lift the bag of rising foam and place the dividers where you need them to hold the bag in place.

The Alpha Cradle Patient Repositioning System, a series of 40 different anatomical, prefabricated forms, is available to fill the needs you encounter on a daily basis. We offer 10 different anatomical molds just for breast patients. Some simply cover the thorax region, while others incorporate immobilization of the head. Our patented extended forms start above the patient’s head and extend below their knees, for maximum control of torso rotation, providing perfect alignment of the patient for each treatment.

We offer different anatomical molds for prostate, lung, head, head & neck (which improves the use of thermoplastic face molds), CNS, extremities, and every piece of anatomy in between. We also have a side form for your decubitus patient. These prefabricated forms are easier to use, and departments that have revolving staff find that these forms are easy for new staff members to adapt to easily.

Using the Alpha Cradle® Mold Maker

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The ACMMII has changed several times since its introduction to the field in 1985. Today's version is colored a more hospital-friendly blue, and includes a carry handle built into the board. Over 23 different sized assorted dividers are provided to make any form from head and neck, breast, torso, prostate, or extremity forms. Patients can be large, small, treated prone or supine, or even laying on their side. Need the patient propped up 15 degrees? Place one of our 15-degree wedges under the bag of foam and your customized form will fit the wedge for each treatment. Timo head holders and other devices can be placed under the foam to incorporate its use with the system.

Forms made on the ACMMII offer numerous advantages over vacuum bags. If you've used them, you'll discover they don't work effectively. They pull away from your patient rather than pushing up against the patient. Most vac bags are so shallow they resemble surf boards, and they don't have a flat base. Commonly, they develop leaks, making them useless. A loved member of the family doesn't belong in a form that several other cancer patients may have used. Our custom molded forms have a flat base. Our forms keep their shape, even if poked or punctured. All of our forms can be customized with a serrated knife, if you need to cut a port. Our forms are customized and tightly hold your patient. Vac bags are loose guides at best. They are positioning forms, not repositioning forms.

The AC325 & AC250 are designed for use with the ACMMII.

Each kit includes a bottle of papi, marked bottle #1, and a bottle of polyol, marked bottle #2. The smaller AC250 contains enough foam to immobilize the torsos of smaller children, or an adult head, head & neck, or upper extremity. The AC325 is our standard size foam. It has been developed to create most adult anatomical molds, including lower extremities, pelvic forms, breast forms, mantle forms, head & shoulder, etc. The ACMMII (Alpha Cradle Mold Maker board) gives you the flexibility to have the patient lay flat, rolled to one side, one or both arms up or down, or any other set-up position needed.



SAFETY FIRST: Wear protective gloves, smock and eye protection. Have patients remove jewelry before making forms. Always follow directions!

Using the ACMII Board



The ACMMII is a 24"x 34" slotted board that comes with 23 assorted dividers to create customized body devices. **Use it to make any type of anatomical device on any size patient**, young or old, in the prone or supine position.

Comfort your patient. Tell your patient what to expect. They must lay still for 15 minutes while their personal customized form rises around them. It will feel comfortably warm as the foam rises and hardens in the position they will need to hold while being treated.



1. Open and spread out the blue polyform bag.



2. Remove the cap and expand bottle #2, leaving the top 3 ribs collapsed. Carefully pour the entire contents of bottle #1 into bottle #2. Discard bottle #1 into a leakproof container.



3. Recap bottle and point it down inside the bag toward the base, away from everyone. Shake vigorously **for ten timed seconds**. Pour entire contents into the bag, collapsing the bottle. The color should be solid. If it is a marbled color, you did NOT shake the bottle hard enough.



4. Spread the rising foam evenly throughout the bag. Carefully push as much air as you can out of the bag, without pushing the foam out. Fold the

open end of the bag underneath. Wait until the foam rises a **full inch** before placing patient on the bag.



5. Use dividers to place the rising foam firmly against the patient, unrolling the bag as necessary. Keep the foam firmly against the patient for 15 minutes, until the form cools and completely hardens. Remove patient and dividers from mold.

IMPORTANT!!!

You **must use the dividers** to keep the bag of foam high and tight on the patient to make deep impressions that will guide your patient back into place. The patient must remain still for 15 minutes. Do not move the foam once it has started hardening; you will damage the form and it will not remain rigid.

STRENGTHENING FORMS: Larger patients can flatten the base of your forms, making them weak and subject to cracking or breaking. To strengthen the forms considerably, use a piece of 1/2" or 3/4" extruded foam just smaller than the width of your patient. Place it into the bag, pour the foam on top of it, then spread it evenly around the added piece. This added piece of extruded polystyrene will strengthen the base dramatically while diverting more foam to the sides of the patient, where it's needed most.

CREATING TIGHT, SECURE FORMS: When making the customized mold, you must make deep impressions and keep them tight against the patient during the foaming process. Unroll the bag if you need to, and work foam into the newly added bag space to make the form higher on the patient. You must use the Alpha Cradle Mold Maker II and dividers to accomplish this. You can also use tape across the patient to hold the dividers secure while the form is being made.

CURING EACH MOLD: While the form hardens, you can feel it cool back to room temperature within 15 minutes (depending upon temperature and atmospheric conditions in the room). Do not allow the patient to get up until the mold is cool (room temperature) to the touch. If the area underneath the patient is still warm, allow it to harden properly before use. This will result in a secure, comfortable tool to quickly reposition your patient each time they come in for treatment.

SPILLS: Prevent spills by following directions! If foam spills onto a hardened surface, immediately wipe off. Residue of the hardened foam can be cleaned with KY Jelly. This tip came from Brent Woodall (RT)(T). If foam spills onto any type of carpet or fabric, DO NOT TOUCH UNTIL IT HAS COMPLETELY HARDENED; doing so will only push the foam into the fabric. After it has cured, try to peel off the foam. KY Jelly may also help remove from hair.

Using Alpha Cradle® Brand Prefabricated Anatomical Forms

The Alpha Cradle® Patient Repositioning System



An Assortment of Forms Developed for Cancer Treatment

What started as two forms to target thorax and head & shoulder treatments has grown into more than 40 different assorted anatomical molds. Molds have been specifically developed for use with the following anatomical sites: breast, prostate, pelvic, head & shoulder, thorax, central nervous system (CNS), head, head & neck, and extremities. Different wedges have also been developed that can be incorporated for use with our forms, while several forms have incorporated 15 degree wedges with their inserts. This way you can leave a part of the insert in place to achieve the wedge effect, or completely remove the insert to treat the patient lying flat. Smithers Medical Products, Inc. has also designed dozens of specialty forms for several



different medical centers around the world. Some of these incorporate changes cut into our already fabricated forms; others use more or less foam with the forms for a particular use, while still others are especially designed for a specific need for a particular patient set-up. Polystyrene supported foam chairs have been built for use with cyclotrons, while other foams have been created for body pods used with cyclotron use. We work quickly and confidentially with medical centers to create whatever meets the specific needs of each department and method of treatment.

Our latest series of forms are our extended forms. Ever have a 300+ pound patient try to get out of a vacuum bag without ruining its shape? Try our extended forms. They can be made so durable that you can walk on them without changing or damaging the form. Nothing on the market keeps your patient's body in constant alignment better than these patented, proven devices. Most breast patients have had surgery by the time they are ready for radiation treatment. Many simply cannot hold an arm up as needed for an entire treatment period. Alpha Cradle brand forms will hold your patient in place, so you don't have to. After they adjust their torso into place, simply place their arm into the mold, pressing their forearm deep into the foam. Now the mold will do all the work, immobilizing your patient, while they lie in their custom-fitted mold very comfortably.

Each kit includes an anatomical shell, a special set of foam specifically designed for the form being used, as well as a special-sized blue polyform bag for optimum use. Custom, hand-made gray bags are also available for more precise accuracy in exact anatomical immobilization and duplication.

SAFETY FIRST: Wear protective gloves, smock and eye protection. Have patient remove jewelry before making forms. Always follow directions!

Tell your patient what to expect.

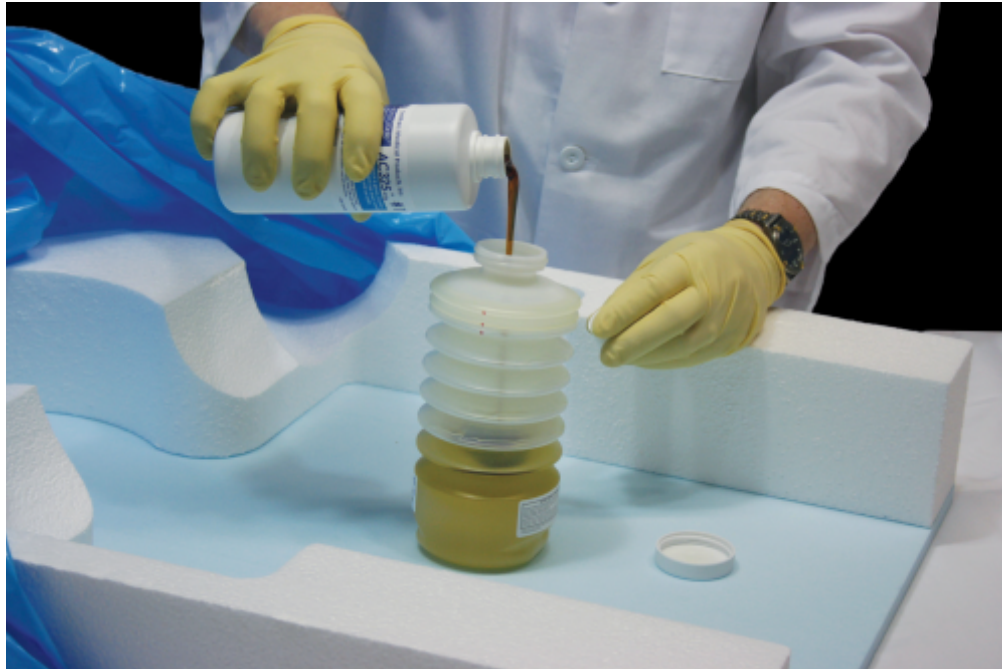
They must lay still for 15 minutes while their personal customized form rises around them. It will feel comfortably warm as the foam rises and hardens in the position they will need to hold while being treated. IF THE FOAM IS TOO HOT, the bottle was not shaken for the appropriate time. Be sure to shake HARD for 10 timed seconds. The mixture color should be solid. If it is a marbled color, you did NOT shake the bottle hard enough.

If you shake the foam too long, the top three ribs will begin to expand and foam may shoot out. If you notice the top ribs expanding, immediately place the bottle, with cap on, in the provided bag. Wrap it in the bag and place in a lined trash receptacle. The foam will harmlessly spread inside the bag.

If this happens, call our office and we will replace the set of foam free of charge. Safety with each bottle is just one more feature that sets us apart from other device manufacturers.



1. Make sure the top 3 red-marked ribs remain collapsed as you remove the cap, then expand the center portion of the bottle.



2. Carefully pour the entire contents of bottle #1 into bottle #2, discarding bottle #1 into a leakproof container.

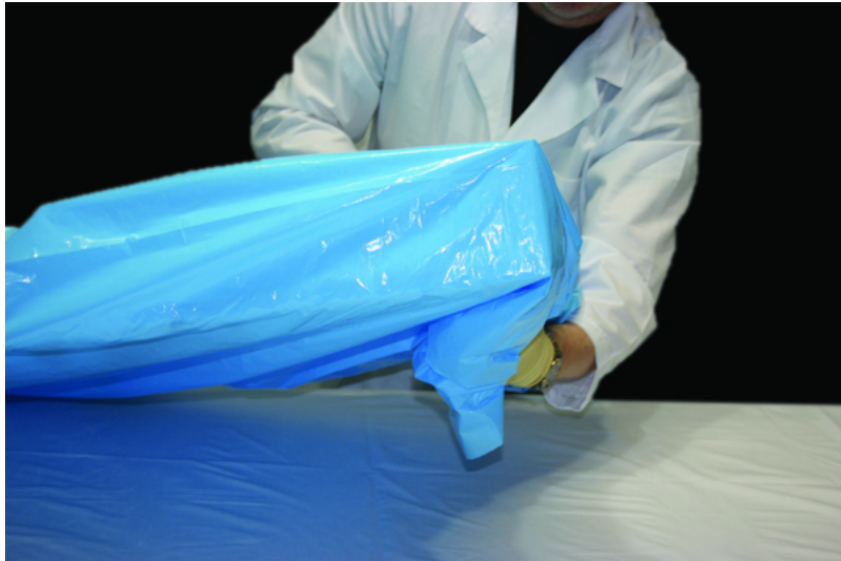


3. Recap the bottle and point it down inside the bag toward the base, away from everyone. The bottle must be shaken vigorously. **Shake the bottle for only ten timed seconds and remove the cap immediately.**

Pour the entire mixture along the edges inside the form. Make sure you also pour foam along the cutout areas for arms and forearms as needed. Collapse the bottle and squeeze all of the foam out of the bottle. Dispose of the bottle in a leak-proof container.



4. Press the bag against the areas of foam, especially around arm guides, edges, and open ends. Fold the corners of the open end of the bag inward, removing as much air as possible without pushing the foam out. This will keep foam from running off of those areas.



5. Carefully lift the end of the form and tuck the folded bag underneath to keep the foam from leaking out of the end of the bag.

Spread the rising foam evenly around the form.



6. Place patient in the desired set-up position. Press the bag down, against the areas of rising foam. Have them hold absolutely still for 15 minutes, until the foam has risen and cooled back to room temperature. Carefully assist your patient out of their form. Let mold cool for another 5 minutes until inside of form has cooled completely.

The completed form is now ready for use.

STRENGTHENING FORMS: After pouring the foam around the edges of the form and placing the form deep into the bag, remove as much air as you can before folding the excess bag underneath the form. Allow the foam to start to rise above the form, then push down, keeping the foam level with the form, forcing it tightly against the patient.

CREATING TIGHT, SECURE FORMS: As the foam begins to rise, inform the patient that the foam can actually lift heads and extremities out of the form. Instruct them to remain motionless as you press them deeply into the foam in the desired treatment set-up position. Keep constant pressure on the patient's anatomy that rises out of the foam, applying gentle yet firm pressure. You must make a deep impression. This may mean putting pressure on top of the patient's shoulders, allowing the foam to rise to the top of the form.

Foam that rises above the white form is useless. It can be diverted to another area where more foam may be needed, or it may be used to make a tight-fitting mold by pressing it down and holding it down for several minutes, until the foam begins to cool.

CURING EACH MOLD: It is critical that the patient *does not move for a full 15 minutes* to allow the form to harden properly. As the form hardens, you can feel it cool to room temperature within 15 minutes from the starting point (depending upon temperature and atmospheric conditions in the room). Do not allow the patient to get up until their new cradle is cool (room temperature) to the touch. If the area underneath the patient is still warm, allow it to cool and harden properly before use. This results in a secure, comfortable tool to quickly reposition them each time they come in for treatment.

Spills: Prevent spills by following directions! If foam spills onto a hardened surface, immediately wipe off. Residue of the hardened foam can be cleaned with KY Jelly. This tip came from Brent Woodall (RT)(T). If foam spills onto any type of carpet or fabric, DO NOT TOUCH UNTIL IT HAS COMPLETELY HARDENED; doing so will only push the foam into the fabric. After it has cured, try to peel it off. KY Jelly may also help remove from hair.