

PRODUCT GUIDE & USER MANUAL


Low Temperature Thermoplastic Pellets

Form rigid, re-moldable custom bite blocks and bolus shapes with easy to use pellets

- Soften in hot water for less than a minute
- Contour directly against the skin or against a plaster mold

RT-7001 Adapt-It™ Thermoplastic Pellets, 1 lb. bag

RT-7004 Adapt-It™ Thermoplastic Pellets, 3 lb. tub

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INTENDED USE

Intended Use

This device is intended to be used in radiation therapy.

! NOTE ! United States Federal law restricts this device to sale by or on the order of a physician.

Patient Target Groups

Patients undergoing radiation therapy, diagnostic imaging procedures.

Intended Users

The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

WARNING LABELS & DESCRIPTIONS

Refer to Qfix.com for a listing of symbols and their definitions.

SERIOUS INCIDENTS

Please report any serious incidents (e.g. incidents which result in or have the potential to result in death or serious injury) to both Qfix and your country's Competent Authority.

WARNING STATEMENTS

! WARNING ! Adapt-It Low Temperature Thermoplastic Pellets are very hot when first removed from the water bath and may burn the skin. Allow softened pellets to cool for 15 to 30 seconds before molding.

! WARNING ! DO NOT place softened pellets directly into the mouth! When inserting pellets into the mouth, **ALWAYS** use a barrier between the teeth and the pellets, such as a plastic bag or plastic film.

! WARNING ! Softened Adapt-It pellets are tacky and may adhere to dry skin, hair, dental compounds, vinyl tabletops, acrylics and other plastics. Lubricate dry skin with lotion, baby oil or Vaseline prior to application.

! WARNING ! Dose depth, deposition, and transition area effects must be evaluated during planning and treatment within a proton therapy environment.

! WARNING ! Verification of patient position must be completed during planning and treatment in a Radiotherapy Environment. Follow standardized setup verification protocols to verify patient position prior to treatment being administered.

INSTRUCTIONS FOR USE

Place the desired quantity of Adapt-It Low Temperature Thermoplastic Pellets into a suitable container to no more than 1/3 of its capacity. Pour hot water, minimum 70°C (160°F), over the pellets. The pellets will soften, turn transparent, and bond to one another. When all of the pellets have become transparent, insert a tongue depressor or spatula into the softened mass of pellets and lift out of the water.

Shake out as much of the water as possible and blot dry on a towel. After the pellets have cooled to a tolerable temperature, knead the softened mass of pellets with your fingers to press out any remaining water. Form into the desired shape and allow to cool and harden. Immerse in cold water to speed up the cooling process.

When forming a bite block, place the softened Adapt-It Low Temperature Thermoplastic Pellets in a small plastic bag such as a sandwich bag prior to inserting in the mouth.

! NOTE ! If Adapt-It Low Temperature Thermoplastic Pellets accidentally bond to acrylic dentures in the patient's mouth, a dentist should drill through the pellets to break the suction, if necessary, and then remove the pellets using a crown remover.

Adapt-It is a trademark of Qfix.