MATRIX
Thermo-shield™
Moldable Thermoplastic Radiation Shielding Material

User Manual
(For MX1 and MX2)

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MATRIX
Moldable Thermoplastic Shielding Material

Overview
MATRIX patented shield is a manually moldable thermoplastic material when heated in a water bath. MATRIX protects healthy tissues while allowing treatment to the exact treatment field during therapy. It may be quickly and repeatedly molded, adapted, shaped, stacked, or thinned directly on the patient at any time during therapy, thereby increasing treatment accuracy and decreasing clinical construction times.

Features
- MATRIX biocompatible shield protects healthy, radiosensitive cells, tissue, hair, lips, eyes, and organelles from radiation therapy while allowing radio-teletherapy to reach the desired tumor field. Its capacity for being readapted, reshaped, thickened, or thinned make this material particularly adaptable for sensitive anatomy.
- Its use in electron, orthovoltage, and brachytherapy, particularly of the head and neck, provides a timesaving factor since it is directly adapted to the patient for a customized treatment shield in approximately 25 minutes.
- Other shielding devices entail lengthy plaster cast construction, cerrobend block fabrication, impressions, or amorphous toxic lead filled with clay, which needs to be reconstructed at each therapy session, cannot be used near surgical sites, and cannot be intra-orally reconstructed. In addition, other devices no not employ backscatter mechanisms nor are they capable of being reconstructed and then re-hardened to capture anatomic detail for exact shield placement.
- Provides a linear attenuation coefficient of approximately 34% of elemental lead used for shielding applied directly to the body.
- Diminishes destructive photon energy to healthy tissues adjacent to the tumor, sparing irreversible damage (i.e. osteoradenonecrosis incidence of mandible of less than 5,000cGy or irreversible salivary gland destruction of less than 4,000cGy) when cerrobend blocking is not feasible or precise.
- Ensures uniform radiodensities, as particles of hydrocarbon and bismuth are both homogenous from the manufacturer. The bismuth-hydrocarbon shield is non-toxic and biocompatible.
- Usage of portals allows the clinician to visually maintain exact area to be irradiated while manually molding thermoplastic shield to anatomic detail (i.e. basal or squamous cell skin carcinomas) of the face, lips, et cetera.
- The portal shape, thickness, or angle may be altered with finger pressure while the thermoplastic shield is warm. This would be particularly useful as malignancy assessment may dictate a larger or smaller field with a different trajectory of teletherapy during some 15-20 patient treatments, or an associated lymphatic chain may need to be irradiated.
- May be disinfected with glutaraldehyde spray for asepsis.
- Can be hand carved, shaped with rotary instruments or cut with hot wire or Exacto hot scalpel technique if desired.
- Available in a 13mm or 16mm thickness.
- Can be constructed in a configuration that allows field of tumor-free tissue with an exact width to be irradiated at tumor excision sites where primary closure was not possible without skin grafts. This technique preserves healthy adjacent tissue, irradiates the wider margins to destroy any “malignant” stray cells, and may allow the surgeon a more conservative excision of tumor-free margins surrounding the malignancy.
- Moldable at temperatures from 123°-128°F.
- Provides greater uniformity in blockage and dosage versus “accelerator electron blocks” when using electrons with field size of 3cm or less, or where slight patient movement is possible.
- Shield and thermoplastic are available in syringes for ease of placement as the clinical situation warrants, allowing the addition of shielding material for greater blocking.
- According to Indiana University Head and Neck Oncology statistics, 43,000 patients are diagnosed with cancer of the head and neck each year. Indications for shield construction in this radiosensitive cellular and anatomically diverse region are clear.

Precautions
Please read and follow all instructions and precautions carefully prior to using this product. Improper use may cause product damage, and patient safety may be compromised.
Radiation Products Design cannot be held responsible for injury to patients or product damage resulting from improper use, abuse, or inadequate maintenance. This product is for external use only.
This product is a medical device, intended for use in hospitals and clinics.
CAUTION: Federal Law restricts the sale of this device to physicians only.

Unpacking/ Packing List

Basic shipment should include MATRIX thermoplastic shielding compound along with instruction manual and MSDS sheet.
This product is individually wrapped to ensure safe delivery to your facility. Unwrap carefully to prevent accidental dropping.

Shipping Damage

Inspect closely for any shipping damage that may have occurred. Promptly notify your freight company and contact Radiation Products Design for appropriate action.

Storage

When not in use, MATRIX should be stored flat in a cool, dry place. No articles should be placed on MATRIX during storage. Do not expose it to direct sunlight, extreme cold, or excessive heat for prolonged periods of time.

Specifications

The shielding compound molds and conforms to human anatomy at 108°-132°F, then sets to a rigid form at 102°F. The only constituent used in the production of the thermoplastic radiation shield is a FDA and ADA approved dental hydrocarbon impression compound for intra-oral usage and elemental bismuth-100 mesh, which is not absorbed through the skin.

Specific Gravity:
Matrix Thermoshield: 4.19 gm/cc
Thermoshield without Bismuth: 1.66 gm/cc

Dimensions:
Solid slabs are 8 x 8cm or 12 x 12cm. Standard Thicknesses are 13mm or 16mm. The application and the demands in matching the shield to treatment energy level determine the thickness. Syringes contain 50cc thermoplastic shielding.

Composition:
Thermoplastic dental compound and bismuth blended in a volume ratio of approximately 66:33. The manufacturing process bonds the dental compound to the bismuth to produce the dense thermoplastic radiation shield.

Other:
MATRIX compound is brown in color and has a chocolate odor.

Environmental Information

Product will maintain proper performance with normal use under the least favorable of the following conditions:

A. Ambient temperature range of 15°-35°C (59°-95°F).
B. Relative humidity range of 30%-75%, including condensation.
C. Atmospheric pressure range of 500-1060 hpa.

Product will not be adversely affected for up to 15 weeks while packaged for transport or storage or if exposed to:

A. Ambient temperature range of -40°-115°C (-40°-234°F).
B. Relative humidity of 10%-100%, including condensation.
C. Atmospheric pressure range of 500-1060 hpa.

Usage

- Single patient use only. Not to be reused!
- External uses only.
- This device is not sterilized.

Note: The material in this device may cause mild sensitization upon contact with the skin of certain sensitive individuals.

Clinically, the shield is warmed in a water bath to 123º-128ºF and molded to the healthy patient anatomy to protect it from electron or photon radiation during therapy. The shield sets at approximately 102ºF and is removed from the patient. The shield is now rigid for accurate anatomical detail and can be placed repeatedly for multiple radiation sessions.

Confirmation of exact radio-resistance at various points where tissues of varying radiosensitivety are located may be calculated utilizing solid water film phantom dosimetry. Utilizing Kodak XV film, the relative density is read with a densitometer. The density of film log l/lo is verified using a water scanner system with diode detector.

In clinical studies, the linear attenuation coefficient on phantom for x-radiation was $0.178cm^{-1}$ for an exposure of 6MV and above $0.144cm^{-1}$ for an exposure of 18MV. This compares to elemental lead linear attenuation of $0.53cm^{-1}$ for 6MV and $0.47cm^{-1}$ for 18MV. The electron particle attenuation for a 12.6mm thick shield in a 9MeV beam was complete. The shield reduced a 12MeV beam approximately 9.7%, while approximately 1mm of elemental lead is capable of stopping a 2Mev beam. Approximately 1.2mm of the biocompatible bismuth-thermoplastic shield was able to stop a 1.0MeV beam, evidencing 38% efficiency of elemental lead. The samples were irradiated to 7,600cGy and subsequently exhibited no loss of linear radiation attenuation and no loss of pliability or moldability when placed in a water bath and refitted to a phantom.

Linear Attenuation Coefficient for X-rays

Pb	Contoured	Compensator	High Flow Bismuth-Thermoplastic
$0.53cm^{-1}$ 6MV	$0.178cm^{-1}$ 34% Pb	$0.25cm^{-1}$ 47% Pb	0.149 28% Pb
$0.47cm^{-1}$ 18MV	$0.144cm^{-1}$	$0.21cm^{-1}$	0.117

Directions for Usage

Complete armamentaria for clinical instruction of thermoplastic radiation shield is recommended as follows:

A. Vaseline
B. Latex gloves
C. Marking pencil
D. Water bath basin- If clinic tap water is able to be regulated at 123º- 128ºF, the blocks may be immersed in a plastic container lined with parchment paper, thusly not requiring a water bath. This would allow shield construction site versatility.
E. Water bath thermometer
F. Non-stick parchment paper
G. Caliper or Boley gauge
H. Thermoplastic shield (the oncology team chooses the length, width, and thickness from the manufactured dimensions.)

To fabricate a 13mm thermoplastic shield, first raise water temperature 10 123º-128ºF. Set the thermoplastic shield on the parchment paper and immerse in basin for 10-12 minutes.

Outline treatment area on patient with a marker for therapy and lightly apply Vaseline to treatment area. Put on latex gloves and very lightly apply Vaseline to gloved fingertips.

Lift the thermoplastic from the paper supporting the material as you lift the corner, place the shield on desired patient anatomy to be shielded and contour as necessary for radiotherapy (approximate working time in 72ºF room is 3-4 minutes). Utilize portal if desired for exacting teletherapy field over a malignant lesion (i.e. basal or squamous cell skin carcinoma).

Allow customized shield to set an additional 6 minutes to assure no distortion upon removal. Total time from removal from bath to removal from the patient for a 10-13mm thick shield is approximately 10-12 minutes.

Verify shield for anatomic correctness on patient once again.

Grossly verify desired ratio-attenuation by measuring shield with Boley gauge or caliper. Elemental lead equivalence is approximately 38% when using a 12MeV beam. Radio-attenuation should be calculated with solid water phantom dosimeter, Kodak XV film and read with densitometer using water scanner system with diode detector or other exact measurement methods.

To use MATRIX thermoplastic syringe, place sheet of parchment paper in bath and raise temperature in bath to 148º-150ºF. Immerse syringe in bath for a minimum of 25-30 minutes. Remove syringe from bath and lift off cap.

Inject directly onto the desired surface to be shielded (patient shield or dental cast). Mold according to desired task:

1. Backscatter electron catch
2. Direct patient “bolus medium” (future consideration)
3. Compensation medium within MATRIX or cerrobend shield (future consideration)

To fabricate backscatter electron shield on side of shield furthest from the radiation source but in contact with tissue, purchase pre-manufactured filled and unfilled thermoplastic shield in syringe or sheet. (This filled thermoplastic shield will have 4mm of unfilled thermoplastic bonded to the surface.) Follow instructions to mold splint.

To make any slight changes necessary in the shield contour, reemerge shield in a water bath at 118º-120ºF for 4-5 minutes. Reapply and contour. Remove 3-4 minutes after patient application.

Generalities & Handling Suggestions: Incidentals

1. The shield may be disinfected with a glutaraldehyde spray if necessary then rinsed with water. Shield may also be rinsed in Methyl alcohol. DO NOT SOAK.
2. Electron backscatter thermoplastic material without bismuth:
   115ºF flow is approximately 80%
   108ºF flow is approximately 40-50%
   103ºF flow is approximately 25-30%
3. The shield may be readapted or thickness increased.
4. DO NOT use vegetable oils as lubricants, the thermoplastic is slightly soluble and will "smudge". Vegetable oil with sunflower and canola oil can be used for counter clean up if necessary.
5. For intra-oral usage, anatomic undercuts must be evaluated, as thermoplastic set is rigid.
6. The linear attenuation coefficient of the **customized** shield should be verified.
7. When molding shield, use care not to thin the peripheral margins.
8. Splints are rigid but brittle if dropped or torqued.
9. Customized shields are constructed quickly and easily in approximately 25 minutes.
10. Usage of portals allows the clinician to visually maintain the area to be irradiated while manually molding thermoplastic shield to anatomical detail.
11. Portal shape, thickness, or angle may be changed with finger pressure while warm. This is particularly useful when malignancy assessment dictates a larger or smaller field with varying teletherapy trajectories over the course of 15-20 patient treatments.
12. Thermoplastic shield temperature may be elevated to 155ºF without detriment to hydrocarbon. However, patient tissue comfort and health must be considered.
13. Thermoplastic shields may be purchased in different sizes and thickness, thus increasing accuracy and decreasing clinical construction time.
14. Gloves should be wet with warm water or very slightly coated with Vaseline to prevent Thermoplastic from sticking.
15. Raise water bath temperature prior to immersion of thermoplastic shield. The metallic bottom of the water bath can unevenly raise the temperature of the shield.
16. Place two sheets of nonstick paper in bottom of the bath, making sure paper is flat and not crumpled.

Reference Data for Electron and Orthovoltage Beams

Electron Beam Attenuation Properties of MATRIX Thermo-Shield

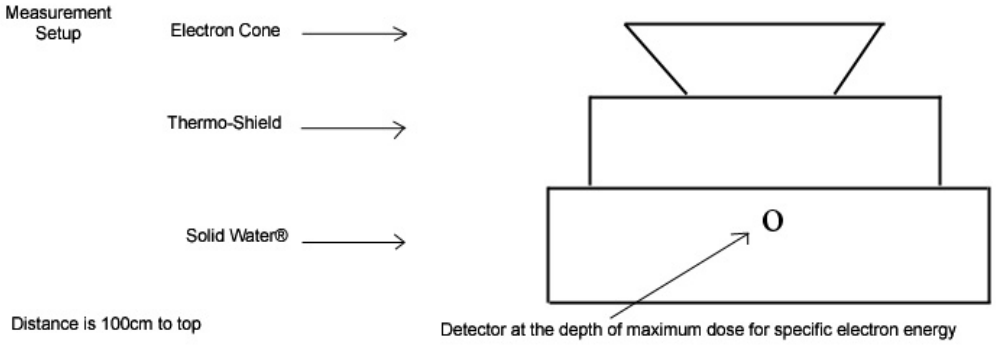


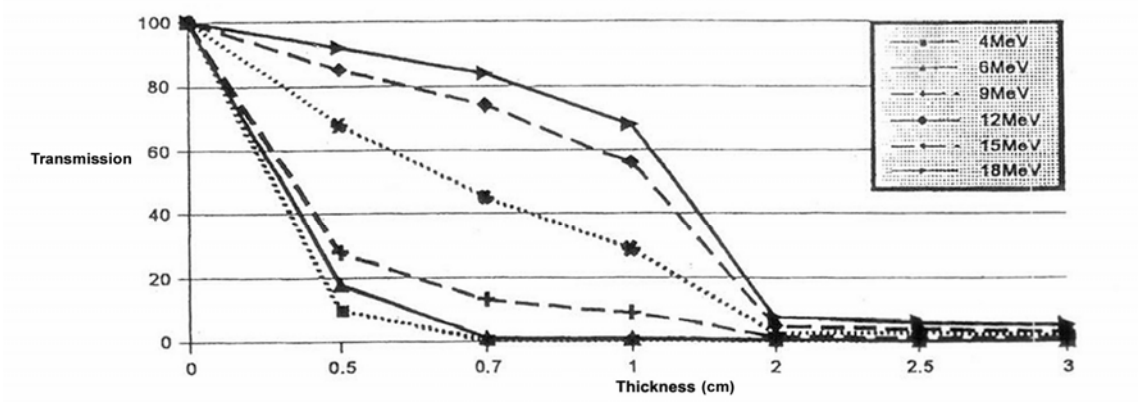
TABLE I. Measurements of electron transmission (percentage) at depth of maximum dose through increasing thickness of Thermo-Shield. For each beam energy, the data are normalized to its corresponding value measured for 0 cm thickness.

	Electron beam energy					
Thickness (cm)	4 MeV	6 MeV	9 MeV	12 MeV	15 MeV	18 MeV
0.00	100.0	100.0	100.0	100.0	100.0	100.0
0.50	10.0	18.0	28.0	68.0	85.0	92.0
0.70	0.4	1.2	13.3	45.0	74.0	83.9
1.00	0.4	0.9	9.0	29.0	56.0	68.0
2.00	0.3	0.6	1.4	2.8	4.9	7.6
2.50	0.2	0.4	1.1	2.5	4.0	6.1
3.00	0.2	0.3	1.0	2.0	3.2	5.2

This data is for reference only and should not be used for clinical purposes.

Attenuation characteristics of a new compensator material: Thermo-Shield for high-energy electron and photon beams
Bhudatt R. Paliwal, [a] Stephen Rommelfanger, and Rupak K. Das
Med. Phys. 25 (4), April 1998 pp.484-487

Relative Transmission at depth of maximum dose in Solid Water® vs. MATRIX Thermo-Shield Thickness



* This data is for reference only and should not be used for clinical purposes.

Electron Dosages

1. Bismuth-thermoplastic compensator
    A. 8.2mm stopped a 9MeV beam completely
    B. 8.2mm reduced a 12MeV beam to 9.7%
    C. Approximately 1mm will stop 1.25MeV beam
2. Bismuth-thermoplastic contoured to patient
    A. 12.6mm stopped a 9MeV beam completely
    B. 12.6mm calculated to reduce a 12MeV beam to 9.7%
    C. For clinical purposes, 1.2mm will stop a 1MeV beam

Orthovoltage Calculations

Calculations are average energy levels and tend to fluctuate for surface as secondary electrons are created. Sample was bismuth-thermoplastic molded to the patient.

	Linear Attenuation	Half-Value thickness
400KVP	$1.18cm^{-1}$	0.58cm
300KVP	$2.02cm^{-1}$	0.34cm
200KVP	$4.94cm^{-1}$	0.14cm

Minimum thickness of Thermo-Shield and lead to ensure less than 5% transmission.

Beam Energy (kVp)	Filter	5 x 5 field size <5% transmission thickness (mm)	10 x 10 field size <5% transmission thickness (mm)
Thermo-Shield			
75	2.0 mm Al	2.0	2.0
100	0.2 mm Cu	3.0	3.5
150	0.35 mm Cu	4.0	4.5
250	0.5 mm Cu	7.0	7.0
250	0.4 mm Th	8.0	8.5
Lead			
75	2.0 mm Al	NA	NA
100	0.2 mm Cu	0.7	0.75
150	0.35 mm Cu	0.9	0.95
250	0.5 mm Cu	1.6	1.7
250	0.4 mm Th	2.0	1.0

Bahmald et al: Dosimetric characteristics of Thermo-Shield material.
Medical Physics, Vol. 30, No. 6, June 2003

Applications

MATRIX Thermo-shield provides effective treatment shielding for a variety of applications:

1. Tumor treatment with electron, orthovoltage, or brachytherapy techniques at intro-oral head and neck sites.
2. To lesson the photon treatment energy levels in healthy tissues to prevent irreversible cellular damage (i.e. salivary glandular tissue < 4,000cGy, or mandible osteoradenonecrosis ≤ 5,000cGy). This would apply only where conventional cerrobend blocking techniques were not automatically feasible or precise.
3. Basal or squamous cell carcinomas, particularly of the face, eliminating facial plaster casts and lead shields.
4. Lip carcinoma.
5. Electron boost following multiple photon sessions (i.e. breast or elsewhere).
6. Kaposi sarcoma.
7. Rhabdomysarcoma of the head and neck.
8. Malignant adema of parotid.
9. Ethmoid and maxillary sinus.
10. Keloid.
11. Nasal vestibule, inferior half-nasal fossa.
12. Karatoacanthoma.
13. Thyroid.
14. Esophageal.
15. Laryngeal.
16. Hypopharynx.
17. Electron shielding of 3cm or less, as such a small field is not uniform in shielding or dosage.
18. The possibility of patient movement while dressed with Thermo-shield is not a critical issue in treatment.
19. Melanoma and associated lymphatics according to staging, anatomy, surgical techniques, etc.
20. Testicular seminoma. Provides precise protection of associated healthy genitalia.
21. Vaginal protection of labia majora and associated radiosensitive, secretory, glandular cells. Provides precise external shielding.
22. Xiphoid process shielding, lung shielding.
23. Precise treatment of suspect lymphatic channel (i.e. pre-auricular chain while protecting ear; axillary chain while protecting the breast; inguinal chain while protecting the genitalia).
24. Protection from multiple diagnostic X-rays near very radiosensitive tissues and germinal cells (i.e. testes, ovaries, lens of the eye, etc).
25. Shield construction for pre-surgical irradiation in approximately 25 minutes.
26. Generalized electron field contouring.

Contact Information

For any help on your radiation oncology treatment needs, please feel free to contact us:

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WARRANTY

Limited One-Year Warranty

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