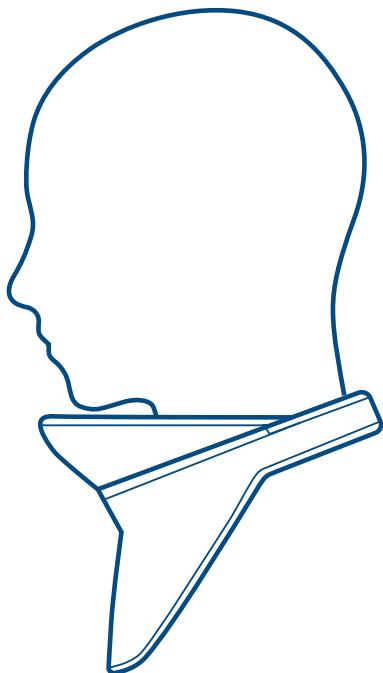


TEXRAY.

MindPeace™

INSTRUCTIONS FOR USE

ISSUE #1 10/2023



CE UK
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CA

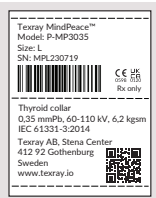
INTENDED USE

MindPeace is a Personal Protective Equipment (PPE), designed to reduce exposure of ionizing scattered X-ray for the thyroid, neck and bottom cranial area of a user present during radiological examinations or surgical interventions.

⚠️ WARNING:

This product shall not be used for Nuclear Medicine and similar as the stated lead equivalence is invalidated by the use of most gamma radiation conditions. It is important to avoid direct beam exposure during any point. It is not possible for Texray to warn the consumer about every possible danger related to use of the product and the consumer must use his or her own common sense and good judgement when using the product.

Example of the inside label:



The thyroid collar label states: Thyroid collar¹⁾ 0,35 mmPb²⁾/60 - 110³⁾ 6,2⁴⁾. IEC 61331-3:2014⁵⁾.

Where:

- 1) PRODUCT TYPE,
- 2) LEAD EQUIVALENT;
- 3) X-RAY TUBE VOLTAGE range;
- 4) AREA DENSITY;
- 5) Applicable standard.

"Rx only" states that Federal law in the United States restricts this device to be sold by or on the order of a physician in that market. Not made with natural rubber latex.

TYPE	NAME	MODEL NUMBER	LEAD EQUIVALENCE (mmPb)	AVAILABLE SIZES
Thyroid collar	MindPeace (with front and side faced flap)	P-MP3035 P-MP3050	0,35 mmPb 0,50 mmPb	S, M, L, XL

RADIATION PROTECTION PERFORMANCE

The performance of MindPeace products are measured according to IEC 61331-3:2014 at 60-110 kV using Modified Broad Beam Geometry and is certified to be in compliance within an allowed +/- 7% manufacturing tolerance.

RECOMMENDATIONS AND LIMITATIONS OF USE

The recommendations given below are general and may be subject to local statutory. If in doubt about proper usage or garment protection values, consult your hospital physicist or radiologist.

PERSONAL FIT AND SIZING

The MindPeace models come in three different sizes. Non-optimal size may lead to inadequate body coverage and discomfort. MindPeace shall be placed within the sterile barrier. Contact local Hygiene Department for local recommendations.

Before sterile dressing, apply MindPeace around the neck with open fastening device, using both hands. Please check that the lower part of MindPeace is facing down. Adjust the fastening device so that the product is tight and comfortable around the neck.

CARE, MAINTENANCE AND INSPECTION

The Warranty of the product is 1 year from date of purchase. Recommended storage and use below 35°C and 85% RH. For cleaning, wipe by hand with a damp cloth with lukewarm water and soap. Rubbing on the same spot may ruin the fabric and shall not be performed. Regular inspection of the product, at least annually, is recommended and local guidelines shall be followed. If damaged, the product shall be replaced.

⚠️ WARNING:

Do not iron, do not dry-clean, do not autoclave, do not use bleach, do not use alkali detergents, do not use alcohol or alcohol based products. Avoid contact with hot surfaces or long direct exposure to hot sunlight, avoid contact with sharp objects. It is important not to modify or change the product as this may affect its radiation protection performance and invalidate warranty. Do not disassemble, cut or pulverize the product.

DISPOSAL AND REPAIR

Disposal of this product shall follow local, state and federal or international regulations where applicable. For repairs or modifications, please contact your representative or Texray directly.

CERTIFICATES

MindPeace follows (EU) 2016/425 (3.9.2.2, Annex II), EC-Type CE (0598) and UKCA (0120) Examination approved.

MindPeace is FDA registered.

ADDITIONAL INFORMATION

For US Limited Warranty, and other technical data please visit Texray website link: www.texray.io/techdata

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