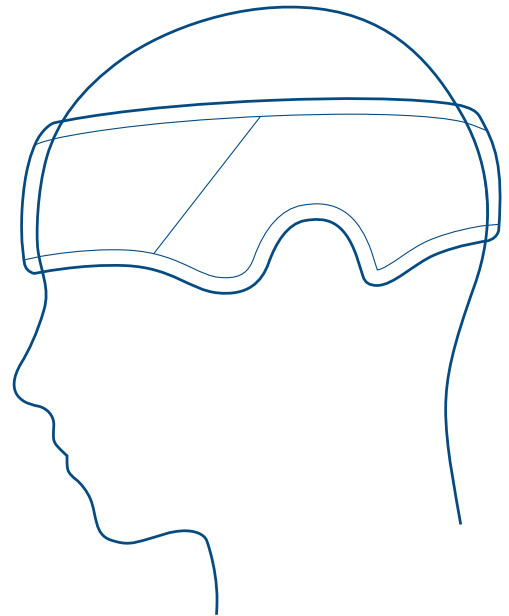


TEXRAY.

HeadPeace™
INSTRUCTIONS FOR USE
ISSUE #14 09/2023



CE **UK**
0598 **CA**
0120

INTENDED USE

HeadPeace is a Personal Protective Equipment (PPE), designed to reduce exposure of ionizing scattered X-ray in the 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:



"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
Head Protection	HeadPeace	P-HP1025	0,25 mm Pb	S, M, L

RADIATION PROTECTION PERFORMANCE

The performance of HeadPeace is measured according to IEC 61331-1:2014 at 70-110 kV using Narrow 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 HeadPeace comes in three different sizes. Non-optimal size may lead to inadequate body coverage and discomfort. HeadPeace can be placed inside or outside the hygiene head cap. Contact local Hygiene Department for local recommendations. Apply HeadPeace towards the forehead with open hook and loop, using both hands. Adjust the hook and loop on the back of your head so that the product is firm and comfortable on the head.

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

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

ADDITIONAL INFORMATION

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



Texray AB
Stena Center
412 92 Göteborg
Sweden
www.texray.io
info@texray.io
©Texray AB 2023

EC-Type Examination by:
SGS Fimko Oy, Takomotie 8,
FI-00380 Helsinki, Finland.
Notified Body No: 0598.

UKCA Type Examination by:
SGS United Kingdom Ltd
Rossmore Business Park
Ellesmere Port, Cheshire CH65 3EN
Notified Body No: 0120.