

REF CATALOG NUMBER

MD MEDICAL DEVICE

Dental X-Ray Aprons

Intended Purpose:

Palmero Healthcare X-ray Aprons are used to protect the patient against x-ray radiation produced by imaging systems. *For Patient Use Only unless otherwise specified.*

Available in a variety of colors for the following applications:

Dental Aprons = .35mm lead equivalency

Main Materials:

Dental Aprons are constructed from:

- Vinyl/Nylon inner and outer layers
- Lead or Antimony/Bismuth barrier layer

Instructions for Use:

USE: Place on patient BEFORE X-raying.

CLEAN: Use soap and water or a vinyl safe cleaner.

DISINFECT: Use only a vinyl safe disinfectant.

DISPOSAL: Recycle following local requirements for disposal of lead-vinyl sheeting.

Warnings and Precautions:

HANDLING: Do not expose the apron to extreme temperatures, submerge in liquids, or place in a dryer.

STORAGE: Do not fold, crease, or drape Apron over sharp corner. Hang it carefully.

CONCEALED DAMAGE: Misuse may cause concealed damage. Aprons should be visually inspected for damage regularly and inspected by radiograph or fluoroscopy annually to ensure continuing integrity.

According to the EU Medical Device Regulation, users / patients are obligated to report serious events with a Medical Device to the manufacturer and to the competent authority of the country in which they occurred.



Hand wash



Do not
bleach



Do not
dry clean



Do not iron



Do not
tumble Dry



Ionizing
radiation
protection

- Module B and Module D, Notified Body: 2895, Shirley Technologies (Europe) Limited, Port Tunnel Business Park, Office 13, Unit 21, Clonshaugh Business & Technology Park, Dublin 17, ROI
- Identifies this product has been certified according to PPE Regulation (EU) 2016/425
- Signifies that this product offers protection against medical x-rays and that the protective material used is at a lead equivalence of 50 kV – 110 kV, as shown on the garment label.
- Materials used in production of products have been tested using methods equivalent to EN61331-1:2014

ISO 9001

This product was manufactured in a plant whose quality management system is registered to ISO 9001:2015

Declaration of Conformity

EU Declaration of Conformity can be accessed online: <https://www.palmerohealth.com/pages/eu-certificates>