



Star Dental Products
1816 Colonial Village Lane
Lancaster, PA 17601-5864
717/291-1161
Fax 717/391-2757
www.dentalez.com

URGENT MEDICAL DEVICE RECALL

May 15, 2003

Dear Customer:

This letter is to advise you that DentalEZ Group/Star Dental, 1816 Colonial Village Lane, Lancaster, Pennsylvania 17601-5864, is initiating a voluntary recall for product label replacement of the Portable HDX Intraoral X-ray Systems manufactured by the DentalEZ Group/StarDental and sold to you by AFP Imaging Corporation. Specifically, we are recalling Portable HDX Intraoral X-ray System, part number 300020, manufactured by us and distributed through AFP Imaging Corporation from August 2000 through July 2002.

This recall is being initiated because the manufacture date label was misrepresented and the serial number and manufacture dates labels may be illegible. These labels have no affect on the safety or operation of the product.

This recall notice from DentalEZ/StarDental requests that you immediately cease distribution of the Portable HDX Intraoral X-ray System and return to DentalEZ Group/StarDental, 1816 Colonial Village Lane, Lancaster, PA 17601-5864, all systems in your possession so that we may affix a corrected label. In the alternative, you may request that we send a representative to visit your facility for the purpose of affixing to the systems in your possession corrected labels or that we send you corrected labels for you to affix to these units. In any case, DentalEZ/StarDental will replace the effected labels at no charge and, if you choose to return the systems to us, we will refund the shipping cost to you. If the systems are returned to us, we will affix new labels and return the systems to you within 10 working days from our receipt of the systems.

We also request that you provide DentalEZ Group/StarDental with a list of the serial numbers for the systems already distributed by you to the field and the addresses for the locations where the systems are currently located. We will send corrected labels directly to those locations with instructions for replacing the labels, at no charge, within one week of receipt of the serial number list and location of the system.

Please complete and return the enclosed form indicating whether you have Portable HDX Intraoral X-ray Systems in your inventory, the serial numbers for those systems and the serial number list and location addresses for systems already distributed by you. Please also indicate on the enclosed form whether you want us to: (1) send a representative to

StarDental 

affix the corrected labels; (2) send to you corrected labels with instructions on how to affix them to the systems in your possession; or (3) whether you prefer to return the systems to us for new labels.

The Management and staff of DentaleZ Group/StarDental apologizes for any inconvenience these actions may have caused your operations. Any questions and concerns should be forwarded to Kay Engle, Regulatory Affairs Supervisor, at StarDental at 866-383-4636, extension 4350.

Randy Arner
VP, Marketing
DentaleZ Group

StarDental 



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Check all that apply:

- | | |
|--|---|
| <input type="checkbox"/> We do not have any DentalEZ Group/Star Dental Portable HDX Intraoral X-ray Systems in our possession. | <input type="checkbox"/> We have provided StarDental with a list of serial numbers and location addresses for the Portable HDX Intraoral X-ray Systems that have been distributed. |
| <input type="checkbox"/> We have Portable HDX Intraoral X-ray System, part number 300020 and are providing a list of the serial numbers to StarDental. | <input type="checkbox"/> Please send a representative to replace the labels.
<input type="checkbox"/> Send us the corrected labels with instructions how to affix the labels
<input type="checkbox"/> We will return the system to StarDental for the label replacement |

Name & Title _____
 Company Name _____
 Phone _____ Fax _____
 Signature _____
 Date _____

Fax back to Kay Engle, Regulatory Affairs Supervisor, 717-391-2757 or mail to:
 StarDental
 1816 Colonial Village Lane
 Lancaster, PA 17601

