

FIELD CORRECTION RESPONSE FORM

Response is Required

CUSTOMER NAME: _____

ADDRESS: _____

CUSTOMER NUMBER: _____

REF.: 2017-007-C

PENTAX Medical Duodenoscope Model ED-3490TK

Replacement of Forceps Elevator Mechanism, O-Rings, Distal End Covering, and Operation Manual Update

- I have read and understand the instructions provided in the customer notification letter.
- The updated Operation Manual has been distributed to all required facility personnel.

| Contact Information | |
|---------------------|--|
| Name | |
| Title | |
| Telephone | |
| Fax Number | |
| Email address | |

| Signature of Receipt and Acknowledgement | Date |
|--|------|
| | |

Upon completion of the form and signing, please return the form by either one of the following methods:

- Faxing this completed form to PENTAX QA/RA Department at 201-799-4063 (alternate 201-391-4189)
- Email a pdf copy of the completed form to customeradvisories@pentaxmedical.com.

If you have any questions regarding this action, please feel free to contact your PENTAX Territory Manager or PENTAX Medical Customer Service at 800-431-5880 (8:30am – 5:00 pm EST, Monday – Friday).

Below is a list of the affected products our records show your facility has purchased. Confirm if your facility still owns them.

| Serial number | Does facility still own? | Serial number | Does facility still own? | Serial number | Does facility still own? |
|---------------|--|---------------|--|---------------|--|
| «M1» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M7» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M13» | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| «M2» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M8» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M14» | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| «M3» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M9» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M15» | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| «M4» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M10» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M16» | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| «M5» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M11» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M17» | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| «M6» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M12» | <input type="checkbox"/> Yes <input type="checkbox"/> No | «M18» | <input type="checkbox"/> Yes <input type="checkbox"/> No |