Asset: TSB-REPLACE 473026-1 SCREW ON EPISCOPE

Material number | Description
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473017-501N | SCOPE ASSY
47301 | EPISCOPE
47300 | EPISCOPE
47351 | EPISCOPE SET
47352 | EPISCOPE SET-EUR (47355)
47354 | EPISCOPE SET (UK)
47356 | EPISCOPE SET (AUS)
47351-C | EPISCOPE SET W/CONV HDNL
47351-SM | EPISCOPE SET W/LI-ION HDNL
47352-BI | EPISCOPE SET W/CONV HDNL
47352-C | EPISCOPE SET W/CONV HDNL
47352-SM | EPISCOPE SET W/LI-ION HDL CE
47354-C | EPISCOPE SET W/CONV HDNL
47354-SM | EPISCOPE SET W/LI-ION HDL,CE
47356-C | EISCOPE SET W/CONV HNDL
47356-SM | EPISCOPE SET W/LI-ION HDL,CE
47357-SM | EPISCOPE SET W/CONV HDNL, CE
Summary: Units coming apart in the field, caused by missing 473026-1 FHMS screw.

Issue: During the failure investigation of units coming apart, it was noted that there was an absence of tumble applied loctite on the threaded area as called out on the component drawing DIR 473026 – Note 3

Action: Replace FHMS screw P/N 473026-1 on EpiScope focusing ring.

1. Any product returned for repair or service which has the screw missing or loose should have the screw replaced. Replace 473026-1 under warranty for all customers presenting the same issue. If the device is returned due to operational failure and we find the screw loose or missing, we will replace the screw under warranty, the rest of the repair would billable. We will continue the warranty replacement process until 2015-12-31.

2. All Service Center inventories of 473026-1 should be examined for the presence of RTV (red or yellow). Non-conforming stock should follow the NMR process. Replacement inventory should be ordered.

Reference to Standards: • 21 CFR Part 820, ISO 13485, MPD SOP-0002

Updates: Technical Manual ☐ Repair Tool ☐ Service Plan ☐ Internet/Intranet ☐ Procedures ☐ Price List ☐ Training Material ☐ Other

Service Strategy: N/A

Required Training: N/A

Required Tools: Torque Driver to accommodate 12 in/oz +/- 2

Required Materials: Conforming 473026-1 FHMS screw

Quality Process for failed units or components: N/A

Procedure: N/A

Quality Documents: All service centers using SAP to record service transactions: For each monitor serviced, record the service activity in SAP.

All other service centers and Field Service: For each monitor serviced, complete and file a service report and attach to the service DHR.
Notes:

1. Contact the Welch Allyn Complaints Department to initiate or process a medical device complaint resulting from this or other issues.
2. Drawings, illustrations, and part numbers in this document are for reference purposes only and subject to change.

End of Bulletin

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D* - Refer to SAP DIR digital signature log for approval details.