December 14, 2009 DIR 80015723Ver. A

URGENT: Field Safety Notice

1. New validated reprocessing instructions and 2. Recommended use of a filter to reduce risk of cross-contamination from reusable accessories

Applies to Welch Allyn Illuminated Sigmoidoscope and Anoscope Systems and Accessories

Dear Welch Allyn Customer,

Disposable rigid sigmoidoscopes and anoscopes help reduce the risk of cross-contamination. But even these disposable systems have *reusable accessories* (the illumination and insufflation systems) that present a potential hazard for cross-contamination and infection.

We are providing with this letter new, validated reprocessing instructions to mitigate the risk of cross-contamination from reusable accessories. We also recommend that you use a disposable filter to further reduce the risk.

Here is the background:

- Disposable sigmoidoscopes and anoscopes significantly reduce the risk of cross-contamination, because they are intended for single use only. However, even disposable systems have a ***reusable bellows and light head***.

- A clinical study published in 2006 concluded, "Sigmoidoscopy using a disposable instrument is not a sterile procedure and may pose a ***risk of patient-to-patient cross-contamination by potentially harboring organisms in the bellows or light head***."[1] (Emphasis added.) Specifically, the study found that a potential risk exists for the reusable bellows or light head portion of the disposable sigmoidoscopes and anoscopes to come into contact with body fluids during clinical use, which can then be ***difficult to effectively disinfect***, and may contribute to cross-contamination.

We are not aware of any adverse events that have been actually attributed to the reprocessing of any components of the Welch Allyn Illuminated Sigmoidoscope and Anoscope Systems. Nonetheless, in light of this study, we have taken proactive steps to mitigate the risk.

Specifically, Welch Allyn is providing revised and validated reprocessing instructions for the Illuminated Sigmoidoscope and Anoscope Systems with consideration for all of the accessories. These revised instructions are consistent with established Centers for Disease Control (CDC) and Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) procedures, but are more specifically adapted to these devices. The revised instructions include validated methods to clean, disinfect, and, where appropriate, sterilize all components of the system, in particular, the inside of the bellows and/or light head.

In addition, we recommend placing a disposable hydrophobic filter between the insufflation bellows and the sigmoidoscope port. This filter will significantly reduce the risk of cross-contamination by creating a barrier which keeps bodily fluids from entering the bellows (see Figure 1.).

The insufflation bulb filter is a disposable single-use only item and must be discarded between patients in order to be effective. The filter does not eliminate the need to properly process the insufflation bellows with each use, but restricts internal contamination and aspiration of fluids. This makes the cleaning, disinfection, or sterilization process more effective.

Please reference catalog number (REF 30210) when ordering the insufflation bulb filter.

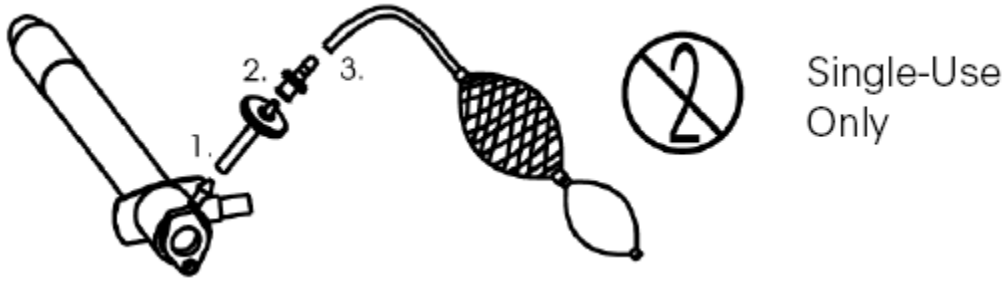

Figure 1. Sigmoidoscope with filter (item #2).

The Illuminated Sigmoidoscope and Anoscope Systems consist of four main components including:

a) The Sigmoidoscope/Anoscope and Obturator (disposable or reusable)
b) The Light Head
c) The Light Handle
d) The Insufflation Tube and Bellows.

Below are the catalog numbers for the various products subject to these revised reprocessing instructions and the recommendation for use of a filter:

Description	**Catalog No.**
Fiberoptic Sigmoidoscope (Adult)	32810, 32820, 32830, 33830, 33220, 33620
Fiberoptic Sigmoidoscope (Pediatric)	32010, 32020, 32410, 32420
Fiberoptic Sigmoidoscope Set	35303, 35323
Disposable Sigmoidoscopes	53130, 53130-B, 53130-F, 53130-JP
Operating Anoscopes	38614, 38619, 38622
Standard Anoscopes	38108, 38114, 38119, 38122
Rotating Anoscopes	38900
Fiber Optic Anoscopes	37019, 37023, 37027
Long Speculum Anoscopes	39614, 39619, 39622
Disposable Anoscopes	53110, 53110-B, 53110-JP
Fiberoptic Light Head, Light Carrier	36019, 38700
Insufflation Bulb	30200
Insufflation Bulb Filter	30210 (10 pack), 30225 (25 pack)
Light Systems	36103, 71000-A, 73210, 73220, 73222, 73224, 73226, 73305, 73322, 73324, 73326, 73500
Suction Tubes	30130, 30140

If you are a distributor, please notify your customers who have received these products of this information. The revised reprocessing instructions are enclosed and can also be found on the Welch Allyn website at

http://www.welchallyn.com/documents/Endoscopy/Cleaning_Instructions_20090917_Endo_doc_no_713512_translations.pdf.

If you use these devices,

1. Reprocess all reusable components of the Illuminated Sigmoidoscope and Anoscopes Systems and their accessories after each use per the revised reprocessing instructions Welch Allyn is providing.
2. Ensure the use of the filter as recommended by Welch Allyn in this field safety notice

If you are a healthcare professional, it is very important that you and/or your institution follow the revised instructions that we are providing. If you are a product distributor, it is important that you pass these revised instructions on to the purchasers of the Welch Allyn Illuminated Sigmoidoscopes and Anoscope Systems.

If you have questions, please contact Welch Allyn Technical Support:

Canada 1-800-561-8797	European Call Center +353-46-906-7790	Germany +49-747-792-7186	Latin America +1-305-669-9003	Singapore +65-6419-8100
United Kingdom +44-207-365-6780 (press Option 2)	Australia +61-29-638-3000	China +86-216-327-9631	France +33-1-6009-3366 (press Option 2)	Japan +81-33-219-0071
Netherlands +31-15-750-5000	South Africa +27-11-777-7555	Sweden +46-85-853-6551		

or your local sales representative.

Sincerely,

[redacted]

Senior Manager, Corporate Regulatory Affairs
Welch Allyn, Inc.

References

[1]D.Z. Lubowski, G.L. Newstead, "Rigid Sigmoidoscopy: A Potential Hazard for Cross-contamination", Surgical Endoscopy (2006) 20; 812-814

Enclosures