



xx September, 2015

**FIELD SAFETY CORRECTIV ACTION:
REVISED LABELING FOR THE OLYMPUS GF-UCT180 GASTROVIDEOSCOPE**

ATTENTION: Endoscopy Departments, Risk Management and Reprocessing Units

Re: OLYMPUS GF-UCT180 Gastrovideoscope updated
reprocessing instructions

Dear Health Care Professional:

Olympus XXX ("XXX") is writing to inform you that XXX is replacing the previously distributed GF-UCT180 Instruction Manual with a **revised Instruction Manual**.

Olympus has reviewed the instruction manual and identified that some parts of the instructions and illustrations contained in the reprocessing procedure were insufficient. Accurate reprocessing instructions are vital for safe use of the product and for this reason, Olympus XXX has taken the decision to revise the instruction manual and replace existing copies with an updated instruction manual.

Key changes in the revised GF-UCT180 instruction manual:

- ✓ When reprocessing GF-UCT180, we added instructions on how to attach the cleaning adapter for the instrument channel port (MAJ-350), to the instrument channel port of the GF-UCT180.
- ✓ The balloon applicator (MAJ-675) and the cleaning brush (MAJ-1534) are designated as equipment to be reprocessed for reuse. We have therefore listed MAJ-675 and MAJ-1534 as reusable equipment to be reprocessed in "7.9 Cleaning, disinfection, and sterilization procedures for reusable parts and reprocessing equipment" in "Chapter 7 Cleaning, Disinfection, and Sterilization Procedure".
- ✓ The cleaning brush (MAJ-1534) is compatible with "Ultrasonic cleaning" and "2-3.5% glutaraldehyde". It is described in the section "6.1 Compatibility summary", "Chapter 6 Compatible Reprocessing Methods and Chemical Agents" of the GF-UCT180/GF-UCT260 IFU.

Action Steps:

Our records indicate that your facility has purchased a GF-UCT180 ultrasound gastrovideoscope. XXX requests you take the following immediate action:

1. Olympus has discontinued previously distributed copies of the GF-UCT180 instruction manual. **Inspect** your inventory of instruction manuals and **discard** any existing inventory of GF-UCT180 instruction manuals.
2. Ensure all reprocessing personnel are completely knowledgeable and **thoroughly** trained on the updated reprocessing instructions contained in the revised instruction manual.
3. Additional copies of the revised GF-UCT180 instruction manual can be obtained by contacting XXX.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact XXX directly at XXX or by e-mail at xxx@xxx.xxx for any additional information on this matter.

Yours sincerely,

Olympus subsidiary/distributor address
Name
Tel

REPLY FORM

Olympus Subsidiary/Distributor
[Dept/Attn]
[Street No.]
[ZIP City]
Date Ref No. EXT-xxx
Field Safety Information: REVISED LABELING FOR THE OLYMPUS GF-UCT180 GASTROVIDEOSCOPE

Dear Sirs and Madams,

We herewith confirm the receipt of your Field Safety Corrective Action and the new instructions for use. We will share this information with the relevant departments.

Name _____

Hospital _____

Department _____

Street _____

Postal Code/ City _____

Date Signature