

Addendum

HIGH FLOW INSUFFLATION UNIT

Model; UHI-4

1. Instructions

The sections below provide updated information on warning of complications related to over insufflation. Changes are summarized below and are denoted by underlined text in the subsequent sections of this Addendum. Other parts of the instruction manual have not changed.

Warning in "Important Information — Please Read Before Use"

WARNING

Excessive flow rates and/or pressures may result in an excessive absorption of CO2 and/or gas embolism. The cavity can be adequately distended using a maximum pressure of 20 mmHg. It is seldom necessary to use a cavity pressure greater than 20 mmHg. Little intravasation should occur at these levels. Pressures over 20 mmHg are rarely necessary and will increase the amount and the rapidity of intravasation of gas. Adequate respiration helps avoid problems related to CO2.

It is recommended to use the lowest intraabdominal pressure allowing adequate visualization of the operative field for each procedure to help reduce risk of complications related to over insufflation. Complications related to over insufflation include gas embolism, arrhythmias (bradycardia, asystole, or cardiac arrest), prolonged or more complex procedures, delay to treatment, pneumothorax, hypoxia, subcutaneous emphysema, kidney or urinary problems. These complications could potentially lead to death.