



To whom it may concern

**Safety Instruction during usage of CODMAN High Speed Drill (HSD) System
Amendment to Instruction for Use**

Dear Customer,

the air hose (Article number 93-5020) of the CODMAN HSD System (Article number 93-5000), also referred to as motor / foot control tubing is used for the supply of compressed air (inner hose) to operate the drill system as well as for recirculation of the expanded air (outer hose). In one recently reported incident, due to an inadvertent unnoticed bend of the air hose during operation of the HSD system the return airflow was reduced resulting in a rapid pressure build-up of the outer hose, which resulted in a burst of the tubing.

After talking to the manufacturer and the German Competent Authority, the Federal Institute of Drugs and Medical Devices (BfArM), we decided to modify the precautions section in the instructions for use, in particular noting the potential for the blockage of the return airflow and to emphasize possible consequences. The modified precaution in the new instruction for use will be worded as follows:

Do not clamp, kink, overpressurize, or sharply bend the motor foot control tubing. These actions block the return airflow and can cause the tubing to burst during use in surgery. The resulting impulse sound could cause noise-induced hearing loss. Injury and damage can also result from the burst tubing or other flying debris.

Please inform all persons working with the CODMAN HSD system on the new precautions and attach this notice to your current instruction for use. As soon as the revised version is available you will receive a new instructions for use. In case you have any additional questions please contact us under Telephone 040 / 5297- 4609.

Yours sincerely

Marketing

Regulatory Affairs

Norderstedt, November 21, 2005

Customer_letter_HSD1.doc

Ethicon GmbH
Geschäftsbereich Codman
Oststraße 1
22844 Norderstedt, Germany

Marketing und Vertrieb
Telefon 040 - 52 97 - 46 04
Telefax 040 - 52 97 - 46 17
e-Mail codinfo@ethde.jnj.com
www.codman.de

Auftragsannahme
Telefon 0180 - 1000 829
Telefax 0800 - 101 61 38

Deutsche Bank AG, Hamburg
BLZ 200 700 00
Konto 096 338 0100

Sitz der Gesellschaft: Norderstedt
Handelsregister Kiel, HRB 1045NO
Geschäftsführer: Anton J. Schmidt, Vorsitzender -
Bodo Brzenk, Dr. Markus Fieber