

HEINE

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Tuesday, October 14, 2008

Dear Valued Distribution Partner,

Recently Heine received certification from Advanced Sterile Products (ASP) that our complete laryngoscope blade handles, bulbs and batteries included, are compatible with all of their STERRAD sterilizers.

The importance of this certification cannot be overstated. For the first time we have handle and cleaning system compatibility that offers 100% sterilization of all components of a handle.

In order to be compatible with the new STERRAD NX sterilizers, we had to alter the composition of the plastic rings on our handles. To mark this production change we have added a production date code to all of the handles that are manufactured with the new rings. These handles have a 2 letter production date code etched on the handle head (see following page for an example). All handles produced since May 2008 have production date codes printed on them, and include STERRAD NX compatible rings. The packaging on these handles also has a new sticker that identifies them as STERRAD compatible (see following page for example).

If you purchased handles prior to May 2008 that do not have date codes etched on them, you can easily upgrade the rings on these handles. New rings are available in packs of 50 each for our standard size, 2.5V stubby, and slim handles.

Please note that if a previous generation handle is accidentally processed in a new STERRAD machine, the result will be a cosmetic alteration in the green rings. No damage will be done to the handle or the sterilizer.

If you have any questions or concerns regarding the new rings or STERRAD in general, please contact your Authorized Heine Distributor.

Thank you for your continued support.

Best Regards,

Christian Berling
National Sales Manager

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New STERRAD Compatible Handle Date Code and Packaging Update

Date Code on STERRAD NT compatible handles.

Handles with the new green rings began production in May of 2008. To designate handles with the new rings, a production date code is now etched into the handle head. The production code is a 2 letter sequence you see below. Any handle with the 2 letter production code has STERRAD NX compatible green rings. If you would like a key to determine the production date based on this code, please contact your Regional Heine Sales Manager.



NEW Handle
Production Date Code.

Packaging on STERRAD compatible handles.

In addition to the production date code on the handle head, all new handle packaging has the following sticker on the outside. This sticker references handle compatibility with all STERRAD sterilizers. While not detailed on the sticker, this compatibility references the ability to put the entire handle (bulbs and batteries) into a STERRAD sterilizer.



If you have any questions regarding the new handles, or how to upgrade existing handles to be STERRAD NX compatible, please contact your Authorized Heine Distributor.

HEINE PRODUCTION DATE CODING SYSTEM KEY

Many HEINE products have a production date code printed on them. The code will consist of 2 upper case letters.

The first letter in the code represents the Month of Manufacture.

The second letter in the code represents the Year of Manufacture.

The code key for the months and years is as follows:

| MONTH CODE | |
|------------|-------|
| Code | Month |
| A | JAN |
| B | FEB |
| C | MARCH |
| D | APRIL |
| E | MAY |
| F | JUNE |
| G | JULY |
| H | AUG |
| J | SEPT |
| K | OCT |
| L | NOV |
| M | DEC |

| YEAR CODE | |
|-----------|------|
| Code | Year |
| A | 1997 |
| B | 1998 |
| C | 1999 |
| D | 2000 |
| E | 2001 |
| F | 2002 |
| G | 2003 |
| H | 2004 |
| J | 2005 |
| K | 2006 |
| L | 2007 |
| M | 2008 |

Example:

A Laryngoscope blade handle with an FM printed on the handle head has a production date of JUNE 2008.



To whom it may concern

Sterilization of Laryngoscope System

Hygiene is an issue where requirements as well as risks are always increasing. The goal is to constantly improve the protection of patients and users from contamination which could be transferred by medical devices.

In the field of intubation we realize that the requirements for the reprocessing of **Laryngoscope Handles** are stronger than ever before.

Until now Heine has only allowed the steam sterilization of the outer sheath of our laryngoscope handles. To improve this situation, we tested and modified our laryngoscope handles to allow for sterilization as a complete system. With the incorporation of a new material* for the green ISO marking ring we can now confirm that

Heine Laryngoscope handles, including all components: outer sheath, inner sheath, bulb, alkaline battery / rechargeable battery, and all green ISO marking elements are approved for Sterrad® Sterilizers (including NX*).

*Heine Laryngoscope handles manufactured from May 2008 on are compatible with STERRAD NX (Date code FM and on). Handles with no date code were manufactured before May 2008 can be upgraded for compatibility with STERRAD NX sterilizers.

This sterilization procedure, also referred to as Low Temperature Gas Plasma Sterilisation, allows for the sterilization of a wide range of medical devices which are not temperature resistant. The manufacturer of the Sterrad System is Johnson & Johnson.

Our Classic+ Laryngoscope Blades and Laryngoscope handles have been tested in Sterrad system sterilizers. After a detailed assessment of the function and appearance we approve these products and all components for currently available Sterrad® sterilizers.

Please see the attached confirmation and the revised Instruction for Use.

Kind Regards,

HEINE OPTOTECHNIK GmbH & Co. KG
Director Quality Management


Claudia Schwieger