

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 23 1996

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

TO: Manufacturers of Laparoscopic Trocars

SUBJECT: Shielded Trocars and Needles
used for Abdominal Access during Laparoscopy

The Food and Drug Administration (FDA) has been carefully evaluating a variety of shielded trocars and needles used to effect abdominal access during laparoscopy for the purposes of pneumoperitoneum and introduction of instruments. In particular, FDA is concerned that labeling these devices as "safety trocars" or needles may provide users a false sense of security that they are safer than trocars not labeled as "safety trocars."

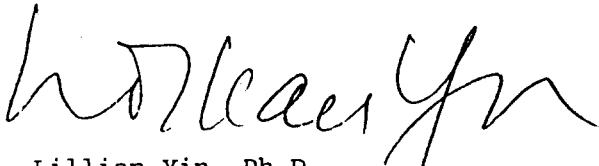
FDA is unaware of any data, published or unpublished, showing that these shielded trocars provide any additional protection from injury to bowel, blood vessels, or other organs, when compared to conventional trocars. In fact, review of FDA's own MDR database, manufacturers's complaint files, and other reports makes it clear that such injuries do occur with shielded trocars, and that the incidence of these injuries is not uncommon.

Therefore, FDA is requesting that - in the absence of clinical data showing reduced incidence of injuries - manufacturers and distributors voluntarily eliminate safety claims from the labeling of shielded trocars and needles. FDA does not object to labeling these devices as "shielded" trocars. Within 30 days of receipt of this letter, please inform the Office of Compliance of your labeling intentions. You may direct such correspondence to:

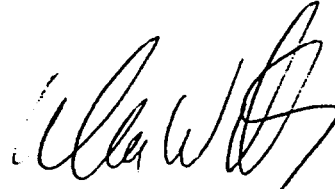
Tim Wells (HFZ-332)
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FDA will consider labeling claims for added safety when appropriate clinical data to support such claims is provided to the Agency. The Office of Device

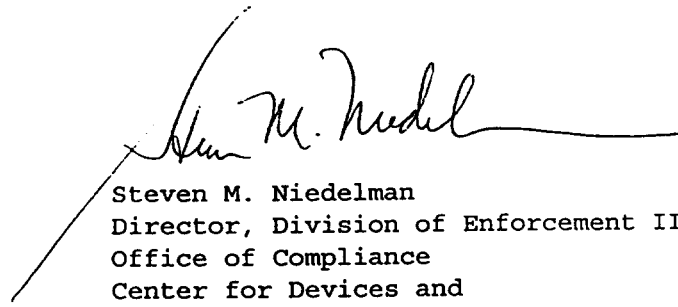
Evaluation (ODE) can provide guidance on appropriate clinical data that would be needed to support safety claims. For further information on clinical studies, you may contact Daniel B. Schultz M.D., at (301) 594-5072.



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