Medical Devices Bureau, Ministry of Health Malaysia
Level 5, Block E6, Complex E,
Federal Government Administrative Centre,
62590 Putrajaya, MALAYSIA.
Tel: 03-8883 2248/2249/2264
Fax: 03-8888 6184

Medical Device / Equipment ALERT: Field Corrective Action

Date Issued : 21st August 2008 **Ref:MDB/A/2008/012**

IMMEDIATE ACTION	
ACTION	√
UPDATE	
INFORMATION REQUEST	

PRODUCT	**Prostiva RF Model 8929 Hand Piece Device.**
CLASS	n/a
USE	Hand Piece Device
SOURCE OF MEDICAL DEVICE RECALL / ALERT	Field Corrective Action Letter dated 4th August 2008 from Medtronic International Ltd. - Malaysia Branch.
ALERTING / RECALLING FIRM	**Medtronic International Limited-Malaysia Branch** **This document is to provide users with information pertaining to the corrective actions being carried out on this model.**
REASON	***Please refer to attachment for details.***
SCENARIO IN MALAYSIA	No details available at this moment.
ACTION	***Please refer to attachment for details.***
RECOMMENDATION	Users of the abovementioned device should contact the distributors/supplier of this device (if available) and **inform the Medical Device Bureau, Ministry of Health** providing the following information:- a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available

CONTACT/ENQUIRIES IN MALAYSIA	**Medtronic International Limited-Malaysia Branch** Miss Debra Anne Anthony Peter, F-39-7 CREST, 3 Two Square, No. 2, Jalan 19/1, 46300 Petaling Jaya Selangor Darul Ehsan. Tel:- 03-79534800 Fax:- 03- 79582202
REFERENCES	***Please refer to attachment for details.***

Medtronic International Ltd. - Malaysia Branch
(993966-P)
F-39-7, CREST,
3 Two Square,
No. 2, Jalan 19/1,
46300 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.
Tel: 603-7953 4800 (10 lines) Fax: 603-7958 2202

August 04, 2008.

To:
DIRECTOR OF MEDICAL DEVICE BUREAU
MINISTRY OF HEALTH MALAYSIA
ENGINEERING SERVICES DIVISION,
Level 2-5, Block E6, Parcel E, Precinct 1,
Federal Government Administration Centre,
62590 Putrajaya,
Malaysia.

Dear Sir,

FIELD CORRECTIVE ACTION - PROSTIVA® RF MODEL 8929 HAND PIECE NEEDLE RETRACTION FAILURE.

Medtronic International Limited is sending the attached communication letters to provide customers with information pertaining to the corrective actions being carried out on PROSTIVA® RF Model 8929 Hand Piece device.

Included in this letter is the important clinician information on PROSTIVA Hand Piece Disassembly Procedure that should be followed in the event the user is unable to retract the needles during a procedure. This field action does not require the return of any PROSTIVA devices or systems. Our distributor has been notified of this Field Correction Action.

Do consult us should you require additional information.

Thank you and kind regards.

Yours Sincerely,

Debra

Debra Anne Anthony Peter
REGULATORY AFFAIRS SPECIALIST
MEDTRONIC INTERNATIONAL, LTD.

Attachment: Customer notification letter dated August 2008.

Medtronic

August 2008

URGENT: MEDICAL DEVICE CORRECTION

IMPORTANT CLINICIAN INFORMATION

PROSTIVA® RF Model 8929 Hand Piece Needle Retraction Failure

Dear Healthcare Provider:

Medtronic is issuing this Urgent Medical Device Correction to notify physicians of reported incidents of needle retraction failure when using the PROSTIVA RF Model 8929 Hand Piece. Included in this letter is the PROSTIVA Hand Piece Disassembly Procedure that should be followed in the event the user is unable to retract the needles during a procedure. The Medtronic PROSTIVA RF Model 8929 Hand Piece is the delivery system component of the PROSTIVA RF Therapy System.

Please note that Medtronic is not asking for the return of any PROSTIVA devices or systems. This information is intended to reduce the risks to patients should this failure mode occur. Existing PROSTIVA Hand Piece Model 8929 Hand Pieces can continue to be used.

Explanation of the Issue

Medtronic has received customer reports of needle retraction failure when using the PROSTIVA Hand Piece Model 8929. Based on the available data, the complaint rate is 0.054% and the rate of patient injury (excessive bleeding) associated with this issue is 0.0073% of devices sold. There have been no reports of patient death associated with this issue. However, if the Hand Piece fails prior to completion of a procedure, the risks to patients include the need to undergo an additional pre-op procedure including local anaesthesia, and if the device is withdrawn with partially deployed needles, the deployed needles may lacerate the patient's urethra wall.

This needle retraction failure is the result of loss of mechanical connectivity between the handle lever and an internal component of the Hand Piece that deploys and retracts the needles. In the rare circumstance that this occurs, you may disassemble or withdraw the Hand Piece according to the following procedure.

PROSTIVA® RF Model 8929 Hand Piece Disassembly Procedure

This disassembly procedure involves separating the metal urethra tube from the plastic handle assembly.

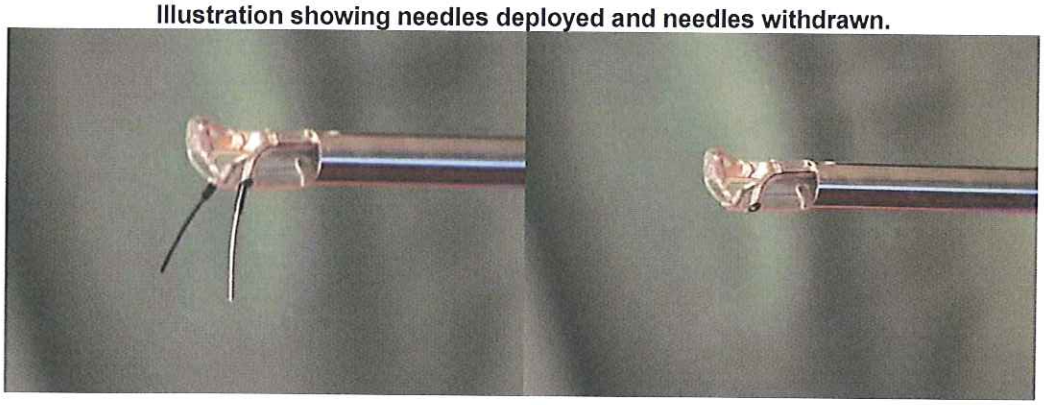
Medtronic recommends that two people work together to disassemble the Hand Piece. It is recommended that one individual grips and stabilizes the metal urethra tube, while another individual rotates the gray plastic Hand Piece.

1. If the handle lever is broken (blue handle lever is loose), use the camera to verify that the needles are deployed. If the needles are not deployed, the Hand Piece can be removed normally.

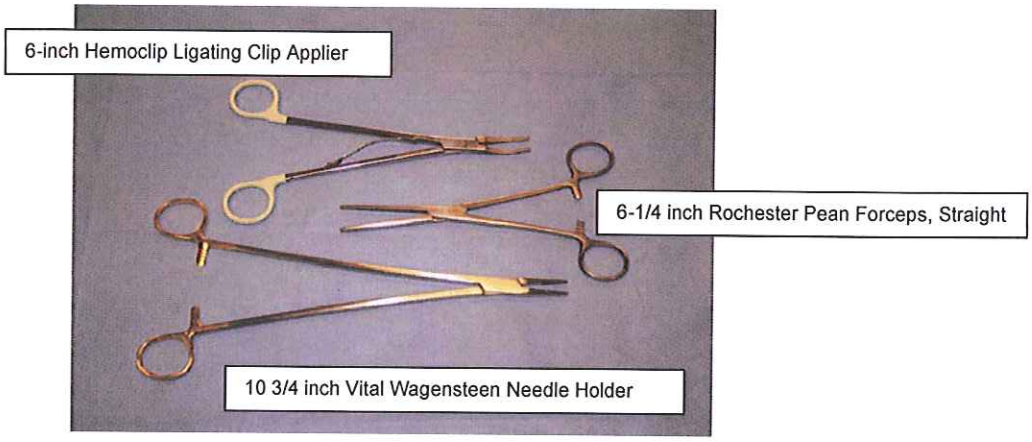
   Note: Do not use the "backup" retraction method described in the Instructions for Use, PROSTIVA RF 8929 Therapy Kit (Document # A11736001 or A11736002) for the failure of the needles to retract due to broken/loose blue handle lever. Follow the instructions described below to retract the needles.

It is critical to avoid movement of the metal urethra tube and the needles while attempting this disassembly procedure.

Illustration showing needles deployed and needles withdrawn.



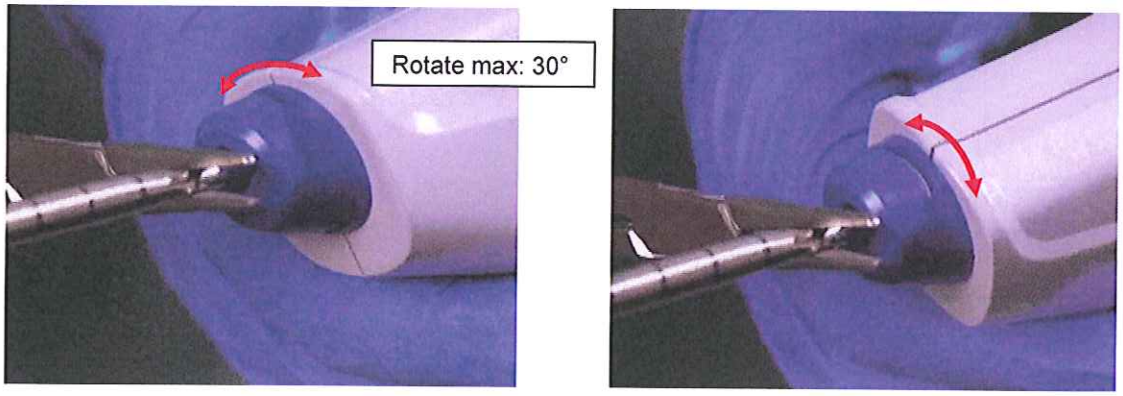
2. Disconnect the camera and light source, remove the telescope from the Hand Piece and disconnect the Hand Piece cable from the generator.
3. Locate a Hemoclip, Clamp, or Needle Holder, with teeth, as illustrated, or an alternate clamping tool. Assure that the clamping device is antiseptically cleaned. This is used to securely stabilize the metal urethra tube.



4. Using a clamping device with teeth, securely clamp the metal urethra tube and stabilize it. It is acceptable to slightly deform the metal urethra tube, but do not flatten or crush the tube completely. Do not allow the metal urethra tube to move in any direction or rotate around its longitudinal axis.

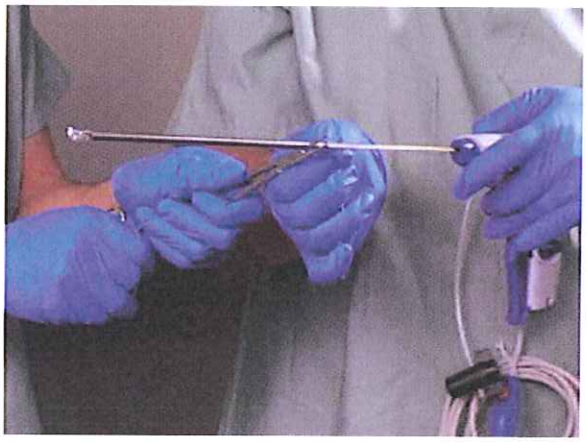
5. Next, **GENTLY** rotate the gray plastic hand piece from side to side around its longitudinal axis to break the adhesive joint. Do not rotate the plastic hand piece beyond 30 degrees in either direction.

The plastic handle cannot fully rotate due to an alignment feature on the metal tube. Do not attempt to rotate beyond 30 degrees in either direction.



6. After the adhesive joint is broken, gently pull straight backward on the plastic hand piece (along the longitudinal axis) while continuing to rotate the plastic hand piece from side to side around its longitudinal axis.

7. Once the hand piece and metal tube are separated by at least 25mm (1 inch), the needles are fully withdrawn from the patient and the metal tube may be removed from the patient. It is not necessary to completely separate the plastic hand piece from the metal tube. Attempting to completely separate the plastic hand piece from the metal tube may cause a sudden jerking motion.



In the event the Hand Piece cannot be disassembled, the failed device with extended needles can be withdrawn from the patient using a straight motion and without side-to-side or rotational movement. This method may result in a straight laceration of the urethra wall caused by the extended needles. In such a case, the physician should use standard of care to monitor and treat the patient for possible excessive bleeding. Physician feedback states that the epithelium is fast growing tissue that can replace itself within two weeks, including after severe trauma such as that associated with TURP (transurethral resection of prostate) or laser ablation.

For Further Assistance
In the United States, contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 or your local Medtronic representative. Outside of the United States, contact your local Medtronic Representative. This information can also be found on our web site at www.MedtronicConnect.com.

Please report any malfunction or adverse event related to this device to Medtronic Technical Services or your local Medtronic Representative. You may also provide a report to the United States FDA MedWatch Program.

You can contact the MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch/how.htm.

We appreciate your assistance with this matter and regret any inconvenience this may have caused you and your patients.

Sincerely,

George Aram
Vice President Quality
Medtronic Neuromodulation