



May 19, 2010

Re: FDA Warning Letters to Storz Medical AG, BTL Industries, Inc. and Medispec, Ltd.

Dear Valued EMS Customer and Swiss DolorClast user:

Committed to maintaining trust in the value of treating your patients with our Radial Shock Wave Therapy RSWT® technology, EMS brings to your attention the U.S. Food and Drug Administration's (FDA) recent decisions to issue Warning Letters to Storz Medical AG, BTL Industries, Inc., and Medispec, Ltd. for marketing their medical devices, the D-Actor® 50, the D-Actor® 200, the BTL-5000, the BTL-6000, and the Radialspec™, respectively, in a manner that violates federal law.

In its Warning Letters concerning each of these products, FDA states they are being marketed "in the United States (U.S.) without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act)."

Copies of these warning letters are available at:

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm210845.htm>

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm211763.htm>

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm207204.htm>

For the reasons stated in the above linked letters, FDA's Office of Compliance declared the D-Actor® 50, the BTL-5000, BTL-6000, and the Radialspec™ devices "adulterated" and "misbranded." FDA also declared the D-Actor® 200 "adulterated" for unapproved uses, as described in its Warning Letter. The FDA also warned all three companies that these devices may be detained without physical examination upon entry to the United States. Further, the FDA warned Storz Medical AG that "failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. Such action includes, but is not limited to, seizure, injunction, and/or civil money penalties."

The FDA's rigorous regulatory regime, purposefully designed to protect the public's health and safety, designates RSWT® as a Class III high-risk medical device when intended to treat plantar fasciitis. We embrace FDA's regulatory framework and others like it in the European Union and across the globe.

EMS has worked diligently for more than 10 years to raise the profile and scientific value of RSWT® internationally by validating with peer reviewed evidence and data the clinical claims of our ballistic shockwave technology.

Our commitment to well-designed clinical trials producing sound medical evidence culminated in the FDA issuing us our Premarket Approval (PMA P050004) for the Swiss DolorClast® in May 2007. The intended use of the Swiss DolorClast®, as approved by FDA, is to treat chronic plantar fasciitis for patients who have failed 6 months of prior conservative therapies, for people 18 years and older.

EMS looks forward to continuing to serve your RSWT® needs with our FDA-approved technology.

**ELECTRO MEDICAL SYSTEMS CORPORATION**

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# SWISS DOLORCLAST® METHOD

→ THE ONLY FDA APPROVED RADIAL SHOCK WAVE THERAPY FOR PAIN RELIEF.



Shock Wave Generation via Ballistic Principle

FDA Approved (Shock Wave Generator: Pain Relief) Under U.S. Regulatory Law

Established Safety and Efficacy (FDA Study and/or Peer Reviewed Published Literature)

Established Treatment Protocol (FDA Study and/or Peer Reviewed Published Literature)

Established Long Term Efficacy (6 month and 12 month follow-up results published)

Number of Clinical Trials Published in the Peer Reviewed Literature in Accordance with the Principles of Evidence Based Medicine

Maximum Shock Wave Energy Delivered (mJ/mm<sup>2</sup>) at 4 Bar Pressure

EMS Swiss DolorClast®

STORZ D-ACTOR® 50\*

STORZ D-ACTOR® 200\*

Medispec Radialspec™

BTL 5000\*

BTL 6000\*

**Yes**

No Evidence

No Evidence

No Evidence

No Evidence

No Evidence

**Yes**

No

No

No

No

No

**Yes**

No

No

No

No

No

**Yes**

No

No

No

No

No

**Yes**

No

No

No

No

No

**11**

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**0.18**

No Evidence

No Evidence

No Evidence

No Evidence

No Evidence

\*As of May 19, 2010, FDA Center for Devices and Radiological Health has concluded that the Storz D-Actor® 50, Storz D-Actor® 200, Medispec Radialspec™, BTL 5000 and BTL 6000 devices are adulterated under section 501(f)(1)(B) of the Act 21 U.S.C. 351 (f)(1)(B) and are also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o).

