DATE: 6-2-2021
ATTENTION! Mizuho Medical co Japan & America

https://www.mizuho.co.jp/en/ Japan FORM>: https://www.mizuho.com/contact-us
https://www.mizuho.com/ America FORM https://www.mizuho.com/contact-us?type=support

sales-dept@mizuhomedical.co.jp < **EMAIL**

To: **Hiroshi Nemoto**, Representative - Director - President & CEO, Mizuho Medical Co Japan & America

Subject: REQUEST FOR COMPANY STATEMENT AND RESEARCH RE: Titanium Aneurysm ClipS INSTALLED IN AMERICANS – **PRIOR** TO THE IMPLEMENTATION OF **1.5+ TESLA** BASED MAGNETIC RESONANCE TECHNOLOGIES

Honorable Sir, my name is Susan Neuhart. I am a retired American.

Your Sugita Titanium Aneurysm Clip - IS installed to my brain's blood vessel structure. (IMAGE)

The clip ["your clip"] was used - by my American Neurosurgeon (Victor Perry MD) to save my life - during an emergency surgery - performed on 12-18-2012. In fact, the installation was related to a Subarachnoid Hemorrhage at my Middle Cerebral Artery [SAH@MCA] stroke event - that I had suffered - in the mountains of North Carolina - near Asheville, NC - USA. I was VERY fortunate [that] DR Perry was on "emergency duty" - that evening.

Based on my subsequent results, Doctor Perry did an excellent job! In conjunction - with your "clip" technology – AND, after a "physical rehabilitation period" - TODAY (nine years later) - I

perform advanced YOGA poses daily - and, maintain a "personal" web site of YOGA pose benefits: (https://hansandcassady.org/)

Now. I am aware - the titanium clip [produced by Mizuho Medical - your company] was approved for use - by the US-FDA (in 1999 - [REFERENCES: 1], 2); The instrument was identified in documentation provided (to me) by the North Carolina hospital - related to my surgery[3, 4]. It is my impression (TODAY), my installed clip was approved for (LESS THAN) 1.5 TESLA ENVIRONMENTS.

However, in recent years - in the USA - several companies have manufactured - and sold - MRI devices [that] utilize magnetic strengths - of (GREATER THAN) 3+ Teslas. [references 5, 6]

No doubt - their product's success - is based on the advantages these new systems offer (image detail, speed...); However, the introduction – of new technology to an EXISTING and "installed base" – AND/OR PRE-EXISTING operating environment bares a level of responsibility. MOREOVER, technology approved - based solely on the predecessor product's characteristics – AND **CLASSIC** "SHIFT-THE-BLAME" POLICIES - is faulty.

AND SO, I personally encountered – (on **5-18-2021)** - at Miami Valley Ohio Hospital North -) - a "situation" - **where** - although I was scheduled - for "back2back" MRI/MRA brain scans - the hospital's "MRI PATIENT SAFETY" team **- due to "safety" concerns -** decided NOT to proceed - related to the MRI device (SCANNER unit) - being of 3+ Tesla strength; **And,** I lacked any specific "authoritative information" - other than the hospital document – given to me - circa December 2012 [3, 4]. [CITE 1, 2 IMAGE]

INDEED, my *"MRI patient Safety team"* contacted my local physicians: GENERAL (Sadikov) & Neuologist (Goldstick)), and others - seeking information.

I know [that] MY "MRI PATIENT SAFETY TEAM made a very "good-faith" effort THAT DAY (5-18-2021). AND, after much subsequent ***personal*** GOOGLE research - I THANK GOD! - [that] they made the correct decision.

You may be aware, several Americans - have been harmed - by lesser clips - during MRI procedures – IN RECENT YEARS. Reference 5: "… **…** For example, **a patient who went blind** from interactions between the metallic … and the static magnetic field of the MR system entered the scanner and underwent the entire MR examination without difficulty. This patient only went blind on exiting the MR system at the completion of the examination. …"

AGAIN. THE TEAM ASSIGNED - FOR MY SAFETY - AT THE CITED FACILITY - DID THE "RIGHT THING" - ON 5-18-2021. [CITE] HOWEVER, IN OTHER SIMILAR CIRCUMSTANCES – UNSUSPECTING AMERICANS HAVE BEEN HARMED.

IN FACT, THE REALITY [THAT] THE Aneurysm CLIP (MANUFACTURED – RELIABLY -BY YOUR COMPANY [https://www.mizuho.co.jp/] - AND SO CAREFULLY PLACED [IN MY BRAIN – [IN YEAR 2012] BY MY VERY SKILLED NEUROSURGEON) WILL LITERALLY "MOVE" AND/OR "REACT" - WHEN EXPOSED TO A SPECIFIC TESLA [MAGNETIC FLUX] STRENGTH AND OTHER MEDICAL PROCEDURES - IS CRITICAL INFORMATION – [THAT] "END USERS" – those with installed aneurysm clips [such as me] - SHOULD HAVE! - WHICH, I WAS SHOCKED TO LEARN (this information) – BY AN INTERNET SEARCH,

OBVIOUSLY, THIS INFORMATION MUST BE DIVULGED AND PUBLICIZED – FOR AMERICANS. **AT A MINIMUM** - AN "ALERT" MESSAGE (TO THE GENERAL PUBLIC) SHOULD BE

ATTEMPTED – AS CLEARLY THOUSANDS - OF AMERICANS – ARE SIMILARLY SITUATED (TO ME).

JUST AS OBVIOUS, IS THE FACT [THAT] **YOU** (OR YOUR COMPANY) ARE NOT TO BLAME! And yet, YOU are a part – of a medical industry – that (I) - a retired, senior American must deal with.

You will be copied on my message – to the US Health and Human Services SECRETARY. This Federal Branch of the USA Government – is charged with "protecting Americans" – AND, it accomplishes a **part** of its "mission" – via the USA Food and Drug Agency (FDA) A US federal "agency" I believe [that] is under its control.

CERTAINLY, SOME ONE MUST TAKE RESPONSIBILITY - FOR THE "INSTALLED BASE" - AND CONTINUED USE - OF "MEDICAL DEVICES "RELIED UPON" – BY THOUSANDS OF AMERICANS.

AND, IF A KNOWN - BUT SILENT - "SHELF-LIFE" EXISTS (on installed "medical devices" – including surgically installed "aneurysm clips") - ONLY, TO SERVE AMERICAN CORPORATE BUSINESS INTERESTS - THEN, PERHAPS LEGAL ACTION IS CALLED FOR – ON A "CLASS-ACTION" LEGAL SCALE. I have not retained legal counsel yet.

REQUEST: Thus, I require a "company letter" - from YOU sir; AND, a cite [if possible] to any appropriately "published research" showing your clip's (Reference 8) behavior - when undergoing MR imaging - in excess of 1.5 Teslas (magnetic flux density); and, the effects (if any) to the humans involved.

NOTE: My request (to you - TODAY) is also being SENT TO and

"Tailored FOR"**:**
1) MEDICAL DEVICE MANUFACTURERS,
2) MEDICAL Safety TRAINING Specialists,
3)MEDICAL Professors & Teachers,
4)MEDICAL Publishers,
5)MEDICAL Research Scientists (in America),
6) academic medical centers,
7) Hospitals & Technology Sites,
8) the US Health and Human Service Organization,
9) AGENTS OF THE US FOOD AND DRUG ADMINISTRATION (FDA)
- AND – 10) a "Research Facility" - in FRANCE.
(https://hansandcassady.org/SEND-TO-MRI-SAFETY.html) I do try to be thorough. Sir, if I have overlooked – an entity [that can be persuasive] – in my quest – please let me know.

In fact, my brain has been Magnetic Resonance (MR) "imaged" - since YOUR ANEURYSM clip's installation [December of 2012]; AND, I am not aware of any issues that arose. Today, I am [in fact] nearing complete Physical & Mental rehabilitation.

However, these previous "good experiences" (utilizing 1.5 -AND LESS – Tesla-based machines) - does not suffice - related to the subsequent technologies – NOW IN USE - in excess of 1.5 Teslas. (Reference 5)

Again, my life MAY have been saved - by the ALERT SAFETY team [that] I encountered 5-18-2021 (7) - Miami Valley Hospital Ohio (MRI imaging Department).

Specifically Sir, [that day] I committed to my " MRI safety" team member ("Michelle") – that, I was personally capable of pursuing – the related "safety" issues. THIS message AND my cited web site pages ARE MY INITIAL "FOLLOW-THROUGH"

EFFORTS. And in fact, I am over-due – to receive an MRI ("routine follow up") – AND – recently complaining of "vertigo" events – during my daily YOGA poses. My physicians continue to want me – to schedule AND COMPLETE AN MRI/MRA SCAN.

Clearly, the "REAL CONCERN"- TODAY - is other Americans – who may not even know what "Tesla Units" are. I only know, because – I had the honor of working with the Asian "inventors" – of SPEED2000 ™ simulation software. Which, this important simulation technology (used in ASIC, board, and IC "package" design efforts) is based on the application of MaxWell's Equations. That is, prior to my "retirement" – I was a "Software Engineering Technical Writer"; AND, I am (today) interested in micro-Wind Turbine technologies; which, Michael Faraday's 1830 experiments involving "magnets" and copper wire – is the historical basis of this technology.

I look forward to hearing from you - or, your agent.

The list of persons this "request" will be tailored for & copied to is available - on my personal web site:
[https://hansandcassady.org/SEND-TO-MRI-SAFETY.html **]**

A html page – summarizing my research – is here:
[https://hansandcassady.org/Brain-Implant-information.html **]**

My US Congressman is: Mike Turner **[OH-10] ;** Sherrod Brown **and** Rob Portman **are my US Senators. I hope my videos – helped to elect US President Biden.** Video**. I can make more videos – if needed. If you hear from their agents – please respond – knowing [that] I am hopeful (Japanese manufactured medical devices – installed to Americans) will not turn into – an "inter-national" incident.**

Finally, I am a retired senior American. However, if I may be of assistance - in making your response [requested above] *"understandable"* - to America's "average citizen" - for "news articles" etc. - please don't hesitate - to request my assistance.

Specifically, I have work experience - to "explain" "complicated things" - to Technology END USERS ... (ABOUT Susan).

My husband (of 39+ years) is the nationally known medical & scientific illustrator: Hans Neuhart . He is retired also - but (I believe) he will help us - too.

WE LOOK FORWARD TO WORKING WITH YOU! Please use my Email address

(SusanCN@hansANDcassady.org

OBVIOUSLY, TIME IS OF THE ESSENCE.

- Sincerely - Susan Marie Neuhart

References cited:

1. https://www.accessdata.fda.gov/cdrh_docs/pdf/k990202.pdf < Sugita Titanium Aneurysm Clip - FDA approval 1999

2. - http://www.mizuhomedical.jp/sugita2.pdf > **SEE pages 3 - 4**, TABLE & TRAY C

3. (AS RECORDED ON IMAGE) >> https://hansandcassady.org/Susan-clip-from-Hans-5-18-2021-NEW-FOR-mri-TEAM.jpg < IMAGE of document
https://hansandcassady.org/Brain-Implant-information.html#Susan's%20SAH@MCA%20Emergency%20Surgery%20&%20Clip

https://hansandcassady.org/Susan-clip-from-Hans-5-18-2021-NEW-FOR-mri-TEAM-TOP-half.jpg

CLIP 11.5 T2 STR 12 MM, 1, 1700110, Sugita, BRAIN

4. (ALL ON ONE LINE < for GOOGLE search) > CLIP 11.5 T2 STR 12 MM 1 1700110 Sugita BRAIN < **GOOGLE**
- http://www.mizuhomedical.jp/sugita2.pdf > SEE pages 3 - 4, TABLE & TRAY C

mailto:sales-dept@mizuhomedical.co.jp :: www.mizuhomedical.co.jp WEB site :: http://www.mizuhomedical.co.jp/contact/ :: http://www.mizuhomedical.co.jp/about/

https://www.mizuho.com/products/vascular-management/clips/aneurysm/titanium-t2/t2-clips :: https://www.mizuho.com/contact-us?type=support < Technical Support America

5. SOURCE: https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf … **TITLE: "...** ACR Manual on MR Safety Version 1.0 **2020**
ACR Committee on MR Safety **... PREFACE** The 2020 edition of the ACR Manual on MR Safety replaces all earlier versions. This document is published in a web-based format so that it can be revised and updated as needed. In 2001, the American College of Radiology (ACR) formed a Blue-Ribbon Panel on Magnetic Resonance (MR) Safety in response to various reports in the medical literature and print media detailing MR imaging (MRI) **adverse events and incidents involving patients, equipment, and personnel.** Initially published in 2002, the ACR MR Safe Practices Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments.
…Subsequently, these guidelines have been reviewed and updated throughout the years to address feedback from the field and installed base as well as **changes in the MRI industry** since the original publication. The ACR Manual on MR Safety represents the consensus of those representing the Committee on MR Safety of the ACR. The ACR Committee on MR Safety comprises professionals representing diverse fields and backgrounds that include research/academic radiologists, private-practice radiologists, MR/medical physicists, MR safety experts, patient safety experts/researchers,

MR technologists, and others. … **... Intracranial aneurysm clips:** If it is unclear whether a patient has an implanted intracranial aneurysm clip, plain films should be obtained. Alternatively, if available, recent cranial plain films or CT or MR examinations should be reviewed to assess for a possible intracranial aneurysm clip. … **In the event that a patient is identified to have an intracranial aneurysm clip, the MR examination should <u>not</u> be performed until it can be documented that the specific manufacturer, model, and type of aneurysm clip within that patient are MR Conditional.**
… All documentation of types of implanted clips, dates, etc, must be in writing and signed by a licensed physician. … **Phone, verbal histories, and/or histories provided by a nonphysician are <u>not</u> acceptable.**
… Electronic copies of operative reports, physician statements, etc, are acceptable as long as a legible physician signature accompanies the requisite documentation. … A written history of the clip describing appropriate testing for ferromagnetic properties (and description of the testing methodology used) prior to implantation by the operating surgeon is also considered acceptable - if the testing follows the standard test methods established by ASTM International. … **All intracranial aneurysm clips manufactured in 1995 or later for which the manufacturer's product labeling continues to claim MR Conditional status may be accepted for MR scanning <u>under the specified conditions</u> without further testing.**
… Implantation date, absent product manufacturing date information, is not sufficient to make a determination of acceptability for MR scanning without further testing. … Clips manufactured prior to 1995 require either pretesting (as per the ASTM International F2503 Standard Practice guidelines)… **A patient with an aneurysm clip (or another implant) may have safely undergone a <u>prior MR examination</u> at any given static magnetic field strength.** This fact is insufficient evidence of the implant's safety and should not be relied on to determine the MR safety status of that aneurysm clip (or other implant) for future MR examinations. **…** For example, **<u>a patient who went blind</u>** from interactions between the metallic foreign body in his retina and the static magnetic field of the MR system entered the scanner and underwent the entire MR examination without difficulty. This patient only went blind on exiting the MR system at the completion of the examination. … Barring the availability of either pretesting or prior MRI-related data for the aneurysm clip in question, the supervising

physician in each case must perform a risk-benefit assessment and review. … Furthermore, for patients with intracranial aneurysm clips with no available ferromagnetic or imaging data, should the risk-benefit ratio favor the performance of the MR examination, the patient or guardian should provide **written informed consent that includes death as a potential risk of the MR procedure prior to permitting that patient to undergo an MR examination** ... US Food and Drug Administration. MedWatch: the FDA Safety Information and Adverse Event Reporting Program 2020. Accessed February 24, 2020. (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reportingprogram (result 404) ... US Food and Drug Administration adverse event reporting program "Medical Device" < Google **RESULT:** https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems ... US Food and Drug Administration. Device advice: comprehensive regulatory assistance 2018. Accessed February 24, 2020. … https://www.fda.gov/medical-devices/device-advicecomprehensive-regulatory-assistance (result 404) **..."**

6. https://hansandcassady.org/Brain-Implant-information.html

7. https://hansandcassady.org/Brain-Implant-information.html#DOCUMENT%20EMAILED%20TO%20HOLLY < Miami Valley Hospital "Safety Team"

8. https://hansandcassady.org/Brain-Implant-information.html#Susan's%20SAH@MCA%20Emergency%20Surgery%20&%20Clip < Hospital Documentation RE: clip

9. "FORM" VERSION OF MESSAGE:

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PRIOR TO THE IMPLEMENTATION OF **1.5+ TESLA** BASED MAGNETIC RESONANCE TECHNOLOGIES

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I look forward to hearing from you - or, your agent.

Please use my Email address

(SusanCN@hansANDcassady.org

OBVIOUSLY, TIME IS OF THE ESSENCE.

- Sincerely - Susan Marie Neuhart

[end]