Metal Implant Adverse Event Reports Made Public by the FDA

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Dental implants are the second most reported device in the history of adverse event reporting

(second only to blood glucose tests).

Through August, 2019 there have been over 2.2 million adverse events reported for dental implants. 2.1 million of these were only recently made available in a data dump of summary reports in June.

1.6 million of these were serious injury reports.

Adverse Events Made Public via the FDA through August 2019

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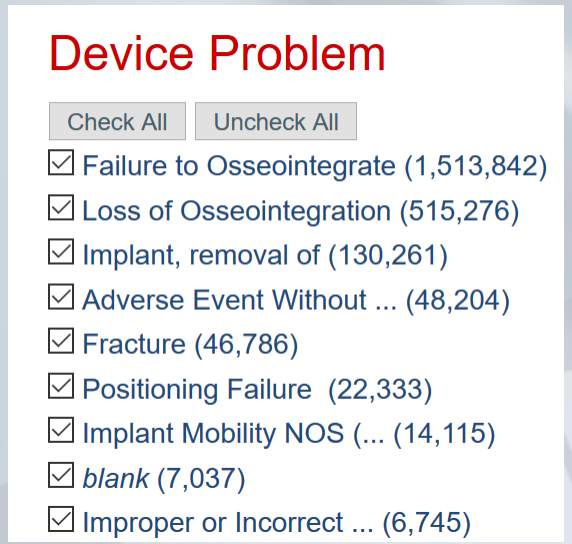
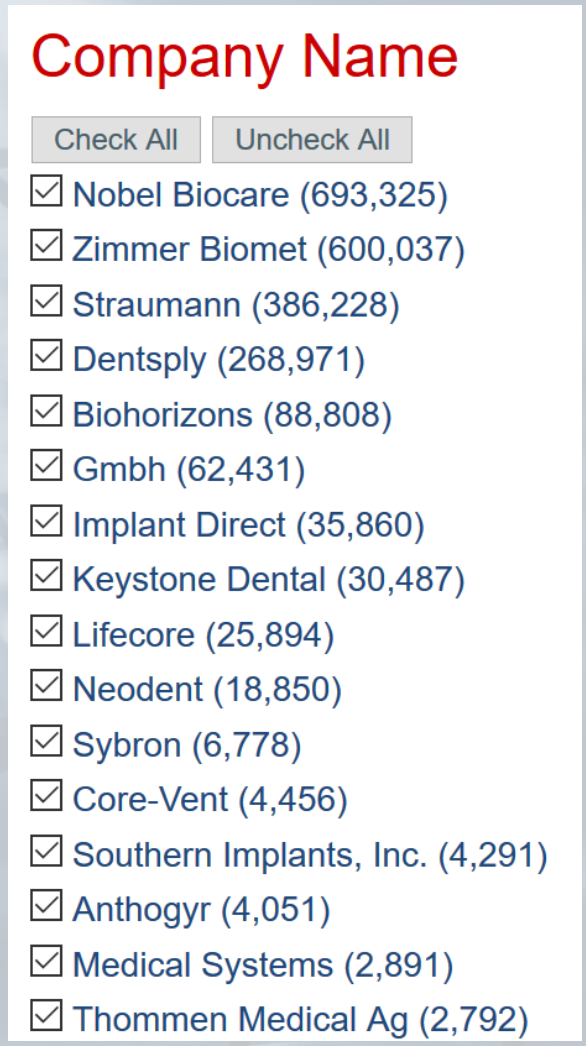
The vast majority of device problems associated with dental implants are due to loss of osseointegration or failure of the implant to integrate with the bone.





There is no single device company reporting these device failures

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One of things that the dental industry has done well is charting. When it comes to other types of implants, the brands are often unclear.

UNKNOWN VERSYS HEAD - Zimmer Biomet , 2017-11-06 , 7005412 [MDR]

Problem(s): Metal Shedding Debris, Corroded

IT WAS REPORTED THE PATIENT HAD A PRIMARY LEFT TOTAL HIP ARTHROPLASTY TO ADDRESS OSTEOARTHRITIS. THE PATIENT WAS THEN REVISED TO ADDRESS A BUILD UP OF METALLIC DEBRIS , ADVERSE LOCAL TISSUE REACTION (ALTR), METALLOSIS , ELEVATED METAL IONS LEVELS, PAIN AND DISCOMFORT, A PSEUDOTUMOR IDENTIFIED IN MRI, AND RELATED PARTICLE DISEASE/TRUNNIONOSIS, INTRA-OPERATIVELY, TISSUE NECROSIS AND PSEUDOTUMOR FORMATION WAS IDENTIFIED, AS WELL AS CORROSION AT THE HEAD/NECK JUNCTION. NO FURTHER INFORMATION HAS BEEN MADE AVAILABLE.

UNKNOWN DEPUY 36X52 ULTIMET LINER - Orthopaedics , 2016-04-13 , 5573887 [MDR]

Problem(s): Insufficient Information, Insufficient Information

THE PATIENT WAS REVISED TO ADDRESS PAIN, INSTABILITY, TRUNNIONOSIS, METALLOSIS AND MALPOSITIONED ACETABULAR CUP. UPDATE REC'D 03/16/2016 - THE PATIENT'S MEDICAL RECORDS WERE RECEIVED. MEDICAL RECORDS WERE REVIEWED FOR MDR REPORTABILITY. ACCORDING TO THE MEDICAL RECORDS, UPON REVISION THE PATIENT WAS FOUND TO HAVE AN ADVERSE LOCAL TISSUE REACTION , A SIGNIFICANT PSEUDOTUMOR FORMATION WITH METALLOSIS AND NECROTIC TISSUE, OSTEOLYSIS AROUND IMPLANT, CORROSION ON THE TAPER, AND A STRIPPED SCREW. AT THIS TIME THE PATIENT'S CUP, HEAD, LINER, STEM,...

Examples of Unknown Hips and Device Problem Codes

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It’s not always clear which device was being reported, but it is often clear that the materials used are causing serious tissue reactions.

UNKNOWN SCREW - Orthopaedics , 2016-04-13 , 5574457 [MDR]

Problem(s): Appropriate Term/Code Not Available, Appropriate Term/Code Not Available

THE PATIENT WAS REVISED TO ADDRESS PAIN, INSTABILITY, TRUNNIONOSIS, METALLOSIS AND MALPOSITIONED ACETABULAR CUP. UPDATE REC'D 03/16/2016 - THE PATIENT'S MEDICAL RECORDS WERE RECEIVED. MEDICAL RECORDS WERE REVIEWED FOR MDR REPORTABILITY. ACCORDING TO THE MEDICAL RECORDS, UPON REVISION THE PATIENT WAS FOUND TO HAVE AN ADVERSE LOCAL TISSUE REACTION , A SIGNIFICANT PSEUDOTUMOR FORMATION WITH METALLOSIS AND NECROTIC TISSUE, OSTEOLYSIS AROUND IMPLANT, CORROSION ON THE TAPER, AND A STRIPPED SCREW. AT THIS TIME THE PATIENT'S CUP, HEAD, LINER, STEM,...

ESSURE - Bayer , 2018-09-12 , 7868197 [MDR]

Problem(s): Adverse Event Without Identified Device or Use Problem

"NTANEOUS" CASE WAS REPORTED BY A LAWYER AND DESCRIBES THE OCCURRENCE OF PELVIC PAIN ("SEVERE AND PERSISTENT PAIN"), GENITAL HAEMORRHAGE ("ABNORMAL BLEEDING (GENERAL)"), HAEMORRHOIDS ("HEMORRHOIDS") AND AUTOIMMUNE DISORDER (" AUTOIMMUNE DISORDER: JOINT PROBLEMS DUE TO NICKEL") IN A (B)(6) FEMALE PATIENT WHO HAD ESSURE INSERTED FOR FEMALE STERILISATION. THE OCCURRENCE OF ADDITIONAL NON-SERIOUS EVENTS IS DETAILED BELOW. THE PATIENT'S CONCURRENT CONDITIONS INCLUDED ASTHMA, PRURITUS, PAP SMEAR ABNORMAL, UTERINE CRAMPS, PAINFUL INTERCOURSE,... ALLERGY

Symptoms shown by searching key terms in adverse event reports

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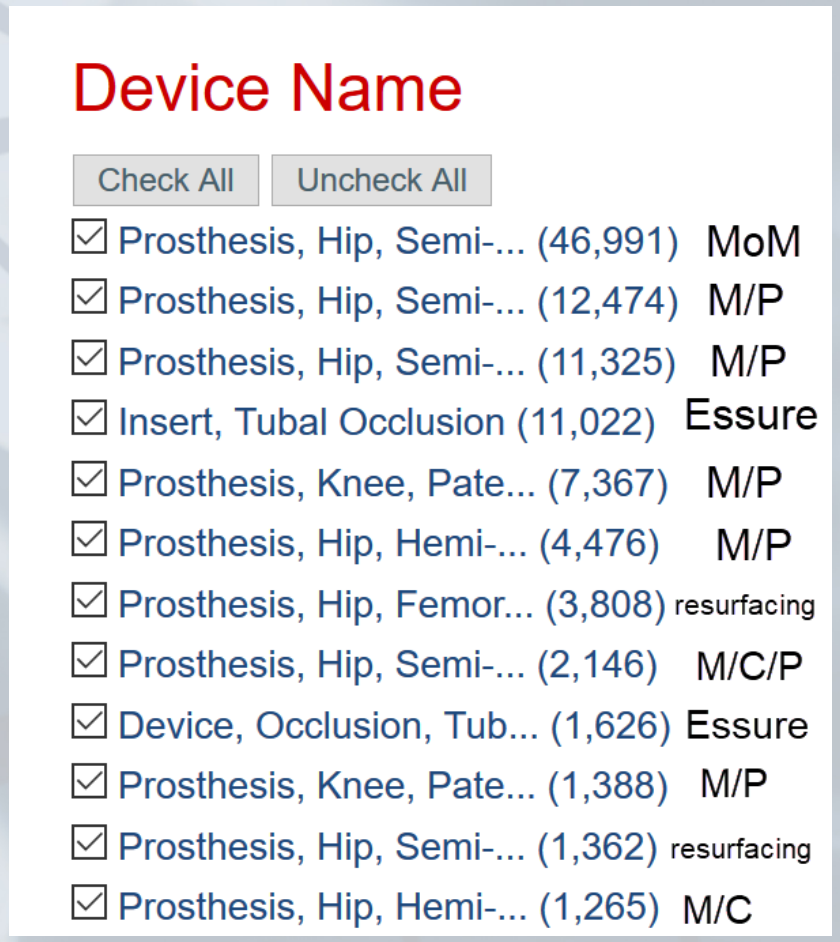
It is not just metal on metal hips that cause autoimmune, allergic and toxicity reactions.

MoM = Metal on Metal

M/P = Metal and Polymer

M/C/P = Metal, Ceramic and Polymer

M/C = Metal and Ceramic



The Office of the Inspector General estimates that only 14% of adverse events are reported to the FDA

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The types of metals used in devices are not regularly included in device labeling.

Often the materials include alloys containing nickel. Women typically know if they are allergic to nickel, but patients are not informed that this metal is going to be implanted in them.

The Unique Device Identifier (UDI) contains a field to collect whether the device contains latex, but not nickel, cobalt, chromium, etc.

Biocompatibility data for devices needs to be considered as soon as possible.

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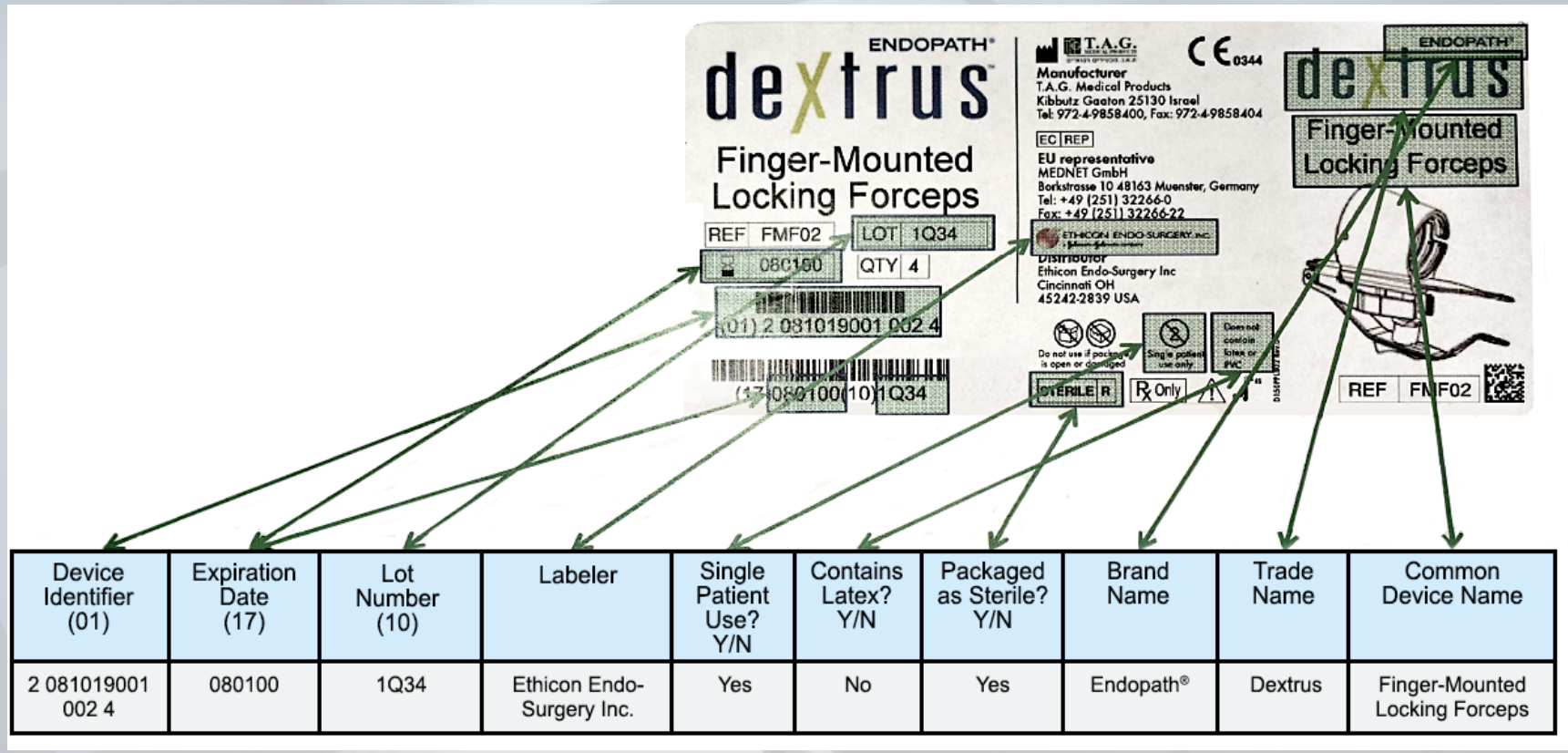
The Unique Device Identifier (UDI) is being integrated into Electronic Health Reports



Device Identifier (01)	Expiration Date (17)	Lot Number (10)	Labeler	Single Patient Use? Y/N	Contains Latex? Y/N	Packaged as Sterile? Y/N	Brand Name	Trade Name	Common Device Name
2 081019001 002 4	080100	1Q34	Ethicon Endo-Surgery Inc.	Yes	No	Yes	Endopath®	Dextrus	Finger-Mounted Locking Forceps

Why not label metals as stringently as you label latex?

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Allergy testing for any device material implanted in the body should be compulsory…even staples and clips.

Not all sensitivities and allergies can be detected in advance, but this will help physicians determine whether sutures or a different type of device/procedure should be considered.

Physicians and other care providers need to know what materials are in the devices they use, and that requires that manufacturers disclose this to the FDA, on the label, and in the UDI Database.

The Unique Device Identifier (UDI) should be updated to include metals and alloys contained in devices. This would allow Electronic Health Records to pull through data to the patient file that would help care providers know what might not compatible with their patient.

And finally: The FDA should strongly consider sending all types of physicians a Dear Doctor Letter to alert them to the systemic issues (allergy, autoimmune, toxicity) caused by metal-containing devices. They should be asked to review relevant patient files for underdiagnosis of these issues and be asked to report adverse events directly to the FDA so that the FDA has better and more information on which to base future regulatory and labeling decisions.