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Urgent Safety Information

Re-design of the Skull Screws (i.e., mounting screws) for Renaissance System Brain Application RBT Base (i.e., mounting platform)

May 28, 2014

Sender:

Manufacturer:
Mazor Robotics Ltd.
PO Box 3104
7 HaEshel St.
Caesarea Park South 3088900
Israel

Receiver:

[redacted]

Identification of the affected medical device:

The affected products are Renaissance System Brain Application Skull Screws made of Titanium.

These are the mounting screws of the RBT Base (the platform for the guiding unit) to the skull.

The screws are transient implants; they are used in the beginning of the surgery to mount the platform to the skull and removed at the end of the surgery.

Product category: transient implants, class IIa

Trade/Model Name: Skull Screws – accessory to the Renaissance System Brain Application

Model Number: MEC1978-01

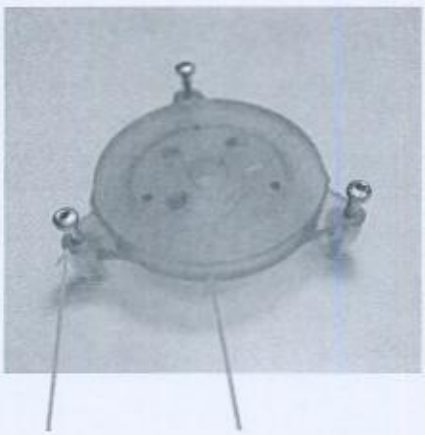
Lots:

1. *20068-001*
2. *19958-001*
3. *19249-001*
4. *18962-001*
5. *17915-001*
6. *17053-001*
7. *16178-001*

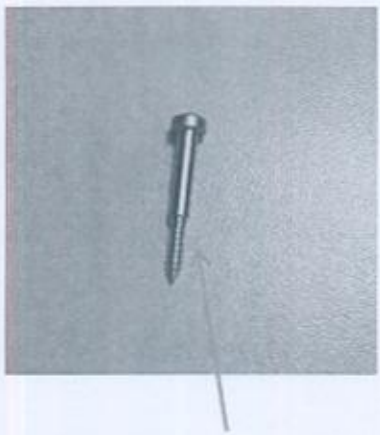
Description of the problem including the enclosed cause determined:

3 Skull Screws connects the RBT Base to the skull in brain surgeries with the Renaissance System Brain Application.

The Titanium Skull Screws are susceptible to breaking under high torque during insertion and removal.



Skull Screw



RBT Base

Skull Screw

Corrective Action:

Redesign Skull Screw – change the raw material to Stainless Steel (SS) 440C. The previous raw material was Titanium (Ti-6Al-4V ELI) which its tensile strength is ~860MPa (=125KSI). The chosen material to replace the Titanium is Stainless Steel (SS) 440C heat treated which has up to ~2000MPa tensile strength (=290KSI) i.e., ~230% stronger.

Risk Evaluation:

The risk for patients during the use of the Titanium Skull Screws: Skull Screws Breakage.
The hazard: Skull Screw breaks during insertion to or removal from the skull
Cause of Failure: Fatigue of material (Titanium)
Harm: may extend operation time, may have a cosmetic implication to the patient (i.e., larger incision)
Mitigation: redesign of Skull Screw – change raw material from Titanium to Stainless Steel

There are no risks for patients that had gone through surgeries with the Titanium Skull Screws. The screws were removed from the patients. The screws are not long term implants but a supporting accessory to the system during the operation.

There is no risk to users or third parties during the ongoing use of the product.

Actions to take by the receiver:

Since Mazor Robotics representative is present at every surgery performed with the assistance of the Renaissance System the user/receiver does not have to take any action.

Mazor Robotics representative has already replaced all the Titanium Skull Screws with the redesigned screws made of Stainless Steel at the site and will notify the site of this change implementation immediately.

How to transfer the information described herein:

Please make sure in your organisation, that all users of the above mentioned products and other persons that need to be informed will receive this Urgent Safety Information. If you provided these products to third parties, please forward a copy of this information to them as well or inform contact person listed below.

Please retain this information until the corrective action has been completed.

The Federal Institute of Drugs and Medical Devices (BfArM) has received a copy of this Urgent Safety Information as well.

Contact person in Germany:

Dr. Roland Peplinski
Vice President Europe

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Sincerely,

[redacted]

Regulatory Affairs & Quality Assurance Manager

[redacted]