National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Notice about Rebound HRD® inguinal hernia mesh implants

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A. van Leeuwenhoeklaan 9
3721 MA Bilthoven
P.O. box 1
3720 BA Bilthoven
The Netherlands
www.rivm.nl/mebi

T +31 30 274 91 11

The Dutch Reporting Centre for Adverse Effects of Medical Implants (MEBI) has received a report about the inguinal hernia mesh implant Rebound Hernia Repair Device (Rebound HRD®, ARB Medical LLC, VS). The report pertained to a bowel perforation caused by the metal ring in the implant that broke. This very serious side effect occurred five years after implantation.

The breaking of the Rebound HRD® and the possibility of a bowel perforation are known problems. For this reason the Rebound HRD® inguinal hernia mesh was withdrawn from the market in 2018. Given the construction of the implant, its location and duration of stay in the body (lifelong), we estimate there is a high risk of the metal ring breaking during the time the implant resides in the body. Therefore, we expect that ensuing side effects will continue to present themselves in patients with this implant. We are issuing this notice to bring this ongoing risk under the attention of all healthcare professionals concerned and carriers of this implant.

The Rebound HRD® consists of a mesh made of synthetic fibres with a metal ring attached along the edge of the mesh. Implanted in a mobile area like the groin, repeated movement of the metal ring in the implant will lead to metal fatigue, which could cause the ring to break. With this in mind, it is likely that in a significant number of cases the ring in the Rebound HRD® could break at any point during the implant's stay in the body. The timeframe within which the metal ring could break is not yet known. Nor is it currently known how high the risk is of organ perforation or other tissue damage after the metal ring breaks.

A total of 3,266 Rebound HRD® devices were sold in the Netherlands between 2014 and 2018. Every year, between 27,000 and 30,000 inguinal hernia meshes are implanted in the Netherlands. The Rebound HRD® devices therefore represent only a small fration (2% to 2.5%) of the total number of inguinal hernia meshes implanted between 2014 and 2018.

We are issuing this notice to ask all healthcare professionals concerned to be alert of the risk of serious side effects in patients who have been implanted with the Rebound HRD® inguinal hernia mesh. People who have been implanted with this implant and experience health complaints (like localised pain) can consult their general practitioner or attending physician. Both healthcare professionals and patients are requested to report any side effects they relate to the Rebound HRD® or to other implants to MEBI, via rivm.nl/mebi.

This notice will be updated if more information becomes available to MEBI about breakage of the ring and the occurrence of side effects like pain or organ perforation.

Rebound HRD® - about the implant

The Rebound Hernia Repair Device (HRD)® (manufactured by ARB Medical LLC., USA) is a type of inguinal hernia mesh implant. Inguinal hernia meshes are implants woven from synthetic wire. Often polypropylene is used for this purpose. Mesh implants are used to strengthen weaknesses in body tissue. In the case of an inguinal hernia, there is a weakness in the abdominal wall through which abdominal contents (fat or intestine) can protrude. In inguinal hernia surgery, an inguinal hernia mesh is implanted to enhance recovery of the inguinal hernia and reduce the risk of the patient developing a new inguinal hernia.

The Rebound HRD® was sold in the Netherlands from 2014 to 2018 inclusive. Following reports in the Netherlands and other countries about the metal ring breaking, the manufacturer recalled all stocks of the product in October 2018. The Notified Body also withdrew the CE mark. From 2014 to 2018 inclusive, 3,266 Rebound HRD® devices were sold in the Netherlands. It is unclear how many of these devices were actually implanted. In total, between 27,000 and 30,000 inguinal hernia meshes are implanted in the Netherlands every year. In other words, the Rebound HRD® represents only a small percentage of the total number of inguinal hernia meshes implanted.

The Rebound HRD® is different to other inguinal hernia meshes because of the thin, flexible, elastic ring present along the edge of the mesh. This ring consists of a multi-strand wire made from nitinol, a shape-memory alloy. A multi-strand wire is more resilient to frequent bending than a solid wire. The ends of the wire are clamped together in the metal sleeve to form the ring. When implanting the device, the ring causes the mesh to unfold and lie flat against the peritoneum. It is also designed to ensure the device stays in place better and is less likely to fold after implantation.

About the metal in ring in the Rebound HRD® breaking

The Rebound HRD® is sensitive to failure due to metal fatigue. This is the conclusion of a failure mode analysis of the Rebound HRD® commissioned by the manufacturer [1]. The article describes two causes. On the one hand, the implant location in the body, because the groin is a mobile area. On the other hand, the construction of the metal ring. The sleeve that clamps together the ends of the nitinol wire introduces a strong transition in material stiffness. Such areas are at particular risk of metal fatigue development. Any metal that is bent repeatedly will develop metal fatigue [1]. To our knowledge, there are no other mesh implants that contain a metal wire.

About the occurrence of organ perforation

In the Netherlands, two cases of bowel perforations occurring after the ring in a Rebound HRD® broke have been reported. A number of other cases have been reported in other countries. One of these was a case in Belgium, about which a case report was published in 2020 [2]. At this time, much is still unclear about the risk of serious tissue damage when a Rebound HRD® breaks. For example, the timeframe within which these implants break, or how many of them break, is still unknown. Another unknown factor is the extent of the risk of serious side effects after the ring breaks. One complicating factor is that broken rings will not necessarily lead to

problems straight away or in the longer term and they may go unnoticed for an unknown period of time. To gain insight into these risks, it is important that all health complaints that may be caused by the Rebound HRD® are reported to MEBI.

Conclusion

This MEBI notice reports about the Rebound HRD® inguinal hernia mesh, which contains a metal ring that can break as a result of metal fatigue. Given the long duration of stay in the body and the mechanism of failure, we consider there is a high risk of the ring breaking during the implant's lifespan. A broken ring may cause tissue damage and organ perforation, resulting in serious, acute health complaints. The timeframe within which the rings break is currently unclear, as is the extent of the risk of (serious) side effects. For these reasons, it is important for patients who have been implanted with a Rebound HRD® and their healthcare professionals to remain vigilant to the possibility that the Rebound HRD® could cause (serious) health complaints. To find out more about the possible risks, we request physicians and patients to report side effects to MEBI.

MEBI operates a voluntary reporting system for the suspected side effects of implants. The frequency at which a side effect occurs cannot be derived from the number of reports received because of their voluntary nature. As such, the number of reports do not provide any information about the risk of a side effect. The objective of a reporting system like MEBI's is to identify signs of possible problems with implants as soon as possible. This paves the way for research, which could be of a large-scale (epidemiological) nature but does not fall within MEBI's remit. Website MEBI: rivm.nl/mebi

References

1. Oliphant R., and Erdman A. Failure Mode Analysis and Design Optimization of a Nitinol Framed Hernia Repair Device. ASME. J. Med. Devices. June 2016; 10(2): 020965. https://doi.org/10.1115/1.4033286
2. Cornette J., Vindevoghel K., and Lange C.P. Sigmoid perforation by broken nitinol memory frame after inguinal hernia repair. Acta Chir Belg. Feb. 2022; 122(1):67-69. doi: 10.1080/00015458.2020.1765670. Epub 2020 May 18. PMID: 32374656