mz Liberec, a.s.

Urgent FIELD SAFETY NOTICE

Ceiling pendant SPR 10

08/05/2015

Device Modification

MATTER:	**The change of the material for the axial segment in ceiling pendant.**
ADDRESSEE:	**All the users and biomedical staff dealing with the ceiling pendants**
DETAILS ON AFFECTED DEVICES:	**Ceiling pendants with compact, spring balanced, tilting and swivelling arms (SPR 10)** **Catalogue number: 093008101** **Manufactured: MZ Liberec a.s.** **Production period: 21.4.2010 – 20.4.2015**

Dear customer,

The purpose of this notification is provide the users of the ceiling pendants SPR 10, type SPR 10-1, SPR 10-2, SPR 10-3, with the preventive alerts. According to our records you received the above mentioned product.

Following notification of an incident of failure of an axial segment of a ceiling pendant component, MZ Liberec is initiating a field safety corrective action. Our company will substitute all the axial segments in the field for the new ones. You should receive these new parts along with this notice. We have also increased the inspections of these components as part of the manufacturing process to prevent reoccurrence of similar incidents in the future. It is important that all users inspect the axial segment components for excessive wear. If the any part of the segment has a thickness of less than 1.7 mm, users should cease using the product immediately.

Technical description of the corrective action:

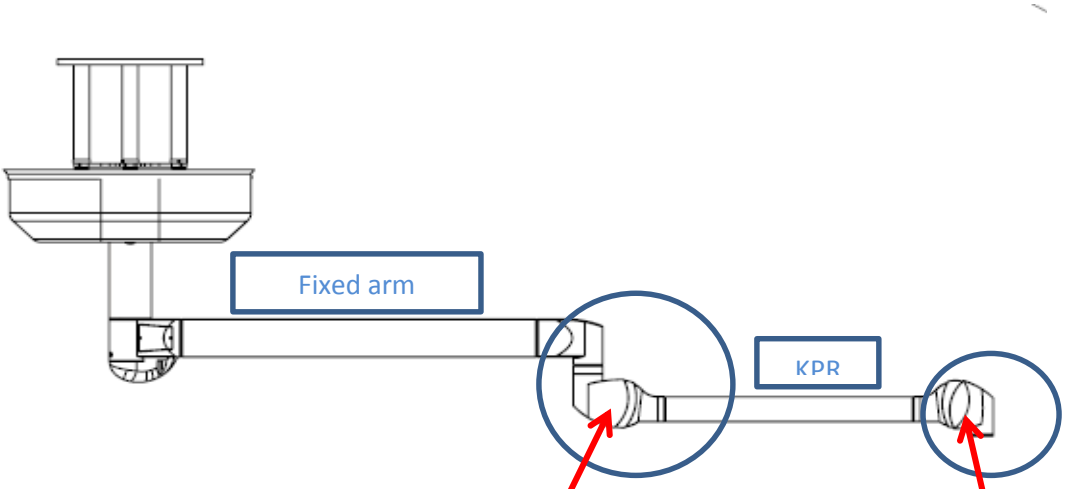
The axial segments will need to be removed and replaced with the new ones supplied to you by MZ Liberec. This process can be safely performed by the user/owner of the device.

MZ Liberec is more than happy to provide support during the installation process by phone or skype. MZ Liberec, a.s. preventively developed a new solution, which (in case of proper installation and periodical performance of the technical safety inspection) shall significantly reduce the risk of the damage of our product. New material and its subsequent heat treatment significantly decrease wear of the axial segment.

The process of the exchange:

1. Take away the plastic casing between the fixed arm and the moveable arm (KPR). Then the KPR must be locked to prevent from unwanted movement (picture 1).

CAUTION: the increased possibility of injury

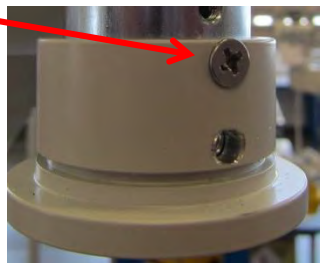


Picture1

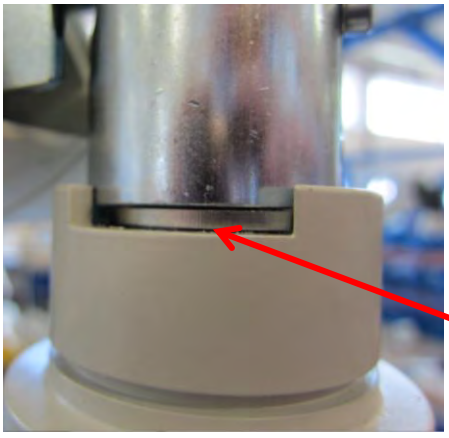
Picture2

2. Taking away the plastic casing from KPR (picture 2) enables to take away with the screwdriver the plastic cover of the axial segments (picture 3).

Picture 3



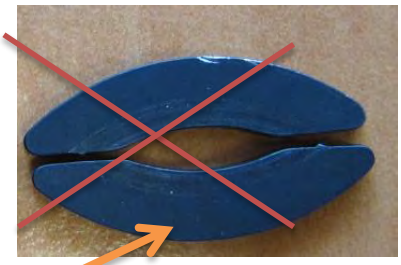
3. After the disengagement of the casing, twist and take away one of the axial segments (picture 4). Replace the original axial segment with the new one. Then you can take away the second axial segment and replace it with the new one in the same way. Be careful when uninstalling the segments. Only in case that one of the axial segment is replaced and the second one is still installed, the manipulation with the pendant is secure and the accessories is not supposed to fall.



Picture4

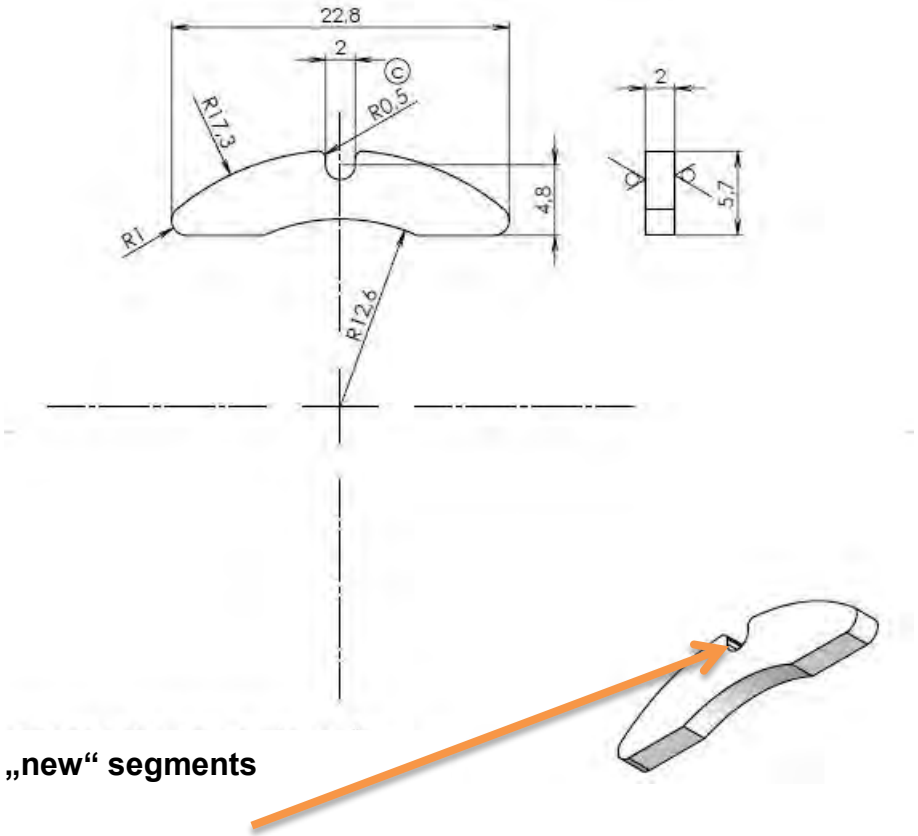
CAUTION: Do not uninstall both the axial segments concurrently, it may cause the fall of the accessories

Pictures for the quick and easy recognition “former” or “new” segments:



„former“ segments

Don´t have the notch on the outer edge segment.



„new“ segments

Have the notch on the outer edge segment.

Reinstallation is performed according to the reverse process (from step 3 to step 1).

This measure must be performed in 6 months since delivery of this notification.

Possible risks:

Continuing to use the old axial segments when they have a thickness of less than 1.7mm may lead to following situations:

1. The fall of the accessories to the operation or examination field.
2. Neglect of the periodic technical safety inspection may lead to grinding through of the axial segments and subsequent disengagement of the whole device during the operation or physical examination of the patient. Such an omission may have serious consequences for the medical staff and the patients.

The measures recommended to the users/health care providers:

The clients are supposed to receive the new segments along with this notice. The clients are required to confirm the delivery of this Field Safety Notice and delivery of the new segments. The confirmation (signed and scanned FSN) please send via email on info@mzliberec.cz. Along with the confirmation please send us the list of serial numbers of the devices placed at your organization.

The above mentioned exchange of the segments must be performed in 6 months since delivery of this notification. Please inform us as soon as the exchange is finished and send us back the former segments. Our company intends to perform additional tests focused on the used segments.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Mr. Martin Hájek, the head of board of directors, MZ Liberec, a.s.

We do apologize for any inconvenience, which may occur in your organization in connection of the usage of the SPR 10. We make every effort to protect the medical staff and the patients. In case of any doubt, do not hesitate to contact our company MZ Liberec a.s, info@mzliberec.cz.

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Martin Hájek
Head of Board of Directors

I hereby confirm receipt of the Field safety notice and new axial segments:

Organization: ……..

Name, function: ……..

Signature: ……