



Urgent Field Safety Notification

Safety information on KARL STORZ Equipment Carts 29005DRB, 29005DRS, 29005GI and Isolation Transformers 29005TBG and 29003TBK on behalf of the company Trumpf Medizinsysteme GmbH & Co.KG

Addresser:

KARL STORZ GmbH & Co. KG
Mittelstrasse 8
78532 Tuttlingen
Germany

Addressee:

This safety information is directed to users and distributors of the Equipment Carts and Isolation Transformers listed below.

Identification of affected medical devices:

Listed by article and serial number

Art.29005DRB							
RW1598	RW1607	RW1621	RW1629	RW1637	RW1646	SW1655	TW1672
RW1599	RW1608	RW1622	RW1630	RW1638	RW1647	SW1656	TW1680
RW1600	RW1610	RW1623	RW1631	RW1639	RW1648	SW1658	TW1684
RW1601	RW1611	RW1624	RW1632	RW1640	RW1649	SW1660	
RW1602	RW1616	RW1625	RW1633	RW1641	RW1651	TW1666	
RW1603	RW1618	RW1626	RW1634	RW1642	RW1652	TW1667	
RW1604	RW1619	RW1627	RW1635	RW1644	SW1653	TW1668	
RW1605	RW1620	RW1628	RW1636	RW1645	SW1654	TW1670	
Art.29005DRS							
RW1267	RW1268	RW1269	RW1270	RW1273	RW1274		
Art.29005GI							
RW1567B	RW1569B	RW1571B	RW1574B	RW1576B	RW1578B	RW1581B	RW1586B
RW1568B	RW1570B	RW1573B	RW1575B	RW1577B	RW1579B	RW1582B	RW1587B
Art.29005TBG							
RW3074	RW3076	RW3078	RW3090	RW3092	SW3094	SW3102	
RW3075	RW3077	RW3089	RW3091	RW3093	SW3099		

Description of the problem, including the determined cause:

The supplier informed KARL STORZ about a potential defect in the products mentioned above.

Our supplier reports that main cords with defective protective conductors were found during final inspection. In the course of the manufacturing process, the stranded wires of the main cord's protective conductor may have been damaged. Depending on changes in cable positioning, this pre-existing damage may lead to the protective conductor losing contact at the IEC receptacle for devices. As the defect occurs only in certain positions, which can vary in between the cable, cables have been properly tested and released despite the potential defect.

In case of an insulation defect in an electrical device that may lead to voltage on the housing, touching the device may result in this voltage being conducted through the body because of the potentially interrupted protective conductor at the cord of the equipment cart.

Measures to be taken by the user:

See attached instructions for exchange of the main cord

Contact person:

You can of course contact us directly:

Safety Officer

Mr. Horst Chr. Weiss

 +49 7461 708 353

Email: Horst.Weiss@karlstorz.com

KARL STORZ GMBH & Co. KG



i. V. Horia Leonescu
- Global VP Quality Management
Regulatory Affairs -



i.A. Horst Chr. Weiss
- Global Director Reprocessing
Sterilization Biocompatibility -

REPLY fax/email to:
KARL STORZ GmbH & Co. KG
Fax: +49 – (0)7461 / 708-75903
Email: incident@karlstorz.com

«Firma_»
«Hr_Frau»«Ansprechpartner1_GL»
«Straße_»

«PLZ_»«Ort_»

Please return this reply including the completed enclosed form to KARL STORZ within 10 working days. Please note that the quantities you report on the enclosed form or return to us must exactly match the total quantity listed on the enclosed form. This is the only way we can account for the whereabouts of 100% of the recalled products to the authorities.

Please mark (☒) the box next to the applicable statement:

We hereby confirm that we have replaced the mains cord of the affected Equipment Carts 29005DRS, 29005DRB, and 29005GI as well as the Isolation Transformers 29005TBG and 29003TBK. The defective cord has been marked as a return from a recall and sent to the KARL STORZ Service Department.

We hereby confirm that we have replaced the mains cord of the affected Equipment Carts 29005DRS, 29005DRB, and 29005GI as well as the Isolation Transformers 29005TBG and 29003TBK. We properly disposed of the defective cord; it is no longer usable.

Number of cords returned or disposed of: _____

Date, place

Stamp / signature