



Urgent Safety Information in Field (Field Safety Notice)

FSN 2022-001

Modification of the reprocessing instruction

Concerning

Suction and Irrigation Instruments

DEWIMED Medizintechnik GmbH

Datum: 15.11.2022

Sender: DEWIMED Medizintechnik GmbH
Unter Hasslen 14
78532 Tuttlingen

Recipient: Distributor and user from below mentioned products

Betroffene See ANNEX I of this Urgent Safety Information Letter.

Produkte:

Dear Customer,

It appears from our records that you have received one or more suction and irrigation instruments with one of the LOT numbers listed below. With this letter we would like to inform you about a corrective action.

Identification of affected medical devices:

A problem has been identified in the instructions for use provided with the Saug und Spülinstrumente from DEWIMED.

Suction tubes are used for flushing and cleaning a wide variety of body fluids in body cavities during surgical interventions. The products are used in all general surgery and all disciplines where the surgical field must be cleaned of secretions and body fluids.

They consist of a stainless steel tube and a hose connection for the suction hose. The suction tubes are connected to all suction/irrigation pumps via the suction hose.

The associated part numbers and description can be found in ANNEX I.

Description of the problem including identified cause:

During a review of the reprocessing instructions for DEWIMED suction and irrigation instruments, it was found that the information of the reprocessing process described there did not yet follow the currently validated process specifications.

DEWIMED then carried out a preliminary investigation and found that the problem with the reprocessing instructions was not related to the products. Therefore, there is no problem with the listed products and therefore no obligation to recall the products.

However, in further investigation, it had to be determined that the reprocessing instruction needs to be updated, as the version currently shipped with the products does not reflect the most current information available.

It was found that the current version, of the reprocessing instruction supplied by DEWIMED has differences in the declared reprocessing information from the information already available.

The change between the versions is mainly related to the change in cleaning media used for cleaning the products



during validation, cleaning temperature as well as rinsing parameters. In both versions, however, only cleaning media that have been proven to be approved for the reprocessing of medical devices were used. The parameters used also always complied with the standard specifications for the reprocessing of reusable medical devices. Since both reprocessing methods involved validated processes and cleaning media approved for medical technology, there was no risk that the products concerned could not be reprocessed safely.

Risk assesment:

A negative impact on medical devices already in circulation cannot be assumed, since validated reprocessing procedures as well as cleaning media approved for medical technology were always involved. The problem has no impact on diagnosis or treatment. Therefore, a negligible health risk is associated with this problem. A recall is not required.

What actions are to be taken by the recipient?

1. Make sure that all your internal and external customers are informed about this corrective action.
2. Please identify the products listed in Annex I and immediately ensure the replacement of the reprocessing instruction from version BB to version O3.
3. Dispose of the invalid reprocessing instruction (version BB)
4. Fill in the attached confirmation form and send it by mail to qm@dewimed.com. Indicate that you have understood and performed the corrective actions.

Disclosure of the information described herein:

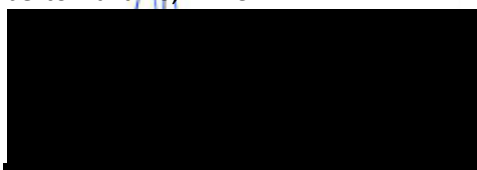
Please ensure in your organization that all users of the products listed in ANNEX I and other persons to be informed are made aware of this Urgent Safety Alert. If you have supplied products to third parties, please forward a copy of this information or inform the contact person indicated below.

Please keep this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contact person:

Gilberto Navarro, PRRC



15.11.2022



Feedback Formular

FSN 2022-001

Suction and Irrigation Instruments

DEWIMED Medizintechnik GmbH

We ask you to return the completed feedback form by mail to:

Department QM/RA – Responsible Person Hr. Gilberto Navarro

Mail: qm@dewimed.de

Please check immediately whether you still hold stocks of the suction and irrigation instruments of DEWIMED Medizintechnik GmbH listed in ANNEX I. Please note that this measure only refers to the products and LOT numbers listed in ANNEX I!

Confirm that you have read and understand this letter and will / have taken the required actions.

We have checked our stocks and carried out the necessary measures, replacement of the reprocessing instruction.

We have checked our stocks and no longer have any of the affected products and lots in stock or in use.

Name of the facility	
Name / Title of the contact person	
Adress	
ZIP CODE, Place	
Phone Number	
Mail address:	

Datum

Unterschrift



ANNEX I - List of related products Suction and Irrigation Instruments

DEWIMED REF	Bezeichnung / Description	LOT
04.140.08	POOLE Saugrohr Ø8mm, 23 Charr.	22101360, 22102111, 22102112, 22103862, 22105490, 22202302, 22205951
04.150.27	YANKAUER Saugrohr, 27cm	21903205, 21903435, 21903423, 21903434, 22100959, 22101214, 22101215, 22102247, 22102114, 22102115, 22102116, 22102117, 22102118, 22102119, 22102120, 22102121, 22102122, 22102123, 22102124, 22102125, 22102126, 22102127, 22102113, 22102041, 22102042, 22206913, 22207314, 22206914, 22202816, 22206915, 22206916, 22207317, 22206911, 22207316, 22202409, 22206912, 22203565, 22203566, 22203567, 22203568, 22203569, 22203571, 22203572, 22203573, 22203574, 22203736, 22207315, 22206917
04.155.35	MAGILL Saugrohr, 24,5cm, Ø3,5mm	22201186
04.155.40	MAGILL Saugrohr, 24,5cm, Ø4mm	22201187
20.170.05	SCHMID Kanuele Gefaess 5 mm	22101213
22.232.12	QUINCKE Kanuele z.Lumbalpunkt.1,2x89mm	21806730
22.302.01	MENGHINI Nadel 1,0 x 35 mm	22205268 22205969
22.302.02	MENGHINI Nadel 1,0 x 70 mm	22205269 22205970
22.302.05	MENGHINI Nadel 1,4 x 70 mm	22205270 22205971
22.302.06	MENGHINI Nadel 1,4 x 100 mm	21805128
22.302.08	MENGHINI Nadel 1,8 x 100 mm	21805129
40.287.13	YASARGIL Saugrohr 2,0 mm 13 cm	21901322
40.287.15	YASARGIL Saugrohr 2,0 mm 15 cm	21901323 21902127
40.287.18	YASARGIL Saugrohr 2,0 mm 18 cm	21702567
40.288.13	YASARGIL Saugrohr 2,5 mm 13 cm	21705910 21901324
40.288.15	YASARGIL Saugrohr 2,5 mm 15 cm	21901325
40.288.18	YASARGIL Saugrohr 2,5 mm 18 cm	21704051
40.289.18	YASARGIL Saugrohr 3,5 mm 18 cm	21704050
40.293.12	FRAZIER Saugrohr 30° 12Ch.12cm	21806793, 21901327, 22102194, 22102445, 22102446, 22103480
40.295.06	FRAZIER Saugrohr 30° 6Ch.19cm	21807392, 21903855, 21904111, 21906737, 21906972, 21907358, 22000785
40.295.07	FRAZIER Saugrohr 30° 7Ch.19cm	21903856, 21906911, 21906918, 21907374, 21907375, 21907692,



DEWIMED REF	Bezeichnung / Description	LOT
		22100215, 22201200, 22205774, 22206241
40.295.08	FRAZIER Saugrohr 30° 8Ch.19cm	22101361, 21808200, 21810704, 21810705, 21900459, 21705677, 21902481, 21902449, 21902450, 21902662, 21907195, 21906738, 22003047, 22003048, 22100206, 22100207, 22101361, 22102155, 22103247, 22103837, 22103869, 22104014, 22105003, 22105088, 22204473, 22204781, 22204881, 22205775, 22205972, 22206242, 22206926
40.295.09	FRAZIER Saugrohr 30° 9Ch.19cm	21806028, 21808480, 21811703, 21808653, 21902663, 21903858, 21903857, 21904112, 21904498, 21906462, 21907391, 21907570, 21906636, 21906912, 22100270, 22100723, 22201201, 22202289, 22205776, 22206243, 22206542
40.295.10	FRAZIER Saugrohr 30° 10Ch.19cm	21806029, 21806524, 21808201, 21808202, 21808655, 21808481, 21811308, 21810706, 21811309, 21810707, 21810708, 21810709, 21811680, 21811681, 21904043, 21905230, 21907376, 21908397, 22003049, 22102156, 22102157, 22102256, 22102257, 22104015, 22200252, 22200253, 22200436, 22201202, 22202290, 22203395, 22203870, 22205777, 22205778, 22206543, 22206930, 22206244
40.295.11	FRAZIER Saugrohr 30° 11Ch.19cm	21904348, 22000530, 22102447, 22103248, 22103424, 22104323
40.295.12	FRAZIER Saugrohr 30° 12Ch.19cm	21808505, 21808482, 21808658, 21810710, 21810711, 21810712, 21810713, 21810714, 21810715, 21810716, 21900050, 21903859, 21906739, 21907359, 21907377, 21907566, 21907378, 21907379, 21908398, 22002787, 22102158, 22104016, 22104324, 22105089, 22105763, 22200054, 22200438, 22201284, 22201285, 22204503
40.297.12	FRAZIER Saugrohr 75° 12Ch.19cm	21206367
44.101.03	BARON Saugrohr 1 mm = 3 Charr.	21805569, 21805864, 21701197, 21902664
44.101.07	BARON Saugrohr 2 mm = 7 Charr.	21700669, 21808498, 21701198, 21811312, 22201169
44.103.01	HOUSE Saug- Spülrohr Fig. 1	21902451, 22003051, 22101840, 22105007, 22204474, 22204475, 22204476, 22204477, 22205779, 22205973, 22206544
44.103.02	HOUSE Saug- Spülrohr Fig. 2	21700999, 21700996, 22201160, 22204478, 22205780, 22205974, 22207263
44.103.03	HOUSE Saug- Spülrohr Fig. 3	21701000, 21700997, 22101841, 22101842, 22201161, 22204479, 22204480, 22204481, 22204482, 22205781, 22205782