



نتقدم بثقة
Moving Forward
with Confidence



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 68 dated 12/4/2023 Regarding NCMDR Field Safety Notice of Flex. Grasping Forceps, Flex. Biopsy Forceps from (mfr: Richard Wolf GmbH).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



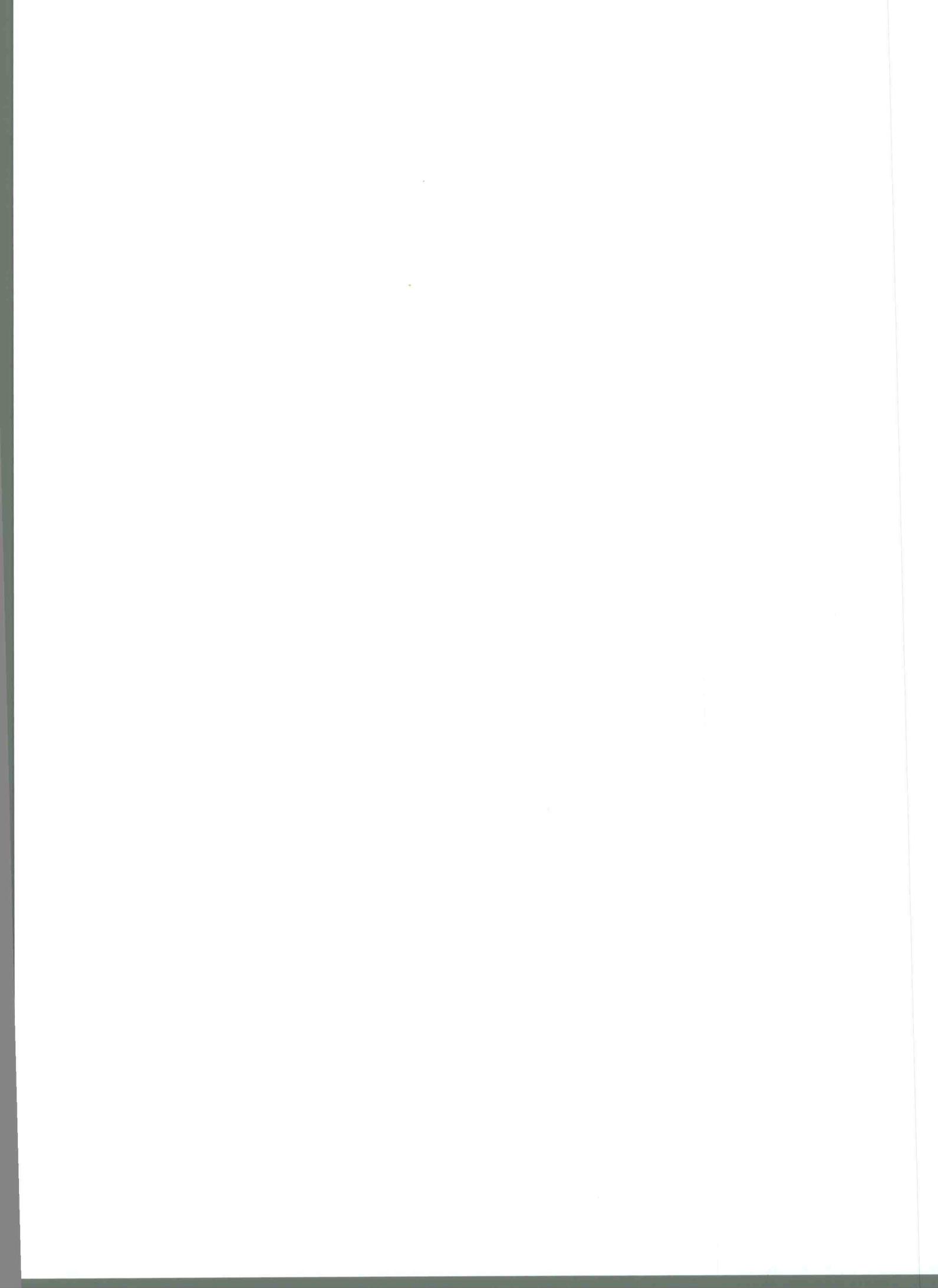
PADDC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

Twitter: dgpa_dc Email: dg-padc@moh.gov.om





Circular No. 68 / 2023

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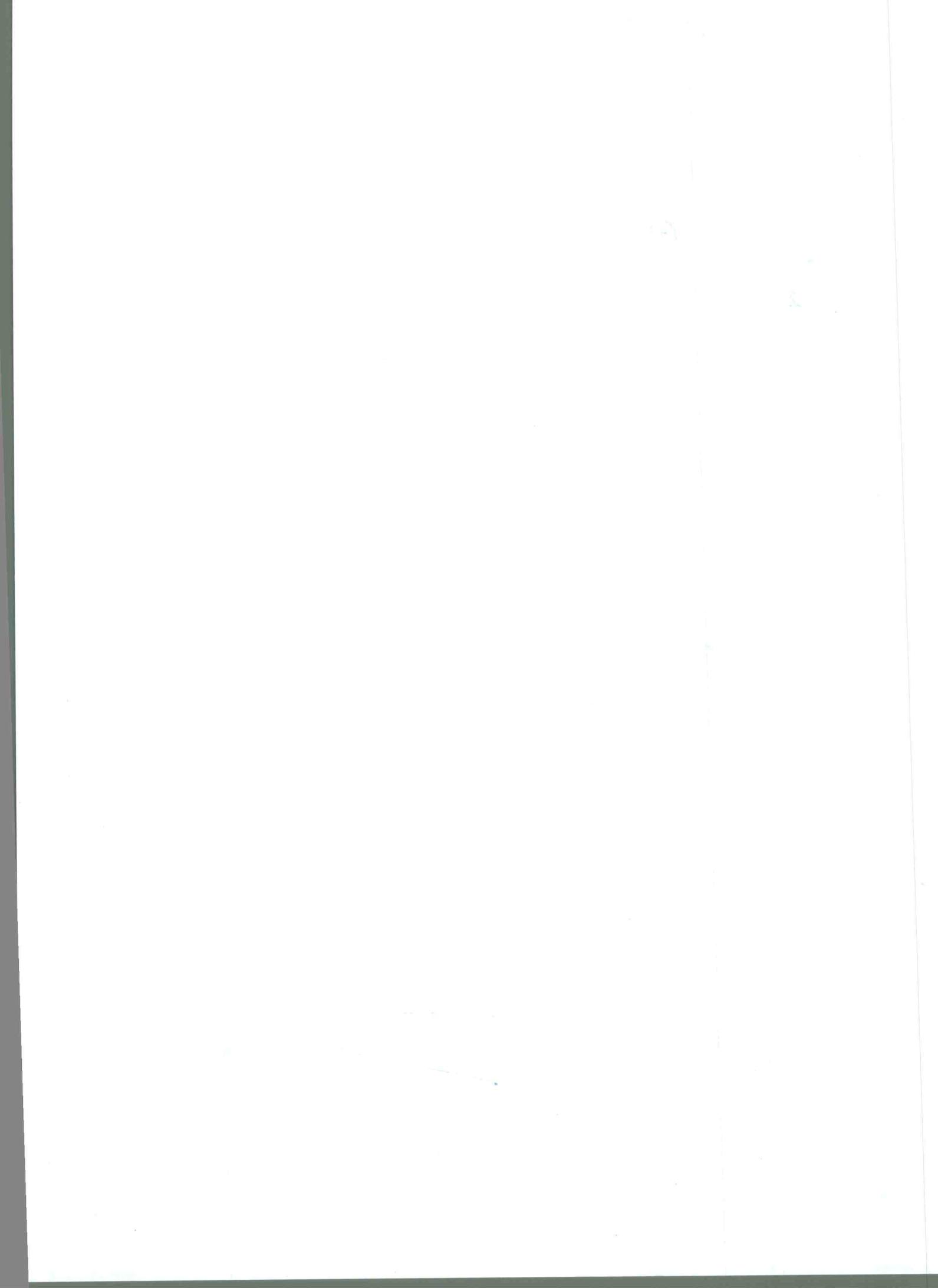
12 -04-2023

Field Safety Notice of Flex. Grasping Forceps, Flex. Biopsy Forceps from Richard Wolf GmbH.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19497
Product	Flex. Grasping Forceps, Flex. Biopsy Forceps.
Description	Biopsy Forceps.
Manufacturer	Richard Wolf GmbH.
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	828051 FLEX. GRASPING FORCEPS 5 FR WL 550 MM 8735685 FLEX. GRASPING FORCEPS 5 FR WL 550 MM 829051 FLEX. BIOPSY FORCEPS 5 FR WL 550 MM 8736685 FLEX. GRASPING FORCEPS 6.6 FR WL 550 MM Affected batches: refer to the attached FSN
Reason	The forceps can no longer be opened during use.
Action	1. Please follow the steps mentioned in the Measures to be taken by the addressee in the attached FSN. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General





Richard Wolf GmbH • Postfach 11 64 - 65 • 75434 Knittlingen, Germany

Department: Customer Service
Administrator: Thilo Musikant

Tel.: +49 70 43 35 4189
Fax: +49 70 43 35 1360
E-mail: thilo.musikant@richard-wolf.com

Your reference • Your correspondence dated • Our reference • Date
QM700020652 15.03.2023

Emergency safety notice

Affected products:

828051 FLEX. GRASPING FORCEPS 5 FR WL 550 MM
8735685 FLEX. GRASPING FORCEPS 5 FR WL 550 MM
829051 FLEX. BIOPSY FORCEPS 5 FR WL 550 MM
8736685 FLEX. GRASPING FORCEPS 6.6 FR WL 550 MM

Dear Sir / Madam,

As part of our continuous product monitoring procedure, our attention has been drawn to potential difficulties that arise when the aforementioned flexible grasping and biopsy forceps are used under certain conditions. According to our records, you operate the potentially affected product. This letter provides information on how to safely use the forceps in the event that the problem being referred to arises during use.

The flexible forceps are used for grasping and manipulating, and for the dissection and biopsy of tissue parts, organs, or foreign bodies via natural, artificial, or surgically created access passages.

The affected forceps are combined with the following products for use on patients:

7305001 FIBER CYSTOSCOPE 15 FR WL 400 MM
7305006 FIBER CYSTOSCOPE 15 FR WL 400 MM
7315001 SENSOR CYSTOSCOPE 16.2 FR WL 400 MM (MAMBA PF)
7315006 SENSOR CYSTOSCOPE 16.2 FR WL 400 MM (MAMBA PF)
73151001 SENSOR CYSTOSCOPE 16.2 FR WL 400 MM (MAMBA EF)
73151006 SENSOR CYSTOSCOPE 16.2 FR WL 400 MM (MAMBA EF)

Affected batches:

Product number:	Batches:
828051	4500377299 4500377299 4500371834 4500374645 4500369724 4500367397 4500363662 4500363096 4500359201 4500356582 4500353558 4500350415 4500347760 4500345769 4500341314 4500341314 4500338447 4500336245 4500334737 4500334002
8735685	4500377618 4500377296 4500374239 4500371819 4500367415 4500363102 4500367414 4500363666 4500363102 4500359744 4500357831 4500354319 4500352415 4500349678 4500344619 4500347121 4500349678 4500348605 4500344619 4500347121 4500344619 4500341300 4500338554 4500337773 4500335110
829051	4500377840 4500377840 4500377840 4500376297 4500371970 4500363663 4500363098 4500361404 4500353562 4500349168 4500347747 4500338560 4500333999
8736685	4500377853 4500371811 4500377297 4500371813 4500367418

	4500367417
	4500363668
	4500363104
	4500359203
	4500356576
	4500353566
	4500352416
	4500350353
	4500347761
	4500347761
	4500346491
	4500344550
	4500341309
	4500338558
	4500334010

The problem

We have received complaints from users stating that the forceps can no longer be opened during use.

Our investigation has shown that the affected forceps can be opened when handled properly. This means that the endoscope and flexible forceps must not be bent at an angle that is not required for the application in question, even when the endoscope tip is fully angled.

If the endoscope tip is fully angled and the endoscope sheath is also bent by more than approximately 90°, it may no longer be possible to fully open the jaw section. From this position onward, use begins to be restricted.

If the proximal forceps sheath is also bent, it is no longer possible to open the forceps; use may even begin to be restricted with a smaller endoscope bending angle (Figure 2).

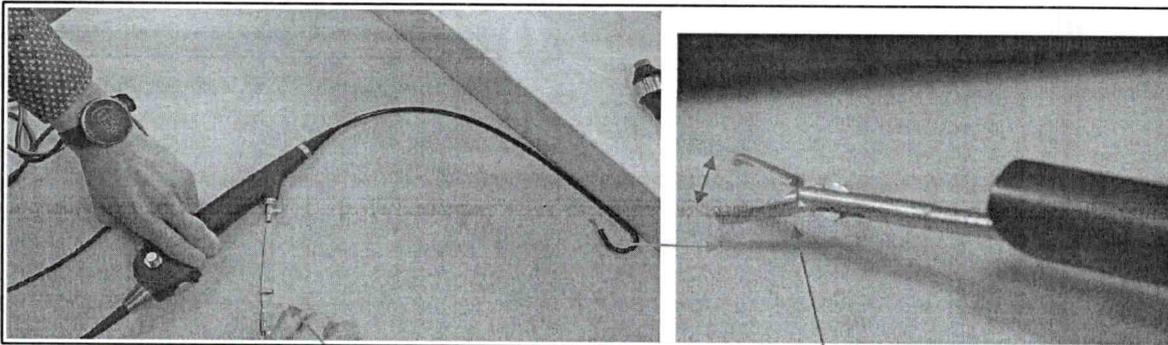


Figure 1

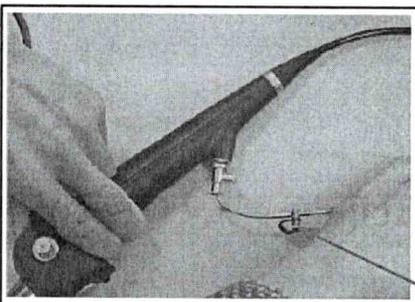


Figure 2

WARNING:

To ensure that you can continue to safely use the products and to prevent exposing patients to improper handling, please perform the following steps.

Measures to be taken by the addressee

Read through both this letter and the attached reference documents (see list of attachments) and keep them on file until the measure has been implemented.

Please follow the steps below:

1. Carry out a visual and function check before each use in accordance with instructions for use GA-S004. Incorrect product reprocessing or care can also lead to a loss of forceps function.
2. Before use, check whether the jaw section can be opened at the angle required for the application.
Alternatively, insert the forceps into the working channel of your endoscope to create the configuration shown in Figure 1 (above). To do this, angle the distal end with the endoscope to the maximum and bend the endoscope sheath another 90°.
If the jaw section can be opened, the forceps are working and can be used without any unnecessary angling.
If the jaw section cannot be opened in this position, the forceps should not be used unless you can work with a reduced angle.
3. If you can no longer open the forceps during use in the patient, move both the proximal endoscope sheath and proximal forceps sheath into a straighter position; i.e., without any additional angling. In this position, the jaw section can still be opened and closed even in distal, fully angled applications.
4. Within your organization, make sure that all users of the product referred to here and any other persons who require this information have been made aware of this emergency safety notice. If you have passed on this product to third parties, please forward a copy of this notice and inform the contact person stated below accordingly.
5. Make sure that this notice is retained within your facility until all the in-house measures required have been implemented.
6. To verify that you have received this emergency safety notice, we require you to return the enclosed **response form by March 31, 2023**. You can send this to us **via e-mail to FSCA700020652@richard-wolf.com**. We also ask that you complete this form even if you no longer have the product in stock. In doing so, you will be confirming receipt of this safety notice and you will not receive any further reminders from Richard Wolf.
7. Please inform Richard Wolf GmbH of any other adverse events.

Richard Wolf is already optimizing the forceps design. Further batches of these forceps can be used with the expected maximum flexibility.

The procedure described here does not expose patients to risks from jaw sections that do not open.

The relevant national authorities have been informed of this **emergency safety notice**.

Your contact for

Questions concerning safety:

Mr. Marco Bruxmeier
Head of Quality Engineering Department

Tel.: +49 7043 35 4011

E-mail: FSCA700020652@richard-wolf.com

Questions concerning the procedure:

Mr. Thilo Musikant
Head of Customer Service Department and Service Center

Tel.: +49 7043 35 4189

E-mail: thilo.musikant@richard-wolf.com

Please accept our apologies for any inconvenience caused by this measure. On behalf of Richard Wolf GmbH, thank you in advance for your support in ensuring its timely implementation.

Yours faithfully,
Richard Wolf GmbH

Marco Bruxmeier
Head of Quality Engineering Department

Thilo Musikant
Head of Customer Service Department and Service Center

Attachments:
Response form