



## Recommendations by the Quality Task Group (109)

# Corrosion: an underestimated risk

Authors B. Amann, T. Appel, M. Bertram, P. Bröcheler, D. Diedrich, C. Faßbender, T. Fengler, A. Forster, K. Gehrmann, M. Härtel, M. Kamer, G. Kirmse, P. Sauer, M. Schreiner, T. Schwibbe, U. Zimmermann, T. Gerasch

qualitaet@dgsv-ev.de

### MD SURFACE CHANGES AND THEIR REPERCUSSIONS (QM)

are among the most important responsibilities of a RUMED.

A **SUCCESSFUL REPROCESSING OUTCOME** can only be assured if all surfaces are intact.

### ■ Introduction

The healthcare system is always in the spotlight and any suspected hygiene scandal is picked up by the media. “Rusty instruments” makes for a catchy headline but the issues involved are complex.

As in many other areas of medicine, medical device (MD) development is experiencing rapid progress. Instrument reprocessing, in particular, requires a high degree of flexibility, expertise and willingness to engage in continuing education and training. Only if these are assured can staff and department heads keep abreast of the constantly fast-paced advancements and resultant regulations.

With regard to patient safety, topics such as **MD SURFACE CHANGES AND THEIR REPERCUSSIONS (QM)** are among those for which the Reprocessing Unit for Medical Devices (RUMED) is responsible. While there has been widespread knowledge of such issues for several years now and, besides, they are a key aspect of the curriculum of the German Society of Sterile Supply (DGSV), a high number of corroded MDs can still be found in some RUMEDs.

The term “corrosion” is derived from the Latin word *corrodere*: to gnaw away, erode, break down. These surface changes present a risk to patients, users and third parties. In the medical setting steel, aluminium and synthetic materials are of special interest; this present Recommendation now focuses on medical devices (MDs) made of steel.

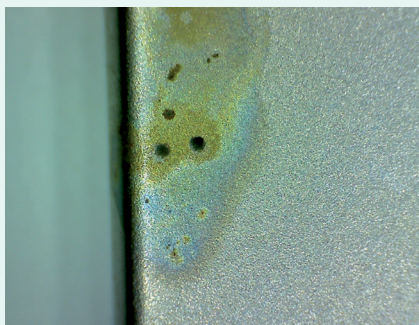
### ■ What are the risks posed by corrosion?

#### 1. Hygiene repercussions

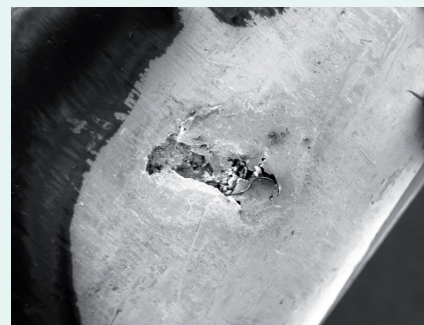
In principle, medical device reprocessing is associated with risks that can be controlled. Pursuant to DIN EN ISO 17664 instrument manufacturers are required to ascertain by means of validation which reprocessing methods are able to demonstrate that their MDs can be cleaned, disinfected and/or sterilized in compliance with the requirements/threshold values set out in the standards regulating the respective processes.

The use of validated processes by a RUMED will assure a **SUCCESSFUL REPROCESSING OUTCOME**. However, reproducibility of the results can only be assured if all surfaces are intact.

Examination of corrosion under a microscope reveals just how difficult it is to assure controlled reprocessing of such an uneven surface, dotted with craters. Furthermore, in the case of pitting corrosion, hidden below the visible pit is an entire cavity where residual soils and microorganisms can persist.



**Fig. 1:** Pitting corrosion of a liver retractor



**Fig. 2:** Pitting corrosion as seen beneath the microscope

This entails a hygiene risk since it adversely affects cleaning, disinfection and sterilization and may lead to infection and impaired wound healing.

**2. Economic repercussions**

If no action is taken to counter its spread, **PROGRESSIVE CORROSION** will impair MD functions or cause MD breakage during use.

This would result in irreparable damage to the instrument which would have to be replaced by a new MD. Timely repair is less expensive than having to offset the cost of complete instrument loss and it contributes to value retention.

The following economic impact may present:

- Possible recourse claims from patients
- MD replacement or repair
- Increasing damage due to corrosion entrainment (no repair)
- Restoration of machinery and equipment (corrosion transfer)
- Possible imposition of regulatory sanctions such as e.g. a reprocessing ban

MD corrosion can spread to other instruments, machinery and equipment (washer-disinfectors [W Ds], steam sterilizers), causing damage. Incipient corrosion that does not have its origin in the respective instrument is designated as “**SECONDARY RUST**” in the Red Brochure (11<sup>th</sup> Edition, Chapter 12.12, page 78)

■ **Why is timely action of paramount importance?**

Corrosion is spread through water and steam to other medical devices and equipment chambers (WDs, sterilizers, etc.) where it results in further corrosion.

Corrosion is like a virus and can thus only be contained when it is, figuratively speaking, sent to quarantine. Only through timely action (withdrawal from circulation/repair of the corroded MDs) can further **SPREAD OF CORROSION** be prevented. Any contact between a non-corroded MD/appliance and corroded MD/appliance must definitely be avoided.

■ **Structured approach**

An analysis of the actual state based on statistics/characteristic number of corroded MDs in a defined period, e.g. per week/month is recommended. These statistics may be useful is distinguishing between sporadic and systemic corrosion, whereby rising numbers point to a systemic problem.

Any sporadic occurrence can be promptly eliminated during daily routine repair exchange.

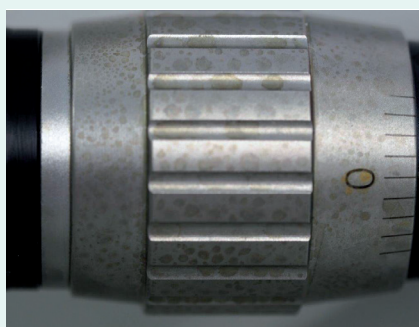
**PROGRESSIVE CORROSION** will impair MD functions.

**SECONDARY RUST** can spread to other instruments or machinery causing damage.

**SPREAD OF CORROSION** can be prevented through timely action (withdrawal and repair).



**Fig. 3:** Example of minor corrosion



**Fig. 4:** Example of minor corrosion



**Fig. 5:** Entrained corrosion



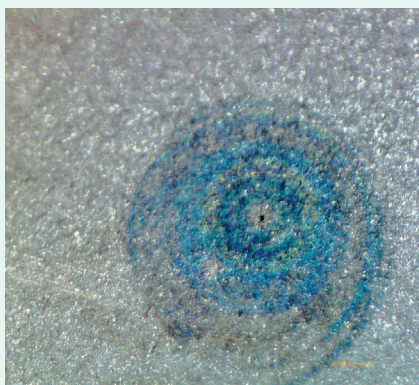
**Fig. 6:** Fretting corrosion



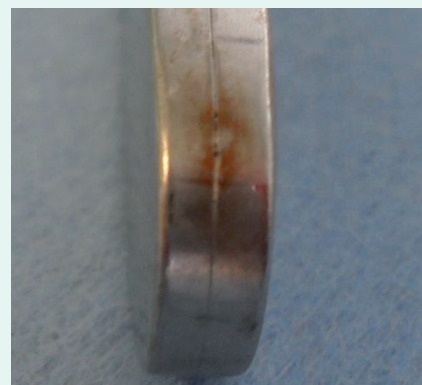
**SPECIALIST QUALIFICATIONS** enable staff to identify surface changes and dispatch the corroded MDs for repair.

If minor corrosion is not timely eliminated and allowed to spread, this will inevitably at some point lead to a worst-case scenario with systemic corrosion or even the demand for restoration of the entire MD complement by the supervisory authorities. Such restoration of all MDs and equipment can, depending on the size of the RUMED, soon result in costs amounting to six- to seven-figure sums.

Professionally qualified staff able to promptly identify such surface changes and dispatch the corroded MDs for repair are needed to prevent such a worst-case scenario. These **SPECIALIST QUALIFICATIONS** should be kept up to date through regular in-house or external training measures.



**Fig. 7:** Pitting corrosion



**Fig. 8:** Crevice corrosion of a forceps

In the event of systemic corrosion the first action must be to identify the cause and eliminate corrosion before restoration of the MDs and reprocessing equipment. The causes are not addressed in this present Recommendation as that topic will be the focus of a forthcoming issue.

#### ■ Measures to counter systemic corrosion

Case-by-case risk assessment and a detailed plan of action represent the key approach to dealing with systemic corrosion. These must be formulated in collaboration with the hospital's infection control team, premises operator, engineering department and with the person(s) responsible for the safety of the medical devices. The whole reprocessing cycle has to be taken into account.

It is generally not recommended that the RUMED itself take independent measures in such cases to eliminate corrosion through the use of process chemicals. Such chemical products only remove the soluble corrosion particles, leaving behind the unevenness and pits on the MD surfaces and again making a reproducible process impossible.

**RESTORATION OF THE MDS** should be entrusted to specialist companies to ensure that unevenness and pits on the MD surfaces are completely removed.

**RESTORATION OF THE MDS** and reprocessing equipment should be entrusted to specialist companies. These must ensure that there is no entrainment of corrosion from unrestored to already restored equipment and MDs.



**Fig. 9:** Corrosion of WD chamber bottom



**Fig. 10:** Corrosion of WD rear chamber wall

## ■ Summary

In addition to the uncontrollable hygiene risks emanating from corrosion, it is also important to safeguard the RUMED operator or user against massive economic damages.

Analogous to a virus, corrosion too is best “nipped in the bud”.

Only if even minimally corroded medical devices are withdrawn and sent for repair can the worst-case scenario described above be avoided. Besides, instruments with only minor corrosion can often be repaired and this is thus much less cost intensive than replacing the entire complement of corroded MDs.

## ■ References

1. EN ISO 17664 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
2. Instrument Preparation Working Group – Red Brochure “Reprocessing of Instruments to Retain Value”