Date: 2019-DEC-11

Urgent Field Safety Notice
EYEJET CTR type 13 (Right), 13 A (Right) and 13 B (Right)

[redacted]

Contact details of local representative (name, e-mail, telephone, address etc.)*
[redacted]

Urgent Field Safety Notice (FSN)
EYEJET CTR type 13 (Right), 13 A (Right) and 13 B (Right)
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Capsular tension ring *The MORCHER capsule rings are sterile non-optical medical devices for the relaxation of the capsular bag after cataract extraction.*
1.	2. Commercial name(s)
	EYEJET CTR type 13 (Right), 13 A (Right) and 13 B (Right)
1.	3. Unique Device Identifier(s) (UDI-DI)
	13 (RIGHT): 04048509104566 |13A (RIGHT): 04048509104580 |13B (RIGHT): 04048509104603
1.	4. Primary clinical purpose of device(s)*
	MORCHER capsule rings should only be used in conjunction with cataract surgery with IOL. The capsule rings are used to stabilize the capsular bag in cases of high myopia, zonolysis, pseudoexfoliation, primary zonular weakness, and defective or missing zonulas.
1.	5. Device Model/Catalogue/part number(s)*
	EYEJET CTR type 13 (Right), 13 A (Right) and 13 B (Right)
1.	6. Software version
	No Software associated with the implant
1.	7. Affected serial or lot number range
	SN 2541111, 2541112, 2541113, 2541114, 2541115, 2541116; see also Attachment Foto Verpackungsfehler in Charge BKADBC.pdf
1.	8. Associated devices
	No further devices associated.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Within a single batch (1350 pcs.), an incorrect labeling was partially used during the labeling process. The incorrect labeling is only in regards to the product variant of the subtypes of the EYEJET CTR type 13 (Right), 13A (Right), 13B (Right) and only on the outer packaging due to a mix-up in the packaging process. Partially, implants of type 13 (Right) labeled 13A (Right) and vice versa. The implants themselves and the sterile primary pack were consistently correct in labeling, only the outer packaging was partially mixed-up. The inconsistence labeling between outer packaging and primary packaging can be easily recognized by the user.
2.	2. Hazard giving rise to the FSCA*
	The two affected types of EYEJET CTR 13 (Right) and 13A (Right) differ only in their inclination of the guiding haptics and by a minimally different size. Both types have the identical intended use, only the implantation of the capsular tension ring can be more complicated from patient to patient, if the wrong ring size is used. There are no known complications related to this incident. Already implanted capsular tension rings do not need to be explanted. There is no increased risk for the patient.
2.	3. Probability of problem arising
	The probability for the affected types delivered to Switzerland is 100%.
2.	4. Predicted risk to patient/users
	The current mix-up of labelling has no additional anticipated risk for the patient and therefore no impact for the patient. Health Hazard Evaluation: Labeling of secondary packaging indicates a wrong product sub-type identification. -> Product (Implant) and the labeling of the primary packaging are correct. There was only a mix-up of outer packaging inside the product family Typ 13. The product family Typ 13 consist of 3 sub-types (13, 13A and 13B). These implants

	differs slightly in size but not in their indication and therefore have no effect on the patient. Only the implantation may vary from patient to patient. Explantation is not required in any case.
2.	5. Further information to help characterise the problem
	-
2.	6. Background on Issue
	Morcher was informed by a Customer about the mix-up of labelling.
2.	7. Other information relevant to FSCA
	-

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	There is no criticality for patients. Implants needs to be removed from market until 31-Dec-2019, if not already implanted.
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Both type of products have the same indication for use – no impact for the patient.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Removal of the affected charge of products.	
3	6. By when should the action be completed?	31-Dec-2019
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?
	No Not appended to this FSN

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	-
4.	**3.** For Updated FSN, key new information as follows:	
	-	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	-	
4	6. Anticipated timescale for follow-up FSN	-
4.	7. Manufacturer information (For contact details of local representative see page 1 of this FSN)	
	a. Company Name	*Morcher GmbH*
	b. Address	*Kapuzinerweg 12 / D-70374 Stuttgart / Germany*
	c. Website address	*http://www.morcher.com*
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	*Foto Verpackungsfehler in Charge BKADBC.pdf*
4.	10. Name/Signature	*E. Morcher (Head of Quality)*  2019-12-11 Stgt, GER

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Vorkommnis Verpackungsfehler in Charge BKADBC

Schweiz

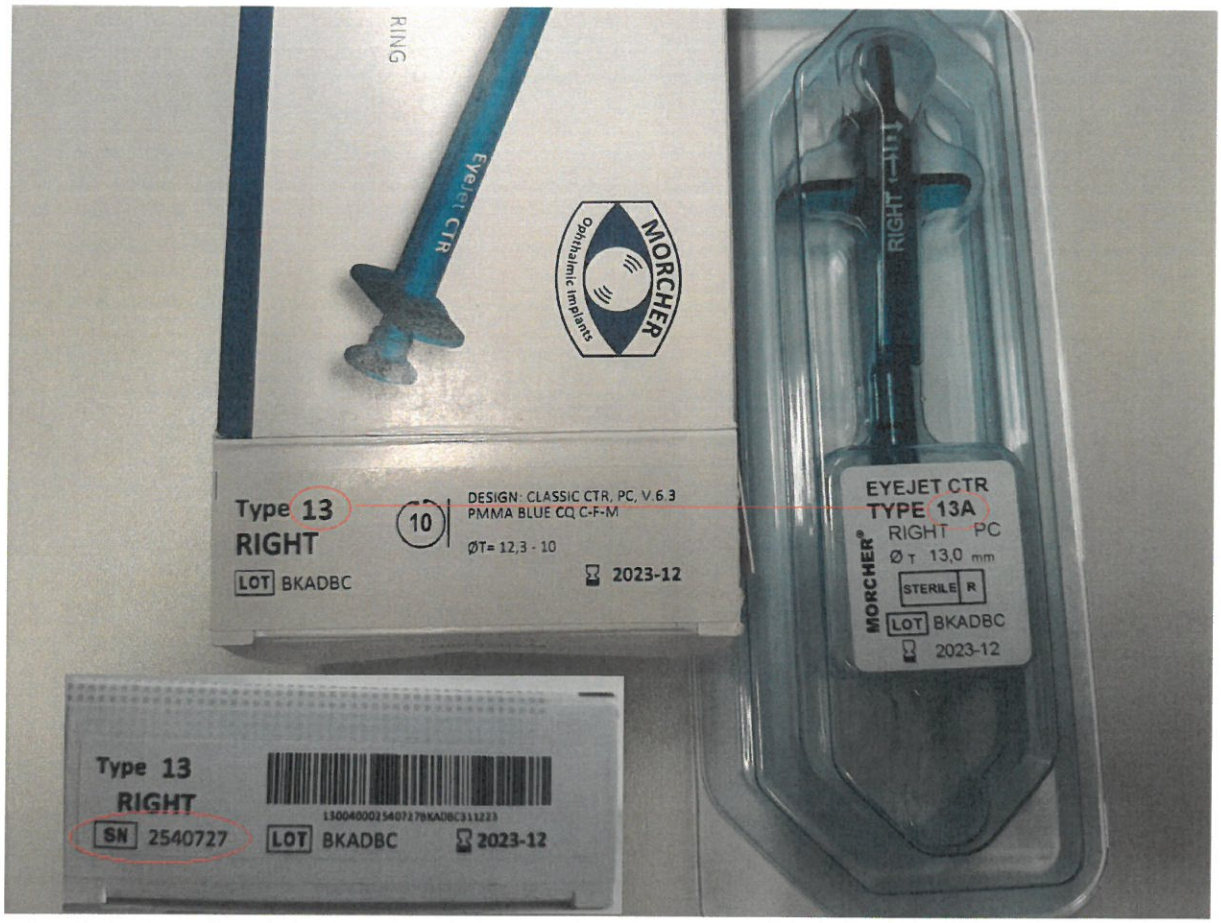

Abbildung 1: Beispiel zur Verdeutlichung

Kennzeichnung der Typenbezeichnung auf Sekundärverpackung (Schachtel) ist falsch zum verpackten Produkt. Richtige Typenbezeichnung auf Primärverpackung.

Betroffene Seriennummern der Charge BKADBC, die an den Kunden in die Schweiz verkauft wurde:

2541111	2541112	2541113
2541114	2541115	2541116

Es wurden sechs (6) EYEJETs CTR der betroffenen Charge BKADBC in die Schweiz geliefert.

Stuttgart, 13.12.2019

Eric Morcher

(Leiter Qualitätsmanagement)