FSN Ref: PR6 FSCA Ref: PR6

Date: 26/05/203

Urgent Field Safety Notice
Device Commercial Name

For Attention of: all affected distributors and users

Contact details of the manufacturer.
Altomed Ltd, 2 Witney Way, Boldon Business Park, Boldon, Tyne and Wear, NE35 9PE, United Kingdom. Quality & Regulatory Manager: … E-Mail: … Tel: …

Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Damato Ruthenium Plaque Template - A sterile device in the form of a dome, designed to be placed over a tumour that is inside the eye to help determine optimal positioning of an eye brachytherapy plaque.
1.	2. Commercial name(s)
	Damato Ruthenium Plaque Template
1.	3. Unique Device Identifier(s) (UDI-DI)
	05055505156900, 05055505156894, 05055505156887
1.	4. Primary clinical purpose of device(s)*
	A sterile device in the form of a dome, designed to be placed over a tumour that is inside the eye to help determine optimal positioning of an eye brachytherapy plaque.
1.	5. Device Model/Catalogue/part number(s)*
	A7075CIB, A7075CIA, A7075COC
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	A7075CIB = 01108, 01301, 01508, 01300. A7075CIA = 01508, 01108, 01300, 01301. A7075COC = 01108, 01107.
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Our international distributor informed us of a complaint they received from one of their customers. The CIB template (REF A7075CIB, LOT 01108) used in surgery did not precisely match up with the suture holes of the related CIB ruthenium plaque supplied. On further investigation it was found that the suture holes on the related ruthenium plaques also do not precisely align with template variants A7075CIA and A7075COC.
2.	2. Hazard giving rise to the FSCA*
	No direct safety issue. Potential for extended surgery time if the related plaque suture holes do not precisely align with the sutures placed using the template.
2.	3. Probability of problem arising
	Assessed as low given that multiple surgeries (estimated less than 200) may have been performed without any reported incident. However, given the potential for extension of surgery time all lot numbers of all three products are being withdrawn as a precaution in order that the basis for the mismatch described can be further investigated and addressed.
2.	4. Predicted risk to patient/users
	Negligible – extended surgical intervention.
2.	5. Further information to help characterise the problem

	n/a
2.	6. Background on Issue
	Altomed were made aware of this issue when our international distributor highlighted a customer complaint that the holes of the template did not fit the holes of the CIB-plaque. This resulted in a two-hour prolonged surgery for one patient, with revised suture holes and extra exposure for patient and personnel. The root cause of the error is not fully known yet, but likely relates to a design specification mismatch between the template dimensions and the dimensions of the related ruthenium plaques with which they are used. Therefore, we are presuming at this stage that all lot numbers are affected.
2.	7. Other information relevant to FSCA
	n/a

	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 Return devices to Altomed. Replacements or credit will be issued.	
3.	2. By when should the action be completed?	As soon as possible
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Yes If any of the affected devices have been used, the attending surgeon should be consulted for an assessment of whether the plaque alignment may have been adversely affected.	
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 Provide further details of the action(s) identified.	

3	6. By when should the action be completed?	As soon as possible
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?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	n/a	
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:	
	n/a	
4	6. Anticipated timescale for follow-up FSN	n/a
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN*)*	
	a. Company Name	**Altomed Limited**
	b. Address	2 Witney Way, Boldon Business Park, Tyne and Wear. NE35 9PE
	c. Website address	**www.altomed.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**PR6 FSN Customer Reply Form/ Distributor Reply Form**
4.	10. Name/Signature	**… QA/RA Manager**

	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.