FSN & FSCA Ref: C31

Date: 1st August 2021

Urgent Field Safety Notice
Damato Ruthenium Plaque Templates A7078

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: Jack Walters E-Mail: jack.walters@altomed.com Tel: +44 (0) 191 519 0111

Urgent Field Safety Notice (FSN)
Damato Ruthenium Plaque Templates A7078
Risk addressed by FSN

Information on Affected Devices	
1	**Device Type**
	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.
2	**Commercial name**
	Damato Ruthenium Plaque Template
3	**Unique Device Identifier(s) (UDI-DI)**
	05055505141258
4	**Primary clinical purpose of device**
	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.
5	**Device Model/Catalogue/part number**
	. A7078.
6	**Software version**
	N/A
7	**Affected serial or lot number range**
	00702
8	**Associated devices**
	n/a

Reason for Field Safety Corrective Action (FSCA)	
1	**Description of the product problem**
	A customer contacted us on 23/07/2021 and informed us that product A7078 lot 00702. They informed us that they have received 9 packs of this product with the inner and outer packaging labelled incorrectly. The labels state 'for use with Ruthenium Plaque / REF Ru6.A04" instead of Ru6.A06.
2	**Hazard giving rise to the FSCA**
	Surgical complications when the intended plaque won't align with the sutures placed using the template, meaning further surgical intervention or even a postponed operation
3	**Probability of problem arising**
	A problem would arise if the template was used on a patient whilst using the wrong corresponding plaque. It is unlikely as the difference in size between the template and corresponding plaque should be obvious as the sutures would not effectively line up with the suture holes on the plaque.
4	**Predicted risk to patient/users**
	Negligible – extended surgical intervention
5	**Further information to help characterise the problem**
	Include any further relevant statistics to help convey the seriousness of the issue.
6	**Background on Issue**
	Altomed were made aware of this issue when one of our distributors highlighted that they have found 9 incorrectly labelled boxes. Thus, we started our investigation and found there were 19 total in this lot number that had the issue. It is not known how many boxes have been used out of the 10 remaining. Our investigation found that this was an issue caused by incorrect labels set up on our packaging subcontractors' system. All other lot numbers have been checked and it is found to only be an issue with this lot. This should have been noticed at Altomed goods in

	inspection however this has been overlooked due to human error. Altomed will now re-train staff to closely inspect all Altomed devices and packaging.
7	**Other information relevant to FSCA**
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

Type of Action to mitigate the risk

A **Action To Be Taken by the User**

1

☒ 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

Users will either need to return the devices to Altomed for re-labelling or you may request replacement labels to re-label yourselves if there is a preferable urgent clinical need. Please contact the manufacturer for advice if you wish to relabel yourself – returning the devices is advised as the preferable course of action.

2	**By when should the action be completed?**	As soon as possible. Altomed has contacted all customers to quarantine devices until they can be re-labelled

3 **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. It is not believed this is likely as the difference in size between the template and the corresponding plaque should have been reasonably obvious.

4	**Is customer Reply Required?** (If yes, form attached specifying deadline for return)	Yes

B **Action Being Taken by the Manufacturer**

1

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☒ IFU or labelling change
☐ Other ☐ None

Returned product will be relabelled and returned to stock as the quality of the devices is unaffected

2	**By when should the action be completed?**	As soon as possible. Before use.
3	**Is the FSN required to be communicated to the patient / lay user?**	No

4 **If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?**

N/A

General Information		
1	FSN Type	New
2	For updated FSN, reference number and date of previous FSN	N/A
3	For Updated FSN, key new information as follows:	
	N/A	
4	Further advice or information already expected in follow-up FSN?	No
5	If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
6	Anticipated timescale for follow-up FSN	N/A
7	Manufacturer information	
	a. Company Name	**Altomed Limited**
	b. Address	**2 Witney Way, Boldon Business Park, Tyne and Wear. NE35 9PE**
	c. Website address	**www.altomed.com**
8	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
9	List of attachments/appendices:	**C31 FSN Customer Reply Form / C31 FSN Distributor Reply Form (as applicable)**
10	Name/Signature	**Jack Walters** ***Quality & Regulatory 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.