Rev 2: February 2020
FSN Ref: FSN-23-01 FSCA Ref: FSCA-23-01

Date: 2023-10-08

Field Safety Notice
Device Commercial Name

For Attention of*:EstheticMed Reusable Customer List

Contact details of local representative (name, e-mail, telephone, address etc.)*
esthetic med GmbH, Patrick Heeb, patrick.heeb@estheticmed.com, +41.44.802.33.88, Switzerland, Chli Ebnet 3, Küssnacht am Rigi, 6403

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

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Tulip Reusable Cannulas
1.	2. Commercial name(s)*
	Tulip Reusable Cannulas
1.	3. Unique Device Identifier(s) (UDI-DI)
	008191270
1.	4. Primary clinical purpose of device(s)*
	Harvesting human adipose tissue
1.	5. Device Model/Catalogue/part number(s)*
	BENXXYYZZCF, CARXXYYZZCF, CBBXXYYZZCF, FLPXXYYZZCF, INFXXYYZZCF, MERXXYYZZCF, MILXXYYZZCF, PYRXXYYZZCF, SORXXYYZZCF, SPOXXYYZZCF, STDXXYYZZCF, STDXXYYZZCF, TSHXXYYZZCF, INJXXYYZZCF
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	N/A
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	FSN is designed to reinforce the importance of the use, care, and inspection of Tulip Cannulas.
2.	2. Hazard giving rise to the FSCA*
	Cannula tip or portion of the cannula may break of while being used in patient which may result in possible required patient intervention if IFU is not followed.
2.	3. Probability of problem arising
	Cannula tips breaking of while being used in a patient is very rare. Since 2020 a projected 566,550 procedures worldwide have taken place using Tulip Harvesting Cannulas. Only 4 have reported becoming broken and only of the 4 in a patient.
2.	4. Predicted risk to patient/users
	Severity of Harm: The potential harm to patients and users ranges from device malfunction and reduced efficacy to potential adverse events which may require surgical intervention, caused by improper inspection, handling or utilization in procedures outside of the device's indication for use.
2.	5. Further information to help characterise the problem
	Over time metal may become fatigued due to repeated forces, heat exposure (autoclaving), or intentional or unintentional bending. This may cause the stem tip to break.
2.	6. Background on Issue
	Tulip Medical Products received notification of an incident involving their Tulip Tonnard Harvester Model: Tulip SL 2.4 from an unauthorized distributor. This report was relayed to Tulip Medical by Swissmedic on April 5, 2023, and relates to a device manufactured

	and sold in 2014. The incident itself involved the tip of a Tonnard SL 2.4mm harvesting cannula breaking during a procedure, necessitating an extended incision to retrieve the fractured tip from the patient. Tulip conducted research into the history of cannula tips breaking during procedures and found no discernible pattern of harvesting cannulas failing in such a manner. Such occurrences would typically require unusual side forces or gradual weakening of the stainless steel over time. We emphasize the importance of adhering to our Instructions for Use (IFU), which detail how to clean, sterilize, care for, and inspect these devices. The IFU includes the following guidance: "Before using any Tulip brand instrument, cannula, or accessory, visually inspect each item to ensure suitability for the intended surgical application(s). Cannulas are susceptible to forces applied during surgery and repeated autoclaving, which can lead to separation, bending, or collapsing. Inspect each device, with un-magnified visual inspection under good lighting conditions usually sufficing. Check all parts for visible contaminants, distortion, or damage, paying particular attention to contaminant "traps," recessed features, cannula tips, and instruments that may have been impacted. It is crucial for users to follow these inspection procedures, as damage can occur during handling and storage. It is evident that unknown conditions during the previous seven years, coupled with inadequate pre-procedure inspections as per the IFU, contributed to this incident. In 2017, Tulip introduced a recommendation to the IFU: "Tulip has validated its reusable cannulas, injectors, and infiltrators for up to 50 autoclave cycles and strongly recommends replacement after 50 autoclave cycles." During the investigation of this incident, it was revealed that this statement was included only in the English translation of the IFU. Although this statement alone did not contribute to the incident, Tulip needs to make sure it is included in all of its translations. Regardless of autoclave cycles, it remains equally essential to thoroughly inspect the device before a procedure, even if it is brand new and has not undergone any autoclave cycles, as cleaning and handling damage can occur at any time. Tulip believes that the current IFU already addresses the primary mitigation for preventing cannula tip failures during procedures.
2.	7. Other information relevant to FSCA
	Tulip plans to revise its IFU to bring greater emphasis to the use, care, and inspection of Tulip Harvesting Cannulas in all IFU languages.

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 Please Review the following – **English:** **Fitness of Use:**

	• **Instruments, cannulas and accessories are vulnerable to forces applied during surgery and/or repeated autoclaving (heat exposure to dis-similar metals) that may cause these devices to separate at their bases, become bent and/or collapse during use. A thorough inspection for signs of cracking or any bending of cannula stems is required.** • **Do not intentionally bend cannula stems. If any cannula stems are bent, cracked, or show signs of wear, remove item from service immediately.** • **Tulip has validated its reusable cannulas, injectors, and infiltrators for up to 50 autoclave cycles and strongly recommends replacement after 50 autoclave cycles.** • **Cannulas removed from their syringes during surgery may cause their mated syringes to produce syringe particulate. Before, during and after use, always inspect the devices and syringes to ensure properly mated surfaces and fitness of use.** • **The decommissioning, or proper disposal of medical devices may be necessary at any time and Tulip Medical Products relies on the user to routinely inspect the devices prior to use to ensure device reliability and fitness for use.** **German:** • **Gebrauchstauglichkeit:** • **Instrumente, Kanülen und Zubehörteile sind anfällig für Kräfte, die während einer Operation und/oder wiederholtem Autoklavieren (Wärmeeinwirkung auf unähnliche Metalle) ausgeübt werden und dazu führen können, dass sich diese Geräte an ihrer Basis lösen, sich verbiegen und/oder während des Gebrauchs zusammenbrechen. Eine gründliche Untersuchung auf Anzeichen von Rissen oder Verbiegungen der Kanülenstiele ist erforderlich.** • **Kanülenstiele nicht absichtlich verbiegen. Wenn Kanülenstiele verbogen oder gerissen sind oder Abnutzungserscheinungen aufweisen, nehmen Sie das Produkt sofort außer Betrieb.** • **Tulip hat seine wiederverwendbaren Kanülen, Injektoren und Infiltratoren für bis zu 50 Autoklavenzyklen validiert und empfiehlt dringend den Austausch nach 50 Autoklavenzyklen.** • **Kanülen, die während der Operation von ihren Spritzen entfernt wurden, können dazu führen, dass die dazugehörigen Spritzen Spritzenpartikel produzieren. Überprüfen Sie die Geräte und Spritzen vor, während und nach dem Gebrauch stets auf einwandfreie Mattierung der Oberflächen und Gebrauchstauglichkeit.** • **Die Außerbetriebnahme oder ordnungsgemäße Entsorgung medizinischer Geräte kann jederzeit erforderlich sein und Tulip Medical Products verlässt sich darauf, dass der Benutzer die Geräte vor der Verwendung regelmäßig überprüft, um die Zuverlässigkeit und Gebrauchstauglichkeit des Geräts sicherzustellen.**
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety.

3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No This section is not applicable	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Tulip Medical Products is reinforcing the importance of the following and translating to German in particular and all appropriate languages.	
3.	6. By when should the action be completed?	Prior to next use of Tulip Reusable Cannulas
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? *	No
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	Black Tie Medical DBA Tulip Medical Products
	b. Address	4360 Morena Blvd. Ste 100, San Diego, CA 92117
	c. Website address	www.Tulipmedical.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Insert Name and Title here and signature below.

	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.