Grace Medical We Listen.

8500 Wolf Lake Drive, Suite 110, Memphis, TN 38133
1.866.472.2363 www.gracemedical.com

URGENT: FIELD SAFETY NOTICE

Cartilage Microtome System

(Product Ref 990-001 and 990-003)

21 June 2019

Attention: Operating Room Supervisors, Materials Management Personnel, and Medical/Surgical/Theatre physicians and nursing staff

This Field Safety Notice affects all Grace Medical, Inc. Microtome Cartilage System (REF 990-001) and Cartilage Microtome Replacement Handle (REF 990-003).

Grace Medical, Inc. is issuing a Field Safety Notice on Cartilage Microtome System REF 990-001 and Cartilage Microtome Replacement Handle REF 990-003, identified below. The Competent Authority is aware of this action.

EFFECTIVE IMMEDIATELY – CARTILAGE MICROTOME

PRODUCT NAME	PRODUCT Ref	LOT NUMBERS	DESCRIPTION
Cartilage Microtome System	**990-001**	**28102, 29406, 30764, 31864, 32949, 34183, 35084, 35325, 37005, 39607, 41016, 41158, 41172, 52056, 54520, 54698, 55104, 55699, 56845, 58602, 60294, 61262, 62920, 64951, 66953, 67019, and 67683**	A portable, manual surgical instrument intended to cut a harvested cartilage specimen (e.g., tragus-derived autograft) to an accurate predetermined thickness for patient implantation during an ear/nose/throat (ENT) procedure (e.g., middle ear surgery). It consists of an adjustable cutting assembly with a handle, base, and thickness dial used in conjunction with a removable ENT cartilage cutter blade. This is a reusable device intended to be sterilized prior to use. This system includes (1) REF 990-003 Cartilage Handle; (1) REF 990-004 Base and Dial; and (1) REF 990-006 Cartilage Support
Cartilage Microtome Replacement Handle	**990-003**	**52940**	Cartilage Handle

Our records indicate that you have ordered the Cartilage Microtome System or the Cartilage Microtome Replacement Handle and received the product subject to this Field Safety Notice. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL PERSONNEL RESPONSIBLE FOR or WHO MAY USE the Cartilage Microtome System** or the Cartilage Microtome Replacement Handle **in your facility.**

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Grace Medical, Inc. is issuing a voluntary Field Safety Notice following reported alleged injury to the finger of a user during attempted removal of a stuck blade in a handle of the device.

Grace Medical, Inc. reminds users instructions supplied with the Microtome Cartilage System REF 990-001 should be followed, also to be familiar with warnings and precautions.

The Cartilage Microtome system is a reusable instrument used in ENT applications to cut harvested cartilage into various thicknesses. It is to be used exclusively with single use disposable, REF 990-002 Stainless PTFE Coated Knife Blades for Cartilage Microtome.

Users are advised to avoid excessive force when inserting or/and removing REF 990-002 Stainless PTFE Coated Knife Blades for Cartilage Microtome into or from the handle. If you experience any difficulties, please use forceps or another suitable instrument to avoid injury.

Additionally, users are reminded the Microtome Cartilage System with REF 990-001 is designed exclusively for use REF 990-002 Stainless PTFE Coated Knife Blades for Cartilage Microtome. Please note, use of any unrecommended blades in combination with the Microtome Cartilage System REF 990-001 may cause injuries and malfunction of the medical device.

PRODUCT SUBJECT TO THIS FIELD SAFETY NOTICE:

Please identify products subject to this Field Safety Notice in your inventory by product REF/LOT number**.**

ACTION REQUIRED:

1. Review shipment and stock records to identify Grace Medical, Inc. Microtome Cartilage System (REF 990-001) and Cartilage Microtome Replacement Handle (REF 990-003) subject to this Field Safety Notice.
2. Circulate this notice to staff at points of use of the device.
3. Contact your local distributor if you require training on use of the Grace Medical, Inc. Microtome Cartilage System (REF 990-001) device, including the Cartilage Microtome Replacement Handle (REF 990-003).

If you have additional questions regarding this Field Safety Notice, please contact our EU Authorised Representative, Quality First International (QFI) at +44 (0) 208 221 2361 or via email to enquires@qualityfirstint.com.

At Grace Medical, Inc., our first priority is to support the needs of our customers and their patients, and that includes promoting the safe and effective use of our products. We recognise that this Field Safety Notice is disruptive to your facility and we apologise for any inconvenience it may cause.

Yours faithfully,

Grace Medical, Inc