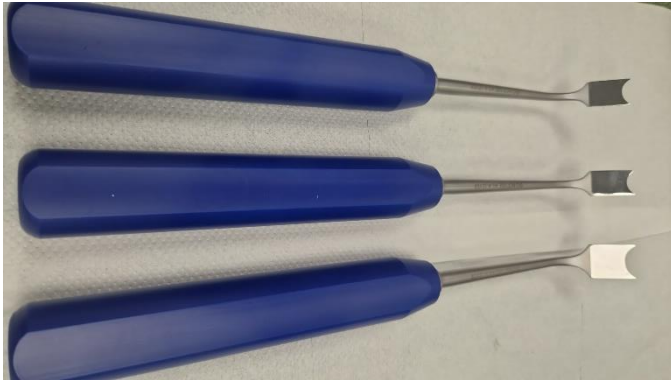


Date: 3rd May 2024**Urgent Field Safety Notice****DEVICE RECALL****For Attention of: Sterile Services, Theatre Managers, Medical Stores**

Contact details of Manufacturer
Surgical Holdings Parkside Centre Potters Way Temple Farm Industrial Estate Southend-on-Sea Essex SS2 5SJ Email: info@surgicalholdings.co.uk
Contact details of Distributor
Murray Surgical Ltd UNIT 23A MOYLE ROAD DUBLIN INDUSTRIAL ESTATE GLASNEVIN DUBLIN 11 Email: info@murraysurgical.ie
Contact details of European Authorised Representative
Advena Tower Business Centre, 2nd Flr., Tower Street Swatar BKR 4013 Email: pprc@advena.mt


Urgent Field Safety Notice – Device Recall

1 Information on Affected Devices	
1.	Device Type
	<p>SH-5889 (SET OF 3 CURVED BLUE ACETAL SUREGRIP HANDLE CHISELS - 2 X 300MM LONG 1 X 270MM LONG - 15MM - 15MM - 20MM.)</p> 
	2. Commercial names
	Ganz Osteotome / Ganz Chisel
	3. Unique Device Identifiers
	SH-5889
	4. Primary clinical purpose of device (s)
	Used for cutting and chiselling bone during orthopaedic surgery.
	5. Device Model/Catalogue/Part Numbers
	SH-5889
	6. Affected Serial or Lot Number Range
	All

2 Reason for Field Safety Corrective Action (FSCA)	
1.	Description of product problem
	<p>This device may be used with a twisting / torsion action. There may be a risk that over time and with repeated use and reprocessing, the handle on the device may loosen and therefore could swivel on the shaft.</p>

	<p>2. Hazard giving rise to FSCA</p>
	<p>Patient Risk: If the handle swivels on the shaft intra operatively, it could expose the patient to harm by misdirection of the blade.</p> <p>An observant surgeon and/or staff is likely to notice the issue prior to use. This may result in a procedural delay while an alternative device is sought.</p> <p>Surgical Holdings has not received any reports of user or patient harm or injury relating to this issue, however, as of the date of this FSN, Surgical Holdings has been notified of the fault by one Customer.</p> <p>As a precaution Surgical Holdings are recalling these devices.</p>
	<p>3. Background on Issue</p>
	<p>Surgical Holdings were notified by a Customer that the device has an ‘unsecured handle allowing misdirection’.</p> <p>The Ganz variant of the osteotome / chisel is often used with a twisting motion.</p> <p>At this time, it is not clear where the issue was identified or if any patient harm occurred. It is understood that based on the Customer's feedback there is the potential for patient harm if the issue is not identified prior to use.</p> <p>It should be noted that devices with a threaded shaft are secured by using medical device adhesive and screwing into the medical grade acetal handle. No other complaints or feedback for this issue have been received to date.</p> <p>It is recommended that Customers inspect devices each time they are reprocessed to ensure these are fit for purpose in line with Surgical Holdings’ Surgical Instrument Reprocessing Guidelines (SF37-E V10, Jan 2024) - Inspection and Function Testing:</p> <ul style="list-style-type: none"> ▪ Visually inspect and check; All instruments for damage and wear; cutting edges are free of nicks and present a continuous edge; jaws and teeth align correctly; all articulated instruments have a smooth movement without excess play; locking mechanisms (such as ratchets) fasten securely and close easily; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components. ▪ Remove for repair or replacement any blunt, worn out, flaking, fractured or damaged instruments. <p>A total of 9 sets of SH-5889 have been placed on the market (the first on 11/01/2013 and the most recent on 16/11/2022). All 9 sets have been supplied to the same Distributor, Murray Surgical Ltd.</p>

3 Type of Action to mitigate the risk	
1. Action To Be Taken by the User	<input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device
2. By when should the action be completed?	31 st May 2024
3. Is customer Reply Required? * <i>(If yes, form attached specifying deadline for return)</i>	Yes – refer to Appendix B
4. Action Being Taken by the Manufacturer The affected devices are being recalled for modification (addition of pin to further secure the handle).	
5. Is the FSN required to be communicated to the patient /lay user?	No

4 General Information	
1. FSN Type	New
2. Further advice or information already expected in follow-up FSN?	No
3. Manufacturer information	
a. Company Name	Surgical Holdings
b. Address	Parkside Centre Potters Way Temple Farm Industrial Estate Southend-on-Sea Essex SS2 5SJ
c. Website address	www.surgicalholdings.co.uk
4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
5. List of attachments / appendices	Appendix A - Products Affected Appendix B - Field Safety Notice Customer Reply Form
6. Name / Signature	Name: Julie Woods Title: Quality Manager 

	Transmission of this Field Safety Notice
	<p data-bbox="276 288 1385 389">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)</p> <p data-bbox="276 432 1385 499">Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p data-bbox="276 542 1385 609">Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p data-bbox="276 651 1385 743">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.</p>

FSN & FSCA Ref: T000519 (HPRA Ref: CRN00F8DD)

Appendix A – Products Affected

Catalogue No.	Product Description	Lot No.
SH-5889	SET OF 3 CURVED BLUE ACETAL SUREGRIP HANDLE CHISELS - 2 X 300MM LONG 1 X 270MM LONG - 15MM - 15MM - 20MM.	ALL

Appendix B

Field Safety Notice Customer Reply Form

Further to the FIELD SAFETY NOTICE T000519 we require you to return this document duly completed and signed as soon as possible and in any case by 31st May 2024, by sending it by email to your distributor (where applicable) and to info@surgicalholdings.co.uk.

1. Field Safety Notice (FSN) information	
FSN Reference number	T000519
FSN Date	3 rd May 2024
Product/ Device name and Product Code	SH-5889 (SET OF 3 CURVED BLUE ACETAL SUREGRIP HANDLE CHISELS - 2 X 300MM LONG 1 X 270MM LONG - 15MM - 15MM - 20MM.)

2. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation	
<input type="checkbox"/> I can confirm receipt of the Field Safety Notice and I have read and understood its content	<i>Customer / Distributor to complete or enter N/A</i>
<input type="checkbox"/> I have performed all actions requested by the FSN	<i>Customer to complete or enter N/A</i>
<input type="checkbox"/> The information and required actions have been brought to the attention of all relevant users and executed	<i>Customer to complete or enter N/A</i>
<input type="checkbox"/> No affected devices in stock	<i>Customer to complete or enter N/A</i>
<input type="checkbox"/> I have replaced the IFU for affected devices	<i>Customer to complete Table 1 or enter N/A</i>
<input type="checkbox"/> I have returned affected devices to the Manufacturer for the IFUs to be replaced	<i>Customer to complete Table 1 or enter N/A</i>

FSN & FSCA Ref: T000519 (HPRA Ref: CRN00F8DD)

<input type="checkbox"/> We have further distributed the product. We have notified all affected healthcare facilities of this FSN	<i>Customer to complete Table 2 or enter N/A</i>
<input type="checkbox"/> I have a query please contact me	<i>Customer to enter contact details if different from above and brief description of query</i>
Print Name:	
Signature	
Date	

4. Return acknowledgement to sender	
Email	quality@surgicalholdings.co.uk
Deadline for returning the Customer reply form	31 st May 2024

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Table 1: List of Devices at our Facility

Quantity	Part Code	Lot Number	

Table 2: List of Distributed Devices

Quantity	Part Code	Lot Number	Name & Address of Hospital / Healthcare Facility