The purpose of this policy is to outline the appropriate action to be taken when TGA/Medsafe registered medical devices for reasons relating to their quality, safety or efficacy are to be removed from supply or use, or subject to corrective action.

This policy applies to any TGA/Medsafe registered medical device that has been confirmed, or suspected of being out of specification by either Stable Orthopaedics Pty Ltd or by our supplier

URPTG – Uniform Recall Procedure for Therapeutic Goods

TGA	
Class I Recall	Occurs when products are potentially life-threatening or could cause a serious risk to health. For E.g. • Wrong product (label and contents are different products) • Microbial contamination of sterile injectable or ophthalmic product • Chemical Contamination with Serious medical consequences • Mix up of some products (”rogues”) with more than one container involved • Wrong active ingredient in a multi-component product with serious medical consequences
Class II Recall	Occurs when product defects could cause illness or mistreatment, but are not Class I. For E.g. • Mislabelling e.g wrong or missing text or figures • Missing or incorrect information – leaflets or inserts • Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences • Chemical/physical contamination (significant impurities, cross contamination, particulates) • Mix up of products in containers (“rogues”) • Non-compliance with specification (e.g. assay, stability, fill/weight) • Insecure closure with serious medical consequences (e.g. cytotoxic, child resistant containers, potent products).
Class III Recall	Occurs when product defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons. E.g. • Faulty packaging e.g. wrong or missing batch number or expiry date • Faulty closure • Contamination – microbial spoilage, dirt or detritus, particulate matter.

Sources of Issue or Concern

Note: Product Recall - Checklist (Appendix 1) should be completed at each stage.

Potential issues and concerns with medical devices (including IVD) may come from several sources including:

Tool	Description	Main Source	Priority
Adverse Event Reports	Reports regarding deficiencies in labelling, instructions for use or packaging, defective components, performance failures, poor construction or design.	• Sponsor • Health professionals • Distributor • End users	High
Risk Management Plans	Summary of known (and identified) safety information about the medical device (including IVD).	• Manufacturer risk assessments • Changes to processes etc	Medium
Audits	Audit reports and feedback conducted by TGA, other regulatory or standards body, sponsors or customers	• Regulatory Body (TGA/Medsafe) • Standards authority • Sponsor • Customers	Medium
Environmental Scanning	Scientific and medical literature, media reports, regulatory news etc	• Media • Academia • Governments • Industry • Consumers	Low

Other sources of potential issues include but not limited to

a) Customer complaints
b) Customer feedback
c) Comments received from the industry regarding the
    - Design
    - Manufacture
    - Performance, and
    - Use of the products.

Another source that shall be reviewed is the

a) **TGA Product Recall -** http://www.tga.gov.au/safety/recalls.htm
b) **TGA Alerts pages** - http://www.tga.gov.au/safety/alerts.htm
c) **Medsafe Product Recall** - https://www.medsafe.govt.nz/hot/ProductRecallInformation/ProductRecallHome.asp

for any potential issues that may affect the Stable Orthopaedics Pty Ltd goods and services.

Advisory Notices

If in the course of the vigilance review, it is determined that there has been:

a) any malfunction or deterioration in the characteristics or performance of a medical device (including IVDs);
b) any inadequacy in the design, production, labelling or instructions for use of any medical device (including IVDs);
c) or any inadequacy in the advertising material for the medical device (including IVDs);
d) or any use in accordance with, or contrary to, the use intended by Stable Orthopaedics for the medical device (including IVDs);

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or information relating to any technical or medical reason for a malfunction or deterioration of a kind that has led to a recall of the medical device (including IVDs) by Stable Orthopaedics Pty Ltd, the Director Regulatory and Quality, as soon as the issue is identified, contact and inform the TGA of the issue.

The timing requirements are as follows:

If the adverse event:	Contact the TGA within
Represents a serious threat to public health	48 Hours
Has led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person	10 days
Relates to an event or other occurrence, a recurrence of which might lead to the death, or a serious deterioration in the state of health of a patient, a user of the device, or another person	30 days

Only adverse events that occur in Australia are required to be reported to the TGA/Medsafe. Adverse events that occur overseas are not required to be reported to the TGA, but records of these should be available in the event of request. Also, any remedial actions arising from overseas adverse events should be reported.

In the event of an adverse event, an initial adverse event report shall be lodged by the Director, Regulatory and Quality with the TGA/Medsafe at the following:

Phone	1800 809 361
Online	http://reporting.tga.gov.au/mdir/mdir03.aspx
	https://www.medsafe.govt.nz/safety/RecallCode.pdf
Email	iris@tga.gov.au
Fax	+61 2 6203 1713

Adverse Event Report

Details that must be reported include:

a) The sponsor's
   - Name
   - Address
   - Contact person
   - Telephone number
   - Fax number

b) The date when the incident came to the knowledge of the:
   - Manufacturer
   - Sponsor

c) Information about the device including:
   - Kind of medical device
   - Commercial name
   - Catalogue number
   - ARTG number (if applicable)
   - Batch number

d) Known details about the event, including the date and patient or user outcome
e) Current Known location of the product involved in the event
f) Contact point of the user where the event occurred
g) Manufacturer/Sponsor comments (if any)
h) Action taken or proposed action and time frame
i) A statement of whether the manufacturer and sponsor are aware of the same type of events having an impact on the current report. This statement should include:
   - Name of any other regulatory authorities to which these events have been reported
   - Date of the reports
   - Number of similar events
   - Number of devices supplied
   - Rate of similar events, if available
   - Any other countries in which the medical device is known to be on sale or supplied

Copies of all correspondence will be retained by the Director, Regulatory and Quality.

Following the issuing of an advisory notice, Stable Orthopaedics Pty Ltd, shall investigate the identified event.

Following the investigation, if any of the following are indicated:

a) Correcting the product on the market;
b) Removing the product from the market; or
c) Advising users of an issue with the product,

The Director, Regulatory and Quality shall contact the Australian Recall Coordinator at the TGA via 02 6232 8636 or email recalls@tga.gov.au for advice, Medsafe; recalls@health.govt.nz

Stages of recall

The following stages should be followed by the Director, Regulatory and Quality with direct reference to the relevant sections of the TGA Uniform Recall procedure (URPTG), current at the time or the Medsafe Recall Code

Stage 1: Notification to the Australian Recall Coordinator/Crisis Management or follow Medsafe Recall Code

Notification to the Australian Recall Coordinator, Conformity Assessment Branch, TGA should be made as follows:

Potential Routine Recall:

Mail "Medicine Problem Report Form" (Appendix I URPTG) to:
Australian Recall Coordinator
Recalls & Secretariat Section
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Potential Urgent Recall:

Fax "Medicine Problem Report Form" (Appendix I URPTG) to:
Australian Recall Coordinator
Recalls & Secretariat Section
Therapeutic Goods Administration
Fax: (02) 6232 8687

Stage 2: Information Required to Assess Recall

Prior to notification to the Australian Recall Coordinator, (or the State Coordinator), gather all relevant information on problem reports, the product and its distribution, and action proposed (using the Medicine Problem or Medicinal Device Incident report forms as the prompt).

Stage 3: Assessment of Recall

No recall, regardless of level should be undertaken without consultation with the Australian Recall Coordinator and without agreement on the recall strategy. The recall will be classified as either "urgent" or "routine" and at what level, i.e. wholesale, hospital, retail or consumer. The level will

be based on such factors as the significance of the hazard (if any), the channels by which the goods have been distributed, and the level to which distribution has taken place.

Stage 4: Recall

Submit letter (refer to Appendix VIII URPTG), advertisements and press release (if applicable) to the Australian Recall Coordinator for approval, before despatch in the distinctive standard red bordered envelope (refer to Appendix VII URPTG).
The recall letter may be sent by mail or facsimile or e-mail (and then also posted if sent by facsimile or e-mail), within 48 hours once approved by the Australian Recall Coordinator.

or follow Medsafe Recall Code

Stage 5: Notification to the Federal Minister Responsible for Consumer Affairs

Where the recall is safety-related, (i.e. there is a risk of harm to patients) notify the minister (via the Consumer Affairs Division of the Department of Treasury). This is a legal requirement. Notification must be done within two (2) days of initiation of the recall.

or follow Medsafe Recall Code

Stage 6: Progress of Recall and Report

At two (2) and six (6) weeks after the initiation of the recall (or at other agreed times) provide the Australian Recall Coordinator with an interim and a final report on the recall. Information to be provided is identified in Section H of URPTG.

or follow Medsafe Recall Code

Stage 7: Follow-up Action

The Australian/New Zealand Recall Coordinator will examine the reports provided above and make an assessment on the effectiveness of the recall action. This will include an investigation into the reason for the recall and the remedial action to prevent a recurrence of the problem.

or follow Medsafe Recall Code

TGA Recall Coordinators (Medical Devices) contact details:

Ph: 02 6232 8636
Fax: 02 6203 1451
Email: recalls@tga.gov.au

www.tga.gov.au/industry/recalls-urptg-17

Medsafe Recall Coordinators (Medical Devices) contact details:

Email: recalls@health.govt.nz.

https://medsafe.govt.nz/profs/PUArticles/RecallsJune2010.htm

This policy will be reviewed on our regular basis to ensure it continues to reflect Stable Orthopaedics Pty Ltd ongoing commitment to supplying a quality product

Document history and change record

Issue	Issue date	Description of change
1.0	May 2018	Initial Issue
2.0	June 2020	Include Medsafe Requirements
3.0	March 2023	Review no updates

Appendix 1

PART A: TO BE COMPLETED BY DIRECTOR, REGULATORY AND QUALITY		
Product/Service:	**Batch No:**	
Notification of Potential Defect Received	Date:	Sign:
Nature of Defect:		
Responsible Director, Regulatory and Quality:		
Stock isolated	Date:	Sign:
End customers with product/service identified	Date:	Sign:
Set-up Initial meeting Stake holders	Date:	Sign:
Recall Team Members:		
Conduct Risk Analysis • **Identified Risk:** • **Risk Rating:** • **Risk Control:** • **Document Risk Control:** • **Implement Risk Control Measures:**	Date:	Sign:
Drafting initial reply to customer	Date:	Sign:
Needs to be reviewed by	Date:	Sign:
Needs to be endorsed by	Date:	Sign:
Other distributors of product identified and advised (if required)	Date:	Sign:

RISK RATING TABLE				
Likelihood (of injury or harm to health)	**Consequences (of any injuries or harm to health)**			
	Insignificant e.g. no injuries	**Moderate e.g. first aid / medical treatment**	**Major e.g. extensive injuries**	**Catastrophic e.g. fatalities**
Very Likely	**High**	**Extreme**	**Extreme**	**Extreme**
Likely	**Moderate**	**High**	**Extreme**	**Extreme**
Moderate	**Low**	**High**	**Extreme**	**Extreme**
Unlikely	**Low**	**Moderate**	**High**	**Extreme**
Highly unlikely (rare)	**Low**	**Moderate**	**High**	**High**

PART B: TO BE COMPLETED BY DIRECTOR, REGULATORY AND QUALITY		
Affected stock/service returned	Date:	Sign:
Testing of product Required	**YES NO N/A**	Sign:
Progress recall meeting	Date:	Sign:
Action to be taken with returned & segregated product/service:		
Action Taken By:	Date:	Sign:
Other products/brands/services which may be at risk identified	**YES NO N/A**	Sign:
Close out recall meeting held	Date:	Sign:
Final Report Submitted to	Date:	Sign:

RECORD OF COMMUNICATION / ACTIONS		
Date/Time:	**Brief details:**	**Person Communicated with / Action by:**

Note: Attach a copy of the completed copy of this checklist to the full recall report