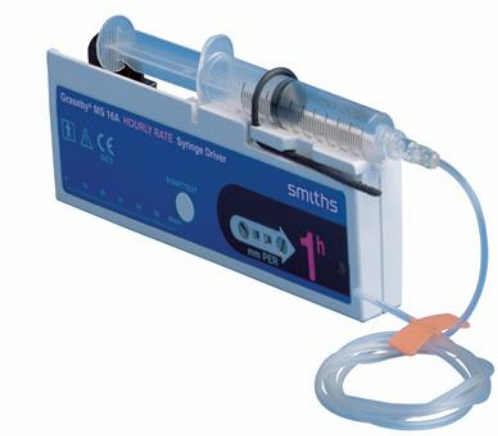
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

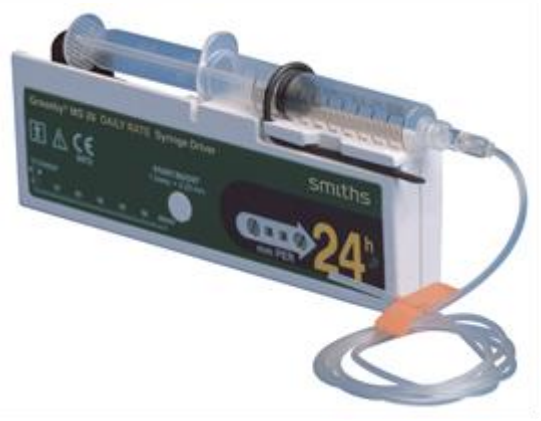
Safety Notice

Medical Devices

Graseby Syringe Drivers (MS16A & MS26) - Update

Priority 2 – Warning





HPRA Safety Notice: SN2019(03) **Issue Date: 28th January 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Smiths Medical	V11396

ISSUE
The HPRA issued a safety notice in April 2014 SN2014(22), detailing the many shortcomings associated with Graseby syringe drivers (MS16A and MS26). The safety notice also advised users that these devices would be discontinued from July 2014.

The HPRA is now reminding users that service and repair support for any Graseby syringe drivers still in use in Ireland will end in **July 2019**.

The HPRA understands that most centres in Ireland have transitioned to alternative devices.

The HPRA strongly recommends that any centre in Ireland still using these devices transfers to an alternative device at the earliest opportunity, and ensures that appropriate training is in place to facilitate a smooth transition to alternative devices.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Forward a copy of this safety notice to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred

2 Consider the following safety features when purchasing alternative syringe drivers
- Rate settings in millilitres (ml) per hour
- Mechanisms to stop infusion if the syringe is not properly and securely fitted
- Alarms that activate if the syringe is removed before the infusion is stopped
- Lock-box covers and/or lock out controlled by password
- Provision of internal log memory to record all pump events

Note: This is not an exhaustive list

3 Contact the HPRA with any concerns

TARGET GROUPS

All wards	Nursing Homes
Carers	Nursing Managers
Clinical Directors	Nursing Staff
Clinical Engineers	Oncology Nurse Specialists
Community Care Managers	Palliative Care Staff
Community Nurses	Purchasing Managers
Hospices	Risk Managers
Hospital Managers / CEOs	Supplies Managers

BACKGROUND

Our previous safety notice SN2014(22) highlighted the various shortcomings associated with these devices which include:-

a) These devices do not use standard measuring units. The MS16A is calibrated in millimetres (mm) per hour and the MS26 is calibrated in mm per 24 hour
b) The two models MS16A and MS26 are visually similar and care is needed to ensure the correct infusion rate is set

c) These devices lack a stop button. The devices can only be stopped by moving the rate switch to 00 or taking out the battery
d) The rate can be changed while the devices are in operation
e) There is no protection against misconnection of the syringe, air entrapment or siphoning. To help prevent tampering of the syringe or the syringe driver, lock boxes are available for use with these devices
f) The occlusion response characteristics of the device are very poor
g) The device does not retain a record of operation and cannot be interrogated
h) A 'prime' button provides maximum infusion rate when depressed. There is no limitation on the number of times this may be activated nor a record of activation

We also informed users that Smiths Medical was discontinuing these devices from July 2014.

The HPRA is issuing this Safety Notice to raise awareness amongst any centres, which may still be using these devices, of the urgent need to transition to alternative devices. This is due to the serious shortcomings associated with these devices and the cessation of service and repair support for any devices still in use in Ireland in **July 2019**.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Smiths Medical
Telephone: +49-89-242959-345
E-mail: eu.rep@smiths-medical.com
Website: www.smiths-medical.com

Enquiries to the **distributor** should be addressed to:

Smiths Medical Ireland
Telephone: +353-1-2941133
E-mail: ireland.customer.service@smiths-medical.com
Website: www.smiths-medical.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie