# Ateria® SafeControl®
# Distributor Pack

**Ateria® SafeControl®**

# Contents

# The Ateria® SafeControl® vision

## A preference over conventional and safety pen needles

We aim to establish Ateria® SafeControl® as the next generation of safety pen needles that is preferred by Healthcare Professionals and buyers because it provides a balance of safety and control during the injection process.

## Unique selling proposition (USP)

Ateria® SafeControl® is the next generation of safety pen needles. It is designed to protect Healthcare Professionals from needlestick injuries and provide confidence in delivering a full medication dose by balancing both safety and control during the injection process.

# Market segmentation 1

Standard pen needle users – Objective: to convert from standard pen needles to safety pen needles.

## Main challenge of standard pen needles

Healthcare Professionals (HCPs) are at risk of needlestick injuries.[1]



Needlestick injuries can have potentially serious physical and psychological consequences

## Solution: Features and benefits of using Ateria® SafeControl®

**1.** Ateria® SafeControl® is a safety pen needle so protects from needlestick injuries.



**Safety guard** for covering the needle after injection to protect from needlestick injuries

**2.** Ateria® SafeControl® uses the same injection technique as conventional pen needles.



**Visible needle** for control during the injection process and using the same technique as with conventional pen needles

# Market segmentation 2

Passive safety pen needle users – objective; switching from passive to manual activation.

## Challenges of passive safety pen needles

Limited control during the injection process as users are uncertain when the passive safety mechanism activates.[2]



Limited control during the injection process[2]

Premature activation of the safety mechanism resulting in uncertainty that the full medication dose has been delivered to the patient.



Premature activation of the safety mechanism[2]

Can't see the needle entering the patient's skin leading to uncertainty of the dose delivery.



Lack of needle visibility[2]

## Solution: Features and benefits of using Ateria® SafeControl®

**1.** Innovative manual push tab means Healthcare Professionals are both protected from needlestick injuries and are in control of the injection process resulting in confidence the full dose has been delivered.



**Innovative manual push tab** for easy, one-handed activation of the safety mechanism

**2.** Visible needle allows Healthcare Professionals see the needle going into the skin, resulting in confidence the full dose has been delivered.



**Visible needle** for control during the injection process and using the same technique as with conventional pen needles

# Product overview

The next generation of safety pen needles, designed to protect Healthcare Professionals from needlestick injuries and provide confidence in delivering a full medication dose by balancing both safety and control during the injection process.

**Visible needle** for control during the injection process and using the same technique as with conventional pen needles

**Innovative manual push tab** for easy, one-handed activation of the safety mechanism

**Green cap** for sterility and protection from the needle prior to injection

Before activation

After activation

**Safety guard** for covering the needle after injection to protect from needlestick injuries

**Dual safety indicator** for visual and audible confirmation

**Needle covered** at both ends to avoid needlestick injuries

# Ateria® SafeControl® Support

- We have a full suite of pre-launch and launch marketing communication collateral available for your market.

- These materials have been developed in conjunction with global market research[2] supporting Ateria® SafeControl® product claims.

- Please speak to your local Owen Mumford representative for information.



Ateria® SafeControl® brochure



Ateria® SafeControl® whitepaper

# Device specifications

## Product data (legislation and reference standards)

| | |
|---|---|
| **CE classification** | IIa |
| **Sterilisation** | Gamma irradiation |
| **Validity** | 5 years |
| **Biocompatibility** | ISO 10993 (2009) |
| **Legislation and reference standards** | ISO 11608-2, ISO 11137, ISO 11607 |

## Pen needle components and relative raw materials

| | |
|---|---|
| **Hub (attaches to pen)** | Polypropylene |
| **Safety guard** | High impact polystyrene |
| **Dual safety indicator** | Polypropylene |
| **Green cap** | Polypropylene |
| **Cannula (needle)** | Stainless steel AISI 304 |

## Dimensional characteristics

| Needle length (mm) | Gauge | Cannula external diameter (mm) | Cannula internal diameter (mm) | Wall thickness (ISO 9626-2) |
|---|---|---|---|---|
| 5 | 30G | 0.30 | 0.19 | Extra thin wall |
| 8 | 30G | 0.30 | 0.19 | Extra thin wall |

# Packaging

There are seven language sets of packaging per variant. Please refer to page 13 or speak to your local Owen Mumford representative for information.
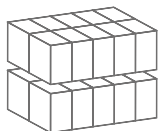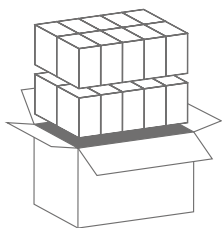


5mm packaging
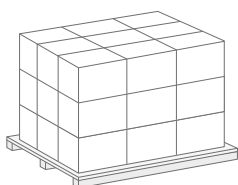


8mm packaging

# Packing and shipping configuration

| Cartons | | |
|---|---|---|
| **Total number of devices per carton** | 100 | |
| **Device weight** | 4.3g per unit | |
| **Carton dimensions** | Width | 139.5mm |
| | Height | 149mm |
| | Depth | 111.75mm / 111.25mm |
| **Total weight of one individual carton** | 430g | |

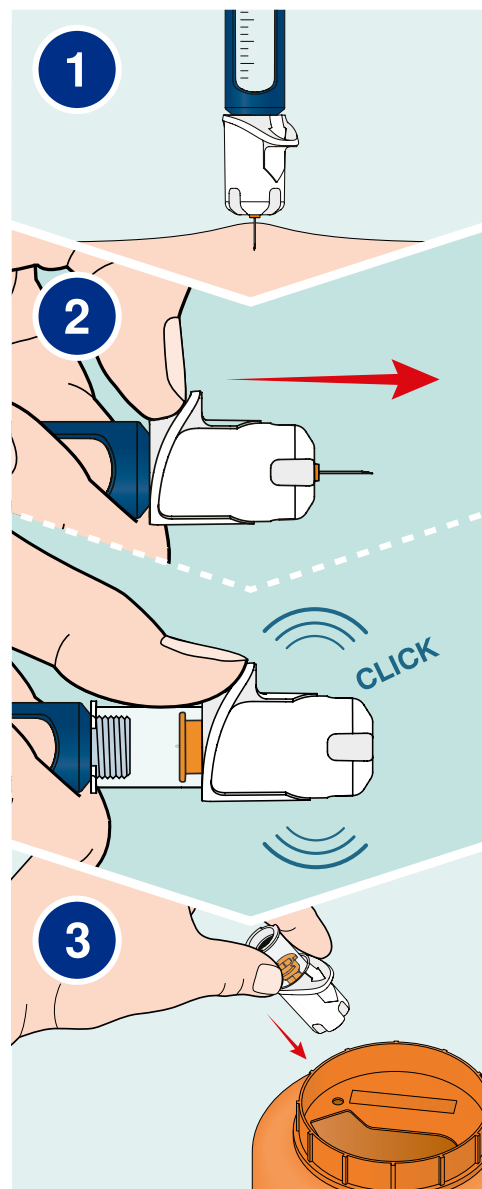| Shipping cases | | |
|---|---|---|
| **Configuration of a case** | 20 cartons in a shipping case | |
| **Total number of devices in a case** | 100 per carton x 20 cartons = 2,000 per case | |
| **Shipping case dimensions** | Width | 579mm |
| | Height | 284mm |
| | Depth | 299mm |
| **Total weight of a filled case** | 2,000 devices x 4.3g/device = 8.6kg | |

| Shipping pallets | |
|---|---|
| **Configuration of a pallet** | 24 cases on a pallet, 4 layers of 6 cases |
| **Total number of devices on a pallet** | 2,000 per case x 24 cases = 48,000 per pallet |

# Instructions for use

**1.** Remove protective seal. Screw needle onto injection pen and remove green cap. Inject as per pen instructions.

**2.** After injection, push the white safety guard away from you until it clicks and covers the needle. You will now see an orange indicator.

**3.** Unscrew needle from the injection pen and dispose of in sharps container.



**CLICK**

How-to-use video can be seen at: safecontrol.com

# Compatibility

owenmumford.com/compatability

**OWEN MUMFORD**

Including:

Autopen® Classic

Autopen® 24

**AstraZeneca**

Including:

Byetta®

**Lilly**

Including:

Forsteo® / Forteo®

KwikPen™

HumaPen® Luxura™ HD

HumaPen® Savvio™

**novo nordisk®**

Including:

Fiasp® FlexTouch®

NovoPen® FlexPen®

NovoPen® FlexTouch®

NovoPen Echo®

NovoPen® 5

Victoza®

**SANOFI**

Including:

AllStar™

Apidra® SoloStar®

ClikSTAR®

Lantus® SoloStar®

Toujeo® SoloStar®

Compatibility data correct as of March 2019.

# Order codes and language sets

| Product description | Code | Devices per carton | Cartons per case | Devices per case | Case weight (kg) | Case size (cm) | Pallet config | Devices per pallet |
|---|---|---|---|---|---|---|---|---|
| **5mm x 0.30mm (30G)** ⋯⋯⋯⋯ **8mm x 0.30mm (30G)** | See table below | 100 | 20 | 2000 | 8.6 | **Width:** 579mm **Height:** 284mm **Depth:** 299mm | 24 (4 layers of 6 cases) | 48,000 |

| Needle length mm | Needle gauge | Description | Language set | Product code |
|---|---|---|---|---|
| **5** | 30 | Ateria® SafeControl® 30G 5mm CE | Bulk | 001870 |
| | | | 1A | 002039 |
| | | | 1B | 002040 |
| | | | 2A | 002041 |
| | | | 2B | 002042 |
| | | | 3A | 002043 |
| | | | 3B | 002044 |
| | | | 4 (Malaysian) | 002045 |
| **8** | 30 | Ateria® SafeControl® 30G 8mm CE | Bulk | 001869 |
| | | | 1A | 002046 |
| | | | 1B | 002047 |
| | | | 2A | 002048 |
| | | | 2B | 002049 |
| | | | 3A | 002050 |
| | | | 3B | 002051 |
| | | | 4 (Malaysian) | 002052 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Set 1A** | English (EN) | French (FR) | N Netherlands (NL) (Dutch) | German (DE) | Italy (IT) (Italian) | Portugal (PT) (Portuguese) |
| **Set 1B** | English (EN) | Denmark (DA) (Danish) | Norway (NO) (Norwegian) | Swedish (SV) | Finland (FI) (Finnish) | Spain (ES) |
| **Set 2A** | English (EN) | French (FR) | Spain (ES) | Portugal (PT) (Portuguese) | Russia (RU) (Russian) | Arabic (AR) |
| **Set 2B** | English (EN) | Hebrew (HE) | Greek (EL) | Turkey (TR) (Turkish) | Ukraine (UK) (Ukrainian) | |
| **Set 3A** | Bulgaria (BG) (Bulgarian) | Croatia (HR) (Croatian) | Czech (CS) (Czech) | Estonia (ET) (Estonian) | Hungary (HU) (Hungarian) | Latvia (LV) (Latvian) |
| **Set 3B** | Lithuania (LT) (Lithuanian) | Romania (RO) (Romanian) | Slovenian (SL) | Slovakia (SK) (Slovakian) | Serbian (SR) | Poland (PL) (Polish) |
| **Malaysian** | English (EN) | Malaysia (MY) | Indonesia (ID) (Indonesian) | China (CN) (Simplified Chinese) | Thailand (TH) (Thai) | Vietnam (VN) |

# Ordering information

## Contact details:

**Asia Pacific**
Shirley Loh – Regional Managing Director
**T :** +60 (0)7 553 9617
**E :** shirley.loh@owenmumford.com

**DACH – Germany, Austria and Switzerland**
Thomas Roßbach – Regional General Manager
**T :** +49 6026 97750
**E :** thomas.rossbach@owenmumford.com

**North America and Caribbean**
Travis Shaw – Executive VP and General Manager
**T :** +1 770 977 2226
**E :** t.shaw@owenmumfordinc.com

**Northern Europe and Rest of World**
Joanne Thompson – Regional General Manager
**T :** +44 1608 645 555
**E :** joanne.thompson@owenmumford.com

**Southern Europe & Northern Africa**
Eric Del Cotto – Regional General Manager
**T :** +33 232 518 870
**E :** eric.delcotto@owenmumford-fr.com

## Ordering lead times:

Please contact your local Owen Mumford representative for information.

## Pricing:

Please contact your local Owen Mumford representative for information.

References
**1.** Motaarefi H, Mahmoudi H, Mohammadi E, Hasanpour-Dehkordi A (2016) Factors Associated with Needlestick Injuries in Health Care Occupations: A Systematic Review.
*J Clin Diagn Res* 10:IE01–IE04.   **2.** Project Saturn A (2017) Online study commissioned with an independent market research agency. Data on file.