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Singapore 639461
Registration No. 201114149N

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URGENT FIELD SAFETY NOTICE

Product Name: **Alaris™ GS, GH, CC, TIVA, PK, Enteral Syringe Pump**
Product codes with prefix (all variants): **8001, 8002, 8003, 8004, 8005, 8007**
Product Name: **Asena™ GS, GH, CC, TIVA, PK Syringe Pumps**
Product codes with prefix (all variants): **8001, 8002, 8003, 8004, 8005**

09 May 2017

Dear Customer,

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Copy: Chairman Medical Board and Head of Departments

Description of the Problem

Based on reports from one customer in late 2016, BD/Carefusion identified a potential risk of syringe siphonage with Alaris Syringe Pumps which have a broken “plunger backplate spring” in the plunger backplate assembly.

It has been identified that a breakage of the plunger backplate spring may allow movement of the syringe plunger within the plunger holder mechanism which could result in siphonage. In some circumstances, this may result in a **clinically significant over infusion. Neonatal and paediatric patients, or those receiving critical drugs, at low infusion rates, would be considered to be the most at risk if small volumes of fluids reach the patient due to siphoning**.

The movement of the syringe within the plunger holder mechanism may cause the following system effects:

a) If the syringe plunger is not held firmly in place within the plunger holder mechanism, movement of the syringe plunger may result in siphonage and an unintended bolus of fluid/medication may occur.

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b) The volume of the overinfusion will be dependent on factors such as the syringe brand, syringe size, syringe stiction (changing levels of friction as the plunger moves) and the height of the pump above the patient. However, based on our analysis of the recommended syringes, the volume of the bolus may be between 0.14ml and 0.78ml.
c) The impact of the overinfusion may have increased clinical significance at lower infusion rates.
d) If the syringe plunger loses contact with the plunger button, the pump will audibly alarm, visually display "Check Syringe", and the infusion will stop.
e) Continued use of the pump following "Check Syringe alarms" may lead to multiple boluses being delivered, and as a result, increase the total volume of fluid delivered via siphonage.

Action Required

1) **The plunger backplate spring (see Appendix 4) should be replaced on syringe pumps older than three (3) years from date of manufacture. To identify the age of the pump, please refer to the label on the rear case, which will identify the date of manufacture.**

2) **The highest priority should be given to clinical areas such as neonatal, paediatric and critical care areas, where critical drugs are delivered at lower infusion rates.**

3) **If you see a "Check Syringe" alarm and there is no identifiable cause, the pump should be removed from clinical use and examined by qualified service personnel in accordance with the Alaris Syringe Pump Technical Service Manual.**

The recommended method of detecting a broken spring is for a qualified service person to open the plunger assembly and visually inspect the spring.

Additional Alarms and Warnings in the Directions For Use (DFU)

As a result of this issue, we have updated the products' Directions For Use (DFU) to provide further clarification of what a "check syringe" alarm indicates, and the actions to take as a result:

> A "Check Syringe" alarm may indicate the incorrect size of syringe has been fitted; the syringe has not been positioned correctly, or has been disturbed during operation, for example, the user opens the syringe clamp, or If the syringe plunger loses contact with the plunger button.
>
> "If there is no identifiable cause for the "Check Syringe" alarm(s) then the pump should be removed from clinical use and examined by qualified service personnel in accordance with the Alaris Syringe Pump Technical Service Manual."

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Preventative Maintenance and Correction

It has been identified that in syringe pumps older than three years, a broken plunger back-plate spring could lead to siphonage. Therefore the back-plate spring should be replaced. To identify the age of the pump, please refer to the label on the rear case, which will identify the date of manufacture. Please refer to the Alaris Syringe Pump Technical Service Manual via the following urls:

Syringe Pump Technical Service Manual MK3

http://www.bd-products.com/assets/supportdocs/protected/TSM_manual/1000SM00001.pdf

Syringe Pump Technical Service Manual MK4

http://www.bd-products.com/assets/supportdocs/protected/TSM_manual/1000SM00024.pdf

The required details are: Username = uk-tech, Password = safe8belt

BD/CareFusion has changed the preventative maintenance recommendations in the Technical Service Manuals. BD/Carefusion has also released an Information Notice (IN0221).

http://www.bd-products.com/assets/supportdocs/protected/information_notices/IN0221.pdf

The required details are: Username = uk-tech, Password = safe8belt

This includes instructions on how to replace the plunger back-plate spring. Customers with Alaris syringe pumps will be requested to review the associated Alaris Syringe Pump Technical Service Manuals (10000SM00001 Issue 31, page 28 and 1000SM00024 Issue 4, page 22).

Preventative maintenance inspections should be performed at least every three years as detailed in the Technical Service Manual.

Prioritisation:

High priority should be given to clinical areas such as neonatal, paediatric and critical care areas, where critical drugs are delivered at lower infusion rates.
Particular attention should be paid to pumps older than 3 years. To identify the age of the pump, please refer to the label on the rear case, which will identify the date of manufacture.

Your competent authority has already been notified of this Field Safety Notice by BD/CareFusion's Authorised EU Representative.
Should you have any questions or require assistance relating to this Field Safety Notice, please contact your Local BD/CareFusion representative.

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Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organisation. If you are no longer in possession of these pumps please pass this notice and all the related documentation on to the current user.

Please also refer to Appendix 3: Frequently Asked Questions.

We sincerely apologise for any inconvenience this action may have caused you or your staff.

Sincerely,

Rose Kwong
Senior Regulatory Affairs & Compliance Executive

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Appendix 1 – To be completed and returned by End User

URGENT FIELD SAFETY NOTICE

(CUSTOMER ACKNOWLEDGEMENT)

Product Name: **Alaris™ GS, GH, CC, TIVA, PK, Enteral Syringe Pump**

Product codes with prefix (all variants): **8001, 8002, 8003, 8004, 8005, 8007**

Product Name: **Asena™ GS, GH, CC, TIVA, PK Syringe Pumps**

Product codes with prefix (all variants): **8001, 8002, 8003, 8004, 8005**

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to your local BD contact.

☐ I have read and understood the contents of this Field Safety Notice and will distribute this notice to all those who need to be made aware.

☐ I have reviewed and I am aware of the changes made to the Technical Service Manual and Directions for Use in relation to this matter.

☐ I will notify BD/CareFusion of the serial numbers of pumps in which the springs have been replaced and if the existing spring was found to be intact.

❑ Other comments:

_____

_____

_____

Completed by:

Name: _____ **Signature / Date:** _____

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

Telephone No.: _____ **Fax No.**: _____

Company stamp:

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Appendix 2 – Affected SKUs

Alaris™ GS, GH, CC, TIVA, PK, Enteral Syringe Pump

Asena™ GS, GH, CC, TIVA, PK

Material description	Material	Product Type
ASENA GS GERMAN	80013DE00	GS
ASENA GS GERMAN	80013DE00-R	GS
ASENA GS SYRINGE PUMP-USED	80013DE00-U	GS
ASENA GS GERMAN + RS232	80013DE01	GS
ASENA GS USED	80013DM00	GS
ASENA GS SPANISH	80013ES00	GS
ASENA GS SPANISH + RS232	80013ES01	GS
ASENA GS FRENCH	80013FR00	GS
ASENA GS FRENCH - USED	80013FR00-U	GS
ASENA GS FRENCH + RS232	80013FR01	GS
ASENA GS ENGLISH	80013GB00	GS
ASENA GS ENGLISH + RS232	80013GB01	GS
ASENA GS ITALIAN	80013IT00	GS
ASENA GS ITALIAN + RS232	80013IT01	GS
ASENA GS DUTCH	80013NL00	GS
ASENA GS DUTCH + RS232	80013NL01	GS
ASENA GS NORWEGIAN	80013NW00	GS
ASENA GS NORWEGIAN + RS232	80013NW01	GS
ASENA GS REFURBISHED	80013RF00	GS
ASENA GS REFURBISHED + RS232	80013RF01	GS
ASENA GS SWEDISH	80013SE00	GS
ASENA GS SWEDISH + RS232	80013SE01	GS
ALARIS® GS UNIVERSAL	80013UN00	GS
ASENA GS SYRINGE PUMP-USED	80013UN00-U	GS
ALARIS® GS UNIVERSAL+RS232	80013UN01	GS
ASENA GS UNIVERSAL+RS232-USED	80013UN01-U	GS
ALARIS GH PLUS SYRINGE PUMP - USED	8002TIG01-U	GH
ALARIS GH PLUS G/RLS SYRINGE PUMP - USED	8002TIG01-G-U	GH
ALARIS GH PLUS GUARDRAILS SYRINGE PUMP	8002TIG01-G	GH
ALARIS GH PLUS SYRINGE PUMP - CN	8002TIG01-CN	GH
ALARIS GH PLUS SYRINGE PUMP	8002TIG01	GH

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Material description	Material	Product Type
ALARIS GH PFS V1.0 - USED	8002PFS01-G-U	GH
ALARIS GH PFS V1.0	8002PFS01-G	GH
ALARIS GH PLUS - USED	8002MED01-U	GH
ALARIS GH PLUS WITH GUARDRAILS - USED	8002MED01-G-U	GH
ALARIS GH PLUS GUARDRAILS SYRINGE PUMP	8002MED01-G	GH
ALARIS GH PLUS SYRINGE PUMP	8002MED01	GH
ALARIS GH PLUS	8002MED00	GH
ASENA GH UNIVERSAL+RS232-USED	80023UN01-U	GH
ASENA GH GUARDRAILS + RS232-USED.	80023UN01-G-U	GH
ALARIS® GH UNIVERSAL GUARDRAILS + RS232	80023UN01-G	GH
ALARIS GH UNIVERSAL+RS232	80023UN01	GH
ASENA GH SYRINGE PUMP-USED	80023UN00-U	GH
ASENA GH UNIVERSAL	80023UN00-G	GH
ALARIS® GH UNIVERSAL	80023UN00	GH
ASENA GH SWEDISH + RS232	80023SE01	GH
ASENA GH SWEDISH	80023SE00	GH
ASENA GH +RS232 - USED	80023RF01	GH
ASENA GH USED	80023RF00	GH
ASENA GH GUARDRAILS + RS232-USED.	80023NW01-G-U	GH
ASENA GH NORWEGIAN + RS232 +GUARDRAILS	80023NW01-G	GH
ASENA GH NORWEGIAN + RS232	80023NW01	GH
ASENA GH NORWEGIAN	80023NW00	GH
ASENA GH DUTCH + RS232	80023NL01	GH
ASENA GH DUTCH	80023NL00	GH
ASENA GH ITALIAN + RS232	80023IT01	GH
ASENA GH ITALIAN	80023IT00	GH
ASENA GH UNIVERSAL+RS232-USED	80023GB01-U	GH
ASENA GH ENGLISH + RS232+GR - USED	80023GB01-G	GH
ASENA GH ENGLISH + RS232	80023GB01	GH
ASENA GH ENGLISH-USED	80023GB00-U	GH
ASENA GH ENGLISH	80023GB00	GH
ASENA GH FRENCH + RS232	80023FR01	GH
ASENA GH SYRINGE PUMP-USED	80023FR00-U	GH
ASENA GH FRENCH	80023FR00	GH
ASENA GH SPANISH + RS232	80023ES01	GH
ASENA GH SPANISH	80023ES00	GH
ASENA GH UNIVERSAL+RS232 - USED	80023DM01	GH
ASENA GH UNIVERSAL - USED	80023DM00	GH
ASENA GH GERMAN + RS232 USED	80023DE31-U	GH
ASENA GH GERMAN + RS232 USED	80023DE01-U	GH
ASENA GH GERMAN + RS232	80023DE01	GH

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Registration No. 201114149N

Material description	Material	Product Type
ASENA GH GERMAN - USED	80023DE00-U	GH
ASENA GH GERMAN	80023DE00-R	GH
ASENA GH GERMAN	80023DE00	GH
ALARIS® CC ENGLISH	80033GB00	CC
ALARIS® CC UNIVERSAL DEDICATED	80033UND0	CC
ALARIS CC UNIVERSAL DEDIC+RS232	80033UND1	CC
ALARIS® CC GUARDRAILS® UNIV. DEDIC+RS232	80033UND1-G	CC
ALARIS® CC	80033UNN0	CC
ASENA CC + RS232	80033UNN1	CC
ASENA CC 110/240V - PLANNING FAMILY	80033VPD1	CC
ALARIS CC PLUS	8003MED01	CC
ALARIS CC PLUS WITH GUARDRAILS	8003MED01-G	CC
ALARIS CC PLUS WITH GUARDRAILS - USED	8003MED01-G-U	CC
ALARIS CC PLUS - USED	8003MED01-U	CC
ALARIS CC PFS V1.0	8003PFS01-G	CC
ALARIS CC PFS V1.0 - USED	8003PFS01-G-U	CC
ALARIS CC PLUS SYRINGE PUMP	8003TIG01	CC
ALARIS CC PLUS SYRINGE PUMP - CN	8003TIG01-CN	CC
ALARIS CC PLUS GUARDRAILS SYRINGE PUMP	8003TIG01-G	CC
ALARIS CC PLUS GUARDRAILS S-PUMP - USED	8003TIG01-G-U	CC
ALARIS CC PLUS SYRINGE PUMP - USED	8003TIG01-U	CC
ASENA TIVA UNIVERSAL+RS232 - USED	80043UN01-U	TIVA
ALARIS TIVA UNIVERSAL+RS232	80043UN01	TIVA
ALARIS® TIVA UNIVERSAL	80043UN00	TIVA
ALARIS PK PLUS (MK4) SYRINGE PUMP -USED	8005TIG01-U	PK
ALARIS PK PLUS (MK4) SYRINGE PUMP	8005TIG01	PK
ALARIS PK PLUS MK4 2E SYRINGE PUMP	8005PK201	PK
ASENA PK UNIVERSAL RS232- USED	80053UN01-U	PK
ALARIS PK + RS232	80053UN01	PK
ALARIS ENTERAL PLUS SYRINGE PUMP MK4	8007ENT01	ENTERAL
ALARIS ENTERAL - USED	8002ENT01-U	ENTERAL
ALARIS ENTERAL	8002ENT01	ENTERAL

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Appendix 3 – Frequently Asked Questions

Alaris™ GS, GH, CC, TIVA, PK & Enteral Syringe Pumps
Asena™ GS, GH, CC, TIVA, PK Syringe Pumps

Frequently Asked Questions (FAQ's) – **For External Use**

Risk of syringe siphonage with Alaris Syringe Pumps

1. Why has this FSN been issued?

Based on reports from one customer in late 2016, BD/CareFusion identified a potential risk of syringe siphonage with Alaris Syringe Pumps that have a broken "plunger backplate spring" in the plunger back plate assembly.

This has resulted in the release of a Field Safety Notice to provide additional information and recommended actions to our customers.

2. Which devices are affected?

Product Name: Alaris™ GS, GH, CC, TIVA, PK and Enteral Syringe Pumps
Product codes with prefix (all variants): 8001, 8002, 8003, 8004, 8005, 8007

Product Name: Asena™ GS, GH, CC, TIVA, PK Syringe Pumps
Product codes with prefix (all variants): 8001, 8002, 8003, 8004, 8005

Note: The design of the IVAC PCAM syringe pump and the Alaris System Syringe Modules are different therefore these products are not included in this action.

3. How did this circumstance occur?

It has been identified that a breakage of the plunger backplate may allow movement of the syringe plunger within the plunger holder mechanism which could result in siphonage. In some circumstances, this may result in a clinically significant overinfusion.

Generally, the larger diameters of syringe produced the higher volumes of siphonage. For this siphonage to occur, the pump must be elevated significantly higher than the patient (significant may be typically 30 cm or more)

One factor in the potential for the spring to break is the frequency of use and the age of the pump (wear and tear). Our analysis of test data has demonstrated that the mean time for the breakages to occur is 5.25 years.

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4. What are the clinical implications of this issue?

The gap between the plunger back-plate and the grippers may cause the following system effects:

a) If the syringe plunger is not held firmly in place within the plunger holder mechanism, movement of the syringe plunger may result in siphonage and a limited unintended bolus of fluid/medication may occur.
b) The extent of the overinfusion due to an undetected "bolus" of fluid will be dependent on the intended infusion rate, and may have increased clinical significance at lower infusion rates, however flow rate is not the cause of siphonage.
c) The volume of the overinfusion will be dependent on factors such as the syringe brand, syringe size, thickness of the syringe 'push-button', syringe stiction (changing levels of friction as the plunger moves), and the height of the pump above the patient. However, based on our analysis of the recommended syringes, the volume of the bolus may be between 0.14ml and 0.78ml.

5. Will the pump alarm?

If the plunger moves sufficiently within the syringe plunger holder mechanism it may lose contact with the plunger detection button, the pump will audibly alarm, visually display "Check Syringe" and the infusion will stop.

As described in the *Directions for Use*, a "Check Syringe" alarm indicates:

> "Incorrect size of syringe has been fitted, the syringe has not been positioned correctly or has been disturbed during operation. Check the syringe location and the position."

"Check Syringe" alarms will also occur if the syringe clamp is opened or the syringe assembly is pulled back during an infusion.

Note: If you see a "Check Syringe" alarm and there is no identifiable cause, the pump should be removed from clinical use and examined by qualified service personnel in accordance with the Alaris Syringe Pump Technical Service Manual.

Continued use of the pump despite ongoing "Check Syringe" alarms may potentially result in the delivery of a small bolus on multiple occasions.

6. Describe any clinical factors that may mitigate the risk:

Best practice when using syringe pumps include:

a. If there is no identifiable cause for the "Check Syringe" alarm(s), the pump should be removed from clinical use, and examined by qualified service personnel. As stated above, continued use of the syringe pump, despite multiple "Check Syringe" alarms, may potentially result in the delivery of a small bolus on multiple occasions.
b. Clamping the administration set whenever it is connected to the patient and the pump is not infusing.

c. Ensure the extension set is properly isolated from the patient, prior to manipulating the syringe or removing it from the pump, to avoid potential siphonage.
d. Place the syringe pump as close to the patient level as possible to minimise the possibility of syringe siphoning due to gravity / head height flow.

e. If it is not possible to keep the pump within about 30 cm above the patient, then consider use of an anti-siphon valve at end of the delivery line. In 2010, the National Patient Safety Agency* (UK) issued a recommendation to use anti-siphon valves within the administration set to prevent free flow or siphonage of infusion fluid, where clinically appropriate.
   **National Patient Safety Agency, A guide to the design of electronic infusion devices Edition 1, 2010, page 81*
f. Place the pump on hold if moving the height of the pump during an infusion.

7. What segment of the population is most at risk?

a. Neonatal and paediatric patients receiving critical drugs would be considered to be the most at risk if small volumes of fluids reach the patient due to siphoning.
b. The risk of harm in most adult populations is considered to be unlikely due to the extremely small volumes that may siphon.
c. Patient populations that are urgently in need of critical infusions may be impacted due to the potential for a delayed start of infusion while a replacement device is acquired; it is recommended that such replacement devices be easily accessible in critical care areas.
d. The risk associated with an unintended bolus will be dependent on the type of fluid/medication being delivered, the amount of the bolus and the patient's clinical condition. Therefore real-time monitoring of the patient's vital signs and hemodynamic status and close clinical supervision in critical care areas will reduce the occurrence of serious adverse events.

8. What should be done if there is an increase in "Check Syringe" alarms?

If there is no identifiable cause for the alarm, then the pump should be removed from clinical use and examined by qualified service personnel in accordance with the Alaris Syringe Pump Technical Service Manual.

9. What actions has BD/CareFusion undertaken to rectify this issue?

BD has updated the Technical Service Manual (TSM) to include replacement of the spring as part of the routine preventative maintenance schedule. This is available via the technical documentation section on our website.

Syringe Pump Technical Service Manual MK3

http://www.bd-products.com/assets/supportdocs/protected/TSM_manual/1000SM00001.pdf

Syringe Pump Technical Service Manual MK4

http://www.bd-products.com/assets/supportdocs/protected/TSM_manual/1000SM00024.pdf

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The required details are: Username = uk-tech, Password = safe8belt

The updated section can be found on page 28 (1000SM00001, Issue 31) and page 22 (1000SM00024, Issue 4).

BD/Carefusion has also released an Information Notice (IN0221).

http://www.bd-products.com/assets/supportdocs/protected/information_notices/IN0221.pdf

The required details are: Username = uk-tech, Password = safe8belt

10.How can the issue be detected?

The most reliable method of detecting a broken spring is for a technical service specialist to open the plunger assembly and visually inspect the spring.

11.Do pumps need to be serviced / have them checked now?

It has been identified that in syringe pumps older than three years, a broken plunger back-plate spring could lead to siphonage. Therefore the back-plate spring should be replaced. For pumps less than 3 years old, please refer to the Alaris Syringe Pump Technical Service Manual.

12.Where can more information be obtained?

Please contact your local BD/CareFusion office if you require any additional information or support. BD/ CareFusion is committed to serving your infusion product needs and our primary objectives continue to be patient safety, exceptional product reliability, and the highest level of customer satisfaction.

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Appendix 4 – Plunger Backplate Spring Replacement

Plunger Backplate Spring Replacement

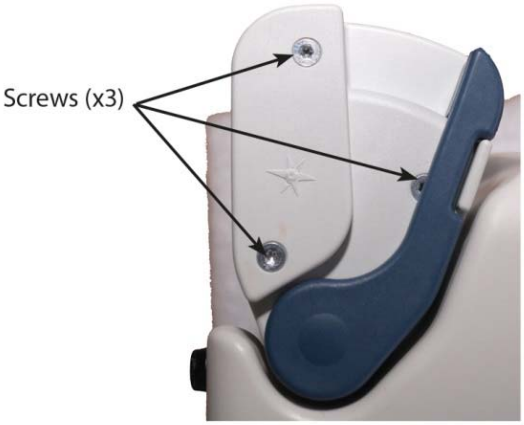
Recommended during every Preventative Maintenance and at the minimum every three years that the plunger backplate spring is replaced.

If the spring had not been replaced during the previous check, the spring needs to be replaced at the next intervention and at each preventative maintenance as recommended.

A kit of 10 replacement springs is available, part number 1000SP01589.

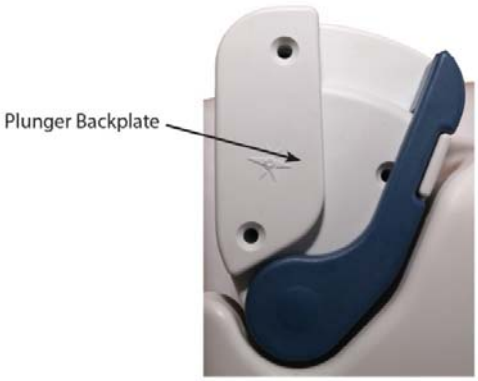
1. Remove the plunger backplate.

   Note: Be cautious when removing as parts may become loose. Placing the Pump in a vertical orientation may assist with maintaining components in place.



2. Visually inspect the interior of the plunger, replace any broken components.
   See Technical Service Manual *Chapter 6 Corrective Maintenance* for further details.

3. Remove three screws holding plunger backplate.



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4. Remove the spring from the plunger backplate.

5. Fit a new spring to the plunger backplate.

6. Refit the plunger backplate.

7. Fit the three screws into the plunger backplate.