



Hillrom™

Hill-Rom S.A.S, ZI du Talhouet
56330 Pluvigner, Francia

Avviso di sicurezza

Baxter

FA-2022-016

Data:
Nome cliente:

FSCA-identifiser: FA-2022-016

Tipo di azione: avviso di sicurezza

Oggetto: Rischio di distacco sponde AD271B

Nome commerciale del prodotto interessato:

Hill-Rom 900, Ampera e Centuris Pro

Dispositivi interessati:

Per i numeri di serie interessati, si veda l'Appendice A

Nome	Modello
Hill-Rom 900	LI900B2
Ampera	LI901A0
Centuris Pro	LI900B1

Potrebbero essere interessati tutti i prodotti fabbricati tra il 20 aprile 2020 e il 10 marzo 2022.

All'attenzione di: Responsabile dei rischi impianto/Amministratore impianto, Amministratore capo impianto, Ingegnere impianto, Responsabile vigilanza, Ingegneria biomedica, Funzionario di collegamento dispositivi medici

Descrizione del problema:

Hillrom, un'azienda Baxter, è venuta a conoscenza di un potenziale problema in cui la sponda dei letti LI900B1, LI900B2 e LI901A0 potrebbe non agganciarsi correttamente. Se la sponda non è agganciata correttamente, può staccarsi, non proteggendo più il paziente da eventuali cadute.

Premessa:

Hillrom produce gruppi letto (modelli LI900B1, LI900B2 e LI901A0) dotati di sponde a $\frac{3}{4}$ AD271B (barriere di sicurezza per il paziente). A febbraio 2022, Hillrom ha individuato una sponda che non si agganciava correttamente alla struttura del letto a causa di una sbavatura nel connettore in plastica. Si veda la Figura 1 sottostante.



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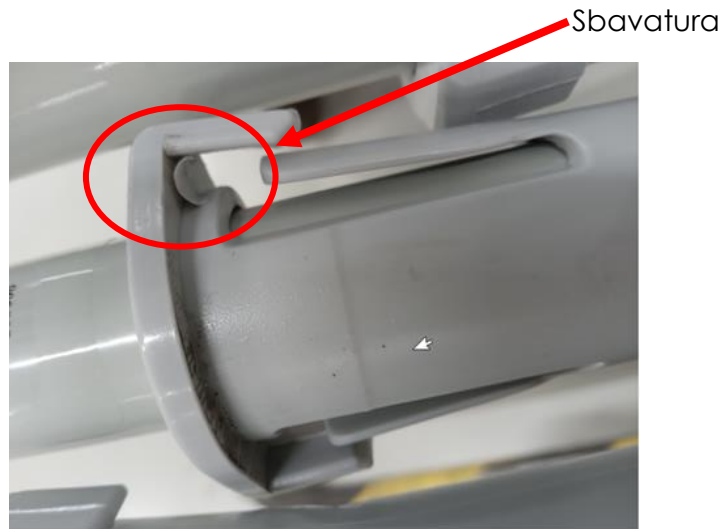


Figura 1: Connettore della sponda con sbavatura

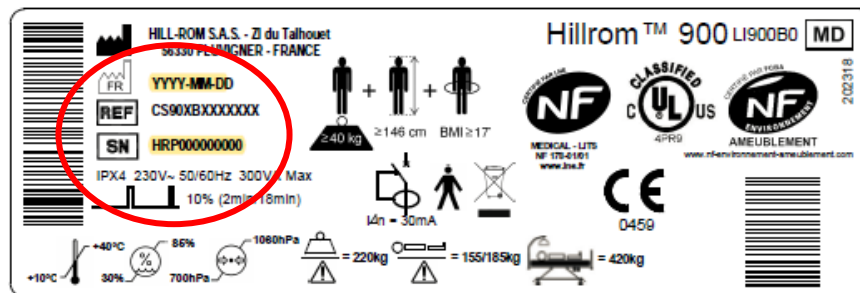
Potenziale rischio:

Se la sponda non è agganciata correttamente può staccarsi, non proteggendo più il paziente da eventuali cadute.

Non vi sono state segnalazioni di questo problema sul campo.

Azioni necessarie da parte dei clienti:

- Indicare se il prodotto interessato (come da Appendice A) è presente nella propria struttura.
Il numero di serie e la data di produzione sono riportati sulla targhetta di identificazione della struttura letto (si veda l'esempio sottostante).



- Seguire le istruzioni per l'uso (IFU) su come disinserire e reinserire la sponda. Assicurarsi di sentire un "clic" per confermare il corretto inserimento. Si vedano le immagini sottostanti



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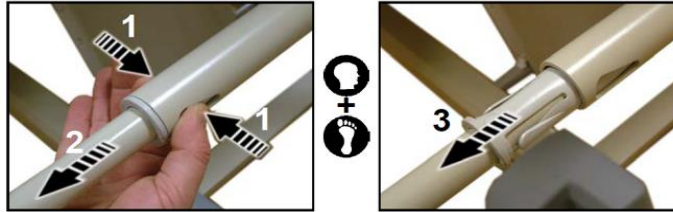
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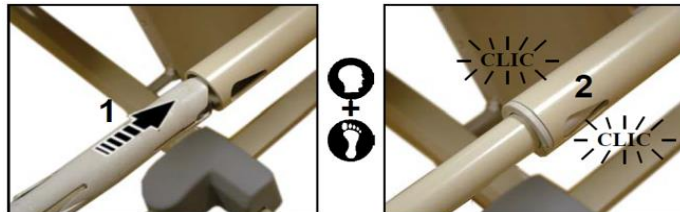
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Rimozione delle sponde lunghe



Installazione delle sponde lunghe



- Restituire il modulo di risposta allegato entro due settimane per confermare l'avvenuta ispezione.

Azioni da intraprendere da parte del distributore:

Si prega di condividere il presente Avviso di sicurezza con i propri utenti finali e di far pervenire il modulo di risposta allegato, debitamente compilato, a hillromPLU016@Sedgwick.com entro due settimane.

Si prega di assistere i propri utenti finali qualora sia richiesta l'ispezione da parte di un tecnico.

Azioni da intraprendere da parte di Hillrom:

Hillrom ha affrontato il problema evitando la formazione di bave nelle produzioni future.

Referente:

In caso di domande relative al presente Avviso di sicurezza, si prega di contattare l'assistenza tecnica Hillrom all'indirizzo e-mail o al numero di telefono riportati di seguito.

Mercato / Regione / Paese	Numero di telefono	E-mail dell'assistenza tecnica
Austria	(+ 43) 2 243 285 50	service-administration.dach@hillrom.com
Germania	(+ 49) 2 0149869500	service.dach@hillrom.com
Svizzera	(+ 41) 8 48 811530	service-administration.dach@hillrom.com
Paesi Bassi	(+ 31) 347 323 532	service.nl@hillrom.com
Spagna	(+ 34) 9 36856000	asistencia@hillrom.com
Italia	(+ 39) 02 950541	fieldaction_italy@hillrom.com

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Francia	(+ 33) 0 820 012345	sav@hillrom.com
Svezia	(+ 46) 20-781030	ordernordic@hillrom.com
Regno Unito/Irlanda	(+ 44) 1530 562176	UKCustomerCare@hillrom.com
Paesi dell'Europa orientale	Contattare il distributore Hillrom locale	

Trasmissione del presente avviso di sicurezza:

Assicurarsi di inoltrare questo avviso a tutto il personale che deve essere informato. Il personale interessato può includere (elenco non esaustivo):

Unità di pronto soccorso	Personale interno addetto alla
Unità di terapia intensiva per adulti	Personale infermieristico specializzato in terapia endovenosa (EV)
Tutti i reparti e tutte le cliniche	Direttori sanitari
Ingegneri biomedici	Direttori esecutivi del servizio
Responsabili della gestione clinica	Unità oncologiche
Sale operatorie ambulatoriali	Unità di terapia intensiva pediatrica
Reparti di ingegneria elettronica e biomedica	Responsabili della gestione del rischio
Negozi e biblioteche di attrezzature	Responsabili delle forniture
Responsabili della salute e della sicurezza	Sale operatorie

Il sottoscritto conferma che il presente avviso è stato comunicato all'Agenzia di Regolamentazione competente.

Cordiali saluti,

Maurice Herve
Direttore Controllo Qualità



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Modulo di risposta / Ricevuta

Oggetto: Rischio di distacco sponde AD271B (FA-2022-016)

È importante restituire il presente modulo/ricevuta a conferma del ricevimento e fornirci le informazioni necessarie.

Compilare quanto segue con le informazioni corrette e **inviare il presente Modulo di risposta** entro due settimane.

Grazie.

Numero cliente Hillrom (se conosciuto): _____

Nome della struttura: _____

Indirizzo della struttura: _____

Città: _____ CAP: _____ Paese: _____

Nome del referente della struttura (in stampatello):

Firma: _____ Data: ____/____/____

Qualifica: _____ Telefono: _____

E-mail: _____

Spuntare le caselle pertinenti:

Abbiamo esaminato e compreso l'Avviso di sicurezza allegato

Dall'ispezione dell'inventario dei nostri prodotti risulta che:

Non abbiamo prodotti potenzialmente difettosi secondo l'Appendice A.

Confermiamo di avere ispezionato e reinserito la sponda e di avere sentito un "click" come da istruzioni per l'uso. Elencare i numeri di serie di seguito.

Confermiamo di avere ispezionato e reinserito la sponda, ma richiediamo che un tecnico Hillrom ne confermi il corretto inserimento come da istruzioni per l'uso. Elencare i numeri di serie di seguito.

Identificare i numeri di serie interessati nella tabella sottostante.

Numero di serie	Numero di serie	Numero di serie

Restituire il modulo di risposta a hillromPLU016@Sedgwick.com entro due settimane.

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56330 Pluvigner, Francia**Avviso di sicurezza****Baxter****FA-2022-016****Appendice A - Numeri di serie interessati**

Numero di serie	Numero di serie	Numero di serie	Numero di serie	Numero di serie	Numero di serie
HRP004109793	HRP004182264	HRP004209574	HRP004237611	HRP004270607	HRP004282433
HRP004109794	HRP004182265	HRP004209577	HRP004237612	HRP004270608	HRP004282434
HRP004109796	HRP004182266	HRP004209578	HRP004237613	HRP004270609	HRP004282435
HRP004109797	HRP004182267	HRP004209585	HRP004240436	HRP004270610	HRP004282436
HRP004109798	HRP004187084	HRP004209587	HRP004240437	HRP004270611	HRP004282437
HRP004109799	HRP004187432	HRP004211298	HRP004239905	HRP004270612	HRP004282438
HRP004109800	HRP004187434	HRP004211299	HRP004239907	HRP004270613	HRP004282439
HRP004109801	HRP004187435	HRP004209169	HRP004240579	HRP004270614	HRP004282450
HRP004109802	HRP004187436	HRP004210782	HRP004240580	HRP004270615	HRP004282451
HRP004109789	HRP004187437	HRP004210787	HRP004240581	HRP004270616	HRP004282456
HRP004109792	HRP004187603	HRP004210788	HRP004240582	HRP004270617	HRP004282457
HRP004109795	HRP004187604	HRP004213472	HRP004240583	HRP004270082	HRP004282458
HRP004109516	HRP004187605	HRP004213473	HRP004240584	HRP004270083	HRP004282459
HRP004109517	HRP004187606	HRP004213711	HRP004240585	HRP004270084	HRP004282460
HRP004109519	HRP004187808	HRP004213712	HRP004240586	HRP004270085	HRP004282461
HRP004109520	HRP004187809	HRP004213713	HRP004239921	HRP004270086	HRP004282462
HRP004109529	HRP004187810	HRP004213714	HRP004241804	HRP004270087	HRP004282497
HRP004109530	HRP004187811	HRP004213715	HRP004241805	HRP004270088	HRP004282498
HRP004109531	HRP004187812	HRP004213716	HRP004242639	HRP004270089	HRP004281987
HRP004109532	HRP004187985	HRP004213766	HRP004242659	HRP004270090	HRP004281988
HRP004109540	HRP004187986	HRP004213767	HRP004240988	HRP004270091	HRP004281989
HRP004109541	HRP004187987	HRP004213768	HRP004240989	HRP004270092	HRP004281990
HRP004109790	HRP004187988	HRP004213769	HRP004240601	HRP004270093	HRP004282387
HRP004109791	HRP004188210	HRP004213770	HRP004240602	HRP004270094	HRP004282388
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HRP004111243	HRP004188380	HRP004213105	HRP004240608	HRP004270637	HRP004282399
HRP004111244	HRP004188381	HRP004213106	HRP004240609	HRP004270638	HRP004282400
HRP004116699	HRP004188382	HRP004213107	HRP004240610	HRP004270639	HRP004282401
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HRP004116706	HRP004188384	HRP004213109	HRP004241415	HRP004270641	HRP004278580
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HRP004116713	HRP004188578	HRP004213111	HRP004241417	HRP004270643	HRP004278582
HRP004116986	HRP004187424	HRP004213112	HRP004243058	HRP004271741	HRP004278583
HRP004116987	HRP004187425	HRP004213440	HRP004243892	HRP004271772	HRP004278584

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HRP004111512	HRP004190020	HRP004213469	HRP004240589	HRP004271791	HRP004278589
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HRP004111237	HRP004186968	HRP004209534	HRP004240593	HRP004271946	HRP004278593
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HRP004145993	HRP004190480	HRP004214221	HRP004248376	HRP004271938	HRP004281248
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